



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 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 for a medicine as early as possible and before marketing authorisation is received.

AWMSG no longer routinely appraise medicines with a minor licence extension for the treatment of children and adolescents (aged up to 18 years) where the medicine is accepted for use by AWMSG or NICE for the same indication in the adult population. Therefore, a Form A is **not** required for new paediatric licence extensions in these circumstances. More information is available on the AWTTTC website at <https://awttc.nhs.wales/submit-for-appraisal>

If none of the criteria below apply, the AWMSG Secretariat will request a submission. To comply with the Process for Industry Engagement, receipt of the submission 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 AWTTTC at: awttc@wales.nhs.uk

Exclusion criteria to identify medicines outside AWMSG remit

1.	<p>For the indication under consideration, the product was granted marketing authorisation prior to:</p> <ul style="list-style-type: none">• 31 October 2002 for high-cost medicines; i.e. those \geq £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.
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2.	<p>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.</p> <p>*To avoid duplication, AWMSG would not usually appraise a medicine if NICE intends to appraise the same medicine for the same indication. 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). Medicines may be excluded from AWMSG appraisal where the NICE appraisal has been suspended or terminated.</p>
3.	<p>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.</p>
4.	<p>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.</p>
5.	<p>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.</p> <p>If any component of the combination product was licensed after 1st October 2010, the medicine is unlikely to be excluded from appraisal.</p>
6.	<p>Product is a new formulation or combination of an existing medicine which is either:</p> <ul style="list-style-type: none"> • an oral formulation intended for patients unable to swallow tablets or capsules, or; • an alternative formulation of a medicine which costs the same or less than the existing medicine*. <p>*New formulations costing more will be considered on case-by-case basis.</p>
7.	<p>Product is a generic, branded generic or hybrid* medicine.</p> <p>*Submission requirements for hybrid medicines will be considered on a case-by-case basis.</p>
8.	<p>Product does not have Prescription Only Medicine (POM) status.</p>
9.	<p>Product is a vaccine considered by the Joint Committee on Vaccination and Immunisation.</p>
10.	<p>Product is used solely for the acute treatment of poisoning.</p>
11.	<p>Biosimilar medicines are not usually appraised by AWMSG. Please see the Position Statement for biosimilar medicines on the AWMSG website for further information.</p>
12.	<p>Product is a medical device; i.e. does not have a licence as a medicine.</p>
13.	<p>Product is a diagnostic agent.</p>
14.	<p>Product is a medical gas.</p>

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, 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.