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Regulation of e-cigarettes: the users' perspective

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We read with great interest the Comments^{1, 2} in *The Lancet Respiratory Medicine*, which debated if, how, and by whom electronic cigarettes (e-cigarettes) should be regulated.

E-cigarettes are increasingly used as substitutes for tobacco cigarettes,³ with some suggestion that the rapidly increasing popularity of e-cigarettes brought about a decrease in tobacco cigarette sales in the USA at the start of 2013.⁴ The main reason for regulation of these products is said to be to ensure that consumers are protected. However, the consumers' perspective has been largely overlooked. For consumers, safety is a concern, but is secondary in view of the hazards of the product (ie, tobacco cigarette) being replaced.⁵ Most consumers would be content with regulations that helped to ensure product consistency and prevent contamination, but see no need to apply the strict regulations used for pharmaceutical products that would lead to unnecessary increases in the price of e-cigarettes.⁶ Our experience suggests that many former smokers who transitioned to an e-cigarette believe that the main goal for regulators should be to keep e-cigarettes available and acceptable as a cigarette replacement. Excessive and ill-conceived regulation will conflict with these basic requirements; it will marginalise e-cigarettes by making them unattractive to smokers and less competitively priced compared with tobacco products.

Future regulatory measures should primarily address quality standards of liquids used in e-cigarettes (e-liquids) and should require 1) evidence that good manufacturing practices have been followed; 2) official documentation reporting contents and concentrations in e-liquids to regulators; and 3) clear, accurate, and detailed labelling about the contents and possible dangers of inappropriate handling (eg, accidental poisoning) associated with e-cigarette use.

Such a regulatory framework already exists; e-liquids can be marketed as dietary supplements, provided that no claims are made about prevention or treatment of disease. Under dietary supplement regulation, manufacturers must show that a product is not dangerous before introduction. Compliance with national good manufacturing practice policies would ensure that e-liquids are produced in a quality manner, do not contain contaminants or impurities, are accurately labelled, and are held under conditions to prevent adulteration. Additional restrictions could be implemented, including a rule requiring e-liquid manufacturers to submit a report to the relevant health authority of serious adverse events linked to the use of their products. With regard to marketing and safety of e-cigarettes' electronics, batteries, and spare parts, these components are already regulated by existing directives.

Therefore, it should be easy to implement reasonable regulation that is in line with consumer's aspirations. However, introduction of such regulation will not be as easy as it seems. The rapidly expanding popularity of e-cigarettes is a threat to the interests of both the tobacco and pharmaceutical industry and to their associated stakeholders. The large revenues generated by tobacco excise taxes are needed by national governments to run their countries and sponsorship for the marketing of anti-smoking drugs and those intended to treat tobacco-related diseases are much needed by pharmaceutical regulatory bodies, health authorities, and medical societies for the running of their statutory activities.

RP has received lecture fees and research funding from Pfizer and GlaxoSmithKline, manufacturers of stop smoking medications; has served as a consultant for Pfizer and Arbi Group Srl, the distributor of the categoria e-cigarette; and currently

serves as Chief Scientific Advisor for LIAF (the Italian Anti-Smoking League). PC declares that he has no conflicts of interest.

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