

Time to stub out misguided e-cigarette regulation

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Smokers are increasingly turning to electronic cigarettes as a means to reduce the health impacts of their addiction. But legislators around the world are far from unified in their approaches to regulating e-cigarettes. Misguided legislation based on concerns that are not backed by sound data may have unintended consequences for public health, experts say. With smoking behind almost six million premature deaths each year, a lot is at stake in the current round of regulation changes.

An article offering details and critique of current legislation, "Achieving appropriate regulations for <u>electronic cigarettes</u>," by communication, legal and <u>public health</u> experts Daniela Saitta, Giancarlo Antonio Ferro and Riccardo Polosa from the University of Catania, Italy appears in the latest *Therapeutic Advances in Chronic Disease*.

Tar, chemicals, and other substances found in tobacco smoke cause most of the health-risks from cigarettes, rather than the nicotine. E-cigarettes aim to circumvent these risks by delivering nicotine without the smoke. Yet despite users seeing the clear benefit from e-cigarettes, members of the health community, the pharmaceutical regulators and governments have voiced concerns. Fears include e-cigarettes encouraging higher nicotine consumption than traditional cigarettes, and perpetuating addiction rather than promoting quitting. The health risks from long-term e-cigarette use are as yet unknown, and e-cig detractors say that these products will appeal to young non-smokers, or make smoking publicly acceptable once again. The authors of the article argue that these claims are mostly theoretical and not backed by scientific



evidence, but are often cited in moves to restrict e-cigarettes.

The authors show that efforts to address these concerns without sound data can lead to unintended consequences: the first draft of the revision of the European Union (EU) legislation proposed in December 2012 attempted to define arbitrary limits to the nicotine content in the liquid of e-cigarettes, a clear indicator of the poor understanding of the problem by legislators.. Only a few months later, the same EU health ministers proposed distinctive amendments to the first draft applying substantial pharmaceutical regulations to e-cigarettes— a move that was rejected by the EU Parliament in October 2013. This would have resulted in higher costs and limiting access (sale via pharmacies only) to consumers. The authors say:

"It is counter-productive and hypocritical to over-regulate a product designed to reduce or eliminate the diseases and early deaths caused by smoking."

Unfortunately, the UK's Medicines and Healthcare Regulatory Agency (MHRA) has moved towards regulating e-cigarettes as medical products. In Canada, <u>electronic products</u> that dispense nicotine by inhalation fall under the Food and Drugs Act of the Health Canada, which means it is illegal to smoke e-cigarettes, and stipulates that it must be approved as a new drug before they can be sold or imported.

Polosa and his co-authors propose that e-cigarette regulators should consider:

- Evidence that good manufacturing practices (GMP) have been followed
- Child-proof caps on fluid containers
- Official documentation reporting on the contents of e-cigarette fluids to regulators



• Clear, accurate and detailed labeling about the contents and the hazards associated with e-cigarette use.

Moreover, regulatory frameworks for electronic products are already available in the EU legislation to cover for the safety issues regarding E-cigarettes' hardware components. The authors note that - regrettably -such legislation may be "impossible to implement" due to the interests of the tobacco and pharmaceutical industries, and even due to revenues generated for governments by taxes on tobacco.

"If these obstacles can be overcome, much misery and suffering can be reduced and millions of lives can be saved," the authors declare.: "E-cigarettes are not a gateway to smoking but a gateway from smoking, and heavy regulation by restricting access to <u>e-cigarettes</u> would just encourage continuing use of much unhealthier tobacco smoking."

More information: "Achieving appropriate regulations for electronic cigarettes," by Daniela Saitta, Giancarlo Antonio Ferro and Riccardo Polosa, published February 04 2014, appears in the journal *Therapeutic Advances in Chronic Disease*.

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