

**ALL WALES MEDICINES STRATEGY GROUP  
MINUTES OF THE AWMSG MEETING HELD ON  
FRIDAY, 13<sup>th</sup> JUNE 2008 COMMENCING 10.30 AM  
AT THE ANGEL HOTEL, ABERGAVENNY**

<b>MEMBERS PRESENT:</b>			<b>Did not participate in</b>
1.	Dr Paul Buss	NHS Consultant	
2.	Dr Geoffrey Carroll	Health Commission Wales	<b>14-15</b>
3.	Mr Jeff Evans	Other professionals eligible to prescribe	
4.	Dr Bruce Ferguson	Trust Medical Director	
5.	Mr Peter Harsant	Industry Representative	
6.	Mr Brian Hawkins	LHB Pharmacist	
7.	Mr Robert Holcombe,	LHB Finance Director	<b>7-10</b>
8.	Cllr Meurig Hughes	Lay member	
9.	Dr Thomas Lau	General Practitioner and prescribing lead	
10.	Dr Brendan Lloyd	LHB Medical Director	
11.	Mr David Morgan	National Public Health Service Wales	
12.	Prof Ceri Phillips	Health Economist	
13.	Mr Dave Roberts	Chief Pharmacist	
14.	Prof Philip Routledge	Clinical Pharmacologist (Chairman)	
15.	Mrs Wendy Warren,	Senior Nurse	

**IN ATTENDANCE:**

13.	Mrs Ruth Lang	Welsh Medicines Partnership
14.	Mrs Carolyn Poulter	Welsh Assembly Government
15.	Mrs Karen Samuels	Welsh Medicines Partnership
16.	Dr Martin Duerden	NMG Chairman (for appraisals only)

*List of Abbreviations:*

ABPI	Association of the British Pharmaceutical Industry
ASAR	AWMSG Secretariat Assessment Report
AWCDG	All Wales Cancer Drugs Group
AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
BMA	British Medical Association
BNF	British National Formulary
CR/ASAR	Company response to the AWMSG Secretariat assessment report
CR/FAR	Company response to the final appraisal report
CR/PAR	Company response to the preliminary appraisal report
CSCG	Cancer Services Co-ordinating Group
CHM	Commission on Human Medicines
DTB	Drug & Therapeutics Bulletin
FAR	Final appraisal report
HCW	Health Commission Wales
HoPMMs	Heads of Pharmacy and Medicines Management
HSW	Health Solutions Wales
LHB	Local Health Board
M&TCs	Medicines & Therapeutics Committees
MHRA	Medicines & Herbals Regulatory Authority
NHSIF	NHS Industry Forum
NICE	National Institute for Health and Clinical Excellence
NMG	New Medicines Group
NPHS	National Public Health Service
PAR	Preliminary appraisal report
PPRS	Prescription Price Regulation Scheme
SAFF	Service and Financial Framework
SMC	Scottish Medicines Consortium
SPC	Summary of Product Characteristics
TDA User Group	Therapeutic Development Appraisal User Group
T&FG	Task and Finish Group
WeMeReC	Welsh Medicines Resource Centre
WMIC	Welsh Medicines Information Centre
WMP	Welsh Medicines Partnership

**1. Welcome and introduction**

The Chairman opened the meeting and welcomed members.

**2. Apologies**

Miss Carwen Wynne Howells, Welsh Assembly Government  
Dr Fraser Campbell, LHB Medical Director

**3. Declarations of interest**

The Chairman asked members to declare any specific, non-specific, personal or non-personal interests. There were none.

**4. Chairman's report**

The Chairman was pleased to announce that Dr Paul Buss, NHS Consultant representative, had been appointed AWMSG Deputy Chairman. Mr Roger Williams, from Morrison Pharmacy department, had been nominated by the Chief Pharmacists as their deputy AWMSG member. The Chairman confirmed the nomination had been approved by the AWMSG Steering Committee.

It was confirmed that the AWMSG Medicines Strategy document had been sent to the Minister with an offer to assist with the prioritisation of the action points.

The Chairman reported he had met the new ABPI President, Mr Chris Brinsmead, Chairman of Astra Zeneca and was very encouraged at the support for engagement in the AWMSG appraisal process in Wales.

The Chairman confirmed that members of WMP had met with the TDA Users Group on Monday, 19<sup>th</sup> May to discuss and progress various issues in relation to the appraisal process. The role of the AWPAG paper relating to the BNF chapters was raised and clarified at this meeting. It was reiterated that their role is to identify prescribing trends and disseminate advice on good prescribing practice to the Service for use at a local level. The Chairman confirmed that these documents are not guidelines, would not be endorsed by the Minister, but would serve to highlight key prescribing messages. The Chairman stated that a title change would help to avoid any confusion in the future.

The Chairman informed members that he and Dr Tessa Lewis had met with the Welsh cardiologists to discuss issues with regard to the shared care of amiodarone. Following the meeting the amiodarone shared care template had been updated and forwarded to the Chairman of the Welsh Cardiovascular Society for final approval, which having been given, meant that it could now be posted on the AWMSG website.

The Chairman reported that the audit template for use by general practices in Wales to review their prescribing of oral anticoagulants and to assess the extent to which they comply with the guidance issued by the NPSA, endorsed by AWMSG in February, had been disseminated to the Service and posted on the AWMSG website as part of the All Wales Prescribing Incentive Scheme.

The Chairman invited Mr Dave Roberts to update members on progress of the All Wales Anticoagulant chart.

Mr Roberts confirmed that progress towards an All Wales Anticoagulation chart has entailed developing a single chart that will be introduced to specified sites on 1<sup>st</sup> July 2008 to reduce variation in prescribing practice in relation to this important medicine. The Group developing the chart consisted of consultant haematologists, junior medical staff, INR lead nurses and INR lead pharmacists. Members were informed that phase two would commence in the Winter of 2008, to coincide with the first anniversary of the 1,000 Lives Campaign. Mr Roberts reassured members that All Trusts involved had taken measures to ensure that their medical staff complete the BMJ-online package on anticoagulation, which uses the Fennerty loading regimen incorporated into the chart.

Mr Roberts informed members that the consultant haematologists on the group have been involved in the development of their Trusts' thromboprophylaxis policies subsequent to the publication of the NICE guidance on venous thromboembolism. Their experiences in developing the anticoagulation chart had convinced them that an All Wales Risk Assessment tool for Thromboprophylaxis of medical patients would be helpful. Mr Roberts suggested to members that the chairs of each Trust's Thromboprophylaxis Group should have a one-day workshop in the Autumn of 2008 to develop an All Wales risk assessment tool and 'prescription sticker'. Other members of the group were also suggested – a general physician, a palliative care consultant, a nurse representative and a pharmacist representative.

AWMSG supported the request to develop an All Wales Risk Assessment Tool for Thromboprophylaxis and the Chairman informed members that an All-Wales Thrombosis Group had been set up to 'highlight the need to establish mechanisms by

which Welsh hospitals can ensure effective implementation of thromboprophylaxis programmes for hospitalized patients'. The Chairman asked that Mr Roberts liaised with this Group in developing the risk assessment tool.

Dr Brendan Lloyd joined the meeting.

The Chairman drew members' attention to the Government's Response to the Health Select Committee's First Report of Session 2007-08 on the National Institute for Health and Clinical Excellence and confirmed that due to time constraints it would not form part of the agenda for discussion at the meeting. He highlighted the need for AWMSG and its members to be aware of the recommendations of the report, and copies were made available to members.

The Chairman announced that Ministerial endorsement had been received for the two appraisals held at the April AWMSG meeting:

**Appraisal 1 – fondaparinux sodium (Arixtra®)**

**Indication:** for the treatment of ST segment elevation myocardial infarction (STEMI)

**Appraisal 2 - fondaparinux sodium (Arixtra®)**

**Indication:** for the treatment of unstable angina or non-ST segment elevation myocardial infarction (UA/STEMI)

It was confirmed that the final appraisal reports had been posted on the AWMSG website and the Service had been informed.

The Chairman reported that a letter had been sent to Astellas Pharma Limited to encourage a re-submission in relation to the appraisal of **Tacrolimus (Advagraf®)** 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. It was confirmed that the Final Appraisal Report undertaken in February would shortly be forwarded to the Minister for endorsement.

The Chairman informed members that Mr David Morgan would be retiring in July and this meeting would be his last. The Chairman thanked Mr Morgan for his work as AWMSG member and Chairman of NHSIF, and wished him well in his retirement.

The following appraisals, to be held at the next AWMSG meeting on Wednesday, 13<sup>th</sup> August 2008, were announced:

**Appraisal 1: Pegfilgrastim (Neulasta®)**

For secondary prophylaxis of neutropenia

**Appraisal 2: Trabectedin (Yondelis®)**

For the treatment of patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents

**Appraisal 3: Anidulafungin (Ecalta®)**

For the treatment of candidaemia and other forms of *Candida* infection (intra-abdominal abscess and peritonitis) in adult patients

**Appraisal 4: Maraviroc (Censenti®)**

Maraviroc, in combination with other antiretroviral medicinal products, is indicated for treatment-experienced adult patients infected with only CCR5-tropic HIV-1 detectable

## **Appraisal 5: Tenofovir disoproxil fumarate (Viread®)**

For chronic hepatitis B in adults

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

The minutes of the previous meeting were checked for accuracy. There were no matters arising.

### **6. Appraisal 1 – ziconotide (Prialt®)**

for severe chronic pain

Start time – 11.00 am

The Chairman welcomed Katy Hayward and Lara Verdian from the applicant company, Eisai Limited.

Members were asked to confirm any declarations of interest – there were none.

The Chairman confirmed that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this, and that a negative recommendation would not impact on the clinical freedom of the prescriber. He explained that a positive recommendation by AWMSG, subsequently endorsed by the Minister for Health & Social Services, places an obligation on Trusts and LHBs in Wales to fund accordingly. He reiterated that AWMSG advice is interim to NICE should it be subsequently published.

The Chairman confirmed the sequence of the appraisal and confirmed that opportunity would be afforded to Eisai Limited to comment on the appraisal and raise relevant issues.

Dr Duerden set the context of the appraisal and provided a brief overview of the discussions held at the New Medicines Group. The relevant issues contained within the PAR, enclosure 2/AWMSG/0608, were highlighted. It was noted that medical expert views provided had suggested there was little experience across Wales with regard to intrathecal (IT) analgesia and additional treatments would be welcomed. Dr Duerden confirmed that despite best efforts by WMP to seek patient interest group views, none had been submitted. Dr Duerden concluded his presentation by confirming that NMG's advice to AWMSG was not to support the use of this medicine within NHS Wales due to lack of evidence of cost-effectiveness.

The Chairman opened the discussion and asked members to consider the evidence in relation to the clinical effectiveness of the new medicine within its licensed indication. There was discussion over the lack of infrastructure to support such treatment. Members were referred to the company response in which the company had identified a small sub-set of refractory patients with non-malignant pain who respond to ziconotide at week 3.

The Chairman asked members to consider the evidence in relation to cost effectiveness and invited Professor Ceri Phillips to bring to the attention of the Committee any relevant issues. Professor Phillips confirmed that the cost per QALY estimates, which initially appear reasonable, are however based on a number of assumptions.

The Chairman invited Katy Hayward and Lara Verdian to raise any specific issues. In her address it was suggested that AWMSG consider its use in the small sub-set of patients who respond to treatment at week 3.

The Chairman invited comment on the broader societal issues and confirmed that no patient interest group submissions had been received.

The Chairman invited representatives of the applicant company to comment on general and specific issues.

Prior to concluding the appraisal, the Chairman received confirmation from the applicant company representatives that all the issues had been discussed and the process had been fair and transparent.

The Chairman closed proceedings at 11.40 am and confirmed that the Committee would proceed with the second appraisal and would retire at the end of the morning appraisal session to vote in private.

### **Appraisal decision**

The recommendation of AWMSG to the Minister for Health & Social Services was announced:

Ziconotide (Prialt<sup>®</sup>▼) is not recommended for the treatment of severe, chronic pain in patients who require intrathecal (IT) analgesia.

#### **Key factor:**

The case for cost effectiveness of ziconotide (Prialt<sup>®</sup>▼) has not been proven.

## **7. Appraisal 2 – buprenorphine/naloxone (Suboxone<sup>®</sup>)**

For the treatment of opioid dependence

Start time 11.45 am

The Chairman confirmed that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this, and that a negative recommendation would not impact on the clinical freedom of the prescriber. He explained that a positive recommendation by AWMSG, subsequently endorsed by the Minister for Health & Social Services, places an obligation on Trusts and LHBs in Wales to fund accordingly. He reiterated that AWMSG advice is interim to NICE should it be subsequently published.

Members were asked to confirm any declarations of interest – there were none.

The Chairman welcomed Mr Carl Gibbons and Mr Andy Stewart from the applicant company, Schering-Plough.

Dr Duerden set the context of the appraisal and provided a brief overview of the discussions held at the New Medicines Group. The relevant issues contained within the PAR, enclosure 3/AWMSG/0608, were highlighted. It was noted that clinical opinion had been sought though no responses had been received. Dr Duerden concluded by confirming that NMG's advice to AWMSG was to support the restricted use of buprenorphine/naloxone (Suboxone<sup>®</sup>) for use in Wales.

The Chairman invited members to comment on issues relation to the clinical effectiveness. Clarification was sought in relation to the wording of the NMG recommendation. The Chairman asked members to consider any outstanding issues in relation to the cost effectiveness and invited Professor Phillips to address the Group. The issue of supervision of treatment was raised and reference was made to NICE

guidance. There were no further broader societal or budget impact issues raised by members.

The Chairman asked representatives of the applicant company to comment on the general and specific issues.

Prior to closing proceedings, the Chairman sought confirmation that Mr Gibbons and Mr Stewart were satisfied that all issues had been adequately discussed and taken into account and the process had been fair and thorough. Confirmation was received and the Chairman thanked the manufacturers for engaging with the AWMSG process.

The Chairman closed proceedings at 12.30 pm and confirmed that the Committee would retire to vote in private.

### **Appraisal decision**

The recommendation of AWMSG to the Minister for Health & Social Services was announced:

Buprenorphine/naloxone (Suboxone<sup>®</sup>) is recommended for restricted use within NHS Wales as substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. In accordance with NICE guidance such treatment should be considered in patients who are unsuitable for maintenance treatment with methadone.

#### **Key factors:**

- The standard buprenorphine preparation is currently recommended by NICE as a cost effective option in eligible people who are unsuitable for maintenance treatment with methadone.
- AWMSG considers that Suboxone<sup>®</sup> should only be used in preference to buprenorphine where there are clear patient or service advantages.

#### **8. Appraisal 3 – deferasirox (Exjade<sup>®</sup>)** For the treatment of chronic iron overload

Start time 12.35 pm

The Chairman confirmed that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this, and that a negative recommendation would not impact on the clinical freedom of the prescriber. He explained that a positive recommendation by AWMSG, subsequently endorsed by the Minister for Health & Social Services, places an obligation on Trusts and LHBs in Wales to fund accordingly. He reiterated that AWMSG advice is interim to NICE should it be subsequently published.

Members were asked to confirm any declarations of interest – there were none.

The Chairman welcomed Ms Karen Jewitt, Ms Susan Graham and Mr Keith Tolley from the applicant company, Novartis Pharmaceuticals Limited.

Dr Duerden set the context of the appraisal and provided a brief overview of the discussions held at the New Medicines Group. The relevant issues contained within the

PAR, enclosure 4/AWMSG/0608, were highlighted. He concluded his presentation by confirming NMG's advice to AWMSG was to support the use of deferasirox (Exjade®).

The Chairman invited members to comment on any issues in relation to the clinical effectiveness. There was discussion over the long term morbidity and mortality data. The Chairman asked members to consider any outstanding issues in relation to the cost effectiveness and invited Professor Phillips to comment, particularly in relation to the time horizons in the utility analysis

The Chairman invited comment on the patient interest group submission from the The UK Thalassaemia Society and any other broader societal issues. It was noted that medical expert opinion was considered.

The Chairman asked representatives of the applicant company to comment on both general and specific issues in relation to outlining the case for the use of this medicine in Wales.

Prior to closing proceedings, the Chairman sought confirmation that applicant company were satisfied that all issues had been adequately discussed and taken into account and the process had been fair and thorough. Confirmation was received and the Chairman thanked the manufacturers for engaging with the AWMSG process.

The Chairman closed proceedings at 1.15 pm and confirmed that the Committee would retire to vote in private.

### **Appraisal decision**

The recommendation of AWMSG to the Minister for Health & Social Services was announced:

Deferasirox (Exjade®▼) is recommended for use within NHS Wales for the treatment of chronic iron overload due to frequent blood transfusions ( $\geq 7$  ml/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older. It is also recommended for the treatment of chronic iron overload due to blood transfusions when desferrioxamine (DFO) therapy is contraindicated or inadequate in the following patient groups:

- in patients with other anaemias,
- in patients aged 2 to 5 years,
- in patients with beta thalassaemia major with iron overload due to infrequent blood transfusions ( $< 7$  ml/kg/month of packed red blood cells).

Deferasirox (Exjade®▼) is not suitable for shared care within NHS Wales.

### **9. Appraisal 4 – lenalidomide (Revlimid®)**

For the treatment of multiple myeloma patients who have received at least one prior therapy.

Start time 2.15 pm

Members were asked to confirm any declarations of interest – there were none.

The Chairman welcomed Tom Oakley and Arran Shearer from the applicant company, Celgene UK.



The Chairman confirmed that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this, and that a negative recommendation would not impact on the clinical freedom of the prescriber. He explained that a positive recommendation by AWMSG, subsequently endorsed by the Minister for Health & Social Services, places an obligation on Trusts and LHBs in Wales to fund accordingly. He reiterated that AWMSG advice is interim to NICE should it be subsequently published.

Dr Duerden set the context of the appraisal and provided a brief overview of the discussions held at the New Medicines Group. The relevant issues contained within the PAR, enclosure 5/AWMSG/0608, were highlighted. It was noted that the medical expert opinions varied. Two patient interest group submissions had been received, one from Rarer Cancers Forum and the other from Myeloma UK. Both these groups had considered the oral therapy component very important, particularly in Wales where ease of use could be improved. Dr Duerden concluded his presentation by confirming NMG's advice was not to support the use of lenalidomide (Revlimid<sup>®</sup>) within NHS Wales.

The Chairman invited members to seek clarification of any outstanding issues in relation to the clinical effectiveness.

The Chairman asked members to consider any outstanding issues in relation to the cost effectiveness and invited Professor Phillips to address the Group. The process for identifying medical expert opinion was clarified. The Chairman invited comment on the budget impact and broader societal issues. The Chairman referred members to the two patient interest group questionnaires received.

The Chairman invited Mr Oakley and Mr Shearer to comment on the general and specific issues which rose during the discussion and any other issues they wished to highlight within the company response.

Prior to closing proceedings, the Chairman sought confirmation from the representatives of the applicant company that they were satisfied that all issues had been adequately discussed and taken into account, and that the process had been fair and thorough. Confirmation was received and the Chairman thanked Mr Oakley and Mr Shearer for engaging with the AWMSG process.

The Chairman closed proceedings at 3.15 pm and confirmed that the Committee would retire to vote in private after the next appraisal.

### **Appraisal decision**

The recommendation of AWMSG to the Minister for Health & Social Services was announced:

Lenalidomide (Revlimid<sup>®</sup>) is not recommended for use within NHS Wales for the treatment of multiple myeloma.

#### **Key factor:**

The case for cost-effectiveness of lenalidomide (Revlimid<sup>®</sup>) has not been proven.

## **10. Appraisal 5 – docetaxel (Taxotere<sup>®</sup>)** Oncology chemotherapy treatment for the head and neck tumour site.

Start time 3.20 pm

Members were asked to confirm any declarations of interest – there were none.

The Chairman welcomed Mr Peter John Davies from the applicant company, Sanofi-Aventis.

Dr Duerden set the context of the appraisal and provided a brief overview of the discussions held at the New Medicines Group. The relevant issues contained within the PAR, enclosure 6/AWMSG/0608, were highlighted. It was noted that the medical expert opinions supported the use of the medicine. A patient interest group submission had been received from the Rarer Cancer Forum. Dr Duerden concluded his presentation by confirming NMG's advice was that docetaxel (Taxotere<sup>®</sup>) should be approved for restricted use within NHS Wales.

The Chairman invited members to seek clarification of any outstanding issues in relation to the clinical effectiveness. There were none. The Chairman asked members to consider any outstanding issues in relation to the cost effectiveness and invited Professor Phillips to highlight any salient points. The Chairman invited comment on the budget impact and broader societal issues.

The Chairman asked Mr Davies to comment on any general or specific issues raised during the discussion or within the company response to the PAR.

Prior to closing proceedings, the Chairman sought confirmation from Mr Davies that he was satisfied that all issues had been adequately discussed and taken into account, and that the process had been fair and thorough. Confirmation was received and the Chairman thanked the applicant company for engaging with the AWMSG process.

The Chairman closed proceedings at 3.45 pm

### **Appraisal decision**

The recommendation of AWMSG to the Minister for Health & Social Services was announced:

Docetaxel (Taxotere<sup>®</sup>) is recommended for restricted use within NHS Wales in combination with cisplatin and 5-fluorouracil (5-FU) for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN).

Docetaxel (Taxotere<sup>®</sup>) should be restricted for use as an induction treatment for patients of good performance status (0 or 1) anticipated to be receiving chemo-radiotherapy.

Docetaxel (Taxotere<sup>®</sup>) is not suitable for shared care within NHS Wales.

#### **11. Report on NHSIF**

The Chairman invited Mr David Morgan to update members in relation to the work of NHSIF. Mr Morgan highlighted salient issues from the minutes of the NHSIF meeting held in April 2008, Enc 7/AWMSG/0608, and confirmed the next meeting in July 2008.

#### **12. Update on AWPAG**

The Chairman invited Dr Tessa Lewis to update members in relation to the work of AWPAG. Dr Lewis highlighted salient issues from the minutes of the AWPAG meeting held in April 2008, Enc 8/AWMSG/0608, and confirmed the next meeting in July 2008. A view was expressed that whilst prescribing indicators in secondary may be of benefit, national prescribing incentives may not be appropriate within secondary care.

**13. Prescribing review – Respiratory Chapter**

Dr Lewis referred members to Enc 9/AWMSG/0608 and asked members to note the good prescribing practice points raised within the AWPAG review of the respiratory chapter. Dr Lewis thanked the HoPMMs for the development of the work programme. The following suggestions were made by members:

- to include a sub-title 'inhaled corticosteroids'
- include a definition of 'ineffective'
- clarify issues relating to editorial process outside of the meeting
- combine the good practice points and the recommendations
- consider audit prioritisation
- review document annually
- document to be dated
- link with 1,000 Lives Campaign.

The Chairman closed the discussion, thanked Dr Lewis and confirmed that the document will be reviewed in twelve months.

**14. Consultation: Proposals to change the structure of the NHS in Wales**

The Chairman tabled a draft response to the consultation and the invited views. A suggestion was made to include a response to questions 1-6. The Chairman reiterated that any views should be forwarded to him outside of the meeting to be included in the AWMSG response before 24<sup>th</sup> June 2008.

**15. Verbal updated on Welsh Analytical Prescribing Unit (WAPSU)**

The Chairman invited Mr Samuels to provide members with an update on WAPSU. Mrs Samuels reported that the first meeting of the Operational Advisory Group had been held in May, with representatives of key stakeholders in attendance. The milestones of project had been agreed. Communication and prioritisation of the work programme will be considered at the next meeting.

**Date of next AWMSG meeting: Wednesday, 13<sup>th</sup> August 2008 at the Angel Hotel, Abergavenny commencing 10.30 am.**