Enclosure No:	**1/AWMSG/0000**
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, 16th DECEMBER 2009 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	**9,10**
4.	Dr Bruce Ferguson	Trust Medical Director	
5.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health	
6.	Dr Brian Hawkins	Senior Primary Care Pharmacist	
7.	Mr Robert Holcombe	LHB Finance representative	**9,10**
8.	Cllr Meurig Hughes	Lay representative	
9.	Dr Thomas Lau	General Practitioner with prescribing lead role	
10.	Prof Ceri Phillips	Health Economist	
11.	Mr Dave Roberts	Chief Pharmacist	
12.	Prof Philip Routledge	Clinical Pharmacologist (Chairman)	**9,10**
13.	Mr Guy Thompson	ABPI (Wales) representative	

IN ATTENDANCE:

14.	Dr Martin Duerden	NMG Chairman
15.	Mrs Vi Turner	Welsh Assembly Government
16.	Ms Kath Haines	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

Mrs Wendy Warren, Senior Nurse
Mrs Debbie Davies, Other professions eligible to prescribe
Mr Jeremy Savage, Welsh Assembly Government
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. There were none.

4. Chairman's report

The Chairman announced that on Wednesday, 9th December the Minister for Health and Social Services outlined her spending priorities for 2010-11 and confirmed that additional resource would be made available for health and social services to focus on speeding up treatment and improving patient care. The bids to broaden AWMSG's remit to include all medicines not on the NICE work programme, and training in relation to improving communication skills for oncologists and front line staff, have been approved and funding to support these initiatives is included in the £801,000 additional revenue. It was confirmed that Assembly officials will work with WMP to take forward the expansion of AWMSG's appraisal remit in readiness for the new financial year.

The Chairman invited AWMSG members and deputies to join NMG on the afternoon of Wednesday, 20th January in Abergavenny to discuss the implications of this announcement.

The Chairman thanked ABPI Wales for hosting a Masterclass on Wednesday, 9th December 2009 at the All Nations Centre when representatives from WMP, AWMSG and NMG updated and informed industry on matters relating to the appraisal process. Representatives from patient organisations were invited to suggest ways for improving communication and increase input into the AWMSG appraisal process.

It was confirmed that on 2nd December advice intended to complement final guidance recently issued by the National Institute for Health and Clinical Excellence (NICE) in relation to renal cell carcinoma (RCC) medicines was forwarded to the Welsh Assembly Government. It was originally submitted as interim advice in May 2009 when NICE guidance was unavailable, and was subsequently modified in light of the recently issued NICE guidance. The document was developed collaboratively by the Welsh Medicines Partnership (WMP) and the All Wales Cancer Drugs Group (AWCDG) to ensure the choice of treatment options to complement final NICE guidance. As it has been overtaken by recent events, the added value of this document is now limited. The Chairman thanked Professor Malcolm Mason for his input and hard work in ensuring contribution from all the renal oncology specialists, and Kath Haines from WMP in delivering the guidelines. He also thanked Mr Damian Heron, Director of the North Wales Cancer Network, for sharing his preliminary work which was used as a starting point for the development of the document.

The Chairman expressed thanks to Mr Dave Roberts and the Chief Pharmacists in Wales, for taking forward the All-Wales Prescription Chart initiative which, together with the associated educational package, has been identified as an example of good practice at a UK national level.

The Chairman announced that the Minister for Health and Social Services has ratified the following AWMSG recommendations:

Mecasermin (Increlex®▼) is recommended for use within NHS Wales for the long – term treatment of growth failure in children and adolescents with severe primary insulin-like growth factor-I deficiency

Methoxy polyethylene glycol-epoetin beta (Mircera®▼) is recommended as an option for use within NHS Wales for the treatment of adults with symptomatic anaemia associated with chronic kidney disease

The Chairman confirmed the Service had been informed and Final Appraisal Reports are available on the AWMSG website.

The Chairman announced the appraisals scheduled for the next AWMSG meeting on Wednesday 3rd March 2010:

Plerixafor (Mozobil®▼) for the treatment of stem cell transplantation in patients with multiple myeloma, non-Hodgkin's lymphoma (NHL)
Manufacturer: Genzyme Therapeutics Limited

Etanercept (Enbrel®▼) for the treatment of moderate to severe plaque psoriasis in children and adolescents
Manufacturer: Wyeth Pharmaceuticals

Patients and carers were invited to provide their views in relation to these medicines to the Welsh Medicines Partnership.

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 – Ranolazine (Ranexa®▼)

For the treatment of stable angina pectoris

Start time 10.45 am

The Chairman invited declarations of interest in relation to A Menarini Pharma UK. There were none.

The Chairman welcomed the applicant company delegates, Dr Ryan Graham and Mr Phil McEwan.

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 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 highlighted 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 was 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, 11th November 2009. The relevant issues contained within the PAR, enclosure **2**/AWMSG/1209, were highlighted. The views of the medical experts were conveyed and note was made of the unmet need in relation to the treatment for stable angina and potential for a reduction in hospitalisation. The patient organisation supported the availability of the medicine as a treatment option.

The Chairman expressed the concerns of NMG in relation to the health economic model and reservations in relation to the information provided in the submission which included dose differences within the clinical trials, the shortness of studies, modest effects in terms of clinical effectiveness and adverse reactions. He concluded his address by confirming the NMG recommendation to AWMSG was that ranolazine (Ranexa®▼) should not be supported for use within NHS Wales for the treatment of stable angina pectoris. He confirmed the view of NMG that the clinical benefits were marginal and the case for the cost-effectiveness of ranolazine (Ranexa®▼) had not been proven. It was the view of NMG that the estimated Incremental Cost Effectiveness Ratio (ICER) was not robust.

The Chairman opened the discussion and confirmed that opportunity would be provided to the applicant company to respond to all the issues raised in the discussion. Members were invited to address any outstanding issues in relation to clinical effectiveness. Reference was made to the limitations in relation to the exercise tolerance, angina attack frequency, evidence in relation to dose related syncope and effects on QTc interval, adverse effects and potential for restricted use within a sub-group of the patient population.

Members were invited to raise issues in relation to the cost effectiveness. Professor Phillips highlighted major concerns in relation to the health economic model presented in the submission. There were no outstanding issues in relation to budget impact.

The Chairman referred members to the patient organisation submission from Heart UK. The lay member welcomed the submission and encouraged collation of more patient views.

Members were referred to the response provided by A. Menarini Pharma UK Limited in relation to the preliminary recommendation and the Chairman invited the company delegates to respond to the discussion and highlight any outstanding salient issues. The option of restricting the availability of the medicine to patients inadequately controlled or intolerant to existing therapy was highlighted. Clarification of the utility weights and sensitivity analyses was obtained.

Prior to closing proceedings, the Chairman sought confirmation that representatives of the applicant company 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 at 11.28 am.

Appraisal decision

The recommendation of AWMSG was announced:

Ranolazine (Ranexa®▼) is not recommended for use within NHS Wales for the treatment of stable angina pectoris. The case for the cost effectiveness of ranolazine (Ranexa®▼) has not been proven.

7. Appraisal 2 – Darunavir (Prezista®▼)

For the treatment of human immunodeficiency virus (HIV)-1 infection in treatment naive patients.

The Chairman invited declarations of interest in relation to Tibotec (Janssen-Cilag) Limited. There were none.

The Chairman welcomed Mrs Lindsay Dearden and Dr Perry Mohammed, representing the applicant company.

It was 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 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.

Start time 11.30 am

Dr Duerden set the context of the appraisal and provided an overview of the discussions held at the NMG meeting on Wednesday, 11th November 2009. The relevant issues contained within the PAR, enclosure **3**/AWMSG/1209, were highlighted. The views of the medical experts were conveyed. Dr Duerden acknowledged the high standard of the patient organisation submission received from the Terrence Higgins Trust. Dr Duerden confirmed NMG's recommendation to AWMSG was that 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. It was noted that NMG considered that darunavir (Prezista®▼) would not be suitable for shared care.

The Chairman opened the discussion and invited members to address issues in relation to clinical effectiveness. The Chairman sought clarification in relation to any allergic reactions. Members were asked to address any outstanding issues in relation to the cost effectiveness information and clarification was sought in relation to the sensitivity analyses and cost per QALY. The potential for a reduction in the predicted budgetary impact was highlighted.

The Chairman referred members to the patient organisation submission and the lay member highlighted the quality of the submissions received from the Terence Higgins Trust.

The company delegates were invited to respond to the issues highlighted in the discussion and afforded opportunity to draw members' attention to any other outstanding matter. Prior to closing proceedings, the Chairman sought confirmation that representatives of the applicant company 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 at 11.49.

Appraisal decision

The recommendation of AWMSG was announced:

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.

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

8. Appraisal 3 - Degarelix (Firmagon®▼)
For the treatment of advanced hormone dependent prostate cancer

Start time 11.50 am

The Chairman welcomed Mr Mark Drabble from the applicant company, Ferring Pharmaceuticals Limited.

Dr Duerden set the context of the appraisal and provided an overview of the discussions held at the NMG meeting on Wednesday, 11th November 2009. The relevant issues contained within the PAR, enclosure **4**/AWMSG/1209, were highlighted. A summary of the medical expert opinion received was conveyed. Dr Duerden confirmed that a patient organisation submission from the West Wales Prostate Cancer Support Group had been considered by NMG members. This submission alluded to the need for more information to be available to patients in relation to potential adverse effects. Dr Duerden explained that the health economic model had not been provided with the submission and the health economist had been unable to verify the information provided by the applicant company in relation to the health economic data. In conclusion, Dr Duerden confirmed NMG's recommendation to AWMSG was that degarelix (Firmagon®▼) for the treatment of advanced hormone dependent prostate cancer should not be recommended for use within NHS Wales. The key factors influencing this recommendation were that the clinical benefit and case for cost effectiveness of degarelix (Firmagon®▼) had not been proven. NMG were also of the opinion that the estimated Incremental Cost Effectiveness Ration (ICER) was not robust.

The Chairman opened the discussion and invited members to address issues in relation to clinical effectiveness. The Chairman informed Mr Drabble that he would be afforded opportunity to comment on the issues raised in the discussion and provide clarification of any other outstanding issues. Members were asked to address issues in relation to the cost effectiveness information. The major concerns of the group in relation to the health economic model provided in the submission were highlighted. The lack of patient outcome and survival data were noted. Mr Drabble updated members on the studies currently underway. The WMP representative confirmed that the applicant company had not provided a response to the AWMSG secretariat assessment report (ASAR) earlier in the appraisal process.

The Chairman referred members to the patient organisation submission from The West Wales Prostate Cancer Support Group. The lay member welcomed the submission and there were no further comments. Members were referred to the summary of medical expert opinion received.

The Chairman referred members to the response to the preliminary recommendation provided by Ferring Pharmaceuticals Limited. Mr Drabble responded to the issues highlighted in the discussion and suggested a potential for on-going dialogue with AWMSG. Prior to closing proceedings, the Chairman sought confirmation that Mr Drabble was 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 at 12.30.

Appraisal decision

The recommendation of AWMSG was announced:

Degarelix (Firmagon®▼) is not recommended for use within NHS Wales for the treatment of advanced hormone-dependent prostate cancer. The case for the cost effectiveness of degarelix (Firmagon®▼) has not been proven

9. Update on AWPAG

Professor Philip Routledge left the meeting and Dr Paul Buss took the Chair. He invited Dr

Tessa Lewis to highlight the salient issues within the draft minutes of the AWPAG meeting held on 21st October 2009, Enc **5/**AWMSG/1209. Dr Lewis confirmed that the national indicator in relation to chiral medicines would be reviewed by AWPAG in January 2010. Dr Lewis drew members' attention to the ongoing work in relation to the prescribing of amiodarone, low molecular weight heparin and the development of an audit in relation to NSAIDs which would be presented to AWMSG at a future meeting. The presentation from Dr Richard Greville, Director of ABPI (Wales) in relation to the medicines supply chain was also highlighted. The Chairman thanked Dr Lewis and members of AWPAG for their valuable contribution to the strategic work programme of AWMSG.

10. Audit of off-label use of cancer medicines

The Chairman invited Mrs Sue Cervetto of the Welsh Medicines Partnership to provide an overview of the audit of off-label use of cancer medicines, Enc **6**/AWMSG/1209. Mrs Cervetto confirmed that the audit had been undertaken at the request of the Implementation Group following the recommendations of the Expert Group in relation to the availability of cancer medicines to determine the nature and extent of off-label use of cancer medicines within NHS Wales. It was confirmed that the audit was confined to the analysis of usage data and did not cover clinical aspects, which had been referred to the Cancer Services Co-ordinating Group and which would report back to the Implementation Group at their next meeting in January. The Chairman suggested that any governance implications should be addressed. He also reiterated the importance of the role of AWMSG in influencing prescribing in the wider context of the NHS in Wales

The date of the next meeting was announced and the meeting closed.

Wednesday, 3rd March 2010 at 10.30am in The Angel Hotel, Abergavenny

Meetings scheduled in 2010:
28th April / 23rd June / 18th August / 13th October / 15th December 2010