E-cigarettes are unregulated, right?

written by Clive Bates | 15 April 2013

When the UK Medicines Regulator (MHRA) consulted in 2010 on whether e-cigarettes should be regulated as medicines, it gave three options: I summarise the first two and quote the third:

Option 1. Regulate as medicines and withdraw unlicensed products in 21 days

Option 2. Regulate as medicines and withdraw unlicensed products in a year (June 2011)

Option 3. *"Do nothing and allow these unregulated products containing nicotine that have not been assessed for safety, quality and efficacy to remain on the market."* [emphasis mine]

See what they did there…? It's either medicines regulation or 'unregulated'. We call this framing bias – and they were rightly criticised for it. But the idea persists that e-cigs are unregulated, and it is the reason why some people think they should be regulated as medicines. In reality, there is very little in the European Union that is 'unregulated'. Most products fall under general consumer protection legislation. Here is a selection of the key EU directives and regulations that already apply (or could be applied) to e-cigarettes and other non-medicinal nicotine containing products:

General safety

General Product Safety Directive 2001/95/EC

The RAPEX system – notification and alerts of dangerous products

Technical Standardisation under Regulation 1025/2012 and related legislation (an option not so far used, but could be used to set performance or design standards)

Packaging and labelling

Dangerous Substances Directive 67/548/EEC

Dangerous Preparations Directive 99/45/EC
Classification, Labelling and Packaging of Substances and Mixtures – the CLP Regulation 1272/2008 applies from 2015.

Chemical safety
Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) 1907/2006

Electrical safety
Low Voltage Directive 2006/95/EC
Electro-Magnetic Compatibility Directive 2004/108/EC
Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU (where appropriate)
Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU
Batteries Directive 2006/66/EC

Weights and measures
Making-up by weight or by volume of certain prepackaged products – Directive 76/211/EEC
Nominal Quantities for Prepacked Products Directive 2007/45/EC

Commercial practice
Sale of consumer goods and associated guarantees 99/44/EC
Distance Selling Directive 97/7/EC
Directive on Electronic Commerce 2000/31/EC
Misleading and Comparative Advertising Directive 2006/114/EC
Unfair Commercial Practices Directive 2005/29/EC

Data protection
Protection of Personal Data – Directive 95/46/EC

(with thanks to ECITA)

What the consumer protection framework doesn't do

- **Therapeutic claims.** It does not validate a therapeutic (ie. health) claim, such as "relieves nicotine withdrawal symptoms" or "prevents cancer". Asserting that using an e-cigarette is an alternative to smoking cigarettes is not therapeutic – see my briefing: *Are e-cigarettes medicines?*. It's a

competitive claim about product utility that says nothing about benefits to health, or modification of physiology (the two reasons to class a product as a medicine). In fact surveys show that smokers are often motivated to switch for other reasons (cost, odour nuisance, social etc) as for perceived benefits for long term health. Companies that wish to make therapeutic claims should be able to apply for a marketing authorisation under the Medicines Directive 2001/83/EC – but that should be an option, and it certainly has potential benefits for vendors willing to go through the process. Companies that wish to make competitive claims need to be able justify them as a fair marketing practice, as with any other claim for any other product. [*note this para updated 16 April 2013*]

- **Guarantee a certain nicotine hit**. It does not require proof that an e-cigarette will deliver a certain quantity of nicotine to the body at a certain speed (ie. validate the so-called "pharmacokinetics"). Some commentators believe it should be mandatory to class them as medicines so they can prove they are adequately potent alternative nicotine delivery devices to rival cigarettes. If vendors believe this to be important and wish to communicate that to the customer, they can simply make a factual evidence-based claim about the product – the consumer is protected by Unfair Commercial Practices Directive (2005/29/EC). If such claims were to be regulated or standardised, it would be better to develop technical standards under consumer protection legislation using Directive 98/34/EC for this.
- **Second guess consumer preferences.** It does not guarantee that people will like the products and switch over from smoking. We normally allow consumer preferences, trial and error, producer innovation, pricing, fair marketing practices, user feedback and third party commentary (ie market forces) to sort out which products consumers will choose, and so which ultimately succeed in the market. Unless their health is at risk or there are unfair practices, consumers do not need so much protection that they have their choices made for them by a regulator – and that is not a good principle for developing the single market.

What now?

- We should ask: if medicines regulation is the answer, what was the question? What problem or opportunity do we have and how will

regulating as a medicine address it? Does that problem need to be solved by a regulator or by consumer preference? Is there an easier lighter touch way of doing it in consumer regulation?

- The Commission could produce guidance on the application of existing EU consumer protection legislation as it applies to nicotine containing products.
- Where specific standards may be justified – ie for contaminants in e-liquids – a standard can be set.
- The Commission should be asked to conduct a detailed study of the evolving nicotine market and assess whether additional legislative measures are necessary – either with specific decisions and standards under consumer protection legislation, or with a purpose built regulatory framework of the type developed for cosmetics (another product that does not fall neatly into any other category).