RESET MANIFESTO

POSITION STATEMENT ON PREFERRED POLICY PRINCIPLES, TO HELP MAXIMISE THE POTENTIAL BENEFIT OF TOBACCO HARM REDUCTION PRODUCTS (SUCH AS ELECTRONIC NICOTINE DELIVERY SYSTEMS OR ENDS), WHILE MINIMISING ITS RISKS

We are independent experts in tobacco and nicotine science and policy. Collectively, we support the Framework Convention on Tobacco Control (FCTC) and sound, evidence-based regulation to prevent and control tobacco-related diseases and premature death;

In this manifesto, we speak especially in support of FCTC Article 1(D), where "tobacco control" means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke";

In addition, we support the plea by former Presidents of the Society for Research on Nicotine and Tobacco (SRNT) in their evaluation of "Balancing Consideration of the Risks and Benefits of E-Cigarettes" . In this critically important article, they state: "Because evidence indicates that e-cigarette use can increase the odds of quitting smoking, many scientists, including this essay's authors, encourage the health community, media, and policymakers to more carefully weigh vaping's potential to reduce adult smoking-attributable mortality. We review the health risks of e-cigarette use, the likelihood that vaping increases smoking cessation, concerns about youth vaping, and the need to balance valid concerns about risks to youths with the potential benefits of increasing adult smoking cessation";

Furthermore, during 2021 a significant letter of one hundred specialists in nicotine science, policy and practice - was published in which WHO was encouraged to reconsider its stance on tobacco harm reduction. We support the content and call of this letter;

There is now a compelling body of evidence that the use of Electronic Nicotine Delivery Systems (ENDS), or otherwise called vaping, is associated with a lower risk to health to the user, as compared to the use of combustible cigarettes. This evidence has led to a growth in support among scientists and public health bodies for the harm reduction potential of vaping products. However, many remain to be convinced that vaping products and e-liquids: are safe; represent a safer alternative to cigarettes; are manufactured to the highest possible quality standards and can be effectively restricted for use only by adult tobacco and nicotine consumers. Actions to address these issues are essential to build belief in and support for vaping globally, such that the practice can achieve its potential role as a safer, viable alternative to cigarettes;

In tobacco control, the MPOWER tool was developed to accelerate the worldwide adoption of proven tobacco control methods. An equivalent is needed in tobacco harm reduction. For example, how the switch to vaping products can be facilitated, for adult smokers who cannot or will not quit smoking;

This statement is to outline **RESET**, a tool to advocate for the preferred principles, which should be considered for sound, risk-proportionate regulation of vaping products:

1. R (Risk-proportionate regulation)

The Royal College of Physicians has highlighted how excessively burdensome regulation (including prohibition) applied to ENDS such as e-cigarettes can actually lead to more smoking.

> *"However, if [a risk averse, precautionary] 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".*

It is necessary for WHO and the FCTC Secretariat to help member countries and parties negotiate this difficult balance, not avoid it altogether by advocating prohibition or the same regulation that applies to cigarettes. Some governments have already adopted these principles, including the United Kingdom. A major UK parliamentary inquiry into e-cigarettes reported on 17 August, 2018. The Members of Parliament concluded:

> *"E-cigarettes present an opportunity to significantly accelerate already declining smoking rates, and thereby tackle one of the largest causes of death in the UK today. […] There should be a shift to a more risk-proportionate regulatory environment; where regulations, advertising rules and tax duties reflect the evidence of the relative harms of the various e-cigarette and tobacco products available".*

For risk-proportionate regulation to work, every area of policy covered by the FCTC, the appropriate approach should be to place the greatest burdens and restrictions on the riskiest products, especially cigarettes, and use regulation to encourage smokers to switch to products such as vaping products or to quit altogether. This would mean in practice:

1.1 The highest taxes on cigarettes but lower tax or no tax on low-risk products, with tax differentials reflecting the likely difference in risk.

1.2 Complete bans on promotion of cigarettes, but controls on content, target audience and placement of promotion for ENDS (given these function as smoking cessation adverts).

1.3 Strong graphic health warnings and plain packaging for cigarettes, but for ENDS only risk-proportionate warnings about nicotine backed by clear communication of the comparative risks of smoking.

1.4 Product regulation of cigarettes focussed on reducing aspects of product appeal, but prudent regulation via product standards to improve and standardise ENDS safety and quality.

1.5 Public health agencies to give realistic information about relative risk and quitting smoking, not simply campaign to reduce ENDS use whatever the impact on smoking.

1.6 Regulatory frameworks that would enhance the accessibility, affordability and acceptability of non-combustible alternatives, such as ENDS, to adult smokers.

2. E (Ensuring intended use of ENDS products)

2.1 Adult-only use: Ensuring that all vaping product devices and e-liquids are equipped with safety features which ensure that the products can only be used by adults, with a minimum recommended age of use of 18. This could include leveraging existing connectivity technologies.

2.2 Design integrity: Manufacturers must ensure the design integrity of their vaping products. Drawing upon the learnings from events such as the US EVALI incident of 2019, they must ensure that their devices cannot be tampered with nor manipulated to enable their use with substances for which they are not designed or intended.

2.3 Youth access prevention: Implement mandatory training on youth access prevention for retailers, ban on marketing to children, severe penalties in case of underage sale violations, age verification technology, banning of descriptors that could be regarded as child-enticing, regulations which only permit those closed systems where the activation of the device meets established child-resistant criteria.

2.4 Prevention of tampering: Regulations need to be in place to restrict or prohibit those open vaping systems which cannot ensure safe refilling of the device/tank. Ultimately, all efforts need to be made to ensure that children and minors cannot ingest the nicotine liquid, either accidentally or by tampering.

3. S (Safety and Quality)

*The **safety & quality*** of vaping products must be ensured as far as possible and enforced through sound regulation. There are three main areas, which manufacturers should focus on and where regulators should ensure conformity with standards:

3.1 Ingredients: Only the highest-quality ingredients should be used in the manufacture of e-liquids. Regulation must control the use of ingredients that are known to be hazardous or toxic for the user in vaping products. Quality standards for e-liquid ingredients should be set to minimise any risk arising from potentially hazardous contaminants. All ingredients need to be toxicologically risk-assessed.

3.2 Emissions testing: Manufacturers should ensure vaping products do not operate at temperatures that cause combustion and do not heat e-liquids at high temperatures that will cause the formation of unintended chemicals. Following the direction and guidance in existing national vaping standards, an agreed list of analytes of concern

should be compiled; emissions should be tested for the presence of these analytes and the results routinely reported to regulators, with data available publicly to inform consumers.

3.3 Certification: Regulators should establish notification requirements and procedures that oblige manufacturers to verify compliance with prescribed quality and safety criteria and to supply evidence of conformity to the relevant authority.

4. E (Environmental considerations)

The environmental impact of ENDS needs to be carefully considered. ENDS manufacturers must address waste collection and recycling as an integral factor in the design and chosen materials for vaping products. Where possible, the use of recycled material should be encouraged in the manufacture of products and their packaging and take-back schemes should be mandated for both pods and devices. At the end of their lifetime, pods and devices should be capable of being recycled either at specific vendors, recycling centres or through postal schemes. Vapers should be incentivised to recycle products, while manufacturers should be penalised if they do not provide proper collection and recycling solutions.

5. T (Traceability)

To combat illicit trade and facilitate proper taxation of ENDS, traceability of ENDS products need to be enhanced. By applying appropriate technologies, relevant stakeholders should help ensure:

5.1 Authentication of genuine products by enforcement agencies

5.2 Traceability of products throughout the supply chains

5.3 Verification of payment of taxes where levied

5.4 Proof of age verification, to ensure youth access prevention

5.5 Improved communication platforms across the total ENDS supply chain

Conclusion

Tobacco harm reduction can help save the lives of adult smokers. The regulation of ENDS should be based on sound, evidence-based science. This statement is intended to stimulate debate and build consensus on what the preferred principles of ENDS regulation should be. We support the basic principles summarised in the acronym RESET: ***Risk-based regulation;***

Ensuring Intended Use**; **Safety & Quality**; **Environmental Consideration** and **Traceability & Authentication.

If these principles were to be adopted for ENDS regulation, this would contribute towards maximising the potential benefits of tobacco harm reduction (including THR products such as ENDS), while reducing its risks. Ultimately, we support RESET to help prevent and control tobacco-related disease and premature deaths.