WHO tobacco meeting – could the FCTC do something useful on vaping?

written by Clive Bates | 2 November 2016

I'm sometimes accused of being a WHO-sceptic, or worse. No more! In the run up to the Framework Convention on Tobacco Control COP-7 meeting in Delhi, 7-12 November, I have been challenged to say something positive about how the FCTC could do useful and constructive things on vaping and tobacco harm reduction from a public health point of view, other than the default answer "absolutely nothing at all".

I sometimes refer to ENDS – Electronic Nicotine Delivery Systems – to mean vaping equipment and liquids, e-cigarettes etc. Apologies.

Here we go…

Options for WHO FCTC involvement in ENDS to be positive for global public health

The FCTC would best serve public health by doing some or all of the following:

- Recognise the opportunity, not just a threat. FCTC needs language that gives due weight to the reality that ENDS are beneficial and displacing high-risk products with low risk. It would be helpful to see at least equal weight given to the opportunities as to the threats. In fact, more weight should be given to the opportunities given what we know from the evidence, summarised admirably by the Royal College of Physicians:

Nicotine without Smoke: tobacco harm reduction, April 2016 and Public Health England: *E-cigarettes – and evidence update, August 2015*. WHO should be at least as concerned with squandering a tangible opportunity as avoiding a hypothetical risk.

- Call for more research and of higher quality. FCTC should encourage and facilitate research with interdisciplinary and international collaboration as necessary, taking a balanced approach to assessing risk and benefits. It could do more to set down standards for research, like recognising that 'dose makes the poison' in toxicology studies, that confounding, reverse causality and selection bias pervade studies of e-cigarette use, that cell and animal studies have limited applicability, that an effect on the cardiovascular system is not evidence of harm etc. WHO could commission a guide to ENDS research methods, that would help researchers avoid some of the more embarrassing mistakes they have made so far.
- Make more of TobReg for scientific assessment. FCTC and WHO should make better use of TobReg to do scientific assessments and constitute this group with more diverse expertise. This would make the process of scientific assessment more transparent, open to challenge and accountable. The quality of the current WHO ENDS paper is so poor (see UKCTAS commentary) and so obviously laden with bias, that it does FCTC parties a real disservice. This failure suggests that a different, more open, commissioning model would be advisable – rather than looking for consultants to provide a pre-ordained answer. This is where a rejuvenated TobReg might be the answer.
- Refashion the surveillance system to reflect changes in the nicotine market. Bring coherence to tobacco and ENDS surveillance (measuring prevalence etc), including coverage in WHO's main surveys (GATS and GYTS), the FCTC surveillance regime and the NCD monitoring framework. Convergence in definitions and survey questions would help with comparative analysis. Surveillance should anticipate developments such as heated tobacco products, novel tobacco and nicotine products and, generally, an expanding portfolio of non-combustible nicotine options. Much could be learnt from England's Smoking Toolkit Survey – currently the most advanced, highest resolution survey of its type. Article 20 of the FCTC (Research, surveillance and exchange of information) provides the basis for the Parties co-ordinating in the way suggested.

- Track and summarise the evolving policy environment. Regular ENDS policy scans would be valuable and should be done under Article 21 of the FCTC (Reporting and exchange of information) by parties individually, but it could be done to a consistent standard with ENDS policies extracted and aggregated into an annual thematic report. This could build on the initiative at John Hopkins Bloomberg School of Public Health in January 2016 [Country Laws Regulating E-cigarettes] – or it could be done by a different centre or as a commercial contract.
- Promote high quality regulation and standard-setting by Parties. If there are decisions or statements from COP-7, it would be helpful for WHO to stress that principles and disciplines of good regulation should underpin ENDS policy – as with all public health policy. These principles and disciplines include 'proportionality' and 'non-discrimination' backed by consultation and impact assessment, including assessment of the unintended consequences of intervention as well consequences of non-intervention.
- Focus on the relationship between the state and citizen. FCTC should go back to public health basics. In modern public health, the role of governments as enabling and empowering citizens to make informed choices in their own interests (e.g. WHO's Ottawa Charter "*Health promotion is the process of enabling people to increase control over, and to improve, their health*"). Such principles run counter to, for example, state-imposed prohibitions on ENDS – which for inexplicable reasons ban much-safer vaping products while the much more harmful cigarettes remain pervasively available. It also suggests that meaningful consumer-friendly risk communication is essential – otherwise, how do people exercise informed choice?
- Improve the tone and be more inclusive. Much communication and rhetoric coming from FCTC meetings feels contemptuous towards those it is notionally trying to help. It would be helpful to stress inclusiveness, consultation and respect for the idea of "*nothing about us, without us*" in health policy [which has been adopted in the NHS]. There has been too little empathy and humility towards smokers and vapers, but a different approach has been taken with other UN initiative (e.g. HIV/AIDS) and English Stop Smoking Services and Public Health England are doing much to address this in the nicotine field. The collaborative SOVAPE model in France suggests is a rising phenomenon. COP-7 could examine

why its rules for observers exclude so many entirely legitimate stakeholders – e.g. consumers or smokers, the supposed beneficiaries of WHO policies, and the thousands of small businesses providing what amounts to a new consumer health technologies.

- Reframe the UN/WHA non-communicable disease targets. The 2025 NCD targets to reduce cancer, heart disease, COPD and other major diseases are virtually impossible to meet. However, the FCTC could do more to shape a more credible response. Target 1 on NCD outcomes (25% reduction in NCD mortality between 2010 and 2025) is unlikely to be reached, but it is a laudable goal to pursue vigorously. Target 5 on tobacco prevalence (30% relative reduction in tobacco prevalence by 2025) requires a global annualised decline in prevalence between 2010 and 2025 that is *three times* (2.35%) the actual annualised decline between 2006 and 2012 (0.8%) [1]. The only plausible game-changer in sight is a tobacco harm reduction approach that replaces high-risk nicotine use with low-risk use. Ideally, an FCTC-led process would examine the strategies for meeting Target 5 (or reducing the scale of failure). This could include a refinement of the target definition to focus on *smoking*, thus bringing the Target 5 *risk factor* objective into better alignment with the Target 1 *health outcome.*

[1] Ng M, Freeman MK, Fleming TD, et al. Smoking prevalence and cigarette consumption in 187 countries, 1980-2012. Jama 2014; 311:183–92. [link] see Supplemental content – table 13 [PDF]

- Reshape the FCTC to recognise the range of risk within tobacco products. It is a major policy error to treat all tobacco products as if they are equally risky, when the range of risk may be 100-fold, and smokers can benefit by switching to lower risk alternatives. Much of the argument above about ENDS also applies to any proposals to regulate non-combustible tobacco products – smokeless tobacco, heated tobacco products, lozenges (etc) or other novel nicotine products. All of which could (and in the case of snus, already does) play a significant role in reducing the disease burden arising from smoking. A major step could be taken in the FCTC by differentiating tobacco products according to risk of harm – the purpose of FCTC being to reduce harm – and so allowing for harm reduction to be included properly in tobacco control. To take an

obvious example, there is no case for taxing heated tobacco products, smokeless tobacco and novel non-combustible tobacco products at anything like the same level as cigarettes.

- Understand and play to WHO and FCTC strengths (and avoid its weaknesses). The FCTC is good at taking well-established policies and helping to generalise these to all countries, establishing global norms and promoting solidarity. As long as these policies are evidence-based, effective in meeting the right goals, and applied in a way that appropriate for modern democracies and consistent with national law, then this is a highly worthwhile function.

But WHO should be aware of its limitations too …

- Let FCTC Parties learn from ENDS and other harm reduction policies before bringing into the FCTC. On the other hand, the FCTC is not a good forum for assessing the merits of new ideas, adopting innovation, trying novel regulatory approaches – this should be left to Parties to try a variety of options, evaluate, adjust and press ahead or reverse as appropriate. That degree of flexibility is much harder to develop in an international convention, where decisions, once taken, are difficult to reverse however bad they turn out to be (note the Europe Union's snus ban). FCTC should therefore avoid doing anything prescriptive on ENDS (WHO's science is robustly contested), heated tobacco products (only now emerging), or reduced-nicotine cigarettes (experimental phase with very mixed results). The policy and science for these technologies should rest with Parties until a consensus is emerging about how such products should regulated and what sort of risk communications should be used. For example, there has been positive developments on standard setting in France (AFNOR Devices and Liquids – 2015) UK (BSI PAS, 2015) these processes are ongoing, promising and need to continue.
- Focus on obligation to 'do no harm' and the dangers of unintended consequences. Until WHO and the parties to the FCTC have extensive practical experience to draw up, there is a danger that interventions could increase smoking, protect the cigarette trade and cause more disease and death – which we must all agree would be a terrible outcome from a tobacco control convention. For example, any move to classify ENDS as tobacco products would be likely to have exactly that effect through

applying excessive regulation designed for products with far greater risk. The Royal College of Physicians, explains as follows:

> *A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg 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, Nicotine without smoke: tobacco harm reduction)*

If only everyone involved in the FCTC just remembered this one quote from RCP, and acted accordingly, then WHO and FCTC would: a) tread very lightly on tobacco harm reduction; b) be and be seen to be a more credible regulatory forum.

Comments, suggestions, disagreements etc… welcome in the comments.