

Letter from sixty-two specialists in nicotine science, policy and practice

*Indian Council of Medical Research
Prof. Balram Bhargava
Secretary, DHR & Director General ICMR*

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White Paper on Electronic Nicotine Delivery System by the Indian Council of Medical Research: A Critical Appraisal of the Scientific Evidence

Dear Prof. Bhargava,

On 31 May 2019, an ad-hoc Expert Committee of the ICMR published its first report on e-cigarettes, [“White Paper on Electronic Nicotine Delivery Systems”](#). Their conclusion recommends a “...complete prohibition on ENDS or e-cigarettes in India in the greater interest of protecting public health”. We are concerned that the ICMR has issued this radical policy recommendation in light of the broad consensus in the scientific community that e-cigarettes are much less harmful than combustible cigarettes including bidis. The major arguments in support of the Committee’s conclusions are: 1) adverse health effects and unknown health risks, 2) risks from second-hand exposure, 3) risk of dual use and initiation of tobacco addiction among non-smokers and e-cigarette use by youth, and 4) lack of effectiveness for smoking reduction and cessation. The scientific arguments advanced by the ICMR Expert Committee requires critical appraisal.

The evidence that e-cigarettes are far less harmful than combustible cigarettes and overall carry a much smaller health risk is clear. Also, clinical evidence is mounting that switching from smoking to e-cigarette use could improve disease conditions. The ICMR White Paper fails to consider the substantial body of literature that demonstrates the harm reduction potential of e-cigarettes and its position is not in line with the recommendations of many authoritative health organizations worldwide. From a health perspective, e-cigarettes represent an important tool for smokers to reduce their risk.

The ICMR claims in their report that second-hand exposure to e-cigarettes has adverse health effects. There is no published scientific evidence of harm to bystanders from exposure to an e-cigarette. The available evidence on e-cigarette aerosol chemistry indicates that any risk of harm, if present, is extremely low, and orders of magnitude lower compared with tobacco smoke. Besides, because the lack of side-stream emissions, e-cigarettes aerosol emissions contributes only minimally to environmental exposure and very unlikely to cause any substantial health concern.

ICMR questions the value of e-cigarettes for smoking reduction and cessation. Negative association is normally found in studies with a high probability of selection bias. Identifying these biases in earlier studies is important to consider when assessing evidence for e-cigarettes and smoking cessation. Notably, results from studies with long-term and daily e-cigarette use consistently report positive associations between e-cigarette use and smoking cessation. The evidence from the newer, better-designed studies support that e-cigarettes have a strong potential for smoking cessation and relapse prevention, particularly for those smokers who fail at cessation or are unwilling to attempt to quit with currently approved

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medications.

Public health is rightly concerned with any potential increase in nicotine use by youth, but concern of increased usage by youth has been driven by misclassification bias in many reports. One-time or experimental use of an e-cigarette is extremely unlikely to increase any risk for developing any disease, particularly given the very low risk profile of e-cigarettes. For public health surveillance, it is critical to survey the prevalence of regular (weekly and daily) e-cigarettes use, e-cigarette use by youth who smoke, and e-cigarette use by never-smoking youth. Another important indicator is changes in smoking prevalence since the introduction during the period of e-cigarettes. The White Paper argues that e-cigarettes are a “gateway” to tobacco cigarette use. The strongest argument against the “gateway” theory is the marked and accelerated decline (by more than 50%) in smoking prevalence among US youth observed since 2011, the period when e-cigarettes became popular. There is no doubt that any use of e-cigarettes by youth is not desirable. However, from a public health standpoint, the relative harm of e-cigarettes must be kept in context because risks related to e-cigarette use are much lower than the risks from smoking. Also, availability of e-cigarettes might act as a “distraction” and deter many youths away from combustible cigarettes.

Because the White Paper is based on uncritical reporting of the evidence it fails to report a balanced overview of the risk-benefit ratio of these new technologies, and grossly misrepresents the actual evidence base. The Committee’s proposal of banning e-cigarette in India is therefore not justified. [A detailed critical appraisal of the White Paper](#) along with suggestions for improving individual as well as public health will be published soon in the Indian Journal of Clinical Practice and is enclosed with this letter for your reference.

We believe the time has come to do something more for smokers who want to quit, and India and its agencies could be a world leader in crafting a new path of e-cigarettes and harm reduction and cessation. New Delhi has the opportunity to improve public health by integrating existing tobacco control policies with the promotion of less harmful forms of nicotine consumption for cigarette substitution. This opportunity will be lost if India bans e-cigarettes, and no new strategies means the tobacco epidemic will continue.

India is the world largest democracy and now its fifth largest economy. The Indian leadership in public health is a natural corollary of its growing international presence. We look forward to a constructive exchange. We urge to ICMR to reconsider its recommendation on a ban, and we hope that this discussion will enable them to understand the science and evidence on e-cigarettes and tobacco control.

Yours sincerely,

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