

Enclosure No:	1/AWMSG/0911
Agenda Item No:	5 – Minutes of previous meeting
Author:	Chairman, AWMSG
Contact:	Tel: 029 20716900 E-Mail: wmp@wales.nhs.uk

ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY, 13th JULY 2011 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY

MEMBERS PRESENT:

**Did not
participate in**

- | | | |
|---------------------------|--|------------|
| 1. Prof Philip Routledge | Chairman | |
| 2. Dr Fraser Campbell | GP with prescribing lead role | |
| 3. Prof David Cohen | Health Economist | |
| 4. Mrs Debbie Davies | Representing other professions eligible to prescribe | |
| 5. Dr Karen Fitzgerald | Consultant in Pharmaceutical Public Health | |
| 6. Ms Ellen Lanham | Community Pharmacist | |
| 7. Dr Brian Hawkins | Senior Primary Care Pharmacist | |
| 8. Mrs Rebecca Richards | Finance Director | |
| 9. Dr Emma Mason | Clinical Pharmacologist | |
| 10. Dr Richard Moore | Hospital Consultant | |
| 11. Mr Christopher Palmer | Lay member | |
| 12. Mr Guy Thompson | ABPI (Wales) representative | |
| 13. Mrs Wendy Warren | Senior Nurse | 1-7 |
| 14. Dr John Watkins | Consultant in Public Health Medicine | 1-5 |
| 15. Mr Roger Williams | Senior Hospital Pharmacist | |

IN ATTENDANCE:

- | | |
|-------------------------|-----------------------------------|
| 16. Dr Robert Bracchi | Chairman, New Medicines Group |
| 17. Prof Ceri Phillips | NMG/AWMSG Link Health Economist |
| 18. Prof Roger Walker | Welsh Assembly Government |
| 19. Mrs Karen Samuels | Welsh Medicines Partnership Board |
| 20. Mrs Ruth Lang | Welsh Medicines Partnership Board |
| 21. Mr Anthony Williams | Welsh Medicines Partnership |
| 22. Dr Claire Davis | Welsh Medicines Partnership |

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
DH	Department of Health
EMA	European Medicines Agency
FAR	Final Appraisal Recommendation
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Boards
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
WMP	Welsh Medicines Partnership

1. Welcome and introduction

The Chairman opened the meeting and welcomed members.

2. Apologies

Dr Phil Banfield, Hospital Consultant

Dr Bruce Ferguson, Medical Director

Dr Brendan Lloyd, Medical Director

Dr Geoffrey Carroll, Welsh Health Specialised Services Committee

Dr Hugo van Woerden, Welsh Health Specialised Services Committee

3. Declarations of interest

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

4. Chairman's report

It was confirmed as reported in June that Ministerial ratification of AWMSG's advice in relation to capecitabine (Xeloda[®]) in combination with oxaliplatin remains outstanding. In addition, ratification of statements of advice and recommendations from the previous meeting has been requested.

The Chairman reported that since the last AWMSG meeting and, in the absence of a submission from the holder of the marketing authorisation, the following statements of advice are being processed:

Bosentan (Tracleer[®]▼) cannot be endorsed for use within NHS Wales for the treatment of class II pulmonary arterial hypertension (license extension)

Nitric oxide (INOmax[®]) cannot be endorsed for use within NHS Wales for the treatment of peri- and post-operative pulmonary hypertension in adults and newborn infants, infants and toddlers, children and adolescents, ages 0-17 years in conjunction to heart surgery

The Chairman confirmed that these medicines could not be endorsed for use within NHS and should not be routinely available within NHS Wales. Members were informed that WMP is

awaiting ratification of these statements and the service would be informed when this has been received.

The Chairman reported that the following appraisals had been scheduled for appraisal at the next meeting on 14th September 2011:

Appraisal 1: sunitinib (Sutent[®]▼) for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours with disease progression in adults.

Applicant Company: Pfizer Ltd

Appraisal 2: dasatinib (Sprycel[®]▼) for the treatment of newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia in the chronic phase.

Applicant Company: Bristol-Myers Squibb

The Chairman reiterated the views of patients, patient organisations and patient carers would be welcomed and suggested that contact could be made with WMP for further information on the future work programme.

5. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy. There were no issues of accuracy and the Chairman signed the minutes as a true record of the previous meeting. There were no matters arising.

6. Appraisal 1 - Fentanyl (Pecfent[®]▼): for the management of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain

The Chairman invited members to declare interests in either the applicant company or the medicine. There were none.

Dr Claire Davis, WMP Appraisal Lead, joined members at the table.

The Chairman announced the statement, pertinent to all appraisals, that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by the Minister for Health and Social Services, places an obligation on Health Boards to fund accordingly. It was confirmed that AWMSG advice is interim to final NICE guidance should this be subsequently published.

The Chairman reiterated that NMG had considered the clinical and cost effectiveness issues in detail and had taken account of medical expert and patient organisation views. Members were reminded not to repeat the detailed discussion held at NMG but to seek clarification of any outstanding issues in relation to clinical or cost-effectiveness, consider the company response to the preliminary recommendation and take into account societal and budget impact issues. He confirmed that members would retire to vote in private and agree the recommendation, which would be subsequently announced.

The Chairman welcomed the delegate from the applicant company, Archimedes Pharma UK Limited.

The Chairman invited Dr Robert Bracchi, Chairman of the New Medicines Group, to provide an overview of the discussions held at the preliminary appraisal and set the context of the appraisal. The views of clinical experts were provided to members. It was confirmed that a patient organisation submission had been received from Myeloma UK. Dr Bracchi confirmed NMG's preliminary recommendation that fentanyl (PecFent[®]▼) should be recommended as an option for use within NHS Wales for the management of breakthrough pain in adults who are

already receiving maintenance opioid therapy for chronic cancer pain. Dr Bracchi relayed NMG's view that fentanyl (PecFent[®]▼) should be initiated by, and remain under the supervision of, a specialist clinician experienced in the management of opioid therapy in cancer patients. NMG were of the view that fentanyl (PecFent[®]▼) may be suitable for shared care within NHS Wales for the above indication.

The Chairman opened the discussion and invited members to highlight issues in relation to the case for clinical effectiveness. The Chairman invited Professor Ceri Phillips to highlight issues in relation to cost effectiveness. The weaknesses of the cost utility analysis were noted. The patient representative drew attention to the main issues from the patient organisation submission. Myeloma UK that highlighted the convenient alternative route of administration and considered the trial data to be effective. There were no outstanding societal or budget impact issues. The Chairman referred members to the summary of clinical expert opinion.

The company delegate was invited to respond to all the issues raised by members in their discussion and offered opportunity to highlight any other outstanding issues.

Prior to concluding the appraisal, the Chairman asked the company delegates to confirm that all the outstanding issues had been addressed and confirmation was given by the delegates that the process had been fair and transparent.

The Chairman thanked Archimedes Pharma UK Ltd for engaging in the appraisal process. Dr Davis left the meeting.

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

Appraisal decision

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

Fentanyl (PecFent[®]▼) is recommended as an option for use within NHS Wales for the management of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain.

Fentanyl (PecFent[®]▼) should be initiated by, and remain under the supervision of, a specialist physician experienced in the management of opioid therapy in cancer patients.

AWMSG is of the opinion that fentanyl (PecFent[®]▼) may be suitable for shared care within NHS Wales for the above indication.

- 7. Appraisal 2 - Ferric carboxymaltose (Ferinject[®]▼) for the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used. The diagnosis must be based on laboratory tests.**

Mr Anthony Williams, WMP Appraisal Lead, joined members at the table.

The Chairman invited members to declare interests in either the applicant company or the medicine. There were none.

The Chairman welcomed the delegates from the applicant company, Vifor Pharma UK Limited.

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 opened the appraisal and 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 context of the appraisal. In his address, Dr Bracchi relayed the views of clinical experts. He confirmed that a joint patient organisation submission had been received from the National Kidney Federation and Welsh Kidney Patients Association which identified the medicine's high safety profile and highlighted benefits to patients and healthcare professionals. Dr Bracchi confirmed NMG's preliminary recommendation that ferric carboxymaltose (Ferinject[®]▼) should be recommended as an option for restricted use within NHS Wales for the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used. The diagnosis must be based on laboratory tests. He relayed NMG's view that ferric carboxymaltose (Ferinject[®]▼) should be restricted for use in non-haemodialysis patients only where other intravenous iron preparations are not suitable. NMG considered that ferric carboxymaltose (Ferinject[®]▼) should not be recommended for use in haemodialysis patients as the case for cost effectiveness has not been proven. NMG's opinion was that ferric carboxymaltose (Ferinject[®]▼) may be suitable for shared care within NHS Wales for the above indication.

Mrs Wendy Warren joined the meeting and the Chairman confirmed that Mrs Warren would be unable to participate in the appraisal.

The Chairman opened the discussion and invited members to highlight issues in relation to the case for clinical effectiveness

The company delegates clarified the choice of comparator and justified their reasons for selecting a cost minimisation analysis. Clarification was sought in relation to nurse time. A comprehensive summary of clinical expert opinion had been provided to members for consideration.

Professor Ceri Phillips highlighted issues within the company's case for cost effectiveness and agreed with the view of NMG that a cost utility study would have been more appropriate as cost minimisation was not considered an appropriate approach.

The patient organisation submission was considered and the lay member highlighted the salient issues from the patient perspective.

The company delegates provided the rationale behind their comments in the company response with regard to shared care and also the wording of NMG's preliminary recommendation. The company delegates responded to all the issues raised in the discussion, both clinical and in relation to the case for cost effectiveness. The positioning of the treatment therapy was reiterated and the applicant company was afforded opportunity to highlight any outstanding issues. Prior to concluding the appraisal, the Chairman asked the company delegates to confirm that all the issues had been addressed, and confirmation was given by the delegates that the process had been fair and transparent.

The Chairman thanked Vifor Pharma UK Limited for engaging in the appraisal process. Mr Williams left the meeting.

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

Appraisal decision

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

Ferric carboxymaltose (Ferinject®▼) is recommended as an option for use within NHS Wales for the treatment of patients with iron deficiency when oral iron preparations are ineffective or cannot be used.

Ferric carboxymaltose (Ferinject®▼) should be restricted for use in non-haemodialysis patients only.

AWMSG is of the opinion that Ferric carboxymaltose (Ferinject®▼) is not suitable for shared care within NHS Wales for the above indication.

The Chairman announced that confirmation of the AWMSG recommendation would be forwarded by WMP on or before Wednesday, 20th July 2011 and the applicant company have until Wednesday, 27th July 2011 to accept the recommendation or lodge a request for an independent review. It was confirmed the process would not be delayed if the applicant company failed to respond to the deadline. It was stated that subject to receiving a request for an independent review within the appropriate timelines, the recommendation would be passed to Welsh Government officials on Thursday, 28th July 2011. The Chairman confirmed that the relevant companies would be informed when Ministerial ratification had been received.

8. All Wales Prescribing Advisory Group (AWPAG)

Prescribing dilemmas: A guide for prescribers

The Chairman invited Dr Tessa Lewis to present Enc 4/AWMSG/0711 Prescribing dilemmas – A guide for prescribers. Dr Lewis confirmed the purpose of the document was to provide guidance for health professionals on prescribing situations not covered by the NHS including private care and private prescriptions; travel; foodstuffs; infertility treatment; minor ailments, homeopathy, erectile dysfunction; prescribing for self and family; visitors from overseas; unlicensed medicines and prescribing outside national guidance. This work had been led and developed by Mrs Louise Howard-Baker who had responded to the comments of AWMSG when the paper had been discussed at a previous meeting. Dr Lewis confirmed the updated paper was being re-presented to AWMSG for endorsement. The Chairman invited comment. Typographic errors and comments in relation to content were noted. There was discussion in relation to Section 2 - members agreed this is a complex area and it was suggested that further clarification of the wording of this section might be required. Dr Lewis agreed to update the document in light of the discussion. The AWPAG Chair confirmed the document would be posted on the AWMSG website and disseminated accordingly. With the changes identified in the discussion, AWMSG endorsed the paper and the Chairman thanked Mrs Howard-Baker and AWPAG members for the development of such a useful resource for prescribers.

9. Patient Access Schemes in NHS Wales – Proposal

The Chairman invited Mrs Karen Samuels to present Enc 5/AWMSG/0711 relating to patient access schemes. AWMSG was requested to consider whether NHS Wales-specific patient access schemes have merit as part of the managed entry of new medicines into NHS Wales. The Chairman invited discussion of the proposal to support the establishment of a group whose remit would be to consider the feasibility, workability and acceptability of a patient access scheme within NHS Wales. The proposed membership of the committee was agreed – a suggestion was made that the clinician representative should be a medical director with an understanding of the unmet need. It was agreed that operational issues and more detail would need to be progressed via the TDAPG. There was cautious enthusiasm and agreement by AWMSG that the proposal be supported in principle.

The date of the next meeting was announced:

Wednesday, 14th September 2011 at The Angel Hotel, Abergavenny