Counterfactual

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Brussels

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Dear Ms Brozmanová

European Union common approach to WHO FCTC COP-7 - ENDS

I am long standing advocate for public health and tobacco control, and was the Director of the UK anti-tobacco organisation Action on Smoking and Health from 1997-2003. I was closely involved in the formation of the WHO Framework Convention on Tobacco Control and responsible for the initiation of the Framework Convention Alliance of NGOs that supports the FCTC. I remain strongly interested in the success of the FCTC and its effectiveness in reducing disease and death. I have no competing interests and, specifically, no conflicts with respect to Article 5.3 of the FCTC.

I am concerned that the approach taken to ENDS by WHO and by the Conference of the Parties is counter-productive and will do harm by denying or obstructing smokers' access to alternatives to cigarettes that is likely to be at least 95-99% less risky to health. I hope that the European Union will use its considerable influence in the FCTC to secure good policy and practice with respect to ENDS.

I understand from the agenda that discussion of the EU approach to FCTC COP-7 is possible at the European Council Working Party on Public Health to be held on Monday 26th September. It would be better to postpone substantive discussion until a later meeting so that experts can provide a critique of the WHO ENDS paper (FCTC/COP/7/11). It would be to everyone's advantage if member states can consider the WHO paper alongside an informed review. However, should the ENDS issue come up for discussion on Monday, I hope the working party will consider the following points, and some constructive proposals for what FCTC could usefully do in the area of ENDS.

1. Risks that WHO FCTC involvement in ENDS will be negative for global public health

The WHO's scientific assessment of ENDS. The WHO's ENDS paper is not a neutral scientific, economic or policy briefing. It contains many deficiencies and errors, and it is likely to be the subject of considerable expert criticism in the coming weeks. I would like to suggest that it is not endorsed or welcomed in its current form by the European Union or relied upon by anyone as a summary of the state of knowledge in this area. The April 2016 report by the Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*, remains a better and more in-depth assessment for delegates as they approach COP-7, and I recommend working party members at least consult the summary and recommendations or that report.

The strengths and weaknesses of the Conference of the Parties. The COP is a good forum for building support and solidarity for implementation of established and proven tobacco control measures for which there is a public health consensus. It is *not* well suited to addressing emerging technologies where the science is contested (often with undeclared ideological biases) and the policy responses have the potential to cause harm. It would be harmful and premature to have any sort of prescriptive or advisory text or any FCTC working groups on ENDS regulation. In this forum, such initiatives would, beyond doubt, produce excessive and counter-productive regulatory proposals. Successful ENDS regulation requires nuance and an eye for unintended consequences, but the FCTC has developed a cultural dynamic that drives its policy philosophy to extreme position.

The appropriate approach to ENDS. The better approach to ENDS policy at present is to let parties gain experience and to share their insights, while at the same time accumulating more informative data and better interpretations of the phenomenon. The understanding of these products has already changed dramatically since 2012 as more data has come in and we have positive effects on population smoking prevalence and overall risk. We should allow the science and understanding to mature further before any firm FCTC interventions are considered.

2. 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:

- **Recognition of opportunity, not just threat**. FCTC needs language that gives due weight to the highly likely reality that ENDS are beneficial and displacing high-risk products with low risk.
- **Research**. FCTC should encourage and facilitate research with interdisciplinary and international collaboration as necessary, taking a balanced approach to assessing risk and benefits
- **Scientific assessment**. Make better use of TobReg to do scientific assessments and constitute it with more diverse expertise. Make the process of scientific assessment more transparent, open to challenge and accountable. The quality of the current ENDS paper and the input to COP-6 does not suggest that WHO's recent practice of hand-picking consultants and delivering an unchallenged paper has been particularly successful.
- **Surveillanc**e. Bring coherence to tobacco and ENDS surveillance, 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.
- **Policy scanning**. Regular ENDS policy scans would be helpful. This could build on the initiative at John Hopkins Bloomberg School of Public Health in January 2016 [Country Laws Regulating E-cigarettes] or a European offer could be made, given the United States is not a party to the FCTC.
- **Better regulation**. In any decision or recommendations, it would be helpful to stress that principles of good regulation should underpin ENDS policy. In the European Union, these include proportionality and non-discrimination backed by consultation and impact assessment, including assessment of the unintended consequences of intervention.
- **Role of the state and citizen**. FCTC should stress the public health 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 state-imposed prohibitions on ENDS.

- **Improve the tone and inclusiveness**. 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 me, without me*" 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 this might find favour in other member states.
- **ENDS and the UN/WHA non-communicable disease targets.** The 2025 NCD targets are virtually impossible to meet and 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 as robustly as possible. 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* objective.

3. Other technologies

Much of the argument above also applies to any proposals to regulate non-combustible tobacco products - smokeless tobacco, heated 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.

For the purposes of your compliance with FCTC Article 5.3, I confirm I have no conflicts of interest with respect to tobacco, pharmaceutical or ENDS industries. I hope views are useful to the Working Party as does its important preparatory work for COP-7. Please let me know if I can provide further information.

Your sincerely,

Clive Bates
Director
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[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]