FRAMEWORK CONVENTION ALLIANCE

POLICY BRIEFING

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Fifth Session of the Conference of the Parties to the
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FCA Policy Briefing

Electronic Nicotine Delivery Systems (ENDS)

FCA recommendations

- Parties should, at a minimum, carefully monitor sales and promotion of ENDS in their respective national markets and report relevant findings to the COP;
- Parties should apply relevant legislation to ENDS with respect to regulatory approval, place of use, taxation and other issues;
- The issue of ENDS should not be referred to the Article 9/10 working group, but will likely need further discussion at future sessions of the COP.

Introduction

ENDS, or electronic cigarettes as they are commonly called,[1] are a relatively recent invention that has attracted considerable media attention in a number of countries. These devices, generally battery-powered, purport to deliver nicotine to the lung via vapour. (Indeed, e-cigarette users in some countries refer to themselves as "vapers".) The extent to which nicotine is actually absorbed via inhalation is unclear, as is the list of other ingredients that various brands of electronic cigarettes may contain.

As the Secretariat's report mentions, the ENDS market is evolving rapidly, with some analysts suggesting it could eventually rival cigarettes for market share.

ENDS have proved challenging to regulators in a number of ways:

1. They are clearly perceived by many users as being substantially less hazardous than cigarettes, and indeed it is plausible – but unproven – that this is the case;
2. One of the attractions of electronic cigarettes appears to be their superficial resemblance to cigarettes;
3. Manufacturers and retailers have generally not sought regulatory approval for their products, which are often marketed via the Internet;
4. Depending on a country's legal framework, electronic cigarettes may be considered a tobacco product or a combination therapeutic drug/medical device, or neither.

[1] Some electronic cigarettes are advertised as containing no nicotine, so the two terms are not exactly equivalent.

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Regulatory approaches to electronic cigarettes vary, as indicated in Annex 1 to the Secretariat's report. To give four examples:

- Brazil's regulatory agency, ANVISA, adopted a specific resolution[2] (= regulation) in 2009 banning the sale, importation and advertisement of "any electronic device for smoking", but the same resolution sets out rules for the potential approval of products (such as toxicological testing and proof of efficacy of any claims made);
- Canada's Department of Health issued a Notice to Stakeholders indicating that market authorization is required before importing, advertising, or selling electronic smoking products and an advisory warning people not to use electronic cigarettes, as none have been approved for use in Canada under the provision of the Food and Drugs Act.[3] By implication, this amounted to a classification of electronic cigarettes as unapproved drugs/medical devices. Manufacturers of electronic cigarettes can submit an application to the Department of Health for approval to sell in Canada, in the same way as manufacturers of nicotine gum and lozenges had to obtain pre-market approval.
- In the UK the medicines regulator (MHRA) carried out a consultation on e-cigarettes in 2010 and decided not to ban them because it did 'not want to see useful products removed from the market'. Further research is underway and a final decision on whether or not to regulate all nicotine-containing products under medicines legislation will not be made until spring 2013. In the interim, the MHRA committed to work with the electronic cigarette industry to develop a self regulatory code of practice to foster high standards of operation. [4]
- In the United States, the courts overturned an attempt by the US Food and Drug Administration (FDA) to regulate electronic cigarettes as drugs/medical devices. Instead, they have been ruled tobacco products, based on US legislative provisions, and the FDA has announced plans to regulate them on this basis.[5]

Considerations

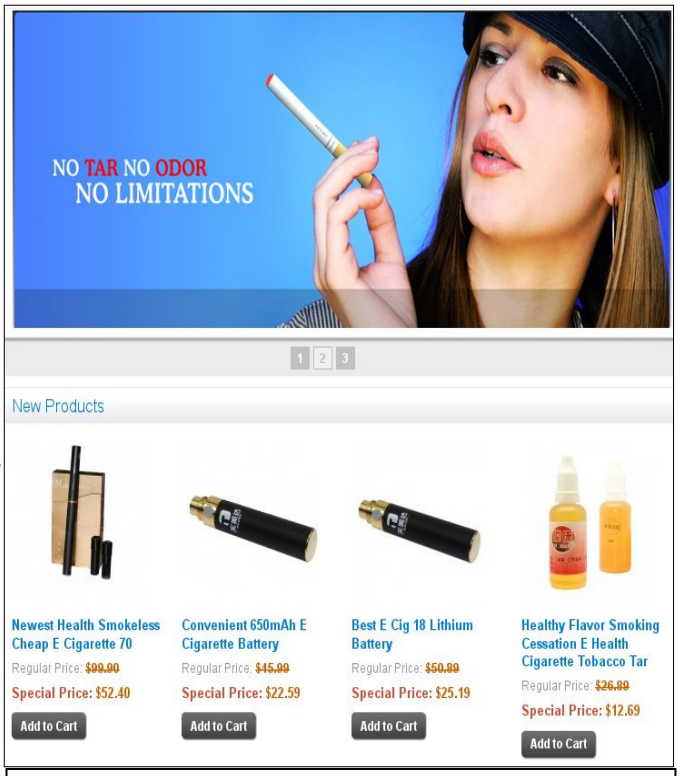
1. Product harmfulness

A recent review in the journal *Tobacco Control* commented:

> On the one hand, nicotine delivered by vapour with few known toxicants should theoretically carry relatively low risks, particularly when compared to cigarettes. The limited data available suggest that the products are not likely to approach the health hazards of cigarettes. However, on the other hand, significant concerns exist with the purity of ingredients employed, device functionality and quality control, the ease with which devices can be modified by users, and the general lack of oversight in manufacturing or marketing.[6]

[2] Resolução-RDC No 46, 28 August 2009. Available on-line at: http://tinyurl.com/8hfsn73.
[3] http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/2009_53-eng.php.
[4] http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617.
[5] US Food and Drug Administration. Regulation of E-cigarettes and Other Tobacco Products. On-line at: http://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm.
[6] O'Connor RJ. Non-cigarette tobacco products: what have we learnt and where are we headed? Tobacco Control 2012; 21:181-190.

This captures the problem well. It is very likely that ENDS are substantially less hazardous than conventional cigarettes, and one could well imagine that a major shift from the conventional to the electronic product would have a considerable public health benefit. On the other hand, in the absence of testing and regulatory oversight, there is no way to know this for sure – and of course there are various scenarios under which electronic cigarettes could actually increase harm to users. (e.g. if used by non-smokers, or to prevent quitting.)



A typical web advertisement for e-cigarettes

2. Marketing

ENDS are frequently promoted via the Internet or, in some countries, through promotional booths (for example in shopping centres). In some countries, there are also extensive online "vaping" communities[7]; it is not clear whether these groups receive funding from e-cigarette manufacturers. Some sites focus on reviewing particular models of electronic cigarettes, while others have a more political agenda, involving the legal status of electronic cigarettes (such as whether they can be used where smoking is prohibited).

Advertisements for electronic cigarettes generally emphasize a number of benefits over conventional cigarettes – such as lack of smoke odour, ability to use where smoking is prohibited and no exposure to "harmful chemicals" for bystanders. Some advertising explicitly claims that electronic cigarettes are less hazardous than cigarettes, or are an effective means of quitting smoking. In the public health community, one concern about ENDS is their potential for counteracting the denormalizing effect of tobacco-control interventions, for example, by making it possible to "smoke" (or at least: "e-smoke") in smoke-free areas.

Electronic cigarettes have been sold in a variety of flavours.

At present, the ENDS market is quite fragmented, with multiple small manufacturers and vendors competing for attention. Major tobacco companies have, in the past, developed their own products that heated rather than burnt tobacco (most notably RJR, with its Premier product, which was launched unsuccessfully in 1988.) Several tobacco companies have signalled their intention to launch new products of this type, possibly using existing cigarette brand names.[8] In the US, in April 2012, tobacco company Lorillard purchased a US electronic cigarette company.[9]

[7] For example: http://www.e-cigarette-forum.com, www.vapersforum.com.
[8] Thompson C and Wembridge M. Big Tobacco Push for Cigarette Alternatives. Financial Times, 12 August 2012.
[9] Lorillard Inc., "Lorillard, Inc. Reports First Quarter 2012 Results and Acquisition of blu ecigs" April 25, 2012. http://investors.lorillard.com/phoenix.zhtml?c=134955&p=irol-newsArticle&ID=1687024&highlight=.

3. Regulatory systems

For a number of years, several observers have highlighted the need for better integration or co-ordination of regulatory approaches to tobacco products and to pharmaceutical nicotine products. Pharmaceutical products are subject to extensive testing, rules about allowable therapeutic claims and various advertising and marketing restrictions. Tobacco products are generally exempt from any health-based testing (that is, they are not required to be below a certain level of risk to be authorized for sale); in most countries there are few regulations about location of sale; and advertising and marketing rules vary depending on Parties' success in implementing FCTC Article 13. It is at least arguable that governments should co-regulate these types of products, particularly in the case of countries that have approved pharmaceutical nicotine for long-term use. For example, in 2002, the Royal College of Physicians of London published a report calling for a unified regulatory authority for tobacco and nicotine products.[10]

In the way they are designed and marketed, ENDS straddle the line between tobacco products and pharmaceutical nicotine. They promise "safe" (or at least safer) delivery of nicotine, like nicotine gum or patches. On the other hand, they are designed to look like cigarettes and are presented as "recreational" products rather than medicines. To date, they have not been submitted for regulatory approval, although that could well change as larger companies become involved in this market segment.

The WHO Study Group on Tobacco Product Regulation recommended in 2010 that ENDS should be "regulated as combination drugs and medical devices and not as tobacco products".[11] This may well be the logical approach in many Parties' legal frameworks. However, Parties may also wish to take the opportunity to undertake a review of their regulatory structures around tobacco and nicotine products. For example, the EU is currently in the process of revising its Tobacco Products Directive and it is understood that regulation of e-cigarettes is one of the issues under consideration.[12]

a) The applicability of the WHO Framework Convention on Tobacco Control

In its report to COP4, the Article 9/10 working group invited the Conference of the Parties to "indicate whether it agrees that electronic nicotine delivery systems are to be considered 'tobacco products' and should be part of future work of the working group."

FCA continues to recommend that the COP <u>not</u> take a position on the specific issue of whether ENDS are tobacco products. As the Secretariat's report indicates, Party practice differs, with some Parties treating electronic cigarettes as drugs/medical devices and others as tobacco products. As this issue is likely to be subject to litigation in a number of Parties over the coming years, a COP finding could be unhelpful. Moreover, given rapid developments in both technology and marketing strategies, preserving flexibility would be prudent.

10 Royal College of Physicians of London. Protecting Smokers, Saving Lives: the case for a tobacco and nicotine regulatory authority. 2002. On-line at: http://www.rcplondon.ac.uk/publications/protecting-smokers-saving-lives.

11 WHO Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: third report of a WHO study group. 2010.

12 http://www.theparliament.com/latest-news/article/newsarticle/eu-moves-towards-plain-packaging-for-tobacco-products/.

Conclusion

FCA encourages individual Parties, at a minimum, to monitor their national markets carefully with respect to sales and promotions of electronic nicotine delivery devices, and to provide relevant information in their reports to the COP, particularly with respect to cross-border (e.g. Internet-based) trade.

In accordance with their particular regulatory framework, Parties should decide whether ENDS are classified as tobacco products or drugs/medical devices, and apply relevant legislation on regulatory approval, place of use, taxation and other issues. Parties should also consider whether this framework requires overhaul.

FCA recommends against referring the issue of ENDS to the Article 9/10 working group. In our view, as we stated at COP4, regulatory difficulties surrounding electronic cigarettes have little to do with Article 9 (which deals with the regulation of contents and emissions of tobacco products) or with Article 10 (which deals with tobacco product disclosures).