Proposal 3: Establish a standards-based regime for low-risk nicotine products

Recommendation 3. Regulate low risk tobacco and nicotine products by setting product standards (chemical, mechanical, thermal, electrical) that reduce individual risk to users while promoting innovation and ensuring the products are an attractive alternative to smoking. These standards would ensure average exposures were at least 90 percent lower than smoking and would make a further public health benefit test unnecessary.

There are many problems with the authorization regime for vaping products introduced by FDA. This should be replaced with a regime that defines transparent industry-wide standards so that everyone involved can understand what is expected of them and how to comply – this is normal practice.

- The FDA's process is extremely burdensome, with demanding evidential requirements and high costs of paperwork. This is compounded by evaluation costs and lengthy delays at the FDA.
- It is an opaque procedure in which the applicant does not know how the application will be evaluated or how pedantic or flexible the FDA's evaluators will be. For example, how high evidential bars will be set, how trade-offs will be made, how inevitable uncertainties will be reconciled. Authorization decisions rest with the FDA and its staff, but like any agency it is vulnerable to politicization of its decision-making and the biases of its decision-makers.
- The authorization requires a 'public health benefit test' to be passed before the product is placed on the market[1] – taken literally or pedantically, this test involves proving a negative and can be almost impossible to meet[2]. Even for products that prove to be very beneficial, it is hard to prove this *before* the product is on sale. However, the public health benefit test may harm public health by erecting a bureaucratic hurdle that keeps beneficial products from the market - see section 5.
- Even an obviously beneficial improvement (e.g. hardware upgrade or adding temperature control) to a product must go through a new authorization. The regime acts as a barrier to innovation, yet innovation is necessary to attract more smokers away from cigarettes, and to make continuing improvements in e-cigarette safety.
- The most dangerous products, cigarettes, have escaped this regime completely[3].

The alternative is to use the approach that is used for most products on the market in the United States – set industry-wide standards. Non-combustible products should comply with standards that govern chemical, thermal, electrical and mechanical risks. To achieve the optimum public health outcome, standards should be carefully set in a way that does not increase the likelihood that those who use low-risk products will relapse to smoking or that fewer smokers will switch.

- **Combustion products.** Combustible products (cigarettes, rolling tobacco, cigars etc) could continue to be regulated under the existing framework of the Tobacco Control Act.
- **Vaping products**. Set standards for testing methods and product characteristics that mitigate the main residual risks, and allow these standards to adapt to new knowledge and advancing technology. The French standards-setting body, AFNOR, has published a range of standards[4], the

British Standards Institute has defined optional standards[5] and the European standardization body, CEN, has commenced work on a four-part standard[6]. Elements of a standards regime could include blacklisted ingredients where there are known health risks[7], maximum concentrations for contaminants, limits to products of thermal decomposition measured in vapor, battery safety standards including covers on loose batteries and battery-charger compatibility[8]. Within the confines of the 1st amendment, limits could be placed on marketing that may appeal to or disproportionately reach under-18s could be imposed. For example, UK guidelines aim to strike a balance between protection of young people and commercial freedom to market an alternative to smoking to adults[9].

- **Heated tobacco products**. The approach would be similar to that for vaping products, though with different standards to reflect the different ingredients and chemical processes involved.
- **Smokeless tobacco / nicotine products**. Set standards for residual toxins, such as tobacco-specific nitrosamines. This approach and an outline standard was recommended by WHO's expert group[10] and a company has established a standard to which it holds its own products[11]. Standards should be moderate to begin with aiming to remove outliers and then tighten up with experience.

FDA has powers to set such standards under Section 907 of the Tobacco Control Act[12]. In all cases, standard consumer protection legislation should be used to address concerns to the extent possible.

References

1 FDA Pre-Market Tobacco Application (PMTA) [link]

2 FDA. Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS) – draft guidance, May 2016 [link]

3 Tobacco products on the market at 15 February 2007 were 'grandfathered' when the Tobacco Control Act was introduced in 2009. Tobacco Control Act §910 [link]

4 AFNOR (France) Electronic cigarettes and e-liquids Part 1: Requirements and test methods for e-cigarettes XP D90-300-1 March 2015 [link] Part 2: Requirements and test methods for e-cigarette liquid XP D90-300-2 March 2015 [link] and Part 3: Requirements and emission-related test methods XP D90-300-3 July 2016 [link]

5 BSI PAS 54115:2015 Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products - Manufacture, importation, testing and labelling - Guide [link] July 2015

6 European Centre for Standardisation, CEN/TC 437 - Electronic cigarettes and e-liquids [link]

7 A blacklist would target carcinogenic, mutagenic, reprotoxic substances and respiratory sensitizers. There are known ingredients of concern, for example: diacetyl (a buttery flavouring), cinnamaldehyde and benzaldehyde. The evidence does not so far support a material health risks at typical exposures, but there is a case for requiring alternatives to be used where these are available.

8 International electrical safety standards are available: IEC 60335-1 (safety of household appliances); IIEC 60335-2-29 (safety of battery chargers); IEC 62133 (safety of portable batteries); IEC 61558 (safety of AC adaptors); IEC 61000 series; and EN 55022 & EN 55024 (for USB chargers & cables)

9 Committee on Advertising Practice (UK), UK Code of Broadcast Advertising: 33. E-cigarettes Broadcast [link]; UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code): 22. E-cigarettes [link]

10 WHO Study Group on Tobacco Product Regulation Report on the Scientific Basis of Tobacco Product Regulation: WHO Technical Report Series, no. 951, 2008 [link]

11 Swedish Match, GOTHIATEK® limits for undesired components [link]

12 Food and Drug Administration, Section 907 of the Federal Food, Drug, and Cosmetic Act - Tobacco Product Standards (2009) [link]