

Enclosure No:	1/AWMSG/1009
Agenda Item No:	Minutes of previous meeting
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**ALL WALES MEDICINES STRATEGY GROUP
MINUTES OF THE AWMSG MEETING HELD ON
WEDNESDAY, 12th AUGUST 2009 COMMENCING 10.30 AM
AT THE ANGEL HOTEL, ABERGAVENNY**

MEMBERS PRESENT:

**Did not
participate in**

- | | | | |
|-----|-----------------------|---|------|
| 1. | Dr Paul Buss | NHS Consultant | |
| 2. | Dr Fraser Campbell | LHB Medical Director | |
| 3. | Dr Karen Fitzgerald | National Public Health Service Wales | |
| 4. | Mr Jeremy Felvus | Industry Representative | 8/11 |
| 5. | Cllr Meurig Hughes | Lay member | 7 |
| 6. | Dr Thomas Lau | General Practitioner and prescribing lead | |
| 7. | Prof Ceri Phillips | Health Economist | |
| 8. | Mr Dave Roberts | Chief Pharmacist | |
| 9. | Prof Philip Routledge | Clinical Pharmacologist (Chairman) | |
| 10. | Mrs Wendy Warren | Senior Nurse | |

IN ATTENDANCE:

- | | | |
|-----|-------------------|-----------------------------|
| 13. | Dr Martin Duerden | NMG Chairman |
| 14. | Mrs Vi Turner | 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
LHB	Local Health Board
M&TCs	Medicines & Therapeutics Committees
MHRA	Medicines & Herbs 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. Members were informed that Mr Jeremy Felvus had been co-opted as industry representative. The Chairman welcomed Mrs Vi Turner representing Welsh Assembly Government.

2. Apologies

Dr Brian Hawkins / Mrs Susan Murphy
Miss Carwen Wynne Howells (Welsh Assembly Government)
Dr Geoffrey Carroll / Dr Hugo Van Woerden (Health Commission Wales representative)
Mr Robert Holcombe / Ms Rebecca Richards (LHB Finance Director representative)
Mr Guy Thompson / Ms Jane Griffin (Industry representative)

Dr Bruce Ferguson (Trust Medical Director representative)
Mr Russell Pope (Welsh Assembly Government)
Mrs Debbie Davies (Other professions allied to medicine eligible to prescribe)

3. **Declarations of interest**

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

Councillor Meurig Hughes declared a personal non-specific interest in Glaxo Smithkline and the Chairman confirmed that Councillor Hughes would not be permitted to participate in the appraisal of ropinirole (Requip XL^{®▼}).

Mr Jeremy Felvus declared an interest in agenda item 8 and elements of Enc 9/AWMSG/0809 in relation to the national prescribing indicators. The Chairman confirmed that Mr Felvus would not be permitted to participate in the appraisal of etravirine (Intelence^{®▼}) and excluded from discussion of Enc 9/AWMSG/0809, the proposed national prescribing indicators.

The Chairman declared a non personal non specific interest in that Astra Zeneca part fund a lecturer post within the Department of Pharmacology in Cardiff University. It was confirmed that this interest did not preclude him from chairing the proceedings.

Mrs Wendy Warren joined the meeting.

4. **Chairman's report**

The Chairman reported that Mr Jeffrey Evans, representing professions allied to medicine eligible to prescribe, had resigned from the Group. The Chairman expressed thanks to Mr Evans for his contribution to the Group.

The Chairman reported that representatives of WMP had met with industry colleagues at the TDA Users Group on Friday 3rd July to discuss issues relating to the appraisal process. These include prioritisation criterion in relation to appraisal selection and the process for dealing with submissions where there is limited information available, e.g. for licence extensions and formulation changes.

Members were informed that the All Wales Prescribing Advisory Group had met on Monday, 6th July when, for the first time, members of NHS Industry Forum had been invited to attend to input into discussions of mutual interest – such as the national prescribing indicators. This novel approach had provided industry colleagues direct input into papers currently in development prior to them being presented to AWMSG, and the feedback received by the Chairman had been positive. The Chairman confirmed that the AWMSG Steering Committee had agreed that this 'merged' approach should be adopted for the next meeting on 21st October 2009.

The Chairman reported that The National Institute for Health and Clinical Excellence had recently revised their supplementary advice to their Appraisal Committees which is to be taken into account when appraising life-extending treatments for patients with short life expectancy, and which are licensed for indications affecting small numbers of patients with incurable illnesses. It was confirmed that the impact of this on AWMSG would be considered by WMP and the AWMSG Steering Committee.

The Chairman announced that the Minister for Health and Social Services had ratified the recommendations of AWMSG in relation to the appraisal held at the June 2009 meeting:

Aliskiren (Rasilez^{®▼}) is not recommended for use within NHS Wales for the treatment of essential hypertension.

Tacrolimus prolonged-release (Advagraf®) is **not recommended** for use within NHS Wales 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.

Aripiprazole (Abilify®) is **recommended** as an option for use within NHS Wales for the treatment of moderate to severe manic episodes in Bipolar I Disorder and for the prevention of a new manic episode in patients who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment.

Subsequent to the AWMSG appraisal, the New Medicines Group confirmed that aripiprazole (Abilify®) may be suitable for shared care when used for long term treatment (i.e. prevention of manic episode) after hospital initiation. This has been included in the final appraisal report.

Bivalirudin (Angiox®▼) (administered with aspirin and clopidogrel) is **recommended** as an option within NHS Wales for the treatment of adult patients with acute coronary syndromes (unstable angina/non-ST segment elevation myocardial infarction [UA/NSTEMI]) planned for urgent or early intervention. Bivalirudin (Angiox®▼) should only be considered as an option where both a glycoprotein IIb/IIIa inhibitor (GPI) plus heparin would be used as an alternative. Bivalirudin (Angiox®▼) should not be used as an alternative where heparin would be used alone. AWMSG is of the view that the main place in therapy for bivalirudin (Angiox®▼) is where there is a high risk of bleeding.

AWMSG had recommended that an All-Wales Guideline for use of anticoagulant interventions in UA/NSTEMI be developed and the use of these treatments should be audited. The Chairman confirmed that representatives of the Welsh Medicines Partnership would be progressing these issues at the next meeting of the New Cardiovascular Drugs Group scheduled for the end of September.

Micafungin (Mycamine®) is **not recommended** for use within NHS Wales for the treatment of invasive candidiasis in adults (including the elderly) and children (including neonates).

The Chairman confirmed that the Final Appraisal Reports had been posted on the AWMSG website and the Service had been notified.

The Chairman announced the following appraisals scheduled for the next AWMSG meeting on 14th October 2009:

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).

Methoxy polyethylene glycol-epoetin beta (Mircera®▼) for the treatment of symptomatic anaemia associated with chronic kidney disease.

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 – paricalcitol (Zemplar®▼) capsules

For the prevention and treatment of secondary hyperparathyroidism associated with chronic renal insufficiency

Start time 10.47 am

The Chairman welcomed Ivana Filipovic, Health Economics Advisor and Lucy Cook, Senior Medical Advisor representing the applicant company, Abbot Laboratories Limited.

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, 15th July 2009. The relevant issues contained within the PAR, enclosure 2/AWMSG/0809, were highlighted. Dr Duerden conveyed the view of the medical expert. He concluded his address by confirming the NMG recommendation to AWMSG was that paricalcitol (Zemplar[®]▼) capsules should not be 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.

The key factors leading to this decision were that NMG considered that the company did not present sufficiently robust evidence regarding the clinical and cost effectiveness of paricalcitol capsules after failure (or intolerance) of alfacalcidol within the restricted population of patients with chronic renal failure (CKD Stage 5) receiving haemodialysis, on which the submission has been based. Dr Duerden conveyed the view that the evidence provided was limited and did not give information on patients who had failed on other vitamin D analogue preparations. NMG were of the opinion that there were many uncertainties in the economic model provided in the company's submission.

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 the licence indication, its place in the clinical pathway and use of haemodialysis. Clarification in relation to surgery and the relative impact of non-drug therapies was sought.

Members were invited to raise any issues in relation to the cost effectiveness information provided. Professor Phillips expressed concern over the data presented and assumptions used to populate the health economic model. Members discussed the budget impact.

The Chairman referred members to the patient organisation submission received from Friends of Renal Care YCG. The lay member expressed disappointment at the lack of response to the numerous WMP requests for patient/patient carer input and expressed his thanks for this

personal response. The Chairman reiterated the on-going challenge for WMP in encouraging patient organisation input into the appraisal process.

The Chairman invited Ivana Filipovic and Lucy Cook to respond to issues highlighted in the discussion. It was suggested that one medical expert view might not be representative of the views of other medical experts across the country. Members were referred to the detailed response provided by Abbott 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 11.32 am.

Appraisal decision

The recommendation of AWMSG was announced:

Paricalcitol (Zemlar[®]) 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.

7. Appraisal 2 – ropinirole (Requip XL[®])

For the treatment of idiopathic Parkinson's disease

Councillor Meurig Hughes left the meeting.

Start time 11.34 am

The Chairman welcomed Manjit Hunjan and James Parker representing the applicant company, GlaxoSmithKline.

Dr Duerden set the context of the appraisal and provided an overview of the discussions held at the NMG meeting on Wednesday, 15th July 2009. The relevant issues contained within the PAR, enclosure 3/AWMSG/0809, were highlighted. The views of the three medical experts were conveyed. Two patient organisations, the European Parkinson's Disease Association and the Parkinson's Disease Society, were considered by NMG and had been provided to AWMSG members. Dr Duerden concluded his address by confirming NMG's recommendation to AWMSG was that ropinirole prolonged-release (Requip XL[®]) should not be recommended for use within NHS Wales for the treatment of idiopathic Parkinson's disease. NMG considered the evidence provided was insufficient to prove equivalent efficacy of both products (immediate release IR and prolonged release PR formulations) on a dose for dose basis. NMG had expressed concern over the potential to adversely affect disease control at the time of switching. NMG were also concerned that the comparators within the cost-minimisation model were inappropriate. These factors had led NMG to consider the case for cost effectiveness of ropinirole prolonged-release (Requip XL[®]) had not been proven.

The Chairman opened the discussion and invited members to address issues in relation to clinical effectiveness. The requirement to prescribe by brand was noted. The Chairman referred members to the patient organisation submissions and the medical expert summary. Members were asked to address any outstanding issues in relation to the cost effectiveness

information. The Chairman invited members to comment on any societal or budget impact issues and then opened the discussion to Manjit Hunjan and James Parker to respond to the issues highlighted in the discussion. The Chairman referred members to the detailed response to the preliminary recommendation provided by GlaxoSmithKline UK.

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 12.35 am.

The recommendation of AWMSG was announced:

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.

Substitution of ropinirole prolonged-release tablets for ropinirole immediate-release may be used as:

- (i) Monotherapy, alone (without levodopa) in idiopathic Parkinson's disease
- (ii) Adjunctive therapy in addition to levodopa to control "on-off" fluctuations which might permit a reduction in the total daily dose of levodopa

In order to limit errors, prolonged-release ropinirole should be prescribed by brand as Requip XL^{®▼}.

AWMSG is of the opinion that ropinirole prolonged-release (Requip XL^{®▼}) may be suitable for shared care in accordance with appropriate guidance.

8. Appraisal 3 – etravirine (Intelence^{®▼})

For the treatment of HIV-1 infected antiretroviral treatment-experienced adults in combination with a boosted protease inhibitor and other antiretroviral medicinal products

Mr Felvus left the meeting.

Start time 12.34 pm

The Chairman reminded members to declare any interests.

The Chairman welcomed Lindsay Dearden, Senior Outcomes Research Manager and Perry Mohammad, Medical Advisor representing Tibotec, a division of Janssen-Cilag Limited.

Dr Duerden set the context of the appraisal and provided an overview of the discussions held at the NMG meeting on Wednesday, 15th July 2009. The relevant issues contained within the PAR, enclosure 4/AWMSG/0809, were highlighted. He conveyed the views of the two clinical experts and confirmed that account had been taken of the comprehensive patient organisation submission received from The Terrence Higgins Trust. Dr Duerden concluded his presentation by confirming the advice of NMG to AWMSG was that Etravirine (Intelence^{®▼}) should not be recommended 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. NMG were unable to verify key information and were of the opinion that there were several uncertainties and limitations in the economic model provided in the company's submission.

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. The Chairman referred members to the patient organisation submission and the medical expert summary. Members were asked to address any outstanding issues in relation to the cost effectiveness information. The Chairman invited members to comment on any societal or budget impact issues and then opened the discussion to Lindsay Dearden and Perry Mohammad to respond to the issues highlighted in the discussion. The Chairman referred members to the detailed response to the preliminary recommendation provided by Tibotec, a division of Janssen-Cilag Ltd. It was noted that some information had unfortunately been provided too late in the appraisal process and hence had not been circulated to AWMSG members.

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 1.17 pm

Appraisal decision

The recommendation of AWMSG was announced:

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.

9. Appraisal 4 – quetiapine (Seroquel XL^{®▼}) For the treatment of schizophrenia in adults

The Chairman invited members to declare any interests – there were none.

The Chairman welcomed Robyn Von Maltzahn, Jill Maria Thompson and Phil Krzyzek representing the applicant company, Astra Zeneca.

Start time 2.45 pm

Dr Duerden set the context of the appraisal and provided an overview of the discussions held at the NMG meeting on Wednesday, 15th July 2009. The relevant issues contained within the PAR, enclosure 5/AWMSG/0809, were highlighted. He conveyed the views of the four clinical experts and confirmed that no patient organisation submission had been received.

Dr Duerden concluded his presentation by confirming the advice of NMG to AWMSG was that quetiapine prolonged-release tablets (Seroquel XL^{®▼}) should be recommended as an option for use within NHS Wales restricted for the treatment of schizophrenia in adults. Dr Duerden confirmed NMG's view that quetiapine prolonged-release tablets (Seroquel XL^{®▼}) may be suitable for shared care within NHS Wales and the budget impact of a positive recommendation should be monitored.

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. The Chairman referred members to the medical expert summary. Members were asked to address any outstanding issues in relation to the cost effectiveness information. The Chairman invited members to comment on any societal or budget impact issues and then opened the discussion to Robyn Von Maltzahn, Jill Maria Thompson and Phil Krzyzek to respond to the issues highlighted in the discussion. The Chairman referred members to the detailed response to the preliminary recommendation provided by AstraZeneca. It was noted that the submission had been based on limited evidence accepted for bioequivalent preparations and was restricted to the treatment of schizophrenia in adults and not for the whole of the licensed indication which included treatment of manic episodes associated with bipolar disorder.

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 3.14 pm and members retired to vote in private.

Appraisal decision

The recommendation of AWMSG was announced:

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

10. Appraisal 5 – filgrastim (Ratiograstim^{®▼})

For the treatment of neutropenia

The Chairman invited members to declare any interests – there were none.

The Chairman welcomed Richard Alexander and Adele Brown representing the applicant company, Ratiopharm GmbH.

Start time 3.15 pm

The Chairman informed members that Dr Duerden context of the appraisal and provided an overview of the discussions held at the NMG meeting on Wednesday, 15th July 2009. The relevant issues contained within the PAR, enclosure 6/AWMSG/0809, were highlighted. It was confirmed that no patient organisation submissions had been considered by the New Medicines Group. The views of four medical experts were conveyed.

Dr Duerden concluded his presentation by confirming NMG's preliminary recommendation to AWMSG was that filgrastim (Ratiograstim[®]▼) should be recommended as an option for use within NHS Wales in the treatment of neutropenia within its licensed indication. Dr Duerden confirmed NMG's view that filgrastim (Ratiograstim[®]▼) would not be suitable for shared care within NHS Wales. Dr Duerden drew attention to the potential for small differences between biosimilars from different manufacturers and/or the reference product (Neupogen[®]) and suggested that post-marketing pharmacovigilance would be essential. It was noted that NMG considered it to be good practice to use the brand name when prescribing biosimilars to avoid automatic substitution and ensure consistency in provision. Attention was drawn to the advice of the European group for blood and bone marrow transplantation (EBMT) not recommending the use of filgrastim (Ratiograstim[®]▼) for PBPC mobilisation in healthy volunteers due to concerns over drug safety in these patients.

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. The Chairman referred members to the medical expert summary. The Chairman confirmed that a comprehensive patient organisation submission from Myeloma UK had been received at very short notice and had been tabled at the meeting. Members were asked to address any outstanding issues in relation to the cost effectiveness information. The Chairman invited members to comment on any societal or budget impact issues and then opened the discussion to Richard Alexander and Adele Brown to respond to the issues highlighted in the discussion. It was confirmed that post - marketing pharmacovigilance would be facilitated by the applicant company as part of the Risk Management Plan. The Chairman referred members to the detailed response to the preliminary recommendation provided by Ratiopharm UK Limited.

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 3.45 pm and members retired to vote in private.

Appraisal decision

The recommendation of AWMSG was announced:

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 $0.5 \times 10^9/L$, and a history of severe or recurrent infections.

- For the treatment of persistent neutropenia (ANC less than or equal to $1.0 \times 10^9/L$) 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.

AWMSG is of the opinion that Filgrastim (Ratiograstim[®]▼) is not suitable for shared care within NHS Wales.

Biosimilars should be prescribed by brand name to avoid automatic substitution and ensure consistency in provision.

The Chairman announced that confirmation of the AWMSG recommendations in the final appraisal reports (FARs) would be forwarded to the applicant companies within five working days. He explained that companies have up to ten days following the AWMSG meeting to accept the recommendation or lodge a request for an independent review which should be submitted in writing to the Chairman via WMP. It was confirmed that the process would not be delayed if there is a failure to respond to the deadline and, subject to receiving a request for an independent review within the appropriate timelines, the final appraisal reports would be passed to the Minister for Health and Social Services. The Chairman reported that on receipt of Ministerial ratification WMP would inform the manufacturers and post the FARs on the AWMSG website. The Chairman thanked the manufacturers for engaging with the AWMSG process and concluded appraisal proceedings

11. Update on AWPAG

The Chairman invited Dr Tessa Lewis to highlight the salient issues within the draft minutes of the AWPAG meeting held on 6th July 2009, Enc 8/AWMSG/0609. No issues were raised. The Chairman welcomed the collaborative working with NHSIF and asked that the thanks of AWMSG be conveyed to members of AWPAG.

Antiplatelet template update : Enc 8/AWMSG/0809

Members were asked to endorse the implementation of the antiplatelet template update. Members welcomed the document. A suggestion was made to include the criteria used when deciding to continue prescribing dipyridamole for longer than 2 years, and highlight the variations in indications within the different brands of clopidogrel. Further clarity regarding the place of oral anticoagulants and antiplatelet agents in prosthetic valve patients was also requested. The Chairman confirmed the endorsement of AWMSG and requested that WMP and the Chair of AWPAG consider the feasibility of including this additional information.

Mr Jeremy Felvus left the room.

National Prescribing Indicators 2010-2011: Enc 9/AWMSG/0809

The Chairman invited Mr Jonathan Simms, Chairman of the Indicator Working Group (a sub-group of AWMSG) to propose the national prescribing indicators for 2010-2011. Mr Simms highlighted salient issues within the document. It was noted that the Generic Prescribing indicator will remain as a local comparator. Mr Simms outlined the discussions in relation to the use of the chiral indicator and confirmed that all comments received had been taken into account. The Chairman confirmed the endorsement of AWMSG. It was noted that the paper will be forwarded to the Welsh Assembly Government. The Chairman thanked members of the All Wales Prescribing Advisory Group for their commitment in developing the AWMSG work programme and closed the meeting.

Date of next AWMSG meeting:

Wednesday, 14th October 2009 at 10.30am at The Angel Hotel, Abergavenny