

EXECUTIVE SUMMARY

The World Health Organisation has commissioned a scientific assessment and policy options report on electronic cigarettes (referred to in the report as Electronic Nicotine Delivery Systems (ENDS) and Electronic Non-Nicotine Delivery Systems (ENNDS)¹) for the Seventh Conference of the Parties of the Framework Convention on Tobacco Control (FCTC COP-7). This paper provides a critique of that assessment. The main concerns with the WHO report are as follows:

- **Positioning ENDS as a threat rather than opportunity.** Overall, the WHO report does not correctly position ENDS primarily as an *alternative* to smoking and instead focusses excessively on risks of ENDS use without adequately recognising the deep reductions in health risks when a smoker switches to ENDS. The FCTC itself recognises ‘harm reduction’ as a key strategy in tobacco control. But with minor exceptions, the WHO report discusses ENDS as a threat, whereas in fact they represent a major opportunity for public health.
- **Failure to quantify risk.** The WHO paper provides a poor assessment of ENDS risks. In terms of toxicology, the discussion is naïve and places excessive emphasis on negligible risks arising from very low exposures. In toxicology, the presence of a potentially harmful agent does not necessarily establish a material risk. This is because the level of exposure matters and “the dose makes the poison”.
- **Inadequate comparisons with smoking.** The WHO paper systematically does not make relevant comparisons with exposures arising from inhaling tobacco smoke or refer to other useful comparators such as occupational exposure limits. However, data from around the world shows that almost all ENDS users are smokers, ex-smokers or would-be smokers. The most relevant comparison for health policy purposes is with smoking.
- **Misrepresenting second hand ENDS vapour risks.** The section on risks of second-hand exposure to ENDS aerosol provides no evidence that such exposures pose any material risks to bystanders. The claim that ENDS have the “*potential to lead to adverse health effects*” in bystanders does not reflect the science behind the cited source unless ‘potential’ is taken to mean *any exposure*, no matter how trivial. Again, the issue is not the presence of particular chemicals, but the magnitude of exposure.
- **Discounting the evidence that ENDS do help smokers quit.** The WHO paper does not properly assess the role that ENDS play in quitting smoking and uncritically repeats several methodological errors found in the literature. Taking the totality of evidence including controlled trials, observational studies, changes in population smoking and ENDS use, the experience of nicotine replacement therapy, and widely reported user experience, there is confidence that ENDS are helping many smokers to quit smoking and not having negative effects like renormalising smoking, reducing quit rates or creating gateway effects.
- **ENDS marketing can be anti-smoking advertising.** The clear majority of ENDS marketing is truthful promotion of a low-risk alternative to smoking. The evidence cited by WHO has been misrepresented and does not make the case for any systematic malpractice by ENDS vendors. However, the WHO paper overlooks that most fundamental point, which is that ENDS marketing is promoting an *alternative to smoking* and may therefore be promoting desirable changes in smoking behaviour. It may also reach people who do not engage with conventional stop-smoking interventions.
- **Flavours are essential to the appeal of ENDS as alternative to smoking.** The section on ‘product characteristics’ attempts to demonstrate a problem with flavours appealing to

¹ The WHO report refers to ENDS and ENNDS, recognising that not all electronic cigarettes contain nicotine. This is correct, but for ease of reading in our *responses* to the WHO report we use the single acronym ENDS, unless we wish specifically to make the distinction between the product categories which we will then make clear.

teenagers. In fact, flavours are integral to the appeal of ENDS to adults as an alternative to smoking. The citations are selective and findings misinterpreted and do not support this claim. Several citations simply reflect opinions or speculation, while important studies have been overlooked. These do not show that any interest amongst teenagers in ENDS flavours is resulting in regular use of ENDS in this age group.

- **Mischaracterisation of the ENDS market and role of tobacco transnationals.** The WHO paper misinterprets the ENDS market, makes misleading and unreferenced statements about the role of transnational tobacco companies in the market and is not grounded in an understanding of how competitive markets function. The WHO report fails to acknowledge the threat of disruptive technology such as ENDS to the commercial viability of the traditional cigarette business. Ironically, the published papers cited in the report point out how regulations, such as those favoured by WHO, actually help the cigarette trade. WHO should be aware of the danger that its policy proposals may provide the traditional tobacco industry with a twin advantage: (1) slowing down the disruption of the cigarette market by ENDS; (2) shaping the ENDS market to suit the ENDS business model favoured by the tobacco industry.
- **Unjustified support for ENDS prohibition.** In the discussion of policy options, the opening paragraph for each policy set implicitly endorses ENDS prohibition. It does this by stating that *“Parties that have not banned the importation, sale, and distribution of ENDS/ENNDs may consider the following options”*. Prohibition is one regulatory option among many that ought to be discussed on its own merits, not taken as a default. The merits of prohibition are exceedingly poor given the pervasive availability of cigarettes in all jurisdictions. WHO should not be endorsing prohibitions, explicitly or implicitly. It is unethical to deny smokers much lower risk options than cigarettes, and there is no scientific support for ENDS prohibition as a public health intervention. The WHO’s framing suggests that a prohibition is something for Parties to progress towards and should not be undone once done. In fact, it is a policy that should be reversed.
- **Policy proposals made with no supporting policy analysis.** Numerous policies are proposed without *any* supporting evidence for their effectiveness or cost-effectiveness. Any policy proposal should be subject to evidence-based justification, options appraisal and analysis of trade-offs or distributional effects, and impact assessment. Policies should be tested for proportionality and possible unintended consequences. The WHO has not applied any policy-making disciplines to its menu of proposed policy options.
- **No assessment of unintended consequences.** There is no recognition of the likelihood of ‘unintended consequences’ arising from the policies proposed in the WHO paper. However, it is very likely that some of the proposed policies would have the effect of *increasing* smoking. The Royal College of Physicians explains this in its 2016 *Nicotine without Smoke* report² as follows:

“A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, e.g. exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult.” (Section 12.10 page 187)

Almost every policy listed in the WHO’s paper could easily have the effect of protecting the incumbent cigarette trade, promoting smoking rather than vaping, and lead to increases in

² Tobacco Advisory Group of the Royal College of Physicians: *Nicotine without smoke - tobacco harm reduction*. RCP 2016. <https://www.rcplondon.ac.uk/file/3563/download?token=uV0R0Twz>

non-communicable diseases. It is very likely that widespread uptake of WHO's policy proposal would 'reduce harm reduction' and therefore increase harm.

- **Transparency and quality.** The WHO report has been made available without the four supporting papers upon which it is supposed to be based. These papers are still undergoing revision during peer review. This is poor scientific practice and does not provide a reliable basis for policy advice.