ALL WALES MEDICINES STRATEGY GROUP
MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY 16th APRIL 2008 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY

MEMBERS PRESENT:

			Did not participate in
1.	Dr Paul Buss	NHS Consultant	
2.	Mr Jeff Evans	Other professionals eligible to prescribe	
3.	Dr Bruce Ferguson	Trust Medical Director	
4.	Mr Peter Harsant	Industry Representative	
5.	Mr Brian Hawkins	LHB Pharmacist	
6.	Cllr Meurig Hughes	Lay member	**6-7**
7.	Dr Thomas Lau	General Practitioner and prescribing lead	**8-14**
8.	Dr Fraser Campbell	LHB Medical Director	
9.	Mr David Morgan	National Public Health Service Wales	
10.	Prof Ceri Phillips	Health Economist	
11.	Mr Dave Roberts	Chief Pharmacist	
12.	Prof Philip Routledge	Clinical Pharmacologist (Chairman)	

IN ATTENDANCE:

13.	Mrs Ruth Lang	Welsh Medicines Partnership
14.	Mrs Carolyn Poulter	Welsh Assembly Government
15.	Mrs Karen Samuels	Welsh Medicines Partnership
16.	Dr Martin Duerden	NMG Chairman (for appraisals only)

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
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
DTB	Drug & Therapeutics Bulletin
FAR	Final appraisal report
HCW	Health Commission Wales
HoPMMs	Heads of Pharmacy and Medicines Management
HSW	Health Solutions Wales
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
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
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

Dr Geoffrey Carroll, representing Health Commission Wales
Mr Robert Holcombe, LHB Finance Director
Miss Carwen Wynne Howells, Welsh Assembly Government
Mrs Wendy Warren, Senior Nurse

3. Declarations of interest

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

4. Chairman's report

The Chairman reported that the AWMSG Secretariat, the Welsh Medicines Partnership, had recently moved offices from the University Hospital of Wales to the Llandough

hospital site. The Chairman apologised for any delays experienced in members receiving their papers as a consequence of this move.

It was reported that the meeting of the All Wales Prescribing Advisory Group had been held yesterday at the Hill Education Centre in Abergavenny. Members were informed that the AWPAG Chair, Dr Tessa Lewis, had invited comment from AWMSG members in relation to a new high level prescribing indicator. The Chairman asked that members email suggestions to the WMP office outside of the meeting. The Chairman confirmed that a full report of the meeting will be made at the next AWMSG meeting when the draft minutes will be available.

The Group was informed that the NHSIF meeting is due to take place next Wednesday, 23rd April. The Chairman confirmed that Agenda item 8 – update on NHSIF – is on the agenda to allow the NHSIF Chairman, Mr David Morgan, opportunity to raise any issues or seek comment from AWMSG prior to their meeting.

The Chairman announced the adjournment of the appraisal of ziconotide injection (Prialt®) for severe chronic pain. It was reported that the manufacturers, Eisai Limited, had submitted in their response to the ASAR additional information which was of large volume and considered potentially significant, and this required critical appraisal by the WMP team prior to it being considered by NMG. A decision was taken by NMG to adjourn this appraisal until the next NMG meeting on Wednesday, 14th May and the appraisal will be undertaken by AWMSG in June.

The Chairman confirmed that a response to the consultation on rare diseases had been submitted to the European Commission on 14th February and will be made available to members upon request.

The Chairman reiterated that any AWMSG guidelines or prescribing templates would be reviewed in light of any newly published NICE guidelines.

It was announced that Ministerial endorsement had been received for the following appraisals held at the February AWMSG meeting:

Intravenous topotecan hydrochloride (Hycamtin®) for use in patients with relapsed small cell lung cancer for whom re-treatment with the first-line regimen is not considered appropriate.
Manufacturer: GlaxoSmithKline

Intravenous topotecan hydrochloride (Hycamtin®) in combination with cisplatin for patients with carcinoma of the cervix recurrent after radiotherapy and for patients with Stage IVB disease.
Manufacturer: GlaxoSmithKline

Epoetin delta (Dynepo®) for treatment of anaemia in patients with chronic renal failure. Dynepo® may be used in patients on dialysis and patients not on dialysis.
Manufacturer: Shire Pharmaceuticals

The Chairman confirmed that the FARs had been posted on the AWMSG website and the Service informed by email.

The Chairman informed the Group that the final appraisal report in relation to **Tacrolimus (Advagraf®)** for the prophylaxis of transplant rejection in adult kidney or liver allograft recipients and the treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients had not been passed to the

Minister for ratification. It was reported that the manufacturer, Astellas Pharma Ltd, had requested a review of the recommendation. The Chairman confirmed the current status is that the process had been suspended pending clarification of best options available.

The Chairman announced the following appraisals would be held at the next AWMSG meeting on Friday, 13th June:

Buprenorphine/naloxone (Suboxone®) for the treatment of opioid dependence
Deferasirox (Exjade®) for the treatment of chronic iron overload
Lenalidomide (Revlimid®) for the treatment of multiple myeloma patients who have received at least one prior therapy
Docetaxel (Taxotere®) oncology chemotherapy treatment for the head and neck tumour site
Ziconotide (Prialt®) for severe chronic pain

5. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy.

Matters arising:

Clarification was sought over the appointment of a Vice Chairman. The Chairman confirmed that a nomination had been received and that members would be invited to indicate their support in relation to this nomination outside of the meeting. There were no other matters arising outside the agenda.

6. Appraisal 1 – fondaparinux sodium (Arixtra®)
Manufacturer: GlaxoSmithKline
Indication: for the treatment of ST segment elevation myocardial infarction (STEMI)

Start time – 10.45 am
Mr Meurig Hughes joined members and declared a personal non-specific interest in GlaxosmithKline. The Chairman confirmed that Mr Hughes would be unable to participate in the appraisal and Mr Hughes left the meeting.

The Chairman welcomed representatives from the applicant company, GlaxoSmithKline, Dr Ravi Jandhyla, Medical Advisor and Dr Manjit Hunjan, Health Outcomes Manager and confirmed that opportunity would afforded them to comment on the appraisal and raise relevant issues.

Professor Routledge confirmed that medical expert views had been sought in relation to the appraisal.

The Chairman confirmed that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this, and that 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 & 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 the sequence of the appraisal and invited Dr Martin Duerden, NMG Chairman, to address the Group. Dr Duerden set the context of the appraisal and provided a brief overview of the discussions held at the New Medicines Group. The relevant issues contained within the PAR, enclosure **2**/AWMSG/0408, were highlighted. Dr Duerden informed members of the differing views of the medical experts in relation to this medicine.

Dr Duerden confirmed the NMG recommendation to support the use of the medicine in Wales. He encouraged more research into non-invasively treated patients to help inform a preferred treatment strategy and suggested that a consensus in approach to management in this treatment area would be welcomed in Wales.

The Chairman opened the discussion and asked members to consider the evidence in relation to the clinical effectiveness of the new medicine within its licensed indication.

There was discussion over the variation in duration of treatment, and the Chairman referred members to the summary of product characteristics. Issues in relation to geographical variation in pathway of care and the serious side effect profile were also raised.

The Chairman asked members to consider the evidence in relation to cost effectiveness and invited Professor Ceri Phillips to bring to the attention of the Committee any relevant issues. Professor Phillips confirmed the cost effectiveness threshold and it was noted that the manufacturers had based the cost on seven days duration of treatment.

The Chairman invited comment on the broader societal issues and confirmed that no patient interest group submissions had been received. Mrs Samuels outlined the process for identifying relevant patient interest groups and confirmed that four organisations had been invited to engage. Members were reassured that WMP are taking steps to improve the engagement of patient interest groups in the AWMSG appraisal process.

Dr Jandhayala and Dr Hunjan were invited to join members and comment on the relevant issues raised in the discussion. Dr Jandhyala responded to queries in relation to the mode of administration and bleeding risk.

The Chairman asked members to consider the issues outlined in the CR/PAR, and invited representatives of the applicant company to comment on general and specific issues. The Chairman confirmed that the amendments suggested in the CR/PAR would be incorporated into the FAR for completeness and accuracy. The Chairman referred members to the budget impact statement provided in the CR/PAR.

Following the discussions, and prior to closing proceedings, Dr Jandhyala confirmed that he was satisfied that all issues had been adequately discussed and taken into account, and that the appraisal process had been thorough and fair.

In the light of the discussions the Chairman asked members to make note of their initial recommendation on their aide-memoir for reference at a later stage.

The Chairman closed proceedings at 11.44 am and confirmed that the Committee would proceed with the second appraisal and would retire at the end of the second appraisal session to vote in private.

7. **Appraisal 2 -** fondaparinux sodium (Arixtra®)
Manufacturer: GlaxoSmithKline
Indication: for the treatment of unstable angina or non-ST segment elevation myocardial infarction (UA/STEMI)

Start time 11.45 am

The Chairman reaffirmed that Mr Hughes the lay member would not be eligible to participate in the appraisal.

Dr Duerden set the context of the appraisal and provided a brief overview of the discussions held at the New Medicines Group. The relevant issues contained within the PAR, enclosure **3**/AWMSG/0408, were highlighted. Dr Duerden confirmed that NMG had noted the range of views of the medical experts and suggested that a consensus approach to managing the condition and a systematic approach to risk assessment should be established. He confirmed the NMG recommendation to support the use of fondaparinux sodium (Arixtra®) for the treatment of unstable angina or non-ST segment elevation myocardial infarction (UA/STEMI).

The Chairman asked members to consider any outstanding issues in relation to the cost effectiveness and invited Professor Phillips to address the Group. Clarity was sought in relation to the cost effective argument. Professor Phillips stated that he believed the cost per QALY estimate to be acceptable.

The Chairman invited members to seek clarification of any outstanding issues in relation to the clinical effectiveness.

The Chairman invited comment on the budget impact and broader societal issues. There was discussion over the need for a systematic approach to its use to reduce the diversity of management practices in Wales, and a suggestion was made that an approach should be made to Welsh Cardiac Network for clarity around the use of this medicine within current practice.

The Chairman asked representatives of the applicant company to comment on the general and specific issues, in particular in relation to safety, utility weighting and robustness of the assumptions made in the model and effect on the sensitivity analysis.

The Chairman drew members' attention to the issues raised in the CR/PAR and invited members to comment on the issues raised. The Chairman confirmed that the suggested amendments in the response would be incorporated in the FAR for completeness and accuracy.

Prior to closing proceedings, the Chairman sought confirmation that Dr Jandhyala and Dr Hunjan were satisfied that all issues had been adequately discussed and taken into account and the process had been fair and thorough. Confirmation was received and the Chairman thanked the manufacturers for engaging with the AWMSG process.

The Chairman closed proceedings at 12.07 pm and confirmed that the Committee would retire to vote in private.

Appraisal decisions

At 1.05 pm the Chairman announced the decision of AWMSG for the following appraisals:

Appraisal 1 – fondaparinux sodium (Arixtra®)
Manufacturer: GlaxoSmithKline
Indication: for the treatment of ST segment elevation myocardial infarction (STEMI)

Fondaparinux (Arixtra®) should be recommended as an option for use in the treatment of ST segment elevation myocardial infarction (STEMI) in patients who are managed with thrombolytics or who are initially to receive no other form of reperfusion therapy.

Treatment with fondaparinux (Arixtra®) and its monitoring/supervision should be retained under secondary care.

AWMSG is of the opinion that fondaparinux (Arixtra®) would not be suitable for shared care within NHS Wales.

Appraisal 2 - fondaparinux sodium (Arixtra®)
Manufacturer: GlaxoSmithKline
Indication: for the treatment of unstable angina or non-ST segment elevation myocardia infarction (UA/STEMI)

Fondaparinux (Arixtra®) should be recommended as an option for use in the treatment of unstable angina or non-ST segment elevation myocardial infarction (UA/NSTEMI) in patients for whom urgent (less than 120 minutes) invasive management (percutaneous coronary intervention [PCI]) is not indicated.

Treatment with fondaparinux (Arixtra®) and its monitoring/supervision should be retained under secondary care.

AWMSG is of the opinion that fondaparinux (Arixtra®) would not be suitable for shared care within NHS Wales.

The Chairman outlined the process and confirmed that the recommendations would be forwarded to the applicant companies within five working days from the meeting.

8. Report on NHSIF

The Chairman invited Mr David Morgan to raise any issues in relation to the NHSIF. Mr Morgan provided a brief overview of the agenda with regard to the meeting on 23rd April.

9. Update on AWPAG

The Chairman informed members that a full report would be made to the Group by the AWPAG Chair at the next meeting, when the AWPAG minutes would be available. He invited members to provide suggestions outside of the meeting for a new a high level indicator for 2009/2010 which will be considered by the indictor working group.

10. AWMSG Prescribing Strategy

The Chairman informed members that the prescribing strategy, enclosure **4**/AWMSG/0408, had been updated in light of comments received during the informal consultation and the changes were highlighted in the revised document. The Group endorsed the strategy. It was agreed that AWMSG would offer to assist in the prioritisation of the actions points. The Chairman confirmed that the document date would be amended accordingly and passed to the Welsh Assembly by the end of April 2008.

11. Prescribing reviews – process for internal consultation

Mrs Samuels confirmed that the enclosure **5**/AWMSG/0408 had been re-presented to AWMSG in response to a request to include a flow diagram clarifying the internal consultation process. Mr Harsant agreed to feed back his comments outside of the meeting. Mr Morgan welcomed the opportunity for NHIF engagement in the process and suggested that some modifications may be required when the process is put to the test.

12. Update on Medusa

The Chairman welcomed Mr Neil Jenkins from Health Solutions Wales. Mr Jenkins highlighted the salient points of enclosure **6**/AWMSG/0408 – an update paper prepared by Mr Robin Burfield. He informed members that initial users now have access to the system and explained the process for role out. He alluded to difficulties currently being experienced within the Swansea Trust due to the different systems in use. There was discussion over automated dispensing systems and Mr Roberts informed members of

benefits in relation to the reduction in dispensing errors and increased pharmacy staff time. Members welcomed the encouraging developments and the Chairman conveyed the Group's thanks to Mr Jenkins and Mr Burfield and closed the discussion.

13. Welsh Analytical Prescribing Unit (WAPSU)

The Chairman invited Mrs Samuels to present the enclosure **7**/AWMSG/0408 to the Group. Mrs Samuels highlighted the salient points from the paper and confirmed that an operational advisory group is currently being established. It was reported that regular updates on the project management plan would be provided at AWMSG meetings. Mrs Poulter briefly clarified the role of the WAPSU and welcomed the establishment of the unit. Mr Harsant suggested that the pharmaceutical industry be included on the list of consultees. There was discussion over infrastructure requirements, deadlines and need for strategic collaborative working. Members expressed their support for the development of the Unit.

14. Consultation: Proposal to change the structure of the NHS in Wales

The Chairman referred members to enclosure **8**/AWMSG/0408 and invited members to submit their comments via email to the WMP office to inform the AWMSG response, to be considered at the next AWMSG meeting in June.

Date of next AWMSG meeting: Friday, 13th June 2008 at the Angel Hotel, Abergavenny commencing 10.30 am.