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REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF FINANCE
BUREAU OF CUSTOMS

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15 March 2024

CUSTOMS MEMORANDUM CIRCULAR
NO. 45-2024

TO : ALL DEPUTY COMMISSIONERS
ALL SERVICE DIRECTORS
ALL DISTRICT AND SUB-PORT COLLECTORS
ALL OTHERS CONCERNED

SUBJECT : IMPLEMENTATION OF THE DEPARTMENT OF TRADE AND
INDUSTRY ADMINISTRATIVE ORDER NO. 22-16 SERIES OF
2022

This has reference to the attached letter dated 12 February 2024 from Atty. Amanda Marie F. Norgales, Assistant Secretary and Supervising Head, Consumer Protection Group, Department of Trade and Industry (DTI) requesting all District Collectors and Sub-Port Collectors of the Bureau of Customs (BOC) to require all importers of **Vaporized Nicotine and Non-Nicotine Products** covered by Republic Act No. 11900 to present a Certificate of Conditional Release (CCR) duly issued by the Bureau of Philippine Standards (BPS), prior to the release of the imported commodities from the BOC, to wit:

"All manufacturers and importers of the covered products shall apply for product registration and certification with the BPS by submitting information demonstrating conformity with the technical regulations set by the office.

Only BPS registered and certified Vaporized Nicotine and Non-Nicotine Products, their devices, and Novel Tobacco Products with the applicable graphic health warning may be sold to the general public. X x x."

Moreover, you are also directed to submit an electronic weekly report to the Port Operations Service, Assessment and Operations Coordinating Group, through pocd@customs.gov.ph starting **01 March 2024** using the attached template (**Annex "A"**), together with the scanned copies of the CCR.

For records purposes, please confirm the dissemination of this circular throughout your offices within fifteen (15) days from receipt hereof.

For strict compliance.



BIENVENIDO Y. RUBIO
Commissioner

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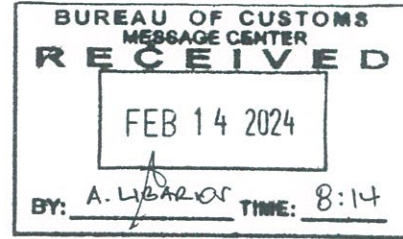


OFFICE OF THE PHILIPPINE DEPUTY COMMISSIONER OF CUSTOMS AND PORT OPERATIONS COORDINATION DIVISION
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12 February 2024

COMMISSIONER BIENVENIDO Y. RUBIO
Bureau of Customs
G/F OCOM Bldg.
Port Area, Manila
E-mail: boc.ocom@customs.gov.ph



Dear Commissioner Rubio:

This has reference to the implementation of the Republic Act (RA) No. 11900 or the "Vaporized Nicotine and Non-Nicotine Products Regulation Act" which lapsed into law on 25 July 2022.

Under RA 11900, it was declared the policy of the State to enact a balanced policy whereby novel consumer products are properly regulated in order to protect the citizens from the hazards of regulated, unregulated and substandard Vapor Products and Heated Tobacco Products. For this purpose, the said law mandates the regulation of the importation, assembly, manufacture, sale, packaging, distribution, use, advertisement, promotion and sponsorship of Vaporized Nicotine and Non-Nicotine Products, and their devices, and Novel Tobacco Products.

The Implementing Rules and Regulations (IRR) of RA 11900, through the DTI Department Administrative Order (DAO) No. 22-16 Series of 2022, provided an eighteen (18)-month transitory period for manufacturers, distributors, importers and retailers of Vaporized Nicotine and Non-Nicotine Products to comply with the law's requirements on product standards and product registration (certification). However, the rest of the executory provisions took effect immediately upon issuance of the IRR on 05 December 2022.

In order to ensure that incoming importations of Vaporized Nicotine and Non-Nicotine Products are complying with the requirements of RA 11900 and its IRR, it is deemed necessary to subject these commodities to the inspection and verification of our Bureau of Philippine Standards (BPS). As such, the DTI, through its Consumer Protection Group, intends to strengthen its coordination with the BOC, being the first line of defense of the country against smuggling and other frauds committed against applicable laws.

In view thereof, the DTI Consumer Protection Group requests the BOC to instruct all of its district and subport collectors to require all importers of Vaporized Nicotine and Non-Nicotine Products covered by RA 11900 to present a **Certificate of Conditional Release** duly issued by the BPS prior to the release of the imported commodities from the BOC.

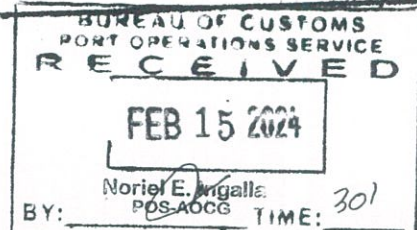
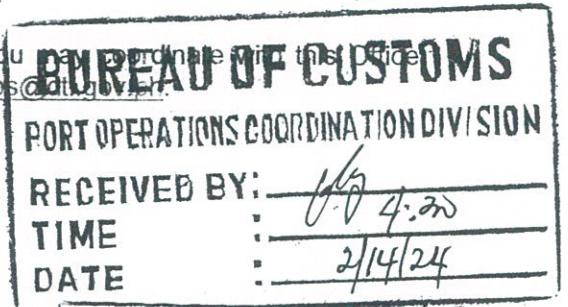
For further assistance and concerns regarding this matter, you may coordinate with this Office through e-mail cpg@dti.gov.ph or to the BPS through e-mail bps@dti.gov.ph.

Thank you for the usual support and cooperation.

Sincerely,

ATTY. AMANDA MARIE F. NOGRALES
Assistant Secretary and Supervising Head
Consumer Protection Group

CONSUMER PROTECTION GROUP





Department Administrative Order No. 22-16
Series of 2022

**IMPLEMENTING RULES AND REGULATIONS OF REPUBLIC ACT NO. 11900 OR
"THE VAPORIZED NICOTINE AND NON-NICOTINE PRODUCTS REGULATION ACT"**

Pursuant to Section 24 of Republic Act No. 11900 (RA11900) the following Implementing Rules and Regulations (IRR) are hereby promulgated and adopted for the guidance, information, and compliance of all concerned:

**RULE I
PRELIMINARY PROVISIONS**

Section 1. Title. This Department Administrative Order (DAO) shall be referred to as "The Implementing Rules and Regulations of Republic Act No. 11900, or the Vaporized Nicotine and Non-Nicotine Products Regulation Act".

Section 2. Scope. This IRR shall apply to any person, natural or juridical, that is engaged in the importation, assembly, manufacture, sale, packaging, distribution, advertisement, promotion, and sponsorship of Vaporized Nicotine and Non-Nicotine Products, and their devices, and Novel Tobacco Products, whether locally manufactured or imported, in an online or offline platform, or purchase or use of the same, as well as to all those responsible for ensuring compliance on public use and in Designated Vaping Areas.

Section 3. Coverage. This IRR shall cover the following products:


- a. Vapor Products or Vapor Products Refills;
- b. Vapor Product Devices;
- c. HTP Consumables;
- d. HTP Devices; and
- e. Novel Tobacco Products.

**RULE II
DECLARATION OF POLICY**

It is hereby declared the policy of the State to protect and promote the right to health of the people and instill health consciousness among them.

It is further declared the policy of the State to enact a balanced policy whereby these novel consumer products are properly regulated using internationally accepted product standards in order to protect the citizens from the hazards of regulated, unregulated and substandard Vapor Products and Heated Tobacco Products.

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Head, Records Section
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CMC NO. 45-2024

For this purpose, the government shall regulate the importation, assembly, manufacture, sale, packaging, distribution, use, advertisement, promotion and sponsorship of Vaporized Nicotine and Non-Nicotine Products, and their devices, and Novel Tobacco Products in order to promote a healthy environment, protect the citizens from any potential hazards of these novel consumer products, reduce the harm caused by smoking, and ensure that the sale to minors and the illicit trade of Vaporized Nicotine and Non-Nicotine Products, and their devices, and Novel Tobacco Products in the country are prevented.

**RULE III
DEFINITION OF TERMS**

For purposes of this IRR, the following terms are defined:

1. **Advertising** – the business of conceptualizing, presenting, making available and communicating to the public, through any form of mass media, any fact, data or information about the attributes, features, quality or availability of consumer products, services or credit. For the purpose of RA11900 and this IRR, advertising shall be understood as Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products advertising and shall not include non-promotional communication intended for informational purposes only.
2. **Buffer Zone** – a ventilated area between the door of a Designated Vaping Area (DVA) not located in an open space and the non-DVA area.
3. **Celebrity** – any natural person who, by his or her accomplishments or fame, or by reason of his or her profession or calling, gives the public a legitimate interest in his or her doings, affairs and character. The term includes anyone who has arrived at a position where public attention is focused upon him or her as a person, such as, but not limited to, actors, athletes and other sports personalities, war heroes, famous inventors, social media influencers and explorers among others.
4. **Child-resistant** – the type of containers that can be opened only by operating, puncturing or removing one of its functional and necessary parts using a tool that is not supplied with the container and comply with the existing standards on child-resistant packaging.
5. **Designated Vaping Area (DVA)** – an assigned indoor or outdoor area where the use of Vaporized Nicotine and Non-Nicotine Products shall be allowed.
6. **Distributor** – any entity to whom Vaporized Nicotine and Non-Nicotine Products, or their devices, or Novel Tobacco Products is delivered or sold for purposes of distribution in commerce, except that such term does not include a manufacturer, retailer or common carrier of such product.
7. **Floor Price** – the minimum price of Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products, taking into account the sum of their excise tax, value-added tax and a reasonable production cost.
8. **Heated Tobacco Products (HTPs)**, also referred to as **Heated Tobacco Product (HTP) Consumables** or **Heat-Not-Burn Product Consumables** – tobacco products that are intended to be consumed through heating tobacco, either electronically or

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Head, Reports Section
Department of Trade & Industry

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through other means, sufficient to release an aerosol that can be inhaled, without combustion of the tobacco. HTP Consumables or Heat-Not-Burn Product Consumables may also include liquid solutions and gels that are part of the product and are heated to generate an aerosol. HTPs may or may not operate by means of an HTP Device

9. **Heated Tobacco Product Device or HTP Device** – the component or combination of components of an HTP System intended to be used in combination with HTP Consumables that generate an aerosol without combustion
10. **Heated Tobacco Product System or HTP System** – an HTP Consumable and HTP Device that are intended to be used together as a system.
11. **Manufacturer** – an establishment engaged in any and all operations involved in the production of Vaporized Nicotine and Non-Nicotine Products, or their devices, or Novel Tobacco Products, including preparatory processing, compounding, formulating, filling, refilling, packaging, repackaging, altering, ornamenting, finishing and labeling for the purpose of its storage, sale or distribution.
12. **Medicinal or Therapeutic Claims** – explicit statements made on any product presented as having properties for directly treating, curing, alleviating, or preventing diseases or disorders in persons.
13. **Minor** – any person below eighteen (18) years old.
14. **Nicotine** – nicotinic alkaloids, including any salt or complex of nicotine, whether derived from tobacco or synthetically produced.
15. **Nicotine Mixture** – the nicotine containing liquid, solid or other non-tobacco substance in the product.
16. **Nicotine Shots** – nicotine in liquid or any other form or substance that is added to or mixed with Vapor Product Refills or cartridges that has the effect of increasing the dosage or nicotine concentration in a refill or cartridge.
17. **Novel Tobacco Products** – all non-combusted substances in solid or liquid form, and innovations, either made partly of tobacco leaf as raw material or containing nicotine from tobacco, intended to be used as a substitute for cigarettes or other combusted tobacco products
18. **Package** – packs, boxes, cartons, or containers of any kind in which Vapor Products or HTPs, or Novel Tobacco Products are contained when offered for sale to consumers.
19. **Point-of-Sale** – any location, physical or online, where an individual can purchase Vaporized Nicotine and Non-Nicotine Products and their devices, or Novel Tobacco Products, which may include a product testing area.
20. **Principal display surface** – the panel of the package that faces the consumer when displayed for sale
21. **Product Demonstration** – the testing of an HTP System or Vapor Product System, or Novel Tobacco Product conducted by a trained product expert who shall explain the

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characteristics, operation and maintenance of the product for the purpose of informing and familiarizing a prospective buyer, who is of legal age for the purpose of RA11900 and this IRR

22. **Product Registration** – the Certificate issued by the Bureau of Philippine Standards (BPS) in accordance with Technical Regulations.
23. **Product Statement** – an explicit communication to consumers in the product label or marketing which pertains to product performance attributes or an objective description of the contents of the product, quantity of chemicals produced, or how a product works or operates.
24. **Promotion** – an event or activity organized by or on behalf of a Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product manufacturer, importer, distributor, or retailer with the aim of promoting a brand of a Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product, which event or activity would not occur if not for the support given to it by or on behalf of the Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product manufacturer, importer, distributor, or retailer. This includes the paid use of Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products bearing the brand names, trademarks, logos, and the like by performers in movies, television and other forms of entertainment as well as in other live promotional events such as fairs, trade shows, concerts, and similar events. For the purpose of RA11900 and this IRR, promotion shall be understood as Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product promotion.
25. **Promotional** – the act of publicizing a product to an individual, group or the general public, or promoting awareness of the product brands, for the sole purpose of increasing sales.
26. **Reduced Risk Statement** – an explicit communication to consumers in the product label or marketing materials which states that the product presents less risk of harm to the user's health or is less harmful to the user's health than continued smoking of combustible cigarettes
27. **Refill** – a container for holding electronic liquid or Nicotine Mixture
28. **Retailer** – any entity which sells or offers to sell any Vaporized Nicotine and Non-Nicotine Products or their devices, or Novel Tobacco Products directly to an individual, group or the general public.
29. **Sponsorship** – any public or private contribution, whether in cash or in kind, from a third party, in relation to an event, team, or activity made with the aim of promoting a brand of Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product, which event, team or activity would still exist or occur without such contribution. For the purpose of RA11900 and this IRR, sponsorship shall be understood as Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product sponsorship
30. **Standard** – a document approved by a recognized body that provides, for common and repeated use, rules, guidelines, or characteristics for products or related processes and production methods, with which compliance is not mandatory

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ANGELICA GABRIEL ESTARTE
Head, Regulatory Technical
Department of Trade and Industry

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- 31 **Tamper-resistant** – the type of packages constructed such that it has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that the product or its packaging has been opened, or otherwise comply with standards on tamper-resistant packaging
- 32 **Technical Regulation** – a document that lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory.
- 33 **Vapor Products**, also referred to as **Vapor Product Refills** – the liquid, solid, or gel, or any combination thereof, which may or may not contain nicotine, that is transformed into an aerosol without combustion by a Vapor Product Device.
- 34 **Vapor Product Device** – a device or a combination of devices used to heat a Vapor Product, to produce an aerosol, mist, or vapor that users inhale. These may include combinations of a liquid solution or gel that are heated and transformed into an aerosol without combustion through the employment of a mechanical or electronic heating element, battery, or circuit, and includes, but is not limited to, a cartridge, a tank, or a device without a cartridge or tank.
- 35 **Vapor Product System**, also referred to as **electronic nicotine or non-nicotine delivery systems** – the specific combination consisting of the Vapor Product Refill and Vapor Product Device which, based on the information made available to the consumer by the provider, are intended to be used together.
- 36 **Vaporized Nicotine or Non-Nicotine Products** – both Heated Tobacco Products and Vapor Products, as defined herein, which are novel consumer goods that generate a nicotine-containing or non-nicotine-containing aerosol without combustion.

**RULE IV
REQUIREMENTS ON PRODUCT PACKAGING**

All Vapor Product Refills, HTP Consumables, and Novel Tobacco Products shall comply with the following packaging requirements

Section 1. Health Warnings

- a. The unit packaging or any outside consumer packaging of Vapor Product Refills, HTP Consumables, or Novel Tobacco Products shall bear the following health warnings:
 - 1. A highly visible, full-color graphic health warning prescribed under Republic Act No. 10643, or "The Graphic Health Warnings Law", consistent with the textual health warning required herein, which shall be printed on fifty percent (50%) of the principal display surfaces of Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products and shall occupy fifty percent (50%) of the front and fifty percent (50%) of the back panel of the packaging, and
 - 2. A textual health warning which states (1) For products that contain nicotine


 DIRECTOR
 DEPARTMENT OF HEALTH
 BUREAU OF TOBACCO CONTROL
 DEPARTMENT OF TRADE AND INDUSTRY

CME NO. 45-2024

"This product is harmful and contains nicotine which is a highly addictive substance. It is not recommended for use by nonsmokers.", and

For products that do not contain nicotine

"This product may contain a substance that is harmful. It is not recommended for use by nonsmokers."

The textual warning shall use no more than twenty percent (20%) of the entire area of the graphic health warning and shall appear in clearly legible type and in contrast by typograph, layout and color, without the use of any border, frame or any other design that will effectively lessen the size of the textual warning.

- b. Nothing shall be printed or applied on a location where the health warning is likely to be obscured or covered, in part or in whole;
- c. No part of the warning may be obliterated, obscured, folded, severed or become unreadable when the package is opened or closed or when a wrapper on the package is removed; and
- d. The Department of Health (DOH) shall issue the template, as well as the guidelines with respect to the specific picture, design, or content of the information, format, and specifications relating to the graphic health warning that must appear on the product packaging.

Section 2. Fiscal Marking

- a. Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products for Domestic Sale.

The internal revenue fiscal marking requirements under Republic Act No. 8424 (RA8424), or the "National Internal Revenue Code of 1997", as amended, and other related regulations, whenever applicable, shall be complied with; *Provided*, that Vapor Product Refills, HTP Consumables or Novel Tobacco Products manufactured or produced in the Philippines for domestic sales or consumption shall only be in such packages and bear such marks or brands as prescribed by the Bureau of Internal Revenue (BIR); *Provided further*, that goods of similar character imported into the Philippines shall likewise be packed and marked in such manner as may be required by the BIR and that in no case shall Vapor Product Refills and/or HTP Consumables intended or offered for export shall be distributed in the local market.

- b. Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products for Export.

Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products intended or offered for export shall only be subject to the requirement that one (1) side panel of any box or packaging of any form that is used to store or hold containers, reams or cartons, or any other Vaporized Nicotine and Non-Nicotine Product and Novel Tobacco Product packaging for shipping or transport, and one (1) side panel of each

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packaging primarily intended for retail sale to consumers, shall contain the following markings and information: "For sale only in", "Made under authority of", tax number assigned by the BIR to the domestic manufacturer that exports these products, and fiscal and regulatory marking requirements of the country where the products will be ultimately sold.

The BIR may allow different and distinct packaging markings requirement for Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products produced or manufactured in the Philippines intended or offered for export to comply with the laws, rules, regulations, and issuances of the country where the Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products will be ultimately sold.

Section 3. Tamper-resistant and Child-resistant Design.

The receptacles of Vapor Product Refills shall be child-resistant, tamper-resistant, and shall be protected against breakage and leakage.

Non-refillable receptacles shall not be tampered with and refilled.

**RULE V
SALE OF VAPORIZED NICOTINE AND NON-NICOTINE PRODUCTS,
THEIR DEVICES, OR NOVEL TOBACCO PRODUCTS**


Section 1. Minimum Age Sales and Purchase. The minimum allowable age for the purchase, sale or use of Vaporized Nicotine and Non-Nicotine Products, their devices, or Novel Tobacco Products shall be eighteen (18) years old.

It shall not be a defense for the person selling or distributing that he or she did not know or was not aware of the real age of the purchaser. Neither shall it be a defense that he or she did not know nor had any reason to believe that the product was for the consumption of a person below eighteen (18) years of age.

Section 2. Proof-of-Age Verification. Retailers shall ensure that no individual below eighteen (18) years of age is allowed to purchase Vaporized Nicotine and Non-Nicotine Products, their devices, or Novel Tobacco Products. It shall be the responsibility of retailers to verify the age of buyers. For this purpose, the presentation of any valid government-issued identification card exhibiting the buyer's photograph and age or date of birth shall be required. Retailers shall ensure direct delivery only to individuals who must be eighteen (18) years old and above.

Section 3. Business Registration Prior to Marketing and Sale.

a. **Online Trade.** E-marketplaces, e-commerce platforms, selling facilities embedded in social media websites/applications, and/or other similar selling platforms shall only allow DTI and BIR duly-registered distributors, merchants or retailers of Vaporized Nicotine and Non-Nicotine Products, their devices, and Novel Tobacco Products to sell in their website or platform pursuant to Section 19 of RA11900. *Provided,* that the BIR and local government unit registration shall be separate from the DTI business name registration, registration with the Securities and Exchange Commission (SEC), or registration with the Cooperative Development Authority (CDA). The distributors, merchants and retailers of products with reduced risk statements medicinal or


 Regino S. Bascara
 Fiscal Regulator
 Department of Trade and Industry

therapeutic claims shall also present the approval from the Food and Drug Administration (FDA) to the e-marketplaces, e-commerce platforms, selling facilities embedded in social media websites/applications, and/or other similar selling platforms before posting of such products pursuant to RA11900 and this IRR.

For duly-registered distributors, merchants and retailers of Vaporized Nicotine and Non-Nicotine Products, their devices, and Novel Tobacco Products selling on their own websites and/or selling platforms, the required government certificates and approvals shall be posted conspicuously at the landing page of their websites and/or selling platforms.

- b. **Brick-and-mortar stores.** Duly-registered distributor, merchants or retailers of Vaporized Nicotine and Non-Nicotine Products, their devices, and Novel Tobacco Products shall conspicuously post in their brick-and-mortar stores the required government certificates and approvals of the products subject of this IRR.

Section 4. Delivery of Vaporized Nicotine and Non-Nicotine Products, their devices, and Novel Tobacco Products Purchased Online. The delivery of Vaporized Nicotine and Non-Nicotine Products, their devices, and Novel Tobacco Products purchased online shall also comply with Section 7 of RA11900 and Section 2 of this Rule. The online seller or distributor shall ensure direct delivery only to individuals who must be eighteen (18) years old and above

Section 5. Sales and Promotion Within School Perimeters. The sale, promotion, advertising, and product demonstration of Vaporized Nicotine and Non-Nicotine Products, or Novel Tobacco Products within one hundred (100) meters from any point of the perimeter of a school, playground or other facility frequented particularly by minors shall be prohibited.

Section 6. Point-of-Sale Signage. Point-of-sale establishments offering, selling, or distributing Vaporized Nicotine and Non-Nicotine Products shall post the following statement in a clear and conspicuous manner:

"The sale or distribution of Vaporized Nicotine and Non-Nicotine Products to or by persons below eighteen (18) years of age is illegal. These products are harmful and contain nicotine which is a highly addictive substance. It is not recommended for use by nonsmokers."
or "Ang pagbenta at pagbili ng Vaporized Nicotine at Non-Nicotine Products sa at ng mga taong wala pang labingwalong (18) taong gulang ay pinagbabawal. Ang mga produktong ito ay nakakasama sa kalusugan at mayroong nicotine, isang nakakalulong na kemikal. Hindi ito inirerekomenda na gamitin ng mga hindi naninigarilyo."

Section 7. Display of Products. Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products shall not be displayed immediately next to products of particular interest to minors.

Section 8. Restriction on the Retail and Sale of Nicotine Shots. The retail or use of nicotine shots and/or concentrates shall be strictly prohibited

Section 9. Floor Price. The BIR shall issue separate Revenue Regulations governing the floor price of Vaporized Nicotine and Non-Nicotine Products, or Novel Tobacco Products.

**RULE VI
RESTRICTIONS ON PRODUCT COMMUNICATION, ADVERTISEMENTS,
AND SPONSORSHIPS**

Section 1. Product Communication Restrictions. Advertisements of Vaporized Nicotine and Non-Nicotine Products, or Novel Tobacco Products and other forms of consumer communication shall be allowed in points-of-sale or retail establishments, through direct marketing, and on the internet; *Provided*, that the following guidelines shall apply:

- a. These shall not be targeted to or particularly appeal to persons under eighteen (18) years of age. Markings or characters that are likely to appeal to the youth such as the use of cartoons, anime, manga, animated characters, youth influencers, personalities and the like are prohibited;
- b. All product communications shall contain the following health warning:

“Government Warning: This product is harmful and contains nicotine which is a highly addictive substance. This is for use only by adults and is not recommended for use by nonsmokers”;

- c. These shall not feature a minor and/or a celebrity or contain an endorsement, implied or express, by a celebrity. Manufacturers, importers, and sellers in their product advertisements are prohibited from contracting celebrities or health professionals to promote or encourage the use of Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products;
- d. Any posts, messages, or images by manufacturers, importers, retailers, and distributors depicting vaping or the use of Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products as a lifestyle that is particularly attractive to minors, or promoting or encouraging vaping or the use of Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products for nonsmokers or minors, or the purchase or use of Vaporized Nicotine and Non-Nicotine Products or the use of Novel Tobacco Products, trademarks, brand names, design, and manufacturer's names as a lifestyle targeted at minors shall be prohibited;
- e. These should not undermine quit-smoking messages and should not encourage non-tobacco or non-nicotine users to use Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products;
- f. These shall not contain any information that is false, or not scientifically substantiated, particularly with regard to product statements, characteristics, health effects, risks or emissions consistent with Section 18 of RA11900 and Rule X of this IRR;
- g. Product testing and/or demonstration shall be allowed in locations that sell Vaporized Nicotine and Non-Nicotine Products or their devices, or Novel Tobacco Products;

- h. Online advertisements on e-commerce platforms shall only be visible after the appropriate age verification measures under RA11900 and this IRR;
- i. No Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product advertisements may be placed on objects or places outside the premises of points-of-sale such as, but not limited to, vehicles of any kind, billboards, posters and streamers.
- j. The sale of Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products that are packaged, labeled, presented, or marketed with flavor descriptors that are proven to unduly appeal particularly to minors shall be prohibited. A flavor descriptor is presumed to unduly appeal to minors if it includes a reference to a fruit, candy brand, dessert, or cartoon character.
- k. No Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product shall have a medicinal or therapeutic claim on its marketing materials or packaging unless such claim is approved by the FDA pursuant to Republic Act No. 9711 (RA9711), or the "Food and Drug Administration (FDA) Act of 2009." No Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product shall have an explicit reduced risk statement unless authorized by the FDA pursuant to the implementing rules and regulations under Section 24 of RA11900;
- l. Reduced risk statements, which are authorized, validated, accepted, or permitted by reliable and mature national regulatory agencies, for Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products shall be taken into consideration by the FDA in its resolution of an application for a reduced risk statement authorization and shall be resolved within eighteen (18) months; and
- m. These restrictions apply to commercial communications only and shall not prevent a company from providing information regarding its company, its products and other non-promotional information on Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products.

Section 2. Restrictions on Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product Promotional Activities. The following restrictions shall apply to any promotional activity related to Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products:

- a. Promotional events and activities, such as, but not limited to, product sampling or product offers, shall only be conducted by trained product experts and must be directed only to persons at least eighteen (18) years of age. No person below eighteen (18) years of age shall participate in such promotions. The participants in such promotions shall be required to provide proof of their age. *Provided*, that the invitation to these promotional events and activities shall contain the appropriate health warnings.
- b. Communications to consumers about promotional events for Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products shall comply with the provisions of RA11900 and this IRR governing Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product advertising. In addition to the required health warning, the age requirement for participation in any promotional activity must be clearly marked on the program materials distributed to consumers.

Handwritten signature and stamp of the Department of Trade and Industry.

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- c. No Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products shall have a medicinal claim on its marketing materials or packaging unless such claim is approved by the FDA pursuant to RA9711;
- d. All stalls, booths, and other displays concerning Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product promotions must be limited to point-of-sale locations or adult-only facilities;
- e. Telecommunications concerning promotional offers, programs or events must include a recorded health warning message in English or Filipino consistent with the warnings specified in RA11900 and this IRR;
- f. No product promotional placement or advertisement shall be made by any manufacturer, distributor, or retailer of any Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product package, including use of the product, in any manner, in a video game or in any television program or motion picture, authorized by regulatory agencies concerned for viewing by the general public;
- g. No promotional merchandise such as, but not limited to, t-shirts, caps, sweatshirts, visors, backpacks, sunglasses, writing implements and umbrellas, may be distributed, sold or offered, directly or indirectly, with the name, logo or other indicia of a Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product brand displayed so as to be visible to others when worn or used;
- h. No name, logo, or other indicia of a Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product brand may appear on promotional merchandise or element of a brand-related marketing activity that is marketed to or likely to be used by minors such as, but not limited to, sports equipment, toys, dolls, video games, and food. The manufacturer or company must take all available measures to prevent third parties from using the company's brand names, logos, or other proprietary symbol on products that are directed toward minors; and
- i. No Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product advertisements may be placed on shopping bags.

Section 3. Restrictions on Sponsorship. The following restrictions shall apply to all Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product promotional sponsorships:

- a. Sponsorships shall be absolutely prohibited in any sport, concert, cultural, or art event.
- b. No person below eighteen (18) years of age may participate in sponsored events. The participants in the sponsored event shall be required to provide proof of age. Invitations to these events shall contain the appropriate health warnings;
- c. Communications to consumers about Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product sponsored events shall comply with the provisions of RA11900 and this IRR governing Vaporized Nicotine and Non-Nicotine Product or Novel

THOMAS TRUJEVICH
Commissioner
BUREAU OF THE COMMISSIONER
Department of Trade & Consumer Protection

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Tobacco Product advertising. In addition to the mandatory health warning, the age requirement for participation in any sponsored event must be clearly marked on the program materials distributed to consumers:

- d. All display materials concerning Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product sponsored events must be limited to point-of-sale locations or adult-only facilities;
- e. Telecommunications concerning sponsored events must include a recorded health warning message in English or Filipino consistent with the warnings specified in RA11900 and this IRR;
- f. No merchandise such as, but not limited to, t-shirts, caps, sweatshirts, visors, backpacks, sunglasses, writing implements, school notebooks, umbrellas and other accessories, may be distributed, sold or offered, directly or indirectly, during the sponsored event, with the name, logo or other indicia of a Vaporized Nicotine and Non-Nicotine Product or Novel Tobacco Product brand;
- g. Such other restrictions on the product sponsorship as determined by the DTI consistent with the provisions of RA11900 and this IRR; and
- h. These restrictions shall only apply to commercial sponsorships and shall not prevent a company from conducting corporate social responsibility-related activities and programs; *Provided*, that such activities shall not bear a Vaporized Nicotine and Non-Nicotine Product and Novel Tobacco Product brand name and logo.

**RULE VII
SMOKING AND VAPING RESTRICTION AWARENESS CAMPAIGN**

Subject to the provisions of RA11900 and this IRR, the DOH, in coordination with other concerned agencies, may undertake smoking and vaping restriction awareness campaigns on the harmful effects of smoking and vaping, which may include information drives and posting of warning sign images in public.

As part of the whole-of-society approach for a genuine smoke- and vape-free environment, the private sector shall also be encouraged to undertake restriction awareness campaigns on smoking and vaping, including, but not limited to, censoring and not supporting advertisements promoting smoking and vaping.

**RULE VIII
PROHIBITION ON THE USE OF VAPORIZED NICOTINE
AND NON-NICOTINE PRODUCTS IN PUBLIC PLACES**

The use of Vaporized Nicotine and Non-Nicotine Products shall be prohibited in all indoor public places except in DVAs, or in point-of-sale establishments for purposes of conducting product demonstrations. In the case of a mall kiosk, product demonstration shall be allowed as long as it has a product testing area.

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The use of Vaporized Nicotine and Non-Nicotine Products shall be absolutely prohibited in the following public places:

1. Centers of youth activity such as play schools, preparatory schools, elementary schools, high schools, colleges and universities, youth hostels and recreational facilities for persons under eighteen (18) years old;
2. Elevators and stairwells;
3. Locations in which fire hazards are present, including gas stations and storage areas for flammable liquids, gas, explosives or combustible materials;
4. Within the buildings and premises of public and private hospitals, medical, dental and optical clinics, health centers, nursing homes, dispensaries and laboratories;
5. Public conveyances and public facilities including airport and ship terminals and train and bus stations, restaurants and conference halls, except for DVAs;
6. Food preparation areas;
7. Churches and other similar places where people congregate for worship; and
8. Within the building and premises of government offices, except for DVAs

**RULE IX
STANDARDS FOR DESIGNATED VAPING AREAS**

The Designated Vaping Areas (DVAs) shall comply with the following standards:

1. Persons below eighteen (18) years of age shall not be allowed within the DVA.
2. Every DVA shall have the following signages highly visible and prominently displayed:
 - a. "Vaping Area" signage; and
 - b. Prohibition on entry of persons below eighteen (18) years of age and pregnant women;
3. Smoking shall not be allowed in DVAs.
4. The number of persons allowed inside shall be controlled by the establishment owner, taking into consideration the size of the DVA and its location;
5. The DVA shall be in an open space in an outdoor area, or in a separate indoor area with proper ventilation;
6. If the DVA is located indoors, there shall be no opening that will allow air to escape from the DVA to the smoke- or vape free area of the building or conveyance, except for a single door equipped with an automatic door closer;

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- 7 The DVA and its ventilation outlets shall not be located in or within ten (10) meters from entrances, exits or any place where people pass or congregate, or in front of air intake ducts;
- 8 The combined area of the DVA and the buffer zone shall not be larger than twenty percent (20%) of the total floor area of the building or conveyance; *Provided*, that in no case shall such area be less than ten (10) square meters;
- 9 No building or conveyance shall have more than one (1) DVA;
- 10 The ventilation system for the DVA, other than in open space and for the buffer zone, shall be independent of all ventilation systems for the rest of the building or conveyance;
- 11 Minors shall not be allowed inside the DVA and the buffer zone; and
- 12 There shall be no selling, serving or offering of food and beverages in the DVA and its buffer zone unless the DVA is located in a point-of-sale.

Provided, that nothing in RA11900 and this IRR shall compel persons in charge of buildings and establishments to establish DVAs nor prevent them from instituting more stringent measures, such as posting health warnings in the DVA or prohibiting the use of Vaporized Nicotine and Non-Nicotine Products in their buildings or establishments to better ensure a vape-free environment in their premises

RULE X PRODUCT STANDARD REQUIREMENTS

The BPS, in consultation with the FDA, shall set the product standards for the safety, consistency, and quality of the covered products requiring registration under Rule I, Section 3 of this IRR; *Provided*, that vapor product with nicotine content shall not exceed sixty-five milligrams per milliliter (65mg/ml). Compliance with the product standards shall be mandatory.

The BPS shall issue separate technical regulations for the covered products.

RULE XI PRODUCT REGISTRATION

All manufacturers and importers of the covered products shall apply for product registration and certification with the BPS by submitting information demonstrating conformity with the technical regulations set by the office.

Only BPS registered and certified Vaporized Nicotine and Non-Nicotine Products, their devices, and Novel Tobacco Products with the applicable graphic health warning may be sold to the general public.

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Department of Trade and Industry

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**RULE XII
PRODUCT WITH MEDICINAL, THERAPEUTIC, AND REDUCED RISK CLAIMS**

Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products bearing an explicit medicinal, therapeutic, or reduced risk claim or statement shall require FDA approval prior to registration and certification from the BPS, pursuant to RA9711.

**RULE XIII
IMMEDIATE RECALL, BAN, OR SEIZURE OF VAPORIZED NICOTINE AND NON-NICOTINE PRODUCTS, THEIR DEVICES, AND OTHER NOVEL TOBACCO PRODUCTS**

Section 1. Recall, Ban, or Seizure by the DTI. The DTI, upon due process, may order the immediate recall, ban or seizure from public sale or distribution of Vaporized Nicotine and Non-Nicotine Products, HTP Devices, Vapor Product Devices, and Novel Tobacco Products for failure to comply with the provisions of RA11900 and this IRR.

Only duly registered Vaporized Nicotine and Non-Nicotine Products or their devices, or Novel Tobacco Products with the applicable graphic health warnings are allowed to be sold, advertised or distributed through whatever means.


For online sales, the Secretary of the DTI, upon due process, shall have the power to issue an order directing a noncompliant website, webpage, online application, social media account, or other similar platform to be taken down preventing online sellers, which are noncompliant with the registration requirements provided under RA11900 or this IRR, from selling online. The Secretary of the DTI shall order the immediate recall, ban or seizure of noncompliant Vaporized Nicotine and Non-Nicotine Products or their devices, and Novel Tobacco Products as provided under this section.

Section 2. Recall, Ban or Seizure by the BIR. The BIR shall order the immediate recall, ban or seizure from public sale or distribution of Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products not registered with the BIR, including those sold online. This is without prejudice to the filing of the appropriate cases and collection of correct taxes and duties, including applicable fines and penalties under RA8424, as amended, and Republic Act No. 10863, or the "Customs Modernization and Tariff Act (CMTA)".

Section 3. Online List of Brands. The DTI and the BIR shall maintain a monthly updated online list of brands of Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products registered with the DTI and the BIR that are eligible to be sold online.

Section 4. Registration Prior to Marketing and Sale. Pursuant to Rule V, Section 3(a) of this IRR, internet websites and/or e-commerce and/or other similar media selling platform providers shall only allow DTI and BIR registered online sellers or retailers in their websites or platforms.

The DTI and the BIR, in consultation with relevant stakeholders, shall design, promulgate and utilize new and emerging innovative tools and technologies to ensure that only registered Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products are made available in the market

AMERICAN SMOKE COMPANY

 Director, Bureau of Product Safety

amc No. 45 - 2024

**RULE XIV
PENALTIES FOR NONCOMPLIANCE**

Section 1. For any violation of Section 15 of RA11900 or Rule VIII of this IRR, if the offender is a person; and Section 17 of the same Act or Rule IX of this IRR, if the offender is a juridical person, the following shall be imposed:

- a. On the first offense, a fine of Five thousand pesos (PHP5,000.00);
- b. On the second offense, a fine of Ten thousand pesos (PHP10,000.00), and
- c. On the third offense, a fine of Twenty thousand pesos (PHP20,000.00) *Provided*, that the business permits and licenses, in the case of a business entity or establishment, shall be revoked or canceled.

Section 2. For any violation of Sections 6, 7, 9, 10, 11 and 20 of RA11900 or Rule V Sections 1, 2, 5, 6, 7 and 8 of this IRR if the offender is a retailer, the following shall be imposed:

- a. On the first offense, any person or any business entity or establishment selling, distributing or purchasing Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products to, for or from a minor shall be fined the amount of Ten thousand pesos (PHP10,000.00) or imprisoned for not more than thirty (30) days, upon the discretion of the court. For succeeding offenses, both penalties shall apply in addition to the revocation of the business licenses or permits in the case of a business entity or establishment;
- b. If the violation is done by an establishment or business entity, the owner, president, manager, or the most senior officers thereof shall be held liable for the offense, and
- c. If a minor is caught selling, buying or using any Vaporized Nicotine and Non-Nicotine Products, or Novel Tobacco Products, the DOH and the Department of Social Welfare and Development (DSWD) shall implement appropriate intervention programs, including, but not limited to, counseling of the minor and the minor's parent or guardian.

Section 3. For any violation of Sections 8, 12, 13, 14 and 18 of RA11900 or Rule V, Section 3, Rule VI, and Rule X of this IRR, if the offender is a manufacturer, distributor, or retailer, the following shall be imposed:

- a. On the first offense, a fine of One Hundred Thousand Pesos (PHP100,000.00);
- b. On the second offense, a fine of Two Hundred Thousand Pesos (PHP200,000.00); and
- c. On the third offense, a fine of Four Hundred Thousand Pesos (PHP400,000.00) or imprisonment of not more than three (3) years, or both, at the discretion of the court, *Provided*, that the business permits and licenses, in the case of a business entity or establishment, shall be revoked or canceled.

Section 4. For any violation of Sections 4 and 5 of RA11900 and Rule IV of this IRR, if the offender is a manufacturer, importer, distributor, or retailer, the following shall be imposed:

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EXECUTIVE SECRETARIAL OFFICE
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- a. On the first offense, a fine of Two Million Pesos (PHP2,000,000.00) and imprisonment of two (2) years;
- b. On the second offense, a fine of Four Million Pesos (PHP4,000,000.00) and imprisonment of four (4) years; and
- c. On the third offense, a fine of Five Million Pesos (PHP5,000,000.00) and imprisonment of six (6) years; *Provided*, that the business permits and licenses, in the case of a business entity or establishment, shall be revoked or canceled

Section 5. Online sellers and distributors of Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products and online platforms that are noncompliant with Section 8 of RA11900 or Rule V, Section 3 of this IRR shall be ordered by the DTI to immediately suspend trading of such products and shall be liable for the fines and penalties imposed under RA11900 and this Rule. The suspension shall continue until the manufacturer, seller, distributor or online platform has complied with the requirements provided under Section 8 of RA11900 or Rule V, Section 3 of this IRR

Section 6. If the offender is a foreign national, the offender shall be deported after service of sentence and/or payment of applicable fines without the need of further deportation proceedings and shall be permanently barred from re-entering the Philippines.

RULE XV ROLES AND RESPONSIBILITIES

Recognizing the importance of a whole-of-society approach in ensuring the effective implementation of RA11900 and this IRR and promoting consumers' welfare and interest, the following shall have their roles and responsibilities:

Section 1. Manufacturers, Importers, Wholesalers, Traders, Distributors, and Retailers.

- a. To strictly comply with the requirements of RA11900 and this IRR and other pertinent laws, policies, and regulations to operate the business;
- b. To ensure that the products being sold in the market conform to the established quality and safety standards;
- c. To strictly ensure that minors shall have no access to Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products nor shall encourage non-smokers to use the products;
- d. To be honest, truthful, and transparent in communication with targeted consumers by providing complete and accurate information about the product such as, but not limited to, product statements, characteristics, health effects, risks, or emissions consistent with the Technical Standards set by the DTI.

Section 2. Consumers

- a. To exercise consumer rights and perform consumer responsibilities. Buy Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products only from reputable

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OF THE
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and legitimate sellers that sell duly registered Vaporized Nicotine and Non-Nicotine Products or Novel Tobacco Products;

- b. To always present any valid government-issued ID exhibiting the consumer's photograph and age or date of birth when required upon purchase of Vaporized Nicotine and Non-Nicotine Products, their devices, or Novel Tobacco Products for proper age verification;
- c. To only use Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products according to the manufacturer's instruction and, where applicable, only in DVAs;
- d. To store Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products properly away from minors; and
- e. To report sellers who are in violation of any of the provisions of RA11900 or this IRR.

Section 3. Owners of buildings and establishments that allow the use of Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products.

- a. To comply with the Standards of DVAs;
- b. To ensure that Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products are used only in DVAs, whenever applicable; and
- c. To ensure that minors have no access to DVAs.

Section 4. Government Agencies

- a. The DTI shall have exclusive jurisdiction over any and all issues, requirements, and subject matters related to Vaporized Nicotine and Non-Nicotine Products, their devices, and Novel Tobacco Products provided in RA11900.
- b. The DOH shall have jurisdiction on the following:
 - 1. Issuance of Graphic Health Warning Templates, as well as the guidelines with respect to the specific picture, design, or content of the information relating to the graphic health warning that must appear on the product packaging;
 - 2. Conduct vaping restriction awareness campaigns with concerned government agencies, and
 - 3. Implement appropriate intervention programs together with the Department of Social Welfare and Development (DSWD) for minors and their parents or guardians caught to be selling, buying or using any Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products.
- c. The FDA shall have exclusive jurisdiction on Vapor Product Refills, Heated Tobacco Product Consumables and Novel Tobacco Products with express therapeutic, medicinal, or reduced risk claims pursuant to RA9711 and RA11900.
- d. The BIR shall have exclusive jurisdiction on the following:

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
OFFICE OF THE SECRETARY
1201 MABINI ST., PASAY CITY, METRO MANILA
TEL. (632) 8861-6000

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- 1. Taxpayer registration;
 - 2. Ensure that revenue stamps affixed on Vaporized Nicotine and Non-Nicotine products and Novel Tobacco Products are not affixed on non-compliant packages, and certify under oath that products are taxed prior to release by the Bureau of Customs (BOC) or a local manufacturer's warehouse;
 - 3. Floor price setting for Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products; and
 - 4. Formulate, draft and publish revenue regulations covering Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products
- e. The DSWD shall implement appropriate intervention programs, including, but not limited to, counseling of the minor and the minor's parent or guardian caught to be selling, buying or using any Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products.
- f. Other Government Agencies

The assistance of the Local Government Units (LGUs) and other law enforcement agencies and the Department of Education (DepEd) may be also requested for the efficient implementation of RA11900 and this IRR.

All government agencies shall strictly ensure that the use of Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products are prohibited within the building and premises of their respective offices, except for DVAs.

**RULE XVI
USE OF LOCAL TOBACCO PRODUCTS**

Manufacturers are encouraged to use local tobacco products for Vapor Products, HTPs and Novel Tobacco Products sold in the Philippines.

**RULE XVII
MISCELLANEOUS PROVISIONS**

Section 1. Budget or Funding. To ensure the efficient and effective implementation of RA11900 and IRR, the implementing agencies shall propose budget allocation annually

Section 2. Transitory Provision. Manufacturers, distributors, importers and retailers of Vaporized Nicotine and Non-Nicotine Products or their devices, and Novel Tobacco Products shall be given an eighteen (18)-month transitory period from the issuance of this IRR to comply with the requirements of product standards and product registration. The rest of the executory provisions are effective immediately

Section 3. Separability Clause. If any provision or any part of this IRR is held invalid or unconstitutional, the remainder of the law or the provisions not otherwise affected shall remain valid and subsisting

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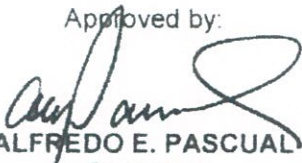
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Section 4. Effectivity. This IRR shall take effect fifteen (15) days after its publication in the Official Gazette or in at least two (2) newspapers of general circulation

Issued on 05 December 2022

Approved by:



ALFREDO E. PASCUAL
Secretary

Recommended by


ATTY. RUTH B. CASTELO
Undersecretary
Consumer Protection Group

ATTY. ANN CLAIRE C. CABOCHAN
Assistant Secretary
Consumer Protection Group


ATTY. M. MARCUS N. VALDEZ II
Director
Consumer Policy and Advocacy Bureau


ATTY. CHERRYL G. CARBONELL
Assistant Director
Consumer Policy and Advocacy Bureau

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APPROVED FOR SIGNATURE

DATE: 05/12/2022