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, 28th APRIL 2010 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY

MEMBERS PRESENT:

			Did not participate in
1.	Dr Hugo Van Worden	Welsh Health Specialised Services representative	
2.	Dr Fraser Campbell	LHB Medical Director	
3	Ms Debbie Davies	representing other professions eligible to prescribe	
4.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health	
5.	Dr Brian Hawkins	Senior Primary Care Pharmacist	
6.	Mr Robert Holcombe	Finance Director	
7.	Cllr Meurig Hughes	Lay representative	
8.	Prof Ceri Phillips	Health Economist	
9.	Prof Philip Routledge	Clinical Pharmacologist (Chairman)	
10.	Mr Guy Thompson	ABPI (Wales) representative	
11.	Mrs Wendy Warren	Senior Nurse	
12	Mr Roger Williams	Chief Pharmacist	

IN ATTENDANCE:

13.	Dr Martin Duerden	NMG Chairman
14.	Mr Russell Pope	Welsh Assembly Government
15.	Mrs Kath Haines	Welsh Medicines Partnership
16.	Mrs Ruth Lang	Welsh Medicines Partnership
17.	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
LHB	Local Health Board
M&TCs	Medicines & Therapeutics Committees
MHRA	Medicines & Herbals Regulatory Authority
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
UHB	University Health Board
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)
Mr Jeremy Savage (Welsh Assembly Government)
Dr Geoffrey Carroll (Dr Hugo Van Worden deputising)
Dr Paul Buss (Hospital Consultant)
Dr Bruce Ferguson (Medical Director)
Dr Tom Lau (GP with prescribing lead role)

3. Declarations of interest

The Chairman asked members to declare any specific, non-specific, personal or non-personal interests pertinent to the agenda.

A non-personal non-specific interest was declared by Debbie Davies in relation to Boehringer Ingelheim Limited.

A personal non-specific interest was declared by Guy Thompson in relation to Sanofi Aventis and the Chairman confirmed that Mr Thompson would be unable to participate in the appraisal of enoxaparin (Clexane®).

4. Chairman's report

The Chairman confirmed that invitations to attend a workshop to be held in Abergavenny on 13th May 2010 had been issued to AWMSG members and other key individuals to ensure broad input and representation into the implementation and development of the broadened appraisal process. An implementation date of 1st October was announced.

The Chairman reported that Dr Martin Duerden had accepted the post of Assistant Medical Director (Primary Care) for Conwy and Denbighshire. As a consequence, Dr Duerden had tendered his resignation as Chairman of the New Medicines Group. The Chair conveyed his his thanks to Dr Duerden, who had chaired NMG since its inception in 2007.

It was reported that WMP had received written confirmation that fixed funding until March 2011 had been made available by Welsh Assembly Government for the delivery of four specific projects under the auspices of the Welsh Analytical Prescribing Support Unit to encourage the safe and effective prescribing across NHS Wales of proton pump inhibitors (PPIs), non steroidal anti-inflammatory medicines (NSAIDs), and hypnotics and anxiolytics. Members were informed that the 4th project involves the monitoring of the managed introduction and uptake of medicines following Ministerial ratification of a positive AWMSG recommendation.

Members were informed that an audit template to monitor the prescribing of NSAIDs, endorsed by AWMSG in March, had been posted on the AWMSG website. The Chairman encouraged practices to submit the data to their HoPMM by 31st October 2010 and asked members to assist in raising awareness of this important audit within their organisations.

The Chairman confirmed that the national indicator paper, available on the AWMSG and Health Solutions Wales website, had been updated in light of AWMSG's decision to remove escitalopram from the chiral indicator basket. Subsequent to the March AWMSG meeting, Lundbeck had provided outline examples of monitoring models used in England, which were considered by AWPAG at their meeting on 21st April. Dr Tessa Lewis, Chair of AWPAG, will be reporting the issues from this meeting to AWMSG in June, as there was insufficient time between the two meetings for the minutes to be prepared and made available to AWMSG. AWPAG had sight of the update to the medicines strategy document which will be presented to AWMSG later in the meeting, and offered to work with WMP in reconsidering the appropriateness and prioritisation of the recommendations.

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

Plerixafor (Mozobil®▼) is recommended as an option for restricted use within NHS Wales in combination with granulocyte-colony stimulating factor (G-CSF) to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma whose cells mobilise poorly.

Plerixafor (Mozobil®▼) should be restricted for use specifically in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM) who have already failed one complete mobilisation attempt. AWMSG is of the opinion that plerixafor (Mozobil®▼) is not suitable for shared care within NHS Wales.

Etanercept (Enbrel®▼) is not recommended for use within NHS Wales for the treatment of chronic severe plaque psoriasis in children and adolescents from the age of eight years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. The cost effectiveness data presented was insufficient for AWMSG to recommend the use of etanercept (Enbrel®▼) in NHS Wales.

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

The Chairman reported that five advisory notices in relation to medicines not endorsed for use have been posted since the last AWMSG meeting. He clarified that notices are issued if appraisal by AWMSG (or NICE) had not been progressed within the required timescale (i.e. 3 months from receipt of the licence):

Amifampridine (Firdapase®▼) for the symptomatic treatment of Lambert-Eaton Myasthenic Syndrome

Quetiapine prolonged release (Seroquel XL®) for the prevention of the recurrence of bipolar disorder

Quetiapine (Seroquel®) for the prevention of the recurrence of bipolar disorder

Silodosin (Siloydyx®/Urorec®) for the treatment of benign prostatic hyperplasia

Tadalafil (Adcirca®) for the treatment of pulmonary arterial hypertension (PAH)

It was confirmed that the notice would be removed on receipt of a full submission (i.e. Form A and B) or when final NICE guidance becomes available.

The Chairman announced the appraisals scheduled for the next AWMSG meeting on **Wednesday 23rd June 2010**:

Sildenafil (Revatio®▼) for the treatment of pulmonary arterial hypertension (WHO functional class II or III) to improve exercise capacity

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

Cetuximab (Erbitux®) for third-line treatment of patients with KRAS wild-type metastatic colorectal cancer

5. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy. It was noted the timings of the appraisals were incorrect. No further changes were made. The Chairman signed the amended minutes as a true record of the previous meeting.

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 UHBs 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

6. Appraisal 1 – Paclitaxel albumin (Abraxane®)

Paclitaxel albumin (Abraxane®) monotherapy is indicated for the treatment of metastatic breast cancer in patients who have failed first-line treatment for metastatic disease and for whom standard, anthracycline-containing therapy is not indicated

The Chairman welcomed delegates representing the manufacturer, Abraxis BioScience 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 invited Dr Martin Duerden to present Enclosure **2**/AWMSG/0410, the preliminary appraisal report from the New Medicines Group Meeting held on Wednesday, 17th March 2010. Salient issues from the report were highlighted.

Dr Duerden provided an overview of the NMG appraisal and confirmed NMG's advice to AWMSG was that paclitaxel albumin (Abraxane®) monotherapy should be 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 whom standard, anthracycline containing therapy is not indicated. He confirmed NMG's opinion that paclitaxel albumin (Abraxane®) would not be suitable for shared care within NHS Wales. NMG had agreed that clinicians should follow the National Institute for Health and Clinical Excellence (NICE) Guidelines CG81 in the consideration of treatment options for metastatic breast cancer. It was noted the summary of product characteristics specifically states that this medicine should be used as monotherapy.

The Chairman opened the discussion and members were guided to raise specific issues in relation to clinical effectiveness and cost effectiveness. The lay member drew members' attention to the comprehensive patient organisation submission from Breast Cancer Care. Members noted the summary of medical expert opinion and the applicant company response to the preliminary appraisal report. On closing the discussion, the Chairman invited delegates from the applicant company to respond to the issues raised and highlight any outstanding issue. Prior to concluding the appraisal the Chairman asked the company delegates to confirm that all the issues had been clarified and that the process had been fair, open and transparent.

Appraisal decision

The recommendation of AWMSG was announced:

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®.

7. Appraisal 2 - Bortezomib (Velcade®▼)

Bortezomib (Velcade®▼) in combination with melphalan and prednisone* is indicated 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).

***** *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.*

The Chairman welcomed delegates representing the manufacturer, Janssen-Cilag 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 invited Dr Martin Duerden to present Enclosure **3**/AWMSG/0410, the preliminary appraisal report from the New Medicines Group Meeting held on Wednesday, 17th March 2010. Salient issues from the report were highlighted. Dr Duerden provided an overview of the NMG appraisal and alluded to the views of the patient support group and the medical expert. In concluding, Dr Duerden confirmed that the view of NMG was that bortezomib (Velcade®▼) should be 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). It was noted NMG was of the opinion that bortezomib (Velcade®▼) is not suitable for shared care within NHS Wales. Dr Duerden conveyed the view of NMG that clinicians should consider recruiting patients for entry into trials, where appropriate.

The Chairman opened the discussion and members invited to raise any outstanding issues in relation to clinical effectiveness. The applicant company delegates were asked to clarify the context of the comparator. There were no outstanding issues in relation to cost effectiveness or budget impact. The lay member drew attention to the comprehensive patient interest group submission from Myeloma UK, in particular the number of patients eligible. Members noted the summary of medical expert opinion. Delegates from the applicant company were invited to clarify issues raised in the discussion and a representative from the Welsh Medicines Partnership responded to the points within the company response to the preliminary appraisal report.

Delegates from the applicant company responded to the issues highlighted by members and provided clarification in relation in to the comparator. Prior to closing the discussion, the company delegates confirmed there were no outstanding issues and agreed the appraisal process had been fair, open and transparent. The Chairman thanked the company for engaging in the AWMSG process and closed the discussion.

Appraisal decision

The recommendation of AWMSG was announced:

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* †.

Additional note:

- Clinicians should consider recruiting patients for entry into trials, where appropriate.

8 Appraisal 3 - Pramipexole (Mirapexin®) prolonged release

For treatment of the signs and symptoms of idiopathic Parkinson's disease (PD), alone (without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or “on off” fluctuations)

The Chairman welcomed delegates representing the manufacturer, Boehringer Ingelheim Ltd.

Members were reminded to declare any interests. A non-personal non-specific interest was declared by Mrs Debbie Davies in relation to Boehringer Ingelheim Ltd. The Chairman confirmed that Mrs Davies would be able to participate in the appraisal.

The Chairman invited Dr Duerden to highlight salient issues contained within Enclosure **4**/AWMSG/0410, the preliminary appraisal report of the New Medicines Group. Dr Duerden provided an overview of the discussions at NMG. It was noted that the views of four specialists had been considered by NMG. A patient organisation questionnaire, submitted by the European Parkinsons Disease Association had supported the availability of pramipexole (Mirapexin®) prolonged release and highlighted the benefits of its use. Dr Duerden concluded by confirming NMG’s view that Pramipexole prolonged release (PR) (Mirapexin prolonged release®) should be 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. The view of NMG was that Pramipexole PR should be initiated by a specialist experienced in the treatment of Parkinson's disease. It was noted that NMG considered that pramipexole PR may be suitable for shared care in accordance with appropriate local guidance. A suggestion was that that in order to limit potential errors, pramipexole PR should be prescribed by brand as Mirapexin prolonged release®.

The Chairman opened the discussion and members sought clarification in relation to clinical effectiveness and cost effectiveness issues. It was confirmed that quality of life data is currently being collated by the company. The lay member welcomed the concise submission from the European Parkinson's Disease Association, particularly the dosage information. There were no comments in relation to the medical expert summary. The Chairman drew members' attention to the response by the applicant company and asked members to consider societal and budget impact issues. The company delegates responded to the discussion and confirmed that the black triangle should be removed. Representatives from WMP confirmed that the report would be amended to reflect this update.

Prior to closing the discussion, the company delegates confirmed there were no outstanding issues and agreed the appraisal process had been fair, open and transparent. The Chairman thanked the company for engaging in the AWMSG process and closed the discussion.

Appraisal decision

The recommendation of AWMSG was announced:

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®.

9 Appraisal 4 - Enoxaparin (Clexane®)

For the treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI) in conjunction with thrombolytic drugs (fibrin or non-fibrin specific).

It was noted that other licensed indications for enoxaparin can be found in the summary of product characteristics (SPC).

It was confirmed that the company submission focused on the use of enoxaparin in patients with STEMI, which is a licence extension

The Chairman welcomed delegates from the manufacturer, Sanofi-Aventis.

The Chairman reminded members to declare interests in either the manufacturer or the medicine. Mr Guy Thompson confirmed a non specific personal interest in that Pfizer produce a competitor product. The Chairman confirmed Mr Thompson would be unable to participate in the appraisal he left the room.

The Chairman invited Professor Ceri Phillips to highlight salient issues within the preliminary appraisal report, Enc **5**/AWMSG/0410. Professor Phillips provided an overview. It was noted that three medical experts had provided views and a completed questionnaire from Anticoagulation Europe (UK) had been received and considered as part of the appraisal process. In concluding his address, Professor Phillips confirmed NMG's advice to AWMSG was that enoxaparin (Clexane®) should be recommended as an option for use within NHS Wales for the treatment of acute ST-segment elevation myocardial infarction (STEMI). NMG

considered that enoxaparin (Clexane®) is not suitable for shared care within NHS Wales. It was noted that the National Institute for Health and Clinical Excellence (NICE) Clinical Guideline on 'Unstable angina and non-ST segment elevation myocardial infarction (NSTEMI)' is anticipated in March 2010.

The Chairman opened the discussion and members were guided to raise specific issues in relation to clinical effectiveness and cost effectiveness. The lay member drew members' attention to the patient organisation submission from Anticoagulation Europe (UK) and confirmed he had no further comment. It was confirmed that MHRA approval in relation to the use of enoxaparin (Clexane®▼) by paramedics was awaited. There were no other outstanding societal issues. Members noted the summary of medical expert opinion and the applicant company response to the preliminary appraisal report. The Chairman invited the company delegates to respond to the issues raised in the discussion and highlight any outstanding issues.

Prior to closing the discussion, the company delegates confirmed there were no outstanding issues and agreed the appraisal process had been fair, open and transparent. The Chairman thanked the company for engaging in the AWMSG process and closed the discussion.

Appraisal decision

The recommendation of AWMSG was announced:
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.

10 Appraisal 5 - Fentanyl (Instanyl®▼)
for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain

The Chairman welcomed delegates representing the manufacturer, Nycomed UK Ltd.

The Chairman reminded members to declare any interests. There were none.

The Chairman invited Dr Duerden to highlight salient issues contained within Enclosure **6**/AWMSG/0410, the preliminary appraisal report of the New Medicines Group. Dr Duerden provided an overview of the discussions at NMG and alluded to the views of the medical experts and patient organisation. He concluded by confirming that NMG was of the opinion that Fentanyl intranasal spray (Instanyl®▼) should 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. NMG was of the opinion that fentanyl intranasal spray (Instanyl®▼) should be initiated by, and remain under the supervision of, a physician experienced in the management of opioid therapy in cancer patients. Dr Duerden conveyed NMG's view that 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.

The Chairman opened the discussion and members sought clarification of issues relating to clinical effectiveness. Delegates from Nycomed UK Ltd responded to the issues raised. Clarification was sought in relation to the safety issues in children and disposal of the medicine. There was a suggestion that the applicant company could feedback to AWMSG in relation to the medicines management in the community. Company delegates justified the use of the

comparator and clarified data provided in relation to dosing. The Chairman invited comments in relation to cost effectiveness. Members noted the comprehensive submission received from Myeloma UK and the lay member confirmed he had no further comment. Medical expert views had been summarised and provided to AWMSG members. There was discussion with regard to the administration and use of the medicine in relation to shared care. Members were referred to the SmPC wording in relation to administering the medicine. Delegates from Nycomed UK Ltd responded to the issues raised in the discussion.

It was noted that the applicant company had not responded to the ASAR during the earlier stages of the appraisal process and had highlighted typographical and technical issues in their response to the PAR. WMP responded to the issues raised and provided clarification of the issues and action taken.

Prior to closing the discussion, the company delegates confirmed there were no outstanding issues and agreed the appraisal process had been fair, open and transparent. The Chairman thanked the company for engaging in the AWMSG process and closed the discussion.

Appraisal decision

The recommendation of AWMSG was announced:

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.

11 Appraisal 6 - Epoetin-ζ (zeta) (Retacrit®▼)

Epoetin zeta (Retacrit®▼) is licensed for use:

- in the treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adult and paediatric patients including:
    - Anaemia associated with chronic renal failure in adult and paediatric patients on haemodialysis and adult patients on peritoneal dialysis.
    - Severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis.
- in the treatment of anaemia and reduction of transfusion requirements in adult patients receiving chemotherapy for solid tumours, malignant lymphoma or multiple myeloma, and at risk of transfusion as assessed by the patient's general status (e.g. cardiovascular status, pre‑existing anaemia at the start of chemotherapy).
- to increase the yield of autologous blood from patients in a predonation programme. Its use in this indication must be balanced against the reported risk of thromboembolic events. Treatment should only be given to patients with moderate anaemia (no iron

deficiency), if blood saving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (four or more units of blood for females or five or more units for males).

It was confirmed the company had limited their submission to the management of symptomatic anaemia of chronic kidney disease (CKD).

The Chairman reminded members to declare any interests in the applicant company, Hospira UK Ltd, or the medicine. There were none.

There were no delegates from Hospira UK Limited at the meeting.

The Chairman invited Professor Ceri Phillips to present Enc **7**/AWMSG/0410 and highlight the salient issues within the preliminary appraisal report. It was noted that no patient organisation submission had been received. An overview of the discussions held at NMG was provided and the views of the medical expert were relayed.

The Chairman opened the discussion and invited members to raise outstanding issues in relation to clinical effectiveness. It was noted that the medicine is a bio-similar product. It was suggested that the lack of a subcutaneous route might be a disadvantage in relation its clinical effectiveness. The Chairman confirmed that the appraisal of this medicine should be within the context of the information received in the submission - the intravenous route. The Chair invited comment in relation to the cost effectiveness and budget impact issues. There were no company delegates available at the meeting to respond to the issues highlighted. The process for identifying medical experts was clarified and the lay member expressed his disappointment that no response had been received from a patient organisation.

Appraisal decision

The recommendation of AWMSG was announced:

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

Key factor influencing the recommendation:
There are several uncertainties and limitations in the economic model provided in the company's submission.

12. Update on AWMSG's Medicines Strategy for Wales

The Chairman invited Mr Jamie Hayes and Mrs Fiona Woods of the Welsh Medicines Partnership to join the meeting. Mr Hayes provided the background to Enc **8**/AWMSG/0410. The Medicines Strategy for Wales was endorsed by AWMSG on 16th April 2008 and submitted to Welsh Assembly Government (WAG). In December 2008 it was reported that the Minister for Health and Social Services had approved the strategy and had asked AWMSG to prioritise the forty-eight recommendations to ensure they were taken forward on behalf of WAG. In consultation with members of the All Wales Prescribing Advisory Group (AWPAG), the NHS Industry Forum (NHSIF) and the AWMSG Steering Committee the recommendations were prioritised and, with the multi-disciplinary support of the Welsh Medicines Partnership (WMP), and in the spirit of collaboration with other NHS partners, Welsh Assembly Government and representatives of the pharmaceutical industry, the work of progressing the recommendations commenced. Mr Hayes highlighted the importance of developing the medicines strategy and asked members to note the progress made to date in taking forward 'Getting the Best

Outcomes from Medicines for Wales'. Members were invited to consider the applicability of current recommendations in light of the recent NHS reorganisation and a changing environment.

The Chairman opened the discussion. Members agreed the update was timely and noted several changes since the development of the strategy. The need to update the document to reflect University Health Boards not Trusts and LHBs was noted. The Public Health Wales representative expressed an interest in working collaboratively with the Welsh Medicines Partnership in relation to data analysis and horizon scanning. Clarification was sought in relation to the remit of WAPSU and the potential for future funding. Members agreed that the establishment of WAPSU essential in terms of the strategic direction of medicines for Wales. WMP representation on the Medicines Management Programme Board (MMPB) was confirmed. The Welsh Assembly Government representative confirmed that a key focus of MMPB was to address efficiency savings and highlighted AWMSG's broader strategic role. It was suggested that all initiatives should be aligned to AWMSG.

It was agreed that WMP would work in conjunction with AWPAG and the AWMSG Steering Committee to review and update the document and capture all work streams. The Chairman confirmed that AWMSG should receive an update on a six monthly basis, and a suggestion was made that exception reporting between the updates would support the development of the recommendations.

Date of next AWMSG meeting:
Wednesday, 23rd June 2010 at 10.30am in The Angel Hotel, Abergavenny

Subsequent dates for 2010:
18th August / 13th October / 15th December