

## ANNEX D

### GLOSSARY

1. **Advertising** shall refer to the conceptualizing, presenting, making available and communication to the public, through any form of media platforms, any fact, data, or information about the attributes, features, quality or availability of consumer products, services, or credit.
2. **Authorization** means a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the manufacture, importation, exportation, sale, offer for sale, distribution, and/or, where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption, or any similar document.
3. **Batch Declaration** refers to the declaration by a marketing authorization holder informing the FDA of a specific batch of FDA-registered vapor products/HTPs refills or cartridges manufactured or imported in the Philippines, prior to release for sale, offer for sale, or distribution of such particular batch into the market.
4. **FDA Electronic Registration Number (FERN)** shall refer to the product authorization issued by the FDA to FDA-licensed companies, firms or non-profit organizations to market heated tobacco products and vapor products.
5. **Industry** refers to manufacturers, traders, distributors (importer, exporter, wholesaler), and retailers of vapor products and/or heated tobacco products.
6. **Ingredient** means any substance or additive that is used for the production/manufacture of the finished product.
7. **Marketing Authorization Holder (MAH)** refers to a company, firm or non-profit organization that has been granted an authorization by the FDA.
8. **Nicotine Shots** refer to nicotine in liquid or any other form/substances 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.

9. **Package** shall refer to packs, boxes, cartons, or containers of any kind used on vapor products, which is offered for sale to consumers.
10. **Post-Marketing Surveillance (PMS)** refers to activities involved in safety, efficacy, and quality monitoring of health products. This shall also include, among others, adverse events reporting, product safety update reporting, collection and testing of health products in the market.
11. **Primary Packaging** refers to any material, including printed material, employed in the packaging of the product, excluding any outer packaging used for transportation or shipment, that is *in direct contact* with the Vapor Product and Heated Tobacco product refill solutions.
12. **Product Claims** shall refer to health or therapeutic claims of a product, which indicates beneficial effects to promote good health by enhancing/improving body function, improving a function, enhancing or preserving health and/or reducing the risk of health-related conditions of diseases.
13. **Product Marketing Authorization** shall refer to FDA-issued product certification such as FERN and Batch Declaration.
14. **Promotion** shall refer to an event or activity organized by or on behalf of an vapor product manufacturer, distributors (importer, exporter, wholesaler), seller or retailer with the aim of promoting vapor products, which event or activity would not occur but for the support given to it by or on behalf of the vapor product manufacturer, distributor (importer, exporter, wholesaler), seller or retailer. It may also refer to the display of vapor products or the manufacturer's name, trademark, logo, and the like on non-vapor products. This includes the paid use of vapor products bearing the brand names, trademarks, logos, and the like in movies, television, and other forms of entertainment.
15. **Refills and Cartridges** are articles, which may or may not contain nicotine, designed to be used in conjunction with vapor product or HTP electronic delivery devices for inhalation.;
16. **Secondary packaging** refers to any material, including printed material, employed in the packaging of the product, excluding any outer packaging used for transportation or shipment, that is *not in direct contact* with the Vapor

Product and Heated Tobacco Product refill solutions (e.g. product inserts, tags, etc.).

**17. Sponsorship** shall refer to any public or private contribution from vapor product industry 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 with or without contribution. This shall also include corporate social responsibility (CSR) activities by the vapor product industry.

**18. Vapor Products** shall mean electronic nicotine and non-nicotine delivery systems (ENDS/ENNDS), which are a combination of (i) a liquid solution or gel, that transforms into an aerosol without combustion through the employment of a mechanical or electronic heating element, battery or circuit that can be used to heat such solution or gel and includes but not limited to (ii) a cartridge, (iii) a tank, and (iv) the device without the cartridge or tank. It is commonly known as nicotine salt/salt nicotine, and conventional ‘freebase’ or classic nicotine, and other similar products.