

**Proposal for the addition of baclofen to the who model list of essential medicines and to the WHO Model list of essential medicines for children for the treatment of spasticity in children and adults with cerebral palsy**

**Comments from the Department of Mental Health, Brain Health and Substance Use**

The application is for inclusion of baclofen for treatment of spasticity in conditions like cerebral palsy (CP). The application proposes the inclusion of intrathecal and oral baclofen on the EML and presents evidence of benefits and safety for children and adults with CP.

The use of intrathecal baclofen is supported by several international and national guidelines. The use of oral baclofen is well established in clinical practice and recommended across some clinical guidelines. The use of oral and intrathecal baclofen is recommended (conditionally) in WHO's 2023 Package of Interventions for Rehabilitation with quality of evidence considered low to moderate.

The application presents evidence from systematic reviews and meta-analyses favoring intrathecal baclofen over placebo and other therapies (i.e., dorsal rhizotomy and extracorporeal shockwave), noting its reversibility and customizable nature.

Evidence for oral baclofen is scarce in the literature and the application has provided the available evidence in the literature for its use. Oral baclofen is commonly used to predict outcomes before considering the more invasive intrathecal therapy, making its access equally important. The availability of oral baclofen is essential for predicting and assessing responsiveness prior to the introduction of the more costly and invasive option of intrathecal baclofen therapy. One systematic review recommended the use of oral baclofen for adults and a specific group of children with CP. This review was also considered in the development of the aforementioned WHO package for rehabilitation. The application also presents the outcomes of a systematic review that indicate a great variability in methodology, among other limitations, which prevented authors from arriving at a definitive conclusion. Further evidence was presented from smaller randomized controlled trials, which favor the use of oral baclofen for people with CP, including improvements in activities of daily living and gross motor function.

Baclofen is also effective for treating spasticity from other conditions like stroke, multiple sclerosis, and spinal cord injury. For example, oral baclofen has also presented superior outcomes compared to placebo for people that suffered spinal cord injuries, although increased efficacy is found for intrathecal administration.

The application highlights baclofen's adverse effects, cost-effectiveness, and affordability, noting that intrathecal baclofen is more expensive but offers overall better outcomes compared to oral baclofen, dorsal rhizotomy (which has uncertain but irreversible consequences) and diazepam (which is heavily sedating). Oral baclofen is more affordable, costing as low as USD 4.50 per month in select countries presented by the application.

Listing baclofen on the WHO Essential Medicines List (EML) will support countries in prioritizing its inclusion in national policies (e.g., national EMLs, standard treatment guidelines, and UHC packages) and procurement plans, which may help to improve appropriate use, availability and affordability, especially in low- and middle-income countries.