Enclosure No:	**1/AWMSG/XXXX**
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, 23rd JUNE 2010 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY

MEMBERS PRESENT:

			Did not participate in
1.	Dr Phillip Banfield	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 Bruce Ferguson	Trust Medical Director	
6.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health	
7.	Dr Brian Hawkins	Senior Primary Care Pharmacist	
8.	Cllr Meurig Hughes	Lay representative	
9.	Dr Thomas Lau	General Practitioner with prescribing lead role	
10.	Prof Philip Routledge	Clinical Pharmacologist (Chairman)	
11.	Mr Guy Thompson	ABPI (Wales) representative	**6**
12.	Mrs Wendy Warren	Senior Nurse	
13	Mr Roger Williams	Chief Pharmacist	

IN ATTENDANCE:

15.	Dr Dyfrig Hughes	Acting NMG Chairman
16.	Mr Jeremy Savage	Welsh Assembly Government
17.	Mrs Fiona Woods	Welsh Medicines Partnership
18.	Mrs Ruth Lang	Welsh Medicines Partnership
19.	Mrs Karen Samuels	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 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 (Mr Roger Williams deputised)
Dr Paul Buss (Dr Phillip Banfield deputised)
Mr Robert Holcombe, Finance representative
Professor Ceri Phillips, Health Economist
Mr Russell Pope, Welsh Assembly Government

3. Declarations of interest

The Chairman asked members to declare any specific, non-specific, personal or non-personal interests pertinent to the agenda. Mr Guy Thompson declared a personal interest in relation to Pfizer Limited and the appraisal of sildenafil (Revatio®▼). The Chairman confirmed that Mr Thompson would be unable to participate in this appraisal.

4. Chairman's report

The Chairman confirmed that a workshop held in Abergavenny on 13th May 2010 had allowed opportunity for key individuals to input into the implementation and development of the broadened appraisal process. It was confirmed an update of progress to date would be presented by Kath Haines, WMP's Project Manager, later in the meeting

The Chairman confirmed that membership and constitutional issues in relation to AWMSG and its sub-groups were under consideration. The Chairman confirmed that the term of office for members appointed at the inception of AWMSG and AWPAG is due to expire. It was announced that WMP would be seeking nominations via Medicines and Therapeutics Committees over the next couple of weeks and a notice would be posted on the AWMSG website.

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

Paclitaxel albumin (Abraxane®) monotherapy **is recommended** as an option for use within NHS Wales for the treatment of metastatic breast cancer in patients who have failed first-line treatment for metastatic disease and for who standard, anthracycline containing therapy is not indicated.

AWMSG is of the opinion that paclitaxel albumin (Abraxane®) is not suitable for shared care within NHS Wales.

Clinicians should follow the National Institute for Health and Clinical Excellence (NICE) Guidelines CG81 in the consideration of treatment options for metastatic breast cancer.

The Summary of Product Characteristics specifically states that this drug should be used as monotherapy.

In order to limit potential errors, paclitaxel albumin (Abraxane®) should be prescribed by brand as Abraxane®.

Bortezomib (Velcade®▼) is recommended as an option for use within NHS Wales in combination with melphalan and prednisone* for the treatment of patients with previously untreated multiple myeloma (MM) who are not eligible for high-dose chemotherapy (HDT) with bone marrow transplant (BMT).

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

***** *The licence and trials specify the use of prednisone. This is not available in the UK, where a direct substitution of prednisolone for prednisone is made as they are considered dose-equivalent*.

Pramipexole prolonged release (Mirapexin prolonged release®) is recommended as an option for use within NHS Wales for the treatment of the signs and symptoms of idiopathic Parkinson's disease, alone or in combination with levodopa.

Pramipexole prolonged release should be initiated by a specialist experienced in the treatment of Parkinson's disease. AWMSG is of the opinion that pramipexole prolonged release may be suitable for shared care in accordance with appropriate local guidance.

In order to limit potential errors, pramipexole prolonged release should be prescribed by brand as Mirapexin prolonged release®.

Enoxaparin (Clexane®) is recommended as an option for use within NHS Wales for the treatment of acute ST-segment elevation myocardial infarction (STEMI).

AWMSG is of the opinion that enoxaparin (Clexane®) is not suitable for shared care within NHS Wales.

Fentanyl intranasal spray (Instanyl®▼) is recommended as an option for use within NHS Wales for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain.

Fentanyl intranasal spray (Instanyl®▼) should only be considered as an option for the management of breakthrough cancer pain when immediate release oral opioids (e.g. morphine, oxycodone) are either inadequate or unsuitable.

Fentanyl intranasal spray (Instanyl®▼) may be suitable for shared care but should be initiated by, and remain under the supervision of, a physician experienced in the management of opioid therapy in cancer patients.

Epoetin zeta (Retacrit®▼) is not recommended for use within NHS Wales for the treatment of anaemia associated with chronic kidney disease, reduction of transfusion requirements in adult patients receiving chemotherapy or to increase the yield of autologous blood from patients in a predonation programme. The case for cost effectiveness of epoetin zeta (Retacrit®▼) has not been proven.

The Chairman confirmed the Final Appraisal Reports had been posted on the AWMSG website and the Service notified.

The Chairman announced the appraisals scheduled for the next AWMSG meeting on Wednesday 18th August 2010:

Epoetin alfa (Binocrit®▼) for the treatment of symptomatic anaemia associated with chronic renal failure.
Manufacturer: Sandoz Ltd

Filgrastim (Zarzio®▼) for the treatment of neutropenia and mobilisation of peripheral blood progenitor cells.
Manufacturer: Sandoz Ltd

Filgrastim (TevaGrastim®▼) for the treatment of neutropenia and mobilisation of peripheral blood progenitor cells.
Manufacturer: Teva UK Ltd

The Chairman announced that the Report of the Implementation Group, Chaired by Professor Roger Walker, Public Health Wales, to progress the recommendations of the Expert Group in relation to Access to Medicines had been released and would be available on the AWMSG website.

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 – Sildenafil (Revatio®▼)

For the treatment of pulmonary arterial hypertension (WHO functional class II or III) to improve exercise capacity
Manufacturer: Pfizer Ltd

The Chairman welcomed the delegate representing the manufacturer, Pfizer Ltd.
Mr Guy Thompson left the meeting.

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 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 Dr Dyfrig Hughes, who had Chaired the NMG preliminary appraisal, to present Enclosure **2**/AWMSG/0610, the preliminary appraisal report from the New Medicines Group Meeting held on Wednesday, 19th May 2010. Salient issues from the report were highlighted.

Dr Hughes provided an overview of the NMG appraisal and confirmed NMG's advice to AWMSG was that Sildenafil (Revatio®▼) should be recommended, within its current licensed indication, as an option for use within NHS Wales for the treatment of pulmonary arterial hypertension (WHO functional class II or III) to improve exercise capacity. NMG had recommended that its use be restricted to a physician experienced in the treatment of PAH at one of the National Commissioning Groups across the UK. NMG was of the opinion that sildenafil (Revatio®▼) would not be suitable for shared care within NHS Wales.

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 relevant benefit of ambrisentan in Class III patients, the reasons for the choice of measures and benefits in practice relating to quality of life. Dr Carroll declared his involvement in studies in relation to PAH and provided clarification to some of the clinical issues raised, particularly in relation to liver impairment and renal impairment. The range of doses used in clinical practice was discussed. The Chairman confirmed the remit of AWMSG is to appraise medicines within their licensed indication. The limitations of the health economic submission were highlighted.

The Chairman asked members to address issues in relation to the case for cost effectiveness and it was noted there had been no formal indirect comparison and the analysis had been limited to one year.

The Chairman invited comment in relation to budget impact. Dr Carroll questioned the estimated patient population used in the submission. and confirmed that currently there 118 patients on the therapy. Dr Carroll highlighted the move towards combination therapy. It was noted that the budget impact in Wales would be significant. Dr Carroll clarified the Welsh context relating to primary investigation for patients. Members discussed the summary of medical expert opinion.

It was confirmed that no patient organisation submission had been received. The lay member expressed disappointment that no submission had been received from patients, their carers or support groups. The AWMSG Secretariat had provided members with a list of patient organisations contacted. Dr Carroll confirmed that patient organisations are fully involved in the development of UK wide treatment pathways for patients.

The Chairman drew members' attention to the company response to the PAR and invited the applicant company delegates to respond to the issues raised by members and to highlight any other relevant information.

The company delegate provided their rationale for using ambrisentan as the comparator and responded to all the issued raised in the discussion. There was an acknowledgement that the company estimate of patient numbers was less than that alluded to in the commissioning report. There was discussion in relation to the wording of the preliminary recommendation and it was confirmed that the views of the independent clinical expert had been sought to ensure that the wording of a potential positive recommendation would be flexible enough to allow for monitoring arrangements to be shared between specialist centres.

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 the company for engaging in the AWMSG process and closed the appraisal.

Mr Guy Thompson joined the meeting.

Appraisal decision

The recommendation of AWMSG was announced:

Sildenafil (Revatio®▼) is recommended, within its current licensed indication, as an option for use within NHS Wales for the treatment of pulmonary arterial hypertension (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.

7. Appraisal 2 - Raltegravir (Isentress®▼)
In combination with other antiretrovirals for the treatment of HIV-1 infection in adults

Manufacturer: Merck Sharpe & Dohme Ltd

The Chairman welcomed delegates representing the manufacturer, Merck Sharpe & Dohme Ltd.

The Chairman asked members to declare any specific, non-specific, personal or non-personal interests pertinent to the agenda. There were none. 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 invited Dr Dyfrig Hughes to present Enclosure **3**/AWMSG/0610, the preliminary appraisal report from the New Medicines Group Meeting held on Wednesday, 19th May 2010. Salient issues from the report were highlighted.

Dr Hughes provided an overview of the NMG appraisal and confirmed NMG's advice to AWMSG was that raltegravir (Isentress®▼) should not be recommended for use within NHS Wales for the treatment of human immunodeficiency virus (HIV-1) infection in treatment-naïve adult patients. Dr Hughes confirmed that NMG considered the case for cost effectiveness of raltegravir (Isentress®▼) had not been made in treatment-naïve patients. Clarification was provided that current AWMSG advice in relation to the use of raltegravir (Isentress®▼) in treatment-experienced adult patients with human immunodeficiency virus (HIV-1) infection would remain unchanged.

The Chairman opened the discussion and members were guided to raise specific issues in relation to clinical effectiveness. Members sought clarification in relation to the scope of the submission and asked the company delegates to explain their interpretation of 'treatment naïve' and 'treatment experienced'. The issue of treatment in small groups of patients was raised. The limitations of the cost effectiveness evidence provided in the submission were highlighted and the appropriateness of the cost minimisation analysis was questioned. Members discussed issues relating to budget impact and considered the views of the medical experts.

The Chairman referred members to the comprehensive patient organisation submission from the Terrence Higgins Trust. The lay member commended the Terrence Higgins Trust in providing a comprehensive and valuable submission.

The Chairman drew members' attention to the applicant company response to the PAR and invited company delegates to respond to the issues raised by members and to highlight any other relevant information. Clarification of the terms treatment naïve and treatment experienced was provided and members were asked to note that the submission had focussed on a small group of 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**.** It was confirmed that the licence did not include pregnant patients.

It was confirmed there had been significant communication between the AWMSG Secretariat and the applicant company during the development of the report and in clarifying the scope of the appraisal.

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 the company for engaging in the AWMSG process and closed the appraisal.

The recommendation of AWMSG was announced:

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.

8 Appraisal 3 - Cetuximab (Erbitux®▼)

For third-line treatment of patients with KRAS wild-type metastatic colorectal cancer

Manufacturer: Merck Serono Ltd

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

The Chairman announced the statement pertinent to all appraisals - 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 invited Dr Dyfrig Hughes to present Enclosure **4**/AWMSG/0610, the preliminary appraisal report from the New Medicines Group Meeting held on Wednesday, 19th May 2010. Salient issues from the report were highlighted.

Dr Hughes provided an overview of the NMG appraisal and confirmed NMG's advice to AWMSG was that cetuximab (Erbitux®▼) should not be recommended for use within NHS Wales for third-line treatment of patients with epidermal growth factor receptor (EGFR)-expressing, Kirsten Rat Sarcoma (KRAS) wild-type metastatic colorectal cancer. NMG considered the case for cost effectiveness had not been proven for the use of cetuximab as either monotherapy or as combination therapy.

Dr Hughes confirmed the view of NMG was that cetuximab (Erbitux®▼) did not meet the criteria for appraising life extending, end of life treatments as the cumulative population for each licensed indication, including head and neck cancer and first-line use in colorectal cancer, was not considered sufficiently small.

The Chairman opened the discussion and members were guided to raise specific issues in relation to clinical effectiveness and cost effectiveness. There was discussion in relation to targeting patients most likely to benefit and perceived benefits in terms of the clinical effectiveness. The views of the medical expert were considered.

Members discussed the applicability of the NICE criteria for appraising life-extending, end of life treatments. Members were informed by the AWMSG Secretariat that medical expert views sought had concurred with the view of the NMG that the submission did not meet the NICE criteria for appraisal of end of life treatments. There was discussion in relation to budget impact and potential for recruitment into future trials.

The lay member expressed disappointment at the lack of a patient organisation submission. The Chairman requested that individual patients or carers should not be identified.

The Chairman referred to the applicant company response to the preliminary appraisal report and invited the delegates to respond to issues raised by members. The delegates addressed all the issues and, prior to closing the discussion, provided the Chairman with confirmation that no issue remained outstanding. The company delegates agreed that the appraisal process had been fair, open and transparent and opportunity had been afforded to them to highlight and respond to the salient issues raised. The Chairman thanked them for engaging in the AWMSG process and closed the discussion.

The recommendation of AWMSG was announced:

Cetuximab (Erbitux®▼) is not recommended for use within NHS Wales for third-line treatment of patients with epidermal growth factor receptor (EGFR)-expressing, Kirsten Rat Sarcoma (KRAS) wild-type metastatic colorectal cancer.

The case for cost effectiveness had not been proven for the use of cetuximab as either monotherapy or as combination therapy.

The Chairman announced that confirmation of the AWMSG recommendations (in the Final Appraisal Reports) would be forwarded to the applicant companies on or before Wednesday, 30th June. It was reiterated that the applicant companies had until Wednesday, 7th July to accept the recommendation or lodge a request for an independent review which should be submitted in writing to the Chairman via the AWMSG Secretariat (WMP). It was confirmed that the process would not be delayed if companies failed to respond within the deadline and, subject to receiving a request for an independent review within the appropriate timelines, the Final Appraisal Report would be passed to the Minister for Health and Social Services on Thursday, 8th July for ratification.

The Chairman concluded appraisal proceedings by thanking the applicant companies for engaging with the AWMSG process.

9 Update from AWPAG

The Chairman invited Dr Tessa Lewis to highlight the salient issues within the draft minutes of the AWPAG meeting held on 21st April 2010, Enc **5/**AWMSG/0610. Dr Lewis drew members' attention to the draft notes and confirmed that the next meeting would be held on 7th July 2010. The Chairman asked that his thanks be conveyed to AWPAG for their hard work and enthusiasm in progressing important issues in relation to prescribing and medicines managements.

10 Report on the National Medicines Management Programme

The Chairman invited Mr Jeremy Savage, Acting Chief Pharmaceutical Adviser, Welsh Assembly Government, to provide an overview of the programme, Enc **6**/AWMSG/0610. Mr Savage confirmed the roles and responsibilities of the National Medicines Management Programme and clarified the alignment of the Programme with the All Wales Medicines Strategy Group, its strategy and the health board leads. Mr Savage provided the background to the establishment of the Programme and explained the work themes. It was noted that three

meetings had been held to date. The main objective of delivering efficiencies out of the use of medicines across Wales was clarified. There was discussion in relation to the focus on delivery, benchmarking, sharing good practice and avoiding duplication of effort. It was noted that the Minister for Health and Social Services had agreed to fund a waste campaign. The industry representative asked whether interaction with industry in relation to the work of the group could be explored. The Chair closed the discussion with a suggestion that a mechanism be established to ensure close communication between the groups so that the programme achieves its objectives and has the support and input of AWMSG and AWPAG.

11 Update report on the broadening of the AWMSG appraisal process

The Chairman invited Mrs Kath Haines, WMP Senior Pharmacist and Project Manager, to update members on progress in relation to broadening the appraisal remit of AWMSG. Mrs Haines referred members to the discussion document, Enc **7**/AWMSG/0610, and reiterated the need to extend the pool of membership for AWMSG and its sub-groups and informed members that a notice would be posted on the AWMSG website and circulated to MTCs seeking nominations. Mrs Haines confirmed that she had attended two MTC meetings to date to update on progress and ensure close communication with the service in developing the broadened remit of AWMSG. Industry engagement and collaborative working via the TDA Users Group was noted.

Date of next AWMSG meeting:
Wednesday, 18th August 2010 at 10.30am in The Angel Hotel, Abergavenny

Subsequent meeting date:
Wednesday 13th October 2010