Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

The AWMSG Independent Review (IR) Process

This policy should be read in conjunction with the following documents:

- The AWMSG Licensed One Wales Medicines Assessment Process
- The AWMSG Off-label One Wales Medicines Assessment Process

Background

The All Wales Medicines Strategy Group (AWMSG) recognises that, in spite of its aim to have a robust, transparent, timely and iterative assessment process, there may be rare occasions when the originator of the request for AWMSG assessment considers there is a genuine cause for concern in relation to the assessment. This may have been due to differences in scientific opinion and/or misinterpretation of information, or that it was felt that there was inadequate opportunity to highlight or clarify a particular issue during the assessment. The independent review (IR) process addresses complaints in relation to *process* and *scientific issues*.

1. Who may request IR?

This process of IR may be triggered by the stakeholder responsible for submitting the request for AWMSG assessment of the medicine in question, which may be an applicant company, healthcare professionals or a patient organisation (collectively referred to throughout this document as 'the applicant').

An IR cannot be requested solely on the basis that a negative recommendation has been issued unless there are concerns relating to either process or scientific issues. If the applicant wishes to submit significant new information, i.e. information which had not been included in the original submission or provided during the assessment process and therefore not considered by LOWMAG/OWMAG, then the case shall in effect be treated as a 'new application'. In such circumstances, the assessment process will be terminated and a reassessment to include the significant new information, would be scheduled.

2. How to request an IR

A request for an IR may be submitted to the AWMSG Chair (via AWTTC) within two weeks of the AWMSG meeting at which the AWMSG endorsement of the recommendation made by LOWMAG or OWMAG was made. The grounds for a review should be set out clearly by the applicant. The final ratification stage of the assessment process will be suspended pending investigation of the IR request. If the AWMSG Chair is unavailable, the AWMSG Vice Chair may deputise and undertake the role of the AWMSG Chair throughout the IR process.

3. Procedure following submission of a request for IR

3.1 If the AWMSG Chair considers the complaint **is justified**, then it is likely that an IR will be undertaken. An IR panel will be convened (see Section 4) who will compare the grounds submitted by the applicant against the relevant original information considered by AWMSG and its subgroup (either LOWMAG or OWMAG) and/or in relation to the process followed. The panel will confirm if the ground or grounds for review have been accepted or not. They will report their findings and the rationale of their decision to the Chair of AWMSG.

If the grounds for review are accepted, the AWMSG Chair will share the reasons with the Chair of LOWMAG or OWMAG (as appropriate) and the AWTTC assessment team. A course of action will be decided by the AWMSG Chair, with input from AWTTC and the Chair of LOWMAG/OWMAG, which will be reported to the AWMSG Steering Committee for agreement. A response will be issued from the Chair of AWMSG to the applicant outlining next steps which may include reassessment by LOWMAG/OWMAG. The AWMSG Chair will report the facts at the next AWMSG meeting.

If the grounds for review are not accepted by the IR Panel, the AWMSG Chair will report this to the AWMSG Steering Committee and, with the agreement of the Steering Committee, the applicant will be informed of this decision by email. The final recommendation endorsed by AWMSG and announced at the public meeting will be forwarded to Welsh Government for ratification. The AWMSG Chair will report the facts at the next AWMSG meeting.

3.2 If the AWMSG Chair considers that there is **no justification** for the complaint, they will report the facts to the AWMSG Steering Committee and, with the agreement of the Steering Committee, the applicant will be informed of this decision by email. The final recommendation, endorsed by AWMSG and announced at the public meeting, will be forwarded to Welsh Government for ratification.

4. The IR Panel

An IR panel will be appointed by AWTTC on advice from the AWMSG Chair and in agreement with the AWMSG Steering Committee. The panel will comprise seven members who were not involved in making the original decision:

- Three current members or alternate members of AWMSG
- Four members appointed from Medicines and Therapeutics Committees (MTCs) and/or other experts in the relevant scientific field who may or may not work in Wales.
- An AWMSG lay member and ABPI Wales representative will be invited to attend.

The IR panel will review the original information considered by LOWMAG/OWMAG and the complaint from the applicant. If required, scientific support will be provided by AWTTC staff who may or may not have been involved in the original assessment. The findings of the IR panel will be documented in the IR report.

The IR panel will report back to the AWMSG Chair who will decide on the next steps and report back to the AWMSG Steering Committee for agreement.

5. Roles and responsibilities

The applicant
In submitting a request for AWMSG review, applicant companies or requesting health professionals have a duty and a responsibility to submit all relevant data and information as requested in the AWTTC submission form. The applicant can attend the IR meeting as an observer, then leave before the panel makes its recommendations.

The AWMSG Chair
The AWMSG Chair will review the applicant's request for IR and make a decision on whether an IR is justified, and an IR Panel is to be convened. The AWMSG Chair will review the IR Panel's recommendations, decide on the most appropriate course of action, with support from AWTTC and the Chair of LOWMAG/OWMAG, and notify the AWMSG Steering Committee of the proposed next steps for their agreement. The AWMSG Chair will inform applicants of the outcome of their request for IR and will report the facts at the next AWMSG meeting.

The AWMSG Steering Committee
The AWMSG Steering Committee will be kept informed of the outcome of all requests for IR by the Chair of AWMSG and will be required to agree any actions proposed by the Chair of AWMSG. The AWMSG Steering Committee will be the final arbiter in all cases.

AWTTC
AWTTC will receive and discuss with the Chair of AWMSG, all written requests for an IR from the applicants and will consider the issues relating to the original assessment. AWTTC will be responsible for convening the IR Panel and providing administrative and professional scientific support.

The AWMSG Independent Review (IR) Process and Timelines*

*Bank holidays may affect timelines. Estimates only.

