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**Ministry of Public Health**

**No. 00000407**

**THE MINISTER OF PUBLIC HEALTH, ACTING**

**WHEREAS:**

**WHEREAS:** Pursuant to the provisions of Art. 154 (1) of the Constitution of the Republic of Ecuador, the Ministers of State are responsible for exercising leadership over public policies in the area of their duty and for issuing the agreements and administrative decisions which such management may require, this being in accordance with the provisions of Art. 17 of the Legal and Administrative System Statute of the Executive Branch, amended through Executive Decree No. 2428, published in Official Gazette No. 536 dated March 18, 2002;

**WHEREAS:** The Constitution of the Republic of Ecuador stipulates:

“Art. 361. – The State shall exercise leadership of the system through the national health authority, shall be responsible for formulating national health policy and shall establish norms, regulate and control all activities related to health, as well as the functioning of entities in the sector.”;

“Art. 364. – Addictions are a public health problem. The State shall be responsible for developing coordination information, prevention and control programs on the use of alcohol, tobacco and drug and psychotropic substances, together with offering treatment and rehabilitation to occasional, habitual and problem users. In no case shall their criminalization nor the breach of their Constitutional rights be allowed. The State shall control and regulate alcohol and tobacco advertising.”

**WHEREAS:** The Tobacco Regulation and Control Act, published in Official Gazette No. 497 dated July 22, 2011, orders:

“Art. 3. – It is up to the National Health Authority, within the sphere of its competence, to formulate and enforce policies and strategies for full compliance with this law.”;

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“Art. 8. – The National Health Authority shall execute the activities necessary for the compliance with this law, notwithstanding those incumbent upon other institutions.”

“Art. 18. – Packaging and Labeling. – On outside packaging and labeling of tobacco products sold within the country there must appear captions and graphic images or warning images showing the damaging effects of their consumption and that adhere to the following provisions:

- a. Warnings shall be prepared and approved by the National Health Authority;
- b. They shall be printed in a rotating manner and rotating each year directly on the packs;
- c. They shall be of high preventive impact, be clear, visible, legible and must not be obstructed by any means;
- d. They shall include graphic images and messages related to the damaging effects of tobacco, must occupy sixty percent (60%) of the principal panels and be located on the lower portion of each panel;
- e. Health information must be printed directly on the pack, occupying seventy [sic] (70%) of one of the side panels;
- f. Information about tobacco components and emissions shall be qualitative only;
- g. Packaging is forbidden in display types of fewer than ten units. In the case of other tobacco products, the pack must contain no fewer than ten grams; and,
- h. Both the warning captions and the text information must appear in the Spanish language.”;

“TRANSITIONAL PROVISION FOUR: An unextendable term of three hundred sixty (360) days is conceded from when this law takes effect for implementation of the norms regarding the packaging of cigarettes or other manufactured or imported tobacco products.”;

**WHEREAS:** Through Executive Decree 1047 dated February 10, 2012, published in Official Gazette No. 648 dated February 27, 2011, the Regulation to the Tobacco Regulation and Control Act is issued, which allows: "Art. 8. - Each year up to March 15, registered producer and import companies shall pick up from the Ministry of Public Health the printed and electronic health warnings with which the product will be marketed”;

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**WHEREAS:** It becomes necessary to issue a statute to define the first round of six health warnings for packs and other containers of tobacco products appearing on the document attached to this Agreement, which includes the Application Manual for same;

**IN EXERCISE OF THE POWERS GRANTED BY ARTICLE 154 OF THE CONSTITUTION OF THE REPUBLIC OF ECUADOR AND ARTICLE 17 OF THE LEGAL AND ADMINISTRATIVE SYSTEM STATUTE OF THE EXECUTIVE BRANCH**

**HE HEREBY AGREES:**

**Art. 1.** – To approve the first round of six health warnings for packs and other containers and packages of tobacco products in effect from July 22, 2012, until July 22, 2013, pursuant to the Annex to this Ministerial Agreement, which pertains to the warnings and their Application Manual.

Health warnings shall be printed in equal proportions and in random fashion directly on all of the surface designated for the purpose on 60% of the principal panels of packs, packages and outside labelling and other wrappers of all brands and brand families of tobacco products in such a way that on each of those brands or brand families the six health warnings in the round are distributed equally.

The health information defined in the attached document shall be printed directly onto one of the side panels of packs and other packages or wrappers, filling 70% of that surface according to the specifications in the respective Manual. That text shall include only qualitative information about the components and emissions of the tobacco products.

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In the case of all remaining packages that do not have two principal panels and side panels, or whose panels have different formats or display types, the legal provision shall be obeyed to print the respective warning on 60% of its principal and most visible panel(s), directly on the surface of any material. If there are no side panels for the health information, it shall be printed next to the health warning in a sufficiently visible and distinctive manner.

**Art. 4** – This Ministerial Agreement is of compulsory performance for all companies producing or importing tobacco products nationally for the purpose of marketing these products. Its breach shall be sanctioned pursuant to Art. 36 of the Tobacco Regulation and Control Act and other prevailing norms.

**Art. 5** – It is hereby ordered that the National Undersecretariat of Health Prevention, Promotion and Equality, the Health Promotion Unit and the Tobacco Control Program, or whoever may serve in their stead from the Ministry of Public Health shall be responsible for enforcement of this Ministerial Agreement, which shall take effect on the date of its signing, notwithstanding its publication in the Official Gazette.

**ISSUED IN THE METROPOLITAN DISTRICT OF QUITO on MARCH 7, 2012**

[Circular stamp: Republic of Ecuador  
General Secretariat  
Ministry of Public Health  
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Carina Vance Mafia  
MINISTER OF PUBLIC HEALTH, ACTING

Overseen by: NJ-OF-PA [two illegible initials]

Prepared by: VMR/AA/EH [two illegible initials]