COMMENTS ON REPORTS OF ELECTRONIC NICOTINE DELIVERY SYSTEM (FCTC/COP/6/10 of 21 July 2014)

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The use of electronic nicotine delivery systems (hereinafter ENDS) has been consistently growing. In order to prevent any negative impact caused by the END prevalence on the current tobacco-control efforts, it is imperative that the WHO Framework Convention of Tobacco Control (hereinafter FCTC) further develops product regulation on the ENDS. The latest report issued by WHO of 21 July 2014 on ENDS (FCTC/COP/6/10 REV.1) (hereinafter Report) has timely provided useful guidance for such a purpose. We congratulate on the achievements of the WHO Study Group on Tobacco Product Regulation (hereinafter TobReg).

In the following part, we would like to share our views regarding the TobReg and offer some points for Parties of the FCTC to consider so as to advance global health.

1. Use of ENDS in public places

According to paragraph 41 of the Report, since the reasonable expectation of bystanders is not a diminished risk in comparison to exposure to second-hand smoke but no risk increase from any product in the air they breathe, ENDS users should be legally requested not to use ENDS indoors, especially where smoking is banned until exhaled vapor is proven to be non-harmful to bystanders and reasonable evidence exists that smoke-free policy enforcement is not undermined.

Second-hand ENDS aerosol contains not only water vapor but also nicotine and some toxins that might impose continuous long-term risks on health. The levels of dangerous chemicals ENDS give off can vary due to the lack of regulations. Therefore, before the effects of secondhand exposure of ENDS aerosol have been further ascertained, we consider that ENDS uses should not be allowed in workplaces and public spaces.

2. Product design and information

According to paragraph 48 of the Report, ENDS should be regulated to:
(a) minimize content and emissions of toxicants;
(b) ensure use of nicotine of pharmacological quality, when nicotine use is intended;
(c) standardize nicotine delivery at levels known to the consumers;
(d) minimize acute nicotine toxicity;
(e) impede product alteration to use of other drugs;
(f) ban ENDS solutions with fruit, candy-like and alcohol-drinks flavours until empirical evidence shows that they are not attractive to minors;
(g) require manufacturers and importers to disclose to governmental authorities information about the contents and emissions of ENDS; and
(h) require registration of manufacturers and importers with governmental authorities.

In regard to the regulations of ENDS contents and emissions, we are in support of the suggestions in the Report, in particular with the ban on ENDS containing certain characterizing flavors. It is a common marketing strategy for ENDS to attract minors by novelties and variability. From the perspective of public health, we suggest that the use of ingredients, such as flavoring agents that help to make ENDS attractive, should be banned.

Additionally, it is advised in the Report to regulate the pharmacological use of nicotine, when its use is intended. Since the WHO has long denied the cessation effect or other therapeutic effects of ENDS, it seems to us that the statement that ENDS can be used for "pharmacological" or "therapeutic" purposes might create greater controversies at this stage.

In regard to information disclosure, the Report proposes to necessitate manufacturers' and importers' disclosure of the contents and emissions of ENDS. We suggest broadening the extent of ENDS disclosure on the basis of FCTC Article 10 and its Partial Guidelines for the Implementation of Articles 9 and 10. For instance, the public disclosure of information about the toxic constituents of ENDS and their emissions might be included.

3. Health claims

According to paragraph 40 of the Report, it is suggested to prohibit manufacturers and third parties from making health claims for ENDS, including the claim that ENDS are smoking cessation aids, until manufacturers provide convincing supporting scientific evidence and obtain regulatory approval. The regulatory standard for cessation claims and approval as cessation aids should remain as an appropriate body of evidence, based on well-controlled clinical trials.
Besides prohibiting health claims, according to paragraph 49 of the Report, there should be health warnings that commensurate with proven health risks. In this regard, the following risk warnings could be considered: potential nicotine addiction; potential respiratory, eyes, nose and throat irritant effect; potential adverse effect on pregnancy (due to nicotine exposure).

According to paragraphs 40 and 49, ENDS health claims should be prohibited and health-warning labels are required except in the case of providing convincing supporting scientific evidence and obtaining regulatory approval. We suggest that the concept and the content of "convincing supporting scientific evidence" should be further elaborated. Also, we suggest that ENDS manufacturers should provide not only scientific evidence showing that there is health benefit to individuals but also empirical proof showing that there are no (short-term and long-term) adverse effects on tobacco control policy if ENDS health claims are approved. With respect to ENDS health warnings, we suggest adding a warning that reads: "ENDS is not a safe subsitute for cigarettes or other tobacco products."

4. Advertising, promotion and sponsorship

According to paragraphs 42 and 43 of the Report, given that the same promotional elements that make ENDS attractive to adult smokers could also make them attractive to children and non-smokers, Parties should contemplate putting in place an effective restriction on ENDS advertising, promotion and sponsorship. Any form of ENDS advertising, promotion and sponsorship must be regulated by an appropriate governmental body. If this is not possible, an outright ban on ENDS advertising, promotion and sponsorship is preferable to the implementation of voluntary codes on ENDS marketing, given the overwhelming evidence that similar codes for tobacco and alcohol products have failed to protect young people from such advertising.

According to paragraph 44 of the Report, advertising, promotion and sponsorship of ENDS with or without nicotine, must, at a minimum: (a) state clearly whether the product contains nicotine or may be used with nicotine

solutions; (b) not make them appealing to or target, either explicitly or implicitly, non-smokers or non-nicotine users, and must therefore indicate that ENDS are not suitable for use by people who do not currently consume tobacco products; (c) not make them appealing to or target, either explicitly or implicitly, minors, including through the selection of media, location or the context in which they appear or through imagery that promotes sexual or sporting prowess; (d) never promote ENDS for non-smokers, and their use should not be portrayed as a desirable activity in its own right; (e) encourage smoking cessation and provide a quitline number if one exists; (f) contain nothing that could reasonably be expected to promote the use of tobacco products … ; (g) not contain health or medicinal claims, unless the product is licensed for those purposes by the appropriate regulatory agency. Electronic cigarettes and other nicotine-containing products should be presented only as an alternative to tobacco, and should include warnings that dual use will not substantially reduce the dangers of smoking; (h) not undermine any tobacco-control measure, including by not promoting the use of ENDS in places where smoking is banned; (i) include factual information about product ingredients other than nicotine and in a way that does not distort evidence of risks; (j) not link these products with gambling, alcohol, illicit drugs or with activities or locations in which using them would be unsafe or unwise.

According to paragraph 45 of the Report, advertising, promotion and sponsorship of ENDS that contain nicotine or may be used with nicotine solutions must: (a) Clearly state the addictive nature of nicotine and that these products are intended to deliver nicotine; (b) Prohibit suggestions that ENDS have positive qualities as a consequence of the addictive nature of the product.

According to paragraph 46 of the Report, all authorized forms of ENDS advertising, promotion and sponsorship must be cleared by the appropriate authority prior to publication/transmission in order to proactively prevent inappropriate marketing, and then be monitored to assess compliance.

According to paragraphs 42-46 of the Report, regulations of ENDS advertising and promotion are divided into two parts: ENDS with and without nicotine. We suggest that a ban on advertisement, promotion and sponsorship of ENDS should be applied to all ENDS without distinction in light of nicotine.

First, the Report seems to suggest that as long as the addictive nature of nicotine is clearly stated without implications of ENDS carrying positive qualities, such advertising is allowed. We tend to consider that advertisement, promotion and sponsorship of ENDS with nicotine should be comprehensively banned in light of FCTC Article 5.2, in which Parties are required to adopt and implement effective measures in preventing nicotine addiction.

Second, since whether an ENDS product contains nicotine cannot be easily distinguished through appearance, advertisement or promotion of ENDS without nicotine might possibly promote the sale or consumption of ENDS with nicotine and impair the tobacco control efforts.

Third, advertisement, promotion and sponsorship of ENDS with or without nicotine are suggested not to appeal to non-smokers or non-nicotine users. But considering the diversity and permeability of modern advertising and promotion channels, users with basic electronic equipment might easily access any information from different sources. Therefore, in the case that no comprehensive ban is established, non-smokers and non-nicotine users might not be easily isolated from the influence of ENDS advertising and promotion.

5. Sale to and by minors

According to paragraph 51 of the Report, retailers should be prohibited from selling ENDS products to minors, and vending machines should be eliminated in almost all locations.

We are in support of the above recommendation. In order to provide full protection for minors, we suggest prohibiting the ENDS sales to persons under the age set by domestic law or eighteen, in light of FCTC Article 16.7

Given certain studies point out that nicotine-absorption would cause premature birth, we consider that preventing the pregnant from being exposed to ENDS merits further consideration. We thus suggest prohibiting the sale of ENDS to pregnant women.

6. Surveillance and monitoring

According to paragraph 50 of the Report, governments are recommended to use or strengthen their existing tobacco surveillance and monitoring systems to assess developments in ENDS and nicotine use by sex and age.

In order to advance public health, we suggest that more restrictive surveillance and controlling measures should be considered to adopt given the fact that ENDS and conventional tobacco products are different in their characteristics. In the case of Taiwan, the marketing of ENDS is governed under the current pharmaceutical regulatory regime. Registration and prior market approval of ENDS are required. No manufacturing or importation of ENDS shall be allowed until a permit license is issued by the relevant authority. This mechanism can help the authorities to assess the impacts of ENDS in advance and monitor and control the distribution of ENDS.

7. Protection from vested commercial interests

According to paragraph 47 of the Report, transparency should be required from ENDS and tobacco companies advocating for and against legislation and regulation, both directly and through third parties. No matter what role the tobacco industry plays in the production, distribution and sale of ENDS, this industry, its allies and front-groups can never be considered to be a legitimate public health partner or stakeholder while it continues to profit from tobacco and its products or represents the interests of the industry. Article 5.3 of the WHO FCTC should be respected when developing and implementing ENDS legislation and regulations.

We consider that Article 5.3 of the FCTC will have an overarching impact on the protection of ENDS regulations from commercial and other vested interests of the ENDS and tobacco industry. It is suggested that the adopted guidelines for implementation of Article 5.3 of the FCTC by Parties should be considered in order to prevent the broad array of strategies and tactics used by the ENDS and tobacco industry to interfere with the setting and implementing of ENDS control measures.

8. Action by the Conference of the Parties

According to paragraph 54 of the Report, the COP is invited to note this report and to provide further guidance.

The introduction of a new separate guideline specifically for ENDS would be useful for Parties to regulate ENDS. We consider that adopting a regulation in the form of protocol could also offer certain positive assistance in establishing enforceable ENDS regulation within the FCTC. For instance, it might help alleviate the difficulties in applying the existing FCTC to ENDS given ENDS do not fall into the scope of the FCTC due to without using the leaf tobacco as raw material. Additionally, under the protocol, it is expected that Parties are required to consider a more comprehensive regulatory framework that specifically accommodates the special characteristics of ENDS.