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Reference: Annex REQUIREMENTS FOR THE COMMERCIALIZATION AND OVERSIGHT OF NICOTINE AND TOBACCO PRODUCTS

ANNEX I

REQUIREMENTS FOR THE COMMERCIALIZATION AND OVERSIGHT OF NICOTINE AND TOBACCO PRODUCTS

CHAPTER I — GENERAL DEFINITIONS FOR THE PURPOSES OF THIS ANNEX

Electronic cigarettes (ECs) or vapes.

Electronic cigarettes consist of two elements:

1. "Electronic Cigarette Device" (ECD): devices that, using a battery and a heating element, heat a liquid to produce an aerosol that is inhaled through a mouthpiece. All accessories are included within this definition.
2. "Liquid Solution for ECDs": liquid solutions with variable nicotine content, designed for use with an electronic device that heats them to temperatures below combustion temperature in order to release an aerosol.

"Heated Tobacco Products" (HTPs).

Heated tobacco products consist of two elements:

1. "HTP Device" (HTPD): devices that, using a battery, heat rods or cartridges, commonly referred to as "sticks," to temperatures reported to be below that required for combustion, in order to generate an inhalable aerosol. All accessories are included within this definition.
2. "Sticks" (rods/cartridges): specially designed cigarettes that are inserted into the electronic heating device.

Nicotine Pouches.

"Nicotine Pouches" (NPs): 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.

Certified laboratory: a laboratory accredited by the Argentine Accreditation Body (OAA), or a foreign laboratory accredited by an accreditation body that is party to a multilateral recognition agreement signed by the Argentine Accreditation Body (OAA), within the corresponding scope.

CHAPTER II — REGISTRATION AND DUE DILIGENCE

Importers or producers must submit a product registration application through the Remote Procedures Platform (TAD), accessible through the official website to be designated for this purpose by the NATIONAL TOBACCO CONTROL PROGRAM, operating under the

NATIONAL DIRECTORATE FOR THE COMPREHENSIVE APPROACH TO NON-COMMUNICABLE DISEASES.

The cost of said application shall be equivalent in Argentine pesos to the consumer retail price of TWO THOUSAND (2,000) packs of TWENTY (20) cigarettes of the highest commercially available value in the country.

At the time of submitting the product registration application, importers or producers must provide the following documentation, as applicable:

a) Documentation evidencing the identity of the applicant and their legal representation in the case of a legal entity;

b) A copy of the product formula, submitted as a sworn affidavit, translated into Spanish and duly legalized and/or apostilled where required if originally in another language, including the concentrations and toxicological data for each component ingredient;

c) A certificate of analysis of the components generated during normal use, issued by a certified laboratory, translated into Spanish and duly legalized and/or apostilled where required. In the case of imported products, an explanation of the method used to measure the ingredients whose maximum concentrations are limited, as well as the method used to determine the measurement of nicotine concentration and the components of the emissions, must be included;

d) Evidence of product approval issued by at least one of the regulatory agencies of the countries listed in Annex I of Decree No. 150/1992, duly legalized and/or apostilled where required;

e) A sworn affidavit containing a general description of the product, a photograph thereof with and without packaging, and the instructions for use in the form in which it will be commercialized. The design of the child-resistant opening mechanism that prevents access by minors and avoids tampering with the product formula must be indicated;

f) A quality control certificate from the manufacturer for each product subject to the approval application. In the case of an imported product, the certificate must be translated into Spanish, legalized and/or apostilled where required, and issued by an authorized laboratory. In the case of a domestically manufactured product, it must be submitted upon completion of the first production batch and certified by an authorized laboratory;

g) A distribution plan for the product to be registered;

h) A sworn affidavit stating that the manufacturer and/or importer assumes responsibility for the quality and safety of the product once commercialized, under normal or reasonably foreseeable conditions of use;

i) A sworn affidavit of compliance with Ministry of Health Resolutions No. 497/2012 and No. 143/2022 and their amendments;

j) A proposed labeling and advertising plan for the products to be registered, in compliance with Ministry of Health Resolution No. 143/2022.

The specific requirements to be submitted for each product type/registry category are detailed below.

A — Electronic Cigarette Device (ECD) or vape:

- Package size enclosing the electronic device, expressed in mm;
- Size of the electronic device, expressed in mm, and type of battery used;
- Type and characteristics of compatible accessories.

All required product information must be submitted in a single document signed by the company's legal representative as a sworn affidavit.

B — Liquid Solution for ECs or vapes:

- Volume of the refill liquid, expressed in ml;
- Nicotine concentration in the liquid, expressed in mg/ml;
- Nicotine concentration and other substances in emissions under normal conditions of use and the method used for measurement.

All required product information must be submitted in a single document signed by the company's legal representative as a sworn affidavit.

C — "Heated Tobacco Product Device" (HTPD):

- Package size enclosing the electronic device;
- Size of the electronic device and type of battery used;
- Type and characteristics of compatible accessories.

All required product information must be submitted in a single document signed by the company's legal representative as a sworn affidavit.

D — "Sticks" for HTPs:

- Size of the stick, expressed in mm;
- Composition of the stick filter;
- Tobacco variety used and curing method;
- Nicotine content per stick in mg, which may not exceed 5 mg, and the method used for quantification;
- Nicotine output per stick under normal conditions of use and the method used for measurement;
- List of substances released per stick during emissions under normal conditions of use and the method used for measurement.

All required product information must be submitted in a single document signed by the company's legal representative as a sworn affidavit.

E — "Nicotine Pouches" (NPs):

- Container size and opening mechanism;
- Size of each pouch (in mm) and number of pouches per package;
- Nicotine content per pouch in mg and the method used for quantification;
- Type of nicotine used (natural, synthetic, nicotine analogue).

All required product information must be submitted in a single document signed by the company's legal representative as a sworn affidavit.

Any false declaration submitted for any category of the Registry shall be deemed a most serious violation, resulting in deregistration until compliance with the regulation is achieved and, additionally, shall be subject to the applicable sanction under current law.

CHAPTER III — SAFETY AND QUALITY REQUIREMENTS

I. Packaging.

Packaging of tobacco and nicotine products must meet the following requirements:

a) Provide information in Spanish regarding instructions for use and storage, contraindications, warnings, and contact details of the producer or importer for any queries or complaints;

b) Not simulate an object attractive to children and/or adolescents (e.g., animal figures, celebrity figures from music and sports, entertainment figures, etc.);

c) State in a clearly visible phrase: "This product has NOT been approved as a smoking cessation aid";

d) Not contain any harm reduction claims, assertions of greater safety, or similar statements suggesting that the product is less harmful than other products not authorized by the health authority;

e) Not include in any packaging materials or on its website the phrase "tobacco-free," which may be misleading to consumers;

f) Not mention ingredients and additives, such as flavorings, fragrances, or any other type of ingredient, with said prohibition extending to legends, images, or figurative signs that refer to such ingredients or their possible sensory effects and/or that may make the product more appealing to children and adolescents or suggest that it poses lesser health risks; all in accordance with Ministry of Health Resolution No. 143/2022;

g) All packaging of liquid solutions for ECDs, as well as refill containers, must feature a tamper-proof and leak-proof opening system, which must also be child-resistant;

h) Bear the registration number assigned by the Ministry of Health;

i) ECDs may not be commercialized unless sold in packaging.

In compliance with Ministry of Health Resolution No. 497/2012 and its amendments, all packaging must contain a health warning occupying FIFTY PERCENT (50%) of the front face and FIFTY PERCENT (50%) of the back face, with a white background and black lettering, and must comply, without exception, with all provisions established by applicable regulations.

II. Electronic devices.

Electronic devices may only be imported and/or commercialized in the country if they meet the following requirements:

a) Not be single-use devices containing pre-filled liquid solutions;

b) Be equipped with batteries complying with the UL8139 standard or the quality and safety standard established by the SECRETARIAT OF INDUSTRY AND COMMERCE under the MINISTRY OF ECONOMY;

c) Have no purpose other than nicotine consumption (must not incorporate electronic games, music playback capabilities, etc.);

d) Include, at the time of commercialization, instructions indicating the correct use of the batteries and their proper disposal;

e) For HTPDs specifically, demonstrate that they do not exceed 400°C combustion temperature.

Packaging: All packaging of these new products must strictly comply with Law No. 26,687, Articles 10 et seq.; Ministry of Health Resolution No. 497/2012 and its amendments, regarding health warnings; and Ministry of Health Resolution No. 143/2022.

III. Ingredients.

1. Liquid solutions:

Liquid solutions may only be imported and/or commercialized in the country if they comply with the following requirements:

a) Use tobacco-derived nicotine and not synthetic nicotine or any nicotine analogue or similar substance;

b) Have a nicotine concentration of less than 20 mg/ml;

c) Not exceed a tank capacity volume limit of 2 ml;

d) The liquids must not contain:

d.i) Ingredients with carcinogenic (categories 1 or 2), mutagenic (categories 1 or 2), or reproductive toxic (category 1) properties, with the exception of nicotine;

d.ii) Ingredients classified as respiratory sensitizers; diethylene glycol or ethylene glycol;

d.iii) Ingredients such as fructose, lactose, maltose, sucrose, potassium acesulfame, aspartame, sodium saccharin, Stevia, vitamins and minerals; radioactive substances; long-chain parabens; triclosan; phenoxyethanol; preservatives that may release formaldehyde;

e) The liquids must not contain concentrations of the following substances exceeding the values set forth below: Diacetyl (22 mg/L), Formaldehyde (22 mg/L), Acrolein (22 mg/L), Acetaldehyde (200 mg/L), Pb (10 mg/L), As (3 mg/L), Cd (1 mg/L), Hg (1 mg/L), Sb (5 mg/L);

f) Use high-purity ingredients and nicotine;

g) Contain no flavorings. Only tobacco aroma shall be authorized;

h) Contain no stimulant compounds associated with energy and vitality, such as caffeine, taurine, anabolics, vitamins, or similar substances;

i) Contain no additives with coloring properties during combustion;

j) Contain no ingredients that, according to objective scientific criteria and international standards, increase the overall inherent toxicity or addictive effect of nicotine.

In the event that undeclared ingredients or additives are incorporated after registration, the producer/importer must submit a new registration application including the updated composition.

2. "Sticks":

Sticks for HTPDs may only be imported and/or commercialized in the country if they comply with the following requirements:

a) The only authorized flavor shall be tobacco;

b) Must not contain ingredients with carcinogenic (categories 1 or 2), mutagenic (categories 1 or 2), or reproductive toxic (category 1) properties, with the exception of nicotine;

c) Must not contain ingredients that, according to objective scientific criteria and international standards, increase the overall inherent toxicity or addictive effect of nicotine.

3. Nicotine Pouches (NPs):

Nicotine Pouches (NPs) may only be imported and/or commercialized in the country if they comply with the following requirements:

a) The substances used in the manufacture of nicotine pouches must be authorized for food use and/or evaluated by recognized expert bodies as generally recognized as safe (GRAS) in food control; or authorized by regulatory authorities for use in oral pharmaceuticals. All consumable ingredients and additives must meet or exceed food-grade quality or pharmaceutical-grade purity standards, respectively;

b) Must not contain ingredients with carcinogenic (categories 1 or 2), mutagenic (categories 1 or 2), or reproductive toxic (category 1) properties, with the exception of nicotine;

c) Must use only tobacco-derived nicotine and NOT synthetic nicotine or any nicotine analogue or similar substance;

d) The nicotine content must not exceed 8 mg of nicotine per pouch. Manufacturers and/or importers may produce and commercialize products in scaled presentations, provided that at all times the maximum established in this subsection is respected and the proportions of the other declared ingredients in the formula are maintained;

e) The only authorized flavors and aromas shall be menthol and tobacco;

f) Nicotine pouches may not contain the following additives: vitamins, minerals, or other ingredients that convey the impression that they are beneficial to health or present a lesser health risk; caffeine, taurine, or other stimulants associated with energy and vitality;

g) Must not contain ingredients that, according to objective scientific criteria and international standards, increase the overall inherent toxicity or addictive effect of nicotine;

h) The following substances may not be added as independent ingredients: agarinic acid, aloin, capsaicin, hypericin, beta-asarone, estragole, hydrocyanic acid, menthofuran, methyleugenol,

pulegone, quassin, safrole, teucrin A, thujone (alpha and beta), coumarin, colchicine, bergamottin (furanocoumarin), 7-dihydroxybergamottin (furanocoumarin), N-nitrosonornicotine (NNN).

The NATIONAL TOBACCO CONTROL PROGRAM may request technical collaboration from the NATIONAL ADMINISTRATION OF DRUGS, FOOD AND MEDICAL TECHNOLOGY (ANMAT), or whichever body may replace it in its functions, regarding additives or substances not specified in the previously detailed list of ingredients. Said Program may decide on the revocation or maintenance of registration based on scientific studies demonstrating or refuting their safety under normal conditions of use.

CHAPTER IV — REGISTRATION FOR COMMERCIALIZATION

Upon submission of the documentation required under this ANNEX, in accordance with the applicable product type, a registration number shall be assigned and notified within FIVE (5) business days following submission, through the Remote Procedures Platform (TAD).

Said registration number shall authorize the commercialization of the relevant product. Notwithstanding the foregoing, the NATIONAL TOBACCO CONTROL PROGRAM, operating under the NATIONAL DIRECTORATE FOR THE COMPREHENSIVE APPROACH TO NON-COMMUNICABLE DISEASES, may at any time revoke said authorization in the event of non-compliance with applicable regulations.

Producers and importers shall be subject to regular inspections aimed at verifying the accuracy of the sworn affidavits submitted in accordance with this regulation.

Any change of corporate name, registered address, change of manufacturer or technical director, closure of the establishment, and/or any other information submitted by sworn affidavit must be reported within THIRTY (30) days of the change through the Remote Procedures Platform (TAD).

Only those products that hold the corresponding registration number may be commercialized in the Argentine Republic; said number must appear on each package of the registered products.

Registration approval shall be valid for FIVE (5) years, and its renewal must be processed, at no cost, through the Remote Procedures Platform (TAD).

Products not expressly provided for in this regulation may not be commercialized, distributed, or imported into the country.

CHAPTER V — MARKET ASSESSMENT AND REGULATORY REVIEW

The NATIONAL TOBACCO CONTROL PROGRAM, operating under the NATIONAL DIRECTORATE FOR THE COMPREHENSIVE APPROACH TO NON-COMMUNICABLE DISEASES, may request periodic information on sales, consumption profiles, and market trends, and adjust regulatory requirements in accordance with current scientific evidence and international standards. It must likewise monitor and assess the evolution of the market for these products. To this end, it may request that manufacturers, importers, assemblers, or distributors submit, within a period of no less than FIFTEEN (15) days, information on:

a) General sales volume data, by brand and product type, for a specific period;

b) Mode of sale of the products; and

c) Age groups of consumers of each product, duly disaggregated by age ranges, for the purpose of monitoring the population consumption profile and assessing the effectiveness of access restrictions for minors.

All requests and the information obtained in compliance therewith shall be publicly accessible, except for information protected by Law No. 25,326 and its amendments and supplementary provisions.

Furthermore, the entity required to submit information may, on a duly substantiated and exceptional basis, request that all or part of the data provided be treated as confidential, so as not to prejudice its commercial interests. The requesting authority may grant such request by means of a reasoned decision.

If confidentiality is granted, the corresponding data shall be excluded from public disclosure, thereby guaranteeing the protection of the legitimate commercial interests of the applicant.

The decision on confidentiality shall be notified to the applicant within THIRTY (30) days of the submission of the confidentiality request. While the request is being processed, the information shall not be publicly disclosed.

CHAPTER VI — AMENDMENTS AND COMPLIANCE WITH INTERNATIONAL STANDARDS

Based on the market information gathered by the NATIONAL TOBACCO CONTROL PROGRAM, operating under the NATIONAL DIRECTORATE FOR THE COMPREHENSIVE APPROACH TO NON-COMMUNICABLE DISEASES, in accordance with the provisions of the preceding section, on the periodic reports prepared regarding the consumption of these products and on the evolution of applicable international standards in this category, the UNDERSECRETARIAT OF HEALTH PLANNING AND PROGRAMMING, upon a proposal by the NATIONAL TOBACCO CONTROL PROGRAM, may order the updating of the minimum requirements for commercialization and establish more stringent conditions for approval.

Where there are reasonable and duly justified grounds, the UNDERSECRETARIAT OF HEALTH PLANNING AND PROGRAMMING may, by means of a reasoned decision, withdraw the marketing authorization for a product and require its manufacturers or importers to cease commercializing it; and may order a prohibition on use and require the manufacturer and/or importer to proceed with the market withdrawal of the product in question.

CHAPTER VII. OTHER PROVISIONS

All matters covered by this ANNEX must be interpreted in accordance with Law No. 26,687 and its implementing regulations.

Once products are registered pursuant to this regulation, importers and/or producers, in each applicable case, must retain and safeguard, for a period of no less than five (5) years, the certificate of analysis of origin for each production batch, which must comply with the protocol submitted at the time of registration of the relevant product.

The NATIONAL TOBACCO CONTROL PROGRAM, operating under the NATIONAL DIRECTORATE FOR THE COMPREHENSIVE APPROACH TO NON-COMMUNICABLE DISEASES, is authorized to request such documents whenever it deems appropriate, and may likewise request technical collaboration from the NATIONAL ADMINISTRATION OF

DRUGS, FOOD AND MEDICAL TECHNOLOGY (ANMAT) for the analysis and validation of such analyses.