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May 20, 2021

Dr. Benedikt Huttner
Secretary of the Expert Committee on the Selection and Use of Essential Medicines
Medicines Selection, IP and Affordability (MIA)
Department of Health Products Policy and Standards (HPS)
20 Avenue Appia
CH-1211 Geneva 27
Switzerland

RE: Applications for varenicline and bupropion to be added to the WHO Model List of Essential Medicines

Dear Secretariat:

Given the global burden of disease caused by tobacco, there is a need to implement proven policies to prevent and reduce tobacco use and to expand access to effective tobacco cessation treatments. These comments reflect our view of the importance that rigorously evaluated tobacco cessation treatments that are found to be effective are made widely available and that barriers to accessing treatment, such as cost, are minimized or removed.

One way of doing so is to include the most effective medicines on the WHO Essential Medicines List with proper safeguards to insure that the addition of new medicines on the list expands the availability of effective medications to all who would benefit from their use.

The Campaign for Tobacco-Free Kids is a non-governmental advocacy organization working to reduce tobacco use and its deadly consequences in the United States and around the world by advocating for public policies that prevent kids from using tobacco, help smokers quit and protect everyone from secondhand smoke.

Providing tobacco cessation assistance and treatment is an important component of the World Health Organization Framework Convention on Tobacco Control (FCTC) and is a complement, not a substitute, to the other demand reduction measures included in the FCTC. Helping people to quit tobacco will have a greater impact if combined with other tobacco control strategies.

Tobacco use continues to pose an enormous threat to public health. While great progress has been made in reducing tobacco use around the world, the WHO estimates that there are currently more than one billion tobacco users worldwide. Globally, nearly 1 in 5 adults (19%) are current smokers. Tobacco use remains the world's leading cause of preventable death, killing more than 8 million people each year. Tobacco use also takes a staggering economic toll - total economic costs of smoking are estimated at \$1.4 trillion USD.

Further with the COVID-19 pandemic currently confronting the world, there has never been a more important time to help tobacco users quit. Based on the latest evidence, the U.S. Centers for Disease Control and Prevention (CDC) found that smoking increases risk for severe illness from COVID-19. Helping more tobacco

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users to quit could also reduce the number of people at risk for serious complications from the COVID-19 pandemic.

Nicotine addiction is a chronic, relapsing disorder and it often takes multiple attempts to quit successfully. The chances of successfully quitting tobacco use increase significantly with evidence-based treatment; however, most tobacco users do not use evidence-based tobacco cessation treatments when making a quit attempt. Increasing tobacco cessation will require multiple strategies, including increasing access to and use of evidence-based cessation treatments.

In determining what tobacco cessation products should be listed on the Essential Medicines List, several criteria should be given priority: The science of the efficacy of the product; the cost of the product to consumers, including low income consumers; the availability of the product to consumers of all incomes; and the overall impact of the availability of the product on increasing access to evidence based effective tobacco cessation medications.

There is strong evidence that varenicline and bupropion are effective in increasing smoking cessation and preventing relapse. In the largest clinical trial to date of more than 8,100 daily smokers (Evaluating Adverse Events in a Global Cessation Study - EAGLES), varenicline was found to be more effective for quitting smoking than placebo, the nicotine patch, or bupropion. In a meta-analysis of 65 randomized controlled trials of bupropion for tobacco cessation, bupropion was found to significantly increase long-term cessation compared to placebo and the level of effectiveness was comparable to NRT. Both varenicline and bupropion are effective if used alone, but may be even more effective when used in combination with nicotine replacement therapy (NRT).

Given the importance of insuring that smokers of all income levels have access to the best available tobacco cessation medications, WHO should consider including all evidence-based tobacco cessation medications on its Essential Medicines List. Including all proven effective tobacco cessation medications is important because tobacco users may respond better to, or prefer, a particular medication over another, and because this will insure that effective tobacco cessation medications are as accessible to as wide a population as possible.

Most tobacco users want to quit and should have access to treatments that give them the best chance to quit successfully. That is especially true during a pandemic of an infectious disease that primarily attacks the lungs. Given that over 80% of the world's 1.3 billion tobacco users live in low- and middle-income countries, tobacco cessation treatments should be made available and accessible to people of all economic levels. Varenicline and bupropion have been shown to be effective at helping smokers quit. If all the other criteria are met and including varenicline and bupropion on WHO's Essential Medicines List won't decrease access to other proven medications, adding these medications to the Essential Medications List has the potential to help reduce the global burden of disease caused by tobacco.

Sincerely,

A handwritten signature in black ink that reads "Matthew L. Myers". The signature is written in a cursive, flowing style.

Matthew L. Myers
President
Campaign for Tobacco-Free Kids