

Towards improving the  
availability of medicines for  
patients in Wales

Expert Group Review

January 2009

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# Executive Summary

## In relation to medicines which have not been approved for use in NHS Wales

Medicines can contribute enormously to the effective treatment of patients with a wide range of illnesses. While most of the one hundred or more new medicines that are marketed each year are available to all NHS patients, some are not. Medicines appraisal is the process by which the NHS decides whether the benefit of a medicine to patients justifies any additional cost for its purchase. This process is conducted in public by the All Wales Medicines Strategy Group (AWMSG) for high cost medicines, cancer medicines, or cardiovascular medicines. Appraisals are also conducted by the National Institute for Health and Clinical Excellence (NICE) on a selected range of medicines for England and Wales. AWMSG coordinates its work with NICE, to avoid unnecessary duplication. Other medicines are considered by locality-based Medicines and Therapeutics Advisory Committees in Wales.

Medicines may not be approved for use in NHS Wales for four main reasons:

- A** they have not yet been appraised either by AWMSG or by NICE.
- B** they have been appraised by AWMSG and not recommended for use in NHS Wales.
- C** they have been appraised by NICE and not recommended for use in the NHS.
- D** they have not received a marketing authorisation in Europe for the purpose for which they are being requested.

To address the first situation (circumstance A), it is essential that the appraisal process used is timely and consistent between appraisal bodies, responsive and open to scrutiny. For these reasons, we propose the following:

**Recommendation 1. AWMSG should complete the appraisal of any medicines not on the NICE programme within six months of receipt of a company submission following marketing authorisation.**

**Action: AWMSG lead with the New Medicines Group (NMG), and the Welsh Medicines Partnership (WMP).**

**Recommendation 2. AWMSG should adopt the supplementary advice relating to appraising life-extending, end of life treatments published by NICE in January 2009.**

**Action: AWMSG lead with the NMG, and WMP.**

Having been appraised by AWMSG or NICE, a small number of medicines are not recommended for general use in the NHS in Wales (circumstance B and C above). In addition, some medicines are used “off-label” (circumstance D above). In all these three situations, funding may sometimes be made available for individual patients as form of exceptional (or exceptionality) funding. However there is evidence of variation in the way the exceptional funding process is conducted across Wales. An all-Wales approach would ensure equity of access for such medicines.

**Recommendation 3. To ensure the robust, consistent, transparent, inclusive, and timely consideration of requests for exceptional funding of medicines, a national guideline for the structures needed and the process employed in Wales should be developed within six months. Data should be collected on the decisions made to inform future policy decisions.**

**Action: AWMSG lead with WMP, the National Public Health Service (NPHS) in Wales, and NHS finance directors.**

Off-label uses fall outside the remit of medicines appraisal bodies like AWMSG and NICE since they are outside the normal marketing authorisation of a medicine. Such uses may however be part of a request for exceptional funding as described above (circumstance C). There may be important issues concerning the relative benefits and risks of a particular treatment. Therefore off-label use must be informed and guided by an authoritative body of

professional opinion, so that the prescriber is able to justify such use to his/her peers.

**Recommendation 4. An audit of the use of off-label cancer medicines should be conducted in Wales including the methods used to provide information to patients in these circumstances.**

**Action: Cancer Services Co-ordinating Group (CSCG) lead with regional cancer networks, and AWMSG.**

If NHS funding is not granted for use of a medicine, and the clinician wishes to prescribe an unfunded medicine, a patient may decide to purchase the treatment themselves. This has been referred to as “co-payment” (or sometimes “top-ups”, “user charges” or “patient contributions”). The issue of co-payments has been comprehensively addressed in England in the recent report *“Improving access to medicines for NHS patients: a report for the Secretary of State for Health by Professor Mike Richards”*. It concludes that speedy appraisal allied to greater flexibility in considering the cost-effectiveness of medicines for rarer cancers when used as life-extending treatments towards the end of life will minimise the number of patients needing to purchase additional medicines. However, if patients do opt to purchase additional medicines, the Richards report recommends that a patient should not lose entitlement to NHS care that they would otherwise have received.

**Recommendation 5. All recommendations of the recent Richards report, *“Improving access to medicines for NHS patients,”* regarding co-payments should be considered in progressing this issue in Wales.**

**Action: Welsh Assembly Government.**

## **In relation to the prescribing of “heroic treatments” in the last months of life**

A distinction must be drawn between “heroic treatments”, which may prolong suffering, and the justifiable active treatment of the disease process using systemic anti-cancer therapies, which may sometimes improve the quality of life. The recent report, “*National Confidential Enquiry into Patient Outcome and Death*” (NCEPOD 2008), examined practice in hospitals in England, Wales, and Northern Ireland, and made recommendations in key areas where important decisions about the care of patients must be made. With regard to end-of-life care, the NCEPOD report recommended that a pro-active rather than reactive approach should be adopted to ensure that palliative care treatments or referrals are initiated early and appropriately. It also highlighted the need for oncologists to enquire at an appropriate time, about any advance decisions a patient may wish to make should they lose the capacity to make their own decisions in the future.

**Recommendation 6. The implications for practice in Wales of the recommendations of the NCEPOD report, which are now being considered by the regional cancer networks, should be reported to the CSCG within the next 12 months. This will inform the work needed to further improve the care of patients towards the end of life.**

**Action: regional cancer networks lead with CSCG, palliative care services, and AWMSG.**

Information on the possible benefits and risks of cancer treatments towards the end of life needs to be shared sensitively with patients. Doctors and other health professionals may not always have had sufficient training in communication of these issues, and written information to support these discussions may not always be available.

**Recommendation 7.** The additional training needs of health professionals to help them effectively communicate with patients about difficult decisions around risks/burdens and benefits of different proposed treatments should be assessed, and an appropriate programme related to end-of-life care should be developed.

**Action:** CSCG lead with regional cancer networks, All Wales Cancer Drugs Group (AWCDG), palliative care services, and AWMSG.

### **In relation to engagement with cancer services, statutory advisory committees, and other appropriate bodies**

The engagement of relevant clinical experts in the work programme is vital to ensure ownership by prescribers of the outcomes of appraisals, and their engagement in exceptional funding processes.

**Recommendation 8.** The working relationships between AWMSG and CSCG, the AWCDG and the regional cancer networks in Wales should be reviewed in order to ensure optimal collaboration and communication.

**Action:** CSCG lead with AWMSG, AWCDG, and regional cancer networks.

In the same way, medicines appraisal bodies need to have close communication with AWMSG to further improve processes and prevent duplication of effort.

**Recommendation 9.** Communication between medicines appraisal bodies in the UK should be further strengthened, and areas for collaboration (e.g. horizon scanning) actively sought.

**Action:** WMP lead with AWMSG, the Scottish Medicines Consortium, NICE, and the Association of British Pharmaceutical Industry (ABPI).

A range of different approaches to allow patients readier access to new medicines have been suggested by pharmaceutical manufacturers and some have been adopted for individual medicines. These are sometimes termed “patient access schemes”, and involve flexible approaches to the pricing and availability of new medicines. It is important that the cost to the NHS of administering and evaluating the outcomes of specific schemes are commensurate with the benefits to patients, and that unnecessary bureaucracy is avoided.

**Recommendation 10. The core principles of schemes (e.g. cost-sharing schemes) that may allow more ready access to appropriate new and innovative medicines for patients in NHS Wales should be agreed within six months.**

**Action: AWMSG lead with WMP, Welsh Assembly Government, and the ABPI.**

### **In relation to informing the public of these issues**

Communication with people in Wales with regard to the availability of medicines is vital. As well as informing the public, it is important to explore how the public can be more closely involved in decision making in this difficult and challenging area.

**Recommendation 11. The communication strategy for medicines in Wales should be further developed to inform the public about medicines; particularly the processes followed for evaluation and funding of new medicines in Wales. Consideration should be given to how the public can be more closely involved in decision making in relation to medicines-related issues in Wales.**

**Action: AWMSG lead with NPHS, Community Health Councils, National Leadership and Innovation Agency for Healthcare, and patient support groups.**

Following the recommendations of this report will require much effort by people within the organisations listed and others, both in assessing the size and nature of the work required, and in developing work programmes to address the issues in a timely fashion. Some recommendations will require resources to be made available in order to make satisfactory progress. However, the recommendations are intended to ensure that people in Wales have access to the most effective medicines as soon as possible after they become available. They are also intended to ensure that patients receive the best possible advice about these medicines so that they can make informed choices with regard to their care.

A handwritten signature in black ink, appearing to read 'P. Routledge', written in a cursive style.

Professor Phil Routledge OBE MD FRCP FRCPE

Chair, AWMSG and Chair, AWMSG Expert Group  
Professor of Clinical Pharmacology, Cardiff University

# Part 1: Background

## Chapter 1 – Introduction

- 1.1** Modern medicines are one of the key tools in healthcare, capable of controlling many conditions and sometimes effecting cures. Each year, approximately one hundred new medicines, or new formulations of existing medicines, receive a marketing authorisation from the European Medicines Evaluation Agency. When these medicines are subsequently launched by the manufacturers, the NHS must decide whether the benefit to patients justifies any additional purchasing cost. The process by which these assessments are made is termed *medicines appraisal*. As a result of medicines appraisal processes, most of these medicines are made available to NHS patients.
- 1.2** Prescribing of medicines is one of the most visible and measurable actions undertaken by the NHS. As detailed in the medicines strategy document produced by the All Wales Medicines Strategy Group (AWMSG) in 2008, there is an average of over 19 primary care prescriptions dispensed per person per year in Wales at a total cost of £574 million. A further £137 million is spent on medicines each year in Welsh hospitals. The total annual cost is over £711 million. When compared to other UK countries, GPs in Wales prescribe more prescription items per head of population, but with a lower cost per prescription item. The trend in medicine use in Wales, therefore, appears to be driven by growth in prescription volume and presumably reflects patient demand and/or need. This increased volume of prescribing is partly countered by a trend for the average cost per prescription item to decrease. There appears, however, to be considerable variation in the use of medicines between the Local Health Boards (LHBs).

- 1.3** It is encouraging that so many of the medicines being produced by innovative pharmaceutical manufacturers are for the treatment of cancer. However, because of the major costs incurred in the development of new medicines they can be expensive and, at the time they are brought to the market, uncertainty may exist about their relative value and appropriate place in therapy. This can make their appraisal for possible use within the NHS an extremely challenging process.
- 1.4** In 1998, the UK Government established the National Institute for Clinical Excellence, now the National Institute for Health and Clinical Excellence (NICE). This organisation gives advice on both the clinical effectiveness and the cost-effectiveness of a selected group of medicines, and this advice has a statutory basis in Wales as well as in England. NHS Trusts and LHBs in Wales are required to fund those medicines that NICE approves within three months of publication of advice. NICE has made major strides in ensuring that effective medicines are widely available in England and Wales, and equity of access to such medicines has also improved as a result of the work of NICE. It has justifiably earned an international reputation for its achievements. However, NICE still only appraises a proportion of the new medicines launched each year, and the appraisal process has sometimes been lengthy or delayed (Barham 2008).
- 1.5** Prior to 2002, advice on whether a medicine (that had not been considered by NICE) should be used in the NHS in Wales was provided by District Drug and Therapeutics Committees around Wales. These have been replaced by locality-based Medicines and Therapeutics Advisory Committees (MTACs), which have an important role in medicines appraisal, and in promoting the safe and effective use of medicines. However with limited access to cost-effectiveness data, appraisal of costly medicines by these committees presents particular difficulties and results in variation in access to some medicines across Wales. There is also concern about delays in the introduction of new, particularly high-cost medicines across Wales.

**1.6** A Task and Finish Group for Prescribing was established in 2000 by the Minister for Health and Social Services to identify barriers to the availability of new medicines and actions that Welsh Assembly Government could take to overcome these. The Group reported a year later with 96 recommendations for improvement. These recommendations have since been implemented, including the formation of an All Wales Medicines Strategy Group (AWMSG). This Group was established in 2002 to advise on the introduction of medicines (particularly high-cost medicines) at national level.

**1.7** The broad aim of AWMSG is to provide expert advice in an effective, efficient and transparent manner to the Assembly on strategic medicines management and prescribing. This enables the Assembly to provide guidance on a standard approach to prescribing issues across Wales whilst permitting local application and reducing duplication of effort.

**1.7.1** The main functions of AWMSG are to:

- Advise the Assembly of future developments in healthcare that involve the use of medicines and that will assist the Assembly in its strategic planning for their potential impact on the NHS in Wales.
- Develop timely, independent and authoritative advice on new medicines and on the cost implications of making these medicines routinely available to the NHS in Wales. This includes making interim recommendations on the place in treatment of medicines if advice from NICE is only likely to be available after more than 12 months.
- Advise the Assembly on the development of a consistent cost-effective prescribing strategy for Wales (with consideration of pharmaceutical developments, NICE guidance, National Service Frameworks, and Welsh epidemiology).
- Advise the Assembly on the implementation and cost-benefits of a range of other strategic recommendations at national and local level within the NHS.

- Advise the Assembly on how consumer groups might be engaged to discuss patient expectations and the impact of these on prescribing by healthcare professionals.

**1.7.2** The medicines strategy, “*Getting the best outcomes from medicines for Wales*“, was recently produced by AWMSG after consultation with representative members from its subgroups – the All Wales Prescribing Advisory Group (AWPAG) and the NHS Industry Forum (NHSIF). The document proposes a vision for the future of prescribing and medicines management in Wales – a vision which focuses on patient outcomes as well as processes.

**1.7.3** The work of AWMSG is supported by a network of individuals working on behalf of The Welsh Medicines Partnership (WMP) which brings together four Welsh organisations, each with its own particular area of expertise on the use of medicines:

- Therapeutics and Toxicology Centre (School of Medicine, Cardiff University)
- Welsh Medicines Information Centre
- Welsh Medicines Resource Centre
- Yellow Card Centre Wales.

This partnership was established in 2002. One of its major aims was to work together to develop timely, independent and authoritative advice on new (particularly high-cost) medicines for consideration by AWMSG.

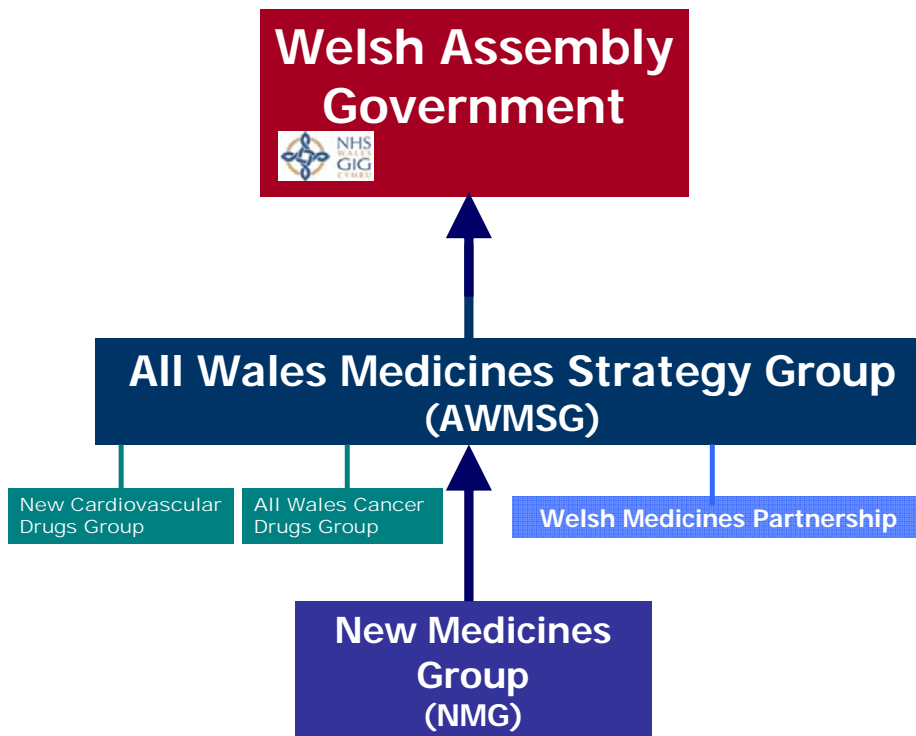
**1.8** AWMSG was initially tasked with the timely appraisal (ideally within 26 weeks of the receipt of a company application) of the clinical and cost-effectiveness of high-cost medicines which were not on the NICE work programme. A high-cost medicine was defined as one likely to cost £2,000 per patient per year or greater (including the costs of administering the medicine). This threshold was set to allow AWMSG to focus on those medicines where decisions had been delayed in the past.

In 2006, AWMSG was asked to expand its process to appraise all medicines for cancer and cardiovascular disorders, in addition to the high-cost medicines (to a maximum of 32 medicines each year). Although every effort is made to ensure that the medicines considered by AWMSG are not already on the NICE work programme, if they are subsequently considered by NICE, these recommendations supersede those of AWMSG. In practice, AWMSG and NICE have reached similar conclusions on the medicines they have both appraised in the majority of instances (Office of Fair Trading 2007).

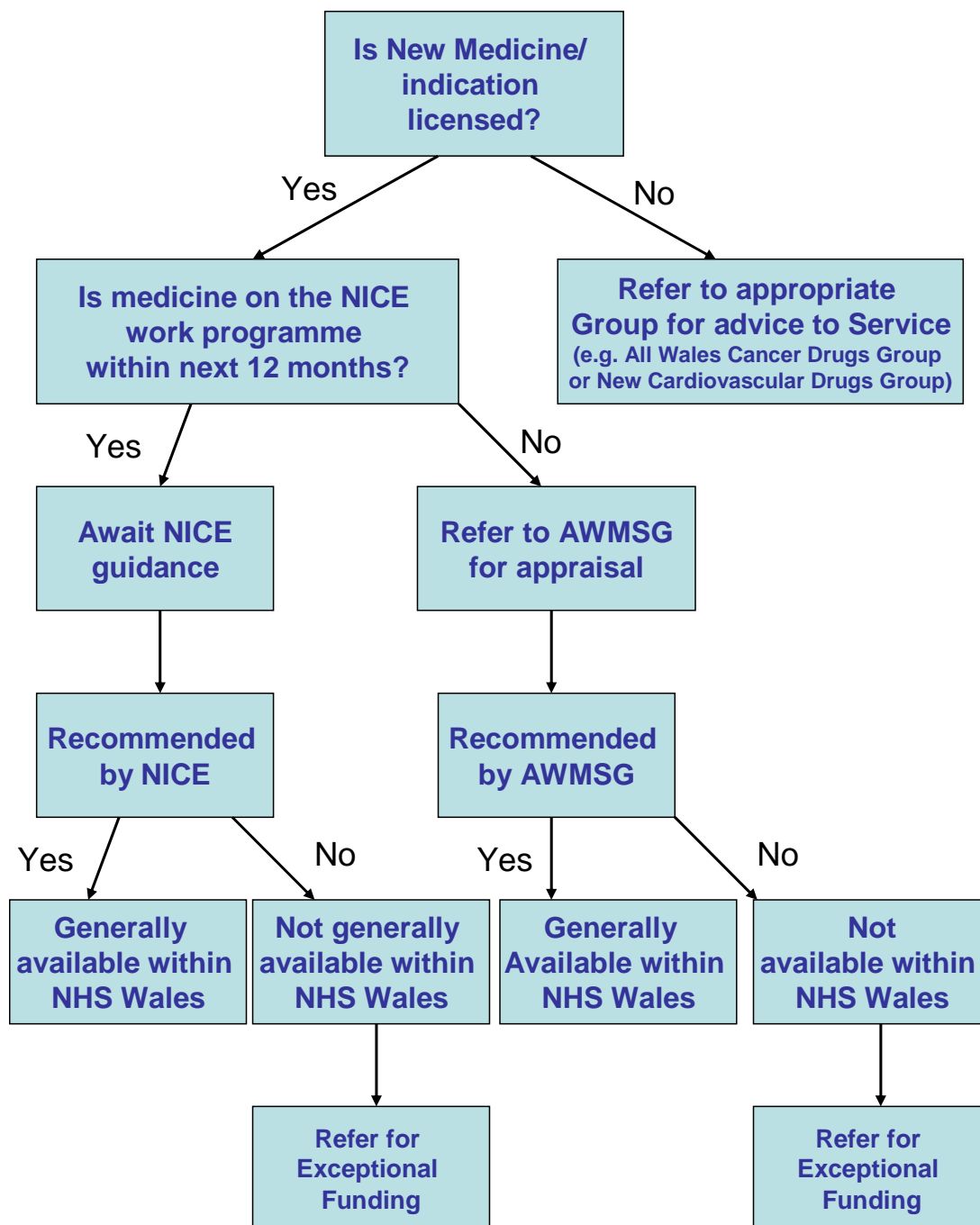
**1.9** AWMSG, like NICE, bases its recommendations regarding the use of a medicine on an assessment of the clinical benefits (likely extension of life and improvements in the quality of life) and the costs associated with its use. These are commonly expressed in terms of the cost of the medicine per quality-adjusted life-year (QALY) gained. Although there is no fixed cost-effectiveness threshold, AWMSG and NICE generally recommend clinically effective new medicines when the incremental cost effectiveness ratio (ICER, i.e. the incremental costs and benefits associated with the new medicine compared to those of an appropriate existing comparator) is lower than £20,000. When the ICER is higher than this, the probability of recommendation is lower, although the medicine may be recommended because of other factors, such as effects on wider societal costs and benefits. AWMSG has always considered these issues when considering its recommendations.

**1.10** The standards achieved by AWMSG and the other national bodies are acknowledged in a recent report by the Office of Fair Trading (OFT) on the Pharmaceutical Price Regulation Scheme (PPRS). Discussing the role of NICE, the Scottish Medicines Consortium (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*" (OFT 2007).

- 1.11** AWMSG recommendations, once endorsed by the Minister for Health and Social Services, must be implemented by the NHS in Wales. Healthcare Standards for Wales states that, “*Healthcare organisations [must] ensure that patients and service users are provided with effective treatment and care that conforms to the...NICE technology appraisals and interventional procedures, and the recommendations of the ...AWMSG*”. NHS Trusts and LHBs in Wales are therefore expected to implement recommendations from the AWMSG within three months of endorsement by the Minister.
- 1.12** Preliminary appraisal of medicines is now conducted by an AWMSG subgroup, the New Medicines Group (NMG), which draws a large number of members from the various MTACs in Wales. The recommendations of the NMG are discussed by AWMSG at its meetings and final recommendations (which may differ from the preliminary recommendations of NMG) are made to the Minister.
- 1.13** The AWMSG programme is also informed by some of the clinical networks in Wales. The All Wales Cancer Drugs Group (AWCDG), established by the Cancer Services Co-ordinating Group (CSCG) in 2006, provides a valuable service in helping to “horizon scan” for new cancer treatments in development. This Group helps to prioritise AWMSG appraisals of medicines for cancer, advises on the most appropriate treatments with which to compare the new medicine, and assist in providing the specialist clinical expertise required for the appraisal process. The New Cardiovascular Drugs Group (NCDG) provides similar advice for the medicines used in their speciality area. The present structure and reporting paths for the AWMSG appraisal process is shown in Figure 1. The journey of a new high-cost, cancer or cardiovascular medicine after marketing authorisation and launch is shown in Figure 2. The appraisal process followed by AWMSG is illustrated in the Appendix.



**Figure 1: Medicines appraisal process in Wales by the All Wales Medicines Strategy Group (2008-9)**



**Figure 2: Process by which new high cost, cancer and cardiovascular medicines are made available in NHS Wales.**

**1.14** Medicines may not be approved for use in NHS Wales for four reasons:

- A. They have not yet been appraised either by AWMSG or by NICE.**
- B. They have been appraised by AWMSG and not recommended for use in NHS Wales.**
- C. They have been appraised by NICE and not recommended for use in the NHS.**
- D. They have not received a Marketing Authorisation in Europe for the purpose for which they are being requested.**

Some of the issues are different in relation to each of these situations. They will be discussed in Chapter 3.

## Chapter 2 – Remit of the review

**2.1** Although the appraisal processes described previously apply to a range of medicines, the issues around cancer medicines are particularly pertinent. New medicines for the treatment of cancer constitute a high proportion of the agents being developed by the pharmaceutical industry at present. Some of these agents may only be associated with modest clinical benefits and yet can be expensive, so their cost-effectiveness is questioned by medicines appraisal bodies in the UK. Where this is the case, AWMSG or NICE may not recommend use of a medicine on the basis of insufficient evidence of cost-effectiveness. Subsequently, these medicines may constitute a significant proportion of requests to LHBs for exceptionality funding for individual cases.

**2.2** This review was established to:

- Develop a programme of work to address the issues related to medicines which have not been approved for use in NHS Wales.
- Develop a programme of work to address the prescribing of “heroic” treatments during the last months of life.
- Engage, initially, with the Cancer Network, the Lead Advisor for Cancer Services and the Lead Cancer Clinician in prioritising cancer treatments.
- Engage with the statutory clinical advisory committees and with other appropriate bodies in developing the programme.
- Advise on how the public may be best informed and engaged in the discussions about these issues.

## Part 2: The present situation

### Chapter 3 – The appraisal and availability of medicines in NHS Wales

**3.1** The appraisal process for medicines in Wales has been described in Chapter 1. Since 2006, all medicines for cancer, cardiovascular disease, and any other “high-cost” medicines have been considered centrally in Wales by AWMSG. The strengths of the present AWMSG process for appraisal of medicines in Wales are considered to be:

**3.1.1** *Access and Timeliness.* High-cost medicines, and more recently medicines for cancer and cardiovascular disease are appraised as close as possible to marketing authorisation by AWMSG. If given a positive recommendation, all NHS Trusts and LHBs in Wales are expected to fund these medicines within three months of the recommendation being endorsed by the Minister for Health and Social Services. To ensure this timeliness when the appraisal programme was increased from 8 to 32 medicines annually, AWMSG began meeting bimonthly rather than quarterly. This has meant that more medicines are available to patients across Wales closer to the product launch.

**3.1.2** *Attention to Patient Perspectives.* Patients’ experience of their medicines and their conditions is a crucial part of the evidence that needs to be considered when making decisions about therapies. AWMSG works in partnership with patient organisations to make sure that the views, needs, and hopes of patients are considered. This input is strengthened by the lay membership of AWMSG and NMG.

**3.1.3** *Inclusiveness.* In addition to the lay membership, membership of AWMSG and NMG is drawn from across Wales, with strong

representation from members of the various MTACs in Wales. The opinion of expert clinicians is sought, normally through established clinical networks. The pharmaceutical industry is also represented by members of AWMSG and NMG.

**3.1.4** *Openness and Transparency.* AWMSG is subject to public scrutiny and holds its meetings in public. In the interests of probity and transparency, members' or meeting participants' declarations of interests are listed on the AWMSG website and, as appropriate, in the minutes of each meeting. Copies of the meeting papers (prior to meetings), and minutes (after each meeting) are available on the AWMSG website: <http://www.wales.nhs.uk/awmsg>.

**3.1.5** *Responsiveness.* There are several opportunities within the process for liaison with the applicant pharmaceutical company to ensure that the final appraisal consideration has addressed all relevant issues. The pharmaceutical manufacturer is also invited to the AWMSG meeting to contribute to the discussion of their new medicine.

**3.1.6** *Robustness and Independence.* A full independent report on the clinical effectiveness and cost-effectiveness of each medicine is produced by WMP, and this forms part of the evidence considered by NMG and AWMSG in a rigorous appraisal process.

**3.2** The weaknesses of the medicines appraisal system in Wales are identified as:

**3.2.1** *The present appraisal process is not comprehensive.* AWMSG does not presently appraise all medicines that are not on the NICE work programme. By only considering high-cost medicines, and medicines for cancer and cardiovascular disease, it is perceived by some that treatment of these conditions might be favoured by AWMSG over other important conditions (e.g. respiratory disorders, diabetes, and other

chronic conditions). Recommendations about availability of medicines for these other conditions must be made separately by each MTAC in Wales. Although NICE proposes to increase the number of appraisals it conducts, there will still continue to be a number of medicines which will not be considered by either NICE or AWMSG under the present arrangements. In Scotland, the SMC seeks to consider all medicines as close to marketing authorisation as possible.

**3.2.2** *The price threshold of £2000 per patient per year to define “high-cost” medicines is also felt by some to be arbitrary.* However, it is acknowledged that AWMSG considers the clinical effectiveness and cost-effectiveness of “ultra-orphan” medicines and has a specific policy for this process. Such “ultra-orphan” medicines are not presently considered by NICE.

**3.2.3** *Avoidable delays.* Not all pharmaceutical companies wishing to introduce medicines into the NHS in Wales submit them to the AWMSG process in a timely fashion. This can result in delays in the appraisal of medicines, and therefore in the availability of medicines to patients. In Scotland, the SMC observed that for medicines scheduled for appraisal and then “not recommended” for use, there was a pattern of increasing use the further SMC advice was issued from the launch date. This suggests that timely advice is important in guiding the NHS about the appropriate and effective use of new medicines (SMC Evaluation Project Team 2008).

**3.2.4** *Suboptimal Engagement.* Although strenuous attempts are already made to ensure clinical engagement in the appraisal process, clinical acceptance of decisions would be improved by even greater involvement of expert clinicians across Wales in the appraisal process. It is also noted that the views of relevant patient organisations, although requested, are not always obtainable in the relatively short-time scales

necessitated by AWMSG's rapid appraisal process. Such advice is important in providing the patient perspective to medicines appraisal.

**3.3** Recent guidance from NICE in relation to appraising life-extending, end-of-life treatments may impact on the way that AWMSG appraises medicines. From 2 January 2009, supplementary advice is available to NICE appraisal committees. This advice applies to life-extending treatments given towards the end of life where the estimated ICER exceeds £30,000, which is generally considered to be the upper end of the range judged to be a cost-effective use of resources in the NHS (NICE 2009). It will apply to medicines licensed, or otherwise indicated for small patient populations, when no alternative treatment with comparable benefits is available through the NHS. This advice may increase the range of cancer treatments available in the NHS.

**3.4** NICE has also recently committed to increasing the number and speed of its appraisals, recognising that it will take time to implement the increased throughput. It is unlikely that, in the short- to medium-term, NICE will review all of the 100 or so new medicines that become available each year, so a complementary process will continue to be required if the NHS in Wales wishes to ensure that all medicines have been appraised nationally prior to introduction into the NHS.

**3.5 The present situation in relation to medicines that have not been appraised by AWMSG or NICE.**

**3.5.1** Since medicines must be appraised in a timely fashion by AWMSG before general use in Wales, delays may arise if manufacturers do not submit applications to AWMSG as close to the marketing authorisation and launch of their product as possible. During the period between launch and appraisal, no clear guidance is available to the NHS in Wales. If an appraisal tends to follow launch after a considerable interval, and so NHS Trusts and LHBs may face an extended period of

uncertainty when approached by clinicians requesting to use these medicines for their patient(s).

**3.5.2** If the manufacturer declines to submit an application to AWMSG, NHS Wales is informed of this situation and a note that the medicine “*has not been approved for general use in Wales due to non-submission*” is posted on the AWMSG website. Nevertheless, uncertainty may still remain in the minds of prescribers about the place and value of the medicine in treatment. If NICE appraisal does not follow, this uncertainty may continue. Although the Assembly can instruct AWMSG to appraise the medicine in the absence of company engagement, using publically available information, this is rarely requested.

### **3.6 The present situation in relation to medicines that have been appraised by AWMSG and not recommended for use in NHS Wales.**

**3.6.1** The majority of appraisals of new medicines by AWMSG result in a positive recommendation. Negative recommendations can be due to insufficient evidence of cost-effectiveness and/or clinical effectiveness, although it is more often the former. The NHS is informed of the recommendation once as it has been ratified by the Minister for Health and Social Services.

**3.6.2** The Welsh Health Circular [WHC (2007) 028] states that:

*“any new medicine can be legally prescribed once it has a licence, if it is thought by a clinician to be the most suitable treatment for an individual patient. An individual clinician should take account of guidance issued by NICE or the AWMSG when exercising their clinical judgement, unless there is evidence to justify not doing so in the light of the particular circumstances of an individual patient.”*

However, in practice, if a medicine is not approved by AWMSG, a request for funding would normally require individual approval from the NHS Trust or LHB as a form of “**exceptional funding**”.

**3.6.3** The process for exceptional funding should have the attributes of an optimal appraisal process, in that it should be easy to access, and timely in its judgements. It should be inclusive, with access to relevant informed clinical opinion and the best available evidence, and transparent in its decision making. Macmillan Cancer Support have surveyed the current processes employed to consider exceptional funding by LHBs in Wales, and as a result of their findings, have advocated a national framework for this process. The results of this survey are shown in Box 1 (page 26).

**3.6.4** If NHS funding is not granted, and the clinician wishes to prescribe an unfunded medicine, a patient may decide to purchase the treatment themselves. This has been referred to as “**co-payment**” (or sometimes as “top-ups”, “user charges” or “patient contributions”). The issue of co-payments has been comprehensively addressed in the recent report, “*Improving access to medicines for NHS patients: a report for the Secretary of State for Health by Professor Mike Richards*”. The findings of the report are discussed in greater detail below (see section 3.9).

### **3.7 The present situation in relation to medicines that have been appraised by NICE and not recommended for use in the NHS.**

The situation is the same as that existing after a negative recommendation by AWMSG; the same option of application for funding for treatment of an individual patient on an exceptional basis applies.

## Box 1. Exceptional Funding Processes in Wales, a survey by Macmillan Cancer Support

In 2008, Macmillan Cancer Support surveyed all local health boards in Wales, in order to get a clearer picture of how exceptional funding processes were working. Overall, responses were received from 18 of the 22 LHBs (82%).

The survey showed the following:

1. *Process name*: all Welsh LHBs said they had a process for exceptional funding treatments; however, there were 15 different names.
2. *Information and availability*: Although the majority of respondents said that information on their exceptional funding process was publicly available, only around a third said that the process was actively promoted to patients.
3. *Panel composition*: only 6% of respondents in Wales said there was an oncologist on the decision-making panel, even in decisions on cancer treatments.
4. *Criteria*: two thirds of LHBs in Wales said they take the patient's personal circumstances into account. Factors taken into account, included age, dependents, and marital status.

Two LHBs in Wales actively take into account local publicity/media activity in their decision-making.

One LHB in Wales said they take into account the point of the financial year at which the application is received.

5. *Process delays*: the majority of LHBs in Wales said that applications for exceptional funding (from application to decision) were dealt with in a month or less, but we are aware of anecdotal evidence which suggests some LHBs can take up to 12 weeks to make a decision.

### **3.8 The present situation in relation to medicines that have not received a marketing authorisation in Europe for the purpose for which they are being requested.**

**3.8.1** On rare occasions, a medicine may not have a marketing authorisation for any clinical indication and, therefore, does not fall within the remit of an appraisal body such as AWMSG or NICE. More often, a medicine may have a marketing authorisation for one particular indication, but a new proposed use falls outside that authorisation. In the latter circumstance, any proposed use is termed “**off-label**” (or “off-licence”). These off-label uses fall out of the remit of medicines appraisal bodies like AWMSG and NICE. If the medicine is also expensive, issues often arise in relation to who will be prepared to pay for its use and it may, therefore, be part of a request to an NHS Trust or LHB for exceptional funding.

**3.8.2** Although off-label use of medicines (use outside the indications described in the Summary of Product Characteristics) is permitted, there may be important issues to consider concerning the relative benefits and risks of treatment. Off-label use must be informed and guided by a respectable and responsible body of professional opinion, so that the prescriber is able to justify such use to his/her peers. It is recognised that the labelling of some groups of medicines (e.g. anti-cancer medicines) is very precise and off-label use (e.g. as part of palliative chemotherapy) may be part of the standards of care (Leveque 2008).

**3.8.3** Health professionals need ready access to the best available information when considering off-label use. Since some medicines may be the subject of requests for exceptional funding for individual patients, those charged with making these decisions also require independent, comprehensive and authoritative information on the likely benefits and risks of the treatment before making a determination. Such information is sometimes difficult to obtain.

**3.8.4** Sometimes the off-label indication will have been identified as a result of a clinical trial. Health Commission Wales' policy on "*Clinical Trials, Post Trial Development and Post-Trial Funding*" (Health Commission Wales 2008) provides useful advice in relation to the funding implications of trials.

**3.8.5** The AWCDG was established in part to address the issues of off-label use of new cancer treatments. One of its roles is to provide advice (when needed) via interim assessments for new cancer medicines, which are licensed for a particular purpose but which are being considered for an off-label indication, and therefore not eligible for review by AWMSG. Such interim assessments are superseded by those of AWMSG or NICE, if and when the medicine obtains a marketing authorisation for the particular indication and is then formally appraised by either of these bodies.

**3.9** In November 2008, "*Improving access to medicines for NHS patients: a report for the Secretary of State for Health by Professor Mike Richards*" was published. This review was established to:

- examine current policy relating to patients who choose to pay privately for medicines that are not funded on the NHS and who, as a result, are required to pay for the care that they would otherwise have received free on the NHS; *and*
- make recommendations on whether and how policy or guidance could be clarified or improved.

**3.9.1** The Richards report provides important data on the situation in relation to exceptional funding requests in England. It notes that in England, applications for medicines on which NICE has yet to issue final guidance appear to be by far the largest category that were subject to requests for exceptional payments. Exceptional case requests for medicines that have been declined by NICE appear to be uncommon. This further highlights the need for early advice on the clinical

effectiveness and cost-effectiveness of new medicines as close to their marketing authorisation and launch as possible. If guidance is forthcoming, it is more likely that requests will then be truly based on the grounds of exceptionality.

**3.9.2** The Richards report also addresses the situation that can occur if exceptional funding is denied, and whether in these circumstances patients should be allowed to top-up their NHS treatment by paying privately for the medicines in question (making a co-payment). Richards recommends that patients should be permitted to receive additional private medicines as long as these are delivered separately to the NHS elements of their care. The report highlights the issue of the competing principles of *equity* – that availability of health services should be the same for all based on their individual need, rather than on their ability to pay – and *personal autonomy* – that people should be allowed to spend their money as they choose. Most respondents to the Richards report felt that patients should not lose their entitlement to NHS care if they opted to purchase additional treatment (Richards 2008).

**3.9.3** A consultation on co-payments for cancer medicines was conducted for the Velindre NHS Trust by the Welsh Institute for Health and Social Care, University of Glamorgan in July 2008 (Longley 2008). Two facilitated discussion groups involved a total of 56 members of the public and members of two Community Health Councils (CHCs) in South East Wales. A majority of participants (56%) also supported the principle of co-payment for cancer medicines, with 36% opposed.

**3.9.4** The Richards report concludes that speedy appraisal allied to greater flexibility in considering the cost-effectiveness of medicines for rarer cancers when used as life-extending treatments towards the end of life will minimise the number of patients needing to purchase additional medicines. It advocates a consistent approach for those few patients who may still wish to purchase additional medicines, and ways to ensure that patients are better informed about the implications of purchasing

additional medicines. Finally it recommends that improved information on additional medicines that have been used should be collected and used to inform patient choices and future policy decisions.

## Chapter 4 – The prescribing of “heroic treatment” in the last months of life

**4.1** The term “heroic treatment” was first used in the scientific literature more than 30 years ago in relation to use of treatments in life-threatening illnesses when there was little or no evidence that they would provide benefit (Anon 1977). While heroic treatment could be used in a variety of conditions, recent focus has been on the use of cancer treatments.

**4.2** A distinction must be drawn between treatment that may prolong suffering, and the justifiable active treatment of the disease process using systemic anti-cancer therapies (SACT), which may improve the quality of life.

**4.3** The principal issues in relation to SACT in the last months of life are well summarised in the foreword to “*For better, for worse?*”, a recent report by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD 2008). It states that:

*“Our contemporary culture does not deal well with death. There is great fear of cancer, and there is folklore surrounding chemotherapy. Consequently, many fears go unspoken between the dying and their families because they are overwhelming. Conversations between cancer patients and their doctors are not easy either. Patients have an inherent desire to trust their doctor and to believe that something positive might happen; most doctors have a compelling desire to not distress their patients. These factors together can lead to some unfortunate management decisions, resulting in “doing something” - perhaps in doing anything - to not let such emotionally needy patients down...”*

**4.4** It is recognised that SACT may be used for palliative rather than curative purposes to relieve symptoms or delay their onset. In these cases, lower doses of anti-cancer medicines are often used to reduce the risk or

severity of adverse effects of the treatment; however, treatment-related toxicity may still occur. There is evidence that patients with cancer are likely to opt for treatments offering only small chance of any benefit (Slevin et al 1990).

**4.5** The NCEPOD report examined practice in hospitals in England, Wales and Northern Ireland, and examined six key areas where important decisions about the care of patients must be made.

- The appropriateness of the decision to treat with SACT.
- The process of care in the prescribing and administration of SACT.
- The safety of care in monitoring for potential toxicity and managing complications.
- End-of-life care.
- Clinical governance, clinical audit, and risk management issues.
- Communication - patient information, multidisciplinary team (MDT) working, and referral pathways.

Although important recommendations were made in relation to all these issues, certain areas are of particular relevance in relation to whether treatments are likely to be of overall benefit to patients, and whether their care is appropriate.

**4.6** The appropriateness of the decision to treat with SACT is of direct relevance to this review. NCEPOD endorsed the Manual for Cancer Services standard that initial clinical management plans for all cancer patients should be formulated within an MDT meeting. They also recommended that the MDT should be responsible for agreeing clinical care pathways, including appropriate chemotherapy regimens, doses and treatment durations. The authors stated that the decisions regarding whether or not to advise SACT should be undertaken by a consultant oncologist / haemato-oncologist after a comprehensive clinical review of

the patient. Finally, they recommended that the decision whether or not to accept treatment should be made by the patient after they have been fully informed of the potential benefits and toxicities and they have had sufficient time to consider their decision and discuss it with their family and carers (NCEPOD 2008).

- 4.7** Because informed consent by the patient is central to the clinical management process, it is vital that patients receive accurate information, and have a full discussion with their oncologists and other members of the MDT about both the likely benefits and the side effects associated with treatment (Munday and Maher 2008). A recent study of 37 consultations with nine oncologists in two centres in England observed that most patients were not given clear information about the survival gain of palliative chemotherapy (Audrey et al 2008).
- 4.8** Such information needs to be shared sensitively with patients. Doctors and other health professionals may need additional training to help them communicate with patients effectively and handle these difficult conversations well (Finlay 2008).
- 4.9** The value of additional written information for patients has already been recognised (Gaston and Mitchell 2005). Such information, including details of possible side effects of the proposed treatment, will help patients to decide whether they wish to receive palliative chemotherapy.
- 4.10** With regard to end-of-life care, the NCEPOD report recommended that a pro-active rather than reactive approach should be adopted to ensure that palliative care treatments or referrals are initiated early and appropriately. It also highlighted the need for oncologists to enquire at an appropriate time, about any advance decisions the patient might wish to make should they lose the capacity to make their own decisions in the future (NCEPOD 2008).

**4.11** In addition, the recent Finlay report recommends that health professionals involved in end-of-life care have access to training in symptom control, communication skills, and methods to ensure continuity of care (Finlay 2008).

## Chapter 5 – Engagement with cancer services, statutory advisory committees, and other appropriate bodies

### Cancer Services

- 5.1** Cancer is common, with approximately 15,000 cancers registered each year in Wales (CSCG 2006). The CSCG report “*Designed to Tackle Cancer in Wales*” highlights that there is a one in three chance of a man being diagnosed with cancer and a two in seven chance of a woman being diagnosed with cancer before their 75th birthday. Although people with some cancers are surviving longer, over 8,000 people die from cancer each year. It is one of the two biggest causes of premature death in Wales, and can have major effects on the quality of life of patients.
- 5.2** Services for people with cancer are planned, organised and delivered in Wales through three cancer networks: North Wales, South-East Wales, and Mid and West Wales Cancer Networks. The CSCG, which was established to formulate and introduce standards for cancer services, liaises with the Networks and their associated groups.
- 5.3** The CSCG has an important all Wales co-ordinating role, advising the Assembly and those who plan and deliver cancer treatment services. It is composed of people drawn from all areas of the NHS, including patients, NHS Trusts, general practitioners, CHCs, and specific professional groups. It works to improve the patient experience by focusing on equity of access and defining minimum standards to apply across Wales.
- 5.4** The CSCG has already moved to improve communication with AWMSG by establishing the AWCDG. This Group provides valuable advice on horizon scanning for new developments in drug treatment for cancer, and helps to decide on priorities for appraisal in the light of service

needs. AWMSG also shares information with the AWCDG concerning medicines that have been identified by other sources of horizon scanning so that there can be better forward planning.

- 5.5** CSCG co-ordinates the development of treatment guidelines by the specialist groups within the cancer networks, and AWMSG has the opportunity (via WMP) to have input into the evidence-based pharmacological and therapeutic aspects of these guidelines.
  
- 5.6** Despite these links, communication difficulties do sometimes arise, and it is crucial to ensure good dialogue if the networks are to have greater clinical and professional engagement in the appraisal system and AWMSG is to have timely access to a sufficiently wide range of expert clinical advice when it appraises cancer medicines. Identifying key individuals with the appropriate expertise is important, and may rely on the use of both formal and informal networks. Engagement should happen at the “grass roots” and be equally resourced across Wales. Where there is a range of specialist opinion on any topic, a consensus stance should be supported by good evidence.
  
- 5.7** It is apparent that members of networks may not always be fully aware of the remit and structure of the appraisal process for medicines in Wales. In addition, the outcomes of specific medicines appraisals may not be sufficiently rapidly communicated to members of the MDTs involved in the specialist cancer area(s) affected by the recommendation.

## Statutory Advisory Committees and other bodies

- 5.8** Communicating with relevant Statutory Advisory Committees (e.g. Welsh Medical Committee, Welsh Pharmaceutical Committee, and committees representing other health professional groups eligible to prescribe) will be crucial to this work programme. Their input and support is vital and so there should be regular engagement with these groups.
- 5.9** Links with the Welsh Assembly Government are also important, including continuing close liaison with the Chief Pharmaceutical Advisor, the Chief Medical Officer and those involved with co-ordination of policies which have medicines-related components.
- 5.10** At a UK level, close dialogue with NICE and the SMC will further improve collaborative working. SMC began a horizon scanning initiative in 2003 so that NHS Scotland could have advance warning of innovative medicines in the pipeline to support financial and service planning. As a first step, collaboration should be sought with SMC, NICE, the Association of the British Pharmaceutical Industry (ABPI), and other interested parties in developing and coordinating horizon scanning. Regular communication between these organisations will help to identify and make progress on shared areas of interest.
- 5.11** The pharmaceutical industry is a vital stakeholder in the process of ensuring that effective medicines are developed and made available to patients. Regular meetings already occur between WMP and the ABPI to ensure that the appraisal process continues to develop appropriately, and that member companies of the ABPI engage with the NHS in Wales through AWMSG. In addition, the ABPI has representation on AWMSG and its subgroups.
- 5.13** A range of different approaches to allow patients readier access to new medicines have been suggested by pharmaceutical manufacturers and

some have been adopted for individual medicines. These are sometimes termed “patient access schemes”, and involve flexible approaches to the pricing and availability of new medicines. It is important that the cost to the NHS of administering and evaluating the outcomes of specific schemes are commensurate with the benefits to patients, and that unnecessary bureaucracy is avoided.

**5.14** The core principles of schemes that may allow more ready access to new and innovative medicines for patients in NHS Wales should be agreed with ABPI.

## Chapter 6 – Informing the public

- 6.1** Communication with people in Wales about the availability of medicines is vital. As well as informing the public, it is important to explore how the public can be more closely involved in decision making in this difficult and challenging area.
- 6.2** Firstly, it is important to spend time engaging public opinion and identifying public perceptions or misunderstandings. Individuals' perspectives, the appropriate use of language and the parameters for discussion are all essential components of this process.
- 6.3** The existing communication strategy relating to medicines should be further developed. This will involve exploring quality and standards of the proposed communication processes, how to obtain authoritative viewpoints, and which NHS organisations are most appropriate to provide these. The strategy should provide balanced communication, allowing a breadth or range of opinions to be discussed.
- 6.4** Ultimately the public, as taxpayers and service users, decide which benefits they value and to what extent, and hence can help to identify priorities. Thus, communication between the healthcare providers and the public might be undertaken to meet several objectives:
- to inform/educate and raise awareness/promote understanding (e.g. effectiveness, opportunity costs, and budget constraints)
  - to spark and capture debate
  - to consult.
- 6.5** To meet these objectives and engage with different audiences, various tools or conduits may be used. These include forums, websites, and the media. Engagement with patient representative groups and the role of the CHCs are also important avenues to explore.

**6.6** The benefits of public involvement in the medicines appraisal process in Wales are outlined by one of AWMSG’s lay members in Box 2.

**6.7** Citizens juries have been discussed as a tool for public engagement. These can provide a framework that is understood, familiar, and generally trusted and can facilitate useful discussion and deliberation on complex issues. Their potential role in the area of new medicines should be explored.

### **Box 2. Comments from a lay member of AWMSG**

*“I have not worked in the health service although I am a lay assessor with Health Care Inspectorate Wales. My background is in the shipping industry (PR) but I am semi-retired and wanted to do something for the community that played to my strengths and that I found interesting and challenging.*

*“I feel it is extremely important that patients and/or members of the public, as taxpayers and people who are affected by the outcomes, are represented when decisions about medicines are made. I try to keep abreast of people’s views, and the issues raised by patient support groups, so that I can try to present the voice of the person “on the street”.*

*“I am impressed by the professionalism and knowledge of the wide range representatives involved with AWMSG. Although I’m not a clinical expert, my opinion is valued and respected – I have always felt very comfortable asking questions.*

*“There is a need for more lay members from across Wales. There are extremely important decisions being made that could affect any one of us. It is a highly rewarding and interesting role that I could recommend to anyone.”*

**Mr John Guy, Deputy Lay Member, AWMSG**

## Part 3: A way forward

### Chapter 7 – Recommendations

#### **In relation to medicines which have not been approved for use in NHS Wales.**

**Recommendation 1.** AWMSG should complete the appraisal of any medicines not on the NICE programme within six months of receipt of a company submission following marketing authorisation.

**Action:** AWMSG lead with the NMG, and WMP.

**Recommendation 2.** AWMSG should adopt the supplementary advice relating to appraising life-extending, end of life treatments published by NICE in January 2009.

**Action:** AWMSG lead with NMG, and WMP.

**Recommendation 3.** To ensure the robust, consistent, transparent, inclusive, and timely consideration of requests for exceptional funding of medicines, a national guideline for the structures needed and the process employed in Wales should be developed within six months. Data should be collected on the decisions made to inform future policy decisions.

**Action:** AWMSG lead with WMP, National Public Health Service (NPHS) in Wales, and NHS finance directors.

**Recommendation 4.** An audit of the use of off-label cancer medicines should be conducted in Wales including the methods used to provide information to patients in these circumstances.

**Action:** CSCG lead with regional cancer networks, and AWMSG.

**Recommendation 5.** All recommendations of the recent Richards report, *“Improving access to medicines for NHS patients,”* regarding co-payments should be considered in progressing this issue in Wales.

**Action:** Welsh Assembly Government.

### **In relation to the prescribing of “heroic treatments” in the last months of life**

**Recommendation 6.** The implications for practice in Wales of the recommendations of the NCEPOD report, which are now being considered by the regional cancer networks, should be reported to the CGSC within 12 months. This will inform the work needed to further improve the care of patients towards the end of life.

**Action:** regional cancer networks lead with CSCG, palliative care services, and AWMSG.

**Recommendation 7.** The additional training needs of health professionals to help them effectively communicate with patients about difficult decisions around risks/burdens and benefits of different proposed treatments should be assessed, and an appropriate programme related to end-of-life care should be developed.

**Action:** CSCG lead with regional cancer networks, the AWCDG, palliative care services, and AWMSG.

### **In relation to engagement with cancer services, statutory advisory committees, and other appropriate bodies**

**Recommendation 8.** The working relationships between AWMSG and CSGC, the AWCDG and the regional cancer networks in Wales should be reviewed in order to ensure optimal collaboration and communication.

**Action: CSCG lead with AWMSG, AWCDG, and regional cancer networks.**

**Recommendation 9. Communication between medicines appraisal bodies in the UK should be further strengthened, and areas for collaboration (e.g. horizon scanning) actively sought.**

**Action: WMP lead with AWMSG, SMC, NICE, and the ABPI.**

**Recommendation 10. The core principles of schemes (e.g. cost-sharing schemes) that may allow more ready access to appropriate new and innovative medicines for patients in NHS Wales should be agreed within six months.**

**Action: AWMSG lead with WMP, Welsh Assembly Government, and the ABPI.**

### **In relation to informing the public of these issues**

**Recommendation 11. The communication strategy for medicines in Wales should be further developed to inform the public about medicines; particularly the processes followed for evaluation and funding of new medicines in Wales. Consideration should be given to how the public can be more closely involved in decision making in relation to medicines-related issues in Wales.**

**Action: AWMSG lead with NPHS, CHCs, National Leadership and Innovation Agency for Healthcare, and patient support groups.**

## Part 4: Appendix

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## Glossary of terms and abbreviations

**ABPI:** see **Association of the British Pharmaceutical Industry**

**All Wales Cancer Drugs Group (AWCDG):** established by the Cancer Services Co-ordinating Group [CSCG] in 2006, to help to “horizon scan” for new cancer treatments in development, to prioritise AWMSG appraisals of medicines for cancer, and to identify and recruit the specialist clinical expertise required for appraisal of such medicines.

**All Wales Medicines Strategy Group (AWMSG):** established in 2002 to bring together NHS clinicians, pharmacists, healthcare professionals, academics, health economists, industry representatives and patient advocates to provide advice on strategic medicines management and prescribing to the Minister for Health & Social Services.

**All Wales Prescribing Advisory Group (AWPAG):** formed in October 2003 to advise AWMSG on strategic developments in primary and secondary care. It assists with monitoring prescribing, advising on prescriber training, and developing prescribing indicators and audits for a national incentive scheme.

**Association of the British Pharmaceutical Industry (ABPI):** the trade association for more than 70 companies in the UK producing prescription medicines. Its member companies research, develop, manufacture and supply more than 80 per cent of the medicines prescribed through the National Health Service (NHS).

**AWCDG:** see **All Wales Cancer Drugs Group**

**AWPAG:** see **All Wales Prescribing Advisory Group**

**Cancer Services Co-ordinating Group (CSCG):** established in early May 1997 to support the overall implementation of the Cameron Report recommendations with working groups, convened as required and expert

clinical advice via the All Wales Cancer Steering Groups.

**CHC: see Community Health Council**

**Community Health Council (CHC):** there are 19 CHCs in Wales which provide help and advice relating to problems with or complaints about NHS services, ensure that local views and needs influence the policies and plans put in place by health providers in the area they serve, monitor the quality of NHS services from a public point of view, and provide information about access to the NHS.

**CSCG: see Cancer Services Co-ordinating Group**

**EMA: see European Medicines Evaluation Agency:**

**European Medicines Evaluation Agency (EMA):** a decentralised body of the European Union with headquarters in London. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

**Exceptional Funding:** funding for a treatment that falls outside the usual commissioning arrangements of an LHB or NHS Trust.

**Horizon-Scan:** the systematic examination of potential future developments (e.g. in treatments) which are at the margins of current thinking and planning.

**Medicines and Therapeutics Advisory Committees (MTACs):** committees which advise NHS Trusts and LHBs across Wales on decisions relating to funding of other medicines which are not appraised by NICE and AWMSG.

**Medicines Appraisal:** the structured evaluation of the properties and effects of a medicine, ideally with consideration of its clinical effectiveness and cost effectiveness when used for the specified indication.

**MTACs: see Medicines and Therapeutics Advisory Committees**

**National Institute for Health and Clinical Excellence (NICE):** established in 1998, it is an independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.

**National Public Health Service (NPHS)**

**NCDG: see New Cardiovascular Drugs Group**

**New Cardiovascular Drugs Group (NCDG)**

**New Medicines Group (NMG):** formed in May 2007 to enable AWMSG to efficiently manage a broadened appraisal process. This group meets every two months to consider the evidence on new medicines, and to provide preliminary recommendations to AWMSG on the introduction of these medicines in Wales.

**NHS Industry Forum:** formed in July 2003 to provide advice to AWMSG on issues regarding the relationship between NHS Wales and the pharmaceutical industry. It monitors financial arrangements, promotional activity, research and development activity, and helps to secure efficient and competitive provision of medicines.

**NHSIF: see NHS Industry Forum**

**NICE: see National Institute for Health and Clinical Excellence**

**NMG: see New Medicines Group**

**NPHS: see National Public Health Service**

**Office of Fair Trading (OFT):** the UK's consumer and competition authority,

which aims to to make markets work well for consumers.

**Off-label:** Use of a medicine outside the terms of its official labelling/license.

**Off-licence:** See off-label

**OFT:** see Office of Fair Trading

**Pharmaceutical Price Regulation Scheme (PPRS):** A voluntary agreement between the UK Government and the Association of the British Pharmaceutical Industry (ABPI) which allows pharmaceutical companies to set their own prices for branded prescription medicines, but with constraints placed upon overall profit.

**PPRS:** see Pharmaceutical Price Regulation Scheme

**QALY:** see Quality-adjusted life-year

**Quality-adjusted life-year (QALY)** A measurement that takes into account the extent to which a treatment both prolongs and improves the quality of a patient's life. A QALY is calculated mathematically by multiplying the number of additional years of life achieved by a treatment by a measure of the quality of life. The cost-effectiveness of treatments can be compared by evaluating the cost of the treatment per QALY gained (cost per QALY).

**SACT:** see Systemic Anti-Cancer Therapy

**Scottish Medicines Consortium (SMC):** Body formed in 2002 to provide advice to NHS Boards and their Area Drug and Therapeutics Committees (ADTCs) across Scotland about the status of all newly licensed medicines, all new formulations of existing medicines and new indications for established products.

**SMC:** see Scottish Medicines Consortium

**Systemic Anti-Cancer Therapy (SACT):** Medicines given orally, subcutaneously or intravenously to treat cancer.

**Ultra Orphan Medicine:** Medicines that are licensed for the treatment of diseases with a UK prevalence of less than 1 in 50,000. This equates to around 60 prevalent cases in Wales.

**Welsh Medicines Partnership (WMP):** A strategic partnership of pharmacists, pharmacologists, physicians, health economists, editors and managers who together provide the day to day support which enables AWMSG to deliver its objectives.

**WMP: see Welsh Medicines Partnership**

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Berwyn Owen	Chair of Welsh Pharmaceutical Committee
Ceri Phillips	Professor of Health Economics, School of Health Science, Swansea University Member, AWMSG
Karen Preece	Director, Mid and West Wales Regional Commissioning Unit
Rebecca Richards	Finance Director, Merthyr Tydfil LHB Member, AWMSG
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Wendy Warren	Nurse Director, Gwent Healthcare Trust Member, AWMSG
Fiona Woods	Director WMP / Welsh Medicines Information Centre

## Organisations submitting evidence

Association of the British Pharmaceutical Industry

Macmillan Cancer Support

Royal Pharmaceutical Society of Great Britain

## Members of the review group

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## AWMSG appraisal process (since April 2007)

