

INFORMATION NOTE FOR APPLICANT COMPANIES ATTENDING AWMSG APPRAISALS

Meeting papers will be posted on the AWMSG website www.awmsg.org approximately ten days in advance of the meeting. Please refer to the agenda for further information on venue, meeting start time and schedule of appraisals; however, please note that the schedule may be subject to change on the day.

On arrival, please sign the visitors' book and take a seat in the public gallery. You are not restricted to the number of colleagues who may attend to observe proceedings in the public gallery, though only two would normally participate in the appraisal. It is recommended that you nominate one individual to respond to cost-effectiveness and budget impact issues, normally a Health Economist, and one individual to respond to clinical-effectiveness and societal issues, normally a medical advisor. Anyone nominated will be expected to answer questions from the committee in relation to their company's submission.

Please note that a positive Preliminary Appraisal Recommendation (PAR) from the New Medicines Group (NMG) may not result in a positive recommendation from AWMSG because each committee has a different remit.

At the start of the appraisal, the Chairman will invite the applicant company delegates to take a seat at a table in front of the AWMSG members. They will be invited to introduce themselves.

The Chairman will invite AWMSG members to confirm any declarations of interest. He will announce that "AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation will not impact on the clinical freedom of the prescriber. However, a positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an obligation on Health Boards to fund accordingly. AWMSG advice is interim to NICE guidance should this be subsequently published".

The Chairman will outline the sequence of events. He will explain that AWMSG is not expected to repeat the detailed discussions held at the New Medicines Group (NMG). AWMSG will focus on the budget impact within NHS Wales and take account of wider societal issues – neither of which formed part of NMG's appraisal.

Prior to concluding the appraisal, the Chairman will ask the applicant company delegates to confirm whether or not they are satisfied that all relevant issues have been addressed and that the process has been fair and transparent. Members will retire in private to vote and agree the recommendation, which the Chairman will subsequently announce (in public).

Confirmation of the AWMSG recommendation to Welsh Government (in the Final Appraisal Report [FAR]) will be forwarded to applicant companies within five working days. You will have up to ten working days following the AWMSG meeting to accept the recommendation or lodge a request for an independent review, which should be submitted in writing to the Chairman via AWTTTC. Failure to respond will not delay the process. The process for independent review is available on the AWMSG website within

the appraisal information section, and further information is available within the Frequently Asked Questions.

Subject to receiving a request for an independent review, the FAR will be passed to Welsh Government when the ten days has expired for ratification. I should reiterate that Welsh Government may or may not endorse the recommendation and we are unable to determine the timescale of this decision. AWTTTC will contact you again when ratification is received.

Thank you for engaging with the AWMSG process. ABPI Cymru Wales will provide a feedback form so that any general comments or suggestions in relation to the AWMSG appraisal process can be fed back via the TDA Partnership Group for consideration/action.

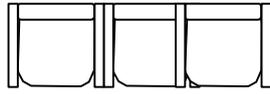
Please do not hesitate to contact me if you wish to discuss the above in more detail.

Ruth Lang (Mrs)
Head of Liaison & Administration
All Wales Therapeutics and Toxicology Centre

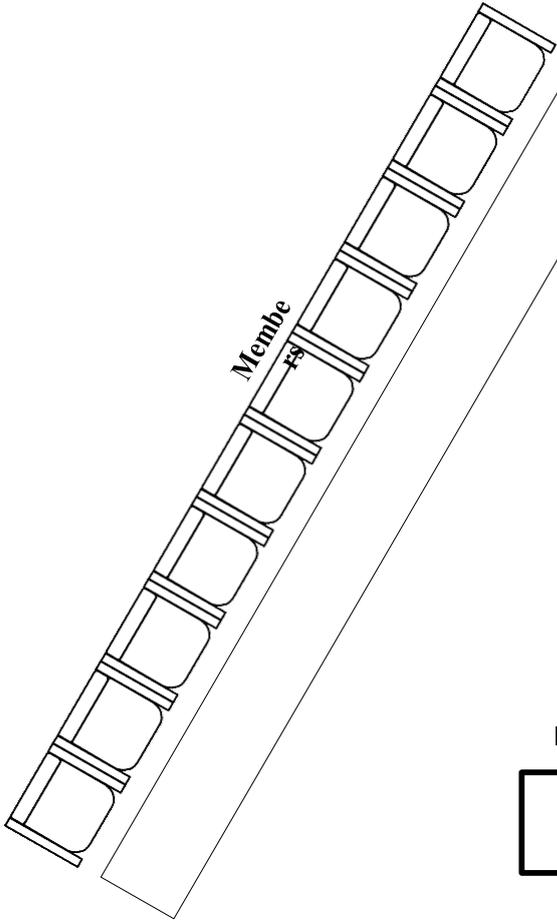
Tel: 02920 716900
awttc@wales.nhs.uk

AWMSG Meeting Layout

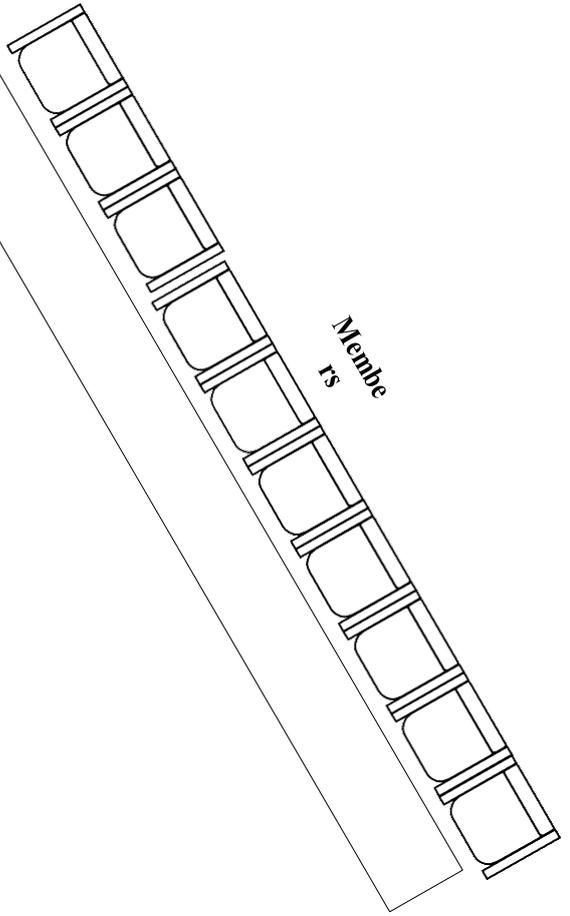
Chairman & Secretariat



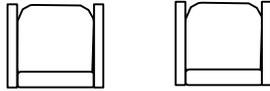
Members



Members



Industry Representatives



Public seating area (30+)

