



**To the Department of Health and FDA of the Republic of Philippines**

I am writing in relation to the public hearing held to obtain comments, views and suggestions about safety and regulation of e-cigarettes in the Philippines.

As Director of the Centre for Tobacco Prevention and Dependence Treatment, at the University of Catania (Italy), and as Scientific Director of LIAF (acronym for Italian No Smoking Association), I have dedicated many years of my clinical and research activity to fight against tobacco smoking. More effective approaches are needed to contrast tobacco smoking and reduce cigarette consumption. Recent scientific evidence shows that e-cigarette are safe and effective substitute of tobacco smoking.

The body of information on the composition of the contents of e-cigarette cartridges, refill fluid and vapour generated by the devices is growing. This indicates wide variation in composition of contents and vapour, but overall there is no evidence that e-cigarettes may expose users to concentrations of toxins sufficient to cause harm (1-6).

**Supporting evidence**

1. Laugesen M: Safety Report on the Ruyan E-cigarette Cartridge and Inhaled Aerosol. Health New Zealand Ltd. Christchurch, New Zealand, 2008. Available at <http://www.healthnz.co.nz>
2. Cahn Z, Siegel M: Electronic cigarettes as a harm reduction strategy for tobacco control: a step forward or a repeat of past mistakes? *J Public Health Policy* 2011, 32:16-31.
3. Etter J-F, Zäther E, Svensson S: Analysis of refill liquids for electronic cigarettes. *Addiction* 2013: online first - doi: 10.1111/add.12235.
4. Goniewicz ML, Knysak J, Gawron M, Kosmider L, Sobczak A, Kurek J, Prokopowicz A, Jablonska-Czapla M, Rosik-Dulewska C, Havel C, Jacob III P, Benowitz N: Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tobacco Control* 2013, doi: 10.1136/tobaccocontrol-2012-050859.
5. Williams M, Villarreal A, Bozhilov K, Lin S, Talbot P: Metal and silicate particles including nanoparticles are present in electronic cigarettes cartomizer fluid and aerosol. *PLoS ONE* 2013,8:e57087. Doi:10.1371/journal.pone.0057987.
6. Romagna G, Allifranchini E, Bocchietto E, Todeschi S, Esposito M, Farsalinos K. Cytotoxicity evaluation of electronic cigarette vapor extract on cultured mammalian fibroblasts (ClearStream-LIFE): comparison with tobacco cigarette smoke extract. *Inhalation Toxicology* 2013, 25:354-361.

There is evidence from case reports (7,8) and user surveys that e-cigarettes help people to quit smoking (9,10). Also a few clinical trials have been published (11-13). For example in smokers not intending to quit the use of e-cigarettes decreased cigarette's consumption and in some it elicited enduring tobacco abstinence. Moreover, no significant side effects were reported and substantial health gains could be achieved by e-cigarette users.

**Supporting evidence**

7. Caponnetto P, Polosa R, Auditore R, Russo C, Campagna D: Smoking Cessation with E-Cigarettes in Smokers with a Documented History of Depression and Recurring Relapses. *International Journal of Clinical Medicine* 2011, 2:281-284.
8. Caponnetto P, Polosa R, Russo C, Leotta C, Campagna D: Successful smoking cessation with electronic cigarettes in smokers with a documented history of recurring relapses: a case series. *Journal of Medical Case Reports* 2011, 5:1-6.
9. Etter J-F, Bullen C: Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy. *Addiction* 2011, 106:2017-2028.
10. Siegel M, Tanwar K, Wood K: Electronic cigarettes as a smoking-cessation tool: results from an online survey. *American Journal of Preventive Medicine* 2011, 40:472-475.

11. Polosa R, Morjaria JB, Caponnetto P, Campagna D, Russo C, Alamo A, Amaradio M, Fisichella A. Effectiveness and tolerability of electronic cigarette in real-life: a 24-month prospective observational study. *Intern Emerg Med*. 2013 Jul 20. [Epub ahead of print]
12. Caponnetto P, Campagna D, Cibella F, Morjaria JB, Caruso M, Russo C, Polosa R. Efficiency and Safety of an eElectronic cigAreTte (ECLAT) as Tobacco Cigarettes Substitute: A Prospective 12-Month Randomized Control Design Study. *PLoS One*. 2013 Jun 24;8(6):e66317.
13. Polosa R, Caponnetto P, Morjaria JB, Papale G, Campagna D, Russo C. Effect of an electronic nicotine delivery device (e-Cigarette) on smoking reduction and cessation: a prospective 6-month pilot study. *BMC Public Health*. 2011 Oct 11;11:786.

Moreover, a number of studies have shown that the risks of second hand vapor from e-cigarette use is very small in comparison to those associated with second hand tobacco smoke (14-16). While second hand smoke must be eliminated in workplaces and public places, the current data provide no justification for eliminating e cigarette use in these places.

#### **Supporting evidence**

14. Schripp T, Markewitz D, Uhde E, Salthammer T: Does e-cigarette consumption cause passive vaping ? *Indoor Air* 2013, 23:25-31.
15. McAuley T, Hopke P, Zhao J, Babaian S: Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality. *Inhal Toxicol* 2012, 24:850-857.
16. Flouris A, Chorti M, Poulianiti K, Jamurtas A, Kostikas K, Tzatzarakis M, Wallave Hayes A, Tsatsakis A, Koutedakis Y: Acute impact of active and passive electronic cigarette smoking on serum cotinine and lung function. *Inhal Toxicol*. 2013, 25:91-101.

The current evidence is thin and more research is clearly needed, but it is likely that these products will prove useful in the fight against tobacco. Therefore the regulatory bodies should carefully consider the public health potential of the e-cigarettes.

My piece of advice with regard to future regulation of these products in your country is that it should primarily address quality standards and monitoring of e-cigarettes and e-liquids and should require 1) evidence that good manufacturing practices (GMP) have been followed; 2) child-proof caps on fluid containers; 3) official documentation reporting on the contents of e-cigarette fluids to regulators; 4) clear, accurate and detailed labeling about the contents and the hazards associated with e-cigarette use. One such regulatory framework already exists; e-liquid may be marketed as dietary supplements providing no claims about preventing or treating disease are made. Under dietary supplements regulation, manufacturers must indicate a product is not dangerous prior to introduction. Being compliant to national GMP policies it is all is required in order to ensure that e-liquids are produced in a quality manner, do not contain contaminants or impurities, are accurately labeled, and held under conditions to prevent adulteration. Additional safety principles can be implemented including a rule requiring that e-liquid manufactures submit reports of serious adverse events linked to the use of their products. Obviously, the simple scheme of dietary supplements regulation must be integrated by the already existing directives about electronic products safety (for example, in the EU, these class of products must comply with CE marking and accompanying Declaration of Conformity before marketing).

The Department of Health and FDA of the Republic of Philippines is strategically positioned to provide Philippino smokers with truthful health information and legal access to a far less hazardous alternative.

Please do not hesitate to contact me if you need more clarifications.

Prof. Riccardo Polosa