



COMMERCIAL ARRANGEMENT SCHEME WALES GROUP REVIEW PROCESS

The All Wales Medicines Strategy Group (AWMSG) recognises that, while it strives to operate a robust, timely and iterative process for evaluating the feasibility of commercial proposals from the pharmaceutical industry, there may be occasions when the originator of a proposal (i.e. the licence holder) believes that concerns exist regarding the assessment undertaken by the Commercial Arrangement Scheme Wales Group (CASWG) and the decision that was made.

Such concerns may arise from differences in perceived misinterpretation of information, a misunderstanding, or a view that there was insufficient opportunity to raise or clarify specific issues either before or during the CASWG meeting. The review process provides a formal mechanism to address concerns raised by the originator of the commercial offering.

Requests for review must be submitted to the CASWG Chair within ten days of the CASWG meeting. Full details of the concerns must be clearly set out in the correspondence requesting a review.

Upon receipt of a request for review, the CASWG Chair will inform the AWMSG Steering Committee. The Committee will then decide if a review is warranted. If the grounds are rejected, CASWG's recommendation will stand. If the grounds are accepted, an independent review panel meeting will be convened.

The review panel will comprise of six deputy members who were not present at the meeting where the commercial offering was originally discussed. Representatives from the Commercial Medicines Access Team (CMAT) – which includes staff from the All Wales Therapeutics and Toxicology Centre (AWTTC) and the Medicines Value Unit (MVU) - may attend to provide support but will not hold voting rights. A review panel chair will be identified by the Steering Committee. The licence holder may be invited to attend part of the meeting to present their reasons for the request for review and input into discussions. Clinicians may be invited to attend all or part of the meeting to discuss the review and/or clarify any outstanding issues.

The review panel will consider the original information presented to CASWG and will take account of the reasons for the request for a review. Support will be provided by CMAT and other AWTTC staff.

Following the meeting, the Chair of the review panel will present the findings to the AWMSG Chair, who will determine subsequent actions and communicate these

decisions to the AWMSG Steering Committee. CASWG remains accountable to the AWMSG Steering Committee, which will decide whether to disseminate CASWG's initial advice to the Service or to take forward additional recommendations provided by the review panel

Roles and responsibilities

In submitting a request to review CASWG's decision as to whether their commercial arrangement can be implemented within NHS Wales, **the licence holder** will submit all relevant data and information as requested by CMAT.

The CASWG Chair will review the request for a review of the decision and will report the facts to the AWMSG Steering Committee.

The AWMSG Steering Committee will consider the complaint and take account of the CASWG Chair's response and will decide whether a review is appropriate.

The Commercial Medicines Access Team will act as the link between the licence holder and the CASWG Chair. They may seek clarification of any issues or request additional information. AWTTTC will be responsible for convening the review panel and providing administrative and professional support.

AWMSG Chair

The AWMSG Chair will receive feedback from the review panel Chair and will decide what steps should be taken. The AWMSG Chair will report back to the Steering Committee and seek agreement of the final decision.

Reviewed: X

Next review date: February 2027