



Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Revised AWMSG process for paediatric minor licence extensions

Action for AWMSG:

To endorse changes to the paediatric minor license extension appraisal process as outlined in the proposed AWMSG position statement.

Purpose:

To improve access to paediatric licence extensions and facilitate access to medicines where the service benefits and/or patient need is greatest.

Context:

Since 2010 the pharmaceutical industry has been encouraged to submit an application for appraisal by AWMSG when certain criteria are met, including extension of the product licence for the treatment of children or adolescents (aged up to 18 years). Currently the appraisal process takes approximately four to six months from the time of the submission to a recommendation being ratified by Welsh Government.

In March 2017, NHS England introduced the Commissioning Medicines for Children in Specialised Services Policy. The policy allows children and adolescents routine access to medicines which are approved in adults by a NICE technology appraisal or NHS England clinical commissioning policy, providing certain criteria are met. In January 2020, the Scottish Medicines Consortium added paediatric licence extensions to their exclusion criteria hence facilitating automatic access in NHS Scotland.

In light of the changes introduced elsewhere in the UK, in December 2020 AWMSG developed the paediatric licence extension process, a simplified version of the limited submission, together with a planned review of the process once sufficient evidence had been captured.

This review demonstrates that since 2014 all minor licence extensions, including medicines submitted via the revised paediatric licence extension process, have received a positive recommendation by AWMSG. Consideration should therefore be given whether routine appraisal of paediatric licence extensions is warranted.



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Proposed AWMSG position statement:

AWMSG will no longer routinely appraise a medicine with a minor licence extension for the treatment of children and adolescents (aged up to 18 years), where the medicine is accepted for use by AWMSG or NICE for the same indication in the adult population.

In these circumstances Health Boards should continue to add paediatric licence extensions to their formularies. This update to the AWMSG process aims to improve access to medicines for children, ensuring they can be made available as soon as is practically possible and aligns with NHS England and NHS Scotland.

AWMSG will no longer expect to routinely receive a submission for a paediatric minor licence extension; however, should the need arise (such as inequity of access in Wales, or uncertainty in the evidence base), then AWMSG reserves the right to appraise a medicine where there is a clear clinical need.