

November 29, 2020

The Secretary of the 23rd Expert Committee on the Selection and Use of Essential Medicines

Essential Medicines Team

Medicines Selection, IP and Affordability (MIA)

Department of Health Products Policy and Standards (HPS)

World Health Organization

20 Avenue Appia

CH-1211 Geneva 27

Switzerland

email: emlsecretariat@who.int

Re: Application to add varenicline to the WHO Essential Medicines List

Dear Secretariat:

As president of the American Thoracic Society, I am writing in support of Pfizer's petition to add varenicline to the World Health Organization Essential Medicines List.

The American Thoracic Society is an international medical professional organization of over 17,000 physicians, scientists, nurses, and respiratory therapists dedicated to the prevention, detection, treatment, cure and research of pulmonary disease, critical care illness and sleep disordered breathing. As pulmonary care providers, we are too familiar with the death, disease and economic displacement caused by tobacco disease. We stand with our WHO colleagues in our shared effort to reduce the global burden of tobacco use.

Unfortunately, the global burden of tobacco use is large. As noted in WHO's recent [report](#), "(t)he 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. More than 7 million of those deaths are the result of direct tobacco use while around 1.2 million are the result of non-smokers being exposed to second-hand smoke." While primary prevention is the best way to interrupt the cycle of tobacco death and disease, physicians and public health professionals need to provide access to effective secondary prevention, like tobacco cessation, to help patients around the world quit nicotine addiction. The ATS recognizes that WHO has already included an extensive list of nicotine replacement treatments on its Essential Medicines List.

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The ATS recently published a clinical practice guideline: [Initiating Pharmacologic Treatment in Tobacco-Dependent Adults - An Official American Thoracic Society Clinical Practice Guideline](#). The ATS guideline, using GRADE methodology to evaluate the available evidence, made the following key recommendations:

- **For tobacco-dependent adults in whom treatment is being initiated, we recommend varenicline over a nicotine patch** (strong recommendation, moderate certainty in the estimated effects).
- **For tobacco-dependent adults in whom treatment is being initiated, we recommend varenicline over bupropion** (strong recommendation, moderate certainty in the estimated effects).
- **For tobacco-dependent adults in whom treatment is being initiated, we suggest varenicline plus a nicotine patch over varenicline alone** (conditional recommendation, low certainty in the estimated effects).
- **For tobacco-dependent adults in whom treatment is being initiated, we suggest varenicline over electronic cigarettes** (conditional recommendation, very low certainty in the estimated effects).
- **In tobacco-dependent adults who are not ready to discontinue tobacco use, we recommend that clinicians begin treatment with varenicline rather than waiting until they are ready to stop tobacco use** (strong recommendation, moderate certainty in estimated effects).
- **For tobacco-dependent adults with co-morbid psychiatric conditions, including substance use disorder, depression, anxiety, schizophrenia and/or bipolar disorder, for whom treatment is being initiated, we recommend varenicline over a nicotine patch** (strong recommendation, moderate certainty in estimated effects).
- **For tobacco-dependent adults for whom treatment is being initiated with a controller, we recommend using extended duration (greater than 12 weeks) over standard duration (6-12 weeks)** (strong recommendation, moderate certainty in estimated effects).

As noted from the above recommendations, the ATS recommends that varenicline be the first drug of choice, either singly or in combination with other treatments, to treat tobacco-dependent adults.

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We further note that varenicline has been on the global market for over 15 years. Physicians and health care providers have experience with the drug and its risk/benefit profile. The EAGLES trial with over 8,000 participants provides unequivocal evidence for the efficacy of varenicline with no additional risk of adverse events, including psychiatric events. Increasing access to this efficacious treatment for smoking cessation would have a dramatic impact on health outcomes.

With the growing evidence of varenicline's efficacy in aiding tobacco cessation, the years of clinical experience in the provider community with the drug and its global availability, we encourage WHO to favorably consider Pfizer's request for inclusion on the Essential Medicines List.

If you have questions or need additional information, please contact Mr. Gary Ewart in the ATS Washington Office (gewart@thoracic.org).

Sincerely,



Juan C. Celedón MD, DrPH, ATSF
President
American Thoracic Society

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