Department of Health

Department for Business Innovation & Skills

From George Freeman MP
Minister for Life Sciences

Freeman.MPST@bis.gsi.gov.uk

Mr A Walker
Senior Coroner
North London Coroner's Court
29 Wood Street
Barnet EN5 4BE

13 August 2015

Dear Mr Walker,

Thank you for your letter of 10 June 2015 following the inquest into the death of Arti Lakhani. I was very sorry to hear of Miss Lakhani's death and wish to extend my sincere condolences to her family.

You report that Miss Lakhani died after drinking a bottle of e-cigarette fluid. Your concern is that the sale of e-cigarette fluid is not regulated or licensed.

There is no doubt that the use of e-cigarettes has increased rapidly since their introduction. 5.5% of the adult population of England used an e-cigarette in the first quarter of 2015, indicating a marked rise from 0.5% in 2011. This measure of use is taken from the Smoking Toolkit Study, compiled from four survey questions and assesses current use for any reason. A very similar estimate is obtained for Great Britain (GB) using the 2015 Action on Smoking and Health (ASH) survey, with 5.4% of the population estimated to be current (defined as people who have tried e-cigarettes and still use them, see Appendix B) e-cigarettes users. This translates to about 2.6 million e-cigarette users in GB in 2015. The ASH survey also assessed trial use and about 17% of the adult GB population was estimated to have tried e-cigarettes.

Enquiries to the National Poisons Information Service (NPIS) about e-cigarettes and their refill solutions have also increased over the same period. A total of 204 enquiries were received by NPIS in 2014, more than the total number of enquiries about these products in the previous six years. 22% of the enquiries involved children aged under five and the majority of exposures (162 of 204) were accidental. Twenty-one enquiries concerned intentional overdoses and the remainder of enquiries included adverse reactions to intended use, recreational abuse and 'therapeutic errors'. Where the individual route of exposure was specified, ingestion was the commonest, although multiple routes of exposure also occur.

Where the clinical features were known at the time of the enquiry, 103 patients had no features of toxicity and 94 had features of only mild toxicity (four were unknown). Two patients had moderate toxicity (one aged 13 months), while another had severe toxicity and was treated in an intensive care unit. Features of toxicity included conjunctivitis, irritation of the oral cavity, anxiety, vomiting, hyperventilation and changes in heart rate.

Since 2011 a small number (21) of reports of harm have been submitted on e-cigarettes through the Medicines and Healthcare Regulatory Agency (MHRA) Yellow Card scheme. This scheme allows patients and health professionals to report adverse events associated with medicines and medical devices. Adverse events reported included pulmonary fibroses, cardiac problems, gastro-intestinal upset, oropharangeal pain and swelling, headache, convulsions and allergic response. Whilst these do not relate to licensed medicinal products, and therefore fall outside of the MHRA's current jurisdiction they have nevertheless been retained within the Sentinel Adverse Drug Reactions (ADR) reporting system for tracking purposes. No assessment of these reports has been made as to possible causal association with the product and no action has been taken as a consequence.

Whilst e-cigarettes are a fairly new product to the mass market there are several generic pieces of existing consumer product legislation that apply to them including:

- The General Product Safety Regulations (2005)
  http://www.legislation.gov.uk/uksi/2005/1803/pdfs/uksi_20051803_en.pdf
  These Regulations impose requirements concerning the safety of products intended for consumers or which are likely to be used by consumers. They require that only safe products are placed on the market and that producers inform customers about the risks of products and to monitor the risks their products pose. Distributers are required to act with due care so as not to supply unsafe products and to co-operate in monitoring the safety of products. Both producers and distributors are required to notify an enforcement authority if a product placed on the market poses risks that are incompatible with the general product safety requirement.

- Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures;
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF

- The Biocidal Product and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (SI 2013/1506).

  These Regulations require manufacturers etc. to classify, label and package hazardous chemicals before placing them on the market so that consumers and other users are informed of the hazards posed and the necessary protective measures that should be taken.

- The Plugs and Sockets etc. (Safety) Regulations (1994) http://www.legislation.gov.uk/uksi/1994/1768/contents/made

- The Batteries and Accumulators (Placing on the Market) Regulations (2008) http://www.legislation.gov.uk/uksi/2008/2164/pdfs/uksi_20082164_en.pdf

  These two sets of Regulations set out additional electrical safety requirements.

There is also an EU wide system (RAPEX) to alert enforcement officers and the trade to any products that do not meet existing product safety requirements and the actions that have been taken by the manufacturers/importers to rectify the problem.

http://ec.europa.eu/consumers/safety/rapex/alerts/main/index.cfm?event=main.search

In addition, in England, the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 were laid at the end of the last Parliament. From 1 October 2015 these will restrict the sale of e-cigarettes and e-liquid refills to those over the age of 18 and to prohibit their purchase by an adult on a minor's behalf .

Further regulation of e-cigarettes and e-liquids is planned. In April 2014 the EU published new rules, which are set out in Directive 2014/40/EC.

http://ec.europa.eu/health/tobacco/docs/dir_201440_en.pdf

The UK is in the process of implementing these rules. They will apply from 20 May 2016.

The new legislation will include a number of new product specific provisions on safety, quality, ingredients, labelling and advertising of e-cigarettes sold as

consumer products and not as quitting aids (medicines), as well as refill mechanisms (e-liquid refills).

Under the new legislation nicotine containing liquids for consumer products must contain no more than 20mg/ml of nicotine and there will be a restriction on the refill containers of 10 ml. Products with higher strengths will be prohibited, unless they make a medicinal claim and are licensed as medicines. In addition refill containers will be required to be packaged in child resistant containers, which also include tamper evident features. These must also meet certain criteria that will reduce the chances of spillage and contact with the nicotine liquid when refilling the tank of any e-cigarette device. These provisions in particular are aimed at reducing accidental contact and/or consumption.

The Directive also sets out requirements as to the information that must accompany electronic cigarettes/refills or form part of their packaging. This includes information on the nicotine content of the liquid, categories of consumers that are not recommended to use the products, information on possible adverse reactions and contraindications and a mandatory health warning: 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'.

Further the Directive will require mandatory notification to the competent authority of a range of product information 6 months in advance of placing them on the UK market. This will improve Government's understanding of the market: improving its ability to monitor, over time, the development of the market and any adverse consequences of consumption.

Finally, the Directive provisions will introduce new restrictions on advertising and promoting these products on TV and radio, in the press or through association by sponsoring large sporting or music events. The aim of these restrictions is to contribute to shaping the environment in which these products are marketed, so that advertising is targeted only at smokers without wider spread promotion and take up by children and non-smokers.

Products with higher strengths of nicotine than 20mg/ml and which make medicinal claims can still be marketed but will need to take the medicinal licence route to market. E-cigarettes licensed as medicines by the Medicines and Healthcare products Regulatory Agency in the UK will be subject to the robust medicines regime. Licensed medicines are subject to separate regulatory rules that cover the safety, quality and efficacy of the products along with other aspects such as advertising, product presentation, post-marketing surveillance, to whom medicines can be supplied, and other aspects relating to their sale and supply.

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There are existing controls on product safety in place which cover e-cigarettes and refill containers. Existing legislation will be supplemented by a product specific regime for e-cigarettes and refills, sold as consumer products, that will be introduced from May 2016. Together, these provide a robust set of rules and should mitigate the risks of inadvertent contact and accidental poisoning from the use of these products. However, it should be recognised that no regulatory regime can protect fully against misuse of products.

I hope that you find this reply helpful and I am grateful to you for bringing the circumstances of Miss Lakhani's death to my attention.

Yours sincerely,

George Freeman.

GEORGE FREEMAN