Enclosure No:	**1/AWMSG/1010**
Agenda Item No:	**5** - Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY, 18th AUGUST 2010 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY

MEMBERS PRESENT:

Did not participate in

1.	Dr Paul Buss	Hospital Consultant
2.	Dr Geoffrey Carroll	Welsh Health Specialised Services Committee
3.	Dr Fraser Campbell	LHB Medical Director
4	Mrs Debbie Davies	Representing other professions eligible to prescribe
5.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health
6.	Mrs Susan Murphy	Senior Primary Care Pharmacist
7.	Cllr Meurig Hughes	Lay representative
8.	Dr Thomas Lau	General Practitioner with prescribing lead role
9.	Prof Ceri Phillips	Health Economist
10.	Prof Philip Routledge	Clinical Pharmacologist (Chairman)
11.	Mr Guy Thompson	ABPI (Wales) representative
12.	Mrs Wendy Warren	Senior Nurse

IN ATTENDANCE:

13.	Professor Dyfrig Hughes	Acting NMG Chairman
14.	Mr Jeremy Savage	Welsh Assembly Government
15.	Mrs Fiona Woods	Welsh Medicines Partnership
16.	Mrs Ruth Lang	Welsh Medicines Partnership
17.	Ms Kath Haines	Welsh Medicines Partnership

List of Abbreviations:

ABPI	Association of the British Pharmaceutical Industry
ASAR	AWMSG Secretariat Assessment Report
AWCDG	All Wales Cancer Drugs Group
AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
BHIVA	British HIV Association
BMA	British Medical Association
BNF	British National Formulary
CR/ASAR	Company response to the AWMSG Secretariat assessment report
CR/FAR	Company response to the final appraisal report
CR/PAR	Company response to the preliminary appraisal report
CSCG	Cancer Services Co-ordinating Group
CHM	Commission on Human Medicines
DoH	Department of Health
DTB	Drug & Therapeutics Bulletin
FAR	Final appraisal report
HCW	Health Commission Wales
HoPMMs	Heads of Pharmacy and Medicines Management
HSW	Health Solutions Wales
IHC	Informing Healthcare
HB	Health Boards
M&TCs	Medicines & Therapeutics Committees
MHRA	Medicines & Healthcare Products Regulatory Agency
NHSIF	NHS Industry Forum
NICE	National Institute for Health and Clinical Excellence
NLIAH	National Leadership and Innovation Agency for Healthcare
NMG	New Medicines Group
NPHS	National Public Health Service
PAR	Preliminary appraisal report
PPRS	Prescription Price Regulation Scheme
SAFF	Service and Financial Framework
SMC	Scottish Medicines Consortium
SPC	Summary of Product Characteristics
TDA User Group	Therapeutic Development Appraisal User Group
T&FG	Task and Finish Group
WAG	Welsh Assembly Government
WAPSU	Welsh Analytical Prescribing Support Unit
WeMeReC	Welsh Medicines Resource Centre
WMIC	Welsh Medicines Information Centre
WMP	Welsh Medicines Partnership

1. Welcome and introduction

The Chairman opened the meeting and welcomed members.

2. Apologies

Mr David Roberts, Chief Pharmacist representative
Mr Robert Holcombe, Finance representative

3. Declarations of interest

The Chairman asked members to declare any specific, non-specific, personal or non-personal interests pertinent to the agenda. There were none.

4. Chairman's report

The Chairman reported that the Interface Pharmacist Group and AWPAG had met during July and an update from Dr Tessa Lewis, Chair of AWPAG, would be presented to AWMSG later in the meeting.

It was reported that on 13th July WMP representatives had met with representatives of Lundbeck UK who offered to work collaboratively with Health Boards in agreeing an appropriate positioning for escitalopram (Cipralex®) in line with NICE guidance and assist in monitoring this in the wider context of the management of depression and anxiety. The Chairman confirmed that opportunity would be extended to Health Boards and Lundbeck to feedback to AWMSG on the progress of this joint working arrangement.

The Chairman announced a new name had been agreed for the group comprising representatives from WMP and the ABPI TDA Users Group who work in partnership to develop and discuss issues relating to process. From 1st October, this group would be known as the TDA Partnership Group.

Members were informed that a limited submission (Form C) had been developed and is being piloted prior to the implementation of the broadened appraisal remit on 1st October. A limited submission may be deemed appropriate in the following circumstances:

- A new formulation e.g. modified release preparation
- A minor licence extension e.g. paediatric use
- If the anticipated usage in NHS Wales is considered by the AWMSG Steering Committee to be of minimal budgetary impact

The Chairman reported that the appraisal documentation had been updated and minor modifications had been made following consultation with colleagues in the Service, Industry and patient representatives, to ensure that the AWMSG health technology appraisal process would meet the needs of patients and the service in NHS Wales.

The Chairman confirmed that applications for new membership to AWMSG and its sub-groups had been received and were being processed. The Chairman extended his personal thanks to Councillor Meurig Hughes and Dr Thomas Lau who had been members of AWMSG since it was established in 2002 and who have served their full term of office, and contributed greatly to the work of the Committee..

The Chairman announced that induction training for new and existing members would be held during the autumn.

The Chairman confirmed that the Minister for Health and Social Services had ratified the following recommendations:

Sildenafil (Revatio®▼) is recommended within its current licensed indication, as an option for use within NHS Wales for the treatment of pulmonary arterial hypertension (PAH) (WHO functional class II or III) to improve exercise capacity.

AWMSG recommends that its use be restricted to a physician experienced in the treatment of PAH in association with a National Commissioning Group designated expert centre.

AWMSG is of the opinion that sildenafil (Revatio®▼) is not suitable for shared care between primary and secondary care within NHS Wales

Raltegravir (Isentress®▼) is recommended in combination with other anti-retroviral medicinal products as an option for restricted use within NHS Wales for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients in accordance with British HIV Association (BHIVA) guidance.

Raltegravir (Isentress®▼) should be restricted for use in patients who are resistant or intolerant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or for whom these options are compromised due to drug-drug interactions.

Current AWMSG advice, No 1808, in relation to the use of raltegravir (Isentress®▼) in treatment-experienced adult patients with human immunodeficiency virus (HIV-1) infection remains unchanged.

AWMSG is of the opinion that raltegravir (Isentress®▼) is not suitable for shared care within NHS Wales.

The Chairman confirmed the final appraisal reports had been posted on the AWMSG website and the Service notified.

Members were informed that ratification of the recommendation in relation to **cetuximab (Erbitux®▼)** for third-line treatment of patients with KRAS wild-type metastatic colorectal cancer remained outstanding. The applicant company, Merck Serono Limited, had requested an independent review on the grounds of 'process' which had been considered by the AWMSG Steering Committee. Communication with Merck Serono Limited is currently ongoing.

The Chairman reported that one statement of advice had been posted since the last AWMSG meeting confirming that colesevelam (Cholestagel®) is not endorsed for use within NHS Wales in combination with ezetimibe, with or without a statin, for the treatment of adult patients with primary hypercholesterolaemia, including patients with familial hypercholesterolaemia. The Chairman confirmed this would be removed on receipt of a submission or when final NICE guidance became available.

The appraisals scheduled for the next AWMSG meeting on 13th October 2010 were announced:

Olanzapine depot (ZypAdhera®) for maintenance treatment of adult patients with schizophrenia, stabilised on oral olanzapine
Applicant company: Eli Lilly & Co

Epoetin theta (Eporatio®) for the treatment of adult patients with symptomatic anaemia associated with chronic renal failure or those with non-myeloid malignancies receiving chemotherapy
Applicant company: Ratiopharm UK Ltd

5. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy. The Chairman signed the minutes as a true record of the previous meeting. There were no matters arising.

6. Appraisal 1 – Epoetin alfa (Binocrit®) for the treatment of anaemia associated with chronic kidney disease

The Chairman invited members to declare interests in either the applicant company or the medicine. There were none.

The Chairman welcomed delegates representing the applicant company, Sandoz Limited.

The Chairman announced the statement, pertinent to all appraisals, that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by the Minister for Health and Social Services, places an obligation on Health Boards to fund accordingly. It was confirmed that AWMSG advice is interim to final NICE guidance should this be subsequently published.

The Chairman reiterated that NMG had considered the clinical and cost effectiveness issues in detail and had taken account of medical expert and patient organisation views. Members were reminded not to repeat the detailed discussion held at NMG but to seek clarification of any outstanding issues in relation to clinical or cost-effectiveness, consider the company response to the preliminary recommendation and take into account societal and budget impact issues. The Chairman confirmed that the applicant company delegates would be invited to respond to and provide clarification of any issues raised. He confirmed that members would retire to vote in private and agree the recommendation, which would be subsequently announced

The Chairman invited Professor Dyfrig Hughes, who had Chaired the NMG preliminary appraisal, to present Enclosure **2**/AWMSG/0810, the preliminary appraisal report from the New Medicines Group Meeting held on Wednesday, 14th July 2010. Salient issues from the report were highlighted.

Professor Hughes provided an overview of the NMG appraisal and confirmed NMG's advice to AWMSG was that epoetin alfa (Binocrit®▼) should be recommended as an option for restricted use within NHS Wales for the treatment of symptomatic anaemia associated with chronic renal failure in adult and paediatric patients:

- Treatment of anaemia associated with chronic renal failure in paediatric and adult patients on haemodialysis and adult patients on peritoneal dialysis

- Treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis

Professor Hughes confirmed that NMG were of the opinion that epoetin alfa (Binocrit®▼) would not be suitable for shared care within NHS Wales and that epoetin alfa (Binocrit®▼) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance.

The Chairman opened the discussion and members were guided to raise specific issues in relation to clinical effectiveness. Clarification was sought in relation to comparable safety with regard to the reference product and the Chairman reminded members that collation of long term safety data is the responsibility of the MHRA. It was noted that there was no data in relation to paediatric patients and that the product is only licensed for intravenous use. The Chairman asked members to raise any issues in relation to cost effectiveness. Clarification was sought that the dose adjustment had been incorporated in to the economic model and that monitoring costs had been included in the budget impact. It was noted that an update to the NICE clinical guideline was expected in 2011 and that clinicians would be expected to adhere to NICE guidance in relation to dosage.

Ms Haines provided the context of the patient organisation submissions. The lay representative welcomed the detail of the patient organisation submissions. There was discussion in relation to the duplication of wording in the two submissions; for clarification it was confirmed that this was based on the same research. Members were asked to consider the views of the clinicians and it was noted that the projections were based on those provided by the Welsh Renal Registry.

It was noted that Sandoz Limited had not provided a written response to the PAR and the Chairman invited the applicant company delegates to respond to the issues raised by members and to highlight any other relevant information. Prior to closing the discussion, the Chairman sought confirmation that there were no outstanding issues and the appraisal process had been fair, open and transparent. The Chairman thanked the company for engaging in the AWMSG process and closed the appraisal.

Appraisal decision

The recommendation of AWMSG was announced:

Epoetin alfa (Binocrit®▼) is recommended as an option for restricted use within NHS Wales in accordance with NICE Clinical Guidance 39 for the treatment of symptomatic anaemia associated with chronic renal failure in adult and paediatric patients:

- Treatment of anaemia associated with chronic renal failure in paediatric and adult patients on haemodialysis and adult patients on peritoneal dialysis

- Treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis

AWMSG is of the opinion that epoetin alfa (Binocrit®▼) is not suitable for shared care within NHS Wales.

Epoetin alfa (Binocrit®▼) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance.

7. Appraisal 2 - filgrastim (TevaGrastim®)
For the treatment of neutropenia and for the mobilisation of peripheral blood progenitor cells

The Chairman welcomed the delegate representing the applicant company, Teva UK Limited.

The Chairman asked members to declare any specific, non-specific, personal or non-personal interests pertinent to the agenda. There were none.

The Chairman alluded to his previous statement and confirmed it was pertinent to all appraisals.

The Chairman invited Professor Dyfrig Hughes to present Enclosure **3**/AWMSG/0810, the preliminary appraisal report from the New Medicines Group Meeting held on Wednesday, 14th July 2010. Salient issues from the report were highlighted.

Professor Hughes provided an overview of the NMG appraisal and confirmed NMG's advice to AWMSG was that filgrastim (TevaGrastim®▼) should be recommended as an option for use within NHS Wales for the treatment of neutropenia:

- For reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and for the reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy.

- For the mobilisation of peripheral blood progenitor cells (PBPC).

- In children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of ≤ 0.5 x 10^9/l and a history of severe or recurrent infections, long term administration of TevaGrastim®▼ is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events.

- For the treatment of persistent neutropenia (ANC ≤ 1.0 x 10^9/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate.

Professor Hughes confirmed that NMG were of the opinion that filgrastim (TevaGrastim®▼) would not be suitable for shared care within NHS Wales and that filgrastim (TevaGrastim®▼) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance. Note was made that due to the potential for small differences between biosimilars from different manufacturers and/or the reference product (Neupogen®) post-marketing pharmacovigilance would be essential and should be facilitated by the Risk Management Plan.

The Chairman opened the discussion and members were guided to raise specific issues in relation to clinical effectiveness and cost effectiveness. Clarification was sought in relation to the risk management plan. The views of the clinical experts were considered. Members noted views of the patient organisation and the lay member welcomed the comprehensive submission from Leukaemia care. A brief positive response to the PAR had been received from Teva UK Limited. The Chairman invited the company delegate to respond to issues raised by members and the delegates addressed all the issues. Prior to closing the discussion, the Chairman was provided with confirmation that no issue remained outstanding and agreement that the appraisal process had been fair, open and transparent. The Chairman thanked Teva UK Limited for engaging in the AWMSG process and closed the discussion.

The recommendation of AWMSG was announced:

Filgrastim (TevaGrastim®▼) is recommended as an option for use within NHS Wales for the treatment of neutropenia:

- For reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and for the reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy.

- For the mobilisation of peripheral blood progenitor cells (PBPC).

- In children and adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of ≤ 0.5 x 10^9/l and a history of severe or recurrent infections, long term administration of TevaGrastim®▼ is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events.

- For the treatment of persistent neutropenia (ANC ≤ 1.0 x 10^9/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate.

AWMSG is of the opinion that filgrastim (TevaGrastim®▼) is not suitable for shared care within NHS Wales. Filgrastim (TevaGrastim®▼) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance.

8 Appraisal 3 - filgrastim (Zarzio®)
For the treatment of neutropenia and for the mobilisation of peripheral blood progenitor cells

The Chairman welcomed delegates representing the applicant company, Sandoz Limited.

The Chairman asked members to declare any specific, non-specific, personal or non-personal interests pertinent to the agenda. There were none. The Chairman alluded to his previous statement pertinent to all appraisals.

The Chairman invited Professor Dyfrig Hughes to present Enclosure **3**/AWMSG/0810, the preliminary appraisal report from the New Medicines Group Meeting held on Wednesday, 14th July 2010. Salient issues from the report were highlighted.

Professor Hughes provided an overview of the NMG appraisal and confirmed NMG's advice to AWMSG was that filgrastim (Zarzio®▼) should be recommended as an option for use within NHS Wales for the treatment of neutropenia:

- For the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia.

- For the mobilisation of peripheral blood progenitor cells (PBPC).

- In children and adults with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of ≤ 0.5 x 109/l, and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events.

- For the treatment of persistent neutropenia (ANC ≤ 1.0 x 109/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other therapeutic options are inappropriate.

Professor Hughes confirmed that NMG were of the opinion that filgrastim (Zarzio®▼) would not suitable for shared care within NHS Wales and that filgrastim (Zarzio®▼) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance. It was noted that due to the potential for small differences between biosimilars from different manufacturers and/or the reference product (Neupogen®), post-marketing pharmacovigilance would be essential and should be facilitated by the Risk Management Plan.

The Chairman opened the discussion and members were guided to raise specific issues in relation to clinical effectiveness. Members were invited to seek clarification in relation to issues around the clinical effectiveness of the medicine and budget impact. Members considered the views of the clinical experts. There were no broader societal issues of note.

The Chairman referred members to the comprehensive patient organisation submission from Leukaemia Care. The lay member had no comments other than to welcome this.

It was noted the applicant company had not provided a written response to the PAR. The Chairman invited company delegates to respond to the issues raised by members and to highlight any other relevant information.

Prior to closing the discussion, the Chairman sought confirmation from the company delegates that there were no outstanding issues and the appraisal process had been fair, open and transparent. The Chairman thanked Sandoz Limited for engaging in the AWMSG process and closed the appraisal.

The recommendation of AWMSG was announced:

Filgrastim (Zarzio®▼) is recommended as an option for use within NHS Wales for the treatment of neutropenia:

- For the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia.

- For the mobilisation of peripheral blood progenitor cells (PBPC).

- In children and adults with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of ≤ 0.5 x 109/l, and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events.

- For the treatment of persistent neutropenia (ANC ≤ 1.0 x 109/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other therapeutic options are inappropriate.

AWMSG is of the opinion that filgrastim (Zarzio®▼) is not suitable for shared care within NHS Wales.

Filgrastim (Zarzio®▼) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance.

9 Implementation Group Report

The Chairman invited Professor Roger Walker, Chairman of the Implementation Group, to update AWMSG on progress in relation to the work of the "Routledge Report" Implementation Group and seek advice on issues to be considered by the Group as they prepare advice for the Minister, particularly in relation to co-payments.

Professor Walker confirmed that the Implementation Group had produced their progress report in relation to "Improving the availability of medicines for patients in Wales" (Routledge report) in March 2010. The Minister for Health and Social Services had subsequently asked that progress with implementation should continue to be monitored to March 2011.

A summary of progress (as of March 2010) on each recommendation was presented:

- **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*. **Implementation status:** Funding approved by the Health Minister to ensure full implementation of the broadening of AWMSG appraisal process which is anticipated to be fully operational by October 2010.

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

advice adopted by AWMSG in February 2009 and subsequently in October 2009.

- **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.*
  Implementation status: Interim guidance outlining the principles for LHBs to adopt in considering and reviewing individual requests for exceptional funding was issued in October 2009 and the process is being further developed, with more guidance to follow in due course.

- **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.*
  Implementation status: Quantitative audit undertaken by the Welsh Medicines Partnership (WMP). All Wales Cancer Drugs Group to give consideration on how best to ensure this off label use is appropriate, evidence based and fair. To complete by December 2010.

- **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.* **Implementation status:** Further policy guidance is required on the issue of co-payments in Wales.

- **Recommendation 6:** *The implications for practice in Wales of the recommendations of the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report, which are now being considered by the regional cancer networks, should be reported to the Cancer Services Coordination Group (CSCG) within the next 12 months. This will inform the work needed to further improve the care of patients towards the end of life.*
  Implementation status: Recommendation implemented. The implications for practice have been considered and reported to CSCG in December 2009. The Implementation Group have received a report on progress against the NCEPOD recommendations and CSCG will continue to monitor progress as part of their performance level agreement with the Welsh Assembly Government and continuing work on chemotherapy.

- **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.* **Implementation status:** Proposed training programme has been developed and funding approved by the Minister for Health and Social Services. Delivery of the training programme will commence in September 2010.

- **Recommendation 8:** *The working relationships between AWMSG and CSCG, the All Wales Cancer Drug Group (AWCDG) and the regional cancer networks in Wales should be reviewed in order to ensure optimal collaboration and communication.*
  Implementation status: Recommendation implemented. The working relationships have been reviewed and arrangements agreed to ensure all parties work closely together. Future schedule of meetings agreed.

- **Recommendation 9:** *Communication between medicines appraisal bodies in the UK should be further strengthened, and areas for collaboration (eg horizon scanning) actively sought.*
  Implementation status: Implementation progressing well and will be ongoing. Communication has been strengthened through newly agreed annual meetings and

development of memoranda of understanding. Further opportunities to progress collaboration are being explored.

- **Recommendation 10:** *The core principles of schemes (eg 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.*
  Implementation status: Implementation progressing strongly with core principles of such schemes being considered alongside developments in NICE and Department of Health.

- **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.*
  Progress on implementation: Recommendation fully implemented. An enhanced communications strategy has been developed and approved by AWMSG in March 2010.

Members were informed that the Minister had noted the Implementation Group had considered issues in relation to 'co-payments' (Recommendation 5). The Group were subsequently invited to fully consider the legal and ethical framework and clarify the procedure for patients wishing to fund private packages of care. Professor Walker confirmed this report would be submitted by November 2010. The variance across Health Boards of implementation of guidelines on co-payments was noted. Professor Walker confirmed that legal advisers were informing the process and invited comment outside of the meeting from AWMSG members and the audience.

Professor Walker confirmed that the Implementation Group, with a revised membership, had reconvened in July 2010 and re-addressed the issue of co-payment. It was noted that the Group are consulting widely with patient groups, charities, individual patients, clinicians and seeking advice on related legal and ethical issues. There was discussion in relation to publicity, requirement for improvement in communications and reduction of waste.

The Chairman closed the discussions and thanked Professor Walker for the update.

10 Update from AWPAG

The Chairman invited Dr Tessa Lewis to highlight the salient issues within the draft minutes of the AWPAG meeting held on 7th July 2010, Enc **5/**AWMSG/0810.

11 Prescribing amiodarone in historical patients

The Chairman invited Dr Lewis to present Enc **7**/AWMSG/0810. It was noted that amiodarone has an important place in the treatment of severe cardiac rhythm disorders where other treatments either cannot be used or have failed. Historically it had been prescribed as a first-line treatment for atrial fibrillation, often started intravenously to treat an acute episode and then continued as tablets; however its use requires regular monitoring due to potential major toxicity. Therapeutic monitoring of a basket of drugs is covered by a National Enhanced Service for Near Patient Testing, but this does not currently include amiodarone. Audit and review of patients taking amiodarone in several areas had revealed inconsistent monitoring. Both primary and secondary care clinicians had recognised that it would be beneficial to review all patients taking amiodarone in Wales to establish the need for ongoing treatment. The document presented to AWMSG had been developed to assist this process.

Dr Lewis provided the background - AWMSG had approved a shared care agreement for amiodarone in June 2008 with recommendations for treatment initiation and therapeutic monitoring by specialists and GPs. Welsh cardiologists had endorsed the shared care agreement in the following circumstances:

Patients receiving amiodarone for life-threatening arrhythmias would normally be reviewed (annually) by cardiologists. For remaining indications where lifelong treatment is appropriate, but hospital review practically difficult, consultants may in individual cases, after agreement with the relevant general practitioner, decide to discharge a patient to primary care monitoring, with urgent access to advice and /or review from the initiating department.

It was confirmed that prescribing support teams and cardiologists had agreed the criteria for reviewing patients and the basis for switching treatment. Pharmacists had completed a review of all the GP clinical records of patients taking amiodarone, collecting the relevant data and subsequently agreeing a management plan with the patient's GP, with cardiologists available to offer advice as necessary.

Recognition was given to AWPAG and the contributors for the invaluable information. AWMSG endorsed the document and agreed that it should be made available to NHS Wales.

12 AWMSG Constitution update

The Chairman referred members to the updated AWMSG Constitution which had been reviewed and updated by the AWMSG Steering Committee to reflect policy and structural changes within NHS Wales. Members were informed that the membership had increased to include a clinical pharmacologist and a community pharmacist. It was noted that the quorum would increase to 9 voting members. The Chairman confirmed that changes to the Constitution required the approval of the Minister for Health and Social Services.

Date of next AWMSG meeting:
Wednesday, 13th October at 10.30am in The Angel Hotel, Abergavenny

Subsequent meeting date:
Wednesday 15th December 2010