

NEWS RELEASE

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FOR IMMEDIATE RELEASE

WHO recognises the public health need for effective and affordable treatments for multiple sclerosis

Multiple Sclerosis (MS) treatments added to WHO's Essential Medicines List for the first time

Today the <u>World Health Organization (WHO) added three disease modifying-therapies</u> (DMTs) for multiple sclerosis (MS) onto its <u>Essential Medicines List</u> for the first time.

With this landmark decision, the WHO acknowledges the critical importance of making MS treatments available in all health systems at all times. It is a significant moment in the history of MS, marking a crucial step towards improving access to MS treatments for people living with MS, particularly those in low- and middle-income countries or low-resource settings, who face significant barriers to accessing MS treatments.

The three treatments added onto the WHO Essential Medicines List are rituximab, cladribine and glatiramer acetate. MSIF and its members stress that the three medicines listed provide a baseline of care but are not the only ones that are effective and important for the treatment of MS. As this is the first time that MS treatments are included, a new section has been created on the list underlining the importance of treating MS.

Although these treatments represent a highly prioritised selection of the DMTs that are currently used to treat MS, this decision lays the foundations for better access to all DMTs around the world.

Effective treatments are crucial to help people with MS, slowing the accumulation of disability, reducing the number of relapses and maintaining independence. Access to a range of DMTs can help people with MS remain in the workforce and actively contribute to society. MS is a complex disease and it is important that different DMTs are made available to suit the needs of the MS population in a country.

In December 2022, MSIF in collaboration with the WHO Collaborating Centre Bologna, applied to add MS treatments to the World Health Organization's Essential Medicines List (EML). This was the result of many years of effort from MS experts across the globe, who undertook a rigorous review of all DMTs for MS to develop recommendations for the application This work was supported by the Cochrane MS group and McMaster GRADE Centre, both groups being internationally regarded as experts in the field of evidence reviews and decision-making.



Together with its members, MSIF has been advocating for the inclusion of MS treatments on the Essential Medicines List. The application was made with the help of two independent panels and endorsed by 15 organisations, including all regional MS research and clinical networks (TRIMS), regional and national neurological academies and the World Federation of Neurology.

This is a great moment for the MS community to celebrate this major step forward for all people with and affected by MS around the world and is a testament to the power of international collaboration. Peer Baneke, Chief Executive Officer of the MS International Federation said:

"This decision is a major milestone for people affected by MS everywhere. We are delighted that the WHO Expert Committee has recognised the importance of including MS treatments on the Essential Medicines List. It is vital for people with MS to get the right treatment at the right time. MSIF and its member organisations around the world believe that the provision of the types of DMT represented by those on the list is the minimum for adequate MS care. Every country now needs to ensure people with MS can access a range of MS treatments at all times."

The WHO's Essential Medicines List is an internationally recognised set of selected medicines to help countries choose how to treat their priority health needs. Countries frequently use the list to develop their own national lists of essential medicines.

There is unequal access to MS treatments globally, with high efficacy treatments particularly poorly available. The main barriers for access are the cost of treatment to the individual, government, healthcare system, or insurance provider¹. There is global consensus that a range of MS treatments should be available in all health systems at all times.

Dr Tarun Dua, Unit Head at the Brain Health, Mental Health and Substance Use Department at the World Health Organization said:

"This important decision will help improve access to MS treatment globally and is strongly aligned with the strategic objectives of WHO's global action plan on neurological conditions.²"

¹ The Atlas of MS – a global survey of MS epidemiology and availability of MS healthcare - showed that in over 70% of countries people with MS face barriers that prevent them from accessing DMTs, and that in around half of the countries a major barrier is the cost to the individual, government, healthcare system, or insurance provider.

² Intersectoral global action plan on epilepsy and other neurological disorders: https://www.who.int/publications/i/item/9789240076624



MSIF and its members will now strive to work with governments, industry, healthcare providers, and patient organisations around the world to make affordable access to the best available treatments and care for people affected by MS a reality.

As the global MS community unites to advocate for change, it is imperative that every country now needs to ensure people with MS can access a range of MS treatments at all times.

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For press enquiries, please contact: Abdelfatah Ibrahim, Head of Communications, Campaigns and Advocacy, on abdelfatah@msif.org

Notes to Editors

About MS

Multiple sclerosis (MS) is a chronic disease that affects over 2.8 million people worldwide. MS is one of the most common diseases of the central nervous system (brain and spinal cord). It is an inflammatory demyelinating condition. This means it is caused by damage to myelin – a fatty material that insulates nerves.

MS symptoms vary widely and include blurred vision, weak limbs, tingling sensations, unsteadiness and fatigue. For some people, MS is characterised by periods of relapse and remission while, for others, it has a progressive pattern. For everyone with MS, it makes life unpredictable.

MS affects two to three times as many women as men. Most people are diagnosed between the ages of 20 and 40, it can significantly impact family and work. As a complex and unpredictable disease, MS can have varying effects on a person's ability to work. However, access to a range of DMTs can help people with MS maintain normal life and actively contribute to society.

There is no drug that can cure MS, but highly effective treatments are available which can modify the course of the disease.

People with MS' stories

Stories of people with MS from around the world showing the impact of the disease and its treatment on them are available on this link: https://www.msif.org/getting-the-healthcare-i-need/



About the MS International Federation

The MS International Federation (MSIF) is a unique movement made up of 47 MS organisations with links to many others around the world. MSIF and its members campaign for increased awareness of MS, support scientific research and improve access to treatments and healthcare. Through organisational development, campaigning and information resources, MSIF supports and collaborates with organisations in countries where there is limited provision for people with MS. The global MSIF movement works together to improve the quality of life of everybody affected by MS. Find out more: www.msif.org

DMTs added to the WHO's Essential Medicines List

The decision about which treatments to include in the application focused on DMTs in low-resource settings and considered the following factors:

- Balance of benefits and harms
- · Certainty of the evidence
- Cost and cost-effectiveness in low-resource settings
- Values, equity, acceptability, feasibility and availability (particularly in low-resource settings)
- The needs of special populations pregnancy, breastfeeding and paediatric MS

It was not feasible to propose all DMTs suitable for treating MS, and the panel had to recommend only a very restricted number of prioritised DMTs. Countries are free to consider which DMTs should be listed on their national list, depending on the local context, barriers and opportunities. The WHO's Essential Medicines List is a model list that can be adapted to the local situation.

The treatments included on the WHO's Essential Medicines List are:

- **Rituximab**: this is an anti-CD20 medication, administered by infusion, that has been used off-label in the treatment of MS for more than two decades. In low-resourced settings, rituximab offers several advantages. It is highly efficacious and suitable across a broad range of disease presentations, including paediatric MS. While currently contraindicated during pregnancy, women's MS experts around the world have used rituximab to provide effective disease management in relation to family planning. Emerging data also suggests safety during breastfeeding. Rituximab is already listed on the WHO EML, is widely available and listed on many national EMLs, and has a lower price across different income settings.
- **Cladribine**: is an oral medication for the treatment of RRMS and active SPMS in adults. Cladribine offers several advantages in low-resourced settings, as it requires only 16-20 days of total treatment distributed over 2 years, and further treatment is



not needed for at least another two years. This significantly reduces the likelihood of treatment disruptions in settings where medication supplies can be erratic. While it is contraindicated to use cladribine during pregnancy and breastfeeding, it may be used to plan around pregnancies given its infrequent dosing. Limitations in low-resourced settings include that people with HIV and TB, as well as pregnant and breastfeeding women and men and women of childbearing age who do not have access to reliable contraception, cannot use this therapy.

Glatiramer acetate: is a treatment for RRMS administered by subcutaneous injection. It has been used off-label in clinical practice in paediatric MS for over twenty-five years. Glatiramer acetate offers several advantages in low-resourced settings, including its lack of monitoring requirements, good safety profile without risk of opportunistic infections, and safety in women of childbearing age, pregnant and breastfeeding women, and paediatric populations. The major drawbacks to its use in these settings are its non-preferred administration route (i.e. injections) and its refrigeration requirement.

Find answers to the most <u>frequently asked questions about our application to add MS</u> treatments to the WHO EML.

An important milestone for neurological disease

Treatments for neurological conditions have been underrepresented on the WHO's Essential Medicine List. In the recent intersectoral global action plan on epilepsy and other neurological disorders, developed by the WHO and adopted by its member states, the WHO calls for the updating of the Essential Medicines List to ensure it is appropriate for neurological conditions. The addition of MS treatments in 2023 sends a strong signal that the treatment needs of people living with neurological conditions must be prioritised by countries across the world.

The list of endorsing organisations

- World Federation of Neurology (WFN)
- African Academy of Neurology (AFAN)
- Indian Academy of Neurology (IAN)
- European Academy of Neurology (EAN)
- American Academy of Neurology (AAN)
- Neurology Society of Ghana (NSG)
- Neurological Association of Zambia (NAZ)
- Nigerian Society of Neurological Sciences (NSNS)
- Neurological Society of Kenya (NSK)
- Neurology Association of South Africa (NASA)
- Middle East and North Africa Committee for Treatment and Research in Multiple Sclerosis (MENACTRIMS)



- Pan-Asian Committee for Treatment and Research in Multiple Sclerosis (PACTRIMS)
- Latin American Committee for Treatment and Research in Multiple Sclerosis (LACTRIMS)
- Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS)
- European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS)