ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF THE AWMSG MEETING HELD ON
WEDNESDAY, 15th DECEMBER COMMENCING 10.30 AM
AT THE ANGEL HOTEL, ABERGAVENNY

MEMBERS PRESENT:

1. Dr Paul Buss Chairman
2. Dr Fraser Campbell General Practitioner
3. Dr Geoffrey Carroll Welsh Health Specialised Services Committee
4. Prof David Cohen Health Economist
5. Mrs Debbie Davies Representing other professions eligible to prescribe
6. Dr Bruce Ferguson Medical Director
7. Dr Karen Fitzgerald Consultant in Pharmaceutical Public Health
8. Dr Brian Hawkins Senior Primary Care Pharmacist
9. Ms Ellen Lanham Community Pharmacist
10 Dr Stuart Linton Hospital Consultant
11. Dr Emma Mason Clinical Pharmacologist 1-6
12. Mr Christopher Palmer Lay representative
13. Mr Guy Thompson ABPI (Wales) representative 7
14. Mrs Wendy Warren Senior Nurse
15. Dr John Watkins Consultant in Public Health Medicine

IN ATTENDANCE:

16. Dr Robert Bracchi NMG Chairman
17. Professor Ceri Phillips NMG Health Economist
18. Mr Jeremy Savage Welsh Assembly Government
19. Mrs Karen Samuels Welsh Medicines Partnership
20. Mrs Ruth Lang Welsh Medicines Partnership
21. Ms Kath Haines Welsh Medicines Partnership

AWMSG draft minutes December 2010 final draft for website
List of Abbreviations:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABPI</td>
<td>Association of the British Pharmaceutical Industry</td>
</tr>
<tr>
<td>ASAR</td>
<td>AWMSG Secretariat Assessment Report</td>
</tr>
<tr>
<td>AWCDG</td>
<td>All Wales Cancer Drugs Group</td>
</tr>
<tr>
<td>AWMSG</td>
<td>All Wales Medicines Strategy Group</td>
</tr>
<tr>
<td>AWPAG</td>
<td>All Wales Prescribing Advisory Group</td>
</tr>
<tr>
<td>BHIVA</td>
<td>British HIV Association</td>
</tr>
<tr>
<td>BMA</td>
<td>British Medical Association</td>
</tr>
<tr>
<td>BNF</td>
<td>British National Formulary</td>
</tr>
<tr>
<td>CR/ASAR</td>
<td>Company response to the AWMSG Secretariat assessment report</td>
</tr>
<tr>
<td>CR/FAR</td>
<td>Company response to the final appraisal report</td>
</tr>
<tr>
<td>CR/PAR</td>
<td>Company response to the preliminary appraisal report</td>
</tr>
<tr>
<td>CSCG</td>
<td>Cancer Services Co-ordinating Group</td>
</tr>
<tr>
<td>CHM</td>
<td>Commission on Human Medicines</td>
</tr>
<tr>
<td>DH</td>
<td>Department of Health</td>
</tr>
<tr>
<td>DTB</td>
<td>Drug &amp; Therapeutics Bulletin</td>
</tr>
<tr>
<td>FAR</td>
<td>Final appraisal report</td>
</tr>
<tr>
<td>HCW</td>
<td>Health Commission Wales</td>
</tr>
<tr>
<td>HoPMMs</td>
<td>Heads of Pharmacy and Medicines Management</td>
</tr>
<tr>
<td>HSW</td>
<td>Health Solutions Wales</td>
</tr>
<tr>
<td>IHC</td>
<td>Informing Healthcare</td>
</tr>
<tr>
<td>HB</td>
<td>Health Boards</td>
</tr>
<tr>
<td>M&amp;TCs</td>
<td>Medicines &amp; Therapeutics Committees</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines &amp; Healthcare Products Regulatory Agency</td>
</tr>
<tr>
<td>NHSIF</td>
<td>NHS Industry Forum</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
</tr>
<tr>
<td>NLIAH</td>
<td>National Leadership and Innovation Agency for Healthcare</td>
</tr>
<tr>
<td>NMG</td>
<td>New Medicines Group</td>
</tr>
<tr>
<td>NPHS</td>
<td>National Public Health Service</td>
</tr>
<tr>
<td>PAR</td>
<td>Preliminary appraisal report</td>
</tr>
<tr>
<td>PPRS</td>
<td>Prescription Price Regulation Scheme</td>
</tr>
<tr>
<td>SAFF</td>
<td>Service and Financial Framework</td>
</tr>
<tr>
<td>SMC</td>
<td>Scottish Medicines Consortium</td>
</tr>
<tr>
<td>SPC</td>
<td>Summary of Product Characteristics</td>
</tr>
<tr>
<td>TDA User Group</td>
<td>Therapeutic Development Appraisal User Group</td>
</tr>
<tr>
<td>T&amp;FG</td>
<td>Task and Finish Group</td>
</tr>
<tr>
<td>WAG</td>
<td>Welsh Assembly Government</td>
</tr>
<tr>
<td>WAPSU</td>
<td>Welsh Analytical Prescribing Support Unit</td>
</tr>
<tr>
<td>WeMeReC</td>
<td>Welsh Medicines Resource Centre</td>
</tr>
<tr>
<td>WMIC</td>
<td>Welsh Medicines Information Centre</td>
</tr>
<tr>
<td>WMP</td>
<td>Welsh Medicines Partnership</td>
</tr>
</tbody>
</table>

1. **Welcome and introduction**
The Chairman opened the meeting and welcomed members.

2. **Apologies**
Prof Philip Routledge  
Ms Rebecca Richards, (deputy not in attendance)  
Mr Roger Williams (deputy not in attendance)

3. **Declarations of interest**
The Chairman asked members to declare any interests pertinent to the agenda. Mr Guy Thompson declared a non-specific personal interest in sildenafil citrate (Revatio®) and the Chairman confirmed he would be excluded from the appraisal and would not vote.

AWMSG draft minutes December 2010 final draft for website
4. **Chairman’s report**

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

**Epoetin theta (Eporatio®) is recommended as an option for restricted** use within NHS Wales for the treatment of adult patients with symptomatic anaemia associated with chronic renal failure only.

AWMSG is of the opinion that epoetin theta (Eporatio®) is not suitable for shared care within NHS Wales for the above indication.

Epoetin theta (Eporatio®) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance.

**Epoetin theta (Eporatio®) is not recommended** for use within NHS Wales for the treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. The case for clinical effectiveness of epoetin theta (Eporatio®) has not been proven in this indication.

**Olanzapine depot (ZypAdhera®) is not recommended** for use within NHS Wales for maintenance treatment of adult patients with schizophrenia sufficiently stabilised during acute treatment with oral olanzapine. The case for cost effectiveness has not been proven.

**Cetuximab (Erbitux®) is not recommended** for use within NHS Wales for third-line treatment of patients with epidermal growth factor receptor (EGFR)-expressing, Kirsten Rat Sarcoma (KRAS) wild-type metastatic colorectal cancer. The case for cost effectiveness had not been proven for the use of cetuximab as either monotherapy or as combination therapy.

The Chairman confirmed that statements of advice had been posted on the AWMSG website in relation to the following medicines which could not be endorsed for use and therefore should not be routinely available within NHS Wales:

- **valganciclovir (Valcyte®) tablets**: Licence extension for 200 days prophylaxis of cytomegalovirus (CMV) disease in CMV-negative kidney transplant patients who have received a transplant from a CMV-positive donor

- **valganciclovir (Valcyte®) oral solution**: Licence extension for 200 days prophylaxis of cytomegalovirus (CMV) disease in CMV-negative kidney transplant patients who have received a transplant from a CMV-positive donor

- **bendamustine (Levact®)** for the treatment of indolent non-Hodgkin's lymphomas as monotherapy in patients who have progressed during or within 6 months following treatment with rituximab or rituximab containing regimen

- **bendamustine (Levact®)** for the front line treatment of multiple myeloma (Durie-Salmon stage II with progress or stage III) in combination with prednisone for patients older that 65 years who are not eligible for autologous stem cell transplantation and who have clinical neuropathy at time of diagnosis precluding the use of thalidomide or bortezomib containing treatment.

- **velaglucerase alpha (VPRIV®)** for long-term enzyme replacement therapy in patients with type 1 Gaucher disease

- **vernakalant (Brinavess®)** for the rapid conversion of recent onset atrial fibrillation to sinus rhythm in adults: for non-surgery patients (atrial fibrillation)
• asenapine (Sycrest®) for the treatment of moderate to severe manic episodes associated with bipolar 1 disorder in adults

• fentanyl (PecFent®) for the management of breakthrough pain (BTP) in adults who are already receiving maintenance opioid therapy for chronic cancer pain

• regadenoson (Rapiscan®) a pharmacological stress agent for radionuclide myocardial perfusion imaging in adult patients unable to undergo adequate exercise stress

• pitavastatin (Livazo®) for the treatment of hypercholesterolaemia and dyslipidaemia

• capsaicin patch (Qutenza®) for the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain

• tenofovir disoproxil fumarate (Viread®) for the treatment of chronic hepatitis B in adults with decompensated liver disease

The appraisals scheduled for the next AWMSG meeting on Wednesday, 16th February 2011 were announced:

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

2. Valsartan (Diovan®) for the treatment of children and adolescents aged between 6 and 18 years with hypertension (limited submission)

3. Darunavir (Prezista®) for the treatment of HIV-1 infection in treatment-experienced children and adolescents (limited submission)

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 previous meeting. There were no matters arising.

6. Appraisal 1: ranolazine (Ranexa®) (Full Submission) for the treatment of stable angina pectoris
The Chairman invited members to declare interests in either the applicant company or the medicine. There were none. The Chairman welcomed delegates representing the applicant company, Menarini Pharma UK SRL.

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. The Chairman confirmed that the applicant company delegates would be invited to respond to and provide clarification of any issues raised. 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 explained the reasons why members of the New Medicines Group had concluded that ranolazine (Ranexa®) as an add-on therapy should be recommended as an option for restricted use within NHS Wales for the symptomatic treatment of patients with stable angina pectoris. NMG considered that treatment should be initiated by a Cardiologist and should be restricted for use in patients who are refractory to standard optimised fourth-line treatment and where revascularisation has been considered and undertaken or is not considered appropriate. NMG suggested that initiation should be supported by appropriate drug-related safety information to ensure the continued safe prescribing of ranolazine (Ranexa®) in primary care. Patient organisation submissions by the British Cardiac Patients Association and HEART UK had been considered by NMG, along with the clinical expert views. Dr Bracchi reported that due to a divergence of views, NMG had not advised AWMSG as to whether the medicine should be available for shared care for this indication.

The Chairman invited Mr Palmer to comment on the submission from a lay/patient perspective. Mr Palmer confirmed he had nothing further to add to the comments provided by the British Cardiac Patients Association and HEART UK.

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 the evidence of clinical outcomes and quality of life. The Chairman invited Professor Ceri Phillips to highlight issues in relation to cost effectiveness and then invited members to raise any outstanding issues. The Chairman asked the company delegates to make a note of the issues raised in the discussion so that they could respond to all the issues and provide clarification. Members considered the summary of clinical expert opinion and discussed the outcomes of the audit noting that it was local, involved small numbers and unpublished. The company delegates provided clarification of the issues raised. Prior to concluding the appraisal, the Chairman asked the company delegates confirmed 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 asked members to make a note of their comments on the aide-memoire and closed the appraisal.

**Appraisal decision**

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

**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.

7. **Appraisal 2 - sildenafil citrate (Revatio®) intravenous solution (Limited Submission)** for treatment of patients with pulmonary arterial hypertension who are currently prescribed oral sildenafil citrate and who are temporarily unable to take oral medicine

Mr Guy Thompson left the room. The Chairman welcomed the delegates representing the applicant company, Pfizer Ltd. He 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.
Mrs Haines provided the background to the limited submission process and explained it had been developed as part of AWMSG’s broadened remit for use when appraising new formulations, minor licence extensions or if the anticipated usage was considered to have no budget impact. Members were informed that the appraisal of six limited submission would be undertaken by AWMSG as part of a pilot, to be reviewed during March 2011. Mrs Haines clarified that the appraisal process and mandatory nature of a positive outcome remained the same as a full submission, and that AWMSG reserved the right to request a full (Form B) submission at any time during the appraisal process. Members were informed that the ASARs took account of the clinical effectiveness and budgetary impact information provided by the applicant companies. Mrs Haines 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, and that comparator costs had been provided.

The Chairman invited Dr Bracchi to set the context outlined in the ASAR. Discussions at NMG were summarised and Dr Bracchi provided the rationale behind NMG’s preliminary recommendation to AWMSG that sildenafil citrate (Revatio®) solution for injection should be 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. It was noted that NMG recommended that use be restricted to a physician experienced in the treatment of pulmonary arterial hypertension. NMG were of the opinion that sildenafil citrate (Revatio®) solution for injection would not be suitable for shared care within NHS Wales for the above indication. Dr Bracchi conveyed that NMG had considered the current vial size (40mg in 50ml) might lead to medication administration error and users should be aware of this concern. It was reiterated that a patient organisation submission had not been actively sought.

Dr Emma Mason joined the meeting. The Chairman opened the discussion and invited members to highlight any issues in relation to the limited submission. The Group sought clarification of the practical arrangements in existence for the treatment of patients and risk management plan. There was discussion over the vial volume and dose per ml, it was confirmed that a 10mg vial would be made available within a couple of months. There was discussion in relation to bioequivalence between the oral and intravenous formulations. The Chairman drew members’ attention to the summary of clinical expert opinion. It was noted that the applicant company had no comment in relation to the preliminary recommendation. Prior to the conclusion of the appraisal the company delegates confirmed that all issues had been adequately discussed and taken into account, and that the process had been fair and transparent.

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

**Appraisal decision**

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

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

8 Appraisal 3 - atazanavir (Reyataz®) (Limited Submission) for the treatment of HIV-1 infected paediatric patients in combination with other antiretroviral medicinal products

There were no delegates representing the applicant company, Bristol-Myers Squibb. Mr Guy Thompson joined the meeting. The Chairman alluded to his previous statement regarding AWMSG advice and confirmed it was pertinent to all appraisals.

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 atazanavir (Reyataz®) capsules, co-administered with low dose ritonavir, should be 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. Dr Bracchi informed the Group that NMG had considered atazanavir (Reyataz®) would not be suitable for shared care within NHS Wales for this indication. Dr Bracchi highlighted NMG’s concern over the potential for drug interactions which, NMG considered should be taken into consideration when prescribing.

The Chairman opened the discussion and invited members to highlight any issues in relation to the limited submission. There were no outstanding issues of note. Members took account of the summary of clinical expert opinion. The Chairman asked members to make a note of their comments on the aide-memoire and closed the appraisal.

Appraisal decision

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

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.

9 Appraisal 4 - tipranavir (Aptivus®) capsules (Limited Submission) co-administered with low dose ritonavir, for the treatment of HIV-1 infection in highly pre-treated adolescents 12 years of age or older with no other therapeutic options

The Chairman confirmed there were no delegates in attendance representing the applicant company, Boehringer Ingelheim Ltd and eluded to his previous statement regarding AWMSG advice.

Dr Bracchi set the context of the appraisal and provided an overview of the ASAR. He summarised discussions held at NMG and explained the rationale behind NMG’s preliminary recommendation to AWMSG that tipranavir (Aptivus®) capsules, co-administered with low dose ritonavir, should be 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. He conveyed NMG’s view that tipranavir should only be used as part of an active combination antiretroviral regimen in patients with no other therapeutic options. Dr Bracchi confirmed that NMG had been of the opinion that tipranavir (Aptivus®) would not be suitable for shared care within NHS Wales for the above indication. Members were asked to note NMG’s concern over the potential for drug interactions which, NMG considered, should be taken into consideration when prescribing.
The Chairman opened the discussion and invited members to highlight any issues in relation to the limited submission. There were no outstanding issues of note. Members took account of the summary of clinical expert opinion. The Chairman asked members to make a note of their comments on the aide-memoire and closed the appraisal.

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

**Appraisal decision**

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

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.

**Appraisal decision**

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

Tipranavir (Aptivus®) oral solution, co-administered with low dose ritonavir for the treatment of HIV-1 infection in highly pre-treated children from 2 to 12 years of age with no other therapeutic options.

The Chairman invited Dr Bracchi to set the context as outlined in the ASAR. Dr Bracchi summarised discussions held at NMG and provided the rationale behind NMG’s preliminary recommendation to AWMSG that tipranavir (Aptivus®) oral solution, co-administered with low dose ritonavir, should be 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. Dr Bracchi explained that NMG had considered tipranavir should only be used as part of an active combination antiretroviral regimen in patients with no other therapeutic options. Members were informed of NMG’s opinion that tipranavir (Aptivus®) oral solution would not be suitable for shared care within NHS Wales for the above indication. Dr Bracchi highlighted NMG’s concern over the potential for drug interactions which, NMG considered, should be taken into consideration when prescribing. Dr Bracchi conveyed the view of NMG that the increased bioavailability of the oral solution should be noted when formulation changes were considered.

The Chairman opened the discussion and invited members to highlight any issues in relation to the limited submission. Some issues raised were directed to the applicant company; however there were no company delegates in attendance. Members took account of the summary of clinical expert opinion. The Chairman asked members to make a note of their comments on the aide-memoire and closed the appraisal.

**Appraisal decision**

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

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.

11 AWPAG update
The Chairman invited Dr Tessa Lewis to highlight the salient issues within the draft minutes of the AWPAG meeting held on Wednesday, 20th October 2010, Enc 7/AWMSG/1210. Dr Lewis drew members’ attention to the work currently on-going in relation to guidance for prescribing medicines for adults who are unable to swallow oral solid dosage forms, prescribing dilemmas and the proposed update to the existing Near Patient Testing Enhanced Service. AWPAG’s input into the Elderly National Service Framework/Medicines and Older People was noted. Dr Lewis confirmed that a paper would be presented to AWMSG in relation to monitored dosage systems at hospital discharge. Dr Lewis highlighted the work in relation to national prescribing indicators and local comparators, and confirmed that the AWMSG national audit on non-steroidal anti-inflammatory drugs would be updated. Members were informed of the intention to develop educational material to support AWPAG’s work in promoting best practice to reduce avoidable harm, waste and variation in prescribing low molecular weight heparin. Dr Lewis informed the Group that AWPAG had considered its actions in relation to Rosiglitazone, following the withdrawal of its licence and confirmed she was considering a way forward in relation to continuing the BNF chapter reviews. Dr Lewis highlighted AWPAG’s support for the establishment of a GP Prescribing Leads Forum and invited nominations. She concluded by informing members that a review would be undertaken of AWMSG’s template for the prescribing of statins.

12 AWPAG paper - Primary Care Guidance: Prescribing medicines for adults who are unable to swallow oral solid dosage forms
The Chairman invited Mr William Duffield, AWPAG’s Vice Chairman, to highlight to salient issues of Enc 8/AWMSG/1210. Mr Duffield presented the guidance, developed by Betsi Cadwaladr University Health Board in conjunction with AWPAG for adult patients having difficulty taking medicines as oral solid dosage forms. Mr Duffield explained that some adults have difficulty swallowing oral solid dosage forms, such as tablets and capsules, and prescribers must work with the patient and/or their carers to address their needs. This may be done by reviewing the patient’s requirements, the use of licensed medicines off label or the use of unlicensed medicines. Mr Duffield suggested the exemplar provided a framework for healthcare professionals to support their prescribing decisions and sought to clarify the individual professional responsibilities in the prescribing, supply and administration of medicines for this group of patients. He clarified the aim of the document was to make an overall contribution to preserving the safety of patients whilst respecting their rights under the equalities legislation. Mr Duffield gave recognition to the co-author, Mr Rory Wilkinson, and asked AWMSG to endorse the document as an example of good prescribing practice to promote uptake of best practice within NHS Wales.

The Chairman opened the discussion and invited comments. Members welcomed the document and their comments were noted by Mr Duffield. The Chairman suggested that Mr Duffield should reflect on the practical issues highlighted in the discussion and update the document accordingly. Mr Duffield confirmed that the proprietary information would be removed so that the document could be made available on the AWMSG website and used as a template for local adoption and adaptation. The Chairman asked that AWPAG consider how the impact of applying guidance could be assessed. Dr Lewis confirmed AWPAG would consider dissemination of the document at their next meeting. The Chairman concluded the discussion by confirming AWMSG’s support and endorsement of Enc 8/AWMSG/1210 as an example of good prescribing practice.

13 AWPAG paper - National Prescribing Indicators 2011/2012
Mr Guy Thompson declared a non-personal specific interest in relation to the NSAID and statin section of Enc 9/AWMSG/1210. The Chairman confirmed that Mr Thompson would be excluded from the discussion of NSAID and statin element of the paper, and confirmed
acceptance for Mr Thompson to participate in the discussion of the remaining elements.

The Chairman invited Mr Duffield to present Enc 9/AMWSG/1210 – a paper setting out the proposed national prescribing indicators for 2011/12 developed by the AWPAG working group. Mr Duffield highlighted the need to retain efficiency and safety principles as a means to monitor Health Board (HB) prescribing patterns across NHS Wales. He explained that the methods and principles used to determine the prescribing indicators and the targets set were included in the enclosure. Mr Duffield invited the Group (AWMSG) to consider the support and implementation of the proposed national prescribing indicators. Mr Duffield provided the background and explained that for many years the performance of the prescribing indicators had been measured by the Welsh Assembly Government (WAG) under the Service and Financial Framework (SaFF) targets. In 2007-08, they were removed from the SaFF, and now form part of the NHS Wales Annual Operating Framework (AOF) and are specified in the efficiency and productivity programme. Members were informed that prior to the establishment of AWMSG, prescribing advisers produced the basket of prescribing indicators to monitor prescribing patterns across Local Health Groups. Mr Duffield asked AWMSG to endorse national indicators as outlined in the document.

The Chairman opened the discussion and invited comments. Members were informed that subsequent to the meeting papers being distributed and posted on the AWMSG website, some valid comments had been received from Pfizer Ltd which were currently being considered. There was discussion in relation to units of measure and suggested amendments were noted by Mr Duffield. Outstanding input from the Antimicrobial Working Group in relation to the antibiotic indicator was highlighted. Mr Duffield agreed to update the paper in light of the comments of the Group and confirmed the intention to submit the paper to Welsh Assembly Government to form part of the NHS Wales Annual Operating Framework (AOF). The Chairman confirmed the endorsement and support of AWMSG in relation to the proposed national indicators as outlined in Enc 9/AMWSG/1210.

14 AWPAG paper - Proposal: Model GMS Local Enhanced Service: Near Patient Testing
The Chairman invited Dr Tessa Lewis, AWPAG Chair, to highlight the salient issues of Enc 10/AMWSG/1210. Dr Lewis provided by background and explained that since 2003 a number of medications have been identified as appropriate for a shared care. A National Enhanced Service (NES) currently provides resource for a small range of such medications to be managed in primary care, however there is currently no national mechanism to update this list. Regions have developed Local Enhanced Services to cover some additional medications but there is significant interregional variation. Dr Lewis explained that in order to support appropriate primary care management, there is a need for all Wales guidance to support local commissioning arrangements. AWPAG recommends medicines in addition to those already included under the GMS near patient testing NES to be appropriate for delivery in this way. Dr Lewis requested AWMSG to consider and support the recommendations outlined in Enc 10/AMWSG/1210, relating to medications that, in addition to existing medications, should have clearly defined local commissioning arrangements within NHS Wales.

The Chairman opened the discussion. There was general agreement that there is a need for consistent advice in relation to monitoring and that inclusion in an enhanced service would increase monitoring in primary care. A suggestion was made to seek the support of the locality based medical directors and include costs in relation to implementation. Dr Lewis noted the suggestions. The Chairman concluded the discussion by confirming AWMSG’s endorsement of the recommendations and support for the outstanding issues, particularly with regard to the cost, to be developed further.

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