

All Wales Medicines Strategy Group

Ten Year Report
2002 to 2012

*"Getting the best outcomes
from medicines for Wales"*

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Foreword

Ten years after the formation of the All Wales Medicines Strategy Group (AWMSG) we review the progress to date, highlighting some of the achievements and outlining AWMSG's strategic vision for the future.

This short report provides the background to the formation of AWMSG, highlighting measures taken to encourage safe and effective prescribing in Wales, and outlining the effects of those measures. Working in partnership with colleagues from within NHS Wales and the pharmaceutical industry, AWMSG has worked to provide Welsh Government with advice relating to medicines management and prescribing, particularly with regard to accessing new medicines. We look forward to continuing close links with our partners to ensure the best outcomes from medicines for the people of Wales.



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Background

The All Wales Medicines Strategy Group (AWMSG) was established in 2002, as a statutory advisory Welsh Assembly-sponsored public body under the 1977 NHS Act, to provide advice on medicines management and prescribing to the Welsh Government's Minister for Health and Social Services in an effective, efficient, and transparent manner. AWMSG, acting in a strategic and advisory capacity, is an authoritative and expert channel through which consensus can be reached on the use of new medicines and on policies that promote the best use of medicines in both primary and secondary care.

Strategic aims and objectives

In January 2008, AWMSG published "A Medicines Strategy for Wales: Getting the best outcomes from medicines for Wales". This document supports the Designed for Life health and social care strategy for Wales. It sets out the following objectives for the medicines sector:

Quality, safety, and effectiveness

- ▶ Medicines used in Wales are acceptably safe, are clinically effective, and cost effective.
- ▶ Systems are in place to support evidence-based prescribing

Access and timeliness

- ▶ The people of Wales have access to clinically effective and cost-effective medicines at the time they need them

Optimal use (patient focus and efficiency)

- ▶ Medicines are used in Wales in a way that will lead to good health outcomes
- ▶ Wastage of medicines is minimised
- ▶ NHS Wales adopts an integrated, whole systems approach to medicines across all health and social care sectors, designed to meet the needs of patients

The following principles guide delivery of these objectives:

Excellent systems

- ▶ The systems that support the use of medicines are people-centered, reflect best practice, are appropriately funded, and ensure safety and efficacy
- ▶ Prescribing and medicines management is integrated seamlessly across all agencies and healthcare sectors

Equity

- ▶ Medicines and other resources are allocated in a manner that reduces inequity of outcome between population groups

Effectiveness

- ▶ The systems for provision of medicines, including the roles and functions of the individuals and organisations involved, are effective in contributing to the objectives of the strategy

Trust and confidence

- ▶ The systems ensure the provision of medicines is timely, robust, and transparent
- ▶ Stakeholders (including the public and consumers) understand and have the opportunity to participate in the decision-making processes used for appraising new medicines

Value for money

- ▶ The systems in the medicines sector operate efficiently, minimise medicines waste, and maximise health outcomes from medicines, given the context of a constrained budget

Affordability

- ▶ The medicines used within NHS Wales and the structures and processes that support their use are appropriately funded and affordable for individuals and the community

Updating the AWMSG Medicines Strategy

The AWMSG Medicines Strategy for Wales set out 48 recommendations relating to medicines use, which are regularly reviewed and prioritised by AWMSG to inform the strategic planning and work programme of the Group.

The Welsh Government has outlined the challenges NHS Wales faces over the next five years in their document "Together for Health" and advised solutions to "develop services to world-class quality on a solid and sustainable long-term basis". Building on 10 years' experience of medicines appraisals and delivering prescribing advice, the All Wales Medicines Strategy Group is now in an ideal position to provide prescribing advice for an integrated NHS to achieve these common goals. A new strategy is being developed and this will outline the strategic direction the AWMSG proposes to take to work in partnership with NHS bodies for the benefit of patients in Wales.

The AWMSG network

AWMSG brings together relevant healthcare consultants and key organisations to form expert panels when considering issues relating to medicines management. Members of AWMSG include specialist physicians, pharmacists, pharmaceutical industry representatives, patient representatives, NHS managers, and academics.

AWMSG is subject to public scrutiny and holds approximately ten meetings a year which members of the public may attend to observe. The process is transparent and papers are posted on the AWMSG website in advance of each meeting:
<http://www.wales.nhs.uk/awmsg>

AWMSG works to develop innovative partnerships that benefit patients and achieve the best outcomes from the use of medicines in Wales.

The AWMSG Secretariat All Wales Therapeutics & Toxicology Centre (AWTTC)

AWMSG's activities are supported by a professional organisation (AWTTC), made up of doctors, pharmacists, life scientists and administrative staff. They also support AWMSG sub-groups informing their work programme and taking forward the recommendations. AWTTC draws on the skills of senior healthcare professionals in NHS Wales, academics, and those of partner organisations across Wales and the UK. Its work consists of the following:

Health Technology Appraisals (HTA)

AWTTC developed and supports the AWMSG health technology appraisal process. In 2011 this process was awarded NHS Evidence Accreditation.

Medicines Management and prescribing

AWTTC provides the professional and administrative support to the All Wales Medicines Strategy Group (AWMSG) and supports the development of its work programme in relation to medicines management and prescribing.

Medicines Safety

The Yellow Card Centre Wales (YCC Wales) is an integral part of AWTTC. The rate of reporting for adverse drug reactions within Wales is currently the highest in the UK.

Education

AWTTC provides educational resources for all prescribers in Wales, including interactive distance-learning modules and training courses for all prescribers (medical and non-medical).

Toxicology

The National Poisons Information Service, a service commissioned by the Health Protection Agency, represents the Toxicology section and supports the 24 hour emergency rota of the UK National Poisons Information Service.

Prescribing Analysis

AWTTC provides analytical and prescribing information to NHS Wales.

Networking

Links with other national organisations include: professional bodies, prescribing committees and Medicine and Therapeutics Committees (MTCs), UK Medicines Information (UKMi), the National Patient Safety Agency (NPSA), the National Institute for Health and Clinical Excellence (NICE), the Scottish Medicines Consortium (SMC), the National Prescribing Centre (NPC) and education and training providers.

AWTTC represents AWMSG on the Oversight and Governance Committee of UK PharmaScan the centralised horizon scanning database that is used to aid planning the introduction of new medicines into the NHS.

AWTTC has also fostered links, on behalf of AWMSG, with the other Health Technology Assessment (HTA) bodies in the UK, namely NICE, the SMC and the HTA body in Northern Ireland. Within Wales, AWTTC works with representatives from ABPI Cymru Wales on the AWMSG appraisal process via the Therapeutic Development Assessment (TDA) Partnership Group.

The AWMSG network *continued*

Members of AWTTTC and the AWMSG network have also represented Wales at NICE and have had input to the innovation pass for novel and ultra-orphan drugs (currently suspended) and patient access schemes via representation on the Patient Access Scheme Liaison Unit Expert Panel.

Engaging with NHS service providers in Wales is crucial to the work of AWMSG and AWTTTC members attend meetings of MTCs when invited, and of the cancer and the cardiovascular clinical networks. Links with the All Wales Renal Managed Network are also in place.

Close working links exist with the National Medicines Management Programme Board (NMMPB) and the All Wales Chief Pharmacists Committee to ensure initiatives within Wales are aligned to support AWMSG strategy efficiently. This partnership approach is continually developing and AWMSG is always looking for further input from interested parties.

AWMSG Sub-groups

Two advisory sub-groups report to AWMSG and provide expert advice:

The New Medicines Group (NMG)

NMG makes preliminary recommendations to AWMSG regarding the introduction of new medicines in NHS Wales. NMG meets regularly in private to consider the clinical effectiveness and cost effectiveness of new medicines. The group reviews independent information prepared by AWTTTC along with written evidence from pharmaceutical companies, clinical experts, and patient organisations. This skilled group consists of experienced doctors, pharmacists, nurses, and health economists, as well as a patient representative.

The All Wales Prescribing Advisory Group (AWPAG)

AWPAG advises AWMSG on clinical developments relating to medicines use in Wales. AWPAG meets quarterly to assess the impact of developments in new medicines and prescribing strategy on clinical

services, to support the AWMSG network in monitoring prescribing patterns, to identify and share examples of "best practice", and to advise on training programs for prescribers. Members, whose roles relate to prescribing, are drawn from the various regions across Wales. Representation from the NHS Industry Forum, an AWMSG sub-group formed in 2003, was formally incorporated into the membership of AWPAG in 2010.

AWMSG Steering Committee

The work of AWMSG is planned via the AWMSG Steering Committee. This committee prioritises the work programme of the parent committee to ensure the efficient use of AWMSG resources. With the remit of AWMSG expanding to encompass the appraisal of all new medicines, this committee has an increasingly important function.

The membership of the Steering Committee reflects the working partnerships that exist between various stakeholders in Wales. It includes:

- ▶ The Chair of AWMSG
- ▶ Chairs of the subgroups - NMG and AWPAG
- ▶ Representatives from AWTTTC
- ▶ Representatives from the Welsh Government
- ▶ Director of the Association of British Pharmaceutical Industry (ABPI) Wales
- ▶ Representative of the Welsh Health Specialist Services Committee
- ▶ Chairman of the All Wales Drugs Contracting Committee
- ▶ Director, National Medicines Management Programme Board
- ▶ Representation from the clinical / specialist networks
- ▶ Representative from the All Wales Chief Pharmacist Committee

The work programme

The various streams of AWMSG activity involve the delivery of both operational and strategic aims.

Advising on new medicines

The AWMSG report "Towards improving the availability of medicines for patients in Wales" provided to the Minister for Health and Social Services in January 2009, recommended broadening the appraisal process in Wales to include all new medicines. Funding was made available for the expansion, and a comprehensive appraisal programme was implemented in October 2010.

The standards achieved by AWMSG and the other national bodies have been acknowledged in the report by the Office of Fair Trading (OFT) on the Pharmaceutical Price Regulation Scheme (PPRS) (2007).

Discussing the role of NICE, SMC, and AWMSG it states that *"the technical expertise that these bodies bring to bear in conducting cost-effectiveness assessments is of world class standard."* It also states that they have made a significant contribution to the cost-effective use of NHS resources and have *"shown themselves able to adapt to changing needs"*.

In October 2011 the high standard of the AWMSG appraisal process was further acknowledged and received accreditation from NICE's Accreditation Programme, NHS Evidence. This allows AWMSG to carry the NHS Evidence Accreditation Mark on any new final appraisal recommendations produced under the accredited process, assuring health and social care professionals that they are accessing some of the best information available to make informed decisions about patient care.

A number of developments are enabling the expanded remit of AWMSG to be managed efficiently.

Following work done by the Horizon Scanning Project Board, *UK PharmaScan* was made available in summer 2010. This is a secure, centralised, horizon-scanning database, hosted by NICE. It provides up to date information, such as clinical trial and regulatory information, on medicines in development. Access to this database supports the role of AWMSG in planning the introduction of new medicines and providing advice and guidance to the NHS. An AWMSG representative attends the *UK PharmaScan* Oversight and Governance Committee.

A "limited submission" process has been developed (via the TDA Partnership Group) to operate alongside the full appraisal process for new medicines in Wales. This process has been applied to new medicines that involve either a new formulation (at a comparable or lower cost), a minor extension to the licence of an existing medicine, or those medicines predicted to have a minimal budgetary impact. One further criterion for inclusion in the limited submission process is a small cost difference compared with appropriate treatment comparator(s).

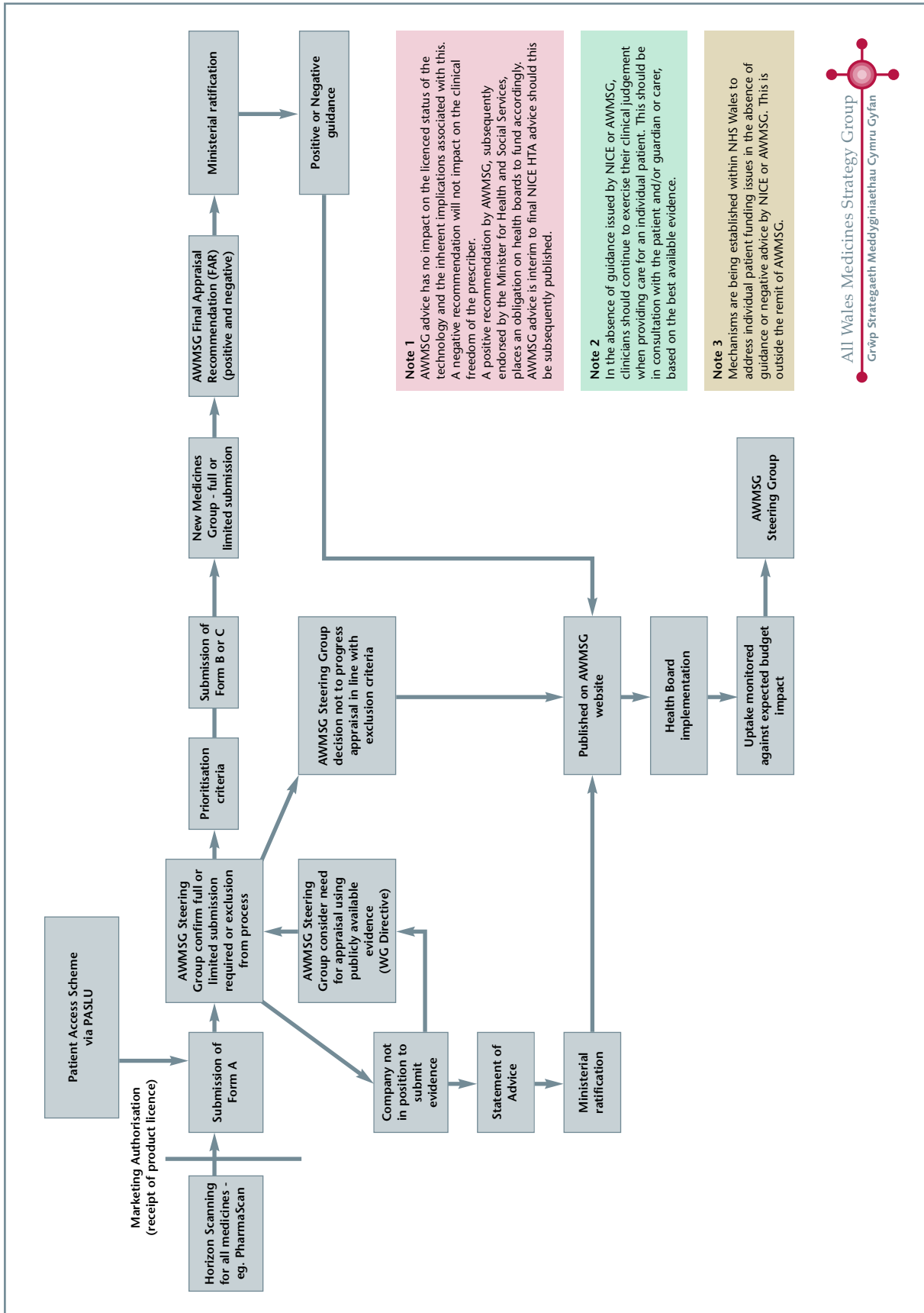
AWMSG has collated and updated its Guidelines for Appraising Medicines. These guidelines discuss explicitly the points considered when appraising a medicine by AWMSG. They also incorporate supplementary advice for appraising life-extending end-of-life medicines, and revised criteria for ultra-orphan medicines.

Appraisals undertaken by AWMSG 2002 - 2012

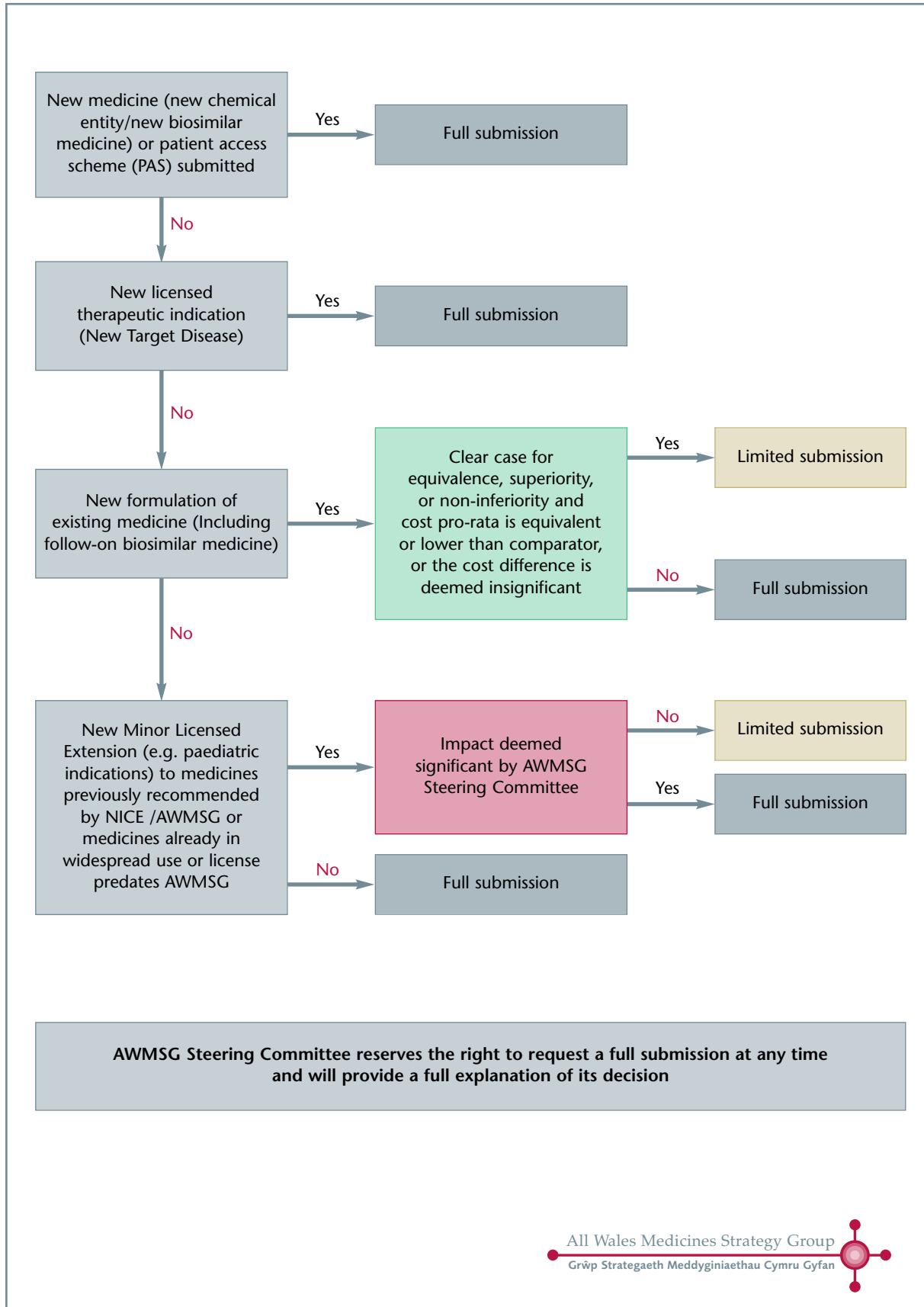
- ▶ **127 appraisals of medicines**
- ▶ **93 recommended (in whole or in part)** (73%)
- ▶ **34 negative recommendations** (27%)

The AWMMSG network *continued*

A flow chart outlining the appraisal principles and process

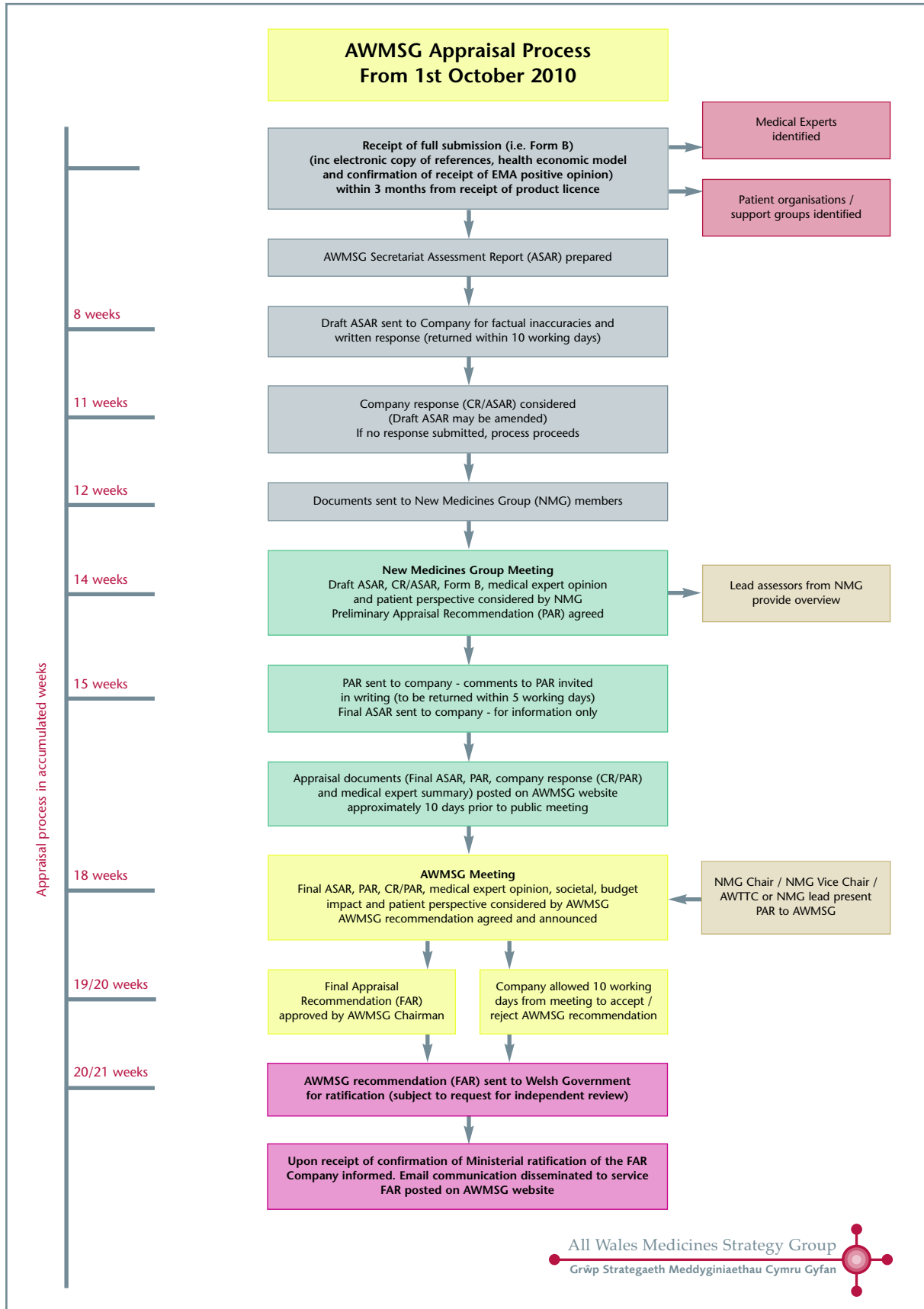


Decision process for full & limited submissions



The AWMSG network *continued*

Appraisal Process flow diagram



AWMSG's Relationship with the National Institute for Health and Clinical Excellence (NICE)

Both NICE and AWMSG recognise that by working together they can enhance and develop timely, independent and authoritative advice on new medicines and/or new licensed indications or formulations for existing medicines, and on the cost implications of making them routinely available on the NHS. A Memorandum of Understanding is currently being developed, the purpose of this is to formally set out a collaboration between NICE and AWMSG. The aim is to join up the strategic planning, development and delivery of advice in England and Wales, avoiding duplication or conflict of work, yet complementing and supporting the work of NICE and AWMSG.

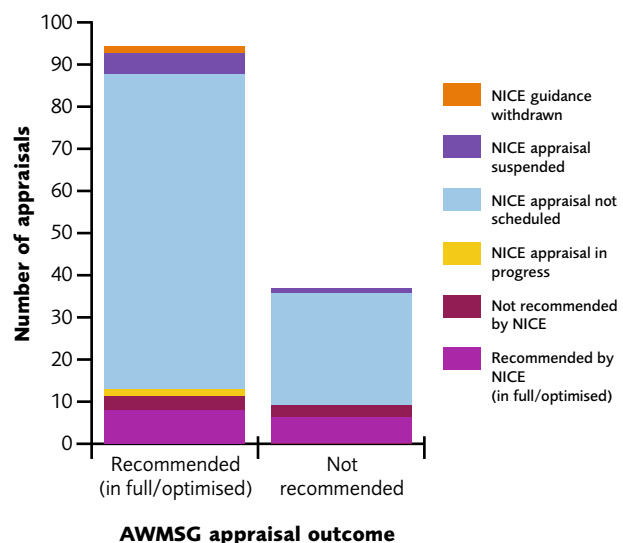
Developments regarding value-based pricing being undertaken by the Department of Health are being followed closely. AWMSG looks forward to actively participating in this development. AWMSG continues to work with NICE on initiatives, such as patient access schemes, that may impact medicines' use.

On 29th November 2011, the Minister for Health and Social Services agreed the establishment of Patient Access Scheme Wales (PASW). The scheme will operate under the auspices of the Patient Access Scheme Wales Group (PASWG) who will advise Welsh Government on the appropriateness of patient access schemes submitted by manufacturers. Welsh Government will then inform the All Wales Medicines Strategy Group (AWMSG) whether the patient access scheme has been approved and can be taken into account during the appraisal of the medicine. The process for submitting a scheme has been aligned to that of the Patient Access Scheme Liaison Unit (PASLU). Representatives of PASLU provided advice and support in this development. A pilot is currently underway, the aim of the scheme being to facilitate patient access in NHS Wales to new medicines that would otherwise not be deemed cost effective.

Appraisal of new medicines 2002–2012

Medicine appraisals conducted by the All Wales Medicines Strategy Group (AWMSG) between 2002 and 2012 were reviewed. Recommendations made by AWMSG were compared with those of NICE and SMC. AWMSG conducted 127 single technology appraisals of medicines during the study period. Of these, 93 medicines were supported (26 with restrictions for optimised use under specific conditions) and 34 were not supported. Recommendations broadly concurred with SMC and NICE for the majority of appraisals. Compared to NICE, the median time advantage gained in Wales for those medicines which were appraised by AWMSG and were subsequently superseded by NICE advice was 575.5 days (approximately 19 months; n = 23; range: 202–1616 days).

AWMSG Appraisals in relation to NICE advice



Where a medicine is not endorsed for use in NHS Wales (because appraisal by AWMSG or NICE has not progressed), Statements of Advice are issued; 31 such statements were issued from April 2011 – March 2012. These medicines should not be prescribed routinely within NHS Wales for the indication stated in the advice notice. Further information on AWMSG's recommendations is available on the AWMSG website. Information produced specifically for patient organisations, pharmaceutical companies and medical experts regarding the appraisal process is also available on the AWMSG website. In addition, there is a "Frequently Asked Questions" resource.

Influencing prescribing and medicines management

The AWMSG network encompasses partnerships with numerous specialist groups. Working either independently or collaboratively, AWMSG has undertaken a number of activities, some of which are ongoing. It has:

- ▶ advised on national prescribing indicators as part of the Clinical Effectiveness Prescribing Programme (CEPP) (see Table 1).
- ▶ Provided advice on the use of local prescribing indicators (i.e. local 'comparators') in Wales.
- ▶ Advised on the detail of the National Medicines Management Programme Board's 14 key focus areas for health boards. These are based on AWMSG's strategic recommendations and the CEPP (see above).
- ▶ Conducted a national clinical consultation on recommendations for prescribing low molecular weight heparins (LMWHs). Specific good practice points were highlighted in support of the recommendations.
- ▶ Developed an educational module on LMWHs for health professionals in NHS Wales.
- ▶ Issued guidance on prescribing amiodarone for patients taking the medicine historically. This has supported establishing a management plan for all current patients.
- ▶ Issued guidance for primary care on prescribing medicines for adult patients who are unable to swallow solid oral dosage forms.
- ▶ Developed a proposal to support local commissioning arrangements for near patient testing (i.e. local enhanced service shared-care prescribing arrangements for medicines not covered by the GMS National Enhanced Service).
- ▶ Initiated work on promoting the safe use of Monitored Dosage Systems following hospital discharge. AWPAG established a working group to assess process issues and identified examples of good practice. Further data collection is currently being undertaken.
- ▶ Developed a guide for prescribers on non-NHS prescribing, covering many prescribing dilemmas.
- ▶ Endorsed the work of the All Wales Drug Chart subgroup in updating the All Wales In-patient Medication Administration Charts, the Prescription Writing Standards, and provision of educational material (specifically, an e-learning package). AWMSG supported the inclusion of the e-learning package in undergraduate training and hospital induction programmes.
- ▶ Liaised with the All Wales Chief Pharmacists Committee and the Interface Pharmacists Group to address prescribing problems, particularly around shared care.
- ▶ Highlighted a campaign to reduce wasted medicines that was launched by the Welsh Government in September 2010.
- ▶ Participated in updating the National Service Framework (NSF) for elderly patients (Medicines and Older People).
- ▶ Supported the 1000 Lives Plus programme.
- ▶ Endorsed the modernisation and introduction of clinically designed information systems to be consistently applied across Wales. Supported the work of Informing Healthcare, now the NHS Wales Informatics Service (NWIS).
- ▶ Collaborated with the Welsh Antimicrobial Resistance Group.
- ▶ Sought engagement with the Vascular Project Group, and the Wales Advisory Group for Diabetes.

► In 2009, AWTTTC bid for resources from the Welsh Government's Invest-to-Save Fund to develop four projects. Their aims were:

1. Encouraging the safe and effective prescribing of hypnotics and anxiolytics.

- A report on the nature and scope of the benzodiazepine and "z" drug prescribing was produced and was submitted to the Welsh Government in October 2010.
- An educational resource was produced to help manage safe withdrawal of benzodiazepines.

2. Encouraging the safe and effective prescribing of NSAIDs.

- AWTTTC / AWMSG promoted the continued uptake of the national audit on NSAIDs (developed with the Primary Care Quality and Information Service (PCQIS) as part of the CEPP)
- Data was analysed to inform an educational initiative on NSAIDs.

3. Encouraging the safe and effective prescribing of PPIs

- An audit pack was developed to review prescribing of the high acquisition cost PPIs and analyse data to inform a targeted educational initiative to improve PPI prescribing.

4. Initiating a system to monitor the managed introduction of medicines appraised by AWMSG

- An audit of medicines not recommended by AWMSG was undertaken and reported.
- An audit of the uptake of medicines recommended by AWMSG was undertaken and reported.

The first three "Invest to Save" prescribing initiatives were associated with more than £2million savings across Wales in 2010-11 and a further £3 million saving is projected for 2011-12. In 2011 funding was made available by Welsh Government for the establishment of the Welsh Analytical Prescribing Support Unit (WAPSU) within AWTTTC. A two year strategic plan is being developed to deliver on medicines management projects which are considered vital to NHS Wales.

AWMSG continues to support, with the Prescribing Support Unit (NHS Wales Shared Services Partnership, Prescribing Services), the development of the Medusa database in line with the Comparative Analysis System for Prescribing Audit.

Influencing prescribing and medicines management *continued*

Table 1 Prescribing indicators from 2002 to 2011

Prescribing Indicators	2002/3	2003/4	2004/5	2005/6	2006/7	2007/8	2008/9	2009/10	2010/11
Generic medicines (% of items)	74	77	79	81	83	84	85	84	84
"Inappropriate generic" medicines (% of items) [Drug basket 08/09]	15	11	10	7	4	2	2	2	2
Low cost statins (% of statins: excludes simvastatin and ezetimibe combination products)	60	57	57	59	65	69	71	72	72
Antibiotics (items/1000 PUs#)	150	146	156	155	163	148	146	146	160
Top 9 antibiotics (% of antibiotic items)	76	76	78	78	78	77	76	76	78
Quinolones (items/1000 PUs)	5	5	5	5	5	5	4	4	4
Trimethoprim 200mg 3 day courses (% of trimethoprim items)	13	14	15	20	23	26	27	28	45
Hypnotics & anxiolytics (DDD\$/1000 patients)	3178	3095	2917	2801	2639	2479	2288	2181	2075
Zolpidem, zopiclone, zaleplon (DDD/1000 patients)	816	834	803	785	747	712	661	649	640
NSAIDs (DDD/1000 PUs)	2896	2933	2889	2800	2592	2565	2456	2380	2389
Ibuprofen & naproxen (items % of NSAIDs)	27	25	29	31	32	36	41	48	56
ACE inhibitors (% of renin angiotensin system agents)	81	79	78	77	76	76	76	75	75
Chiral drugs (% of chiral & parent (racemic) medicine)	15	19	19	17	14	10	7	6	5
Chiral drugs (items/1000 PUs)	7	9	9	10	10	8	7	7	6

Figures are taken from the quarter ending March in each financial year.

Shading indicates the indicators that were included in the incentive scheme for the relevant year.

PU = prescribing unit § DDD = defined daily dose

Looking forward

*There are no doubt challenging times ahead, but **AWMSG** continues to build relationships and work in partnership with colleagues in NHS Wales, the pharmaceutical industry and other UK health technology appraisal bodies for the benefit of patients in Wales.*

***AWMSG** recognises the contribution of its members, past and present, patient organisations and clinicians, and members of sub-groups who have all contributed to the work programme.*