

The Secretary and Committee Members
24th Expert Committee on the Selection and Use of Essential Medicines
Department of Health Products Policy and Standards (HPS)
Access to Medicines and Health Products (MHP)
World Health Organization
14 April 2023

Dear Committee Members,

Re: Application for inclusion of 17- β -oestradiol tablets in adolescents for the induction of puberty on the WHO Model List of Essential Medicines (April 2023)

The technical unit supports the inclusion of 17- β -oestradiol tablets to the WHO Essential Medicines List as an option to enable induction of puberty in adolescents with certain relevant differences in sex development (DSD), including Turner syndrome, as well as adolescent females who have undergone certain oncology treatments resulting in primary ovarian failure (POF), and other adolescent females with POF. The use of 17- β -oestradiol can support prevention of bone loss.

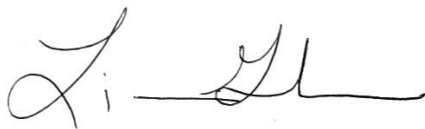
The technical unit notes the potential harm related to oestrogen therapy delivered to adolescents at too-high a dose, and expresses concern about the current availability of adolescent-appropriate dosages in either tablet or patch form.

The technical unit also notes the importance of holistic care to individuals with differences of sex development throughout the life course including during adolescence. This includes interdisciplinary support to account for adolescents' mental and emotional well-being and development in addition to their physical health and development.

As highlighted in the proposal, WHO does not currently have clinical guidelines on induction of puberty in adolescents, and this response should not be construed as a WHO recommendation.

Finally, the technical unit notes the application's mention of a previous inclusion of a synthetic estrogen in the EML for hormone replacement therapy related to menopause, before its 2011 removal. Though beyond the remit of the current proposal, the technical unit would welcome external appraisal of the current evidence around oestrogen-only and combined oestrogen- progestogen hormone replacement therapy to determine whether it warrants introduction to the EML for relief of menopausal symptoms.

Sincerely,



Lianne Gonsalves, PhD
Scientist
Sexual Health and Reproductive Cancers Unit
Department of Sexual and Reproductive Health and Research
World Health Organization