Tobacco harm reduction – a note to WHO's expert commitee

written by Clive Bates | 4 December 2013

The WHO Study Group on Tobacco Product Regulation 'TobReg' is meeting in Rio de Janeiro 4-6 December. This group is important – or it will be if WHO listens to it and acts on its advice. Its previous reports have added to understanding and pointed the way to a rational approach to regulating reduced risk tobacco and nicotine products. However, there are rumours that WHO finds its advice unwelcome and its account of the truths inconvenient, and would like to replace it with working groups from the parties to the FCTC. I hope that does not happen.

So I would like to write a note to the TobReg to encourage it to keep up its good work, and to keep the focus on the billion deaths WHO expects to be caused by smoking in the 21st Century.

> *Dear TobReg members*
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> *I hope your stay in Rio proves to be productive for global health. The most likely way this can happen is through TobReg articulating a science and ethics based approach to tobacco harm reduction. To that end, I would like to propose 10 points for you to keep in mind during your discussions:*
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> *1. WHO estimates that one billion people will die from tobacco related diseases in the 21st Century. The organisation should have a mission to reduce that awful toll above all else, and be ready to swallow hard and make uncomfortable choices needed to do it. Though WHO sets ambitious targets for reducing tobacco use and non-communicable diseases, it does not at present have a credible plan that would deliver on these. The tobacco control community discusses 'the endgame' for tobacco but many of the ideas lack credibility and would not survive the serious scrutiny they have not so far received. Tobacco harm reduction is, however, a highly plausible strategy for reducing the burden of disease caused primarily by smoking. One investment analyst sees e-cigarette use overtaking cigarettes in the United States by 2023. That would be*

transformational, and even if bullish, it should alert us to the potential.

2. There is not really a continuum of risk with nicotine products – there is a discontinuity between combustible tobacco and products that deliver nicotine without combustion. The latter are lower risk by one to three orders of magnitude and good science and policy should recognise that and not lump them together. WHO too easily sets targets and policies for all tobacco, even though a smoker who switches from smoking to using a smokeless tobacco product would have greatly reduced risk. There is a continuum of risk within the non-combustible tobacco products and regulation can reduce some of these risks, but it should not do that at the expense of making these products less attractive as alternatives to smoking.

3. In practice, WHO and the public health establishment have been extremely negative about the idea of 'tobacco harm reduction'. The papers on harm reduction submitted to COP-5 by the WHO secretariat were wholly negative and without any balancing discussion of the considerable potential opportunity and the beneficial effects already realised. WHO's stance is typical of many health organisations, such IUATLD. There is no justification for this negativity or for deliberately downplaying the public health potential. The risks and benefits should always be considered together.

1. *FCTC/COP/5/12: Control and prevention of smokeless tobacco products*
2. *FCTC/COP/5/13: Electronic nicotine delivery systems, including electronic cigarettes*
3. *IUATLD statement on e-cigarettes*

4. The field of tobacco harm reduction is plagued by 'asymmetric loss aversion' – an excessive weighting of minor or implausible risks, often accompanied by exaggeration, whilst ignoring or denying benefits. It is important to take a symmetrical view of risks and benefits. A lost health benefit is a harm. Restrictive policies that prevent the realisation of benefits are causing harm – perhaps more harm than the restrictions were designed to prevent. This symmetry is critical in determining optimum regulation for harm-reduction products. It can also be expressed as the problem of a double negative: tough on harm reduction alternative = easy on smoking and harm.

5. The best 'proof of concept' for tobacco harm reduction so far comes from

Sweden (and more recently Norway), where a form of smokeless tobacco, snus, is the primary cause of the lowest rates of smoking found in any developed country – and low rates of smoking-related disease and mortality as result. This should be a reason for careful scientific interest and learning, and, frankly, some humility in policy-making. The success with snus in Sweden is instructive and has several important characteristics that :

- *The beneficial public health effect was entirely created in the private sector – through choices made by producers and consumers acting in their own interest – there was no public spending or health-care system endorsement.*
- *The products involved were not positioned as 'health' products, medicines, smoking cessation products etc.*
- *There was minimal regulation of the product itself, though the main company involved imposed its own standards voluntarily*
- *The public health establishment opposed it and managed to have the product banned in the European Union outside Sweden – something they continue to support to this day*
- *It may be uncomfortable to acknowledge this, but the tobacco industry and its smokeless tobacco product played a positive role (for which it was relentlessly punished by regulators in Europe)*

6. There are broadly four categories of non-combustible nicotine delivery: medicinal NRT; non-tobacco nicotine products like e-cigarettes; smokeless tobacco products that are not heated; 'heat not burn' tobacco products. All are potentially useful in addressing the one billion person death toll. In public health terms it is counterproductive to regulate these products very differently, simply because they are or are not medicines, or are or are not tobacco products. They should be treated according to the risks they impose, and with a reference point recognising the risks they displace (i.e. from smoking cigarettes).

7. Though harm reduction products are undeniably far less risky, there are concerns about 'population effects' (where the availability of low risk products induce harmful or beneficial changes in aggregate smoking behaviour). These concerns are also used tactically by interests opposed to harm reduction strategies – perhaps because they are difficult or impossible to resolve in advance of the products being on the market (maybe for several decades).

Again there are important symmetries to consider: harm reduction products, can be exits from smoking and nicotine use, displace smoking in teenagers and denormalise smoking. For every negative population effect there are one or more positive population effects.

8. Sweden and Norway's experience of population effects showed these effects to beneficial: snus was used as an alternative to smoking, a diversion from smoking initiation and as pathway to complete cessation. Evidence of the type recently presented by CDC showing rising use of e-cigarettes in school children is not evidence of a gateway effect or even of any harm – it may in fact be beneficial to health. For a gateway effect to be real and harmful, a product like an e-cigarette must cause someone to smoke who otherwise would not, and then not be used by them later to stop smoking. In fact of all the possible pathways for lifetime nicotine use and abstinence created by the introduction of harm reduction products, the one that leads to lifelong smoking that would not have otherwise occurred is among the least plausible. The CDC data actually showed experimentation with e-cigarettes primarily among existing smokers; use rose in line with use in the general population and over the same period smoking fell in American schools. The data are actually consistent with e-cigarette use displacing smoking – a more likely pathway than e-cigarette use causing smoking.

9. The precautionary principle is much cited, but often abused as a basis for taking restrictive action in conditions of uncertainty. The European Commission guidance on the precautionary principle is more subtle – and requires a careful assessment of the costs and risks of intervention as well as non-intervention – it requires a symmetrical judgement about risks of non-intervention and unintended consequence of intervention. In Europe, it could now be invoked in active support of lifting the ban on snus.

10. The process of regulatory policy-making and legislation is important. It should involve options appraisal, evidence based justification, impact assessment, consultation and scrutiny or challenge of some form. In particular it should involve the views of the intended beneficiaries and should recognise and respect their appetite for risk and their wants and needs. The principle of 'nothing about me, without me' is a good one in public health. Expert judgement is part of the picture but it should not be the final word. Regulation of tobacco products is not a purely technocratic exercise, it is a societal

intervention and involves a range of value judgements – including implied risk appetites, the boundaries between role of the state and the agency of the individual and moral judgements about recreational drug use. WHO and much of the health establishment has done little to engage with tobacco or nicotine users and has a poor understanding of what they want and think is important – that should change.

I hope you have a productive meeting

Clive Bates