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18 June 2015

Legislative proposals to strengthen tobacco control

Dear Members of the Panel on Health Services,

I am writing in relation to the "Legislative proposals to strengthen tobacco control" to be discussed at the special meeting on Monday, 6 July 2015. I would like to comment on the proposals to further ban non-nicotine electronic cigarettes. In my view, a policy of denying smokers access to much less harmful alternatives is unjust and acts against the rights and best interest of smokers and public health.

My name is Riccardo Polosa, and I am Director of the Centre for Tobacco Prevention and Dependence Treatment, at the University of Catania (Italy) and Honorary Professor of Medicine at The University of Southampton (United Kingdom). As Scientific Director of LIAF (translated acronym for Italian No Smoking Association), I have dedicated many years of my clinical and research activity to fight against tobacco smoking.

I am the author of more than 550 scientific publications, 330 of which are peer-reviewed articles and book chapters relating to respiratory medicine, clinical immunology, tobacco addiction, and tobacco harm reduction. I have led several clinical trials alternative products to tobacco smoking, including electronic cigarettes and in 2014, I was identified as the most prolific academic author in the field of electronic cigarettes. (see Zyoud, S.H., *et al.*, *Worldwide research productivity in the field of electronic cigarette: a bibliometric analysis*, BMC Public Health 2014).

When I first started investigating these products in late 2009, I was myself quite skeptical about their potential and I even discouraged their use without knowing very much about them. But I quickly changed my opinion when I found that many smokers using these products were quitting for good and felt much better in health and spirit. It was such a rewarding experience to have them thanking me for having won the most important battle of their life. Since then I have been working with great enthusiasm to evaluate in more detail these products, determined to understand how to maximize their beneficial effects. I am now convinced that more effective approaches are needed to reduce the disease burden of tobacco smoking. Electronic cigarettes are a recent development and represent an opportunity to improve globally the health of millions of smokers by reducing the burden of smoking-related diseases.

With any emerging behavior associated with exposure to inhalational agents, there is legitimate cause for concern and a need for study of potential harm. However, this potential risk must be taken in context of known harm of cigarette smoking in individuals who are already smoking. Indeed - under normal conditions of use - vapour toxicology is by far less problematic than that of conventional cigarettes (1), e-vapor products are at least 95% less harmful compared to combustible cigarettes (2) and exclusive ECs users have significantly lower urine levels of tobacco smoke toxicants and carcinogens compared to cigarette smokers (3).

E-cigarettes do not generate smoke by burning tobacco, and therefore deliver nicotine with far fewer harmful chemicals. Many public health experts and organizations have concluded that e-cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco smoking

to electronic cigarettes. In addition, e-cigarettes are used almost entirely by smokers and former smokers who switch from cigarettes, while the use among never smokers and minors is negligible (4). Last but not least, there is now emerging evidence that abstaining from smoking may produce significant respiratory health gains in “healthy” smokers as well as in asthmatic smokers who switch to regular ECs use (5).

Consequently, many jurisdictions, most prominently the United States and the European Union, chose not to ban e-cigarettes or regulate them as medicines but rather to regulate them as alternatives to cigarettes and other burned tobacco products.

In the EU, e-cigarettes will be regulated under the new Tobacco Product Directive (2014/40/EU). As the EU Commission stated, *“The new legislation does not ban e-cigarettes, nor was there ever a plan to ban such products. Not only will consumers still be able to buy and use e-cigarettes, but they will benefit from improved safety and quality requirements.”*(6)

The rules for e-cigarettes under the new Directive require, among other things:

- Notification when an e-cigarette is intended to be placed on the market;
- Mandatory safety and quality standards for nicotine content, ingredients and devices as well as refill mechanisms;
- Obligatory consumer information leaflets;
- Restrictions on advertising; and
- A system to monitor adverse effects of e-cigarettes.

On April 25, 2014, the US Food and Drug Administration (FDA) proposed a new rule that would extend the agency’s tobacco authority to cover e-cigarettes. In the proposal, the FDA states that *“[e]merging technologies such as the e-cigarette may have the potential to reduce the death and disease toll from overall tobacco product use depending on who uses the products and how they are used.”*(7)

Under the proposed rule, e-cigarette manufacturers would be, among other things, required to:

- Register with the FDA and report product and ingredient listings;
- Only market new products after FDA review;
- Only make direct and implied claims of reduced risk if the FDA confirms that scientific evidence supports the claim and that marketing the product will benefit public health as a whole. In addition, under the proposed rule, e-cigarettes would be required to carry a health warnings and their sale to minors would be prohibited.

1. Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Ther Adv Drug Saf.* 2014 Apr;5(2):67-86.
2. Nutt DJ, Phillips LD, Balfour D, Curran HV, Dockrell M, Foulds J, et al. Estimating the harms of nicotine-containing products using the MCDA approach. *Eur Addict Res.* 2014;20:218–25.
3. Hecht SS, Carmella SG, Kotandeniya D, Pillsbury ME, Chen M, Ransom BW, et al. Evaluation of toxicant and carcinogen metabolites in the urine of e-Cigarette users versus cigarette smokers. *Nicotine Tob Res.* 2014; [Ahead of print].
4. Farsalinos KE, Romagna G, Tsiapras D, Kyrzopoulos S, Voudris V. Characteristics, perceived side effects and benefits of electronic cigarette use: a worldwide survey of more than 19,000 consumers. *International Journal of Environmental Research and Public Health.* 2014;11(4):4356-4373.
5. Polosa R. Electronic cigarette use and harm reversal: emerging evidence in the lung. *BMC Med.* 2015 Mar 18;13:54. doi: 10.1186/s12916-015-0298-3.
6. European Commission, E-cigarettes Myth Buster,

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

7. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, A Proposed Rule by the Food and Drug Administration on 25 April 2014

<https://www.federalregister.gov/articles/2014/04/25/2014-09491/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>.

In conclusion, e-cigarettes are an opportunity not to be missed. Future research can help make electronic cigarettes more effective as smoking substitutes and will better define and further reduce residual risks from use to as low as possible, by establishing appropriate quality control and standards.

My piece of advice with regard to future regulation of these products in Hong Kong is that it should primarily address quality standards of liquids used in e-cigarettes (e-liquids) and should require: 1) evidence that good manufacturing practices (GMP) have been followed; 2) official documentation reporting contents and concentrations in e-liquids to regulators; and 3) clear, accurate, and detailed labeling about the contents and the possible dangers of products handling (e.g. accidental poisoning) that may derive from improper e-cigarette use.

As members of the Legislative Council of Hong Kong you have the duty to provide Hong Kong smokers with truthful health information and legal access to a far less hazardous alternative to tobacco smoking. Indeed, it is of paramount importance that government and trusted health authorities provide accurate and truthful information about the relative risks of smoking and alternatives to smoking. If the public is misled about the risks of e-cigarettes and other products that have the harm reduction potential, millions of smokers will be dissuaded from switching to these much less hazardous alternatives.

I would be very happy to discuss with you the research and the evolving evidence on e-cigarettes in more detail.

Please do not hesitate to contact us if you need more clarifications or information.

Yours sincerely,

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