All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

INDEPENDENT REVIEW (IR) PROCESS

(reviewed June 2015)

Background to the Independent review (IR) process

The All Wales Medicines Strategy Group (AWMSG) recognises that, in spite of its' aim to have a robust, transparent, timely and iterative appraisal process for all newly licensed medicines that fall within its appraisal criteria, there may be rare occasions when an applicant company considers there is a genuine cause for concern in relation to the appraisal. This may have been due to differences in scientific opinion and/or misinterpretation of information. Alternatively, applicant companies may consider they had inadequate opportunity to highlight or clarify a particular issue during the appraisal. An independent review process has therefore been developed which addresses complaints in relation to *process* and *scientific issues*. This process of IR may be triggered by the applicant company, within ten days from the appraisal and announcement of the final appraisal recommendation, using the procedures set out below.

1. Procedure to address complaints relating to "process"

1.1 Complaints may relate to whether sufficient time was given to the applicant company to address specific issues. Such concerns are now less likely to occur than when the appraisal process was first introduced, since time for dialogue between the All Wales Therapeutics and Toxicology Centre (AWTTC) and the applicant company is now an integral part of the process. Also, applicant companies are invited to input into the appraisal at AWMSG and highlight pertinent issues. Nevertheless, the applicant company may still occasionally feel that insufficient time or opportunity was given for discussion of relevant issues, and that the process was thus flawed.

1.2. In such circumstances, the applicant company should request an IR, outlining the grounds for a review, which should be submitted to the AWMSG Chairman (via AWTTC). The appraisal process will be suspended pending investigation of the complaint.

1.3 If it is considered by the Chairman that there is no justification for the complaint, the Chairman will report the facts to the AWMSG Steering Committee and, with the agreement of the Steering Committee, AWTTC will inform the applicant company of this decision by email. Ten working days after the date of the email, the Final Appraisal Recommendation announced at the public meeting will be forwarded to Welsh Government for ratification. The AWMSG Chairman will report the facts at the next AWMSG meeting. The process complaint may be referred to Welsh Government or the TDA Partnership Group.

1.4 If the Chairman considers the complaint is justified, then it is likely that an IR will be undertaken. Refer to the 'Procedure to address complaints relating to the AWMSG appraisal process' flow diagram.

2. Procedure to address scientific disputes

2.1 In the event that an applicant company considers there has been a difference in scientific opinion and/or interpretation of information, a request for an IR may be submitted to the AWMSG Chairman (via the Secretariat, AWTTC) within ten days of the AWMSG meeting and announcement of the Final Appraisal Recommendation (FAR).

2.2 The grounds for a review should be set out clearly by the applicant company.

2.3 AWTTC will acknowledge receipt of the applicant company's IR request and will pass it to the AWMSG Chairman. The appraisal process will be suspended pending investigation of the complaint.

2.4 In light of a negative AWMSG recommendation, if the applicant company wish to submit significant new information, i.e. information which had not been included in the company's original submission and therefore not considered by AWMSG, then the case shall in effect be treated as a 'new application' and the case will not be considered for an IR. In this case, the appraisal process would continue in that the FAR would be forwarded to Welsh Government for ratification; however, a reappraisal by AWMSG, to include the significant new information, would be scheduled.

2.5 The Chairman will investigate the complaint. The facts will be reported to the next meeting of the AWMSG Steering Committee. With the agreement of the Chairman, and subsequently the Steering Committee, an IR may be conducted.

2.6 **If the grounds are accepted by the IR Panel**, then the recommendation of the IR Panel will be that AWMSG should reappraise the medicine.

If the grounds are not accepted by the IR Panel, the Chairman will report the facts to the AWMSG Steering Committee and, with the agreement of the Steering Committee, AWTTC will inform the applicant company of this decision by email. Ten working days after the date of this email, the Final Appraisal Recommendation announced at the public meeting will be forwarded to Welsh Government for ratification. The AWMSG Chairman will report the facts at the next AWMSG meeting. The scientific dispute may be referred to Welsh Government or the TDA Partnership Group.

3. The IR Panel:

3.6 An IR panel will be appointed by the Secretariat on advice from the AWMSG Chairman and in agreement with the AWMSG Steering Committee. The panel will comprise of seven members:

- Three members appointed from AWMSG and/or the New Medicines Group (NMG) past or present (ideally but not necessarily an AWMSG member who, by reason of absence, had not been involved in the original appraisal). One of these individuals will be appointed to chair the panel. AWMSG/NMG deputy members may also be appointed to the panel.

- 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.

- A lay member and ABPI Wales representative will be invited to attend.

3.7 The IR panel will review the original information considered by AWMSG and also the complaint by the applicant company. Should scientific support and advice be required then this shall be provided by AWTTC, this may or may not be provided by personnel involved in the original review. The findings of the IR panel will be summarised in an IR report.

3.8 The IR panel will report back to AWMSG who will remain the final arbiter in all cases. If the grounds are accepted by the IR Panel, then the recommendation of the IR Panel will be that AWMSG should reappraise the medicine

4. Roles and responsibilities of the applicant company

4.1 In submitting an application to AWMSG, applicant companies have a duty and a responsibility to submit *all relevant data* in that application, as they do to the licensing authority.

4.2 The applicant company will be invited to attend the IR meeting and will leave prior to the vote.

5. Roles and responsibilities of AWMSG

5.1 AWMSG will receive and consider the recommendations of the IR panel at a future meeting. AWMSG will remain the final arbiter of the IR in all cases.

5.2 In the event that an AWMSG member participates in an IR, then he/she may participate in a subsequent reappraisal by AWMSG, but will not vote.

6. Roles and responsibilities of AWTTC

6.1 AWTTC will receive and discuss with the Chairman of AWMSG, all written requests for an IR from applicant companies, or other interested parties, and will consider the issues relating to the original appraisal. The Chairman will consider the grounds and decide whether or not his Committee's recommendation should be reviewed. He will inform the AWMSG Steering Committee.

6.2 AWTTC will be responsible for convening the IR panel and providing administrative and professional scientific support.