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| **Enclosure No**: | **1/AWMSG/0212** |
| **Agenda Item No**: | **5** – Minutes of previous meeting |
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# ALL WALES MEDICINES STRATEGY GROUP

## MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY, 7th DECEMBER 2011 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY

**MEMBERS PRESENT:**

**Did not participate in**

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| 1. | Prof Philip Routledge | Chairman |
| 2. | Dr Philip Banfield | Hospital Consultant |
| 3. | Dr Fraser Campbell | GP with prescribing lead role |
| 4. | Prof David Cohen | Health Economist |
| 5. | Mrs Debbie Davies | Representing other professions eligible to prescribe |
| 6. | Dr Bruce Ferguson | Medical Director (Vice Chairman) |
| 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 Emma Mason | Clinical Pharmacologist |
| 11. | Mr Christopher Palmer | Lay member |
| 12. | Ms Rebecca Richards | Finance Director |
| 13. | Mr Christian Smith | Nurse Director |
| 14. | Mr Guy Thompson | ABPI (Wales) representative |
| 15. | Dr John Watkins | Consultant in Public Health Medicine |
| 16. | Mr Roger Williams | Senior Hospital Pharmacist |

**IN ATTENDANCE:**

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| 17. | Professor Roger Walker | Welsh Government |
| 18. | Mrs Karen Samuels | Welsh Medicines Partnership Board |
| 19. | Mrs Ruth Lang | Welsh Medicines Partnership Board |
| 20. | Mrs Kath Haines | Welsh Medicines Partnership / WAPSU |

**List of Abbreviations:**

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| ABPI | Association of the British Pharmaceutical Industry |
| ASAR | AWMSG Secretariat Assessment Report |
| AWMSG | All Wales Medicines Strategy Group |
| AWPAG | All Wales Prescribing Advisory Group |
| CHMP | Committee for Medicinal Products for Human Use |
| DH | Department of Health |
| EMA | European Medicines Agency |
| FAR | Final Appraisal Recommendation |
| GP | General Practitioner |
| HAC | High Acquisition Cost |
| HB | Health Boards |
| 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 |
| WMP | Welsh Medicines Partnership |

**1. Welcome and introduction**

The Chairman welcomed members.

**2. Apologies**

Wendy Warren (Christian Smith deputising)
Dr Geoffrey Carroll (no deputy in attendance)

**3. Declarations of interest**

The Chairman asked members to declare any interests pertinent to the agenda. Dr Fraser Campbell confirmed a personal non-specific interest in Boehringer-Ingelheim and the Chairman confirmed that Dr Campbell would be unable to participate in appraisal of alteplase (Actilyse® 2 mg Cathflo). Professor Routledge confirmed a non-personal non-specific interest in Astra Zeneca in that a post within the Department of Pharmacology, Cardiff University is part-funded by Astra Zeneca (through the ABPI Clinical Pharmacology Training scheme) and part-funded by Welsh Government. Members agreed that Professor Routledge could chair the appraisal and it was confirmed he would not vote.

**4. Chairman's report**

The Chairman informed members that the latest AWMSG annual report 2010-2011 had been published. A copy had been provided to all members and an electronic version is available to download from the AWMSG website.

It was reported that on Thursday, 24th November 2011, the AWMSG Steering Committee considered Janssen-Cilag's request for an independent review of AWMSG's advice that paliperidone palmitate (Xeplion®) prolonged release suspension for injection should not be recommended for use within NHS Wales for the maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone; or in selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, without prior stabilisation with oral treatment when psychotic symptoms are mild to moderate and a

long-acting injectable treatment is needed. Members were informed that the steering committee considered that the grounds for review had not been met. The Chairman confirmed that AWMSG's recommendation would be forwarded to Welsh Government for ratification.

The Chairman reported that AWMSG's recommendations and the statements of advice reported in November were awaiting ratification.

The Chairman confirmed that in the absence of a submission from the holder of the marketing authorisation within the appropriate timescales, statements of advice are currently in preparation for the following:

Human normal immunoglobulin (Kiovig®) for immunomodulation in adults, and children and adolescents (0-18 years) in multifocal motor neuropathy

Telavancin (Vibativ®) for the treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by methicillin resistant Staphylococcus aureus (MRSA), only in situations where it is known or suspected that other alternatives are not suitable.

The Chairman announced the appraisals scheduled for the next meeting on Wednesday, 8th February 2012:

Appraisal 1: Linagliptin (Trajenta®) for the treatment of type 2 diabetes mellitus to improve glycaemic control in adults
Applicant Company: Boehringer Ingelheim / Eli Lilly and Company Ltd

Appraisal 2: Entecavir (Baraclude®) for the treatment of chronic hepatitis B virus infection in adults with decompensated liver disease
Applicant Company: Bristol-Myers Squibb Pharmaceuticals Ltd

Appraisal 3: Trastuzumab (Herceptin®) for the treatment of patients with HER2-positive early breast cancer following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel, or the treatment of patients with HER2-positive early breast cancer in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin
Applicant Company: Roche Products Ltd

Appraisal 4: 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
Applicant Company: Astellas Pharma Ltd

Appraisal 5: Icatibant acetate (Firazyr®) for the symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults with C1-esterase-inhibitor (C1-INH) deficiency
Applicant Company: Shire Human Genetic Therapies

Appraisal 6: Abiraterone (Zytiga®) in combination with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen
Applicant Company: Janssen-Cilag Ltd

The Chairman reminded members to declare to WMP any interest in relation to the appraisal scheduled. The Chairman invited patients, patient organisations and patient carers to submit their views and contact WMP 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. There were no matters arising and the Chairman signed the minutes as a true record of the proceedings.

**6. Appraisal 1: Alteplase (Actilyse® 2 mg Cathflo) thrombolytic treatment of occluded central venous access devices including those used for haemodialysis**

Dr Campbell left the meeting. The Chairman invited members to declare interests in either the applicant company or the medicine – there were none.

Dr David Jarrom, WMP assessment lead, joined members.

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 confirmed that the three appraisals scheduled had been considered eligible for a limited submission. The Chairman confirmed that, in line with this process, evidence of budgetary impact in comparison to the existing comparator product(s) should be demonstrated. The Chairman asked members to consider the evidence and highlight any societal issues, and take account of NMG's preliminary recommendation and the company response to this. It was confirmed that clinical expert views would be provided, where available. The Chairman clarified that views of patients have been invited but would not be actively sought within the limited submission process. The Chairman confirmed that the applicant company delegates would be invited to provide clarification of any outstanding issues. It was confirmed that following consideration of the evidence, AWMSG would retire to vote in private and agree the final recommendation which would be subsequently announced and, subject to a request for an independent review, would be forwarded to Welsh Government for ratification. The Chairman highlighted that monitoring of budget impact would be essential and AWMSG reserved the right to request a full submission in the future, if the budget impact exceeded that estimated in the submission.

The Chairman welcomed delegates from the applicant company, Boehringer Ingelheim Ltd

Dr Jarrom set the context of the appraisal and highlighted relevant issues within the ASAR. He relayed NMG's view that alteplase (Actilyse® Cathflo® 2 mg) should be recommended as an option for use within NHS Wales for the thrombolytic treatment of occluded central venous access devices including those used for haemodialysis. NMG's view that alteplase (Actilyse® Cathflo® 2 mg) is not suitable for shared care within NHS Wales was noted.

The Chairman opened the appraisal proceedings and invited AWMSG members to raise any outstanding issues in relation to the case for clinical effectiveness. It was noted that no clinical expert or patient organisation views had been provided and the lay member confirmed there were no outstanding issues from a patient perspective. The Chairman invited comment in relation to budget impact and societal issues - there were no outstanding issues of note. The applicant company delegates responded to all the issues highlighted by AWMSG in their discussion and afforded opportunity to comment on any other relevant aspect of the appraisal. Prior to concluding the appraisal, the Chairman asked the delegates from Boehringer Ingelheim Ltd to confirm that all the outstanding issues had been addressed and they agreed that the process had been fair and transparent. The Chairman thanked Boehringer Ingelheim Ltd for engaging in the appraisal process. Members were asked to make a note of their recommendation and the Chairman moved on to the second appraisal.

**Appraisal decision**
The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had come to the following decision:

**Alteplase (Actilyse® Cathflo® 2 mg) is recommended as an option for use within NHS Wales for the thrombolytic treatment of occluded central venous access devices including those used for haemodialysis.**

**AWMSG is of the opinion that alteplase (Actilyse® Cathflo® 2 mg) is not suitable for shared care within NHS Wales.**

**7. Appraisal 2: Saxagliptin (Onglyza®▼) as an add-on combination therapy for use in adult patients with type 2 diabetes mellitus with moderate or severe renal impairment to improve glycaemic control**

The Chairman invited members to declare interests in either the applicant company or the medicine if they had not already done so – there were no additional declarations.

Mrs Susan Cervetto, WMP Appraisal Lead, joined members. The Chairman welcomed delegates from the applicant company, Bristol-Myers Squibb Pharmaceuticals Ltd/AstraZeneca UK Ltd.

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.

Mrs Cervetto set the context of the appraisal and highlighted relevant issues within the ASAR. She drew members' attention to the views of the clinicians. She relayed NMG's view that saxagliptin (Onglyza®) should be recommended as an option for use within NHS Wales as an add-on combination therapy for use in adult patients with type 2 diabetes mellitus with moderate or severe renal impairment to improve glycaemic control. It was noted that NMG considered saxagliptin (Onglyza®) may be suitable for shared care within NHS Wales.

The Chairman opened the appraisal proceedings and invited AWMSG members to raise any outstanding issues in relation to the case for clinical effectiveness. A summary of clinical expert views had been provided to members for consideration. No patient organisation views had been received and the lay member confirmed there were no outstanding issues from a patient perspective. The Chairman invited comment in relation to budget impact and societal issues. Clarification was sought in relation to the interpretation of data in table 1 and 2. There was discussion in relation to patient drop out rates and clarification of the differences between the study groups. The Chairman adjourned the appraisal to allow the company delegates sufficient time to seek clarification of an outstanding issue highlighted in the discussion. The appraisal was re-adjourned following appraisal 3. The applicant company delegates responded to the issues highlighted by AWMSG in their discussion and were afforded opportunity to comment on any other relevant aspect of the appraisal. Prior to concluding the appraisal, the Chairman asked the delegates to confirm that all the outstanding issues had been addressed and they agreed that the process had been fair and transparent. The Chairman thanked Bristol-Myers Squibb and AstraZeneca Alliance for engaging in the appraisal process.

**Appraisal decision**
The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had come to the following decision:

**Saxagliptin (Onglyza®) is recommended as an option for use within NHS Wales as an add-on combination therapy for use in adult patients with type 2 diabetes mellitus with moderate or severe renal impairment to improve glycaemic control.**

**AWMSG is of the opinion that saxagliptin (Onglyza®) may be suitable for shared care within NHS Wales.**

**8. Appraisal 3: Sodium valproate (Episenta®) for the treatment of manic episode in bipolar disorder when lithium is contraindicated or not tolerated. In patients who respond, consider continuation of treatment**

The Chairman invited members to declare interests in either the applicant company or the medicine that had not previously been declared.

Dr David Jarrom, WMP Appraisal Lead, re-joined members.

The Chairman confirmed that Beacon Pharmaceuticals had declined the invitation to attend the appraisal and respond to any issues highlighted by AWMSG.

The Chairman invited Dr Jarrom to set the context of the appraisal. Dr Jarrom highlighted relevant issues within the ASAR and drew members' attention to the salient issues raised by the clinicians. He concluded his address by relaying NMG's view that sodium valproate (Episenta®) should be recommended as an option for use within NHS Wales for the treatment of manic episode in bipolar disorder when lithium is contraindicated or not tolerated. The continuation of treatment after manic episode could be considered in patients who have responded to sodium valproate (Episenta®) for acute mania. Dr Jarrom confirmed that NMG considered that sodium valproate (Episenta®) may be suitable for shared care within NHS Wales.

The Chairman opened the appraisal proceedings and invited AWMSG members to raise any outstanding issues in relation to the case for clinical effectiveness. It was noted that no patient organisation views had been provided and the lay member confirmed there were no outstanding issues from a patient perspective. The Chairman invited comment in relation to budget impact and societal issues - there were no outstanding issues of note.

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

**Appraisal decision**
The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had come to the following decision:

**Sodium valproate (Episenta®) is recommended as an option for use within NHS Wales for the treatment of manic episode in bipolar disorder when lithium is contraindicated or not tolerated. The continuation of treatment after manic episode could be considered in patients who have responded to sodium valproate (Episenta®) for acute mania.**

**AWMSG is of the opinion that sodium valproate (Episenta®) may be suitable for shared care within NHS Wales.**

The Chairman concluded the appraisal proceedings by confirming that the AWMSG recommendations would be forwarded by WMP to the applicant companies on or before

Wednesday, 14th December 2011 and that the applicant companies had until Wednesday, 21st December 2011 to accept the recommendation or lodge a request for an independent review, the grounds for which should be submitted to the Chairman in writing. It was confirmed the process would not be delayed if the applicant companies failed to respond to the deadline. It was stated that subject to receiving a request for an independent review within the appropriate timelines, the recommendations would be passed to Welsh Government officials on Thursday, 22nd December 2011. The Chairman confirmed that the applicant companies would be informed when ratification had been received from Welsh Government.

The appraisal proceedings were closed.

**9. National Prescribing Indicators 2012/13**

The Chairman invited Dr Tessa Lewis, Chair of AWPAG, and Mrs Kath Haines, Head of WAPSU, to present the national indicators proposed for 2012-2013. Dr Lewis thanked Mrs Haines for leading on the development of the document. Members were informed that an AWPAG working group had convened to review the 2011-2012 indicators to ensure they were still valid and reflected best practice. Additionally, the Antimicrobial Stewardship Forum had input into the antibiotic indicator review. Mrs Haines highlighted that the targets should be challenging but achievable, encouraging all health boards to achieve prescribing rates in the best quartile. It was noted that the targets were not absolute values and could be achieved on movement towards the upper or lower quartile, depending on the indicator. Members were informed that targets will be set based on the prescribing data for general practices for the quarter ending 31st December 2011. Mrs Haines confirmed that quality and productivity indicators introduced in 2011 as part of the Quality and Outcomes Framework are not applicable for 2012-2013; however, it was proposed that targets for the AWMSG national prescribing indicators should be based on the same criteria. Members were provided with graphs to show progress against the current target and were invited to comment. There was discussion in relation to the appropriateness and validation of prescribing measures, benchmarking and monitoring of both national indicators and local comparators. Members expressed their views, particularly in relation to moving the PPI indicator from a national indicator to a local comparator. There was general agreement to support the branded prescribing of opioids. Mr Thompson relayed the views of colleagues within the pharmaceutical industry and highlighted the focus of indicators in England. The Chairman concluded the discussion by endorsing the paper and confirming AWMSG's support of the national indicators proposed.

**10. Patient information at the point of discharge / Medicine Reminder Charts**

The Chairman welcomed Mrs Jane Barnard, the patient representative on AWPAG. He invited Dr Lewis, Chair of AWPAG to highlight the salient issues of Enc **6**/AWMSG/1211. It was noted that the paper relates to recommendations 14 and 34 of AWMSG's Medicines Strategy for Wales in supporting the electronic communication of patient medicines information on admission and discharge from hospital, highlighting risk to health outcomes of poor concordance, developing ways to improve concordance and engaging patients in better utilisation of medicines. Dr Lewis provided the background and explained that AWPAG had considered the provision of medicines reminder charts after Mrs Barnard had shared experiences of patients when discharged from hospital. A medicines chart template was provided and members were asked to support the proposal that MTCs, or other multi-professional groups within health boards, review or implement processes to promote the provision of patient-held medicines reminder charts and a contact telephone number for the hospital pharmacy helpline. Also AWMSG was asked to support the proposal that Welsh Government give consideration to the availability of the appropriate information technology software so that patient-held reminder charts may be printed at discharge from hospital and within the community. Dr Lewis made a note of suggested modification to the documentation. Professor Walker confirmed Welsh Government's commitment to electronic discharge. There was general support for the initiative and recognition of the potential role Community Pharmacy might play in delivering the service. The Chairman closed the discussion by confirming

AWMSG's endorsement of the proposals.

**11. Hypnotics and Anxiolytics Education Pack – Feedback**

The Chairman invited Mrs Kath Haines, Head of WAPSU, to provide feedback in relation to the on-line survey undertaken to assess the impact of the hypnotics and anxiolytics educational pack which was launched in April 2011. The educational pack and prescribing toolkit had been produced by WMP to support and promote the appropriate use of hypnotics and anxiolytics in NHS Wales. It was noted that the information pack is available on AWMSG website. The key messages from the survey included:

- Communication to health boards and lead primary care pharmacists is reasonably successful, although not all primary care pharmacists were aware of the document.
- The educational pack is not being extensively used, but this may be because it is not considered a priority by health boards at present.
- Communication with GPs: Is the message getting out to GP practices?
- This area of review is not a priority for many of the health boards in the current financial climate. The work is considered time intensive for little financial gain.
- Health boards require more information regarding associated cost / health implications of long term treatment with hypnotics and anxiolytics, which may be a useful tool to use with managers, GPs, and patients.
- Engage with hospital chief pharmacists to encourage review of hospital policies for anxiolytic and hypnotic prescribing both in the acute sector and psychiatry.
- Consider ways to communicate messages directly with the public.
- Develop an audit tool for GPs wanting to look at this area, with recommendations for management of different patient groups to be included in the pack.
- Consider undertaking educational sessions for groups of GPs / health board pharmacists to share key messages and recommendations for review.

The Chairman invited members to comment and provide direction to ensure the education pack has the maximum impact. There was an acknowledgement that reducing prescribing of hypnotics and anxiolytics would improve safety and save on cost, and a suggestion was made that it might be useful to identify where the medicine is initiated within the toolkit. The Chairman confirmed AWMSG's support to promote the messages and raise awareness in relation to the positive impact on prescribing.

**12. The Chairman announced the date of the next AWMSG meeting on Wednesday, 8th February 2012 (venue to be confirmed)**