

Enclosure No:	1/AWMSG/0312
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, 8th FEBRUARY 2012 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY

MEMBERS PRESENT:

**Did not
participate in**

- | | | |
|---------------------------|--|--------------|
| 1. Prof Philip Routledge | Chairman | |
| 2. Prof David Cohen | Health Economist | |
| 3. Mrs Debbie Davies | Representing other professions eligible to prescribe | |
| 4. Mr Stefan Fec | Community Pharmacist | |
| 5. Dr Karen Fitzgerald | Consultant in Pharmaceutical Public Health | |
| 6. Ms Jane Griffin | ABPI (Wales) representative | 6 |
| 7. Dr Brian Hawkins | Senior Primary Care Pharmacist | 1-9 |
| 8. Mr Robert Holcombe | Finance Director (deputy) | 11-12 |
| 9. Dr Stuart Linton | Hospital Consultant (deputy) | |
| 10. Dr Emma Mason | Clinical Pharmacologist | |
| 11. Mr Christopher Palmer | Lay member | |
| 12. Dr John Watkins | Consultant in Public Health Medicine | |
| 13. Dr William Whitehead | GP with prescribing lead role | |
| 14. Mr Roger Williams | Senior Hospital Pharmacist | 6 |

IN ATTENDANCE:

15. Professor Roger Walker, Welsh Government
16. Mrs Karen Samuels, Welsh Medicines Partnership
17. Mrs Ruth Lang, Welsh Medicines Partnership
18. Dr Robert Bracchi, NMG Chairman

WELSH MEDICINES PARTNERSHIP APPRAISAL LEADS:

19. Mrs Sabrina Rind
20. Dr Claire Davis
21. Mrs Susan Cervetto
22. Mrs Gail Woodland

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
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

Dr Bruce Ferguson, Medical Director
Dr Brendan Lloyd, Deputy Medical Director representative
Dr Philip Banfield, Hospital Consultant
Dr Fraser Campbell, GP with prescribing lead role
Ms Ellen Lanham, Community Pharmacist
Ms Rebecca Richards, Finance Director

It was reported that Dr Brian Hawkins would be arriving late

Not in attendance

Dr Geoffrey Carroll, Welsh Health Specialised Services Committee
Mrs Wendy Warren, Senior Nurse

3. Declarations of interest

The Chairman asked members to declare any interests pertinent to the agenda. Dr Stuart Linton declared a personal non-specific interest in Roche Pharmaceuticals. The Chairman confirmed that Dr Linton would not participate in the appraisal of trastuzumab (Herceptin[®]▼). Ms Jane Griffin reported a personal specific interest in relation to Boehringer-Ingelheim and the Chairman confirmed that she would not participate in the appraisal of linagliptin (Trajenta[®]▼).

4. Chairman's report

The Chairman confirmed that on 15th December 2011, WMP had received confirmation that the Minister for Health and Social Services accepted the proposal to establish a Patient Access Scheme Wales Group (PASWG). The Minister had also approved the appointment of Professor Marcus Longley as Chairman of PASWG. The aim was clarified - to enable NHS

Wales to benefit from schemes designed to improve cost effectiveness and facilitate patient access in Wales to new medicines. The Chairman clarified that two of the six appraisals scheduled - abiraterone (Zytiga[®]▼) and icatibant acetate (Firazyr[®]▼) - formed part of the Patient Access Scheme Wales pilot and proceedings would be conducted in private.

The Chairman announced the resignation from AWMSG of Mr Guy Thompson, ABPI (Wales) member and Dr Hugo VanWoerden, deputy representative from Welsh Health Specialised Services Committee. The Chairman thanked Mr Thompson and Dr Van Woerden for their valuable contribution to the Group.

It was announced, to mark 10 years of AWMSG and the launch of the All Wales Therapeutics and Toxicology Centre a conference would be held at the Wales Millennium Stadium on Thursday 24th May 2012.

The Chairman reported, with the broadening of AWMSG's remit to appraise all new medicines not on the NICE work programme, and the establishment of WAPSU, that there will be a focus on implementation. He confirmed an approach had been made to the Chairman of the National Medicines Management Programme Board (NMMPB) with a proposal to establish an implementation group reporting to AWMSG which would encompass the role of NMMPB. Members were informed that NMMPB had been established in 2010 as part of 12 National Programmes that supported the implementation of new Health Boards in Wales, with a remit of responding to financial pressures. The proposal put forward was that AWMSG would identify individuals within its professional network to lead in the development of implementation and support the work of a new sub-group of AWMSG, the All Wales Medicines Implementation Group (AWMIG). The group would be supported professionally and administratively by resources from within the All Wales Therapeutics and Toxicology Centre (AWTTC). It was proposed that the NMMPB Chairman would be a full voting member of AWMSG and the AWMSG Steering Committee.

The Chairman reported on Thursday, 2nd February 2012 he attended the Health and Social Care Committee's seminar on Access to Medicines in Wales to outline the work of AWMSG.

It was reported that on 12th January 2012 the service had been informed that Welsh Government ratification had been received in relation to the following recommendations:

Tapentadol prolonged release (Palexia[®] SR▼) is recommended as an option for restricted use within NHS Wales, only in the following subpopulation within its licensed indication: Patients with severe chronic pain, in whom morphine sulphate modified release has failed to provide adequate pain control or is not tolerated. **Tapentadol prolonged release (Palexia[®] SR▼) is not recommended** for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics, outside of the subpopulation described above. AWMSG is of the opinion that **tapentadol prolonged release (Palexia[®] SR▼)** should be initially prescribed by a specialist*. Prescribing may be continued in primary care with appropriate communication and specialist input. (*Specialist implies specialist team or GP with special interest (GPwSI) with appropriate accreditation from the specialist faculty).

Collagenase *Clostridium histolyticum* (Xiapex[®]▼) is recommended as an option for restricted use within NHS Wales for the treatment of Dupuytren's contracture in adult patients with a palpable cord. **Collagenase *Clostridium histolyticum* (Xiapex[®]▼)** should be restricted for use as an alternative to fasciectomy in a subset of adult patients with a total of two or less affected joints per hand where percutaneous needle fasciotomy is not appropriate, using up to three injections per cord, with no more than six injections per patient. AWMSG is of the opinion that **collagenase *Clostridium histolyticum* (Xiapex[®]▼)** is not suitable for shared care within NHS Wales for the above indication.

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.

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.

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.

On 19th January 2012 the service had been informed that Welsh Government ratification had been received in relation to the following recommendations:

Dasatinib (Sprycel®▼) for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia in the chronic phase is not recommended for use within NHS Wales. The case for cost effectiveness has not been proven.

Rosuvastatin (Crestor®) is not recommended for use within NHS Wales for the prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors. The clinical and cost effectiveness evidence provided was not sufficient for AWMSG to recommend its use.

Paliperidone palmitate (Xeplion®▼) prolonged release suspension for injection is not 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. The case for cost effectiveness has not been proven.

The Chairman informed members that there may be occasions when the holder of the marketing authorisation may not be in a position to progress a submission to AWMSG for appraisal. It was confirmed, in the absence of AWMSG advice or final NICE guidance, a Statement of Advice would be issued to inform NHS Wales of medicines which cannot be endorsed for use within NHS Wales. It was reported that AWMSG advice, ratified by Welsh Government, had been issued in relation to the following medicines and the Chairman reiterated that the medicines should not be prescribed routinely within NHS Wales.

Ciprofloxacin (Cetraxal®) cannot be endorsed for use within NHS Wales for the treatment of acute otitis externa due to susceptible isolates of Pseudomonas aeruginosa or Staphylococcus aureus.

Nomegestrol acetate/estradiol (Zoely®) cannot be endorsed for use for use within NHS Wales for oral contraception.

Epoetin zeta (Retacrit®▼) cannot be endorsed for use for use within NHS Wales for the reduction of exposure to allogeneic blood transfusions in adult non-iron deficient patients prior to major elective orthopaedic surgery, having a high perceived risk for transfusion complications.

Human normal immunoglobulin (Kiovig®) cannot be endorsed for use within NHS Wales for immunomodulation in adults, and children and adolescents (0 -18 years) in multifocal motor neuropathy.

Telavancin (Vibativ®) cannot be endorsed for use within NHS Wales for the treatment of adults with nosocomial pneumonia 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.

It was highlighted that in these circumstances, healthcare professionals should make clinical decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer and informed by the summary of product characteristics of any drug they are considering.

A number of statements of advice are currently in preparation and the draft minutes of this meeting will detail the full licence indications. Statements relating to the following medicines will be forwarded to Welsh Government on 23rd February 2012 unless a Form B or Form C submission is received by WMP prior to that date.

Eslicarbazepine acetate (Zebinix®▼) for adjunctive therapy in adults with partial-onset seizures, with or without secondary generalisation.

Everolimus (Votubia®▼) for the treatment of patients aged 3 years and older with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery.

Human normal immunoglobulin (Aragam®) for replacement therapy in primary immunodeficiency syndromes such as: congenital agammaglobulinemia and hypogammaglobulinemia; common variable immunodeficiency; severe combined immunodeficiency and Wiskott Aldrich syndrome; myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinemia and recurrent infections; children with congenital AIDS and recurrent infections; immunomodulation; idiopathic thrombocytopenic purpura; children or adults at high risk of bleeding or prior to surgery to correct the platelet count; Guillain Barré syndrome; Kawasaki disease; allogeneic bone marrow transplantation.

Pemetrexed (Alimta®) monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following induction therapy with pemetrexed in combination with cisplatin.

Dihydroartemisinin/piperaquine phosphate (Eurartesim®) for the treatment of uncomplicated *Plasmodium falciparum* malaria in adults, children and infants 6 months and over and weighing 5 kg or more.

Colecalciferol (Fultium-D3®) for the prevention and treatment of vitamin D deficiency, or as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.

Hydrocortisone MR (Plenadren®) for the treatment of adrenal insufficiency in adults.

Dexmedetomidine (Dexdor®▼) for the sedation of adult ICU patients requiring a sedation level not deeper than arousal in response to verbal stimulation.

Everolimus (Afinitor®▼) for the treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumours of pancreatic origin in adults with progressive disease.

The Chairman announced the appraisals scheduled for the next meeting to be held in Cardiff on Wednesday, 21st March 2012:

Esomeprazole (Nexium® IV) for gastric antisecretory treatment when the oral route is not possible, such as gastro-oesophageal reflux disease (GORD) in patients with erosive reflux oesophagitis and/or severe symptoms of reflux for children and adolescents aged 1-18 years of age.

Adalimumab (Humira®▼) in combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 4 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs. Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

The Chairman reminded members to declare to WMP any interests in relation to the appraisals 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. No changes were made. The Chairman signed the minutes as a true record of the proceedings.

6. Appraisal 1:

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.

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

Dr Claire Davis, WMP assessment lead, joined members.

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. Mr Roger Williams announced he had attended a training day within the last twelve months hosted by Boehringer Ingelheim Limited. The Chairman confirmed that Mr Williams would not be able to participate in the appraisal and he left the meeting. There were no additional declarations of interest. Ms Jane Griffin left the meeting.

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 welcomed delegates from the applicant company, Boehringer Ingelheim Limited/Eli Lilly and Company Limited

Dr Davis set the context of the appraisal and provided members with an overview of the submission as detailed in the [ASAR](#). It was confirmed that a patient organisation submission by Diabetes UK Cymru and an individual patient submission had been considered by NMG.

The Chairman invited Dr Robert Bracchi, NMG Chairman to relay the views of NMG. It was noted that the evidence provided by the applicant company had been restricted to a sub-population of patients within the licensed indication. Dr Bracchi confirmed NMG's preliminary recommendation was that linagliptin (Trajenta[®]▼) should not be recommended 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.

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.

Dr Bracchi informed members that NMG had not been persuaded that a cost-minimisation analysis was the appropriate economic analysis, as therapeutic equivalence and equivalent outcomes had not been adequately demonstrated. He confirmed NMG had considered that the evidence presented in the submission was insufficiently robust for NMG to recommend its use.

Professor David Cohen highlighted issues in relation to the case for cost effectiveness. Following this discussion, the Chairman invited AWMSG members to discuss the case for clinical effectiveness. The Chairman drew members' attention to the [clinical expert summary](#). The lay member, Mr Chris Palmer, relayed the views of Diabetes UK Cymru and the individual patient. No outstanding budget impact or societal issues were noted.

The applicant company delegates responded to the issues highlighted by AWMSG in their discussion. They provided the rationale in relation to the choice of comparator and, in summary, highlighted the therapeutic advantages of the technology. Prior to concluding the appraisal, the Chairman asked the delegates from Boehringer Ingelheim Limited/Eli Lilly and Company Limited to confirm all outstanding issues had been addressed. The delegates agreed that the process had been fair and transparent and thanked AWMSG for the opportunity to participate in the appraisal. The Chairman thanked Boehringer Ingelheim Limited/Eli Lilly and Company Limited for engaging in the appraisal process. Members were asked to make a note of their recommendation on their aide memoire and the Chairman moved on to the second appraisal. Ms Griffin and Mr Williams re-joined 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 not recommended 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.

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**

The evidence presented in the submission was insufficiently robust for AWMMSG to recommend its use.

7. Appraisal 2:

Entecavir (Baraclude[®]▼) for the treatment of chronic hepatitis B virus infection in adults with decompensated liver disease

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 of interest.

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

Mrs Cervetto set the context of the appraisal and highlighted relevant issues within the [ASAR](#). She confirmed that a patient organisation submission had not been received. Mrs Cervetto alluded to the summary of [clinical expert opinion](#) that had been provided to members. The Chairman invited Dr Bracchi to relay the views of NMG. Dr Bracchi confirmed NMG's view that entecavir (Baraclude[®]▼) should be recommended as an option for use within NHS Wales for the treatment of chronic hepatitis B virus infection in adults with decompensated liver disease. NMG suggested that treatment should normally be initiated following dialogue with a specialist liver unit and they were of the opinion that entecavir (Baraclude[®]▼) would be suitable for specialist only prescribing within NHS Wales for the above indication.

The Chairman opened the discussion. Professor David Cohen commented on the case for cost effectiveness and then the Chairman moved the discussion to the case for clinical effectiveness. Clarification was sought in relation to dose, patient numbers and cost variance between the tablet and oral solution. The lay member confirmed that there were no outstanding issues from a patient perspective. The Chairman invited comment in relation to budget impact and societal issues.

The applicant company delegates responded to issues identified by AWMMSG and were invited to highlight relevant aspects of their submission. In summarising, they reiterated the unmet clinical need. 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 for engaging in the appraisal process and closed the appraisal.

Appraisal decision subsequently announced

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

Entecavir (Baraclude[®]▼) is recommended as an option for use within NHS Wales for the treatment of chronic hepatitis B virus infection in adults with decompensated liver disease. Oral solution should only be used in circumstances where the tablet form is not a clinical option.

Treatment should normally be initiated following dialogue with a specialist liver unit.

AWMSG is of the opinion that entecavir (Baraclude[®]▼) is suitable for specialist only

prescribing within NHS Wales for the above indication.

8. 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

Dr Linton left the meeting and the Chairman invited members to declare interests in either the applicant company or the medicine that had not previously been declared. There were none.

Mrs Sabrina Rind, WMP Appraisal Lead, joined members.

The Chairman confirmed that Roche Products Limited had submitted a response to the PAR, however had declined the invitation to attend and participate in the discussions.

Mrs Rind set the context of the appraisal and highlighted relevant issues within the [ASAR](#). Mrs Rind clarified that a limited submission had been considered appropriate due to the anticipated minimal budgetary impact of trastuzumab (Herceptin[®]▼) for the above indication in NHS Wales. In line with the AWMSG limited submission process, a patient organisation submission was not actively sought.

The Chairman invited Dr Bracchi to relay the views of NMG. Dr Bracchi confirmed NMG's advice to AWMSG was that trastuzumab (Herceptin[®]▼) should be recommended as an option for use within NHS Wales for the treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive early breast cancer:

- following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel or;
- as part of a treatment regimen in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin.

Dr Bracchi confirmed that NMG were of the opinion that trastuzumab (Herceptin[®]▼) would be suitable for specialist only prescribing within NHS Wales for the above indication.

The Chairman invited Professor David Cohen to comment on the case for cost effectiveness. The Chairman drew members' attention to the [clinical expert summary](#). There were no outstanding clinical or societal issues of note.

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:

Trastuzumab (Herceptin[®]▼) is recommended as an option for the treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive early breast cancer. This submission covers the licence extensions for treatment with trastuzumab:

- following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel;
- in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin.

AWMSG is of the opinion that trastuzumab (Herceptin[®]▼) is suitable for specialist only prescribing within NHS Wales for the above indication.

Dr Linton re-joined the meeting. Dr Brian Hawkins arrived.

**9. 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**

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 of interest. Mrs Gail Woodland, WMP Appraisal Lead, joined members. The Chairman welcomed delegates from the applicant company, Astellas Pharma Limited.

Mrs Woodland set the context of the appraisal and highlighted relevant issues within the [ASAR](#). It was confirmed that patient organisation submissions had been sought but not received.

The Chairman invited Dr Bracchi to relay the views of NMG. Dr Bracchi highlighted that the company had provided evidence of the cost effectiveness of capsaicin patch (Qutenza[®]▼) as an add-on treatment in patients who were refractory to or intolerant of usual first or second line treatments. Dr Bracchi concluded his address by confirming NMG's view that Capsaicin patch (Qutenza[®]▼) should not be recommended as monotherapy. NMG considered that capsaicin patch (Qutenza[®]▼) should be recommended as an option for restricted use within NHS Wales for the treatment of peripheral neuropathic pain (PNP) in non-diabetic adults in combination with other medicinal products for pain and in patients who have not received adequate benefit from, or are intolerant to, alternative/conventional treatments. Dr Bracchi relayed NMG's view that capsaicin patch (Qutenza[®]▼) would be suitable for specialist only prescribing within NHS Wales for the above indication and patches should be administered by healthcare professionals who have completed the approved training and in a specialist clinic setting.

The Chairman invited Professor David Cohen to comment on the case for cost effectiveness.

The Chairman opened the discussion and invited AWMSG members to raise any outstanding issues in relation to the case for clinical effectiveness. The issue of collection of long term safety data was discussed. The Chairman drew members' attention to the [clinical expert summary](#) provided to members for consideration. The Chairman invited comment in relation to budget impact and societal issues. Members sought clarification in relation to the delivery of healthcare. No patient organisation views had been received - the lay member confirmed there were no outstanding issues from a patient perspective.

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 Astellas Pharma Limited for engaging in the appraisal process.

Appraisal decision subsequently announced

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

Capsaicin patch (Qutenza[®]▼) is not recommended for use alone for the treatment of peripheral neuropathic pain (PNP) in non-diabetic adults.

Capsaicin patch (Qutenza[®]▼) is recommended as an option for restricted use within NHS Wales for the treatment of peripheral neuropathic pain (PNP) in non-diabetic adults in combination with other medicinal products for pain and in patients who have not received adequate benefit from, or are intolerant to, alternative conventional treatments.

The company submission provided evidence on the cost effectiveness of capsaicin

patch (Qutenza®▼) as an add-on treatment in patients who were refractory to or intolerant of usual first or second line treatments.

Capsaicin patches (Qutenza®▼) should be administered by healthcare professionals who have completed the approved training and in a specialist clinic setting.

AWMSG is of the opinion that capsaicin patch (Qutenza®▼) is suitable for specialist only prescribing within NHS Wales for the above indication.

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, 15th February and that the applicant companies had until Wednesday, 22nd February 2012 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, 23rd February 2012. The Chairman confirmed that the applicant companies would be informed when ratification had been received from Welsh Government.

10. The Chairman announced the **date of the next AWMSG meeting on Wednesday, 21st March 2012 at Cardiff's Metropolitan University** and closed public proceedings. It was confirmed that the remainder of the meeting would be held in private.

Mr Robert Holcombe left the meeting.

11. **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**

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 of interest.

Mrs Susan Cervetto, WMP Appraisal Lead, joined members. The Chairman welcomed delegates from the applicant company, Shire Human Genetic Therapies.

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. The Chairman invited Dr Bracchi to relay the views of NMG. Dr Bracchi confirmed NMG's view that icatibant (Firazyr®▼) should be recommended as an option for use within NHS Wales for the symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (with C1 esterase inhibitor deficiency). It was suggested by NMG that a positive recommendation should only apply in circumstances where the approved Wales patient discount scheme is utilised. Members were informed that NMG were of the opinion that icatibant (Firazyr®▼) would be suitable for specialist only prescribing within NHS Wales for the above indication. Dr Bracchi relayed NMG's view that icatibant (Firazyr®▼) did not satisfy the AWMSG criteria for ultra orphan drug status.

The Chairman invited Prof David Cohen to comment on the case for cost effectiveness. A

number of issues were discussed including ten year horizon, confidence intervals, utility values and number of patches used. The Chairman invited AWMSG members to raise any outstanding issues in relation to the case for clinical effectiveness. There was discussion over dosing regimens, supplementary placements, delivery of care and treatment intervals. The Chairman referred members to the summary of clinical expert views. A patient organisation submission by HAE UK had been received and the Chairman invited the lay member to highlight the salient issues within the submission.

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. They highlighted the unmet clinical need and the advantages of this treatment to the patient. 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. A statement was read summarising the key issues and the delegates thanked AWMSG the opportunity to engage in the process. The Chairman closed the proceedings and thanked Shire Human Genetic Therapies 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 agreed the following recommendation would be forwarded to Welsh Government:

Icatibant (Firazyr[®]▼) is recommended as an option for use within NHS Wales for the symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (with C1 esterase inhibitor deficiency).

This recommendation applies only in circumstances where the approved Wales patient access scheme is utilised.

AWMSG is of the opinion that icatibant (Firazyr[®]▼) is suitable for specialist only prescribing within NHS Wales for the above indication.

12. 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

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 of interest.

Mrs Sabrina Rind, WMP Appraisal Lead, joined members. The Chairman welcomed delegates from the applicant company, Janssen-Cilag 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 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 Rind set the context of the appraisal and highlighted relevant issues within the ASAR. The Chairman invited Dr Bracchi to relay the views of NMG. Dr Bracchi confirmed that the AWMSG policy for appraising life-extending, end-of-life medicine had been applied by NMG. He highlighted the salient issues considered by NMG in making their preliminary recommendation

and confirmed that NMG's advice to AWMSG was that abiraterone (Zytiga[®]▼) with prednisone or prednisolone should be recommended for use within NHS Wales for the treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. It was proposed that a recommendation supporting its use would apply only in circumstances where the approved Wales Patient Scheme for access to medicines (WPS) is utilised. It was noted that NMG were of the opinion that abiraterone (Zytiga[®]▼) would be suitable for specialist only prescribing within NHS Wales for the above indication.

The Chairman invited Professor David Cohen to comment on the case for cost effectiveness. Professor Cohen talked through the salient issues and confirmed that in relation to EOL criteria there is no specific definition of what constitutes a 'small' patient population. There was discussion in relation to patient numbers and prevalence data. The Chairman drew members' attention to the summary of clinical expert views and invited AWMSG members to raise any outstanding issues in relation to the case for clinical effectiveness. A patient organisation submission by The Prostate Cancer Charity, Prostate Cancer Cardiff Support Group, The West Wales Prostate Cancer Support Group and two patient's submissions had been provided to members for consideration. The lay member provided an overview of the patient view. Budget impact and societal issues were considered by the Group.

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 Janssen-Cilag Limited 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 agreed the following recommendation would be forwarded to Welsh Government:

Abiraterone (Zytiga[®]▼) with prednisone or prednisolone is recommended for the treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.

This recommendation applies only in circumstances where the approved Wales Patient Scheme for access to medicines is utilised.

AWMSG is of the opinion that abiraterone (Zytiga[®]▼) is suitable for specialist only prescribing within NHS Wales for the above indication.

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, 15th February 2012. The timelines for accepting the recommendations or lodging a request for an independent review were confirmed. 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. The Chairman confirmed that the applicant companies would be informed when ratification had been received from Welsh Government.

The Chairman closed the meeting.