

MINISTRY OF HEALTH
Resolution 565/2023
RESOL-2023-565-APN-MS
City of Buenos Aires, 03/23/2023

IN VIEW OF File EX-2019-87576983-APN-DD#MSYDS, National Law No. 26.687, Decree No. 602/2013, and

WHEREAS:

The impact of tobacco consumption in the Argentine Republic was estimated in 45,000 deaths (14% of all deaths), 19,000 cancer diagnoses, 33,000 cases of pneumonia, 11,000 strokes and 61,000 hospitalized for cardiovascular disease, and more than 100,000 people who each year become ill with COPD.

It also generates an annual direct medical cost of more than \$196 billion (Argentine pesos in 2020), a lost labor productivity cost of more than \$91 billion, and informal care costs of more than \$75 billion. In total, these smoking costs are equivalent to more than 1.2% of the country's gross domestic product (GDP).

Smoking is also a cause of loss of productivity due to illness, disability and premature death.

In view of the data presented herein, it is imperative to implement public policies and positive actions to protect the health of the population in relation to the consumption of tobacco products and/or substitute or alternative products that contribute to perpetuating tobacco consumption or endanger people's health.

The right to health is closely related to the right to life, being this the basic human right of the person, which is recognized and guaranteed by our Magna Carta; inasmuch as man is the axis and center of the entire legal system, therefore its protection is a constitutional mandate for public authorities.

Our National Constitution, with the reform of 1994, incorporated in its article 75, paragraph 22, numerous instruments of international law that recognize the right of the human being to health, such as article 25 of the Universal Declaration of Human Rights; article 12 of the International Covenant on Economic, Social and Cultural Rights; article 5 of the International Convention on the Elimination of All Forms of Racial Discrimination; article 12 of the Convention on the Elimination of All Forms of Discrimination against Women; and article 24 of the Convention on the Rights of the Child.

The Committee on Economic, Social and Cultural Rights, in its General Comment No. 12, recognized that health is a fundamental human right and indispensable for the exercise of other human rights and that every human being has the right to the enjoyment of the highest attainable standard of health that enables him/her to live in dignity.

In a context of shrinking consumption of tobacco products in many countries around the world, tobacco companies and other companies have introduced new alternative products in the market, such as electronic devices for smoking or inhaling aerosols with or without nicotine, which are the so-called electronic cigarettes (EC) and more recently heated tobacco products (HTPs).

The so-called "heated tobacco products" consist of a tobacco stick (HeatStick) and a battery-powered tobacco heating device.

These devices are promoted to be used as a replacement for conventional cigarettes, especially in places where smoking is prohibited, on the grounds that they are devoid of the deleterious effects of tobacco combustion products.

Based on the risks posed by the use of electronic cigarettes, the National Administration of Medicines and Medical Technology (ANMAT for its acronym in Spanish) by Provision 3226/2011, prohibited the importation, distribution, marketing and advertising or any form of promotion throughout the national territory of the electronic nicotine delivery system called "Electronic Cigarette", extending the such prohibition to any type of accessory for such system or device, as well as cartridges containing nicotine.

According to independent research, heated tobacco products produce aerosols containing nicotine and other chemical substances such as acetaldehyde, acrolein, and formaldehyde, which are harmful and potentially harmful to health.

Since nicotine is a highly toxic drug with strong addictive properties, the use of these devices, in addition to the potential risk it represents for individuals with cardiovascular pathologies, may induce dependence on the drug in new users.

Evidence supports that novelty products such as HTPs and similar products are especially attractive to children and adolescents, and their introduction into the market has the potential to lead to tobacco initiation in non-smoking youth and adults, threatening the achievements already obtained in tobacco control through previously implemented public policies.

Both the World Health Organization and the Food and Drug Administration (FDA) of the United States have expressed their concern for the rapid expansion of the consumption of these novel products among high school students in several countries of the world.

In Argentina, the consumption of electronic cigarettes showed relatively low values, reaching 1.1% of the adult population according to the National Survey of Risk Factors 2018, although an alarming percentage of use was observed among adolescents, which, according to the Global Youth Tobacco Survey 2018, reached 7% of the population aged 13 to 15 years.

Although the global youth smoking survey shows in Argentina a downward trend in the prevalence of cigarette smoking among adolescents aged 13 to 15 years, which went from 24.5% in 2007 to 19.6% in 2012 and 18.0% in 2018, such a decrease is not the same when considering the substitution by electronic cigarettes. Substitution by electronic cigarettes exclusively reached 3% of adolescents, which would bring the total prevalence in 2018 to 21%, and alert that the incorporation of new products to the market, such as HTPs, could further increase the prevalence of tobacco use in its various forms among young people.

In conclusion, the independent scientific evidence available on HTPs is sufficient for this Ministry to assess the potential risk to the health of the population and the development of addictive behaviors in young people, making it necessary to make use of the precautionary principle, which supports the adoption of protective measures in the event of well-founded suspicions that certain products or technologies create a serious risk to public health or the environment.

The SUB-SECRETARIAT OF HEALTH STRATEGIES and the SECRETARIAT OF ACCESS TO HEALTH have agreed to this proposal.

The GENERAL DIRECTION OF LEGAL AFFAIRS has intervened within its competence.

The present measure is issued in use of the powers conferred by the Law of Ministries No. 22,520, as amended and supplemented, and by Law No. 26,687.

Therefore,

THE MINISTER OF HEALTH

DECIDES:

ARTICLE 1.- The importation, distribution, commercialization, advertising and any form of promotion and sponsorship of electronic systems or devices intended to inhale tobacco vapors or aerosols, commonly known as "Heated Tobacco Products", is hereby prohibited throughout the Argentine territory, and such prohibition shall be extended to any type of accessory intended for the operation of such systems or devices, as well as tobacco cartridges and sticks to be heated in such systems.

ARTICLE 2°.- Violations to this Resolution shall be dealt with in accordance with the provisions of Resolution No. 425/2014 of the Ministry of Health, as amended by Resolution No. 83/2019 of the former Secretariat of Government of Health, in addition to the penalties that may apply due to the application of other regulations such as the Customs Code.

SECTION 3 - This Resolution shall become effective from the day following its publication in the Official Gazette.

SECTION 4 - The provincial authorities and the authorities of the Autonomous City of Buenos Aires, the Secretariat of Commerce, the Federal Administration of Public Revenues (AFIP), the National Customs Office, the National Communications Agency (ENACOM), the Secretariat of International Economic Relations and/or any other competent agency of the Ministry of Foreign Affairs, International Trade and Worship shall be notified. Be it published, sent to the National Directorate of the Official Registry and filed.

Carla Vizzotti

e. 03/27/2023 No. 19066/23 v. 03/27/2023

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