Dr Margaret Chan Director General World Health Organisation Geneva

CC: FCTC Secretariat, Parties to the FCTC, WHO Regional Offices

26 May 2014

Dear Dr Chan

# Reducing the toll of death and disease from tobacco – tobacco harm reduction and the Framework Convention on Tobacco Control (FCTC)

We are writing in advance of important negotiations on tobacco policy later in the year at the FCTC Sixth Conference of the Parties. The work of WHO and the FCTC remains vital in reducing the intolerable toll of cancer, cardiovascular disease and respiratory illnesses caused by tobacco use. As WHO has stated, up to one billion preventable tobacco-related premature deaths are possible in the 21st Century. Such a toll of death, disease and misery demands that we are relentless in our search for all possible practical, ethical and lawful ways to reduce this burden.

It is with concern therefore that a critical strategy appears to have been overlooked or even purposefully marginalised in preparations for FCTC COP-6. We refer to 'tobacco harm reduction' - the idea that the 1.3 billion people who currently smoke could do much less harm to their health if they consumed nicotine in low-risk, non-combustible form.

We have known for years that people 'smoke for the nicotine, but die from the smoke': the vast majority of the death and disease attributable to tobacco arises from inhalation of tar particles and toxic gases drawn into the lungs. There are now rapid developments in nicotine-based products that can effectively substitute for cigarettes but with very low risks. These include for example, e-cigarettes and other vapour products, low-nitrosamine smokeless tobacco such as snus, and other low-risk non-combustible nicotine or tobacco products that may become viable alternatives to smoking in the future. Taken together, these tobacco harm reduction products could play a significant role in meeting the 2025 UN non-communicable disease (NCD) objectives by driving down smoking prevalence and cigarette consumption. Indeed, it is hard to imagine major reductions in tobacco-related NCDs without the contribution of tobacco harm reduction. Even though most of us would prefer people to quit smoking and using nicotine altogether, experience suggests that many smokers cannot or choose not to give up nicotine and will continue to smoke if there is no safer alternative available that is acceptable to them.

We respectfully suggest that the following principles should underpin the public health approach to tobacco harm reduction, with global leadership from WHO:

- Tobacco harm reduction is part of the solution, not part of the problem. It could make a significant contribution to reducing the global burden of non-communicable diseases caused by smoking, and do so much faster than conventional strategies. If regulators treat low-risk nicotine products as traditional tobacco products and seek to reduce their use without recognising their potential as low-risk alternatives to smoking, they are improperly defining them as part of the problem.
- 2. Tobacco harm reduction policies should be evidence-based and proportionate to risk, and give due weight to the significant reductions in risk that are achieved when a smoker switches to a low risk nicotine product. Regulation should be proportionate and balanced to exploit the considerable health opportunities, while managing residual risks. The architecture of the FCTC is not currently well suited to this purpose.
- 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.
- 4. Targets and indicators for reduction of tobacco consumption should be aligned with the ultimate goal of reducing disease and premature death, not nicotine use per se, and therefore focus primarily on reducing smoking. In designing targets for the noncommunicable disease (NCD) framework or emerging Sustainable Development Goals it would be counterproductive and potentially harmful to include reduction of low-risk nicotine products, such as e-cigarettes, within these targets: instead these products should have an important role in *meeting the targets*.
- 5. Tobacco harm reduction is strongly consistent with good public health policy and practice and it would be unethical and harmful to inhibit the option to switch to tobacco harm reduction products. As the WHO's Ottawa Charter states: "Health promotion is the process of enabling people to increase control over, and to improve, their health". Tobacco harm reduction allows people to control the risk associated with taking nicotine and to reduce it down to very low or negligible levels.
- 6. It is counterproductive to ban the advertising of e-cigarettes and other low risk alternatives to smoking. The case for banning tobacco advertising rests on the great harm that smoking causes, but no such argument applies to e-cigarettes, for example, which are far more likely to reduce harm by reducing smoking. Controls on advertising to non-smokers, and particularly to young people are certainly justified, but a total ban would have many negative effects, including protection of the cigarette market and implicit support for tobacco companies. It is possible to target advertising at existing smokers where the benefits are potentially huge and the risks minimal. It is inappropriate to apply Article 13 of the FCTC (Tobacco advertising, promotion and sponsorship) to these products.

- 7. It is inappropriate to apply legislation designed to protect bystanders or workers from tobacco smoke to vapour products. There is no evidence at present of material risk to health from vapour emitted from e-cigarettes. Decisions on whether it is permitted or banned in a particular space should rest with the owners or operators of public spaces, who can take a wide range of factors into account. Article 8 of the FCTC (Protection from exposure to tobacco smoke) should not be applied to these products at this time.
- 8. The tax regime for nicotine products should reflect risk and be organised to create incentives for users to switch from smoking to low risk harm reduction products. Excessive taxation of low risk products relative to combustible tobacco deters smokers from switching and will cause more smoking and harm than there otherwise would be.
- 9. WHO and national governments should take a dispassionate view of scientific arguments, and not accept or promote flawed media or activist misinterpretations of data. For example, much has been made of 'gateway effects', in which use of low-risk products would, it is claimed, lead to use of high-risk smoked products. We are unaware of any credible evidence that supports this conjecture. Indeed, similar arguments have been made about the use of smokeless tobacco in Scandinavia but the evidence is now clear that this product has made a significant contribution to reducing both smoking rates and tobacco-related disease, particularly among males.
- 10. WHO and parties to the FCTC need credible objective scientific and policy assessments with an international perspective. The WHO Study Group on Tobacco Product Regulation (TobReg) produced a series of high quality expert reports between 2005 and 2010. This committee should be constituted with world-class experts and tasked to provide further high-grade independent advice to the WHO and Parties on the issues raised above.

The potential for tobacco harm reduction products to reduce the burden of smoking related disease is very large, and these products could be among the most significant health innovations of the 21<sup>st</sup> Century – perhaps saving hundreds of millions of lives. The urge to control and suppress them as tobacco products should be resisted and instead regulation that is fit for purpose and designed to realise the potential should be championed by WHO. We are deeply concerned that the classification of these products as tobacco and their inclusion in the FCTC will do more harm than good, and obstruct efforts to meet the targets to reduce non-communicable disease we are all committed to. We hope that under your leadership, the WHO and FCTC will be in the vanguard of science-based, effective and ethical tobacco policy, embracing tobacco harm reduction.

We would be grateful for your considered reaction to these proposals, and we would like to request a meeting with you and relevant staff and a small delegation of signatories to this letter. This statement and any related information will be available on the Nicotine Science and Policy web site (http://nicotinepolicy.net) from 29 May 2014.

Yours sincerely,

# Signatories this statement at 26 May 2014

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