All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

AWMSG criteria for appraising a medicine

AWMSG appraise all newly licensed medicines, new indications and new formulations unless the criteria set out in the table below apply. These 'exclusion criteria' provide broad guidance on medicines that might be considered outside the role and remit of AWMSG and may be unlikely to progress to formal appraisal. When one or more of the criteria apply, health boards may consider whether individual medicines are appropriate for local formulary inclusion.

To determine whether a medicine will be appraised by AWMSG, the marketing authorisation holder is asked to complete an initial submission (Form A). Form A should be submitted for all newly licensed medicines, and each new indication and/or formulation, regardless of whether one or more of the criteria below apply. In Form A you will be asked to indicate which, if any, of the criteria apply (refer to guidance notes to fill in Form A). Form A should be submitted **before marketing authorisation is received,** and ideally within one month of receiving a positive opinion from the Committee for Medicinal Products for Human Use (CHMP).

If none of the criteria below apply, the AWMSG Secretariat will request a full submission (Form B) or a limited submission (Form C). To comply with the Process for Industry Engagement, receipt of Form B or Form C is required **within three months of receiving marketing authorisation**.

AWMSG Steering Committee reserves the right to request a submission for a product at any time if there is a clinical need for advice. If there is any uncertainty as to whether a product falls outside the remit of AWMSG please contact AWTTC at: awttc@wales.nhs.uk

Exclusion criteria to identify medicines outside AWMSG remit

1.	**For the indication under consideration, the product was granted marketing authorisation prior to:** • **31 October 2002 for high-cost medicines; i.e. those ≥ £2,000 per patient per year;** • **1 April 2007 for all cardiovascular, malignant disease and immunosuppressant medicines (BNF chapters 2 and 8);** • **1 October 2010 for all other medicines.** Please refer to FAQs on the AWMSG website for further information.
2.	**The National Institute for Health and Care Excellence (NICE) has published or intends to publish guidance (STA/MTA/HST) for the same product and indication(s)*. Medicines may also be excluded from AWMSG appraisal if they need to be prescribed alongside a NICE approved medicine providing they were considered in the assessment of the cost-effectiveness of the approved medicine during the NICE appraisal. These will be assessed on a case by case basis.**

*To avoid duplication, AWMSG would not **usually** appraise a medicine if NICE intends to appraise the same medicine for the same indication within 12 months of the date of marketing authorisation. There are occasions where the AWMSG Steering Committee may request a submission ahead of NICE advice. If an interim accelerated appraisal would be beneficial for your product, please provide an estimated submission date in the initial submission (Form A).

AWMSG Secretariat: All Wales Therapeutics & Toxicology Centre
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3.	**The marketing authorisation holder, product trade name or manufacturer has changed, with no changes to the licensed indication, formulation, route of administration, pharmacokinetics/pharmacodynamics, posology or cost.**
4.	**Marketing authorisation is solely for a new strength or strengths of an existing, available, generic or branded generic product, with no associated change to the licensed indication or route of administration.**
5.	**Combination products that are comprised of medicines licensed prior to 1st October 2010, even if the individual components have not previously been appraised by NICE or AWMSG.** If any component of the combination product was licensed after 1st October 2010, the medicine is unlikely to be excluded from appraisal.
6.	**Product is a new formulation or combination of an established medicine which is either:** • **an oral formulation intended for patients unable to swallow tablets or capsules, or;** • **an alternative formulation of an established medicine which costs the same or less than the existing established medicine***. *New formulations costing more will be considered on case-by-case basis.
7.	**Product is a generic or branded generic authorised under Article 10 of Directive 2001/83/EC.**
8.	**Product does not have Prescription Only Medicine (POM) status.**
9.	**Product is a vaccine considered by the Joint Committee on Vaccination and Immunisation.**
10.	**Product is used solely for the acute treatment of poisoning.**
11.	**Biosimilar medicines are not usually appraised by AWMSG. Please see the Position Statement for biosimilar medicines on the AWMSG website for further information.**
12.	**Product is a medical device; i.e. does not have a licence as a medicine from the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA).**
13.	**Product is a diagnostic agent.**
14.	**Product is a medical gas.**
15.	**Product is classified as a blood product. However, AWMSG reserves the right to request a submission for a new blood product that has a medicinal licence from the MHRA or EMA, and where a clinical and cost-effectiveness assessment is required by NHS Wales.**
16.	**Product is a preparation for fluid and electrolyte imbalance.**
17.	**Product is used as a supportive intervention for surgical procedures, diagnostic procedures or wound management.**

If you are unsure whether your product meets any of these criteria, please contact Ruth Lang, Head of Liaison & Administration at the All Wales Therapeutics & Toxicology Centre. Email: awttc@wales.nhs.uk or telephone: 029 21826900.