Enclosure No:	
Agenda Item No:	Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP
MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY, 14th OCTOBER 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
4.	Mrs Debbie Davies	Representing other professions eligible to prescribe
5.	Dr Bruce Ferguson	Trust Medical Director
6.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health
7.	Ms Jane Griffin	ABPI (Wales) representative
8.	Dr Brian Hawkins	Senior Primary Care Pharmacist
9.	Mr Robert Holcombe	LHB Finance representative
10.	Cllr Meurig Hughes	Lay representative
11.	Dr Thomas Lau	General Practitioner with prescribing lead role
12.	Prof Ceri Phillips	Health Economist
13.	Mr Dave Roberts	Chief Pharmacist
14.	Prof Philip Routledge	Clinical Pharmacologist (Chairman)
15.	Mrs Wendy Warren	Senior Nurse

IN ATTENDANCE:

13.	Dr Martin Duerden	NMG Chairman
14.	Mr Russell Pope	Welsh Assembly Government
15.	Ms 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
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

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 welcomed Mrs Jane Griffin to her first AWMSG meeting.

The Chairman informed members that the Minister for Health and Social Services had received and noted the report of the Implementation Group with regard to improving access to medicines and its budgetary implications are currently under consideration.

It was reported that on Tuesday, September 15th 2009 WMP representatives had been invited to present a case for the funding of the Welsh Analytical Prescribing Support Unit. The outcome is awaited.

The Chairman expressed thanks to The Bevan Foundation for hosting a conference on Thursday, 1st October to address issues relating to access to new medicines.

Members were informed that the TDA Users Group had met earlier in the month to discuss issues relating to the appraisal process. It was announced that ABPI Wales will be hosting a meeting on Wednesday, 9th December at the All Nations Centre when representatives from WMP, AWMSG and NMG will update and inform industry on matters relating to the appraisal process in Wales.

It was confirmed that the National Prescribing Indicators, endorsed by AWMSG at the last meeting, had been forwarded to Health Solutions Wales and uploaded to the AWMSG website.

The Chairman confirmed that dates for AWMSG meetings during 2010 had been posted the AWMSG website. It was noted the February meeting is postponed to **Wednesday 3rd March 2010**.

The Chairman reported that Ministerial ratification of the recommendations made by AWMSG in relation to the appraisals held at the August 2009 meeting had been confirmed.

Paricalcitol (Zemplar®▼) capsules are not recommended for use within NHS Wales for the treatment of secondary hyperparathyroidism associated with chronic renal insufficiency (chronic kidney disease (CKD) Stages 3 and 4) patients and chronic renal failure (CKD Stage 5) patients on haemodialysis or peritoneal dialysis. Insufficient evidence of clinical and cost effectiveness was presented for AWMSG to recommend its use within NHS Wales.

Ropinirole prolonged-release (Requip XL®▼) is recommended for use within NHS Wales for the treatment of idiopathic Parkinson's disease in patients already taking ropinirole immediate-release tablets (Requip®) and in whom adequate symptomatic control has been established.

Etravirine (Intelence®▼) is recommended as an option for use within NHS Wales for the treatment of HIV-1 infected, antiretroviral treatment-experienced adults in combination with a boosted protease inhibitor and other antiretroviral medicinal products. Treatment should be initiated by a specialist in accordance with BHIVA guidelines. Etravirine (Intelence®▼) is not recommended for use as first line therapy. AWMSG is of the opinion that etravirine (Intelence®▼) is not suitable for shared care within NHS Wales.

Quetiapine prolonged-release tablets (Seroquel XL®▼) are recommended as an option for use within NHS Wales for the treatment of **schizophrenia in adults**. In order to limit errors, prolonged-release quetiapine should be prescribed by brand name, as Seroquel XL®▼. AWMSG is of the opinion that quetiapine prolonged-release tablets (Seroquel XL®▼) may be suitable for shared care within NHS Wales.

Quetiapine prolonged-release tablets (Seroquel XL®▼) are not endorsed for the treatment of manic episodes associated with **bipolar disorder** within NHS Wales. AstraZeneca UK Ltd is not in a position to progress a submission to AWMSG for its appraisal in this indication. As a result, AWMSG cannot provide advice to the Minister for Health and Social Services.

Filgrastim (Ratiograstim®▼) is recommended as an option for use within NHS Wales in the treatment of neutropenia:

- For the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and for the reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia.

- For the mobilisation of peripheral blood progenitor cells (PBPC).

- To increase neutrophil counts and to reduce the incidence and duration of infection-related events in patients with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of 0.5 x 10^9/L, and a history of severe or recurrent infections.

- For the treatment of persistent neutropenia (ANC less than or equal to 1.0 x 10^9/L) in patients with advanced human immunodeficiency virus (HIV) infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate.

It was noted the Final Appraisal Reports had been posted on the AWMSG website and confirmation of Ministerial ratification communicated to the service.

Three appraisals scheduled for the next AWMSG meeting on 16th December were confirmed as follows:

Ranolazine (Ranexa®▼) for the treatment of stable angina pectoris
Manufacturer - A Menarini Pharma UK

Darunavir (Prezista®▼) for the treatment of human immunodeficiency virus (HIV)-1 infection in treatment naive patients.
Manufacturer - Tibotec (Janssen-Cilag) Ltd

Degarelix (Firmagon®▼) for the treatment of advanced hormone dependent prostate cancer
Manufacturer - Ferring Pharmaceuticals (UK)

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 – Mecasermin (Increlex®▼)

For the treatment of growth failure in children and adolescents with severe primary deficiency (low blood levels) of a hormone, insulin-like growth factor-1 (IGF-1).

Start time 10.55 am

The Chairman confirmed that representation from the applicant company, Ipsen Limited, to input into the discussions had been declined.

The Chairman announced the statement pertinent to all appraisals scheduled.
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.

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 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, 16th September 2009. He confirmed the view of NMG that the submission met the AWMRG criteria for ultra orphan drug status. The relevant issues contained within the PAR, enclosure **2**/AWMSG/1009, were highlighted. Dr Duerden conveyed the view of the medical expert. The availability of limited information was noted. He concluded his address by confirming the NMG recommendation to AWMSG was that mecasermin (Increlex®▼) should be supported 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. He confirmed the view of NMG that mecasermin (Increlex®▼) would not be suitable for shared care within NHS Wales. It was noted that NMG recommended monitoring of the long term effects of mecasermin treatment and the inclusion of releant information into a Registry.

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. There was discussion in relation to potential for substitution of growth hormone and duration of treatment. The issue of collation of data was raised and confirmation was provided of the establishment of a European Increlex growth registry.

Members were invited to raise any issues in relation to the cost effectiveness. Professor Phillips confirmed that the applicant company had been explicit in their uncertainty of the health economic data provided in the submission. Issues in relation to budget impact were invited.

The Chairman confirmed that a submission from a relevant patient organisation had not been received and the lay member expressed disappointment at the lack of response to the numerous WMP requests for patient/patient carer input. The Chairman reiterated the on-going challenge for WMP in encouraging patient organisation input into the appraisal process.

Members were referred to the response provided by Ipsen Limited in relation to the preliminary recommendation.

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:

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

Treatment should be initiated and monitored by physicians who are experienced in the diagnosis and management of patients with growth disorders.

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

Additional notes:

- AWMSG considers that mecasermin (Increlex®▼) meets the AWMSG criteria for ultra orphan drug status.

- AWMSG recommends that there should be careful monitoring of the long term effects of mecasermin (Increlex®▼) treatment and that information should be collated and included in the already-established European Registry.

7. Appraisal 2 – Methoxy polyethylene glycol-epoetin beta (Mircera®▼)
For the treatment of symptomatic anaemia associated with chronic kidney disease

Start time 11.30 am

The Chairman welcomed Hok Pang and Stuart Robinson representing the applicant company, Roche Products Limited.

Dr Duerden set the context of the appraisal and provided an overview of the discussions held at the NMG meeting on Wednesday, 16th September 2009. The relevant issues contained within the PAR, enclosure **3**/AWMSG/1009, were highlighted. The views of one medical expert were conveyed. Benefits in terms of ease of administration were acknowledged. WMP confirmed that a further medical expert questionnaire had been received subsequent to the NMG meeting and had therefore not been included in the meeting papers. It was noted that the individual supported the availability of the medicine as a treatment option. A patient organisation submission from the National Kidney Federation had been provided to AWMSG members.

Dr Duerden concluded his address by confirming NMG's recommendation to AWMSG was that Methoxy polyethylene glycol-epoetin beta (Mircera®▼) should be recommended as an option for use within NHS Wales for the treatment of symptomatic anaemia associated with chronic kidney disease. It was noted that NMG were of the opinion that Methoxy polyethylene glycol-epoetin beta (Mircera®▼) is suitable for shared care within NHS Wales.

The Chairman opened the discussion and invited members to address issues in relation to clinical effectiveness. The clinical advantages in relation to compliance, convenience, ease of administration, reduction in travel and nursing time were noted.

The Chairman referred members to the patient organisation submission and the medical expert summary. These responses outlined the benefits and potential cost savings.

Members were asked to address any outstanding issues in relation to the cost effectiveness information. There was discussion over the appropriate use of a cost minimisation analysis.

The Chairman invited members to comment on any societal or budget impact issues and then opened the discussion to Hok Pan and Stuart Robinson to respond to the issues highlighted in the discussion.

The Chairman referred members to the response to the preliminary recommendation provided by Roche Products Limited. It was confirmed that a paediatric licence was not being pursued at the present time.

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.

The recommendation of AWMSG was announced:

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.

AWMSG is of the opinion that methoxy polyethylene glycol-epoetin beta (Mircera®▼) is suitable for shared care within NHS Wales.

8. AWMSG Constitution update

The Chairman asked members to note Enc **4**/AWMSG/1009, the updated AWMSG Constitution.

9. Updated NICE supplementary information for appraising life-extending, end of life treatments

The Chairman asked members to note Enc **5**/AWMSG/1009, the revised National Institute for Health and Clinical Excellence supplementary information for appraising life-extending, end of life treatments.

10. Informing Healthcare (IHC)

The Chairman invited Mrs Cheryl Way, Pharmacy and Medicines Management Lead for Informing Healthcare to present Enc **6**/AWMSG/1009. Mrs Way asked AWMSG to consider the work being undertaken by IHC in relation to recommendation 14 of the AWMSG Medicines Strategy for Wales which states that systems need to be developed for electronically communicating patient medicines information on admission and discharge from hospital. The lack of available resource to support the development, piloting and delivery of electronic recording of prescribing was highlighted. Members suggested that potential benefits such as the reduction of adverse reactions, improved management of patients and efficiencies should be included within the business case. Members expressed their support and commended the development of this work. The Chairman suggested that the enclosure be tabled at the next AWMSG Steering Committee meeting so that AWMSG's support for the formulation of a strategy for the delivery and implementation of electronic reporting/ prescribing could be addressed.

11. Development of a Drug Formulary System for Wales

The Chairman invited Mr Robin Burfield of Health Solutions Wales to present Enc **7**/AWMSG/1009 and explain the background. AWMSG's strategy for prescribing and medicines management recommends that all involved with prescribing and medicines management will work together to ensure equity of access to the most appropriate and cost-effective medicines for the people of Wales. This will be delivered through innovative services by a high quality workforce designed to meet the needs of all patients within all levels of health care, as outlined in *Designed for Life*.

Mr Burfield outlined the development of a drug formulary system for NHS Wales and explained the need to support the selection of drugs within the medicines management module of the Welsh Clinical Portal currently being developed by IHC. It was noted that the system would include recommendations of AWMSG and NICE guidance alongside the formulary for each local health board. It was explained that each LHB would maintain their formulary independently, though the facility for cross linkage would be available. It was noted that the first release of the system is anticipated in January 2010. Linkage with primary care prescribing systems was confirmed. Members expressed their support for the electronic updating and publishing of formularies to promote consistency of prescribing messages and medicines management. The Chairman confirmed the support of AWMSG for the development of the work being undertaken by colleagues in Health Solutions Wales

12. Date of next AWMSG meeting:
Wednesday, 16th December 2009 at 10.30am in The Angel Hotel, Abergavenny

Dates for 2010:
3rd March / 28th April / 23rd June / 18th August / 13th October / 15th December