

Essential medicines for patients with multiple sclerosis

Although neurological disorders are the leading cause of disability and the second cause of deaths worldwide, access to affordable drugs to treat neurological patients is appallingly low in most countries. To guide countries in their national drug policies, WHO has compiled the Model List of Essential Medicines (EML) biennially since 1977. According to WHO, essential medicines satisfy the priority health-care needs of the population and are selected on the bases of public health relevance, safety, efficacy, and cost-effectiveness. Although the number of medicines on this list more than doubled between 1977 and 2019, reaching 460 drugs, only a fraction of them are for neurological disorders. Medicines on the WHO EML have increased global availability compared with those not on the list; therefore, there is a pressing need to include more neurological treatments on the WHO EML.

An application to include three disease-modifying therapies for multiple sclerosis (glatiramer acetate, fingolimod, and ocrelizumab) on the WHO EML was submitted last year by the Multiple Sclerosis International Federation (MSIF), an alliance of national multiple sclerosis organisations, in collaboration with the World Federation of Neurology; several WHO departments were also engaged in the application process. Multiple sclerosis is the most common inflammatory neurological disease in young adults. Untreated, relapses of neurological symptoms and disease progression can cause severe disability and increase the risk for premature death. Disease-modifying therapies effectively reduce the inflammatory activity, relapse rate, and disability progression. Fifteen disease-modifying therapies for multiple sclerosis have been approved by the US Food and Drug Administration and the European Medicines Agency, yet no drugs on the WHO EML are indicated for multiple sclerosis, and access to treatment is limited in many countries (eg, these drugs are either not licensed or not covered by health insurance).

Unfortunately, despite the high volume of public support letters from various professional societies, such as the American Academy of Neurology, the Clinton Health Access Initiative, and the International Paediatric Study Group of Multiple Sclerosis, and from neurologists working in low-income settings, the WHO Expert Committee on Selection and Use of Essential Medicines did not recommend the addition of any of the three disease-modifying therapies to the 2019 WHO EML. The

Committee noted that there was no clear-cut superiority of these drugs over other multiple sclerosis drugs in terms of safety, efficacy, and affordability, and commonly used drugs (eg, natalizumab) and off-label medications (eg, rituximab) were excluded from the application. However, in a report published on Sept 27, 2019, the Committee now stresses the pressing need for effective and affordable treatments for patients with multiple sclerosis and welcomes a revised application in 2 years' time.

When a drug appears on the WHO EML, that is a strong indication to countries that this treatment is effective and should be made available. However, this action alone will not necessarily translate into better clinical care for people with multiple sclerosis. Accurate and timely diagnosis, which is vital for improving long-term outcomes, requires training of health-care professionals to recognise signs and symptoms, and the necessary infrastructure, equipment, and tests to enable differential diagnosis. The management of patients with multiple sclerosis requires both appropriate treatment choices and regular monitoring of effectiveness and potential side-effects. However, in many regions, there is a shortage of neurologists, and facilities and treatment options remain unavailable, unreliable, or unaffordable.

To address these challenges, adequate funding is needed for national health-care systems in low-income settings. Treatment guidelines that consider the different resource levels available in each setting are also essential. Additionally, easily accessible training and peer-support for neurological specialisation would enhance multiple sclerosis care worldwide. The cost of treatment could be tackled either through negotiations with the pharmaceutical industry and differential pricing (ie, the drug price varies according to several parameters such as affordability), voluntary licensing through organisations such as the Medicines Patent Pool, or by looking at the potential of repurposing medicines already available in low-income settings for other diseases.

With increasing incidence and prevalence of multiple sclerosis globally, especially in low and middle-income countries, it is essential to ensure that people with multiple sclerosis have timely access to safe and effective treatments. Repeated strong global advocacy efforts through organisations such as the WHO are needed to reduce the global burden of multiple sclerosis. ■ *The Lancet Neurology*



For more on the **global burden of neurological disorders** see **Articles** *Lancet Neurol* 2019; **18**: 459–80

For the **WHO EML** see <https://www.who.int/medicines/publications/essential-medicines/en/>

For the **impact of the WHO EML on availability of medicines** see *PLoS One* 2014; **9**: e87576

For the **multiple sclerosis WHO EML application** see https://www.who.int/selection-medicines/committees/expert/22/applications/s8.1_multiple sclerosis DMT2.pdf?ua=1

For more on the **Multiple Sclerosis International Federation** see <https://www.msif.org/>

For more on the **global burden of multiple sclerosis** see **Articles** *Lancet Neurol* 2019; **18**: 269–85

For the **public letters in favour of the multiple sclerosis WHO EML application** see <https://www.who.int/selection-medicines/committees/expert/22/applications/multiple-sclerosis-disease-modifying-therapies/en/>

For the **report of the WHO Expert Committee on Selection and Use of Essential Medicines** see https://www.who.int/medicines/publications/essentialmedicines/UNEDITED_TRS_2019_EC22_Sept.pdf?ua=1

For more on **differential pricing** see **Articles** *Lancet* 2002; **359**: 2105–07

For more on the **Medicines Patent Pool** see <https://medicinespatentpool.org/>