

Review of "Electronic Nicotine Delivery Device (ENDS)"

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Overall. The definition provided is helpful but there are a few remaining ambiguities, most notably with respect to the inclusion or exclusion of heated tobacco products within this definition. I think the set of definitions in this field should be looked at together for coherence, and speculate whether they could be built from a set of elemental variables.

Device? Strictly, ENDS are not devices, but device-liquid combinations. It is possible to put a non-nicotine liquid in a refillable vaping device that is also designed for nicotine (i.e. a flavoured e-liquid with no nicotine). So a device only becomes an ENDS when paired with liquid or class of liquids that contain nicotine. The same hardware is not an ENDS if not using a nicotine liquid. Not all devices are hand-held: there are electronic hookah pipes using nicotine liquids, for example, that stand on a table or the floor.

Humectant? The function of the propylene glycol or glycerol in the e-liquid is not primarily as a *humectant* but as: (1) *a diluent* (to create a chosen nicotine concentration) and, (2) *an excipient* (a inert carrier for the active ingredients - flavours and nicotine). While these agents can also be humectants, that is not their primary function in ENDS.

Clarity over excipient names. There is great confusion about the names of excipients and an opportunity for clarity here:

"...one or more excipients, which may include propylene glycol (PG), glycerol or other excipients. Glycerol is also referred to as glycerine, glycerin or, most commonly, vegetable glycerin (VG).

Arbitrary choice of one technical description. The proposed definition includes a piece of technical information about how the heating is activated (by switch or by suction), but why this information rather than any other technical aspects? For example, the products may be fixed or variable power; they may be disposable or refillable, they may or may not have temperature control. What about distinguishing ENDS from a metered drug delivery system, given the dose is controlled by the user and this is a common misperception?

Inclusion or exclusion of heated tobacco products? A further question is whether this definition is clear in its distinction from other products that would not usually be thought of as ENDS. For example, the proposed definition could conceivably include some types of heated tobacco products. The question is whether some HTPs are a subset of ENDS (they are electronic, use liquids and deliver nicotine) or a separate category. I would favour the latter as they are already treated separately, for example by WHO and they are a tobacco product for regulatory and excise purposes in jurisdictions like the European Union. There are three types of heated tobacco product (air heated, direct heated and indirectly heated vapour) and the last two contain liquids that transport tobacco flavour and nicotine to the user.

Evaluation of the full landscape of definitions. It would be helpful to see a group of device definitions posted together so that their interactions and coherence can be considered as a whole. For example:

- Tobacco product
- Nicotine product
- ENDS
- ENNDS (Electronic Non-Nicotine Delivery System - used by WHO)
- Heated tobacco product
- Personal vaporiser / Vaping product (which may use THC or CBD)
- Vape pen (e.g. THC cart)
- E-cigarette
- Inhaler (e.g. the Voke or other pharma products)

Could definitions in this field be assembled from 'elemental' components that would be sufficient to completely categorise any device or substance? The key variables across this landscape seem to be as follows (I am uncertain if this is complete):

- the drug (nicotine, other psychoactive substance, or none);
- the drug-containing substance (plant-based - cannabis plant or tobacco - or a refined extract of the psychoactive agent - nicotine, THC, CBD etc);
- combusted, heated or unheated;
- method of administration (inhaled, sucked, chewed, ingested, injected, transdermal)
- with or without a liquid carrier.

Perhaps by defining the elemental components of definitions in this way, you could combine them to provide a definition of any product or category. This is just a suggestion for the authors to consider.

