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Dr. Tedros Adhanom Ghebreyesus
Director-General
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Application: “A.19 Methylphenidate – attention deficit hyperactivity disorder”

Dear Members of the WHO Expert Committee,

I hope this letter finds you well.

This application proposes the addition of methylphenidate to the WHO Model List of Essential Medicines for the treatment of children and adolescents between the ages of 6 and 17 years with Attention-Deficit/Hyperactivity Disorder (ADHD).

ADHD is a global public health concern, affecting an estimated 5-7% of children worldwide. It is associated with a reduced quality of life, lower educational attainment, and increased risks of unintentional injuries and mental health disorders. No alternative medicines are included on the WHO Essential Medicines List (EML) for this indication.

To support this application, we present the best available evidence on the efficacy, effectiveness, and safety of methylphenidate, including long-term studies exceeding 52 weeks. These trials demonstrate significant symptom reduction and sustained long-term benefits with appropriate monitoring. While non-serious adverse events have been noted, such as mild cardiovascular effects, no significant increase in serious adverse events has been identified.

The WHO 2023 mhGAP guideline recommends methylphenidate as part of a comprehensive ADHD treatment plan. Including methylphenidate in the EML would help ensure access to this essential treatment, particularly in low- and middle-income countries (LMICs), where ADHD remains underdiagnosed and untreated. Integrating psychiatry into primary healthcare supports the feasibility of proper prescription and monitoring.

Additionally, concerns about stimulant misuse and diversion are addressed with evidence from recent studies. Proper prescribing guidelines and monitoring can mitigate these risks while ensuring treatment reaches those most need.

Key reasons for inclusion in the EML:

1. **Unmet Need:** ADHD is a significant global health concern with no listed pharmacological treatments on the WHO EML.

2. **Proven Efficacy and Safety:** Decades of research confirm methylphenidate's effectiveness and manageable safety profile when adequately monitored. The **American Academy of Pediatrics (AAP), the National Institute for Health and Care Excellence (NICE), and WHO guidelines** all recognize methylphenidate as a standard treatment for moderate-to-severe ADHD.
3. **Improved Outcomes:** Treatment enhances academic performance and social functioning and reduces long-term risks of comorbid mental health disorders and substance abuse:
 - Studies show significant symptom reduction (70-80%) in children who take methylphenidate compared to placebo.
 - Improves Education and Social Outcomes
 - Children with untreated ADHD struggle in school, have lower academic achievements, and are more likely to drop out.
 - Methylphenidate helps improve focus, working memory, and impulse control, allowing children to reach their full potential.
 - Enhances social interactions, reducing the risk of bullying and social isolation.
 - Reduces Risk of Dangerous Long-Term Consequences
 - Untreated ADHD is associated with higher rates of substance abuse, criminal behavior, and mental health disorders in adulthood.
 - Early intervention with methylphenidate lowers the risk of developing secondary problems like depression, anxiety, and conduct disorders
4. **Health Equity:** Many LMICs lack access to ADHD diagnosis and treatment; inclusion in the WHO EML would facilitate affordability and accessibility.
 - **Without WHO Essential Medicine status**, many national health systems do not include methylphenidate in their public health programs, leaving millions of children without treatment. Making methylphenidate an essential medicine would increase affordability and accessibility, ensuring more children get the necessary care.
5. **Economic Benefits:** The cost of untreated ADHD includes educational failure, increased healthcare use, and lost productivity.
 - Methylphenidate is cost-effective and encourages generic production.
 - Methylphenidate is inexpensive compared to the long-term societal costs of untreated ADHD (such as school failure, juvenile detention, and lost productivity).
 - The economic cost of untreated ADHD is estimated to be in the billions due to increased healthcare use, lost wages, and criminal justice expenses.
 - Including it in the WHO Essential Medicines List would encourage generic production, lowering prices even further.
6. **Alignment with WHO Goals:** Recognizing ADHD as a legitimate condition requiring medical treatment supports WHO's mission for universal health coverage and childhood well-being.
7. **Decades of research** show that **methylphenidate is the most effective first-line medication** for ADHD, improving focus, impulse control, and academic and

social outcomes. More than 60 years of clinical use have demonstrated that methylphenidate is safe and well-tolerated when prescribed and monitored appropriately.

8. Strong Safety Profile When Used Properly:

- Side effects like appetite suppression and mild insomnia are manageable, especially when weighed against the risks of untreated ADHD.
- The risk of misuse is **low in children when prescribed appropriately** and can be further reduced with responsible prescribing practices.

9. Addresses Stigma and Promotes Mental Health Equity:

- Many countries still **stigmatize ADHD and deny children access to treatment** due to misconceptions.
- The WHO's endorsement would **legitimize ADHD as a serious medical condition** and improve global awareness.
- Including methylphenidate on the Essential Medicines List would encourage **governments to invest in mental health services for children**.

10. Aligns with WHO's Goals for Universal Health Coverage and Child Development:

- WHO aims to **promote mental health and ensure all children receive healthcare**.
- Recognizing methylphenidate as essential aligns with **Sustainable Development Goals (SDGs)** on education, health equity, and childhood well-being.
- Many healthcare systems, especially in LMICs, **lack standard ADHD treatment protocols**.

11. Thus, including methylphenidate in the Essential Medicines List will Help Healthcare Systems **Standardize ADHD Treatment**. The List would provide **clear WHO-endorsed guidelines** for diagnosis and treatment, ensuring **consistent and evidence-based care** globally.

In summary, by including methylphenidate in the WHO Model List of Essential Medicines, millions of children and adolescents will gain access to life-changing treatment, promoting better mental health outcomes globally.

Thank you for your time and consideration. Please do not hesitate to contact me if you require any further information.

Sincerely,

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