LOST OPPORTUNITY

In addition to other shortcomings, the new EU Tobacco Products Directive sets e-cigarettes' nicotine threshold too low to tempt smokers away from tobacco.

By Jeannie Cameron

On May 19, the new, long-awaited EU Tobacco Products Directive (TPD) went into force. The review process began in 2009, and stakeholders were full of anticipation. There was hope in many quarters that the TPD would pick up what the World Health Organization (WHO) had missed in its Framework Convention on Tobacco Control (FCTC)—a tobacco harm-reduction policy, the old chestnut that continues to elude regulators the world over.

Unfortunately, what emerged a few months ago was "all gas and no lemonade." The directive is a mess not only in terms of the missed policy opportunity but also from a legal perspective. For example, the definitions are not even in alphabetical order. Key terms such as *nicotine-containing liquid* remain undefined and, bizarrely, e-cigarettes—which are nicotine and noncombustible products—are addressed in the same article as herbal cigarettes (which contain no nicotine and are combustible products).

Almost all areas of the TPD are poorly drafted and defy the principles of proportionality so enshrined as a fundamental element of EU policy. But perhaps the most disturbing problem with the TPD is its nicotine policy. The European Commission's original proposal contained a chapter titled "Nicotine-containing products," (NCPs) and defined them as products consumed through inhalation, ingestion or other methods to which nicotine is either added during the manufacturing process or self-administered by the user before and during consumption. This definition would have included e-cigarettes and all novel nicotine lifestyle products on the market, such as disposable smoke-free and heat-free nicotine inhalators like the Similar brand sold on Ryanair. At present, these products are outside the TPD definition. Their manufacturers will most likely self-regulate to comply with the directive in good faith.

NCPs, such as e-cigarettes, currently fall outside the scope of the prevailing Tobacco Products Directive 2001, and EU member states have taken different approaches to regulating these products. Some regulate them as medicinal products, others apply provisions used for tobacco products, while yet others have no specific legislation at all. The draft TPD proposal appeared to change that by seeking to harmonize NCPs and place them in the tobacco domain, albeit with their own definition. The fact that nicotine comes from tobacco was to some reason enough.

However, somewhere along the way between the commission's draft proposal and the final text that emerged from the European Parliament, NCPs disappeared, and just one type of NCP—the e-cigarette—was included in the directive for regulation.

The TPD stipulates that NCPs will be considered as medicinal only if they contain more than 20 mg/mL nicotine—or if the manufacturer *wants* them to be regulated as such. This outcome was positive insofar as e-cigarettes are permitted to be sold as consumer products, in the same way that cigarettes are, provided they feature an adapted health warning. But if e-cigarette manufacturers make smoking-cessation claims about their products, they will have to apply for a medical license.

Misinterpretation

The 20 mg/mL nicotine threshold was reportedly established by considering the nicotine content of nicotine-replacement therapies (NRTs) for smoking cessation that have already received a market authorization under the medicinal products' legislation.[1] Recital 38 of the TPD says, "Nicotine-containing liquid should only be allowed to be placed on the market under this directive, where the nicotine concentration does not exceed 20 mg/mL. This concentration allows for a delivery of nicotine that is comparable to the permitted dose of nicotine derived from a standard cigarette during the time needed to smoke such a cigarette. In order to limit the risks associated with nicotine, maximum sizes for refill containers, tanks and cartridges should be set."

In its one-page e-cigarette information flyer published with the announcement of the new TPD, the European Commission claims that an e-cigarette with a concentration of 20 mg/mL

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What were they smoking?

delivers approximately 1 mg of nicotine in five minutes, which is equivalent to the time needed to smoke a traditional cigarette. According to the commission, this information is based on research by Dr. Konstantinos Farsalinos et al., published in the 2013 paper *Evaluation of electronic cigarette use (vaping) topography and estimation of liquid consumption*.[2]

In fact, Farsalino's research does not make that claim. Instead, his research shows that 20 mg/mL e-liquid provides less than one-third of the nicotine delivered by one tobacco cigarette, and that 50 mg/mL is needed to be roughly equivalent. He presented this finding to the U.S. Food and Drug Administration on Dec. 19, 2013, and informed the EU in January that the organization had misinterpreted his research—a fact confirmed by other studies.[3]

Unfortunately, the 20 mg/mL restriction makes e-cigarettes a nonviable alternative for heavy tobacco smokers—something that concerns many public health advocates. Dependent smokers will need higher nicotine levels to abandon traditional cigarettes. Current research indicates that 45 mg/mL would result in blood plasma nicotine levels approaching those achieved through tobacco smoke.

The e-cigarette company Totally Wicked says its data suggests a nicotine level of 36 mg/mL is sufficient to satisfy the nicotine cravings of heavy smokers. "There has been no evidence of harm from the 20,000 bottles of 54 mg/mL and 72 mg/mL nicotine concentrates we sold in 2013, so we judge that concerns about dangers from toxicity at lower levels are unfounded." The risks are being misrepresented and overstated when considering the equivalence of e-cigarettes and conventional cigarettes.

Ingredient disclosure

The TPD requires manufacturers and importers of tobacco products to notify the relevant authorities of any planned nicotine product launches. The notification must be submitted in electronic form six months before the intended introduction and must be accompanied by a detailed description of the product in question as well as information on ingredients. This is also required for any changes to existing products. Six months is a long time in an era of rapid innovation, however. When new and effective products are developed, it would make more sense to introduce them to the market as quickly as possible.

As part of the notification, the TPD requires e-cigarette manufacturers and importers to submit to authorities information on nicotine dosing and uptake. Most of this is simply irrelevant to e-cigarettes and NCPs, and the provision appears to have been included only because it relates to tobacco products—it is, after all, a *tobacco* products directive.

For example, Article 20.2 (b) requires a listing of all ingredients contained in, and emissions resulting from, the use of e-cigarettes. The ingredients must be notified by brand name, type and quantity. However, there is no standard test for emissions from an e-cigarette or an NCP. Until such a test is developed, there can be no requirement to produce emissions results, because they would be meaningless.

Similarly, Article 20.3 (f) requires e-cigarette manufacturers to ensure consistency in the delivery of their products' nicotine dosages. This, too, is meaningless because the user controls the nicotine dose in the same way the smoker controls the nicotine dose with cigarettes. Consistent delivery of nicotine doses is neither achievable nor desirable. Smokers, vapers and users of NCPs are alike in that they self-regulate their nicotine uptake. The EU drafters were unaware of this fundamental fact—or chose to ignore it—rendering the policy largely ineffective.

TPD Recital (39) states, "Only electronic cigarettes that deliver nicotine doses at consistent levels should be allowed to be placed on the market. Delivery of nicotine doses at consistent levels under normal conditions of use is necessary for health protection, safety and quality purposes, including to avoid the risk of accidental consumption of high doses."

Fifteen of the world's most eminent nicotine scientists, including Farsalinos, wrote to the EU in January, stating the medicinal concept of "consistent delivery" is inappropriate for a consumer product that is used freely. According to them, users of cigarettes, oral tobacco and NCPs spontaneously determine their nicotine intake according to individual and momentary needs. The nicotine intakes of different individuals consuming the same e-cigarette can differ by a factor of 20, the scientists wrote. Thus, while quality control of individual brands is needed to ensure consistency of nicotine content, trying to ensure consistent deliveries makes little sense. No such demands have been placed on tobacco cigarettes or oral tobacco. The same scientists suspect that the risk of accidental consumption of high nicotine doses is low, with some believing it is physically impossible.[4]

Further, and more perversely, TPD Article 20.4 (i) requires that the nicotine content of the e-cigarette and the dose delivery mandated under Article 20.3 also be disclosed on the product

packaging, despite Article 13.1 (a) requiring that nicotine content levels be removed from tobacco cigarette packets on the basis that they are misleading. Go figure.

TPD Article 13 is written specifically for tobacco products and explicitly excludes any reference to tar, carbon monoxide and nicotine content. If tobacco products do not have to inform consumers of their nicotine content, then why do e-cigarettes and other NCPs have to? The same is true of the requirement to provide information on toxins—they are required for e-cigarettes but not required for conventional cigarettes. In an ideal world, NCPs should have their own labeling regime, disclosing information that is relevant to consumers. Tobacco packaging requirements are simply not applicable. Why did the TPD drafters allow this to happen?

Products regulated under the TPD, including e-cigarettes, will be subject to the same advertising and marketing restrictions as tobacco. This scenario has been described as one where "everyone is involved but no one is responsible." On the one hand, the EU Parliament appears to acknowledge that e-cigarettes and NCPs provide smokers with a useful alternative to combustible tobacco, and has therefore opted for fewer restrictions. On the other, manufacturers will not be allowed to communicate this message to consumers.

If EU regulators were motivated primarily by public health, they should be encouraging alternatives to tobacco smoking, especially if those alternatives have demonstrated they are effective and able to offer consumers a lower risk.

The TPD could have put in place a framework for the legitimate marketing of potentially reduced-harm NCPs. What justification is there for prohibiting the online marketing of such products? What justification does the EU have for suppressing awareness of potentially reduced-harm options?

If the protection of human health is the EU's objective, then the TPD is a failure. It had so much potential to deliver a credible regulatory framework for nicotine policy and it fell short. The 20 mg/mL nicotine threshold seems to be set only to satisfy the interests of pharmaceutical companies. If public health were the objective, the TPD would have enabled e-cigarettes and NCPs to deliver nicotine in the way consumers need it to be able to give up cigarettes. If the EU really is concerned about public health, it needs to amend its anomalous draft. And it should start by raising the nicotine threshold for e-cigarettes and other nicotine-containing consumer products. TR

[1] Directive 2001/83 of the European Parliament and of the Council of Nov. 6, 2001, on the Community code relating to medicinal products for human use OJ L 311, 11.28.2001, p. 67–128.

[2] *International Journal of Environmental Research and Public Health* 2013; 10: 2500-14

[3] Vansickel & Eissenberg, 2012; Hajek, Goniewicz, Phillips, Myers-Smith, West, McRobbie report to MHRA 2013; Dawkins & Corcoran 2014; Nides, Leischow, Bhatter, Simmons 2014

[4] [2] *Journal of the National Cancer Institute* 2001 Jan. 17; 93(2):134-8. Nicotine yield from machine-smoked cigarettes and nicotine intakes in smokers: evidence from a representative population survey. Jarvis M.J., Boreham R., Primatesta P., Feyerabend C., Bryant A.

Photo: Timothy Donahue

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