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| <b>Enclosure No:</b>   | <b>1/AWMSG/0711</b>                           |
| <b>Agenda Item No:</b> | <b>5 – Minutes of previous meeting</b>        |
| <b>Author:</b>         | Chairman, AWMSG                               |
| <b>Contact:</b>        | Tel: 029 20716900<br>E-Mail: wmp@wales.nhs.uk |

## **ALL WALES MEDICINES STRATEGY GROUP**

### **MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY, 15<sup>th</sup> JUNE 2011 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY**

#### **MEMBERS PRESENT:**

**Did not  
participate in**

1. Prof Philip Routledge Chairman
2. Dr Philip Banfield Hospital Consultant
3. Prof David Cohen Health Economist
4. Mrs Debbie Davies Representing other professions eligible to prescribe
5. Mr Stefan Fec Community Pharmacist
6. Dr Bruce Ferguson Medical Director
7. Dr Karen Fitzgerald Consultant in Pharmaceutical Public Health
8. Dr Emma Mason Clinical Pharmacologist
9. Dr Brian Hawkins Senior Primary Care Pharmacist
10. Mr Christopher Palmer Lay member
11. Mr Guy Thompson ABPI (Wales) representative
12. Dr Hugo van Woerden Welsh Health Specialised Services Committee
13. Dr John Watkins Consultant in Public Health Medicine
14. Dr William Whitehead` General Practitioner
15. Mr Roger Williams Senior Hospital Pharmacist

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#### **IN ATTENDANCE:**

16. Dr Robert Bracchi Chairman, New Medicines Group
17. Prof Ceri Phillips NMG/AWMSG Link Health Economist
18. Prof Roger Walker Welsh Assembly Government
19. Mrs Karen Samuels Welsh Medicines Partnership
20. Ms Kath Haines Welsh Medicines Partnership
21. Mrs Sabrina Rind Welsh Medicines Partnership
22. Dr Claire Davies Welsh Medicines Partnership

## List of Abbreviations:

|                       |   |
|-----------------------|---|
| ABPI                  | Association of the British Pharmaceutical Industry    |
| ASAR                  | AWMSG Secretariat Assessment Report                   |
| AWMSG                 | All Wales Medicines Strategy Group                    |
| AWPAG                 | All Wales Prescribing Advisory Group                  |
| DH                    | Department of Health                                  |
| EMA                   | European Medicines Agency                             |
| FAR                   | Final Appraisal Recommendation                        |
| GP                    | General Practitioner                                  |
| HAC                   | High Acquisition Cost                                 |
| HB                    | Health Boards   |
| M&TCs                 | Medicines & Therapeutics Committees                   |
| NICE                  | National Institute for Health and Clinical Excellence |
| NMG                   | New Medicines Group                                   |
| PAR                   | Preliminary Appraisal Recommendation                  |
| SMC                   | Scottish Medicines Consortium                         |
| TDA Partnership Group | Therapeutic Development Appraisal Partnership Group   |
| T&FG                  | Task and Finish Group                                 |
| WG                    | Welsh Government                                      |
| WAPSU                 | Welsh Analytical Prescribing Support Unit             |
| WMP                   | Welsh Medicines Partnership                           |

### 1. Welcome and introduction

The Chairman opened the meeting and welcomed members.

### 2. Apologies

Mrs Rebecca Richards, Finance Director

Mr Rob Holcombe, Deputy Finance Director

Mrs Wendy Warren, Senior Nurse

It was reported Mr Roger Williams would be arriving late.

### 3. Declarations of interest

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

### 4. Chairman's report

The Chairman reported in April 2011, AWMSG recommended that histamine dihydrochloride (Ceplene<sup>®</sup>▼) should not be recommended for use within NHS Wales for maintenance therapy for adult patients with acute myeloid leukaemia in accordance with its licensed indication. The case for clinical effectiveness and cost effectiveness had not been proven.

Subsequent to the appraisal, the applicant company had requested an independent review of the recommendation. The AWMSG Steering Committee considered the request and concluded there were no grounds for a review. It was confirmed the FAR would be forwarded to Welsh Government for ministerial ratification.

At the April meeting AWMSG also recommended that capecitabine (Xeloda<sup>®</sup>) in combination with oxaliplatin should be recommended as an option for use within NHS Wales for the adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer. AWMSG considered that capecitabine (Xeloda<sup>®</sup>) was not suitable for shared care within NHS Wales for the above indication. It was reported that the process of ratification in relation to capecitabine (Xeloda<sup>®</sup>) medicine had been delayed and Ministerial endorsement of this recommendation had not been received.

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

Clopidogrel (Plavix®) cannot be endorsed for use within NHS Wales in combination with aspirin for the prevention of atherothrombotic and thromboembolic events in adult patients with atrial fibrillation

Conestat alfa (Ruconest®) cannot be endorsed for use within NHS Wales for the treatment of acute angioedema attacks in adults with hereditary angioedema due to C1 esterase inhibitor deficiency

Entecavir (Baraclude®) cannot be endorsed for use within NHS Wales for the treatment of chronic hepatitis B in adults with decompensated liver disease

Tegafur/gimeracil/oteracil (Teysuno®) cannot be endorsed for use within NHS Wales for the treatment of advanced gastric cancer in adults when given in combination with cisplatin.

The Chairman confirmed that these medicines could not be endorsed for use within NHS and should not be routinely available within NHS Wales. Members were informed that WMP is awaiting ratification of the statements and the service would be informed when this has been received.

The Chairman reported that the following appraisals had been scheduled for appraisal at the next meeting on 13<sup>th</sup> July 2011:

Fentanyl (Pecfent®▼) for the management of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain

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

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

Members were informed that the appraisal documentation in relation to the limited submission process had been reviewed and would be uploaded to the AWMSG website over the next few days.

The Chairman congratulated Mrs Kath Haines on her secondment to Head of the Welsh Analytical Prescribing Support Unit (WAPSU).

## **5. Minutes of previous meeting**

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

## **6. Appraisal 1 - Valganciclovir (Valcyte®) (tablets): licence extension for 200 days prophylaxis of cytomegalovirus (CMV) disease in CMV-negative kidney transplant patients who have received a transplant from a CMV-positive donor**

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

Mrs Sabrina Rind, WMP Appraisal Lead, joined members at the table.

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

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

The Chairman welcomed the delegates from the applicant company, Roche Products Limited.

The Chairman invited Dr Robert Bracchi, Chairman of the New Medicines Group, to provide an overview of the discussions held at the preliminary appraisal. Dr Bracchi set the clinical context as outlined in the ASAR. In his address, Dr Bracchi relayed the views of clinical experts. He confirmed that a patient organisation submission had been received from the National Kidney Federation. He concluded his address by confirming NMG's preliminary recommendation that valganciclovir (Valcyte<sup>®</sup>) (tablets) should be recommended as an option for use within NHS Wales for 200 days prophylaxis of cytomegalovirus (CMV) disease in CMV-negative kidney transplant patients who have received a transplant from a CMV-positive donor. Dr Bracchi relayed NMG's view that valganciclovir (Valcyte<sup>®</sup>) tablets would not be suitable for shared care within NHS Wales for the above indication.

The Chairman opened the discussion and invited members to highlight issues in relation to the case for clinical effectiveness. There was discussion in relation to dosing regimens, follow-up data, secondary endpoints and screening programmes. The Chairman referred members to the summary of clinical expert opinion and the lay member highlighted the salient issues within the patient organisation submission

The Chairman invited Professor Ceri Phillips to highlight issues in relation to cost effectiveness. Clarification was sought in relation to the incremental cost effectiveness ratio and associated treatments costs. There were no societal or budget impact issues.

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

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

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

## **Appraisal decision**

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

**Valganciclovir (Valcyte®) tablets are recommended as an option for use within NHS Wales for 200 days prophylaxis of cytomegalovirus (CMV) disease in CMV-negative kidney transplant patients who have received a transplant from a CMV-positive donor.**

**AWMSG is of the opinion that valganciclovir (Valcyte®) tablets are not suitable for shared care within NHS Wales for the above indication.**

### **7. Appraisal 2 - Valganciclovir (Valcyte®) (powder for oral solution): licence extension for 200 days prophylaxis of cytomegalovirus (CMV) disease in CMV-negative kidney transplant patients who have received a transplant from a CMV-positive donor**

The Chairman opened the appraisal and invited Dr Robert Bracchi, Chairman of the New Medicines Group, to provide an overview of the discussions held at the preliminary appraisal. Dr Bracchi set the clinical context as outlined in the ASAR. In his address, Dr Bracchi relayed the views of clinical experts. He confirmed that a patient organisation submission from the National Kidney Federation had been received. He confirmed that after considering the evidence of clinical effectiveness and cost effectiveness, NMG's recommendation was that valganciclovir (Valcyte®) (powder for oral solution) should be recommended as an option for restricted use within NHS Wales for 200 days prophylaxis of cytomegalovirus (CMV) disease in CMV-negative kidney transplant patients who have received a transplant from a CMV-positive donor. He relayed NMG's view that valganciclovir (Valcyte®) powder for oral solution should be restricted for use in patients who cannot take tablets or with a CrCl<10 (ml/min). Members were informed that NMG was of the opinion that valganciclovir (Valcyte®) powder for oral solution would not be suitable for shared care within NHS Wales for the above indication.

The Chairman opened the discussion and invited members to highlight issues in relation to the case for clinical effectiveness. The issue of wastage was discussed. Professor Ceri Phillips highlighted issues within the company's case for cost effectiveness. A comprehensive summary of clinical expert opinion had been provided to members for consideration. The patient submission was considered and the lay member was invited to highlight any salient issues from the patient perspective.

The company delegates responded to all the issues raised in the discussion, both clinical and in relation to the case for cost effectiveness. The positioning of the treatment therapy was reiterated and the applicant company was afforded opportunity to highlight any outstanding issues. Prior to concluding the appraisal, the Chairman asked the company delegates to confirm that all the issues had been addressed, and confirmation was given by the delegates that the process had been fair and transparent.

The Chairman thanked Roche Products Ltd for engaging in the appraisal process. Mrs Rind left the meeting.

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

## **Appraisal decision**

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

**Valganciclovir (Valcyte®) powder for oral solution is recommended as an option for restricted use within NHS Wales for 200 days prophylaxis of cytomegalovirus (CMV)**

**disease in CMV-negative kidney transplant patients who have received a transplant from a CMV-positive donor.**

**Valganciclovir (Valcyte®) powder for oral solution is restricted for use in patients who cannot take tablets or with a CrCl<10 (ml/min).**

**AWMSG is of the opinion that valganciclovir (Valcyte®) powder for oral solution is not suitable for shared care within NHS Wales for the above indication.**

**8. Appraisal 3 - Tacrolimus (Advagraf®) for the prophylaxis of transplant rejection in adult kidney or liver allograft recipients. Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients.**

The Chairman welcomed Dr Claire Davis, WMP Appraisal Lead.

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

The Chairman welcomed the delegates from the applicant company, Astellas Pharma Limited

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

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

The Chairman invited Dr Robert Bracchi, Chairman of the New Medicines Group, to provide an overview of the discussions held at the preliminary appraisal. Dr Bracchi set the clinical context as outlined in the ASAR and relayed the discussions held at NMG.

Mr Roger Williams joined the meeting at 11.30 am. The Chairman confirmed that Mr Williams would be unable to participate in the appraisal.

It was noted that the company submission provided evidence of the clinical and cost effectiveness of tacrolimus (Advagraf®) within a restricted population of patients within the licensed indication. The submission excluded the treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients.

In his address, Dr Bracchi relayed the views of clinical experts in relation to disease prevalence, current treatment options and unmet clinical needs. Dr Bracchi confirmed NMG's preliminary recommendation that tacrolimus (Advagraf®) should not be recommended for use within NHS Wales for the prophylaxis of transplant rejection in adult kidney or liver allograft recipients. NMG considered the evidence provided had not demonstrated sufficient additional benefit compared to Prograf® to outweigh the risks of its introduction into clinical practice.

The Chairman opened the discussion and invited members to highlight issues in relation to the case for clinical effectiveness. There was extensive discussion in relation to potential dosing and medication errors, relative effectiveness and adverse events. The applicant company was provided opportunity to respond to the clinical issues raised.

Professor Walker confirmed his role was to represent Welsh Government at AWMSG and observe the proceedings. He confirmed he would not be participating in the vote. Professor Walker sought clarification in relation to the safety issues noted in the preliminary recommendation. The Chairman confirmed the role and remit of AWMSG in relation to the appraisal.

The lay member drew members' attention to the salient issues within the patient organisation submission received from the National Kidney Federation.

A comprehensive summary of clinical expert had been provided to members for consideration and discussion.

The company delegates responded to all the issues raised in the discussion, both clinical and in relation to cost effectiveness. Specific issues raised within the company response to the preliminary recommendation were addressed individually. Members noted that extensive work had been undertaken by the applicant company to reduce medication errors. The company delegate suggested that Astellas would be happy to support an audit of the introduction of the medicine should AWMSG consider a positive recommendation.

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

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

### **Appraisal decision**

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

**Tacrolimus (Advagraf®) is recommended as an option for restricted use within NHS Wales for the prophylaxis of transplant rejection in adult kidney or liver allograft recipients and the treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients.**

**Tacrolimus (Advagraf®) is restricted for use as prophylaxis of transplant rejection in adult kidney or liver allograft recipients.**

**Tacrolimus (Advagraf®) should be prescribed by brand name to reduce the risk of medication errors.**

**AWMSG is of the opinion that tacrolimus (Advagraf®) may be suitable for shared care.**

## **9. Welsh Health Specialised Services Committee**

The Chairman invited Dr Hugo van Woerden to provide an update to AWMSG on Welsh Health Specialised Services Committee (WHSSC) and explain how the organisation relates to AWMSG within the new structures. Members were informed that WHSSC was established on 1<sup>st</sup> April 2010 and was constituted by statutory instrument as a sub-committee of the seven Health Boards in Wales to undertake the joint planning of Specialised and Tertiary Services. The Committee is supported by a management team known as the Welsh Health Specialised

Services Team (WHSST) which delivers the actions agreed by the Joint Committee. WHSSC is hosted by Cwm Taf health board. Dr van Woerden confirmed the membership and provided a summarised list of the services in which WHSSC are involved. It was confirmed that NICE technology appraisals are mandatory within NHS Wales although, it was noted that NICE guidance (i.e. treatment pathways) are advisory within NHS Wales. Members agreed that the current stance should be maintained in relation to AWMSG and NICE advice.

The Chairman confirmed he has requested a meeting with the newly appointed Minister for Health and Social Services to discuss the activities of the All Wales Medicines Strategy Group (AWMSG) and the support it provides the Minister and Welsh Government.

**10. All Wales Prescribing Advisory Group (AWPAG)**

Dr Tessa Lewis presented the draft minutes of the AWPAG held on 14<sup>th</sup> April 2011. It was confirmed that the Non NHS Prescribing – A Guide for Prescribers document would be presented to AWMSG in July. Dr Lewis informed of work currently in progress including antimicrobial prescribing in Wales, the national prescribing indicators and local comparators, the clinical effectiveness prescribing programme (incentive scheme) and patient information at the point of discharge.

**Date of next meeting: Wednesday, 13<sup>th</sup> July 2011 at The Angel Hotel, Abergavenny**