Game on: MEPs slug it out on regulation of e-cigarettes

written by Clive Bates | 3 September 2013

An exchange of letters between members of the critical centre-right political grouping (European People's Party) is very revealing. First is from Karl-Heinz Florenz, the German MEP with a close relationship with the anti-e-cigarette lobbyists in Brussels and Germany. Then a response from Fabrizio Bertot MEP an influential Italian MEP. Updated 5 Sept: a letter from e-cigarette vendor Zandera taking up some of Florenz's points.

30 August 2013

Dear colleagues,

on 10 July 2013, the ENVI committee voted that all nicotine-containing products (NCPs) should be treated as medicinal products. Nicotine replacement therapies (NRTs), such as nicotine patches or chewing gum, are regulated under Directive 2001/83/EC already today. The same provisions as for NRTs should now apply to E-cigarettes which are also nicotine-containing products. Also the European Commission and the Council are in favour of regulating them under the pharmaceutical legislation above a certain nicotine threshold.

I believe that we need to ensure that e-cigarettes are produced and marketed in line with public health goals and that they are safe for consumers.

We have discussed this issue for many months and at several occasions and heard from leading experts at the workshop in the European Parliament on 7 May 2013 (see http://www.europarl.europa.eu/ep-live/de/committees/video?event=20130507-1230-COMMITTEE-ENVI). The aim is not and has never been to ban e-cigarettes,

sell them only in pharmacies or have them prescribed by a doctor.

Alternative forms of delivering the drug nicotine that are less toxic than tobacco should be welcomed. However, all forms of nicotine, including e-cigarettes, must be properly regulated to ensure that they meet appropriate standards of safety, quality and efficacy.

Why do we need to regulate e-cigarettes:

· ***Growing market**: E-cigarettes are a booming market in the EU with entry of new players, big advertising campaigns and new shops selling these products.*

· ***No clear legislative framework**: These products currently fall under the General Product Safety Directive designed for basic consumer products such as furniture. This is not reassuring in terms of safety for e-cigarettes, which contain nicotine, an addictive and toxic drug. There is potential for accidental misuse or abuse resulting from poor control of product labelling and for poor dosing information and use at excessive levels.*

· ***Internal market issue**: There are significant discrepancies in the regulation of e-cigarettes in the member states. There is little legal certainty but a need for a level playing field. We cannot continue to subject different nicotine-containing products – nicotine replacement therapies (e.g. nicotine patches) on the one hand and e-cigarettes on the other hand – to different regulatory regimes, although they have the same features. This would be a breach of the equal treatment principle.*

· ***Serious concerns of the WHO and EU regarding the health and safety risks**: The WHO strongly advices consumers on its Web site not to use electronic cigarettes until they are deemed safe and effective and of acceptable quality by a competent national regulatory body (seehttp://www.who.int/tobacco/communications/statements/eletronic_cigarettes/en/index.html). The UK Medicines and Healthcare Products Regulatory Agency (MHRA), for example, concluded in a June 2013 report that NCPs currently on the market do not meet appropriate standards of safety, quality and efficacy. The UK will thus regulate e-cigarettes as medicines.*

· ***Limited data**: Studies demonstrate huge variations in nicotine content*

levels, including nicotine found in e-cigarettes labeled as nicotine-free. There is a need for good manufacturing practices and to confirm the efficacy of the products. Long-term studies on the health effects of e-cigarettes are missing given the novelty of the products.

· ***Underage use**: There is a worrying trend that young people are using e-cigarettes at an early age because it is "fashionable" or "cool". Studies carried out in Poland, Hungary and France showed that non-smoking children experimented with e-cigarettes. 13% of 13-15 years olds have, for example, used e-cigarettes in Hungary. These products can be a gateway for nicotine addiction. We need to combat nicotine addiction, not promote it.*

· ***Inappropriate marketing practices**: Non-smokers may be attracted to use nicotine as e-cigarettes are positioned for "lifestyle" use. We need to establish the application of marketing practices that mitigate the risk of non-tobacco nicotine products becoming a gateway to tobacco products and of the establishment of a "nicotine market" in parallel to the "tobacco market".*

Why is pharmaceutical legislation the most appropriate solution for e-cigarettes:

· ***Legal certainty**: The EU and its member states have a great deal of pharmaceutical legislation experience. We have existing administrative structures. We have guidance which is tried and tested. The level of legal certainty we will achieve through this type of regulation will be much greater than any other type.*

· *Medicines regulation has been proven **to ensure the quality, safety, and purity** of drugs.*

· *Medicines regulation allows **actionable surveillance** if problems are uncovered.*

This approach ensures that consumers will have confidence that e-cigarettes are safe and effective and are marketed in a way that supports and advances public health rather than encouraging new nicotine users.

However, this approach is often criticized due to the fact that pharmaceuticals can only be sold in pharmacies in some member states, for example in

Germany. In these countries, e-cigarettes would then be less available than normal tobacco cigarettes. The distribution of pharmaceuticals is regulated in the member states and a matter of subsidiarity, which we cannot change in the tobacco products directive. 18 member states, however, allow that pharmaceuticals can be sold outside pharmacies (e.g. in supermarkets or drugstores).

I hope the information above provides you with more clarity why a regulation of e-cigarettes is necessary and why e-cigarettes should fall under the pharmaceutical legislation.

If you have further questions, please do not hesitate to contact me or my office.

Best regards,

Karl-Heinz
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Now the response from Fabrizio Bertot MEP, which was sent earlier today (3 Sept) as a response to Florenz copied to all members of the EPP – both letters are now circulating widely in Brussels.

Hi dear Karl-Heinz,

After having read with attention your mail, I would like to express some considerations.

As everyone in the European Parliament, we find the deaths of 700,000 Europeans each year from smoking unacceptable, and there is broad agreement that we should reduce smoking as much and as quickly as possible.

However, I disagree that regulating e-cigarettes as medicines as you recommended would help. In fact it would work against public health, protect the cigarette industry and severely damage a dynamic and disruptive new industry.
I would like to ask you to consider the following:

– E-cigarette use is growing very rapidly for a good reason: after years of smoking many users have found a new product that provide a satisfactory substitute for smoking (maybe in public places where national legislations allow it) but present around 99% less risk to health and present no risk to people around them.

– We should not make the wrong comparisons. E-cigarettes are not medicines competing with NRT patch and gum for someone trying to quit smoking. They are competing with cigarettes to provide a satisfying way of taking nicotine but with a tiny fraction of the health risk.

– The General Product Safety Directive is not only designed for household goods, it creates a general duty to ensure safety for all products placed on the EU market. There are in fact at least 17 directives, decisions and regulations on e-cigarettes: too much I suppose.

– We know beyond any doubts that e-cigarettes are much less toxic. There have been reports of toxins found in e-cigarettes, but these are at extremely low levels and also found in NRT and many foods. Nicotine itself is addictive, but has a health risk profile similar to caffeine; as you know, I'm not a smoker, but don't ask me to go in pharmacies for having a coffee twice a day…

– Those proposing medicines regulation have not explained in detail which are the impacts. Actually, it would be extremely damaging to the e-cigarettes market and industry.

The effect would be:

– Remove the vast majority of the existing products from the market, because the costs and complexity of securing medicines marketing authorizations would be too great. The Commission has argued that medicines regulators would not permit flavors, yet these are vitally important to appeal the smokers.

– Overwhelm most of the small and medium enterprises involved in e-cigarettes production. By requiring pharmaceutical grade facilities and processes for manufacturing and distribution, most of the existing supply chain would be scrapped and large investments needed. Only large firms – primarily those entering the market from the tobacco industry – would have the deep pockets to rebuild the supply chain from scratch.

– Impose many regulatory burdens that do not apply to their primary competitors, the cigarettes makers. For example, pharmacokinetic testing and pharmacovigilance.

– In many member states classification as a medicine would mean that e-cigarettes could be sold only in pharmacies or limited retail settings where medicines are sold. It makes no sense to make the much safer products available in fewer places and at limited times compared to cigarettes.

– While medicines regulation will not create a general ban, many users will experience a ban on the products they are using.

– This directive is an internal market measure. But I cannot see how making much easier to sell cigarettes (Article 17) makes any sense. Why should it be easier to sell nicotine simply because it is sold in the form of cigarettes? In fact Article 17 on novel tobacco products should provide a proportionate and non-discriminatory basis for disclosure on e-cigarettes, along with the other generally applicable regulations mentioned earlier.

– Of course safeguards are necessary to protect children: member states and the industry itself should do what is necessary. But while cigarettes are widely available, why should we impose excessive and counterproductive limitations on

much safer products? Tobacco shops are a highly regulated distribution network that strictly contains the selling of tobacco products to young consumers. By this way, it would be better to give each Member States the choice to regulate the selling of e-cigarettes according to the sales network of tobacco products.

– We should also consider the fiscal treatment. In ItalyInizio modulo
In Italy e-cigarettes are subject to the same excise rate (58.5 per cent) of traditional tobacco products, and therefore are also identified as such by the consumer.

– Definitively, e-cigarettes containing nicotine are nothing else but a substitute of traditional cigarettes, made also, but not only, for help smokers to quit smoking. They are not a medicine at all. So I think that we should leave to the tobacco shops the possibility to sell both traditional and e- cigarettes. Finding in the same place the two products, could also suggest to the smokers to switch from traditional, and dangerous, cigarettes to much safer e-cigarettes

Best regards

Fabrizio Bertot

The only thing that I could clarify on this is that Article 17 refers to 'novel tobacco products' not cigarettes. But it is interesting he focusses on this, because Article 17 makes it much easier to place a novel nicotine product on the market if it contains tobacco than if it contains no tobacco. Absurd!!

Updated 5 September: a letter from the e-cigarette vendor Zandera to all MEPs following up on Florenz' points.

Dear MEP,

You may have seen that Karl Heinz Florenz has been criticised by Fabrizio Bertot over his support for medicinal regulation of e-cigarettes. Here are 3 issues which you may want to raise with Mr Florenz:

1. The Safety of E-Cigarettes

Karl-Heinz Florenz does not quote a single academic study to support his view that safety issues justify medicinal regulation of e-cigarettes. You might ask him

to give his thoughts on the following:

- *Drexel University, August 2013: "the study released today confirms that chemicals in e-cigarettes pose no health concern for users or bystanders"*
- *Hajek, Lancet, July 2013: "the chemicals that make cigarettes dangerous are either absent or present only in trace concentrations"*
- *Inhalation Toxicology, October, 2012: "the study indicates no apparent risk to human health from e-cigarette emissions"*
- *Professor Robert West of University College London: "the risk is negligible, and compared with smoking there is no contest"*
- *Professor John Britton of the Royal College of Physicians: "if all the smokers in Britain stopped smoking cigarettes and started smoking e-cigarettes we would save 5 million deaths"*

2. Equal Treatment for E-Cigarettes

Karl-Heinz Florenz calls for "a level playing field" between e-cigarettes and the nicotine replacement therapy (NRT) products like the gum and patches produced by pharmaceutical companies. But the "playing field" e-cigarettes compete on is against tobacco cigarettes. And financial experts say e-cigarettes are winning:

- *EU Sales in 2012: e-cigarettes replaced the equivalent of over 2.5 billion tobacco cigarettes across the EU (based on the Commission's figures)*
- *Wells Fargo, January 2013: within 10 years there could be more e-cigarette users than tobacco smokers*
- *The Guardian Newspaper, 9 July 2013: shares in British American Tobacco and Imperial Tobacco are downgraded because e-cigarettes are reducing cigarette sales*
- *Goldman Sachs, August 2013: e-cigarettes are a key disruptive technology undermining tobacco companies' business model*

There is no evidence that NRT products, introduced 30 years ago, have reduced cigarette sales. One of the reasons e-cigarettes have been so successful is because their regulation has been light enough to allow innovation. By contrast medicinal regulation has been so expensive for pharmaceutical companies that

it has stopped them from innovating their nicotine products: "NRT products represent a classic example of the stifling effect of medicinal regulation. There have been no major improvements since they were introduced" Hajek, Lancet, July 2013.

3. Legal Certainty

Karl-Heinz Florenz says that medicinal regulation of e-cigarettes would provide legal certainty. Yet the classification of e-cigarettes as medicines has already been rejected by four courts in the EU. In addition, a former Advocate-General to the European Court of Justice, Sir Francis Jacobs, said in July 2013 that medicinal regulation is "a very extreme and intrusive form of regulation" that is likely to be annulled.

Let me be transparent. I work for the UK e-cigarette company Zandera Ltd which supports the creation of a regulatory framework for product quality & safety across the EU. Has Karl Heinz Florenz been transparent with you?

Kind regards,
Charles Hamshaw-Thomas