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NATIONAL ADMINISTRATION OF DRUGS, FOOD AND MEDICAL TECHNOLOGY

Disposition 2543/2026

DI-2026-2543-APN-ANMAT#MS

City of Buenos Aires, April 30, 2026

HAVING REVIEWED File No. EX-2026-25858775-APN-DGA#ANMAT, Law No. 26,687, its Implementing Regulation Decree No. 602 of May 28, 2013, Decree No. 1490 of August 20, 1992 and its amendments, Ministry of Health Resolutions No. 1124 of August 4, 2006 and No. 565 of March 23, 2023; ANMAT Disposition No. 3226 of May 6, 2011; the FRAMEWORK TECHNICAL COOPERATION AGREEMENT BETWEEN THE MINISTRY OF HEALTH OF THE NATION AND THE NATIONAL ADMINISTRATION OF DRUGS, FOOD AND MEDICAL TECHNOLOGY (ANMAT) of January 9, 2026 (CONVE-2026-03299298-APN-MS); SUPPLEMENTARY ACT No. 1 of February 18, 2026 (IF-2026-17154819-APN-SSRSYA#MS), and;

WHEREAS:

Law No. 26,687 regulates the advertising, promotion and consumption of tobacco products for the purpose of preventing and addressing the harm they cause to the population.

Implementing Regulation Decree No. 602/2013 empowers the MINISTRY OF HEALTH, as the Enforcement Authority, to issue supplementary or interpretive regulations aimed at ensuring compliance with the law being regulated.

Within the scope of the MINISTRY OF HEALTH, the NATIONAL TOBACCO CONTROL PROGRAM operates, having been established by Ministerial Resolution No. 1124/2006, and is responsible for designing, coordinating, and implementing strategies and actions aimed at reducing the demand for tobacco and nicotine products.

By ANMAT Disposition No. 3226/2011, this National Administration prohibited the importation, distribution, commercialization, and advertising or any form of promotion throughout the national territory of the electronic nicotine delivery system known as "electronic cigarette," with said prohibition extending to all accessories for such system or device, as well as to cartridges containing nicotine.

Subsequently, by Resolution No. 565/2023, the Ministry of Health resolved to prohibit 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," with said prohibition extending to all accessories designed for the operation of such systems or devices, as well as to cartridges and tobacco rods intended to be heated in said systems.

Given the development and growing market presence of new tobacco products and related products, such as heated tobacco products, electronic nicotine delivery devices, and other analogues, the MINISTRY OF HEALTH and the NATIONAL ADMINISTRATION OF DRUGS, FOOD AND MEDICAL TECHNOLOGY (ANMAT) entered into the FRAMEWORK TECHNICAL COOPERATION AGREEMENT BETWEEN THE MINISTRY OF HEALTH OF THE NATION AND THE NATIONAL ADMINISTRATION OF DRUGS, FOOD AND MEDICAL TECHNOLOGY (ANMAT) (CONVE-2026-03299298-APN-MS).

Said Agreement is intended to establish a framework for cooperation and technical collaboration between the parties, in order to coordinate actions 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 Supplementary Act No. 1 (IF-2026-17154819-APN-SSRSYA#MS) to the aforementioned Agreement, consideration was given to the fact that the evidence gathered and updated by the NATIONAL TOBACCO CONTROL PROGRAM, as presented in the "Technical Report on New Tobacco and Nicotine Products" (IF-2025-140503413-APN-DNAIENT#MS), establishes that no tobacco or nicotine product is harmless; that these products carry risks associated with nicotine dependence and potential adverse effects; and that, in particular, it is necessary to strengthen the State's capacity to control product attributes, access, consumer information, and marketing practices, especially with respect to children and adolescents.

Notwithstanding the foregoing, it was determined in the aforementioned Supplementary Act No. 1 that accumulated experience has shown that absolute prohibition schemes, in the face of dynamic markets with a high capacity for product substitution, may favor the persistence of informal and illegal distribution channels, involving products of unknown origin, without control over composition, nicotine concentration, emissions, additives, or manufacturing conditions, thereby increasing health risks and complicating a comprehensive approach to the phenomenon.

Following that line of reasoning, it was considered in the aforementioned Act that it is necessary to adopt a risk assessment and risk management-based regulatory approach that allows for a transition from a prohibition-centered scheme toward a regime of strict sanitary control, with clear rules, authorization requirements, technical standards, and oversight mechanisms, without disregarding the principle of public health protection or the prevention of initiation of use.

In light of these considerations, within the framework of Supplementary Act No. 1, the MINISTRY OF HEALTH committed to promoting the issuance of the corresponding administrative act in order to repeal Resolution No. 565/2023, so as to establish a new regulatory framework that, while maintaining the objective of protecting public health, sets forth conditions for control, registration, oversight, and appropriate restrictions on the commercialization of new nicotine and tobacco products, in accordance with the technical guidelines of the National Tobacco Control Program.

In this regard, it is necessary to proceed with the repeal of ANMAT Disposition No. 3226/11; said repeal being a commitment undertaken within the framework of the Supplementary Act No. 1 referred to in the preceding Whereas clause; and one that is not intended as the mere elimination of a prohibition, but rather is part of the pursuit of a new regulatory framework given the ineffectiveness of the regulatory framework that is the subject of this measure.

The head authority of the National Institute of Drugs and the Directorate of Legal Affairs have intervened within their respective areas of competence.

This measure is issued pursuant to the powers conferred by Decree No. 1490/92 and its amendments.

Therefore,

**THE ADMINISTRATOR OF THE NATIONAL ADMINISTRATION OF DRUGS,
FOOD AND MEDICAL TECHNOLOGY ORDERS:**

ARTICLE 1. — ANMAT Disposition No. 3226/2011 is hereby repealed, for the reasons set forth in the Whereas clauses.

ARTICLE 2. — This Disposition shall enter into force upon its publication in the Official Gazette.

ARTICLE 3. — Notify provincial authorities and the authorities of the Autonomous City of Buenos Aires, and the Revenue and Customs Control Agency (ARCA). Publish, submit to the National Directorate of the Official Registry. Upon completion, transfer to temporary custody.

Luis Eduardo Fontana

e. 04/05/2026 No. 28768/26 v. 04/05/2026