All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

AWMSG PROCESS FOR INDUSTRY ENGAGEMENT

Background:
The All Wales Medicines Strategy Group (AWMSG) aims to provide advice in relation to all licensed medicines that fall within its appraisal criteria within 6–9 months of the medicine receiving its licence. It is important that the Pharmaceutical Industry is aware of the process and timelines for submission of evidence and the consequence of nonsubmission. In December 2009, Welsh Government announced that funding would be available from April 2010 for AWMSG to broaden its remit to provide advice on ALL new medicines not on the National Institute for Health and Care Excellence (NICE) work programme. To avoid duplication of effort, AWMSG would not normally consider undertaking an appraisal if NICE intend to publish final technology appraisal guidance (STA or MTA) for the same medicine and indication(s) within 12 months of the date of marketing authorisation. AWMSG advice is interim to that of NICE, should NICE subsequently publish guidance as an STA or MTA. This process has been applied to all medicines that receive their licence from 1st October 2010 onwards.

Submitting Form A:
The applicant company is expected to engage with the AWMSG Appraisal Process by completing and submitting Form A. Form A should be completed for all newly licensed products, each new indication and/or formulation and regardless of whether the product fits one or more of the exclusion criteria or if a submission has been forwarded to NICE or the Scottish Medicines Consortium (SMC). It provides the information required by the AWMSG Steering Committee to decide whether the medicine requires appraisal. Form A should be submitted before marketing authorisation is received, and ideally within one month of receipt of positive opinion from the Committee for Medicinal Products for Human Use (CHMP). In the event that the AWMSG criteria for appraisal is met (refer to AWMSG exclusion criteria for more details), Form B will be requested. If a limited submission is appropriate, Form C will be requested. **Early submission of Form A is encouraged**.

The onus for engagement lies with the applicant company. However, the All Wales Therapeutics and Toxicology Centre (AWTTC) 'horizon scanning process' also informs the AWMSG appraisal process. AWTTC identifies medicines expected to receive marketing authorisation within 18 months and may choose to refer the company to the AWMSG appraisal process.

Submitting Form B:
Form B, should be submitted following request and written confirmation (via email or letter) of appraisal scope from AWTTC, as soon as marketing authorisation is granted and, at the very latest, within three months of receipt. On receipt of the Form B submission, AWTTC will confirm in writing (via email or letter) whether the submission is consistent with the scope agreed and clarify the appraisal schedule.

Submitting Form C:
Form C is a limited submission that may be appropriate for significant new formulations, minor licence extensions of existing products, if the anticipated usage in NHS Wales is considered to be of minimal budgetary impact or if the estimated difference in cost compared with the appropriate comparator(s) is small. Form C should be submitted following request and written confirmation (via email or letter) of appraisal scope from AWTTC, as soon as marketing authorisation is granted and, at the very latest, within three months of receipt. On receipt of the Form C submission, AWTTC will confirm in writing (via email or letter) whether the submission is consistent with the scope agreed and clarify the appraisal schedule.

What are the consequences if a full or limited submission for appraisal is requested by AWTTC but not received?
In the event that a company submission is requested and is not forthcoming within the three month deadline, the following two options are available to AWMSG:

a) In the absence of a submission from the holder of the marketing authorisation, AWMSG will issue a statement of advice (posted on the AWMSG website) confirming **the medicine cannot be endorsed for use within NHS Wales** – *a decision made by the AWMSG Steering Committee.* This statement will be ratified by Welsh Government.

b) AWMSG will appraise the medicine using publicly available information – *if directed to do so by the AWMSG Steering Committee.*

The AWMSG Steering Committee takes into account specialist network opinion, demand from within NHS Wales and policy imperatives when making its decision on how best to proceed with regard to nonsubmissions.

The format of the statement of advice is as set out in the attached document template. It should be noted that the statement will be removed on receipt of a submission to AWMSG (i.e. the complete submission [Forms A and B or Forms A and C]) or updated when final NICE technology appraisal guidance becomes available.

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Generic name (Trade name®) Formulation

Name of applicant company

Month Year

Statement of Advice

This product is currently not marketed in the UK.

In the absence of a submission from the holder of the marketing authorisation, generic name (Trade name®) cannot be endorsed for use within NHS Wales for the treatment of full indication.

Advice context:
The All Wales Medicines Strategy Group (AWMSG) takes into account the National Institute for Health and Care Excellence (NICE) future work programme when considering whether a product will be appraised. To avoid duplication of effort, AWMSG would not normally consider undertaking an appraisal if NICE intends to publish final technology appraisal guidance (STA/MTA/HST) for the same product and indication(s) within 12 months of the date of marketing authorisation. AWMSG advice is interim to that of NICE, should NICE subsequently publish guidance.

The above medicine cannot be endorsed for use within NHS Wales as a technology appraisal by NICE or AWMSG has not been undertaken. The medicine should NOT be prescribed routinely within NHS Wales for the indication stated above.

In the absence of guidance issued by NICE or AWMSG, clinicians should continue to exercise their clinical judgement when providing care for an individual patient. This should be in consultation with the patient and/or guardian or carer, based on the best available evidence.

This statement will be removed on receipt of a submission (i.e. the full submission [Forms A and B] or limited submission [Forms A and C]) or updated when final technology appraisal guidance from NICE becomes available.