

<b>Enclosure No:</b>	<b>1/AWMSG/0712</b>
<b>Agenda Item No:</b>	<b>5 – Minutes of previous meeting</b>
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## **ALL WALES MEDICINES STRATEGY GROUP**

### **MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY 20<sup>th</sup> JUNE 2012 COMMENCING 10.30 AM AT CARDIFF METROPOLITAN UNIVERSITY, LLANDAFF CAMPUS, WESTERN AVENUE, CARDIFF CF5 2YB**

#### **VOTING MEMBERS PRESENT:**

**Did not  
participate in**

- |                          |  |          |
|--------------------------|--|----------|
| 1. Bruce Ferguson        | Medical Director & Chairman                          |          |
| 2. Dr Phil Banfield      | Hospital Consultant                                  |          |
| 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 Emma Mason         | Clinical Pharmacologist                              |          |
| 8. Mrs Susan Murphy      | Senior Primary Care Pharmacist                       |          |
| 9. Mr Christopher Palmer | Lay member   |          |
| 10. Mr Christian Smith   | Senior Nurse   | <b>8</b> |
| 11. Mr Robert Thomas     | ABPI Wales   |          |
| 12. Dr John Watkins      | Consultant in Public Health Medicine                 |          |
| 13. Dr Bill Whitehead    | GP with prescribing lead role                        |          |
| 14. Dr Phil Webb         | Welsh Health Specialised Services Committee          |          |
| 15. Mr Roger Williams    | Senior Hospital Pharmacist                           |          |

#### **IN ATTENDANCE:**

16. Mrs Karen Samuels, All Wales Therapeutics & Toxicology Centre
17. Mrs Ruth Lang / Miss Samantha Webster  
All Wales Therapeutics & Toxicology Centre

#### **AWTTC APPRAISAL LEADS:**

18. Mrs Sabrina Rind, Senior Appraisal Pharmacist
19. Mr Anthony Williams, Senior Appraisal Pharmacist
20. Mrs Susan Cervetto, Senior Appraisal Pharmacist
21. Dr Claire Davies, 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
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 and confirmed that Mr Robert Thomas had been appointed ABPI Wales representative and was attending his first AWMSG meeting. The Chairman confirmed Mr Phil Webb had been appointed as deputy to Dr Geoffrey Carroll, representing Welsh Health Specialised Services Committee.

**2. Apologies**

Professor Philip Routledge  
Dr Geoffrey Carroll  
Mrs Rebecca Richards  
Mr Robert Holcombe  
Dr Fraser Campbell  
Professor Roger Walker

**3. Declarations of interest**

The Chairman reminded members to declare any interests pertinent to the agenda.

**4. Chairman's report**

The Chairman reported on 24<sup>th</sup> May the AWMSG Conference had been held in the Millennium Stadium. He thanked the Minister for Health & Social Services for her attendance and support of the work of AWMSG. The Chairman also thanked the speakers, delegates and all who worked hard to make sure the event was a successful and enjoyable occasion.

It was confirmed, on 18<sup>th</sup> May the service had been informed that the Welsh Government had ratified the following AWMSG recommendation:

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.

Members were informed that Welsh Government had ratified AWMSG's recommendations from the previous AWMSG meeting on 9<sup>th</sup> May in relation to midazolam (BUCCOLAM®), fluorouracil/salicylic acid (Actikerall®) and atorvastatin (Lipitor®) chewable tablets. It was noted that AWTTC were in the process of uploading the final appraisal reports to the AWMSG website, informing the relevant companies and disseminating the following recommendations to the Service.

Midazolam (BUCCOLAM®) is recommended as an option for use within NHS Wales for the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to < 18 years). For infants between 3–6 months of age treatment should be in a hospital setting where monitoring is possible and resuscitation equipment is available. Midazolam (BUCCOLAM®) should be prescribed by brand name to reduce the risk of medication errors.

Fluorouracil/salicylic acid (Actikerall®) is recommended as an option for use within NHS Wales for the topical treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (grade I/II) in immunocompetent adult patients.

Atorvastatin (Lipitor®) chewable tablets are recommended as an option for use within NHS Wales:

- as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (corresponding to types IIa and IIb of the Fredrickson classification) when response to diet and other non-pharmacological measures is inadequate.
- to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable.
- for the prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

The Chairman confirmed, in the absence of a submission from the holder of the marketing authorisation, the following Statements of Advice had been ratified by Welsh Government and therefore should not be prescribed routinely within NHS Wales for the indications stated.

Mitotane (Lysodren®) for the symptomatic treatment of advanced (unresectable, metastatic or relapsed) adrenal cortical carcinoma. The effect of Lysodren on non-functional adrenal cortical carcinoma is not established.

Aminolevulinic acid (Ameluz®) for the treatment of actinic keratosis of mild to moderate intensity on the face and scalp (Olsen grade 1 to 2).

Interferon beta-1a (Rebif®) for the treatment of patients with a single demyelinating event with an active inflammatory process, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis.

Vandetanib (Caprelsa®) for the treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. For patients in whom rearranged during transfection (RET) mutation is not known or is negative, a possible lower benefit should be taken into account before individual treatment decision.

The Chairman confirmed a number of statements of advice were in preparation and statements relating to the following medicines would be forwarded to Welsh Government should a Form B or Form C submission not be received by WMP within the next fourteen days.

Miglustat (Zavesca®) for the oral treatment of adult patients with mild to moderate type 1 Gaucher disease. Miglustat may be used only in the treatment of patients for whom enzyme replacement therapy is unsuitable

Insulin detemir (Levemir®) for the treatment of diabetes mellitus in children aged 2-5 years

Vildagliptin (Galvus®) for the treatment of type 2 diabetes as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance

Ulipristal acetate (Esmya®) for the pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment is limited to 3 months

Exenatide (Byetta®) as adjunctive therapy to basal insulin with or without metformin and/or pioglitazone in adults who have not achieved adequate glycaemic control with these agents

Infliximab (Remicade®) for the treatment of severely active ulcerative colitis, in children and adolescents aged 6 to 17 years, who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies

The Chairman confirmed the appraisals scheduled for the next meeting to be held in Cardiff on Wednesday, 18<sup>th</sup> July 2012:

#### Appraisal 1: Full Submission

Darunavir (Prezista®) 800 mg once daily, co-administered with low dose ritonavir for the treatment of HIV-1 infection in antiretroviral therapy experienced adults with no darunavir resistance associated mutations and who have plasma HIV RNA <100,000 copies/mL and CD4+ cell count ≥100 cells x 10<sup>6</sup>/l

Applicant Company: Janssen-Cilag Ltd

#### Appraisal 2: Full submission

Dexmedetomidine (Dexdor®) for sedation of adult ICU (intensive care unit) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale (RASS) 0 to -3)

Applicant Company: Orion Pharma (UK) Ltd

#### Appraisal 3: Full Submission

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

Applicant Company: Novartis Pharmaceuticals UK Ltd

Appraisal 4: Limited Submission

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

Applicant Company: Sigma-Tau Pharma Ltd

Appraisal 5: Limited Submission

Emtricitabine/rilpivirine/tenofovir (Eviplera®) for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load  $\leq$  100,000 HIV-1 RNA copies/ml

Applicant Company: Gilead Sciences Ltd

Appraisal 6: Limited Submission

Saxagliptin (Onglyza®) for the treatment of adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with insulin (with or without metformin) when this regimen alone with diet and exercise does not provide adequate glycaemic control

Applicant Company: Bristol-Myers Squibb Pharmaceuticals/AstraZeneca UK

The Chairman reminded members to declare to AWTTTC any interests in relation to the appraisals scheduled. The Chairman invited patients, patient organisations and patient carers to submit their views and contact 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. No changes were made. The Chairman signed the minutes as a true record of the proceedings.

**6. Appraisal 1: Full Submission**

**Belatacept (Nulojix®▼) for prophylaxis of graft rejection in adults receiving a renal transplant, in combination with corticosteroids and a mycophenolic acid**

Mrs Susan Cervetto, AWTTTC assessment lead, joined members.

The Chairman welcomed delegates from the applicant company, Bristol-Myers Squibb Pharmaceuticals.

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 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 Mrs Cervetto to set the context of the appraisal. Mrs Cervetto 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 the National Kidney Federation. Mrs Cervetto relayed the view of NMG that belatacept (Nulojix®▼) should not be recommended as an option for use within NHS Wales, in combination with corticosteroids and a mycophenolic acid, for prophylaxis of graft rejection in adults receiving a renal transplant. NMG considered the case for cost effectiveness had not been proven as there were several uncertainties and limitations in the economic model provided in

the company's submission.

Prior to opening the discussion, the Chairman sought clarification from Dr Watkins that he had no declarations of interest in relation to the appraisal, as he had arrived at the meeting shortly after the commencement of Mrs Cervetto's address.

Members sought clarification in relation to the choice of comparator and rejection rates. It was confirmed there are no on-going monitoring requirements other than routine clinical monitoring. Mrs Samuels highlighted the AWTTC definition of comparator is what is considered current practice meaning the medicine that would potentially be displaced, and although not ideal this could on agreement with AWTTC include an unlicensed medicine.

The Chairman invited comment in relation to the case for cost-effectiveness. Professor Cohen highlighted the limitations in the company submission and acknowledged the positive aspects. There were no outstanding budget impact issues. The contracting issue in relation to home care provision had not been taken account of within the submission.

The patient representative drew member's attention to the salient issues within the patient organisation submission provided by the National Kidney Federation.

The Chairman drew members' attention to the company response to the preliminary recommendation and invited the company delegates to respond to the issues highlighted by AWMSG in their discussion

Prior to concluding the appraisal, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Bristol-Myers Squibb Pharmaceuticals 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:

**Belatacept (Nulojix<sup>®</sup>) is not recommended as an option for use within NHS Wales, in combination with corticosteroids and a mycophenolic acid, for prophylaxis of graft rejection in adults receiving a renal transplant. The case for cost effectiveness has not been proven.**

#### **7. Appraisal 2: Limited submission Nevirapine (Viramune<sup>®</sup>) 400 mg prolonged release tablets in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infected adults**

Dr Claire Davis, AWTTC assessment lead, joined members.

The Chairman welcomed delegates from the applicant company, Boehringer Ingelheim Limited.

The Chairman reminded members to declare any interests. There were none.

The Chairman referred to his previous statement 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 set the context of the appraisal and outlined the sequence of events. He confirmed that the application had been considered eligible for a limited submission. In line with this process, evidence of budgetary impact in comparison to the existing comparator product(s) should be demonstrated. He directed members to consider the evidence and highlight any societal issues, take account of NMG's preliminary recommendation and the company response. He confirmed that clinical expert and patient views would be included, where available. He explained, in the event that AWMSG wished to explore any issues within the submission, then the applicant company delegates would be invited to provide clarification. However, if AWMSG considered there were no outstanding issues, they would retire to vote in private and agree the final recommendation, which would be subsequently announced and forwarded to Welsh Government for ratification. The Chairman reiterated that monitoring of budget impact would be essential and AWMSG reserved the right to request a full submission should the budget impact exceed that estimated in the limited submission.

Dr Davies confirmed the licensed indication - nevirapine (Viramune®) prolonged release tablets in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus type 1 (HIV-1) infected adults, adolescents, and children three years and above and able to swallow tablets.

Prolonged-release tablets are not suitable for the 14-day lead-in phase for patients starting nevirapine. Other nevirapine formulations, such as immediate-release tablets or oral suspension should be used.

Most of the experience with Viramune® is in combination with nucleoside reverse transcriptase inhibitors (NRTIs). The choice of a subsequent therapy after Viramune® should be based on clinical experience and resistance testing.

Dr Davies informed members that AWTTC had requested two separate submissions from the company - one relating to adults and a separate submission relating to adolescents and children – to ensure separation of data so that NMG and AWMSG could consider the two sub-populations separately. It was noted that AWTTC had produced two separate ASARs and that NMG had produced a single preliminary appraisal recommendation to cover the entire licensed indication for adults, adolescents and children.

Dr Davies set the context of the appraisal and highlighted relevant issues within the [ASAR](#). She confirmed that the submission had met the criteria for a limited submission in that it was for a new formulation with a pro-rata or lower cost per treatment. Dr Davies relayed the views of the [clinical experts](#) and confirmed that no patient submission had been received. Dr Davies confirmed that NMG had supported the use of this medicine for the adult population.

The Chairman invited members to raise any outstanding issues in relation to the limited submission. There were none. There were no societal or budget impact issues of note.

8.

### **Appraisal 3: Limited submission**

**Nevirapine (Viramune®) 50 mg, 100 mg, 400 mg prolonged release tablets in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infected adolescents and children three years and above and able to swallow tablets**

Dr Davies set the context of the appraisal and highlighted relevant issues within the [ASAR](#). She confirmed that the submission had met the criteria for a limited submission in that it was for a new formulation with a pro-rata or lower cost per treatment. Dr Davies relayed the views of the [clinical expert summary](#) and confirmed that no patient submission had been received. Dr Davies confirmed that NMG had supported the use of this medicine for the adult population.

The Chairman invited members to raise any outstanding issues in relation to the limited submission. There were none. There were no societal or budget impact issues of note.

The company delegates clarified that use would be independent of viral load and there were no issues in relation to bioavailability differences in patient sub-populations.

Prior to concluding the appraisal, the Chairman asked the company 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 Boehringer Ingelheim Ltd 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, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

**Nevirapine (Viramune®) prolonged release tablets are recommended as an option for use within NHS Wales in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus type 1 (HIV-1) infected adults, adolescents, and children three years and above and able to swallow tablets.**

**Prolonged release tablets are not suitable for the 14-day lead-in phase for patients starting nevirapine. Other nevirapine formulations, such as immediate release tablets or oral suspension should be used.**

**Most of the experience with Viramune® is in combination with nucleoside reverse transcriptase inhibitors (NRTIs). The choice of a subsequent therapy after Viramune® should be based on clinical experience and resistance testing.**

#### **9. Appraisal 4: Full Submission**

**Rilpivirine (Edurant®) in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment naive adult patients with a viral load  $\leq$  100,000 HIV-1 RNA copies/ml**

Mr Anthony Williams, AW TTC assessment lead, joined members.

The Chairman welcomed delegates from the applicant company, Janssen-Cilag Ltd.

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 referred to his previous statement, 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 Mr Williams to set the context of the appraisal. Mr Williams 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 the Terrence Higgins Trust. Mr Williams relayed the view of NMG that rilpivirine (Edurant®) should be recommended as an option for use within NHS Wales for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load  $\leq$  100,000 HIV-1 RNA copies/ml, in combination with other antiretroviral medicinal products. It was noted NMG were of the opinion that rilpivirine (Edurant®) would be appropriate for specialist only prescribing within NHS Wales for the above indication.



The Chairman invited comments in relation to clinical effectiveness and, subsequently, cost effectiveness. There were no specific issues of note and limited comment in relation to the submission. Mr Palmer highlighted the advantages of the medicine as set out in the submission from the Terrence Higgins Trust. It was noted that Janssen-Cilag had no comment in relation to NMG's preliminary recommendation to support its use, and no issues were highlighted from the company perspective at the meeting.

Prior to concluding the appraisal, the Chairman asked the company 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 Ltd 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, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

**Rilpivirine (Edurant<sup>®</sup>▼) is recommended as an option for use within NHS Wales for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load  $\leq 100,000$  HIV-1 RNA copies/ml, in combination with other antiretroviral medicinal products**

#### **10. Appraisal 5: Limited Submission**

**Rifaximin (Xifaxanta<sup>®</sup>▼) for the treatment of travellers diarrhoea that is not associated with any of: fever, bloody diarrhoea, eight or more unformed stools in the previous 24 hours, occult blood or leucocytes in the stool. Rifaximin (Xifaxanta<sup>®</sup>) may shorten the duration of diarrhoea when this is associated with non-invasive strains of E.coli**

Mrs Sabrina Rind, AWTTTC assessment lead, joined members.

The Chairman welcomed one delegate from the applicant company, Norgine Pharmaceuticals Ltd.

The Chairman reminded members to declare any interests. There were none.

The Chairman referred to his previous statement 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 set the context of the appraisal and outlined the sequence of events. He confirmed that the application had been considered eligible for a limited submission. In line with this process, evidence of budgetary impact in comparison to the existing comparator product(s) should be demonstrated. He directed members to consider the evidence and highlight any societal issues, take account of NMG's preliminary recommendation and the company response. He confirmed that clinical expert and patient views would be included, where available. He explained, in the event that AWMSG wished to explore any issues within the submission, then the applicant company delegates would be invited to provide clarification. However, if AWMSG considered there were no outstanding issues, they would retire to vote in private and agree the final recommendation, which would be subsequently announced and forwarded to Welsh Government for ratification. The Chairman reiterated that monitoring of budget impact would be essential and AWMSG reserved the right to request a full submission

should the budget impact exceed that estimated in the limited submission.

The Chairman invited Mrs Rind 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 relayed the view of NMG that rifaximin (Xifaxanta<sup>®</sup>) should be recommended as an option for use within NHS Wales for the treatment of travellers' diarrhoea that is not associated with any of: fever, bloody diarrhoea, eight or more unformed stools in the previous 24 hours, occult blood or leucocytes in the stool. Rifaximin (Xifaxanta<sup>®</sup>) may shorten the duration of diarrhoea when this is associated with non-invasive strains of E.coli. It was noted that NMG were of the opinion that rifaximin (Xifaxanta<sup>®</sup>) may be appropriate for prescribing by all prescribers within NHS Wales for the above indication. It was confirmed that the submission had met the AWMSG criteria for a limited appraisal as the anticipated usage in NHS Wales was considered to be of low budgetary impact as use would be minimal.

The Chairman invited comment. Members noted the studies showed comparable efficacy with ciprofloxacin in diarrhoea due to non-invasive pathogens. It was highlighted that use would be minimal. A suggestion was made that this medicine might offer a useful alternative to current treatment options. It was noted that no patient organisation submission had been received. There were no outstanding issues of note.

Prior to concluding the appraisal, the Chairman asked the company delegate to confirm that all the outstanding issues had been addressed and they agreed that the process had been fair and transparent. The Chairman thanked Norgine Pharmaceuticals Ltd 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, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

**Rifaximin (Xifaxanta<sup>®</sup>) is recommended as an option for use within NHS Wales for the treatment of travellers' diarrhoea that is not associated with any of: fever, bloody diarrhoea, eight or more unformed stools in the previous 24 hours, occult blood or leucocytes in the stool or to shorten the duration of diarrhoea when this is associated with non-invasive strains of E.coli**

The Chairman confirmed that the final appraisal recommendations would be forwarded to the relevant companies on or before Wednesday, 27<sup>th</sup> June 2012. He confirmed that the applicant companies had until Wednesday, 4<sup>th</sup> July to accept the recommendation or lodge a request for an independent review, the grounds for which should be submitted in writing to the Chairman via the All Wales Therapeutics & Toxicology Centre. He explained the process would not be delayed if the companies failed to respond by the deadline. Subject to receiving a request for an independent review within the appropriate timelines, the recommendation would be passed to Welsh Government. The Chairman informed the company delegates they would be informed when ratification of AWMSG's recommendation had been received.

The Chairman thanked the applicant companies for engaging with the AWMSG process and confirmed that the appraisal proceedings had been concluded.

#### **11. AWPAG Update (draft minutes - April 2012)**

The Chairman invited Dr Tessa Lewis, AWPAG Chair, to present the draft minutes of the AWPAG meeting held in April 2012. Members were informed that Mrs Louise Howard-Baker had been appointed Vice Chair. It was confirmed that the analgesics patient information leaflet had been uploaded to the AWMSG website and would be disseminated via email to appropriate individuals within NHS Wales. Dr Lewis highlighted work in progress in relation to the steroid replacement therapy card, repeat prescribing audit, warfarin monitoring and MDS standards

which were being presented to AWMSG later in the meeting. Members were informed that the local comparators had been finalised and disseminated. It was noted that guidance in relation to contraceptives would be presented to AWMSG at the next meeting. A suggestion was made that AWMSG should recommend the reinstatement of the Drugs & Therapeutics Bulletin and promote the e-library. Members supported this suggestion. There was interest in developing an antibiotic national audit for 2013.

## **12. CEPP Repeat Prescribing Audit**

The Chairman welcomed Dr Susanna Jacks, AWPAG GP member, and invited her to present the AWPAG audit which had been developed in conjunction with Jackie Reynolds. Dr Jacks confirmed the aim, to improve the quality of repeat prescribing policies and systems by giving general practitioners the opportunity to reflect on their repeat prescribing procedures and compare how current repeat prescribing reflects the practice policy and repeat prescribing best practice standards. It was noted that the audit pertained to Recommendation 38 of the All Wales Medicines Strategy Group (AWMSG) Medicines Strategy for Wales.

The Chairman asked for clarification in relation to collation of information, reporting and presentation of the results following completion of the audit. It was confirmed that a survey of uptake would be undertaken. Dr Lewis agreed to take the suggestion back to AWPAG regarding the national collation of audit results, development of operational standards, model repeat prescribing policy and a training toolkit. There was discussion in relation to implementation and training requirements.

The Chairman closed the discussion by confirming AWMSG's endorsement of the audit as part of the AWMSG Clinical Effectiveness Prescribing Programme. It was confirmed the audit would be uploaded to the AWMSG website and disseminated to the Service.

## **13. Warfarin Monitoring**

The Chairman invited Dr Lewis to present Enc 9/AWMSG/061, a paper outlining best practice in relation to the monitoring of warfarin therapy. Dr Lewis confirmed the aim - to reduce harm to patients and reduce variations in service provision and to promote the safe and effective monitoring of warfarin therapy in Wales. It was noted the paper pertained to recommendations 18 and 34 of the AWMSG Medicines Strategy for Wales, and the work had been led by Dr Lewis and Dr Sarah Lewis. The issues had been considered at an All Wales multi-professional warfarin meeting and progressed via AWPAG. The Chairman opened the discussion and clarification was sought in relation to implementation. Dr TL Lewis indicated Welsh Government interest in reviewing service specifications in light of the recommendations within the document. There was discussion in relation to Table 2 and the inclusion of 'pregnancy' - Dr TL Lewis clarified the emphasis of the table was intended to be duration of treatment and agreed to amend the wording of the table. The Chairman confirmed AWMSG's support of the work and highlighted the need to raise awareness and influence practice within health boards. The paper was endorsed subject to the update to Table 2. It was confirmed that the paper would be uploaded to the AWMSG website and disseminated via email to NHS Wales.

## **14. Monitored Dosage System (MDS) Standards**

Dr T Lewis and Dr Jacks introduced Enc 10/AWMSG/0612 and provided the background. In March 2011 AWMSG had endorsed minimum standards for patients admitted to hospital on an MDS and who continue to require one at discharge. It was suggested that these be interim measures for those hospitals which were unable to provide discharge medication directly, and offered a simpler model with fewer hand-offs compared with other models (hand-offs are defined as places in the patient care process where the patient, or the patient's information, is passed from one member to another; hand-offs are not only inefficient, they are also a source of clinical error and should be eliminated wherever possible). Subsequent to the implementation of the minimum standards, it had been considered that the process could be simplified further, though it was noted that establishing a satisfactory process may require considerable resources. AWPAG undertook two small surveys - the findings had been

summarised and key themes developed into standards of good practice which AWMSG was asked to endorse.

The Chairman opened the discussion. Members agreed there was a need for clarification of how the issue of MDS is managed at the interface, particularly when there are changes in medication. It was noted that the Royal Pharmaceutical Society guidelines were expected to be issued imminently. Dr Jacks emphasised that the standards presented aim to address the problems associated with the use of MDS. It was suggested that implementation of these standards by Social Services would be imperative. The Chairman asked members to consider how the document should be promoted to ensure effective use. There was discussion in relation to implementation. It was proposed that a toolkit or training pack could be developed to support implementation. A suggestion was made to route the paper through 1,000 Lives. It was also suggested that MTCs in Wales be asked to report on action taken within six months. Members agreed that the document would benefit from the addition of a discharge planning statement and, subject to this amendment, the document was endorsed.

**15. Date of next meeting**

The Chairman confirmed the date of the next meeting - Wednesday, 18<sup>th</sup> July 2012 in Cardiff and the meeting closed.