#### MINISTRY OF THE POPULAR POWER FOR HEALTH

# BOLIVARIAN REPUBLIC OF VENEZUELA MINISTRY OF THE POPULAR POWER FOR HEALTH OFFICE OF THE MINISTER

CARACAS, JUNE 28, 2023 213°, 164° Y 24°.

#### **RESOLUTION N° 414**

Acting under the powers conferred by Articles 65 and 78, numerals 2 and 19 of the Decree with Rank, Value and Force of the Organic Law of the Public Administration; in accordance with Articles 83 and 326 of the National Constitution of the Bolivarian Republic of Venezuela, and pursuant to Articles 2, 5 and 25 of the Organic Law of Health, this Ministerial Office

## **WHEREAS**

Health is a fundamental social right, an obligation of the State. The State shall guarantee it as part of the right to life. The State shall promote and develop policies to raise the quality of life, collective well-being, and access to services. The foregoing is based on the principle that all people in general, without distinction, have the right to health protection; on the State duty to actively participate in the promotion or defense of health; and on the duty to comply with health and sanitation measures established by law in accordance with international treaties and conventions signed and ratified by the Republic.

#### **WHEREAS**

The Security of the Nation is based on the Principle of Co-responsibility between the State and civil society, in order to comply with the principles of independence, democracy, equality, peace, freedom, justice, solidarity, environmental promotion and conservation, and recognition of human rights, as well as in the progressive satisfaction of the individual and collective needs of Venezuelan men and women, on the basis of a sustainable and productive development with full coverage for the national community. This principle of coresponsibility is exercised in the economic, social, political, cultural, geographic, environmental, and military spheres.

#### WHEREAS

Health is a fundamental and constitutional social right aimed towards the collective well-being, which demands access to goods and services provided by the Executive Branch, which exercises its authority within the framework of the National Health System.

#### **WHEREAS**

The Third Socialist Plan for the Economic and Social Development of the Nation (2019-2025), published in the Official Gazette of the Bolivarian Republic of Venezuela No 6,446 Extraordinary dated April 08, 2019, sets forth that it is the duty of the State to ensure health, through the continuous strengthening of the welfare of the population, the consolidation of all levels of care and services of the National Public Health System, and the living conditions throughout the population residing in the national territory.

#### **WHEREAS**

The Ministry of Health is the governing and planning body of the national public administration and is responsible for the exercise, technical direction, and elaboration of administrative rules, as well as the coordination and supervision of the services destined for the defense of health and in strict compliance with the Law.

#### WHEREAS

Studies and clinical trials by doctors and scientists carried out in the Bolivarian Republic of Venezuela have reached the conclusion that the Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS, contain potentially toxic substances, which cause addiction and are harmful to health, as well as increase the risk of heart diseases, pulmonary disorders, among other pathologies. Likewise, scientific information provided by duly qualified personnel within the national territory indicates that the aerosols generated by the Conventional Heated Tobacco products (Conventional and Herbal HTP), in addition to having glycerin and propylene glycol, contain other toxic substances that are sometimes found at higher levels than in smoke from burning tobacco, such as glycidol, pyridine, dimethyl trisulfide, acetoin, and methylglyoxal. These latter substances are not present in the smoke of conventional cigarettes.

#### WHEREAS

It is imperative for the Venezuelan State to guarantee the rights of the people against the risks caused by products that may enter the national territory, whose commercialization and distribution may be considered harmful or dangerous for the health of the Venezuelan population, by exercising its authority within the scope of its competencies, while upholding the constitutional guarantees, contributing and promoting the public policies of the National Public Health System.

#### **WHEREAS**

It is necessary to prohibit these electronic devices because the Venezuelan State's view is to provide protection, safeguard, and defense of the human rights to life, health, and integrity of the individual.

#### **WHEREAS**

It is the competence of the National Executive Power to adopt the measures it deems necessary for the adequate implementation of the policies in matters of Sanitary Control, therefore, the total prohibition of Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), consumables and other accessories, as well as Conventional Heated Tobacco Products (Conventional and Herbal HTC), is hereby adopted.

#### **DECIDES**

To issue the following:

RESOLUTION PROHIBITING THE MANUFACTURE, STORAGE, DISTRIBUTION, CIRCULATION, COMMERCIALIZATION, IMPORTATION, EXPORTATION, USE AND CONSUMPTION, ADVERTISING, PROMOTION AND SPONSORSHIP OF ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS), ELECTRONIC NON-NICOTINE DELIVERY SYSTEMS (ENNDS), CONSUMABLES, TANKS OR CARTRIDGES, REFILLABLE CONSUMABLE CONTAINERS AND OTHER ACCESSORIES, HEATED AND CONVENTIONAL TOBACCO PRODUCTS (CONVENTIONAL AND HERBAL HTP) AND SIMILAR PRODUCTS

## Object.

**Article 1.** The purpose of this Resolution is to set forth the prohibition of the manufacture, storage, distribution, circulation, commercialization, importation, exportation, use, consumption, advertising, promotion, and sponsorship of Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), Consumables, Tanks or Cartridges, Refillable Consumable Containers and Other Accessories, Conventional Tobacco Products (Conventional and Herbal HTP); and similar products throughout the national territory, in order to set mechanisms for the protection of people's health.

**Sole Paragraph:** Likewise, as of the date of publication of this resolution in the Official Gazette of the Bolivarian Republic of Venezuela, the Ministry of Popular Power for Health, as the Governing and Planning Body of the national public administration, especially in Health Control policy, as well as all its entities and/or centralized and decentralized bodies, shall refrain from issuing and/or granting registrations, import permits, export permits, transit and special customs regimes throughout the national territory.

## Scope of application

**Article 2.** The present Resolution is applicable to all natural or legal persons who carry out activities related to the manufacture, storage, circulation, distribution, commercialization, importation, exportation, use, consumption, advertising, promotion, and sponsorship of Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), Consumables, Tanks or Cartridges, Refillable Consumable Containers and Other

Accessories, Conventional Heated Tobacco Products (Conventional and Herbal HTP); and similar products throughout the national territory.

Definitions

**Article 3.** For the purposes set forth in this Resolution, the following definitions are established:

- Storage: Use of spaces or private enclosures to safeguard or deposit Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), as well as their components, substances, and accessories.
- Circulation: Set of actions and procedures carried out to move, transit or deliver the products or merchandise to any geographic space of the national territory.
- Commercialization: Set of actions and procedures carried out to introduce the products or merchandise into the distribution system, according to the existing legal mechanisms.
- Distributor: Legal entity in charge of distributing and/or commercializing Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), consumables and other accessories.
- Refillable consumable container: A container filled with nicotine or non-nicotine consumable liquid, which can be used to refill a tank or cartridge of Electronic Nicotine Delivery Systems (SEAN) and Electronic Non-Nicotine Delivery Systems (ENNDS).
- Export: Selling and/or donating goods and services produced or generated in one country to buyers abroad, regarding all products that originate in one nation and are sent to another nation.
- Manufacturing: Assembly of electronic systems or devices, liquids, disposable cartridges or tanks, equipment, and accessories, made in its own name or in the name of a third party, intended for the delivery or not of nicotine, and marketed through natural and/or legal persons in any geographic space of the national territory.
- Imports: it refers to the purchase and/or donation of goods and services to a foreign country for use in the national territory, and applies to everything that enters the given country and comes from a foreign country.
- Nicotine: It is an organic compound, of the alkaloid type, found mainly in the leaves
  of the tobacco plant (*Nicotiana tabacum*), but it can also be produced synthetically.
  It is the substance responsible for dependence and addiction since it acts at the level
  of the central nervous system.

- Product: Includes Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), consumables, tanks or cartridges, refillable consumable containers, and other accessories.
- Conventional HTP: Manual or electronic devices intended only for burning tobacco by means of combustion.
- HTP Herbals: Manual or electronic devices intended only for burning herbs by means of combustion.
- Flavorings: Substances of natural (vegetable) or artificial origin, capable of acting on the senses of taste and smell, either to reinforce the characteristic, inherent flavor, or to confer a new flavor and/or specific aroma, to make it more palatable or pleasant.
- Electronic Nicotine Delivery Systems (ENDS) and Electronic Non-Nicotine Delivery Systems (ENNDS): Electronic nicotine or non-nicotine delivery devices, consisting of four (4) elements: a cartridge or reservoir, containing a liquid solution (consumable) with or without nicotine; a heating element (vaporizer), a power source (rechargeable battery or not); and a mouthpiece, through which nicotine or non-nicotine vapor doses are released. Electronic Nicotine Delivery Systems (ENDS) can be disposable or refillable, with a refill container and reservoir, or with single-use cartridges.

## Prohibition, Restriction, Promotion, Advertising and Sponsorship

**Article 4.** Any type of advertising, promotion and sponsorship or any form of dissemination that in any way incites the acquisition of the Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), Consumables, Tanks or Cartridges, Refillable Consumable Containers and Other Accessories, Conventional Heated Tobacco Products (Conventional and Herbal HTP), and similar products, is prohibited. Any promotion, advertising and sponsorship that incites the use and human consumption of its compounds or liquid substances is equally prohibited.

**Sole Paragraph:** All natural and legal persons are prohibited from any transaction through Internet or other means of sale through telecommunication or any other technology regarding Electronic Non-Nicotine Delivery Systems (ENNDS), Consumables, Tanks or Cartridges, Refillable Consumable Containers and Other Accessories, Conventional Heated Tobacco Products (Conventional and Herbal HTP); and analogous products provided for in the present Resolution.

**Article 5.** All State agencies, as well as the owners, employees and administrators of establishments, stores, premises, private and/or public institutions, regardless of their use, including public transportation, are obliged to ensure compliance with this article in the

national territory. Therefore, they must permanently display a **PUBLIC ANNOUNCEMENT** whose dimensions are equal to or greater than 80 centimeters (width) X 50 centimeters (length). It must have the following text:

"IT IS PROHIBITED TO SELL OR PROVIDE IN ANY WAY TO THE GENERAL PUBLIC ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS), ELECTRONIC NON-NICOTINE DELIVERY SYSTEMS (ENDS), CONSUMABLES, TANKS OR CARTRIDGES, REFILLABLE CONSUMABLE CONTAINERS AND OTHER ACCESSORIES, CONVENTIONAL HEATED TOBACCO PRODUCTS (CONVENTIONAL AND HERBAL HTP), AND ANALOGOUS PRODUCTS. WHOEVER SELLS, SUPPLIES OR DELIVERS PRODUCTS THAT MAY CAUSE PHYSICAL OR CHEMICAL DEPENDENCE WILL BE SANCTIONED AND PUNISHED IN ACCORDANCE WITH THE LEGISLATION, RESOLUTIONS AND REGULATIONS IN FORCE IN THE BOLIVARIAN REPUBLIC OF VENEZUELA."

**Sole Paragraph:** The foregoing text must be displayed together with the number and date of this Resolution and with the number and date of its publication in the Official Gazette of the Bolivarian Republic of Venezuela.

**Article 6.** The owners, employers and administrators of the interior or closed areas of workplaces and/or public places, whatever their use, including public transportation, have the obligation to watch over the faithful compliance of the present resolution, in order to protect the population from the harmful effects of Electronic Non-Nicotine Delivery Systems (ENNDS), Consumables, Tanks or Cartridges, Refillable Consumables Containers and Other Accessories, Conventional Heated Tobacco Products (Conventional and Herbal HTP); and similar products.

## Campaigns.

**Article 7.** As expressions of the organized, participatory and protagonist Popular Power, the states, municipalities, and communal councils shall implement campaigns aimed at strengthening the right of every person to the protection of health, to a healthy and safe environment, free from the consumption of the substances prohibited in this Resolution, directed to contributing to the full development and welfare of the Venezuelan population, in accordance with the provisions of this resolution.

# **Plans and Programs**

Article 8. The Ministry of Popular Power for Health, as well as other competent bodies, shall design and develop plans, programs, projects and campaigns oriented to the prevention, information and awareness related to the use and consumption of Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), Consumables, Tanks or Cartridges, Refillable Consumable Containers and Other Accessories, Conventional Tobacco Products (Conventional and herbal HTP), and similar products. These plans, programs, projects, and campaigns shall raise awareness of the serious damages and their sequels to health produced by the consumption of the substances prohibited in this

Resolution, to promote collective awareness of the fundamental right to health protection and to a healthy and safe environment.

**Article 9.** Educational institutions and public and private radio and television media shall implement information programs on the danger and effects of Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS), consumables, Tanks or Cartridges, Refillable Consumable Containers and Other Accessories, Conventional Tobacco Products (Conventional and Herbal HTP), and similar products. The supervision of these programs will be in charge of the ministries with authority in matters of Education, Communication, and Information, as well as other competent bodies.

**Article 10.** It is prohibited the manufacturing, storage, distribution, circulation, commercialization, import, export, use, consumption, advertising, promotion and sponsorship, retail, and wholesale consumption of the products referred to in the present Resolution; even when performed at a distance or through similar procedures, such as telephonic, digital, electronic, and other similar means. Likewise, it is prohibited to deliver, supply, or distribute free of charge the products subject to this Resolution.

**Article 11.** Any natural or legal person who contravenes or infringes the prohibition set forth in this Resolution shall be subject to the sanctions provided in the legal system in force, whose penalties shall be determined by the Ministry of Popular Power for Health according to the scope of its competence, as Governing and Planning Body of the National Public Administration, especially regarding the policy of Sanitary Control.

**Article 12.** Resolution No. 362 dated May 31, 2023, published in the Official Gazette of the Bolivarian Republic of Venezuela No. 42,641 dated June 1, 2023, and any other provision that contravenes this Resolution, is hereby derogated.

**Article 13.** This Resolution shall become effective as of its publication in the Official Gazette of the Bolivarian Republic of Venezuela.

## Communicate and publish.

[stamp]
[signature]

MAGALY GUTIERREZ VIÑA

MINISTER OF THE POPULAR POWER FOR HEALTH

Decree No 4,639 dated February 9, 2022,

Official Gazette No 42,315 of February 9, 2022.