Enclosure No:	**1/AWMSG/0410**
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, 3rd MARCH 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 representative	
3.	Dr Fraser Campbell	LHB Medical Director	
4	Ms Debbie Davies	representing other professions eligible to prescribe	
5	Mr Jeremy Felvus	ABPI (Wales) representative	7,10,11
6.	Dr Bruce Ferguson	Trust Medical Director	
7.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health	
8.	Dr Brian Hawkins	Senior Primary Care Pharmacist	9
9.	Cllr Meurig Hughes	Lay representative	
10.	Dr Thomas Lau	General Practitioner with prescribing lead role	
11.	Prof Ceri Phillips	Health Economist	9
12.	Mr Dave Roberts	Chief Pharmacist	
13.	Prof Philip Routledge	Clinical Pharmacologist (Chairman)	
14.	Mrs Wendy Warren	Senior Nurse	

IN ATTENDANCE:

15.	Dr Martin Duerden	NMG Chairman
16.	Mr Jamie Hayes	Welsh Medicines Partnership
17.	Mrs Ruth Lang	Welsh Medicines Partnership
18.	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
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 Guy Thompson, ABPI Wales representative
Mr Rob Holcombe, LHB Finance representative
Mr Russell Pope, Welsh Assembly Government
Mr Jeremy Savage, 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.

Professor Ceri Phillips declared a personal specific interest in agenda item 9.
Mr Brian Hawkins declared a personal specific interest in agenda item 9.
Mr Jeremy Felvus declared interests in agenda items 7, 10 and 11.

The Chairman confirmed that the members would not participate in the discussion of the relevant agenda item.

4. Chairman's report

The Chairman reported that the Minister for Health and Social Services had ratified the AWMSG's recommendations in relation to the appraisals held in December 2009:

Ranolazine (Ranexa® ▼) is **not recommended** for use within NHS Wales for the treatment of stable angina pectoris.

Darunavir (Prezista®▼) co-administered with low dose ritonavir **is recommended** as an option for use within NHS Wales for the treatment of human immunodeficiency virus (HIV)-1 infection in treatment naive patients.

Degarelix (Firmagon®▼) is **not recommended** for use within NHS Wales for the treatment of advanced hormone-dependent prostate cancer.

Members were informed that the Final Appraisal Reports had been published on the AWMSG Website and the Service notified. The Chairman informed members that in addition to the FARs, Advisory Notices are routinely published on the AWMSG website to inform NHS Wales of medicines not endorsed for use, because appraisal by AWMSG or NICE had not been progressed.

The Chairman confirmed that a draft Implementation Update Report had been provided to AWMSG members for comment. The document outlined progress made in relation to implementing AWMSG's broadened appraisal remit prior to funding becoming available. Members were informed that the update would be provided to Professor Roger Walker, Chairman of the Implementation Group and Welsh Assembly Government officials. The Chairman reiterated the need for the establishment of WMP's infrastructure prior to a significant increase in the number of appraisals.

The Chairman informed members that WMP is awaiting written confirmation of funding allocated under the 'invest to save initiative' to progress four specific projects under the auspices of the Welsh Analytical Prescribing Support Unit and within the financial year 2010/2011.

The Chairman confirmed written confirmation of AWMSG's support for Informing Healthcare's Invest-to-save bid for a pilot electronic medicines management scheme had been submitted to the Welsh Assembly. It was noted that electronic medicines management is one of the recommendations in the Medicines Strategy and it is hoped that the development of such a system would promote safe and effective prescribing for patients in Wales.

5. Minutes of previous meeting

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

6. Appraisal 1 – Plerixafor (Mozobil®▼)

For mobilisation of haematopoietic stem cells for subsequent autologous transplantation.

The Chairman welcomed two delegates who had been nominated by Genzyme Therapeutics Limited to represent the company at the appraisal.

Prior to the commencement of the appraisals, the Chairman reminded members to declare any interests in relation to the appraisal.

The Chairman announced the statement pertinent to all appraisals - it was confirmed that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this, and a negative recommendation would not impact on the clinical freedom of the prescriber. He explained that a positive recommendation by AWMSG, subsequently endorsed by the Minister for Health and Social Services, places an obligation on Trusts and LHBs in Wales to fund accordingly. He reiterated that AWMSG advice is interim to NICE should it be subsequently published.

The Chairman confirmed that in making their recommendation to AWMSG, the New Medicines Group (NMG) had considered the clinical effectiveness and cost effectiveness issues in detail. He reminded members there would be no requirement for AWMSG to repeat the detailed discussions held at NMG. The Chairman directed AWMSG to seek clarification of any outstanding issue in relation to clinical or cost-effectiveness, the company response to the preliminary recommendation, the clinical expert summary, the patient organisation submission and take account of any societal or budget impact issues.

Dr Duerden set the context of the appraisal and provided an overview of the discussions held at the NMG meetings on Wednesday, 20th January 2010. The relevant issues contained within the PAR, enclosure **2**/AWMSG/0310 were highlighted. Dr Duerden highlighted the potential adverse effects of the medicine. It was noted that the medical experts supported its availability within NHS Wales as a prescribing option. Submissions from the Lymphoma Association, Myeloma UK and Leukaemia CARE all supported the use of the treatment and had provided valuable information from a patient perspective.

Dr Duerden concluded his address by confirming the NMG recommendation to AWMSG was that plerixafor (Mozobil®▼) should be 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. It was suggested that 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. It was the view of NMG that plerixafor (Mozobil®▼) would not be suitable for shared care.

The Chairman opened the discussion and confirmed that opportunity would be provided to the company delegates to respond to all the issues raised in the discussion. Members were invited to address outstanding issues in relation to clinical effectiveness. It was noted that the submission was restricted to a specific group of patients and questions were raised in relation to the use of the medicine beyond its licensed indication and outside any potential restriction in its use.

Professor Ceri Phillips provided an overview from a health economic perspective and the Chairman opened the discussion to AWMSG to raise issues in relation to cost-effectiveness. It was confirmed that the health economic model provided reflected the clinical management of

patients. It was noted that the cost per QALY did not include treatment of adverse effects. Issues in relation to budget impact were invited.

The Chairman referred members to the patient organisation submission from Leukaemia CARE, Myeloma UK and the Lymphoma Association and invited the lay member to comment. Mr Hughes welcomed the receipt of three patient organisation submissions and added no further comment.

The company delegates were invited to respond to the discussion and asked whether they wished to highlight any issues. Prior to closing proceedings, the Chairman sought confirmation that the company delegates were satisfied that all issues had been adequately discussed and taken into account and that the process had been fair and transparent. Confirmation was received.

The Chairman closed the discussion.

Mr Jeremy Felvus left the meeting

Appraisal decision

The recommendation of AWMSG was announced:

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.

The Chairman announced

- Tumour cell mobilisation, specifically in poor mobilisers, requires evaluation of progression free survival (as well as other long-term outcomes) by use of a registry, as requested by the Committee for Medicinal Products for Human Use (CHMP).

- AWMSG recommends that Health Boards establish a process to monitor uptake and compliance with this recommendation.

The Chairman confirmed that the AWMSG ultra orphan policy would be re-defined in light of the broadening of the remit of the health technology appraisal process in Wales.

7. Appraisal 2 – Etancercept (Enbrel®▼)
For the treatment of chronic plaque psoriasis in children and adolescents
Manufacturer: Pfizer Limited

The Chairman welcomed two delegates who had been nominated by Pfizer Limited to represent the company at the appraisal.

Dr Duerden set the context of the appraisal and provided an overview of the discussions held at the NMG meeting on Wednesday, 20th January 2010. A comprehensive overview of the clinical condition was relayed. The relevant issues contained within the PAR, enclosure **3**/AWMSG/0310, were highlighted and the views of the medical experts were conveyed. Dr Duerden stated that the patient submissions had been particularly useful in considering the patient perspective. It was noted that the evidence provided in the submission had been limited. In concluding his address, Dr Duerden reported the recommendation of NMG to AWMSG was that etanercept (Enbrel®▼) should not be 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 Chairman invited Professor Phillips to provide an overview of the case for cost-effectiveness. Professor Phillips highlighted the limitations from a health economic perspective. The Chairman invited the company delegates to respond to the issues raised. It was acknowledged that the inconsistencies identified in the appraisal report had not been addressed by the applicant company and remained outstanding. Professor Phillips confirmed that sensitivity analyses not been undertaken as the appropriate health economic model had not been provided with the submission when required for consideration.

The Chairman opened the discussion and invited members to address issues in relation to clinical effectiveness. Patient organisation submissions from the Psoriasis and Psoriatic Arthritis Alliance and an individual patient submission had been made available to members. Councillor Meurig Hughes gave recognition to the submissions received, particularly the comprehensive individual patient submission, and had nothing further to add.

The Chairman invited members to comment on societal and budget impact issues and opened the discussion to the delegates from Pfizer to respond to the issues highlighted in the discussion. The limitations of the submission and the health economic evidence provided were acknowledged by the company delegates.

Prior to closing proceedings, the Chairman sought confirmation that the company delegates were satisfied that all issues had been adequately discussed and taken into account and that the process had been fair and transparent. Confirmation was received.

The Chairman closed the discussion.

The recommendation of AWMSG was announced:

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.

8. Update on AWPAG

The Chairman invited Dr Tessa Lewis to highlight the salient issues within the draft minutes of the AWPAG meeting held on 27th January 2010, Enc **4/**AWMSG/0310. Dr Lewis confirmed that the AWMSG template for prescribing statins had been reviewed and the updated document is available on the AWMSG website. It was confirmed the document will be reviewed in December 2010. Dr Lewis confirmed that AWPAG supported the proposal that a target be developed for 28 day prescribing. Members were informed that the presentation made by Helen Adams on mapping prescribing was welcomed by AWPAG members.

Professor Ceri Phillips and Dr Brian Hawkins left the meeting.

9. Chiral indicator review

The Chairman welcomed Mr Steve Turley, Managing Director of Lundbeck and invited him to join the discussion.

The Chairman invited Mr Jonathan Sims to present an overview of Enc 5/AWMSG/0310. Mr Sims provided the background to the review paper and conveyed the view of AWPAG that escitalopram should be retained within the chiral indicator basket for the year 2010/2011 with clarification of the wording to reflect that clinicians should exercise their clinical judgement when providing care for an individual patient. Clarification of the role of the national indicators in reinforcing prescribing messages was provided. Members were invited to express their views and it was noted that there were no negative or zero targets. The industry member alluded to the difference in interpretation of the available evidence and welcomed the transparent approach adopted by the Chairman. In his address, the Managing Director of Lundbeck acknowledged his support of the need for rational prescribing and expressed opposition to the inclusion of escitalopram within the chiral indicator basket. Lundbeck welcomed the opportunity to work with AWMSG to establish more appropriate control of the prescribing of escitalopram. Members sought clarification of the potential alternatives. On behalf of Lundbeck, the Managing Director concluded his address by thanking AWMSG for the opportunity to address the group and asked members to consider a mutually acceptable approach.

The Chairman closed the discussion and members retired to vote in private.

On re-convening the meeting, the Chairman announced **it was agreed** that the national indicator paper endorsed by AWMSG at the meeting on 12th August 2009 should be amended in light of the review of the chiral indicator. AWMSG agreed that the chiral indicator should be retained: However, in light of the new evidence presented, escitalopram should not be included in the basket for that indicator.

Mr Jeremy Felvus left the meeting

10. Prescribing low molecular weight heparin (LMWH)

The Chairman invited Dr Tessa Lewis to provide an overview of Enc **6**/AWMSG/0310. Dr Lewis expressed thanks to Mr Trevor Batt for his input into the development of the paper and for attending the meeting. Dr Lewis explained that historically patients requiring subcutaneous heparin anticoagulation have received treatment through specialists and the acute sector. In recent years LMWH has effectively replaced the routine use of unfractionated heparin in the majority of patients. Use of LMWH has enabled once or twice daily subcutaneous injection, a reduced requirement for monitoring and the potential for patient self-administration. Outpatient deep vein thrombosis (DVT) clinics have been established. It was reported that the paper had been developed in light of the concern expressed at the increased volume of prescribing in primary care, the lack of information and guidance to support prescribers and the divergence of professional views in relation to the most appropriate place for the prescribing of LMWH. It was noted there was work to be undertaken in developing the educational issues highlighted within the document. The Chairman opened the discussion and invited comment on each recommendation.

Recommendation 1

LMWH treatment for four weeks or less should be prescribed and monitored by the initiating physician (any indication).

Recommendation 2

Where there is a need to monitor LMWH treatment by measuring the anti-Xa level, patients should be prescribed and followed up regularly by specialist services.

Recommendation 3

Treatment doses of LMWH prescribed for venous thromboembolism (VTE) in cancer patients (i.e. patients undergoing cancer therapy or those who have metastatic disease) are suitable for shared care for up to six months of treatment.
Shared care should be agreed in writing with an invitation to participate by consultant and response from the General Practitioner.

Recommendation 4

Treatment doses of LMWH for VTE in pregnancy should be 'hospital only' prescribing.

Recommendation 5

Prophylactic doses of LMWH in pregnancy for medical conditions (excluding the indication of obesity) should normally be prescribed by Secondary Care. Mechanisms need to be agreed locally to support adequate supply between appointments (30-42 days). Further discussions are needed regarding the prescribing of prophylactic doses for obese patients.

AWMSG endorsed the recommendations of Enc **6**/AWMSG/0310 and congratulated AWPAG on producing an excellent resource for prescribers in NHS Wales.

11. Clinical Effectiveness Prescribing Programme (CEPP) All Wales Audit – Towards appropriate NSAID prescribing

The Chairman invited Dr Susanna Jacks to present an overview of Enc 7/AWMSG/0310. Dr Jacks informed members that quality improvement toolkits have been developed to assist general practices in collating and auditing information. These are produced with reference to evidence based practice and Welsh priorities. They should be seen as good practice and are intended to improve data quality and aid development within the practice. Improvements in practice will be optimised by multidisciplinary involvement in the audit and team discussion of the results. It is recommended that action plans following audit are reviewed within 6 months and re-audit undertaken if possible in 6-12 months.

Dr Jacks explained that the audit had been developed by the All Wales Prescribing Advisory Group (AWPAG) in conjunction with the Primary Care Quality and Information Service (PCQIS). It is intended that the document will be used by primary care general practitioners to highlight safety issues associated with NSAID prescribing, particularly in patients with a higher risk of side effects. Members were informed that the audit will be published in the National Public Health Service (NPHS) document database (PCQI) and will also be linked from the AWMSG website and the NPHS e-bulletin. Dr Jacks sought the endorsement of the Non-Steroidal Anti-Inflammatory Drug (NSAID) audit as part of the All Wales Medicines Strategy Group's (AWMSG's) Clinical Effectiveness Prescribing Programme (CEPP); formerly known as the Prescribing Incentive Scheme.

Following clarification and discussion, the Chairman confirmed the endorsement of AWMSG and thanked Dr Jacks and AWPAG for developing the audit in conjunction with PCQIS.

12. Communication Strategy update

The Chairman invited Mr Jamie Hayes, WMP Communication Lead, to provide an overview of the update to the AWMSG/WMP communication strategy. Mr Hayes highlighted the need to improve communication and establish a sound communication framework to support the work

programme and broadened remit of AWMSG. Mr Felvus suggested that Industry comments in relation to the strategy be tabled at the next TDA Users Group. Mrs Wendy Warren offered to assist with the methodology for implementation of the document. Mr Hayes updated members on a recent meeting with the Director of Communications and Director of External Affairs at the National Institute for Health and Clinical Excellence. The Chairman concluded the discussion by inviting members to provide comment to WMP outside of the meeting.

Date of next AWMSG meeting:
Wednesday, 28th April at 10.30am in The Angel Hotel, Abergavenny

Subsequent dates for 2010:
23rd June / 18th August / 13th October / 15th December