

# MEMORANDUM

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|--------------------|---------------|-------------------|--|--------------|---------------|
| <b>From:</b>       | Director, HPR | <b>To:</b>        | Director, HPS  | <b>Date:</b> | 28 April 2021 |
| <b>Our ref:</b>    |               | <b>Attention:</b> |  |              |               |
| <b>Your ref:</b>   |               | <b>Through:</b>   |  |              |               |
| <b>Originator:</b> | HPR/TFI       | <b>Subject:</b>   | INCLUSION OF VARENICLINE<br>TARTRATE (CHAMPIX®) IN THE WHO<br>MODEL LIST OF ESSENTIAL<br>MEDICINES (EML) |              |               |

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In relation to the application of Varenicline Tartrate (CHAMPIX®) as a smoking cessation treatment, submitted in November 2020 by Pfizer Inc, to be included in the WHO Model List of Essential Medicines (EML), WHO/HPR considers that the inclusion of Varenicline as an essential medicine could result in important advantages in helping smokers 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. Adoption and implementation of comprehensive evidence-based measures including helping tobacco users quit, in line with WHO Framework Convention on Tobacco Control (WHO FCTC) is the only way to reduce tobacco use in society.

The importance of helping tobacco users quit has been reflected in the Article 14 of the 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 COVID-19 pandemic has further disrupted cessation services that are already scarce and weakened public health systems worldwide. As part of COVID response, WHO/HPR launched the yearlong 'Commit to Quit' Campaign and has been promoting a variety of options to support tobacco users who want to quit, which include increasing digital behavioural counselling services, nicotine replacement therapy (nicotine gum and patch already added to WHO EML since 2009), submitting an application for Bupropion to be included on WHO EML. The successful inclusion of Varenicline 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 varenicline was more effective than bupropion or nicotine patch in helping smokers. Varenicline was predicted to be more effective and less costly from the healthcare payer perspective over a 20 year or lifetime horizon, relative to bupropion, nicotine replacement therapy, or unaided quitting.

Varenicline is indicated as an aid to smoking cessation in adults 18 years and older and it has received regulatory approval in 116 countries. The most common adverse effects of varenicline are nausea, headache, abnormal dreams, and insomnia and they are generally acceptable and manageable.

WHO/HPR is planning to develop a WHO tobacco cessation and treatment guideline to promote proper use of tobacco cessation medications including varenicline. The WHO guideline is expected to be available in 2022.

Essential medicines are intended to be available at a price the individual and the community can afford. Should varenicline be added to the WHO EML, it is a possibility that multiple generic sources of varenicline will be in market and the cost is likely to decrease. WHO and Pfizer Inc are currently discussing the supply of varenicline to 10 high tobacco-use burden countries free of charge or at an affordable price to ensure access by groups of lower socioeconomic status and populations most in need.

### **Conclusion:**

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

Dr Rüdiger Krech