



SINPIA

**Società Italiana di Neuropsichiatria
dell'Infanzia e dell'Adolescenza**

April 3rd, 2025

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 Italian Association of Child and Adolescent Neuropsychiatry (SINPIA) would like to express their strongest 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".

The evidence supporting the efficacy, effectiveness, and tolerability of methylphenidate in children is thoughtfully reported and described in the application. From this evidence, it is clear that methylphenidate is not only one of the medications with the highest effect sizes from randomized controlled trials in neuropsychiatry and overall medicine, but also one of the most effective in the real world, with studies using sophisticated designs (such as evaluating target trial-like settings) showing its benefits in improving key health outcomes such as mortality, physical incidents, traffic accidents, and academic and job performance.

As a medication, methylphenidate is associated with possible side effects, but evidence and clinical experience show that, in the majority of cases, it is possible to manage such side effects without stopping the treatment. The persistence of evidence in the long term is supported by discontinuation trials, which show the continued positive effect size over the years. Needless to say, methylphenidate should be considered within the framework of a multimodal approach, including psychoeducation and non-pharmacological treatments as needed.

Besides the scientific considerations, we would like to highlight the experience, somewhat unique, with methylphenidate in Italy. Methylphenidate was first licensed in Italy in 1990, but then removed from the market in 1994 due to concerns about its potential for abuse, which an increasing body of research has shown to be minimal if taken orally. Following overwhelming positive evidence, it was reintroduced in 2003. During the period when methylphenidate was unavailable, we witnessed very unfavourable practices, ranging from a lack of treatment for ADHD to the use of non-evidence-based interventions, which has been highly detrimental for thousands of patients and their families in the country.

With the mental health of all children worldwide as a priority, we do not wish for this to occur in other countries. As such, we strongly endorse the inclusion of methylphenidate in the WHO Model List of Essential Medicines.

Sincerely,

Prof. Elisa M. Fazzi
President SINPIA

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