

Should e-cigarettes be regulated as a medicinal device?



There are more than 1 billion smokers worldwide. About half of individuals who continue smoking will die prematurely because of toxins in tobacco smoke. Over the past few years, smokers in economically developed countries have been showing growing interest in electronic cigarettes (ECs) that are designed to deliver nicotine without these toxins.

Initial reactions to ECs focused on potential risks.¹ Increasingly though, commentators are pointing out that there is little indication of harm, whereas the potential benefits are substantial.²⁻⁴ Research into switching from cigarettes to snus (Swedish smokeless tobacco)^{5,6} and into long-term use of nicotine-replacement treatments (NRTs)^{7,8} shows that, except in pregnancy, nicotine intake from a non-smoked source is associated with low or no health risks. The chemicals that make cigarettes dangerous are either absent in ECs or present only in trace concentrations.⁹⁻¹²

Europe is now at an important crossroad. One possible path ahead is to continue to regulate ECs as any other consumer product. The other path, currently under consideration by the proposed Updated Tobacco Products Directive of the European Commission is to regulate them as medicinal devices.

The main arguments for such regulation include consumer safety, the need for precise product labelling, and equal terms on which to compete with NRTs. Strict controls would also restrict the development and spread of ECs and alleviate a concern that if ECs flourish, this would renormalise smoking. If such medicinal regulation had no other consequence, these arguments might have some merit. The unintended consequences, however, could be severe and none of the above arguments are strong.

One, in terms of the safety of ECs, there is no credible risk that normally used ECs can poison the user with nicotine. Much more dangerous chemicals such as bleach rely on packaging and common sense rather than on medicinal licensing.

Another aspect of safety is the presence of unauthorised dangerous compounds. In Europe, EC users are already protected by general product and safety regulations and labelling requirements. For example, medicinal licensing is not needed to ensure toys do not contain lead. Of course, it is possible that some unexpected ill effects of ECs might emerge, but

the key point is that compared with hypothetical risks that seem unlikely in view of current knowledge about ECs, we know the product ECs are replacing is seriously dangerous. If any new risks emerge, then appropriately tighter regulation can be implemented.

Two, there are questions about the need for precise labelling of nicotine content. Nicotine delivery from ECs is determined not just by the nicotine content in the liquid of ECs, but also by characteristics of heating elements and other technical features and even more so by the individual's frequency and depth of inhalations.¹³ Nicotine concentrations in liquid, therefore, have only a very rough relation to how much nicotine a user absorbs. As with cigarettes, such labelling conveys little useful information to users.

Three, in terms of market competition, ECs are a consumer product competing with cigarettes. The success of ECs would be detrimental to sales not just of cigarettes but also of smoking cessation products. Protection of such markets, however, should not be high on the public health agenda.

Four, regarding attracting non-smokers and renormalising smoking, so far there are very few cases of never smokers using ECs regularly whereas many smokers have switched to ECs.¹⁴ These electronic products have not been attracting children,¹⁵ and, although sales to children should be banned, medicinal licensing is not needed to achieve this aim. Many of the never smokers are likely to try smoking tobacco, so it would be neither surprising nor a public health problem if some tried ECs instead.

It is difficult to understand how use of ECs would imply that cigarettes are also acceptable. The two are clearly different. Availability of a safer alternative to cigarettes is likely to strengthen rather than weaken denormalisation of smoking.

There are three main arguments against mandatory medicinal licensing of ECs, apart from the most obvious one that they are consumer products rather than medicines.

One, medicinal licensing requirements would hinder further EC development, which is essential for ECs to become a full replacement for cigarettes. Small improvements would require new licensing applications, the innovation timescale would increase



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greatly and the costs of innovation would be prohibitive. NRTs represent a classic example of the stifling effect of medicinal regulation. There have been no major improvements since they were introduced 30 years ago.

Two, the costs of ECs would increase because compliance with pharmaceutical standards for manufacturing and handling medicinal licensing are expensive processes, which cigarettes do not have to comply with. The large tobacco companies may become the only players with sufficient resources. Small agile innovators would go out of business. Tobacco companies might not want ECs to develop further because this would undermine sales of cigarettes. ECs would become more expensive than cigarettes, remain unattractive to most smokers, and would be sold in packaging emphasising unlikely dangers. Cigarettes would remain a more attractive and cheaper product.

Three, standard consumer protection regulations exist in Europe and many other countries to ensure consumer products are safe, fit for purpose, and as described. Such frameworks also allow specific directives to address particular risks. For example, the requirements to make tamper-proof containers or prohibit sales to children are not restricted to medicines.

In conclusion, since ECs are a recreational consumer product that are competing with much more dangerous cigarettes, which are not regulated as medicines, mandatory medicinal regulation is not required for public safety and can harm public health by restricting the ability of ECs to compete with cigarettes in the marketplace. Excessive regulation of ECs would protect the market monopoly of cigarettes and have the potential consequences of disease in and death of millions of smokers who were prevented from moving on to the next generation of ECs. For the first time in the history of the tobacco control movement, a realistic possibility is emerging that the tobacco problem might get resolved, and that this could happen with minimal or no government involvement or expenditure. Regulators of medicines should hold their fire.

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