From: Richard Hyslop [richard@endeavourpublicaffairs.co.uk]
Sent: 27 June 2013 23:55
To: "Undisclosed-Recipient:;"@ham03.websitewelcome.com
Subject: Why regulating electronic cigarettes as a medicinal product actually constitutes a ban
Attachments: Why regulating electronic cigarettes as a medicinal product actually constitutes a ban.pdf

Dear ENVI committee member,

Please find attached a one page briefing paper that very clearly sets out why our client, Totally Wicked Ltd, concludes that regulating electronic cigarettes as a medicinal product actually constitutes a ban, a position supported by the European Parliaments own Legal Affairs committee.

We hope that you will take the time to read this short briefing which is based on significant experience in the electronic cigarette industry, legal advice, and a relevant case study.

If you have any questions please do not hesitate to contact us.

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Why regulating electronic cigarettes as a medicinal product actually constitutes a ban

Officials in the European Commission, health ministers in Council, and MEPs in the European Parliament strenuously deny that they plan to ban e-cigarettes. They state they only plan to regulate them "appropriately".

Regulating e-cigarettes as a medicinal product is effectively imposing a ban:

Medicines regulation adds costs, imposes burdens, applies restrictions, and holds back innovation. It creates a default prohibition and requirement for approval before products can be sold. The time and cost it would take to achieve approval would drive many e-cigarette manufacturers out of business and would leave cigarettes, with their proven dangers, as the only easily marketed source of nicotine.

The European Parliament's own Legal Affairs Committee makes this clear, "Article 18 of the proposal prohibits nicotine-containing products (NCP) such as e-cigarettes containing a certain nicotine level if they are not authorised pursuant to Directive 2001/83/EC (the Medicinal Products Directive). It is, however, quite unclear if these products (*which are much less harmful than tobacco products*) even fall under the scope of the Medicinal Products Directive. For products which do not fall under the Directive, this would effectively constitute a ban. Banning products which are less harmful than tobacco products and which can be a means of smoking cessation is certainly not in line with the public health aims of the proposal."

On 21 June 2013, EU health ministers agreed that e-cigarettes containing one milligram (mg) of nicotine or more would be classified as medicinal products requiring EU marketing approval. However, a typical smoker, smoking 20 cigarettes a day, is likely to need between 18 to 24 milligrams of nicotine per millilitre for an electronic cigarette to offer a plausible alternative to conventional tobacco products. The market effect of the health ministers' proposal would be that consumers would be denied the choice which is currently available and without any intervention is rapidly transforming the smoking demographic to a significantly safer alternative in the electronic cigarette.

Consider the facts:

There are at least 5,000 different e-cigarettes on the market at present, the majority being refill variants. The entry into force of licensing will reduce this to zero. Licenses are extremely restricted in their applicability. There is no possibility of a single license for several products. Based on the experience of Intellicig, which is owned by British American Tobacco, each single product will take at least three years and at least £2 million to achieve a license for.

Case study – Intellicig

Intellicig is currently the only UK electronic cigarette manufacturer that has sought to have its product licensed as a medicinal product. Intellicig has grossly underestimated the costs and timescale, and has had to modify its time plan by a factor of two (the initial estimate was less than two years), and its cost estimates by a factor of 20 (the initial budget was £95,000), and it is not over yet. Despite having spent £2 million and taken three years, intellicig is still arguably no closer to getting a license than it was three years ago.

If the EU imposes pharmaceutical licensing, legal e-cigarette sales will end. This will leave tobacco cigarettes as the only freely available, yet deadly source of recreational nicotine. Safe e-cigarette nicotine delivery will be left behind a restricted access medicinal regulation regime, offering unattractive products at inflated prices and significantly reducing the usage of a product that is saving thousands of lives every day. It is estimated that compared to the current market, medicinal regulation would mean that in the next five years, perhaps one or two e-cigarette products may become available. These would only be available via a pharmacy and, to enable the manufacturer to recoup licensing costs, would cost approximately £30-£40 per single unit, putting them significantly beyond the reach of the average smoker.

Classifying e-cigarettes as a medicinal product only benefits the tobacco and pharmaceutical industries. The European smoker will continue to die through the lack of any easily available safe alternative to the cigarette.

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