

## **NATIONAL FOOD, DRUG, AND MEDICAL TECHNOLOGY ADMINISTRATION**

### **Provision 3226/2011**

**Prohibits the commercialization and use in all the national territory of a specific product.**

Buenos Aires, 6/5/2011

**HAVING REGARD TO** File No. 1-47-2409-11-1 of the Registry of this National Administration of Drugs, Foods and Medical Devices (ANMAT); and

#### **TAKING INTO CONSIDERATION:**

That at present, smoking is the most significant cause of preventable death in the world, due to pathologies such as cancer, especially in lungs, kidneys, pancreas, bladder; COPD (chronic obstructive pulmonary disease) and/or cardiovascular pathologies.

That the World Health Organization (WHO) sponsored the Framework Convention on Tobacco Control (FCTC), whose text was approved by the 56<sup>th</sup> World Health Assembly in May 2003 and entered into force in February 2005, being a legal instrument governed by the International Law and mandatory for countries that sign and ratify it.

That the objective of this Convention is to protect present and future generations from the devastating health, social, environmental, and economic consequences of tobacco use and exposure to the smoke it generates.

That consequently, the countries adhering to said framework convention have generated State policies tending to diminish the use of tobacco and trying to prevent new generations of young people from starting smoking. Some of these policies are tax increases, ban on advertising, promotion and sponsorship, the creation of smoke free environments, the obligation on tobacco companies to place on the main faces of cigarette packages legends highlighting the severe health consequences of tobacco consumption, the conduct of campaigns to raise awareness on the deleterious effects of smoking, and adherence to campaigns led by various non-governmental organizations.

That the deleterious effects of smoking are due, in part, to the combustion products originated in the act of smoking and also to the powerfully addictive effect of nicotine, which is rapidly absorbed and produces pleasant effects by acting on specific neuronal circuits of the brain and making it very difficult to stop smoking.

That most smokers are addicted to nicotine, which has direct deleterious effects on the cardiovascular system.

That with the purpose of facilitating tobacco cessation, in addition to psychological support and in order to attenuate the withdrawal syndrome, different procedures have been developed based on the administration of nicotine in various forms (chewing gum, inhalation sprays, patches), or drugs that activate the neural circuits that mediate the action of nicotine.

That the commonly called "electronic cigarettes", consist of a device similar to the conventional cigarette, provided with a microelectronic mechanism that vaporizes cartridges that may contain variable quantities of nicotine, essential oils of tobacco, aromatic substances, propylene glycol, glycerol, and other substances.

That they have been designed to be used as cigarette replacements in places where smoking is prohibited, and some of their producers propose them as a strategy to stop smoking, further

arguing that they are devoid of the deleterious effects of tobacco combustion products.

That on the Internet, some of these nicotine dispensing devices are promoted as "...products created to improve the quality of life. With the appearance of a cigarette and the advantage of not having tobacco or tar. Flavor to cigarette and steam smoke simulator, being able to be used in any place since it does not have neither smell nor damages the health".

That on the contrary, being nicotine a highly toxic drug with strong addictive properties, the use of these dispensers, in addition to the potential risk it represents for individuals with cardiovascular pathologies, can induce drug dependence in new users.

That in the conclusions and recommendations contained in the document prepared by the World Health Organization (WHO) Study Group on the Regulation of Tobacco Products in which the November 2008 electronic cigarette is examined, it is argued that the safety and degree of nicotine absorption through these products has not been established.

That in the same document, it is mentioned that currently, the evidence is insufficient to conclude that electronic cigarettes are an effective aid to quit smoking or that they release enough nicotine to be used in smoking cessation, there being insufficient evidence to determine that they are safe for human consumption.

That it is also argued that smokers who try to quit smoking can use electronic cigarettes instead of treatments based on scientific evidence, and in the event that these products are not effective as nicotine replacement substances, their use could delay smoking cessation and contribute to an increased risk attributable to diseases directly related to smoking.

That the aforementioned Study Group also considers that some manufacturers have stated that electronic cigarettes can legally be used in public places where smoking is prohibited, while the WHO strongly recommends that they should not be exempt from "clean air" laws, which restrict places where smoking is not permitted, until adequate evidence is provided to demonstrate to regulatory authorities that the use of the product does not expose non-users to toxic emissions.

That it is also considered in these conclusions and recommendations that electronic cigarettes could perpetuate the smoking behavior by what has been called "dual-use". On the one hand, it maintains nicotine dependence in environments where smoking is prohibited, with one of the positive consequences of smoking restrictions being the denormalization of tobacco consumption of products and the consequent increase in quitting. On the other hand, it can discourage people who want to quit smoking, as users can maintain their nicotine addiction despite the smoking restrictions and go back to smoking, where such restrictions are absent.

That the WHO Study Group on Tobacco Product Regulation analyzed electronic nicotine delivery systems and prepared a report on the subject which the Director-General submitted to the WHO Executive Board at its 126<sup>th</sup> session in January of 2010 and whose recommendations were submitted to the Conference of the Parties to the Framework Convention on Tobacco Control (Fourth Meeting, Punta del Este, Uruguay, between November 15<sup>th</sup> and 20<sup>th</sup>, 2010).

That some of the conclusions were that "the safety and magnitude of nicotine uptake has not been demonstrated; that the products were marketed as smoking cessation aids, but there is no scientific data to validate this assertion; and that direct administration to the lungs could be dangerous and, irrespective of the effects of nicotine, it was of great importance to address lung administration in scientific studies", and that "research data are not currently sufficient to determine whether these systems can be used to help quit smoking, whether they create or sustain addiction, and whether they give smokers ingredients other than nicotine".

That the same Study Group recommended that clinical trials, behavioral and psychological studies, and pharmacovigilance be carried out on an individual and population-scale to clear up

these unknowns.

That, besides, the Group established that until scientifically proven, claims that these products have beneficial health effects, reduce harm, or can be used as an aid to smoking cessation should be prohibited.

That the Food and Drug Administration (FDA) of the United States found in these electronic devices carcinogenic ingredients (such as nitrosamines) and other toxic chemicals dangerous to health, such as ethylene glycol, used as an antifreeze for cars. And, in a statement of July 2009, the FDA admitted that, to date, "it is not known exactly what concentration of nicotine and other toxicants are inhaled by people who smoke electronic cigarettes and there are no clinical studies on the effects of electronic cigarettes on the health of smokers and exposed non-smokers", and therefore advise against their use.

That also, faced with the evidence that electronic cigarettes are being sold in different flavors, aimed at a young audience, the same international agency admitted its concern that these cigarettes can be sold on the Internet without age requirements for it and without a prospectus that includes the possible adverse effects on health.

That consequently with the purpose of protecting public health, it is appropriate to prohibit the import, distribution, commercialization and advertising or any form of promotion throughout the national territory of the electronic nicotine administration system known as "Electronic Cigarette", extending such prohibition to all type of accessory for such system or device, as well as cartridges containing nicotine.

That the measure to be adopted has been agreed with the Coordinator of the National Tobacco Control Program of the Ministry of Health of the Nation.

That the Directorate of Medical Technology, the National Institute of Medicines and the Directorate of Legal Affairs have taken the intervention of its competence.

That it acts in exercise of the faculties conferred by Decrees No. 1490/92 and 425/10.

**Therefore,**

**THE COMPTROLLER  
OF THE NATIONAL FOOD, DRUG, AND MEDICAL TECHNOLOGY ADMINISTRATION  
DECREES:**

**Article 1°** - Prohibits the import, distribution, commercialization, and advertising or any form of promotion throughout the national territory of the electronic nicotine administration system known as "Electronic Cigarette", extending such prohibition to all types of accessories for such system or device, as well as cartridges containing nicotine.

**Article 2°** - This provision shall enter into force on the day following that of its publication in the Official Gazette.

**Article 3°** - Register; give to the National Directorate of the Official Register for publication. Communicate to the provincial authorities and those of the Autonomous Government of the City of Buenos Aires, to the Chambers and representative professional entities; to the Direction of Planning and Institutional Relations. Communicate to the National Customs Directorate, an organ of the Federal Administration of Public Revenues (AFIP). Accomplished, file PERMANENT.  
- Carlos A. Chiale.