IACAPAP
International Association for Child and Adolescent Psychiatry and Allied Professions

16 April 2025 Ref: IACAPAP-25-L151

WHO Expert Committee on Selection and
Use of Essential Medicines
emlsecretariat@who.int

RE: Application reference: A.19 Methylphenidate – attention deficit hyperactivity disorder

Dear Members of the Essential Medicines for Children Committee,

The International Association for Child and Adolescent Psychiatry and Allied Professions (IACAPAP) would like to express our strong support for the inclusion of methylphenidate in the WHO Model List of Essential Medicines for the treatment of children and adolescents between the ages of 6 to 17 years with Attention Deficit/Hyperactivity Disorder (ADHD), and the corresponding application "A.19 Methylphenidate – attention deficit hyperactivity disorder".

Our support is based on the following two reasons:

1) **It is time to prioritize the best interest of children and adolescents living with ADHD and their families worldwide.** In the last few years and more intensively in the last year, there is an endless debate between academic experts on technical issues about the quality of investigations (i.e., randomized clinical trials, meta-analyses, longitudinal studies) supporting the efficacy and tolerability of methylphenidate for ADHD. Issues like how to assess the quality of reports and blindness among others are central in the debate (1-6). Each side finds potential methodological flaws in the science produced by the other side claiming that their arguments illuminate "*the scientific truth*" that should guide decisions on prescribing methylphenidate to youths with ADHD. Here, it is fundamental that we disclose that one of the signatories of this letter (LAR) has been part of this debate. Although IACAPAP values scientific debate, it cannot obfuscate our focus from our ultimate shared goal,

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which is the wellbeing of youth with ADHD, worldwide. Every scientist knows that methodological problems exist in all investigations and methodological decisions on study design choices are inherent to all studies including those that support the psychiatric medications currently on the List of Essential Medicines. These decisions, such as how to score quality of studies based on existent scales, are influenced by investigators´ beliefs. Thus, this endless debate about such issues is not productive.

It is time to acknowledge that **we will not have "the almost perfect" long-term investigation on the effectiveness of methylphenidate for youths with ADHD, considering that the perfect one does not and will not exist.** No IRB or ethics committee worldwide would allow children with ADHD to be treated with placebo for one year. This is the reason why, even 28 years ago, the MTA (7) did not include a placebo arm as this was not considered acceptable by the US National Institute of Mental Health or to the IRBs at the study sites. This situation occurs because IRBs and probably almost all medical associations and all international guidelines, including the most conservative ones like NICE in the UK (8) consider that there is enough science to endorse methylphenidate as a central part of the treatment for moderate to severe ADHD in youths. They, along with the IACAPAP as an association of mental health professionals dedicated to youths, recognize that issues on tolerability (9) and misuse (10) especially in less favored environments should be considered and surveilled when using methylphenidate. However, evidence has suggested that, in most continents, undertreatment is a more pressing problem than overtreatment (11). In addition, the WHO has proposed strategies to integrate therapeutic approaches and stricter prescription monitoring in less favored settings to face the risk of misuse in the mhGAP (12). Again, the general understanding is crystalline: the global evidence from science and more than 80 years of clinical practice clearly support the place of methylphenidate in the treatment of the disorder in children and adolescents. We should avoid getting stuck on endless discussions around the quality of randomized clinical trials, meta-analyses and the search for the perfect trial, when a growing number of investigations support the beneficial impact of psychopharmacological treatment **on even the most important outcome in health (i.e., early mortality)**, being methylphenidate the protagonist in medications prescribed in these studies (13,14).

Perhaps most importantly, we need to listen to the voice of people with lived experience. They are shouting in the same direction as medical associations and all international guidelines. In summary, while the evidence is not perfect, **it is far better than several medications included for mental disorders and some other clinical conditions in the WHO Model List of Essential Medicines**. We think that it is time that the committee reflects on the probability of almost the whole world being wrong in asserting

the efficacy and safety of methylphenidate. While it is possible, it is highly improbable! In addition, should the reading of a small group of investigators be the core influence on the decision about this issue that affects the life of so many youths worldwide? Are this small group of investigators looking for the best evidence to protect our children from inadequate treatment or are they always looking for nuances and one level above of evidence just to ensure that their antipsychiatry beliefs live on inside committee decisions?

Even considering the extremely improbable possibility of getting an IRB approval for an "almost perfect study", we would not get funded to do it. Research funding agencies do not fund this type of long-term investigation with medication and industry has no interest in medications without patent protection. We at IACAPAP have engaged with private donors, research funding agencies, and industry about conducting such a study. The response is always the same, that **they will not fund such a project because they view it as unnecessary and unethical given the substantial data available about the drug's safety and efficacy.**

2) It is time to give equitable conditions for children and adolescents living with ADHD in Low-Middle Income Countries (LMIC). Let´s face the reality as it is: Excluding methylphenidate from the List of Essential Medicines does not impact most of the children and adolescents living in high-income countries. The health systems in most of these countries already pay/reimburse methylphenidate as a treatment for ADHD. However, 90% of children and adolescents live in LMICs (15). In these countries, government decisions on which medication would be available for the population without cost are heavily based on the WHO Model List of Essential Medicines. Those clinicians, like some of the signatories of this letter, who provide clinical care for children and adolescents with ADHD in public health systems in countries like Brazil and Nigeria have seen first-hand how WHO's exclusion of methylphenidate harms the educational and family functioning of children with ADHD. They have no effective medicine to prescribe after trying non-pharmacological interventions without success, something that is frequent and not rare. Moreover, because methylphenidate is not available in these countries, we see colleagues prescribing antipsychotics for ADHD, even for preschool children. Such practices only magnify the harms caused by excluding methylphenidate from the List of Essential Medicines. It is time for the committee to reflect on these issues too!

Discarding all the arguments brought to the table from an immense and diverse group of actors, including the most important of all, people with lived experience, reminds us about an old and highly cited meta-

analyses in British Medical Journal (16) on parachute use to prevent death and major trauma related to gravitational challenge. Quoting the authors in their conclusions: "…*the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomized controlled trials. …We think that everyone might benefit if the most radical protagonists of evidence-based medicine organized and* ***participated*** *in a double blind, randomized, placebo controlled, crossover trial of the parachute".*

Sincerely,

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