

Application for inclusion of nicotine lozenges and mouth spray in the WHO Essential Medicines List

Dear EML Secretariat,

In relation to the application for new formulations of NRT (nicotine lozenges and mouth spray) to be included in the WHO Model List of Essential Medicines (EML), submitted in December 2022 by Johnson & Johnson, WHO/HPR considers that the inclusion of nicotine lozenges and mouth spray as essential medicines could result in important advantages in helping tobacco users quit.

The tobacco epidemic is one of the biggest public health threats the world has ever faced, killing more than 8 million people a year around the world. There are currently over 1.3 billion tobacco users in the world and over 80% of them live in low- and middle-income countries, where the burden of tobacco-related illness and death is heaviest.

The importance of helping tobacco users quit has been reflected in the Article 14 of the WHO Framework Convention on Tobacco Control (WHO FCTC) and its guideline, which calls for countries to develop a comprehensive tobacco cessation and treatment system to provide tobacco users a variety of tobacco cessation interventions including evidence-based medications. However, these tobacco cessation measures are poorly implemented, especially in low- and middle-income countries, despite considerable demand. Among the 1.3 billion tobacco users in the world, 70% do not have access to comprehensive tobacco cessation services.

The successful inclusion of two new formulations of NRT in the WHO EML would widen the choice of options for tobacco users who want to quit.

This proposal is supported by high population needs, strong evidence on efficacy and comparative cost-effectiveness. Evidence showed that the efficacy of nicotine lozenges in smoking cessation was similar to that of nicotine gum, and nicotine mouth spray might have greater relative efficacy than other forms of NRT. The most common adverse effects of nicotine lozenges and nicotine mouth spray are minor mouth and throat irritation, hiccups, nausea, and headache and they are generally acceptable and manageable.

WHO/HPR is developing a WHO clinical treatment guideline for tobacco cessation in adults to guide proper use of tobacco cessation medications including NRT. The WHO guideline is expected to be available by the end of 2023.

Essential medicines are intended to be always available within the health systems, with assured quality and at a price the individual and the community can afford. Should nicotine lozenges and nicotine mouth spray be added to the WHO EML, it is possible that more countries will consider adding them to their national essential medicines lists, which is the first step to ensure access in a country.

Conclusion:

Considering the above-mentioned arguments, WHO/HPR recommends inclusion of nicotine lozenges and nicotine mouth spray in the WHO Model List of Essential Medicines for adult smokers to quit.

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