Tobacco and related products: manufacture, presentation and sale

2012/0366(COD) - 20/05/2016 - Follow-up document

The Commission presents a report on the potential risks to public health associated with the use of refillable electronic cigarettes in accordance with Directive 2014/40/EU.

The report **identifies the particular risks that may be associated with refillable e-cigarettes and their refill containers**. It does not consider the potential public health impact of e-cigarettes in general.

The document was prepared with input from the **PRECISE study** prepared by an external contractor, and analysed **277 cases of nicotine poisoning** reported to poison centres in eight EU Member States (Austria, Hungary, Ireland, Lithuania, Netherlands, Portugal, Sweden and Slovenia) from January 2012 to March 2015.

The contractor performed chemical analysis on e-cigarette samples. It also conducted a survey amongst the e-cigarette industry to determine what they believed to be the main risks associated with refillable e-cigarettes

The Commission identified **four main risks** related to the use of refillable e-cigarettes, these being:

- accidental **ingestion of e-liquid** (particularly with young children);
- **dermal contact,** where e-liquid contains nicotine and other products irritating to the skin (propylene glycol and flavours);
- mixing or **customisation** of liquids, where users blend their own e-liquid at home by purchasing ingredients separately;
- risks due to using **untested combinations of e-liquid and device** or hardware customisation.

Possible risks to health: the report concludes that the use of refillable electronic e-cigarettes, and the potential exposure to **e-liquids** containing nicotine in high concentrations, **may pose risks to public health**. Based on the limits set out in the Tobacco Products Directive, refillable e-cigarette devices can contain up to 40 mg nicotine and refill containers can hold up to 200 mg nicotine. There is, therefore, **a particular risk for young children** if they accidently ingest e-liquid especially from a refill container.

Measures to reduce risk: in the context of current scientific knowledge, the Commission considers that the measures relating to refillable e-cigarettes provided for in the Tobacco Products Directive and secondary legislation, combined with national regulation, provide an **adequate and proportionate framework** for the mitigation of such risks. This does not, however, preclude the need for **further study of these products** and their safety for consumers (in particular concerning poisoning from accidental ingestion of e-liquid and the hazard profile of flavours).

The rather high percentage of poisonings involving adults over the age of 18 (57%) also suggests the need to **increase awareness amongst citizens** on the toxicity of the e-liquids containing nicotine, perhaps through national educational campaigns.

Member States and the Commission should **carefully monitor the market** of refillable e-cigarettes, as well as the notifications received under Article 20(2) of the TPD.

Lastly, the report suggests that **further research** on certain aspects of e-cigarettes relevant to refillables, such as emissions testing and the safety of flavours or mixtures of flavours, should also be carried out. Additional research on these topics would benefit all users of e-cigarettes (whether they are disposable, rechargeable and refillable).