FRAMEWORK CONVENTION ALLIANCE

POLICY BRIEFING

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FCA Policy briefing

Electronic Nicotine Delivery Systems

Key Recommendations

- Parties should take careful note of the WHO report to COP on ENDS.
- Because of differences in regulatory systems and national circumstances, it will be difficult to reach consensus at COP6 on specific regulatory approaches to ENDS.
- Some overarching concerns and principles may be widely shared, and could be noted in a COP decision.
- Careful monitoring of new evidence and national regulatory experience is essential.
- An expert report on emerging scientific evidence and lessons learnt from national regulatory experience should be prepared for COP7.

Introduction

Electronic nicotine delivery systems, more commonly known as e-cigarettes[1], have been discussed by COP on two previous occasions – at COP4 and COP5. On both occasions, Parties requested further reports (see FCTC/COP/5/13 and FCTC/COP/6/10) – an indication that this is an area where products and marketing strategies are changing rapidly and Parties are trying a variety of approaches to regulate them.

E-cigarettes are devices that provide nicotine in aerosol form, usually by heating a mixture containing propylene glycol, nicotine and (in most cases) flavourings. E-cigarettes were originally designed with a view to providing nicotine in a familiar, cigarette-like form without the numerous toxic gases and particles produced by the incomplete combustion that occurs when cigarettes are smoked.

E-cigarettes are sometimes manufactured to physically resemble cigarettes, such as through the inclusion of a red LED at the tip of the device that turns on when the user draws a puff from the device, thus mimicking a lit cigarette. (The LED can also be other colours such as blue or green.) Such "cigalikes" can be disposable or rechargeable.

More recently, innovation has led to e-cigarette devices which are considerably larger than cigarettes and contain reservoirs for "e-liquid", the propylene glycol/nicotine mixture that the devices then heat to produce an inhalable aerosol. In some countries, these are frequently referred to as 'vapourisers' rather than electronic cigarettes.

1 The term "ENDS", while broader and more accurate than "e-cigarettes", is very rarely used outside the public health community. Users and manufacturers typically refer to e-cigarettes or "vapourisers".

Refillable devices add significant complexity to the regulation of e-cigarettes, as they can be, and frequently are, sold separately from the liquid. The devices themselves may thus not be subject to existing regulations on nicotine-containing products.

Areas of agreement

As mentioned in the WHO report, "ENDS are the subject of a public health dispute among bona fide tobacco-control advocates", with some seeing e-cigarettes as a potential technological response to the problem of tobacco use, some seeing them as a tobacco industry manoeuvre to re-invent themselves as partners of public health and re-normalise smoking, some seeing them as both, and some taking a variety of positions in between.

It is perhaps worth mentioning some of the areas on which, despite these disputes, there appears to be widespread agreement.

First, *e-cigarettes are almost certainly considerably less hazardous for individuals than cigarettes*. (As the WHO report puts it, "it is very likely that average ENDS use produces lower exposures to toxicants than combustible products.")

Second, *the population impact of e-cigarettes depends not just on the extent of this reduction in hazard, but also on the extent and impact of dual use, on the uptake of e-cigarettes by never-smokers, on the impact of e-cigarette use on continuing or prospective smokers, and on the impact on non-users*. (There is, however, widespread disagreement about the likelihood and impact of dual use, of use by never-smokers, or of the re-normalisation of smoking.)

Third, *because of the fragmentation and novelty of the e-cigarette market, which at a global level features thousands of brands and manufacturers, and the lack of quality controls and adherence to good manufacturing practices, there is wide variation in product characteristics, nicotine delivery, temperature to which the e-liquid is heated and other characteristics*. This makes it hard to draw definitive conclusions about safety, effectiveness as a substitute for cigarette products and even possible hazard to bystanders (e.g. via nicotine poisoning due to sale of e-liquid in non-child-proof containers). Studies on e-cigarette products are frequently several innovation cycles behind by the time they are published.

Regulatory approaches

Many Parties draw regulatory distinctions between tobacco products, pharmaceutical or therapeutic products and general consumer products (which are frequently subdivided into multiple other categories).

E-cigarettes can fall into any one of these categories, depending on the specifics of how national laws are drafted – and on the decisions taken by regulators. As detailed in paragraphs 30-32 of the WHO report, Parties vary widely in the approach they take to the classification of e-cigarettes.

As tobacco products. They contain nicotine, which is virtually always derived from tobacco products (including nicotine in pharmaceutical nicotine replacement products); they are frequently advertised in ways that recall tobacco advertising, i.e. as lifestyle-enhancing recreational devices; and, in some countries at least, tobacco companies have attempted to grab control of the e-cigarette market by buying up e-cigarette manufacturers or launching their own e-cigarette brands.

As therapeutic products*.* On the other hand, as mentioned, e-cigarettes were originally designed as a way to provide nicotine without the harmful by-products of tobacco combustion – exactly the same idea that underlies such pharmaceutical products as nicotine patches, nicotine gum, nicotine lozenges and nicotine inhalers. However, rarely have e-cigarette manufacturers applied for licences for their products as pharmaceuticals – although in the United Kingdom, regulators are now encouraging them to do so. The first cigalike nicotine product, which is a nicotine inhaler rather than an e-cigarette, has now been licensed as a therapeutic device, and an e-cigarette is currently going through the licensing process.

As general consumer products*.* Finally, unlike pharmaceutical nicotine products, e-cigarettes are generally not marketed as a temporary solution to help people quit smoking – they are clearly meant for long-term use, are frequently presented as being fun and enjoyable in their own right, and are sometimes also marketed as a "bridge" product, to be used by smokers where smoking is not allowed. Where e-cigarettes are classified as general consumer products, they are not subject to the type of regulations that apply either to tobacco products or to therapeutic products, although general product safety and liability rules apply; however to date there has been a lack of enforcement of these rules in many jurisdictions. In addition, e-cigarettes without nicotine are widely available and heavily promoted in some Parties.

In a category of their own. It is worth noting that regulators can also choose to create a new regulatory category for e-cigarettes, or classify individual products differently depending on how they are marketed and tested.

Prohibited products*.* Parties can also prohibit the sale and/or use of ENDS entirely – a choice which a number of countries have made, as the WHO report notes.

In FCA's view, it would not be possible to achieve a COP consensus on the regulatory classification of e-cigarettes. Parties' legal frameworks and regulatory traditions vary too widely, and there is wide and probably irreversible variation in Parties' decisions to date on how to classify these products.

Lack of uniformity on regulatory classification does not necessarily prevent Parties from agreeing on some broad principles, and even on some specific regulatory measures that might be implemented no matter what the regulatory framework.

Some principles

Like Parties, FCA member organisations vary considerably in their views and proposals on the regulation of e-cigarettes. We do, however, agree on some broad principles or concerns:

1. The global burden of death and disease from tobacco is primarily caused by smoking.
2. While quitting tobacco use is paramount, quitting nicotine use altogether is the best option.
3. For those unable to quit tobacco, switching to alternative sources of nicotine that are less harmful can reduce, often very substantially, the harm smoking causes to the individual.
4. The benefits of such an approach would be maximised if uptake were limited to existing smokers who are unable to quit.
5. The risks of such an approach would be minimised by taking measures to limit uptake by never-smokers, in particular amongst young people, to protect non-users, and to discourage long-term dual use.

6. There could be negative unintended consequences from over-regulation just as there could be from under-regulation.
7. The involvement of tobacco companies in the production and marketing of e-cigarettes is a matter of particular concern as there is an irreconcilable conflict of interest between those profiting from the sale of tobacco and public health.

Differences of opinion in the tobacco control community appear to stem largely from different estimates of the relative importance of principles 3-7.

Some see the risk of cigarette manufacturers being able to return to lifestyle advertising and rehabilitate their reputation – and by implication, that of their tobacco products – via clever cross-marketing with e-cigarettes – as being so large as to swamp the theoretical benefit from the movement to e-cigarettes of smokers who are unable to quit nicotine. Others think the health benefit for such smokers is large enough to trump such concerns – and believe that, at any rate, smokers will massively move to e-cigarettes if they are given clear information about these benefits.

Similarly, while there may be agreement in principle that e-cigarettes can be both over-regulated and under-regulated, there are wide differences in views on what constitutes excessive or insufficient regulation.

Moreover, in practice Parties differ widely in the resources and technical expertise they have at their disposal to deal with the e-cigarettes issue. A regulatory approach that might be appropriate in a high-resource setting – involving, say, extensive testing of products and surveillance of marketing practices – might be entirely impractical in a low-resource setting.

The way ahead

After discussing e-cigarettes already at two sessions of the COP, some Parties may be eager to reach agreement at COP6 on basic principles – or even on a subset of specific measures to regulate e-cigarette production, marketing and use.

In FCA's view, the principles we have outlined above could provide a starting point for reaching a consensus on principles.

With respect to reaching consensus on a specific subset of measures to regulate e-cigarettes, we are sceptical that this is feasible or advisable at present.

In the negotiations that led to the original FCTC, and in those that led to the development and adoption of guidelines on many of the articles of the Convention, Parties have rightly sought to codify and recommend those tobacco control interventions that have a strong evidence base and, in most cases, have already been implemented and evaluated in at least one, if not multiple jurisdictions. It was possible in these circumstances to reach consensus on best practice.

In the case of e-cigarettes, we are not convinced the evidence base or national experience exists to definitively recommend, at the global level, a detailed list of specific approaches to many of the complicated regulatory issues these products raise. Parties need to weigh the different regulatory principles involved and try what looks most promising in their own context.

But we are hopeful this will change in future, as Parties gather more experience and evidence.

In order to facilitate this future consensus, it is particularly important that COP6 agree on a mechanism for organised exchange of information. We would suggest some type of expert body to examine both new scientific evidence *and* lessons learnt from Party experience. This body should:

- Contain a mix of scientific experts (e.g. on toxicology, addiction, cessation treatment, marketing, behavioural research, etc.), people with regulatory expertise and people with extensive experience in tobacco control, including a good understanding of the tobacco industry;
- Include civil society representatives;
- Have access to relevant and up-to-date evidence (including, as needed, the possibility of exchanges with relevant Parties about their regulatory experience).

E-cigarettes present both a challenge and an opportunity to Parties, and it is clearly likely to take some time before a consensus is reached on the appropriate regulatory balance to strike. In the meantime, FCA encourages Parties to closely monitor use of e-cigarettes, developments in tobacco use prevalence, and the impact of various regulatory measures.