

Enclosure No:	1/AWMSG/0513
Agenda Item No:	5 – Minutes of previous meeting
Author:	Chairman, AWMSG
Contact:	Tel: 029 20716900 E-Mail: awttc@wales.nhs.uk

ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY 20th MARCH 2013 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY, NP7 5EN

VOTING MEMBERS PRESENT:

Did not
participate in

- | | | |
|-----|---|-------|
| 1. | Professor Philip Routledge Chairman | |
| 2. | Dr Pippa Anderson Health Economist | |
| 3. | Dr Geoffrey Carroll Welsh Health Specialised Services Committee | 10-13 |
| 4. | Mrs Debbie Davies Healthcare Professional eligible to prescribe | |
| 5. | Miss Anne Hinchliffe Consultant in Pharmaceutical Public Health | |
| 6. | Ms Alison Hughes Managed Sector Primary Care Pharmacist | |
| 7. | Ms Ellen Lanham Community Pharmacist | |
| 8. | Dr Stuart Linton Hospital Consultant | |
| 9. | Dr Emma Mason Clinical Pharmacologist | 10-13 |
| 10. | Mr Christopher Palmer Lay Member | |
| 11. | Mr Christian Smith Senior Nurse | 10-13 |
| 12. | Mr Robert Thomas ABPI Wales | |
| 13. | Mr Roger Williams Managed Sector Hospital Pharmacist | 6 |
| 14. | Dr William Whitehead GP with Prescribing Lead role | |

IN ATTENDANCE:

16. Professor Roger Walker, Chief Pharmaceutical Officer, Welsh Government
17. Dr Robert Bracchi, NMG Chairman
18. Mrs Karen Samuels, Head of HTA & Medicines Management, AWTTTC
19. Mrs Ruth Lang, Head of Liaison & Administration, AWTTTC

ALL WALES THERAPEUTICS & TOXICOLOGY CENTRE (AWTTC) APPRAISAL LEADS:

- 20. Mrs Sabrina Rind, Senior Appraisal Pharmacist
- 21. Dr Claire Davis, Senior Appraisal Scientist
- 21. Dr Stephanie Francis, Senior Appraisal Scientist

List of Abbreviations:

ABPI	Association of the British Pharmaceutical Industry
ASAR	AWMSG Secretariat Assessment Report
AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
AWTTC	All Wales Therapeutics & Toxicology Centre
BMA	British Medical Association
CHMP	Committee for Medicinal Products for Human Use
DH	Department of Health
EMA	European Medicines Agency
FAR	Final Appraisal Recommendation
FDA	US Food and Drug Administration
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Boards
HTA	Health Technology Appraisal
IR	Independent Review
MHRA	Medicines and Healthcare products Regulatory Agency
MMPB	Medicines Management Programme Board
M&TCs	Medicines & Therapeutics Committees
NICE	National Institute for Health and Clinical Excellence
NMG	New Medicines Group
PAR	Preliminary Appraisal Recommendation
SMC	Scottish Medicines Consortium
TDAPG	Therapeutic Development Appraisal Partnership Group
T&FG	Task and Finish Group
WG	Welsh Government
WAPSU	Welsh Analytical Prescribing Support Unit
WPAS	Welsh Patient Access Scheme
WMP	Welsh Medicines Partnership

1. Welcome and introduction

The Chairman welcomed AWMSG members and members of the public.

2. Apologies

Professor David Cohen (Dr Pippa Anderson deputising)
Dr Brendon Lloyd, Medical Director (deputy member)
Mrs Susan Murphy (Ms Alison Hughes deputising)
Dr Karen Fitzgerald (Miss Anne Hinchliffe deputising)
Mr Stuart Davies, Finance Director
Professor John Watkins, Public Health (Wales)

3. Declarations of interest

The Chairman reminded members to declare any interests pertinent to the agenda. Mr Roger Williams declared a personal specific interest in that he had participated on an advisory panel in relation to linagliptin (Trajenta[®]▼). The Chairman confirmed that Mr Williams would be unable to participate in the appraisal of this medicine and would leave the room during the appraisal.

4. Chairman's report

The Chairman reported the launch of the new version of the All Wales national in-patient prescription chart had been held at the Academic Building Llandough on 27th February 2013 at the Academic Building in Llandough. He explained to the audience that AWMSG had first commissioned the All Wales Chief Pharmacists Committee (AWCPC) to produce a single national inpatient prescription chart in 2004, and it was first introduced across Wales in October of that year. The latest version, developed by the Safety and Quality Sub-Group of AWCPC, has been developed in partnership with the Royal College of Physicians and will be supported by an updated version of the e-learning training package. The Chairman expressed thanks to Dr Ruth Hussey who had supported the initiative and attended the launch; also, representatives of AWCPC, the Royal College of Physicians (Wales) and all those involved in the collaboration.

The Chairman informed members that online access to the Drug and Therapeutics Bulletin via the NHS Wales e-Library for Health was currently available for a trial period

<http://www.wales.nhs.uk/sitesplus/878/page/42380>.

It was confirmed that access is restricted to authorised NHS Wales personnel. The Chairman encouraged members to promote and encourage uptake within their organisations and it was noted the trial period was set to run until 5th May 2013. The Chairman highlighted the importance of the Drug & Therapeutics Bulletin in providing rigorous and independent evaluations of, and practical advice on, individual treatments and the overall management of disease for doctors, pharmacists and other healthcare professionals.

The Chairman confirmed Welsh Government ratification had been received for the following AWMSG advice:

Racecadotril (Hidrasec[®]▼) granules for oral suspension are not recommended for use within NHS Wales for the complementary symptomatic treatment of acute diarrhoea in infants (older than 3 months) and children. AWMSG was not convinced that the case presented for clinical and cost effectiveness supported the use of this medicine in NHS Wales.

Vildagliptin (Galvus[®]) is recommended as an option for use within NHS Wales for the treatment of type 2 diabetes mellitus as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

C1 inhibitor (Cinryze[®]▼) is recommended as an option for use within NHS Wales for the treatment and pre-procedure prevention of angioedema attacks in adults and adolescents with hereditary angioedema, and routine prevention of angioedema attacks in adults and adolescents with severe and recurrent attacks of hereditary angioedema who are intolerant to or insufficiently protected by oral prevention treatments or who are inadequately managed with repeated acute treatment.

Insulin glargine (Lantus[®]) 100 units/ml solution for injection is recommended as an option for use within NHS Wales for the treatment of diabetes mellitus in children aged 2 to less than 6 years.

In the absence of a submission from the holder of the marketing authorisation, the Chairman confirmed the following medicines could not be endorsed for use within NHS Wales:

Vildagliptin/metformin hydrochloride (Eucreas[®]) for the treatment of type 2 diabetes mellitus in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled with metformin and a sulphonylurea. Treatment of type 2 diabetes mellitus as triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control.

Decitabine (Dacogen^{®▼}) for the treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia, according to the World Health Organisation classification, who are not candidates for standard induction chemotherapy.

Botulinum toxin type A (Botox[®]) for the management of urinary incontinence in adults with neurogenic detrusor overactivity resulting from neurogenic bladder due to spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are not adequately managed with anticholinergic therapy and who are already catheterising or who are willing to catheterise if required.

Tadalafil (Cialis[®]) 5 mg for the treatment of the signs and symptoms of benign prostatic hyperplasia in adult males.

Brentuximab vedotin (Adcetris^{®▼}) for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma following autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option; as well as for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL).

Alipogene tiparvovec (Glybera[®]) for the treatment of adult patients diagnosed with familial lipoprotein lipase deficiency (LPLD) and suffering from severe or multiple pancreatitis attacks despite dietary fat restrictions. The diagnosis of LPLD has to be confirmed by genetic testing. The indication is restricted to patients with detectable levels of LPL protein.

Vildagliptin (Galvus[®]) for the treatment of type 2 diabetes mellitus in adults as triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these agents do not provide adequate glycaemic control. Vildagliptin is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control.

The Chairman highlighted the medicines for which the holder of the licence had not provided a submission within the appropriate timescale. It was confirmed that unless a Form B or Form C submission is received within the next fourteen days Welsh Government consent would be sought to issue advice that the following medicines could not be endorsed for use:

Hydromorphone hydrochloride (Palladone[®]) injection for the relief of severe pain in cancer. Hydromorphone hydrochloride is indicated in adults and adolescents aged > 12 years.

Everolimus (Votubia^{®▼}) for the treatment of adult patients with renal angiomyolipoma associated with tuberous sclerosis complex who are at risk of complications (based on factors such as tumour size or presence of aneurysm, or presence of multiple or bilateral tumours) but who do not require immediate surgery.

Linaclotide (Constella[®]) for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation in adults.

Tapentadol (Palexia[®]) for the relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics.

Povidone iodine (Minims[®] Povidone Iodine) for cutaneous peri-ocular and conjunctival antisepsis prior to ocular surgery to support postoperative infection control.

Oxycodone (OxyNorm Dispersa[®]) for the treatment of moderate to severe pain in patients with cancer and postoperative pain and treatment of severe pain requiring the use of a strong opioid.

Ciprofloxacin/dexamethasone (Cilodex[®]) for the treatment of the following infections in adults and children: acute otitis media in patients with tympanostomy tubes (AOMT); acute otitis externa (AOE). Consideration should be given to official guidance on the appropriate use of antibacterial agents.

The Chairman urged the holders of the licence to engage in the appraisal process within the appropriate timescales, 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 in Abergavenny on Wednesday, 8th May 2013.

Appraisal 1: Full Submission

Acidinium bromide (Eklira[®] Genuair[®]) as a maintenance bronchodilator treatment to relieve symptoms in patients with chronic obstructive pulmonary disease

Applicant Company: Ammirall Limited

Appraisal 2: Full Submission

Ferumoxytol (Rienso[®]) for the intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease. The diagnosis of iron deficiency must be based on appropriate laboratory tests

Applicant Company: Takeda UK Limited

Appraisal 3: Full Submission

Ingenol mebutate (Picato[®]) for the cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults

Applicant Company: LEO Pharma UK

Appraisal 4: Limited Submission

Linagliptin/metformin (Jentaduo[®]) for the treatment of adult patients with type 2 diabetes mellitus:

- as an adjunct to diet and exercise to improve glycaemic control in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of linagliptin and metformin; and
- in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea

Applicant Company: Boehringer Ingelheim Limited/Eli Lilly & Company Limited

Appraisal 5: Limited Submission

Darunavir (Prezista[®]) for oral suspension co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in antiretroviral treatment (ART)-experienced paediatric patients aged 3-6 years and at least 15 kg body weight

Applicant Company: Janssen-Cilag Limited

Appraisal 6: Full Submission

(to be appraised in private as the submission includes a Welsh Patient Access Scheme)

Ivacaftor (Kalydeco[®]) for the treatment of cystic fibrosis in patients age 6 years and older who have a G551D mutation in the CFTR gene

Applicant Company: Vertex Pharmaceuticals UK Limited

Appraisal 7: Full Submission

(to be appraised in private as the submission includes a Welsh Patient Access Scheme)

Perampanel (Fycompa[®]) for adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older

Applicant Company: Eisai Limited

The Chairman reminded members to declare any interests pertinent to these appraisals scheduled.

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 AWTTTC 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

**Linagliptin (Trajenta[®]▼) for the treatment of type 2 diabetes mellitus to improve glycaemic control in adults:
as monotherapy**

- in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment;

as combination therapy

- in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control;
- in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control; and
- in combination with insulin with or without metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.

The Chairman welcomed representatives from the applicant company, Boehringer Ingelheim Limited / Eli Lilly & Company Limited.

Mr Roger Williams left the meeting as he had declared a personal specific interest. The Chairman invited the remaining members to declare any interests in either the applicant company or the medicine if they had not already done so. There were no further declarations of interest.

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 Claire Davis, AWTTTC assessment lead, to set the context of the appraisal. Dr Davis 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 been received from Diabetes UK Cymru.

The Chairman invited 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 linagliptin (Trajenta[®]▼) should be recommended as an option for use within NHS Wales for the treatment of type 2 diabetes mellitus to improve glycaemic control in adults:

The Chairman invited comment in relation to the case for clinical effectiveness. Clarification was sought in relation to long-term efficacy studies and long-term effects. There was discussion over the choice of comparator and the applicant company were asked to highlight the advantages of this treatment compared to other currently available treatment options. The Chairman asked members if there were any issues within the clinical expert report that required further clarification. There were none. The Chairman invited Dr Anderson to comment on the case for cost-effectiveness. Dr Anderson commended the applicant company on the innovative, externally validated, meta-analysis. She then drew attention to the uncertainties and limitations of using a cost minimisation analysis and alluded to the benefits of an alternative approach. She invited the representatives of the applicant company to respond to the issues raised, and provide a rationale for their chosen approach. There were no outstanding budget impact issues. Mr Palmer relayed the view of Diabetes UK that people with diabetes should have equal access to the best diabetes care and health outcomes available on the basis of clinical need and appropriateness. In their submission, Diabetes UK Cymru suggested that linagliptin (Trajenta[®]▼) might offer advantages to some patients compared to other treatments. The applicant company representatives confirmed support of NMG's preliminary recommendation. They responded to all the issues raised in the discussion and, prior to concluding the appraisal, the Chairman offered the delegates final opportunity to address AWMSG members. They agreed that the appraisal process had been fair and transparent.

The Chairman thanked Boehringer Ingelheim Limited / Eli Lilly & Company Limited for engaging in the appraisal process and proceeded to the next appraisal. Mr Williams rejoined the meeting.

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:

Linagliptin (Trajenta[®]▼) is recommended as an option for use within NHS Wales for the treatment of type 2 diabetes mellitus to improve glycaemic control in adults:

as monotherapy

- in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment;

as combination therapy

- in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control;
- in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control; and
- in combination with insulin with or without metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.

7. Appraisal 2

Pazopanib (Votrient[®]▼) for the treatment of adult patients with selective subtypes of advanced soft tissue sarcoma who have received prior chemotherapy for metastatic disease or who have progressed within 12 months after (neo) adjuvant therapy

The Chairman welcomed representatives from the applicant company, GlaxoSmithKline.

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 invited Dr Stephanie Francis, AWTTTC assessment lead, to set the context of the appraisal. Dr Francis 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 been received from Sarcoma UK.

The Chairman invited 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 pazopanib (Votrient[®]▼) should not be recommended for use within NHS Wales for the treatment of adult patients with selective subtypes of advanced soft tissue sarcoma (STS) who have received prior chemotherapy for metastatic disease or who have progressed within 12 months after (neo) adjuvant therapy. NMG considered the company submission did not present convincing evidence to demonstrate that pazopanib (Votrient[®]▼) is clinically effective and cost-effective compared to existing treatment options. NMG noted several uncertainties and limitations in the indirect treatment comparison and economic model provided in the company's submission. NMG agreed that the AWMSG criteria for appraising life-extending, end-of-life medicines did not apply to pazopanib (Votrient[®]▼) for the indication under consideration. An additional extension to life of at least three months compared to current NHS treatment was not demonstrated. NMG considered that pazopanib (Votrient[®]▼) did not satisfy the AWMSG criteria for ultra orphan drug status.

The Chairman invited comment in relation to the case for clinical effectiveness. There was brief clarification over the delivery of care. It was agreed that the anticipated patient numbers were consistent with the clinical expert summary. There was discussion over drop-out rates within the trials. The Chairman invited Dr Anderson to comment on the case for cost-effectiveness. She drew attention to the uncertainties and limitations within the submission. She suggested that the approach taken by the applicant company in demonstrating cost effectiveness had been simplistic and a more complex approach may have been more appropriate. It was noted that the level of uncertainty within the submission presented a considerable challenge. The company delegates were invited respond to the issues highlighted. They acknowledged the uncertainties within the submission and highlighted that, with this being an extremely rare disease, there was limited data available. A rationale for the selection of comparator was provided, and members were informed that unadjusted indirect comparisons were undertaken by the company as they considered this form of analysis was appropriate although they recognised the inherent limitations. The company delegates highlighted the advantages of pazopanib (Votrient[®]▼) being the only oral medication available which offered clinicians in Wales an additional treatment option for patients with limited pathways. The Chairman referred members to the patient organisation submission from Sarcoma UK and Mr Palmer drew members' attention to the salient issues highlighted within it. Members acknowledged this was a very informative patient organisation submission. There were no outstanding budget impact or societal issues.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates to highlight any additional information. Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked GlaxoSmithKline 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:

Pazopanib (Votrient[®]▼) is not recommended for use within NHS Wales for the treatment of adult patients with selective subtypes of advanced soft tissue sarcoma (STS) who have received prior chemotherapy for metastatic disease or who have progressed within

12 months after (neo) adjuvant therapy. The case for cost effectiveness has not been proven.

8. Appraisal 3

Glycopyrronium bromide (Seebri[®] Breezhaler[®]▼) as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease

The Chairman welcomed the representatives of the applicant company Novartis Pharmaceuticals UK 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.

The Chairman invited Mrs Sabrina Rind, AWTTTC 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](#). She confirmed that no submission from a patient organisation had been received.

The Chairman invited Dr Bracchi to relay the main points of discussion from NMG. Dr Bracchi confirmed NMG's view that glycopyrronium bromide (Seebri[®] Breezhaler[®]▼) should be recommended as an option for use within NHS Wales as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.

The Chairman asked members if there were any outstanding issues in relation to the case for clinical effectiveness. There was brief discussion over the studies. The Chairman referred members to the clinical expert summary and no further clarification was sought in relation to the case for clinical effectiveness. The Chairman invited Dr Anderson to comment on the case for cost-effectiveness. Dr Anderson highlighted the areas of uncertainty in the submission and explained the limitations of using a cost minimisation analysis. The company delegates responded and provided the rationale as to why they had used this approach. There were no outstanding budget impact issues. The Chairman asked members if there were any outstanding societal issues that required clarification. Ease of use, particularly important for elderly patients, was noted. Mr Palmer informed members of the organisations contacted by AWTTTC and confirmed that no submission had been received. The applicant company delegates responded to the issues raised in the discussion and had no further comments. Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Novartis Pharmaceuticals UK Limited for engaging in the appraisal process and proceeded to the next appraisal.

Members in the public gallery were asked to leave the meeting, as the following appraisal involved a Wales Patient Access Scheme and proceedings were confidential.

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:

Glycopyrronium bromide (Seebri[®] Breezhaler[®]▼) is recommended as an option for use within NHS Wales as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.

9. Appraisal 4 (proceedings held in private)

Aztreonam lysine (Cayston[®]) for suppressive therapy of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis aged 6 years and older

The Chairman welcomed delegates from the applicant company Gilead Sciences 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 reminded members of the need for confidentiality, as the submission contained a Wales Patient Access Scheme. The Chairman repeated the statement announced at the commencement of the appraisal session.

The Chairman invited Dr Stephanie Francis, AWTTTC assessment lead, to set the context of the appraisal. Dr Francis provided an overview of the submission as detailed in the [ASAR](#) and relayed the views of the [clinical experts](#). She confirmed that a patient organisation submission had been received from the Cystic Fibrosis Trust.

The Chairman invited Dr Bracchi to provide a brief synopsis of discussion at NMG. He relayed the preliminary recommendation that aztreonam lysine (Cayston[®]) should be recommended as an option for restricted use within NHS Wales. It was confirmed the recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised. NMG considered aztreonam lysine (Cayston[®]) should be restricted for third-line use in patients in whom nebulised colistimethate sodium and nebulised tobramycin are not tolerated or are not providing satisfactory therapeutic benefit; a subpopulation within its licensed indication for suppressive therapy of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis aged six years and older. It was the view of NMG that aztreonam lysine (Cayston[®]) should not be recommended for use within NHS Wales outside of this subpopulation.

The Chairman invited comment in relation to the case for clinical effectiveness. It was noted the indication under consideration by AWMSG was different to that in the trial population. There was discussion regarding the number of patients eligible for treatment in Wales. There was general agreement that the dose of three times a day may pose practical issues for patients receiving multiple treatments. The Chairman invited Dr Anderson to comment on the case for cost-effectiveness. Dr Anderson commented on the applicability of the economic model and highlighted the areas of uncertainty. The company delegates from Gilead responded to the issues highlighted in the discussion and explained they had made their submission relevant to NHS Wales. There were no outstanding budget impact or societal issues. The Chairman referred members to the clinical expert summary. The Chairman referred members to the patient organisation submission from the Cystic Fibrosis Trust and Mr Palmer drew members' attention to the salient issues highlighted within it. Clarification was provided by the applicant company delegates that aztreonam lysine (Cayston[®]) is expected to be used in patients intolerant to currently available nebulised therapies.

The Chairman referred to the applicant company response to the preliminary recommendation and it was noted that Gilead fully supported the preliminary recommendation. Prior to concluding the discussion and, having offered final opportunity to address AWMSG, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Gilead Limited for engaging in the appraisal process 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:

Aztreonam lysine (Cayston[®]) is recommended as an option for restricted use within NHS Wales. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.

Aztreonam lysine (Cayston®) should be restricted for third-line use in the following subpopulation within its licensed indication for suppressive therapy of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis aged six years and older:

- **Patients in whom nebulised colistimethate sodium and nebulised tobramycin are not tolerated or are not providing satisfactory therapeutic benefit.**

Aztreonam lysine (Cayston®) is not recommended for use within NHS Wales outside of this subpopulation.

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 in the absence of 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 of January 2013 meeting)

The Chairman invited Dr Tessa Lewis to present the draft minutes of the AWPAG meeting held on 17th January 2013 - [Enc 6/AWMSG/0313](#). Dr Lewis highlighted the work currently on-going and confirmed that another AWPAG meeting had been held in March, and the minutes of this meeting would be presented to AWMSG in May.

11. AWMSG National Prescribing Indicators 2013–2014: Supporting information for prescribers

Dr Lewis asked AWMSG to support the document as an implementation tool summarising the All Wales Medicines Strategy Group (AWMSG) National Prescribing Indicators for 2013–2014, and highlighting the associated key messages and supporting materials. It was noted the full [National Prescribing Indicators 2013-2014 document and supporting](#) evidence is available on the AWMSG website. The Chairman opened discussion and members welcomed the summary document. Suggestions noted included linking to the antibiotic audit, if subsequently endorsed by AWMSG. Dr Lewis agreed to check the link to the template for prescribing statins within NHS Wales and reconsider the wording on switching between opioid treatments. A suggestion was made that it be included on the GP IT systems as a decision aid and there was general agreement that consistency of information provided to health boards in Wales was crucial. It was suggested that with the integrated pharmacy teams, AWTTTC should explore implementation of this document as a decision aid on GP IT systems and the cascading of prescribing information to hospital consultants with the All Wales Chief Pharmacists Committee. Members welcomed data comparisons with primary care trusts in England, as well as health boards in Wales. The Chairman closed discussion and confirmed AWMSG's strong support for dissemination of the document.

12. CEPP National Audit: Focus on Antibiotic Prescribing

Dr Lewis acknowledged the work of Dr Sean Young in initiating and piloting the audit and supporting the subsequent development. She asked AWMSG to consider the antibiotic audit for endorsement as a Clinical Effectiveness Prescribing Programme (CEPP) national audit for 2013–2014. Dr Lewis clarified the purpose - to promote antibiotic prescribing in accordance with existing guidelines. AWMSG was asked to support the audit which reviews the quality and quantity of antibiotic prescribing.

The paper pertained to recommendation 38 of the All Wales Medicines Strategy Group (AWMSG) Medicines Strategy for Wales¹:

“NHS Trusts and LHBs should review their interface medicines management systems in line with best practice and develop a plan to tackle problem areas.”

Dr Lewis provided the background and explained that in September 2011, a joint multi-professional workshop was held involving the Antimicrobial Stewardship Forum and AWPAG/AWTTTC representatives. The workshop aimed to support movement relating to the AWMSG antimicrobial national prescribing indicator. A nominal group technique was used. Participants were asked to identify three key messages or interventions that would support the appropriate prescribing of antimicrobials. At the end of the workshop, delegates voted on the themes identified. There was strong support for the message "To use the guidelines (national, local, electronic) in primary and secondary care and justify deviation". Dr Lewis confirmed an audit draft was considered by AWPAG in July 2012 and subsequently updated. The updated document was considered by AWPAG in January 2013. A pilot of the audit had been undertaken and demonstrated improvement in the choice of antibiotic prescribed.

The Chairman opened discussion and members agreed the audit offered a good balance between cost and quality, whilst tackling a national priority to reduce the prescribing of antimicrobials. There was discussion over the understanding of prescribing behaviour within out-of-hours medical services. There was also general agreement that an end date should be displayed on any delayed prescriptions. The Chairman asked for feedback on the uptake of AWMSG national audits. There was unanimous support of the audit and Professor Walker agreed to explore mechanisms for encouraging implementation within NHS Wales.

13. Date of next meeting:

The Chairman confirmed the date of the next AWMSG meeting on **Wednesday 8th May 2013** at the earlier time of **9.30 am** in **Abergavenny** and closed the meeting.