FORM A GUIDANCE NOTES

This document provides guidance to applicant companies on the completion of Form A. Separate guidance notes are available on the completion of Form B and Form C, available under 'all appraisal documents' on the AWTTC website (https://awttc.nhs.wales).

If you have any queries when completing Form A, please contact Ruth Lang, Head of Liaison and Administration for the AWMSG secretariat (the All Wales Therapeutics and Toxicology Centre [AWTTC]) on 029 218 26900 or email AWTTC@wales.nhs.uk.

The function and timing of Form A

Form A should be completed for all new licensed products, each new indication and/or formulation and will form the basis of the decision as to whether the medicine meets the criteria for appraisal by AWMSG. In general, a separate submission form for each indication is preferred, and facilitates the development of a coherent case for each indication. However, this may not be appropriate when indications are closely related, e.g. a medicine licensed for different grades of severity of the same disease.

Form A should be submitted for your medicine as early as possible and before marketing authorisation is received. Information provided will be treated as confidential and will only be available to members of AWTTC and AWMSG.

AWMSG no longer routinely appraises 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. Please see section 5 for more information.

Completing Form A

Form A should be completed in full, with justification if this is not possible. Only sections 1, 2 and 9 need to be completed if the applicant company is of the view that the medicine is likely to be excluded from appraisal. Information should be included in the relevant section of the form where possible and any appendices should be clearly labelled with the corresponding question. The evidence quoted should be referenced throughout the form and a list of all references should be provided, together with electronic copies.

It is vital that any data submitted (including prevalence, incidence and cost) are Wales-specific in order for AWMSG to appropriately appraise medicines for use within NHS Wales. Data from any other UK country, or elsewhere, will not be accepted where Wales-specific data are available. It is important to clearly highlight any data/information that the company consider to be commercial/academic in confidence and, where possible, to provide a date beyond which this data/information will no longer be considered as such.

The following guidance notes are divided into nine sections and should be referred to when completing the corresponding sections of Form A.

1. Product information

1.1 General information

a) The Marketing authorisation (MA) holder should be entered. Please also highlight the company name(s) to be included on all documentation relating to the appraisal and recommendation if this differs from the MA holder.
b) The generic name should be entered under 'Approved name of medicine'.
c) The brand or marketing name should be inserted under 'Trade name'.
d) The formulation(s), strength(s) and route(s) of administration should be entered accordingly.
e) The new licensed indication should be stated in full, in line with the Summary of Product Characteristics (SPC).
f) Please state the indication covered in the submission if it differs from the full indication in Section 1.1e.
g) If the licence has been amended, please provide details accordingly. Changes might include new indication, new target group or a change in the place of therapy.

1.2 Regulatory status

This part of the form should be completed as fully as possible, ensuring that the information provided is specific to the full indication under consideration (e.g. relates to the licence extension). Details will remain confidential until after licence. Launch date will only be used in order to prioritise workload by AWMSG and an estimated time period would be acceptable. Please indicate whether the medicine is likely to be included under the early access to medicines scheme (EAMS).

2. Exclusion criteria

2.1 Overview

Please indicate whether, in your view, one or more of the AWMSG exclusion criteria apply. The AWMSG exclusion criteria to identify medicines outside AWMSG remit for appraisal can be found under 'all appraisal documents' on the AWTTC website. The relevant document is listed under the subheading 'appraisal process information'. Only sections 1, 2 and 9 need be completed if the applicant company are of the view that the medicine is likely to be excluded from appraisal. If the applicant company believes that the product meets these criteria, it is important to clearly explain the reasoning behind this. Please move to Section 3 if, in your view, the exclusion criteria do not apply.

2.2 Exclusion criterion 2: The National Institute for Health and Care Excellence (NICE) intends to publish final guidance (Single Technology Appraisal [STA] / Multiple Technology Appraisal [MTA] / Highly Specialised Technology [HST]) for the same product and indication(s) within 12 months from the date of marketing authorisation

Please complete if, in your view, exclusion criterion 2 applies. It is important to indicate whether the medicine is likely to be referred to NICE, giving as much information as possible regarding the status of any submission and the projected timelines.

2.3 Exclusion criterion 6: Product is a new formulation of an established medicine

Please complete if, in your view, exclusion criterion 6 applies.

2.4 Exclusion criterion 7: Product is a generic, branded generic or hybrid medicine.

Please complete if, in your view, exclusion criterion 7 applies. Submission requirements for hybrid medicines are considered on a case-by-case basis, if required please contact AWTTC for further advice.

3. Cost and patient eligibility

3.1 Patient Access Schemes (PAS); Wales and Department of Health (DOH)

Please provide details of any patient access scheme associated with the medicine. Patient Access Schemes will only be considered following positive advice from the Patient Access Scheme Liaison Unit (PASLU) and approval from the Department of Health (DOH) and incorporation into a positive NICE Final Appraisal Determination (FAD) or Final Evaluation Determination (FED), or following approval of a Wales Patient Access Scheme (WPAS) by Welsh Government.

3.2 Commercial Access Agreement (CAA) and Market Access Agreement (MAA)

Please indicate whether the medicine is associated with a CAA or MAA within NHS England, and, where this is the case, whether a similar arrangement will be offered to NHS Wales.

3.3 Cost

a) The proposed price per patient per year should be calculated based on maximum body weight/body surface area and/or dose, based on list price. This information will remain confidential until after launch.
b) If applicable, state the proposed price based on maximum dose per patient per year/treatment course (excluding VAT), based on WPAS/DOH PAS price.
c) Any additional costs associated with the use of this medicine should be identified and calculated on a ‘per patient per year’ basis.

3.4 Patient eligibility

The company should provide estimates of cost and number of patients eligible in relation to the condition for which this medicine is likely to be prescribed. The figures provided must be as accurate as possible and reference sources must be stated, highlighting paragraphs and page numbers accordingly.

It is vital that companies submit specific Welsh data in order for AWMSG to appropriately appraise medicines for use within NHS Wales. Data from any other UK country, or elsewhere, will not be accepted where Wales-specific data are available.

4. Comparator and place in therapy

a) The applicant company should suggest comparator treatment(s) based on current standard care in NHS Wales, i.e. what is considered to be ‘routine practice’ and may potentially be displaced. Comparators licensed for the indication under consideration should usually be included; however AWMSG will also consider unlicensed comparators where it is deemed appropriate to do so. For some medicines, it may be appropriate to consider more than one comparator (e.g. if practice is varied or if current therapy is unlicensed).
b) The anticipated place this medicine will have in therapy should be outlined accordingly.

5. Licence extensions for paediatric use

AWMSG no longer routinely appraises minor paediatric licence extensions that meet the following criteria:

- The licence extension is for use of the medicine in patients aged under 18 years
- The medicine has been accepted for use in adults (aged 18 years and older) by AWMSG or the National Institute for Health and Care Excellence (NICE); and that advice or guidance must still apply
- The licence extension matches the adult indication that was accepted for use by AWMSG or NICE, except for the target age group of patients

For paediatric licence extensions meeting these criteria, submission of a Form A is **not** required. Health Boards should continue to add these paediatric licence extensions to their formularies.

Not all medicines with a licence extension for use in children will meet the criteria outlined above and, in these cases, a Form A should be completed as a limited or full submission may be required.

AWMSG reserves the right to request a limited or full submission in relation to any medicine at any time during the process. The decision of AWMSG in this respect is final and binding.

Should you have any doubts as to whether the medicine for the indication under consideration meets all three criteria, please contact the AWTTC office for further advice before continuing to complete the form.

6. Limited Submission details

6.1 Overview

Please complete Sections 6.1a to 6.1c. If you have answered yes to any of these questions, then a full submission (Form B) is likely to be required. The final decision as to whether a full submission (Form B) or a limited submission (Form C) is required is that of AWMSG.

The company should indicate whether they consider their submission meets the criteria for a limited submission and, if so, on what grounds.

A limited submission (Form C) may be deemed appropriate by AWMSG in any of the following circumstances (where a product is not a new chemical entity or for a new licensed therapeutic indication [New Target Disease]):

- **A new formulation which has a pro-rata or lower cost per treatment**
  e.g. slow release, new chemical salt of established medicine
- **A licence extension which is deemed minor by AWMSG**
- **If the anticipated usage in NHS Wales is considered by AWMSG to be of minimal budgetary impact**
- **If the estimated difference in cost compared with the appropriate comparator(s) is deemed by AWMSG to be small**

AWMSG reserves the right to request a full submission in relation to any medicine at any time during the process. The decision of AWMSG in this respect is final and binding.

6.2 Limited submission criterion 1: Significant new formulation

Please complete if, in your view, limited submission criterion 1 applies.

6.3 Limited submission criterion 3: Anticipated minimal budgetary impact in NHS Wales

Please complete if, in your view, limited submission criterion 3 applies.

6.4 Limited submission criterion 4: Estimated small difference in cost compared to comparator(s)

Please complete if, in your view, limited submission criterion 4 applies.

7. Medicines developed to treat rare diseases and severe conditions

a) The applicant company should indicate in their submission if they consider the submission is for a medicine for a rare or very rare disease. Applicant companies should refer to the AWMSG appraisal process for a medicine for a rare disease, available under '[all appraisal documents]' on the AWTTC website.

b) When appraising a medicine, AWMSG will consider the severity of the condition being treated. Severity is defined by the future health losses of people living with the condition who are receiving standard NHS care (other current treatments or best supportive care). To assess the severity of a condition, AWMSG will consider both absolute and proportional quality-adjusted life-year (QALY) shortfalls. When making a submission to AWMSG, the applicant company should make it clear that it considers the severity modifier is applicable.

8. Additional information

Please indicate whether you anticipate that this medicine would be supplied by a home healthcare provider. Homecare is a service that delivers ongoing medicine supplies and, where necessary, associated care. It is initiated by a hospital prescriber and the medicine is delivered direct to the patient's home. The purpose of the homecare service is to improve patient care and choice for their clinical treatment.

9. Contact details

The name and position of the person responsible for completing Form A should be entered. The main point of contact should be identified. This need not be the person making the submission. The purpose is to identify a single contact point for enquiries about the submission. It need not be someone who can directly answer enquiries, but the contact person should have sufficient knowledge to be able to relay enquiries to the appropriate person within the company. An additional contact, such as the Medical Director, should also be identified.

PLEASE ENSURE THAT THE SPC (OR DRAFT SPC) IS INCLUDED WITH FORM A WHERE POSSIBLE.

FORM A MUST BE SUBMITTED ELECTRONICALLY TO AWTTC.

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