

**PE1774/B**

UK Government submission 27 February 2020

Thank you for your correspondence of 23 January 2020 regarding petition PE1774. The Parliamentary Under Secretary of State for Prevention has asked me to reply on her behalf.

Although not risk free, research shows e-cigarettes are effective in helping smokers quit. The Government welcomes the development of products that have the potential to reduce the harm of tobacco while consistently highlighting that quitting smoking and nicotine use completely is the best way to improve health.

In the UK, e-cigarettes are highly regulated under the Tobacco and Related Products Regulations 2016 (TRPR) and The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 (England) (Wales). The regulations aim to reduce the risk of harm to children; to protect against any risk of renormalisation of tobacco use; and to provide assurance on relative safety for users. Regulations also include restrictions to mainstream TV and radio advertising, prevention of sale to under 18s and limits to both tank sizes and nicotine content of these products.

The TRPR came into force on 20 May 2016 at which time the Medicines and Healthcare products Regulatory Agency (MHRA) launched Yellow Card reporting for nicotine containing e-cigarettes. The Scheme collects reports of suspected adverse reactions associated with e-cigarettes. The Yellow Card reporting form has been designed with smart fields to ask, where appropriate, whether a patient is pregnant, and is also able to capture reports where the patient was exposed to e-cigarettes in utero.

Following lung injury associated with the use of e-cigarette or vaping products reported in the United States of America (as mentioned in the petition background information), in January 2020, the MHRA published a Drug Safety Update<sup>1</sup> article calling for healthcare professionals to be vigilant for suspected adverse reactions associated with the use of e-cigarettes or vaping (including lung injury) and to report these to the MHRA via the Yellow Card Scheme. The article also provided case definitions for vaping related lung injury to allow the healthcare professionals to identify probable and possible cases of this.

As of 13 February 2020, the MHRA has received a total of 115 Yellow Card reports relating to nicotine containing e-cigarettes, with 92 of these reports being received after the TRPR came into force. Two of these reported reactions were in pregnant women. All reports received are reviewed as part of the MHRA's ongoing safety monitoring.

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<sup>1</sup> Drug Safety Update volume 13, issue 6: January 2020: 1 available at: <https://www.gov.uk/drug-safety-update/e-cigarette-use-or-vaping-reporting-suspected-adverse-reactions-including-lung-injury>

A Yellow Card report is not proof of a side effect occurring, but a suspicion by the reporter that the e-cigarette may have been the cause. Other factors such as underlying illness and medical history must be taken into account.

Under the TRPR, e-cigarette producers are required to maintain a vigilance system for collecting reports of adverse reactions and safety concerns relating to their products. Producers are required to inform the MHRA if they have reason to believe one of their products is not safe, or of good quality.

The MHRA continually review all safety reports received associated with e-cigarettes and follow up for more information where permission has been given. All available information is assessed, including data from published literature, industry and other national competent authorities and, where necessary, expert advice would be sought. Should any important safety issues be identified associated with e-cigarettes, the MHRA would take regulatory action and communicate as appropriate.

Following deaths in the USA from users of e-cigarettes, the World Health Organization introduced a new clinical code to be used for vaping related disorder in September 2019. This will allow for more detailed information on vaping related illnesses to be collected worldwide.

We continue to keep the evidence under review and Public Health England's next evidence review on e-cigarettes will be published next month.

I hope this response provides the information you required on the regulations of e-cigarettes.