



## **WSMI Position Paper on electronic nicotine delivery systems** **(‘Electronic cigarettes’)**

The World Self-Medication Industry is a federation of around 50 member associations representing manufacturers and distributors of nonprescription medicines on all continents.

WSMI members are world leaders in the manufacture and supply of Nicotine Replacement Therapy (NRT) products. NRT is a nicotine delivery medicine which helps people to stop smoking by acting at brain nicotine receptors, thus reducing withdrawal symptoms. It delivers nicotine ‘cleanly,’ unaccompanied by the major carcinogens and other toxic substances in tobacco and its combustion products.

NRT products have been intensively researched and developed for effectiveness, safety, adverse effects, cost and cost-effectiveness. NRT products include presentation forms such as the transdermal patch, chewing gum, inhaler, sprays, tablets and lozenges, all of which have a medically proven efficacy and safety profile in helping smokers to quit. There is strong, consistent scientific and clinical evidence that use of NRT products increase the rate of success in quitting smoking.

For more than 20 years NRT has been registered and available as a medicine to treat tobacco dependence in many countries. In 2009 the World Health Organisation (WHO) approved the inclusion of NRT transdermal patches and chewing gums into the 16<sup>th</sup> WHO Model List of Essential Medicines<sup>1</sup> based upon a comprehensive review of the available evidence, and the recommendations of an Expert Committee on the Selection and Use of Essential Medicines.<sup>2</sup> This inclusion represents endorsement of the value of NRT as a therapy to treat tobacco addiction, and of the scientific evidence supporting its use.

WSMI (and WHO) supports pharmacotherapy only where scientific studies demonstrate predictable outcomes under specified conditions and when products have been approved as safe and effective by medicines regulatory agencies. By contrast, electronic nicotine delivery systems such as electronic cigarettes are not endorsed or registered as medicines and lack scientific evidence supporting their use. As expressed by the WHO<sup>3</sup>:

*“There is insufficient evidence currently to assess whether electronic nicotine delivery systems may be used to aid cessation, create or sustain addiction, or deliver constituents other than nicotine to smokers. Clinical trials, behavioural and psychological studies, and post-marketing studies at individual and population levels are needed to answer*

<sup>1</sup> See: [http://www.who.int/selection\\_medicines/committees/expert/17/sixteenth\\_adult\\_list\\_en.pdf](http://www.who.int/selection_medicines/committees/expert/17/sixteenth_adult_list_en.pdf)

<sup>2</sup> See: [http://www.who.int/selection\\_medicines/committees/expert/17/application/NRT\\_inclusion.pdf](http://www.who.int/selection_medicines/committees/expert/17/application/NRT_inclusion.pdf)

<sup>3</sup> See: [http://apps.who.int/gb/ebwha/pdf\\_files/EB126/B126\\_37-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/EB126/B126_37-en.pdf)



*these questions. Claims for health benefits, reduced harm, or use in smoking cessation should be prohibited until they are scientifically proven...*

*...[Electronic nicotine delivery systems] may create public health risks if they sustain nicotine dependence by allowing nicotine intake where smoking is prohibited or if they increase initiation and transition to cigarette smoking among those who would not otherwise have used tobacco. Smokers who attempt to quit may use electronic nicotine delivery systems in place of more evidence based treatments, thereby potentially contributing to delayed smoking cessation and increased risk of smoking-attributable disease..."*

Electronic nicotine delivery systems that are designed for the purpose of direct nicotine delivery to the respiratory system fall in a regulatory gap in many countries, escaping regulation as medicines (because no medical claims are made) and avoiding the controls applicable to tobacco products (because they do not contain tobacco).

WSMI believes that electronic nicotine delivery systems and any other product containing nicotine must be properly reviewed and regulated in the interests of consumer safety. WSMI believes that there is a strong case to ban unregistered electronic nicotine delivery devices, which have given rise to a number of concerns including strong concerns that they may deliver highly inconsistent and irregular dosing. WSMI therefore calls upon national authorities to carry out market surveillance and enforcement activities to ensure that only safe products are put on the market and to suspend marketing of products for which no safety evaluations have been made.