Enclosure No:	**1/AWMSG/0311**
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 FEBRUARY COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY

MEMBERS PRESENT:

Did not participate in

1.	Prof Philip Routledge	Chairman
2.	Dr Hugo Van Woerden	Welsh Health Specialised Services Committee
3.	Ms Pippa Anderson	Health Economist
4.	Mrs Debbie Davies	Representing other professions eligible to prescribe
5.	Dr Bruce Ferguson	Medical Director
6.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health
7.	Dr Brian Hawkins	Senior Primary Care Pharmacist
8.	Mr Stefan Fec	Community Pharmacist
9	Dr Philip Banfield	Hospital Consultant
10.	Dr Emma Mason	Clinical Pharmacologist
11.	Mr Christopher Palmer	Lay representative
12.	Mr Guy Thompson	ABPI (Wales) representative
13.	Mr Christian Smith	Senior Nurse
14.	Mr Roger Williams	Senior Pharmacist

IN ATTENDANCE:

15.	Dr Robert Bracchi	NMG Chairman
16.	Professor Ceri Phillips	NMG/AWMSG Link Health Economist
17.	Professor Roger Walker	Welsh Assembly Government
18.	Mrs Karen Samuels	Welsh Medicines Partnership
19.	Mrs Ruth Lang	Welsh Medicines Partnership
20.	Mrs Susan Cervetto	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
DH	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
HB	Health Boards
M&TCs	Medicines & Therapeutics Committees
MHRA	Medicines & Healthcare Products Regulatory Agency
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

Ms Rebecca Richards, Finance Director
Dr John Watkins, Public Health Wales
Prof David Cohen, Health Economist
Dr Fraser Campbell, General Practitioner
Mrs Wendy Warren, Senior Nurse
Ms Ellen Lanham, Community Pharmacist
Dr William Whitehead

3. Declarations of interest

The Chairman asked members to declare any interests pertinent to the agenda. There were none.

4. Chairman's report

The Chairman welcomed Professor Roger Walker who had recently taken up the appointment of Chief Pharmaceutical Officer for Wales. The Chairman welcomed members and each member introduced themselves.

The Chairman announced that the Minister for Health and Social Services had ratified the recommendations made by AWMSG at the preceding December meeting:

Ranolazine (Ranexa®▼) as an add-on therapy is recommended as an option for restricted use within NHS Wales for the symptomatic treatment of patients with stable angina pectoris. Treatment should be initiated by a Cardiologist. Ranolazine (Ranexa®▼) should be restricted for use in patients who remain symptomatic despite treatment with all other pharmacological anti-anginal therapies and where revascularisation has been considered and undertaken or is not considered appropriate.

Sildenafil citrate (Revatio®▼) solution for injection is recommended within its current licensed indication as an option for use within NHS Wales for the treatment of patients with pulmonary arterial hypertension (PAH) who are currently prescribed oral sildenafil citrate and who are temporarily unable to take oral medicine, but are otherwise clinically and haemodynamically stable. AWMSG recommends that its use be restricted to a physician experienced in the treatment of PAH. Sildenafil citrate (Revatio®▼) solution for injection is not suitable for shared care within NHS Wales for the above indication.

Atazanavir (Reyataz®▼) capsules, co-administered with low dose ritonavir, are recommended as an option for use within NHS Wales for the treatment of HIV-1 infected paediatric patients 6 years of age and older in combination with other antiretroviral medicinal products. Atazanavir (Reyataz®▼) is not suitable for shared care within NHS Wales for the above indication.

Tipranavir (Aptivus®▼) capsules, co-administered with low dose ritonavir, are recommended as an option for use within NHS Wales, for combination antiretroviral treatment of HIV-1 infection in highly pre-treated adolescents 12 years of age or older with virus resistant to multiple protease inhibitors. Tipranavir (Aptivus®▼) should only be used as part of an active combination antiretroviral regimen in patients with no other therapeutic options. Tipranavir (Aptivus®▼) capsules are not suitable for shared care within NHS Wales for the above indication.

Tipranavir (Aptivus®▼) oral solution, co-administered with low dose ritonavir, is recommended as an option for use within NHS Wales for combination antiretroviral treatment of HIV-1 infection in highly pre-treated children from 2 to 12 years of age with virus resistant to multiple protease inhibitors. Tipranavir (Aptivus®▼) should only be used as part of an active combination antiretroviral regimen in patients with no other therapeutic options. Tipranavir (Aptivus®▼) oral solution is not suitable for shared care within NHS Wales for the above indication.

The Chairman confirmed that statements of advice had been posted on the AWMSG website in relation to the following medicines. The Minister for Health and Social Services has endorsed that the following medicines should not be routinely available within NHS Wales until appraisal by AWMSG or NICE has been undertaken:

Abarelix (Plenaxis®) for the initiation of hormonal castration in patients with advanced or metastatic hormone-dependent prostate cancer, if androgen suppression is appropriate

Telmisartan/amlodipine (Twynsta®) as an add on therapy for the treatment of essential hypertension in adults whose blood pressure is not adequately controlled on amlodipine and replacement therapy for the treatment of essential hypertension in adults already receiving telmisartan and amlodipine from separate tablets

Sevelamer carbonate (Renvela®) powder for oral suspension for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis and in those with chronic kidney disease not on dialysis

The Chairman confirmed there are no appraisals scheduled for the next AWMSG meeting on Wednesday, 16th March 2011. The agenda would consist of strategic matters and other medicines management issues.

5. Minutes of previous meeting

The Chairman thanked Dr Paul Buss for chairing the December meeting, the minutes of which were checked for accuracy. Members approved the minutes and the Chairman signed them as a true record. There were no matters arising.

6. Appraisal 1: Appraisal 1: Filgrastim (Nivestim®▼) (full submission)
for the treatment of neutropenia and mobilisation of peripheral blood progenitor cells

The Chairman invited members to declare interests in either the applicant company or the medicine. There were none. The Chairman confirmed that the applicant company, Hospira UK Ltd, had declined the invitation to participate in the appraisal.

The Chairman announced the statement, pertinent to all appraisals, that 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 Health Boards 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 had 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. He confirmed that members would retire to vote in private and agree the recommendation, which would be subsequently announced

The Chairman invited Dr Robert Bracchi, Chairman of the New Medicines Group, to provide an overview of the discussions held at the preliminary appraisal. Dr Bracchi set the clinical context outlined in the ASAR and confirmed that the applicant company had submitted a cost minimisation health economic model. He relayed the views of medical experts and support of patient organisations - Leukaemia Care and Breast Cancer Care. He explained the reasons why members of the New Medicines Group had concluded that filgrastim (Nivestim®▼) should be recommended as an option for use within NHS Wales for the treatment of neutropenia.

Dr Bracchi confirmed that NMG were of the opinion that filgrastim (Nivestim®▼) would not suitable for shared care within NHS Wales for the above indication. It was noted that NMG considered filgrastim (Nivestim®▼) should be prescribed by brand name to avoid automatic substitution and that this would assist with pharmacovigilance.

NMG had highlighted that due to the potential differences between biosimilars from different manufacturers and/or the reference product (Nivestim®▼), post-marketing pharmacovigilance

would be essential and should be facilitated by the Risk Management Plan outlined in the Committee for Medicinal Products for Human Use assessment report. It was also confirmed that until the required efficacy and safety data becomes available, the European group for blood and bone marrow transplantation (EBMT) does not recommend the use of biosimilar granulocyte-colony stimulating factors (G-CSFs) for mobilisation of stem cells in healthy donors for stem cell transplantation.

The Chairman opened the discussion and invited members to highlight any issues in relation to the case for clinical effectiveness. Members sought clarification in relation to equivalent costs and issues relating to the clinical management of the patient. It was confirmed that the reference product had been used as the comparator.

The Chairman invited Professor Ceri Phillips to highlight issues in relation to cost effectiveness and invited members to raise any outstanding issues. Mr Palmer was invited to comment on the patient organisation submission and convey his views from a lay perspective. Members considered and discussed the summary of clinical expert opinion.

Following the discussion, the Chairman asked members to make a note of their comments on the aide-memoire provided. He confirmed that members would retire to vote at the end of the appraisal session and the recommendation would be subsequently announced.

Appraisal decision

AWMSG's recommendation to the Minister for Health and Social Services was announced:

Filgrastim (Nivestim®▼) is recommended as an option for use within NHS Wales for 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. The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy.

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

- In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of 0.5 × 10^9/l and a history of severe or recurrent infections, long term administration of (Nivestim®▼) is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events.

- For the treatment of persistent neutropenia (ANC less than or equal to 0.5 × 10^9/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate.

- Filgrastim (Nivestim®▼) is not suitable for shared care within NHS Wales for the above indication.

- Filgrastim (Nivestim®▼) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance.

7. Appraisal 2 - Valsartan (Diovan®▼) (limited submission)
for the treatment of hypertension in children and adolescents 6 to 18 years of age

The Chairman confirmed that the applicant company, Novartis Pharmaceuticals Ltd, had declined the invitation to participate in the appraisal proceedings. There were no declarations of interest. The Chairman alluded to his previous statement regarding AWMSG advice and confirmed it was pertinent to all appraisals. He reiterated AWMSG's remit in relation to the limited submission.

Members were informed that the ASARs took account of the clinical effectiveness and budgetary impact information provided by the applicant company. The Chairman confirmed the remit of AWMSG was to consider and discuss the budget impact and consider any societal issues, as this fell outside the remit of NMG. Members noted that a cost effectiveness model was not required for a limited submission, and that comparator costs had been provided.

The Chairman invited Dr Bracchi to set the context outlined in the ASAR. Dr Bracchi confirmed it was a limited sunmission for a licensed extension and provided an overview of the submission. Discussions at NMG were summarised and Dr Bracchi provided the rationale behind NMG's preliminary recommendation to AWMSG that valsartan (Diovan®▼) tablets should not be recommended for use within NHS Wales for the treatment of hypertension in children and adolescents 6 to 18 years of age. NMG considered there was insufficient evidence of clinical effectiveness in the submission for NMG to recommend its use. AWMSG members were reminded that patient organisation submissions are not actively sought as part of a limited submission.

The Chairman opened the discussion and invited members to highlight any issues in relation to the limited submission. The Group sought re-clarification of the limited submission process and the process applied to identifying the most suitable comparator. Mrs Samuels clarified the process issues and stated that the limited submission process is currently in pilot and feedback would be sought from NMG, AWMSG and the applicant companies. The mandatory nature of AWMSG decisions was reiterated.

The Chairman asked that members consider the submission as presented and make a decision based on its merits. The Chairman encouraged members not take account of any other external influences. Discussions in relation to efficacy, clinical effectiveness and the practical implications of undertaking an appraisal based on limited data took place.

Members considered the summary of clinical expert opinion where it stated that currently there was no unmet clinical need.

The Chairman referred members to the applicant company's response to the PAR and reaffirmed that unfortunately the company were not present to respond to the issues raised in the discussion or highlight any aspects of their response.

Following the discussion, the Chairman asked members to make a note of their comments on the aide-memoire and concluded the appraisal.

Appraisal decision

AWMSG's recommendation to the Minister for Health and Social Services was announced:

Valsartan (Diovan®▼) tablets are not recommended for use within NHS Wales for the treatment of hypertension in children and adolescents 6 to 18 years of age.
The submission contained insufficient evidence for AWMSG to recommend its use.

8 **Appraisal 3 – Darunavir (Prezista®▼)** (limited submission)
for the treatment of HIV-1 infection in treatment-experienced children and adolescents

The Chairman welcomed the delegates representing the applicant company, Janssen-Cilag Ltd There were no declarations of interest. The Chairman outlined the process for the applicant company to respond to the issues raised.

Dr Bracchi was invited to set the context of the appraisal outlined in the ASAR. Discussions held at NMG were summarised and Dr Bracchi provided the rationale behind NMG's advice that darunavir (Prezista®▼) should be recommended as an option for use within NHS Wales, co-administered with low dose ritonavir, in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in antiretroviral treatment (ART)-experienced children and adolescents from the age of 6 years and at least 20 kg body weight. He relayed NMG's view that darunavir (Prezista®▼) should be prescribed in accordance with Paediatric European Network for Treatment of Aids (PENTA) guidelines and confirmed that NMG were of the opinion that darunavir (Prezista®▼) would not be suitable for shared care within NHS Wales for the above indication.

The Chairman opened the discussion and invited members to highlight any issues in relation to the submission. Members sought clarification in relation to safety data and comparative efficacy. It was confirmed that a limited submission does not require cost effectiveness information. Members took account of the summary of clinical expert opinion and members sought clarity from the applicant company in relation to the experts' estimate of patient numbers. There were no societal issues of note. It was confirmed that a patient organisation submission had not been actively sought.

The applicant company representatives addressed members' concerns in relation to comparative efficacy, safety data, and clinical pathway.

At the end of the discussion the representatives of the applicant company confirmed that the process had been fair and transparent and that all issues had been addressed.

The Chairman asked members to make a note of their comments on the aide-memoire provided and closed the appraisal session.

Appraisal decision

AWMSG's recommendation to the Minister for Health and Social Services was announced:

Darunavir (Prezista®▼) co-administered with low dose ritonavir, in combination with other antiretroviral medicinal products, is recommended as an option for use within NHS Wales for the treatment of human immunodeficiency virus (HIV-1) infection in antiretroviral treatment (ART)-experienced children and adolescents from the age of 6 years and at least 20 kg body weight. Darunavir (Prezista®▼) should be prescribed in accordance with Paediatric European Network for Treatment of Aids (PENTA) guidelines. Darunavir (Prezista®▼) is not suitable for shared care within NHS Wales for the above indication

9 **Department of Health consultation – A new value-based approach to the pricing of branded medicines**
The Chairman provided the background to the agenda item and confirmed that in response to an Office of Fair Trading Consultation in 2007, AWMSG had endorsed the value based pricing approach as an appropriate mechanism for responding to the assessment of clinical and cost effective medicines.

The Chairman confirmed that the coalition government had asked that the issue of value based

pricing be explored and the Department of Health consultation had been provided to members for consideration. The Chairman suggested that members submit their views to the Secretariat to inform a response from AWMSG. He proposed that a draft response be circulated to members for comment outside of the meeting. The Health Economist member confirmed that the views of the AWMSG/NMG health economists would be submitted as a consensus view and should be included as part of the AWMSG formal response. The ABPI Wales representative highlighted the support of Wales Industry Group of UK-wide value based pricing and suggested that other aspects should also be incorporated into the consideration of the value of new medicines. Members agreed that AWMSG should respond from an NHS Wales perspective. The Welsh Assembly Government representative confirmed the involvement of AWMSG in any future UK process. The Chairman asked members to email comments to WMP within the next ten days.

10 Prescribing Dilemmas Guidance

The Chairman confirmed that Mrs Louise Howard Baker had been invited to AWMSG to provide the background to Enc6/AMSG/0211. Members were informed the document provided guidance for health professionals in relation to prescribing situations not covered by the NHS, including private care, private prescriptions, travel, foodstuffs, infertility treatments, minor ailments, homeopathy, erectile dysfunction, prescribing for self and family, visitors from overseas, unlicensed medicines and prescribing outside national guidance. The All Wales Prescribing Advisory Group had collated information from a number of former local health board and trust policies into a single guidance document. AWMSG was asked to consider and support the guidance for health professionals in order to promote good medical practice. AWMSG members welcomed the guidance document which offered a single source of a compilation of good practice information. Members sought clarification of a number of outstanding issues which were noted. The Chairman confirmed that these outstanding issues should be addressed and the document re-presented to AWMSG at a future meeting. The Chairman acknowledged the valuable contribution of Mrs Louise Howard-Baker and the All Wales Prescribing Advisory Group in the development of an important reference document.

11 The Chairman confirmed the date of next AWMSG meeting:
Wednesday, 16th March 2011 at 10.30am in The Angel Hotel, Abergavenny