AWMSG MASTERCLASS 2018
QUESTION AND ANSWERS

Thank you to all who attended the All Wales Medicines Strategy Group (AWMSG) Masterclass on 21 November 2018. It was great to meet you all and we hope you found the day useful and insightful.

During the Masterclass an electronic Q&A poll was set up for you to ask questions throughout the day. As agreed at the event we have provided answers to the questions, which can be found below.

Should you have any further enquiries please do not hesitate to contact Ruth Lang (Head of Liaison & Administration) at awttc@wales.nhs.uk.

1) What is the approach if the current standard of care in Wales is unlicensed or used off-label? What is the weighting for a fully licensed product?

If the current standard of care in Wales is an unlicensed medicine, or a licensed medicine used off-label, then it would be accepted as the comparator if it was the medicine that would be displaced. It would be appropriate for sensitivity analyses to be conducted for other licenced comparator treatments, where appropriate.

2) What is the difference between IPFR and One Wales?

The Individual Patient Funding Request Process enables a clinician to make a request to a health board to fund NHS healthcare for individual patients who fall outside the range of services and treatments that a health board has arranged to routinely provide, or commission. This can include a request for any type of healthcare including a specific service, treatment, medicine, device or piece of equipment.

The One Wales Interim Commissioning Process enables interim commissioning decisions to be made in relation to licensed and unlicensed medicines for a clearly defined and specific patient cohort in the absence of NICE or AWMSG health technology assessment advice. It is intended that this process would be utilised rarely when there is a clearly identified clinical need and provided that certain criteria have been met (refer to awttc.org for further information).

3) If the company has indicated that they want to submit a WPAS, does the WPAS need to be sent in before Form B or at the same time?

Ideally, a Wales Patient Access Scheme should be submitted before the Form B.

4) Why would AWMSG come to a different decision to the New Medicines Group?

The remit of the two groups are different. The New Medicines Group considers the clinical and cost effectiveness of the medicine. AWMSG additionally considers the wider societal issues and budget impact.

5) Can I submit a Form A if the price of the medicine has not been agreed?

Yes you can submit Form A if the price of the medicine has not been agreed. It would be helpful to include an estimate of expected price, or an anticipated cost range, where possible.

6) Can the submission be restricted to a sub-population of the appraised indication?

AWMSG appraises the medicine for the whole of the appraised indication. The marketing authorisation holder can draw attention to a specific sub-population if the evidence to support its use is particularly good.

7) Can a company submit additional information during the appraisal process?

All the evidence should routinely be submitted with Form B. On occasion AWTTC may request additional information and may agree to accept information at a later stage.

8) Can the appraisal process be stopped if there is a need to clarify an outstanding issue?

Yes. AWMSG reserves the right to suspend the process in order to clarify any outstanding issues.

9) In Eifiona's case study 1, there was an existing treatment of same class available. Would there be an expectation for the company to factor this in at all? Unlikely to have data comparing the two but indirect comparisons could have been made.

Yes, the analysis in Form B should factor in all relevant comparators. Indirect treatment comparisons can be undertaken when there is lack of good quality head-to-head data.

10) Would the AWMSG consider utility data derived from EQ-5D-5L?

The EQ-5D-3L is currently preferred by AWMSG, pending further validation of the EQ-5D-5L. Any 5L analyses can be included as a scenario.

11) Would AWMSG appraise a medicine if it has not been launched in the UK?

Yes. The final appraisal recommendation published on the AWMSG website would include a note that the medicine has not yet been launched in the UK (this would be removed on confirmation of UK launch date).

12) Are NICE Clinical Guidelines mandatory in Wales?

No. Only NICE health technology appraisal guidance and NICE HST advice is mandatory within NHS Wales.

13) What if AWMSG recommends a medicine and NICE subsequently appraises the same medicine and comes to a different decision?

NICE health technology appraisal guidance supersedes AWMSG advice.

14) Will all the speaker slides be made available after the Masterclass?

Yes, the slides will be available on the AWMSG website (http://www.awmsg.org/masterclass.html)