Systematic reviews for the update of the WHO Guideline on country pharmaceutical pricing policies

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WHO guideline on country pharmaceutical pricing policies, second edition. Web Annex A. Systematic reviews for the update of the WHO Guideline on country pharmaceutical pricing policies

ISBN 978-92-4-001189-2 (electronic version)

This publication forms part of the WHO guideline entitled *WHO guideline on country pharmaceutical pricing policies, second edition*. It is being made publicly available for transparency purposes and information, in accordance with the *WHO handbook for guideline development*, 2nd edition (2014).

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Acknowledgements

The authors are grateful for the review and suggestions of colleagues associated with the Guideline Development Group and WHO: Fatima Suleman, Lisa Bero, Sabine Vogler, Kiu Tay-Teo. Colleagues at York Health Economics Consortium (YHEC) who contributed to the extensive search process include Ross Birtles, Mick Arber, Chris Bartlett, James Mahon. Additionally, Deborah Toppenberg-Pejcic assisted with the screening of grey literature at country level. The authors are grateful to Prof. Zaheer Babar, Prof. Jaime Espin and Dr. Kalipso Chalkidou for constructive remarks on earlier drafts of the technical topics.

Abbreviations and acronyms

ACE	Angiotensin-converting enzyme
ACEI	Angiotensin-converting-enzyme inhibitors
AMNOG	Arzneimittelmarkt-Neuordnungsgesetz
ARV	Antiretroviral
ASL	Aziende Sanitarie Locali (local hospitals)
ATC	Anatomical Therapeutic Chemicals
CBA	Controlled Before-After
CDSR	Cochrane Database of Systematic Reviews
CEA	Cost-Effectiveness Analysis
CHC	Community Health Centre
CPB	Central Purchasing Bodies
CRD	Centre for Reviews and Dissemination
DARE	Database of Abstracts of Reviews of Effects
DDD	Defined Daily Dose
DID	Difference-in-Differences
DPCO	Drug Price Control Order
DRG	Diagnosis Related Group
DRP	Drug list Rearrangement Project
EPOC	Cochrane Effective Practice and Organisation of Care
ERP	External Reference Pricing
EU	European Union
GDP	Gross Domestic Product
GDR	Generic Dispensing Ratio
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GPRM	Global Price Reporting Mechanism
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
GRP	Generic Reference Pricing
HAI	Health Action International
HHI	Herfindahl-Hirschman Index
HIV	Human Immunodeficiency Virus
HMIC	Healthcare Management Information Consortium
HTA	Health Technology Assessment
IMSS	Mexican Social Security Institution
INN	International Non-proprietary Name
INRUD	International Network of Rational Use of Drugs
IPSA	International Political Science Abstracts
IRIS	International Repository for Information Sharing
IRP	Internal Reference Pricing
ITS	Interrupted Time Series
KRW	Korean Won
LILACS	Health information from Latin America and the Caribbean countries
LMIC	Low- and Middle-Income Countries

MEA	Managed Entry Agreement
MOH	Ministry of Health
MUR	Medicine use review
NGO	Non-Governmental Organization
NHSEED	NHS Economic Evaluation Database
NHI	National Health Insurance
NPS	National Patient Sample
NRCT	Non-randomized Controlled Trial
NSAIDS	Nonsteroidal Anti-Inflammatory Drugs
OECD	Organisation for Economic Co-operation and Development
OTC	Over-The-Counter
PAHO	Pan American Health Organization
PBS	Pharmaceutical Benefit Scheme
PMPM	Per Member Per Month
PPRI	Pharmaceutical Pricing and Reimbursement Information
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomized Controlled Trial
RM	Repeated Measures
RP	Reference Pricing
SEP	Single Exit Price
SF	Substandard or falsified (medical products)
SPS	Single Price System
TRP	Therapeutic Reference Pricing
UK	United Kingdom
URL	Uniform Resource Locator
USA	United States of America
USD	United States Dollar
VAT	Value-Added tax
VBP	Value-Based Pricing
VPP	Voluntary Pooled Procurement
WHO	World Health Organization
YHEC	York Health Economics Consortium
ZMPD	Zero Mark-up Drug Policy

1 Background

Pharmaceutical pricing policies are a set of written principles or requirements, agreed or adopted by a public institution (e.g. a government) or a group of purchasing organizations/individuals (e.g. health services), for managing the prices of pharmaceutical products. Governments in many countries have implemented pricing policies to ensure affordability of medicines to patients and healthcare systems.

In recent years, high prices of pharmaceutical products have posed challenges in high- and low-income countries alike. In many instances, high prices of pharmaceutical products have led to significant financial hardship for individuals and negatively impacted on healthcare systems' ability to provide population-wide access to essential medicines.

In view of these problems and the overall mission of the World Health Organization (WHO), WHO has mandates to support countries in ensuring that medicines are affordable, by providing policy guidance on pricing of pharmaceutical products, as requested by Member States. These mandates include:

- World Health Assembly (WHA) decision WHA71(8), which requested the Director-General to elaborate a road map report that outlines the programming of WHO's work on access to medicines and vaccines for the period 2019–2023. Guidance on pricing policy is one of the key milestones/deliverables specified in this road map: "policy guidance for more effective pricing policies to improve the affordability of essential health products to health systems and individuals";

- WHO 13th General Programme of Work includes various areas of work relating to pricing to improve access to medicines, vaccines and health products (i.e. fair pricing);

- WHO Regional Committees Resolutions relating to access to medicines have also noted the importance of having robust policies on the pricing of health products; and

- The United Nations (UN) Sustainable Development Goals (SDGs) recognise the importance of achieving universal health coverage, through "financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all" (SDG 3.8).

In 2015, WHO published a guideline on country pharmaceutical pricing policies ("2015 Guideline"). This guideline was developed based on an evidence review conducted in 2010. Since 2010, the body of literature documenting the effects of various government pricing policies has increased. To ensure the guideline recommendations reflect the current evidence base, WHO has commissioned this systematic review to provide an updated synthesis of the relevant evidence for the existing guideline, and to answer additional policy questions relating to pricing of pharmaceutical products.

1.1 Objectives

The overall objective of this review is to assess the effects of ten pharmaceutical pricing policies, implemented individually or in combination by an institution or a group of organizations, on price, volume, availability, and affordability of pharmaceutical products, to health systems and patients, with consideration to a set of prespecified less quantifiable outcomes and other contextual factors.

The specific objectives are:

- To the extent possible, estimate the effect size of pricing policy or policies on each prespecified outcome;
- To the extent possible, develop Grading of Recommendations, Assessment, Development and Evaluation (GRADE) evidence profiles for each research question, with a view to assessing the overall strength, direction and quality of the evidence; and
- To the extent possible, describe any practical and contextual considerations, based on an assessment of qualitative evidence pertaining to countries' experiences, that might impact the implementation of pricing policies.

1.2 Structure of the report

The report is structured in 13 sections, starting with a brief background section (the present section). Section 2 describes the search methodology in detail, as well as the overall results of the literature search in an aggregated form. Individual search results for the ten policy topics are then covered in individual sections, together with conclusions on individual topics: section 3 describes pooled procurement; section 4 describes value-based pricing; section 5 describes discounts for single-source pharmaceuticals; section 6 describes cost-plus pricing; section 7 describes tax exemptions or tax reductions for pharmaceuticals; section 8 describes interventions promoting the use of quality assured generic and biosimilar medicines; section 9 describes reference pricing; section 10 describes interventions promoting price transparency; section 11 describes mark-up regulation across the pharmaceutical supply and distribution chain; and section 12 describes tendering and negotiation. Finally a common bibliography to all reviews is presented in section 13. This is followed by detailed appendices on the search strategies and execution (appendix A), and a list of studies excluded with reasons at the full text level (appendix B).

2 Search methodology and results

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2.1 Introduction

The systematic reviews were undertaken according to the principles of systematic reviewing embodied in the Cochrane Handbook (*1*) and guidance document published by the Centre for Reviews and Dissemination (CRD) which offers approaches for a range of study designs beyond randomized clinical trials (RCTs) (*2*).

The systematic reviews on the ten pharmaceutical policies, identified based on the 2015 Guideline and through consultations with experts on pharmaceutical pricing internal and external to WHO, address the following two overall research questions:

1. Which pharmaceutical pricing policies are effective in managing the prices of pharmaceutical products, with consideration to their impacts on the volume, availability and affordability of these products?

2. What contextual factors and implementation strategies may influence the effects of a specific pricing policy?

There are ten eligible policies or strategies within the scope of this review, as defined in Table 2.1 (internal and external reference pricing are addressed under the umbrella term "reference pricing"). The review scope included studies comparing any of the eligible interventions against other interventions, options or strategies, or a counterfactual in the absence of comparator interventions, including historical comparisons. Single policies, or combinations of policies, were considered eligible. Studies not describing any comparator or counterfactual were not eligible for inclusion.

Table 2.1 Definitions of policy interventions

Term	Definition (from (*3*) unless otherwise stated)
Reference pricing	Reference pricing, also known as benchmark pricing, refers to the approach of understanding the appropriateness of prices of medicines based on selected benchmark prices, either from other jurisdictions (e.g. countries or other administrative regions) or a group of comparable medicines in the same system/formulary.
External reference pricing	External reference pricing (ERP; also known as international reference pricing) refers to the practice of using the price of a pharmaceutical product (generally ex-manufacturer price, or other common point within the distribution chain) in one or several countries to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country. Reference may be made to single-source or multisource supply products (*4*)

Internal reference pricing	The practice of using the prices of identical medicines (ATC 5 level) or similar products (ATC 4 level) or even with therapeutic equivalent treatment (not necessarily a medicine) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country.
Value-based pricing	Countries set prices for new medicines and/or decide on reimbursement based on the therapeutic value the medicines confer, usually assessed through health technology assessment (HTA).
Cost-plus pricing	Pricing policy that takes into account production costs, promotional expenses, research & development, administration costs, overheads and a profit to determine a price.
Mark-up regulation across the pharmaceutical supply and distribution chain	Setting price thresholds means specifying maximum prices, also referred to as price caps or price ceilings, or specifying maximum mark-up percentages. A mark-up represents the additional charges and costs that are applied to the price of a commodity in order to cover overhead costs, distribution charges, and profit. In the context of the pharmaceutical supply chain, policies might involve regulation of wholesale and retail mark-ups as well as pharmaceutical remuneration.
Promoting price transparency	The sharing, disclosure and dissemination of information related to medicine prices to the public and relevant parties to ensure accountability. Full price transparency includes the publication of medicine prices at all price types (e.g. ex-factory prices, pharmacy retail prices), the disclosure of the net transaction prices of medicines between the suppliers (e.g. manufacturers, service providers) and the payers/purchasers (governments, consumers), the sharing and publication of the contents of pricing arrangements, such as risk-sharing schemes and other managed-entry agreements, including the actual pricing and input factors that determine a medicines prices (e.g. production costs, R&D costs, added therapeutic value). (adapted from (*5*))
Price discounts for single source pharmaceuticals	Discount is the general term to describe a price reduction granted to specified purchasers under specific conditions prior to purchase. Different types of price reductions include a rebate (payment made to the purchaser after the transaction has occurred), or upon meeting certain pre-agreed terms and conditions as specified in so-called managed-entry agreements. The latter arrangements are usually classified into financial-based MEA (e.g. flat discounts, price-volume agreements, capping) and performance-based MEA (e.g. risk-sharing agreement, coverage with evidence development). Single source pharmaceuticals are pharmaceutical products supplied by a company that holds the patent rights, exclusive marketing rights, or supply agreements in a specific jurisdiction.
Promoting the use of quality assured generic and biosimilar medicines	Strategies directed at patients, prescribers or pharmacists to encourage the use of generic or similar biological medicines.
Tendering and negotiation	An approach that determines prices through tendering or negotiation among suppliers of medicines that are identical or comparable in chemical composition, pharmacological mechanisms and therapeutic use, taking into account factors such as quality and supply conditions. Tendering is any formal and competitive procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous. Negotiation refers to "discussion aimed at reaching an agreement" (*6*)

Pooled procurement	Pooled procurement refers to the arrangement where financial and non-financial resources are combined across various purchasing authorities to create a single entity for purchasing health products (e.g. medicines) on behalf of the individual purchasing authorities (*5*)
Tax exemptions or tax reductions for pharmaceuticals	Tax is a compulsory transfer of money from private individuals, institutions or groups to the government. It may be levied upon wealth or income (direct taxation) or in the form of surcharges on prices (indirect taxation). It may be paid to the central government (central taxation) or to the local government (local taxation). There are two main categories of tax: direct taxes, which are levied by governments on the income of individuals and corporations, and indirect taxes, which are added to the prices of goods and services. Direct taxes, along with social security taxes, generally make up about two-thirds of total government revenue in high-income countries. In low-income countries, indirect taxes, on international trade or on the purchase of goods and services, are major sources of government revenue. Policies relevant to pharmaceutical products might involve the reduction of taxes on medicines, or the exemption of medicines from taxes, particularly sales taxes (*4*)

2.2 Search strategies

The search strategy was developed as a single strategy addressing all ten topics of the review. The strategy was initially developed in MEDLINE syntax and subsequently translated to other databases, as detailed further below.

A MEDLINE (OvidSP) search strategy was designed to identify eligible studies and is presented in Figure 2.1 (all strategies are reported in Appendix A).

The main structure of the search strategy (simplified) comprised 12 concepts:

- non-specific pharmaceutical pricing policies (search lines 1 - 29)
- pharmaceuticals (search line 30)
- reference pricing (search lines 31 - 35)
- value-based pricing (search lines 36 – 42)
- cost-plus pricing (search lines 43 – 49)
- setting a price threshold / regulation of mark-ups in the pharmaceutical supply and distribution chain (search lines 50 – 61)
- promoting price transparency (search lines 62 - 71)
- pooled procurement (search lines 72 - 78)
- price discounts for single source pharmaceuticals (search lines 79 - 83)
- competitive pricing based on tendering and negotiation (search lines 84 - 93)

- tax exemptions or tax reductions for pharmaceuticals (search lines 94 - 103)

- promoting the use of quality assured generic and biosimilar medicines (search lines 105 - 109)

The concepts were combined (simplified) as follows:

(non-specific pharmaceutical pricing policies) OR

(pharmaceuticals AND (reference pricing OR value-based pricing OR cost-plus pricing OR setting price a threshold / regulation of mark-ups in the pharmaceutical supply and distribution chain OR promoting price transparency OR pooled procurement OR price discounts for single source pharmaceuticals OR competitive pricing based on tendering and negotiation OR tax exemptions / tax reductions for pharmaceuticals)) OR

(promoting the use of quality assured generic and biosimilar medicines).

The strategy excluded animal studies from MEDLINE using a standard algorithm (search line 111). The strategy also excluded some publication types that are unlikely to yield relevant study reports (editorials, news items and letters) (search line 112). The strategy was restricted to studies published from 2004 to date. The strategy was not restricted by language.

Figure 2.1 Search strategy for Ovid MEDLINE(R)ALL

1 Drugs, Essential/ec (279)
2 Drugs, Essential/ and (pricing or price or prices or priced or cost$ or economic$ or pharmacoeconomic$).ti,ab,kf. (275)
3 1 or 2 (378)
4 Drug Costs/ (15469)
5 Economics, Pharmaceutical/ (2886)
6 Drug Prescriptions/ec (2860)
7 Prescription Drugs/ec (1216)
8 fees, pharmaceutical/ or prescription fees/ (2368)
9 Drug Substitution/ec (170)
10 Insurance, Pharmaceutical Services/ec (1349)
11 Drug Approval/ec or exp Pharmaceutical preparations/ec or exp vaccines/ec or Biological Products/ec or Drugs, Generic/ or Biosimilar Pharmaceuticals/ (16705)
12 Reimbursement Mechanisms/ and (Drug Industry/ or Drug Approval/ or Legislation, Drug/ or "Drug and Narcotic Control"/) (211)
13 Commerce/ and (Drug Industry/ or Drug Approval/ or Legislation, Drug/ or "Drug and Narcotic Control"/) (1609)
14 "Cost Control"/ and (Drug Industry/ or Drug Approval/ or Legislation, Drug/ or "Drug and Narcotic Control"/) (458)
15 Commerce/ and (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic$ or vaccine$1 or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$).ti,ab,kf. (3124)

16 "Cost Control"/ and (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic$ or vaccine$1 or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$).ti,ab,kf. (2543)
17 or/4-16 (39602)
18 (pricing or price or prices or priced).ti,ab,kf. (37679)
19 (policy or policies or arrangement$1 or framework$1 or frame-work$1 or intervention$1 or law or laws or legal$ or legislat$ or measure or measures or measurement or measurements or mechanism$1 or order or orders or plan or plans or planning or principle or principles or procedure$1 or program or programme or programmes or programs or regulat$ or requirement$1 or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic$).ti,ab,kf. (9665806)
20 17 and 18 and 19 (3186)
21 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine$1) and pricing).ti. (619)
22 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine$1) adj6 pricing).ab,kf. (926)
23 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine$1) and (price or prices or priced)).ti. (1391)
24 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine$1) and ((pricing or price or prices or priced) adj6 (policy or policies))).ab,kf. (430)25 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine$1) and ((pricing or price or prices or priced) adj3 (arrangement$1 or framework$1 or frame-work$1 or intervention$1 or law or laws or legal$ or legislat$ or measure or measures or measurement or measurements or mechanism$1 or order or orders or plan or plans or planning or principle or principles or procedure$1 or program or programme or programmes or programs or regulat$ or requirement$1 or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic$))).ab,kf. (825)
26 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine$1) and (price regulation$1 or price difference$1 or price differential$ or price dispersion or average price$1 or retail price$1 or wholesale price$1 or expected price$1 or net price$1 or transaction price$1 or price type$1 or price component$1 or cif price$1 or freight price$1 or pharmacy price$1 or pharmacist$ price$1 or end price$1 or consumer price$1 or final price$1 or reimbursement price$1 or list price$1 or actual price$1)).ab,kf. (1106)
27 or/21-26 (4018)
28 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic$ or vaccine$1 or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$) and (cost-control or cost-containment or cost-setting)).ti,ab,kf. (1380)

29 3 or 20 or 27 or 28 (7233)
30 (or/4-14) or Drugs, Essential/ or (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic$ or vaccine$1 or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$).ti,ab,kf. (2588239)
31 (reference adj6 (pricing or price or prices or priced)).ti,ab,kf. (514)
32 ((benchmark$ or bench-mark$) adj6 (pricing or price or prices or priced)).ti,ab,kf. (53)
33 (international price adj (comparison$ or comparat$)).ti,ab,kf. (13)
34 (factory$ price$1 or manufacturer$ price$1 or exfactory$ price$1 or exmanufacturer$ price$1).ti,ab,kf. (82)
35 or/31-34 (636)
36 Technology Assessment, Biomedical/ and (17 or Drugs, Essential/) (262)
37 (value-based and (pricing or price or prices or priced)).ti,ab,kf. (288)
38 (value-based and reimbursement).ti,ab,kf. (454)
39 ((value or values) adj6 (pricing or price or prices or priced)).ti,ab,kf. (885)
40 ((hta or htas or technology assessment$ or technology appraisal$) and (pricing or price or prices or priced)).ti,ab,kf. (379)
41 ((economic evaluation$ or cost-consequence$ or cost-minimization or cost-minimisation or cost-effectiveness or cost-utility or cost-benefit$) and (pricing or price or prices or priced) and (based or set or sets or setting)).ti,ab,kf. (1825)
42 or/36-41 (3494)
43 (cost-plus or costplus or costs-plus or costsplus).ti,ab,kf. (151)
44 (((cost or costs) adj3 based) and (pricing or price or prices or priced)).ti,ab,kf. (722)
45 (((cost or costs) adj3 (produc$ or promot$ or expense$ or research$ or develop$ or administrat$ or overhead$ or over-head$ or profit$1)) and (pricing or price or prices or priced)).ti,ab,kf. (1439)
46 (((expense or expenses) adj3 (produc$ or promot$ or research$ or develop$ or administrat$ or overhead$ or over-head$ or profit$1)) and (pricing or price or prices or priced)).ti,ab,kf. (44)
47 ((pricing or price or prices or priced) adj3 (set or sets or setting)).ti,ab,kf. (519)
48 ((pricing or price or prices or priced) adj3 (control$ or containment)).ti,ab,kf. (621)
49 or/43-48 (3264)
50 ((pricing or price or prices or priced) adj6 threshold$).ti,ab,kf. (136)
51 ((pricing or price or prices or priced) adj6 maximum$).ti,ab,kf. (175)
52 ((pricing or price or prices or priced) adj6 (cap or caps or capped or capping or ceiling$)).ti,ab,kf. (146)
53 (mark-up$1 or markup$1).ti. (187)
54 ((mark-up$1 or markup$1) adj3 control$).ab,kf. (8)
55 ((mark-up$1 or markup$1) and (regulat$ or manipulat$ or supply or supplies or distribut$ or wholesale$ or prescrib$ or prescrip$ or dispens$ or pricing or price or prices or priced or cost$ or economic$ or pharmacoeconomic$)).ab,kf. (389)
56 ((supply chain$ or distribution) adj cost$).ti,ab,kf. (101)
57 ((supply chain$ or distribution) adj6 (pricing or price or prices or priced)).ti,ab,kf. (231)
58 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription

or prescriptions or generic$ or vaccine$1 or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$) adj6 margin$1).ti,ab,kf. (501)
59 (profit margin$1 or gross margin$1).ti,ab,kf. (598)
60 (cost-price$1 or purchase-price$1 or purchasing-price$1 or selling price$1).ti,ab,kf. (700)
61 or/50-60 (3004)
62 Disclosure/ and (17 or Drugs, Essential/) (84)
63 ((pricing or price or prices or priced or discount$ or rebate$1) adj6 (publish$ or publication)).ti,ab,kf. (301)
64 ((pricing or price or prices or priced or discount$ or rebate$1) adj6 (disclos$ or disseminat$ or communicat$ or shar$)).ti,ab,kf. (508)
65 ((pricing or price or prices or priced or discount$ or rebate$1) and (transparen$ or accountab$)).ti,ab,kf. (883)
66 (((publish$ or publication or disclos$ or disseminat$ or communicat$ or shar$) adj6 information$1) and (pricing or price or prices or priced or discount$ or rebate$1)).ti,ab,kf. (271)
67 managed entry.ti,ab,kf. (71)
68 (("access with evidence development" or conditional coverage or conditional treatment continuation or "coverage with evidence development" or "only in research" or "only with research" or outcome guarantee$1 or patient access scheme$1 or patient access agreement$1 or patient access arrangement$1 or "pattern or process care" or performance-based agreement$1 or performance-based scheme$1 or performance-based arrangement$1 or performance-based health outcome reimbursement or performance-linked reimbursement or price volume agreement$1 or price volume arrangement$1 or price volume scheme$1) adj6 (publish$ or publication or disclos$ or disseminat$ or communicat$ or shar$)).ti,ab,kf. (11)
69 (risk sharing scheme$1 or risk sharing agreement$ or risk sharing arrangement$1).ti,ab,kf. (183)
70 (("access with evidence development" or conditional coverage or conditional treatment continuation or "coverage with evidence development" or "only in research" or "only with research" or outcome guarantee$1 or patient access scheme$1 or patient access agreement$1 or patient access arrangement$1 or "pattern or process care" or performance-based agreement$1 or performance-based scheme$1 or performance-based arrangement$1 or performance-based health outcome reimbursement or performance-linked reimbursement or price volume agreement$1 or price volume arrangement$1 or price volume scheme$1) and (transparen$ or accountab$)).ti,ab,kf. (18)
71 or/62-70 (2173)
72 (pool$ adj6 (procur$ or purchas$)).ti,ab,kf. (149)
73 (joint$ adj6 (procur$ or purchas$)).ti,ab,kf. (105)
74 (group$ adj3 (procur$ or purchas$)).ti,ab,kf. (774)
75 ((share or shares or sharing or shared) adj6 (procur$ or purchas$)).ti,ab,kf. (256)
76 (collectiv$ adj6 (procur$ or purchas$)).ti,ab,kf. (36)
77 (combin$ adj6 (procur$ or purchas$)).ti,ab,kf. (200)
78 or/72-77 (1478)
79 ((pricing or price or prices or priced) adj6 (discount$ or reduction$1)).ti,ab,kf. (1265)
80 ((pricing or price or prices or priced) and rebate$1).ti,ab,kf. (168)
81 flat discount$.ti,ab,kf. (1)
82 (("access with evidence development" or conditional coverage or conditional treatment continuation or "coverage with evidence development" or "only in research" or "only with research" or outcome guarantee$1 or patient access scheme$1 or patient access agreement$1 or patient access

arrangement$1 or "pattern or process care" or performance-based agreement$1 or performance-based scheme$1 or performance-based arrangement$1 or performance-based health outcome reimbursement or performance-linked reimbursement or price volume agreement$1 or price volume arrangement$1 or price volume scheme$1) and (discount$ or reduction$1 or rebate$1)).ti,ab,kf. (71)
83 or/79-82 (1430)
84 Drug Industry/ and (Economic Competition/ or Competitive Bidding/ or Contract Services/) (684)
85 (competitive adj (pricing or price or prices)).ti,ab,kf. (136)
86 ((pricing or price or prices or priced or purchas$) and (tender or tenders or tendering or tendered)).ti,ab,kf. (175)
87 ((pricing or price or prices or priced or purchas$) adj6 (bid or bids or bidder$1 or bidding)).ti,ab,kf. (129)
88 ((pricing or price or prices or priced or purchas$) adj6 negotiat$).ti,ab,kf. (529)
89 ((pricing or price or prices or priced or purchas$) adj3 (discuss$ or agree$)).ti,ab,kf. (348)
90 ((pricing or price or prices or priced or purchas$) adj6 (offer or offers or offered or offering)).ti,ab,kf. (590)
91 ((pricing or price or prices or priced or purchas$) and procur$).ti,ab,kf. (688)
92 (preferential adj3 (pricing or price or prices or priced)).ti,ab,kf. (19)
93 or/84-92 (3072)
94 Drug Costs/ and exp Taxes/ (32)
95 ((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) adj6 (reduc$ or exempt$ or remov$)).ti,ab,kf. (2225)
96 (((duty or duties) adj6 (reduc$ or exempt$ or remov$)) and (pricing or price or prices or priced)).ti,ab,kf. (5)
97 ((duty or duties) adj3 (reduc$ or exempt$ or remov$)).ti,ab,kf. (291)
98 ((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) adj3 free).ti,ab,kf. (198)
99 ((duty or duties) adj3 free).ti,ab,kf. (58)
100 ((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) adj6 (policy or policies or arrangement$1 or framework$1 or frame-work$1 or intervention$1 or law or laws or legal$ or legislat$ or measure or measures or measurement or measurements or mechanism$1 or order or orders or plan or plans or planning or principle or principles or procedure$1 or program or programme or programmes or programs or regulat$ or requirement$1 or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic$)).ti,ab,kf. (4283)
101 (((duty or duties) adj6 (policy or policies or arrangement$1 or framework$1 or frame-work$1 or intervention$1 or law or laws or legal$ or legislat$ or measure or measures or measurement or measurements or mechanism$1 or order or orders or plan or plans or planning or principle or principles or procedure$1 or program or programme or programmes or programs or regulat$ or requirement$1 or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic$)) and (pricing or price or prices or priced)).ti,ab,kf. (19)
102 ((prescription$ adj3 charge$) and (pricing or price or prices or priced or cost$)).ti,ab,kf. (56)
103 or/94-102 (6415)
104 30 and (35 or 42 or 49 or 61 or 71 or 78 or 83 or 93 or 103) (6937)
105 (Drugs, Generic/ or Biosimilar Pharmaceuticals/) and (Drug Utilization/ or Cost-Control/) (394)
106 ((generic$ or non-proprietary or nonproprietary or INN or tier 1 or tier1 or tier one or off-patent$ or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$) and (pricing or price or prices or priced)).ti,ab,kf. (1647)

107	((generic$ or non-proprietary or nonproprietary or INN or tier 1 or tier1 or tier one or off-patent$ or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$) and (cost-saving$ or cost-shar$)).ti,ab,kf. (573)
108	((generic$ or non-proprietary or nonproprietary or INN or tier 1 or tier1 or tier one or off-patent$ or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$) and (prescribing-cost$ or prescription-cost$ or dispensing-cost$)).ti,ab,kf. (79)
109	or/105-108 (2390)
110	29 or 104 or 109 (12385)
111	exp animals/ not humans/ (4615097)
112	(news or editorial or letter).pt. (1738229)
113	110 not (111 or 112) (11473)
114	limit 113 to yr="2004 - 2019" (8302)

Key to Ovid symbols and commands:

$	Unlimited right-hand truncation symbol
$N	Limited right-hand truncation - restricts the number of characters following the word to N
ti,ab,kf	Searches are restricted to the Title, Abstract and Keyword Heading Word, fields
adjN	Retrieves records that contain terms (in any order) within a specified number (N) of words of each other
/	Searches are restricted to the Subject Heading field
exp	The subject heading is exploded
*	The subject heading is searched as a major descriptor only
or/1-3	Combines sets 5 to 33 using OR

Table 2.2 shows the resources searched for the review.

Table 2.2 Resources searched

Database / information source	Interface / URL	Coverage
Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily	OvidSP	Biomedical and healthcare journal literature
Embase	OvidSP	Biomedical and pharmaceutical journal literature
Cochrane Database of Systematic Reviews (CDSR)	Cochrane Library / Wiley	Healthcare systematic reviews
Epistemonikos	https://www.epistemonikos.org/en/	Healthcare systematic reviews
Database of Abstracts of Reviews of Effects (DARE)	CRD Database	Systematic reviews that evaluate the effects of health and social care interventions and the delivery and organisation of health and social care services
Health Technology Assessment (HTA) Database	CRD Database	Completed and ongoing health technology assessments

Social Science Citation Index	Web of Science	Multidisciplinary social science journal literature
LILACS	http://lilacs.bvsalud.org	Latin American & Caribbean Health Sciences Literature
EconLit	OvidSP	Economic literature. Includes journals, dissertations and working papers
NHS Economic Evaluation Database (NHS EED)	CRD Database	Economic evaluations of health care interventions
INRUD (International Network for Rational Use of Drugs) Bibliography	https://www.zotero.org/groups/659457/inrud_biblio/items	Database of published and lished articles, books reports and other documents focusing on rational use of medicines, mainly in developing countries
OECD iLibrary Books (freely accessible content only)	OECD iLibrary	OECD iLibrary is the online library of the Organisation for Economic Cooperation and Development (OECD). Themes include economics and health. Includes monographs, series publications, conference proceedings, policy reviews, guidelines and manuals, reference books, statistical annuals and outlooks
International Political Science Abstracts (IPSA)	Sage	Abstracts of articles in the field of political science published in journals
WHO IRIS (Institutional Repository for Information Sharing)	https://apps.who.int/iris/	Database of WHO documentation
World Bank Documents & Reports	http://documents.worldbank.org/curated/en/home	Database of publically available World Bank documents. Includes formal publications and working papers.
World Bank Open Knowledge Repository	https://openknowledge.worldbank.org/	World Bank's repository for its open access research and knowledge products
World Bank eLibrary (freely accessible content only)	https://elibrary.worldbank.org/	Contains the full collection of all World Bank publications and research. Some content is only available to subscribers.
IDEAS	https://ideas.repec.org/	Economic database based on RePEc (Research Papers in Economics). Includes working papers and journal articles
Essential Medicines and Health Products Information Portal (WHO)	https://apps.who.int/medicinedocs/en/	WHO portal for articles related to essential medicines and health products
Open Grey	http://www.opengrey.eu/	Database of grey literature
Global Index Medicus	http://www.globalhealthlibrary.net/php/index.php)	Database of literature produced by and within low- and middle- income countries

In addition to searching the above resources, we also carried out the following supplementary search activities to identify any additional eligible studies that may not have been retrieved by the database searches:

- Targeted searches of the following webpages:
  - Organisation for Economic Co-operation and Development (OECD) Social Issues Migration Health webpages: https://www.oecd-ilibrary.org/social-issues-migration-health;
  - Department of International Development (UK) website: https://www.gov.uk/government/organisations/department-for-international-development;
  - Health Action International (HAI) Publications webpage: http://haiweb.org/publications-page/; http://www.haiweb.org/medicineprices/;
  - Health Action International (HAI) Medicines Prices webpage: http://www.haiweb.org/medicineprices/;
  - MI4A Market Information for Access to Vaccines webpage: https://www.who.int/immunization/programmes_systems/procurement/v3p/platform/en/;
  - WHO Collaborating Centre for Pricing and Reimbursement Policies webpage: https://ppri.goeg.at/publications;
  - European Observatory on Health Systems and Policies webpage: http://www.euro.who.int/en/about-us/partners/observatory/publications/policy-briefs-and-summaries;
  - EC initiatives in pricing and reimbursement webpage: https://ec.europa.eu/growth/sectors/healthcare/competitiveness/products-pricing-reimbursement/initiatives_en; and
  - European Commission DG Sanco webpage: https://ec.europa.eu/health/human-use_en.
- Checking the reference lists of any included study and relevant systematic reviews published in the last five years.
- Expert contact (including the independent review panel and references from GDG members reviewing the reports).

Reviewers at Utrecht University and WHO carried out searches in the following resources based on instructions provided by the YHEC team:

- IDEAS
- Essential Medicines and Health Products Information Portal (WHO)
- Open Grey
- World Bank Documents & Reports
- World Bank Open Knowledge Repository

A WHO consultant information specialist also performed a limited search for evaluation reports of specific pricing policies within the scope of this review, published on the website of individual jurisdictional governments (Table 2.3). The same screening criteria and process, as specified in the following sections, was applied to assess the relevance and eligibility of the reports.

Table 2.3 Complementary search for grey literature

Organization type	Description
Jurisdictional government	AFR: South Africa, Botswana, Rwanda, Tanzania, Kenya, Zambia, Ethiopia, AMR: Costa Rica, Colombia, Mexico, Jamaica, Barbados, Chile, Dominica, Cuba, Dominican Republic, EMR: Saudi Arabia, UAE, Morocco, Oman, Qatar EUR: Israel, Slovenia, Croatia, Czech Republic, Malta, Andorra, Monaco, San Marino, Finland, Austria, Germany, France, Switzerland, Luxembourg, Netherlands, Iceland, Spain, Portugal, Italy, Greece, Ireland, Belgium SEAR: Thailand, India, United Kingdom WPR: Australia, Taiwan province of China, Hong Kong, China, New Zealand, Singapore, Malaysia, Japan
UN or international organizations	UNICEF, UNDP, ICRC/IFRC, USAID, OFDA, DANIDA
Think tanks	RAND Drug Policy Research Center, Global Initiative for Drug Policy Reform, Brookings Center for Health Policy, Global Commission on Drug Policy, Centre for Global Development

The grey literature was primarily searched using advanced searching techniques such as limiting to specific governmental and organizational domains, such as site:gc.ca "pharmaceutical pricing" for the Canadian government, or site:undp.org pharmaceutical pricing policy for UNDP. Where appropriate, exact phrase searches were used to increase focus (search terms enclosed in quotation marks, as in the Canadian example), while other searches were left open without quotation marks (e.g. UNICEF). All searches were limited to PDF file type (for example, site:gov.uk generic drug policy filetype:pdf) as this focuses the search on documents, rather than blogs, press releases, or general web content. Search results were scanned for relevance in the order returned until no relevant results were found on 2 consecutive results pages.

Google Translate was used to generate non-English search terms, and Google's search results translation service was used for translating non-English search results to English to the extent possible. For some languages (Malay for example), the results pages were copied and pasted into Google Translate directly because Google did not detect the language to translate from.

2.3 Running the searches and downloading results

We conducted searches using each database or resource listed above, translating the agreed Ovid MEDLINE strategy appropriately. Translation included consideration of differences in database interfaces and functionality, in addition to variation in indexing languages and thesauri. The searches were conducted between 05/09/2019 and 21/10/2019. Appendix A contains the full strategies (including search dates) for all sources searched.

Where possible, we downloaded the results of searches in a tagged format and loaded them into bibliographic software (EndNote) (*7*). The results were deduplicated using several algorithms and the duplicate references held in a separate EndNote database for checking if required. Results from resources that did not allow exporting in a format compatible with EndNote were saved in Word or Excel documents as appropriate and manually deduplicated.

2.4 Study selection

The record assessment involved a number of stages:

- A single researcher assessed the search results according to their relevance in providing information on the review, and removed the obviously irrelevant records based on titles and abstracts such as those that were about treatment effectiveness rather than pricing policy. This was undertaken within Endnote. Records were tagged as included/excluded if excluded at the title/abstract stage.
- The titles and abstracts of potentially eligible records were assessed for relevance against the protocol criteria by double independent reviewer selection with disagreements adjudicated by a third reviewer. This was undertaken within Covidence (*8*). Covidence allowed record tagging which meant at this stage we made an initial categorization of the studies according to the review question they informed. Once completed we went back and tagged the EndNote library with the include/exclude decisions and grouped records within EndNote by exclusion reason.
- We obtained the full text of potentially relevant studies and these were assessed for relevance against the protocol criteria by double independent reviewer selection with disagreements adjudicated by a third reviewer. This was undertaken in Covidence. Studies were tagged by the review question they informed, so that they could be grouped for assessment at the next stage.
- Full texts were then subjected to a second eligibility check before data extraction by Utrecht University, and further full texts found to be ineligible were excluded at this stage.

The use of a single search strategy meant references excluded at title/abstract level could not be reported per review topic. Similarly, an initial screening and categorization of full texts obtained for eligibility assessment was undertaken by YHEC, and details of these full texts are not reported per review topic. The second and detailed full text screening was undertaken by Utrecht University, and details of full texts excluded at this stage, along with reasons for exclusion, are reported for each review topic in relevant sections.

We recorded the number of records included and removed at each stage in a PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram (see section 2.9). Studies excluded after assessment of the full document for each review are listed in a table with the reason for exclusion for each reference (see annex B).

We obtained electronic or paper copies of potentially relevant full papers either free of charge on the internet, via Utrecht University or via WHO.

2.5 Eligibility criteria

A pharmaceutical product, commonly referred interchangeably with drug, medicine or pharmaceutical, is defined as any manufactured or refined substance for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient (adapted from WHO glossary[1]). For the purpose of this review, the scope includes medicines (both small molecules and biological products) and vaccines for human use.

[1] WHO. WHO glossary [Internet]. Available from: ttps://www.who.int/medicines/areas/coordination/English_Glossary.pdf

Studies reporting the following primary outcomes were eligible for inclusion: price (or expenditure as a proxy), volume, availability, affordability. Studies reporting the primary outcomes were also assessed for information on any secondary outcome: transparency, system efficiencies, and adverse outcomes (shortages, quality issues, safety issues, unethical conduct, illegal conduct, equity). Definitions of the primary and secondary outcomes are listed in Table 2.4 and Table 2.5, respectively.

Table 2.4 Definitions of primary outcomes

Term	Operational definition	Measurement unit
Price	Price components, observed or derived, along the value chain from manufacturer, distributor or service providers to patients	Absolute or percentage changes in reported currency unit(s) or price indices. Expenditure or sales data (aggregate of price and volume) as a proxy for price and volume if these are not individually reported.
Volume	Quantity provided or used	Number of units sold, supplied, prescribed, dispensed, or consumed
Availability	A patient is able to obtain when needed, for free or for a fixed fee, a pharmaceutical product which is listed on the national formulary	Presence-absence binary measurement and qualitative assessment as reported, e.g. a medicine is available when it is found in this facility by the data collector on the day of the visit
Affordability	"the ability to purchase a necessary quantity of a product or level of a service without suffering undue financial hardship" World Bank cited by Lancet Commission on Essential Medicines (*9*,*10*)	For health system: Proportion of spending on medicines compared to historical expenditure on medicines or other health products and services, or as reported in the literature For individual patients: The number of days' wages needed to pay for the cost of treatment, using wage benchmarks such as salary of the lowest paid government worker and national minimum wage, or as reported in the literature

Table 2.5 Definitions of secondary outcomes

Term	Operational definition	Measurement unit
Transparency	See price transparency above in Table 2.1.	Qualitative description, as presented in literature
Efficiency	Agency for Healthcare Research and Quality definition: Avoiding waste, including waste of equipment, supplies, ideas, and energy. Allocative efficiency: Allocating resources in such a way as to provide the optimal mix of goods and services to maximise the benefits to society Technical efficiency: Using the least amount of resources or the right combination of inputs to produce a given mix of goods and services	As measured and presented in literature or qualitative description, as presented in literature Qualitative measures of process efficiency, e.g. timeliness, resource-intensiveness
Shortage	European Medicines Agency definition: a shortage of a medicinal product occurs when there are changes to either demand or supply of the medicine, so that clinical need can no longer be met. A medicine shortage causes temporary unavailability. The total stock across all levels of the national	As measured and presented in literature or qualitative description, as presented in literature

	supply chain, across all geographical regions, cannot meet demand during a medicine shortage	
Quality of pharmaceutical products	Whether products are substandard or falsified (SF) WHO's definitions: Substandard: Also called "out of specification", these are authorized medical products that fail to meet either *internationally accepted* quality standards or specifications, or both. Falsified: Medical products that deliberately/fraudulently misrepresent their identity, composition or source.	Occurrence of SF products
Safety	Institute of Medicine definition: the prevention of harm to patients	As measured and presented in literature
Unethical conduct	Business or professional conduct that contravenes social norms or social responsibilities	Qualitative description, as presented in literature
Illegal conduct	Business or professional conduct that contravenes the law	Qualitative description, as presented in literature
Equity	Differences in [access or] health that are avoidable and also considered unfair or unjust	Qualitative assessment, including assessing differences in the relative effect size of the intervention; assessing indirectness of evidence to disadvantaged populations and/or settings.

Studies conducted in any country or jurisdiction (e.g. administrative regions) were eligible. A subgroup of interest was studies that focus on low and middle income countries (LMIC's). Outcomes in both public, private and mixed public-private settings were of interest.

Publications published in the last 15 years (2004 to 2019) were eligible for inclusion.

Searches and screening were conducted without language restriction. Non-English literature was considered based on the same screening criteria. Abstracts and full texts in non-English languages were assessed by native speakers from within the project team or WHO.

The following study designs comparing interventions to at least one comparator or counterfactual were eligible:

- randomized trial
- non-randomized trial
- observational studies, including:
    - cohort studies or panel data analysis
    - comparative time series design, including interrupted time series (ITS) and repeated measures (RM) study
    - controlled before-after study

Study designs were categorized based on the methods presented, rather than solely the description provided by the authors. Study designs encountered during the search which were compatible with the designs above were also included, such as difference-in-difference analyses.

Existing systematic reviews on relevant pharmaceutical pricing policies and their findings were not directly extracted or incorporated into the current systematic reviews because of potential differences in scope and methodology. However relevant systematic reviews published in the last five years were incorporated in the reference checking process, and where relevant cited in the discussion sections of the present review.

The inclusion and exclusion criteria for the review are summarized in Table 2.6

Table 2.6 Summary of inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Intervention	Ten pharmaceutical pricing policy interventions, as specified and defined in Table 2.1	Studies without one of the ten prespecified policy interventions
Outcome	Studies including price, volume, availability or affordability as primary outcome	Studies without one of the four primary outcomes
Study design	Randomized trial, non-randomized trial, and observational studies with at least one comparator or counterfactual	All other study designs that do not include at least one comparator or specifying a counterfactual. These include case series.
Countries	All countries	None
Settings	All settings	None
Time period	2004-2019 (publication date)	Studies with publication date before 1 January 2004
Language	All languages	None

2.6 Data collection and analysis

Data from included studies was extracted using a standard data extraction form, including information on study details, population/setting/subjects, interventions, outcomes and results. The data extraction form was based on a template from the Cochrane Consumers and Communication Group and incorporated elements of the Cochrane Effective Practice and Organisation of Care (EPOC) data extraction guidance (*11*). The data extraction form was piloted in one review topic before proceeding to full data extraction.

For each study topic, one researcher extracted data, and the extraction was checked by a second researcher. Risk of bias was assessed according to the EPOC guidelines (*12*) by the extracting researcher, and checked by a second researcher.

2.7 Risk of bias assessment

Due to the nature of pricing policies, i.e. often jurisdiction-wide and openly reported, we expected to find very few RCTs. Rather, we anticipated most studies to be observational: cohort studies, panel data analysis, controlled before-after (CBA), interrupted time series (ITS) and repeated measures (RM) studies.

Bias assessment criteria were adapted to study design (randomized-, non-randomized trials and controlled before-after studies assessed in the same way; interrupted time-series and repeated measures studies assessed in the same way; and a set of assessment criteria applied to all study types). Any RCTs identified were assessed with the risk of bias tool for RCTs described in the Cochrane Handbook for Systematic

Reviews of Interventions (*1*). This tool recommends the explicit reporting of the following elements: random sequence generation; allocation sequence concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data, selective outcome reporting; and funding/sponsorship.

Observational studies were assessed using the guidance given by Cochrane EPOC (*12*). This guidance considers two groupings of observational studies:

- Observational studies with a control group: Non-randomized trials and controlled before-after studies. EPOC recommends to use a subset of the RCTs criteria as described in Chapter 8 of the Cochrane Handbook. Additionally, it is recommended to assess whether baseline outcome measurements are similar, whether baseline characteristics are similar, and whether the study was adequately protected from contamination.
- Interrupted time-series and Repeated Measures: EPOC recommends to use a subset of the RCT criteria as described in Chapter 8 of the Cochrane Handbook, and in addition the following items: if the intervention was independent of other changes; if the shape of the intervention effect was pre-specified; and if the intervention affected data collection.

Two researchers assessed risk of bias, resolving conflicts through discussion. An explanation of the bias domains is presented in Table 2.7.

2.8 Data synthesis and analysis

Summary tables according to the EPOC Worksheets for preparing a Summary of Findings table (SoF) using GRADE (*13*) were generated for individual interventions and sub-interventions, summarizing the strength of evidence for each outcome.

Table 2.7 Risk of bias domains

Bias domain	Explanation
Random sequence generation	"Low risk" if a random component in the sequence generation process is described (e.g. referring to a random number table). "High risk" when a non-random method is used (e.g. performed by date of admission). Non-randomised trials and controlled before-after studies should be scored "High risk". "Unclear risk" if not specified in the paper.
Allocation concealment	"Low risk" if the unit of allocation was by institution, team or professional and allocation was performed on all units at the start of the study; or if the unit of allocation was by patient or episode of care and there was some form of centralised randomisation scheme, an on-site computer system or sealed opaque envelopes were used. Controlled before-after studies should be scored "High risk". "Unclear risk" if not specified in the paper.
Baseline outcome measurements similar	"Low risk" if performance or patient outcomes were measured prior to the intervention, and no important differences were present across study groups. In randomised trials, "Low risk" if imbalanced but appropriate adjusted analysis was performed (e.g. analysis of covariance). "High risk" if important differences were present and not adjusted for in analysis. If randomised trials have no baseline measure of outcome, it is "Unclear risk".
Baseline characteristics similar	"Low risk" if baseline characteristics of the study and control providers are reported and similar. "Unclear risk" if it is not clear in the paper (e.g. characteristics are mentioned in text but no data were presented). "High risk" if there is no report of characteristics in text or tables or if there are differences between control and intervention providers.

Protection against contamination	"Low risk" if allocation was by community, institution or practice and it is unlikely that the control group received the intervention. "High risk" if it is likely that the control group received the intervention (e.g. if patients rather than professionals were randomised). "Unclear risk" if professionals were allocated within a clinic or practice and it is possible that communication between intervention and control professionals could have occurred (e.g. physicians within practices were allocated to intervention or control).
Intervention independent	Low risk" if there are compelling arguments that the intervention occurred independently of other changes over time and the outcome was not influenced by other confounding variables/historic events during study period. If Events/variables identified, note what they are. "High risk" if reported that intervention was not independent of other changes in time.
Appropriate analysis	"Low risk" if data were analyzed appropriately e.g. if autoregressive integrated moving average (ARIMA) models were used OR time series regression models were used to analyze the data and serial correlation was adjusted/tested for OR reanalysis performed. "High risk" if the outcomes were not analyzed appropriately. "Unclear risk" if not specified in the paper.
Pre-specified shape of effect	"Low risk" if point of analysis is the point of intervention OR a rational explanation for the shape of intervention effect was given by the author(s). Where appropriate, this should include an explanation if the point of analysis is NOT the point of intervention. "High risk" if it is clear that the condition above is not met.
Intervention to affect data collection	"Low risk" if reported that intervention itself was unlikely to affect data collection (for example, sources and methods of data collection were the same before and after the intervention). "High risk" if the intervention itself was likely to affect data collection (for example, any change in source or method of data collection reported).
Incomplete outcome data	"Low risk" if missing outcome measures were unlikely to bias the results (e.g. the proportion of missing data was similar in the intervention and control groups/pre- and post-intervention periods or the proportion of missing data was less than the effect size i.e. unlikely to overturn the study result). "High risk" if missing outcome data was likely to bias the results. "Unclear risk" if not specified in the paper (not assuming 100% complete data unless stated explicitly).
Knowledge of allocated intervention	"Low risk" if the authors state explicitly that the primary outcome variables were assessed blindly, or the outcomes are objective. Primary outcomes are those variables that correspond to the primary hypothesis or question as defined by the authors. "High risk" if the outcomes were not assessed blindly. Score "Unclear risk" if not specified in the paper.
Selective outcome reporting	"Low risk" if there is no evidence that outcomes were selectively reported (e.g. all relevant outcomes in the methods section are reported in the results section). "High risk" if some important outcomes are subsequently omitted from the results. "Unclear risk" if not specified in the paper.
Other bias	"Low risk" if there is no evidence of other risk of biases.

GRADE evidence levels were determined by considering the body of evidence available for each (sub-) intervention. Domains of scoring included risk of bias, inconsistency, indirectness, imprecision, and "other". In risk of bias, as a general rule, we did not downgrade bodies of evidence where 50% or more of studies were of predominantly low risk of bias. Bodies of evidence with higher prevalence of high or unclear risk of bias were downgraded at the discretion of the authors. We downgraded for inconsistency if identified studies reported conflicting results in terms of directionality of evidence. We downgraded for indirectness if the outcomes reported were proxies for the main outcomes of interest. We downgraded for imprecision if results supporting claims of a positive/negative effect were not statistically significant, or if it was not tested whether the results deviated from chance. We upgraded studies in the "other" domain if strong observational study designs were used (ITS, RM, panel data/regression analysis), according to precedence in

the literature (*14*). The resultant certainty of the evidence was expressed as high, moderate, low or very low (Table 2.8).

Substantial expected differences in the characteristics and contexts of included studies meant we did not plan to undertake a meta-analysis. Instead we provided a narrative summary describing the quality of the studies, the relationship between studies and patterns discerned in the data.

Table 2.8 Certainty of the evidence (GRADE)

⊕⊕⊕⊕	**High**	This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different** is low.
⊕⊕⊕◯	**Moderate**	This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different** is moderate.
⊕⊕◯◯	**Low**	This research provides some indication of the likely effect. However, the likelihood that it will be substantially different** is high.
⊕◯◯◯	**Very low**	This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different** is very high.

** Substantially different = a large enough difference that it might affect a decision

2.9 Overall search results

2.9.1 Studies identified and selected

The searches and other sources identified 46,038 records (Table 2.9). Following deduplication, 32,011 records remained for assessment.

31,011 records were rejected based on screening of the titles and abstracts within EndNote (by one reviewer) and within Covidence by two reviewers independently.

1,000 records were initially screened by two reviewers independently at YHEC using information from the full text within Covidence. Full text screening was finalised by two reviewers from Utrecht. A total of 944 records were rejected.

56 records were considered eligible for the review.

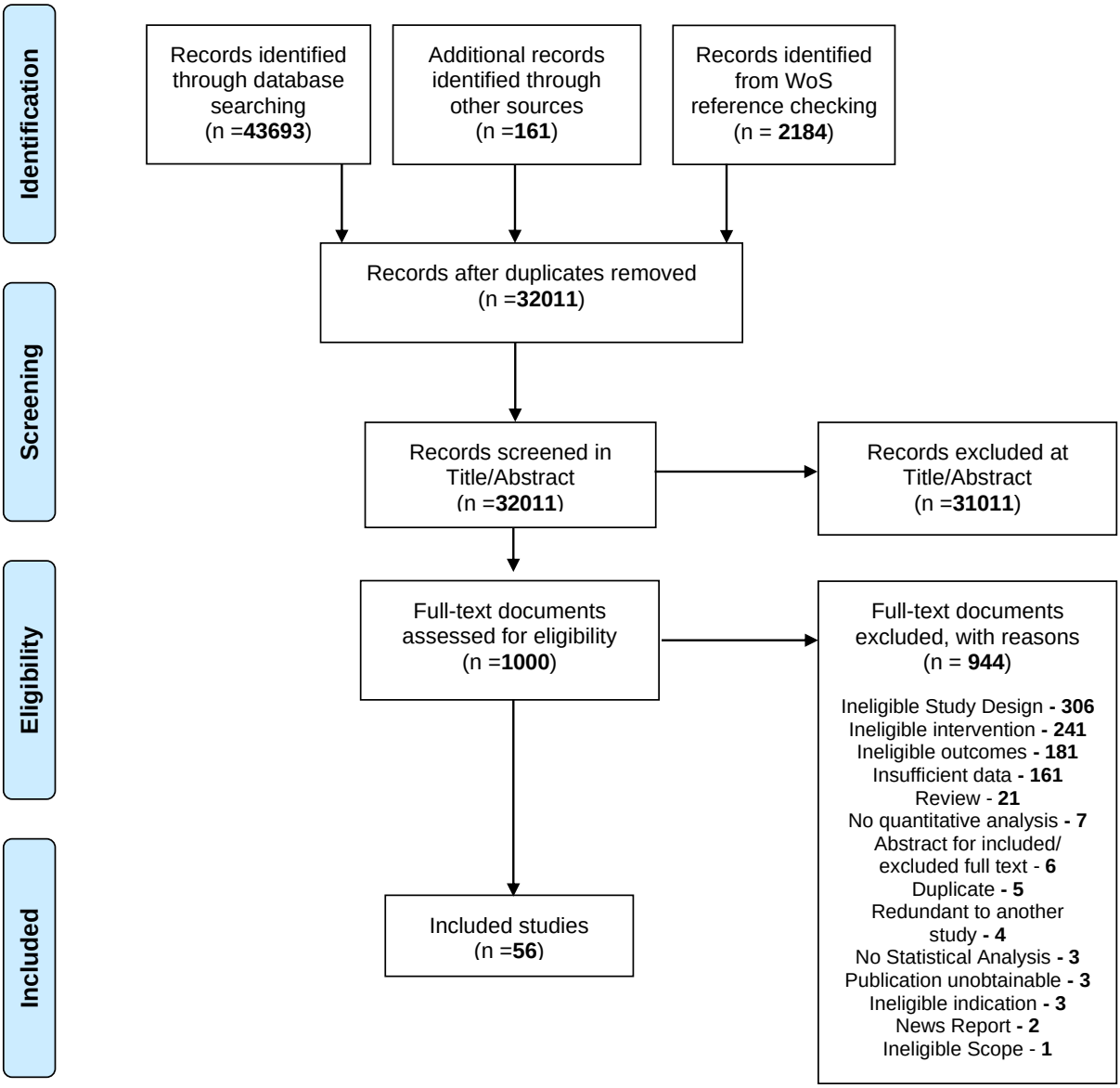
The number of included studies per review topic are reported in the relevant sections. Some studies are included in several topics, and consequently the total from all 10 topics does not sum to 56.

The PRISMA study selection flow chart is shown in Figure 2.2.

Table 2.9 Literature search results

Resource	Number of records identified
Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily	8,302
Econlit	2,046
Embase	18,858
Cochrane Database of Systematic Reviews (CDSR)	25
NHS Economic Evaluation Database (NHS EED)	2,568
Database of Abstracts of Reviews of Effects (DARE)	24
Health Technology Assessment (HTA) Database	66
INRUD (International Network for Rational Use of Drugs) Bibliography	454
OECD iLibrary Books (freely accessible content only)	19
World Bank eLibrary (freely accessible content only)	1,572
Epistemonikos	264
International Political Science Abstracts (IPSA)	68
WHO IRIS (Institutional Repository for Information Sharing)	2,129
European Observatory on Health Systems and Policies webpage	2
WHO Collaborating Centre for Pricing and Reimbursement Policies webpage	58
Health Action International (HAI) Medicines Prices webpage	14
Health Action International (HAI) Publications webpage	22
MI4A Market Information for Access to Vaccines webpage	0
EC initiatives in pricing and reimbursement webpage	3
European Commission DG Sanco webpage	0
IDEAS	136
Open Grey	1
World Bank Documents & Reports	5
World Bank Open Knowledge Repository	2
Essential Medicines and Health Products Information Portal (WHO)	17
Global Index Medicus	3075
Social Science Citation Index	4,033
Department of International Development (UK) website	0
LILACS (searched as part of Global Index Medicus – see above)	N/A
Organisation for Economic Co-operation and Development (OECD) Social Issues Migration Health webpages (This is included when searching the OECDiLibrary – see above)	N/A
Reference list checking	2184
Limited search for evaluation reports of specific pricing policies within the scope of this review, published on the website of individual jurisdictional governments	91
Total number of records retrieved	46,038
Total number of records after deduplication	**32,011**

Figure 2.2 PRISMA chart for the study selection process



2.10 Discussion of search methods and results

2.10.1 Strengths and limitations of the search

Strengths

The search was conducted in a wide range of information resources. Selection of resources was informed by discussion within the research team. Literature on pharmaceutical pricing policies has relevance to both healthcare, economics and policy research. The range of databases searched therefore included general healthcare databases, specific economics databases and databases relevant to government policy. We were aware that there were already a number of systematic reviews published on certain intervention topics which could be valuable to draw on for this work. The search resources therefore also include dedicated databases of systematic reviews. We knew from references included in existing reviews on the topic that relevant literature is often published or made available outside journal publishing channels, and would therefore not be found in bibliographic databases such as MEDLINE and Embase. The search resources therefore included sources which contain health technology assessments, working papers, dissertations, unpublished articles and other grey literature made available outside standard journal publications. The potential importance of grey literature was also reflected by the supplementary search approaches used (reference list checking, expert contact and targeted searches of selected websites) all of which are valuable ways to identify both journal literature and grey literature. The database searches were also complemented by bibliography searches. The wide range of search sources and approaches used increased the likelihood of identifying a greater number of relevant studies.

The initial database strategy was developed for Ovid MEDLINE. This strategy was subsequently translated for the other databases searched. The strategy contained a range of terms designed to retrieve records that referred to non-specific pharmaceutical pricing policies, or to the specific pharmaceutical pricing policies of interest. Searching in this way increased the likelihood of identifying a greater number of relevant studies.

The appropriate balance between sensitivity and precision for the database strategy was discussed within the research team. The draft Ovid MEDLINE strategy was reviewed and discussed a number of times, and revised following input from team members. The strategy went through a number of iterations before the final version was reached. The final strategy was designed to be appropriate to the project resource and timeline context, and aimed to balance sensitivity with precision. The final Ovid MEDLINE strategy was peer-reviewed by a second Information Specialist for errors in spelling, syntax and line combinations. The iterative and collaborative approach to strategy development increased the likelihood of achieving a final strategy which was appropriately robust, yet retrieved record numbers which were manageable within project resources.

The performance of the Ovid MEDLINE strategy was assessed before running the final search by checking the stategy's ability to retrieve records for known, potentially relevant studies. Records in MEDLINE were sought for studies included in a selection of five relevant systematic or evidence-based reviews (*15–19*). Sixty-one records for included studies could be identified in MEDLINE. The MEDLINE strategy (before date

limits were applied) retrieved 52 of the 61 records, meaning that 9 were not retrieved. Abstracts for the 9 non-retrieved records were reviewed by the research team to ascertain if the studies would be potentially eligible for inclusion in this review. None of the 9 were judged to be potentially eligible for inclusion. A similar exercise was conducted for the 2015 WHO Pricing Policy Guidelines (*4*). There were 132 citations in the Guidelines reference list. Records for 80 of these citations could be found in MEDLINE. The strategy (before date limits were applied) retrieved 55 of the 80 records, meaning that 25 were not retrieved. Abstracts for the 25 non-retrieved records were reviewed by the research team to ascertain if the studies would be potentially eligible for inclusion in this review. None of the 25 were judged to be potentially eligible for inclusion. Testing the performance of the strategy in this way before running the final searches increased the likelihood of achieving a final strategy that had appropriate sensitivity.

The Ovid MEDLINE strategy was translated for the other databases searched. In the context of an approach to database search strategy design which balanced sensitivity and precision, database searches were complemented by a range of supplementary search approaches (outlined above - including reference-list checking, expert contact, website searches and citation searches). These supplementary approaches were designed to identify additional relevant studies that may have been missed by the main database searches. Including these supplementary approaches complemented the balanced approach to database searches.

Limitations

The searches informed ten systematic reviews. Given the number, scope and nature of the topics, developing a robust bibliographic database strategy without retrieving large numbers of records was challenging. There were a number of different search approaches which could be taken and (as with most database search strategies) a range of ways in which both sensitivity and precision could be increased. Project timelines and resources meant that the strategy was required to achieve a balance of sensitivity and precision which delivered an appropriately robust search whilst retrieving record numbers which were manageable. To achieve this, a number of pragmatic decisions were taken whilst developing the main database search strategy. The pragmatic decisions decreased the number of records retrieved, but may have increased the risk of missing relevant records. The pragmatic decisions were explicitly discussed within the research team, and were judged to be acceptable within the project context. The search development process, performance testing and supplementary search approaches outlined above were designed to mitigate the increased risk of missing relevant studies, but the pragmatic decisions which informed the main database strategy could be viewed as a limitation of the search methods. Examples of pragmatic decisions include:

- Focusing the search to retrieve database records where the pharmaceutical context was made explicit in the database record through the inclusion of non-specific pharmaceutical terms. Apart from vaccines, the strategy was only designed to retrieve records which included generic, non-specific pharmaceutical terms. A more sensitive approach would just search on pricing policies without this explicit context.
- Not constructing the search: pharmaceuticals (all variant terms) AND pricing (all variant terms).
- Restricting the drug subject heading terms to an explicit economics context (for example, by combining with economics subject headings or attaching economics subheadings).

- Throughout the strategy, focusing the pricing context terms on explicit 'pricing' (including pricing, price, prices, priced). Not, for example, looking for records which included potential variant economics terms which could indication a relevant pricing context (for example: costs, fees, charges, expenditure, spending, reimbursement).
- Not including subject headings potentially relevant to a policy context.
- Not including subheadings potentially relevant to a policy context (e.g. lj, st, td).
- For terms on interventions for promoting the use of generic and biosimilar medicines, designing the search to focus on retrieval of records where 'pricing' / 'price' / 'prices' / 'priced' was explicit in the database record - not just searching on terms for generic and biosimilar medicines alone, or searching on a wider range of terms for specific promotion policies.
- Throughout the strategy, restricting the use of subject headings to specific contexts by attaching subheadings, rather than searching on the subject heading by itself.
- Throughout the strategy, restricting the textword searches by combining terms with highly focused proximity operators (adj, adjN), rather than combing with AND. The use of adj in this way is designed to only retrieve records that contain terms within a specified number of words of each other. It therefore limits the number of potential variant descriptions the search is designed to capture.
- Throughout the strategy, designing the strategy to capture terms which seemed most likely to be relevant, and which facilitated the balanced search approach, rather than all possible variants.

As noted above, the search resources included database and information sources additional to core biomedical databases such as MEDLINE and Embase. These included sources for grey literature published outside journal channels. Although important to include such resources, many have very limited search and exporting functionality. They are often not designed to be used for complex or detailed searches, or for the exporting of results in ways which facilitate efficient results processing in the context of a systematic review. This can make them challenging to search, and challenging to retrieve results from, robustly and efficiently. Within this context the research team had to use search methods which were reasonably robust, but which facilitated efficient execution, result processing and result screening. This context was discussed within the research team and it was agreed that for resources where search and exporting functionality was limited, a targeted search approach would be taken. This would generally mean searching on a much more limited range of terms than were found in the main database strategies and, where appropriate, focusing on records which explicitly referred to 'pricing'. Supplementary search approaches as outlined above (including reference list checking and expert contact) were designed to mitigate the risk of missing relevant studies, but the pragmatic search approaches taken to resources with poor search and export functionality may be viewed as a limitation of the search methods.

3 Pooled procurement

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3.1 Background

Pooled procurement is defined here as « combining financial and non-financial resources across various purchasing authorities in order to create greater purchasing power through economies of scale and better negotiation position » (*5*). Pooled procurement can encompass different levels of integration, ranging from the sharing of information among procurers e.g. about prices, to fully integrated contracting and procurement (*20*). Well known examples of pooled procurement at the international level are the Pan American Health Organization Strategic Fund for vaccine procurement, which aggregates demand for 41 countries in the Latin American and Caribbean region (*21*), and the Global Drug Facility which aggregates demand in the area of tuberculosis medicines (*22*).

The present review also addresses the topic of tendering and negotiation (see section 12), which covers related concepts. For clarification, and according to the definition above, pooled procurement is considered the situation where existing procurement arrangements, such as procurement processes at lower administrational levels, are pooled or consolidated to higher levels of aggregation, such as more centralized administrational levels.

The underlying rationale for pooled procurement is a combination of several factors. Aggregation of demand is intended to achieve lower prices by strengthening purchasing power, while sharing of information and capacity among procurers is intended to improve efficiency of the procurement process (*23*). Pooled procurement benefits are proposed to include reductions in unit prices, improved quality assurance, reduction of corruption in the procurement process, reduction of operating costs and increased access to medicines (*24*)

The effects of pooled procurement can thus be considered both internally within an organization/group of organizations, and externally within the market. Aggregation of the purchasing process among organizations can lead to more streamlined procurement and reduce transaction costs, while aggregation of demand can lead to more favorable prices for the purchasing organizations (*25*).

While procurement volume is often intuitively linked to lower prices and pooling is among other things a strategy for increasing volume, published evidence suggests higher volume in itself is not always sufficient to achieve lower prices (*26*). Additionally, it is suggested an undesirable long-term effect might be reduced competitiveness and shortages if prices are unsustainably low (*27*,*28*), and that lack of consistent demand for particular products or services may act as a barrier to attracting the best suppliers (*29*).

A recent report by the WHO Regional Office for Europe on procurement of medicines in the European region reviewed the interaction between procurement practices and prices across the region, and in particular examined the issue of within- and cross-border collaboration on procurement to improve access to medicines (*30*). The report addressed strategic procurement as an overarching concept, which includes many issues relevant to pooled procurement, including minimizing repetitive purchases, increasing economies of scale, and reducing transaction costs. The report cited a relatively limited and context-specific evidence body for the effectiveness of many such procurement practices, but highlighted the importance and high level of interest in efficient procurement in light of rising pharmaceutical expenditures (*30*).This chapter details the evidence on pooled procurement.

3.2 Results

3.2.1 Excluded studies

A total of 30 references on the topic of pooled procurement were assessed at full text level. Of these, 24 references were excluded at the full text stage. Almost all (n=21) were excluded on study design, of which nine were uncontrolled before/after design (*31–39*), four were cross-sectional analyses comparing prices among different datasets (*40–42*) or different settings (*43*), six were descriptive analyses of price developments or policies (*44–49*), and two were projections of potential savings (*50,51*). Of the remaining references not excluded on study design, one was a working paper preceding one of the studies included in this review (*52*), one was a duplicate reference of another study excluded as uncontrolled before/after (*32*), one addressed an intervention on supplier consolidation in the context of pooled procurement but did not address pooled procurement as an intervention (*53*).

3.2.2 Characteristics of included studies

Six studies met the inclusion criteria, published between 2012 and 2019 (Table 3.1). Two studies were difference-in-difference analyses (*54,55*) and four studies were panel data/regression analyses (*56–59*). Four studies were set in single countries: Italy (*54,57*), France (*56*) and Brazil (*59*), and two studies examined data from multiple countries: one study using Global Price Reporting Mechanism (GPRM) data from 107 countries globally (*55*), and one study using data from Philippines, South Africa, Serbia, Tunisia, Senegal, Zambia and Kerala state in India (*58*). Five studies examined public sector procurement (*54–57,59*) and one study a mix of public/private sector procurement (*58*).

The subjects of study were all commodities/services procured in three studies (*54,57,59*), the antiretroviral efavirenz in one study (*55*), innovative inpatient medicines in one study (*56*) and essential medicines[2] in one study (*58*). Five studies assessed the impact on price (*55–59*) and one study assessed the impact on expenditure and availability of services provided (*54*). A description of the interventions studied is provided in Table 3.2.

Pooled procurement at the regional level was examined in three studies (*54,56,57*), at the national level in one study (*58*), by agencies at mixed (federal, state, city) levels in one study (*59*), and internationally between countries in one study (*55*).

[2] Not further specified by the authors

Additional details of interventions are provided across studies in Table 3.3. The three studies addressing regional pooled procurement analyse data from public hospitals in the context of regional procurement bodies, which implement pooled procurement on behalf of participating hospitals. All three studies are in the European setting (Italy, France). Pooled procurement of pharmaceuticals and medical supplies among different levels of government is addressed only in the Brazilian setting, and international pooled procurement only among Global Fund recipient countries in the specific case of efavirenz. One study addressed national pooled procurement, using data from several countries.

Table 3.1 Study characteristics

	Study types	Number of studies	Notes/references
Study type	Difference-in-differences	2	(*54,55*)
	Panel data/regression	4	(*56–59*)
Setting	Europe	3	Italy (*54,57*), France (*56*)
	Latin America	1	Brazil (*59*)
	Multiple countries/global	2	Global Price Reporting Mechanism data from 107 countries (*55*), data from Philippines, South Africa, Serbia, Tunisia, Senegal, Zambia and Kerala state in India (*58*)
	Public sector	5	(*54–57,59*)
	Public and private sector	1	(*58*)
Subjects	All medicines/services	3	All recorded data (*54,57,59*)
	Antiretrovirals	1	Efavirenz (*55*)
	Innovative medicines	1	Outside-DRG hospital medicines (*56*)
	Essential medicines	1	Not specified (*58*)
Interventions	Regional pooled procurement	3	Between hospitals (*54,56,57*)
	National pooled procurement	1	Centralized procurement (Central Medical Stores) (*58*)
	Mixed levels	1	Federal, state, city (*59*)
	International	1	Voluntary pooled procurement within Global Fund (*55*)
Outcomes	Price	5	Incoterms and ex-works (*55*), medicine unit prices (*56–59*)
	Expenditure	1	Total hospital expenditure per capita (*54*)
	Supply of health services	1	Level of service provision to population (*54*)

The risk of bias assessment is presented in Table 3.4. One out of six studies was scored as low risk of bias for "incomplete outcome data", as the extent of missing outcome data was rarely assessed.[3] Five out of six studies were scored as low risk of bias for "knowledge of allocated intervention", which in this context is interpreted as objectivity of outcomes.[4] Six out of six studies were scored as low risk of bias for "selective

[3] For "incomplete outcome data" bias: "Low risk" if missing outcome measures were unlikely to bias the results (e.g. the proportion of missing data was similar in the intervention and control groups/pre- and post-intervention periods or the proportion of missing data was less than the effect size i.e. unlikely to overturn the study result). "High risk" if missing outcome data was likely to bias the results. "Unclear risk" if not specified in the paper (not assuming 100% complete data unless stated explicitly).

[4] "Low risk" if the authors state explicitly that the primary outcome variables were assessed blindly, or the outcomes are objective. Primary outcomes are those variables that correspond to the primary hypothesis or question as defined by the authors. "High risk" if the outcomes were not assessed blindly. Score "Unclear risk" if not specified in the paper.

outcome reporting", meaning the results of the studies were reported according to the analysis plan presented in methods.[5]

High risk of bias was observed in a single domain in two studies. Barbosa *et al*. (*59*) excluded 16.5% of observations as errors in the data, assuming that prices paid above the reserve price could not be correct. It is not clear whether this assumption is justified, or whether prices higher than the reserve price are possible in practice. As this systematically removes higher prices from the sample, the risk of incomplete outcome data was judged as high. Baldi *et al*. (*57*) were not able to include volume as a covariate in their regression model due to missing data, which could be a potentially important factor in the variation in price. The completeness of outcome data was not reported (*55–58*) in most studies, leading to an unclear risk of bias assessment for this domain.

[5] "Low risk" if there is no evidence that outcomes were selectively reported (e.g. all relevant outcomes in the methods section are reported in the results section). "High risk" if some important outcomes are subsequently omitted from the results. "Unclear risk" if not specified in the paper.

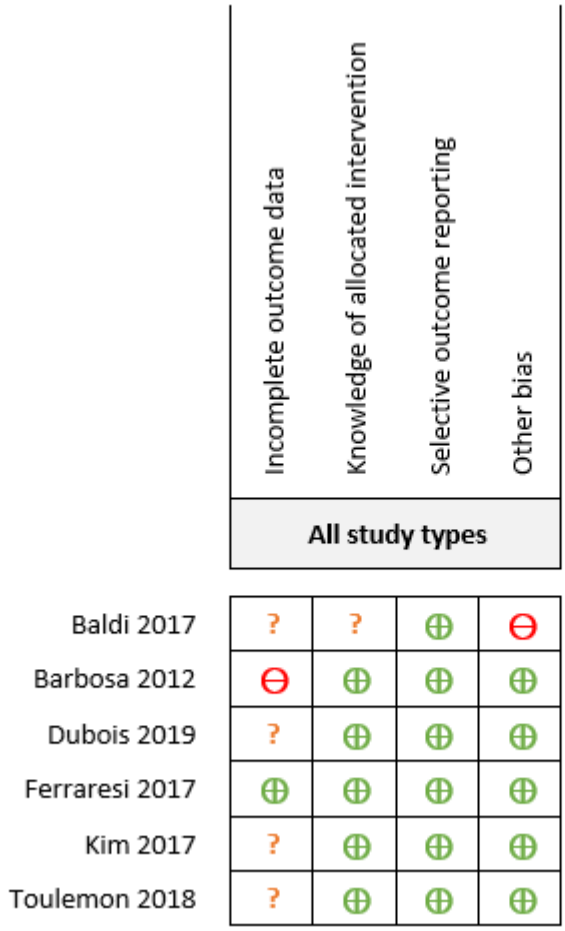
Table 3.2 Description of interventions by category of intervention and study

	Intervention	Study begin	Study end
Regional pooled procurement			
Baldi 2017 (*57*)	Analysis of the impact of centralized procurement on tender prices of selected pharmaceuticals relative to decentralized and hybrid procurement systems. Includes an analysis on the impact of institutional quality (governance, corruption) on the relationship between centralized procurement and price reduction. Institutions examined are individual local hospitals (aziende sanitarie locali, ASL); groups of ASLs; and centralized regional bodies (Centrali di Committenza Regionale). The dataset contained 52 procurers and 41 Anatomical Therapeutic Chemical classes (ATC classes).	2009	2012
Ferraresi 2017 (*54*)	Analysis of the impact of introducing regional Central Purchasing Bodies (CPB) to centralize purchasing of goods and services by local hospitals in Italy (ASLs). The study included 19 Regions and 2 Autonomous Provinces, of which eight did not introduce the intervention during the study period. The analysis was on total expenditure of the 144 ASL's within regions which did/did not adopt the intervention.	2001	2012
Toulemon 2018 (*56*)	Analysis of the impact of regional purchasing groups for hospitals in France on the price of medicines. Four regions created a purchasing group between 2009-2014, containing 48 of the total 125 hospitals studied. The analysis focused on innovative high-cost medicines outside the scope of reimbursement through the Diagnosis Related Group (DRG) system, i.e. medicines on the supplementary medicines list (""liste en sus/Liste hors Groupe homogène de séjour"").	2009	2014
National pooled procurement			
Dubois 2019 (*58*)	Public and private sector procurement data from LMICs was analysed to determine the effect of centralized pooled procurement on prices for selected pharmaceutical products. The sample covers seven low-middle income countries with diverse drug procurement systems: four middle income countries – the Philippines, three States in South Africa (KwaZulu-Natal, North West and Eastern Cape), Serbia, and Tunisia – and three low income countries –Senegal, Zambia, and the state of Kerala in India. The study includes 40 molecules across 16 therapeutic areas.	2015	2017
Mixed level pooled procurement			
Barbosa 2012 (*59*)	Analysis of the impact of implementing pooled procurement among government agencies on price of medicines. The intervention was introduced with the Brazilian Price Registration System, a pooled procurement system in which several public agencies and entities organize joint competitive bidding to purchase goods, and suppliers offer goods and services at uniform prices and terms for all members of the group. Prices of 5,248 different products were studied.	2004	2009
International pooled procurement			
Kim 2017 (*55*)	Analysis of the impact of voluntary pooled procurement (VPP) across countries organised by the Global Fund on the price of 600mg efavirenz. This study examines the impact of VPP among 25 countries procuring through VPP compared with 82 countries procuring outside of VPP.	2004	2013

Table 3.3 Intervention details across studies

Country	Organizational level/intervention	Type of organizations pooling procurement	Type of goods/services studied
Italy (Ferraresi *et al.*)	Regional (Regional Central Purchasing Bodies, "Centrali di Committenza Regionali")	Local public hospitals ("Aziende Sanitarie Locali")	All categories of expenditure from hospital balance sheets, categorized into expenditure on: health goods, health services, non-health goods and non- health services.
Italy (Baldi *et al.*)	Regional (Regional Central Purchasing Bodies, "Centrali di Committenza Regionali") Groups of local public hospitals ("hybrid" procurement)	Local public hospitals ("Aziende Sanitarie Locali")	43 hospital pharmaceuticals
France (Toulemon)	Regional purchasing groups	Public hospitals, excluding "local hospitals" of small size	Pharmaceuticals reimbursed outside of the Diagnosis Related Group system (accounting for approx. 55% of hospital pharmaceutical expenditure in 2011)
India, Philippines, Senegal, Serbia, South Africa, Tunisia, Zambia (Dubois *et al.*)	National pooled public procurement (as implemented in study countries)	All public entities procuring pharmaceuticals which are present in the IQVIA (IMS Health) dataset	40 pharmaceuticals across 16 therapeutic areas
Brazil (Barbosa *et al.*)	Enabling different public entities to procure goods/services jointly through procurement pools	Federal, state and local government	Pharmaceuticals and medical supplies
International (Kim *et al.*)	Procurement Services Agent receives and aggregates requests from multiple countries with product specifications, quantities and delivery dates	Global Fund principle recipient countries	Efavirenz

Table 3.4 Risk of bias of included studies



3.2.3 Effect of interventions

3.2.3.1 Impact of regional pooled procurement

Three studies assessed the impact of regional (sub-national) pooled procurement on price or expenditure (see Table 3.1). The GRADE quality assessment and summary of findings for regional pooled procurement are given in Table 3.5 and Table 3.6. The overall certainty of evidence was rated as moderate. Brief details of the individual studies are included below, followed by main results on the impact of regional pooled procurement.

Table 3.5: Certainty assessment (GRADE) of evidence for each outcome: Regional procurement

No. of studies (references)	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
Price: 2 (*56*,*57*)	Panel data (I), Regression analysis (I)	Moderate risk (-0.5)[6]	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Expenditure: 1 (*54*)	DID (I)	Low risk (0)	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Volume							
Outcome: Availability							
Outcome: Affordability							

[6] One study (Toulemon *et al.*) was mostly low risk of bias. One study (Baldi *et al.*) was low risk in one domain, and high risk in one domain. The objectivity of the data (unclear risk) could not be clearly established from the study, however the data is collected by the Italian Authority for the Supervision of Public Contracts (AVCP) for the calculation of reference prices, which suggests a higher likelihood of good quality data.

Table 3.6 Summary of findings: Regional pooled procurement

Regional pooled procurement vs individual procurement

Medicines: All medical products/services, inpatient innovative medicines

Settings: France, Italy

Intervention: Regional pooled procurement

Comparison: Individual procurement

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Price	Coefficients for pooled procurement were significant and negative (-0.201, p<0.001; -0.021, p<0.05) in two studies (*56*,*57*).	2	Moderate ⊕⊕⊕◯	Regional pooled procurement probably results in lower prices.
Expenditure	Coefficient positive and not significant for health products (0.02), but significant and negative for health services (-0.06, p<0.01) in one study (*54*).	1	Moderate ⊕⊕⊕◯	Regional pooled procurement probably results in lower expenditure on health services
Volume				
Availability				
Affordability				

Ferraresi *et al.* (*54*) examined the impact of centralised procurement on expenditures of local hospitals in Italy. The introduction of regional Central Purchasing Bodies (CPB) to provide procurement of commodities and services for local hospitals was undertaken gradually in the decade following year 2000. The authors examined the effect of introducing CPB during 2000-2012 on the expenditure of local hospitals on health goods (incl. pharmaceuticals, vaccines, chemical products, surgical devices), health services, and non-health goods and services. Hospitals in the intervention group were compared with hospitals not undergoing the intervention.

Baldi *et al.* (*57*) examined the effect of centralization of procurement in the Italian setting. The intervention was the same as that studied by Ferraresi *et al.* Baldi *et al.* used price data from 2009-2012 on 43 molecules collected via interviews in 2012. The interviews were originally undertaken by the Italian Authority for the Supervision of Public Contracts as an input to determining reference prices for goods procured by public health purchasers. The molecules studied were procured centrally by CPBs, in hybrid settings (groups of ASL's purchasing together), or by individual ASL's. Similar to Ferraresi *et al.* this study compared hospitals in the intervention group (centralized, hybrid) with hospitals not undergoing the intervention.

Toulemon *et al.* (*56*) studied the introduction of regional purchasing groups among French public hospitals, using hospital-level purchase data for the period 2009-2014. The study focused on innovative inpatient medicines reimbursed through the *liste en sus*, also called *Liste hors GHS*, or the group of medicines reimbursed separately from the Diagnosis Related Group (DRG) tariff.

All three studies examined main results using a regression model, with the logarithm of price dependent on covariates including dummy variables for pooled procurement, and controls. Two out of three studies (Baldi *et al.*, Toulemon *et al.*) reported negative and statistically significant coefficients representing pooled procurement for the regression on price as dependent variable (*56*,*57*). The third study reported a negative and significant coefficient on prices of all purchase types (health/non-health goods and services), but on disaggregation only the coefficient for health services was negative and significant, others are positive but non-significant (Ferraresi *et al.*).

Two of these studies examined contextual factors hypothesised to impact the effect of pooled procurement as part of the quantitative analysis. Baldi *et al.* evaluated the impact of governance and institutional quality. Their analysis showed a positive and significant coefficient for the interaction between both governance, institutional quality and corruption with centralized/hybrid procurement, suggesting existing good governance, high institutional quality and low corruption were associated with less impact on price from pooled procurement. Toulemon *et al.* examined the impact of market concentration, and found the price reduction from pooled procurement was marginal in monopolized medicines (-0.02%), whereas it was substantial for multi-source medicines (-8.7%).

One of the included studies examined potentially adverse outcomes of pooled procurement. Ferraresi *et al.* examined the impact of pooled procurement on the supply of health services, considering that a reduction in expenditures resulting from pooled procurement might be due to a reduction in service provision. A regression analysis was used with per capita first aid centers, physicians, nurses, inpatient beds and day beds as the dependent variable, and pooled procurement and suitable controls as the independent variable. All coefficients were non-significant, except per capita nurses which was negative and significant (-0.09, $p<0.05$). The analysis suggests price reductions from regional pooled procurement were not likely to be due to decreased service coverage, although a reduction in the supply of nurses could not be ruled out.

In terms of barriers to implementation, Ferraresi *et al.* describe the background for the introduction of regional purchasing bodies. The legislation was adopted in 2006, coming into force for competitive bidding starting in April 2012. However the mandatory implementation was formally postponed three times, first until the end of 2012, subsequently until January 2014 and January 2015, meaning implementing in practice was gradual. These observations suggest barriers to implementation in this context, although such barriers were not further explored.

3.2.3.2 Impact of national pooled procurement

One study assessed the impact of national centralized procurement, see Table 3.1 (*58*). GRADE quality assessment and summary of findings are given in Table 3.7 and Table 3.8. The overall evidence was rated as moderate.

Table 3.7: Certainty assessment (GRADE) of evidence for each outcome: National procurement

No. of studies (references)	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
Price: 1 (*58*)	Panel data (I)	Low risk (0)	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Volume							
Outcome: Availability							
Outcome: Affordability							

Table 3.8 Summary of findings: National pooled procurement

National pooled procurement vs individual procurement

Medicines: Basket of 40 essential[7] medicines

Settings: India (Kerala), Philippines, Senegal, Serbia, South Africa, Tunisia, Zambia

Intervention: National pooled procurement

Comparison: Individual procurement

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Price	Public centralized procurement was associated with a negative and significant change in average unit price (-40% to -44%, p<0.001). The price reduction was smaller in more concentrated markets (coefficient for interaction centralized procurement x HHI = 1.2602, p<0.05; for centralized procurement = -1.1874, p<0.001; collectively contributing -1.1874+HHI*1.2602).	1	Moderate ⊕⊕⊕◯	National pooled procurement probably results in lower prices.
Volume				
Availability				
Affordability				

Dubois *et al.* (*58*) studied the association between national centralized procurement and price in a sample of seven countries: state of Kerala (India), the Philippines, Senegal, Serbia, South Africa, Tunisia and Zambia. Of these, public purchases were fully centralized through Central Medical Stores in Tunisia and Zambia, while the public sector procured through both centralized and decentralized processes in the Philippines, Serbia and South Africa; only private sector sales were observable in Senegal and Kerala region in India. The study was based on 2015-2017 (2013-2016 for Serbia) data from IQVIA (formerly IMS), and covered 40 molecules across 16 therapeutic areas.

The analysis of Dubois *et al.* (see Dubois *et al.*) was a regression on the logarithm of average unit price, with national centralized procurement as a dummy variable along with controls. The regression coefficient was negative and significant, and corresponded to an average price reduction of 40-44% for centralized procurement. The authors also assessed the impact of market concentration. In their analysis, this was represented by interacting the public centralized procurement variable (coefficient -1.1874, p<0.001) with the Herfindahl-Hirschman Index (HHI)[8] index. The coefficient for the interaction term centralized procurement x

[7] "essential" is not defined by the study authors

[8] Herfindahl-Hirschman Index is a measure of market concentration, higher values denoting less competitive markets

HHI was 1.2602 ($p<0.05$). The contribution to the dependent variable (price) was then -1.1874+HHI*1.2602, which is negative for low values of HHI but positive for high values of HHI (high market concentration). Thus, a higher HHI index was associated with lower price reductions from centralized procurement, converging towards zero price reduction for a HHI index of 94% (indicating a monopolized market).

3.2.3.3 Impact of mixed level pooled procurement

One study assessed the impact of pooled procurement among government agencies at federal, state and city administrational levels (*59*). GRADE quality assessment and summary of findings are given in Table 3.9 and Table 3.10. The overall evidence was rated as moderate.

Table 3.9: Certainty assessment (GRADE) of evidence for each outcome: Mixed level pooled procurement

No. of studies (references)	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
Price: 1 (*59*)	Panel data (I)	Moderate risk (-0.5)[9]	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Volume							
Outcome: Availability							
Outcome: Affordability							

[9] A large proportion of observations are dropped from the dataset of Barbosa *et al.* (*334*), as they are considered errors. These are observations where the procurement price is higher than the reserve price. This was more common in the data for individual procurement (45% of observations) than pooled procurement (11% of observations). This would appear to systematically bias the total sample, with more high price products being dropped from the individual procurement sample. The effect of this would likely reduce the effect of pooled procurement in reducing prices.

Table 3.10 Summary of findings: Mixed level pooled procurement

Pooled procurement across government levels vs individual procurement

Medicines: All medicines procured

Settings: Brazil

Intervention: Public sector pooled procurement

Comparison: Individual procurement

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Price	Pooled public procurement was associated with a negative and significant coefficient (-0.0701, p<0.01). Adding state agencies to the procurement pool was associated with price increase (coefficient for pooled procurement = -0.0729, p<0.01; adding state agencies = 0.0948, p<0.001). Coefficient for number of competitors is negative and significant (-0.203, p<0.001)	1	Moderate ⊕⊕⊕◯	Pooled procurement across administrational levels probably results in lower unit prices. Adding procurers with specific attributes (e.g. credit risk) to the procurement pool probably results in higher prices.
Volume				
Availability				
Affordability				

Barbosa *et al.* (*59*) examined pooled procurement across governmental levels following introduction of the Brazilian Price Registration System, see Table 3.1. This enables public agencies and entities to purchase goods or contract services together through joint competitive bidding, in which suppliers make offers at uniform prices and contract terms for all members within the "pool". The study analysed a dataset of Brazilian public procurement transactions from 2004 to 2009, including data on all federal transactions (pooled and individual procurement), and city and state transaction from pools in which the federal government was a partner.

The impact of pooled procurement (see Barbosa *et al.*) was estimated with a regression model on the logarithm of unit price, with pooled procurement as a dummy variable along with controls. Pooled procurement was associated with a negative and significant coefficient. The authors also hypothesized pooled procurement could lead to higher prices if the pool includes purchasers with higher credit risk (risk of non-payment for suppliers). State level agencies were considered to have higher credit risk. The regression coefficient for state-level participation in a purchasing pool was positive and significant, suggesting pooled procurement may increase prices if the procurement pool includes purchasers with

certain attributes (here the assumption is that credit risk is the main determinant of the effect, however the analysis cannot rule out an effect of other attributes of state level participants).

The effect of competition was also examined. The number of competitors in the market was associated with a significant and negative coefficient, suggesting more competition leads to lower prices in the context of pooled procurement.

3.2.3.4 Impact of international pooled procurement

One study assessed the impact of pooled procurement in the international context (*55*). GRADE quality assessment and summary of findings are given in Table 3.11 and Table 3.12. The overall evidence was rated as moderate.

Table 3.11: Certainty assessment (GRADE) of evidence for each outcome: International pooled procurement

No of studies (references)	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
Price: 1 (*55*)	DID (I)	Low risk (0)	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Volume							
Outcome: Availability							
Outcome: Affordability							

Table 3.12 Summary of findings: International pooled procurement

Voluntary international pooled procurement vs individual country procurement

Medicines: Efavirenz 600mg

Settings: Global Price Reporting Mechanism database

Intervention: Voluntary pooled procurement

Comparison: Individual procurement

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Price	The coefficient for both Incoterm (-0.213, p<0.001) and ex-works (-0.177, p<0.001) price was significant and negative.	1	Moderate ⊕⊕⊕◯	International voluntary pooled procurement probably results in lower prices.
Volume				
Availability				
Affordability				

Kim *et al.* examined the effect of a voluntary pooled procurement (VPP) scheme organised by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) on the price of the antiretroviral drug efavirenz (see Kim *et al.*). The WHO Global price report mechanism (GPRM) data used in the study contains information on ex-works and International Commercial Terms (incoterms) prices for all participating countries. Out of 107 countries providing data, 25 countries procured efavirenz using VPP.

Voluntary pooled procurement among countries, facilitated by GFATM, was associated with a negative and significant coefficient both at the Incoterm[10] and ex-works price level. Details of the Incoterms were not reported, except for the majority of VPP transactions being ex-works (68%) and a smaller proportion being CIP (Carriage And Insurance Paid To; 14%) and FCA (Free Carrier: 13%). Incoterm prices were reported as one group in the results. The coefficient corresponded to a price reduction of 16.2% (ex-works) and 19.1% (Incoterms) in the VPP group relative to no VPP.

[10] International Commercial Terms specifying the contractual arrangements on freight and insurance between buyer and seller. Incoterms includes ex-works price and 10 other rules: FCA (Free Carrier); CPT(Carriage Paid To); CIP (Carriage And Insurance Paid To); DAT (Delivered At Terminal); DAP (Delivered At Place); DDP (Delivered Duty Paid); FAS (Free Alongside Ship); FOB (Free On Board); CFR (Cost and Freight); CIF (Cost, Insurance and Freight).

3.3 Authors' conclusions

3.3.1 Summary of main results

In this review, six studies examining the price of goods/services procured under pooled arrangements at different levels of administration all supported an association between pooled procurement and lower prices/expenditures. One of these studies (*54*) found a significant and negative effect on prices of health services, but not on health goods procured.

Two studies support the hypothesis that pooled procurement is beneficial in competitive markets, but with lower to zero benefit as markets become more concentrated/monopolized (*58,60*). Correspondingly, a third study found a significant and negative coefficient for the effect of number of competitors on price (*59*), also supporting a greater impact of pooled procurement in competitive markets.

One study found the benefits of pooled procurement were more pronounced in purchasers with lower institutional quality or higher levels of corruption (*57*).

One study found evidence to suggest participation of purchasers with lower credit rating could increase prices (*59*).

3.3.2 Overall completeness and applicability of evidence

Several factors may limit the applicability of this evidence. Firstly, half (three of six) of the studies examine a high-income settings. Three studies use data from LMIC's, focusing each on mixed level, national and international pooled procurement. The medicines studied in these three publications are relatively narrow samples in two cases: one study included only one medicine (efavirenz), and the other a basket of 40 medicines. In contrast, the mixed-level study set in Brazil included data on all medicines procured.

The study on consolidation of suppliers/distributors set in Hubei province, China, appears highly context specific. The situation addressed is putative crowding of the market place with distributors/suppliers, and the proposed solution is various types of consolidated contracts to increase volume of business for distributors/suppliers. This is the only study examining availability of medicines following pooled procurement.

None of the studies identified addressed effects of pooled procurement on the volume, availability or affordability of medicines, or on potential adverse outcomes of pooled procurement.

3.3.3 Quality of the evidence

The risk of bias was judged as low in the majority of the evidence. In five of the six studies, risk of bias was low across at least three out of four domains.

The quality of evidence was judged as moderate in all cases. According to EPOC guidelines, all observational evidence is initially assigned a low quality score. According to our assessment methodology, strong study designs have the possibility of being upgraded. All studies examined here adopted rigorous study designs, and transparently reported their methods and analytical approaches. As such, the methodological quality was considered moderate.

3.3.4 Agreement/disagreement with other reviews

In their study of procurement strategies, Waning *et al.* in 2009 (*26*) identified a gap in empirical evidence, noting "*While some surveys and desk reviews have described potential pooled procurement mechanisms in developing countries, insufficient empirical research has been carried out to validate pooled procurement and identify the conditions under which it can operate most efficiently*". The present review confirms the lack of empirical evidence until 2012, where the first study included in our review was published.

As argued by Huff-Rouselle (*24*) in her 2012 review and informant interview report, price benefits of pooled procurement may be equally a function of purchasing power and the ability to make prompt payment. If payments to suppliers are compromised by participating countries not adhering to the agreement, pooled procurement might in fact cause prices to increase. Analogously, the author suggests price benefits from prominent examples of pooled procurement such as the PAHO Strategic Fund may be the result of strong financial backing of donors, or equally that these initiatives do not allow non-paying countries to participate in the 'pool'. This notion is supported by one study of the present review, which suggests participation of less credit-worthy participants in a pool could indeed increase prices (*59*).

A recent (2017) review by Seidman and Atun (*61*) of procurement and supply chain interventions more broadly included 11 references on centralized procurement. Upon inspection, the review did not identify any of the six studies included here, and none of the references in their review (*31*,*32*,*36*,*41*,*49*,*62–67*) were eligible for inclusion in the present review due to study design (uncontrolled before/after and descriptive/non-quantitative analyses). However, from their review, the authors suggest national (centralized) pooled procurement and international pooled procurement has the potential to deliver cost savings across multiple settings. Although the study designs informing this conclusion are weak, the directionality of the evidence is nonetheless consistent with that of the present review.

A scoping review of literature from Latin American countries by Soares *et al.* (*68*) identified two studies on "pooled purchasing". One was also covered by Seidman and Atun, the other was not an eligible study design for the present review. The objectives of the review by Soares *et al.* were to examine the scope and aspects discussed in peer-reviewed papers on public procurement in South American countries, and as such results are not comparable with the present review.

We are not aware of further reviews on the topic.

3.3.5 Authors conclusions: implications for practice; implications for research

The empirical evidence suggests pooled procurement is probably effective in lowering prices. This effect may be less pronounced in highly concentrated (monopolized) markets. Benefits of pooled procurement may be more pronounced in settings with lower institutional quality/higher corruption, and less pronounced if procurement pools include purchasers with poor payment records.

Future research is required to further substantiate these findings using robust study designs. In particular, recognizing that established systems of pooled procurement such as the Organisation of Eastern Caribbean States (OECS) Pharmaceutical Procurement System (*69*) and the Gulf Cooperation Council (*41*) exist, future work should systematically elucidate the institutional, contextual and competitive conditions under which pooled procurement is effective in reducing prices. This seems particularly relevant for the several regions currently working towards implementing pooled procurement, including to our knowledge the East African

Community (*70*), the Southern African Development Community (*71*) and the Association of Southeast Asian Nations (*72*). Furthermore, the African Continental Free Trade Area (AfCFTA) may present longer term opportunities for pooled procurement across the continent (*73*). The emergence of regional initiatives in high income countries, such as the Beneluxa initative (*74*), also present valuable opportunities for learning.

4 Value based pricing

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4.1 Background

Value-based pricing (VBP) is defined as a policy to « set prices for new medicines and/or decide on reimbursement based on the therapeutic value the medicines confer » (*3*), usually assessed in the context of Health Technology Assessment (HTA).

Economic analysis has been part of reimbursement decisions for the past two to three decades, the earliest examples of the practice appearing in the early 1990s, as reviewed by Drummond (*75*). The role of HTA bodies has been to make recommendations on the future use of new (and existing) technologies, using a transparent process with a set of defined rules (*76*). The process of HTA allows a systematic assessment of the clinical and economic value of a new technology, including an assessment of appropriate indications and the proportionality between additional costs and benefits. This in turn can be used to negotiate a value-based price (*77*). Although HTA and VBP is adopted in many European countries, recommendations resulting from the assessment of the same technology can differ widely across countries. While relative effectiveness evaluation is always undertaken, the scope of economic assessment (cost-effectiveness and budget impact) tends to vary, and has an impact on resulting recommendations (*78*).

Variants of VBP and HTA are adopted in a broad range of countries, and the definitions of "value" and "innovation" tend to differ, though some concepts such as severity, unmet need or rarity of illness are commonly referred to, and are often associated with a higher willingness to pay (*79*). However processes, procedures and outcomes of assessments, including both reimbursement decisions and the time taken to reach decisions, varies considerably across countries (*80*). VBP is often used in conjunction with other pricing policies, although the objectives of such policies are not always consistent. Specifically, external price referencing has the objective of setting prices relative to other (similar) countries, whereas VBP is intended to set locally appropriate prices (*79*).

VBP can also be considered in the context of disinvestment, using the same principles to assess clinical and economic value of technologies that may no longer represent value for money. This can include full delisting in which technologies are no longer reimbursed, restricting use to specific sub-populations and/or (sub)indications where the technology is cost-effective, or setting prices at a level where the technology becomes cost-effective (*81*)

Initially implemented in high-income settings, countries across the world including in Asia (*82*,*83*) and Latin America (*84*) are increasingly adopting VBP policies. The present section reviews the evidence on effectiveness of VBP policies globally.

4.2 Results

4.2.1 Excluded studies

Of the 10 studies assessed at full text level, seven were excluded. One was a review (*81*), two were commentaries with no data (*85*,*86*), and four were excluded on study design: a comparative assessment of HTA processes and outcomes across Europe (*80*), a descriptive overview of the Swedish reimbursement system (*87*), a stakeholder survey and evaluation of outcomes of the HTA process in South Korea (*82*), and a theoretical/empirical economic analysis of the impact of VBP on welfare in the pharmaceutical market (*88*).

4.2.2 Characteristics of included studies

Three studies met the inclusion criteria, published between 2011 and 2017 (Table 4.1). The study designs are interrupted time series (ITS) (*89*), repeated measures (RM) (*90*) and panel data analysis (*91*). One study was in the South Korean setting (*89*), and two studies compared the impact of different pricing policies across countries in Europe, the Americas, the Far East and Oceania (*90*,*91*).

The subjects of study were antihyperlipidemic drugs in one study (*89*), angiotensin-converting enzyme (ACE) inhibitors in one study (*91*), and expenditures related to all prescription medicines in the third study (*90*). The intervention was a national procedure for disinvestment of cost-ineffective pharmaceuticals in one study (*89*), and an assessment of the macro-level impact of cost-effectiveness analysis/VBP in two studies (*90*,*91*). One study assessed the impact on volume (*89*), two studies assessed the impact on expenditure (*89*,*90*) and two studies assessed the impact on unit prices (*89*,*91*). Details of the interventions studied are given in Table 4.2.

The risk of bias assessment for the three studies is presented in Table 4.3. All studies for which the domain was assessed exhibited high risk of bias for the domain "Intervention independent" due to multiple ongoing policies with an impact on utilization (*89*), or price and expenditure levels (*90*). None of the three studies provided an assessment of missing data, leading to an unclear risk of bias for "incomplete outcome data" (*89*–*91*). Other assessments of unclear or high risk of bias included selection of medicines not typically used within the antihyperlipidemic indication (*89*), the use of an analytical approach not specifically intended to measure the effect of the VBP intervention but rather evolution of expenditure over time (*90*), and lack of expenditure controls and reimbursement rates in the analysis, which were considered potential confounders (*91*). Overall, the risk of bias was assessed as low in two out of eight domains in one study (*90*), two out of four domains in one study (*91*), and five out of eight domains in one study (*89*).

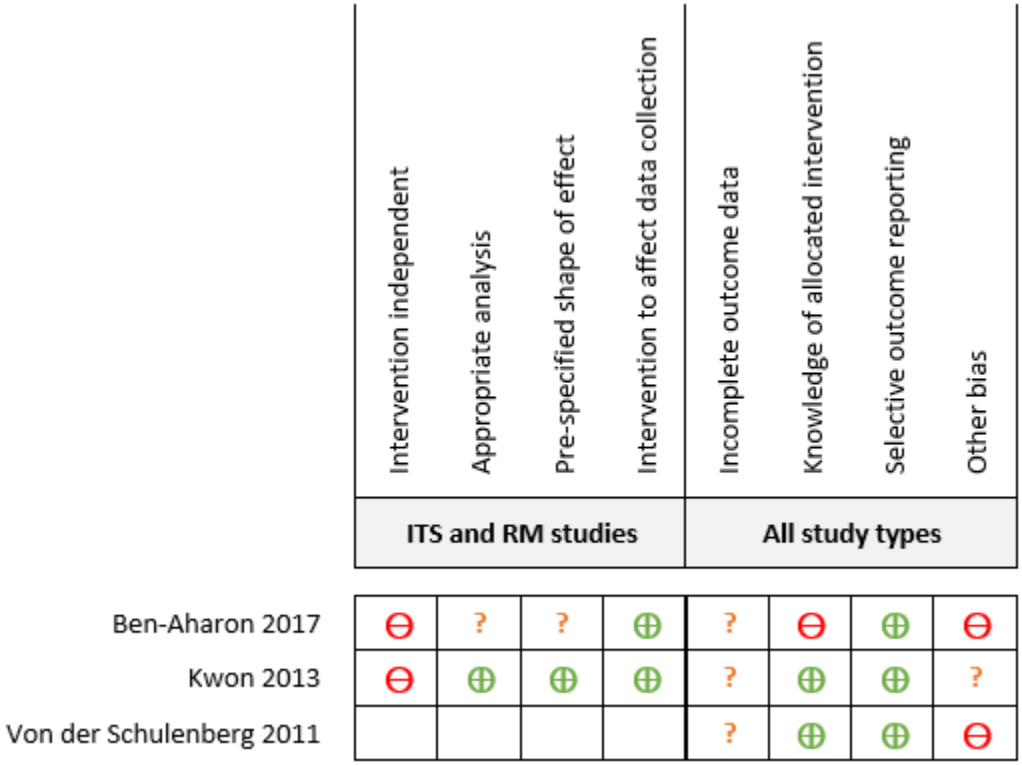
Table 4.1 Study characteristics

	Study types	Number of studies	Notes/references
Study type	Interrupted Time Series	1	(*89*)
	Repeated Measures study	1	(*90*)
	Panel data analysis	1	(*91*)
Setting	South Korea	1	(*89*)
	Multiple countries	2	The Americas, Europe, the Far East and Oceania (*90*); Europe (Denmark, France, Germany, the Netherlands, Sweden, United Kingdom) (*91*)
Subjects	Antihyperlipidemic agents	1	(*89*)
	Antihypertensive agents	1	ACE inhibitors across Europe (Denmark, France, Germany, the Netherlands, Sweden, United Kingdom) (*91*)
	Policies in multiple Countries	1	Prescription medicine expenditure across the Americas, Europe, the Far East and Oceania (*90*)
Interventions	Price cut for cost-ineffective drugs	1	(*89*)
	VBP as a cost control policy alongside other national pricing policies	2	External and internal reference pricing, VBP, profit control, no regulation (*90*); Reference pricing, mandatory generic substitution, generic price control, mark-up regression, profit control clawback, cost-efficiency analysis (*91*)
Outcomes	Volume	1	Medicines prescribed in defined daily doses per month (*89*)
	Expenditure	2	Local currency per month (*89*); Prescription medicine expenditure per capita (*90*)
	Price	2	Unit prices (*89*); Price of originators and generics (*91*)

Table 4.2 Description of interventions by category of intervention and study

	Intervention	Study begin	Study end
Value based pricing as a general cost control policy			
Von der Schulenburg 2011 (*91*)	Study of the impact of cost-effectiveness analysis (CEA) in decisions regarding reimbursement of medicines. Countries assessed as using CEA were Sweden, the Netherlands, Denmark and the United Kingdom, while France and Germany were considered not to use CEA. The relative impact of CEA versus other cost control policies was determined with a regression model.	2015	2017
Ben-Aharon 2017 (*90*)	Analysis of the association between cost control policies and total pharmaceutical expenditure across countries. Countries with VBP were Sweden, and Germany from year 2011. Countries were categorized with a single type of cost control mechanism.	2008	2012
Value based pricing as a disinvestment mechanism			
Kwon 2013 (*89*)	Analysis of antihyperlipidemic medicines in South Korea in the context of both patent expiration and the Drug list Rearrangement Project (DRP), introduced in 2007 as a value-based approach to de-list cost-ineffective medicines. Medicines not found to be cost-effective were subjected to price cuts.	2006	2010

Table 4.3 Risk of bias of included studies



4.2.3 Effect of interventions

4.2.3.1 Impact of VBP as a general cost control policy

Two studies assessed the impact of VBP as a general price (*91*) or expenditure control policy (*90*). The GRADE quality assessment is given in Table 4.4, and the summary of findings in Table 4.5. The overall quality of evidence for the price outcome was assessed as moderate, and the evidence for the expenditure outcome was assessed as very low. Brief details of the individual studies are included below, followed by main results on the impact of VBP as a general cost control policy.

Table 4.4 Certainty assessment (GRADE) of evidence for each outcome: VBP as a general cost control policy

No of studies	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
Expenditure (*90*)	Repeated measures (I)	High risk (-1)[11]	No serious inconsistency (0)	Moderate indirectness (-0.5)[12]	Serious imprecision (-1)[13]	Study design (+0.5)[14]	**Very low** ⊕○○○
Price (*91*)	Panel data (I)	Moderate risk (-0.5)[15]	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕○
Outcome: Volume							
Outcome: Availability							
Outcome: Affordability							

[11] The one study informing this outcome was assessed as low risk of bias in only two out of eight domains, and high risk of bias in three domains

[12] The study assesses impact of policies on total pharmaceutical expenditure. VBP is generally applied to innovative and high-cost medicines, and consequently much of total pharmaceutical expenditure is not expected to be impacted by VBP. A more direct measure of effect would have been e.g. expenditure on high-cost medicines.

[13] The findings of the study with respect to VBP are qualitative, and no assessment of statistical significance is presented.

[14] The repeated measures study design is generally considered robust, but the implementation and analysis in this case is lacking rigor

[15] The study by von der Schulenberg *et al*. did not assess extent of missing data, leading to an unclear risk of bias (though the data was from a commercial source). Additionally the risk of "other bias" was scored as high, mostly due to statistical significance of results changing with the model specification.

Table 4.5 Summary of findings: VBP as a general cost control policy

VBP vs other price control policies

Medicines: Antihypertensives, all prescription medicines

Settings: Europe (Denmark, France, Germany, the Netherlands, Sweden, United Kingdom); Americas, Europe, the Far East and Oceania

Intervention: VBP as a general cost control policy

Comparison: All other existing cost control policies

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Prescription drug expenditure per capita	The impact of VBP in Germany was inconclusive due to the short follow-up period reported. The specific impact of VBP on Sweden was not reported (*90*).	1	Very low ⊕◯◯◯	We are uncertain of the effect of VBP on prescription drug expenditure because the certainty was assessed as very low.
Price of antihypertensives	The regression coefficient for CEA on price as the dependent variable was significant and negative (-0.050, p<0.05) (*91*)	1	Moderate ⊕⊕⊕◯	Prices for antihypertensives are probably lower in countries using CEA as a general cost control policy
Volume				
Availability				
Affordability				

Ben Aharon *et al.* 2017 (*90*) examined the association between price regulation methods and health/medicines expenditure metrics. The authors categorized each study country into a single pricing policy type, and only Sweden and Germany were categorized as VBP countries. The UK was categorized as a profit control country due to the Pharmaceutical Pricing Regulation Scheme, despite the presence of HTA processes.

Von der Schulenburg *et al* 2011 (*91*) undertook a panel data analysis across six European countries to identify associations between pricing policies and price levels. Their analysis included coefficients for reference pricing, generic substitution, regressive pharmacy remuneration, clawbacks and CEA. Sweden, the Netherlands, Denmark and the UK are categorized as countries using CEA, while France and Germany are not. At the time of analysis, Germany had not yet implemented the Arzneimittelmarkt-Neuordnungsgesetz (AMNOG) reform.

The results of Ben Aharon *et al*. are inconclusive with respect to the effect of VBP (see Ben-Aharon *et al.*). A VBP intervention was only introduced in one country during the study period (AMNOG in Germany) and this occurred in the last year of the data series (2011), yielding insufficient data post-intervention. Results for the only other country categorized as implementing VBP (Sweden) were not reported.

The estimates of the regression model of von der Schulenburg *et al.* (*91*) result in a negative and significant coefficient for CEA of -0.05 ($p<0.05$, see Von der Schulenburg *et al.*), suggesting the use of CEA results in lower prices for ACE inhibitors. The relative magnitude of the CEA coefficient was approximately half of that for reference pricing (0.09, $p<0.1$).

4.2.3.2 Impact of VBP as a disinvestment tool

One study assessed the impact of VBP in the context of disinvestment. The GRADE quality assessment and summary of findings are given in Table 4.6 and Table 4.7. The evidence was assessed as moderate. Brief details of the study are included below, followed by main results on the impact of VBP as a disinvestment tool.

Table 4.6 Certainty assessment (GRADE) of evidence for each outcome: VBP as a disinvestment tool

No of studies (references)	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
Price: 1 (*89*)	ITS (I)	Low risk (0)[16]	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Expenditure: 1 (*89*)	ITS (I)	Low risk (0)	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Volume							
1 *(89)*	ITS (I)	Low risk (0)	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Availability							
Outcome: Affordability							

[16] The risk of bias was only considered to be high in the "intervention independent" domain. Unclear risk of bias in "incomplete outcome data" resulted from authors not checking the extent of missing data, and unclear risk of "other bias" from the selection of anti-hypertensive drugs not routinely used in this therapeutic area. However the majority of domains were considered to exhibit low risk of bias.

Table 4.7 Certainty assessment (GRADE) of evidence for each outcome: impact of VBP as a disinvestment tool

VBP as a disinvestment tool vs no VBP-based disinvestment

Medicines: Antihyperlipidemics

Settings: South Korea

Intervention: VBP-based disinvestment

Comparison: No VBP-based disinvestment

Outcomes	Impact*	No. of studies	Certainty of the evidence (GRADE)†	Comments
Price				
Price	A reduction in unit prices was reported for medicines undergoing VBP assessment in the context of delisting	1	Moderate ⊕⊕⊕◯	The evidence suggests VBP is probably effective in lowering unit prices in the context of systematic delisting.
Expenditure	VBP (in the absence of rational prescribing) did not lead to lower overall expenditure.	1	Moderate ⊕⊕⊕◯	The evidence is inconclusive. Despite a reduction in unit costs, concurrent events (e.g. changes in prescription patterns) appeared to confound the impact of VBP on expenditure.
Volume				
Volume	Level (negative sign) and slope (positive sign) changes were significant following two rounds of price cuts in South Korea for the group of drugs not subjected to price cuts (sample included newly introduced generics). When excluding newly introduced generics, the results were not significant.	1	Moderate ⊕⊕⊕◯	The evidence is inconclusive. Changes in volume are only observed for medicines not undergoing VBP intervention.
Availability				
Affordability				

Kwon *et al.* 2013 (*89*) assessed the impact of implementing VBP as disinvestment tool on antihyperlipidemic agents in the setting of South Korea. The Drug list Rearrangement Project (DRP) was implemented in 2007 to delist (remove from reimbursement) medicines that appeared to be cost-ineffective. Both DRP and patent expiry affected prices over the course of the study. Three interventions occurred over the study

period. Briefly, atorvastatin lost patent protection in July 2008, and two rounds of price cuts in the context of DRP occurred in April 2009 and January 2010.

Kwon *et al.* assessed the impact of VBP on both unit price, expenditure and volume. A positive overall growth in volume was identified in the baseline period (slope of 491.23 thousand DDD/month) which did not change significantly after either intervention, suggesting an overall growth in utilization over time.

Expenditure on antihyperlipidemic pharmaceuticals rose over time, with positive expenditure growth (slope) after the third intervention (KRW 599.67 million per month, $p<0.1$, see Kwon *et al.*). In the subgroup analysis, statistically significant positive expenditure growth was only observed in the group of medicines without price cuts applied through DRP after the third intervention (KRW 278.11 million per month, $p<0.1$), suggesting overall expenditure growth was driven by this subgroup, which included newly introduced generics. Excluding new generics from the sample resulted in a non-significant change in slope of expenditure after the third intervention (KRW 149.58 million per month). These observations were attributed to generics entering the market at a predetermined price point, which was higher than existing medicines on the market.

Examining the subgroup of antihyperlipidemics in which price cuts were applied through DRP, no significant change in the level or slope of expenditure was observed until after the second price cut, at which time the expenditure level dropped (KRW -18,409 million per month, $p<0.1$). At the same time, the unit price level changed by KRW -577.86 per DDD per month ($p<0.05$), possibly explaining the reduction in expenditure, although the change in unit price slope was positive (KRW 10.85 per DDD per month, $p<0.05$) suggesting some growth in unit prices after the second price cut.

Overall, while the DRP related price cuts appeared to control expenditure in the group of medicines undergoing the intervention, the intervention did not appear to control overall expenditure due to increased utilisation and generics entering the market at high price points.

4.3 Authors' conclusions

4.3.1 Summary of main results

Three studies examined the impact of VBP, here in the context of CEA, on prices, expenditure and volume.

The findings of Ben Aharon *et al.*(*90*) were not considered informative for the present review as meaningful data was missing. However von der Schulenburg *et al.* (*91*) found prices of ACE inhibitors were lower in countries using CEA for price setting, controlling for other price regulation mechanisms.

Kwon *et al.* (*89*) finds that VBP in the context of disinvestment did not contribute to lower overall expenditure on antihyperlipidemics in South Korea, and the study highlighted the complex interplay between different pharmaceutical policies. Specifically, the impact of generic entry and price setting appeared to counteract price control through a VBP-based mechanism.

4.3.2 Overall completeness and applicability of evidence

The evidence identified on VBP was focused on European countries (*91*) and South Korea (*89*), and specifically addressed two pharmaceutical classes. Additionally, VBP in a European context generally forms

part of market access regulation, whereas in South Korea VBP was used in the context of disinvestment. These factors make generalizability challenging.

4.3.3 Quality of the evidence

Kwon *et al* (*89*) and von der Schulenburg *et al.* (*91*) exhibited limited risk of bias. Although these studies were transparently reported, both lacked information on missing data.

The major limitation in all identified studies was in assessing the impact of VBP in isolation from other policies.

4.3.4 Agreement/disagreement with other reviews

The WHO Guideline on Country Pharmaceutical Pricing Policies of 2015 (*4*) reviewed a small number of studies relevant to VBP.[17] These references discussed, for example, the quality of HTA submissions, the relative merits of HTA versus reference pricing, transferability of economic assessments and availability of locally relevant economic evidence. However as in the present review, none of those references examined the impact of VBP on the primary outcomes examined here. The systematic review of studies reporting on the use of cost-effectiveness as a criterion in drug selection and the role of pharmacoeconomics in the allocation of resources, also preceding the guideline,[18] was unpublished and not available for comparison.

As concluded in the Guideline (*4*) Annex J on the use of HTA, much of the academic literature on HTA does not focus on pricing outcomes, but rather on the processes and outcomes of HTA. We are not aware of any reviews assessing the impact of VBP on price, volume, availability of affordability of medicines.

4.3.5 Authors conclusions: implications for practice; implications for research

The available empirical evidence suggests VBP is probably effective in lowering unit prices for certain classes of medicines, but is not necessarily sufficient to control overall expenditure. This conclusion is supported by only two studies, and further research is required to substantiate the findings.

In the context of Europe, where there is an established tradition of using HTA in several countries, VBP is a method of setting launch prices of innovative medicines. From the perspective of the present review, this makes it challenging to assess the impact of VBP on prices, as there is no counterfactual scenario (no "before" price). Comparison across countries with/without VBP systems are similarly challenging, as countries commonly adopt several pharmaceutical policies concurrently. Finally, VBP is widely viewed more as a method for balancing reward for innovation and cost (*79*), as opposed to a pure cost control measure.

As demonstrated by Kwon *et al*. (*89*), assessing the effectiveness of VBP as a pricing policy may be more feasible in the context of disinvestment. With disinvestment becoming a more widely debated topic (*81*), systematic assessment of the value of treatments currently reimbursed in health systems globally may provide an opportunity for further research on the effectiveness of VBP.

[17] See table ES6.1 within the reference

[18] Cited as Pillay T, "Value based price determination – pharmacoeconomics – WHO/HAI review series on pharmaceutical pricing policies and interventions. Unpublished."

5 Discounts for single source pharmaceuticals

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5.1 Background

A price discount for a single source pharmaceutical is broadly defined as « a price reduction granted to specified purchasers under specific conditions prior to purchase », with examples including rebates (payment made to the purchaser after the transaction has occurred), or price reductions upon meeting certain pre-agreed terms and conditions as specified in so-called managed-entry agreements (MEA's). The latter arrangements are usually classified into financial-based MEA (e.g. flat discounts, price-volume agreements, capping) and performance-based MEA (e.g. risk-sharing agreement, coverage with evidence development). Single source pharmaceuticals are pharmaceutical products supplied by a company that holds the patent rights, exclusive marketing rights, or supply agreements in a specific jurisdiction (*92*).

Discounts are considered relative to the public list price of a pharmaceutical, and are generally expected to be greater for purchasers with greater bargaining power by virtue of size or market concentration (*93*,*94*), such as monopsonistic purchasers (e.g. national health systems) or actors with the ability to shift market shares (e.g. Pharmacy Benefits Managers or other formulary decision makers).

Discounts have become a mechanism for firms to maintain price differentiation across countries, by allowing them to negotiate confidential discounts with individual countries while maintaining a fixed list price (*95*). For this reason, discounted prices can often not be disclosed by public payers (*96*), and the topic of discounting is consequently closely linked with the topic of price transparency (see 'Promoting Price Transparency').

A survey of MEAs in Eastern European countries found the most common form of MEA was confidential discounting. This study also found budget impact was the main concern driving the adoption of MEAs, and many MEAs were for oncology medicines (*97*), suggesting affordability is a driving factor for the engagement in confidential discounting. Across Europe, various forms of discounts and rebates are used in the majority of countries, both in the in-patient and out-patient settings, with discounts ranging from 0-50% (*98*).

This chapter details the evidence on price discounts.

5.2 Results

5.2.1 Excluded studies

Three references on the potential impact of price discounts for single source pharmaceuticals were assessed at full text level. Two out of three papers assessed were uncontrolled before/after analyses, and were excluded on study design (*99*,*100*). One paper was a commentary with limited data (*101*).

5.2.2 Characteristics of included studies

During full-text screening, no studies were identified that met the inclusion criteria.

5.3 Authors' conclusions

5.3.1 Agreement/disagreement with other reviews

Our review and a targeted search did not uncover any existing reviews on the effectiveness of price discounts for single source pharmaceuticals.

5.3.2 Authors conclusions: implications for practice; implications for research

There is a lack of evidence to determine whether discounting of single source pharmaceuticals as a pharmaceutical policy is effective in controlling price, volume, availability or affordability.

A survey of 31 European countries showed that various forms of discounting is common throughout Europe, both on single- and multi-source pharmaceuticals. Types of discounting in practice are broad and include negotiated discounts, unilateral price control at specific points of the supply chain (e.g. ex-factory or wholesale/retail), bundling of multiple products and refunds to the public payer depending on sales volume. The majority (25 of 31) of countries surveyed report some form(s) of discounting, and price reductions in the in- and out-patient sectors are the most frequent form of discounts. Moreover, individual negotiations are the most common contractual arrangements, and in most cases, the negotiated discounts are confidential (*98*).

The lack of transparency of net prices is a challenge for further research. Studies using international prices for comparison can for example use data from the Global Price Reporting Mechanism (GPRM) database, which is a publicly available resource of transaction data for HIV, tuberculosis and malaria commodities (*102*). Other examples of transaction databases exist, such as the Management Sciences for Health International Medical Products Price Guide (*103*). However to our knowledge, there is very limited opportunity to routinely source net price data on single-source pharmaceuticals, particularly innovative high-cost treatments which are subject to systematic launch sequencing and where confidential net prices are a mechanism for achieving differential pricing across countries (*104*). For this reason, information on net price levels either for research or for use by public payers in a negotiating situation is not readily available.

Related to the difficulty of obtaining net price data, there may be legal obstacles to studying the topic of discounts. For example, an evaluation of the MEA mechanism in Belgium undertaken by the Belgian Health Care Knowledge Centre (KCE) was terminated due to the threat of legal action from industry stakeholders (*105*), highlighting the sensitive nature of net price transparency.

Discounts are increasingly used in the context of introduction of new technologies in health systems. A survey of payers in North America, Europe and Australasia found the use of confidential price discounts was common, in particular for specialty pharmaceuticals (*96*). Among surveyed representatives of nine Canadian provinces, the most frequently cited theme contributing to the use of Product Listing Agreements involving confidential discounts was a recommendation in the context of Health Technology Assessment (*106*). A survey of Central and Eastern European countries found confidential discounts was the most common form of MEA, and that concerns around finite resources (budget impact) was the most common rationale for implementing MEA's (*97*).

Additionally, the type of discounts negotiated may have an impact on enforceability of the contract, with more complex contracts being more difficult to implement, and discounts based on e.g. utilization patterns being vulnerable to disagreement between the contracting parties (*106,107*). As such, although the concept of price discounting is straightforward, the contract and implementation details might influence the effectiveness of the policy.

We are not aware of a substantial literature body on the magnitude of discounts in practice. Existing work has addressed, for example, discounts on oncology drugs (*108*) and hospital medicines more broadly (*109*). Respondents and authors of these survey studies also raise the issue of net price confidentiality, and note that price discounts do not generally seem to follow predictable rules, such as a correlation between price and Gross Domestic Product (GDP) per capita (*108*). Furthermore, a diverse pattern of discounting was observed, including apparently commercial strategies to familiarize patients with specific medicines before hospital discharge by providing them for free, the use of year-end rebates as opposed to simple discounts, and the existence of certain products which were not discounted at all. These practices were observed to differ across countries (*109*). These studies were performed in the context of hospital procurement, which is only one of the many mechanisms for implementing discounts.

The present review, however, did not identify evidence to support or refute the rationale of discounting (confidential nor transparent) as a pharmaceutical policy to control price, volume, availability or affordability, despite the practice being widespread.

6 Cost-plus pricing

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6.1 Background

Cost-plus pricing, also known as cost-based pricing, is defined here as a pricing policy that « considers the costs associated with the inputs required for the production of goods or services » (*5*). The setting of prices through cost-plus pricing is commonly done at the ex-manufacturer level, but may also be applied for setting reimbursement, retail or wholesale prices (*5*). To determine the final price, the national authority requires actual cost information to the point at which the price would be set and national authority and manufacturer or wholesaler would generally need to negotiate on a mutually-acceptable profit margin additional to the estimated costs (*5,110*). Reportedly, it may be difficult to obtain actual information from manufacturers as the approach is resource intensive and susceptible to manipulation by accounting practices (*110*). Due to these drawbacks, many industrialized countries employing price control mechanisms have switched to other options (*110*), although the model has been proposed for innovative therapies and orphan drugs, which are generally not considered cost-effective (*111*). This mechanism helps to protect patient populations with rare diseases by determining reasonable prices for these medicines, which is currently considered a challenge (*111,112*).

Some examples of cost-plus pricing are the system employed in Japan, which applies a fixed formula to calculate prices at ex-factory level for pharmaceuticals with no comparator on the market (*113*), the cost-plus pricing approach in India restricting the price of essential medicines to a maximum of twice the cost of their production (*114*), and the cost-plus method in Australia for setting reimbursement rates by granting a profit margin of usually 30% on manufacturing costs (*115*).

It is suggested that an undesirable effect of cost-plus pricing might be reduced incentive for manufacturers to invest in R&D, as only investments in a small proportion of pharmaceuticals actually reaching the market would be recovered, whereas costs of failed R&D efforts would not be compensated (*112*). Shortages may also issue from this mechanism, as monopolist manufacturers might exit the market due to insufficient returns (*5*). Taken together with the practical challenge of obtaining reliable cost information and concerns that the manipulation of cost information by the manufacturer may result in higher price, the effects of cost-plus pricing on medicine prices and availability need to be assessed.

This chapter details the evidence on cost-plus pricing.

6.2 Results

During initial screening of titles and abstracts, no studies meeting the inclusion criteria were identified. No studies made it to the stage of full-text screening. Ultimately, no studies were included for this topic.

6.3 Authors' conclusions

6.3.1 Agreement/disagreement with other reviews

The unpublished WHO/HAI policy review on cost-plus pricing, which was part of the review series on pharmaceutical pricing policies and interventions, also investigated the effectiveness of this pricing policy (*4*). Although cost-price pricing was defined somewhat differently, it being described as a method for setting retail prices[19], this policy review similarly indicated that there is no literature available assessing cost-plus pricing.

We are not aware of further reviews on the topic.

6.3.2 Authors conclusions: implications for practice; implications for research

There is a lack of robust quantitative and comparative evidence assessing the impact of cost-plus pricing. It remains uncertain what the impact of cost-plus pricing on prices, volumes, availability and affordability of medicines is, both in high- as well as in low-income countries. Research is required to substantiate the use of this pricing policy using robust study designs, particularly since this method may be increasingly used for innovative therapies and orphan medicines (*111*).

[19] Definition of cost-plus pricing as provided in the WHO/HAI policy review: a method for setting retail prices of medicines by taking into account production cost of a medicine together with allowances for promotional expenses, manufacturer's profit margins, and charges and profit margins in the supply chain (*4*)

7 Tax exemptions or tax reductions for pharmaceuticals

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7.1 Background

Tax exemptions or tax reductions for pharmaceuticals are ways to reduce prices of medicines. Taxation is defined as « a compulsory transfer of money from private individuals, institutions or groups to the government. It may be levied upon wealth or income (direct taxation) or in the form of surcharges on prices (indirect taxation). It may be paid to the central government (central taxation) or to the local government (local taxation) » (*3*,*4*).

In high-income countries, direct taxes together with social security taxes, are responsible for about two-third of the government revenue. Indirect taxes, on international trade or on the purchase of goods and services, are major sources of government revenue for low-income countries (*4*).

An assessment of import tariffs in over 150 countries showed that around 60% of countries levied import tariffs on finished pharmaceuticals. Import tariffs are considered a regressive tax, and are generally implemented either to protect local pharmaceutical industry or to raise government revenues, although the revenue generated by these taxes is relatively modest, amounting to less than 0.1% of Gross Domestic Product (GDP) (*116*).

The series of policy reviews carried out by WHO/HAI as part of the 2015 pricing policy guideline development included a review on sales taxes on medicines (*117*). This review discusses the principles of and current use of taxation, in particular the use of sales taxes and value-added tax (VAT). Differences were noted between high– and low-income countries. In Europe, VAT on medicines ranges from 0-25%. Often a lower VAT rate is used for medicines compared to standard goods and sometimes prescription medicines may even be exempted. In low- and middle-income countries, domestic taxation including VAT and other taxes (such as state tax, community tax, excise duties, etc) on medicines vary and range from 2.9%-34%. This review did not identify any published evidence assessing the impact of reductions or exemptions of taxes on pharmaceutical products.

Taxes affect the final price of medicines, which in turn can affect affordability and utilization when patients pay a share of the costs of medicines out-of-pocket (*118*). Taxes on pharmaceutical products are therefore relevant determinants of access to medicines in some contexts. However the interplay between taxes and other costs added throughout the supply chain, such as dispensing fees and margins (*119*), means the final impact of tax exemptions or reductions are not necessarily straightforward to determine.

This chapter presents the evidence for the current review on tax exemptions or tax reductions.

7.2 Results

7.2.1 Excluded studies

Only two studies were assessed at full text level and both were excluded after full text screening. One study was a review paper preceding the working paper by WHO/HAI on sales taxes on medicines (*117*), the second study was excluded because the intervention did not meet the definition of tax exemption or reduction (*120*).

7.2.2 Characteristics of included studies

During full-text screening, no studies were identified that met the inclusion criteria.

7.3 Authors' conclusions

7.3.1 Agreement/disagreement with other reviews

Tax exemptions/reductions for pharmaceutical products was also considered in the 2015 pharmaceutical policy guideline (*4*), and the associated policy review undertaken in 2011 (*117*). The policy review and guideline did not identify evidence on the impact of tax exemptions/reductions for pharmaceuticals, but cited a body of evidence which was largely descriptive. Our review confirms the evidence gap, identifying no evidence for the impact of tax reductions or exemptions on price, volume, availability or affordability of medicines.

7.3.2 Authors conclusions: implications for practice; implications for research

Taxation of pharmaceutical products is relatively prevalent, though some countries apply a lower or zero VAT rate for pharmaceuticals (*121*). While such taxes affect the final price of pharmaceuticals, in contrast to other pricing policies examined in other chapters of this work, the additional expense due to tax is returned to government treasury, where in theory it can be reallocated back to healthcare expenditure or other beneficial use. Future work elucidating the impact of tax exemptions/reductions on price, volume, availability or affordability of medicines might therefore consider a broader perspective of impacts.

8 Promoting the use of quality assured generic and biosimilar medicines

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8.1 Background

Since the 1990s, public authorities such as public payers or Ministries of Health are promoting the use of quality assured generic medicines as a strategy to reduce public health expenditures as well as to lower patients' out-of-pocket expenditures. As stated by former WHO Director General Dr. Chan "*Generic products serve public health in multiple ways. In terms of improving access to medicines, price and quality go hand in hand. Generic products are considerably less expensive than originator products, and competition among generic manufacturers reduces prices even further. Generics serve the logic of the pocket. An affordable price encourages good patient compliance, which improves treatment outcome and also protects against the emergence of drug resistance*" (*122*). Further, the use of less expensive generics generates savings which creates financial headroom for innovative medicines and allows sustainable treatment of more patients with less financial resources (*123*,*124*). As shown by Cameron *et al*, for many countries there is potential to achieve savings if generic medicines are used rather than originator brands. The authors projected savings ranging from 9.3% to 88.7% if the lowest-priced generics were used for different low- and middle-income countries (*125*).

Literature has described several supply- and demand-side policy interventions to promote the use of generic medicines. Supply-side interventions include 1) medicine regulations, 2) trade and intellectual property policies, 3) pricing policies and 4) purchasing policies (*122*). Examples of pricing policies are *generic price linkage* defined as "practice of setting the price of a generic in relationship to the original product medicine, usually at a certain percentage lower than the original medicine price" and *reference pricing* defined as "a reimbursement policy in which identical medicines (ATC 5 level) or similar medicines (ATC 4 level) are clustered (reference group)" (*126*) (see 'Reference Pricing' for both types of pricing policies). Demand-side interventions are targeted at prescribers, pharmacists, and the public and typically include 1) reimbursement policies (such as co-payment plans), 2) prescribing policies, 3) dispensing policies and 4) policies impacting patients. Examples of prescribing policies include *INN-prescribing* defined as "requirements for prescribers (e.g. physicians) to prescribe a medicine by its international non-proprietary name (INN)" and of dispensing policies including *(mandatory) generic substitution* defined as "the practice of substituting a medicine with a less expensive medicine" and any kind of *awareness and educational campaigns* (*126*).

The heterogeneity of generic policies and the complex pharmaceutical market dynamics may lead to great variation in the differences between prices of generic medicines and originators as well as between countries and consequently may not always lead to desired savings in public expenditures or lowered out-of-pocket expenses. Vogler *et al*. showed that "*countries (e.g. Denmark, Sweden) with strong generic policies, particularly based on competition and involving elements of enforcement, tend to have higher differences between originator and generic prices*" (*127*).

This chapter details the evidence on the effects of demand-side policies including "strategies directed at patients, prescribers or pharmacists to encourage the use of generic or similar biological medicines". In addition, it includes one intervention related to marketing authorisation of generic medicines that can have an impact on retail prices of generic medicines.

8.2 Results

8.2.1 Excluded studies

The systematic literature review resulted in 57 studies at full text level. In total 41 studies were excluded. The main reason for exclusion (n = 37) was inappropriate study design (*122*,*128–163*). Other reasons for exclusion included incorrect intervention (n = 3 (*164–166*) and missing data as only the abstract was available (*167*) (n = 1). Out of the 41 excluded studies, four looked at impacts on biosimilar medicines but could not be included due to inappropriate study design.

8.2.2 Characteristics of included studies

Sixteen studies met the inclusion criteria; characteristics of the included studies are described in Table 8.1. Studies were published between 2006 and 2016. One study was a randomized trial (*168*) which had the strongest design. Seven studies were however interrupted time series analyses (*169–175*), of which one study also included a repeated measures study (*169*). Five studies used panel data/regression analyses (*91*,*176–179*), three studies used a difference-in-differences design (*180–182*). The majority of studies (n= 9) analysed data from European countries, including Belgium (*172*), Finland (*173*,*174*), Portugal (*175*), Spain (*179*), and Sweden (*169*,*170*,*176*). Von den Schulenburg *et al*. studied data from Denmark, France, Germany, Netherlands, Sweden, and the United Kingdom (UK) (*91*). Two studies looked at the United States (US) (*168*,*181*), one at Taiwan (*178*), one at Argentina (*171*), and one at Chile (*182*). In addition, two studies examined data from multiple counties: one study used data from 16 OECD countries (*180*), another study used data from the US, the UK, Germany, France and Spain, Italy, Japan, Canada, Brazil and Mexico (*177*).

Five studies looked at multiple selected medicines as their study subjects (*168*,*171*,*172*,*181*,*182*), four studies (*170*,*176*,*177*,*179*) looked at all medicines on the market; three studies examined cardiovascular drugs (*91*,*169*,*178*), another three looked at antipsychotic drugs (*173–175*), and one study examined substitutable drugs (*176*). Fourteen out of the sixteen included studies assessed the impact on price (*91*,*169–171*,*173*,*174*,*176–182*), and seven studies assessed the impact on volume of generics used in relation to originator products (*168*,*169*,*171*,*172*,*175*,*177*,*178*).

The interventions included in the studies can be grouped into five main sub-categories: 1) dispensing policies (n = 6) (*91*,*170*,*173*,*174*,*176*,*180*); 2) reimbursement policies (n= 4, examining the effect of nil or reduced co-payments (*172*,*181*), examining the effect of a reimbursement scheme based on reference

pricing (*178*) or examining the effects of information campaigns (*175*)), 3) prescribing policies (n = 4) (*168*, *169*,*171*,*179*), 4) mixed demand-side policy measures (n = 1) (*177*); and 5) market entry regulations (n = 1) (*182*).

Table 8.1 Study characteristics

	Study types	Number of studies	Notes/references
Study type*	Randomized trail	1	(*168*)
	Interrupted time series	7	(*169–175*) [20]
	Regression analysis/ Panel data	5	(*91*,*176–179*)
	Difference-in-differences	3	(*180–182*)
	Repeated measures	1	*(169)* [19]
Setting	Europe	9	Sweden (*169*,*170*,*176*), Spain (*179*), Belgium (*172*), Finland (*173*,*174*), multiple EU-countries (Denmark, France, Germany, Netherlands, Sweden, United Kingdom) (*91*), Portugal (*175*)
	America	2	USA (*168*,*181*)
	Asia	1	Taiwan (*178*)
	South America	2	Chile (*182*), Argentina (*171*)
	Multiple countries/global	2	Australia, Austria, Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, Japan, Netherlands, Portugal, Sweden, Switzerland, and United States (*180*), USA, the UK, Germany, France and Spain, Italy, Japan, Canada, Brazil and Mexico (*177*)
Subjects	All medicines	4	All prescribed pharmaceuticals (*170*,*176*,*179*), single molecule prescription drugs (*177*)
	All substitutable drugs	1	All recorded data (*176*)
	Cardiovascular drugs	3	Angiotensin receptor blocker (*169*), ACE-inhibitors (*91*), beta blocking agents, calcium channel blockers, and ACE-inhibitors (*178*)
	Antipsychotic drugs	3	(*173–175*)
	Multiple selected medicines	5	192 medicines from the WHO essential medicines list (*171*), acid blocking agents and statins (*172*), antidiabetics and antihyperlipidemic (*181*), medicines required to demonstrate bioequivalence (*182*)[21], top 25 medications (*168*)
Interventions	Dispensing policies	7	(*91*,*170*,*173*,*174*,*176*,*180*)
	Reimbursement policies	4	(*172*,*175*,*178*,*181*)
	Prescribing policies	3	(*168*,*169*,*171*,*179*)
	Mixed measures	1	(*177*)
	Market entry regulations	1	(*182*)
Outcomes*	Price	14	(expenditure/DDD) (*169*), Expenditure (*170*,*178*), cost/capita and price/prescription (*179*), cost/DDD (*173*,*174*,*176*), retail price (*182*), pharmaceutical price

[20] The article by Godman 2013 includes two types of studies: the interrupted time series study analyses changes in prescriptions; the repeated measures study analyses utilisation. Therefore, the sum of studies according to the study design does not add up to 16 studies.

[21] Atorvastatin, Carvedilol, Ciprofloxacine, Citalopram, Fluoxetine, Venlafaxine, Sertraline, Glibenclamide, Metformine, Paroxetine, Prednisone, Valsartan, Alprazolam, Amlodipine, Azitromicine, Carbamazepine, Clonazepam, Clorfenamine, Enalapril, Ibuprofen, Ketoprofen, Losartan, Micofenolate, Nevirapine, Olanzapine, Quetiapine, Risperidone, Ritonavir, Zidovudine

			(*91*,*171*,*180*), normalized generic price (*177*), cost change (*181*)
	Volume	7	Utilization (*169*,*171*), prescriptions (*178*), monthly sales volume (*175*,*181*), volume share (*177*), generic dispensing ratio (*168*)

Abbreviations: ACE-inhibitors = Angiotensin-converting enzyme, ATC = Anatomical Therapeutic Chemical, EU = European Union, DDD = daily defined dose, UK = United Kingdom, USA = United States of America

* Please note that double counts of studies are possible as multiple outcomes were reported in a number of studies.

The risk of bias assessment is presented in Table 8.2. For studies describing *dispensing policies*, the studies generally showed low risk of bias in most domains. Some domains were, however, associated with a higher risk of bias: one study did not have an appropriate analysis and was therefore rated as high risk, two studies had incomplete reporting on outcome data and were consequently rated as high risk and three studies were rated as high risk in other biases due to missing analysis of specific assumptions or lack of details about the intervention per country.

The overall risk of bias for the sub-category *reimbursement policies* is generally low in most domains. However, some domains were rated as high risk: for two studies the measurement of effect of the intervention may have been influenced by co-interventions being implemented within the study period, resulting in the data to be insufficient to distinguish between the impact of one intervention from another. One study used an inappropriate analysis and was therefore rated as high risk. All four studies insufficiently reported on outcome data and were therefore either rated as "moderate or high risk". Another study was rated as high risk due to selective reporting of outcomes.

For *prescribing measures*, the studies generally showed low risk in most domains. However, one study showed a high risk due to co-interventions happening during the same time as the main intervention and another study was rated as high risk as the baseline outcome measures were insufficiently described. All four studies were rated either as high or moderate risk due to incomplete reporting of the outcome data; and three of the four studies were rated as high or unclear risk for other biases such as insufficient data and low datapoints in the analysis.

Both studies included in the categories *mixed demand-side measures and market entry policies* generally showed a high risk of bias. Danzon *et al*. presented with a high risk in the majority of categories including intervention independent, pre-specified shape of effect, incomplete outcome data and selective outcome reporting. The study reported on multiple regulatory and reimbursement policies in different countries without describing details on the intervention in each country. Balmaceda *et al*. was rated as high risk due to incomplete reporting of outcome data, selective outcome reporting and other biases.

Table 8.2 Risk of bias of included studies

		Random sequence generation	Allocation concealment	Baseline outcome measurements similar	Baseline characteristics similar	Protection against contamination	Intervention independent	Appropriate analysis	Pre-specified shape of effect	Intervention to affect data collection	Incomplete outcome data	Knowledge of allocated intervention	Selective outcome reporting	Other bias
		RCT, NRCT and CBA studies					**ITS and RM studies**				**All study types**			
1	Andersson 2007						⊕	⊖	⊕	⊕	⊕	⊕	⊕	?
	Bergman 2016										?	⊕	⊕	⊖
	Buzzelli 2006										⊖	⊕	⊕	⊖
	Koskinen 2014						⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	Koskinen 2015						⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	Von der Schulenberg 2011										?	⊕	⊕	⊖
2	Chen 2008										?	⊕	⊕	?
	Clark 2014										?	⊕	?	⊕
	Fraeyman 2013						⊖	⊕	⊕	⊕	⊖	⊕	⊖	?
	Leopold 2014						⊖	⊖	⊕	⊕	?	⊕	⊕	⊕
3	Bhargava 2010	?	⊕	⊖	⊕	?					⊖	⊕	⊕	?
	Godman 2013						⊖	⊕	⊕	⊕	?	⊕	⊕	⊕
	Lee 2013						?	⊕	⊕	⊕	⊖	⊕	?	⊖
	Moreno-Torres 2011										?	⊕	⊕	⊖
4	Danzon 2011						⊖	⊕	⊖	⊕	⊖	⊕	⊖	?
5	Balmaceda 2015										⊖	⊕	⊖	⊖

Notes: 1 = dispensing policies, 2 = reimbursement policies, 3 = prescribing policies, 4 = mixed measures, 5 = market entry measures

Table 8.3 Description of interventions by category of intervention and study

	Intervention	Study begin	Study end	Known co-interventions
Dispensing policies				
Andersson 2007 (*170*)	In October 2002 Sweden introduced a mandatory generic substitution policy (with an opt out/restriction allowed by physician or pharmacist)	2000	2004	None reported
Bergman 2016 (*176*)	In Sweden, pharmacists' are obliged to dispense the lowest-cost generic substitute available, *widened substitution group, and well-defined exchange groups.*	2006	2011	Price cap, definition of substitution groups, allowance to dispense 2nd or 3rd generic in a stock out
Buzzelli 2006 (*180*)	In 16 OECD countries pharmacists' right or obligation to substitute the prescribed drug with a cheaper generic version with the same active chemical ingredients.	1970	2002	None reported
Koskinnen 2014 (*173*)	Finland introduced a mandatory generic substitution policy: pharmacies have the right or obligation to substitute the prescribed medicine with a cheaper equivalent drug and Reference Pricing	2006	2010	Generic Reference Pricing
Koskinnen 2015 (*174*)	Finland introduced a mandatory generic substitution policy: pharmacies have the right or obligation to substitute the prescribed medicine with a cheaper equivalent drug and Reference Pricing	2006	2011	Generic Reference Pricing
Von der Schulenburg 2011 (*91*)	In six European countries mandatory generic substitution policies were introduced: Pharmacists obligation to substitute the prescribed drug with a cheaper generic version with the same active chemical ingredient	1991	2006	Other policies were included in the regression model (incl. reference pricing, mark-up regression, profit control, clawback, tax funding, cost-efficiency analysis)
Reimbursement policies				
Chen 2008 (*178*)	In 2001 Taiwan introduced a reimbursement scheme based on an internal reference pricing generic grouping method	2000	2002	None reported
Clark 2014 (*181*)	In the US the introduction of nil patient co-payments in a major employer	2008	2011	None reported

Fraeyman 2013 (*172*)	In Belgium, the introduction of low (or nil) patient co-payments	1997	2009	Reference pricing, maximum bill, change in reimbursement conditions
Leopold 2014 (*175*)	In 2010, Portugal launched a television and radio information campaign to promote the use of generic medicines	2007	2011	6% deduction of the maximum retail price, harmonization of reimbursement rates
Prescribing policies				
Bhargava 2010 (*168*)	Physician practice sites in Illinois (USA) received incentives to distribute generic medicine vouchers	2006	2008	Academic detailing program
Moreno-Torres 2011 (*179*)	Spain introduced cost containment policies plus physician incentives (up to 35% increase of variable remuneration) to improve prescribing	1995	2006	Markup adjustment, negative lists of medicines, compulsory reduction of ex-factory prices, reference pricing
Godman 2013 (*169*)	In Sweden, incentives to/penalties for physicians were introduced and interventions are grouped into 4 subgroups: Education, engineering, economics, and enforcement	ITS 2007 RM 2010	2011 2011	Multiple related to education, engineering, economics, and enforcement
Lee 2013 (*171*)	In 2002, Argentina introduced a "Generic Law" mandating prescribers to use the international nonproprietary name (INN) when writing prescriptions	1995	2010	None reported
Mixed measures				
Danzon 2011 (*177*)	Different regulatory and reimbursement policies in multiple countries that include pharmacy (dispensing policies) and physician (prescribing policies) driven markets.	1998	2009	Pharmacy reimbursement based on price, discounts to pharmacies, generic reference pricing, patient co-payment incentive, regulated generic price
Market entry regulation				
Balmaceda 2015 (*182*)	In Chile bioequivalence requirements to guarantee therapeutic equivalence between multisource products in the market were introduced	2009	2014	None reported

8.2.3 Effect of interventions

A short description of each intervention and known co-interventions of the sixteen included studies is presented in Table 8.3. In addition, a short description of the results are included in each summary of findings table. Please note that results are described according to five sub-groups of interventions: dispensing policies, prescribing policies, reimbursement policies, mixed measures and market entry regulations; with the majority of studies (n= 7) aimed at pharmacists.

8.2.3.1 Impact of dispensing policies

Six studies assessed the impact of dispensing policies on price and volume of generic medicines (*91*,*170*,*173*,*174*,*176*,*180*). GRADE quality assessment and summary of findings are given in Table 8.4 and Table 8.5.

Table 8.4 Certainty assessment (GRADE) of evidence for each outcome: Impact of dispensing policies

No. of studies	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
Price: 5	Panel data (II), DID (I), ITS (II)	High risk (-1)[22]	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)[23]	Study design (+1)	**Low** ⊕⊕◯◯
Expenditure: 1	ITS (I)	Low risk (0)	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Volume							
Outcome: Availability							
Outcome: Affordability							

[22] Buzzelli 2006 had a high overall risk of bias because of the lack of transparency on the time of the intervention per country and the lack of reporting results at country level. Von der Schulenburg 2011 was also scored as high overall risk of bias because no sensitivity analysis has been done, some assumptions have not been tested, and some confounders have not been taken in to account. Therefore, the overall risk of bias for this outcome was scored as high risk (-1)

[23] The study by Bergman 2016 reported not significant results. However, since the other two studies reporting on this outcome were significant, the assessment for imprecision is not serious

Table 8.5 Summary of findings: Impact of dispensing policies

Strategies to promote pharmacist's use of generics through dispensing policies

Medicines: all medicines, Cardiovascular drugs, antipsychotic drugs, all substitutable medicines
Settings: Multiple countries/global, Europe (Sweden, Finland)
Intervention: Measures to promote dispenser use of generics through dispensing policies
Comparison: no policy, initial period of the intervention

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Price	Mandatory substitution policy significantly decreased prices of off-patent drugs (-26.58%, -26.66%) and of originator drugs over the life cycle of the drug (-21.89%, -21.26%) (*91*). A different study showed a significant reduction in pharmaceutical prices of 3.1% , but it was not accompanied by a significant reduction in pharmaceutical expenditure (*180*).	2	Low ⊕⊕◯◯	Interventions that promote or regulate generic substitution may result in lower prices.
Price/DDD	The introduction of generic substitution alone and in combination with reference pricing was associated with a reduction in price/DDD (p-value: <0.0001) in two studies ranging from 20 to more than 60% price reductions. Generic substitution alone had a larger effect on price reduction than reference pricing. (*173*,*174*). Another study showed a significant reduction in price of substitutable drugs p<0.1 (-6.57%) (*176*)	3	Low ⊕⊕◯◯	Interventions that promote or regulate generic substitution may result in lower prices per DDD.
Pharmaceutical expenditure	The implementation of generic substitution was associated with a significant decrease both for patients' and society's expenditures (p-value: <0.0001) (*170*).	1	Moderate ⊕⊕⊕◯	Mandatory substitution may decrease the patients' and society's expenditure
Volume				
Availability				
Affordability				

The outcome variable *price* was assessed in five studies through the variables unit price (n = 2) and price per DDD (n =3). The overall certainty of evidence was rated as low. These studies reported statistically significant decreases of the prices/costs of generic medicines. However, these studies differed on the medicines examined as well as in the magnitude of the reported effect. Three studies reported more than 20% reduction in the prices of medicines (*91*,*173*,*174*) after the implementation of generic substitution. In contrast, other studies reported less than 7% reduction in the prices of medicines (*176*,*180*), little to no effect on pharmaceutical expenditure (*180*).

The outcome variable *expenditure* was assessed in one study with an overall moderate certainty of evidence. The study (*170*) showed statistically significant decreases of patient's and society's pharmaceutical expenditure.

8.2.3.2 Impact of reimbursement policies

Four studies assessed the effect of reimbursement policies on price and volume of generic medicines; including changes in co-payment plans, information campaigns and the implementation of a reimbursement scheme based on reference pricing. GRADE quality assessment and summary of findings are given in Table 8.6 and Table 8.7. Please note that several studies reported on multiple outcomes.

Table 8.6 Certainty assessment (GRADE) of evidence for each outcome: Reimbursement policies

No. of studies	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
Expenditure: 3	DID (I), ITS (I), Panel data (I)	Moderate risk (-0,5)[24]	No serious inconsistency (0)	No serious indirectness (0)	Moderate imprecision (-0,5)[25]	Study design (+1)	**Low** ⊕⊕◯◯
Outcome: Volume							
3	ITS (II) Panel data (I)	Moderate risk (-0,5)[26]	No serious inconsistency (0)	No serious indirectness (0)	Moderate imprecision (-0,5)[27]	Study design (+1)	**Low** ⊕⊕◯◯
Outcome: Availability							
Outcome: Affordability							

[24] The risk of bias was high for one study (Fraeyman 2013) due to selective outcome reporting, incomplete outcome data and the lack of transparency on the time of the intervention per country. The other two studies included had low risk of bias.
[25] Two studies (Clark 2014, Fraeyman 2013) failed to report SDs or confidence intervals around the point estimates. Therefore it was downgraded with 0.5.
[26] One study (Fraeyman 2013) was rated as high risk due to selective outcome reporting, incomplete outcome data and lack of transparency on the time of the intervention per country. For this reason, the overall risk of bias was downgraded by 0.5.
[27] Two studies (Fraeyman 2013, Buzzelli 2006) failed to report SDs or confidence intervals around the point estimates. Therefore, it was downgraded by 0.5.

Table 8.7 Summary of findings: Reimbursement policies

Price-focused regulations vs no regulation

Medicines: Acid blocking agents and statins, antidiabetics and antihyperlipidemics, cardiovascular medicines, and all substitutable drugs

Settings: United States, Belgium, Taiwan

Intervention: **Reimbursement policies through change in co-payments and reimbursement scheme based on reference pricing**

Comparison: medicines without intervention: comparison group not targeted by the intervention, medicines with no intervention or before the intervention.

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Cost for payers (*181*)	Lower co-payment plans which were accompanied by a case management and/or wellness program were associated with significant lower prescription cost for antihyperlipidemic medication (P<0.001). The prescription cost in the antidiabetic group was not associated with significant prescription cost reductions (P=0.95).	1	Moderate ⊕⊕⊕○	Lower co-payment plans may decrease prescription cost. The program was associated with cost savings for payers.
Cost for patients (co-payment) (*172*)	The proportion of patient contributions for medicines increased; however, the amount of co-payment per DDD decreased. The co-payment amounts for brand and generic medicines converged over time. Therefore, there was no incentive to choose generic versions.	1	Very low ⊕○○○	Although the proportion of patient contributions for pharmaceuticals increased, the amount of co-payment per DDD decreased. Over time, these amounts converged for name-brand and generic versions of both molecules.
Daily and total drug expenditure (*178*)	Grouping in reference pricing was associated with a reduction in daily drug expenses (ranging from 5.8% to 14.8%) (p<0.01); while there was no reduction in the comparison group. The total drug expenditure significantly increased in the intervention and comparison group; for the intervention group the expenditure increase was smaller (from 47 – 60%) than for	1	Moderate ⊕⊕⊕○	The intervention may decrease daily expenses and control the total drug expenditure

	the comparison group (from 63-91.6%) (p<0.01)			
Volume				
Number of DDDs sold (172)	Distinction in the maximum co-payment level (MCL) was associated with a stagnation in the growth of the generic proportion in medicines utilization. The prescription of generics was discouraged after the increase of MCL for generics.	1	Very low ⊕○○○	A change in reimbursement conditions for generics coincided with an increase in the generic proportion associated with a change in reference pricing. Significance not reported
Prescriptions (178)	The number of prescriptions significantly increased in both groups (p<0.05)	1	Moderate ⊕⊕⊕○	The intervention can lead to expanded volume of drugs prescribed
Volume per 100 000 people per month (175)	Change in level: "no discontinuity in level of sales at the time of intervention"; -3550 (95% CI: -7354, 254), 2.3% of predicted sales.	I	Moderate ⊕⊕⊕○	The intervention can lead to increased use of generics and slightly decreased overall sales.
Availability				
Affordability				

Abbreviations: DDD = defined daily dose, maximum co-payment level (MCL), NA = not applicable

The outcome *price* was assessed in two studies through the variables cost for payers and cost for patients.. The overall certainty of evidence was rated as low. These studies showed that the interventions reduced the price of medicines. Fraeyman et al. and Clark et al. examined the effects of changes in co-payment in the costs of using generic medicines (*172*,*181*). Clark et al. additionally observed that changes in co-payment plans lead to a statistically significant decrease in prescription costs for the payers for antihyperlipidemics, while there was no statistically association for antidiabetics (*181*). Fraeyman et al. reported that, although the amount of co-payment per DDD decreased, over time the co-payment amounts for branded and generic products converged resulting in maximum co-payment levels that discouraged the use of generic medicines (*172*).

The outcome variable *expenditure* was assessed in one study with a moderate overall certainty of evidence. Chen et al. assessed the effects of a pricing system on pharmaceutical expenditure (*178*). This study reported that the introduction of reference pricing to group generic medicines lead to statistically significant reductions in daily drug expenditure (*178*).

The outcome *volume* was assessed in three studies. The overall certainty of studies were rated as low. through the variables number of DDDs sold, numbers of prescriptions and volume per 100 000 people per month (*172*,*175*,*178*). These studies have differing results. One study reported that the change in the maximum co-payment level did not result in an increase of generic utilization but to the stagnation in the growth of generic utilization (*172*). The study analyzing reference pricing system to group generics reported

that the intervention was associated with a statistically significant decrease in daily expenses. Leopold et al. showed increased use of generic medicines and slightly decreased overall sales.

8.2.3.3 Impact of prescribing policies

Four studies examined the effects of interventions that promote generic prescribing on price and volume (*168,169,171,179*). GRADE quality assessment and summary of findings are given in Table 8.8 and Table 8.9. Please note that several studies reported on multiple outcomes.

Table 8.8 Certainty assessment (GRADE) of evidence for each outcome: Impact of prescribing policies

No. of studies	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
Price: 2	ITS (II)	High risk (-1)[28]	No serious inconsistency (0)	No serious Indirectness (0)	No serious imprecision (0)	Study design (+1)	**Low** ⊕⊕◯◯
Outcome: Volume							
4	ITS (III), RCT (I)	Moderate risk (-0,5)[29]	No serious inconsistency (0)	No serious Indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Availability							
Outcome: Affordability							

Abbreviations: ITS = interrupted time series analysis, NA = not applicable, RA = regression analysis, RM = repeated measure study

[28] Both studies included presented with a high risk of bias. Moreno-Torres 2011 examined too many interventions in a short time frame which makes it hard to assess the impact of the individual interventions. Lee 2013 was published as an abstract and therefore limited details are given about the methodology.

[29] Moreno-Torres 2011 examined too many interventions in a short time frame which makes it hard to assess the impact of the individual interventions. Lee 2013 was published as an abstract and therefore limited details are given about the methodology. Godman had low bias risk. Therefore, this criteria was downgraded by only 0.5.

Table 8.9 Summary of findings: Impact of interventions prescribing policies

Strategies to improve prescribing practices vs no intervention

Medicines: All medicines, angiotensin receptor blockers (ARBs), top 25 medications

Settings: Spain, Sweden, USA

Intervention: Incentives to improve prescribing practices

Comparison: Before implementation of intervention

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Price per prescription (*179*)	Regulations to promote physicians use of generics were not associated with a decrease in the price per prescription (p>0.1).	1	Low ⊕⊕◯◯	Regulations to promote physicians use of generics may lead to little or no difference in price per prescription
Price (*171*)	Regulations to mandate INN prescribing was associated with a significant price decrease of medicines of 1.1.%. This policy caused 7.9% price decrease in generic medicines over brand medicines.	1		Regulations to mandating INN prescription may lead to the decrease in prices, particularly for generic medicines.
Volume				
Utilization (*169*,*171*)	Multiple demand-side interventions are associated with significant higher utilisation after generic reimbursement (171). The use of INN prescribing was associated with a decrease in utilization of brand medicines, while it increased for generic medicines (173)	1	Moderate ⊕⊕⊕◯	Multiple demand-side interventions may improve physician prescribing behaviour of generic medicines.
Prescriptions per capita (*179*)	Incentives to improve prescribing practices were not associated with an effect on the number of prescriptions per capita.	1		The coefficient of this intervention on prescriptions per capita was positive but not significant (P>0.1)
Generic dispensing ratio (GDR) (*168*)	The combination of a generic medication voucher program plus academic detailing resulted in a small but statistically significant increase in GDR of 1.77 percentage points compared with academic detailing alone.	1		Generic medication voucher programs in combination with academic detailing probably increases the use of generics
Availability				
Affordability				

The outcome variable *price* was assessed in two studies through the variables price per unit and price per prescription. The overall certainty of evidence was rated as low. One study (*179*) examined the impact of economic incentives to improve physician's prescribing habits on the price of generic medicines. This type of economic incentives were not associated with a decrease in the cost per capita or price per prescription. This effect was not statistically significant. Another study analyzed the effect of mandatory INN prescribing on the price and use of generic medicines (*171*). This study reported that this policy did not have an effect on the prices of all medicines studied. However, over all years studied, the prices (statistically) significantly decreased by 1.1%, and causing greater price decreases in generic medicines than in branded medicines.

The outcome variable volume was assessed in four studies, through the variables utilization, prescription per capita and generic dispensing ratio. The overall certainty of evidence was moderate. One study also reported on use and showed that although the use of generic medicines stayed stable or increased, the use of brand medicines decreased over time (*171*). Another study (*169*) examined the influence of four types of measures ('4Es') in prescription practices: education, engineering, economic, and enforcement. This study reported that these types of measures to promote generic prescribing were associated with a significant increase of utilization of generic medicines (97% of losartan prescriptions were the generic version); in contrast, the study by Moreno-Torres et al. (*179*) did not report on any significant effect of economic incentives associated with an increase in the prescription of generic medicines. The fourth study showed that the combination of a generic medication voucher program plus academic detailing resulted in a small but statistically significant increase in the generic dispensing ratio of 1.77 percentage points compared with academic detailing alone.

8.2.3.4 Impact of mixed measures

One study examined the effect of the use of policies aimed at pharmacists and/or physicians to encourage the use of generic medicines (*177*). GRADE quality assessment and summary of findings are given in Table 8.10 and Table 8.11.

Table 8.10 Certainty assessment (GRADE) of evidence for each outcome: Mixed policy interventions to promote use of generics

No. of studies	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
Price: 1	RM (I)	High risk (-1)[30]	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Low** ⊕⊕◯◯
Outcome: Volume							
1	RM (I)	High risk (-1)	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Low** ⊕⊕◯◯
Outcome: Availability							
Outcome: Affordability							

[30] Overall high risk of bias because of selective outcome, and the paper excluded data that might affect the risk of bias. The authors only included single molecule prescriptions in retail pharmacies therefore excluding a lot of potential data of hospital pharmacies and other medicines. And the data do not permit precise measurement of individual policy effects.

Table 8.11 Summary of findings: Mixed policy interventions to promote use of generics

Mixed policy interventions changes to promote use of generics: from physician driven market to pharmacist driven market

Medicines: All substitutable drugs

Settings: Multiple countries: United States, United Kingdom, Germany, France, Spain, Italy, Japan, Canada, Brazil, Mexico

Intervention: Mixed policy interventions changes to promote the use of generics by pharmacists

Comparison: Initial period

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Generic Price (*177*)	Pharmacy-driven policy changes in 9 countries (the UK, Germany, France and Spain, Italy, Japan, Canada, Brazil and Mexico) were associated with significant decreased prices. The UK showed the largest decline in generic prices (33%).	1	Low ⊕⊕◯◯	Mixed pharmacy-driven policy interventions may decrease generic prices
Volume				
Volume share (*177*)	Pharmacy-driven policy changes in the US, the UK, France and Brazil were associated with significant increased generic market shares. France had the largest growth in market share (18.8%).	1	Low ⊕⊕◯◯	Mixed pharmacy-driven policy interventions may improve promote use of generics
Availability				
Affordability				

This study by Danzon *et al*. (*177*) examined the performance of the generic market in physician-, and pharmacy-driven markets (i.e. measures focused on physician's prescription patterns and/or pharmacy's dispending patterns) in 10 countries (the US, the UK, Germany, France and Spain, Italy, Japan, Canada, Brazil and Mexico). The study reports negative and significant coefficients on generic prices due to policy changes towards a pharmacy-driven market in all the countries except for the US which already had very low generic prices as mentioned in the study. The UK had the largest decline in generic prices (33%), followed by Italy, Spain, Brazil, and France (25-29%).

This study also reports that the generic share of volume increased significantly in the US, UK, France, and Brazil. The authors mention that the growth in generic volume share in Brazil is almost entirely due to a growth in unbranded generics. France had the largest growth (18.8%), followed by the US (18.2%) and the UK (15.5%). The total percent savings were modest in Germany, Italy, and Spain. The modest savings due to

generic volume and price in Italy and Spain may be due to reference price reimbursement systems, which encourage the originator to drop its price. This indicates that pharmacy-driven, unbranded generics can yield significant savings for payers.

The authors concluded that, although the data did not allow measurement of the effects of individual policies, policies that aim at shifting generic markets from physician-driven towards pharmacy-driven markets can result in significant savings to payers.

8.2.3.5 Impact of market entry regulations

Only one study assessed the impact of market entry regulations, specifically the implementation of bioequivalence requirements (*182*), on the prices of generic medicines. GRADE quality assessment and summary of findings are given in Table 8.12 and Table 8.13.

Table 8.12 Certainty assessment (GRADE) of evidence for each outcome: Market entry regulation

No. of studies	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
Price: 1	CBA (I)	High risk (-1)[31]	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	NA	**Very low** ⊕○○○
Outcome: Volume							
Outcome: Availability							
Outcome: Affordability							

[31] Overall high risk of bias because of consists of multiple limitations. The data source lacked data of price variability in generics without their own brand, which are reported as an average total price, this could affect the estimation of both the point effect estimator and its confidence interval.

Table 8.13 Summary of findings: Market entry regulation

Bioequivalence requirements vs no intervention

Medicines: 29 selected medicines

Settings: Chile

Intervention: Bioequivalence requirements

Comparison: medicines not affected by the intervention (medicines used as control)

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Retail price (*182*)	The implementation of bioequivalence was significantly associated with a variation of price in 14 out of 29 medicines that were required to demonstrate bioequivalence. The change was positive for 7 of the medicines. It is not generalizable to all of the medicines or to a group or class.	1	**Very low** ⊕○○○	It is uncertain whether the implementation of bioequivalence requirements as part of their generic policy leads to price changes because the certainty of the evidence is very low
Volume				
Availability				
Affordability				

Balmaceda et al. (*182*) reported that the magnitude and significance of the effect of bioequivalence on the price of generic medicines was not clear since the effect varied between medicines. For some medicines, the estimated effect was positive suggesting an increase in prices; for some medicines the effect was statistically significant and the magnitude of the effect was greater than for other medicines. For other medicines, the estimated effect was negative suggesting a decrease in prices; for some medicines within this group the effect was statistically significant and the magnitude of the effect was greater than for other medicines. The reported results are not generalizable to all medicines or to a group or class as some medicines experienced different magnitudes and types of effects. The overall certainty of evidence was rated as very low.

8.3 Authors' conclusions

8.3.1 Summary of main findings

Of the sixteen included studies in this systematic review, the majority of studies assessed the impact of generic substitution on the promotion of generic use. The remaining studies looked at the effects of interventions influencing prescribing, reimbursement, mixed interventions and market entry regulations. Around half of the studies in this systematic literature review used an interrupted time series study design and others used panel or regression data and difference-in-difference designs. One study was a randomized control trail. In summary, despite a heterogeneity of the policies three of the sub-interventions (reimbursement, prescribing and dispensing policies) lead to an increase in generic medicine use. The effects on price were not as clear. The different policies found in this review include:

- Reimbursement policies such as changes in co-payments for reimbursed medicines and grouping of generic medicines following a generic reference pricing system. These policies lead to a decrease in prices for the payer but lead to increases in patients' co-payments. At the same time these interventions lead to an increase in generic use.
- Interventions aimed at physicians to encourage generic prescribing which lead to an increase in generic utilization but had no clear effect on price.
- The most frequently assessed intervention was mandatory generic substitution, which clearly resulted in reduced prices of generic medicines and thus of pharmaceutical expenditure as well as an increase in generic medicines use.
- Regulations on market entry which did not show any clear effects.

8.3.2 Overall completeness and applicability of evidence

Several factors may limit the applicability of this evidence. First, the majority of studies (n = 9) examined high income countries in Europe and the United States of America. Only one study assessed data from Asia and two from Latin America and none from Africa. Secondly, five out of fourteen studies focused on assessing the effects of the intervention on only one group of medicine. This limits generalizability of the results as findings might be linked to contextual factors for the specific medicine group (i.e. prescription guidelines). Thirdly, many of the studies (n = 8) mentioned that other co-interventions happened around the same time as the main intervention.

Considering that the majority of eligible studies described effects in high-income countries with solidarity-based health insurance systems, it was interesting to note that only one study assessed the impact of generic medicines' use on patients' co-payments and one on overall societal costs. For this reason, several studies were ranked as "high risk" in the risk of bias assessment.

Another shortcoming is the lack of research and evidence on the promotion of biosimilar medicines use and substitution. While the systematic literature review identified four studies on biosimilar use, they had to be excluded as they did not comply with the inclusion criteria. Discussions on the substitution policies for biosimilar medicines are ongoing and will hopefully in future lead to the performance of strong studies.

8.3.3 Quality of evidence

The majority of studies had interrupted time series or repeated measures study designs and the majority of outcomes were ranked as "low risk". The categories "incomplete outcome data", "intervention independent" and "other risks" were ranked in several studies as "high risk". This can be explained by the fact that several interventions were assessed while other co-interventions happened, that methods were unclear or co-founding factors or limitations were not considered.

The certainty of evidence was judged either as "low" or "very low" in the majority of studies. Reasons for these low ratings were due to missing details on methods such as information on seasonality. However, all studies examined here adopted rigorous study designs and transparently reported their methods and analytical approaches.

8.3.4 Agreement/disagreement with other reviews

While this systematic literature review excluded other literature reviews (n =7), it is still worth comparing results and critically discussing possible shortcomings.

In addition to the result we presented, Babar *et al*. (*150*) identified the following strategies: "*…education, financial incentives, advertising to promote generic medicines, free generic medicine trials, administrative forms and medicines use review (MUR)"*. However, the authors concluded that "*There was limited literature available and further work is required to develop a range of interventions to support the uptake of generic medicines within and across different countries*."

A report by Health Action International (HAI) from 2016 (*122*) specifically focused on assessing policy options to promote generic medicines use in LMICs. The authors concluded that a pre-requisite for LMICs to promote generic medicine use include "*assurance of quality medicines, facilitation of market entry of generics and alignment of demand-side policies such as prescribing by the generic name, generic substitution, financial incentives for pharmacy and medicines outlet personnel to dispense/sell low-priced generic medicines, and continued education of consumers about generic medicines*." Some of these mentioned points (such as alignment of demand-side policies) confirm the findings of this review.

A review on the use of biosimilars in Europe by Swartenbroekx *et al.* (*183*) confirmed that few studies are available on biosimilar uptake *"…the literature reviewed provided little evaluation of the effectiveness of these policies in terms of biosimilar uptake or potential savings."* A chapter on biosimilars in the "Arzneiverordnungs-Report 2019" elaborates on different strategies countries implemented to promote the use of biosimilars. Most European countries (except Germany, Denmark, Great Britain and the Netherlands) apply price linkage policies in which the price of the biosimilar product is set based on a lower percentage of the reference product. (*184*) (more information in chapter 'Reference pricing')

8.3.5 Authors conclusions: implications for practice; implications for research

The empirical evidence suggests policies to promote the use of generic medicines, including dispensing, prescribing and reimbursement policies, to be effective in increasing generic use. In addition, mandatory generic substitution and reimbursement policies i.e. changes in co-payment plans had a positive effect on lowering price of generic medicines. However, robust evidence is missing for low- and middle-income

countries on the use of generic medicines as well as on the promotion of biosimilars use. Future research is required to further substantiate these findings using robust study designs.

9 Reference Pricing

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9.1 Background

Reference pricing, also known as "benchmark pricing", is defined here as « the approach of understanding the appropriateness of prices of medicines based on selected benchmark prices, either from other jurisdictions (e.g. countries or other administrative regions) or a group of comparable medicines in the same system/formulary » (*4*). There are two main concepts of reference pricing with different policy aims that need to be distinguished: internal versus external reference pricing.

Internal reference pricing (IRP) refers to "the practice of using the prices of identical medicines (ATC 5 level, also known as generic reference pricing (GRP)) or similar products (ATC 4 level also known as therapeutic reference pricing (TRP)) or even with therapeutic equivalent treatment (not necessarily a medicine) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country" (*3*). This policy is typically applied by health systems with a health insurance scheme as IRP sets reimbursement limits (reference prices) and thus encourages the use of less costly medicines (often generic medicines). For pharmaceuticals that are more expensive then the reference price (often originators), patients have to pay the difference between the reference price and the actual price out-of-pocket. This makes patients aware of price differences and gives them choice whether to use a medication with or without additional co-payments (*14*). Another form of internal reference pricing is (generic) price link, which refers to "the practice of setting the price of a generic in relationship to the original product medicine, usually at a certain percentage lower than the original medicine price. The design of this generic price link policy may vary, with different percentages for the different generics, and in some cases the prices of original medicines might also be part of the policy" (*3*). This pricing policy can be applied independent of a national reimbursement system and may also be used to price biosimilars.

External or international reference pricing (ERP) refers to "the practice of using the price of a pharmaceutical product (generally ex-manufacturer price, or other common point within the distribution chain) in one or several countries to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country"(*3*). ERP is a pricing policy and aims to set and possibly to lower the prices of prescription medicines. ERP is very common in Europe and frequently used in low- and middle-income countries (LMICs), their methods however vary to a great extent with respect to the calculation of the reference price and the selection of countries in the basket (*185,186*). Countries commonly apply ERP at the ex-manufacturer price level and mainly to originator products. In some countries ERP is the main pricing policy while other countries only use ERP for supportive information in their pricing process (*187*). This heterogeneous nature of reference pricing needs to be considered when comparing outcomes across

countries. Previously published literature discussed whether ERP drives prices down and whether applying specific launch sequences starting in countries with high gross domestic product (GDP) might minimize price decreases. Other relevant aspects of ERP included the role of the type of price and source used within ERP as well as the role of price revisions as an essential driver of price change over time. Finally, literature looked at consequences of ERP on patient access to medicines and on the level of affordability for each country (*188–190*).

This chapter details the evidence on reference pricing identified in the present systematic literature review.

9.2 Results

9.2.1 Excluded studies

77 articles were identified at full text level of which 51 were excluded after careful assessment of the full content. The main reasons for exclusion (n=40) were inappropriate study design (*104,131,134,142,152,163,191–224*), five studies examined an incorrect intervention (*225–229*) and three studies had incomplete data as only the abstract was available (*230–232*). For three studies, authors reported data in a working paper or report and later reported the same data in peer reviewed literature. We only extracted data from the most recent document and excluded the redundant study (*233–235*).

9.2.2 Characteristics of included studies

Twenty-six studies published between 2004 and 2019 were included in this systematic review (Table 9.1). The most common study designs were interrupted times series analysis (n=11, (*18,173–175,236–242*)) and repeated measures studies (n=7, (*243–249*)). The majority of studies examined reference pricing in European countries (n=17), ranging from Belgium (*247*), Denmark (*243*), Finland (*173,174,175*), Germany (*249,250*), Italy (*246,251*), Norway (*252,253*), Slovenia (*240*), Spain (*179,237*) to Sweden (*176,239*). One of these studies looked at multiple European countries (*91*). Five studies focused on Asia (*238*) and four on the USA/Canada (Arkansas/USA (*244*), British Columbia/Canada (*245,248,254*)) and none on Africa or Latin America.

The most common intervention was generic referencing (n=11, (*173,174,179,237,238,243,246,247,252–254*)), followed by therapeutic referencing (n=8, (*175,239,240,244,248–251*)). A few studies looked at a mix of generic and therapeutic referencing (n=2, (*91,245*)). Price thresholds in terms of originator or generic price links were examined in five studies (*236,241,242,255,176*). Of note, an identical intervention, known as the Single Price System (SPS) which was implemented in South-Korea in 2012, was studied in three of the papers (*236,241,242*). None of the included studies examined external reference pricing.

Twelve studies assessed either all medicines on the market (n=6, (*176,179,241,249,255,257*)) or multiple ATC groups (n=6, (*239,240,246,247,252,253*)), the remaining fourteen studies looked at single medicine groups such as ACE-inhibitors (*91,248,254*), antipsychotic medications (*173–175*), nonsteroidal anti-inflammatory drugs (*238,245*), proton-pump inhibitors (*244*), antidiabetics (*242*) and statins (*77,237,243*).

While price was the outcome assessed in almost all (n = 25) included studies (*18,91,173,174,179,237–254,176,257*), eighteen studies also examined volume as an outcome (*18,175,236–246,248,250–252,254*). Leopold et al. (*179*) was the only study which looked at the effect on volume. There were no studies reporting on the impact of reference pricing on availability and affordability, or any other secondary outcomes (e.g. transparency, system efficiencies, adverse outcomes).

Table 9.1 Study characteristics

	Study types	Number of studies	Notes/references
Study design	Interrupted times series analysis	11	(*18,173–175,236–242*)
	Repeated measures study	7	(*243–249*)
	Panel data analysis	4	(*91,252,253,176*)
	Difference-in-difference analysis	3	(*250,251,254*)
	Regression analysis	1	(*179*)
Setting	Asia	5	Taiwan (*238*), South Korea (*18,236,241,242*)
	Europe	17	Belgium (*247*), Denmark (*243*), Finland (*173,174,175*), Germany (*249,250*), Italy (*246,251*), Norway (*252,253*), Slovenia (*240*), Spain (*179,237*), Sweden (*239,256*), multiple EU-countries (*91*)
	USA/Canada	4	Arkansas/USA (*244*), British Columbia/Canada (*245,248,254*)
Subjects	All medicines	6	(*179,249*), all recorded data (*18,241,242*), all medicines used by hypotensive patients (*236*), all off-patent originator medicines (*176*)
	Multiple ATC group / medicines	6	(*239,240,246,247,252,253*)
	ACE-inhibitors	3	(*91,248,254*)
	Antipsychotic medications	3	(*173–175*)
	Nonsteroidal anti-inflammatory	2	(*238,245*)
	Antidiabetics	1	(*242*)
	Proton-pump inhibitors	1	(*244*)
	Statins	3	(*237,243,250*)
	Others	1	Public/private expenditure (*251*)
Interventions	Generic price referencing (ATC 5 level)	11	(*173,174,179,237,238,243,246,247,252–254*)
	Therapeutic price referencing (ATC 4 level)	8	(*170,175,240,244,248–251*)
	Mix of generic and therapeutic referencing	2	(*91,245*)
	(Generic) price linkage	5	(*236,241,242,255,176*)
Outcomes*	Price	25	(*18,91,173,174,179,236–254,176*)
	Volume	18	(*18,175,236–246,248,250–252,254*)

Abbreviations: ACE-inhibitors = Angiotensin-converting enzyme, ATC = Anatomical Therapeutic Chemical, EU = European Union, USA = United States of America

* Please note that double counts of studies are possible as multiple outcomes were reported in a number of studies.

Table 9.2 provides an overview of the risk of bias of the 26 included studies with specific explanations for each sub-intervention.

For *GRP* the studies generally showed overall low risk of bias in most domains. Some domains were, however, associated with high risk: for two studies the measurement of the effect of the intervention may have been influenced by co-interventions being implemented during the study period, resulting in the data

to be insufficient to distinguish between the impact of one intervention from another. One study was rated as high risk in the domain appropriate analysis uncertainties remain regarding the timepoints used to estimate slopes in the regression analysis. Another study presented a high risk of bias in pre-specified shape of effect, as the point of analysis was after the point of intervention. Three studies reported incomplete outcome data and were therefore categorized as "high risk". In addition, one study was rated as "high risk" in the category "selective outcome reporting" as changes in level of drug costs were not reported during one point in the analysis. Finally, five studies were rated as high risk in the category other biases; three of those were rated as high risk due to co-interventions that happened during the same time; the other two did not mention any limitations of the study and low external validity due to a narrow sample.

The eight included studies in the category *TRP* were associated with low risk in most of the domains except for the following domains: Two studies were ranked as "high risk" in the domain intervention independent due to other interventions that were implemented during the same time as the intervention under investigation potentially posing a risk of bias. Four studies were ranked as "high risk" in the category "appropriate analysis" as authors did not provide enough detail on which methods were used to analyse the data. Three studies did not report properly on the outcomes and were therefore ranked as "high risk" in the domain incomplete outcome data. One study was ranked as "high risk" in the category pre-specified shape of the effect. The four studies were ranked as "high risk" in the category "other bias" due to missing reporting on the risk of bias, co-founding factors and effects due to seasonality.

For the category *mix of generic and therapeutic reference pricing* both included studies showed overall low risk of bias in most of the domains. However, one study was ranked as "high risk" in the domain intervention independent due to several co-interventions happening during the observation period potentially limiting the generalizability of the results. Another study was ranked as "high risk" in the domain other biases as only one assumption was tested in the model leaving out other assumption which limits the generalisability of the results.

For *price linkage*, the studies generally showed low risk of bias in most domains. Some domains were, however, associated with a higher risk of bias: for two studies the measurement of effect of the intervention may have been influenced by co-interventions being implemented within the study period, resulting in the data to be insufficient to distinguish between the impact of one intervention from another. One study presented a high risk of bias in pre-specified shape of effect, as the point of analysis was one month later than the point of intervention. Incomplete outcome data was not addressed in four studies, resulting in an unclear risk of bias.

Table 9.2 Risk of bias of included studies

		ITS and RM studies				All study types			
		Intervention independent	Appropriate analysis	Pre-specified shape of effect	Intervention to affect data collection	Incomplete outcome data	Knowledge of allocated intervention	Selective outcome reporting	Other bias
Generic reference pricing	Adriaen 2008	⊖	⊕	⊖	⊕	⊖	⊕	⊕	⊖
	Brekke 2009					⊕	⊕	⊕	⊖
	Brekke 2015					⊕	⊕	⊕	?
	Ghislandi 2013	⊕	⊕	⊕	⊕	⊖	⊕	⊕	⊕
	Grootendorst 2006					⊕	⊕	⊕	⊖
	Hsiao 2010	⊕	⊖	⊕	⊕	?	⊕	⊖	⊖
	Kaiser 2014	⊕	⊕	⊕	⊕	⊖	⊕	⊕	⊕
	Koskinen 2014	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	Koskinen 2015	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	Moreno-Torres 2011					?	⊕	⊕	⊖
	Puig-Junoy 2007	⊖	⊕	⊕	⊕	⊕	⊕	⊕	⊕
Therapeutic reference pricing	Andersson 2006	⊖	⊕	⊖	⊕	⊖	⊕	⊕	⊕
	Armeni 2016					⊖	⊕	⊕	⊕
	Johnson 2011	⊕	⊖	⊕	⊕	⊖	⊕	⊕	⊖
	Leopold 2014	⊕	⊖	⊕	⊕	?	⊕	⊕	⊕
	Mardetko 2018	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊖
	Schneeweiss 2004	⊕	⊖	⊕	⊕	⊕	⊕	⊕	⊖
	Stargardt 2005	⊖	⊖	⊕	⊕	?	?	?	⊕
	Stargardt 2010					⊕	⊕	⊕	⊖
Mixed	Grootendorst 2005	⊖	⊕	⊕	⊕	⊕	⊕	⊕	?
	Von der Schulenberg 2011					?	⊕	⊕	⊖

Price linkage	Bergman 2016					?	⊕	⊕	?
	Kwon 2019	⊖	⊕	⊕	⊕	?	⊕	⊕	⊕
	Lee 2012	⊖	⊕	⊖	⊕	?	⊕	⊕	?
	Suh 2018	⊕	⊕	⊕	⊕	?	⊕	⊕	⊕
	Yoo 2015	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕

Abbreviations: ITS = interrupted-time-series, RM = repeated measures

Table 9.3 Description of interventions by category of intervention and study

	Intervention	Study begin	Study end	Known co-interventions
Generic reference pricing				
Adriaen 2008 (*247*)	In Belgium, reference-pricing on the active substance level was introduced in June 2001. "Over time, the Belgian Government has progressively reduced the reference price from 84 per cent (until July 2002), 80 per cent (until January 2003) to 74 per cent of the price of the originator medicine at the time of patent expiry (until July 2005). The current level stands at 70 per cent of the price of the originator medicine. The reference-pricing system was enlarged in 2005 with reference groups including all pharmaceutical forms and dosages of originator and generic medicines containing the same active substance. Additionally, the law offers the possibility to set a reference price for a class of medicines with a similar therapeutic indication."	July'01	Dec'05	Reduction of turnover of pharmaceutical companies by 2%, price competition between generic medicines, public tender for off-patent originator and generic medicines
Brekke 2009 (*252*)	Norway introduced a RP system in March 2003 for a sub-sample of off-patent pharmaceuticals facing generic competition (initially covering six chemical substances: Citalopram (depression), Omeprazol (antiulcer), Cetirizin (allergy), Loratadin (allergy), Enalapril (high blood pressure) and Lisinopril (high blood pressure) and since June 2004 Simvastatin (high cholesterol)) The drugs were classified into clusters based on chemical substance. The RP price was calculated as the sales-weighted sum of producer prices. The government performed quarterly price revisions. By the end of 2004, the government terminated the RP system.	2001	2004	Price cap as part of reference pricing
Brekke 2015 (*253*)	In 2005, Norway re-introduced a reference pricing scheme for prescription drugs that have lost patent protection and are subject to generic competition. The reference price is set as a fixed discount on the price cap of the original brand-name drug in the period prior to patent expiration and generic entry. The initial discount is 35 percent and effective when generic competition takes place. After six months the discount is increased to around 60 or 80 percent depending on the sales value of the drug. Eventually, after (at least) 18 months the regulator can increase the discount up to a maximum of 90 percent for the substances with the highest sales value.	2003	2013	Co-payment / fixed percentage reimbursement, price cap, generic entry
Ghislandi 2013 (*246*)	In Italy, GRP was introduced at national level in 2001. The reference price is the lowest available final price.	1999	2009	Price cuts as part of the reference price system in 2002, 2005 and 2006

Grootendorst 2006 (*254*)	In April 1994 British Columbia introduced generic reference pricing to all multi-sourced products (Type 1 RP) and in November 1995 therapeutic RP to NSAIDs (Type 2 RP). The study estimates the impact of both types of RP on British Columbia's Pharmac's expenditure on antihypertensive drugs for its senior beneficiaries.	1994	2001	None reported
Hsiao 2010 (*238*)	The Taiwanese NHI imposes direct price controls on drugs by fixing the reimbursement prices product by product. Every one or two years, the NHI implements the price regulation including reference pricing and generic grouping to re-set (usually decrease) the reimbursement price of each product. This study examines the effects of the two price regulations implemented, April 2001 and March 2003 on the use and expenditure of NSAID.	2001	2004	Two new drug entries and a safety warning (time period of these co-interventions were excluded from analysis)
Kaiser 2014 (*243*)	In 2005, Denmark switched from an external to an internal reference price system relevant for all drugs (on- and off-patented). Before the reform, the reference price was determined as the European average price of substitute products (or the product's domestic price if that was lower). Since the reform, the reference price has been defined as the domestic price of the cheapest substitute product.	Sep'03	Sep'06	Before and after the intervention changes in co-payments, generic substitution, price celling
Koskinen 2014 (*173*)	As described in Koskinen 2015	2006	2010	Generic substitution as part of RP
Koskinen 2015 (*174*)	In April 2003, Finland introduced generic substitution and in April 2009 a reference pricing system. "Reference prices are determined quarterly and are calculated by adding €1.50 to the price of the most inexpensive product within the group if the cheapest product is priced below €40.00. If the cheapest product is priced at €40.00 or more, a sum of €2.00 is added."	Jan'01	Sep'11	Generic substitution as part of RP
Moreno-Torres 2011 (*179*)	Spain introduced changes to its RP system in January 2004, namely the reference price was calculated as the average of the three lowest costs per day of treatment for each form of administration of an active ingredient, according to its defined daily dose.	1995	2006	Mark-up adjustment, negative lists of medicines, compulsory reduction of ex-factory prices, generic prescribing incentives
Puig-Junoy 2007 (*237*)	In January 2004, Spain introduced changes to its generic reference pricing system, and the Andalusian Public Health Service introduced two additional competing reimbursement policies.	Jan'01	Oct'04	Sep'–1 - Maximum consumer price (MCP) potentially for all statins in the APHS Aug'–1 - Cerivastatin withdrawal from the market Jan'–2 - First generic entry for simvastatin

				Oct'–2 - Entry of an extended release form of Fluvastatin Jan'–3 - MCP plus economic prescribing incentives for off-patent statins in the APHS Jan'–4 - First generic entry for pravastatin
Therapeutic reference pricing				
Andersson 2006 (*239*)	Sweden introduced five policy reforms in the reimbursement system of pharmaceuticals during the years 1986–2002; three concerned increased patient co-payment (January 1, 1991; January 1, 1995 and June 1, 1999), one the introduction of reference based pricing and increased co-payment (January 1, 1993) and one a new structure of the reimbursement schedule (January 1, 1997).	1986	2002	Co-payments and a new pharmaceutical benefits scheme
Armeni 2016 (*251*)	In 2001, Italy introduced a generic reference pricing system and applied it to the same molecule–package pair. Therapeutic reference pricing, instead, was introduced as a policy option implementable by regional governments in 2006.	2000	2014	Co-payments, prescription quotas
Johnson 2011 (*244*)	On September 2005 the Arkansas State Employee Benefits Division adopted reference pricing for the entire PPI class, including coverage for esomeprazole. The reference-pricing strategy provided coverage of any drug in the PPI class at the price per unit for the least expensive drug.	2004	2009	Co-payments (contractual discount + dispensing fee) Coverage exclusion of Esomeprazole
Mardetko 2018 (*240*)	In 2003 Slovenia introduced generic reference pricing (GRP). In 2013, the reference pricing system was extended, namely therapeutic reference pricing (TRP) was introduced. For medicines included in GRP, the maximum reimbursable price is determined for each class of bioequivalent medicines every 2 months and it is set to the lowest price within the class. TRP system is based on therapeutic classes of medicines where the reference medicine and consequently the maximum reimbursable price is set on the medicine with the best ratio between its costs and effectiveness.	2011	2015	None reported
Leopold 2014 *(175)*	On April 1, 2009 Finland implemented a therapeutic RP system. For each substitution group, a reference price was set at the price of the least expensive medicine in the cluster, with patients having to pay the difference for higher cost medications out-of-pocket.	2007	2011	Delisting of anti-psychotic medicine
Schneeweiss 2004 (*248*)	On January 1, 1997 British Columbia introduced RP to ACE inhibitors. Under the policy, benazepril, cilazapril, enalapril, fosinopril, and lisinopril were subject to patient cost-sharing above the reference price of CAN $27 per 30-day supply ("cost-share ACEI"), although patients were exempted from RP if medically	1995	1998	None reported

	warranted through a prior authorization process. The lower-cost drugs captopril, quinapril, and ramipril remained free of cost-sharing ("free ACEI").			
Stargardt 2005 (*249*)	The German reference pricing system was implemented in different levels and pharmaceuticals were grouped according to certain criteria: 1989 level 1 - same active ingredient, 1992 level 2 - pharmacological comparable, therapeutically comparable, chemically similar, pharmaceuticals with only one active substance, 1993 level 3 - therapeutically comparable, combination of different active substances.	1989	2004	Other policy intervention as well as changes in prescribed volume occurred during the study period
Stargardt 2010 (*250*)	Statins were included in the German reference pricing scheme on 1 January 2005. Co-payments due to RP for atorvastatin ranged from € 18.17 per package (30 mg/30 units) to € 109.00 per package (80 mg/100 units).	2003	2006	Changes in regular co-payments
Mix of generic and therapeutic reference pricing				
Grootendorst 2005 (*245*)	In April 1994 British Columbia introduced generic reference pricing to all multi-sourced products (Type 1 RP) and in November 1995 therapeutic RP to NSAIDs (Type 2 RP). The study estimates the impact of both types of RP on British Columbia's Pharmacare's expenditure on NSAID for its senior beneficiaries.	Feb'93	June'01	Delisting of medicines from reimbursement list
Von der Schulenburg 2011 (*91*)	A multitude of interventions (including reference pricing) is studied in six European countries (Denmark, France, Germany, Netherlands, Sweden, United Kingdom).	1991	2006	A multitude of intervention is studied and integrated in the empirical model (reference pricing, mandatory substitution, generics price control, mark-up regression, profit control, clawback, tax funded health care system, cost-efficiency analysis). Beside those, other policies are mentioned.
(Generic) price linkage				
Bergman 2016 (*256*)	In Sweden, the price of off-patents is capped at 35% of the on-patent price	2006	2011	The obligation to substitute towards the lowest-cost generic (October 2009); "the groups within which substitution should be made were defined in an unambiguous way" (February 2010); "pharmacies were allowed to dispense the second- or even third-lowest-cost generic if the regulating authority declared a national stock-out of the first-hand choice" (May 2010).

Kwon 2019 (*241*)	In South Korean the single price system[32]: off-patents were priced at 70% of the on-patent prices, and generics were priced at 85% of their off-patent counterparts. One year after patent expiration, both off-patents and their generics were priced at 53.55% of the on-patent prices	2007	2016	The Outpatient Prescription Incentive Program (OPIP, October 2010), "an incentive program for prescribers who have achieved savings in their pharmaceutical expenditure compared to the year before"; The Benefit Enhancement Plan (BEP, September 2013), enhancing drugs' likelihood of being reimbursed; The Risk Sharing Agreement (RSA, January 2014), facilitating access to new medicines.
Lee 2012 (*255*)	In Korea the Pharmaceutical Expenditure Rationalisation Plan (PERP): "a positive list and formal request for economic evidence in reimbursement decisions (…); and a price agreement for new chemical entities". The price agreement "would consider economic evidence as the most crucial parameter of pricing". A price cut of 20% is implemented on all off-patents when the first generic counterpart is submitted for listing	2003	2008	A change in co-payment schemes (August 2007).
Suh 2018 (*242*)	In South Korea the single price system[iv]: off-patents were priced at 70% of the on-patent prices, and generics were priced at 85% of their off-patent counterparts. One year after patent expiration, both off-patents and their generics were priced at 53.55% of the on-patent prices	2009	2013	The Outpatient Prescription Incentive Program (OPIP, October 2010), "an incentive program for prescribers who have achieved savings in their pharmaceutical expenditure compared to the year before".
Yoo 2015 (*236*)	Single price system[iv]: off-patents were priced at 70% of the on-patent prices, and generics were priced at 85% of their off-patent counterparts. One year after patent expiration, both off-patents and their generics were priced at 53.55% of the on-patent prices	2011	2013	The Outpatient Prescription Incentive Program (OPIP, October 2010), "an incentive program for prescribers who have achieved savings in their pharmaceutical expenditure compared to the year before"; The introduction of guidelines for antihypertensive drugs (January 2013); The Benefit Enhancement Plan (BEP, September 2013), enhancing drugs' likelihood of being reimbursed.

[32] The single price system is described in multiple papers, each investigating the price system implemented in 2012 in South Korea

9.2.3 Effect of interventions

A short description of each intervention and known co-interventions of the twenty-six included studies is presented in Table 9.3. Please note that results are categorized according to four sub-groups of interventions: generic reference pricing, therapeutic reference pricing, mix of generic and therapeutic reference pricing and (generic) price linkage. None of the included studies assessed the effects of external reference pricing.

9.2.3.1 Impact of generic reference pricing

In total, eleven studies assessed the impact of generic reference pricing (GRP) on the outcomes price and/or volume. The GRADE quality assessment and summary of findings for generic reference pricing are given in Table 9.4 and Table 9.5.

Table 9.4 Certainty assessment (GRADE) of evidence for each outcome – Generic Reference Pricing

No. of studies (references)	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
Price: 9	ITS (III), panel data (II), regression analysis (I), RM (III)	Low risk (0)	No serious inconsistency (0)	No serious indirectness (0)	Moderate imprecision (-0.5)[33]	Study design (+1)	**Moderate** ⊕⊕⊕◯
Expenditure: 2	DID (I), ITS (I)	Moderate risk (-0.5)[34]	No serious inconsistency (0)	Serious indirectness (-1)[35]	Moderate imprecision (-0.5)[36]	Study design (+1)	**Very low** ⊕◯◯◯
Outcome: Volume							
7	DID (I), ITS (II), panel data (I), regression analysis (I), RM (II)	Low risk (0)	No serious inconsistency (0)	No serious indirectness (0)	Moderate imprecision (-0.5)[37]	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Availability							
Outcome: Affordability							

Abbreviations: DID = difference-in-difference, ITS = interrupted time series, RM = repeated measure study

[33] Three studies (Kaiser 2014 and Adriaen 2007) report large SD/SEs relative to the effect size. Imprecision is difficult to assess in one study (Puig-Junoy 2007) due to a lack of reported estimates of confidence.
[34] The point of analysis in the study by Hsiao et al. seems inappropriate and may have affected magnitude of results. Therefore, the risk of bias was lowered by -0.5.
[35] Expenditure is a proxy for price, resulting in a downgrade for indirectness.
[36] One studies (Grootendorst 2006) reports wide confidence intervals relative to the effect size. Imprecision is difficult to assess in one study (Hsiao 2010) due to a lack of reported estimates of confidence.
[37] One study (Kaiser 2014) reports a large SD relative to the effect size. Imprecision is difficult to assess in three studies (Puig-Junoy 2007, Grootendorst 2006 and Hsiao 2010) due to a lack of reported estimates of confidence.

Table 9.5 Summary of findings table – Generic Reference Pricing

Summary of findings for Generic Reference Pricing

Medicines: overall, antipsychotics, statins, NSAIDS

Settings: Italy, Finland, Spain (and Catalonia), Norway, Canada (British Columbia), Denmark, Taiwan

Intervention: Generic Reference Pricing (GRP)

Comparison: medicines without intervention: before the intervention or not affected by the intervention (not affected by intervention: 1-aripiprazole, pravastatin, ceriastatin, fluvastatin, atorvastatin; medicines in regions without GRP).

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments	Notes
Price					
Cost/DDD and price/DDD	The introduction of the intervention was associated with a decrease in prices (173,174,243,246,252). In two studies, the trend and level changes were negative and highly significant (173,174) while another study reported positive and not significant level and trend changes (237). However, two studies showed that the effect of generic substitution in reducing prices is larger than the effect of reference pricing (173,174).	6	Moderate ⊕⊕⊕○	The introduction of GRP probably leads to lower prices, but the effect of generic substitution may be more effective in decreasing prices.	*Koskinen 2014*: level and trend change after GRP were negative. For level change the impact was highly significant; trend change was also highly significant in general, except for Clozapine (P=0.9). The relative effect of GRP in the reduction in the prices of medicines ranged 29.9% to 66.3%. A larger effect is also attributed to the simultaneous implementation of generic substitution. *Koskinen 2015*: level and trend change after GRP was negative and highly significant. The relative effect of GRP in the reduction in the prices of medicines ranged 24.6% to 50.6%. A larger effect is also attributed to the simultaneous implementation of generic substitution; generic substitution had a larger effect on price reductions than RP. *Puig-Junoy 2007*: the inclusion of lovastatin under the RP system resulted in a negative and significant ($p<0.10$) change in trend; the change in level was positive and significant ($p<0.05$). the inclusion of simvastatin under the RP system resulted in a positive and significant ($p<0.10$) change in trend; the change in level was positive and significant ($p<0.10$). Significant changes in other statins were not observed.

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments	Notes
					Brekke 2009: the introduction of GRP led to a significant average price decrease of 18% on branded products and 8% on generics (P<0.01). *Ghislandi 2013*: positive DID for all medicines and highly significant; with significant price drops of more than 13% in average for medicines under GRP. *Kaiser 2014:* the effect of the intervention is negative (price decrease) and significant, translated into an average price decrease by 48%. The decrease of prices is smaller for branded products that for generics medicines.
Price differential	The intervention contributes to driving prices down, and its effect was significant (247).	1		The introduction of GRP probably leads to decreases in price	*Adriaen 2008:* the intervention drives price reductions of generic medicines, raising price differentials between originator and generic medicines over time. F-test was significant indicating that aspects including the intervention explain differentials.
Average price	The effect of the intervention is associated with a significant decrease of prices (253).	1		The introduction of GRP probably leads to decreases in price	*Brekke 2015*: the estimated effect of RP is negative and significant, resulting in reduction of prices of approximately 50% in average.
Cost per prescription	The introduction of the intervention was associated with a decrease in pharmaceutical expenditure, but not significant (179).	1		The introduction of GRP probably leads to little difference in prices	*Moreno-Torres 2011*: only RP systems 2 and 4 had negative coefficients; the negative coefficient for RP system 4 was significant (P<0.01).
Cost per ambulatory visit	The introduction of the intervention was associated with a decrease in cost/ambulatory visit, but not significant (238).	1	Very low ⊕◯◯◯	It is uncertain if the introduction of GRP leads to lower costs, because the certainty of evidence is very low	*Hsiao 2010*: approx. 20% decrease in the cost of ambulatory visits, P= 0.62. Not significant
Total expenditure	The introduction of the intervention was associated with a decrease in pharmaceutical expenditure, but with an unclear significance (254).	1		It is uncertain if the introduction of GRP leads to lower total expenditure, because	*Grootendorst 2006*: the effect of GRP in medicines was associated with lower prices resulting in a decrease in expenditure. The estimated effect of GRP on the decrease of expenditure ranged from 7.8 (95%CI: -22.6; 2.7) to 9.9 million euros (95%CI: -14.7; -0.9).

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments	Notes
				the certainty of evidence is very low	
Volume					
DDDs	One study reported that after the second introduction of the intervention the volume of medicines used increased significantly (238). Other studies reported that, although the introduction of the intervention did not have an effect on the overall volume of medicines used, the intervention had an effect in the increased use of generic/low-cost medicines and a decrease in brand/high-cost medicines (243,253). However, one study reported that the increase in use of/switch to generic medicines was not accelerated by the intervention and its effect was not significant (246).	4	Moderate ⊕⊕⊕◯	The introduction of GRP probably leads to increased use of low-cost generics and decrease of high-cost/ brand medicines	*Hsiao 2010*: there was no significant (P=0.63) change in the prescribing volume of medicines after the implementation of RP regulation. But there was a significant (P=0.05) increase of volume (7%) after the introduction of the second regulation. *Ghislandi 2013*: the switching patterns from old to new molecules was not significant and was not accelerated by the introduction of GRP. *Kaiser 2014*: the effect of the reform on sales/quantity of medicines differed between types of medicines. It had a negative effect on brand products (decrease of quantities by 21.4%) and an increase in parallel imports and generics (by 61.5% and 19.7% respectively). Significance is not reported. *Brekke 2015*: RP is associated with a significant increase in volume of approximately 30%.
DDDs per 100 seniors per month	The introduction of the intervention was associated with a significant increase of the volume of medicines used (254).	1		The introduction of GRP probably leads to increased use of medicines	*Grootendorst 2006*: the introduction of RP did not affect dispensing volumes and was not significant. But the RP had an effect on the type of medicines dispensed. Low-cost and fully reimbursed medicines increased in volume, while partially reimbursed and higher-cost decreased; significance unknown.
No. of prescriptions per capita	The revision of the RP system was associated with a positive and significant impact on the number of prescriptions per capita. However, other RP systems were not associated	1		The introduction of GRP probably leads to little difference in use of medicines	*Moreno-Torres 2011:* the coefficients of RP systems 1, 2 and 3 were positive, while the coefficients of RP systems 4 and 5 were negative. All coefficients were not significant, except for the coefficient of RP system 3, which was significant (P<0.01). The effect of RP system 3 on the prescriptions was of approximately 5%.

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments	Notes
	with an effect on the number of prescriptions per capita (179).				
Sales volume per 1000 inhabitants	The intervention's effect caused a decrease of sales volume, which was significant (237).	1		The introduction of GRP probably leads to decreased use of medicines	*Puig-Junoy 2007*: a reduction in sales volume was found after including medicines into the RP system ranging from 2 to 7% for different medicines. The revision of the RP resulted in a 12% decline in the volume of medicines. These results were significant.
Availability					
Affordability					

The effect on *price* was assessed in nine studies with several studies reporting on multiple outcomes[38]; expressed as the variables cost or price per DDD (n=6), average price (n=1), price differential (n=1) and cost per prescription (n = 1). The overall certainty of evidence of these studies was rated as moderate.

Eight of the included studies showed that GRP may lead to decreases of prices and one study had inconclusive results whether GRP leads to lower prices due to low evidence. In specific for cost per DDD, the studies showed decreases in prices. In two studies by Koskinen *et al.*, the relative effect of GRP was associated with a decrease in the prices of medicines ranging from 29 to more than 60% (*173*,*174*). However, these findings need to be considered in light of the co-intervention generic substitution. Hence, the authors noted that the additional impact of reference pricing over and above previously implemented generic substitution was low. Another study reported that GRP was not effective in reducing the price of medicines with a price below the reference level (*237*). The effect of the intervention on average prices and on price differentials was associated with a significant decrease of prices (*247*,*253*). However, the effect of the intervention on cost per prescription was associated with little decreases on prices.

The effect on *pharmaceutical expenditure* was assessed in two studies including the variables cost per ambulatory visit (n=1) and total pharmaceutical expenditure (n=1). The overall certainty of evidence of both studies was rated as very low mainly due to study design and effects of co-interventions. Both studies had inconclusive results of whether GRP decreases expenditure: the introduction of the intervention on ambulatory visit was associated with a 20% decrease in cost/ambulatory visits however with non-significant findings (*238*). The effect of GRP was associated with lower prices resulting in a decrease in expenditure but with unclear significance. The estimated effect of GRP on the decrease of expenditure ranged from 7.8 to 9.9 million euros

The outcome *volume* was assessed in seven studies, expressed as quantity in DDD (n=4), DDD per 100 per month (n = 1), number of prescriptions per capita (n=1), and sales volume per 1000 inhabitants and sales ratios (n=1). The overall certainty of evidence is moderate. The effect of the intervention on volume was however not clear. Some studies reported that the intervention had an effect on increased use of generic/low-cost medicines and a decrease in brand/high-cost medicines, although the introduction of the intervention did not have an effect on the overall volume of medicines used (*243*,*254*). Hsiao et al 2010 showed that there was no significant (P=0.63) change in the prescribing volume of medicines after the implementation of RP regulation. But there was a significant (P=0.05) increase of volume (7%) after the introduction of the second regulation. Grootendorst et al 2006 showed the introduction of the intervention was associated with a significant increase of volume of medicines used (254). However, one study reported that the increase in use of/switch to generic medicines was not accelerated by the intervention and its effect was not significant (*246*). Another study by Moreno-Torres et al 2011 reported that the revision of the reference price system was associated with a positive and significant impact on the number of prescriptions per capita. However, other reference price systems did not show an effect on the number of prescriptions per capita (179).Puig-Junoy et al 2007 showed on the other hand that the intervention's effect caused a significant decrease of sales volume (237).

[38] The study by Brekke 2015 reported on 2 outcomes: average prices and pharmaceutical expenditure.

9.2.3.2 Impact of therapeutic reference pricing

Eight studies assessed the impact of therapeutic reference pricing (TRP) on price and volume. The GRADE quality assessment and summary of findings for therapeutic price referencing are given in Table 9.6 and Table 9.7.

Table 9.6 Certainty assessment (GRADE) of evidence for each outcome – Therapeutic Reference Pricing

No. of studies (references)	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
Price: 5	ITS (II), RM (III)	Low risk (0)	No serious inconsistency (0)	No serious indirectness (0)	Moderate imprecision (-0.5)[39]	Study design (+1)	**Moderate** ⊕⊕⊕◯
Expenditure: 2	DID (II)	Moderate risk (-0.5)[40]	No serious inconsistency (0)	Serious indirectness (-1)[41]	Moderate imprecision (-0.5)[42]	Study design (+1)	**Very low** ⊕◯◯◯
Outcome: Volume							
7	DID (II), ITS (III), RM (II)	High risk (-1)[43]	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Low** ⊕⊕◯◯
Outcome: Availability							
Outcome: Affordability							

Abbreviations: DID = difference-in-difference analysis, ITS = interrupted time series, RM = repeated measure study

[39] Imprecision is difficult to assess in three studies (Johnson 2011, Schneeweiss 2014 and Stargardt 2005) due to a lack of reported estimates of confidence.
[40] One study presented with a overall low risk of bias, whereas the study by Stargardt was associated with a high risk of bias.
[41] Expenditure is a proxy for price, resulting in a downgrade for indirectness.
[42] One study (Armeni 2016) reports a large SD relative to the effect size.
[43] The risk of bias was assessed to be substantial in four of seven studies.

Table 9.7 Summary of findings table – Therapeutic Reference Pricing

Therapeutic reference pricing vs no intervention

Medicines: all medicines; acetic acid derivatives and related substances; NSAIDs; selective serotonin reuptake inhibitors; antidepressants; inhibitors of uric acid production; selective beta-2-adrenoreceptor agonists; broncholidators; insulin; proton pump inhibitors; angiotensin-converting-enzym inhibitors (ACEI); lipid-lowering agents; statins; anti-ulcerants; hypoglycemics; antihyperlipidemics; antipsychotics; antihypertensives.
Settings: Sweden, USA (Arkansas State), Slovenia, South Africa, Italy, Germany, Finland, Canada (British Columbia), the Netherlands, New Zealand
Intervention: Therapeutic reference pricing
Comparison: medicines without intervention: before the intervention or not affected by the intervention

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments	Notes
Price					
Price per milligram	Prices paid by the insurer did not change after the introduction of the intervention. This result is not significant (248)	1	Moderate ⊕⊕⊕◯	TRP probably leads to little difference in prices.	*Schneeweiss 2004*: this study report the average price charged to the insurer. The introduction of the intervention was not associated with differences or decreases in the prices of medicines charged to the insurer. These results are not significant (P>0.10).
(Reimbursable) price per unit	The intervention was associated with a substantial decrease in costs for the insurer, particularly immediately after its introduction and was less substantial over time (240).	1		TRP probably results in a decrease in costs shortly following the intervention.	*Mardetko 2018*: "The TRP was found to be an effective means of causing a substantial costs reduction immediately after its introduction." "After the introduction of TRP the trends in decreasing costs became less steep." "Significant cost reduction occurs immediately after TRP introduction". Significance values are not reported; however, the text mentions that the cost reduction and changes in slope were significant.
Cost/DDD	The introduction of the intervention is associated with a reduction of the costs of medicines (239).	1		TRP probably results in a decrease in costs shortly following the intervention	*Andersson 2006*: the introduction of the intervention was associated with a reduction of costs for most groups. Results were statistically significant.

Cost per claim	The intervention was associated with a substantial decrease in costs for the insurer (244).	1		TRP probably results in a decrease in costs shortly following the intervention. Whether this decrease may be sustained for a longer period of time remains uncertain, because the evidence is contradictory in different subgroups.	*Johnson 2011*: three results (sub-outcomes) relate to this outcome: net cost/claim; average charged/claim; cost per member per month. The overall results for these three sub-outcomes report that the net cost per claim and the average charged/claim decreased after the implementation of TRP. Significance of these results is not reported.
Price index	The introduction of the intervention is associated with a decrease of the price index of those products affected by the intervention. Significance is unclear (249).	1		TRP probably leads to a decreased price index.	*Stargardt 2005*: the introduction of the intervention was associated with a decrease of price index for those medicines under the intervention. No significance was reported.
Public and private monthly expenditure	The introduction of the intervention was associated with a long term effect resulting in a significant increase in pharmaceutical expenditure, both in the public and private sectors (251).	1	Very low ⊕◯◯◯	It remains uncertain what the effect of TRP is, because the certainty of evidence is very low	*Armeni 2016*: this study compares public and private expenditures. The effect of the introduction of TRP resulted in increases of public expenditures and decreases of private expenditures. The effect of TRP after 6 months resulted in a statistically significant increase in public (3.7%) and private expenditures (6.9%), being the private expenditure greater.
Pharmaceutical expenditure	The intervention was associated with a significant reduction and increased savings in medicines expenditure and is influenced by switching behavior to medicines under the intervention (250).	1		It remains uncertain what the effect of TRP is, because the certainty of evidence is very low	*Stargardt 2010:* The authors reported that it is unclear to determine savings resulting from the intervention with any certainty. However, switching behavior due to the introduction of the intervention suggests an increase in savings in pharmaceutical expenditure. No significance is reported.
Volume					
DDDs	It is unclear if the introduction of the intervention had an effect on volume. However, for two medicine groups the volume increased, though the effect in the shift and level in slope differ, and is significant (239).	2	Low ⊕⊕◯◯	It remains uncertain what the effect of TRP on DDDs as different studies come to different conclusions.	*Andersson 2006*: for all pharmaceuticals and most medicine groups, the effect of RP is not reported on the outcome 'volume'. For Acetic acid derivatives the shift in level was negative and significant. For serotonin reuptake inhibitors, the shift in slope was positive and significant. Though, judging by the graphs, both medicine groups

	The introduction of the intervention is associated with a significant increase in volume, associated, as well, with switching from higher-priced to lower-priced medicines (250).				seem to have experienced an (significant) increase in volume due to RP. *Stargardt 2010*: users of medicines showed a significant increase in dispensed DDDs. Of the patients treated with high cost medicine affected by RP (atorvastatin kept price above RP) more than 80% switched to lower cost medicines; the results on prescription switch were significant. This also resulted in the decrease of the market share of the high-cost medicine (atorvastatin).
DDDs per 1000 inhabitants per month	Although the introduction of the intervention did not have an effect on overall medicine utilization, there was an increase in the use of fully reimbursed medicines under the intervention (240).	1		TRP may result in an increase of the use of fully reimbursed medicines.	*Mardetko 2018*: After the introduction of TRP the medicine consumption did not differ considerably; however, there was an increase (at least 15%) in the proportion of prescriptions for fully reimbursed medicines. Significance was not reported.
Units per capita per month	The introduction of the intervention is associated with a significant increase in volume, associated, as well, with switching from higher-priced to lower-priced medicines. In the long run, the effect is greater in the public sector while it decreases in the private sector (251).	1		TRP may result in a switch to lower-priced medicines.	*Armeni 2016*: the effect of the intervention in public and private volumes was positive and significiant. In the public sector, the effect increased after 6 months (from 2.5 to 3.4%), while it decreased in the private sector(from 5.5 to 1.6%). Results are significant.
No. of prescriptions	The introduction of the intervention is associated with a significant increase in volume, associated, as well, with switching from higher-priced to lower-priced medicines (250).	1		TRP may result in an increase of the number of prescriptions.	*Stargardt 2010*: For patients who continued to be treated with atorvastatin, the number of prescriptions increased by 1.19 during the follow-up period. For switchers to another statin and patients who switched more than once during the follow-up period, the number of prescriptions for statins increased by 1.43 and 1.15 respectively."
Claims per 100 members	The introduction of the intervention was not associated with an overall change in medicine utilization (244).	1		TRP may result in an overall change of medicine utilization.	*Johnson 2011*: Overall, utilization was not adversely affected by RP, and utilization did not change over the period of study. The introduction of the intervention in the treatment group was associated with more utilization of medicines in comparison with the control group. Significance not reported. During the first months after the intervention, utilization dropped, but after several months utilization gradually increased. Significance not reported.

Proportion of patients starting with medication	The introduction of the intervention was associated with the increase of use of certain type of medicines, e.g. medicines free of cost-sharing by patients (248). Significance was not reported.	1		TRP may result in an increase of fully reimbursed medicines.	*Schneeweiss 2004*: after the introduction of RP, the proportion of medicines free of patient cost-sharing increased substantially from 17% to 47.1%, coupled with a decrease in cost-sharing medicines. Significance is not reported.
Generic dipensing ratio	The introduction of the intervention was associated with an increase in the use of generic medicines (175).	1		TRP may result in an increased use of generic medcines.	*Leopold 2014:* The intervention lead to increased use of generic medicine and a slight decrease in sales.
Availability					
Affordability					

Abbreviations: ACEI = angiotensin-converting-enzyme inhibitors CBA = controlled before / after study, DDD = defined daily dose, DID = difference-in difference analysis, ITS = interrupted time series analysis, NSAIDS = Nonsteroidal Anti-inflammatory Drugs, OTC = over the counter, PMPM = per member per month, RM = repeated measure study, RP = reference pricing, Std = standard, TRP = therapeutic reference pricing, USA = United States of America

The outcome *price* was assessed in five studies through the variables price per milligram, reimbursable price per unit, cost per DDD, cost for claim and price index. Several studies[44] (n= 4) reported on multiple price outcomes. The overall certainty of evidence was rated as moderate.

The majority of studies reported that therapeutic reference pricing leads to decreased prices. However, most of these studies did not report statistical significance levels. In specific: one study reported on the price paid by the insurer (price per milligram) which however did not change after the introduction of the intervention. The results were not significant. One study reported on reimbursable price per unit and showed substantial decreases, particularly immediately after its introduction and was less substantial over time. Studies assessing the cost per DDD reported that the introduction of TRP was associated with a reduction of costs of medicines (*239*).

One study showed that costs per claim increased probably resulted in a decrease in costs shortly following the intervention. Whether this decrease may be sustained for a longer period of time remains uncertain, because the evidence is contradictory in different subgroups. Another study showed that the introduction of the intervention resulted in a decrease of the price index of those products affected by the intervention. Significance was unclear.

The outcome *expenditure* was assessed in two studies and the overall certainty of evidence was rated as very low. It therefore remains uncertain what the effects of TRP is on pharmaceutical expenditure.

The outcome *volume* was reported by seven studies, whereas several studies reported on multiple outcomes.[45] Volume was assessed through the variables DDDs, DDDs per 1000 inhabitants per month, units per capita per month, number of prescriptions, claims per 100 members, proportion of patients starting with medication and generic dispensing ratio. The overall certainty of evidence was rated as low. While there was no clear effect on overall medicine utilization, an increase of volume was observed in certain medicine groups such as generics, reimbursed medicines and medicines free of cost-share. It was reported that the introduction of the intervention was associated with a significant increase in volume and utilization of fully reimbursed or low-cost medicines due to switching from one type of medicine (e.g. high-cost medicines) to another (e.g. low-cost medicines) (*240*,*250*,*251*). In the long run, the effect was greater in the public sector while it decreases in the private sector (*251*).

[44] The studies by Johnson 2011, Mardetko 2018, and Stargardt 2010 reported on multiple outcomes related to price

[45] The studies by Mardetko 2018 and Johnson 2011 reported on multiple outcomes related to volume

9.2.3.3 Impact of mix generic and therapeutic reference pricing

Two studies assessed the impact of a mix of generic and therapeutic reference pricing on price and volume. The GRADE quality assessment and summary of findings for the mix of generic and therapeutic reference pricing are given in Table 9.8 and Table 9.9.

Table 9.8 Certainty assessment (GRADE) of evidence for each outcome – Mix of therapeutic reference pricing and generic reference pricing

No. of studies (references)	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
2	Panel data (I), RM (I)	Low risk (0)	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Volume							
1	RM (I)	Low risk (0)	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Availability							
Outcome: Affordability							

Abbreviations: NA= not applicable, RM = repeated measure study

Table 9.9 Summary of findings table – Therapeutic Reference Pricing and Generic Reference Pricing

Mix of Generic reference pricing and therapeutic reference pricing vs no intervention

Medicines: NSAIDS; ACE Inhibitors

Settings: Canada (British Columbia); Denmark, France, Germany, Netherlands, Sweden and United Kingdom

Intervention: Mixed reference pricing

Comparison: medicines without intervention: before the intervention or not affected by the intervention

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments	Notes
Price					
Unit price	The introduction of GRP and TRP showed mixed effects on price. For some medicines, the effect is positive, while for others it is negative. One study reported that GRP was more effective on reducing prices (*19*); while another study reported negative effect (reduction of prices) on off-patent medicines (*20*).	2	Moderate ⊕⊕⊕◯	Results on the effectiveness of GRP and TRP are inconclusive, due to variable outcomes.	*Grootendorst 2005*: the estimate effect of GRP was positive and significant only in unrestricted medicines; in restricted medicines the estimate effect was negative and siginificant only for 1st line restricted medicines. The estimate effect of TRP was negative in unrestricted and restricted medicines. The effect is significant (P<0.001) on 2nd line restricted medicines only. TRP was more effective than GRP on reducing prices. *Von der Schulenberg 2011*: for patent (originator) medicines, (T&G)RP have a positive and significant estimated effect (P<0.01); over the whole lifecyle of originator medicines, the estimated effect of (T&G)RP is negative and significant (P<0.05). The evidence on RP is inconclusive
Volume					
Days of therapy dispensed per 1000 seniors	The introduction of GRP and TRP did not affect the total volume of NSAIDs dispensed and results were not significant and modest. (*19*)	1	Moderate ⊕⊕⊕◯	The effects of GRP and TRP were inconclusive.	*Grootendorst 2005:* the prescription of medicines decreased for all medicines, but the prescription of unrestricted (fully reimbursed) medicines doubled after the introduction of TRP. The effect of TRP and GRP on utilization of restricted NSAIDs was negative and thus associated with reductions of utilization; the effects of GRP were significant (P<0.05), and not significant for TRP (P>0.1).
Availability					

Affordability

Abbreviations: ACEI angiotensin-converting-enzyme inhibitors, NSAIDS = Nonsteroidal Anti-inflammatory Drugs, RP = reference pricing, TRP = therapeutic reference pricing

The outcome *price* was assessed by two studies[46], expressed as unit price (n=2). The overall certainty of the evidence was moderate. The effects on price were inconclusive. One study reported that TRP was more effective in reducing prices than GRP (*245*), another study showed that TRP and GRP had a statistically significant effect in reducing prices of off-patent medicines only (*91*).

The outcome *volume* was reported once, expressed as days of therapy dispensed per 100 seniors. The introduction of GRP and TRP did not affect total volume of NSAIDs dispensed. Results were not significant and modest. (*245*). The overall certainty of evidence was rated as moderate.

9.2.3.4 Impact of (generic) price linkage

Five studies assessed the impact of price links, on price and volume. The GRADE quality assessment and summary of findings for this subtopic are given in Table 9.10 and Table 9.11. The overall certainty of evidence was rated as moderate for both price and volume. Brief details of the individual studies are included below, followed by main results on the impact of (generic) price linkage.

Table 9.10 Certainty assessment (GRADE) of evidence for (generic) price linkage for each outcome

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
5	ITS (IV), regression analysis (I)	Low	No important inconsistency	Moderate indirectness (-0.5)[47]	No serious imprecision	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Volume							
4	ITS (IV)	Low	No important inconsistency	No serious indirectness	No serious imprecision	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Availability							
Outcome: Affordability							

[46] The study by Grootendorst 2005 reported on 2 outcomes for Price: unit price and pharmaceutical expenditure.
[47] 40% of the included studies report expenditure, which is a proxy for price

Table 9.11 Summary of findings table for (generic) price linkage for each outcome

(Generic) price linkage vs no intervention

Medicines: Antidiabetics; antihypertensives; all medicines

Settings: South Korea, Sweden

Intervention: (Generic) price linkage

Comparison: No policy

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE) †	Comments
Price				
Unit price	A price link was associated with a -41.68 (p<0.0001) KRW (-0.026 USD) immediate change in unit prices for all medicines (241). In a second study, the implementation of the price link coincided with another intervention. A -0.11 (p>0.05) KRW (-0.0001 USD) immediate change in unit prices for all medicines was observed (255). There was little evidence of changes in trends after the policy intervention in either study, with continuingly positive (p>0.1) slopes.	2	**Moderate** ⊕⊕⊕○	Introduction of price-cuts probably initially leads to slightly lower prices, but the effect is likely to be transient.
Cost per DDD	The estimated effect of the 35% price-cap on off-patent medicines in the 3 months after the intervention equals a monthly 7.87% (p<0.05) decrease in cost per DDD. Long-term effects were not measured in the study (176).	1		A price-cap of 35% on off-patent medicines probably decreases prices in the short-run but not in the long-term.
Monthly cost per patient	A single price system* for originators and generics 1 year after generic entry was associated with a -1.38 to -3.38# USD (p<0.001) immediate change in monthly costs per patient for antihypertensives and antidiabetics, respectively (242). There was a 0.11 USD (106.9 KRW, p<0.1) trend in costs each month for antidiabetics, whereas the opposite was found for antihypertensives, with a -0.01 USD (p<0.05) trend per month (236).	2		A single price system probably results in a decrease in costs shortly following the intervention. Whether this decrease may be sustained for a longer period of time remains uncertain, because the evidence is contradictory in different subgroups.
Volume				
Units per patient	The simultaneous implementation of a price agreement for new chemical entities and a price cut of 20% on off-patent medicines after generic entry was associated with an immediate	1	**Moderate** ⊕⊕⊕○	The simultaneous implementation of a price agreement for new chemical entities and a price cut of 20% on off-patent medicines after generic entry does probably

	decrease of -1.12 (p>0.05) units per patient (255). Following the interventions, there was a slightly negative (p>0.05) trend.			not lead to a difference in utilisation.
Monthly DDDs per patient	A single price system* for originators and generics 1 year after generic entry was associated with a change in immediate dispensation of medicines of -1.56 to 0.0018 (p>0.1) DDDs per patient (242). The subsequent trend was found to be increased by 0.0015 DDDs per person per month (p<0.001) in the first study. In a second study, a trend change of -0.01 DDDs per patient per month (p>0.05) was observed (236).	2		Uniform price-cuts probably lead to no immediate difference in utilisation. The trend of daily drug utilisation of hypertensives probably slightly increases after the intervention. Utilisation of antidiabetics is probably not affected by this policy.
Units per month	A single price system* was associated with a 18.06 million units (p>0.1) being prescribed less immediately after implementation (241). There was a subsequent trend of a 8.98 million (p>0.1) reduction in the amount of units prescribed per month.	1		Uniform price-cuts probably lead to no immediate difference in prescription volume. The trend of prescription is probably not affected by the policy.
Availability				
Affordability				
* The single price system is studied in three distinct papers, each regarding the 2012 South-Korean Single Exit Price. Results should be interpreted together. # -3380 KRW				

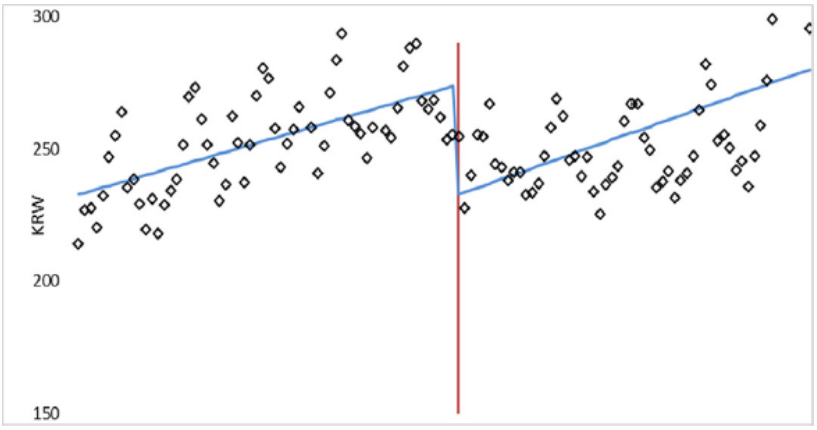
Lee et al. examine a policy implemented in South-Korea in December 2006 (*255*). Besides a 20% price cut on off-patent pharmaceuticals, the policy consists of a price agreement for new chemical entities and a positive reimbursement list. Insurance claims data is used to assess the impact on price and volume of all recorded data. For the second outcome, sub-analyses for antihypertensives and antihyperlipidemics are also performed. Although the study period comprised data from 2003 to 2008, the interpretation of the post-intervention data is restricted to only 7 months due to a co-intervention to have taken place in August 2007.

Kwon et al., Suh et al. and Yoo et al. examine the effect of the single price system (SPS) consecutively implemented in 2012 in South-Korea (*236*,*241*,*242*). The latter two studies focused on a subgroup of patients, with a more limited time period included for analysis (2009-2013 and 2011-2013 respectively), while the former included monthly data for a decade to examine the impact on all medicines. The data was provided by the National Health Insurance (NHI), covering 97% of the population (*241*).

Suh et al. likewise explored the NHI system and complemented it with data from Medical Aid, an insurance program covering the remaining 3% of the population, but restricted their analysis to adult beneficiaries with at least one claim of diabetes mellitus (*242*). The impact of the SPS was assessed on both price and volume. A co-intervention was implemented before the SPS, in October 2010.

Yoo et al. focused their analysis on a random 1% sample of patients diagnosed with primary hypertension from the National Patient Sample (NPS), which included data from the general population as well as the low-income segment (*236*).

Figure 9.1 unit prices of all medicines (2007-2016), segmented by the SPS in April 2012.

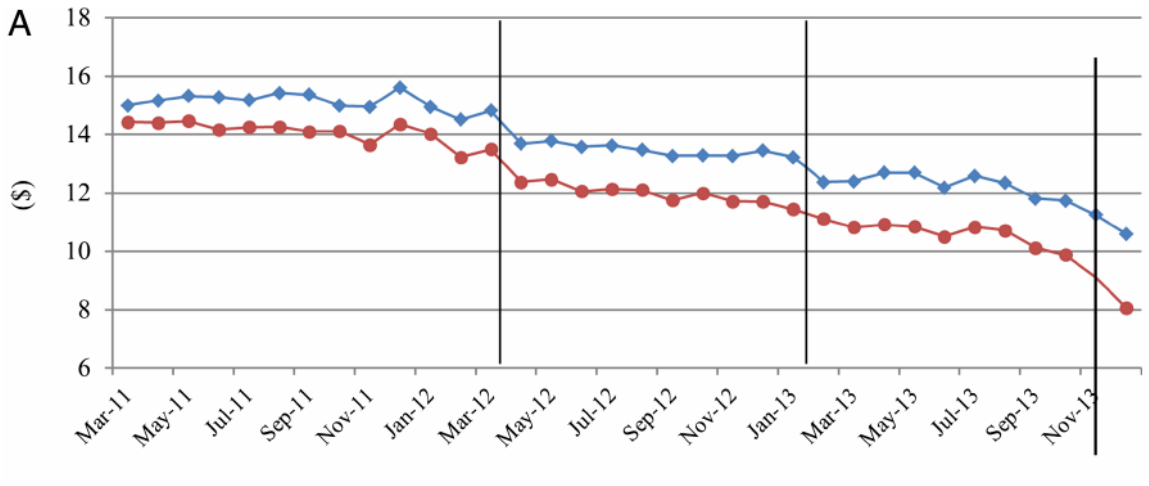


The four ITS studies each report a change in level and a change in trend at the time of intervention. Lee et al. observed a 0.11 Korean Won (KRW) reduction in unit price, equal to -0.0001 USD[48], immediately after implementation of the intervention ($p>0.05$). Kwon et al. reported a 41.68 KRW drop in unit prices (-0.026 USD, $p<0.0001$) post-policy (see Figure 11.2). There was little evidence of changes in trends after the policy interventions in either study, though with a tendency towards an upturn in the trend (increasingly positive trend) of unit prices after the interventions of 0.16 KRW ($p=0.656$) and 0.82 ($p>0.1$) respectively.

Suh et al. and Yoo et al. examined the impact of the SPS on monthly costs per patient. The studies reported a 1.3 USD ($p<0.001$) and 3380 KRW (-3.38 USD, $p<0.001$) reduction in costs in the month (May 2012) after the intervention for both antidiabetics and antihypertensives (see Figure 11.3). In the case of antidiabetics, this was mainly because of the antidiabetics that had their prices cut (a 3670 KRW average decrease, $p<0.001$), whereas costs for antidiabetics that had not undergone the intervention seemed to increase slightly (233 KRW, $p>0.1$). The trend in costs for antidiabetics showed a switch to an increasing trend from -2.1 to 104.8 KRW per month (0.11 USD, $p<0.1$). The opposite was reported for patients using antihypertensives, with monthly costs lowered by 0.0149 USD ($p=0.048$) per month.

[48] Calculated based on exchange rate provided in paper.

Figure 11.3 Antihypertensive drug costs, segmented by the SPS in April 2012, the introduction of guidelines for antihypertensive drugs (January 2013) and the benefit Enhancement Plan (September 2013).



The fifth study by Bergman et al. studies the impact of a 35% price reduction on off-patent originator and generic pharmaceuticals in July 2009 on price, using pharmacy level dispensing data from the period 2006-2011 (*256*). Due to multiple co-intervention, the first of which was enacted in October 2009, the impact of the intervention may be difficult to distinguish from other effects.

Bergman et al. applied a regression model to estimate the effect of the price link on the logarithm of the cost per defined daily dose (DDD), including costs as the dependent variable and adding covariates with continuous values or as dummy variables, such as the intervention studied. It reports outcomes as coefficients, from which a relative change in price was calculated by the authors. The impact of the policy intervention was estimated to be a 7.87% reduction in costs per DDD.

Volume-related outcomes are reported by the four ITS studies. Lee et al. found that the intervention was associated with little change in level (-1.12 units per patient, $p>0.05$) and no change in trend (-0.05, $p>0.05$). However, a subgroup analysis of antihyperlipidemic originator drugs showed a tendency towards an increase in slope after the new pricing system (0.16, $p=0.081$), whereas other subgroups were reported to present only negligible differences.

Kwon et al. observed an 18.06 million units ($p=0.922$) being prescribed less in the month after enactment of the SPS and a subsequent trend change of an 8.98 million ($p=0.127$) reduction in the quantity of units prescribed per month (Figure 11.4). On a patient basis, a 1.4 DDD drop was seen in antidiabetics targeted by the new pricing system in the month when it was introduced ($p<0.05$) (242). Besides this, no major changes were observed in the trend for use of targeted antidiabetics nor in the level and trend of overall antidiabetics or antidiabetics not targeted ($p>0.1$). Yoo et al. reported a minor increase of 0.0018 ($p=0.225$) DDDs per hypertensive patient and a somewhat larger difference in trend, which increased with 0.0015 ($p<0.001$) DDDs after the drug price reduction (Figure 11.5).

9.3 Authors' conclusions

9.3.1 Summary of main results

Of the twenty-six studies included in this systematic review, eleven studies assessed the impact of generic reference pricing, eight the impact of therapeutic reference pricing, two of mixed effects of generic and therapeutic reference pricing and five studies of generic price link on price and volume. No studies looked at the effects of external reference pricing on price and volume. The majority of studies used either repeated measures or interrupted time series designs. In summary, despite a heterogeneity in the policies all four sub-interventions (generic reference pricing, therapeutic reference pricing and generic price linkage) led to a decrease in price while the effects on volume were not as clear; increases in volume could only be shown for certain medicines such as low-cost medicines. To be more specific:

- Generic reference pricing (GRP) lowered prices and increased the volume of generics, low-cost medicines and parallel imports and at the same time decreased volume of originator and high-cost medicines.
- Therapeutic reference pricing (TRP) lowered pharmaceutical expenditure, the costs for the insurer and the price of medicines; but increased the cost for the patient. Volume effects were not clear, except for increased volume of reimbursable medicines, generics and medicines free of cost-sharing.
- The impact of a mix of generic and therapeutic reference pricing on price was not clear, showing slightly more savings in TRP; and an increase in volume for reimbursable medicines.
- The five studies that investigated the impact of (generic) price linkage on prices all support an association between this approach and initially lower prices. Long-term beneficial effects on prices are unlikely, as is an association between this mechanism of price setting and prescription quantities. The general lack of effect of the interventions was attributed to a change in utilisation patterns through a shift to pharmaceutical products left untargeted by the policy, as it was not complemented with demand-side measures aimed at prescription behaviour.

9.3.2 Overall completeness and applicability of evidence

Several factors may limit the applicability of this evidence. Firstly, the majority of studies (n = 21) examined high income countries (either in Europe or in the United States of America and Canada). Only five studies assessed data outside from Europe namely from Asia No studies looked at the effects of reference pricing in Latin America and in Africa. One reason for the lack of studies in these areas is that internal reference pricing systems are reimbursement policies influencing co-payment requirements. However, in Latin American countries there is no co-payments as reimbursable medications are fully reimbursed. (*259*) Secondly, half of the studies focused on assessing the effects of the intervention on only one medicine group. This limits generalizability of the results as findings might be linked to contextual factors for the specific medicine group (i.e. prescription guidelines). Thirdly, many of the studies (n=23) mentioned that other co-interventions happened around the same time as the main intervention reference pricing. For this reason, several studies were ranked as "high risk" in the risk of bias assessment. In addition, the majority of studies focused on assessing the effects of price defined as cost/price or pharmaceutical expenditure, but only two studies looked at the effects of costs for patients (*240*,*244*). Lastly, three of the studies on price linkage are on the same intervention. This reduces generalizability of the results.

Additional factors that were not considered in any of the studies include: 1) consideration of effects over time, i.e. the majority of studies focused on short-term effects but did not look at long-term consequences, and 2) consideration of administrative costs of operating a reference price system, i.e. maintaining either of the reference pricing systems requires access to data and human resource.

One unexpected result of this systematic literature review is that none of the included studies assessed the impact of external reference pricing (ERP). This is especially surprising as ERP is one of the most commonly used pricing policy in Europe and many other countries globally (*260*). During the full text screening process studies that potentially looked at ERP were excluded due to weak study designs (e.g. lack of pre-intervention data) or due to primary outcomes that were not part of the study protocol (e.g. spill-over effects of ERP such as launch delays).

9.3.3 Quality of the evidence

The quality of evidence was assessed through ranking the risk of bias as well as the assessment of the certainty of evidence. The risk of bias was moderately different for the various study designs and its categories. While most studies were ranked as "low risk" for the majority of categories, "random sequence generation" and "allocation of concealment" was judged as "high risk" in several studies. It is also worth noticing, that many studies were ranked "high risk" in the category "intervention independent". As mentioned, eight studies reported that other co-interventions were relevant during the assessment. Finally, "other risk of bias" was scored "high risk" in eight studies as methods were unclear or co-founding factors or limitations were not considered.

All studies examined here adopted rigorous study designs and transparently reported their methods and analytical approaches.

The evidence on price linkage was predominantly from ITS studies, which presented with a low risk of bias, the main objection being the occasional brief time between the intervention and co-interventions happening closely in time to the intervention of interest. According to EPOC guidelines, all observational evidence is initially assigned a low quality score. However most studies examined here adopted rigorous study designs, and transparently reported their methods and analytical approaches. As such, the methodological quality was considered high. As such, the quality of the evidence of (generic) price linkage was judged as moderate.

9.3.4 Agreement/disagreement with other reviews

While this systematic literature review focused on studies with strong study designs excluding other literature reviews, it is worth reflecting on arguments made in literature to compare with present results. Hence, the following statements need to be considered with an understanding that these reviews considered different methodologies.

Overall, other reviews generally agreed with our results and presented a few additional discussion points which can be considered as food for thoughts.

Relevant arguments for internal reference pricing (including generic and therapeutic reference pricing): Acosta *et al.* also found that *"…IRP may reduce expenditures in the short term by shifting drug use from cost share drugs to reference drugs. Reference pricing may reduce related expenditures with effects on reference*

drugs but the effect on expenditures of cost share drugs is uncertain…[and] may increase the use of reference drugs and may reduce the use of cost share drugs. The analysis and reporting of the effects on patients' drug expenditures were limited in the included studies and administration costs were not reported. Reference pricing effects on health are uncertain due to lack of evidence." (*14*) The findings by Dylst *et al.* also support our conclusions "*reference pricing drives down prices of drugs subject to the system and the use of these drugs has increased*" (*261*). They then also specify *"reference pricing creates short-term savings but the long-term growth of drug expenditure has not been reduced by reference pricing."* Similar findings are presented by Galizzi *et al.* "*RP was generally associated with a decrease in the prices of the drugs subject to the policy. In particular, price drops seem to have been experienced in virtually every country that implemented a generic RP (GRP) policy…both therapeutic RP (TRP) and GRP have been associated with significant and consistent savings in the first years of application…and generic market shares significantly increased*" (*199*). Finally, a review by Puig-Junoy *et al.* noted that there is a shortcoming regarding studies "*providing evidence on overall social welfare…on prescriber and dispenser time and on industrial research and development (dynamic efficiency)*" (*262*).

Even though, this literature review did not include any studies on external reference pricing, it is still worth mentioning a few key considerations from different literature reviews: A systematic literature review by Fontrier *et al.* concluded that "*Across countries, ERP may cause launch delays, price instability and lead to price convergence. However, these effects cannot be solely attributed to ERP, as there may be other factors at play, such as the size and the GDP of a country and other regulations in place, which can trigger these effects or reduce their effect*" (*198*). A report by Vogler *et al.* came to the conclusion that "*ERP has proven to be effective in generating, sometimes substantial, savings for public payers. The extent of savings has considerably depended on the methodology applied. There are lost opportunities due to discounts, rebates and similar arrangements in the reference countries that are not considered in ERP*." They further point out that "*ERP is likely to have a negative impact* [on patient access] *since it incentivises the pharmaceutical industry to first launch in higher-priced countries and delay, and refrain from entering the market in lower-priced countries, and may also inhibit them from offering medicines at lower prices in lower-priced countries*" (*186*). In addition, the 2011 WHO/HAI working paper on external reference pricing adds the following points to the discussion: "[ERP requires] *considerable resources (human and material) to analyse the data…it may be difficult to identify the same medicine precisely due to different commercial names, dosage form, strength and packaging…price comparisons are made much more complex because of the heterogeneous nature of distributors" profit margins, pharmacists, taxes, etc. …and confidential agreements between manufacturers and purchasers often provide buyers with discounts or other benefits. If the results obtained from such negotiating processes are not transparent, it becomes harder to predict their impact in reference countries."* The authors then conclude that "*one consequence of ERP is that it puts pressure on countries that are selected by others as a reference country to keep prices high, especially if they want an early market entry of new products*…[and that] *the main alleged negative effects include: 1) higher prices in low-income countries that, in the absence of ERP policies, might benefit from lower prices, and 2) delays in the launching of new medicines in countries with low-priced medicines*" (*263*).

9.3.5 Authors conclusions: implications for practice; implications for research

The empirical evidence suggests internal reference pricing, including generic and therapeutic reference pricing as well as (generic) price linkage, may be effective in initially lowering prices. Though this effect is likely to be transient in the case of generic price linkage.

However, these savings may only be achieved in the short run suggesting a need for updating reference pricing policies frequently. At the same time caution should be given to the fact that therapeutic referencing may increase patient cost-sharing. The effects of reference pricing on volume was not clear. While volume of generics, low-cost medicines, parallel imports and medicines with free of cost-sharing increased as a consequence of generic and therapeutic reference pricing, volume of originators and high-cost medicines decreased. However, given the heterogeneous nature of the interventions (i.e. different calculation methods of the reference price) and the high financial administrative burden of operating a reference pricing system these conclusions should be considered within the context of each country.

Future research is required to further substantiate these findings using robust study designs. In particular, focusing on assessing impacts on low- and middle-income countries outside of Europe and on savings over time. Future research should also consider weighing investments into maintaining or running a reference pricing system against possible savings.

None of the included studies in this systematic review looked at external reference pricing (ERP). While we cite several points to consider from other reviews on ERP, these findings are difficult to judge in the absence of evidence on the usefulness of ERP. Future research is therefore needed to further develop the evidence of the impact of ERP on price and volume of reimbursable medications. In specific, a robust analysis with real-world data of spill-over effects of ERP such as launch delays or impacts on prices in other countries and globally would be needed.

10 Promoting price transparency

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10.1 Background

Price transparency is defined here as « the sharing, disclosure and dissemination of information related to medicine prices to the public and relevant parties to ensure accountability » (adapted from (*5*)). Full price transparency includes the publication of medicine prices at all price types (e.g. ex-factory prices, pharmacy retail prices), the disclosure of the net transaction prices of medicines between the suppliers (e.g. manufacturers, service providers) and the payers/purchasers (governments, consumers), the sharing and publication of the contents of pricing arrangements, such as risk-sharing schemes and other managed-entry agreements, including the actual pricing and input factors that determine a medicines prices (e.g. production costs, R&D costs, added therapeutic value).

Transparency is interwoven with various pricing policies examined in the present review series. For instance, the potential lack of transparency in the regulation of mark-ups could allow for higher prices (see 'Mark-up regulation across the pharmaceutical supply and distribution chain') (*4*). Likewise, decreased price transparency could impair the effectiveness of external reference pricing schemes and result in higher medicine prices (see 'Reference Pricing') (*4*). In addition, use of discounts has reportedly hindered price transparency, including the level of price competition (see 'Discounts for Single Source Pharmaceuticals') (*5*). A lack of price transparency may even give rise to corruption, especially in healthcare systems with weak governance, as confidential agreements may compromise accountability (*5*,*264*).

The underlying rationale for improving price transparency is that it would improve economic efficiency, as conventional economic theory indicates; assist policymakers and researchers through reliable price information; empower buyers to negotiate more strategically; and increase accountability of manufacturers for prices (*265*).

A well-known example of a transparency measure is the Single Exit Price (SEP) implemented in 1996 in South-Africa, which consists of an ex-factory price, a logistics fee and Value Added Tax (*266*). Its objective was to clarify to logistics service providers or medicine dispensers at which price a manufacturer may sell a pharmaceutical (*266*). Another initiative to enhance transparent pricing is the 'M' (Manufacturer) and 'W' (Wholesaler) scheme in the United Kingdom. Introduced in 2005, the scheme reflected average costs and prices of generics, based on quarterly surveys of transaction prices between manufacturers, wholesalers and pharmacists (*267*). Yet another example is the EU Transparency directive which requires the publication of the list prices of all reimbursable medicines in Europe (*268*).

While greater transparency in prices is assumed to contribute to improved access to medicine (*269*), arguments have also been made that more transparency could lead to an increase in prices for lower-income countries, as manufacturers might apply uniform pricing for all countries to refrain from the appearance of unfair pricing (*270*). Other harmful effects proposed are discouraged entry in poorer markets, reduced competition and lessened incentives for investments (*270*).

This chapter details the evidence on policies promoting price transparency.

10.2 Results

10.2.1 Excluded studies

A total of nine references on the topic of price transparency were assessed at full text level. Of these, six references were excluded at this stage. The majority of these (n=4) were not deemed eligible due to study design: three studies had missing pre-intervention data (*159*,*271*,*272*) and one study employed a 'base case' forecast scenario, calculating hypothetical savings instead of real savings (*273*). One study was excluded because of a lack of reporting primary outcomes (*335*). Another study was excluded as it was a narrative review that focused on measures to encourage prescription of generic drugs, which was considered off-topic (*137*).

10.2.2 Characteristics of included studies

A total of three references met the inclusion criteria at full text screening. Notably, two of these references regard the same study[49] (*274*,*275*). The studies were published in 2018 and 2019. Both studies had an interrupted time series design, one set in the private sector in South Africa (*274*,*275*) and one examined data from in the United Kingdom (*276*). The former study looked at the top 50 medicines in the private sector and examined the effects of publicly available data on price (*274*,*275*). The other study looked at antibiotics and inhaled corticosteroids and examined the effects of a cost-feedback approach on expenditure (*276*). Characteristics of the studies are provided in Table 10.1.

Table 10.1 Study characteristics

	Study types	Number of studies	Notes/references
Study type	Interrupted time series	2	(*274–276*)
Setting	Europe	1	United Kingdom (*276*)
	South Africa	1	(*274*,*275*)
Subjects	Antibiotics and inhaled corticosteroids	1	(*276*)
	Top-50 medicines dispensed in private sector by volume	1	(*274*,*275*)
Interventions	Cost-feedback	1	(*276*)
	Publicly available prices	1	(*274*,*275*)
Outcomes	Price	2	Weekly expenditure, weekly cost per patient (*276*); Relative price changes (*274*,*275*)

[49] Moodley 2019a and Moodley 2019b are part of the same study, but published separately. One paper addresses originator pharmaceuticals (*275*) (*274*,*275*)while the other addresses both originator and generic pharmaceuticals (*274*). These references will from this point on be considered as one study.

The risk of bias assessment for the included studies is presented in Table 10.2. Both showed in most domains a low risk of bias. The study by Moodley *et al.* was however rated as high risk in the category intervention independent as they may have been influenced by co-interventions being implemented during the study period, resulting in the data to be insufficient to distinguish between the impact of one intervention from another.

Table 10.2 Risk of bias of included studies

		Intervention independent	Appropriate analysis	Pre-specified shape of effect	Intervention to affect data collection	Incomplete outcome data	Knowledge of allocated intervention	Selective outcome reporting	Other bias
		ITS and RM studies				**All study types**			
1	Langley 2018	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕
2	Moodley 2019	⊖	⊕	⊕	?	?	⊕	⊕	?

Notes: 1 = cost-feedback approaches aimed at prescribers, 2 = publicly available prices

Table 10.3 Description of interventions by category of intervention and study

	Intervention	Study begin	Study end	Known co-interventions
Cost-feedback approaches aimed at prescribers				
Langley 2018 (*276*)	Cost-feedback approach to prescribers in a hospital setting	1999	2014	None reported
Publicly available prices				
Moodley 2019 (*274,275*)	Price transparency in the context of the South African Single Exit Price (SEP) policy	1999	2014	Multiple aspects of price control interventions implemented alongside the single exit price policy

10.2.3 Effect of interventions

A short description of each intervention and known co-interventions of the included studies is presented in Table 10.3. Please note that results are categorized according to two sub-groups of interventions: impact of cost-feedback to the prescribers and impact of publicly available prices.

10.2.3.1 Impact of cost-feedback to prescribers

One study assessed the impact of cost-feedback to prescribers. The GRADE quality assessment is given in Table 10.4, and the summary of findings in Table 10.5 The overall quality of the evidence was assessed as moderate. Brief details of the study are included below, followed by main results on the impact of cost-feedback to prescribers.

Table 10.4 Certainty assessment (GRADE) of evidence for each outcome: cost-feedback to prescribers

No of studies	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
1	ITS (I)	Low risk (0)	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Volume							
Outcome: Availability							
Outcome: Affordability							

Table 10.5 Summary of findings table – cost-feedback to prescribers

Cost-feedback to prescribers vs no intervention

Medicines: Antibiotics and inhaled corticosteroids

Settings: United Kingdom

Intervention: Cost-feedback to prescribers

Comparison: No policy

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Weekly cost per patient	A cost-feedback approach was associated with a -3.75£ (95% CI: (−6.52 to −0.98, p=0.008) immediate change in costs for antibiotics. No difference was observed for inhaled corticosteroids. There was a 0.10£ (0.02 to 0.18, p=0.015) increase in trend for antibiotics after the intervention, whereas the approach was associated with a -0.03 (–0.06 to –0.01, p=0.11) change in trend for inhaled corticosteroids.	1	Moderate ⊕⊕⊕◯	It is uncertain if a cost-feedback approach leads to a difference in costs, because the evidence is inconclusive.
Volume				
Availability				
Affordability				

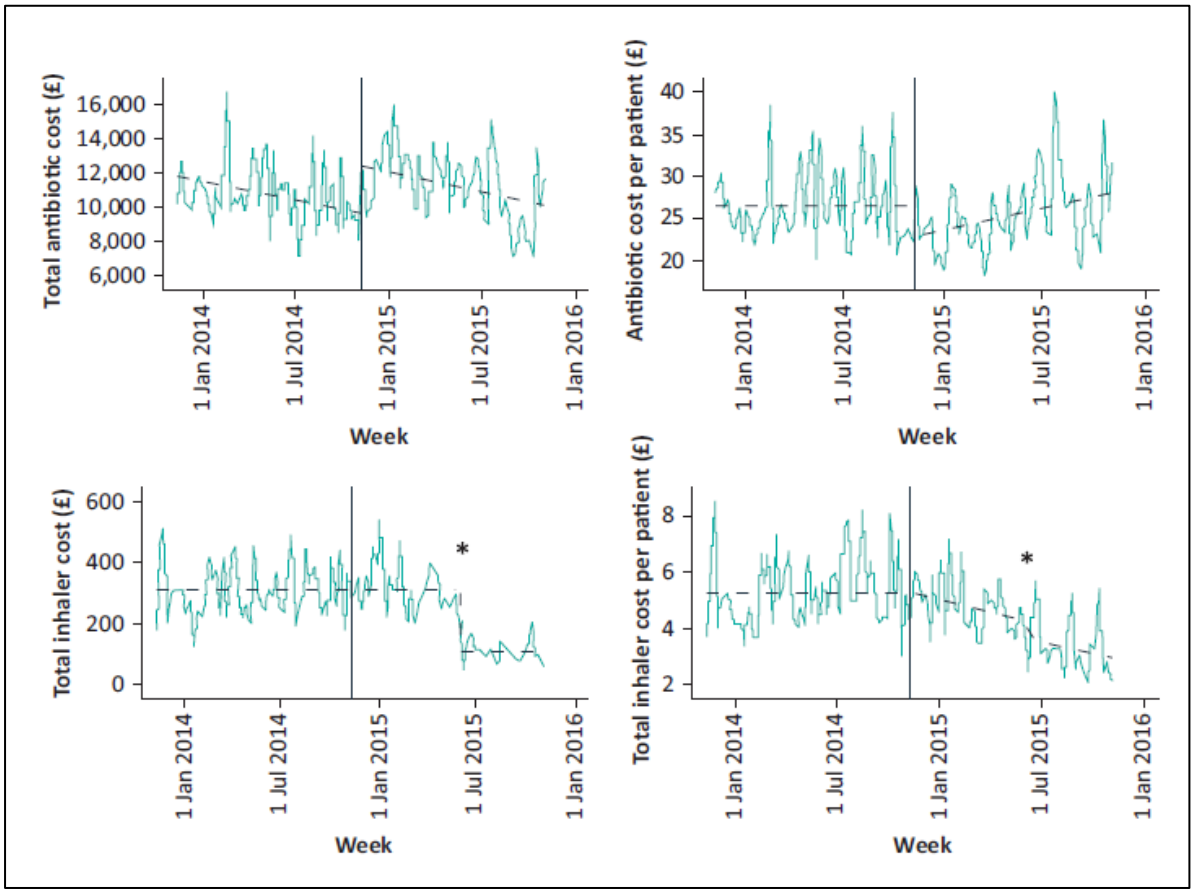
The study by Langley *et al.* examined the impact of a cost-feedback approach in a hospital setting. Clinicians were provided with extra information on the costs of drugs during prescribing, with the simple aim of informing them of the costs of their decision without intending to direct their prescription behaviour. The intervention was implemented in November 2014 in the hospital's electronic prescribing system, which permitted the costs of the medicine of choice to be added to the display that the prescribing clinician sees immediately prior to selecting the drug.

The results of the study were contradictory (see Figure 10.1). Immediately after implementation of the intervention, weekly expenditure on antibiotics increased with 2807.50£ (p<0.001), although no change was observed in trend. A decrease of -3.75£ (p=0008) in weekly antibiotic costs per patient was observed after the intervention, whereas the trend slightly increased with 0.10£ (p=0.015). Having taken doxycycline as an example of a low-cost and much used antibiotic, the authors observed the hypothesized initial increase in weekly doxycycline costs per patient of 0.003 (p<0.001), which was not sustained in a change in trend.

Changes in costs of inhaled corticosteroids were little. Although a small change in trend was seen in weekly costs per patient of -0.03 (p=0.11), no other changes were observed.

The initial increase in prescribing of doxycycline after the intervention was considered evidence that there was a change in physician behavior by the authors and that the lack of sustained response to the cost information was not a consequence of the intervention not being seen by prescribers. The authors were unable to explain the contradictory results.

Figure 10.1 Changes in the costs of antibiotics and inhaled corticosteroids per patient per week. The vertical lines represent the implementation of the cost-feedback intervention. *Represents the introduction of the inhaled corticosteroid protocol, for which the model was adjusted



10.2.3.2 Impact of publicly available prices

One study examined the impact of publicly available prices in the context of the South African Single Exit Price (SEP) policy. The GRADE and summary of findings tables are presented in Table 10.6 and Table 10.7. The overall level of evidence was rated as moderate. Brief details of the study are included below, followed by main results on the impact of publicly available prices.

Table 10.6: Certainty assessment (GRADE) of evidence for publicly available prices

No of studies	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
1	ITS (I)	Low risk (0)[50]	No serious inconsistency (0)	No serious indirectness (0)	No serious imprecision (0)	Study design (+1)	**Moderate** ⊕⊕⊕◯
Outcome: Volume							
Outcome: Availability							
Outcome: Affordability							

[50] One reference presented with low risk in half of the domains. The domains "intervention to affect data collection", "incomplete outcome data" and 'other bias" were assessed to have an unclear risk of bias due to the source of data being unclear, and lack of assessment of missing data. The domain "intervention independent" was assessed to have a high risk, as there appeared to be multiple aspects of price control interventions implemented alongside the SEP. The second reference was similar to the first, except that the analysis method was not reported. However the two references are by the same authors, using the same dataset and methodology. As the analysis is appropriately reported in one of the studies (low risk of bias) but with less detail in the other (unclear risk), it is reasonable to assume both studies are of equal quality. Overall the risk of bias is considered low for the two studies collectively.

Table 10.7 Summary of findings for publicly available prices

Publicly available prices vs no intervention

Medicines: Global and Regional Core, and supplementary lists of medicines from WHO/HAI survey methodology

Settings: South Africa private sector

Intervention: Price transparency at national level (Single Exit Price)

Comparison: No policy

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Price of medicines	Medicine prices in all samples (global core, regional core, supplementary list) were reduced immediately following the SEP policy for both generic and originator medicines. Mean reduction was greater for generics. Global core percentage price reduction ranged from 2.45%-39.12% for originator medicines and 18.50%-91.5% for generics. Regional core reduction was 1.77%-42.17% for originators and -0.70%-78.03% for generics. Supplementary list price reduction was 11.68%-55.86% for originators and 9.78%-78.49% for generics. Continued benefit on medicine prices through a negative change in trend was observed in 26 out of 50 originator medicines and 23 out of 73 generic medicines.	1	Moderate ⊕⊕⊕◯	The Single Exit Price policy is probably effective in reducing prices of originator and generic medicines immediately after implementation. Benefits are probably sustained in originator medicines, whereas long term effects of the Single Exit Price policy on generic medicines are probably variable.
Volume				
Availability				
Affordability				

The study by Moodley *et al.* examined the impact of the 2004 Single Exit Price (SEP) policy on medicine prices. The SEP consists of a mandatory disclosure for each medicine of the weighted average of all sales prices after taking into account all discounts and off-invoice rebates. The policy applies to private sector sales to distributors and dispensers, as the public sector generally uses tendering procedures for pharmaceuticals. The disclosed prices are subsequently made available on the South African Medicine Price Registry website (*277*).

In the study by Moodley *et al.*, 50 originator medicines included in the study were selected based on the WHO/HAI methodology, consisting of 14 medicines in the Global Core list, 15 medicines in the Regional Core list, and 21 medicines in the supplementary list based on local needs. For the generic medicines,

multiple products were included for each originator product, resulting in 84 generics examined. Annual price changes were tracked for five years before the implementation of the policy and for ten years following the intervention.

For the originator medicines, 10 out of 14 Global Core, 11 out of 15 Regional Core and 14 of 21 supplementary list medicines exhibited significant ($p<0.05$) price reductions immediately following the SEP policy (*275*). For the generic medicines, 26 out of 29 Global Core, 23 out of 26 Regional Core and 17 out of 18 supplementary list medicines exhibited statistically significant ($p<0.05$) price reductions following the SEP policy (*274*). Results on changes in level are shown in Table 10.8.

Table 10.8 Reported changes in level for originator and generic medicines

	Range	Mean	SD	IQR
Originator medicines				
Global core	2.45%-39.12%	19.87%	10.62%	10.2%
Regional core	1.77%-42.17%	23.38%	12.43%	15.65%
Supplementary list	11.68%-55.86%	22.97%	16.26%	17.34%
Generic medicines				
Global core	18.50%-91.5%	62.46%	18.64%	24.81%
Regional core	-0.70%-78.03%	44.62%	23.04%	37.41%
Supplementary list	9.78%-78.49%	48.37%	19.44%	27.53%

Results on observed changes in trends are presented in Table 10.9. As Trend 1 and Trend 3 are the two trends that describe a decrease in trend, these are considered indicative of a continued benefit on medicine prices over time. For originator medicines, 7 out of 14 Global Core, 5 out of 15 Regional Core and 14 of 21 supplementary list medicines exhibited significant decreasing trends following the intervention (Trend 1 and Trend 3). For the generic medicines, 5 out of 29 Global Core, 14 out of 26 Regional Core and 4 out of 18 supplementary list medicines showed negative and significant ($p<0.05$) changes in trend following the SEP policy, indicating a continued benefit on medicine prices over time.

Table 10.9 Reported changes in trend for originator and generic medicines*

	Originator medicines (n)				Generic medicines (n)		
	Trend 1	**Trend 2**	**Trend 3**	**Total**	**Positive**	**Negative**	**Total**
Global core	8	3	3	14	15	14	29
	5	*3*	*2*	*10*	*12*	*5*	*17*
Regional core	7	2	6	15	9	17	26
	3	*2*	*2*	*7*	*2*	*14*	*16*
Supplementary list	17	2	2	21	11	7	18
	13	*2*	*1*	*16*	*6*	*4*	*10*
Total	32	7	11	50	35	38	73
	21	*7*	*5*	*33*	*20*	*23*	*43*

Non-italic numbers present the total number of medicines associated with a certain trend, *italic* numbers represent the number of medicines showing a significant (at the 5% level) trend.

*Trend 1: prior to the intervention, medicines showed an increasing trend. Upon introduction of the SEP the medicines showed an immediate drop in prices and a subsequent lower rate of increase than before. Trend 2: medicine prices were decreasing prior to the intervention. After introduction of the SEP, medicines showed an increasing trend. Trend 3: medicines that were withdrawn between 4 and 9 years after introduction of the SEP. These medicines showed a decrease in trend between the intervention and their withdrawal. Positive: a positive change in trend, indicating an increase in prices long-term. Negative: a negative change in trend, indicating an decrease in prices long-term.

10.3 Authors' conclusions

10.3.1 Summary of main results

One study examined the impact of price transparency measures for prescribers, here in the context of a cost-feedback approach for prescribers, on hospital expenditure. The findings of Langley *et al.* were considered inconclusive, as results were contradictory for which no reasonable explanation could be given. The study does however show that a cost-feedback approach results in a change in prescription behavior.

One study reported on price changes following implementation of a national price transparency measure in South Africa, the Single Exit Price (*274,275*). These studies found that prices of a variety of products were considerably reduced in both originator and generics medicines.

10.3.2 Overall completeness and applicability of evidence

Some of the evidence identified on price transparency measures is limited in applicability. The study examining effects of a cost-feedback system was set in a high-income country with no co-payment requirements by patients. Hence, while these results may be applicable to similarly funded healthcare systems, generalizability to other healthcare systems in which patients' ability to pay is of importance may be challenging. Furthermore, the study focused on two groups of therapeutics only. As prescription of antibiotics in such a high-income setting is expected to be highly regulated and guided by antibiotic susceptibility, results may not be applicable to other therapeutics.

The study set in South Africa showed the impact of a national policy on transparency in a single upper-middle income country. This is to our knowledge the only evidence examining the impact of transparency on medicine prices.

10.3.3 Quality of the evidence

The study by Langley *et al.* was well-designed with an overall low risk of bias and data was transparently reported. The study by Moodley *et al.* was well designed and transparently reported, although details of the data sources and prices used were unclear.

10.3.4 Agreement/disagreement with other reviews

While this systematic literature review focused on studies with strong study designs excluding other literature reviews, it is worth reflecting on arguments made in literature to compare with the present results. Hence, the following statements need to be considered with an understanding that these reviews considered different methodologies.

A comprehensive technical report on the impact of pricing approaches on cancer medicines by the WHO examines evidence relating to the impact of transparency measures (*5*). The authors indicate that there is a lack of evidence on the effectiveness of transparency measures in improving price outcomes, which is in line with the present review. Nevertheless, improved transparency is encouraged, on account of good governance (*5*). An expert review identified studies that addressed the actual paid prices of medicines used in in-patient or out-patient care from the health care payer, health provider, or patient perspective. They included 33 observational studies. The designs of these studies were heterogeneous, making it difficult for the authors to compare results. The study confirmed that there is little evidence on what the difference is

between published list prices and actually paid prices. In high-income, mostly European countries, price negotiations is an important strategy to regulate prices. Transparency of actual prices is limited due to increased use of confidential medicine price arrangements (*278*).

We are not aware of further reviews on the topic.

10.3.5 Authors conclusions: implications for practice; implications for research

The currently available evidence on price transparency measures for prescribers is inconclusive. Hence, the impact of transparency measures remains theoretical thus far.

Evidence for national transparency policies is limited to the South African experience. The evidence shows substantial effect on official medicine prices, although further research would be needed to elucidate any adverse impacts on the pharmaceutical market, and whether price reductions proliferate through the supply chain to end users (patients) as intended.

The lack of robust quantitative and comparative evidence assessing the impact of policies improving price transparency calls for further research, which is needed to assess the impact of a wide range of transparency measures, with a particular focus on potential harmful effects, both in high- as well as in low-income countries.

11 Mark-up regulation across the pharmaceutical supply and distribution chain

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11.1 Background

The prices of medicines are affected by many factors throughout the pharmaceutical supply and distribution chain, such as the manufacturer's selling prices, wholesale and retail mark-ups along the supply chain and extending to pharmacies' remuneration. Policies attempting to reduce the prices of medicines and facilitating access to medicines may involve regulation of each of these aspects. Subject of the present chapter are price and mark-up thresholds.

Price thresholds also referred to as price caps or ceiling prices, are defined here as the setting of fixed maximum pharmaceutical prices (*279*). The method used in setting the maximum price varies from one country to another, but mechanisms often applied include linking the on-patent price to either originator or generic price through a fixed percentage, controlling reimbursement rates of medicines and price cuts on retail or ex-factory prices. Price thresholds may apply broadly to all pharmaceuticals or to specific groups of medicines (*279*).

A mark-up represents the additional charges and costs which are applied by wholesalers, retailers and pharmacies to medicines to cover overhead costs, distribution charges, and a profit (*280*). These mark-ups can represent 40% of the final price (*281*), with retail mark-ups reported to be as high as 90% of the price ultimately paid by the patient in one instant (*282*). Regulating maximum mark-ups throughout the pharmaceutical distribution chain, which may be applied as percentages or a fixed amount, is therefore another approach which may be addressed in attempt to reduce the prices of medicines paid for by the patient. Measures controlling mark-up thresholds may encompass different methods of regulation, including fixed percentage mark-ups and regressive mark-ups (*280*).

This chapter details the evidence on mark-up regulations across the pharmaceutical supply and distribution chain as identified in the present systematic review.

11.2 Results

11.2.1 Excluded studies

A total of 42 studies made it to the full text level of which 31 studies were excluded at this stage. Of these, two were review papers related to the topic at hand and one a review paper was off-topic (*211*,*283*,*284*),

One other was the preceding working paper by WHO/HAI on mark-ups (*280*). Three studies were excluded on intervention (*285–287*) and another three because of a lack of reporting primary outcomes (*288–290*). The remaining 21 studies were not deemed eligible based on study design, the majority of these (resembling) uncontrolled before-after studies (*100*,*133*,*219*,*222*,*257*,*291–295*). Others were excluded as descriptive policy analyses not including an intervention (*296*,*297*), (cross-sectional) price surveys (*298–301*), studies not including data before the intervention (*302–304*), a forecast scenario (*273*) or due to unclear description of the methods used (*210*).

11.2.2 Characteristics of included studies

Eleven studies met the inclusion criteria, published between 2008 and 2018. Table 11.1 gives an overview of the characteristics of the included studies. Several studies (n=3) had an interrupted time series (ITS) design (*175*,*305*,*306*). Three studies were difference-in-difference (DID) analyses (*307–309*) and in another four studies a panel data/regression analysis was performed (*91*,*179*,*310*,*311*). The remaining study was a controlled before-after (CBA) study (*312*).

Ten studies were set in single countries: China (*305*,*306*,*308*,*309*,*311*,*312*), India (*307*), Spain (*179*), Portugal (*175*) and Taiwan (*310*). One study examined data from multiple countries, being set in the European Union and including data from Denmark, France, Germany, the Netherlands, Sweden and the United Kingdom (*91*).

The subjects of study were all medicines dispensed in six studies (*179*,*306*,*308*,*309*,*311*,*312*), antidiabetics (or a selection of these) in two studies (*305*,*307*), antipsychotics in one study (*175*), ACE-inhibitors in one study (*91*) and all medicines dispensed to patients diagnosed with hypertension in one study (*310*). The greater part of the studies, being nine in its entirety, assessed the impact on price, or, in its absence, expenditure as a proxy (*91*,*179*, *306–312*). Two of these studies also reported volume related outcomes (*179*,*310*). Two studies assessed the impact on volume only (*175*,*305*). None of the studies presented data on availability or affordability.

Price thresholds in the sense of a cap on the reimbursement rate (*310*), retail prices (*175*,*305*) or ex-factory prices (*179*,*307*) selectively applying to a specific group of products were assessed in five studies.[51] Mark-up thresholds were examined in seven studies. (*91*,*179*,*306*,*308*,*309*,*311*,*312*). The impact of a policy prohibiting the charging of mark-ups in the hospital sector was examined in five studies (*306*,*308*,*309*,*311*,*312*). These five studies pertain to a single intervention, the Zero Mark-up Drug Policy (ZMDP) in China. An overview of all the interventions examined is presented in Table 11.3.

The risk of bias assessment for all of the included studies is presented in Table 11.2. The risk of bias was assessed individually for each outcome in the studies. However, the risk of bias was generally graded the same for the different outcomes within a study. In one study, the risk of bias for the separate outcomes yielded different GRADE scores and were therefore presented separately in the table.

The included studies on price caps were associated with a high risk of bias. The DID study presented with high risk of bias as assumptions in the model applied were only partially tested and the intervention was

[51] PPRI: Price cap: a cost-containment measure that fixes ex-ante the maximum price of a pharmaceutical, e.g. taking into consideration inflation rates and production costs. Companies are allowed to choose any price below this threshold and, in exchange, authorities refrain from further control of company data (profit margins, sales etc.).

likely to have affected the measurements at baseline. Chu et al. analysed the outcomes of price and volume using different models. The results of the price model presented high risk of seasonal variation and there was a lack of clustering in the model, reducing the reliability of the results. The volume model raised the same concerns and also presented with insufficient explanatory power and a high risk of bias due to suspected selective outcome reporting. Another study employing a regression model (*179*) presented with high risk by cause of a multitude of (co-)interventions to have been implemented shortly after another, allowing insufficient time for the effects of each intervention to be measured separately. Again, as none of the studies reported on incomplete outcome data, the risk of bias was unclear for this domain.

Table 11.1 Study characteristics

	Study types	Number of studies	Notes/references
Study type	Controlled before/after	1	(*312*)
	Difference-in-difference	3	(*307–309*)
	Interrupted time series	3	(*175*,*305*,*306*)
	Panel data/regression	4	(*91*,*179*,*310*,*311*)
Setting	Europe	3	Portugal (*175*), Spain (*179*), EU (Denmark, France, Germany, Netherlands, Sweden, United Kingdom) (*91*)
	Asia	8	China (*305*,*306*,*308*,*309*,*312*)(*311*) India (*307*), Taiwan (*310*)
Subjects	All medicines	7	All recorded data (*179*,*306*,*308*,*309*,*312*)(*311*), all medicines used by hypertensive patients (*310*)
	Antidiabetics	2	Metformin (*307*), insulins and oral hypoglycaemics (*305*)
	Antipsychotics	1	(*175*)
	Cardiovascular	1	ACE inhibitors (*91*)
Intervention	Price cap	5[52]	Selective price control through a cap on reimbursement rates, retail prices or ex-factory prices (*175*,*179*,*305*,*307*,*310*)
	Mark-up threshold	7[52]	No mark-up on medicines sold through hospitals, wholesale/retail mark-up reduction or regressive pharmacy mark-ups (*91*,*179*,*306*,*308*,*309*,*312*)(*311*)
Outcomes	Price	9	Price outcomes: price per prescription (*179*,*310*)(*311*), originator price (*91*), normalized price (*307*) Expenditure outcomes: cost per capita (*179*), monthly hospitalisation expenditure per patient (*306*), cost per outpatient visit (*308*,*309*,*312*), cost per inpatient visit (*308*,*309*)
	Volume	4	Units sold per 1000 population (*305*), units sold per 100 000 population (*175*), number of prescriptions (*179*), frequency prescribed (*310*)

For mark-up thresholds, the studies presented with varying limitations. A controlled before-after study demonstrated high risk in several domains, as is inherent to the study design. Additionally, there seemed to be some selectiveness in reporting of results and data sources were segmented, possibly leading to differences in data collection. Two DID studies presented only minor limitations. The quality of evidence of the ITS study was moderate, with an overall low risk of bias. The regression study raised concerns about the independent occurrence of the interventions. The risk of multicollinearity in the model was assessed as high in the panel data study. Furthermore, there were doubts regarding the validity of the model used as assumptions in the model were left untested and sensitivity analyses were not performed. Incomplete

[52] Moreno-Torres et al. investigate the impact of multiple interventions, including a price cap and mark-up thresholds, on price and volume. Results for both interventions are assessed separately hereafter.

outcome data was assessed in only one study. Overall, the studies for mark-up thresholds carried a high risk of bias.

Table 11.2 Description of interventions by category of intervention and study

		Random sequence generation	Allocation concealment	Baseline outcome measurements similar	Baseline characteristics similar	Protection against contamination	Intervention independent	Appropriate analysis	Pre-specified shape of effect	Intervention to affect data collection	Incomplete outcome data	Knowledge of allocated intervention	Selective outcome reporting	Other bias
		RCT, NRCT and CBA studies					**ITS and RM studies**				**All study types**			
Price caps	Bhaskarabhatla 2017										?	⊕	⊕	⊖
	Chu 2011 - price										?	⊕	⊕	⊖
	Chu 2011 - volume										?	⊕	⊖	⊖
	Leopold 2014						⊖	⊖	⊕	⊕	?	⊕	⊕	⊕
	Lu 2013						?	⊕	⊕	⊕	?	⊕	⊕	⊖
	Moreno-Torres 2011										?	⊕	⊕	⊖
Mark-up thresholds	Cheng 2012	⊖	⊖	?	⊖	⊕					?	⊕	⊖	⊖
	Fu 2018										⊕	⊕	⊕	?
	Li 2008										?	⊕	⊖	⊖
	Moreno-Torres 2011										?	⊕	⊕	⊖
	Von der Schulenberg 2011										?	⊕	⊕	⊖
	Yang 2017						⊕	⊕	⊕	⊕	?	⊕	⊕	⊕
	Zhou 2015										?	⊕	⊕	?

Table 11.3 Description of interventions by category of intervention and study

	Intervention	Study begin	Study end	Known co-interventions
Price cap				
Bhaskarabhatla 2017 *(307)*	The drug price control order (DPCO): "selectively applies price controls to some formulations of the chosen medicines" and "uses a market-based approach to determine the ceiling price".	2007	2015	NA
Chu 2011 *(310)*	The profit margin of a subset of drugs in the formulary is narrowed, based on the r-zone mechanism: "no adjustment is necessary if the market price is higher than or equal to (1 - r) x the current drug reimbursement rate. (…) Otherwise, the adjusted price is equal to the market price + r x the current reimbursement rate." "In 2000, the target r-zone specified by the NHI was 30%, and the final target r-zone was set at 15%."	1999	2000	NA
Leopold 2014 *(175)*	A long-term 6% deduction of the maximum retail price on medicines that had not already lowered prices earlier. "This deduction did not affect the final consumer price and is a statutory discount granted by industry and supply chain actors to the public payer."	2007	2011	Implemented simultaneously with 1) "a television and radio campaign to promote generics ("you save, we all save"), informing the public about the preferred use of generics due to lower prices of generics as compared to originals" and 2) the harmonization of reimbursements rates for antipsychotics to 90% of charges.
Lu 2013 (*305*)	New maximum retail prices for specific insulin products and several oral hypoglycaemic products.	1999	2009	NA
Moreno-Torres 2011[53] (*179*)	Compulsory reduction of ex-factory prices: "a unilateral reduction of the manufacturer's maximum selling price"	1995	2006	Mark-up adjustments (March 1997; June 1999; August 2000; March 2005; March 2006); Changes in the reference pricing system (December 2000; May 2002; May 2003; January 2004; August 2004); Prescription Quality Improvement Program (April 2004), encouraging the use of drugs with proven efficacy and generics.

[53] Moreno-Torres et al. investigate multiple policy changes in Spain.

Mark-up threshold				
Cheng 2012 (*312*)	The zero mark-up drug policy (ZMDP)[54], which removed the previously allowed 15% profit margin for drug sales at public hospitals.	2006	2009	The National Essential Medicines Policy (NEMP), which aims to increase the availability of cost-effective medicines.
Fu 2018 *(308)*	"The zero mark-up drug policy (ZMDP)[vi], which removed the previously allowed 15% profit margin for drug sales at public hospitals."	2009	2014	The National Essential Medicines Policy (NEMP), which aims to increase the availability of cost-effective medicines; A new standard for inpatient reimbursement (May 2011).
Li 2008 *(311)*	"The zero mark-up drug policy (ZMDP)[vi], which removed the previously allowed 15% profit margin for drug sales at public hospitals."	2007	2007	The National Essential Medicines Policy (NEMP), which aims to increase the availability of cost-effective medicines.
Moreno-Torres 2011[v] *(179)*	Reduction of wholesale and retail mark-ups	1995	2006	Compulsory reduction of ex-factory prices (November 1999; July 2001; March 2005; March 2006); Changes in the reference pricing system (December 2000; May 2002; May 2003; January 2004; August 2004); Prescription Quality Improvement Program (April 2004), encouraging the use of drugs with proven efficacy and generics.
Von der Schulenberg 2011 (*91)*	Regressive pharmacy mark-ups: "Carefully designed regressive pharmacy margins make dispensing cheaper products more profitable for pharmacists, hence encouraging them to dispense generics rather than originators."	1991	2006	Multiple interventions are studied and integrated in the analytical model (reference pricing, mandatory substitution, generics price control, mark-up regression, profit control, clawback, tax funded health care system, cost-efficiency analysis)
Yang 2017 *(306)*	The zero mark-up drug policy (ZMDP)[vi], which removed the previously allowed 15% profit margin for drug sales at public hospitals.	2009	2013	The National Essential Medicines Policy (NEMP), which aims to increase the availability of cost-effective medicines; A new standard for inpatient reimbursement (May 2011).
Zhou 2015 *(309)*	The zero mark-up drug policy (ZMDP)[vi], which removed the previously allowed 15% profit margin for drug sales at public hospitals.	2010	2011	The National Essential Medicines Policy (NEMP), which aims to increase the availability of cost-effective medicines; A new standard for inpatient reimbursement (May 2011).

[54] The zero mark-up drug policy is described in multiple papers, each investigating the mark-up system implemented in phases in China

11.2.3 Effect of interventions

11.2.3.1 Impact of price caps

Five studies assessed the impact of price caps on price and volume. The price caps where implemented on different levels; ex-factory prices, reimbursement prices and retail prices. The GRADE quality assessment and summary of findings for this subtopic are given in Table 11.6 and Table 11.7. The overall certainty of evidence was rated as low, due to a substantial risk of bias arising from the section 'other biases'. Brief details of the individual studies are included below, followed by main results on the impact of price caps.

Table 11.6 Certainty assessment (GRADE) of evidence for price caps for each outcome

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
3	DID (I),regression analysis (II)	High (-1)[55]	No important inconsistency	No serious indirectness	No serious imprecision	Design (+1)	**Low** ⊕⊕◯◯
Outcome: Volume							
4	ITS (II), regression analysis (II)	High (-1)[56]	No important inconsistency	Serious indirectness (-1)[57]	No serious imprecision	Design (+1)	**Very low** ⊕◯◯◯
Outcome: Availability							
Outcome: Affordability							

[55] All three studies present with a high risk of bias due to manipulation of baseline prices in the period before regulation (Bhaskarabhatla et al.), a lack of correction for seasonal influences and possible confounder (Chu et al.) and the examination of a large number of interventions within a short time-window (Moreno-Torres et al.).

[56] The overall risk of bias was assessed to be high due to a lack of correction for seasonal influences and possible confounder (Chu et al.), other changes which may be of great influence and the market volume not considered in the analysis (Lu et al.) and the examination of a large number of interventions within a short time-window (Moreno-Torres et al.).

[57] One of the studies uses pharmaceutical purchasing data of hospitals. Another study reports on the number of prescriptions per capita, which is a proxy for volume. In a third study, a price cap is implemented simultaneously with a campaign to promote use of generic medicines and harmonization of reimbursement rates, which greatly reduces generalizability.

Table 11.7 Summary of findings for price caps for each outcome

Price caps vs no intervention

Medicines: Metformin; antidiabetics; antipsychotics; all medicines

Settings: China, India, Portugal, Spain, Taiwan

Intervention: Price caps

Comparison: No policy

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Cost per 500 milligram per unit	The coefficient estimate* was negative (p<0.01), indicating that the growth rate of the price of the regulated formulation declined post-intervention relative to the baseline period.	1	Low ⊕⊕◯◯	A price cap on ex-factory prices may lead to a decrease in prices.
Cost per prescription	Coefficients for the reduction of ex-factory prices were negative (p<0.05) for 2 out of 4 repeated measures. An adjustment in reimbursement rate was associated with a positive (p<0.05) coefficient*, implying a negative effect of the intervention.	2		A price cap may increase prices in the short-term. Whether repeated price control measures lead to a difference in prices remains uncertain.
Volume				
Frequency that reduced-price drugs were prescribed	The coefficient estimate* of the policy was negative (p<0.01).	1	Very low ⊕◯◯◯	It remains uncertain if an adjustment in reimbursement rate leads to a reduction in prescribing of targeted medicines because the certainty of evidence is very low.
No. of standard units sold per 1000 population per quarter	Selective price control of retail prices were associated with a non-significant# change in immediate utilisation of insulins and oral hypoglycaemics. Utilisation of insulins increased, with a 0.06 (95% CI 0.04-0.08) to 0.18 (95% CI 0.12-0.23) increase in trend. A first price cap was not associated with a significant# change in utilisation trend of oral hypoglycaemics. A second regulation lead to a 10.31 (95% CI 5.65-14.98) units per quarter increase.	1		It is uncertain whether selective price caps lead to a difference in utilisation, because the certainty of evidence is very low..
No. of standard units sold per 100 000 population per month	A price cap on retail prices, concurrently with a campaign to promote use of generics and harmonized reimbursement rates, was associated with a 4686 (95% CI -8913, -458) reduction in sales. No change in trend was observed.	1		It remains uncertain whether a price-cap on retail prices may lead to a reduction in utilisation of antipsychotics, due to the very low certainty of evidence,

No. of prescriptions per capita	The coefficient for the reduction of ex-factory prices was positive ($p<0.1$). Coefficients were slightly positive ($p>0.1$) for three following measures.	1		It is uncertain if a price-cap on ex-factory prices increases utilization, because the certainty of evidence is very low.
Availability				
Affordability				
*The impact of a price cap on price is calculated by regression, with (natural logarithm of) price as the dependent variable, and a policy dummy variable with suitable controls as independent variables. The impact of a price cap on volume is calculated by a probit regression, with a dummy variable that indicates whether or not reduced-price drugs were prescribed as the dependent variable, and a policy dummy variable with suitable controls as independent variables. # No p-values or confidence intervals are reported for the, as stated by the authors, non-significant outcomes in the study.				

Moreno-Torres et al. and Bhaskarabhatla et al. both examined the impact of compulsory reduction of ex-factory prices on pharmaceutical expenditure and prices, respectively. It is not clear if the interventions were once off price reductions or a regulation that had effect in a longer time-frame. The study by Moreno-Torres et al. did a comprehensive study in public sector pharmacies in Catalonia, analysing a dataset of monthly totals charged by pharmacies for outpatient prescriptions from 1995 to 2006 provided by Catalan Health Services. The study not only examined the impact of four progressive price reductions enforced during this period, but simultaneously explored the effect of another 12 co-interventions, consisting of modifications to the reference pricing system, incentives to improve prescribing practices and mark-up adjustments (the results of which are discussed in more detail below). Notably, two of four price reductions coincided with mark-up adjustments (March 2005, March 2006) (*179*).

Bhaskarabhatla et al. studied the effect of the Drug Price Control Order (DPCO) on prices in India, using purchasing data of medicines by patients, obtained from India's retail trade association, the AIOCD (*307*). The 2013 DPCO selectively applied control to some formulations of a chosen medicine, excluding other formulation of the same molecule. According to the authors, it "failed to distinguish the generally costlier time-release formulations of the regulated medicines from the non-time-release ones." The authors "chose to study because the incentive for firms to coordinate on prices and manipulate the prospective ceiling price is large in the market for a medicine such as Metformin". Coordination was suspected to have occurred because the order and the medicines to be subjected to it were announced long before its enactment. The 1000 mg formulation, which was left untargeted by the intervention, was employed as control.

Chu et al. examined the effect of an 'r-zone' mechanism on the price and utilization of medicines by hypertensive patients in the Taipei region of Taiwan (*310*). The r-zone mechanism was applied to adjust reimbursement rates of drugs by using a specific formula. Details on this formula can be found in Table 11.3. The purpose of this formula was to decrease profit margins. The study described a cautious initial implementation due to "strong opposition from hospitals/ physicians and uncertainty about patients' health outcomes", only targeting products with low levels of utilization. The study exploited hospital-level data comprising of insurance claims for outpatient visits from four months before and after the intervention.

Lu et al. examined the price caps set on retail prices of insulins and oral hypoglycemics in 2001 and 2006 in the Chinese hospital-sector, which is responsible for approximately 80% of drug sales (*305*). In the 2001 price cap, only 7 (all human non-mixed insulins) of 62 insulin products were capped, and 12 out of 233 oral

hypoglycemics. The price cap policy was expanded to include 6 (all animal non-mixed products) of 65 insulins and 87 of 228 oral hypoglycemics. Using IMS Health data from 1999 to 2009, the number of units sold was studied.

In the study by Leopold et al. the effect of a 6% deduction of the maximum retail price on medicines that had not lowered prices earlier in Portugal in the period from January 2007-December 2011 (*175*). This price reduction did not affect consumer prices, but the discount was transferred to the public payer. This intervention coincided with two other interventions that were not price caps, but these interventions might have distorted the effect seen after the price cap. This is also the main drawback of this particular study. The study focused its analysis on volume of antipsychotic medicines sold per capita by using IMS health data.

Bhaskarabhatla et al. applied a regression model on the average normalized price of metformin within a DID methodology to estimate the effect of the control order. The model included dummies for both intervention and control group and several time periods preceding the regulation to explore if the effect would be different across time periods. Results were presented as coefficient estimates. The interaction between the intervention group dummy and the period dummy captured the DID effect.

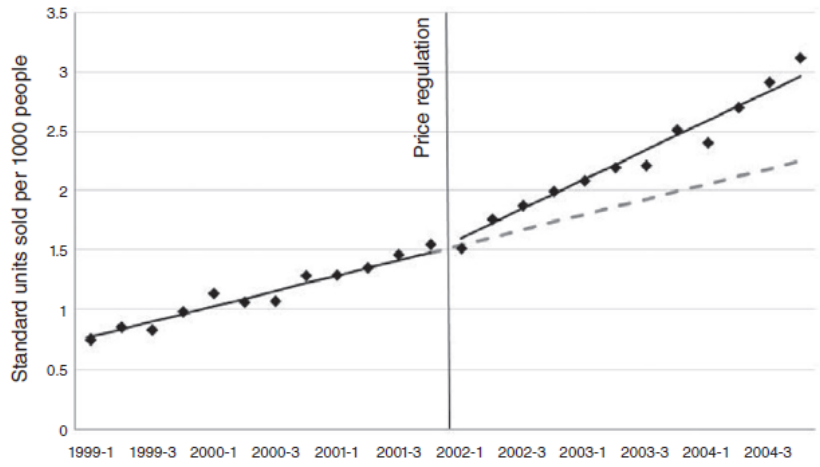
The coefficient estimate in the post-intervention period was negative ($p<0.01$), indicating that the price of the targeted formulation decreased compared to the baseline period. However, coefficients were estimated to be positive ($p<0.01$) between the baseline period and the intervention, suggesting that the price of metformin 500 mg increased during this time relative to the 1000 mg formulation and the baseline period and hence implying coordination on prices by firms. It appears that due to the market-based approach of setting the ceiling price, manufacturers increased their prices close to the intervention of a price cap. This led to a higher ceiling price post-intervention. Furthermore, the authors hypothesized that limiting the scope of the regulation to only some formulations and the failure to differentiate between specific groups of products, had hindered the effectiveness of the policy. Due to the deliberate choice for metformin, these results should thus be interpreted with caution as these results might not apply to other groups of medicines.

Moreno-Torres et al. and Chu et al. both report results as coefficient estimates of a regression model on the price of a prescription. The coefficients for four consecutive measures reducing ex-factory prices were negative ($p<0.05$; $p>0.1$; $p<0.001$; $p>0.1$). Regardless of a 1.73% decline in costs per prescription reported for the first price reduction, Moreno-Torres speculate that the lack of effect observed for the repeated measures may be the consequence of increased use (higher DDDs prescribed per capita) and a switch from targeted products to unaffected ones. Besides prices, Moreno-Torres et al. also report on the number of prescriptions after the reductions in ex-factory prices. Coefficients were found to be positive ($p<0.1$; $p>0.1$; $p>0.1$; >0.1), which confirms that use was increased.

The adjustment in reimbursement rate was associated with a positive ($p<0.05$) coefficient, despite a 53.48% reduction in the cost of targeted drugs per prescription. Concurrently, the frequency that targeted products were prescribed, estimated using a probit model, was negative ($p<0.01$). Chu et al. thus hypothesize that prescribers responded to the policy by switching to drugs outside of the scope of the regulation. This is unlikely to be the result of manufacturers influencing physicians' prescribing behavior, because drug procurement was relocated to hospitals instead of individual prescribers. In order to achieve higher profits, hospitals are thought to negotiate lower prices from pharmaceutical companies and influence prescription patterns.

Lu et al. applied an ITS design on the number of antidiabetic standard units quarterly sold per 1000 population and reported a change in level and in trend at the time of the consecutive regulations. The first price control was not associated with a significant[58] change in utilization of both insulins and oral hypoglycemics in the first quarter after implementation. An increase in trend of 0.06 (95% CI 0.04-0.08) standard units sold per 1000 people was reported for insulins, although no significant change in trend was seen in human non-mixed insulins nor in oral hypoglycemics (see Figure 11.6). The price control in 2006 was not associated with a statistically significant change in level for both groups of antidiabetics, but trends were reported to have increased with 0.18 (95% CI 0.12-0.23) for insulins (animal non-mixed insulins: 0.01 (95% CI 0.01-0.02)) and with 10.31 (95% CI 5.65-14.98) for oral hypoglycemics. The price regulations were hypothesized to have triggered relative increases in market volume sold of products not subjected to price reductions over products that were, as hospitals relied on profits from pharmaceutical sales. Nevertheless, the slightly increased sales volumes may indicate improved access to medicine due to the regulations, according to the authors.

Figure 11.6 Sales volume of all insulin products (1999-2004), segmented by the price cap in 2001.



Leopold et al. used an ITS design to estimate the effect on change in level and in trend in sale volume of antipsychotics. It was concluded that there was a direct decrease of 4686 (95% CI -8913, -458) in sales. No change in trend was observed. The price policy reforms that took place in Portugal need to be placed in the context of an economic recession. The price reduction did not benefit the patients, and there were even increases in co-payment. As psychiatric patients are very vulnerable for non-adherence, the authors suggest that decreases in antipsychotic medicines use in this group of patients may have been an undesirable effect. However, it could also be that off-label use was limited, which is a more desirable policy effect. The authors were not able to give any data to support or confute this hypothesis.

[58] No p-values or confidence intervals are reported for outcomes that are considered to be not significant. A description of when results are considered to be significant is not provided by the authors.

11.2.3.2 Impact of mark-up thresholds

Seven studies assessed the impact of mark-up thresholds on price. The GRADE quality assessment and summary of findings for this subtopic are given in Table 11.8 and Table 11.9. The overall certainty of evidence was rated as low, due to an overall high risk of bias. Brief details of the individual studies are included below, followed by main results on the impact of mark-up thresholds.

Table 11.8 Certainty assessment (GRADE) of evidence for mark-up thresholds for each outcome

No of studies	Design	Risk of bias	Inconsistency	Indirectness[1]	Imprecision	Other[2]	Certainty (overall score)[3]
Outcome: Price							
7	CBA (I), DID (II), ITS (I), panel data (I), regression analysis (II)	High (-1)[59]	No important inconsistency	Moderate indirectness (-0.5)[60]	No serious imprecision	Design (+1)[ix]	**Low** ⊕⊕◯◯
Outcome: Volume							
1	Regression analysis (I)	High (-1)[61]	No important inconsistency	Serious indirectness (-1)[62]	No serious imprecision	Design (+1)[ix]	**Very low** ⊕◯◯◯
Outcome: Availability							
Outcome: Affordability							

[59] The overall risk of bias was assessed to be high due to fragmented data sources (Cheng et al.), an inappropriate analysis that did not take into account the changes in the number of medicine on a prescription nor time (Li et al.), the examination of a large number of interventions within a short time-window (Moreno-Torres et al.) and the lack of sensitivity analyses (Von der Schulenburg et al.)

[60] More than 50% of the included studies report expenditure, which is a proxy for price

[61] The overall risk of bias was assessed to be high due to the examination of a large number of interventions within a short time-window (Moreno-Torres et al.)

[62] The study reports on the number of prescriptions per capita, which is a proxy for volume.

Table 11.9 Summary of findings for mark-up threshold

Mark-up threshold vs no intervention

Medicines: ACE inhibitors; all medicines

Settings: China, Spain, EU (Denmark, France, Germany, Netherlands, Sweden, United Kingdom)

Intervention: Mark-up threshold

Comparison: No policy

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Originator price	Regressive pharmacy mark-ups are associated with a negative (p<0.01) coefficient.	1	Low ⊕⊕○○	Regressive pharmacy mark-ups may lead to price reductions.
Price/cost per prescription	Wholesale and/or retail mark-up reductions are associated with negative (p<0.05) coefficients[#]. A zero-mark-up policy* was associated with a negative (p=0.001) coefficient estimate.	2		Wholesale and/or retail mark-up reductions may decrease prices.
Drug expenditure per outpatient visit	One study found a -6.3% (p<0.01) difference in drug expense per outpatient visit after implementation of a zero-mark-up policy*. Another study found an initial slight decrease of 0.7%[$], after which the expenditure increased again.	2		A zero-mark-up policy may increase expenditure in the medium-run.
Drug expenditure per inpatient visit	A zero mark-up policy* was associated with a -9.0% (p<0.01) to -3.9% (p<0.01) change in drug expenditure.	2		A zero mark-up policy may lead to a reduction in drug expenditure.
Monthly hospitalisation expenditure	A zero mark-up policy* was associated with a change in immediate monthly average hospitalisation expenditure of -40.26 RMB (-6.30 USD, p>0.1). A negative change in trend was observed, with -16.49 RMB (-2.58 USD, p<0.01) per month.	1		A zero mark-up policy may lead to no difference in immediate expenditure. It may reduce expenditure on the long term.
Volume				
No. of prescriptions per capita	The coefficient for the reduction of mark-ups was positive (p<0.1). Coefficients were slightly positive (p>0.1) for four following measures.	1	Very low ⊕○○○	It is uncertain if mark-up adjustments result in a change in utilization, because the certainty of the evidence is very low.
Availability				
Affordability				

*The zero mark-up policy is studied in four distinct papers, each regarding the 2012 Chinese zero mark-up policy. Results should be interpreted together.

The study reports results for five repeated interventions, with p-values respectively being p<0.001, p<0.05, p<0.001, p<0.001 and p>0.1.

$ No measure of confidence or p-value given by the authors for this outcome.

As described above, Moreno-Torres et al. examined the impact of five mark-up adjustments (March 1997; June 1999; August 2000; March 2005 and March 2006) as well as other co-interventions implemented in Catalonia on the price per prescription ad number of prescriptions per capita (*179*). Coefficients were estimated to be negative (p<0.001; p<0.05; p<0.001; p<0.001 and p>0.1 respectively) for prices and positive (p<0.1; p>0.1; p>0.1; p>0.1 and p>0.1 respectively) for the number of prescriptions. Medium-term savings were estimate to account for 2.75% (March 1997) and 2.78% (August 2000) savings per insured person.

Von der Schulenberg et al. studied the association between regressive pharmacy mark-ups and originator prices of ACE inhibitors in a sample of European countries (Denmark, France, Germany, Netherlands, Sweden, United Kingdom). Of these, Sweden, Denmark and the United Kingdom employed regressive mark-ups during the whole period under study (1991-2006), whereas France temporarily paused the system between 1999 and 2003 and Germany implemented it for the first time in 2003. The impact of a mix of other supply- and demand-side measures were investigated as well, which were all included in the model of the regression analysis. Data on prices were obtained from the IMS Midas database (*91*).

The analysis of Von der Schulenberg et al. applied panel data estimation with a regression model on the logarithm of originator price, with regressive pharmacy mark-up as a dummy variable along with controls. Four models were created, each employing a different method to assess the impact of generics: availability of generics on the market, the number of generic products on the market, the price of generic medicines or a combination of these[63]. The estimated coefficient was negative (p<0.01) and reveals that the policy had a negative impact on the prices.

The five remaining studies by Cheng et al., Fu et al., Yang et al., Zhou et al. and Li et al. each studied the impact of the Zero Mark-up Drug Policy (ZMDP) in China on prices of pharmaceutical products in primary healthcare institutions and in the hospital sector. The ZMDP was piloted and successively implemented across the country in phases. The studies therefore addressed different aspects and settings of the policy.

Cheng et al. investigated the effects of a threefold distinct implementation methods in community healthcare centres in Beijing during an early pilot phase. Because the policy removed the previously allowed 15% mark-up on pharmaceutical products, compensation for the mark-up loss was needed. The first method was through a fixed subsidy, providing full financial support but not allowing CHCs to keep any surplus. A second strategy relied on an income-linked subsidy and covered staff expenses, but not the full operational costs. Within the third group, the compensation was based on self-financing with government purchasing services of providing zero mark-up medicines. All 70 participating health centres individually provided data (*312*).

[63] Results of the model which is believed to reflect the situation over the life-cycle of an originator product best, are described above. This random-effects model captured the impact of the policy both before as well as after the intervention and included the number of generic products on the market as explanatory variable. Results for other models were comparable and can be found in the appendix.

Cheng et al. employed a design which resembled a controlled before-after design to assess the impact of the policy on the cost per visit. Although the study did not include a group that had not undergone the intervention, comparison between the three groups was possible. The costs initially decreased in 2007 with 0.7% compared to the year before, after which they increased again by 11.6% and 10.0% relative to the previous year. The primary drop in costs is mainly due to centres receiving a fixed subsidy, in which a reduction of 18.7% is observed (p=0.001), though subsequently rising with 17.1% and 6.3%. The impact of the policy is less pronounced in centres receiving an income-linked subsidy, with consecutive relative changes of -1.9% (p=0.001), 7.6% and 8.5%. Compensation by government purchasing services led to increasingly high prices despite the implementation of the policy with yearly escalation of between 16.7% to 25.2%.

The overall lack of effect of the ZMDP is hypothesized to be due to the Beijing Health Bureau's expectations that the medicines targeted by the policy would be able to meet the majority of the demand for medicines, which proved not to be the case. This effect is more pronounced in facilities receiving government purchasing services, which have a strong incentive to generate revenue and are more likely to procure medicines outside of the list and provided medical services instead of pharmacy services. The contrary is seen in facilities on a fixed budget.

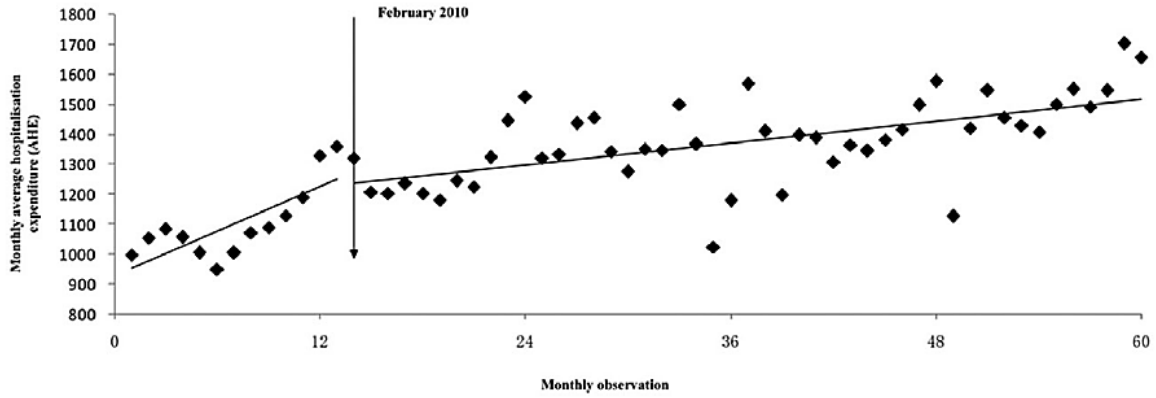
Within the study by Zhou et al., the impact of the ZMDP was studied after piloting in the public general hospital setting. Hospital-level data was obtained for 2010 and 2011 from two hospitals in the Shaanxi province. The policy had been implemented in Ningshan county in December 2010, whereas Zhenping county hospital functioned as reference. These hospitals also provided patient records, which were randomly sampled. However, as the information system for outpatient services had not been established in Zhenping county hospital at the time, the outpatient records from Zhenping county hospital were not retrieved in this study (*309*).

Because both the hospital-level data and individual patient data were available, the authors conducted analyses in two approaches, accordingly. Applying the DID methodology on the hospital data, the ZMDP was associated with a 11.73% and 3.9% reduction in per-visit drug expense for outpatient and inpatient visits, respectively. In order to control both observable and unobservable confounding factors, linear regression models on individual patient data were subsequently employed to analyse the effects of the ZMDP. The proportion that drug expense was reduced after implementing the ZMDP was 7.35% (SE 1.62, p<0.01) for outpatient visits and -3.92% (0.66, p<0.01) for inpatient visits. The differences in outpatient drug expenses are due to the fact that data from the reference hospital was unavailable for the regression model.

Yang et al. examined the effect of the ZMDP in primary health institutions in the rural county of Fufeng, Shaanxi province, on monthly average hospitalization expenditure. Health institutions received subsidies to compensate for their loss of potential drug revenue. Data for 2009 to 2013 were obtained from the New Rural Cooperative Medical Scheme (NRCMS), an insurance scheme covering between 96% and 99% of the population (*306*).

An ITS design was employed to examine the effects. The ZMDP was associated with a -40.26 RMB (-6.30 USD[iv], RSE 44.20, p=0.366) change in level and a -16.49 RMB (-2.58 USD, RSE 6.09, p=0.009) change in trend (see Figure 11.7). According to the authors, a contextual factor to be taken into consideration is that rural health facilities relied heavily on drug revenue. After implementation of the ZMDP, these facilities sought to offset this loss by increasing diagnostic fees, care fees, surgery fees and treatment fees, accounting for the modest slowing of the growth rate.

Figure 11.7 Trend in average hospitalization expenditure in primary health institutions in Fufeng County, segmented by the ZMDP in February 2010.



Fu et al. likewise examined the effects of the ZMDP. Instead of providing subsidies, loss of revenue was compensated by the government by raising fees for medical services, which had previously been set far below actual prices. The study was somewhat more comprehensive than other studies examining the same policy. It included data from county-level public general hospitals in mainland China for 2009 to 2014. Exploiting the temporal and cross-sectional variations, this allowed for the association between the intervention and drug expenditure to be studied. The yearly data was obtained from the Annual Statistical Reports on China's Public Hospitals (*308*).

To estimate the impact of the ZMDP, a regression model on the logarithm of expenditure, being amongst others the drug expenditure per outpatient and inpatient visits, with the policy as a dummy variable along with various controls, was employed in a DID structure. Drug expenditure per outpatient visit was reported to decline by 6.3% ($p<0.01$), whereas total expenditure decreased by only 2.5% ($p>0.1$). As for inpatient care, the introduction of the ZMDP was associated with a 9.0% ($p<0.01$) reduction in drug expenditure and a -1.2% ($p>0.1$) change in total expenditure.

According to the authors, as the reduction in drug expenditures were far below 15%, this implied that either larger quantities of drugs or medicines outside of the scope of the policy had been prescribed. It is reported that hospitals with greater reliance on drug revenues before the reform indeed showed increased expenditures for medical services, which was unintended by policymakers. The authors suggest that the ZMDP had led to increased use of medical services with higher price-cost margins to compensate for loss of drug revenue.

Li et al. performed a regression analysis to assess if there was a difference in average price before and after the introduction of the ZMDP in community health service institutions in Chengdu. They found that the intervention was associated with a negative coefficient estimate of -0.417 ($p=0.001$). In this paper it was noted that was a high level of subsidy from the government, which helped with the success of the intervention. However, there was a lack of high-level health resources, resulting in less patients going to community health service institutions.

11.3 Authors' conclusions

11.3.1 Summary of main results

The eleven studies included in this review examine the setting of maximum prices through different mechanisms. Five studies examined the impact of price caps on selected medicines. Two studies employing regression models support a correlation between price caps and reduced growth rates of prices, though one study reported otherwise. Two studies found an association between control of retail and ex-factory prices and increased use of medicines, whereas two studies reported declining prescription quantities of targeted medicines.

Seven studies analyse the effects of measures targeting mark-ups. Each supports the association between these measures and reduced prices of medicines, either immediately or long-term. Three studies found that the benefits of policies regulating mark-ups were reduced by facilities compensating loss in drug revenue by increased use more-expensive medicines or other medical services.

11.3.2 Overall completeness and applicability of evidence

Several factors may limit the applicability of the evidence. First, the majority of studies investigate policies in a high income setting (n=4) or upper-middle income countries (n=6). A single study focused on a lower-middle come country. Furthermore, the effects of one intervention were examined in five studies, each with a slightly different focus but on the same intervention nevertheless.

One study examined the effects of a reduction in ex-factory prices in a narrow sample, which included only one medicine (metformin). Another four studies considered data from antidiabetics, antipsychotics or antihypertensive patients. These are chronic conditions, which makes it problematic to extrapolate the results to other conditions that are not chronic, such as infectious diseases. These are especially relevant in most low-income countries. The majority of the studies included data on all medicines prescribed, making the results more generalisable.

Expenditure was solely used in four studies, instead of data on actual prices of medicines. As expenditure inherently includes a measure of volume, separate changes cannot be discerned. None of the studies identified addressed effects of price setting on affordability or availability.

11.3.3 Quality of the evidence

The risk of bias was assessed to be highly variable. In general, studies employing an interrupted time series design presented with a low risk of bias, the main objection being the occasional brief time between the intervention and co-interventions happening closely in time to the intervention of interest. According to EPOC guidelines, all observational evidence is initially assigned a low quality score. However most studies examined here adopted rigorous study designs, and transparently reported their methods and analytical approaches. As such, the methodological quality was considered high. As such, the quality of the evidence of ITS analyses was predominantly judged as moderate.

Studies employing a regression model or a difference-in-difference methodology were assessed variably regarding the risk of bias. Although mostly a strong design, some studies presented with crucial issues threatening the internal validity of the results, such as assumptions made in the models that were left unsubstantiated or tested, lack of control for seasonal variation and the high number of interventions

examined in the study period. One study had a controlled before-after design. Due to the lack of a real control, e.g. a group having undergone no policy change, and other biases some of which are inherent to the study design, the risk of bias was judged to be high. Therefore, the overall quality of the evidence was deemed to be low.

11.3.4 Agreement/disagreement with other reviews

A literature review by Puig-Junoy from 2010 evaluated the impact of direct price-caps on generic drugs and measures regulating the reimbursement rate of medicines through reference pricing (*211*). In the literature search, a single reference was identified that individually analysed the impact of price-cap regulation, herein defined as a fixed percentage of the originator product price. This exhaustive pharmaceutical sector inquiry commissioned by the European Commission analysed data on multiple policies in 17 European countries. Another three references analysed markets that combined reference pricing with generic price caps. Puig-Junoy suggested that although price caps lead to price reductions relative to prices before generic entry, price caps cause a levelling off of generic prices at a level that is higher than without this measure. It also indicated that the policy may not be favourable to price competition and generic penetration.

As suggested in the working paper on the regulation of mark-ups within the review series on Pharmaceutical Pricing Policies and Interventions by Ball et al., the regulation of mark-ups as part of a more comprehensive regulatory strategy is likely to result in reduced medicine prices (*280*). However, regulation of mark-ups alone, without regulation of either the ex-factory or retail price will probably not lead to lower prices, nor in the absence of adequate enforcement. In addition, the authors suggest that policies targeting mark-ups may have unintended consequences on the availability, sale or use of medicines, especially in more remote areas. Manufacturers may shift production and sales to more profitable lines and the availability of essential medicines may be adversely affected. These findings are in line with those in the present review, that reduced prices due to mark-up regulation were indeed observed, however the biggest challenge seems to be the prescribing behavior through which facilities aim to offset their loss in drug revenue.

A recent (2018) review by Deng et al. assessed the zero mark-up drug policy in China (*283*). This review analysed the characteristics, progress, achievements, challenges, and recommendations of the reform by using the policy diffusion theory. The assessment of achievements of the policy measure was not performed systematically and included only four references. Upon inspection, the paper included one study included in the present review (Zhou et al.). None of the four remaining references were eligible for inclusion due to study design. Nevertheless, from their reform, the authors suggest that the ZMDP has resulted in considerable achievements in regards to the reduction in medical costs and patient burden. Although the number of studies included in the review are limited and the study designs informing this conclusion are mostly weak, the direction of the evidence is nonetheless consistent with that of the present review.

We are not aware of further reviews on the topic.

11.3.5 Authors conclusions: implications for practice; implications for research

The empirical evidence suggests that regulating mark-ups may be effective in reducing prices. Evidence on price caps is inconsistent.

Though considerable evidence has been produced in recent years, with all studies that met the inclusion criteria being published between 2008 and 2018, further research is still required to elucidate the

effectiveness of price cap policies at various levels (reimbursement rate, retail level or ex-factory prices) using robust study designs. Additional research should focus on low-income countries in particular, as evidence in these countries is sparse, not systematically collected, and where is exists often of low quality.

12 Tendering and negotiation

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12.1 Background

Tendering and negotiation is defined here as a pricing policy that « determines prices through tendering or negotiation among suppliers of medicines that are identical or comparable in chemical composition, pharmacological mechanisms and therapeutic use, taking into account factors such as quality and supply conditions ». Tendering is any formal and competitive procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous (adapted from (*5*)). Traditionally, tendering has been employed in the inpatient sector, but its application for outpatient care has been increasing in recent years (*260*). Negotiation refers to a discussion aimed at reaching an agreement (*6*), and may for instance be applied for negotiating reimbursement prices between authorities and manufacturers or direct negotiation between hospitals and manufacturer or wholesaler (*260*).

Though similar procurement methods, tendering and negotiation are distinct approaches. For one, in competitive negotiation, the buyer approaches the supplier, whereas the opposite is typical for tenders, for which a call is launched (*313*). Tenders are generally categorized as open or restricted tenders. Open tenders are open for bidding to all interested suppliers and may be suitable when multiple reputable suppliers are available and likely to be interested. Restricted tenders are, as the name implies, restricted to certain suppliers who have registered with the government or who have been prequalified. This approach may be favourable when a substantial number of suppliers have registered and there is capacity for managing such a resource intensive option (*313*). Competitive negotiation may be suitable for low-price or small-volume items or when specific terms are required by the buyer. An experienced purchasing office is appropriate in order to achieve the lowest prices. As this approach typically takes less time than tendering, it may also be employed for emergency purchases to supplement tenders (*313*).

Both tendering and negotiation are much applied purchasing methods. Indeed, twenty-three member countries (mainly EU countries) of the Pharmaceutical Pricing and Reimbursement Information (PPRI) network use tendering as a dominant procurement strategy for hospital sector medicines and eighteen PPRI countries use it for procuring off-patent medicines in the outpatient sector (*121*). A well-known example of tendering is the so-called 'preferred medicines scheme' introduced in the Netherlands, whereby public tendering is employed to choose specific products that are considered favourable over other products with the same active ingredients for a limited time (*260*). Negotiation for individual discounts on off-patent medicines is applied by German sickness funds (*260*). Other examples are the tendering system used by Mexico's social insurance programmes for generic medicines (*314*), and authorities in El Salvador applying

joint tendering for the purchasing of medicines on the national Essential Medicines List for public and NGO health facilities (*313*).

In theory, tendering and negotiation may achieve considerable savings when there are multiple potential suppliers for similar products, purchasing power of the buyers is high and information is complete and reliable (*315*,*316*). Reportedly, when generic medicines are available on the market, prices obtained through tendering may be reduced as far as the level of marginal production costs (*316*). A further advantage would be increased transparency, at least in countries where prices are made public (*315*). In many existing schemes depending on tendering or negotiations, this is currently not the case due to confidentiality agreements (*260*). However, concerns regarding the sustainability of this concept have been raised, as the low prices could force some manufacturers out of the market, ultimately resulting in increased prices.

This chapter details the evidence on tendering and negotiation.

12.2 Results

12.2.1 Excluded studies

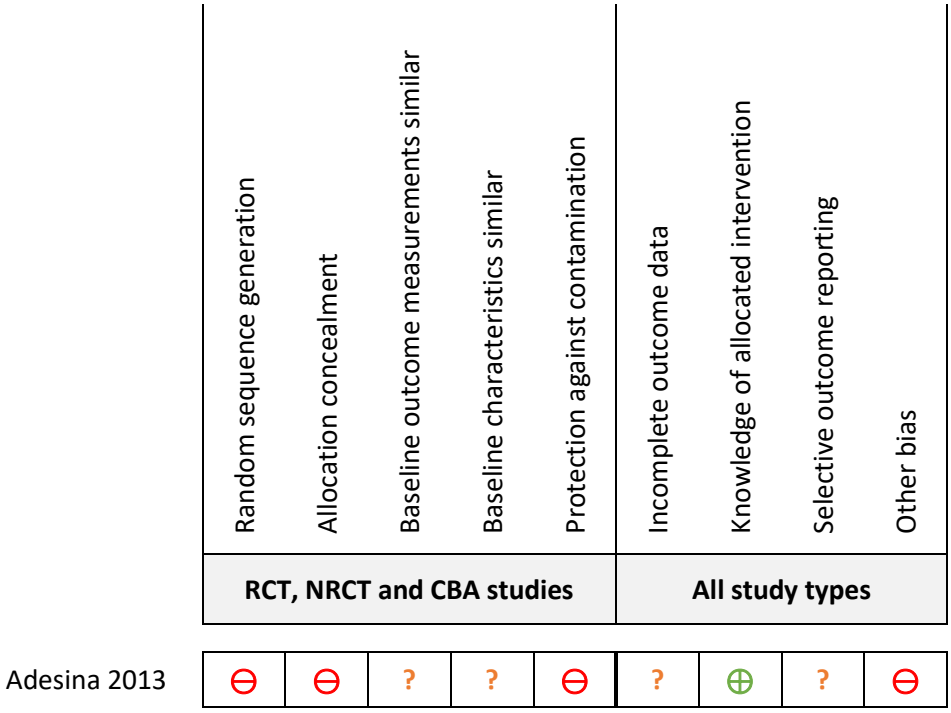
A total of 23 references on the topic of tendering and negotiations were assessed at full text level. Of these 22 studies were excluded at this stage. For four of these studies, only (conference) abstracts could be retrieved (*194*,*317–319*). As these provided insufficient data, required for a complete understanding of the methodology and the grading of the evidence, all four were excluded. The remaining 18 studies were not deemed eligible on study design, of which three resembled an uncontrolled before/after design (*294*,*320*,*321*), four were cross-sectional analyses or price surveys without a temporal comparison (*298*,*322–324*), three were descriptive analyses of price development or policies (*47*,*62*,*325*), one was a projection of potential savings (*326*) and one a case study in which literature was also reviewed (*327*). The six studies that remained (*26*,*328–332*) applied compelling analyses (e.g. DID, regression analyses, RM). One study (*329*) analysed the impact of tendered procurement by NGOs on reducing prices of originator and generic drugs using a DID design. Waning *et al.* used a generalized linear regression model showing how negotiations by Clinton Foundation's HIV/AIDS Initiative (CHAI) have resulted in lower generic antiretroviral (ARV) drug prices (*26*). Another study (*322*) is a repeated measures analysis stating that tendering should be used as a cost-containment policy by comparing tendered price and pharmacy purchasing price in Cyprus. Wouters *et al.* (*332*) performed a descriptive analysis of South Africa's tender contracts and concluded that tendering is effective in lowering drug prices. Similarly, Qendri *et al.* (*331*) and Curto *et al.* (*328*) showed that tendering can be used as an effective cost containment strategy lowering drug prices with higher competition. However, these six studies investigated the long-term influence of tendering policies that had been implemented long before the study period (*26*,*328–332*). Hence, despite strong study designs of these six studies, it is difficult to attribute observed effects (if any) to the intervention since circumstances may have changed considerably including other interventions. For this reason, all six studies were finally excluded.

12.2.2 Characteristics of included studies

During full-text screening, one study met the inclusion criteria (*333*). This was a controlled before-after study in the setting of Mexico, examining prices of patented antiretrovirals (ARVs) before and after the introduction of a commission to negotiate prices.

The risk of bias assessment is presented in Table 12-1. The study was assessed as having high or unclear risk of bias across all except one domain.

Table 12.1 Risk of bias of included studies



11.2.3. Effect of interventions

The included study assessed the impact of negotiated discounts on the prices of patented ARVs. The GRADE quality assessment is given in Table 12-2, and the summary of findings are presented in Table 12-3.

Table 12-2 Certainty assessment (GRADE) of evidence for each outcome

No of studies	Design (number)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Certainty (overall score)
Outcome: Price							
1	CBA (I)	High risk (-1)	No serious inconsistency (0)	No serious indirectness (0)	Serious imprecision (-1)[64]	NA	**Very low** ⊕○○○
Outcome: Volume							
Outcome: Availability							
Outcome: Affordability							

[64] No analysis was undertaken to determine statistical significance of the observed effect, nor the impact of existing secular trends, which appeared substantial from the data presented.

Table 12-3 Summary of findings table for price negotiations for each outcome

Price setting vs no intervention

Medicines: Anti-retrovirals (ARVs)

Settings: Mexico

Intervention: Commission to undertake joint price negotiation

Comparison: No policy

Outcomes	Impact	No. of studies	Certainty of the evidence (GRADE)	Comments
Price				
Average annual price per patient	Reduction in price of between 13% and 56% compared with pre-commission prices. Empirically similar price reductions observed in control group.	1	Very low ⊕○○○	We are uncertain of the effect of this intervention, as the quality of evidence was assessed as very low
Volume				
Availability				
Affordability				

The study by Adesina *et* al. (*333*) was a controlled before-after study, examining the price of patented antiretrovirals (ARVs) in Mexico before and after the introduction of an Inter-Institutional Commission between the Ministry of Health and the Mexican Social Security Institution (IMSS) with a mandate to negotiate prices and achieve discounts on patented medicines. Procurement prices in Mexico of thirteen ARVs were compared with international procurement prices for upper-middle income countries from the Global Price Reporting Mechanism database.

The study presented descriptive results suggesting a reduction in prices in the intervention group in Mexico following implementation of the negotiation commission of between 13% and 56% compared with pre-commission prices. However, detailed relative reductions were not reported for the control group, and the authors note a greater overall post-intervention price reduction in the control group compared with the intervention group (average of 45% reduction in control group vs 38% in the intervention group). Indeed, inspection of absolute price levels (presented graphically) before/after the intervention suggests empirically similar price reductions between the two groups. Additionally, a downward trend in prices before the intervention was not taken quantitatively into account. Finally, it remains unclear why the authors compared average annual prices in the intervention country with median annual prices in the control group.

12.3 Authors' conclusions

12.3.1 Summary of main results

Adesina *et al.* (*333*) presented data on prices before and after the establishment of the Inter-Institutional Commission in Mexico for the negotiation of patented ARV prices. The analysis was descriptive and did not take into account pre-intervention trends or the post-intervention price change in the control group. The price reduction appeared comparable in the intervention and control groups (*333*).

12.3.2 Overall completeness and applicability of evidence

The evidence for effectiveness of price negotiation as a pharmaceutical policy is very limited. Several factors may limit the applicability of the available evidence: the one study identified in this review is limited to ARV procurement in an upper-middle income country.

12.3.3 Quality of the evidence

The risk of bias of the included study was assessed as high or unclear in the vast majority of domains. The study does not measure the difference in baseline prices between control and intervention groups, nor assess the trends in prices in both groups. The control group countries are not fully specified, and the study does not assess whether similar policies exist in the control countries. No overall assessment is presented of the relative price change in the intervention versus control group, and no statistical analysis is undertaken to distinguish observed changes from chance. Overall, the quality of the evidence was judged to be very low.

12.3.4 Agreement/disagreement with other reviews

A recent review of the literature by Vogler et al (*327*), supplemented with information from stakeholder interviews, suggested that tendering for off-patent pharmaceuticals is able to achieve cost savings with the possible limitation of subsequent shortages. The authors argued that a well-designed tendering system should include back-up mechanisms and a robust and organisational framework. Ideally, tendering for off-patent medicines should be complemented with demand-side measures promoting generic use.

An economic paper on cost-containment policies in public pharmaceutical spending in the EU (*27*) from 2012 suggested that tendering is a well-established and successful tool for purchasing inpatient medicines and increasingly for ambulatory care, which has achieved considerable savings in expenditure. It is indicated that price itself is an essential criterion for winning a tender.

We are not aware of further reviews on the topic.

12.3.5 Authors conclusions: implications for practice; implications for research

There is insufficient evidence to determine whether tendering and negotiation pharmaceutical policies are effective in controlling price, volume, availability or affordability.

There is a lack of robust quantitative and comparative evidence assessing the implementation of tendering and competitive negotiation. Although some evidence suggest savings can be achieved through tendering, the impact on volumes, availability and affordability remains inconclusive, as does the effectiveness of competitive negotiation. Further research is required to substantiate the implementation of these pricing policies using robust study designs, particularly in a low-income setting.

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Appendix A: Search Strategies

A.1: Source: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily

Interface / URL: OvidSP

Database coverage dates: 1946 to September 04, 2019

Search date: 05/09/19

Retrieved records: 8302

Search strategy:

1 Drugs, Essential/ec (279)

2 Drugs, Essential/ and (pricing or price or prices or priced or cost$ or economic$ or pharmacoeconomic$).ti,ab,kf. (275)

3 1 or 2 (378)

4 Drug Costs/ (15469)

5 Economics, Pharmaceutical/ (2886)

6 Drug Prescriptions/ec (2860)

7 Prescription Drugs/ec (1216)

8 fees, pharmaceutical/ or prescription fees/ (2368)

9 Drug Substitution/ec (170)

10 Insurance, Pharmaceutical Services/ec (1349)

11 Drug Approval/ec or exp Pharmaceutical preparations/ec or exp vaccines/ec or Biological Products/ec or Drugs, Generic/ or Biosimilar Pharmaceuticals/ (16705)

12 Reimbursement Mechanisms/ and (Drug Industry/ or Drug Approval/ or Legislation, Drug/ or "Drug and Narcotic Control"/) (211)

13 Commerce/ and (Drug Industry/ or Drug Approval/ or Legislation, Drug/ or "Drug and Narcotic Control"/) (1609)

14 "Cost Control"/ and (Drug Industry/ or Drug Approval/ or Legislation, Drug/ or "Drug and Narcotic Control"/) (458)

15 Commerce/ and (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic$ or vaccine$1 or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$).ti,ab,kf. (3124)

16 "Cost Control"/ and (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic$ or vaccine$1 or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$).ti,ab,kf. (2543)

17 or/4-16 (39602)

18 (pricing or price or prices or priced).ti,ab,kf. (37679)

19 (policy or policies or arrangement$1 or framework$1 or frame-work$1 or intervention$1 or law or laws or legal$ or legislat$ or measure or measures or measurement or measurements or mechanism$1 or order or orders or plan or plans or planning or principle or principles or procedure$1 or program or programme or programmes or programs or regulat$ or requirement$1 or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic$).ti,ab,kf. (9665806)

20 17 and 18 and 19 (3186)

21 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine$1) and pricing).ti. (619)

22 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine$1) adj6 pricing).ab,kf. (926)

23 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine$1) and (price or prices or priced)).ti. (1391)

24 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine$1) and ((pricing or price or prices or priced) adj6 (policy or policies))).ab,kf. (430)

25 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine$1) and ((pricing or price or prices or priced) adj3 (arrangement$1 or framework$1 or frame-work$1 or intervention$1 or law or laws or legal$ or legislat$ or measure or measures or measurement or measurements or mechanism$1 or order or orders or plan or plans or planning or principle or principles

or procedure$1 or program or programme or programmes or programs or regulat$ or requirement$1 or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic$))).ab,kf. (825)

26 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine$1) and (price regulation$1 or price difference$1 or price differential$ or price dispersion or average price$1 or retail price$1 or wholesale price$1 or expected price$1 or net price$1 or transaction price$1 or price type$1 or price component$1 or cif price$1 or freight price$1 or pharmacy price$1 or pharmacist$ price$1 or end price$1 or consumer price$1 or final price$1 or reimbursement price$1 or list price$1 or actual price$1)).ab,kf. (1106)

27 or/21-26 (4018)

28 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic$ or vaccine$1 or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$) and (cost-control or cost-containment or cost-setting)).ti,ab,kf. (1380)

29 3 or 20 or 27 or 28 (7233)

30 (or/4-14) or Drugs, Essential/ or (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic$ or vaccine$1 or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$).ti,ab,kf. (2588239)

31 (reference adj6 (pricing or price or prices or priced)).ti,ab,kf. (514)

32 ((benchmark$ or bench-mark$) adj6 (pricing or price or prices or priced)).ti,ab,kf. (53)

33 (international price adj (comparison$ or comparat$)).ti,ab,kf. (13)

34 (factory$ price$1 or manufacturer$ price$1 or exfactory$ price$1 or exmanufacturer$ price$1).ti,ab,kf. (82)

35 or/31-34 (636)

36 Technology Assessment, Biomedical/ and (17 or Drugs, Essential/) (262)

37 (value-based and (pricing or price or prices or priced)).ti,ab,kf. (288)

38 (value-based and reimbursement).ti,ab,kf. (454)

39 ((value or values) adj6 (pricing or price or prices or priced)).ti,ab,kf. (885)

40 ((hta or htas or technology assessment$ or technology appraisal$) and (pricing or price or prices or priced)).ti,ab,kf. (379)

41 ((economic evaluation$ or cost-consequence$ or cost-minimization or cost-minimisation or cost-effectiveness or cost-utility or cost-benefit$) and (pricing or price or prices or priced) and (based or set or sets or setting)).ti,ab,kf. (1825)

42 or/36-41 (3494)

43 (cost-plus or costplus or costs-plus or costsplus).ti,ab,kf. (151)

44 (((cost or costs) adj3 based) and (pricing or price or prices or priced)).ti,ab,kf. (722)

45 (((cost or costs) adj3 (produc$ or promot$ or expense$ or research$ or develop$ or administrat$ or overhead$ or over-head$ or profit$1)) and (pricing or price or prices or priced)).ti,ab,kf. (1439)

46 (((expense or expenses) adj3 (produc$ or promot$ or research$ or develop$ or administrat$ or overhead$ or over-head$ or profit$1)) and (pricing or price or prices or priced)).ti,ab,kf. (44)

47 ((pricing or price or prices or priced) adj3 (set or sets or setting)).ti,ab,kf. (519)

48 ((pricing or price or prices or priced) adj3 (control$ or containment)).ti,ab,kf. (621)

49 or/43-48 (3264)

50 ((pricing or price or prices or priced) adj6 threshold$).ti,ab,kf. (136)

51 ((pricing or price or prices or priced) adj6 maximum$).ti,ab,kf. (175)

52 ((pricing or price or prices or priced) adj6 (cap or caps or capped or capping or ceiling$)).ti,ab,kf. (146)

53 (mark-up$1 or markup$1).ti. (187)

54 ((mark-up$1 or markup$1) adj3 control$).ab,kf. (8)

55 ((mark-up$1 or markup$1) and (regulat$ or manipulat$ or supply or supplies or distribut$ or wholesale$ or prescrib$ or prescrip$ or dispens$ or pricing or price or prices or priced or cost$ or economic$ or pharmacoeconomic$)).ab,kf. (389)

56 ((supply chain$ or distribution) adj cost$).ti,ab,kf. (101)

57 ((supply chain$ or distribution) adj6 (pricing or price or prices or priced)).ti,ab,kf. (231)

58 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic$ or vaccine$1 or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$) adj6 margin$1).ti,ab,kf. (501)

59 (profit margin$1 or gross margin$1).ti,ab,kf. (598)

60 (cost-price$1 or purchase-price$1 or purchasing-price$1 or selling price$1).ti,ab,kf. (700)

61 or/50-60 (3004)

62 Disclosure/ and (17 or Drugs, Essential/) (84)

63 ((pricing or price or prices or priced or discount$ or rebate$1) adj6 (publish$ or publication)).ti,ab,kf. (301)

64 ((pricing or price or prices or priced or discount$ or rebate$1) adj6 (disclos$ or disseminat$ or communicat$ or shar$)).ti,ab,kf. (508)

65 ((pricing or price or prices or priced or discount$ or rebate$1) and (transparen$ or accountab$)).ti,ab,kf. (883)

66 (((publish$ or publication or disclos$ or disseminat$ or communicat$ or shar$) adj6 information$1) and (pricing or price or prices or priced or discount$ or rebate$1)).ti,ab,kf. (271)

67 managed entry.ti,ab,kf. (71)

68 (("access with evidence development" or conditional coverage or conditional treatment continuation or "coverage with evidence development" or "only in research" or "only with research" or outcome guarantee$1 or patient access scheme$1 or patient access agreement$1 or patient access arrangement$1 or "pattern or process care" or performance-based agreement$1 or performance-based scheme$1 or performance-based arrangement$1 or performance-based health outcome reimbursement or performance-linked reimbursement or price volume agreement$1 or price volume arrangement$1 or price volume scheme$1) adj6 (publish$ or publication or disclos$ or disseminat$ or communicat$ or shar$)).ti,ab,kf. (11)

69 (risk sharing scheme$1 or risk sharing agreement$ or risk sharing arrangement$1).ti,ab,kf. (183)

70 (("access with evidence development" or conditional coverage or conditional treatment continuation or "coverage with evidence development" or "only in research" or "only with research" or outcome guarantee$1 or patient access scheme$1 or patient access agreement$1 or patient access arrangement$1 or "pattern or process care" or performance-based agreement$1 or performance-based scheme$1 or performance-based arrangement$1 or performance-based health outcome reimbursement or performance-linked reimbursement or price volume agreement$1 or price volume arrangement$1 or price volume scheme$1) and (transparen$ or accountab$)).ti,ab,kf. (18)

71 or/62-70 (2173)

72 (pool$ adj6 (procur$ or purchas$)).ti,ab,kf. (149)

73 (joint$ adj6 (procur$ or purchas$)).ti,ab,kf. (105)

74 (group$ adj3 (procur$ or purchas$)).ti,ab,kf. (774)

75 ((share or shares or sharing or shared) adj6 (procur$ or purchas$)).ti,ab,kf. (256)

76 (collectiv$ adj6 (procur$ or purchas$)).ti,ab,kf. (36)

77 (combin$ adj6 (procur$ or purchas$)).ti,ab,kf. (200)

78 or/72-77 (1478)

79 ((pricing or price or prices or priced) adj6 (discount$ or reduction$1)).ti,ab,kf. (1265)

80 ((pricing or price or prices or priced) and rebate$1).ti,ab,kf. (168)

81 flat discount$.ti,ab,kf. (1)

82 (("access with evidence development" or conditional coverage or conditional treatment continuation or "coverage with evidence development" or "only in research" or "only with research" or outcome guarantee$1 or patient access scheme$1 or patient access agreement$1 or patient access arrangement$1 or "pattern or process care" or performance-based agreement$1 or performance-based scheme$1 or performance-based arrangement$1 or performance-based health outcome reimbursement or performance-linked reimbursement or price volume agreement$1 or price volume arrangement$1 or price volume scheme$1) and (discount$ or reduction$1 or rebate$1)).ti,ab,kf. (71)

83 or/79-82 (1430)

84 Drug Industry/ and (Economic Competition/ or Competitive Bidding/ or Contract Services/) (684)

85 (competitive adj (pricing or price or prices)).ti,ab,kf. (136)

86 ((pricing or price or prices or priced or purchas$) and (tender or tenders or tendering or tendered)).ti,ab,kf. (175)

87 ((pricing or price or prices or priced or purchas$) adj6 (bid or bids or bidder$1 or bidding)).ti,ab,kf. (129)

88 ((pricing or price or prices or priced or purchas$) adj6 negotiat$).ti,ab,kf. (529)

89 ((pricing or price or prices or priced or purchas$) adj3 (discuss$ or agree$)).ti,ab,kf. (348)

90 ((pricing or price or prices or priced or purchas$) adj6 (offer or offers or offered or offering)).ti,ab,kf. (590)

91 ((pricing or price or prices or priced or purchas$) and procur$).ti,ab,kf. (688)

92 (preferential adj3 (pricing or price or prices or priced)).ti,ab,kf. (19)

93 or/84-92 (3072)

94 Drug Costs/ and exp Taxes/ (32)

95 ((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) adj6 (reduc$ or exempt$ or remov$)).ti,ab,kf. (2225)

96 (((duty or duties) adj6 (reduc$ or exempt$ or remov$)) and (pricing or price or prices or priced)).ti,ab,kf. (5)

97 ((duty or duties) adj3 (reduc$ or exempt$ or remov$)).ti,ab,kf. (291)

98 ((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) adj3 free).ti,ab,kf. (198)

99 ((duty or duties) adj3 free).ti,ab,kf. (58)

100 ((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) adj6 (policy or policies or arrangement$1 or framework$1 or frame-work$1 or intervention$1 or law or laws or legal$ or legislat$ or measure or measures or measurement or measurements or mechanism$1 or order or orders or plan or plans or planning or principle or principles or procedure$1 or program or programme or programmes or programs or regulat$ or requirement$1 or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic$)).ti,ab,kf. (4283)

101 (((duty or duties) adj6 (policy or policies or arrangement$1 or framework$1 or frame-work$1 or intervention$1 or law or laws or legal$ or legislat$ or measure or measures or measurement or measurements or mechanism$1 or order or orders or plan or plans or planning or principle or principles or procedure$1 or program or programme or programmes or programs or regulat$ or requirement$1 or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic$)) and (pricing or price or prices or priced)).ti,ab,kf. (19)

102 ((prescription$ adj3 charge$) and (pricing or price or prices or priced or cost$)).ti,ab,kf. (56)

103 or/94-102 (6415)

104 30 and (35 or 42 or 49 or 61 or 71 or 78 or 83 or 93 or 103) (6937)

105 (Drugs, Generic/ or Biosimilar Pharmaceuticals/) and (Drug Utilization/ or Cost-Control/) (394)

106 ((generic$ or non-proprietary or nonproprietary or INN or tier 1 or tier1 or tier one or off-patent$ or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$) and (pricing or price or prices or priced)).ti,ab,kf. (1647)

107 ((generic$ or non-proprietary or nonproprietary or INN or tier 1 or tier1 or tier one or off-patent$ or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$) and (cost-saving$ or cost-shar$)).ti,ab,kf. (573)

108 ((generic$ or non-proprietary or nonproprietary or INN or tier 1 or tier1 or tier one or off-patent$ or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$) and (prescribing-cost$ or prescription-cost$ or dispensing-cost$)).ti,ab,kf. (79)

109 or/105-108 (2390)

110 29 or 104 or 109 (12385)

111 exp animals/ not humans/ (4615097)

112 (news or editorial or letter).pt. (1738229)

113 110 not (111 or 112) (11473)

114 limit 113 to yr="2004 - 2019" (8302)

A.2: Source: Econlit

Interface / URL: OvidSP

Database coverage dates: 1886 to August 29, 2019

Search date: 10/09/19

Retrieved records: 2046

Search strategy:

1 (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic$ or vaccine$1 or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$).ti,ab,kw. (15149)

2 (pricing or price or prices or priced).ti,ab,kw. (164564)

3 (cost-control or cost-containment or cost-setting).ti,ab,kw. (587)

4 (value-based and reimbursement).ti,ab,kw. (21)

5 (cost-plus or costplus or costs-plus or costsplus).ti,ab,kw. (168)

6 (mark-up$1 or markup$1).ti,ab,kw. (2681)

7 ((supply chain$ or distribution) adj cost$).ti,ab,kw. (549)

8 margin$1.ti,ab,kw. (8698)

9 ((discount$ or rebate$1) adj6 (publish$ or publication)).ti,ab,kw. (15)

10 ((discount$ or rebate$1) adj6 (disclos$ or disseminat$ or communicat$ or shar$)).ti,ab,kw. (281)

11 ((discount$ or rebate$1) and (transparen$ or accountab$)).ti,ab,kw. (101)

12 (((publish$ or publication or disclos$ or disseminat$ or communicat$ or shar$) adj6 information$1) and (discount$ or rebate$1)).ti,ab,kw. (88)

13 managed entry.ti,ab,kw. (3)

14 ("access with evidence development" or conditional coverage or conditional treatment continuation or "coverage with evidence development" or "only in research" or "only with research" or outcome guarantee$1 or patient access scheme$1 or patient access agreement$1 or patient access arrangement$1 or "pattern or process care" or performance-based agreement$1 or performance-based scheme$1 or performance-based arrangement$1 or performance-based health outcome reimbursement or performance-linked reimbursement).ti,ab,kw. (61)

15 (risk sharing scheme$1 or risk sharing agreement$ or risk sharing arrangement$1).ti,ab,kw. (168)

16 (pool$ adj6 (procur$ or purchas$)).ti,ab,kw. (57)

17 (joint$ adj6 (procur$ or purchas$)).ti,ab,kw. (105)

18 (group$ adj3 (procur$ or purchas$)).ti,ab,kw. (100)

19 ((share or shares or sharing or shared) adj6 (procur$ or purchas$)).ti,ab,kw. (379)

20 (collectiv$ adj6 (procur$ or purchas$)).ti,ab,kw. (19)

21 (combin$ adj6 (procur$ or purchas$)).ti,ab,kw. (123)

22 flat discount$.ti,ab,kw. (0)

23 (purchas$ and (tender or tenders or tendering or tendered)).ti,ab,kw. (52)

24 (purchas$ adj6 (bid or bids or bidder$1 or bidding)).ti,ab,kw. (62)

25 (purchas$ adj6 negotiat$).ti,ab,kw. (28)

26 (purchas$ adj3 (discuss$ or agree$)).ti,ab,kw. (130)

27 (purchas$ adj6 (offer or offers or offered or offering)).ti,ab,kw. (182)

28 (purchas$ and procur$).ti,ab,kw. (313)

29 ((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) adj6 (reduc$ or exempt$ or remov$)).ti,ab,kw. (8244)

30 ((duty or duties) adj3 (reduc$ or exempt$ or remov$)).ti,ab,kw. (83)

31 ((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) adj3 free).ti,ab,kw. (401)

32 ((duty or duties) adj3 free).ti,ab,kw. (141)

33 ((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) adj6 (policy or policies or arrangement$1 or framework$1 or frame-work$1 or intervention$1 or law or laws or legal$ or legislat$ or measure or measures or measurement or measurements or mechanism$1 or order or orders or plan or plans or planning or principle or principles or procedure$1 or program or programme or programmes or programs or regulat$ or requirement$1 or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic$)).ti,ab,kw. (24888)

34 ((prescription$ adj3 charge$) and cost$).ti,ab,kw. (1)

35 or/2-34 (199177)

36 1 and 35 (2853)

37 ((non-proprietary or nonproprietary or INN or tier 1 or tier1 or tier one or off-patent$) and (pricing or price or prices or priced)).ti,ab,kw. (62)

38 ((generic$ or non-proprietary or nonproprietary or INN or tier 1 or tier1 or tier one or off-patent$ or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$) and (cost-saving$ or cost-shar$)).ti,ab,kw. (33)

39 ((generic$ or non-proprietary or nonproprietary or INN or tier 1 or tier1 or tier one or off-patent$ or biosimilar$ or bio-similar$ or biogeneric$ or follow-on biologic$ or subsequent entry biologic$ or similar biologic$) and (prescribing-cost$ or prescription-cost$ or dispensing-cost$)).ti,ab,kw. (0)

40 or/37-39 (92)

41 36 or 40 (2904)

42 book review.pt. (2707)

43 41 not 42 (2904)

44 limit 43 to yr="2004 - 2019" (2046)

A.3: Source: Embase

Interface / URL: embase.com
Database coverage dates: 1974 to date*

Search date: 13/09/19

Retrieved records: 18858

Search strategy:

* Embase contains three databases:

- The Embase database: Contains biomedical literature from 1974 to present.
- The MEDLINE database: Covers journals from 1966 to present.
- Embase Classic: The Embase back file covering almost 2 million biomedical and pharmacological citations drawn from over 3,000 international titles from between 1947 and 1973.

Note: The search strategy as shown below is the run search strategy as displayed in the Embase.com. interface.

#113 #112 AND [2004-2019]/py 18858

#112 #109 NOT (#110 OR #111) 23556

#111 'editorial'/de OR 'letter'/de 1635114

#110 ('animal'/de OR 'animal experiment'/de OR 'animal model'/de OR 'animal tissue'/de OR 'nonhuman'/de) NOT 'human'/exp 6239806

#109 #29 OR #103 OR #108 24759

#108 #104 OR #105 OR #106 OR #107 5503

#107 (generic*:ti,ab,kw OR 'non-proprietary':ti,ab,kw OR nonproprietary:ti,ab,kw OR inn:ti,ab,kw OR 'tier 1':ti,ab,kw OR tier1:ti,ab,kw OR 'tier one':ti,ab,kw OR 'off-patent*':ti,ab,kw OR biosimilar*:ti,ab,kw OR 'bio-similar*':ti,ab,kw OR biogeneric*:ti,ab,kw OR 'follow-on biologic*':ti,ab,kw OR 'subsequent entry biologic*':ti,ab,kw OR 'similar biologic*':ti,ab,kw) AND ('prescribing-cost*':ti,ab,kw OR 'prescription-cost*':ti,ab,kw OR 'dispensing-cost*':ti,ab,kw) 132

#106 (generic*:ti,ab,kw OR 'non-proprietary':ti,ab,kw OR nonproprietary:ti,ab,kw OR inn:ti,ab,kw OR 'tier 1':ti,ab,kw OR tier1:ti,ab,kw OR 'tier one':ti,ab,kw OR 'off-patent*':ti,ab,kw OR biosimilar*:ti,ab,kw OR 'bio-similar*':ti,ab,kw OR biogeneric*:ti,ab,kw OR 'follow-on biologic*':ti,ab,kw OR 'subsequent entry biologic*':ti,ab,kw OR 'similar biologic*':ti,ab,kw) AND ('cost-saving*':ti,ab,kw OR 'cost-shar*':ti,ab,kw) 1262

#105 (generic*:ti,ab,kw OR 'non-proprietary':ti,ab,kw OR nonproprietary:ti,ab,kw OR inn:ti,ab,kw OR 'tier 1':ti,ab,kw OR tier1:ti,ab,kw OR 'tier one':ti,ab,kw OR 'off-patent*':ti,ab,kw OR biosimilar*:ti,ab,kw OR 'bio-similar*':ti,ab,kw OR biogeneric*:ti,ab,kw OR 'follow-on biologic*':ti,ab,kw OR 'subsequent entry biologic*':ti,ab,kw OR 'similar biologic*':ti,ab,kw) AND (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw) 3323

#104 ('generic drug'/de OR 'biosimilar agent'/de) AND ('drug utilization'/de OR 'cost control'/de) 1862

#103 #30 AND (#35 OR #42 OR #49 OR #61 OR #70 OR #77 OR #82 OR #92 OR #102) 14506

#102 #93 OR #94 OR #95 OR #96 OR #97 OR #98 OR #99 OR #100 OR #101 8469

#101 ((prescription* NEAR/3 charge*):ti,ab,kw) AND (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw OR cost*:ti,ab,kw) 92

#100 (((duty OR duties) NEAR/6 (policy OR policies OR arrangement* OR framework* OR 'frame-work*' OR intervention* OR law OR laws OR legal* OR legislat* OR measure OR measures OR measurement OR measurements OR mechanism* OR order OR orders OR plan OR plans OR planning OR principle OR principles OR procedure* OR program OR programme OR programmes OR programs OR regulat* OR requirement* OR rule OR rules OR scheme OR schemes OR standard OR standards OR strategies OR strategy OR strategic*)):ti,ab,kw) AND (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw) 28

#99 ((tax OR taxes OR taxed OR taxing OR taxation OR tariff OR tariffs OR vat) NEAR/6 (policy OR policies OR arrangement* OR framework* OR 'frame-work*' OR intervention* OR law OR laws OR legal* OR legislat* OR measure OR measures OR measurement OR measurements OR mechanism* OR order OR orders OR plan OR plans OR planning OR principle OR principles OR procedure* OR program OR programme OR programmes OR programs OR regulat* OR requirement* OR rule OR rules OR scheme OR schemes OR standard OR standards OR strategies OR strategy OR strategic*)):ti,ab,kw 5625

#98 ((duty OR duties) NEAR/3 free):ti,ab,kw 78

#97 ((tax OR taxes OR taxed OR taxing OR taxation OR tariff OR tariffs OR vat) NEAR/3 free):ti,ab,kw 247

#96 ((duty OR duties) NEAR/3 (reduc* OR exempt* OR remov*)):ti,ab,kw 351

#95 (((duty OR duties) NEAR/6 (reduc* OR exempt* OR remov*)):ti,ab,kw) AND (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw) 11

#94 ((tax OR taxes OR taxed OR taxing OR taxation OR tariff OR tariffs OR vat) NEAR/6 (reduc* OR exempt* OR remov*)):ti,ab,kw 2711

#93 'drug cost'/de AND 'tax'/de 292

#92 #83 OR #84 OR #85 OR #86 OR #87 OR #88 OR #89 OR #90 OR #91 5001

#91 (preferential NEAR/3 (pricing OR price OR prices OR priced)):ti,ab,kw 24

#90 (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw OR purchas*:ti,ab,kw) AND procur*:ti,ab,kw 1071

#89 ((pricing OR price OR prices OR priced OR purchas*) NEAR/6 (offer OR offers OR offered OR offering)):ti,ab,kw 744

#88 ((pricing OR price OR prices OR priced OR purchas*) NEAR/3 (discuss* OR agree*)):ti,ab,kw 586

#87 ((pricing OR price OR prices OR priced OR purchas*) NEAR/6 negotiat*):ti,ab,kw 1001

#86 ((pricing OR price OR prices OR priced OR purchas*) NEAR/6 (bid OR bids OR bidder* OR bidding)):ti,ab,kw 184

#85 (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw OR purchas*:ti,ab,kw) AND (tender:ti,ab,kw OR tenders:ti,ab,kw OR tendering:ti,ab,kw OR tendered:ti,ab,kw) 405

#84 (competitive NEXT/1 (pricing OR price OR prices)):ti,ab,kw 200

#83 'drug industry'/de AND ('purchasing'/exp OR 'competition'/de OR 'competitive behavior'/de) 1205

#82 #78 OR #79 OR #80 OR #81 2417

#81 ('access with evidence development':ti,ab,kw OR 'conditional coverage':ti,ab,kw OR 'conditional treatment continuation':ti,ab,kw OR 'coverage with evidence development':ti,ab,kw OR 'only in research':ti,ab,kw OR 'only with research':ti,ab,kw OR 'outcome guarantee*':ti,ab,kw OR 'patient access scheme*':ti,ab,kw OR 'patient access agreement*':ti,ab,kw OR 'patient access arrangement*':ti,ab,kw OR 'pattern or process care':ti,ab,kw OR 'performance-based agreement*':ti,ab,kw OR 'performance-based scheme*':ti,ab,kw OR 'performance-based arrangement*':ti,ab,kw OR 'performance-based health outcome reimbursement':ti,ab,kw OR 'performance-linked reimbursement':ti,ab,kw OR 'price volume agreement*':ti,ab,kw OR 'price volume arrangement*':ti,ab,kw OR 'price volume scheme*':ti,ab,kw) AND (discount*:ti,ab,kw OR reduction*:ti,ab,kw OR rebate*:ti,ab,kw) 171

#80 'flat discount*':ti,ab,kw 1

#79 (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw) AND rebate*:ti,ab,kw 338

#78 ((pricing OR price OR prices OR priced) NEAR/6 (discount* OR reduction*)):ti,ab,kw 2068

#77 #71 OR #72 OR #73 OR #74 OR #75 OR #76 1966

#76 (combin* NEAR/6 (procur* OR purchas*)):ti,ab,kw 299

#75 (collectiv* NEAR/6 (procur* OR purchas*)):ti,ab,kw 38

#74 ((share OR shares OR sharing OR shared) NEAR/6 (procur* OR purchas*)):ti,ab,kw 387

#73 (group* NEAR/3 (procur* OR purchas*)):ti,ab,kw 958

#72 (joint* NEAR/6 (procur* OR purchas*)):ti,ab,kw 142

#71 (pool* NEAR/6 (procur* OR purchas*)):ti,ab,kw 209

#70 #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 3590

#69 ('access with evidence development':ti,ab,kw OR 'conditional coverage':ti,ab,kw OR 'conditional treatment continuation':ti,ab,kw OR 'coverage with evidence development':ti,ab,kw OR 'only in research':ti,ab,kw OR 'only with research':ti,ab,kw OR 'outcome guarantee*':ti,ab,kw OR 'patient access scheme*':ti,ab,kw OR 'patient access agreement*':ti,ab,kw OR 'patient access arrangement*':ti,ab,kw OR 'pattern or process care':ti,ab,kw OR 'performance-based agreement*':ti,ab,kw OR 'performance-based scheme*':ti,ab,kw OR 'performance-based arrangement*':ti,ab,kw OR 'performance-based health outcome reimbursement':ti,ab,kw OR 'performance-linked reimbursement':ti,ab,kw OR 'price volume agreement*':ti,ab,kw OR 'price volume arrangement*':ti,ab,kw OR 'price volume scheme*':ti,ab,kw) AND (transparen*:ti,ab,kw OR accountab*:ti,ab,kw) 39

#68 'risk sharing scheme*':ti,ab,kw OR 'risk sharing agreement*':ti,ab,kw OR 'risk sharing arrangement*':ti,ab,kw 384

#67 (('access with evidence development' OR 'conditional coverage' OR 'conditional treatment continuation' OR 'coverage with evidence development' OR 'only in research' OR 'only with research' OR 'outcome guarantee*' OR 'patient access scheme*' OR 'patient access agreement*' OR 'patient access arrangement*' OR 'pattern or process care' OR 'performance-based agreement*' OR 'performance-based scheme*' OR 'performance-based arrangement*' OR 'performance-based health outcome reimbursement' OR 'performance-linked reimbursement' OR 'price volume agreement*' OR 'price volume arrangement*' OR 'price volume scheme*') NEAR/6 (publish* OR publication OR disclos* OR disseminat* OR communicat* OR shar*)):ti,ab,kw 34

#66 'managed entry':ti,ab,kw 175

#65 (((publish* OR publication OR disclos* OR disseminat* OR communicat* OR shar*) NEAR/6 information*):ti,ab,kw) AND (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw OR discount*:ti,ab,kw OR rebate*:ti,ab,kw) 399

#64 (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw OR discount*:ti,ab,kw OR rebate*:ti,ab,kw) AND (transparen*:ti,ab,kw OR accountab*:ti,ab,kw) 1339

#63 ((pricing OR price OR prices OR priced OR discount* OR rebate*) NEAR/6 (disclos* OR disseminat* OR communicat* OR shar*)):ti,ab,kw 812

#62 ((pricing OR price OR prices OR priced OR discount* OR rebate*) NEAR/6 (publish* OR publication)):ti,ab,kw 731

#61 #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 4461

#60 'cost-price*':ti,ab,kw OR 'purchase-price*':ti,ab,kw OR 'purchasing-price*':ti,ab,kw OR 'selling price*':ti,ab,kw 1040

#59 'profit margin*':ti,ab,kw OR 'gross margin*':ti,ab,kw 801

#58 ((drug OR drugs OR pharmaceutical OR pharmaceuticals OR biopharmaceutical OR biopharmaceuticals OR medicine OR medicines OR medication OR medications OR medicament OR medicaments OR prescription OR prescriptions OR generic* OR vaccine* OR biosimilar* OR 'bio-similar*' OR biogeneric* OR 'follow-on biologic*' OR 'subsequent entry biologic*' OR 'similar biologic*') NEAR/6 margin$):ti,ab,kw 809

#57 (('supply chain*' OR distribution) NEAR/6 (pricing OR price OR prices OR priced)):ti,ab,kw 315

#56 (('supply chain*' OR distribution) NEXT/1 cost*):ti,ab,kw 167

#55 ('mark-up':ab,kw OR 'mark-ups':ab,kw OR markup*:ab,kw) AND (regulat*:ab,kw OR manipulat*:ab,kw OR supply:ab,kw OR supplies:ab,kw OR distribut*:ab,kw OR wholesale*:ab,kw OR prescrib*:ab,kw OR prescrip*:ab,kw OR dispens*:ab,kw OR pricing:ab,kw OR price:ab,kw OR prices:ab,kw OR priced:ab,kw OR cost*:ab,kw OR economic*:ab,kw OR pharmacoeconomic*:ab,kw) 557

#54 (('mark-up' OR 'mark-ups' OR markup*) NEAR/3 control*):ab,kw 12

#53 'mark-up':ti OR 'mark-ups':ti OR markup*:ti 201

#52 ((pricing OR price OR prices OR priced) NEAR/6 (cap OR caps OR capped OR capping OR ceiling*)):ti,ab,kw 232

#51 ((pricing OR price OR prices OR priced) NEAR/6 maximum*):ti,ab,kw 376

#50 ((pricing OR price OR prices OR priced) NEAR/6 threshold*):ti,ab,kw 242

#49 #43 OR #44 OR #45 OR #46 OR #47 OR #48 5689

#48 ((pricing OR price OR prices OR priced) NEAR/3 (control* OR containment)):ti,ab,kw 941

#47 ((pricing OR price OR prices OR priced) NEAR/3 (set OR sets OR setting)):ti,ab,kw 818

#46 (((expense OR expenses) NEAR/3 (produc* OR promot* OR research* OR develop* OR administrat* OR overhead* OR 'over-head*' OR profit*)):ti,ab,kw) AND (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw) 78

#45 (((cost OR costs) NEAR/3 (produc* OR promot* OR expense* OR research* OR develop* OR administrat* OR overhead* OR 'over-head*' OR profit*)):ti,ab,kw) AND (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw) 2558

#44 (((cost OR costs) NEAR/3 based):ti,ab,kw) AND (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw) 1553

#43 'cost-plus':ti,ab,kw OR costplus:ti,ab,kw OR 'costs-plus':ti,ab,kw OR costsplus:ti,ab,kw 227

#42 #36 OR #37 OR #38 OR #39 OR #40 OR #41 6934

#41 ('economic evaluation*':ti,ab,kw OR 'cost-consequence*':ti,ab,kw OR 'cost-minimization':ti,ab,kw OR 'cost-minimisation':ti,ab,kw OR 'cost-effectiveness':ti,ab,kw OR 'cost-utility':ti,ab,kw OR 'cost-benefit*':ti,ab,kw) AND (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw) AND (based:ti,ab,kw OR set:ti,ab,kw OR sets:ti,ab,kw OR setting:ti,ab,kw) 3729

#40 (hta:ti,ab,kw OR htas:ti,ab,kw OR 'technology assessment*':ti,ab,kw OR 'technology appraisal*':ti,ab,kw) AND (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw) 1068

#39 ((value OR values) NEAR/6 (pricing OR price OR prices OR priced)):ti,ab,kw 1426

#38 'value-based':ti,ab,kw AND reimbursement:ti,ab,kw 706

#37 'value-based':ti,ab,kw AND (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw) 561

#36 'biomedical technology assessment'/de AND (#17 OR 'essential drug'/de) 763

#35 #31 OR #32 OR #33 OR #34 1375

#34 'factory* price*':ti,ab,kw OR 'manufacturer* price*':ti,ab,kw OR 'exfactory* price*':ti,ab,kw OR 'exmanufacturer* price*':ti,ab,kw 332

#33 ('international price' NEXT/1 (comparison* OR comparat*)):ti,ab,kw 23

#32 ((benchmark* OR 'bench mark*') NEAR/6 (pricing OR price OR prices OR priced)):ti,ab,kw 105

#31 (reference NEAR/6 (pricing OR price OR prices OR priced)):ti,ab,kw 1004

#30 #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR 'essential drug'/de OR drug:ti,ab,kw OR drugs:ti,ab,kw OR pharmaceutical:ti,ab,kw OR pharmaceuticals:ti,ab,kw OR biopharmaceutical:ti,ab,kw OR biopharmaceuticals:ti,ab,kw OR medicine:ti,ab,kw OR medicines:ti,ab,kw OR medication:ti,ab,kw OR medications:ti,ab,kw OR medicament:ti,ab,kw OR medicaments:ti,ab,kw OR prescription:ti,ab,kw OR prescriptions:ti,ab,kw OR generic*:ti,ab,kw OR vaccine*:ti,ab,kw OR

biosimilar*:ti,ab,kw OR 'bio-similar*':ti,ab,kw OR biogeneric*:ti,ab,kw OR 'follow-on biologic*':ti,ab,kw OR 'subsequent entry biologic*':ti,ab,kw OR 'similar biologic*':ti,ab,kw 3739114

#29 #3 OR #20 OR #27 OR #28 13940

#28 (drug:ti,ab,kw OR drugs:ti,ab,kw OR pharmaceutical:ti,ab,kw OR pharmaceuticals:ti,ab,kw OR biopharmaceutical:ti,ab,kw OR biopharmaceuticals:ti,ab,kw OR medicine:ti,ab,kw OR medicines:ti,ab,kw OR medication:ti,ab,kw OR medications:ti,ab,kw OR medicament:ti,ab,kw OR medicaments:ti,ab,kw OR prescription:ti,ab,kw OR prescriptions:ti,ab,kw OR generic*:ti,ab,kw OR vaccine*:ti,ab,kw OR biosimilar*:ti,ab,kw OR 'bio-similar*':ti,ab,kw OR biogeneric*:ti,ab,kw OR 'follow-on biologic*':ti,ab,kw OR 'subsequent entry biologic*':ti,ab,kw OR 'similar biologic*':ti,ab,kw) AND ('cost-control':ti,ab,kw OR 'cost-containment':ti,ab,kw OR 'cost-setting':ti,ab,kw) 2084

#27 #21 OR #22 OR #23 OR #24 OR #25 OR #26 7211

#26 (drug:ab,kw OR drugs:ab,kw OR pharmaceutical:ab,kw OR pharmaceuticals:ab,kw OR biopharmaceutical:ab,kw OR biopharmaceuticals:ab,kw OR medicine:ab,kw OR medicines:ab,kw OR medication:ab,kw OR medications:ab,kw OR medicament:ab,kw OR medicaments:ab,kw OR prescription:ab,kw OR prescriptions:ab,kw OR vaccine*:ab,kw) AND ('price regulation*':ab,kw OR 'price difference*':ab,kw OR 'price differential*':ab,kw OR 'price dispersion':ab,kw OR 'average price*':ab,kw OR 'retail price*':ab,kw OR 'wholesale price*':ab,kw OR 'expected price*':ab,kw OR 'net price*':ab,kw OR 'transaction price*':ab,kw OR 'price type*':ab,kw OR 'price component*':ab,kw OR 'cif price*':ab,kw OR 'freight price*':ab,kw OR 'pharmacy price*':ab,kw OR 'pharmacist* price*':ab,kw OR 'end price*':ab,kw OR 'consumer price*':ab,kw OR 'final price*':ab,kw OR 'reimbursement price*':ab,kw OR 'list price*':ab,kw OR 'actual price*':ab,kw) 2448

#25 (drug:ab,kw OR drugs:ab,kw OR pharmaceutical:ab,kw OR pharmaceuticals:ab,kw OR biopharmaceutical:ab,kw OR biopharmaceuticals:ab,kw OR medicine:ab,kw OR medicines:ab,kw OR medication:ab,kw OR medications:ab,kw OR medicament:ab,kw OR medicaments:ab,kw OR prescription:ab,kw OR prescriptions:ab,kw OR vaccine*:ab,kw) AND (((pricing OR price OR prices OR priced) NEAR/3 (arrangement* OR framework* OR 'frame-work*' OR intervention* OR law OR laws OR legal* OR legislat* OR measure OR measures OR measurement OR measurements OR mechanism* OR order OR orders OR plan OR plans OR planning OR principle OR principles OR procedure* OR program OR programme OR programmes OR programs OR regulat* OR requirement* OR rule OR rules OR scheme OR schemes OR standard OR standards OR strategies OR strategy OR strategic*)):ab,kw) 1650

#24 (drug:ab,kw OR drugs:ab,kw OR pharmaceutical:ab,kw OR pharmaceuticals:ab,kw OR biopharmaceutical:ab,kw OR biopharmaceuticals:ab,kw OR medicine:ab,kw OR medicines:ab,kw OR medication:ab,kw OR medications:ab,kw OR medicament:ab,kw OR medicaments:ab,kw OR prescription:ab,kw OR prescriptions:ab,kw OR vaccine*:ab,kw) AND (((pricing OR price OR prices OR priced) NEAR/6 (policy OR policies)):ab,kw) 808

#23 (drug:ti OR drugs:ti OR pharmaceutical:ti OR pharmaceuticals:ti OR biopharmaceutical:ti OR biopharmaceuticals:ti OR medicine:ti OR medicines:ti OR medication:ti OR medications:ti OR medicament:ti OR medicaments:ti OR prescription:ti OR prescriptions:ti OR vaccine*:ti) AND (price:ti OR prices:ti OR priced:ti) 2166

#22 ((drug OR drugs OR pharmaceutical OR pharmaceuticals OR biopharmaceutical OR biopharmaceuticals OR medicine OR medicines OR medication OR medications OR medicament OR medicaments OR prescription OR prescriptions OR vaccine*) NEAR/6 pricing):ab,kw 1829

#21 (drug:ti OR drugs:ti OR pharmaceutical:ti OR pharmaceuticals:ti OR biopharmaceutical:ti OR biopharmaceuticals:ti OR medicine:ti OR medicines:ti OR medication:ti OR medications:ti OR medicament:ti OR medicaments:ti OR prescription:ti OR prescriptions:ti OR vaccine*:ti) AND pricing:ti 959

#20 #17 AND #18 AND #19 7647

#19 policy:ti,ab,kw OR policies:ti,ab,kw OR arrangement*:ti,ab,kw OR framework*:ti,ab,kw OR 'frame-work*':ti,ab,kw OR intervention*:ti,ab,kw OR law:ti,ab,kw OR laws:ti,ab,kw OR legal*:ti,ab,kw OR legislat*:ti,ab,kw OR measure:ti,ab,kw OR measures:ti,ab,kw OR measurement:ti,ab,kw OR measurements:ti,ab,kw OR mechanism*:ti,ab,kw OR order:ti,ab,kw OR orders:ti,ab,kw OR plan:ti,ab,kw OR plans:ti,ab,kw OR planning:ti,ab,kw OR principle:ti,ab,kw OR principles:ti,ab,kw OR procedure*:ti,ab,kw OR program:ti,ab,kw OR programme:ti,ab,kw OR programmes:ti,ab,kw OR programs:ti,ab,kw OR regulat*:ti,ab,kw OR requirement*:ti,ab,kw OR rule:ti,ab,kw OR rules:ti,ab,kw OR scheme:ti,ab,kw OR schemes:ti,ab,kw OR standard:ti,ab,kw OR standards:ti,ab,kw OR strategies:ti,ab,kw OR strategy:ti,ab,kw OR strategic*:ti,ab,kw 12219088

#18 pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw 53760

#17 #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 171301

#16 'cost control'/de AND (drug:ti,ab,kw OR drugs:ti,ab,kw OR pharmaceutical:ti,ab,kw OR pharmaceuticals:ti,ab,kw OR biopharmaceutical:ti,ab,kw OR biopharmaceuticals:ti,ab,kw OR medicine:ti,ab,kw OR medicines:ti,ab,kw OR medication:ti,ab,kw OR medications:ti,ab,kw OR medicament:ti,ab,kw OR medicaments:ti,ab,kw OR prescription:ti,ab,kw OR prescriptions:ti,ab,kw OR generic*:ti,ab,kw OR vaccine*:ti,ab,kw OR biosimilar*:ti,ab,kw OR 'bio-similar*':ti,ab,kw OR biogeneric*:ti,ab,kw OR 'follow-on biologic*':ti,ab,kw OR 'subsequent entry biologic*':ti,ab,kw OR 'similar biologic*':ti,ab,kw) 14573

#15 'commercial phenomena'/de AND (drug:ti,ab,kw OR drugs:ti,ab,kw OR pharmaceutical:ti,ab,kw OR pharmaceuticals:ti,ab,kw OR biopharmaceutical:ti,ab,kw OR biopharmaceuticals:ti,ab,kw OR medicine:ti,ab,kw OR medicines:ti,ab,kw OR medication:ti,ab,kw OR medications:ti,ab,kw OR medicament:ti,ab,kw OR medicaments:ti,ab,kw OR prescription:ti,ab,kw OR prescriptions:ti,ab,kw OR generic*:ti,ab,kw OR vaccine*:ti,ab,kw OR biosimilar*:ti,ab,kw OR 'bio-similar*':ti,ab,kw OR biogeneric*:ti,ab,kw OR 'follow-on biologic*':ti,ab,kw OR 'subsequent entry biologic*':ti,ab,kw OR 'similar biologic*':ti,ab,kw) 5663

#14 'cost control'/de AND ('drug industry'/de OR 'drug approval'/de OR 'legislation, drug'/de OR 'drug control'/de OR 'drug and narcotic control'/de) 2752

#13 'commercial phenomena'/de AND ('drug industry'/de OR 'drug approval'/de OR 'legislation, drug'/de OR 'drug control'/de OR 'drug and narcotic control'/de) 3919

#12 'reimbursement mechanisms'/de AND ('drug industry'/de OR 'drug approval'/de OR 'legislation, drug'/de OR 'drug control'/de OR 'drug and narcotic control'/de) 2381

#11 ('drug approval'/de OR 'drug'/exp OR 'vaccine'/exp OR 'biological product'/de) AND 'economics'/de OR 'generic drug'/de OR 'biosimilar agent'/de 21742

#10 'health insurance'/de AND 'economics'/de 23463

#9 'drug substitution'/de AND 'economics'/de 55

#8 ('prescription'/de OR 'prescription drug'/de OR 'drug'/exp) AND 'fee'/de 848

#7 'prescription drug'/de AND 'economics'/de 491

#6 'prescription'/de AND 'economics'/de 2152

#5 pharmacoeconomics/lnk OR 'pharmacoeconomics'/de 82162

#4 'drug cost'/de 74843

#3 #1 OR #2 438

#2 'essential drug'/de AND (pricing:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR priced:ti,ab,kw OR cost*:ti,ab,kw OR economic*:ti,ab,kw OR pharmacoeconomic*:ti,ab,kw) 401

#1 'essential drug'/dd_pe 86

A.4: Source: CDSR

Interface / URL: Cochrane Library / Wiley
Database coverage dates: Issue 9 of 12, September 2019

Search date: 06/09/2019

Retrieved records: 25

Search strategy:

#1 ((pricing or price or prices or priced) AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines)):ti 25

#2 ((pricing or price or prices or priced) NEAR/6 (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines)):ab 313

#3 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ((pricing or price or prices or priced) NEAR/6 (policy or policies))):ti,ab 16

#4 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ((pricing or price or prices or priced) NEAR/3 (arrangement or arrangements or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic*))):ti,ab 35

#5 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ("price regulation" or "price regulations" or "price difference" or "price differences" or "price differential" or "price differentials" or "price dispersion" or "average price" or "average prices" or "retail price" or "retail prices" or "wholesale price" or "wholesale prices" or "expected price" or "expected prices" or "net price" or "net prices" or "transaction price" or "transaction prices" or "price type" or "price types" or "price component" or "price components" or "cif price" or "cif prices" or "freight price" or "freight prices" or "pharmacy price" or "pharmacy prices" or "pharmacist price" or "pharmacist prices" or "pharmacists price" or "pharmacists prices" or "end price" or "end prices" or "consumer price" or "consumer prices" or "final price" or "final prices" or "reimbursement price" or "reimbursement prices" or "list price" or "list prices" or "actual price" or "actual prices")):ti,ab 134

#6 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND (cost-control or cost-containment or cost-setting)):ti,ab 69

#7 #1 or #2 or #3 or #4 or #5 or #6 490

#8 (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics"):ti,ab 318691

#9 ((reference or benchmark or benchmarks or bench-mark or bench-marks) NEAR/6 (pricing or prices or price or priced)):ti,ab 43

#10 ("international price comparison" or "international price comparisons" or "comparative price" or "comparative prices" or "factory price" or "factory prices" or "factories price" or "factories prices" or "manufacturer price" or "manufacturer prices" or "manufacturers price" or "manufacturers prices" or "exfactory price" or "exfactory prices" or "exfactorys price" or "exfactorys prices" or "exmanufacturer price" or "exmanufacturer prices" or "exmanufacturers price" or "exmanufacturers prices"):ti,ab 8

#11 (value-based and (pricing or price or prices or priced or reimbursement)) or ((value or values) NEAR/6 (pricing or price or prices or priced)):ti,ab 74

#12 (("economic evaluation" or "economic evaluations" or cost-consequence or cost-consequences or cost-minimization or cost-minimisation or cost-effectiveness or cost-utility or cost-benefit or cost-benefits) and (pricing or price or prices or priced) and (based or set or sets or setting)):ti,ab 500

#13 (cost-plus or costplus or costs-plus or costsplus):ti,ab 24

#14 (((cost or costs) NEAR/3 (based or produc* or promot* or expense* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits)) AND (pricing or price or prices or priced)):ti,ab 262

#15 ((expense or expenses) NEAR/3 (produc* or promot* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits)) AND (pricing or price or prices or priced):ti,ab 4

#16 ((pricing or price or prices or priced) NEAR/3 (set or sets or setting or control* or containment or preferential)):ti,ab 43

#17 ((pricing or price or prices or priced) NEAR/6 (threshold or thresholds or maximum or maximums or cap or caps or capped or capping or ceiling or ceilings or discount* or reduction*)):ti,ab 154

#18 (mark-up or mark-ups or markup*):ti 0

#19 ((mark-up or mark-ups or markup*) NEAR/3 control*):ab 0

#20 ((mark-up or mark-ups or markup*) AND (regulat* or manipulat* or supply or supplies or distribut* or wholesale* or prescrib* or prescrip* or dispens* or pricing or price or prices or priced or cost or costs or costing or costed or economic or economics or pharmacoeconomic or pharmacoeconomics)):ti,ab 5

#21 (("supply chain" or "supply chains" or distribution) NEAR/3 (cost or costs or costed or costing)) OR (("supply chain" or "supply chains" or distribution) NEAR/6 (price or prices or priced or pricing)):ti,ab 213

#22 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics") NEAR/6 (margin or margins)):ti,ab 56

#23 ("profit margin" or "profit margins" or "gross margin" or "gross margins" or "cost price" or "cost prices" or "purchase price" or "purchase prices" or "purchasing price" or "purchasing prices" or "selling price" or "selling prices"):ti,ab 73

#24 ((pricing or price or prices or priced or discount or discounts or rebate or rebates) NEAR/6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)):ti,ab 60

#25 ((pricing or price or prices or priced or discount or discounts or rebate or rebates) AND (transparen* or accountab*)):ti,ab 30

#26 ((pricing or price or prices or priced) AND (rebate or rebates or rebated)):ti,ab 7

#27 (((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR/6 (information*)) AND (pricing or price or prices or priced or discount or discounts or rebate or rebates)):ti,ab 10

#28 ("managed entry"):ti,ab 2

#29 (("access with evidence development" or “conditional coverage” or “conditional treatment continuation” or "coverage with evidence development" or "only in research" or "only with research" or “outcome guarantee” or “outcome guarantees” or “patient access scheme” or “patient access schemes” or “patient access agreement” or “patient access agreements" or "patient access arrangement” or "patient access arrangements" or "pattern or process care" or “performance-based agreement” or “performance-based agreements” or “performance-based scheme” or “performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or "performance-based health outcome reimbursement" or “performance-linked reimbursement” or "price volume agreement" or "price volume agreements" or “price volume arrangement” or “price volume arrangements" or “price volume scheme” or “price volume schemes”) NEAR/6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)):ti,ab1

#30 ("risk sharing scheme" or "risk sharing schemes" or "risk sharing agreement" or "risk sharing agreements" or "risk sharing arrangement" or "risk sharing arrangements"):ti,ab 6

#31 (("access with evidence development" or “conditional coverage” or “conditional treatment continuation” or "coverage with evidence development" or "only in research" or "only with research" or “outcome guarantee” or “outcome guarantees” or “patient access scheme” or “patient access schemes” or “patient access agreement” or “patient access agreements" or "patient access arrangement” or "patient access arrangements" or "pattern or process care" or “performance-based agreement” or “performance-based agreements” or “performance-based scheme” or “performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or "performance-based health outcome reimbursement" or “performance-linked reimbursement” or "price volume agreement" or "price volume agreements" or “price volume arrangement” or “price volume arrangements" or “price volume scheme” or “price volume schemes”) AND (transparen* or accountab* or discount* or reduction* or rebate*)):ti,ab17

#32 ((pool* OR joint* or share or shares or sharing or shared or collectiv* or combin*) NEAR/6 (procur* or purchas*)) OR tiab(group* NEAR/3 (procur* or purchas*)):ti,ab 48

#33 ("flat discount" or "flat discounts" or "competitive pricing" or "competitive price" or "competitive prices"):ti,ab 2

#34 ((pricing or price or prices or priced or purchas*) AND (tender or tenders or tendering or tendered or procur* or (prescription* NEAR/3 charge*))):ti,ab 33

#35 ((pricing or price or prices or priced or purchas*) NEAR/6 (bid or bids or bidder* or bidding or negotiat* or offer or offers or offered or offering)):ti,ab 73

#36 ((pricing or price or prices or priced or purchas*) NEAR/3 (discuss* or agree*)):ti,ab 13

#37 ((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) NEAR/6 (reduc* or exempt* or remov* or policy or policies or arrangement or arrangement or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic* or duty OR duties) NEAR/6 (reduc* or exempt* or remov* or policy or policies or arrangement or arrangement or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic*) AND (pricing or price or prices or priced)):ti,ab 18

#38 ((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat or duty or duties) NEAR/3 free):ti,ab 8

#39 #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 1327

#40 #8 and #39 623

#41 ((generic* or non-proprietary or nonproprietary or INN or "tier 1" or tier1 or "tier one" or off-patent* or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics") AND (pricing or price or prices or priced or cost-saving or cost-savings or cost-share or cost-sharing or "prescribing cost" or "prescribing costs" or "prescription cost" or "prescription costs" or "dispensing cost" or "dispensing costs")):ti,ab 189

#42 #7 or #40 or #41 with Cochrane Library publication date from Jan 2004 to present, in Cochrane Reviews 25

A.5: Source: NHS EED

Interface / URL: CRD

Database coverage dates: Information not found. Bibliographic records were published on NHS EED until 31st March 2015. Searches of MEDLINE, Embase, CINAHL, PsycINFO and PubMed were continued until the end of the 2014.

Search date: 13/09/2019

Retrieved records: 2568

Search strategy:

Search	Hits
1	(((pricing or price or prices or priced) AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines)):TI) 10
2	((pricing or price or prices or priced) NEAR6 (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines)) 538
3	((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) NEAR6 (pricing or price or prices or priced)) 933
4	(((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ((pricing or price or prices or priced) NEAR6 (policy or policies)))) 8
5	((((policy or policies) NEAR6 (pricing or price or prices or priced)) AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines))) 9
6	((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ((pricing or price or prices or priced) NEAR3 (arrangement or arrangements or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic*))) 68
7	((((arrangement or arrangements or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic*) NEAR3 (pricing or price or prices or priced)) AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines))) 162

8 (((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ("price regulation" or "price regulations" or "price difference" or "price differences" or "price differential" or "price differentials" or "price dispersion" or "average price" or "average prices" or "retail price" or "retail prices" or "wholesale price" or "wholesale prices" or "expected price" or "expected prices" or "net price" or "net prices" or "transaction price" or "transaction prices" or "price type" or "price types" or "price component" or "price components" or "cif price" or "cif prices" or "freight price" or "freight prices" or "pharmacy price" or "pharmacy prices" or "pharmacist price" or "pharmacist prices" or "pharmacists price" or "pharmacists prices" or "end price" or "end prices" or "consumer price" or "consumer prices" or "final price" or "final prices" or "reimbursement price" or "reimbursement prices" or "list price" or "list prices" or "actual price" or "actual prices"))) 1279

9 (((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND (cost-control or cost-containment or cost-setting))) 97

10 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 2233

11 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) 34233

12 ((reference or benchmark or benchmarks or bench-mark or bench-marks) NEAR6 (pricing or prices or price or priced)) 60

13 ((pricing or prices or price or priced) NEAR6 (reference OR benchmark or benchmarks or bench-mark or bench-marks)) 22

14 (("international price comparison" or "international price comparisons" or "comparative price" or "comparative prices" or "factory price" or "factory prices" or "factories price" or "factories prices" or "manufacturer price" or "manufacturer prices" or "manufacturers price" or "manufacturers prices" or "exfactory price" or "exfactory prices" or "exfactorys price" or "exfactorys prices" or "exmanufacturer price" or "exmanufacturer prices" or "exmanufacturers price" or "exmanufacturers prices")) 19

15 (((value-based and (pricing or price or prices or priced or reimbursement)) OR ((value or values) NEAR6 (pricing or price or prices or priced)))) 186

16 ((pricing or price or prices or priced) NEAR6 (value or values)) 91

17 ((pricing or price or prices or priced) NEAR6 (based or set or sets or setting)) 297

18 ((based or set or sets or setting) NEAR6 (pricing or price or prices or priced)) 841

19 ((cost-plus or costplus or costs-plus or costsplus)) 41

20 ((based or produc* or promot* or expense* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits) NEAR6 (pricing or price or prices or priced)) 790

21 ((pricing or price or prices or priced) NEAR6 (based or produc* or promot* or expense* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits)) 312

22 (((expense or expenses) NEAR3 (produc* or promot* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits)) AND (pricing or price or prices or priced)) 28

23 (((produc* or promot* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits) NEAR3 (expense or expenses)) AND (pricing or price or prices or priced)) 34

24 ((pricing or price or prices or priced) NEAR3 (set or sets or setting or control* or containment or preferential)) 19

25 ((set or sets or setting or control* or containment or preferential) NEAR6 (pricing or price or prices or priced)) 247

26 ((pricing or price or prices or priced) NEAR6 (threshold or thresholds or maximum or maximums or cap or caps or capped or capping or ceiling or ceilings or discount* or reduction*)) 1683

27 ((threshold or thresholds or maximum or maximums or cap or caps or capped or capping or ceiling or ceilings or discount* or reduction*) NEAR6 (pricing or price or prices or priced)) 858

28 ((mark-up or mark-ups or markup*):TI) 0

29 (((mark-up or mark-ups or markup*) NEAR3 control*)) 0

30 (control* NEAR3 (mark-up or mark-ups or markup*)) 0

31 ((mark-up or mark-ups or markup*) AND (regulat* or manipulat* or supply or supplies or distribut* or wholesale* or prescrib* or prescrip* or dispens* or pricing or price or prices or priced or cost or costs or costing or costed or economic or economics or pharmacoeconomic or pharmacoeconomics)) 39

32 (("supply chain" or "supply chains" or distribution) NEAR3 (cost or costs or costed or costing)) 291

33 ((cost or costs or costed or costing) NEAR3 ("supply chain" or "supply chains" or distribution)) 42

34 (("supply chain" or "supply chains" or distribution) NEAR6 (price or prices or priced or pricing)) 5

35 ((price or prices or priced or pricing) NEAR6 ("supply chain" or "supply chains" or distribution)) 2

36 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics") NEAR6 (margin or margins)) 1

37 (("profit margin" or "profit margins" or "gross margin" or "gross margins" or "cost price" or "cost prices" or "purchase price" or "purchase prices" or "purchasing price" or "purchasing prices" or "selling price" or "selling prices")) 124

38 ((pricing or price or prices or priced or discount or discounts or rebate or rebates) NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 226

39 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 (pricing or price or prices or priced or discount or discounts or rebate or rebates)) 1586

40 ((pricing or price or prices or priced) AND (rebate or rebates or rebated)) 16

41 (((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 (information*)) AND (pricing or price or prices or priced or discount or discounts or rebate or rebates)) 248

42 ((information*) NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) AND (pricing or price or prices or priced or discount or discounts or rebate or rebates)) 132

43 (("managed entry")) 2

44 (("access with evidence development" or "conditional coverage" or "conditional treatment continuation" or "coverage with evidence development" or "only in research" or "only with research" or "outcome guarantee" or "outcome guarantees" or "patient access scheme" or "patient access schemes" or "patient access agreement" or "patient access agreements" or "patient access arrangement" or "patient access arrangements") NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 0

45 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 ("access with evidence development" or "conditional coverage" or "conditional treatment continuation" or "coverage with evidence development" or "only in research" or "only with research" or "outcome guarantee" or "outcome guarantees" or "patient access scheme" or "patient access schemes" or "patient access agreement" or "patient access agreements" or "patient access arrangement" or "patient access arrangements")) 0

46 (("performance-linked reimbursement" or "price volume agreement" or "price volume agreements" or "price volume arrangement" or "price volume arrangements" or "price volume scheme" or "price volume schemes") NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 0

47 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 ("performance-linked reimbursement" or "price volume agreement" or "price volume agreements" or "price volume arrangement" or "price volume arrangements" or "price volume scheme" or "price volume schemes")) 0

48 (("performance-based agreement" or "performance-based agreements" or "performance-based scheme" or "performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or "performance-based health outcome reimbursement") NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 0

49 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 ("performance-based agreement" or "performance-based agreements" or "performance-based scheme" or "performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or "performance-based health outcome reimbursement")) 0

50 ((pattern NEAR3 process care) NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 0

51 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 (pattern NEAR3 process care)) 0

52 (("risk sharing scheme" or "risk sharing schemes" or "risk sharing agreement" or "risk sharing agreements" or "risk sharing arrangement" or "risk sharing arrangements")) 2

53 (("access with evidence development" or "conditional coverage" or "conditional treatment continuation" or "coverage with evidence development" or "only in research" or "only with research" or "outcome guarantee" or "outcome guarantees")) 11

54 (("patient access scheme" or "patient access schemes" or "patient access agreement" or "patient access agreements" or "patient access arrangement")) 28

55 (((pattern NEAR1 process NEAR0 care))) 0

56 (("patient access arrangements" or "performance-based agreement" or "performance-based agreements" or "performance-based scheme" or "performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or "performance-based health outcome reimbursement" or "performance-linked reimbursement" or "price volume agreement" or "price volume agreements" or "price volume arrangement" or "price volume arrangements" or "price volume scheme" or "price volume schemes")) 0

57 (#53 OR #54 OR #55 OR #56) 39

58 ((transparen* or accountab* or discount* or reduction* or rebate*)) 15589

59 (#57 AND #58) 2

60 ((pool* or joint* or share or shares or sharing or shared or collectiv* or combin*) NEAR6 (procur* or purchas*)) 3

61 ((procur* or purchas*) NEAR6 (pool* or joint* or share or shares or sharing or shared or collectiv* or combin*)) 6

62 (group* NEAR3 (procur* or purchas*)) 5

63 ((procur* or purchas*) NEAR3 group*) 4

64 (("flat discount" or "flat discounts" or "competitive pricing" or "competitive price" or "competitive prices")) 2

65 ((pricing or price or prices or priced or purchas*) AND (tender or tenders or tendering or tendered or procur* or (prescription* NEAR3 charge*) or (charge* NEAR3 prescription))) 74

66 ((pricing or price or prices or priced or purchas*) NEAR6 (bid or bids or bidder* or bidding or negotiat* or offer or offers or offered or offering)) 21

67 ((bid or bids or bidder* or bidding or negotiat* or offer or offers or offered or offering) NEAR6 (pricing or price or prices or priced or purchas*)) 26

68 ((pricing or price or prices or priced or purchas*) NEAR3 (discuss* or agree*)) 10

69 ((discuss* or agree*) NEAR3 (pricing or price or prices or priced or purchas*)) 19

70 (((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) NEAR6 (reduc* or exempt* or remov* or policy or policies or arrangement or arrangement or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic* or duty duties)) AND (pricing or price or prices or priced)) 37

71 (((reduc* or exempt* or remov* or policy or policies or arrangement or arrangement or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic* or duty duties) NEAR6 (tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat)) AND (pricing or price or prices or priced)) 36

72 (((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat or duty or duties) NEAR3 free)) 0

73 (Free NEAR3 (tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat or duty or duties)) 0

74 ((pricing or price or prices or priced or discount or discounts or rebate or rebates) AND (transparen* or accountab*)) 942

75 ((margin or margins) NEAR6 (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines or biosimilar or

biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) 0

76 #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71 OR #72 OR #73 OR #74 OR #75 5380

77 #11 AND #76 3976

78 (generic* or non-proprietary or nonproprietary or INN or "tier 1" or tier1 or "tier one" or off-patent* or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics") AND (pricing or price or prices or priced or cost-saving or cost-savings or cost-share or cost-sharing or "prescribing cost" or "prescribing costs" or "prescription cost" or "prescription costs" or "dispensing cost" or "dispensing costs") 380

79 #10 OR #77 OR #78 4743

80 (#10 OR #77 OR #78) IN DARE FROM 2004 TO 2019 24

81 (#10 OR #77 OR #78) IN NHSEED FROM 2004 TO 2019 2568

82 (#10 OR #77 OR #78) IN HTA FROM 2004 TO 2019 66

A.6: Source: Source: DARE

Interface / URL: CRD
Database coverage dates: Last updated Issue 2 of 4, April 2015

Search date: 13/09/2019

Retrieved records: 24

Search strategy:

Search Hits

1 (((pricing or price or prices or priced) AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines)):TI) 10

2 ((pricing or price or prices or priced) NEAR6 (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines)) 538

3 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) NEAR6 (pricing or price or prices or priced)) 933

4 (((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ((pricing or price or prices or priced) NEAR6 (policy or policies)))) 8

5 ((((policy or policies) NEAR6 (pricing or price or prices or priced)) AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines))) 9

6 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ((pricing or price or prices or priced) NEAR3 (arrangement or arrangements or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic*))) 68

7 ((((arrangement or arrangements or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic*) NEAR3 (pricing or price or prices or priced)) AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines))) 162

8 (((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ("price regulation" or "price regulations" or "price difference" or "price differences" or "price differential" or "price differentials" or "price dispersion" or "average price" or "average prices" or "retail price" or "retail prices" or "wholesale price" or "wholesale prices" or "expected price" or "expected prices" or "net price" or "net prices" or "transaction price" or "transaction prices" or "price type" or "price types" or "price component" or "price components" or "cif price" or "cif prices" or "freight price" or "freight prices" or "pharmacy price" or "pharmacy prices" or "pharmacist price" or "pharmacist

prices" or "pharmacists price" or "pharmacists prices" or "end price" or "end prices" or "consumer price" or "consumer prices" or "final price" or "final prices" or "reimbursement price" or "reimbursement prices" or "list price" or "list prices" or "actual price" or "actual prices"))) 1279

9 (((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND (cost-control or cost-containment or cost-setting))) 97

10 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 2233

11 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) 34233

12 ((reference or benchmark or benchmarks or bench-mark or bench-marks) NEAR6 (pricing or prices or price or priced)) 60

13 ((pricing or prices or price or priced) NEAR6 (reference OR benchmark or benchmarks or bench-mark or bench-marks)) 22

14 (("international price comparison" or "international price comparisons" or "comparative price" or "comparative prices" or "factory price" or "factory prices" or "factories price" or "factories prices" or "manufacturer price" or "manufacturer prices" or "manufacturers price" or "manufacturers prices" or "exfactory price" or "exfactory prices" or "exfactorys price" or "exfactorys prices" or "exmanufacturer price" or "exmanufacturer prices" or "exmanufacturers price" or "exmanufacturers prices")) 19

15 (((value-based and (pricing or price or prices or priced or reimbursement)) OR ((value or values) NEAR6 (pricing or price or prices or priced)))) 186

16 ((pricing or price or prices or priced) NEAR6 (value or values)) 91

17 ((pricing or price or prices or priced) NEAR6 (based or set or sets or setting)) 297

18 ((based or set or sets or setting) NEAR6 (pricing or price or prices or priced)) 841

19 ((cost-plus or costplus or costs-plus or costsplus)) 41

20 ((based or produc* or promot* or expense* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits) NEAR6 (pricing or price or prices or priced)) 790

21 ((pricing or price or prices or priced) NEAR6 (based or produc* or promot* or expense* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits)) 312

22 (((expense or expenses) NEAR3 (produc* or promot* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits)) AND (pricing or price or prices or priced)) 28

23 (((produc* or promot* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits) NEAR3 (expense or expenses)) AND (pricing or price or prices or priced)) 34

24 ((pricing or price or prices or priced) NEAR3 (set or sets or setting or control* or containment or preferential)) 19

25 ((set or sets or setting or control* or containment or preferential) NEAR6 (pricing or price or prices or priced)) 247

26 ((pricing or price or prices or priced) NEAR6 (threshold or thresholds or maximum or maximums or cap or caps or capped or capping or ceiling or ceilings or discount* or reduction*)) 1683

27 ((threshold or thresholds or maximum or maximums or cap or caps or capped or capping or ceiling or ceilings or discount* or reduction*) NEAR6 (pricing or price or prices or priced)) 858

28 ((mark-up or mark-ups or markup*):TI) 0

29 (((mark-up or mark-ups or markup*) NEAR3 control*)) 0

30 (control* NEAR3 (mark-up or mark-ups or markup*)) 0

31 ((mark-up or mark-ups or markup*) AND (regulat* or manipulat* or supply or supplies or distribut* or wholesale* or prescrib* or prescrip* or dispens* or pricing or price or prices or priced or cost or costs or costing or costed or economic or economics or pharmacoeconomic or pharmacoeconomics)) 39

32 (("supply chain" or "supply chains" or distribution) NEAR3 (cost or costs or costed or costing)) 291

33 ((cost or costs or costed or costing) NEAR3 ("supply chain" or "supply chains" or distribution)) 42

34 (("supply chain" or "supply chains" or distribution) NEAR6 (price or prices or priced or pricing)) 5

35 ((price or prices or priced or pricing) NEAR6 ("supply chain" or "supply chains" or distribution)) 2

36 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics") NEAR6 (margin or margins)) 1

37 (("profit margin" or "profit margins" or "gross margin" or "gross margins" or "cost price" or "cost prices" or "purchase price" or "purchase prices" or "purchasing price" or "purchasing prices" or "selling price" or "selling prices")) 124

38 ((pricing or price or prices or priced or discount or discounts or rebate or rebates) NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 226

39 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 (pricing or price or prices or priced or discount or discounts or rebate or rebates)) 1586

40 ((pricing or price or prices or priced) AND (rebate or rebates or rebated)) 16

41 (((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 (information*)) AND (pricing or price or prices or priced or discount or discounts or rebate or rebates)) 248

42 ((information*) NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) AND (pricing or price or prices or priced or discount or discounts or rebate or rebates)) 132

43 (("managed entry")) 2

44 (("access with evidence development" or "conditional coverage" or "conditional treatment continuation" or "coverage with evidence development" or "only in research" or "only with research" or "outcome guarantee" or "outcome guarantees" or "patient access scheme" or "patient access schemes" or "patient access agreement" or "patient access agreements" or "patient access arrangement" or "patient access arrangements") NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 0

45 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 ("access with evidence development" or "conditional coverage" or "conditional treatment continuation" or "coverage with evidence development" or "only in research" or "only with research" or "outcome guarantee" or "outcome guarantees" or "patient access scheme" or "patient access schemes" or "patient access agreement" or "patient access agreements" or "patient access arrangement" or "patient access arrangements")) 0

46 (("performance-linked reimbursement" or "price volume agreement" or "price volume agreements" or "price volume arrangement" or "price volume arrangements" or "price volume scheme" or "price volume schemes") NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 0

47 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 ("performance-linked reimbursement" or "price volume agreement" or "price volume agreements" or "price volume arrangement" or "price volume arrangements" or "price volume scheme" or "price volume schemes")) 0

48 (("performance-based agreement" or "performance-based agreements" or "performance-based scheme" or "performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or "performance-based health outcome reimbursement") NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 0

49 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 ("performance-based agreement" or "performance-based agreements" or "performance-

based scheme" or "performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or "performance-based health outcome reimbursement")) 0

50 ((pattern NEAR3 process care) NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 0

51 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 (pattern NEAR3 process care)) 0

52 (("risk sharing scheme" or "risk sharing schemes" or "risk sharing agreement" or "risk sharing agreements" or "risk sharing arrangement" or "risk sharing arrangements")) 2

53 (("access with evidence development" or "conditional coverage" or "conditional treatment continuation" or "coverage with evidence development" or "only in research" or "only with research" or "outcome guarantee" or "outcome guarantees")) 11

54 (("patient access scheme" or "patient access schemes" or "patient access agreement" or "patient access agreements" or "patient access arrangement")) 28

55 (((pattern NEAR1 process NEAR0 care))) 0

56 (("patient access arrangements" or "performance-based agreement" or "performance-based agreements" or "performance-based scheme" or "performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or "performance-based health outcome reimbursement" or "performance-linked reimbursement" or "price volume agreement" or "price volume agreements" or "price volume arrangement" or "price volume arrangements" or "price volume scheme" or "price volume schemes")) 0

57 (#53 OR #54 OR #55 OR #56) 39

58 ((transparen* or accountab* or discount* or reduction* or rebate*)) 15589

59 (#57 AND #58) 2

60 ((pool* or joint* or share or shares or sharing or shared or collectiv* or combin*) NEAR6 (procur* or purchas*)) 3

61 ((procur* or purchas*) NEAR6 (pool* or joint* or share or shares or sharing or shared or collectiv* or combin*)) 6

62 (group* NEAR3 (procur* or purchas*)) 5

63 ((procur* or purchas*) NEAR3 group*) 4

64 (("flat discount" or "flat discounts" or "competitive pricing" or "competitive price" or "competitive prices")) 2

65 ((pricing or price or prices or priced or purchas*) AND (tender or tenders or tendering or tendered or procur* or (prescription* NEAR3 charge*) or (charge* NEAR3 prescription))) 74

66 ((pricing or price or prices or priced or purchas*) NEAR6 (bid or bids or bidder* or bidding or negotiat* or offer or offers or offered or offering)) 21

67 ((bid or bids or bidder* or bidding or negotiat* or offer or offers or offered or offering) NEAR6 (pricing or price or prices or priced or purchas*)) 26

68 ((pricing or price or prices or priced or purchas*) NEAR3 (discuss* or agree*)) 10

69 ((discuss* or agree*) NEAR3 (pricing or price or prices or priced or purchas*)) 19

70 (((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) NEAR6 (reduc* or exempt* or remov* or policy or policies or arrangement or arrangement or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic* or duty duties)) AND (pricing or price or prices or priced)) 37

71 (((reduc* or exempt* or remov* or policy or policies or arrangement or arrangement or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic* or duty duties) NEAR6 (tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat)) AND (pricing or price or prices or priced)) 36

72 (((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat or duty or duties) NEAR3 free)) 0

73 (Free NEAR3 (tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat or duty or duties)) 0

74 ((pricing or price or prices or priced or discount or discounts or rebate or rebates) AND (transparen* or accountab*)) 942

75 ((margin or margins) NEAR6 (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) 0

76 #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49

OR #50 OR #51 OR #52 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71 OR #72 OR #73 OR #74 OR #75 5380

77 #11 AND #76 3976

78 (generic* or non-proprietary or nonproprietary or INN or "tier 1" or tier1 or "tier one" or off-patent* or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics") AND (pricing or price or prices or priced or cost-saving or cost-savings or cost-share or cost-sharing or "prescribing cost" or "prescribing costs" or "prescription cost" or "prescription costs" or "dispensing cost" or "dispensing costs") 380

79 #10 OR #77 OR #78 4743

80 (#10 OR #77 OR #78) IN DARE FROM 2004 TO 2019 24

81 (#10 OR #77 OR #78) IN NHSEED FROM 2004 TO 2019 2568

82 (#10 OR #77 OR #78) IN HTA FROM 2004 TO 2019 66

A.7: Source: Source: HTA

Interface / URL: CRD
Database coverage dates: Information not found. From 31 March 2018, the HTA database remains available, but CRD are no longer adding new records to it. INAHTA will be taking over production and the next phase of the database development. Updating and addition of new records will resume on their new platform, when it is ready.

Search date: 13/09/2019

Retrieved records: 66

Search strategy:

Search Hits

1 (((pricing or price or prices or priced) AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines)):TI) 10

2 ((pricing or price or prices or priced) NEAR6 (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines)) 538

3 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) NEAR6 (pricing or price or prices or priced)) 933

4 (((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ((pricing or price or prices or priced) NEAR6 (policy or policies)))) 8

5 ((((policy or policies) NEAR6 (pricing or price or prices or priced)) AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines))) 9

6 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ((pricing or price or prices or priced) NEAR3 (arrangement or arrangements or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic*))) 68

7 ((((arrangement or arrangements or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic*) NEAR3 (pricing or price or prices or priced)) AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines))) 162

8 (((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ("price regulation" or "price regulations" or "price difference" or "price differences" or "price differential" or "price differentials" or "price dispersion" or "average price" or "average prices" or "retail price" or "retail prices" or "wholesale price" or "wholesale prices" or "expected price" or "expected prices" or "net price" or "net prices" or "transaction price" or "transaction prices" or "price type" or "price types" or "price component" or "price components" or "cif price" or "cif prices" or "freight price" or "freight prices" or "pharmacy price" or "pharmacy prices" or "pharmacist price" or "pharmacist prices" or "pharmacists price" or "pharmacists prices" or "end price" or "end prices" or "consumer price" or "consumer prices" or "final price" or "final prices" or "reimbursement price" or "reimbursement prices" or "list price" or "list prices" or "actual price" or "actual prices"))) 1279

9 (((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND (cost-control or cost-containment or cost-setting))) 97

10 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 2233

11 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) 34233

12 ((reference or benchmark or benchmarks or bench-mark or bench-marks) NEAR6 (pricing or prices or price or priced)) 60

13 ((pricing or prices or price or priced) NEAR6 (reference OR benchmark or benchmarks or bench-mark or bench-marks)) 22

14 (("international price comparison" or "international price comparisons" or "comparative price" or "comparative prices" or "factory price" or "factory prices" or "factories price" or "factories prices" or "manufacturer price" or "manufacturer prices" or "manufacturers price" or "manufacturers prices" or "exfactory price" or "exfactory prices" or "exfactorys price" or "exfactorys prices" or "exmanufacturer price" or "exmanufacturer prices" or "exmanufacturers price" or "exmanufacturers prices")) 19

15 (((value-based and (pricing or price or prices or priced or reimbursement)) OR ((value or values) NEAR6 (pricing or price or prices or priced)))) 186

16 ((pricing or price or prices or priced) NEAR6 (value or values)) 91

17 ((pricing or price or prices or priced) NEAR6 (based or set or sets or setting)) 297

18 ((based or set or sets or setting) NEAR6 (pricing or price or prices or priced)) 841

19 ((cost-plus or costplus or costs-plus or costsplus)) 41

20 ((based or produc* or promot* or expense* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits) NEAR6 (pricing or price or prices or priced)) 790

21 ((pricing or price or prices or priced) NEAR6 (based or produc* or promot* or expense* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits)) 312

22 (((expense or expenses) NEAR3 (produc* or promot* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits)) AND (pricing or price or prices or priced)) 28

23 (((produc* or promot* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits) NEAR3 (expense or expenses)) AND (pricing or price or prices or priced)) 34

24 ((pricing or price or prices or priced) NEAR3 (set or sets or setting or control* or containment or preferential)) 19

25 ((set or sets or setting or control* or containment or preferential) NEAR6 (pricing or price or prices or priced)) 247

26 ((pricing or price or prices or priced) NEAR6 (threshold or thresholds or maximum or maximums or cap or caps or capped or capping or ceiling or ceilings or discount* or reduction*)) 1683

27 ((threshold or thresholds or maximum or maximums or cap or caps or capped or capping or ceiling or ceilings or discount* or reduction*) NEAR6 (pricing or price or prices or priced)) 858

28 ((mark-up or mark-ups or markup*):TI) 0

29 (((mark-up or mark-ups or markup*) NEAR3 control*)) 0

30 (control* NEAR3 (mark-up or mark-ups or markup*)) 0

31 ((mark-up or mark-ups or markup*) AND (regulat* or manipulat* or supply or supplies or distribut* or wholesale* or prescrib* or prescrip* or dispens* or pricing or price or prices or priced or cost or costs or costing or costed or economic or economics or pharmacoeconomic or pharmacoeconomics)) 39

32 (("supply chain" or "supply chains" or distribution) NEAR3 (cost or costs or costed or costing)) 291

33 ((cost or costs or costed or costing) NEAR3 ("supply chain" or "supply chains" or distribution)) 42

34 (("supply chain" or "supply chains" or distribution) NEAR6 (price or prices or priced or pricing)) 5

35 ((price or prices or priced or pricing) NEAR6 ("supply chain" or "supply chains" or distribution)) 2

36 ((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics") NEAR6 (margin or margins)) 1

37 (("profit margin" or "profit margins" or "gross margin" or "gross margins" or "cost price" or "cost prices" or "purchase price" or "purchase prices" or "purchasing price" or "purchasing prices" or "selling price" or "selling prices")) 124

38 ((pricing or price or prices or priced or discount or discounts or rebate or rebates) NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 226

39 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 (pricing or price or prices or priced or discount or discounts or rebate or rebates)) 1586

40 ((pricing or price or prices or priced) AND (rebate or rebates or rebated)) 16

41 (((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 (information*)) AND (pricing or price or prices or priced or discount or discounts or rebate or rebates)) 248

42 ((information*) NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) AND (pricing or price or prices or priced or discount or discounts or rebate or rebates)) 132

43 (("managed entry")) 2

44 (("access with evidence development" or "conditional coverage" or "conditional treatment continuation" or "coverage with evidence development" or "only in research" or "only with research" or "outcome guarantee" or "outcome guarantees" or "patient access scheme" or "patient access schemes" or "patient access agreement" or "patient access agreements" or "patient access arrangement" or "patient access arrangements") NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 0

45 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 ("access with evidence development" or "conditional coverage" or "conditional treatment continuation" or "coverage with evidence development" or "only in research" or "only with research" or "outcome guarantee" or "outcome guarantees" or "patient access scheme" or "patient access schemes" or "patient access agreement" or "patient access agreements" or "patient access arrangement" or "patient access arrangements")) 0

46 (("performance-linked reimbursement" or "price volume agreement" or "price volume agreements" or "price volume arrangement" or "price volume arrangements" or "price volume scheme" or "price volume schemes") NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 0

47 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 ("performance-linked reimbursement" or "price volume agreement" or "price volume agreements" or "price volume arrangement" or "price volume arrangements" or "price volume scheme" or "price volume schemes")) 0

48 (("performance-based agreement" or "performance-based agreements" or "performance-based scheme" or "performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or "performance-based health outcome reimbursement") NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 0

49 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 ("performance-based agreement" or "performance-based agreements" or "performance-based scheme" or "performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or "performance-based health outcome reimbursement")) 0

50 ((pattern NEAR3 process care) NEAR6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)) 0

51 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares) NEAR6 (pattern NEAR3 process care)) 0

52 (("risk sharing scheme" or "risk sharing schemes" or "risk sharing agreement" or "risk sharing agreements" or "risk sharing arrangement" or "risk sharing arrangements")) 2

53 (("access with evidence development" or "conditional coverage" or "conditional treatment continuation" or "coverage with evidence development" or "only in research" or "only with research" or "outcome guarantee" or "outcome guarantees")) 11

54 (("patient access scheme" or "patient access schemes" or "patient access agreement" or "patient access agreements" or "patient access arrangement")) 28

55 (((pattern NEAR1 process NEAR0 care))) 0

56 (("patient access arrangements" or "performance-based agreement" or "performance-based agreements" or "performance-based scheme" or "performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or "performance-based health outcome reimbursement" or "performance-linked reimbursement" or "price volume agreement" or "price volume agreements" or "price volume arrangement" or "price volume arrangements" or "price volume scheme" or "price volume schemes")) 0

57 (#53 OR #54 OR #55 OR #56) 39

58 ((transparen* or accountab* or discount* or reduction* or rebate*)) 15589

59 (#57 AND #58) 2

60 ((pool* or joint* or share or shares or sharing or shared or collectiv* or combin*) NEAR6 (procur* or purchas*)) 3

61 ((procur* or purchas*) NEAR6 (pool* or joint* or share or shares or sharing or shared or collectiv* or combin*)) 6

62 (group* NEAR3 (procur* or purchas*)) 5

63 ((procur* or purchas*) NEAR3 group*) 4

64 (("flat discount" or "flat discounts" or "competitive pricing" or "competitive price" or "competitive prices")) 2

65 ((pricing or price or prices or priced or purchas*) AND (tender or tenders or tendering or tendered or procur* or (prescription* NEAR3 charge*) or (charge* NEAR3 prescription))) 74

66 ((pricing or price or prices or priced or purchas*) NEAR6 (bid or bids or bidder* or bidding or negotiat* or offer or offers or offered or offering)) 21

67 ((bid or bids or bidder* or bidding or negotiat* or offer or offers or offered or offering) NEAR6 (pricing or price or prices or priced or purchas*)) 26

68 ((pricing or price or prices or priced or purchas*) NEAR3 (discuss* or agree*)) 10

69 ((discuss* or agree*) NEAR3 (pricing or price or prices or priced or purchas*)) 19

70 (((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) NEAR6 (reduc* or exempt* or remov* or policy or policies or arrangement or arrangement or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic* or duty duties)) AND (pricing or price or prices or priced)) 37

71 (((reduc* or exempt* or remov* or policy or policies or arrangement or arrangement or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic* or duty duties) NEAR6 (tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat)) AND (pricing or price or prices or priced)) 36

72 (((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat or duty or duties) NEAR3 free)) 0

73 (Free NEAR3 (tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat or duty or duties)) 0

74 ((pricing or price or prices or priced or discount or discounts or rebate or rebates) AND (transparen* or accountab*)) 942

75 ((margin or margins) NEAR6 (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) 0

76 #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71 OR #72 OR #73 OR #74 OR #75 5380

77 #11 AND #76 3976

78 (generic* or non-proprietary or nonproprietary or INN or "tier 1" or tier1 or "tier one" or off-patent* or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics") AND (pricing or price or prices or priced or cost-saving or cost-savings or cost-share or cost-sharing or "prescribing cost" or "prescribing costs" or "prescription cost" or "prescription costs" or "dispensing cost" or "dispensing costs") 380

79 #10 OR #77 OR #78 4743

80 (#10 OR #77 OR #78) IN DARE FROM 2004 TO 2019 24

81 (#10 OR #77 OR #78) IN NHSEED FROM 2004 TO 2019 2568

82 (#10 OR #77 OR #78) IN HTA FROM 2004 TO 2019 66

A.8: Source: INRUD

Interface / URL: https://www.zotero.org/groups/659457/inrud_biblio/items
Database coverage dates: N/A

Search date: 13/09/2019

Retrieved records: 454

Search strategy:

The search was conducted via the tags used to index papers and the results were as follows:

Price - 333
Pricing - 121

All references were downloaded and imported into Endnote.

A.9: Source: OECDiLibrary

Interface / URL: https://www.oecd-ilibrary.org/search/advancedsearch
Database coverage dates: N/A

Search date: 17/09/2019

Retrieved records: 19

Search strategy:

46 results identified and 15 results downloaded

from (Title contains 'drug OR drugs OR pharmaceutical OR pharmaceuticals') OR from (Abstract contains 'drug OR drugs OR pharmaceutical OR pharmaceuticals') AND from (Abstract contains 'pricing OR price OR prices OR priced') AND from (IGO collection contains 'OECD') published between 2004 and 2019

20 results identified and 4 results downloaded

from (Title contains 'biopharmaceutical OR biopharmaceuticals OR medicine OR medicines OR medication OR medications') OR from (Abstract contains 'biopharmaceutical OR biopharmaceuticals OR medicine OR medicines OR medication OR medications') AND from (Abstract contains 'pricing OR price OR prices OR priced') AND from (IGO collection contains 'OECD') published between 2004 and 2019

15 results identified and 0 results downloaded

from (Title contains 'medicament OR medicaments OR prescription OR prescriptions OR vaccine OR vaccines OR biosimilar OR biosimilars') OR from (Abstract contains 'medicament OR medicaments OR prescription OR prescriptions OR vaccine OR vaccines OR biosimilar OR biosimilars') AND from (Abstract contains 'pricing OR price OR prices OR priced') AND from (IGO collection contains 'OECD') published between 2004 and 2019

0 results identified

from (Title contains 'bio-similar OR bio-similars OR biogeneric OR biogenerics') OR from (Abstract contains 'bio-similar OR bio-similars OR biogeneric OR biogenerics') AND from (Abstract contains 'pricing OR price OR prices OR priced') AND from (IGO collection contains 'OECD') published between 2004 and 2019

0 results identified

from (Title contains '"follow-on biologic" OR "follow-on biologics" OR "subsequent entry biologic" OR "subsequent entry biologics" OR "similar biologic" OR "similar biologics"') OR from (Abstract contains '"follow-on biologic" OR "follow-on biologics" OR "subsequent entry biologic" OR "subsequent entry biologics" OR "similar biologic" OR "similar biologics"') AND from (Abstract contains 'pricing OR price OR prices OR priced') AND from (IGO collection contains 'OECD') published between 2004 and 2019

A.10: Source: World Bank eLibrary

Interface / URL: https://elibrary.worldbank.org/action/doSearch
Database coverage dates: N/A

Search date: 20/09/2019

Retrieved records: 1572

Search strategy:

Search via advanced search with the following terms

(drug or drugs or pharmaceutical or pharmaceuticals) AND (pricing or price or prices or priced) 1100 records identified and downloaded

(biopharmaceutical or biopharmaceuticals or medicine or medicines) AND (pricing or price or prices or priced)

24 records identified and downloaded

(medication or medications or medicament or medicaments) AND pricing or price or prices or priced

45 records identified and downloaded

prescription or prescriptions or vaccine or vaccines) AND (pricing or price or prices or priced) 400 records identified and downloaded

biosimilar 1

biosimilars 1 - duplicate

bio-similar 0

bio-similars 2

biogeneric 1 - not relevant

biogenerics 1 - not relevant

"follow-on biologic" 0

"follow-on biologics" 0

"subsequent entry biologic" 0

"subsequent entry biologics" 0

"similar biologic" 0

"similar biologics" 0

A.11: Source: Epistemonikos

Interface / URL: https://www.epistemonikos.org
Database coverage dates: N/A

Search date: 23/09/2019

Retrieved records: 264

Search strategy:

(advanced_title_en:((drug OR drugs OR pharmaceutical OR pharmaceuticals OR biopharmaceutical OR biopharmaceuticals OR medicine OR medicines OR medication OR medications OR medicament OR medicaments OR prescription OR prescriptions OR vaccine OR vaccines OR biosimilar OR biosimilars OR bio-

similar OR bio-similars OR biogeneric OR biogenerics OR "follow-on biologic" OR "follow-on biologics" OR "subsequent entry biologic" OR "subsequent entry biologics" OR "similar biologic" OR "similar biologics")) OR advanced_abstract_en:((drug OR drugs OR pharmaceutical OR pharmaceuticals OR biopharmaceutical OR biopharmaceuticals OR medicine OR medicines OR medication OR medications OR medicament OR medicaments OR prescription OR prescriptions OR vaccine OR vaccines OR biosimilar OR biosimilars OR bio-similar OR bio-similars OR biogeneric OR biogenerics OR "follow-on biologic" OR "follow-on biologics" OR "subsequent entry biologic" OR "subsequent entry biologics" OR "similar biologic" OR "similar biologics"))) AND (advanced_title_en:((pricing OR price OR prices OR priced)) OR advanced_abstract_en:((pricing OR price OR prices OR priced))) [Filters: classification=systematic-review, protocol=no, min_year=2004, max_year=2019]

A.12: Source: International Political Science Abstracts

Interface / URL: https://journals-sagepub-com.proxy.library.uu.nl/home/iab
Database coverage dates: N/A

Search date: 23/09/2019

Retrieved records: 68

Search strategy:

All drug or drugs or pharmaceutical or pharmaceuticals within International Political Science Abstracts Since 2004

63 records identified and downloaded

[All biopharmaceutical or biopharmaceuticals or medicine or medicines] within International Political Science Abstracts Since 2004

0 records

[All medication or medications or medicament or medicaments] within International Political Science Abstracts Since 2004

0 records

All prescription or prescriptions or vaccine or vaccines within International Political Science Abstracts Since 2004

5 records identified and downloaded

biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics" Within International Political Science Abstracts Since 2004

0 records

A.13: Source: WHO IRIS (Institutional Repository for Information Sharing)

Interface / URL: https://apps.who.int/iris/
Database coverage dates: Information not found

Search date: 09/10/19 (searches 1 – 31) – 10/10/19 (searches 32 - 81)

Retrieved records: 2129

Search strategy:

Search functionality context

No detailed search help pages were identified, but the available search support video confirmed that phrase searching was supported using quotation marks. There was minimal additional information on supported search syntax. After contacting the WHO Librarian it was also confirmed that:

- The interface supports the use of Boolean AND / OR
- The interface supports searching on nested terms using Boolean (i.e. it is possible to search on term A AND (term B OR term C OR term D))
- The interface automatically searches on variants for the term entered (for example, a search on price also searches for prices / pricing / priced – a search on any one of these terms will retrieve the same number of results). Test searches indicated the same applied for phrases (e.g. a search on "pooled purchasing" retrieved the same number of records as a search on "pooled purchases").

There was a cap (500) on the number of records that could be exported at one time and problems were experienced when trying to export larger result numbers in several small sets. When exported into EndNote, most records contain minimal information.

The limited search functionality meant that complex, multi-line searches were not possible. However, in the context of this project, broad, simple, sensitive searches were also not possible without returning unmanageable record numbers. From test searches, it appeared the default search "All of Iris" searches for

terms across the full text of documents. This means that result numbers may be large when searching on frequently used terms. For example, a default test search on (drug OR pharmaceutical) AND pricing retrieved 11,255 records. Whilst the advanced search offers some focusing options (e.g. title searches, MeSH searches), options are limited.

Search approach taken

Within this search functionality context, options for a balanced search approach were discussed within the research team. It was decided that the main search approach would use WHO IRIS advanced search settings to retrieve records that were indexed with key MeSH headings / subject headings (searches 1 – 6 below), records that were indexed with other relevant MeSH headings and which also contained the term 'pricing (searches 7 – 22 below), or records which contained the term 'pricing' in the title field (search 23 below). These searches would be supplemented by a range of pragmatic MeSH-based or phrase-based searches on terms relating to non-specific drug pricing policies or the specific pricing policies of interest (searches 24 – 81 below). It was felt that this represented a balanced approach in keeping with that outlined in the research protocol.

The following searches were conducted separately using the search interface at: https://apps.who.int/iris/. Each results file was imported into an empty EndNote library (6232 records). Records with a date before 2004 in the EndNote 'year' field (1699) were removed – leaving 4533 records. The results were then deduplicated using EndNote default settings. Identified duplicate records (2404) were removed, leaving 2129 records. The 2129 remaining records were retrieved for further assessment.

Search 1: Using advanced search filters restricted to subject (MeSH) contains pricing

20 records identified and downloaded

Search 2: Using advanced search filters restricted to:

subject contains pricing

subject (MeSH) Not contains pricing

0 records

Search 3: Using advanced search filters restricted to subject (MeSH) equals drug costs

155 records identified and downloaded

Search 4: Using advanced search filters restricted to:

subject Equals drug costs

subject MeSH Not equals drug costs

25 records identified and downloaded

Search 5: Using advanced search filters restricted to: subject (MeSH) Equals Economics, Pharmaceutical

33 records identified and downloaded

Search 6: Using advanced search filters restricted to:

subject Equals economics, pharmaceutical

subject (MeSH) Not equals economics, pharmaceutical

13 records identified and downloaded

Search 7:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals Drugs, Essential

318 records identified and downloaded

Search 8:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals Drug Prescriptions

1 records identified and downloaded

Search 9:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals Prescription Drugs

9 records identified and downloaded

Search 10:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals fees, pharmaceutical

9 records identified and downloaded

Search 11:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals prescription fees

0 records

Search 12:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals Drug Substitution

0 records

Search 13:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals Insurance, Pharmaceutical Services

0 records

Search 14:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals Drug Approval

3 records identified and downloaded

Search 15:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals Biological Products

20 records identified and downloaded

Search 16:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals Drugs, Generic

19 records identified and downloaded

Search 17:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals Biosimilar Pharmaceuticals

0 records

Search 18:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals Reimbursement Mechanisms

4 records identified and downloaded

Search 19:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Subject (MeSH) equals Commerce

Subject (MeSH) equals Drug Industry

5 records identified and downloaded

Search 20:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Subject (MeSH) equals Commerce

Subject (MeSH) equals Legislation, Drug

4 records identified and downloaded

Search 21:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Subject (MeSH) equals Commerce

Subject (MeSH) equals Drug and Narcotic Control

2 records identified and downloaded

Search 22:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals Cost Control

12 records identified and downloaded

Search 23: Using advanced search filters restricted to title contains pricing

96 records identified and downloaded

Search 24: Searched 'All of IRIS': "drug pricing policy" OR "pharmaceutical pricing policy" OR "biopharmaceutical pricing policy" OR "medicine pricing policy" OR "medication pricing policy" OR "medicament pricing policy" OR "prescription pricing policy" OR "vaccine pricing policy" OR "generics pricing policy" OR "biosimilar pricing policy" OR "bio-similar pricing policy" OR "biogeneric pricing policy" OR "follow-on biologic pricing policy" OR "subsequent entry biologic pricing policy" OR "similar biologic pricing policy"

221 records identified and downloaded

Search 25: Searched 'All of IRIS': "reference pricing" AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

383 records identified and downloaded

Search 26: Searched 'All of IRIS': ("benchmark pricing" OR "bench-mark pricing" OR "international price comparison" OR "international price comparator" OR "factory price" OR "manufacturer price" OR "exfactory price" OR "exmanufacturer price") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

222 records identified and downloaded

Search 27:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals Technology Assessment, Biomedical

24 records identified and downloaded

Search 28: Searched 'All of IRIS': ("value-based pricing" OR "value based reimbursement") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

25 records identified and downloaded

Search 28: Searched 'All of IRIS': ("cost-plus" OR costplus OR costsplus) AND pricing AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

119 records identified and downloaded

Search 29: Searched 'All of IRIS': ("price threshold" OR "threshold price" OR "maximum price" OR "price maximum" OR "price cap" OR "capped price" OR "price ceiling" OR "ceiling price" OR "supply chain price" OR

"distribution price" OR "distribution chain price") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

213 records identified and downloaded

Search 30: Searched 'All of IRIS': pricing AND "mark-up" AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

426 records identified and downloaded

Search 31:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to: Subject (MeSH) equals Disclosure

2 records identified and downloaded

Search 32: Searched 'All of IRIS': ("price transparency" OR "pricing transparency" OR "transparent prices" OR "transparency of prices") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

170 records identified and downloaded

Search 33: ("price publishing" OR "publishing prices" OR "price publication" OR "publication of prices" OR "price disclosure" OR "disclosing prices" OR "disclosure of prices" OR "price dissemination" OR "disseminating prices" OR "dissemination of prices" OR "price communication" OR "communicating prices" OR "communication of prices" OR "price sharing" OR "sharing prices" OR "sharing of prices" OR "pricing accountability") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

418 records identified and downloaded

Search 34: Searched 'All of IRIS': pricing AND ("discount transparency" OR "discounting transparency" OR "transparent discounts" OR "transparency of discounts" OR "discount publishing" OR "publishing discounts" OR "discount publication" OR "publication of discounts" OR "discount disclosure" OR "disclosing discounts"

OR "disclosure of discounts" OR "discount dissemination" OR "disseminating discounts" OR "dissemination of discounts" OR "discount communication" OR "communicating discounts" OR "communication of discounts" OR "discount sharing" OR "sharing discounts" OR "sharing of discounts" OR "discount accountability") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

42 records identified and downloaded

Search 35: Searched 'All of IRIS': pricing AND ("rebate transparency" OR "transparent rebates" OR "transparency of rebates" OR "rebate publishing" OR "publishing rebates" OR "rebate publication" OR "publication of rebates" OR "rebate disclosure" OR "disclosing rebates" OR "disclosure of rebates" OR "rebate dissemination" OR "disseminating rebates" OR "dissemination of rebates" OR "rebate communication" OR "communicating rebates" OR "communication of rebates" OR "rebate sharing" OR "sharing rebates" OR "sharing of rebates" OR "rebate accountability") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

8 records identified and downloaded

Search 36:

Searched 'All of IRIS': pricing AND ("managed entry" OR "risk sharing scheme" OR "risk sharing agreement" OR "risk sharing arrangement") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

99 records identified and downloaded

Search 37:

Searched 'All of IRIS': ("access with evidence development" OR "conditional coverage" OR "conditional treatment continuation" OR "coverage with evidence development" OR "outcome guarantee" OR "patient access scheme" OR "patient access agreement" OR "patient access arrangement" OR "pattern or process care" OR "performance-based agreement" OR "performance-based scheme" OR "performance-based arrangement" OR "performance-based health outcome reimbursement" OR "performance-linked reimbursement" OR "price volume agreement" OR "price volume arrangement" OR "price volume scheme") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR

prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

49 records identified and downloaded

Search 38: Searched 'All of IRIS': pricing AND "pooled procurement" AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

538 records identified and downloaded

Interface stated 538 returned results. Not possible to download more than 500 records, so chose 'Selective export' option with the intention of selected results by page ('Select all on page) with settings at 100 records per page. For each page, there were initial discrepancies between the number of results downloaded and the number of results that shoulh have been downloaded. Each file had to be downloaded a number of times and the exported number checked before the full page could be confirmed as downloaded.

Search 39:

Search 'All of IRIS': pricing AND "pooled purchasing" AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

79 records identified and downloaded

Search 40:

Search 'All of IRIS': pricing AND ("joint procurement" OR "joint purchasing" OR "group procurement" OR "group purchasing" OR "shared procurement" OR "shared purchasing" OR "collective procurement" OR "collective purchasing" OR "combined procurement" OR "combined purchasing") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

438 records identified and downloaded

Search 41: Searched 'All of IRIS': ("price discounts" OR "discounted prices" OR "price rebate" OR "flat discount") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR

prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

206 records identified and downloaded

Search 42:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Subject (MeSH) equals Economic Competition

0 records

Search 43:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Subject (MeSH) equals Competitive Bidding

0 records

Search 44:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Subject (MeSH) equals Drug Industry

Subject (MeSH) equals Contract Services

0 records

Search 45: Searched 'All of IRIS': "competitive pricing" AND (tender OR negotiation) AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

259 records identified and downloaded

Search 46

Searched 'All of IRIS': pricing AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

Restricted using Advanced filters to:

Title contains: negotiation

14 records identified and downloaded

Search 47

Searched 'All of IRIS': pricing AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

Restricted using Advanced filters to:

Title contains: tender

0 records

Search 48:

Searched 'All of IRIS': "preferential pricing" AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

181 records identified and downloaded

Search 49:

Searched 'All of IRIS': pricing AND ("tax reduction" OR "reduction of tax" OR "taxation reduction" OR "reduction of taxation" OR "tariff reduction" OR "reduction of tariff" OR "VAT reduction" OR "reduction of VAT" OR "duty reduction" OR "reduction of duty") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

162 records identified and downloaded

Search 50:

Searched 'All of IRIS': pricing AND ("tax exemption" OR "exemption of tax" OR "taxation exemption" OR "exemption of taxation" OR "tariff exemption" OR "exemption of tariff" OR "VAT exemption" OR "exemption of VAT" OR "duty exemption" OR "exemption of duty") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

269 records identified and downloaded

Search 51:

Searched 'All of IRIS': pricing AND ("tax removal" OR "removal of tax" OR "taxation removal" OR "removal of taxation" OR "tariff removal" OR "removal of tariff" OR "VAT removal" OR "removal of VAT" OR "duty removal" OR "removal of duty") AND (drug OR pharmaceutical OR biopharmaceutical OR medicine OR medication OR medicament OR prescription OR generic OR vaccine OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic")

69 records identified and downloaded

Search 52:

Restricted using Advanced filters to:

Subject (MeSH) equals Drugs, Generic

Subject (MeSH) equals Drug Utilization

1 records identified and downloaded

Search 53:

Restricted using Advanced filters to:

Subject (MeSH) equals Drugs, Generic

Subject (MeSH) equals Cost-Control

0 records

Search 54:

Restricted using Advanced filters to:

Subject (MeSH) equals Biosimilar Pharmaceuticals

0 records

Search 55:

Searched 'All of IRIS': "generic pricing" OR "non-proprietary pricing" OR "nonproprietary pricing" OR "tier 1 pricing" OR "tier1 pricing" OR "tier one pricing" OR "off-patent pricing" OR "biosimilar pricing" OR "bio-similar pricing" OR "biogeneric pricing" OR "follow-on biologic pricing" OR "subsequent entry biologic pricing" OR "similar biologic pricing"

138 records identified and downloaded

Search 56:

Searched 'All of IRIS': "generic drug pricing" OR "non-proprietary drug pricing" OR "nonproprietary drug pricing" OR "tier 1 drug pricing" OR "tier1 drug pricing" OR "tier one drug pricing" OR "off-patent drug pricing" OR "biosimilar drug pricing" OR "bio-similar drug pricing" OR "biogeneric drug pricing" OR "follow-on biologic drug pricing" OR "subsequent entry biologic drug pricing" OR "similar biologic drug pricing"

15 records identified and downloaded

Search 57:

Searched 'All of IRIS': "generic pharmaceutical pricing" OR "non-proprietary pharmaceutical pricing" OR "nonproprietary pharmaceutical pricing" OR "tier 1 pharmaceutical pricing" OR "tier1 pharmaceutical pricing" OR "tier one pharmaceutical pricing" OR "off-patent pharmaceutical pricing" OR "biosimilar pharmaceutical pricing" OR "bio-similar pharmaceutical pricing" OR "biogeneric pharmaceutical pricing" OR "follow-on biologic pharmaceutical pricing" OR "subsequent entry biologic pharmaceutical pricing" OR "similar biologic pharmaceutical pricing"

3 records identified and downloaded

Search 58:

Searched 'All of IRIS': "generic biopharmaceutical pricing" OR "non-proprietary biopharmaceutical pricing" OR "nonproprietary biopharmaceutical pricing" OR "tier 1 biopharmaceutical pricing" OR "tier1 biopharmaceutical pricing" OR "tier one biopharmaceutical pricing" OR "off-patent biopharmaceutical pricing" OR "biosimilar biopharmaceutical pricing" OR "bio-similar biopharmaceutical pricing" OR "biogeneric biopharmaceutical pricing" OR "follow-on biologic biopharmaceutical pricing" OR "subsequent entry biologic biopharmaceutical pricing" OR "similar biologic biopharmaceutical pricing"

0 records

Search 59:

Searched 'All of IRIS': "generic medicine pricing" OR "non-proprietary medicine pricing" OR "nonproprietary medicine pricing" OR "tier 1 medicine pricing" OR "tier1 medicine pricing" OR "tier one medicine pricing" OR "off-patent medicine pricing" OR "biosimilar medicine pricing" OR "bio-similar medicine pricing" OR "biogeneric medicine pricing" OR "follow-on biologic medicine pricing" OR "subsequent entry biologic medicine pricing" OR "similar biologic medicine pricing"

26 records identified and downloaded

Search 60:

Searched 'All of IRIS': "generic medication pricing" OR "non-proprietary medication pricing" OR "nonproprietary medication pricing" OR "tier 1 medication pricing" OR "tier1 medication pricing" OR "tier one medication pricing" OR "off-patent medication pricing" OR "biosimilar medication pricing" OR "bio-similar medication pricing" OR "biogeneric medication pricing" OR "follow-on biologic medication pricing" OR "subsequent entry biologic medication pricing" OR "similar biologic medication pricing"

0 records

Search 61:

Searched 'All of IRIS': "generic medicament pricing" OR "non-proprietary medicament pricing" OR "nonproprietary medicament pricing" OR "tier 1 medicament pricing" OR "tier1 medicament pricing" OR "tier one medicament pricing" OR "off-patent medicament pricing" OR "biosimilar medicament pricing" OR "bio-similar medicament pricing" OR "biogeneric medicament pricing" OR "follow-on biologic medicament pricing" OR "subsequent entry biologic medicament pricing" OR "similar biologic medicament pricing"

0 records

Search 62:

Searched 'All of IRIS': "generic prescription pricing" OR "non-proprietary prescription pricing" OR "nonproprietary prescription pricing" OR "tier 1 prescription pricing" OR "tier1 prescription pricing" OR "tier one prescription pricing" OR "off-patent prescription pricing" OR "biosimilar prescription pricing" OR "bio-similar prescription pricing" OR "biogeneric prescription pricing" OR "follow-on biologic prescription pricing" OR "subsequent entry biologic prescription pricing" OR "similar biologic prescription pricing"

0 records

Search 63:

Searched 'All of IRIS': "pricing of generic" OR "pricing of non-proprietary" OR "pricing of nonproprietary" OR "pricing of tier 1" OR "pricing of tier1" OR "pricing of tier one" OR "pricing of off-patent" OR "pricing of biosimilar" OR "pricing of bio-similar" OR "pricing of biogeneric" OR "pricing of follow-on biologic" OR "pricing of subsequent entry biologic" OR "pricing of similar biologic"

201 records identified and downloaded

Search 64:

Searched 'All of IRIS': pricing AND ("promoting generic" OR "generic promotion" OR "promotion of generic" OR "promoting non-proprietary" OR "non-proprietary promotion" OR "promotion of non-proprietary" OR "promoting nonproprietary" OR "nonproprietary promotion" OR "promotion of nonproprietary" OR "promoting tier 1" OR "tier 1 promotion" OR "promotion of tier 1" OR "promoting tier1" OR "tier1 promotion" OR "promotion of tier1" OR "promoting tier one" OR "tier one promotion" OR "promotion of tier one" OR "promoting off-patent" OR "off-patent promotion" OR "promotion of off-patent" OR "promoting biosimilar" OR "biosimilar promotion" OR "promotion of biosimilar" OR "promoting bio-similar" OR "bio-similar promotion" OR "promotion of bio-similar" OR "promoting biogeneric" OR "biogeneric promotion" OR "promotion of biogeneric" OR "promoting follow-on biologic" OR "follow-on biologic promotion" OR "promotion of follow-on biologic" OR "promoting subsequent entry biologic" OR "subsequent entry biologic promotion" OR "promotion of subsequent entry biologic" OR "promoting similar biologic" OR "similar biologic promotion" OR "promotion of similar biologic" OR "subsequent entry biologic" OR "similar biologic")

364 records identified and downloaded

Search 65:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: generic

17 records identified and downloaded

Search 66:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: "non-proprietary"

0 records

Search 67:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: nonproprietary

1 record identified and downloaded

Search 68:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: INN

3 records identified and downloaded

Search 69:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: "tier 1"

0 records

Search 70:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: tier1

0 records

Search 71:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: "tier one"

0 records

Search 72:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: "off-patent"

0 records

Search 73:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: biosimilar

5 records identified and downloaded

Search 74:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: "bio-similar"

0 records

Search 75:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: biogeneric

0 records

Search 76:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: "follow-on biologic"

0 records

Search 77:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: "subsequent entry biologic"

0 records

Search 78:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: "similar biologic"

0 records

Search 79:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: "cost-saving"

0 records

Search 80:

Searched 'All of IRIS': pricing

Restricted using Advanced filters to:

Title contains: "cost-sharing"

0 records

Search 81:

Searched 'All of IRIS': pricing AND (generic OR "non-proprietary" OR nonproprietary OR INN OR "tier 1" OR tier1 OR "tier one" OR "off-patent" OR biosimilar OR "bio-similar" OR biogeneric OR "follow-on biologic" OR "subsequent entry biologic" OR "similar biologic") AND ("prescribing-cost" or "prescription-cost" or "dispensing-cost")

75 records identified and downloaded

A.14: Source: European Observatory on Health Systems and Policies

Interface / URL: http://www.euro.who.int/en/about-us/partners/observatory/publications/policy-briefs-and-summaries
Database coverage dates: N/A

Search date: 24/09/2019

Retrieved records: 2

Search strategy:

All policies on the webpage were copied into a Word document and screened by reviewers prior to these being imported into Endnote.

A.15: Source: WHO Collaborating Centre for Pricing and Reimbursement Policies webpage

Interface / URL: https://ppri.goeg.at/
Database coverage dates: N/A

Search date: 24/09/2019

Retrieved records: 58

Search strategy:

Searched the website on the following search terms. The results were copied into Word to be screened and the results were imported into Endnote

drug

drugs

pharmaceutical

pharmaceuticals

biopharmaceutical

biopharmaceuticals

medicine

medicines

medication

medications

medicament

medicaments

prescription

prescriptions

vaccine

vaccines

biosimilar

biosimilars

bio-similar

bio-similars

biogeneric

biogenerics

"follow-on biologic"

"follow-on biologics"

"subsequent entry biologic"

"subsequent entry biologics"

"similar biologic"

"similar biologics"

A.16: Source: Health Action International (HAI) Medicines Prices webpage

Interface / URL: http://www.haiweb.org/medicineprices/news/index.html
Database coverage dates: N/A

Search date: 26/09/2019

Retrieved records: 14

Search strategy:

All publications listed were copied into a Word document and screened, the relevant results were added to the Endnote library.

A.17: Source: Health Action International (HAI) Publications webpage

Interface / URL: https://haiweb.org/publicationsarchive/
Database coverage dates: N/A

Search date: 24/09/2019

Retrieved records: 22

Search strategy:

The following search terms were searched individually, the results were copied into a Word document and screened, and the relevant results were then added to Endnote.

drug

drugs

pharmaceutical

pharmaceuticals

biopharmaceutical

biopharmaceuticals

medicine

medicines

medication

medications

medicament

medicaments

prescription

prescriptions

vaccine

vaccines

biosimilar

biosimilars

bio-similar

bio-similars

biogeneric

biogenerics

"follow-on biologic"

"follow-on biologics"

"subsequent entry biologic"

"subsequent entry biologics"

"similar biologic"

"similar biologics"

A.18: Source: MI4A Market Information for Access to Vaccines webpage

Interface / URL:
https://www.who.int/immunization/programmes_systems/policies_strategies/en/
Database coverage dates: N/A

Search date: 26/09/2019

Retrieved records: 0

Search strategy:

All policies were copied into Word and screened for relevance, no relevant results were retrieved.

A.19: Source: EC initiatives in pricing and reimbursement webpage

Interface / URL: https://ec.europa.eu/growth/sectors/healthcare/competitiveness/products-pricing-reimbursement/initiatives_en
Database coverage dates: N/A

Search date: 26/09/2019

Retrieved records: 3

Search strategy:

All the results were copied from Commission Initiatives in Pricing and Reimbursement webpage into a Word document. The results were screened and the relevant results were imported into Endnote.

A.20: Source: European Commission DG Sanco webpage

Interface / URL: https://ec.europa.eu/health/human-use_en.
Database coverage dates: N/A

Search date: 26/09/2019

Retrieved records: 0

Search strategy:

Searched the webpage for the following terms, no results were retrieved.

drug

drugs

pharmaceutical

pharmaceuticals

biopharmaceutical

biopharmaceuticals

medicine

medicines

medication

medications

medicament

medicaments

prescription

prescriptions

vaccine

vaccines

biosimilar

biosimilars

bio-similar

bio-similars

biogeneric

biogenerics

"follow-on biologic"

"follow-on biologics"

"subsequent entry biologic"

"subsequent entry biologics"

"similar biologic"

"similar biologics"

A.21: Source: IDEAS

Interface / URL: https://ideas.repec.org/search.html
Database coverage dates: N/A

Search date: 23/09/2019

Retrieved records: 136

Search strategy:

Search was conducted in the whole record. The results were screened for eligibility and downloaded 136 potentially relevant results.

A.22: Source: Open Grey

Interface / URL: http://www.opengrey.eu/search/
Database coverage dates: N/A

Search date: 23/09/2019

Retrieved records: 1

Search strategy:

The search was conducted using the search box and the results were screened for eligibility and 1 potentially relevant result was downloaded.

A.23: Source: World Bank Documents and Reports

Interface / URL: http://documents.worldbank.org/curated/en/docadvancesearch
Database coverage dates: N/A

Search date: 24/09/2019

Retrieved records: 5

Search strategy:

Search was conducted in the keyword field in the advanced search. The results were screened for the eligibility and 8 results were downloaded, 4 were duplicates.

A.24: Source: World Bank Open Knowledge Repository

Interface / URL: https://openknowledge.worldbank.org/discover
Database coverage dates: N/A

Search date: 24/09/2019

Retrieved records: 2

Search strategy:

Search was conducted in the whole record. The titles and abstracts were screened for eligibility and downloaded 5 potentially relevant results. After screening the full text, 2 potentially relevant results remained.

A.25: Source: WHO Essential Medicines and Health Products Information Portal (WHO)

Interface / URL: https://apps.who.int/medicinedocs/en/q/
Database coverage dates: N/A

Search date: 24/09/2019

Retrieved records: 17

Search strategy:

Search was conducted in the keyword field in the advanced search. The results were screened for the eligibility and 17 results were downloaded.

A.26: Source: Global Index Medicus

Interface / URL: http://www.globalhealthlibrary.net/php/index.php
Database coverage dates: N/A

Search date: 27/09/2019

Retrieved records: 3,075

Search strategy:

A series of searches was undertaken, and where possible previous searches were excluded to remove duplicates.

tw:((pricing OR price OR prices OR priced or "cost control" or "cost containment" or "cost setting") AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic OR generics or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) AND (

year_cluster:("2019" OR "2018" OR "2017" OR "2016" OR "2015" OR "2014" OR "2013" OR "2012" OR "2011" OR "2010" OR "2009" OR "2008" OR "2007" OR "2006" OR "2005" OR "2004"))

1436 records retrieved

tw:((reimbursement or "cost plus" or costplus or "costs plus" or costsplus or costs-plus or markup or markups or "mark up" or mark ups" or mark-up or mark-ups) AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic OR generics or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) AND (year_cluster:("2019" OR "2018" OR "2017" OR "2016" OR "2015" OR "2014" OR "2013" OR "2012" OR "2011" OR "2010" OR "2009" OR "2008" OR "2007" OR "2006" OR "2005" OR "2004"))

0 records retrieved

tw:(("supply chain" or "supply chains" or "distribution cost" or "distribution costs" or "profit margin" or "profit margins") AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic OR generics or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) AND (year_cluster:("2019" OR "2018" OR "2017" OR "2016" OR "2015" OR "2014" OR "2013" OR "2012" OR "2011" OR "2010" OR "2009" OR "2008" OR "2007" OR "2006" OR "2005" OR "2004"))

50 records retrieved excluding results from other sets

tw:((discount or discounts or rebate or rebates or "managed entry") AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic OR generics or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) AND (year_cluster:("2019" OR "2018" OR "2017" OR "2016" OR "2015" OR "2014" OR "2013" OR "2012" OR "2011" OR "2010" OR "2009" OR "2008" OR "2007" OR "2006" OR "2005" OR "2004")) NOT set 1

42 records retrieved

tw:(("access with evidence development" or "conditional coverage" or "conditional treatment continuation" or "coverage with evidence development" or "only in research" or "only with research" or "outcome guarantee" or "outcome guarantees" or "patient access scheme" or "patient access schemes" or "patient access agreement" or "patient access agreements" or "patient access arrangement" or "patient access arrangements" or pattern or "performance-based agreement" or "performance-based agreements" or "performance-based scheme" or "performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or reimbursement or "price volume") AND (publish* or publication or disclos* or disseminat* or communicat* or shar*) and (drug or drugs or pharmaceutical or pharmaceuticals

or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic OR generics or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) AND (year_cluster:("2019" OR "2018" OR "2017" OR "2016" OR "2015" OR "2014" OR "2013" OR "2012" OR "2011" OR "2010" OR "2009" OR "2008" OR "2007" OR "2006" OR "2005" OR "2004"))

507 records retrieved (excluding set1)

tw:(("risk sharing" or (pool* AND (procur* OR purchas*))) AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic OR generics or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) AND (year_cluster:("2019" OR "2018" OR "2017" OR "2016" OR "2015" OR "2014" OR "2013" OR "2012" OR "2011" OR "2010" OR "2009" OR "2008" OR "2007" OR "2006" OR "2005" OR "2004"))

17 records retrieved excluding set 1

tw:((procur* OR purchas*) AND (share or shares or sharing or shared or collectiv* or combin* or pool* or joint* or group*) and (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic OR generics or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) AND (year_cluster:("2019" OR "2018" OR "2017" OR "2016" OR "2015" OR "2014" OR "2013" OR "2012" OR "2011" OR "2010" OR "2009" OR "2008" OR "2007" OR "2006" OR "2005" OR "2004"))

879 records retrieved excluding set 1

tw:((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat or duty or duties) AND (reduc* or exempt* or remov* or free) and (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or generic OR generics or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")) AND (year_cluster:("2019" OR "2018" OR "2017" OR "2016" OR "2015" OR "2014" OR "2013" OR "2012" OR "2011" OR "2010" OR "2009" OR "2008" OR "2007" OR "2006" OR "2005" OR "2004"))

88 records retrieved excluding set 1

tw:((pricing or prices or price or priced or "cost saving" or "cost savings" or "cost sharing" or "prescribing cost" or "Prescribing costs" or "prescription cost" or "prescription costs" or "dispensing cost" or "dispensing costs") and (generic OR generics or non-proprietary or nonproprietary or inn or "tier 1" or tier1 or "tier one" or off-patent or "off patent" or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent

entry biologics" or "similar biologic" or "similar biologics")) AND (year_cluster:("2019" OR "2018" OR "2017" OR "2016" OR "2015" OR "2014" OR "2013" OR "2012" OR "2011" OR "2010" OR "2009" OR "2008" OR "2007" OR "2006" OR "2005" OR "2004"))

8 records retrieved excluding set 1

A.27: Source: Social Science Citation Index

Interface / URL: Web of Science
Database coverage dates: N/A

Search date: 24/09/2019

Retrieved records: 4,033

Search strategy:

42 4,033 (#41) AND DOCUMENT TYPES: (Article OR Book OR Book Chapter OR Data Paper OR Proceedings Paper OR Retracted Publication OR Retraction OR Review)

41 4,757 #40 OR #39 OR #7

40 1,304 TS=((generic* or non-proprietary or nonproprietary or INN or "tier 1" or tier1 or "tier one" or off-patent* or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics") AND (pricing or price or prices or priced or cost-saving or cost-savings or cost-share or cost-sharing or "prescribing cost" or "prescribing costs" or "prescription cost" or "prescription costs" or "dispensing cost" or "dispensing costs"))

39 2,216 #38 AND #8

38 45,333 (#37 OR #36 OR #35 OR #34 OR #33 OR #32 OR #31 OR #30 OR #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9) AND DOCUMENT TYPES: (Article OR Book OR Book Chapter OR Data Paper OR Proceedings Paper OR Retracted Publication OR Retraction OR Review)

37 385 TS=((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat or duty or duties) NEAR/3 free)

36 13,521 TS=((tax or taxes or taxed or taxing or taxation or tariff or tariffs or vat) NEAR/6 (reduc* or exempt* or remov* or policy or policies or arrangement or arrangement or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic*)) or TS=(((DUTY OR DUTIES) NEAR/6 (reduc* or exempt* or remov* or policy or policies or arrangement or arrangement or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order

or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic*)) AND (pricing or price or prices or priced))

35 915 TS=((pricing or price or prices or priced or purchas*) NEAR/3 (discuss* or agree*))

34 4,437 TS=((pricing or price or prices or priced or purchas*) NEAR/6 (bid or bids or bidder* or bidding or negotiat* or offer or offers or offered or offering))

33 2,105 TS=((pricing or price or prices or priced or purchas*) AND (tender or tenders or tendering or tendered or procur* or (prescription* NEAR/3 charge*)))

32 328 TS=("flat discount" or "flat discounts" or "competitive pricing" or "competitive price" or "competitive prices")

31 1,298 TS= ((pool* OR joint* or share or shares or sharing or shared or collectiv* or combin*) NEAR/6 (procur* or purchas*)) OR TS=(group* NEAR/3 (procur* or purchas*))

30 52 TS=(("access with evidence development" or “conditional coverage” or “conditional treatment continuation” or "coverage with evidence development" or "only in research" or "only with research" or “outcome guarantee” or “outcome guarantees” or “patient access scheme” or “patient access schemes” or “patient access agreement” or “patient access agreements" or "patient access arrangement” or "patient access arrangements" or "pattern or process care" or “performance-based agreement” or “performance-based agreements” or “performance-based scheme” or “performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or "performance-based health outcome reimbursement" or “performance-linked reimbursement” or "price volume agreement" or "price volume agreements" or “price volume arrangement” or “price volume arrangements" or “price volume scheme” or “price volume schemes”) AND (transparen* or accountab* or discount* or reduction* or rebate*))

29 207 TS=("risk sharing scheme" or "risk sharing schemes" or "risk sharing agreement" or "risk sharing agreements" or "risk sharing arrangement" or "risk sharing arrangements")

28 10 TS=(("access with evidence development" or "conditional coverage" or "conditional treatment continuation" or "coverage with evidence development" or "only in research" or "only with research" or "outcome guarantee" or "outcome guarantees" or "patient access scheme" or "patient access schemes" or "patient access agreement" or "patient access agreements" or "patient access arrangement" or "patient access arrangements" or "pattern or process care" or "performance-based agreement" or "performance-based agreements" or "performance-based scheme" or "performance-based schemes" or "performance-based arrangement" or "performance-based arrangements" or "performance-based health outcome reimbursement" or "performance-linked reimbursement" or "price volume agreement" or "price volume agreements" or "price volume arrangement" or "price volume arrangements" or "price volume scheme" or "price volume schemes") NEAR/6 ((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)))

27 84 TS="managed entry"

26 1,536 TS=(((publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares)NEAR/6 (information*)) AND (pricing or price or prices or priced or discount or discounts or rebate or rebates))

25 368 TS=((pricing or price or prices or priced) AND (rebate or rebates or rebated))

24 1,633 TS=((pricing or price or prices or priced or discount or discounts or rebate or rebates) AND (transparen* or accountab*))

23 3,289 TS=((pricing or price or prices or priced or discount or discounts or rebate or rebates) NEAR/6 (publish* or publication or disclos* or disseminat* or communicat* or share or shared or sharing or shares))

22 2,146 TS=("profit margin" or "profit margins" or "gross margin" or "gross margins" or "cost price" or "cost prices" or "purchase price" or "purchase prices" or "purchasing price" or "purchasing prices" or "selling price" or "selling prices")

21 61 TS=((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics") NEAR/6 (margin or margins))

20 3,941 TS=(("supply chain" or "supply chains" or distribution) NEAR/3 (cost or costs or costed or costing)) OR TS=(("supply chain" or "supply chains" or distribution) NEAR/6 (price or prices or priced or pricing))

19 1,057 TS=((mark-up or mark-ups or markup*) AND (regulat* or manipulat* or supply or supplies or distribut* or wholesale* or prescrib* or prescrip* or dispens* or pricing or price or prices or priced or cost or costs or costing or costed or economic or economics or pharmacoeconomic or pharmacoeconomics))

18 246 TI=(mark-up or mark-ups or markup*) OR TS= ((mark-up or mark-ups or markup*) NEAR/3 control*)

17 4,527 TS=((pricing or price or prices or priced) NEAR/6 (threshold or thresholds or maximum or maximums or cap or caps or capped or capping or ceiling or ceilings or discount* or reduction*))

16 3,970 TS=((pricing or price or prices or priced) NEAR/3 (set or sets or setting or control* or containment or preferential))

15 86 TS= (((expense or expenses) NEAR/3 (produc* or promot* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits)) AND (pricing or price or prices or priced))

14 4,026 TS= (((cost or costs) NEAR/3 (based or produc* or promot* or expense* or research* or develop* or administrat* or overhead* or over-head or over-heads or profit or profits)) AND (pricing or price or prices or priced))

13 138 TS=(cost-plus or costplus or costs-plus or costsplus)

12 961 TS=(("economic evaluation" OR "economic evaluations" or cost-consequence or cost-consequences or cost-minimization or cost-minimisation or cost-effectiveness or cost-utility or cost-benefit or cost-benefits) AND (pricing or price or prices or priced) AND (based or set or sets or setting))

11 4,362 TS=(value-based and (pricing or price or prices or priced or reimbursement)) OR TS=((value or values) NEAR/6 (pricing or price or prices or priced))

10 93 TS= (“international price comparison" or "international price comparisons" or "comparative price" or "comparative prices" or "factory price" or "factory prices" or "factories price" or "factories prices" or "manufacturer price" or "manufacturer prices" or "manufacturers price" or "manufacturers prices" or "exfactory price" or "exfactory prices" or "exfactorys price" or "exfactorys prices" or "exmanufacturer price" or "exmanufacturer prices" or "exmanufacturers price" or "exmanufacturers prices")

9 1,230 TS=((reference OR benchmark or benchmarks or bench-mark or bench-marks) NEAR/6 (pricing or prices or price or priced))

8 237,237 TS=(drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines or biosimilar or biosimilars or bio-similar or bio-similars or biogeneric or biogenerics or "follow-on biologic" or "follow-on biologics" or "subsequent entry biologic" or "subsequent entry biologics" or "similar biologic" or "similar biologics")

7 2,854 #6 OR #5 OR #4 OR #3 OR #2 OR #1

6 361 TS=((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND (cost-control or cost-containment or cost-setting))

5 434 TS=((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ("price regulation" or "price regulations" or "price difference" or "price differences" or "price differential" or "price differentials" or "price dispersion" or "average price" or "average prices" or "retail price" or "retail prices" or "wholesale price" or "wholesale prices" or "expected price" or "expected prices" or "net price" or "net prices" or "transaction price" or "transaction prices" or "price type" or "price types" or "price component" or "price components" or "cif price" or "cif prices" or "freight price" or "freight prices" or "pharmacy price" or "pharmacy prices" or "pharmacist price" or "pharmacist prices" or "pharmacists price" or "pharmacists prices" or "end price" or "end prices" or "consumer price" or "consumer prices" or "final price" or "final prices" or "reimbursement price" or "reimbursement prices" or "list price" or "list prices" or "actual price" or "actual prices"))

4 629 TS=((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ((pricing or price or prices or priced) NEAR/3 (arrangement or arrangements or framework or frameworks or frame-work or frame-works or intervention or interventions or law or laws or legal* or legislat* or measure or measures or measurement or measurements or mechanism or mechanisms or order or orders or plan or plans or planning or principle or principles or procedure or procedures or program or programme or programmes or programs or regulat* or requirement or requirements or rule or rules or scheme or schemes or standard or standards or strategies or strategy or strategic*)))

3 300 TS=((drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines) AND ((pricing or price or prices or priced) NEAR/6 (policy or policies)))

2 2,112 TS=((pricing or price or prices or priced) NEAR/6 (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines))

1 1,061 TITLE: (((pricing or price or prices or priced) AND (drug or drugs or pharmaceutical or pharmaceuticals or biopharmaceutical or biopharmaceuticals or medicine or medicines or medication or medications or medicament or medicaments or prescription or prescriptions or vaccine or vaccines)))

A.28: Source: Department of International Development (UK) website

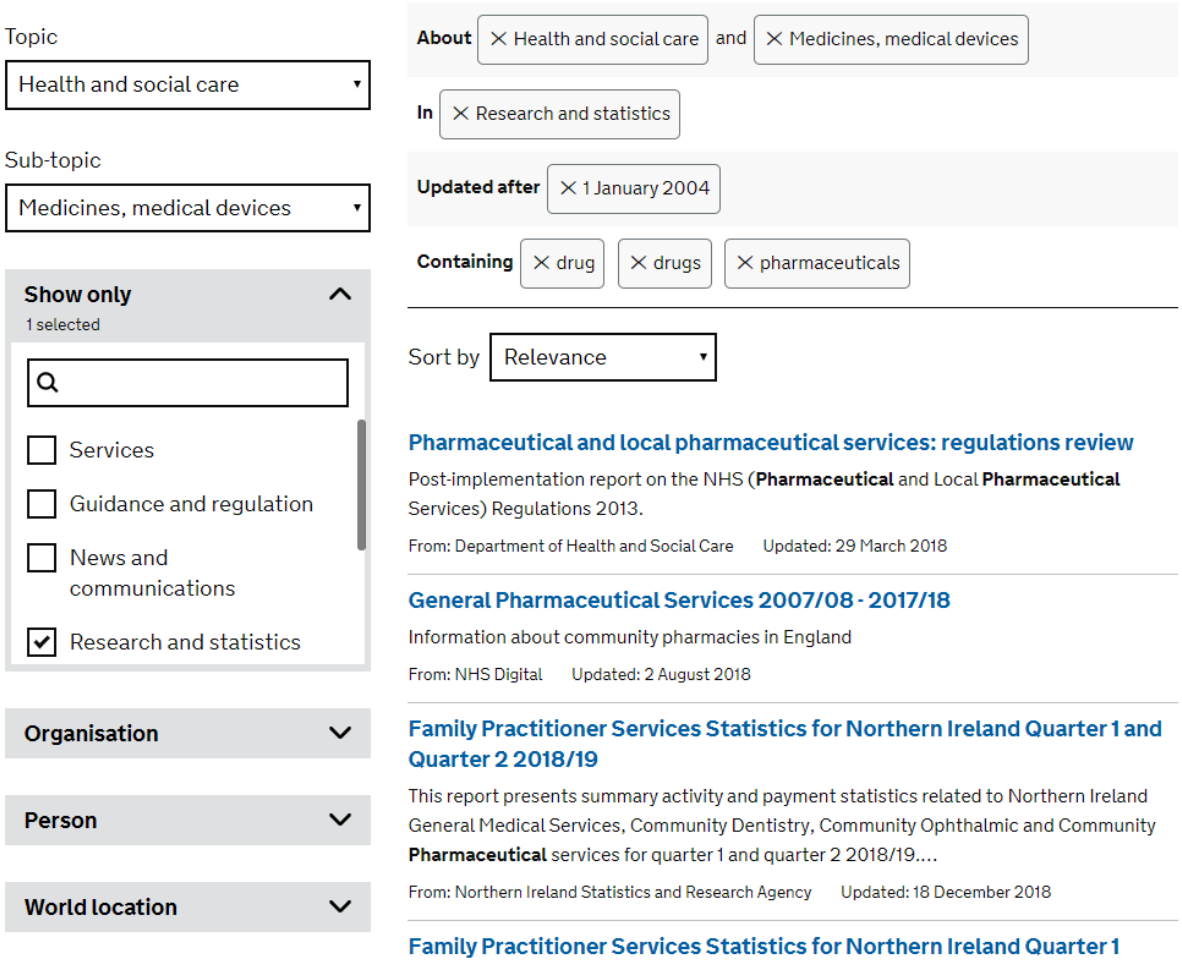
Interface / URL: https://www.gov.uk/government/organisations/department-for-international-development
Database coverage dates: N/A

Search date: 21/10/2019

Retrieved records: 8 – none relevant

Search strategy:

The following screenshot shows the search that was undertaken. Results were restricted records updated after 2004. No relevant records were downloaded.



A.29 Reference checking

The reference lists of the included studies (Table A.1) were obtained from Web of Science and downloaded.

The 2184 records were loaded into an EndNote library. After deduplication within this set, 698 duplicates were identified and put into the full duplicates library.

459 records that were pre-2004 were excluded.

1027 records were loaded into the EndNote library and were then deduplicated against the full library. 460 duplicates were detected and moved to the duplicates library.

A list of the 567 remaining records (with their abstracts) was screened for relevant references.

Utrecht rejected 562 records based on title and abstract, another 4 were rejected after examination of the full texts.

Utrecht selected 1 record for extraction.

Table A.1: Reference checking

Reference	Number of references[1]	Number of references[2]
Aalto-Setala V. The impact of generic substitution on price competition in Finland. Eur J Health Econ. 2008;9(2):185-91.	15	11
Abbas A, Vella Szijj J, Azzopardi LM, Serracino Inglott A. Orphan drug policies in different countries. J Pharm Health Serv Res. 2019;10(3):295-302.	0	0
Abdel Rida N, Mohamed Ibrahim MI, Babar ZUD, Owusu Y. A systematic review of pharmaceutical pricing policies in developing countries. J Pharm Health Serv Res. 2017;8(4):213-26.	53	34
Abramson RG, Harrington CA, Missmar R, Li SP, Mendelson DN. Generic drug cost containment in medicaid: lessons from five state MAC programs. Health Care Financ Rev. 2004;25(3):25-34.	12	0
Abuelkhair M, Abdu S, Godman B, Fahmy S, Malmstrm RE, Gustafsson LL. Imperative to consider multiple initiatives to maximize prescribing efficiency from generic availability: Case history from Abu Dhabi. Expert Rev Pharmacoeconomics Outcomes Res. 2012;12(1):115-24.	57	46
Ackermann AC, Reinaud F, Ando G, Izmirlieva M. Impact of 2011 German health care reform on prices. Value Health. 2014;17(7):A422.	0	0
Acosta A, Ciapponi A, Aaserud M, Vietto V, Austvoll-Dahlgren A, Kosters JP, et al. Pharmaceutical policies: effects of reference pricing, other pricing, and purchasing policies. Cochrane Database Syst Rev. 2014(10):CD005979.	0	0

[1] Number of references listed in reference
[2] Number of references retrieved from Web of Science

Adesina A, Wirtz VJ, Dratler S. Reforming antiretroviral price negotiations and public procurement: the Mexican experience. Health Policy Plan. 2013;28(1):1-10.	33	8
Adriaen M, De Witte K, Simoens S. Pricing strategies of originator and generic medicines following patent expiry in Belgium. J Generic Med. 2008;5(3):175-87.	0	0
Ahmad NS, Hatah E, Makmor-Bakry M. Association between medicine price declaration by pharmaceutical industries and retail prices in Malaysia's private healthcare sector. J Pharm Policy Pract. 2019;12:15.	0	0
Akehurst RL, Abadie E, Renaudin N, Sarkozy F. Variation in health technology assessment and reimbursement processes in Europe. Value Health. 2017;20(1):67-76.	17	8
Alabbadi I, Hammad EA. The impact of generic entry and price competition in Jordanian public health sector. J Generic Med. 2014;11(3-4):123-28.	0	0
Al-Abbadi I, Qawwas A, Jaafreh M, Abosamen T, Saket M. One-year assessment of joint procurement of pharmaceuticals in the public health sector in Jordan. Clin Ther. 2009;31(6):1335-44.	0	0
Alexandre RF, Schneiders RE, Xavier LC, Barros SC, Nascimento Jr JM, Gadelha CAG. High-cost medicines in Brazil: centralized purchase for optimization of budgetary resources and increasing access in the public health system. Value Health. 2014;17(3):A31.	0	0
Ali GK, Yahia Y. Controlling medicine prices in Sudan: the challenge of the recently established medicines regulatory authority. East Mediterr Health J. 2012;18(8):811-20.	0	0
Alonso Castro V, Lopez Centeno B, Pinar Palacios JL, Martin Casasempere I, Gil Martin A, Aranguren Oyarzabal A, et al. Centralised purchasing as a strategic line for the rationalisation of pharmaceutical expenditure in a regional health service. Eur J Hosp Pharm. 2018;25:A21-A22.	0	0
Alpert A, Duggan M, Hellerstein JK. Perverse reverse price competition: average wholesale prices and medicaid pharmaceutical spending. J public econ. 2013;108:44-62.	35	14
Amaral SM, Blatt CR. Municipal consortia for medicine procurement: impact on the stock-out and budget. Rev Saude Publica. 2011;45(4):799-801.	5	4
Andersson K, Bergstrom G, Petzold MG, Carlsten A. Impact of a generic substitution reform on patients' and society's expenditure for pharmaceuticals. Health Policy. 2007;81(2-3):376-84.	34	30
Andersson K, Petzold MG, Sonesson C, Lonnroth K, Carlsten A. Do policy changes in the pharmaceutical reimbursement schedule affect drug expenditures? Interrupted time series analysis of cost, volume and cost per volume trends in Sweden 1986-2002. Health Policy. 2006;79(2-3):231-43.	0	0
Andia T, Gaviria A, Gomez C, Jaramillo LF, Marquez S, Rodríguez I, et al. First evaluation of colombian's external reference pricing system. Value Health. 2014;17(3):A15.	0	0
Anell A, Persson U. Reimbursement and clinical guidance for pharmaceuticals in Sweden: do health-economic evaluations support decision making? Eur J Health Econ. 2005;6(3):274-9.	0	0
Anggriani Y, Ibrahim MIM, Suryawati S, Shafie AA. The impact of Indonesian generic medicine pricing policy on medicine prices. J Generic Med. 2013;10(3-4):219-29.	0	0
Ansaripour A, Franken M, Uyl-de Groot C, Kalo Z, Redekop WK. Is external reference pricing a threat to international equal affordability? Value Health. 2016;19(7):A759-A60.	0	0

Arinaminpathy N, Cordier-Lassalle T, Lunte K, Dye C. The global drug facility as an intervention in the market for tuberculosis drugs. Bull World Health Organ. 2015;93(4):237-48A.	23	17
Armeni P, Jommi C, Otto M. The simultaneous effects of pharmaceutical policies from payers' and patients' perspectives: Italy as a case study. Eur J Health Econ. 2016;17(8):963-77.	26	18
Augurzky B, Gohlmann S, Gress S, Wasem J. Effects of the German reference drug program on ex-factory prices of prescription drugs: a panel data approach. Health Econ. 2009;18(4):421-36.	12	11
Austvoll-Dahlgren A, Aaserud M, Vist G, Ramsay C, Oxman AD, Sturm H, et al. Pharmaceutical policies: effects of cap and co-payment on rational drug use. Cochrane Database Syst Rev. 2008(1)	0	0
Avdi E. The effect of pricing policies and cost-containment measures in Albanian health insurance scheme. Romanian Econ Bus Rev. 2013;8(3):61-78.	0	0
Babar ZU, Gammie T, Seyfoddin A, Hasan SS, Curley LE. Patient access to medicines in two countries with similar health systems and differing medicines policies: implications from a comprehensive literature review. Res Social Adm Pharm. 2019;15(3):231-43.	0	0
Babar ZU, Kan SW, Scahill S. Interventions promoting the acceptance and uptake of generic medicines: a narrative review of the literature. Health Policy. 2014;117(3):285-96.	48	25
Bae EY, Hong JM, Kwon HY, Jang S, Lee HJ, Bae S, et al. Eight-year experience of using HTA in drug reimbursement: South Korea. Health Policy. 2016;120(6):612-20.	22	12
Baldi S, Vannoni D. The impact of centralization on pharmaceutical procurement prices: the role of institutional quality and corruption. Reg. Stud. 2017;51(3):426-38.	38	14
Ball D. Review series on pharmaceutical pricing policies and interventions: working paper 3: the regulation of mark-ups in the pharmaceutical supply chain. Amsterdam, The Netherlands 2011. Available from: https://haiweb.org/wp-content/uploads/2015/07/Working-Paper-3-Regulation-of-Mark-ups.pdf.	0	0
Barbosa K, Fiuza EPS. Demand aggregation and credit risk effects in pooled procurement: evidence from the Brazilian public purchases of pharmaceuticals and medical supplies. Escola Econ São Paulo. 2012:1-46.	0	0
Bastani P, Imanieh MH, Dorosti H, Abbasi R, Dashti SA, Keshavarz K. Lessons from one year experience of pooled procurement of pharmaceuticals: exploration of indicators and assessing pharmacies` performance. DARU. 2018;12:12.	0	0
Beall RF, Kuhn R, Attaran A. Compulsory licensing often did not produce lower prices for antiretrovirals compared to international procurement. Health Aff. 2015;34(3):493-501.	39	15
Becker B, Kruppert S, Kostev K. Economic prescribing of corticosteroid nasal sprays in Germany: comparison of mometasone and budesonide nasal sprays on the basis of the DDD, the PDD and reference prices. Int J Clin Pharmacol Ther. 2013;51(1):12-8.	17	5

Ben-Aharon O, Shavit O, Magnezi R. Does drug price-regulation affect healthcare expenditures? Eur J Health Econ. 2017;18(7):859-67.	21	8
Bennie M, Godman B, Bishop I, Campbell S. Multiple initiatives continue to enhance the prescribing efficiency for the proton pump inhibitors and statins in Scotland. Expert Rev Pharmacoecon Outcomes Res. 2012;12(1):125-30.	31	17
Bergman MA, Granlund D, Rudholm N. Reforming the Swedish pharmaceuticals market: consequences for costs per defined daily dose. Int J Health Econ Manag. 2016;16(3):201-14.	0	0
Bestehorn K, Greiner W. Effects of the introduction of fixed prices for statins on lipid levels in Germany. J Public Health. 2008;16(3):215-19.	0	0
Bhaskarabhatla A, Chatterjee C, Anurag P, Pennings E. Mitigating regulatory impact: the case of partial price controls on metformin in India. Health Policy Plan. 2017;32(2):194-204.	65	32
Bocquet F, Loubiere A, Fusier I, Cordonnier AL, Paubel P. Competition between biosimilars and patented biologics: learning from European and Japanese experience. Pharmacoeconomics. 2016;34(11):1173-86	37	17
Brekke KR, Canta C, Straume OR. Does reference pricing drive out generic competition in pharmaceutical markets? Evidence from a policy reform. NHH Dept Econ. 2015(11)	31	21
Brekke KR, Holmas TH, Straume OR. Margins and market shares: pharmacy incentives for generic substitution. Eur. Econ. Rev. 2013;61:116-31.	22	17
Brinkman A. Plan savings from stepped-generic copayment reduction. J Manag Care Pharm. 2011;17(7):566.	0	0
Bumpas J. Study on comparative efficiencies in vaccine procurement mechanisms. World Bank. 2008:1-62.	0	0
Buzzelli C, Kangasharju A, Linnosmaa I, Valtonen H. Impact of generic substitution on pharmaceutical prices and expenditures in OECD countries. J Pharma Finance Econ Policy. 2006;15(1):41-63.	0	0
Casanova-Juanes J, Mestre-Ferrandiz J, Espin-Balbino J. Competition in the off-patent medicine market in Spain: The national reference pricing system versus the regional system of tendering for outpatient prescription medicines in Andalusia. Health Policy. 2018;122(12):1310-15.	0	0
Čatić T, Jusufović R, Tabakovic V, Begovic B. Impact of price regulation ordinance on top 20 prescribed medicines prices in Bosnia and Herzegovina. Value Health. 2018;21:S157.	0	0
Chachoua L, Achour L, Hanna E, Borrisov B, Toumi M. Orphan drug prices in europe: impact of external reference pricing. Value Health. 2018;21:S313.	0	0
Chan A, Kitchen J, Scott A, Pollock D, Marshall R, Herdman L. Implementing and delivering a successful biosimilar switch programme - the Berkshire West experience. Future Healthc J. 2019;6(2):143-45.	0	0

Chaves GC, Castro C, Oliveira MA. Public procurement of hepatitis C medicines in Brazil from 2005 to 2015. Cienc. 2017;22(8):2527-38.	29	2
Chen CL, Chen L, Yang WC. The influences of Taiwan's generic grouping price policy on drug prices and expenditures: evidence from analysing the consumption of the three most-used classes of cardiovascular drugs. BMC Public Health. 2008;8:118.	21	12
Chen Y, Hu S, Dong P, Kornfeld A, Jaros P, Yan J, et al. Drug pricing reform in China: analysis of piloted approaches and potential impact of the reform. J Mark Access Health Policy. 2016;4	0	0
Cheng W, Fang Y, Fan D, Sun J, Shi X, Li J. Study on the effect of «zero mark-up» policy on medicines in Beijing community health facilities. Pharma Policy Law. 2012;14(2-4):177-86.	0	0
Cho MH, Yoo KB, Lee HY, Lee KS, Kwon JA, Han KT, et al. The effect of new drug pricing systems and new reimbursement guidelines on pharmaceutical expenditures and prescribing behavior among hypertensive patients in Korea. Health Policy. 2015;119(5):604-11.	27	20
Chokshi M, Farooqui HH, Selvaraj S, Kumar P. A cross-sectional survey of the models in Bihar and Tamil Nadu, India for pooled procurement of medicines. WHO South-East Asia j. 2015;4(1):78-85.	0	0
Choksi P. A regression analysis of the impact of patient access schemes. Value Health. 2013;16(3):A268.	0	0
Chu HL, Liu SZ, Romeis JC. Assessing the effects of drug price reduction policies on older people in Taiwan. Health Serv Manage Res. 2011;24(1):1-7.	0	0
Clark B, DuChane J, Hou J, Rubinstein E, McMurray J, Duncan I. Evaluation of increased adherence and cost savings of an employer value-based benefits program targeting generic antihyperlipidemic and antidiabetic medications. J Manag Care Pharm. 2014;20(2):141-50.	46	33
Coma A, Zara C, Godman B, Agusti A, Diogene E, Wettermark B, et al. Policies to enhance the efficiency of prescribing in the Spanish Catalan region: impact and future direction. Expert Rev Pharmacoecon Outcomes Res. 2009;9(6):569-81.	0	0
Costa-Font J, McGuire A, Varol N. Regulation effects on the adoption of new medicines. Empir. Econ. 2015;49(3):1101-21.	40	25
Creese A. Review series on pharmaceutical pricing policies and interventions: working paper 5: sales taxes on medicines. Amsterdam, The Netherlands 2011. Available from: https://haiweb.org/wp-content/uploads/2015/08/Taxes-final-May2011a1.pdf.	0	0
Csanádi M, Kaló Z, Prins CPJ, Grélinger E, Menczelné Kiss A, Fricke FU, et al. The implications of external price referencing on pharmaceutical list prices in Europe. Health Policy Technol. 2018;7(3):243-50.	0	0

Curto S, Ghislandi S, van de Vooren K, Duranti S, Garattini L. Regional tenders on biosimilars in Italy: an empirical analysis of awarded prices. Health Policy. 2014;116(2-3):182-7.	16	6
Dalen DM, Furu K, Locatelli M, Strom S. Generic substitution: micro evidence from register data in Norway. Eur J Health Econ. 2011;12(1):49-59.	19	13
Dalen DM, Strom S, Haabeth T. Price regulation and generic competition in the pharmaceutical market. Eur J Health Econ. 2006;7(3):208-14.	0	0
Danzon PM, Epstein AJ. Effects of regulation on drug launch and pricing in interdependent markets. Adv Health Econ Health Serv Res. 2012;23:35-71.	0	0
Danzon PM, Furukawa MF. Cross-national evidence on generic pharmaceuticals: pharmacy vs. Physician-driven markets. National Bureau of Economic Research, Inc, NBER Working Papers: 17226. 2011. Available from: https://www.nber.org/papers/w17226.	0	0
Danzon PM, Ketcham JD. Reference pricing of pharmaceuticals for Medicare: evidence from Germany, The Netherlands, and New Zealand. Front Health Policy Res. 2004;7:1-54.	30	13
Danzon PM, Mulcahy AW, Towse AK. Pharmaceutical pricing in emerging markets: effects of income, competition and procurement. Health Econ. 2015;24(2):238-52.	21	9
de Jager H, Suleman F. The impact of generics and generic reference pricing on candesartan and rosuvastatin utilisation, price and expenditure in South Africa. Int J Clin Pharm. 2019;41(1):81-87.	0	0
Degrassat-Theas A, Bensadon M, Rieu C, Angalakuditi M, Le Pen C, Paubel P. Hospital reimbursement price cap for cancer drugs: the French experience in controlling hospital drug expenditures. Pharmacoeconomics. 2012;30(7):565-73.	12	1
Deng J, Tian H, Guo Y, Ma T, Sun Y, Zhang S, et al. A retrospective and prospective assessment of the zero-markup drug reform in China from the perspective of policy diffusion. Int J Health Plann Manage. 2018;33(4):e918-e29.	31	4
DeRoeck D, Bawazir SA, Carrasco P, Kaddar M, Brooks A, Fitzsimmons J, et al. Regional group purchasing of vaccines: review of the pan American health organization EPI revolving fund and the Gulf cooperation council group purchasing program. Int J Health Plann Manage. 2006;21(1):23-43.	14	2
Díaz-Rojas JA, Rodríguez-Márceles M, Rodríguez-Romero A, Brown P. Impact of group purchasing in cooperative of hospital in Colombia, using a price index from 1999 to 2012. Rev. colomb. ciencias quim. farm. 2013;42(1):80-102.	0	0
Djambazov SN, Vekov TY, Petrov D. Price control of out-patient cancer drugs in Bulgaria, 2010-2011: reference based pricing and public tenders verse reference based pricing only. Value Health. 2014;17(7):A660.	0	0
Djambazov SN, Vekov TY, Petrov D. National health insurance fund drug expenditure in Bulgaria, 2007-2012: reference based pricing alone or in combination with other approaches to pricing. Value Health. 2014;17(7):A432.	0	0

Do Amaral SMS, Blatt CR. Municipal consortia for medicine procurement: Impact on the stockout and budget. Rev Saude Publica. 2011;45(4):799-801.	5	4
Drummond M, Jonsson B, Rutten F, Stargardt T. Reimbursement of pharmaceuticals: reference pricing versus health technology assessment. Eur J Health Econ. 2011;12(3):263-71.	25	6
Dubois P, Lefouili Y, Straub S. Pooled procurement of drugs in low and middle income countries. 2019. Available from: https://www.cgdev.org/publication/pooled-procurement-drugs-low-and-middle-income-countries.	0	0
Duggan M, Morton FMS. The distortionary effects of government procurement: evidence from medicaid prescription drug purchasing. Q. J. Econ. 2006;121(1):1-30.	27	17
Dutta A, Bandyopadhyay S. Policy intervention for access to medicine: does it work similarly for poor and non-poor? Int J Health Plann Manage. 2019;34(1):e557-e68.	0	0
Dylst P, Vulto A, Simoens S. The impact of reference-pricing systems in Europe: a literature review and case studies. Expert Rev Pharmacoecon Outcomes Res. 2011;11(6):729-37.	37	23
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Zhang H, Hu H, Wu C, Yu H, Dong H. Impact of china's public hospital reform on healthcare expenditures and utilization: a case study in ZJ province. PLoS ONE. 2015;10(11):1-19.	69	27
Zhou Z, Su Y, Campbell B, Zhou Z, Gao J, Yu Q, et al. The financial impact of the 'zero-markup policy for essential drugs' on patients in county hospitals in western rural China. PLoS ONE. 2015;10(3):1-17.	38	11
Vrijens F, Van de Voorde C, Farfan-Portet M, Polain M, Lohest O. The reference price system and socioeconomic differences in the use of low cost drugs. KCE reports C. 2010;126:1-88.	0	0
DoHA. The Impacts of Pharmaceutical Benefits Scheme Reform. Department of Health and Ageing 2010. Available from: https://www1.health.gov.au/internet/main/publishing.nsf/Content/4BC52286D3009386CA257BF000209AD5/$File/PwC%20The%20Impacts%20of%20PBS%20Reform.pdf.	0	0

Appendix B: Excluded studies

List of excluded studies

Reference	Exclusions Reasons
Aalto-Setala V. The impact of generic substitution on price competition in Finland. Eur J Health Econ. 2008;9(2):185-91.	Ineligible Study Design
Abramson RG, Harrington CA, Missmar R, Li SP, Mendelson DN. Generic drug cost containment in medicaid: lessons from five state MAC programs. Health Care Financ Rev. 2004;25(3):25-34.	Ineligible Study Design
Abuelkhair M, Abdu S, Godman B, Fahmy S, Malmstrm RE, Gustafsson LL. Imperative to consider multiple initiatives to maximize prescribing efficiency from generic availability: Case history from Abu Dhabi. Expert Rev Pharmacoeconomics Outcomes Res. 2012;12(1):115-24.	Ineligible Study Design
Ahmad NS, Hatah E, Makmor-Bakry M. Association between medicine price declaration by pharmaceutical industries and retail prices in Malaysia's private healthcare sector. J Pharm Policy Pract. 2019;12:15.	Ineligible Study Design
Akehurst RL, Abadie E, Renaudin N, Sarkozy F. Variation in health technology assessment and reimbursement processes in Europe. Value Health. 2017;20(1):67-76.	Ineligible Study Design
Alabbadi I, Hammad EA. The impact of generic entry and price competition in Jordanian public health sector. J Generic Med. 2014;11(3-4):123-28.	Ineligible Study Design
Al-Abbadi I, Qawwas A, Jaafreh M, Abosamen T, Saket M. One-year assessment of joint procurement of pharmaceuticals in the public health sector in Jordan. Clin Ther. 2009;31(6):1335-44.	Ineligible Study Design
Alexandre RF, Schneiders RE, Xavier LC, Barros SC, Nascimento Jr JM, Gadelha CAG. High-cost medicines in Brazil: centralized purchase for optimization of budgetary resources and increasing access in the public health system. Value Health. 2014;17(3):A31.	Ineligible Study Design
Ali GK, Yahia Y. Controlling medicine prices in Sudan: the challenge of the recently established medicines regulatory authority. East Mediterr Health J. 2012;18(8):811-20.	Ineligible Study Design
Alonso Castro V, Lopez Centeno B, Pinar Palacios JL, Martin Casasempere I, Gil Martin A, Aranguren Oyarzabal A, et al. Centralised purchasing as a strategic line for the rationalisation of pharmaceutical expenditure in a regional health service. Eur J Hosp Pharm. 2018;25:A21-A22.	Ineligible Study Design
Amaral SM, Blatt CR. Municipal consortia for medicine procurement: impact on the stock-out and budget. Rev Saude Publica. 2011;45(4):799-801.	Ineligible Study Design
Andrus JK, Sherris J, Fitzsimmons JW, Kane MA, Aguado MT. Introduction of human papillomavirus vaccines into developing countries - international strategies for funding and procurement. Vaccine. 2008;26 Suppl 10:K87-92.	Ineligible Study Design

Anell A, Persson U. Reimbursement and clinical guidance for pharmaceuticals in Sweden: do health-economic evaluations support decision making? Eur J Health Econ. 2005;6(3):274-9.	Ineligible Study Design
Anggriani Y, Ibrahim MIM, Suryawati S, Shafie AA. The impact of Indonesian generic medicine pricing policy on medicine prices. J Generic Med. 2013;10(3-4):219-29.	Ineligible Study Design
Annemans L. A proposal for value informed, affordable ("via") prices for innovative medicines. J Med Econ. 2019:1-5.	Ineligible Study Design
Anonymous. Generic price controls in Newfoundland and Labrador pose economic threat: PANL. Can Pharm J (Ott). 2008;141(2):81-82.	Ineligible Study Design
Anonymous. Abstracts from the 3rd International PPRI conference 2015: pharmaceutical pricing and reimbursement policies: challenges beyond the financial crisis. J Pharma Policy Pract. 2015;8 Suppl 1:E1-P29.	Ineligible Study Design
Anonymous. AMCP partnership forum: biosimilars--ready, set, launch. J Manag Care Spec Pharm. 2016;22(4):434-40.	Ineligible Study Design
Anonymous. AMCP partnership forum: advancing value-based contracting. J Manag Care Spec Pharm. 2017;23(11):1096-102.	Ineligible Study Design
Ansaripour A, Franken M, Uyl-de Groot C, Kalo Z, Redekop WK. Is external reference pricing a threat to international equal affordability? Value Health. 2016;19(7):A759-A60.	Ineligible Study Design
Antonanzas F, Oliva J, Pinillos M, Juarez C. Economic aspects of the new Spanish laws on pharmaceutical preparations. Eur J Health Econ. 2007;8(3):297-300.	Ineligible Study Design
Arinaminpathy N, Cordier-Lassalle T, Lunte K, Dye C. The global drug facility as an intervention in the market for tuberculosis drugs. Bull World Health Organ. 2015;93(4):237-48A.	Ineligible Study Design
Ashigbie PG, Azameti D, Wirtz VJ. Challenges of medicines management in the public and private sector under Ghana's national health insurance scheme - a qualitative study. J Pharma Policy Pract. 2016;9:6.	Ineligible Study Design
Austvoll-Dahlgren A, Aaserud M, Vist G, Ramsay C, Oxman AD, Sturm H, et al. Pharmaceutical policies: effects of cap and co-payment on rational drug use. Cochrane Database Syst Rev. 2008(1)	Ineligible Study Design
Avdi E. The effect of pricing policies and cost-containment measures in Albanian health insurance scheme. Romanian Econ Bus Rev. 2013;8(3):61-78.	Ineligible Study Design
Azzopardi-Muscat N, Schroder-Back P, Brand H. The european union joint procurement agreement for cross-border health threats: what is the potential for this new mechanism of health system collaboration? Health Econ. Policy Law. 2017;12(1):43-59.	Ineligible Study Design
Babar ZU, Kan SW, Scahill S. Interventions promoting the acceptance and uptake of generic medicines: a narrative review of the literature. Health Policy. 2014;117(3):285-96.	Ineligible Study Design
Bach PB, Pearson SD. Payer and policy maker steps to support value-based pricing for drugs. JAMA. 2015;314(23):2503-4.	Ineligible Study Design
Bae EY, Hong JM, Kwon HY, Jang S, Lee HJ, Bae S, et al. Eight-year experience of using HTA in drug reimbursement: South Korea. Health Policy. 2016;120(6):612-20.	Ineligible Study Design

Baker BK. Patents, pricing, and access to essential medicines in developing countries. Virtual Mentor. 2009;11(7):527-32.	Ineligible Study Design
Baldwin P. The prescription drug cost-containment debate: the outcome affects us. Consult Pharm. 2018;33(11):668.	Ineligible Study Design
Balotsky ER. Where strategy and ethics converge: pharmaceutical industry pricing policy for medicare part D beneficiaries. J. Bus. Ethics. 2009;84:75-88.	Ineligible Study Design
Bardey D, Bommier A, Jullien B. Retail price regulation and innovation: reference pricing in the pharmaceutical industry. J Health Econ. 2010;29(2):303-16.	Ineligible Study Design
Barlas S. Value purchasing programs make plodding progress: drug manufacturers question some pay-for-performance methodologies. P T. 2016;41(9):562-89.	Ineligible Study Design
Barlas S. Early Biosimilars Face Hurdles to Acceptance: The FDA Has Approved Few, So Lack of Competition Is Keeping Prices High. P T. 2016;41(6):362-5.	Ineligible Study Design
Barlas S. Health care price transparency initiatives are all the rage but burgeoning efforts suffer from myriad shortcomings. P T. 2018;43(12):744-68.	Ineligible Study Design
Barth J, Hammerschmidt T, Vollmar J, Bierbaum M, Schoffski O. [Mechanics and effects of European reference pricing for vaccines in Germany according to 130a Abs. 2 SGB V: an analysis using the example of influenza vaccines]. Gesundheitswesen. 2014;76(4):e7-e13.	Ineligible Study Design
Bastani P, Imanieh MH, Dorosti H, Abbasi R, Dashti SA, Keshavarz K. Lessons from one year experience of pooled procurement of pharmaceuticals: exploration of indicators and assessing pharmacies` performance. DARU. 2018;12:12.	Ineligible Study Design
Baulinet C, Duraffourg M, Vanackere S. La Fiscalité spécifique applicable aux produits de santé et à l'industrie qui les fabrique. Rapport de l'IGAS et de l'IGF. 2012:1-239.	Ineligible Study Design
Beall RF, Kuhn R, Attaran A. Compulsory licensing often did not produce lower prices for antiretrovirals compared to international procurement. Health Aff. 2015;34(3):493-501.	Ineligible Study Design
Becker B, Kruppert S, Kostev K. Economic prescribing of corticosteroid nasal sprays in Germany: comparison of mometasone and budesonide nasal sprays on the basis of the DDD, the PDD and reference prices. Int J Clin Pharmacol Ther. 2013;51(1):12-8.	Ineligible Study Design
Bennie M, Godman B, Bishop I, Campbell S. Multiple initiatives continue to enhance the prescribing efficiency for the proton pump inhibitors and statins in Scotland. Expert Rev Pharmacoecon Outcomes Res. 2012;12(1):125-30.	Ineligible Study Design
Bocquet F, Loubiere A, Fusier I, Cordonnier AL, Paubel P. Competition between biosimilars and patented biologics: learning from European and Japanese experience. Pharmacoeconomics. 2016;34(11):1173-86.	Ineligible Study Design
Brekke KR, Canta C, Straume OR. Reference pricing with endogenous generic entry. J Health Econ. 2016;50:312-29.	Ineligible Study Design
Brekke KR, Holmas TH, Straume OR. Margins and market shares: pharmacy incentives for generic substitution. Eur. Econ. Rev. 2013;61:116-31.	Ineligible Study Design
Bretthauer B. The generic medicines market in Germany. J Gen Med. 2012;9(1):9-12.	Ineligible Study Design
Bumpas J. Study on comparative efficiencies in vaccine procurement mechanisms. World Bank. 2008:1-62.	Ineligible Study Design

Burki TK. A new strategy to reduce US drug prices. Lancet Oncol. 2018;17:17.	Ineligible Study Design
Caliari T, Ruiz RM. Os gastos públicos com medicamentos no período de 2002 a 2006. Rev. adm. saúde. 2010;12(49):167-76.	Ineligible Study Design
Casanova-Juanes J, Mestre-Ferrandiz J, Espin-Balbino J. Competition in the off-patent medicine market in Spain: The national reference pricing system versus the regional system of tendering for outpatient prescription medicines in Andalusia. Health Policy. 2018;122(12):1310-15.	Ineligible Study Design
Čatić T, Jusufović R, Tabakovic V, Begovic B. Impact of price regulation ordinance on top 20 prescribed medicines prices in Bosnia and Herzegovina. Value Health. 2018;21:S157.	Ineligible Study Design
Cernuschi T, Furrer E, Schwalbe N, Jones A, Berndt ER, McAdams S. Advance market commitment for pneumococcal vaccines: putting theory into practice. Bull World Health Organ. 2011;89(12):913-18.	Ineligible Study Design
Chan A, Kitchen J, Scott A, Pollock D, Marshall R, Herdman L. Implementing and delivering a successful biosimilar switch programme - the Berkshire West experience. Future Healthc J. 2019;6(2):143-45.	Ineligible Study Design
Chang F, Luo XY, Cui PL. Value-based new drugs pricing of typical countries and the inspiration to China. Chi J New Drugs. 2015;24(18):2047-51.	Ineligible Study Design
Chang F, Sun J. International reference pricing of new drugs in Japan and the inspiration to China. Chi J New Drugs. 2014;23(5):510-12+22.	Ineligible Study Design
Chaves GC, Castro C, Oliveira MA. Public procurement of hepatitis C medicines in Brazil from 2005 to 2015. Cienc. 2017;22(8):2527-38.	Ineligible Study Design
Chen J, Sang XD, Ren QY, Shi LW. Policies to promote use of generic drugs in developed countries. Chi J New Drugs. 2017;26(24):2887-91.	Ineligible Study Design
Cho MH, Yoo KB, Lee HY, Lee KS, Kwon JA, Han KT, et al. The effect of new drug pricing systems and new reimbursement guidelines on pharmaceutical expenditures and prescribing behavior among hypertensive patients in Korea. Health Policy. 2015;119(5):604-11.	Ineligible Study Design
Chokshi M, Farooqui HH, Selvaraj S, Kumar P. A cross-sectional survey of the models in Bihar and Tamil Nadu, India for pooled procurement of medicines. WHO South-East Asia j. 2015;4(1):78-85.	Ineligible Study Design
Choksi P. A regression analysis of the impact of patient access schemes. Value Health. 2013;16(3):A268.	Ineligible Study Design
Chu HL, Liu SZ, Romeis JC. Changes in prescribing behaviors after implementing drug reimbursement rate reduction policy in Taiwan: implications for the medicare system. J Health Care Finance. 2008;34(3):45-54.	Ineligible Study Design
Coma A, Zara C, Godman B, Agusti A, Diogene E, Wettermark B, et al. Policies to enhance the efficiency of prescribing in the Spanish Catalan region: impact and future direction. Expert Rev Pharmacoecon Outcomes Res. 2009;9(6):569-81.	Ineligible Study Design
Conti RM. Eliminate cost-plus reimbursement for drugs. Clin Adv Hematol Oncol. 2014;12(1):66.	Ineligible Study Design

Coronado J, Jimenez-Martin S, Marin PL. Multimarket contact in pharmaceutical markets. Department of Economics and Business, Universitat Pompeu Fabra, Economics Working Papers. 2007.:	Ineligible Study Design
Costa-Font J, McGuire A, Varol N. Regulation effects on the adoption of new medicines. Empir. Econ. 2015;49(3):1101-21.	Ineligible Study Design
Costello MM. Negotiating pharmaceutical prices: a change in Chinese health policy. World Health Popul. 2016;16(4):5-8.	Ineligible Study Design
Creese A. Review series on pharmaceutical pricing policies and interventions: working paper 5: sales taxes on medicines. Amsterdam, The Netherlands: 2011. Available from: https://haiweb.org/wp-content/uploads/2015/08/Taxes-final-May2011a1.pdf.	Ineligible Study Design
Csanádi M, Kaló Z, Prins CPJ, Grélinger E, Menczelné Kiss A, Fricke FU, et al. The implications of external price referencing on pharmaceutical list prices in Europe. Health Policy Technol. 2018;7(3):243-50.	Ineligible Study Design
Curto S, Ghislandi S, van de Vooren K, Duranti S, Garattini L. Regional tenders on biosimilars in Italy: an empirical analysis of awarded prices. Health Policy. 2014;116(2-3):182-7.	Ineligible Study Design
Dalen DM, Strom S, Haabeth T. Price regulation and generic competition in the pharmaceutical market. Eur J Health Econ. 2006;7(3):208-14.	Ineligible Study Design
Dana KN, Hertig JB, Weber RJ. Drug pricing transparency: the new retail revolution. Hosp Pharm. 2017;52(2):155-59.	Ineligible Study Design
Danzon PM, Epstein AJ. Effects of regulation on drug launch and pricing in interdependent markets. Adv Health Econ Health Serv Res. 2012;23:35-71.	Ineligible Study Design
Danzon PM, Ketcham JD. Reference pricing of pharmaceuticals for Medicare: evidence from Germany, The Netherlands, and New Zealand. Front Health Policy Res. 2004;7:1-54.	Ineligible Study Design
Danzon PM, Mulcahy AW, Towse AK. Pharmaceutical pricing in emerging markets: effects of income, competition and procurement. Health Econ. 2015;24(2):238-52.	Ineligible Study Design
de Boer R. PBS reform - a missed opportunity? Aust Health Rev. 2009;33(2):176-85.	Ineligible Study Design
de Jager H, Suleman F. The impact of generics and generic reference pricing on candesartan and rosuvastatin utilisation, price and expenditure in South Africa. Int J Clin Pharm. 2019;41(1):81-87.	Ineligible Study Design
De Witte J. Kiwi: de vogel die nooit zal kunnen vliegen? Catholic University Leuven; 2011.	Ineligible Study Design
Degrassat-Theas A, Bensadon M, Rieu C, Angalakuditi M, Le Pen C, Paubel P. Hospital reimbursement price cap for cancer drugs: the French experience in controlling hospital drug expenditures. Pharmacoeconomics. 2012;30(7):565-73.	Ineligible Study Design
Delahunty M. An empirical study of market-based purchasing policies for generic pharmaceuticals in Sweden. GaBI Journal. 2016;5(4):187-87.	Ineligible Study Design
Delahunty M. Strategies used to delay or prevent access to affordable generic drugs in the US. GaBI Journal. 2016;5(4):188-88.	Ineligible Study Design
DeRoeck D, Bawazir SA, Carrasco P, Kaddar M, Brooks A, Fitzsimmons J, et al. Regional group purchasing of vaccines: review of the pan American health	Ineligible Study Design

organization EPI revolving fund and the Gulf cooperation council group purchasing program. Int J Health Plann Manage. 2006;21(1):23-43.	
DeSwaef A, Antonissen Y. PPRI Pharma Profile Belgium. Vienna: Pharmaceutical Pricing and Reimbursement Information. 2008	Ineligible Study Design
Díaz-Rojas JA, Rodríguez-Márceles M, Rodríguez-Romero A, Brown P. Impact of group purchasing in cooperative of hospital in Colombia, using a price index from 1999 to 2012. Rev. colomb. ciencias quim. farm. 2013;42(1):80-102.	Ineligible Study Design
Djambazov SN, Vekov TY, Petrov D. Price control of out-patient cancer drugs in Bulgaria, 2010-2011: reference based pricing and public tenders verse reference based pricing only. Value Health. 2014;17(7):A660.	Ineligible Study Design
Djambazov SN, Vekov TY, Petrov D. National health insurance fund drug expenditure in Bulgaria, 2007-2012: reference based pricing alone or in combination with other approaches to pricing. Value Health. 2014;17(7):A432.	Ineligible Study Design
DoHA. The Impacts of Pharmaceutical Benefits Scheme Reform. Department of Health and Ageing: 2010. Available from: https://www1.health.gov.au/internet/main/publishing.nsf/Content/4BC52286D3009386CA257BF000209AD5/$File/PwC%20The%20Impacts%20of%20PBS%20Reform.pdf.	Ineligible Study Design
Drummond M, Jonsson B, Rutten F, Stargardt T. Reimbursement of pharmaceuticals: reference pricing versus health technology assessment. Eur J Health Econ. 2011;12(3):263-71.	Ineligible Study Design
Duggan M, Morton FMS. The distortionary effects of government procurement: evidence from medicaid prescription drug purchasing. Q. J. Econ. 2006;121(1):1-30.	Ineligible Study Design
Dusetzina SB, Bach PB. Prescription drugs-list price, net price, and the rebate caught in the middle. JAMA. 2019;321(16):1563-64.	Ineligible Study Design
Dusetzina SB, Conti RM, Yu NL, Bach PB. Association of prescription drug price rebates in medicare part D with patient out-of-pocket and federal spending. JAMA Intern Med. 2017;177(8):1185-88.	Ineligible Study Design
Dutta A, Bandyopadhyay S. Policy intervention for access to medicine: does it work similarly for poor and non-poor? Int J Health Plann Manage. 2019;34(1):e557-e68.	Ineligible Study Design
Dylst P, Vulto A, Simoens S. The impact of reference-pricing systems in Europe: a literature review and case studies. Expert Rev Pharmacoecon Outcomes Res. 2011;11(6):729-37.	Ineligible Study Design
Dylst P, Vulto A, Simoens S. Barriers to the uptake of biosimilars and possible solutions: a Belgian case study. Pharmacoeconomics. 2014;32(7):681-91.	Ineligible Study Design
Enemark U, Alban A, Seoane-Vasquez E, Seiter A. Purchasing pharmaceuticals. Spending Wisely. 2005:251-66.	Ineligible Study Design
EuGene KIM, Younhee KIM. Review of Programs for Improving Patient's Access to Medicines. Korean Journal of Clinical Pharmacy. 2018:40-50.	Ineligible Study Design
Ewen M, Al Sakit M, Saadeh R, Laing R, Vialle-Valentin C, Seita A, et al. Comparative assessment of medicine procurement prices in the United Nations relief and works agency for Palestine refugees in the near east (UNRWA). J. 2014;7(1):13.	Ineligible Study Design

Fang Y, Wagner AK, Yang S, Jiang M, Zhang F, Ross-Degnan D. Access to affordable medicines after health reform: evidence from two cross-sectional surveys in Shaanxi Province, western China. Lancet Glob. Health. 2013;1(4):e227-37.	Ineligible Study Design
Faunce TA. Reference pricing for pharmaceuticals: is the Australia-United States free trade agreement affecting Australia's pharmaceutical benefits scheme? Med J Aust. 2007;187(4):240-2.	Ineligible Study Design
Feng C, Penglei CUI, Qiang XIA, Jianyun Z. Medicine reference price system in Germany and its implication for healthcare payment stand-ard in China. Chinese Journal of Health Policy. 2015:55-60.	Ineligible Study Design
Flodmark CE, Lilja K, Woehling H, Jarvholm K. Switching from originator to biosimilar human growth hormone using dialogue teamwork: single-center experience from Sweden. Biol Ther. 2013;3:35-43.	Ineligible Study Design
Flume M, Bardou M, Capri S, Sola-Morales O, Cunningham D, Levin LA, et al. Approaches to manage 'affordability' of high budget impact medicines in key EU countries. J Mark Access Health Policy. 2018;6(1):1478539.	Ineligible Study Design
Flume M, Bardou M, Capri S, Sola-Morales O, Cunningham D, Levin LA, et al. Feasibility and attractiveness of indication value-based pricing in key EU countries. J Mark Access Health Policy. 2016;4	Ineligible Study Design
Fontrier AM, Gill J, Kanavos P. International impact of external reference pricing: should national policy-makers care? Eur J Health Econ. 2019;09:09.	Ineligible Study Design
Fraeyman J, Van Hal G, De Loof H, Remmen R, De Meyer GR, Beutels P. Potential impact of policy regulation and generic competition on sales of cholesterol lowering medication, antidepressants and acid blocking agents in Belgium. Acta Clin Belg. 2012;67(3):160-71.	Ineligible Study Design
Frank RG, Zeckhauser RJ. Excess prices for drugs in medicare: diagnosis and prescription. HKS Working Paper. 2018:1-44.	Ineligible Study Design
Fürst J. The Slovenian reference price system. Pharmaca. 2005;43(2-3):102-08.	Ineligible Study Design
Gaebel K, Toeg N, Levine M. Clinical and economic effects of a therapeutic substitution policy for proton pump inhibitors in aboriginal patients in northern communities in Canada's northwest territories. Dis Manag Health Out. 2008;16(3):175-82.	Ineligible Study Design
Gagnon MA. The role and impact of cost-sharing mechanisms for prescription drug coverage. CMAJ. 2017;189(19):E680-E81.	Ineligible Study Design
Galizzi MM, Ghislandi S, Miraldo M. Effects of reference pricing in pharmaceutical markets: a review. Pharmacoeconomics. 2011;29(1):17-33.	Ineligible Study Design
Gallien J, Rashkova I, Atun R, Yadav P. National drug stockout risks and the global fund disbursement process for procurement. Prod. Oper. Manag. 2017;26(6):997-1014.	Ineligible Study Design
Gandjour A. Reference pricing and price negotiations for innovative new drugs : viable policies in the long term? Pharmacoeconomics. 2013;31(1):11-4.	Ineligible Study Design
Garau M, Towse A, Danzon PM. Pharmaceutical pricing in Europe: is differential pricing a win-win solution? OHE. 2011;11/01:1-6.	Ineligible Study Design

Garcia-Alonso MD, Garcia-Marinoso B. The strategic interaction between firms and formulary committees: effects on the prices of new drugs. J Health Econ. 2008;27(2):377-404.	Ineligible Study Design
Garuoliene K, Godman B, Gulbinovic J, Wettermark B, Haycox A. European countries with small populations can obtain low prices for drugs: Lithuania as a case history. Expert Rev Pharmacoecon Outcomes Res. 2011;11(3):343-9.	Ineligible Study Design
Geng DF, Saggi K. International effects of national regulations: external reference pricing and price controls. J. Int. Econ. 2017;109:68-84.	Ineligible Study Design
Ghislandi S, Krulichova I, Garattini L. Pharmaceutical policy in Italy: towards a structural change? Health Policy. 2005;72(1):53-63.	Ineligible Study Design
Gilman BH, Kautter J. Consumer response to dual incentives under multitiered prescription drug formularies. Am J Manag Care. 2007;13(6 II):353-59.	Ineligible Study Design
Gilman BH, Kautter J. Impact of multitiered copayments on the use and cost of prescription drugs among Medicare beneficiaries. Health Serv Res. 2008;43(2):478-95.	Ineligible Study Design
Godman B, Bishop I, Finlayson AE, Campbell S, Kwon HY, Bennie M. Reforms and initiatives in Scotland in recent years to encourage the prescribing of generic drugs, their influence and implications for other countries. Expert Rev Pharmacoecon Outcomes Res. 2013;13(4):469-82.	Ineligible Study Design
Godman B, Burkhardt T, Bucsics A, Wettermark B, Wieninger P. Impact of recent reforms in Austria on utilization and expenditure of PPIs and lipid-lowering drugs: implications for the future. Expert Rev Pharmacoecon Outcomes Res. 2009;9(5):475-84.	Ineligible Study Design
Godman B, Shrank W, Andersen M, Berg C, Bishop I, Burkhardt T, et al. Policies to enhance prescribing efficiency in europe: findings and future implications. Front Pharmacol. 2010;1:141.	Ineligible Study Design
Godman B, Shrank W, Andersen M, Berg C, Bishop I, Burkhardt T, et al. Comparing policies to enhance prescribing efficiency in Europe through increasing generic utilization: changes seen and global implications. Expert Rev Pharmacoecon Outcomes Res. 2010;10(6):707-22.	Ineligible Study Design
Godman B, Wettermark B, van Woerkom M, Fraeyman J, Alvarez-Madrazo S, Berg C, et al. Multiple policies to enhance prescribing efficiency for established medicines in Europe with a particular focus on demand-side measures: findings and future implications. Front Pharmacol. 2014;5:106.	Ineligible Study Design
Godman B, Wettermark B, Vlahovic-Palcevski V, Schwabe U, Gulbinovic J, Laius O, et al. Impact of reforms to enhance the quality and efficiency of statin prescribing across 20 European countries. Basic Clin Pharmacol Toxicol. 2009;105:35.	Ineligible Study Design
Goldberg L, Sun J, Roman B, Voloudakis M. Retrospective analysis of generic dispensing rates, gross cost, and drug therapy continuation rates following implementation of a value formulary. J Manag Care Pharm. 2012;18(7):556-57.	Ineligible Study Design
Goldstein DA, Sarfaty M. Cancer drug pricing and reimbursement: lessons for the United States from around the world. Oncologist. 2016;21(8):907-9.	Ineligible Study Design
Gomez-Dantes O, Wirtz VJ, Reich MR, Terrazas P, Ortiz M. A new entity for the negotiation of public procurement prices for patented medicines in Mexico. Bull World Health Organ. 2012;90(10):788-92.	Ineligible Study Design

Goncalves R, Rodrigues V, Vasconcelos H. Reference pricing in the presence of pseudo-generics. Int J Health Econ Manag. 2015;15(3):281-305.	Ineligible Study Design
González García G, De la Puente C, Tarragona S. Medicamentos: salud, política y economía; 2005.	Ineligible Study Design
Gorsh B, Prasla K, Godley P, Chaddick J. Economic impact of copayment waivers on a generic to generic conversion program. J Manag Care Pharm. 2011;17(3):247.	Ineligible Study Design
Gray AL. Medicine pricing interventions - the South African experience. South Med Rev. 2009;2(2):15-19.	Ineligible Study Design
Greß S, Wasem J, Niebuhr D. Pricing and reimbursement of prescription drugs in German social health insurance. CESifo DICE Report. 2006;4(2):39-47.	Ineligible Study Design
Gupta R, Shah ND, Ross JS. Generic drugs in the United States: policies to address pricing and competition. Clin Pharmacol Ther. 2019;105(2):329-37.	Ineligible Study Design
Habl C, Schneider P, Németh G, Šebesta R. Euripid guidance document on external reference pricing (ERP). European Commission, Consumer, Health and Food Executive Agency 2018.	Ineligible Study Design
Hakonsen H, Horn AM, Toverud EL. Price control as a strategy for pharmaceutical cost containment - what has been achieved in Norway in the period 1994-2004? Health Policy. 2009;90(2-3):277-85.	Ineligible Study Design
Hammerschmidt T. Analysis of German new drug prices after AMNOG in relation to European prices. Gesundheitswesen. 2017;22(1):43-53.	Ineligible Study Design
Han S, Feng L, Zhang YY. Study of settling differential margin mode for hospital medicine selling in China. Chinese Pharmaceutical Journal. 2011;46(9):710-13.	Ineligible Study Design
Han S, Liang H, Su W, Xue Y, Shi L. Can price controls reduce pharmaceutical expenses? a case study of antibacterial expenditures in 12 Chinese hospitals from 1996 to 2005. Int J Health Serv. 2013;43(1):91-103.	Ineligible Study Design
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