

WHO position on ENDS (e-cigarettes)

A critique of the use of science and communication of risk

**A briefing for stakeholders in the
Sixth Conference of the Parties (COP-6) of the
Framework Convention on Tobacco Control
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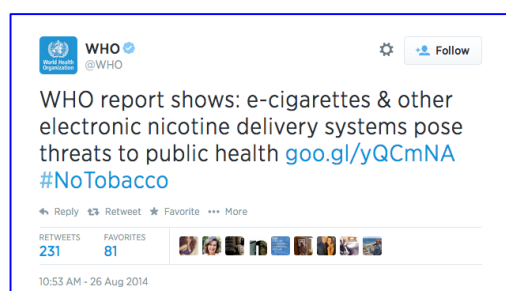
This document discusses a WHO paper on Electronic Nicotine Delivery Systems (ENDS) prepared for the Sixth Conference of the Parties (COP-6) of the Framework Convention on Tobacco Control (FCTC)¹ to be held in Moscow, 13-18 October 2014 – and related public communications.

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¹ WHO, FCTC/COP/6/10 Electronic Nicotine Delivery Systems, published 26 August 2014 [\[link\]](#)

1 WHO on overall impact on public health

Overall, in its public communication WHO portrays e-cigarettes as a threat to public health.



Although in the COP-6 paper WHO (at para 2) notes both ‘promise and threat’, the communications and a selective approach to the science in the paper have contrived to be highly negative. The WHO paper ignored the reviews that had optimistic or open-minded conclusions. The most authoritative recent reviews have concluded:

Polosa R & Farsalinos K (2014)²: *Currently available evidence indicates that electronic cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco to electronic cigarettes. Research will 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.*

Hajek P et al (2014)³: *EC aerosol can contain some of the toxicants present in tobacco smoke, but at levels which are much lower. Long-term health effects of EC use are unknown but compared with cigarettes, EC are likely to be much less, if at all, harmful to users or bystanders. EC are increasingly popular among smokers, but to date there is no evidence of regular use by never-smokers or by non-smoking children. EC enable some users to reduce or quit smoking.*

The reader of WHO’s paper or, even more so its twitter followers, would be hard pressed to draw comparable conclusions – not least because neither of the reviews above was cited by WHO in its paper for COP-6. WHO relied heavily on analysis from academics commissioned by WHO itself^{4 5}. This body of work has been subjected to substantive peer-reviewed criticism from leading academics in the field, published in the journal *Addiction*, on 4th September 2014⁶. The authors were very

² Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Ther Adv Drug Saf* 2014;5:67–86. [doi:10.1177/2042098614524430](https://doi.org/10.1177/2042098614524430)

³ Hajek P, Etter J-F, Benowitz N, et al. Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction* 2014;;n/a–n/a. [doi:10.1111/add.12659](https://doi.org/10.1111/add.12659)

⁴ Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. *Circulation*. 2014;129: e490–e492. [doi:10.1161/CIRCULATIONAHA.114.008545](https://doi.org/10.1161/CIRCULATIONAHA.114.008545)

⁵ Grana R, Benowitz N, Glantz SA. [Background Paper on E-cigarettes](#) (Electronic Nicotine Delivery Systems): Prepared for the 7th Meeting of the WHO Study Group on Tobacco Product Regulation. December 2013.

⁶ McNeill A, Etter J-F, Farsalinos K, et al. A critique of a WHO-commissioned report and associated article on electronic

critical of this key document that provides the scientific underpinning to WHO's paper for COP-6⁷. Professor Ann McNeill, lead author and Professor of Tobacco Addiction from King's College London, says:

We were surprised by the negativity of the commissioned review, and found it misleading and not an accurate reflection of available evidence. E-cigarettes are new and we certainly don't yet have all the answers as to their long-term health impact, but what we do know is that they are much safer than cigarettes, which kill over 6 million people a year worldwide. Furthermore, the review appears to have informed the policy recommendations published in last week's WHO report on e-cigarettes. Any policies surrounding e-cigarettes must be evidence based and like any product, e-cigarettes should be subjected to some form of regulation. However, the WHO's approach will make it harder to bring these products to market than tobacco products, inhibit innovation and put off smokers from using e-cigarettes, putting us in danger of foregoing the public health benefits these products could have.

2 WHO on cardiovascular disease

WHO asserts that nicotine or ENDS "may contribute to cardiovascular disease" (para 13b and [tweeted](#)).



This is not a realistic or balanced statement of the evidence despite the qualification with 'may'. It certainly has not been placed in context with smoking, which certainly causes a great deal of cardiovascular disease – over 18,000 premature deaths in England in 2011⁸. The evidence on cardiovascular disease arising from *nicotine* (as opposed to *smoking*) is summarised as follows⁹

A major misconception, commonly supported even by physicians, is that nicotine promotes cardiovascular disease. However, it has been established that nicotine itself has minimal effect in initiating and promoting atherosclerotic heart disease [Ambrose and Barua, 2004]. It does not promote platelet aggregation [Zevin et al. 1998], does not affect coronary circulation [Nitenberg and Antony, 1999] and does not adversely alter the lipid profile

cigarettes. *Addiction* 2014. [doi:10.1111/add.12730](https://doi.org/10.1111/add.12730)

⁷ Kings College London. Press Release. *WHO-commissioned report on e-cigarettes misleading, say experts*, 5 September 2014 [[link](#)]

⁸ In England in 2011 14% of all circulatory disease mortality was attributable to smoking. 23% of smoking related mortality was attributable to circulatory disease – 18,100 deaths. Health and Social Care Information Centre, *Statistic on Smoking in England, 2012*. [[link](#)]

⁹ Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Ther Adv Drug Saf* 2014;5:67–86. [doi:10.1177/2042098614524430](https://doi.org/10.1177/2042098614524430)

[Ludviksdottir et al. 1999]. An observational study of more than 33,000 smokers found no evidence of increased risk for myocardial infarction or acute stroke after NRT subscription, although follow up was only 56 days [Hubbard et al. 2005]. Up to 5 years of nicotine gum use in the Lung Health Study was unrelated to cardiovascular diseases or other serious side effects [Murray et al. 1996]. A meta-analysis of 35 clinical trials found no evidence of cardiovascular or other life-threatening adverse effects caused by nicotine intake [Greenland et al. 1998]. Even in patients with established cardiovascular disease, nicotine use in the form of NRTs does not increase cardiovascular risk [Woolf et al. 2012; Benowitz and Gourlay, 1997].

In the light of this assessment, why did WHO raise what is likely to be a negligible or trivial risk in unquantified statements, and tweet these to the wider public?

3 WHO on cancer and tumour promotion

Although the tweet above states that nicotine in e-cigarettes may “promote cancer tumours”, the tweet did not mention the important fact that nicotine does not cause or initiate cancer and is not classified as a carcinogen by the International Agency for Research on Cancer (though this is noted in the COP-6 paper). However, to say “promote cancer tumours” in an unqualified and unquantified communication is bound to mislead, as few would know the specialised mean of ‘promote’ in this sentence or just how tenuous the evidence is to support it or how low the risk is. The unnecessary use of the word ‘cancer’ to qualify ‘tumour’ in the tweet serves to make the claim more frightening. Again, no reference is made to the smoking-related cancer premature death toll – 37,400 in England¹⁰, which is the relevant comparator. The claim for tumour promotion is not actually referenced in WHO’s COP-6 paper, but it is likely to be based on studies in cell cultures or mice exposed to very high doses of nicotine. Professor Konstantinos Farsalinos commented on such studies as follows¹¹:

*This argument (as well as the attached references) is based on nothing more than laboratory studies, mostly in cultured cells and few in animals. For example, Grando et al¹². delivered nicotine to rats at levels similar to the daily intake of snus users. They found several types of cancer to be developed, but the nicotine levels were so high for the animals that half of them died due to nicotine overdose (“In an initial proof-of-concept study, we injected A/J mice subcutaneously with the **dose of nicotine lethal to 50% of animals tested (LD50)** (emphasis added)*

The US Surgeon General, in detailed review of the evidence published in 2014 concluded¹³:

¹⁰ In England in 2011 28% of all cancer mortality was attributable to smoking. 47% of smoking related mortality was attributable to cancer – 37,400 deaths. Health and Social Care Information Centre, Statistic on Smoking in England, 2012. [\[link\]](#)

¹¹ E-cigarette research blog. *Abuse of evidence and argument: a response to Stanton Glantz' criticisms of an expert letter to WHO on tobacco harm reduction*, 12 June 2014 [\[link\]](#)

¹² Grando SA. Connections of nicotine to cancer. [Nature Reviews Cancer](#) 2014;14:419–429).

¹³ U.S. Department of Health and Human Services. *The Health Consequences of Smoking: 50 Years of Progress*. A Report of the Surgeon General. 2014. P.116 [\[link\]](#)

There is insufficient data to conclude that nicotine causes or contributes to cancer in humans [...]

It is *possible* that there is a small adverse effect from nicotine use on people *who already have cancer*, but by far the largest cancer effect comes from non-nicotine carcinogens present in tobacco smoke but not present in e-cigarettes, or present at very much lower levels. WHO's communication would have the aim or effect of implying a much larger and stronger link between nicotine and cancer than there actually is.

4 WHO on particulates

As part of its case for banning ENDS use in public places, WHO draws attention to disease risk arising from fine or ultrafine 'particulates' in para 16(b). Tobacco smoke really does contain particulates – these are particles of smouldering burnt tobacco residues with highly reactive surface chemistry, and they contribute to risks arising from both active and passive smoking. Vapour aerosol consists of droplets of liquid and its surface chemistry is very different to tobacco smoke for the obvious reason that it does not contain burning tobacco. Carl Phillips describes the distinction clearly¹⁴

While droplets are particulates in the broadest sense of the term, in the context of environmental pollution that term generally refers to fine solid particles that can lodge in or be absorbed through the lungs intact. A liquid, of course, just dilutes into the bloodstream or other bodily liquids, regardless of particle size and deposition location. Thus, the extensive discussion of particulate size, let alone the explicit claims about health implications, is highly misleading.

WHO refers (in para 16b) to its environmental air quality guidelines¹⁵ to argue that 'particulates' from e-cigarettes are harmful. But again, the sources of air pollutants are very different chemically to e-cigarette vapour – they arise for example from diesel engines, biomass combustion, power station emissions, degrading road surfaces and so on. It is simply not correct to characterise risk by the size of the particles alone without some reference to the chemistry and without taking account of the liquid state of vapour aerosol.

Water vapour? WHO argues (para 17) that "*ENDS aerosol is not merely water vapour as is often claimed in the marketing for these products*". The reason that water vapour is sometimes mentioned by critics of WHO and its underpinning science is to make the point that water droplets (i.e. 'particulates') can be very fine, but they pose no threat because they do not have aggressive reactive chemistry¹⁶. No-one should claim that the e-cigarette vapour is water vapour, and it is hard to find evidence that companies do, in reality, make this claim.

¹⁴ Phillips C, Letter re fatal flaws in Schober et al. paper on environmental vapour, 29 January 2014 [\[link\]](#)

¹⁵ WHO air quality guidelines for particulate matter, ozone, nitrogen dioxide and sulfur dioxide: summary of risk assessment. Geneva: World Health Organization; 2006. [\[link\]](#)

¹⁶ Zhou Y, Benson JM, Irvin C, Irshad H, Chen YS. Particle size distribution and inhalation dose of shower water under selected operating conditions. *Inhalation Toxicology* 2007, 19(4):333-342.

5 WHO on vapour toxicity

WHO states that indoor vaping should be banned by law in public places (para 41). However, WHO has selectively cited the scientific literature on risks to bystanders and not established that the presence of hazard substances in tiny amounts to a material risk – it is *exposure* that makes for a risk (see para 16(a) and (b) – in which WHO implicitly admits it has no basis for claiming that these exposures cause harm). Without any justifiable reason, WHO has not cited the most authoritative overall assessment of vapour toxicity to date, which concluded that active vaping was low risk, and that exposure to bystanders would be “orders of magnitude less”¹⁷:

Current state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. However, the aerosol generated during vaping as a whole (contaminants plus declared ingredients) creates personal exposures that would justify surveillance of health among exposed persons in conjunction with investigation of means to keep any adverse health effects as low as reasonably achievable. Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern. (emphasis added)

Again, selective citation of the literature without any contextual framework for risk has served to exaggerate the risks and give the appearance of justifying a policy that has no evidential support in reality. In the COP-6 paper WHO justifies a ban on vaping in public places as follows:

...the reasonable expectation of bystanders is not a diminished risk in comparison to exposure to second hand smoke but no risk increase from any product in the air they breathe, ENDS users should be legally requested not to use ENDS indoors, especially where smoking is banned until exhaled vapour is proven to be not harmful to bystanders and reasonable evidence exists that smoke free policy enforcement is not undermined.

This framing is flawed in several ways: (1) if followed it would not allow for road transport, power stations, heavy industry, cooking indoors; (2) proving zero risk is impossible; (3) the test is already met if a reasonable view of the evidence and the tolerability of risk is taken; (4) the history of reversing tobacco control measures when evidence shows they are unjustified or actively harmful is very poor – the EU ban on snus is an example; (5) it takes no account of adverse impacts that might arise from extra smoking if such bans reduce the rate of switching to ENDS or promote relapse.

6 Failure to consider *risks* of an indoor vaping ban

Though it has no science to justify an indoor vaping ban, WHO still insists it should be implemented in law rather left to the discretion of owners and operators of public places. That opens questions about where it is appropriate to use the coercive powers of the law – should a pub, restaurant, vape shop, airport, etc be *compelled* to ban vaping if there is no plausible harm to bystanders? WHO is making unarticulated value judgements about the role of the state and purpose of the law.

¹⁷ Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks, *BMC Public Health* 2014;**14**:18. doi:10.1186/1471-2458-14-18 [\[Link\]](#)

However, the biggest public health failing is *not to consider the risks arising from unintended consequences of a vaping ban*. This may be illustrated with an observation from Professor John Britton, who is Director, UK Centre for Tobacco & Alcohol Studies. Professor Britton states in a radio interview¹⁸:

...the risks to others of electronic cigarette vapour are extremely low. I would rather that someone was using an electronic cigarette than smoking a cigarette, and if use indoors is important to help them stay off smoking, then why not?

However, WHO proposes banning use of e-cigarettes indoors, even though there is no evidence of material risk to bystanders (see above). If Professor Britton's statement is correct, then WHO will have made e-cigarettes less appealing to smokers meaning fewer will 'stay off smoking', more will relapse and fewer will switch. The consequence of that will be more smoking, more cigarette sales and more avoidable harm. It is no coincidence that the Department of Health in England rapidly rejected this WHO proposal following WHO's announcement¹⁹. The Department is aware of the public health risk of banning e-cigarette use and wishes to take a more nuanced approach.

7 Unbalanced commentary on 'gateway effect' and 'renormalisation'

Most neutral observers would expect that the introduction of much safer alternatives to cigarettes would be beneficial in a market where ~20% adults smoke – allowing nicotine users to reduce risks substantially while posing little danger to bystanders and non-smokers. However, it is possible to construct scenarios in which the emergence of low-risk products somehow makes the situation worse: via a 'gateway effect' and 'renormalisation' of smoking. WHO states (para 23):

Areas of legitimate concern include avoiding nicotine initiation among non-smokers and particularly youth while maximizing potential benefits for smokers. Such concerns are referred to as the gateway and renormalization effects.

7.1 The gateway effect – more likely to be an 'exit'

This is the idea that use of e-cigarettes will cause young people to take up and continue to smoke who would not otherwise have smoked. There is not a single piece of evidence from anywhere in the world that suggests this is happening, and WHO does not cite any despite saying there are 'concerns' about it (para 24). The gateway idea still persists. For example, much media coverage was created in the United States over National Youth Tobacco Survey Data showing a rise in e-cigarette use²⁰.

This raises concern that there may be young people for whom e-cigarettes could be an entry point to use of conventional tobacco products, including cigarettes.

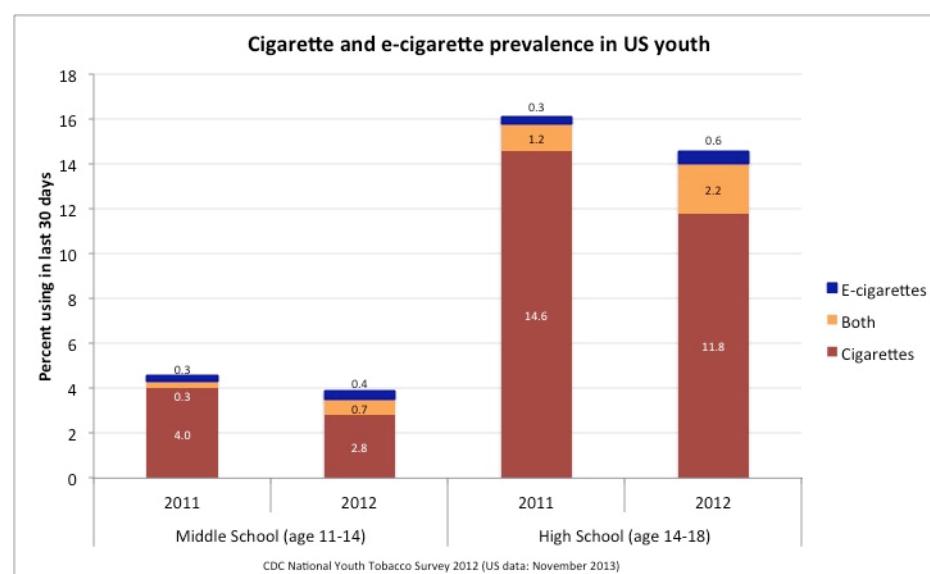
In fact the data show no sign of a gateway effect, and a rise in use among adolescents would be

¹⁸ BBC Six O'Clock News (Radio) 26 August 2014 ([BBC iPlayer at 13 min 56 sec](#))

¹⁹ Reported in The Guardian: E-cigarettes: no indoor smoking ban planned in England despite WHO call, 26 August 2014 ([link](#))

²⁰ CDC E-cigarette use more than doubles among U.S. middle and high school students from 2011-2012, 5 September 2013 ([link](#))

expected to mirror the rise in use among adults. In reality, US teenage smoking prevalence fell sharply as e-cigarette use increased and e-cigarette use was concentrated among existing smokers²¹. Similar effects were found in France²². That offers the possibility that e-cigarettes are suppressing smoking and is beneficial. Though it is not possible to draw causal conclusions, the association is more obviously consistent with e-cigarette use driving down smoking than increasing it. The relevant data are shown in the chart below.



To its credit, WHO was careful not to claim a gateway effect had been found, and stuck to saying this was uncertain. The big failing in WHO's presentation of this issue is not to present the issue *symmetrically*: it is possible (and far more likely) that e-cigarettes will act as an 'exit gateway' – displacing smoking, diverting smoking onset and promoting quitting. WHO has focussed exclusively on the risk of a negative gateway effect, but not the opportunity of a beneficial effect – or the risk that its proposed policies will mean the opportunity is lost. Though the 'precautionary principle' is often cited as a reason to impose controls where there are unknowns, it cannot be applied here – this is because the controls themselves may have harmful effects if the gateway is, as seems likely, an 'exit'.

7.2 Renormalisation of smoking

This idea has no basis in evidence – it is pure speculation. UK based researchers concluded²³:

Evidence conflicts with the view that electronic cigarettes are undermining tobacco control or 'renormalizing' smoking, and they may be contributing to a reduction in smoking prevalence through increased success at quitting smoking

Again, WHO ignores the potential and much more likely upside: that e-cigarette use will normalise e-

²¹ CDC MMWR Tobacco Product Use Among Middle and High School Students — United States, 2011 and 2012, 15 November 2013. [\[link\]](#)

²² Survey reported in English on *Le blog de Jacques LeHouezec*, 16 May 2014. [\[link\]](#)

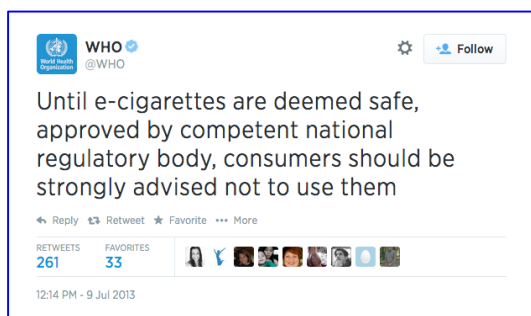
²³ West R. Brown J, Beard E. *Trends in electronic cigarette use in England*. Smoking Tool Kit Study. 13 June 2014 [\[link\]](#)

cigarettes as alternatives to smoking, make tougher smoking policies more acceptable by offering a humane alternative to smokers and hence contribute to the decline of smoking.

8 Poor advice to smokers on use of e-cigarettes

WHO has repeatedly advised against use of e-cigarettes. In tweets in 2013 and 2014 it says:

9 July 2013



26 August 2014



However, in its own paper (para 22) it somewhat reluctantly accepts that some experts see potential value:

However, at the individual level, experts suggest that in some smokers who have failed treatment, have been intolerant to it or who refuse to use conventional smoking cessation medication, the use of appropriately-regulated ENDS may have a role to play in supporting attempts to quit

Fortunately millions of vapers have ignored both WHO and the 'last resort' advice of experts cited here. The most comprehensive study so far of 'real world' use of e-cigarettes showed²⁴

People attempting to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter nicotine replacement therapies such as patches or gum

Survey data commissioned by Action on Smoking and Health²⁵ also supports a good news story about people quitting smoking –perhaps as many as 700,000:

ASH estimates that there are currently 2.1 million adults in Great Britain using electronic cigarettes, Of these, approximately 700,000 are ex-smokers while 1.3 million continue to use tobacco alongside their electronic cigarette use. Electronic cigarette use amongst never smokers remains negligible

So what is WHO's ethical and public health justification for advising against use of e-cigarettes? This is an example of where its advice is likely to cause more harm than good.

²⁴ Brown J, Beard E, Kotz D, Michie S, and West R (2014) Real-world effectiveness of e-cigarettes when used to aid smoking cessation: A cross-sectional population study. *Addiction*109: [doi: 10.1111/add.12623](https://doi.org/10.1111/add.12623).

²⁵ ASH (UK) Use of electronic cigarettes in Britain, July 2014 [\[link\]](#)

9 Quality of policy analysis

WHO makes a number of recommendations for policies, and it is possible that these may be adopted uncritically in some countries, especially developing countries, which rely on WHO for policy advice. The serious problem with this approach is that the usual disciplines of policy making have not been practiced and the recommendations simply asserted – in particular little account has been taken of the potential unintended consequence that such policies may be a *de facto* protection of cigarettes sales from competition, diminish the appeal of switching and so increase harm and cause avoidable deaths.

9.1 Inadequate policymaking practice and process

Many Parties to the FCTC may wonder just how well founded these policies really are. It is not apparent that WHO has followed any of the usual policy-making disciplines:

- Systematic review of the evidence
- Options development and appraisal
- Justification of the policy choices with reference to evidence
- Assessment of benefits, cost and burdens – and unintended consequences
- Consultation with users, producers and relevant public health experts

The European Union, UK governments, US FDA would all publish substantial justifications and background analysis²⁶. Why should developing countries expect less? Academic research has shown that WHO is generally prone to making strong recommendations based on weak evidence²⁷.

9.2 Inadequate recognition or assessment of unintended consequences

The concern that restrictive e-cigarette policies would protect cigarette sales and cause more harm than good was flagged to WHO in a letter to the Director General of the WHO, Dr Chan, of 26 May 2014²⁸ by 53 specialists in nicotine science and public health policy, proposing ten principles for managing low risk alternatives to smoking. The third principle reads as follows:

3. On a precautionary basis, regulators should avoid support for measures that could have the perverse effect of prolonging cigarette consumption. Policies that are excessively restrictive or burdensome on lower risk products can have the unintended consequence of protecting cigarettes from competition from less hazardous alternatives, and cause harm as a result. Every policy related to low risk, non-combustible nicotine products should be assessed for this risk.

The table below lists several of the policy proposals made by WHO with a statement of possible unintended consequences. WHO shows little sign that it has recognised any of these.

²⁶ For example the Department of Health (England) consultation document and impact assessment for a single measure – standardized packaging for cigarettes – runs to over 50 pages. [\[link\]](#)

²⁷ Alexander PE, Bero L, Montori VM, *et al.* World Health Organization recommendations are often strong based on low confidence in effect estimates. *J. Clin. Epidemiol.* 2014;**67**:629–34. [\[link\]](#)

²⁸ Letter to Dr Chan, Director General WHO, Reducing the toll of death and disease from tobacco – tobacco harm reduction and the Framework Convention on Tobacco Control 26 May 2014 [\[context\]](#)[\[letter\]](#)

Policy proposal	Para	Unintended consequence
Prohibit health claims unless regulatory approval	40	Denies smokers real world truthful information about relative risk and may cause more smoking. It is uncontroversial that e-cigarettes are safer than smoking – the debate is over where in the range 95-100% less risky. Erects high and unnecessary regulatory barrier to truthful communication.
Ban e-cigarette use in public places	41	Diminishes value proposition of e-cigarettes, make vaping less attractive relative to smoking, May promote relapse in existing vapers. Likely to lead to more smoking.
Restrictions on advertising, promotion and sponsorship	42-46	Reduces capacity of e-cigarette brands to compete with cigarettes, and diminishes means to communicate value proposition to smokers. May reduce means to communicate innovation or build trusted brands. May turns ads into bland public information notices. Some restrictions are undoubtedly justified, but the negative effects should always be considered.
Protect from vested commercial interests	47	These products are legal and legitimate and likely to be significantly beneficial for health at individual and population level. The danger of excluding the manufacturers is poor policy made on the basis of incomplete information.
Product design	48	There are numerous subtle trade-offs in product design. For example, the perfectly safe product that no-one wants to buy may be worse for health if it means more people smoke. Excessive design regulation can impose high costs, burdens and restrictions, slow innovation and drive good products and firms out of the market through 'regulatory barriers' to entry. Very high spec regulations will tend to favour high volume, low diversity commoditised products made by tobacco or pharmaceutical companies. Regulation can adversely reshape the market.
Impede product alteration to use of other drugs	48(e)	This might require 'closed systems' to be made mandatory (as proposed by tobacco company RJ Reynolds with this justification, but probably for anti-competitive reasons). But this has the effect of removing the 'open system' 2 nd and 3 rd generation products from the market. Many vapers report these are more effective alternatives to smoking. Note vaping may be a safer way to take other drugs than smoking – so there may be a harm reduction benefit to drug users.
Ban fruit, candy, alcohol drinks flavours	48(f)	Significant risk that loss of these broad flavour categories will cause relapse among e-cigarette users, fewer smokers switching, development of DIY and black market flavours. Flavours would become branded 'scorpion venom' rather than literally described. A further risk is that adolescents will simply switch to a different flavour – like tobacco - and the availability of what WHO considers to be attractive to minors is not an important factor in adolescent experimentation.
Health warnings	49	Alarmist health warnings, even if technically correct, may obscure much more important messages about relative risk compared to smoking – information that is not provided in official communications and WHO wants to prevent manufacturers making claims about.
Surveillance and monitoring	50	Data is always valuable, providing the results are assessed and reported honestly. In some cases (CDC in the US for example) data is misused to draw erroneous conclusions and to create fear and doubt about ENDS in the public.
Sales to minors	51	There is near universal support for this. However it is worth noting that NRT is made available to people over 12 years – because young smokers also need to quit. For licensed ENDS this may be an option in the future.
Regulatory framework – regulate as both a tobacco product and as a medical product	52	The problem is that ENDS are neither tobacco products nor medicines – they are consumer products that are for people who wish to use the recreational drug nicotine with less harm and cost. Using ill-fitting or excessive regulation designed for a different purpose would be simply limit the development of competitive alternatives to cigarettes. It is like insisting on classifying a dolphin as both a fish and a bird.

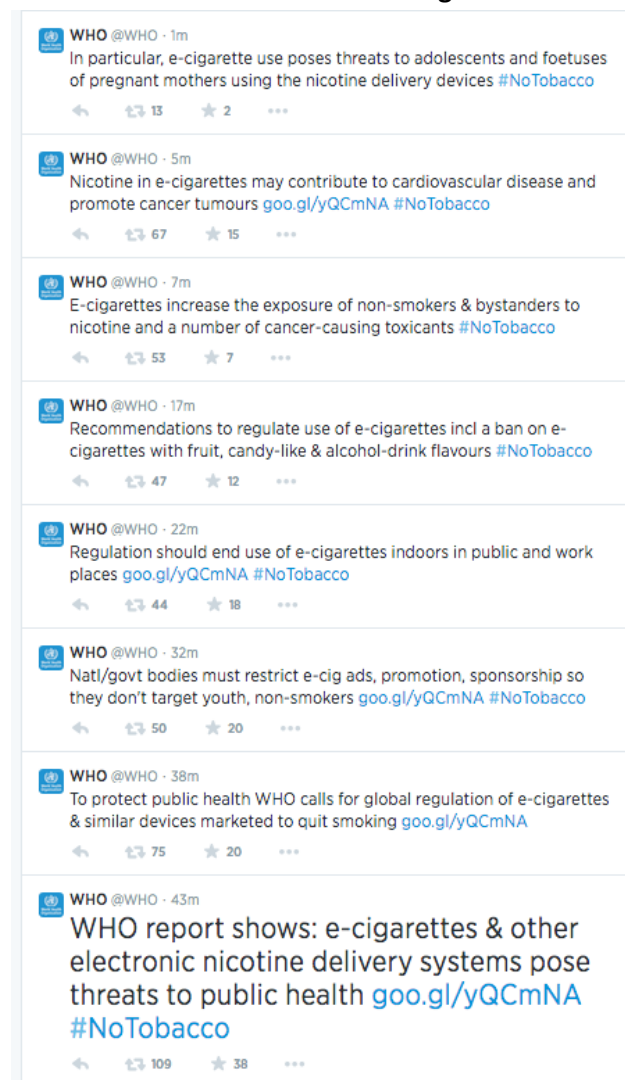
This is not necessarily to argue against the policy proposal, but to state that good policymaking requires these effects to be considered and a balance struck. There is no sign in the COP-6 document that WHO has even recognised these unintended consequences, let alone assessed them and found an appropriate balance.

10 Quality of WHO's communication of risk

10.1 WHO's public communication of risk

Though the COP-6 paper recognises 'promise' well as 'threat' (para 2), WHO's communication with the public and media has been wholly negative about e-cigarettes and the idea that a low risk alternative to smoking might be valuable for public health. For example, it is only possible to see the negative in its Twitter stream, which reaches 1.46 million followers (see below).

WHO ENDS tweets on 26 August 2014



Immediate reaction by expert scientists. Although some of these statements are technically correct, in its totality this communication is highly misleading, negative and disproportionate. Professor Konstantinos Farsalinos, a leading researcher and expert on e-cigarette science describes this twitter storm as follows²⁹:

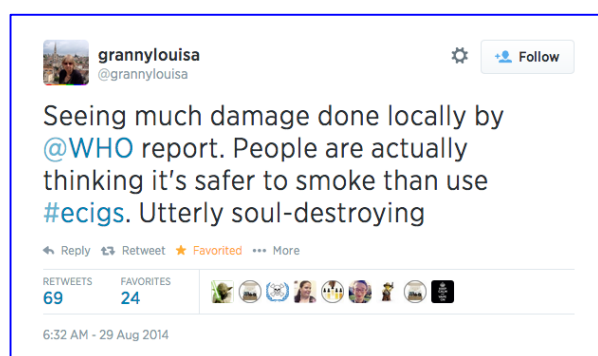
²⁹ Farsalinos K. Disgraceful propaganda by WHO staff against e-cigarettes in social media. 26 August 2014 [[link](#)]

The messages were a collection of fear-mongering, scientifically unbased, confusing and misleading claims about the risks posed by e-cigarettes. Of note, they avoid to mention that all the risks mentioned are higher by orders of magnitude when someone smokes, therefore, in reality, it will be beneficial for a smoker to switch to e-cigarette use.

Immediate consequences in news coverage. There is no doubt that communication like WHO's tweets will adversely change the perception of risk of e-cigarette use relative to smoking. We did not have to wait long for this to happen. The following article was published a day later in the UK newspaper, The Telegraph³⁰:

'I thought my e-cigarette was a miracle. Turns out, I was smoking the equivalent of 40-a-day'

Immediate impact on smokers' behaviour. This view is wrong and potentially dangerous. The result has already been felt in the English NHS services, which assist smokers in quitting. One NHS specialist³¹ [tweeted](#) the following about the impact of WHO's communication onslaught:



10.2 In India WHO says it is false to claim e-cigarettes not as harmful as cigarettes

In India, its Geneva-based representative was told the mass circulation Hindu newspaper that e-cigarettes were no less harmful than smoking³²:

Dr. Vinayak Mohan Prasad, project manager for Tobacco Control in WHO in Switzerland told The Hindu that smart marketing and inadequate information on the nicotine content in e-cigarettes has created a false impression that these devices are not as harmful as regular cigarettes. (emphasis added)

In a separate comment in India, a WHO official appears to suggest that e-cigarettes should be banned in India because inhaling nicotine is dangerous (it is not)³³:

However, not many people know that it has a potential of killing as inhaling nicotine could be dangerous. It is also very harmful for the passive smokers. So it has been decided to

³⁰ Telegraph online 27 Aug 2014 [[link](#)]

³¹ Louise Ross, twitter handle [@grannylouisa](#) and works for Leicester Stop Smoking Services

³² The Hindu. WHO cautions India over e-cigarettes. 29 August 2014 [[link](#)]

³³ Deccan Chronicle, E-cigarettes set to be banned in India soon. 19 August 2014. [[link](#)]

completely ban this menace by bringing strong legislation,” a senior official and spokesperson of FCTC secretariat told Deccan Chronicle.

10.3 In the Philippines WHO claims e-cigarettes more dangerous than smoking

In the Philippines, a WHO spokesman implied that they were *more dangerous* than cigarettes because they did not have filters. Dr Florante Trinidad, technical officer at Tobacco-Free Initiative WHO Western Pacific Region, stated on national television³⁴:

The most dangerous thing about this product (e-cigarette) is that the nicotine goes directly to the lungs while regular cigarettes have a filter. With this delivery device the nicotine goes directly to the lungs.

This betrays simultaneous confusion over the origins of smoking-related harm, the role of cigarette filters, and the advantages of e-cigarettes. It could not be more misleading.

10.4 WHO supports e-cigarette bans in South East Asia (but not a cigarette ban)

At the **South East Asia regional meeting on the WHO FCTC** in Delhi³⁵, at which WHO provided ‘technical assistance’, the 4-day conference proposes a ban on e-cigarettes, but without banning the much more harmful smoking cigarettes:

On the issue of ENDS countries of the Region recognized the adverse impact of ENDS on human health that sustain and perpetrate nicotine addiction and resolve to take appropriate action/measures in line with obligations under Article 5.2(b) of the WHO FCTC to prevent and reduce nicotine addiction including through banning ENDS. (emphasis added)

10.5 WHO misleads the European Parliament as it makes law on e-cigarettes

WHO gave a presentation to the European Parliament at a key point in the development of the Tobacco Products Directive. Dr Roberto Bertollini, Chief Scientist and WHO representative to the European Union presented to MEPs “*Latest evidence from the WHO on e-cigarettes*”.

The presentation was described by Professor Jean François Etter, a prominent researcher and 30 years an expert in public health and smoking prevention at the University of Geneva as follows³⁶:

Roberto Bertollini made a presentation at the EU workshop which was appalling. His presentation consisted in cherry-picking negative studies, studies that show that e-cigarettes are bad, and deliberately omitting studies that suggest that e-cigarettes could be useful in helping people quit smoking. So I confronted him on that and he didn’t like it... [...] If a student had presented such a work to me I would have given him a very bad grade. WHO after all is here to protect the health of the public, so by taking such an approach they are not doing their job.

Professor Etter’s concerns are justified. The following slide in Dr Bertollini’s presentation to the

³⁴ See YouTube: <https://www.youtube.com/watch?v=GgayDbRiCUM> and commentary by Konstantinos Farsalinos [\[link\]](#)

³⁵ Government of India, Press Information Bureau. Regional Meeting on Implementation of the WHO FCTC for South-East Asia Region concluded. 26 July 2013. [\[link\]](#)

³⁶ Professor Etter interviewed: YouTube: <https://www.youtube.com/watch?v=duVDY9oBb7Q>

European Parliament³⁷ stands out:

Recent Findings on Toxicity

- At least 10 toxicants can be identified and quantified in electronic cigarettes¹, including **known carcinogens** and **diethylene glycol**, an ingredient used in antifreeze.
- In Turkey, **propylene glycol** (which is potentially toxic) was found in all ENDS samples, **tobacco specific N-nitrosamines** (powerful carcinogens) in a majority of samples²
- E-cigarettes release **toxins** into the air, including acetic acid, acetone, isoprene, formaldehyde and acetaldehyde, averaging around **20%** of what the conventional cigarette produces³
- All e-cigarettes that the FDA has detained and examined meet the definition of a **combination drug-device** product under the Federal Food, Drug, and Cosmetic Act¹.

1. U.S. FDA <http://www.fda.gov/newsroom/pressannouncements/ucm173222.html>, Republic of Korea
2. FAME Laboratory, Institute of Human Performance and Rehabilitation, Center for Research and Technology, Thessaly, Trikala, Greece
3. Indoor Air, Germany

Why is this misleading?

1. The presence of a toxicant does not make a product toxic to humans – it depends on dose and exposure, not where it is detectable. Toxins and carcinogens are in fact present everywhere – for example in ambient air, drinking water, NRT products and coffee. The statement is meaningless without some form of quantification. Studies were available at the time³⁸:
We found that the e-cigarette vapours contained some toxic substances. The levels of the toxicants were 9–450 times lower than in cigarette smoke and were, in many cases, comparable with trace amounts found in the reference product [NRT].
2. Propylene glycol is described as ‘potentially toxic’. In fact PG is an approved EU food additive (E1520), Generally Regarded As Safe (GRAS) for inhalation by the US FDA, and used in a wide range of consumer and pharmaceutical products.
3. Tobacco Specific Nitrosamines (TSNAs) usually arise from tobacco flavours or the tobacco derived nicotine used in the e-cigarettes that most smokers are using to start with. They are present at very low levels. Dr Bertollini does not mention that the levels are similar as in NRT products and that a 15/day smoker would have exposure approximately 1800 times higher³⁹.
4. The claim that *e-cigarettes release toxins into the air averaging around 20% of what the conventional cigarette produces* is completely unfounded and it is not possible to trace the source of this claim. Most toxins found in cigarette smoke are not present in e-cigarette vapour at all or are present at much lower levels than would give a 20% average. Professor Robert West and Dr Jamie Brown of UCL, in an editorial for the British Journal of General Practice, give the following assessment⁴⁰:

³⁷ Bertollini R. WHO Europe. Presentation to European Parliament Workshop on E-cigarettes, 7 May 2013. [\[link\]](#)

³⁸ Goniewicz ML, Knysak J, Gawron M, *et al.* Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tob Control* 2013;;1–7. [doi:10.1136/tobaccocontrol-2012-050859](https://doi.org/10.1136/tobaccocontrol-2012-050859) (e-published March 2013)

³⁹ Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Ther Adv Drug Saf* 2014;5:67–86. [doi:10.1177/2042098614524430](https://doi.org/10.1177/2042098614524430)

⁴⁰ West R, Brown J. Electronic cigarettes: fact and faction. *Br J Gen Pract* 2014;64:442–3. [doi:10.3399/bjgp14X681253](https://doi.org/10.3399/bjgp14X681253)

*In fact, toxin concentrations are almost all well below 1/20th that of cigarette smoke.
(emphasis added)*

There is a very substantial difference between *around 20%* and *well below 1/20th*.

5. In the *Sottera* case, FDA was found by the US Court of Appeal DC Circuit to be acting unlawfully when it defined e-cigarettes as ‘combination drug devices’ and refused to allow import of these products⁴¹. This judgement was in 2010. Dr Bertollini’s presentation was in 2013.

Every statement on Dr Bertollini’s slide is either factually incorrect, misleading or a non-sequitur, yet WHO was brought into the process of determining regulation of alternatives to cigarettes that covers the European Union, where 700,000 people die annually from smoking related disease.

Tom Pruen, the Chief Scientific Officer at ECITA, and an expert from the UK-based Electronic Cigarette Industry Trade Association, has provided a detailed critique of WHO’s presentation to the European Parliament⁴². He ruefully concludes:

Sadly, the WHO demonstrated that they themselves are woefully ill-informed on this subject – not a good position from which to attempt to educate others.

10.6 WHO’s communication with parties to the FCTC

Although there are caveats in the COP-6 paper it still creates a misleadingly negative impression about the risks and benefits of ENDS through the following mechanisms:

- WHO provides analysis based on selective and biased portrayal of the science (discussed at length above). Even if statements made are not always literally false, they will have the effect of misleading the public, media or health authorities with partial truths or statements made without appropriate context or caveats.
- WHO has no coherent framework for discussing relative risk – to smokers, vapers and non-users and appears to place little weight on the health of smokers or nicotine users, or on the ethics of denying or obstructing access to much safer products.
- WHO has a pronounced focus on minor or implausible risks while underplaying potentially large benefits. A further consequence is to understate the risk that benefits will be foregone because of restrictive policies. None of WHO’s communication would leave the reader with the impression remotely similar to that offered by a more straightforward expert assessment of risk, stating at least 20 times lower risk than smoking⁴³:

*...e-cigarette use from popular brands can be expected to be at least 20 times safer
(and probably considerably more so) than smoking tobacco cigarettes in terms of
long-term health risks.*

⁴¹ U.S. Court of Appeals for the D.C. Circuit, in *Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010) [\[link\]](#)

⁴² Pruen T. Why the WHO is not qualified to attempt to educate people about electronic cigarettes. ECITA [\[link\]](#)

⁴³ West R. Hajek P. Brown J. Arnott D. Electronic cigarettes: what we know so far. Evidence to the All Party Parliamentary Group on Smoking and Health. 10 June 2014 [\[link\]](#)

11 Inappropriate use of a *tobacco* treaty to regulate ENDS

It is not clear why ENDS are a matter for discussion at all under the Framework Convention on Tobacco Control. E-cigarettes do not contain tobacco, but the FCTC objective is focussed exclusively (and rightly) on tobacco and tobacco smoke:

Article 3

Objective

The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke. (emphasis added)

It is not just a matter of definitions: the FCTC is fundamentally incompatible with regulation of ENDS as an alternative to smoking. This is because its key provisions are all aimed to reduce, prevent or eliminate tobacco. While it is desirable to do that for combustible tobacco (cigarettes etc) it is undesirable to apply the same approach to products that are much safer than smoking.

12 One-sided principles governing ENDS

In the COP6 paper paragraph 36, WHO suggests four principles to consider in regulation of ENDS.

36. When designing a regulatory strategy for ENDS, governments should bear in mind the following general regulatory objectives:

- (a) impede ENDS promotion to and uptake by non-smokers, pregnant women and youth;*
- (b) minimize potential health risks to ENDS users and non-users;*
- (c) prohibit unproven health claims from being made about ENDS; and*
- (d) protect existing tobacco-control efforts from commercial and other vested interests of the tobacco industry.*

Regrettably, these reflect WHO's biases. Despite its recognition that it is unsure whether ENDS are a promise or a threat (para 2), these principles reveal unambiguous positioning as a threat. In fact the most important principle of regulation should be to encourage smokers to switch and to avoid providing implicit protection to cigarette sales. This is where the greatest health gains are to be made. The reference to pregnant women and youth is unnecessary - if they are smokers, ENDS are a far better option than continued smoking. All claims should be true and substantiated, not just health claims. A more specific risk related to the tobacco industry should be articulated rather than a reassertion of Article 5.3 of the convention, which applies anyway. The following principles would therefore be a significant improvement:

- (a) the public health imperative:** secure the optimum health outcomes from ENDS by incentivising smokers to switch, while controlling risks to ENDS users and non-users;*
- (b) the appropriate target population:** ensure ENDS promotion is focussed on adult smokers;*
- (c) truthful marketing:** require any claim made for ENDS to be true and substantiated; and*
- (d) support for tobacco control:** avoid ENDS regulation that protects cigarette sales or favours the ENDS products of tobacco companies at the expense of independent suppliers*

13 Recommendations

These recommendations are addressed to WHO, the FCTC Secretariat, Parties to the FCTC and to public interest NGO stakeholders.

13.1 WHO should restore an objective approach to science

It is difficult to provide a rational explanation for the negativity and bias that appears hard wired into WHO's approach to tobacco harm reduction, despite the great promise that many experts recognise. The final comment on this is from Professor Robert West and Dr Jamie Brown, in their recent editorial in the British Journal of General Practice⁴⁴:

This brings us back to the question as to why some individuals and bodies involved in public health are so opposed to e-cigarettes. It may be a concern over how things might turn out in the future given commercial incentives, puritanical ethics, distaste for any industry profiting from a psychoactive drug, inappropriate application of a medical rather than a public health model, or even just a gut feeling that e-cigarettes are bad. Whatever the reasons, it is important that interpretation of the evidence and communication with policy makers and the public is not distorted by a priori judgements.

13.2 WHO should take formal independent scientific advice

Before going any further with inadequately grounded risk communications or policy recommendations, WHO and parties to the FCTC should wait until the specialist WHO Study Group on Tobacco Product Regulation (TobReg) has reported in 2015. This group is preparing its 5th technical report series, which will be presented at the January 2015 WHO Executive Board 136th session⁴⁵. This group should be constituted with credible world experts that encompass all the perspectives on these issues. WHO should avoid the temptation to commission advice from scientists it expects to give a particular orientation to their assessment.

13.3 Parties should not bring ENDS into the FCTC

There is no case to bring ENDS under the FCTC:

- For the *technical* reason that ENDS are not tobacco products and should not be treated as such. The Framework Convention on Tobacco Control should remain focussed on its main mission, which is already very challenging.
- For the *strategic* reason that ENDS are a way of *reducing* tobacco consumption, improving health and contributing to UN NCD objectives. The FCTC focuses on prevention and reduction – not substitution – and it has not been effective at supporting harm reduction.

13.4 Parties should insist that WHO improves the quality its policy making and advice

Parties to the FCTC should expect WHO make policy recommendations only if it follows the established disciplines of quality policy-making. Policy recommendations should emerge from a deliberative process – involving evidence assessment, options appraisal, impact assessment and consultation. Policy recommendations to parties to the FCTC should not just be the asserted

⁴⁴ West R, Brown J. Electronic cigarettes: fact and faction. *Br J Gen Pract* 2014;**64**:442–3. [doi:10.3399/bjgp14X681253](https://doi.org/10.3399/bjgp14X681253)

⁴⁵ WHO Tobacco Free Initiative 7th Meeting of the WHO Study Group on Tobacco Product Regulation, 2013 [[link](#)]

opinions of WHO staff.

13.5 Stakeholders should treat WHO policy recommendations with caution

Though its policies are built on weak evidential and analytical foundations, WHO makes strongly prescriptive policy recommendations (para 40-52). Yet WHO acknowledges (para 2) great uncertainty and that:

...the recommendations and evidence presented in this report are therefore subject to rapid change

In reality, once implemented 'tobacco control' policies are politically very difficult to reverse, even if there is evidence they are harmful to health and welfare. They should therefore be adopted with great care.

13.6 WHO should apply much stronger quality control to its public risk communications

WHO needs to strike a more objective and evidence-based balance between emphasis on minor risks and recognition of great potential – some of its communications have been blatantly misleading and potentially dangerous. In its communication with the public, WHO needs to be factually correct. However, being merely factually correct is not sufficient. It also must take care to ensure its communications are proportionate, properly placed in a framework of relative risk and are unlikely to be misunderstood by ordinary members of the public or non-specialists. WHO's representatives need to be far more disciplined in their public statements and communication of risk to the public, media, politicians and member governments.

13.7 COP-6 Declaration should be based on revised principles governing ENDS regulation

The following principles should form the basis of a declaration from the Sixth Conference of The Parties of the FCTC.

1. Noting the report of the Convention Secretariat on Electronic Nicotine Delivery Systems (ENDS) (WHO FCTC/COP/6/10 Rev.1);
2. Recognising that the global burden and threat of non-communicable diseases can be dramatically reduced by reducing tobacco smoking and exposure to tobacco smoke;
3. The Parties recognise both the promise and threat of ENDS, and undertake to regulate these products in a way that minimise risks and maximises the opportunity to reduce smoking and the burden of non-communicable disease to the greatest extent possible. The following principles should govern the regulation of ENDS.

(a) the public health imperative: *secure the optimum health outcomes from ENDS by incentivising smokers to switch, while controlling risks to ENDS users and non-users;*

(b) the appropriate target population: *ensure ENDS promotion is focussed on adult smokers;*

(c) truthful marketing: *require any claim made for ENDS to be true and substantiated; and*

(d) support for tobacco control: *avoid ENDS regulation that protects cigarette sales or favours the ENDS products of tobacco companies at the expense of independent suppliers*

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Disclaimer. Views expressed in this report do not necessarily reflect the views of former employers or affiliates. Clive Bates has no competing interests with respect to tobacco, pharmaceutical, ENDS industries or the World Health Organization.

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⁴⁷ McNeill A, Foulds J, Bates C. Regulation of nicotine replacement therapies (NRT): a critique of current practice. *Addiction* 2001;**96**:1757–68. [doi:10.1080/09652140120089508](https://doi.org/10.1080/09652140120089508)

⁴⁸ Bates C. Taking the nicotine out of cigarettes--why it is a bad idea. *Bull World Health Organ* 2000;**78**:944. [[link](#)]

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