Unofficial Translation

Official Gazette Number 35901- First Section - Monday May 4th 2026

MINISTRY OF HEALTH

Resolution 549/2026

RESOL-2026-549-APN-MS

City of Buenos Aires, April 30, 2026

HAVING REVIEWED File No. EX-2025-139783038-APN-SSPYPS#MS, the Ministries Act No. 22,520 (consolidated text by Decree No. 438 of March 12, 1992) and its amendments, Law No. 26,687, Decrees No. 602 of May 28, 2013 and No. 891 of November 1, 2017, Ministerial Resolutions No. 1124 of August 4, 2006, No. 425 of March 20, 2014 and No. 565 of March 23, 2023, ANMAT Disposition No. 3226 of May 6, 2011, and

WHEREAS:

Pursuant to Article 23 of the Ministries Act No. 22,520 (consolidated text Decree No. 438/1992) and its amendments, the Ministry is vested with competence over all matters inherent to the health of the population and the promotion of healthy behaviors within the community, empowering it to exercise sanitary police powers with respect to products, technologies, equipment, instruments, and procedures related to health; to intervene with a preventive approach in reducing morbidity caused by toxic substances and chemical risks at all stages of the life cycle; and to participate in the development of plans aimed at the prevention and detection of endemic and non-communicable diseases.

By Resolution No. 1124/2006 of this Ministry of Health, the NATIONAL TOBACCO CONTROL PROGRAM was established with the objective, among others, of keeping the prevalence of tobacco consumption low through measures that prevent the initiation of use and promote cessation among existing smokers.

Law No. 26,687 on the Regulation of Advertising, Promotion and Consumption of Tobacco Products, enacted on June 1, 2011, sets forth the following objectives: "a) Reduce the consumption of tobacco products; b) Minimize the exposure of individuals to the harmful effects of tobacco product smoke; c) Reduce the health, social and environmental harm caused by tobacco use; d) Prevent the initiation of tobacco use, particularly among children and adolescents; e) Raise awareness among present and future generations of the consequences of tobacco product consumption and exposure to tobacco product smoke."

By Disposition No. 3226/2011 of the NATIONAL ADMINISTRATION OF DRUGS, FOOD AND MEDICAL TECHNOLOGY (ANMAT), the importation, distribution, commercialization, and advertising or any form of promotion throughout the national territory of the electronic nicotine delivery system known as the "electronic cigarette" was prohibited, with said prohibition extending to all accessories for such system or device, as well as to cartridges containing nicotine.

Decree No. 602/2013, the implementing regulation of Law No. 26,687, provides in the second paragraph of Article 3 of Annex I thereof: "…The following shall be considered products that may be identified with tobacco products: (…) b) Smoking elements or accessories: such as cigarette holders, water pipes or hookahs, electronic smoking devices and their accessories, tobacco pouches, ashtrays, etc.…"

Resolution No. 565/2023 of the Ministry of Health established a nationwide prohibition on the importation, distribution, commercialization, advertising, and any form of promotion and sponsorship throughout Argentina of electronic systems or devices intended for inhaling tobacco vapors or aerosols, commonly referred to as "Heated Tobacco Products."

Heated tobacco products (hereinafter HTPs) consist of devices that, by means of an electrical system, heat a specially designed cigarette containing reconstituted tobacco, generating an aerosol that is inhaled by the user.

Electronic cigarettes (hereinafter ECs) are devices that, using a battery and a heating element, heat a liquid to produce an aerosol that is inhaled through a mouthpiece. Said liquid may contain varying concentrations of nicotine or chemical analogues that mimic its pharmacological effect.

Nicotine pouches (hereinafter NPs) are small pouches made of permeable cellulose containing nicotine of natural or synthetic origin, together with other substances, intended for placement in the oral cavity, between the gum and the lip, without producing combustion or aerosol. Unlike other products and conventional cigarettes, NPs do not cause harm to third parties.

The aforementioned Resolution No. 565/2023 was issued in response to the novelty of HTPs and was grounded in the precautionary principle, which supports the adoption of protective measures in the face of well-founded suspicions that certain products or technologies pose a serious risk to public health or the environment.

Said precautionary measure cannot be deemed absolute or permanent, being subject to limits and the ongoing duty of review and study.

It is necessary to move more expeditiously in the implementation of proven tobacco control policies, and to adapt and strengthen the existing regulatory framework in order to address aspects not expressly covered by current regulations regarding marketing strategies for tobacco and nicotine products directed at the general population, with a focus on children and adolescents, and to establish specific regulatory standards for new nicotine products, such as electronic cigarettes.

Consumption of new products, particularly electronic cigarettes, is increasing globally, such that countries including the United Kingdom of Great Britain and Northern Ireland, the United States of America, and the Eastern Republic of Uruguay include questions about their use in their surveillance surveys, particularly among adolescent populations, which has allowed for the quantification of the growth of these products.

In the same vein, and even in the absence of regulation of new products, the results of the seventh national study on psychoactive substance use among secondary school students produced by the Argentine Drug Observatory (SEDRONAR, 2025) show that among the secondary school population, e-cigarettes and vaping devices rank third among the most commonly consumed substances, with a consumption rate of 35.5%.

These results have demonstrated that said products are effectively being consumed and are accessible to the population, making a regulatory framework necessary to provide the State with adequate tools to oversee their content and manufacturing conditions, while also deterring and preventing illicit trade, smuggling, and artisanal manufacturing for commercial purposes without adherence to minimum quality and safety standards.

Given the pressing need to implement public policies and affirmative actions to protect the health of the population in relation to the consumption of tobacco products and/or substitute or

alternative products that promote tobacco consumption or endanger human health, these products must be regulated with specific monitoring for each product type.

Since no tobacco product is harmless, specific regulation is required for each product in accordance with its characteristics, underscoring the need for ongoing oversight and periodic monitoring in order to establish guidelines for decision-making, tobacco use prevention, and the promotion of smoking cessation.

HTPs, ECs and NPs, as tobacco products or their equivalents, fall within the scope of Law No. 26,687, pursuant to subsection b) of Article 4 of the National Law, which provides: "b) Tobacco products: preparations that use tobacco, in whole or in part, as a raw material and are intended to be smoked, sucked, chewed, sniffed, inhaled or used as snuff."

Given that each of these products operates differently and that models and technologies evolve at a rapid pace, ongoing and product-specific study and monitoring is required, informed by the data and results yielded by such monitoring processes, with a view to systematizing the surveillance of new developments.

Given that the aforementioned law provides for the regulation of tobacco products, new products must be treated as equivalent thereto, with their specific scope restricted accordingly, and in light of all the foregoing, a shift in the regulatory approach governing these products is warranted.

A policy based on the registration and tracking of these products strengthens the capacity to ensure traceability throughout the production and distribution chain, guarantee adequate health labeling and effective oversight of quality standards, and design and implement public policies oriented toward a comprehensive approach to risk factors and the potential health, social, and environmental harm associated with tobacco use.

Regulating these products entails applying standards based on the proven experience of countries that have already regulated them, and those aligned with the objectives of Law No. 26,687, including a ban on single-use ECs, restrictions on ingredients, additives, flavorings, and fragrances across all new products, and expanded packaging restrictions.

The population must be informed of the relative risk differences among all products related to the conventional cigarette, whether they contain pure heated tobacco or no tobacco, with or without nicotine, and deceptive advertising in all its forms must be avoided, in accordance with the objectives of the aforementioned Law No. 26,687.

In alignment and coherence with the public policy being implemented by the aforementioned NATIONAL TOBACCO CONTROL PROGRAM, a policy of continuous monitoring and control is recommended, with all forms of inducement to consumption by minors and all deceptive or unauthorized advertising expressly prohibited.

This Ministry of Health and the NATIONAL ADMINISTRATION OF DRUGS, FOOD AND MEDICAL TECHNOLOGY (ANMAT) entered into a Framework Technical Cooperation Agreement on January 9, 2026, in order to coordinate joint actions with the NATIONAL TOBACCO CONTROL PROGRAM related to the analysis, evaluation, regulation, oversight, research, and monitoring of new tobacco products and related products, with the objective of protecting public health.

By means of the Supplementary Act of January 14, 2026, entered into under the aforementioned Agreement, the parties committed to advancing the necessary amendments to existing regulations in order to promote a specific protective approach with respect to new tobacco

products, coordinate the application of the regulations to be issued, exchange technical and scientific information, and monitor the implementation of the commitments undertaken.

Likewise, in order to ensure minimum quality and safety standards, the parties agreed that it is reasonable to require importers and/or manufacturers to complete the corresponding registration and submit certificates of origin quality, as well as supporting documentation to verify the authenticity of the product, compliance with technical specifications, and traceability of the supply chain.

In light of the foregoing, it is appropriate to approve the REQUIREMENTS FOR THE REGISTRATION, COMMERCIALIZATION AND OVERSIGHT OF TOBACCO AND NICOTINE PRODUCTS.

The NATIONAL TOBACCO CONTROL PROGRAM, operating under the NATIONAL DIRECTORATE FOR THE COMPREHENSIVE APPROACH TO NON-COMMUNICABLE DISEASES, has issued its opinion within the scope of its competence.

The UNDERSECRETARIAT OF HEALTH PLANNING AND PROGRAMMING and the SECRETARIAT OF HEALTH MANAGEMENT have expressed their approval.

The following bodies have intervened within their respective areas of competence: the NATIONAL ADMINISTRATION OF DRUGS, FOOD AND MEDICAL TECHNOLOGY (ANMAT); the DIRECTORATE OF IMPORTS under the SECRETARIAT OF INDUSTRY AND COMMERCE; the UNDERSECRETARIAT OF CONSUMER PROTECTION AND FAIR TRADE; the UNDERSECRETARIAT OF PUBLIC REVENUES and its subordinate NATIONAL DIRECTORATE OF TAXES, all under the MINISTRY OF ECONOMY; the UNDERSECRETARIAT OF ENVIRONMENT under the CHIEF OF STAFF'S OFFICE and its subordinate DIRECTORATE OF WASTE; the NATIONAL COMMUNICATIONS ENTITY (ENACOM); and the GENERAL SUBDIRECTORATE OF OVERSIGHT of the REVENUE AND CUSTOMS CONTROL AGENCY (ARCA).

The CHIEF OF STAFF'S OFFICE has likewise intervened within its area of competence in accordance with the provisions of Article 12 of Decree No. 891/2017.

The GENERAL DIRECTORATE OF LEGAL AFFAIRS has intervened within its area of competence.

This measure is issued pursuant to the powers conferred by the Ministries Act No. 22,520 and its amendments and supplementary provisions, Law No. 26,687, and Decree No. 602/2013.

Therefore,

THE MINISTER OF HEALTH RESOLVES:

ARTICLE 1. — Ministry of Health Resolution No. 565 of March 23, 2023 is hereby repealed.

ARTICLE 2. — The REQUIREMENTS FOR THE REGISTRATION, COMMERCIALIZATION AND OVERSIGHT OF TOBACCO AND NICOTINE PRODUCTS, set forth in ANNEX IF-2026-41759647-APN-SSPYPS#MS, which forms an integral part of this measure, are hereby approved.

ARTICLE 3. — For all purposes of this Resolution, electronic or mechanical devices, or other presentations that, without qualifying as such, may be identified or associated with them, whose

use has been approved by the competent Health Authority, and which serve as substitutes for the experience of consuming tobacco or nicotine in any form, whether for inhaling, exhaling, chewing, sucking, or keeping lit, etc., shall comply with this regulation and applicable law on an equivalent basis. Products approved for medicinal use by the NATIONAL ADMINISTRATION OF DRUGS, FOOD AND MEDICAL TECHNOLOGY (ANMAT) are expressly excluded.

ARTICLE 4. — Products referred to in Article 3 of this Resolution that are manufactured, commercialized, imported, or distributed within the national territory must comply with the provisions of Law No. 26,687, its implementing regulation Decree No. 602/2013, the requirements approved by this Resolution, and applicable law in the relevant field.

ARTICLE 5. — The REGISTRY OF TOBACCO AND NICOTINE PRODUCTS (RTNP) is hereby created for the purpose of establishing a unified computerized database of the actors, products, and packaging of said products, as well as compliance with the procedures established by Law No. 26,687 and its implementing regulations; all with the aim of ensuring traceability and safety in the use of tobacco and nicotine products, and reducing the health harm caused by tobacco use.

The REGISTRY (RTNP) shall contain the following categories:

a. Electronic Cigarette Device (ECD).

b. Liquid Solutions for ECDs.

c. Heated Tobacco Product Device (HTPD).

d. Sticks.

e. Nicotine Pouches (NPs).

The UNDERSECRETARIAT OF HEALTH PLANNING AND PROGRAMMING shall organize the operation of said Registry within FORTY-FIVE (45) days from the date of issuance of this regulation.

ARTICLE 6. — The UNDERSECRETARIAT OF HEALTH PLANNING AND PROGRAMMING is hereby authorized to issue clarifying, operational, and/or supplementary regulations as may be necessary for the implementation of this Resolution.

ARTICLE 7. — This Resolution shall enter into force upon its publication in the Official Gazette.

ARTICLE 8. — Notify, publish, submit to the National Directorate of the Official Registry, and file.

Mario Iván Lugones

NOTE: The Annex(es) forming part of this Resolution are published in the online edition of the Official Gazette at www.boletinoficial.gob.ar.