



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

MAR 12 2014

ADMINISTRATIVE ORDER

No. 2014 - 0008

SUBJECT: Rules and Regulations on Electronic Nicotine Delivery System (ENDS) or Electronic Cigarettes

I. RATIONALE/BACKGROUND

The right to health is one of the fundamental rights enshrined in Article II of the Constitution. Section 15 states that "the State shall protect and promote the right to health of the people and instill health consciousness among them."

Under Republic Act (RA) No. 7394 or the Consumer Act of the Philippines, "It is the policy of the State to protect the interest of the consumer, promote his general welfare and to establish standards of conduct for business and industry. Towards this end, the State shall implement measures to achieve the following objectives: a) Protection against hazards to health and safety; b) Protection against deceptive, unfair and unconscionable sales acts and practice; c) Provision of information and education to facilitate sound choice and the proper exercise of rights by consumer." Article 10, on Injurious, Dangerous and Unsafe Products, of the same RA provides that, "Whenever the departments find, by their own initiative or by petition of a consumer, that a consumer product is found to be injurious, unsafe and dangerous, it shall, after due notice and hearing, make the appropriate order for its recall, prohibition or seizure from public sale or distribution. Provided that, in the sound discretion of the Department it may declare a consumer product to be imminently injurious, unsafe or dangerous, and order its immediate recall, ban or seizure from public sale or distribution, in which case the seller, distributor, manufacturer or producer thereof shall be afforded a hearing within forty-eight (48) hours from such order."

Section 3 of RA No. 9711 or the FDA Act of 2009 declares that, "It is hereby declared a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiative that are aimed, directed and designed to protect and promote the right to health of the Filipino people." Section 5 of the FDA Act of 2009 provides that, "Section 4 of RA No. 3720, as amended, is hereby further amended to read as follows: Sec. 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration (FDA) in the Department of Health (DOH). Said administration shall be under the Office of the Secretary and shall have the following functions, powers and duties: xxx (k) After due process, to order the ban, recall, and/or withdrawal of any health product found to have caused the death, serious illness or serious injury to the consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive, and to require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization."

A handwritten signature in black ink, appearing to be "M. L. ...", is written over the footer area.

The WHO Framework Convention on Tobacco Control was ratified by the Republic of the Philippines in 2005 and entered into force on 4 September 2005. Specifically, under Article 5 on the General Obligations, Article 5.3 states that, "In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law."

RA No. 9711 defines 'health products' as food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA. It also defines 'health-related device' as any device not directly used in health care but has been determined by the FDA to adversely affect the health of the people. As the national competent authority on health products and health-related device, the FDA has put in place systems and processes for licensing the establishments, issuing market authorization for products, approving labels and labeling materials, conducting inspection and post-marketing surveillance, approval of promotional and advertisement materials, and laboratory testing.

The World Health Organization has clearly stated that the safety and efficacy of ENDS or electronic cigarettes as smoking cessation aid have not yet been scientifically demonstrated. The potential risks they pose for the health of users remain undetermined. WHO stated that "until such time as a given ENDS is deemed safe and effective and of acceptable quality by a competent national regulatory body, consumers should be strongly advised not to use electronic nicotine delivery systems including e-cigarettes."

Electronic cigarette or ENDS products and its manufacturers and distributors are hereby regulated to ensure protection of the safety and welfare of consumers. The timely and appropriate regulation of ENDS or electronic cigarettes underscores the primacy of public health and reaffirms its primary function to promote, protect, preserve, and restore the health of the people.

II. OBJECTIVES

Consistent with the policy of the State to promote the right to health of all the people and instill health consciousness among them, this Administrative Order is being issued with the following objectives:

- a. To ensure the safety, efficacy and quality of electronic cigarette or ENDS as health product or consumer product, and
- b. To serve as guidelines for electronic cigarette or ENDS manufacturers and distributors in securing a FDA license to operate and a Certificate of Product Registration (CPR).

III. SCOPE AND COVERAGE

This Administrative Order shall apply to all FDA-licensed establishments which seek to apply for a market authorization or CPR of all electronic cigarette or ENDS in the country. Electronic cigarettes or ENDS are combination drugs and medical devices and are not tobacco product or conventional cigarettes and shall comply with the FDA standards and requirement for health products to ensure the safety, efficacy and quality.



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IV. DEFINITION OF TERMS

For the purpose of this Administrative Order, the following terms are defined:

1. Electronic cigarettes or ENDS (electronic nicotine delivery systems) are a category of consumer products designed to deliver nicotine to the lungs after one end of a plastic or metal cylinder is placed in the mouth, like a cigarette or cigar, and inhaled to draw a mixture of air and vapors from the device into the respiratory system. They contain electronic vaporization systems, a rechargeable battery and charger, electronic controls and replaceable cartridges that may contain nicotine and other chemicals. Some brands are claimed to deliver a range of nicotine concentrations or no nicotine at all.
2. Ingredient cartridge means the concentrations of chemicals including propylene glycol, nicotine and several others, used to produce the odors and flavors that simulate those of cigarettes. The manufacturers have not fully disclosed the chemical combinations included during the manufacture or synthesized during electronic vaporization that produce the sensory effects of cigarettes. Furthermore, the manufacturers have not proven that constituent chemicals, which include organic chemicals that may be acceptable for use in foods and cosmetics, are safe for inhalation when vaporized and delivered to the lung.
3. Smoking cessation aid means an FDA-approved medicine, drug products or articles, used or employed to treat nicotine dependence or addiction or as an intervention to help people quit smoking.
4. FDA shall mean the Philippine Food and Drug Administration.
5. Drug means articles that are a) recognized in official pharmacopoeias and formularies, including official homeopathic pharmacopoeias, or any documentary supplement to any of them, which are recognized and adopted by the FDA; b) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; c) intended to affect the structure of any function of the body of human beings or animals (other than food; or d) intended for use as a component of any articles specified in clauses (a), (b), or (c).
6. Health-related device means any device not directly used in health care, but has been determined by the FDA to adversely affect the health of the people.

V. REGULATORY STANDARDS AND POLICIES

The following standards and policies shall be implemented by the FDA for ENDS or electronic cigarettes, as shown in Annex 1 of this Administrative Order:

1. Electronic cigarettes or ENDS are combination drugs and medical device and are not tobacco products and shall be regulated as medicinal product.
2. Electronic cigarettes or ENDS shall pass the safety, efficacy and quality evaluation of the FDA before a market authorization is issued as health product and health-related device.



3. Clinical trials shall be allowed by the FDA, subject to the existing rules and regulations on clinical trial application and approval process, including ethical approval process. Patients or subjects may enroll following the requirements of Good Clinical Practice, to protect the rights, health and interest of the patients or subjects.
4. The FDA shall require a LTO from the manufacturers and distributors before applying for a Certificate of Product Registration.
5. A CPR shall be required as market authorization before a product is used or offered for sale.
6. The FDA shall evaluate the safety, efficacy and quality of the device and ingredient cartridge of ENDS or electronic cigarettes. Standards for drugs and drug products shall be used by the FDA in evaluating ENDS.
7. The cartridge containing the ingredients or what the industry call as "electronic juice" shall pass the safety, efficacy and quality standards of the FDA. As appropriate, the mixture of ingredients in the cartridge shall be subjected to safety evaluation and the quality. The delivery of the dose of nicotine shall be subjected to pharmaceutical standard.
8. The device that produces the mist shall pass the safety, efficacy and quality as a health-related device. Manufacturers shall meet the requirements of the current Good Manufacturing Practice (cGMP).
9. Both the cartridge and device shall be made child-proof to prevent accidental ingestion or leakage of ingredients and misuse of the device.
10. Claims of "cessation aid to smoking" or "less harmful alternative or reduced harm compared to smoking" shall be acceptable provided that health product safety, efficacy and quality standards are met and all FDA requirements are complied with by the FDA-licensed establishments.
11. Application for a CPR shall not be construed as approval of the application. Based on the outcome of the FDA evaluation, the application for a CPR may be disapproved. The FDA shall inform the applicant on the deficiencies of requirements or the reason(s) behind the disapproval of the application.
12. If ENDS and electronic cigarettes have been issued CPRs as market authorization, the FDA shall conduct Post-Market Surveillance and regulate the advertisement, promotion of the health product and the marketing activities of establishments.
13. ENDS or e-cigarettes are not exempted from 'clean air laws,' which restrict the places in which cigarette smoking is allowed, until adequate evidence is provided that use of the product will not expose nonusers to toxic emissions.

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14. The FDA shall issue specific guidelines, including requirements on the issuance of the License to Operate and Certificate of Product Registration as well as for other purposes to ensure implementation of this Administrative Order.

VI. MONITORING AND SURVEILLANCE

Regardless of the outcome of the CPR application and evaluation of ENDS or electronic cigarette, the use of ENDS or electronic cigarettes in public areas shall not be allowed in areas or facilities that prohibit smoking.

The DOH shall implement the provisions of the RA 7394, or the Consumer Act of the Philippines, in monitoring the effects of prolonged exposure and against promotion of dual use and/or gateway to cigarette use, with the FDA. As provided by RA 9711, the Director General of the FDA may call on the assistance of any Department office or agency and deputize members of the Philippine National Police or any law enforcement agency for the effective implementation of the FDA Act of 2009.

VII. SEPARABILITY CLAUSE

If, for any reason, any section or provision of this Order is declared invalid, illegal or unconstitutional, such invalidity or unconstitutionality shall not affect the other provisions of this Order, which shall remain in full force and effect.

VIII. REPEALING CLAUSE

The provisions of other existing provisions or issuances found inconsistent or contrary with this Order are hereby repealed or modified accordingly.

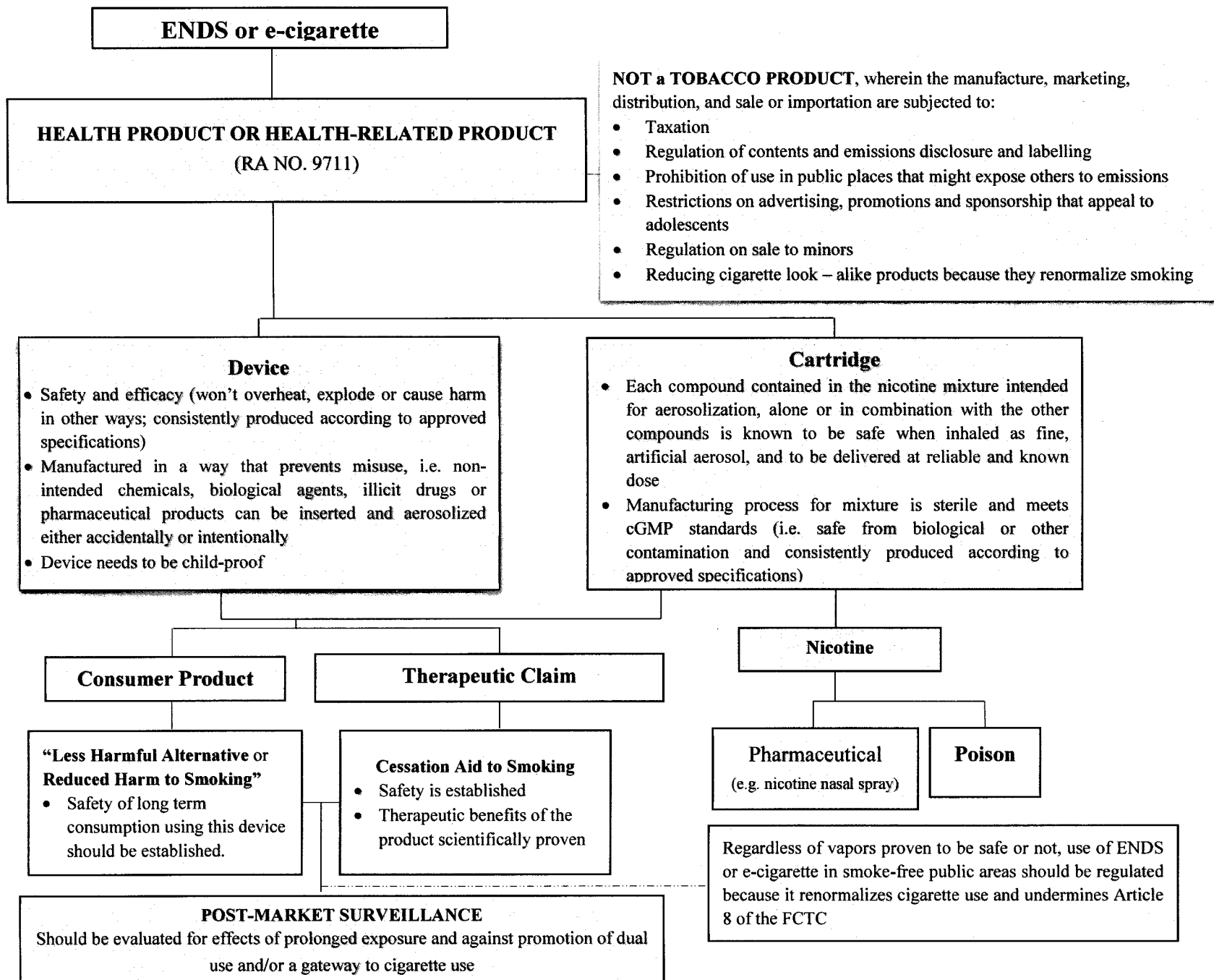
IX. EFFECTIVITY

This Order shall take effect fifteen (15) days following the date of its publication in a newspaper of general circulation.



ENRIQUE T. ONA, MD
Secretary of Health

ANNEX 1



ENDS or e-cigarette

**HEALTH PRODUCT OR HEALTH-RELATED PRODUCT
(RA NO. 9711)**

NOT a TOBACCO PRODUCT, wherein the manufacture, marketing, distribution, and sale or importation are subjected to:

- Taxation
- Regulation of contents and emissions disclosure and labelling
- Prohibition of use in public places that might expose others to emissions
- Restrictions on advertising, promotions and sponsorship that appeal to adolescents
- Regulation on sale to minors
- Reducing cigarette look – alike products because they renormalize smoking

Device

- Safety and efficacy (won't overheat, explode or cause harm in other ways; consistently produced according to approved specifications)
- Manufactured in a way that prevents misuse, i.e. non-intended chemicals, biological agents, illicit drugs or pharmaceutical products can be inserted and aerosolized either accidentally or intentionally
- Device needs to be child-proof

Cartridge

- Each compound contained in the nicotine mixture intended for aerosolization, alone or in combination with the other compounds is known to be safe when inhaled as fine, artificial aerosol, and to be delivered at reliable and known dose
- Manufacturing process for mixture is sterile and meets cGMP standards (i.e. safe from biological or other contamination and consistently produced according to approved specifications)

Consumer Product

"Less Harmful Alternative or Reduced Harm to Smoking"

- Safety of long term consumption using this device should be established.

Therapeutic Claim

Cessation Aid to Smoking

- Safety is established
- Therapeutic benefits of the product scientifically proven

Nicotine

Pharmaceutical

(e.g. nicotine nasal spray)

Poison

Regardless of vapors proven to be safe or not, use of ENDS or e-cigarette in smoke-free public areas should be regulated because it renormalizes cigarette use and undermines Article 8 of the FCTC

POST-MARKET SURVEILLANCE

Should be evaluated for effects of prolonged exposure and against promotion of dual use and/or a gateway to cigarette use