March 14, 2023

Dear WHO Expert Committee on Essential Medicines,

Re: Application for Multiple Sclerosis Disease-Modifying Therapies to be listed on the WHO essential medicines list, A.10 Cladribine, glatiramer, and rituximab - multiple sclerosis - EML

The Clinton Health Access Initiative's (CHAI) successful approach to advancing health care worldwide has fundamentally changed how many organizations approach global health. Starting in 2002, our focus was to substantially improve drug and diagnostics access to people living with HIV by dramatically reducing the cost of care and partnering by 1) working with innovator and generic companies, stringent regulatory agencies and various government and non-profit organizations to secure licenses to patented products, to lower the cost of manufacturing, and to ensure healthy and sustainable markets; and 2) working in country with ministries of health, clinicians, and clinics to improve the quality and availability of care. Millions of lives have been saved by the work of CHAI and its many partners. Since then, we have applied similar methodologies to various areas, including malaria, hepatitis, tuberculosis, family planning and reproductive health, and three non-communicable diseases: diabetes, cardiovascular disease, and several types of cancer.

Since 2019, MSIF has been developing a revised application to the WHO essential medicines list, by systematically assessing all 30 Disease-Modifying Therapies (DMTs) used for MS. The information below highlights the rigorous approach taken to nominate rituximab, cladribine, and glatiramer acetate for addition to the EML for the treatment of MS.

The selection has been made by an independent, international and multidisciplinary panel, with high representation from low- and middle-income countries. The WHO Collaborating Centre in Evidence-Based Research Synthesis and Guideline Development in Bologna is a co-applicant contributed greatly to the work and, alongside the Cochrane MS Group has led the systematic reviews and evidence synthesis. The GRADE evidence-to-decision framework was used to make recommendations with the support of co-Chairs from the GRADE-McMaster Centre. The three medicines were selected using the following criteria; balance of benefits and harms, the certainty of the evidence, cost and cost-effectiveness in low-resource settings, values, equity, acceptability, feasibility and availability in low-resource settings, and the needs of special populations – pregnancy, breastfeeding and paediatric MS. Fifteen MS and neurological organizations across the world have endorsed the application, demonstrating the quality and applicability of the application.

We have reviewed the highly rigorous evidence-based process MSIF underwent to nominate these compounds and agree with the rationale for narrowing down an initial list of 30 candidates to these definitive therapies. CHAI feels strongly that WHO should expand the EML to include MS therapies. Given this background, we support the MSIF application to add rituximab, cladribine and glatiramer acetate to the EML for the treatment of MS.

CHAI has experience with catalyzing the development, access, and uptake of small and large Cost of Goods Sold (COGS) by diversifying supply sources, optimizing manufacturing processes, and shaping the market to achieve scale even for complicated markets such as this; and 2) stimulate treatment delivery through various market incentives.

The inclusion of the proposed DMTs to the WHO EML will allow MSIF, CHAI, and others to explore opportunities to accelerate the introduction of new therapies for MS patients in resource-limited settings and maximize the uptake and accessibility of MS DMTs globally.

Sincerely,

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The Clinton Health Access Initiative