ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY
12TH DECEMBER 2012 COMMENCING 10.30 AM AT THE
ANGEL HOTEL, ABERGAVENNY, NP7 5EN

VOTING MEMBERS PRESENT:

1. Professor Philip Routledge Chairman
2. Professor David Cohen Health Economist
3. Mrs Debbie Davies Healthcare Professional eligible to prescribe
4. Mr Stuart Davies Finance Director
5. Dr Karen Fitzgerald Consultant in Pharmaceutical Public Health
6. Mrs Ellen Lanham Community Pharmacist
7. Dr Stuart Linton Hospital Consultant
8. Ms Alison Hughes Managed Sector Primary Care Pharmacist
9. Dr Emma Mason Clinical Pharmacologist
10. Mr Christopher Palmer Lay Member
11. Mr Steve Turley ABPI Wales
12. Professor John Watkins Public Health Wales
13. Dr William Whitehead GP with prescribing lead role
14. Professor Roger Walker, Chief Pharmaceutical Officer, Welsh Government
15. Dr Robert Bracchi, NMG Chairman
16. Mrs Karen Samuels, Head of HTA & Medicines Management, AWTTC
17. Mrs Ruth Lang, Head of Liaison & Administration, AWTTC

IN ATTENDANCE:

18. Mrs Sabrina Rind, Senior Appraisal Pharmacist
19. Dr David Jarrom, Senior Appraisal Scientist

Not in attendance:
Dr Geoffrey Carroll, Welsh Health Specialised Services Committee
List of Abbreviations:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABPI</td>
<td>Association of the British Pharmaceutical Industry</td>
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<tr>
<td>ASAR</td>
<td>AWMSG Secretariat Assessment Report</td>
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<tr>
<td>AWMSG</td>
<td>All Wales Medicines Strategy Group</td>
</tr>
<tr>
<td>AWPAG</td>
<td>All Wales Prescribing Advisory Group</td>
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<td>AWTTTC</td>
<td>All Wales Therapeutics &amp; Toxicology Centre</td>
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<td>BMA</td>
<td>British Medical Association</td>
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<td>CHMP</td>
<td>Committee for Medicinal Products for Human Use</td>
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<td>DH</td>
<td>Department of Health</td>
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<td>EMA</td>
<td>European Medicines Agency</td>
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<td>FAR</td>
<td>Final Appraisal Recommendation</td>
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<td>FDA</td>
<td>US Food and Drug Administration</td>
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<td>GP</td>
<td>General Practitioner</td>
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<td>HAC</td>
<td>High Acquisition Cost</td>
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<td>HB</td>
<td>Health Boards</td>
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<tr>
<td>HTA</td>
<td>Health Technology Appraisal</td>
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<td>IR</td>
<td>Independent Review</td>
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<td>MHRA</td>
<td>Medicines and Healthcare products Regulatory Agency</td>
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<td>MMPB</td>
<td>Medicines Management Programme Board</td>
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<td>M&amp;TCs</td>
<td>Medicines &amp; Therapeutics Committees</td>
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<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
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<td>NMG</td>
<td>New Medicines Group</td>
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<td>PAR</td>
<td>Preliminary Appraisal Recommendation</td>
</tr>
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<td>SMC</td>
<td>Scottish Medicines Consortium</td>
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<td>TDAPG</td>
<td>Therapeutic Development Appraisal Partnership Group</td>
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<td>T&amp;FG</td>
<td>Task and Finish Group</td>
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<td>WG</td>
<td>Welsh Government</td>
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<td>WAPSU</td>
<td>Welsh Analytical Prescribing Support Unit</td>
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<td>WPAS</td>
<td>Welsh Patient Access Scheme</td>
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<td>Welsh Medicines Partnership</td>
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1. **Welcome and introduction**
   The Chairman welcomed members and, in particular, Ms Alison Hughes, who was attending her first AWMSG meeting as Managed Sector Primary Care Pharmacist, deputising for Mrs Susan Murphy.

2. **Apologies**
   Mrs Susan Murphy, Managed Sector Primary Care Pharmacist
   Dr Bruce Ferguson, Medical Director
   Dr Brendon Lloyd, Medical Director (deputy)
   Mr Roger Williams, Managed Sector Hospital Pharmacist
   Mr John Terry, Managed Sector Hospital Pharmacist (deputy)
   Mr Christian Smith, Senior Nurse
   Dr Fraser Campbell, GP with Prescribing Lead role

3. **Declarations of interest**
   The Chairman reminded members to declare any interests pertinent to the agenda.

4. **Chairman’s report**
   The Chairman confirmed that Dr Bruce Ferguson had announced his retirement and would be stepping down as AWMSG member. He extended thanks to Dr Ferguson for his invaluable contribution to the Group and for undertaking the role as Vice Chairman.

   The Chairman confirmed ratification had been received from Welsh Government in relation to following AWMSG advice:
Fidaxomicin (Dificlir®) is recommended as an option for restricted use within NHS Wales. Fidaxomicin (Dificlir®) should be restricted for use in the following subpopulations within its licensed indication for the treatment of adults with Clostridium difficile infections (CDI), also known as C. difficile-associated diarrhoea (CDAD):

- Patients with severe CDI
- Patients with recurrence of CDI

Fidaxomicin (Dificlir®) should be prescribed on the advice of a consultant microbiologist, consistent with Health Protection Agency guidance. Fidaxomicin (Dificlir®) is not recommended for use within NHS Wales outside the specified subpopulations.

Insulin detemir (Levemir®) is recommended as an option for use within NHS Wales for the treatment of diabetes mellitus in children aged 2–5 years.

Degarelix (Firmagon®) is recommended as an option for use within NHS Wales for the treatment of adult male patients with advanced hormone-dependent prostate cancer. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.

In the absence of a submission from the holder of the marketing authorisation, the Chairman reported that the Minister for Health and Social Services had ratified the following statements of advice:

Adalimumab (Humira®) cannot be endorsed for use for the treatment of adults with severe axial spondyloarthritis who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs.

Zonisamide (Zonegran®) cannot be endorsed for use as monotherapy in the treatment of partial seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy.

The Chairman informed members that a number of statements of advice were in preparation. It was confirmed that in the absence of a Form B or Form C submission within the next fourteen days a statement confirming the following medicines cannot be endorsed for use within NHS Wales would be forwarded to Welsh Government for ratification:

- Etanercept (Enbrel®) for the treatment of polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate; treatment of psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate; and treatment of enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy.

- Zolpidem tartrate (Edluar®) for the short term treatment of insomnia.

- Imiquimod (Zyclara®) 3.75% cream for the topical treatment of clinically typical, visible or palpable actinic keratoses of the full face or balding scalp in adults when other topical treatment options are contraindicated or less appropriate.

Adalimumab (Humira®) for the treatment of moderately active Crohn’s disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.
Ceftaroline fosamil (Zinforo®) for the treatment of the following infections: complicated skin and soft-tissue infections (cSSTI) and community-acquired pneumonia (CAP).

Teduglutide (Revestive®) for the treatment of adult patients with short-bowel syndrome. Patients should be stable following a period of intestinal adaptation after surgery.

Catridecacog (Novothirteen®) for the long term prophylactic treatment of bleeding in patients 6 years and above with congenital factor XIII A-subunit deficiency.

Lidocaine/tetracaine (Pliaglis®) for dermal anaesthesia.

Lubiprostone (Amitiza®) for the treatment of chronic idiopathic constipation and associated symptoms in adults, when response to diet and other non-pharmacological measures are inappropriate.

The Chairman urged the holders of the licence to engage in the AWMSG appraisal process so that patients in Wales can have timely access to new clinically-effective and cost-effective medicines.

The Chairman announced the appraisals scheduled for the next AWMSG meeting to be held on Wednesday, 6th February 2013.

Appraisal 1: Full Submission
Racecadotril (Hidrasec®) granules for oral suspension for the complementary symptomatic treatment of acute diarrhoea in infants (older than 3 months), and in children, together with oral rehydration, and the usual support measures, when these measures alone are insufficient to control the clinical condition
Applicant Company: Abbott Healthcare Products Ltd

Appraisal 2: Full Submission
Vildagliptin (Galvus®) for the treatment of type 2 diabetes as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance
Applicant Company: Novartis Pharmaceuticals UK Ltd

Appraisal 3: Full Submission
C1 inhibitor (Cinryze®) for the treatment and pre-procedure prevention of angioedema attacks in adults and adolescents with hereditary angioedema (HAE) and for routine prevention of angioedema attacks in adults and adolescents with severe and recurrent attacks of hereditary angioedema (HAE), who are intolerant to or insufficiently protected by oral prevention treatments, or patients who are inadequately managed with repeated acute treatment
Applicant Company: ViroPharma Ltd

Appraisal 4: Limited Submission
Insulin glargine (Lantus®) for the treatment of diabetes mellitus in children aged 2 to less than 6 years (licence extension)
Applicant Company: Sanofi-Aventis Ltd

The Chairman asked members to declare any interest in relation to the appraisals scheduled for December to AWTTC prior to the meeting.

The Chairman invited patients, patient organisations and patient carers to submit their views in relation to medicines scheduled for appraisal, and suggested they contact Ruth Lang at AWTTC for further information in relation to the future work programme.
5. Minutes of previous meeting
The minutes of the previous meeting were checked for accuracy. The Chairman signed the minutes as a true record of the meeting.

6. Appraisal 1: Full Submission
Argatroban (Exembol®) for anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy

The Chairman welcomed representatives from the applicant company, Mitsubishi Pharma Europe Limited.

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. There were none.

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 Welsh Government officials, 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 invited Dr David Jarrom, AWTTC assessment lead, to set the context of the appraisal. Dr Jarrom provided an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. Members were informed that a patient organisation submission had not been received.

The Chairman asked Dr Bracchi, NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Bracchi briefly summarised the issues discussed at NMG and relayed the view of NMG members that argatroban (Exembol®) should be recommended as an option for use within NHS Wales for anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy. The diagnosis should be confirmed by the HIPAA (heparin induced platelet activation assay) or an equivalent test. However, such confirmation must not delay the start of treatment. Dr Bracchi confirmed NMG's view that argatroban (Exembol®) would be appropriate for specialist only prescribing within NHS Wales.

The Chairman invited comment in relation to the case for clinical effectiveness. Members sought clarification in relation to the composite primary endpoints, amputation rates and the patient populations within the study. The company delegates responded to the issues raised.

Professor Cohen commented on the case for cost-effectiveness as outlined in the ASAR. He clarified his role as the AWMSG health economist and confirmed he had not been included in discussions held at NMG. He provided members with a comprehensive overview of the submission and suggested that the case for cost-effectiveness had not been demonstrated in the submission. In response, the company delegates explained the difficulties in obtaining robust health economic evidence in relation to this submission and highlighted the benefits from a clinical perspective. There was concern over the quality of the study, the reliability of the utility analysis and comparative information. Dr Bracchi explained that NMG also had concerns in relation to the case for cost-effectiveness; however, the clinical benefits had outweighed their concern. The budget impact projection was considered and discussed. The summary of clinical expert views was scrutinised and it was noted that the experts within NHS Wales considered that argatroban (Exembol®) was the predominant and preferred heparin-induced thrombocytopenia treatment. Clarification was sought in relation to monitoring facilities. There were no outstanding societal issues and it was noted that no patient organisation submission had been received.
The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates from Mitsubishi Pharma Europe Limited to raise any issues they considered might not have been adequately addressed during the appraisal. Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Mitsubishi Pharma Europe Limited for engaging in the appraisal process and proceeded to the next appraisal.

**Appraisal decision subsequently announced:**
The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

**Argatroban (Exembo®)** is recommended as an option for use within NHS Wales for anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy.

The diagnosis should be confirmed by the HIPAA (heparin induced platelet activation assay) or an equivalent test. However, such confirmation must not delay the start of treatment.

7. **Appraisal 2: Full Submission**

Eplerenone (Inspra®) film coated tablets in addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with NYHA class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤ 30%)

The Chairman welcomed the representatives of the applicant company, Pfizer Limited.

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so, and alluded to the statement pertinent to all appraisals.

Mrs Sabrina Rind, the AWTTC assessment lead, set the context of the appraisal and highlighted relevant issues within the ASAR. It was confirmed that a patient organisation submission had not been received. Mrs Rind relayed the views of the clinical experts.

The Chairman invited Dr Bracchi to give an overview of the relevant issues identified in the preliminary appraisal. Dr Bracchi confirmed that NMG considered eplerenone (Inspra®) should be recommended as an option for use within NHS Wales in addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with New York Heart Association (NYHA) class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤ 30%). NMG were of the opinion that Eplerenone (Inspra®) may be appropriate for prescribing by all prescribers within NHS Wales for the above recommendation.

Members discussed the case for clinical effectiveness and clarification was sought in relation to the biological plausibility of the study. The company delegates confirmed the study had been terminated and that patients were not being followed up. There was discussion relating to the study selection and inclusion criteria. Dr Bracchi confirmed that NMG had taken account of the issue of gynaecomastia when considering their preliminary recommendation. The summary of clinical expert views was considered in detail and there was discussion over treatment options and unmet need. Mr Chris Palmer, the lay member, referred members to the list of patient organisations contacted by AWTTC and expressed disappointment that no patient views had been received.
The Chairman invited members to consider the case for cost-effectiveness. It was noted that the AWTTC health economist had experienced difficulty in running the model and Professor Cohen suggested the inability to replicate results when running a complex model might present problems in the future. Professor Cohen confirmed that the case for cost-effectiveness had been clearly demonstrated. Members took account of the budget impact and there was discussion over the growth rates in Table 3. The company delegates clarified the rationale in estimating the number of eligible patients in Wales and the inclusion of implant device costs within the figures. The company delegates confirmed that selecting patients for the study had been problematic and acknowledged that the absence of a head to head trial made comparison extremely difficult. There were no outstanding societal issues.

The delegates from Pfizer Limited responded to the issues raised in the discussion and, prior to closing the appraisal, the Chairman invited them to make any concluding remarks. The Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Pfizer Limited for engaging in the appraisal process.

**Appraisal decision subsequently announced**

The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

Eplerenone (Inspra®) is recommended as an option for use within NHS Wales in addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with New York Heart Association (NYHA) class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤ 30%).

8. Appraisal 3: Limited Submission

Sildenafil citrate (Revatio®) powder for oral suspension for the treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease.

The Chairman welcomed delegates from the applicant company Pfizer Limited. The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. There were none.

The Chairman repeated the statement announced at the commencement of the appraisal session and confirmed it was pertinent to all appraisals. He explained the format of appraising a limited submission and highlighted that evidence relating to budgetary impact in comparison to the existing comparator product should be discussed. He reiterated that AWMSG reserved the right to request a full submission, should the budget impact exceed that estimated in the limited submission.

The Chairman invited Mrs Sabrina Rind, AWTTC assessment lead, to set the context of the appraisal. Mrs Rind provided an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. Members were informed of the patient organisations approached by AWTTC; Mrs Rind confirmed that a patient organisation submission had not been received.

The Chairman asked Dr Bracchi to relay the view of NMG. Dr Bracchi confirmed NMG’s preliminary recommendation that sildenafil (Revatio®) powder for oral suspension should be recommended as an option for use within NHS Wales for the treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease.
Dr Bracchi confirmed that NMG had noted the FDA safety alert and had obtained further advice from the MHRA and clinical experts to inform their decision. It was noted NMG were of the opinion that Sildenafil (Revatio®) powder for oral suspension would be appropriate for specialist only prescribing within NHS Wales for the above indication.

The Chairman asked members if there were any outstanding issues in relation to the case for clinical effectiveness. The issue of the safety alert by the FDA was considered, and the information provided by the MHRA was taken into account. The company delegates were unable to confirm the number of children receiving the high dose in the study. The orphan drug classification was confirmed. The views of the clinical experts were scrutinised and taken into consideration. There were no outstanding societal issues of note and no patient organisation submission had been received. It was confirmed, when comparing the cost with the comparator treatment, there was no difference.

The Chairman alluded to the applicant company response to the preliminary recommendation. It was noted that Pfizer Limited had been fully supportive of the preliminary recommendation issued by NMG on 7th November. Having responded to the issues raised in the appraisal, the company delegates confirmed they were satisfied that all the issues had been adequately discussed and the process had been fair and transparent.

The Chairman closed the discussion.

**Appraisal decision subsequently announced**
The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

**Sildenafil (Revatio®) 10 mg/ml powder for oral suspension** is recommended as an option for use within NHS Wales for the treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease.

9. **Appraisal 4: Limited Submission**

Bortezomib (Velcade®) 3.5mg subcutaneous injection for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplantation; and in combination with melphalan and prednisone for the treatment of patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant

The Chairman welcomed delegates from the applicant company Janssen Cilag Limited. The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. There were none.

The Chairman repeated the statement announced at the commencement of the appraisal session and confirmed it was pertinent to all appraisals. He explained the format of appraising a limited submission and highlighted that evidence relating to budgetary impact in comparison to the existing comparator product should be discussed. He reiterated that AWMSG reserved the right to request a full submission, should the budget impact exceed that estimated in the limited submission.

The Chairman invited Dr David Jarrom, AWTTC assessment lead, to set the context of the appraisal. Dr Jarrom provided an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. Dr Jarrom confirmed a patient organisation submission had been received from Myeloma UK.
The Chairman asked Dr Bracchi to relay the view of NMG. Dr Bracchi confirmed NMG’s preliminary recommendation that bortezomib (Velcade®) 3.5 mg subcutaneous injection should be recommended as an option for use within NHS Wales for the treatment of adult patients with progressive multiple myeloma who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplantation; and in combination with melphalan and prednisone for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant. It was confirmed that NMG were of the opinion that bortezomib (Velcade®) subcutaneous injection would be appropriate for specialist only prescribing within NHS Wales for the indication under consideration.

The Chairman invited members to raise any outstanding issues relating to the case for clinical effectiveness. Mr Chris Palmer highlighted the salient issues raised in the patient organisation submission, a copy of which had been circulated to members for information. There were no outstanding issues relating to budget impact. The company delegates highlighted the clinical benefits and the Chairman referred to their response to the preliminary recommendation. Prior to concluding the appraisal, and having responded to the issues in the appraisal, the company delegates confirmed they were satisfied that all issues had been adequately discussed and the process had been fair and transparent.

The Chairman closed the discussion and members retired to vote in camera.

**Appraisal decision subsequently announced**

The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

**Bortezomib (Velcade®) 3.5 mg subcutaneous injection is recommended as an option for use within NHS Wales:**

- for the treatment of adult patients with progressive multiple myeloma who have received at least 1 prior therapy and who have already undergone or are unsuitable for bone marrow transplantation;
- in combination with melphalan and prednisone for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant.

The Chairman confirmed that confirmation of AWMSG’s recommendations would be forwarded to the applicant companies within five working days. He confirmed the deadline for lodging a request for an independent review (IR) was fourteen days from the announcement of the recommendation and clarified that, subject to receiving a request for an IR; the recommendations would be passed to Welsh Government for ratification.

The appraisal session was concluded.

**10. AWPAG Update (draft minutes – October 2012)**

The Chairman invited Dr Tessa Lewis to present the draft minutes of the AWPAG meeting held on 25th October 2012 - Enc 6/AWMSG/1212. Dr Lewis highlighted the work currently on-going relating to the review of the implementation of AWMSG guidance and national audits, and the updating of the guidelines for prescribing gluten-free products. Dr Lewis confirmed that AWPAG would be considering local comparators at the meeting in January 2013, and would also be considering information technology services. Dr Lewis confirmed that AWPAG had considered the therapeutic priorities for 2013–2014 and handed over to Mrs Kate Jenkins, representing the Welsh Analytical Prescribing Support Unit.

AWMSG draft minutes  
Prepared by AWTTC
11. **National Prescribing Indicators 2013–2014**

Mrs Jenkins provided an overview of Enc 7/AWMSG/1212 and explained that the national prescribing indicators agreed by AWMSG and Welsh Government were required to be evidence based, clear, easily understood and applicable at practice level. The associated targets addressed efficiency as well as quality. It was noted the paper had been circulated widely for comment prior to being presented to AWMSG for endorsement.

Members welcomed the paper as a tool for debate when discussing clinical choices regarding the management of disease and in improving quality of care. There was a suggestion that wording relating to the clinical freedom of the prescriber could be strengthened. There was discussion regarding the inclusion of an indicator for chronic respiratory disease. Mrs Jenkins confirmed that this had been considered by the working group, but discounted on account of there being no meaningful easily monitoring parameters. It was suggested that inclusion within the local comparators might be an appropriate way to trial an indicator related to inhaled steroid prescribing. Clarification was sought in relation to the dissemination of the document. It was confirmed that the paper would be circulated via email to all M&TCs and Chief Pharmacists in NHS Wales, and included in the AWMSG update report issued via the Chief Medical Officer’s newsletter.

The Chairman closed the discussion and confirmed AWMSG’s wholehearted support of the national prescribing indicators for 2013–2014 as presented in Table 1 of the paper.

12. **Date of next meeting**

The Chairman confirmed the date of the next meeting on **Wednesday, 6th February 2013 in Cardiff Metropolitan University** and the meeting closed.