DRAFT ABBREVIATED ADVISORY OF THE WHO STUDY GROUP ON TOBACCO PRODUCT REGULATION (WHO TobReg) CONCERNING ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS)

Recent worldwide media attention given to the increased global market prevalence and use of a "cigarette-like" product known as the "electronic cigarette" prompted WHO to release a public statement and hold a press briefing in Geneva on 19 September 2008 to clarify that WHO does not support the use of this product as a legitimate cessation aid (please find the official WHO press release at: http://www.who.int/mediacentre/news/releases/2008/pr34/en/index.html).

WHO's public comment refuting claims by manufacturers that WHO endorses the use of these electronic, nicotine-filled vapourizers as a smoking cessation tool triggered a response from the global tobacco control community requesting a concrete set of recommendations from WHO to assist Member States to adopt a clear position and take appropriate action. This request stemmed from the fact that these delivery systems pose potentially significant public health concerns and raise important questions in tobacco control policy. As stated, an alarmingly rapid market penetration of this unapproved product in various WHO Regions has elevated this to a pressing issue given its unknown safety and efficacy. Furthermore, these products have proliferated with a broad range of claims and in a vacuum of information to guide regulators, policy-makers, and consumers.

In accordance with the critical importance of this issue, WHO TFI, as Secretariat and Coordinating Body of the WHO Study Group on Tobacco Product Regulation (WHO TobReg), charged the Expert Group to deliberate on the public health implications and regulatory issues concerning the electronic cigarette during its 5th annual meeting in Durban, South Africa, in November 2008. The outcome of these deliberations, which is currently being finalized by the members of the Study Group, addressed the broader category of Electronic Nicotine Delivery Systems (ENDS) that have been designed for the purpose of nicotine delivery to the respiratory system. I am providing a provisional draft copy of WHO TobReg's scientific recommendation on this issue below for your information only. Kindly note that the recommendation is currently being distributed among the members of the Expert Group in advance of publication in the 3rd volume of the WHO TobReg Technical Report Series available in late 2009.

DRAFT TobReg Scientific Recommendation: Devices designed for the purpose of nicotine delivery to the respiratory system where tobacco is not necessary for their operation

Conclusions

1. ENDS have the potential to deliver nicotine, but the extent of nicotine uptake and their safety have not been established.

2. ENDS might cause and sustain addiction, however, evidence on the potential for them to be addictive and the frequency with which addiction occurs does not currently exist.

3. ENDS have been offered for smoking cessation and may have the potential to be effective in this use; however, scientific evidence sufficient to establish cessation efficacy and safety of use is not yet available.

4. There are safety concerns that nicotine delivery to the lung may result in stronger toxicological, physiological and addictive effects, and these concerns must be addressed with scientific studies.

5. Lung delivery of other medications have raised concerns that relate to safety of lung delivery of medications independent of the effects of nicotine, and these concerns must be addressed with scientific studies.

Recommendations for Regulatory Policy

1. ENDS should be regulated as nicotine delivery systems and not as tobacco products.

2. Definition and safety of ENDS should be provided by manufacturers and retailers and established by regulatory authorities prior to sale and marketing.

3. Claims implying health benefits or reduced harm relative to cigarettes should be prohibited unless the safety of these devices when used as intended are proven scientifically to the satisfaction of regulatory authorities.

4. Claims that ENDS aid smoking cessation should be prohibited unless the efficacy of these devices when used as intended are proven scientifically to the satisfaction of regulatory authorities.

5. ENDS should not be exempt from clean air laws that prohibit smoking until existing uncertainties about their emissions are resolved.

Recommendations for Clinical Trials and Other Research Needed for Regulatory Approval

1. Research is needed on the delivery and absorption of nicotine with ENDS use, both acutely and chronically, in order for regulators to establish the dosage and formulation for regulatory approval.

2. Research is needed on the behavioral and physiological consequences of using ENDS.

3. The dependence potential (also known as “abuse liability”) relative to cigarettes and nicotine replacement medications needs to be studied.

4. Short and long term effects of human exposure to determine potential harm needs to be monitored.

5. Post-marketing studies need to be conducted to determine patterns of use, such as dual use, monitor adverse effects, and the individual and population effects on initiation and cessation.

Furthermore, WHO TFI has recently been informed by its Member States that manufacturers of electronic cigarettes have begun promoting this class of products as "an alternative to smoking" in place of the term

that has traditionally been used, namely, "electronic cigarettes." This shift in marketing strategy is specifically designed to circumvent expanding national regulatory mechanisms which encompass products marketed as "electronic cigarettes." In light of this development, WHO will ensure that the aforementioned recommendations will envelope these nicotine delivery devices independent of the advertising/promotion strategies employed by manufacturers.

WHO continues to strongly encourage its Member States to prohibit manufacturers from marketing electronic cigarettes as legitimate tobacco cessation aids endorsed by WHO. Furthermore, Member States should ensure that the manufacturers of these products comply with all existing regulatory requirements to preclude unsubstantiated claims that may derail public health efforts in tobacco control.

In summary, there is currently not enough scientific evidence to recognize electronic nicotine delivery devices as legitimate smoking cessation devices. These devices still need to satisfy regulatory criteria for safety and efficacy in tobacco dependence management and treatment. Research is needed on the delivery and absorption of nicotine in relation to these devices, both acutely and chronically, in order for regulators to establish the dosage and formulation for regulatory approval. This class of products should be regulated as nicotine delivery systems and must meet the scientific, efficacy and safety criteria established by regulatory authorities prior to sale and marketing.