

## The medicines appraisal process in Wales

### Introduction

As pressures on prescribing budgets grow, the job of ensuring that decisions around the use of medicines are rational, fair, and cost-effective becomes increasingly important. The managed introduction of new medicines in Wales, of which the medicines appraisal process is a part, aims to ensure that valuable NHS resources are used responsibly to benefit patients. This document discusses medicines appraisal in Wales, including the process itself, the role of the All Wales Medicines Strategy Group, and the roles of other groups involved.

### What is medicines appraisal?

Each year, approximately one hundred new medicines, or new formulations of existing medicines, receive a marketing authorisation from the European Medicines Agency. Medicines appraisal is the process by which the NHS decides whether the benefit to patients of a particular medicine justifies any additional cost for its purchase.

### Who is responsible for medicines appraisal in Wales?

In Wales, a new medicine may be appraised by one of the following bodies:

- A The All Wales Medicines Strategy Group (AWMSG).
- B The National Institute for Health and Clinical Excellence (NICE).
- C Locality-based medicines and therapeutics advisory committees.

### What is AWMSG?

AWMSG was established in 2002 to provide advice on prescribing and medicines management to Wales' Minister for Health and Social Services in an effective, efficient, and transparent manner. Members of AWMSG include general practitioners, specialist

### Summary

- ◆ In the past, the AWMSG appraisal process focussed on new high-cost medicines and all new medicines for cancer and cardiovascular disease.
- ◆ In 2010, the appraisal process will be extended to **all new licensed** medicines, with no cost threshold, providing that an assessment is not on the intended work programme for NICE within the succeeding twelve months.
- ◆ AWMSG recommendations on the clinical and cost-effectiveness of new medicines are interim to NICE, should NICE subsequently issue guidance.
- ◆ Health boards are expected to implement NICE guidance and statutory funding directives apply with regards NICE technology appraisals. Since April 2009, health boards have also had a legal requirement to implement AWMSG recommendations within three months.
- ◆ If a licensed medicine is not approved by AWMSG or NICE, a request for funding would normally require individual patient case approval from a health board based on "exceptional" needs. This may also be the case for use of a medicine "off-label". The process for considering such requests is currently under review in Wales.

physicians, pharmacists, nurses, representatives of the pharmaceutical industry, lay representatives, NHS managers, and health economists. Members are appointed by the AWMSG Steering Committee by individual nomination, nomination by colleague or appropriate representative committees or organisations, or as a response to open advertisement. Appointments are approved by the Minister for Health and Social Services or nominated representative.

Three advisory subgroups report to AWMSG and provide expert advice: the New Medicines Group (NMG), the NHS Industry Forum (NHSIF), and the All Wales Prescribing Advisory Group (AWPAG).

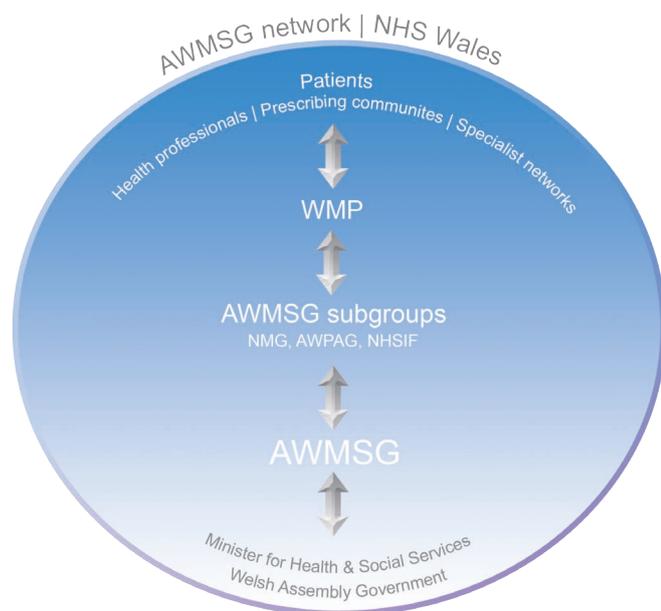
The work of AWMSG is primarily supported by the Welsh Medicines Partnership (WMP), which includes the following four organisations:

- Cardiff University Department of Pharmacology, Therapeutics and Toxicology.
- Welsh Medicines Information Centre.
- Welsh Medicines Resource Centre (WeMeReC).
- Yellow Card Centre (YCC) Wales.

A large proportion of WMP’s work is supporting the activities of AWMSG and its subgroups – informing its work programme and taking forward the Group’s recommendations.

### What is the remit of AWMSG?

Advising on new medicines is just one aspect of the remit of AWMSG; the Group also works to influence medicines management and prescribing, and to advise the Welsh Assembly Government on the medicines strategy for Wales. The formation of AWMSG has allowed the use of medicines for disease management to be guided by a national strategy that reflects the best current evidence and is responsive to the policies and priorities of the Welsh Assembly Government.



### How do AWMSG recommendations relate to NICE guidance?

In establishing its procedures and an appraisal process for new medicines, AWMSG has drawn on the experience of other national bodies such as NICE and the Scottish Medicines Consortium (SMC). The role of AWMSG in advising on new medicines is complementary to that of NICE, and Wales continues to act in accordance with all NICE technology appraisal guidance, clinical guidelines, and guidance on interventional procedures. AWMSG recommendations on the clinical and cost-effectiveness of new medicines are interim to NICE, should NICE subsequently publish guidance.

Health boards are expected to implement NICE guidance and statutory funding directives apply with regards NICE technology appraisals. Since April 2009, health boards have also had a legal requirement to implement recommendations of AWMSG within three months.

### Does AWMSG appraise all new medicines?

Initially, the AWMSG appraisal process focussed on high-cost medicines (i.e. those costing > £2000 per patient per year with associated costs of administration). From April 2007, the process has also included new medicines for cancer and cardiovascular disease, with no cost threshold. However, in 2010, AWMSG will appraise **all new licensed** medicines, with no cost threshold, providing that it is not on the intended work programme for NICE within the succeeding twelve months (see the later section on *Horizon scanning and programme planning*). The decision as to whether a change in indication or formulation is “significant” and hence requires appraisal is made by the AWMSG Steering Committee on a case-by-case basis.

Ultra-orphan drugs (i.e. those that are licensed for the treatment of disease states with a UK prevalence of less than 1 in 50 000) are also considered for appraisal on a case-by-case basis. AWMSG does not appraise medicines that do not have a UK product licence nor does it consider “off-label” uses of licensed medicines. *See figure in Appendix 1.*

## What is the AWMSG process for medicines appraisal?

AWMSG is the first public body in the UK to develop an “open” therapeutic appraisal process, having met in public since 2002. The pharmaceutical industry (via membership of the Association of the British Pharmaceutical Industry [ABPI] Cymru Wales Therapeutic Development Appraisal [TDA] User Group) regularly meets with representatives from WMP. These meetings provide two-way communication to inform process improvement and methodology relating to the appraisal of new therapeutic technologies in Wales. AWMSG also engages with clinical experts, economists, financial and clinical service providers, patient interest groups, and lay representatives in a transparent manner – its meetings are open to the public and the minutes are made publicly available.

### 1. Horizon scanning and programme planning

AWMSG monitors reported research and development, on an ongoing basis, for new medicines that are suitable for appraisal. A product will not normally be considered for appraisal if NICE intends to publish final guidance within twelve months of the projected submission to AWMSG. Pharmaceutical companies are expected to make an initial submission to AWMSG before the marketing authorisation for their product has been received. This initial submission provides the information required by the AWMSG Steering Committee to decide whether the medicine requires full appraisal. Welsh clinical networks and commissioners provide input to the AWMSG Steering Committee, to help to prioritise new medicine submissions suitable for appraisal. This is a continuing process which is constantly under review to ensure the appraisal programme is responsive to service need of clinicians and patients in Wales. AWMSG provides medicines and therapeutics advisory committees with a confidential report detailing the products that are expected to be appraised during the following year.

### 2. Assessment Report

For appraisal of a new medicine, the pharmaceutical company is expected to submit a case based on clinical effectiveness data and estimates of cost-effectiveness. It is the responsibility of the company to ensure that the full submission is made within three months of receipt of the marketing authorisation, to ensure its timely consideration. A team from WMP then collates all the key evidence and evaluates the clinical and economic information submitted by the

pharmaceutical company. AWMSG seeks up to six medical expert nominations via the appropriate Welsh specialist clinical group or clinical network. Medical experts are invited to explain the clinical context and outline where, in their view, the new medicine sits within current therapy.

### 3. Appraisal by NMG

NMG is a subgroup of AWMSG. This group meets every two months to consider the clinical and cost-effectiveness of new medicine submissions, along with written evidence from pharmaceutical companies, medical experts, and patient interest groups. NMG provides an appraisal report and a preliminary recommendation to AWMSG regarding a new medicine submission. The pharmaceutical company is sent this report and the initial recommendation from NMG and is invited to respond in writing.

### 4. AWMSG Appraisal

Final recommendations regarding new medicines are agreed at AWMSG meetings. AWMSG considers NMG recommendations, pharmaceutical company responses, medical expert opinions, and patients' perspectives. Presently, meetings take place six times a year, at regular intervals, and are open to the public. The minutes of each meeting are made available on the AWMSG website. Manufacturers have five to ten working days within which to accept or reject an AWMSG recommendation before it is forwarded to the Minister for Health and Social Services for ratification. There is an established independent review process to address any complaints from a pharmaceutical company regarding an AWMSG decision.

### 5. Ministerial Approval

For a new medicine to be recommended within NHS Wales, The Minister for Health and Social Services must agree with and ratify the AWMSG decision.

## How are AWMSG decisions communicated?

Once a decision has received ministerial approval, it is communicated to key audiences. WMP informs the companies of the ministerial ratification. A notice is posted on the AWMSG website and disseminated via email to a broad circulation. It may also be published in the *Chief Medical Officer's Update*. This process of communication is currently being reviewed as it has been recognised that it could be improved.

## What are the implications of a positive endorsement of a treatment?

If the Minister endorses the positive AWMSG recommendation, then treatment and funding should follow at a local level across Wales. Since April 2009, health boards have had a legal requirement to implement recommendations of AWMSG within three months.

## What happens if a treatment does not receive a positive endorsement?

A medicine may not have a positive endorsement for use in NHS Wales for four main reasons:

- A** It has not yet been appraised by AWMSG (due to non-engagement by the pharmaceutical company) or by NICE.
- B** It has been appraised by AWMSG and not recommended for use in NHS Wales.
- C** It has been appraised by NICE and not recommended for use in the NHS.
- D** It does not have a marketing authorisation in Europe for the purpose for which it has been requested.

If a licensed medicine is not approved by AWMSG or NICE, a request for funding would normally require individual patient case approval from a health board based on “exceptional” needs. This may also be the case for use of a medicine “off-label”. The process for considering such requests is currently under review in Wales.

## Can patients get involved in the appraisal process?

Yes, the input of patients is encouraged. WMP undertakes a search to identify relevant patient organisations; companies are also asked to list relevant patient organisations on their submission forms. The appraisal committee is informed of the “patient perspective” of a therapy area and current therapy options; patients and carers of patients who have the same health problems or illnesses and have experience of the use of currently available medicines input their comments, either directly to WMP (see contact details below), or via the patient organisations.

## Conclusion

The AWMSG appraisal process is robust, transparent, and timely allowing NHS Wales access to authoritative advice in relation to the availability of new medicines. The whole AWMSG appraisal process takes around six months and can be timed so that the medicine can be endorsed for NHS Wales as soon as possible after the product is licensed within the UK. In some cases this will be ahead, or in advance, of NICE guidance – a time in which patients can benefit if an effective and appropriate medicine can be made available, or in which monies that would be spent inappropriately or inefficiently could be saved.

## How do I find out more about AWMSG and the medicines appraisal process in Wales?

For more information please contact the Welsh Medicines Partnership’s Liaison Manager.

Tel: (029) 2071 6903

E-mail: [wmp@wales.nhs.uk](mailto:wmp@wales.nhs.uk)

## Information Sources

At <http://www.wales.nhs.uk/sites3/home.cfm?OrgID=371>

All Wales Medicines Strategy Group. All Wales Medicines Strategy Group 2002-2008. Getting the best outcomes from medicines in Wales.

All Wales Medicines Strategy Group. 3<sup>rd</sup> Report April 2008.

All Wales Medicines Strategy Group. AWMSG policy on ultra-orphan drugs.

All Wales Medicines Strategy Group. Towards improving the availability of medicines for patients in Wales. Expert Group Review. January 2009.

All Wales Medicines Strategy Group. Industry engagement in the AWMSG appraisal process. February 2010.

At <http://www.dtb.bmj.com/content/47/4>

Anon. The licensing of medicines in the UK. Drug and Therapeutics Bulletin; 47(4): 45-48.

Appendix 1. Pathway for the appraisal of a new medicine in Wales

