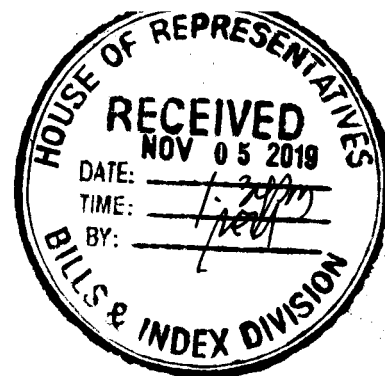


Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
First Regular Session

House Bill No. **5310**



Introduced by Representative ROBERT ACE S. BARBERS

EXPLANATORY NOTE

Electronic Nicotine or Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS), commonly referred to as "Vapor Products", are a new technology that is altering the dynamics of the wider tobacco industry. Consumer preferences and behaviors are changing, but regulations have not kept pace with this rapidly growing industry.

This Act aims to mitigate and monitor the risks of Vapor Products by imposing strict product standards and comprehensive restrictions on their sales, distribution, marketing, and use. For clarity, this Act does not seek to regulate Heated Tobacco Products.

Vapor Products have been defined as battery-powered devices that heat a solution, blend or gel, which may or may not contain nicotine, to a temperature that allows the production of vapor.¹ The liquid commonly consists of propylene glycol, vegetable glycerin, water, flavorings and nicotine, and the vapor produced dissipates into the air almost instantaneously.

There are over 16 million smokers in the Philippines, causing PHP 269 billion in healthcare costs² and 118,000 deaths every year.³ The majority of these smokers report that they want to quit, but very few are successful in doing so.⁴ It is possible that Vapor Product technology can play a role in addressing this problem, in concert with strict tobacco control efforts. However, we need to carefully consider its potential effects to ensure we are not trading one harmful product for another.

The major risks of the product category are: exploding and malfunctioning devices; toxic and harmful ingredients; deceptive marketing tactics; malicious marketing and sales to minors; potential gateway effects to smoking and narcotics; and the possibility of significant negative health impacts, including deaths.

To address these potential risks, we need to take urgent and decisive action.

Regarding potential benefits, there is emerging scientific evidence that Vapor Products are less harmful than combustible cigarettes and can switch smokers away from

¹ World Health Organization, WHO Report on the Global Tobacco Epidemic, 2019, <https://apps.who.int/iris/bitstream/handle/10665/326043/9789241516204-eng.pdf>.

² Tobacco Atlas: Philippines, Accessed on April 3 2019.

³ Tobacco Atlas: Deaths, Accessed on April 3 2019

⁴ Global Adult Tobacco Survey, Comparison Factsheet: Philippines 2009 and 2015, <https://www.who.int/tobacco/surveillance/survey/gats/comparison-factsheet-2009-2015.pdf?ua=1>.

combustible cigarettes⁵ Proponents argue that these products can offer a viable alternative to combustible cigarettes because it mimics the experience of smoking and has a similar nicotine delivery profile, but does not produce the same level of carcinogens as from burning tobacco.⁶ A number of independent scientific and public health organizations have supported this argument; however, there is not sufficient evidence on their long-term health effects. As a result, some countries have put in place laws that regulate the distribution, sales, marketing, and consumption of these products.

In order to safeguard the public health and welfare of the Filipino people, it is prudent for lawmakers to impose stringent requirements. Hence, the passage of this bill is earnestly sought.



REP. ROBERT ACE S. BARBERS
2nd District, Surigao del Norte

⁵ Ann McNeill et al., "Evidence Review of E-Cigarettes and Heated Tobacco Products 2018: A Report Commissioned by Public Health England," (London: Public Health England, 2018).

⁶ Scott Gottlieb and Mitchell Zeller, "A Nicotine-Focused Framework for Public Health," 377, no. 12 (2017). <https://doi.org/10.1056/NEJMp1707409>.

HOUSE OF REPRESENTATIVES
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EIGHTEENTH CONGRESS
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House Bill No. 5310

Introduced by Representative ROBERT ACE S. BARBERS

**AN ACT REGULATING THE MANUFACTURE, USE, SALE, PACKAGING,
DISTRIBUTION AND ADVERTISEMENT OF VAPOR PRODUCTS
AND FOR OTHER PURPOSES**

Be it enacted by the Senate and the House of Representatives of the Philippines in Congress assembled:

SECTION 1. *Short Title.* This Act shall be known as the "Vapor Products Regulation Act of 2019"

SECTION 2. *Policy.* – It is the policy of the State to protect the interests of consumers, promote their general welfare and to establish standards to regulate the industry.

SECTION 3. *Scope.* — This Act shall apply to all individuals, enterprises and businesses which seek to manufacture, distribute, import, export, sell, offer for sale, and/or use Vapor Products. It shall also provide for the standards to be implemented by the IAC-V in the monitoring and regulation of Vapor Products.

This Act shall not apply to heated tobacco products.

SECTION 4. *Purpose.* — It is the objective of this Act to:

- a. Minimize risks posed by Vapor Products;
- b. Prohibit sale of Vapor Products to Minors;
- c. Monitor potential risks of Vapor Products;
- d. Protect consumers' right of equal access to new technology and innovative products; and
- e. Create an Inter-Agency Committee on Vapor Products to oversee the implementation of the provisions of this Act.

SECTION 5. *Definition of Terms.* — As used in this Act;

- a. "Advertisement" — refers to any visual and/or audible message disseminated to the public about or on a particular product that promotes and gives publicity by words, designs, images or any other means through broadcast, electronic, print or whatever form of mass media, including outdoor advertisements, such as but not limited to signs and billboards. For the purpose of this Act, advertisement shall be understood as Vapor Products advertisement;

- b. "Advertising" — refers to 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 Vapor Products.

For the purpose of this Act, advertising shall be understood as Vapor Products advertising. This shall specifically refer to any messages and images promoting the use of Vapor Products; the purchase or use of Vapor Products; and Vapor Products trademarks, brand names, design and Manufacturer's names;

- c. "Carcinogenic" — refers to properties that can induce cancer or an increase in the incidence of cancer occurring after exposure to a substance or mixture as defined under the GHS;
- d. "Closed-System" — refers to an E-device with a tank that is not intended by the manufacturer to be refillable or that is intended by the Manufacturer to be used with Pods designed by the Manufacturer;
- e. "COC-V" — refers to the Congressional Oversight Committee on Vapor Products, whose members are set out in Section 30;
- f. "Commissioner" — refers to the Commissioner of the Bureau of Internal Revenue;
- g. "Distributor" — refers to any person to whom a Vapor Product is delivered or sold for purposes of distribution in commerce, except that such term does not include a Manufacturer or retailer or common carrier of such product;
- h. "DTI" — refers to the Department of Trade and Industry;
- i. "Design" — refers to any composition of lines or colors or any three-dimensional form, whether or not associated with lines or colors, provided that such composition or form gives a special appearance to and can serve as a pattern for an industrial product, but shall exclude designs dictated essentially by technical or functional considerations to obtain a technical result;
- j. "E-device" — refers to an electronic device that delivers E-liquid in aerosol form into the mouth and lungs when inhaled. It is also referred to as an aerosolizing apparatus;
- k. "E-liquid" — refers to any liquid solution or gel whether containing nicotine or not, that is encased in a Receptacle;
- l. "Emission" — refers to the vapor, mist or aerosol that is produced when the E-liquid is heated by the E-device;

- m. "GHS" – refers to the Globally Harmonized System of Classification and Labelling of Chemicals issued by the United Nations;
- n. "Health Claims" – refers to any representation to consumers that the use of Vapor Products reduces risk of disease or health-related conditions or that Vapor Products are a smoking cessation aid;
- o. "HPHC" – refers to harmful and potentially harmful constituents;
- p. "IAC-V" – refers to the Inter-Agency Committee on Vapor Products created under this Act;
- q. "Ingredient" – refers to any substance used as a component in the manufacture or preparation of an E-liquid;
- r. "Label/labeling" means the display of written, printed or graphic matter on any Vapor Products, its immediate container, tag, literature or other suitable material affixed thereto for the purpose of giving information as to the identity, components, ingredients, attributes, directions for use, specifications and such other information as may be required by this Act;
- s. "Minor" — refers to any person below eighteen (18) years old;
- t. "Manufacture" means any and all operations involved in the production, including preparation, propagation, processing, formulating, filling, packing, repacking, altering, ornamenting, finishing or otherwise changing the container, wrapper or labeling of a Vapor Product in the furtherance of the distribution of the same from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer;
- u. "Manufacturer" means any person who manufactures, assembles or processes Vapor Products, except that if the goods are manufactured, assembled or processed for another person who attaches his own brand name to the Vapor Products, the latter shall be deemed the manufacturer.
- v. "Mutagenic" – refers to properties that may cause heritable gene mutations, including heritable structural and numerical chromosome aberrations in germ cells occurring after exposure to a substance or mixture as defined under the GHS;
- w. "Open-System" – refers to an E-device with a tank that a user can refill with an E-liquid of their choosing;
- x. "Package" or "Packaging" - refers to any container or wrapping in which any Vapor Product is enclosed for use in the delivery or display of that Vapor Product to retail purchasers; but does not include: (i) shipping containers or wrappings used solely for the transportation of any Vapor Product in bulk or in big quantities by manufacturers, packers, or processors to wholesale retail distributors thereof; (ii) shipping containers or outer wrappings used by retailers to ship or deliver any product to retail

customers if such containers and wrappings bear no printed matter pertaining any particular product; and (iii) the wrappers or containers of Vapor Products sold in small quantities by small retail stores to the consumer which by tradition are wrapped with ordinary paper;

- y. "Person" — refers to an individual, partnership, corporation or any other business or legal entity;
- z. "Pod" — refers to a sealed, pre-filled and disposable bottle, container or cartridge containing E-liquid, in which the E-liquid is intended by the Manufacturer to be inaccessible by the user through customary or reasonably foreseeable handling or use, that is attached or inserted into the E-device;
- aa. "Point-of-Sale" — refers to any location, including online, at which an individual can purchase or otherwise obtain Vapor Products;
- bb. "Principal Display Surface" — refers to any of the following:
 - (i) In the case of a package and carton that has at least two (2) equal sized sides or surfaces, other than the top and bottom, that may be displayed or visible under normal or customary conditions of sale or use, the areas of each of the two (2) largest surfaces;
 - (ii) In the case of a spherical, cylindrical or conical container of Vapor Products products, the two (2) largest surfaces that are predominantly displayed; and
 - (iii) In the case of a package and carton that do not have a particular side or surface that is predominantly displayed or visible under normal or customary conditions of sale or use or those that are not described under subsections 1 and 2, fifty percent (50%) of the three (3) dominant sides or the total surface thereof, whichever is bigger, which will ensure that the Warnings are visibly shown.
- cc. "Promotion" — means techniques intended for broad consumer participation which contain promises of gain such as prizes, in cash or in kind, as a reward for the purchase of a Vapor Product or winning in a contest, game, tournament and other similar competitions which involve determination of winner/s. It also means techniques purely intended to increase the sales, patronage and/or goodwill of a product.
- dd. "Public Conveyances" — refer to modes of transportation servicing the general population, such as, but not limited to, elevators, airplanes, buses, taxicabs, ships, jeepneys, light rail transits, tricycles, and similar vehicles;
- ee. "Receptacle" — refers to Pods and Refills and excludes tanks of E-devices which are used to contain E-liquids.

- ff. "Refill" — refers to a bottle or container containing E-liquid, in which the E-liquid is intended by the Manufacturer to be accessible by the user through customary or reasonably foreseeable handling or use;
- gg. "Reprotoxic" — refers to properties that may cause adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring, occurring after exposure to a substance or mixture as defined under the GHS;
- hh. "Retailer" — refers to any person who or entity that sells Vapor Products to individuals for personal consumption;
- ii. "Selfie" — refers to a photograph that one has taken of oneself, typically with a smartphone or webcam;
- jj. "Sponsorship" — refers to any public or private contribution to a third party in relation to an event, team or activity made with the aim of promoting a brand of Vapor Products, which event, team or activity would still exist or occur without such contribution. For the purpose of this Act, sponsorship shall be understood as Vapor Products sponsorship;
- kk. "Vaping" — refers to the act of inhaling the vapor, mist or aerosol produced by the Vapor Products;
- ll. "Vapor Product" — as the context may require, refers to an E-device (whether Closed-System or Open System), E-liquid, Receptacles, its accessories or any combination thereof;
- mm. "Warning" — refers to the textual warning specified in Section 12a(i), which shall be required in lieu of the health warnings required by Republic Act No. 11346 in relation to Republic Act No. 10643 or the Graphic Health Warnings Law.

MINIMIZE RISKS POSED BY VAPOR PRODUCTS

SECTION 6. *Notification to the IAC-V.* — Any Person who wishes to engage in the activity of manufacturing, selling, offering for sale, importing, exporting, distributing or transferring Vapor Products shall notify the IAC-V of its intention at least three (3) months prior to doing so.

SECTION 7. *Product Standards.* — No Person shall manufacture, sell, offer for sale, import, export, distribute or transfer any Vapor Product unless:

- a. the E-device operates in such a way that when used as intended, delivers controlled heating during the entire process of consumption of the E-liquid;

- b. the E-device complies with all applicable electrical safety standards as promulgated by the Bureau of Product Standards of the Department of Trade and Industry;
- c. the tank of Open-System E-devices and Refills are child-resistant, tamper resistant, protected against leakage or breakage and have a mechanism that ensures refilling without leakage;
- d. the tanks of E-device and Pods shall only be permitted to have a maximum volume of two (2) milliliters while Refills shall only be permitted to have a maximum volume of thirty (30) milliliters; and
- e. the Manufacturer provides a written declaration to the IAC-V at least three (3) months prior to manufacturing, selling, offering for sale, importing, exporting, distributing or transferring a Vapor Product that (i) the Vapor Product complies with the standards set out in Section 7 of this Act and (ii) they shall bear full responsibility for the quality and safety of the Vapor Product when placed on the market and used under normal or reasonably foreseeable conditions.

SECTION 8. *Regulation of Ingredients and Emissions.* — No Person shall manufacture, sell, offer for sale, import, export, distribute or transfer any E-liquid unless it complies with the following:

- a. if the E-liquid contains nicotine, propylene glycol or glycerol, each ingredient should be within the specifications of an accepted pharmacopoeia, as set out in Annex A of this Act;
- b. does not contain additives that have Carcinogenic, Mutagenic or Reprotoxic properties in unburnt form under the prevailing GHS revision;
- c. does not contain vitamins or other additives that are promoted or marketed to create the impression that the product has a health benefit or presents reduced health risks;
- d. does not contain caffeine, taurine, or other additives and stimulant compounds that are associated with energy and vitality;
- e. does not contain additives having coloring properties for Emissions;
- f. does not contain additives such as diacetyl and 2,3-Pentandione, which are known to pose a risk to human health when used in Vapor Products. The IAC-V may, through the issuance of rules and regulations, prohibit any other additives that are, after notice and hearing, proven to have caused death, serious illness or injury, or to pose grave and imminent risk to consumer safety and public health when used in Vapor Products under normal consumption patterns;

- g. the maximum nicotine absorbed by the body does not exceed that of a reference cigarette or the E-liquid does not contain more than sixty-five milligrams of nicotine per milliliter;
- h. additives not prohibited under the preceding sub-sections, such as but not limited to flavorants, should be of at least food grade purity;
- i. does not contain any dangerous drugs, as enumerated under Republic Act No. 9165, otherwise known as the Comprehensive Dangerous Drugs Act of 2002; and
- j. the Manufacturer provides a written declaration to the IAC-V at least three (3) months prior to manufacturing, selling, offering for sale, importing, exporting, distributing or transferring an E-liquid that that (i) the E-liquid complies with the standards set out in Section 8 of this Act and (ii) they shall bear full responsibility for the quality and safety of the E-liquid when placed on the market and used under normal or reasonably foreseeable conditions.

The sale, offer for sale, import, export, distribution or transfer of any nicotine shots and/or concentrates shall be strictly prohibited.

SECTION 9. *Flavors.* — The manufacture, importation, sale and distribution of Vapor Products containing flavors shall be prohibited, except for tobacco or menthol flavors. The IAC-V may, through the issuance of rules and regulations, permit additional flavors.

SECTION 10. *Prior submission of data and information to IAC-V.* — In addition to the requirement to notify before undertaking any activity under Section 6, no Vapor Product shall be manufactured, sold, offered for sale, imported, exported, distributed or transferred unless the following has been submitted to the IAC-V at least three (3) months prior to the commencement of these activities:

- a. a full statement and report of the components of the E-device;
- b. a full statement and report of the ingredients of the E-liquids, except for the ingredients of flavorants, which are considered confidential or trade secret and can be described in the report by the name of the flavorant, provided that the Manufacturer or importer (as the case may be) provides a written declaration to the IAC-V that they would disclose the composition of the flavorant to the IAC-V in confidence in the event of a safety problem with the product;
- c. for Closed-System Vapor Products, a report listing the known HPHCs in the E-liquid and a toxicological analysis of the HPHCs in Emissions produced when the E-device is used with the Pod;
- d. for Refills, a report listing the known HPHCs in the E-liquid and toxicological analysis of the HPHCs in Emissions produced when used with three (3) compatible E-devices. The toxicological analysis should be

performed using E-devices that are known to be typically used with the Refill on the market;

- e. for Open-System E-devices, a toxicological analysis of the HPHCs in Emissions produced when used with three (3) compatible Refills. The toxicological analysis should be performed using Refills that are known to be typically used with the E-device on the market;
- f. samples of the E-device and/or Receptacle, as the IAC-V may reasonably require;
- g. specimens of the Packaging proposed to be used for the E-device and/or Receptacle; and
- h. the Manufacturer's written declaration required under Section 7(e) and/or Section 8(j) and/or Section 10(a).

The IAC-V shall establish a list of HPHCs within three (3) months of the effectivity of this Act, and periodically revise the list as appropriate; provided however that the list must be supported by substantial scientific evidence and shall not be formulated or revised without prior notice to and consultation with the public and interested stakeholders.

SECTION 11. *Advertisements, Sponsorships and Promotions.* — The following restrictions shall apply:

- a. *Advertisements.* — All forms of advertising shall be prohibited except for advertising at points-of-sale. All advertisements at points-of-sale shall comply with the following restrictions:
 - (i) shall not be aimed at or particularly appeal to Minors;
 - (ii) shall not feature a celebrity (which includes social media influencers) or contain an endorsement, whether express or implied, by a celebrity;
 - (iii) shall contain only text and/or a visual of the Vapor Product, without any other accompanying images or visuals unrelated to the Vapor Product; and
 - (iv) shall include the Warning.

The limitations in this sub-Section apply only to advertisements and shall not prevent the use of company websites to provide information regarding a company. This sub-Section shall not prohibit business-to-business transactions conducted online and other similar medium between Vapor Products manufacturers, distributors, importers, exporters and retailers.

- b. *Promotions.* — The following restrictions shall apply to all promotions:

- (i) all communications to consumers about promotions shall comply with the provisions of Section 11(a) governing advertisements;
 - (ii) no Minor may participate in promotions. All participants must be required to provide a valid government-issued photo identification for verification; and
 - (iv) in addition to the Warning, the age requirement for participation in any promotion must be clearly marked on the program materials distributed to consumers.
- c. *Sponsorships.* — Manufacturers, distributors, importers, exporters and retailers of Vapor Products are prohibited from providing any Sponsorship. This sub-Section shall not prohibit any donations or sponsorships made in connection with programs that are permitted under Section 21 of this Act.
- d. *Sampling.* — The distribution of samples of Vapor Products to Minors is prohibited.

SECTION 12. *Packaging and Labelling.* — All Vapor Products shall comply with the following requirements:

- a. *Packaging.* — the Packaging of Vapor Products shall:
- (i) carry the Warning on the Principal Display Surface:

“THIS PRODUCT CONTAINS NICOTINE, WHICH IS A HIGHLY ADDICTIVE SUBSTANCE.”;
 - (ii) The Warning shall be contained within a frame, which shall occupy 30% of the lower part of the Principal Display Surface. The Warning shall occupy a total area of not less than fifty percent (50%) of the frame;
 - (iii) Nothing shall be printed or applied on a location where it is likely to obscure or cover, in part or in whole, the Warning;
 - (iv) No part of the Warning may be destroyed, obscured, folded, severed or become unreadable when the Packaging is opened or closed or when a wrapper on the Packaging is removed;
 - (v) In addition to the Warning, the following textual health warnings should also be included on the Packaging:
 - (1) “This product is not suitable for use by pregnant women, nursing mothers, children, persons with respiratory or cardiovascular diseases.”; and
 - (2) “Intended only for adult smokers.”;

- (vi) for Receptacles, specify the nicotine content in the format of "XX mg of nicotine / ml" and the actual volume in milliliters of the E-liquid; and
 - (vii) not contain cartoon characters or subjects that depict humans or animals with comically exaggerated features or that attribute human or unnatural characteristics to animals, plants or other objects.
- b. *Design of Vapor Products.* — The Design of the E-device and/or Receptacle shall not be of a color, shape, pattern, configuration or artistic appearance that is similar to toys or objects meant specifically for Minors.
- c. *Labels.* —
 - (i) The Label for Vapor Products shall comply with the minimum labelling requirements for consumer products as set out under Article 77 of Republic Act No. 7394 otherwise known as the Consumer Act of the Philippines; and
 - (ii) for Receptacles, all ingredients used in quantities of 0.1% or more by volume of the final formulation of the E-liquid shall be listed on the Label, except for the ingredients of flavorants, which are considered confidential or trade secret, and can be described on the Label by the name of the flavorant provided that the requirements of Section 10(a) are complied with.
- d. *Instructions for Use.* — a leaflet or insert for E-device containing:
 - (i) instructions for handling;
 - (ii) instructions for proper use;
 - (iii) telephone number to call in case of accidents, injury or illness arising from the use of the Vapor Product;
 - (iv) instructions for maintenance of the product; and
 - (v) warnings on:
 - (1) risks of improper usage;
 - (2) the product is not suitable for use by pregnant women, nursing mothers, children, persons with respiratory or cardiovascular diseases;
 - (3) risks of prolonged contact with the skin;
 - (4) risks of ingestion; and
 - (5) addictive quality of nicotine.

SECTION 13. *Health Claims.* — Vapor Products which make Health Claims shall be excluded from the scope of this Act and shall be regulated by the Food and Drug Administration of Philippines as pharmaceutical products under existing laws and regulations.

SECTION 14. *Signage.* — All points-of-sale selling, offering for sale, distributing or transferring Vapor Products to consumers shall post the following statement in a clear and conspicuous manner:

“SALE OR DISTRIBUTION OF VAPOR PRODUCTS TO MINORS IS A
CRIMINAL ACT PUNISHABLE BY IMPRISONMENT AND/OR FINE.”

SECTION 15. *Prohibited Vaping Areas.* — Use of Vapor Products shall be absolutely prohibited in the following places:

- a. Centers of youth activity such as playschools, preparatory schools, elementary schools, high schools, colleges and universities, youth hostels and recreational facilities for Minors;
- b. Elevators and stairwells;
- c. Locations in which fire hazards are present, including gas stations and storage areas for flammable liquids, gas, explosives or combustible materials;
- d. Within the buildings and premises of public and private hospitals, medical, dental, and optical clinics, health centers, nursing homes, dispensaries and laboratories; and
- e. Public conveyances and public facilities including airport and ship terminals, train and bus stations, restaurants and conference halls.

PROHIBIT SALE OF VAPOR PRODUCTS TO MINORS

SECTION 16. *Prohibition of sale to Minors.* — The following acts shall be prohibited:

- a. The sale, offer for sale, distribution or transfer of Vapor Products by any Person to Minors;
- b. purchasing, or otherwise receiving Vapor Products from a Minor; and
- c. The purchase, distribution or transfer of Vapor Products by Minors, or on behalf of a Minor.

It shall not be a defense for the Person selling, offering for sale, distributing or transferring Vapor Products that he/she did not know or was not aware of the real age of the Minor. Neither shall it be a defense that he/she did not know nor had any reason to believe that the Vapor Product was for the consumption of the Minor to whom it was sold, distributed or transferred.

SECTION 17. *Age Verification.* — Retailers shall:

- a. ascertain that no individual purchasing Vapor Products is a Minor; and

- b. verify the age of a potential customer prior to sale by requiring the presentation of a valid government issued identification card exhibiting the customer's photograph, as well as his/her age and/or date of birth.

SECTION 18. *Location of sale.* — The sale, offer for sale, distribution or transfer of Vapor Products is prohibited within one hundred (100) meters from any point of the perimeter of a school, public playground or other facility frequented particularly by Minors.

SECTION 19. *Online sales.* — No Person shall sell, offer for sale, distribute or transfer any Vapor Products online unless the following requirements are met:

- a. compliance with all requirements specified in Republic Act No. 8792, also known as the "E-Commerce Act", and the Rules and Regulations for Consumer Protection in a Transaction Covered by the Consumer Act of the Philippines through Electronic Means under the E-Commerce Act;
- b. compliance with all requirements specified under Republic Act No. 10173, also known as the "Data Privacy Act of 2012", and its implementing rules and regulations;
- c. access is restricted to Persons eighteen (18) years of age or older. Access will be deemed to be age-restricted if a Person cannot complete a purchase unless the Person provides a copy of his/her valid government-issued photo identification for verification and provides a contemporaneous selfie for face-based biometrics verification;
- d. an independent audit firm has certified compliance with the two-step age verification requirements set out in this sub-Section; and
- e. such Person has submitted the certification prescribed under Section 19(d) to the IAC-V prior to carrying out online sales.

MONITOR POTENTIAL RISKS OF VAPOR PRODUCTS

SECTION 20. *Post-Market Requirements.* —

- a. Manufacturers in the Philippines and importers of foreign products shall be required to establish and maintain post-market records on adverse health events, including putting in place suitable mechanisms for consumers to report any adverse health events. The IAC-V may from time to time require Manufacturers and importers to submit the list of adverse health events, whether serious or non-serious, arising in the Philippines from the use of Vapor Products; and
- b. In the event that a Vapor Product has been withdrawn from a market outside of the Philippines as a result of the occurrence of an adverse health event, the Manufacturer or importer shall immediately notify the IAC-V.

SECTION 21. *Corporate Social Responsibility Programs.* — All large taxpayers, as defined under Section 245 of Republic Act No. 8424, otherwise known as the Tax Reform Act of 1997, doing business and engaged in manufacturing, distributing, importing, exporting or retail sale of Vapor Products in the country, whether domestic or foreign, are hereby mandated to allocate funds to:

- a. youth usage monitoring and prevention programs, as may be prescribed by the IAC-V in the implementing rules and regulations; and
- b. corporate social responsibility projects for the benefit of the community.

All local government units where corporate social responsibility activities are conducted shall extend whatever assistance is necessary for these large taxpayers to implement their corporate social responsibility activities, provided always that the name of the company may only be mentioned in the roster of sponsors but not in any advertisement.

SECTION 22. *Transparency and Disclosure of Information.* — In the event any Person has reason to believe that any Manufacturer, Distributor, importer, or exporter is not compliant with the requirements provided in this Act, such Person may require the relevant Manufacturer, Distributor, importer, exporter to disclose such data, information, notifications, written declarations or reports as prescribed in Sections 6, 7, 8 and 10, to demonstrate their compliance with all standards and requirements prescribed therein. Provided, however, that such requests must be reasonable, and made in good faith and solely for the purpose of determining such compliance. Provided, further, that this Section shall not be construed as requiring Manufacturers, Distributors, importers, and exporters to provide copies of such data, information, notifications, written declarations or reports to the Person requesting therefor, or to disclose any trade secrets or proprietary information, or to generate or produce reports, studies, summaries or other information or documents which are not otherwise available or existing, or to disclose data or information in excess of or in addition to those disclosed or submitted by them to the IAC-V pursuant to this Act.

In case of any failure or refusal by a Manufacturer, Distributor, importer, or exporter, without any justifiable reason, to disclose the data, information, notifications, written declarations or reports validly requested pursuant to this Section, the Manufacturer, distributor, importer, exporter shall, in addition to the penalties provided in Section 23 of this Act, be liable to the requesting Person for damages in the amount of One Hundred Thousand Pesos (P100,000.00) to Five Hundred Thousand Pesos (P500,000), at the discretion of the court.

PENAL PROVISIONS

SECTION 23. *Penalties for non-compliance.* — The following penalties shall individually apply to Manufacturers, importers, distributors, sellers and buyers found to be in violation of this Act, as well as to their agents/representatives, as may be applicable:

- a. On the first offense, a fine of not more than One Hundred Thousand Pesos (P100,000.00);

- b. On the second offense, a fine of not less than One Hundred Thousand Pesos (P100,000.00) but not more than Two Hundred Thousand Pesos (P200,000.00); and
- c. On the third offense, a fine of not less than Two Hundred Thousand Pesos (P200,000.00) but not more than Five Hundred Thousand Pesos (P500,000.00), imprisonment of not more than five (5) 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, may be revoked or cancelled.

If the offender is a corporation, partnership or any juridical person, the penalty shall be imposed upon the responsible officers, as the case may be, who participated in, or by their gross negligence, allowed the violation of this Act.

SECTION 24. *Violations by Minors.* — If a minor is caught selling, buying or using a Vapor Product, the provisions of Republic Act No. 9344, otherwise known as An Act Establishing A Comprehensive Juvenile Justice And Welfare System, Creating The Juvenile Justice And Welfare Council Under The Department Of Justice, Appropriating Funds Therefor And For Other Purposes, shall apply.

SECTION 25. *Confiscation.* — Vapor Products found in the market for sale or distribution but are in violation of the provisions of this Act shall be subject to confiscation by the Philippine National Police.

SECTION 26. *Foreign National.* — If the guilty offender is a foreign national, he shall be deported after service of sentence and/or payment of applicable fines without need of further deportation proceedings and shall be permanently barred from re-entering the Philippines.

INTER-AGENCY COMMITTEE ON VAPOR PRODUCTS

SECTION 27. *Inter-Agency Committee.* — An Inter-Agency Committee on Vapor Products, which shall, except as otherwise provided in this Act, have the exclusive power, jurisdiction and function to regulate Vapor Products and to administer and implement the provisions of this Act, is hereby created.

SECTION 28. *Members of the IAC-V.* — The IAC-V shall have the following members:

- a. Secretary of the DTI, who shall also be the chair of the IAC-V;
- b. Secretary of the Department of Health (DOH);
- c. Secretary of the Department of Agriculture (DA);
- d. Secretary of the Department of Justice (DOJ);
- e. Secretary of the Department of Finance (DOF);
- f. Secretary of the Department of Science and Technology (DOST);
- g. The Administrator of the National Tobacco Administration (NTA);
- h. The Commissioner of the Bureau of Customs (BOC);
- i. A representative from the Office of the Presidential Legal Counsel;

- j. A representative from the Vapor Products industry to be nominated by legitimate and recognized associations of the industry; and
- k. A representative from a non-government organization (NGO) involved in public health promotion nominated by DOH in consultation with the concerned NGO's;

The Department Secretaries may designate their Undersecretaries as their authorized representatives to the IAC-V.

SECTION 29. *Creation of a Congressional Oversight Committee.* — A Congressional Oversight Committee on Vapor Products (COC-V) co-chaired by the Senate Committee on Trade and the House Committee on Trade shall be constituted to monitor and review the implementation of this Act for a period not exceeding three (3) years. The COC-V shall be comprised of one representative from each of the following bodies:

a. Senate

- (i) Committee on Health and Demography
- (ii) Committee on Economic Affairs
- (iii) Committee on Science and Technology
- (iv) Committee on Ways and Means
- (v) Committee on Agriculture

b. House of Representatives

- (i) Committee on Health
- (ii) Committee on Economic Affairs
- (iii) Committee on Science and Technology
- (iv) Committee on Ways and Means
- (v) Committee on Agriculture

SECTION 30. *Compliance Monitoring.* — Not later than one (1) year after the date of the effectivity of this Act, and annually thereafter, the IAC-V shall submit to the President of the Philippines and to both Houses of Congress a Compliance Monitoring Report on the compliance of the manufacturers, importers, distributors and retailers on all applicable laws and ordinances with respect to the manufacture, import, export, sale, offer for sale and distribution of Vapor Products. The report shall contain pertinent information on the methods, goals and implementation program of said Persons with respect to the requirements of this Act.

SECTION 31. *Transitory Period.* — A transitory period of three (3) months from the date of effectivity of this Act shall be provided to allow all Manufacturers, Distributors, importers, exporters, sellers and retailers of Vapor Products to comply.

SECTION 32. *Implementing Rules and Regulations.* — Within six (6) months from the date of effectivity of this Act, the IAC-V shall submit implementing rules and regulations to the COC-V for its review. The COC-V shall approve the implementing rules and regulations within ninety (90) working days of receipt thereof, provided that

the non-issuance of implementing rules and regulations will not suspend the effectivity of this Act nor the introduction of Vapor Products in the Philippines.

SECTION 33. *Appropriations* – The amount necessary to implement the provisions of this Act shall be charged against the current year's appropriations of the concerned national government agencies. Thereafter, such funds as may be necessary for the continued implementation of this Act shall be included in the budgets of the concerned national government agencies under the annual General Appropriations Act.

SECTION 34. *Separability Clause*. — If any provision or part hereof is held invalid or unconstitutional, the remainder of the law or the provision not otherwise affected shall remain valid and subsisting.

SECTION 35. *Repealing Clause*. — All existing laws, presidential decree or issuance, executive order, letter of instruction, administrative order, rule or regulation contrary to or inconsistent with the provisions of this Act are hereby repealed, modified, or amended accordingly.

SECTION 36. *Effectivity Clause*. — This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation.

ANNEX A -

Accepted Pharmacopoeia

The most recent editions, including all errata, supplements, revisions and addenda, of the following standards:

Item	Name	Abbreviation
1	European Pharmacopoeia	(Ph.Eur.)
2	Pharmacopée française	(Ph.F.)
3	Pharmacopoeia Internationalis	(Ph.I.)
4	The British Pharmacopoeia	(B.P.)
5	The Canadian Formulary	(C.F.)
6	The National Formulary	(N.F.)
7	The Pharmaceutical Codex: Principles and Practices of Pharmaceuticals	
8	The United States Pharmacopoeia	(U.S.P.)