ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF THE AWMSG MEETING HELD ON TUESDAY, 12th
JUNE 2007 COMMENCING 10.30 AM
AT THE ANGEL HOTEL, ABERGAVENNY, NP7 5EN

MEMBERS PRESENT:

1. Dr Robert Bracchi  General Practitioner & Prescribing Lead
2. Dr Paul Buss  Consultant Physician
   Gwent Healthcare Trust
3. Dr Fraser Campbell  LHB Medical Director
   Gwynedd LHB
4. Mr Jeffrey Evans  Other healthcare professionals eligible to prescribe
   Podiatrist, UWIC
5. Dr Bruce Ferguson  Trust Medical Director
   Bro-Morgannwg
6. Dr Brian Hawkins  LHB Pharmacist
   Rhondda Cynon Taf
7. Mr Peter Harsant  Industry Representative
8. Cllr Meurig Hughes  Lay member
9. Mr David Morgan  Consultant in Pharmaceutical Public Health
   National Public Health Service, North Wales Region
10. Prof Ceri Phillips  Professor of Health Economics, School of Health
   Science, University of Wales Swansea
11. Ms Rebecca Richards  LHB Finance Director, Merthyr Tydfil LHB
12. Prof Philip Routledge  Professor of Clinical Pharmacology, Cardiff
   University and Acting AWMSG Chairman
13. Mr Dave Roberts  Chief Pharmacist
   Cardiff and Vale NHS Trust
14. Mrs Wendy Warren  Nurse Director
   Gwent Healthcare Trust
1. **Welcome, introductions and personalia**
   The Chairman opened the meeting and welcomed those present.

2. **Apologies**
   Dr Tom Lau, General Practitioner & Prescribing Lead
   Mr Rob Holcombe, LHB Finance Director

3. **Declarations of interest**
   The Chairman asked members to declare any specific, non-specific, personal or non-personal interests.
Professor Ceri Phillips confirmed he advised the manufacturers during the developmental stage of Preotact®. The Chairman confirmed that Dr Dyfrig Hughes, the deputy health economist member, had been unable to attend the meeting. Under these circumstances, and with the agreement of the manufacturers, the Chairman allowed Professor Ceri Phillips to receive members’ direct questions but stated that Professor Phillips would not be able to participate in the general discussions and would not be eligible to vote.

4 Minutes of previous meeting

The Chairman noted that members have had opportunity to comment on points of accuracy prior to the meeting.

Matters arising:

A member expressed concern that sorafenib (Nexavar®) had been made available to a patient from North Wales after AWMSG had recommended that this medicine should not be supported for use within NHS Wales. It was confirmed there had been a delay in receipt of Ministerial endorsement of AWMSG’s advice and the decision to make this medicine available had been made prior to receiving confirmation of ministerial ratification. The Chairman confirmed that a notice confirming receipt of Ministerial ratification had been circulated to the Service and will be posted on the AWMSG website.

Ms Carwen Wynne-Howells, Councillor Meurig Hughes and Mrs Carolyn Poulter joined the meeting.

Members expressed concern at the reduced availability of the adult edition of the British National Formulary (BNF). The Chairman relayed the concern of Gwent Local Medical Committee at this decision and that of Gwent Partnership Medicines and Therapeutics Committee who had requested that AWMSG advise Welsh Assembly to reconsider this decision. The Welsh Assembly Government representative confirmed that the provision of the BNF and Drug Tariff is currently under review and a needs-assessment exercise would be undertaken by Welsh Assembly Government.

It was noted that Welsh Assembly Government will be submitting a response to the Office of Fair Trading – Market Study of the PPRS. The Chairman confirmed that ten responses from AWMSG members had been received by WMP. The responses had been anonymised and forwarded to Welsh Assembly Government to inform their response. The Chairman confirmed that, on behalf of AWMSG, he will be submitting a response before the deadline for receipt of responses at the end of the June 2007.

The Chairman reported that Welsh Assembly Government had identified funding for the commissioning of the editing of the AWPAG prescribing reviews of the BNF chapters. Members welcomed this development.

5 Chairman's report

The Chairman announced the appraisals to be held at the August meeting of AWMSG.

Darunavir (Prezista®)

Manufacturer: Tibotec (a division of Janssen-Cilag Ltd

Indication: Co-administered with 100 mg ritonavir, is indicated in combination with other antiretroviral treatment of human immunodeficiency virus (HIV-1) infection in highly pre-treated adult patients.
**Sunitinib (Sutent®)**
Manufacturer: Pfizer Ltd
Indication: Treatment of advanced and/or metastatic renal cell carcinoma

**Tipranavir (Aptivus®)**
Manufacturer: Boehringer Ingelheim
Indication: Aptivus, co-administered with low dose ritonavir, is indicated for combination antiretroviral treatment of HIV-1 infection in highly pre-treated adult patients with virus resistant to multiple protease inhibitors

**Co-careldopa (Duodopa®)**
Manufacturer: Solvay Healthcare Ltd
Indication: Treatment of advanced levodopa-responsive Parkinson’s disease with motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson med products have not given satisfactory results.

Members were asked to declare any interests in any of the above – there were none.

**General issues:**

The Chairman confirmed receipt of Dr David Gozzard’s resignation from AWMSG and announced that Dr Ferguson had agreed to act as Trust Medical Director representative on the Group. The Chairman thanked Dr Gozzard for his invaluable input into the Committee. Dr Ferguson confirmed he would seek a nomination for a deputy member from his professional colleagues.

The Chairman reiterated that endorsement of the AWMSG recommendation in relation to sorafenib (Nexevar) had been received. An email has been issued to the Service and a notice will be posted on the AWMSG website.

The Chairman informed members that a useful meeting had been held with Mr David Brickwood and Dr Richard Greville of ABPI on Wednesday, 16th May at ABPI offices in Whitehall. The Chairman was encouraged by this example of partnership working to develop a process acceptable to all stakeholders.

The Chairman announced that training seminars had been held on 19th March and 4th May for all members and deputies of AWMSG and NMG. Feedback received had been positive. The Chairman thanked Professor Ceri Phillips and Dr Dyfrig Hughes for their input into the training days.

It was confirmed that the TDA Users Group will be reviewing feedback in relation to changes to the appraisal process after two cycles at their meeting in August.

The Chairman informed members that the inaugural meeting of the NMG had been held on 17th May in Abergavenny. Dr Duerden stated that all members had attended and the level of discussion had been well-informed, wide-ranging and constructive. Dr Duerden commented that the process had also been robust.

The Chairman announced that an information note in relation to cystic fibrosis – interface issues had been disseminated to LHBs on 5th May 2007 outlining issues relating to the prescribing of tobramycin nebulised solution (Tobi) and dornase alfa (Pulmozyme) and informing of AWMSG’s endorsement to the opt-in approach. The original draft minutes circulated to members were subsequently updated to provide increased clarity in this respect and were posted on the AWMSG website. It was noted that Cardiff LHB, the Vale
of Glamorgan LHB and Cardiff & Vale NHS Trust have recently developed a shared care template for dornase alfa (Pulmozyme). Members noted the need for review and monitoring of these arrangements to ensure that the funding elements are appropriately apportioned.

Professor Routledge opened the appraisal proceedings and asked members to declare any interests pertinent to the appraisals. The Chairman reminded members of the declaration previously made by Professor Phillips. There were no other declarations of interest from any members of the Group eligible to vote. The Chairman confirmed that the WMP independent review team were not present at the meeting.

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. AWMSG advice is interim to NICE should it be subsequently published.

**Appraisal 1: clofarabine (Evoltra®) – Start time 11.00 am**

Manufacturer: Bioenvision Ltd

Indication: Treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients who have relapsed or are refractory after receiving at least two prior regimens and where there is no other treatment option anticipated to result in a durable response.

Scope: An assessment of the cost and clinical effectiveness of clofarabine (Evoltra®) in relation to its licensed indication and the place of clofarabine (Evoltra®) in relation to current treatment strategies available in NHS Wales.

The Chairman invited Mr Mark Fisher, Country Manager (UK & Ireland), Bioenvision Limited to introduce himself.

The Chairman invited Dr Martin Duerden to outline the context of the technology before opening the discussion.

Dr Duerden commented that on reflection he felt that the present indication should be mentioned explicitly in the recommendation.

Members were reassured that the appraisal had been undertaken robustly and medical input had been acknowledged. It was noted that no reference had been made to SMC advice in the PAR.

The Chairman invited Professor Ceri Phillips to highlight any salient points in relation to the cost effectiveness issues discussed at the NMG. Professor Phillips confirmed that the level of discussion at NMG had been thorough, the report was analysed extensively and the questioning had been sharp and to the point.

It was noted that the budget impact analysis had not been reviewed by NMG. The Chairman reiterated the role of AWMSG is to consider societal and budget impact issues. Members were asked to consider the patient interest group submission. Dr Duerden informed members there had been very able lay representation at NMG. The positive report of the patient interest group submission was noted.

The Chairman referred members to the CR/PAR and the recommendation that its use be supported as a treatment bridge whilst awaiting stem cell transplant.
The Chairman invited Mr Fisher to comment on the discussion and raise any issues he felt should be brought to the attention of AWMSG.

Members were asked to suggest changes to the PAR. The inconsistency in the spelling of clofarabine was noted. The Chairman confirmed that the recommendation in the FAR will specify the licensed indication and make reference to the use of the medicine as a treatment bridge.

In the light of the discussions the Chairman asked members to make note of their initial recommendation on their aide memoir for reference at a later stage.

The Chairman closed proceedings at 11.35 am.

7 **Appraisal 2: dexrazoxane (Savene®) – Start time 11.36 am**
Manufacturer: TopTarget (Denmark)
Indication: Treatment of anthracycline extravasation.
Scope: An assessment of the cost and clinical effectiveness of dexrazoxane (Savene®) in relation to its licensed indication and the place of dexrazoxane (Savene®) in relation to current treatment strategies available in NHS Wales.

The Chairman asked members to declare any interest in the manufacturer or the technology. None were declared.

The Chairman informed members that the company response to the NMG preliminary recommendation had been received at a very late stage. A copy had been emailed and posted to all members. A further copy was provided to one member who had not had sight of the document. The Chairman confirmed that there were no representatives from the manufacturers present at the meeting.

The Chairman invited Dr Martin Duerden to outline the context of the technology before opening the discussion. Dr Duerden suggested removing the reference to safety in the recommendation. Dr Duerden confirmed that medical expert option had been received, although the opinion proffered was outside the license indication. No patient interest group submission had been received. Professor Ceri Phillips commented on the health economic aspects of the PAR.

The Chairman drew members’ attention to the CR/PAR. Members considered each issue raised by the manufacturers in their written response.

In the light of the discussions the Chairman asked members to make note of their initial recommendation on their aide memoir.

The appraisal was concluded at 11.50 am

8 **Appraisal 3: parathyroid hormone (Preotact®) – Start time 12.05 pm**
Manufacturer: Nycomed UK
Indication: Treatment of severe osteoporosis in postmenopausal women.
Scope: An assessment of the cost and clinical effectiveness of parathyroid hormone (Preotact®) in relation to its licensed indication and the place of parathyroid hormone (Preotact®) in relation to current treatment strategies available in NHS Wales.

The Chairman asked members to declare any interest in the manufacturer or the technology. None were declared other than those declared by Professor Ceri Phillips at the start of the meeting.
Dr Duerden outlined the concerns of NMG in relation to this submission.

The Chairman invited members to raise issues of an efficacy, safety and clinical nature. Dr Duerden confirmed a varied response from medical experts.

The Chairman invited Professor Phillips to comment on the robustness of the health economic model used by the manufacturers. It was noted that there was a lack of comparator data. Members were invited to direct questions in relation to cost effectiveness to Professor Phillips. It was confirmed there is likely to be an underestimate in the number of clinical vertebral fractures in Wales.

Professor Ceri Phillips left the meeting. The Chairman invited members to raise any issues in relation to the patient interest group submission. There were none. The Chairman welcomed and introduced representatives from the manufacturers, Nycomed Limited.

Dr Jeff Dalton, Medical Director
Ms Anita Sinha, Product Manager
Dr Jonathan Belsey, Managing Director JB Medicine (health economic author)

The Chairman drew members’ attention to the issues raised in the CR/PAR and invited members’ comment on each of the issues.

The Chairman asked Dr Dalton to comment on the issues raised and bring to the attention of members any other relevant issues. There was discussion on self-administration and the specifically designed pen for osteoporosis patients, management of raised calcium levels and storage of product.

In the light of the discussions the Chairman asked members to make note of their initial recommendation.

The Chairman concluded the appraisal at 12.55 pm.

9 Appraisal 4: Emtricitabine (Emtriva®) - Appraisal start time 12.56 pm
Manufacturer: Gilead Sciences Ltd
Indication: Treatment of HIV-1 infected adults and children in combination other antiretroviral agents.
Scope: An assessment of the cost and clinical effectiveness of emtricitabine (Emtriva®) in relation to its licensed indication and the place of emtricitabine (Emtriva®) in relation to current treatment strategies available in NHS Wales.

The Chairman welcomed representatives from Gilead Sciences Limited, Dr Claudio Avila and Mr Ruairi O'Donnell, and asked them to introduce themselves.

The Chairman asked members to declare any interests in Gilead Sciences Ltd. There were none.

The manufacturers confirmed their willingness for the appraisal of Emtricitabine (Emtriva®) and emtricitabine/tenofovir (Truvada®) to be considered together.

Professor Ceri Phillips returned to the table.

Dr Martin Duerden informed members of the reasons why NMG had come to the decision to recommend the use of these technologies within NHS Wales. Members noted the need
for good compliance.
The Chairman invited Professor Ceri Phillips to confirm the robustness of the discussions at NMG in relation to cost effectiveness issues. Members noted the relevance of the cost effectiveness model was not evident in either submission and the data was relatively out of date.

The Chairman invited the representatives from the manufacturers to respond to the issues raised during the discussion.

The Chairman invited members to address any issues in relation to budget impact. Members noted the varied support for the availability of the product from the medical expert opinion submitted to the Welsh Medicines Partnership.

The Chairman referred members to the patient interest group submission. It was noted that the Terence Higgins Trust had submitted a very well-informed response.

The Chairman referred members to the CR/PAR and addressed each issue.

The Chairman invited Dr Avilo to respond to the issues raised.

The Chairman invited further comments from members. There were none.

The Chairman concluded the appraisal at 1.30 pm.

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Appraisal 5: Emtricitabine/tenofovir (Truvada®)
Manufacturer: Gilead Sciences Ltd
Indication: Truvada is a fixed dose combination of Emtricitabine and tenofovir disoproxil fumarate. It is indicated in antiretroviral combination therapy for the treatment of HIV-1 infected adults.
Scope: An assessment of the cost and clinical effectiveness of emtricitabine/tenofovir (Truvada®) in relation to its licensed indication and the place of emtricitabine/tenofovir (Truvada®) in relation to current treatment strategies available in NHS Wales.

Appraisal conclusions:

At 2.10 pm the meeting resumed and the Chairman announced the decision of AWMSG in relation to the appraisals undertaken.

The Chairman informed the manufacturers that they have up to ten days following this meeting to accept or reject the recommendation and lodge an application for possible independent review which should be submitted in writing to the Chairman via WMP. The Chairman confirmed that the AWMSG Secretariat (WMP) will confirm in writing the recommendation to be made to the Minister for Health & Social Services within five working days from this meeting.

Appraisal 1: clofarabine (Evoltra®)
AWMSG supported the following recommendation:

NMG’s advice to AWMSG is that:

**Clofarabine** should be recommended for use within NHS Wales for paediatric patients with acute lymphoblastic leukaemia (ALL) in accordance with the licensed indication, where the intention is to proceed to stem cell transplant (that is, not for palliative care use). The NMG would wish to review data on clorafabine and
experiences and outcomes from its use, in two year’s time.

**Appraisal 2: dexrazoxane (Savene®)**

**AWMSG supported the following recommendation:**

NMG’s advice to AWMSG is that:

**Dexrazoxane** should not be recommended for use within NHS Wales for the treatment of anthracycline extravasation due to lack of sufficiently robust clinical effectiveness, health economic, and safety data.

**Appraisal 3: parathyroid hormone (Preotact®)**

**AWMSG did not support the following recommendation:**

NMG’s advice to AWMSG is that:

**Preotact®** should be not be recommended for use within NHS Wales for the treatment of osteoporosis in postmenopausal women at high risk of fractures, as the case for cost and clinical effectiveness has not been adequately proven relative to alternative treatments.

Its restricted use was supported – the precise wording to be finalised and agreed by members of AWMSG and forwarded to the manufacturers following the meeting.

**Appraisal 4: Emtricitabine (Emtriva®)**

**AWMSG supported the following recommendation:**

NMG’s advice to AWMSG is that:

**Emtricitabine** should be recommended for use within NHS Wales as an option for the treatment of HIV-1 infected adult patients for use in treatment-naïve patients, in line with current BHIVA guidelines. It should only be prescribed by HIV specialists.

To recommend that AWMSG ask the manufacturers for a further submission relating to paediatric use.

**Appraisal 5: Emtricitabine/tenofovir (Truvada®)**

**AWMSG supported the following recommendation:**

NMG’s advice to AWMSG is that:

**Truvada®** should be recommended for use within NHS Wales as an option for the treatment of HIV-1 infected adult patients for use in treatment-naïve patients, in line with current BHIVA guidelines. It should only be prescribed by HIV specialists.

The Chairman confirmed that the AWMSG advice will not be passed to the Minister until the ten days has expired and the company has had opportunity to formally respond to the Final Appraisal Report.

The Chairman thanked the manufacturer’s representatives for engaging with the AWMSG process and closed the appraisal proceedings.
Report on AWPAG
The Chairman invited Mrs Nicola John, Chair of AWPAG, to present Enc 7/AWMSG0607. Mrs John conveyed the concern of AWPAG at the reduced availability of the BNF. Mrs John drew members’ attention to Appendix 1 – the proposed prescribing indicators for the financial year 2008/2009 and explained that the AWPAG Indicator Working Group had agreed to build on the indicators developed over the past few years. Members were informed that AWPAG recognise the benefits of working with secondary care to develop indicators to reflect practice across primary and secondary care. There was a suggestion to consider the broader issues of aligning the indicators to more strategic pathways of healthcare. Mrs John invited secondary care input on to the working party to work through a set of indicators for the following financial year and made note to report member’s comments to the indicator working group. Members were asked to endorse this paper. A point was made that colleagues in NHSIF had not had opportunity to comment on the paper prior to it being presented to AWMSG. It was noted that tight timelines did not allow consultation and that the paper had not been shared with NHSIF in previous years. It was agreed that Mrs Poulter would confirm the deadline for receipt of the paper and, if timescales permitted, the paper could be presented to NHSIF at their next meeting in July 2007 to allow opportunity for wider consultation from the sub-groups of AWMSG. The Chairman requested that members provide comment to himself and Mrs John as AWPAG Chair. Issues concerning effective liaison between the two sub-groups in relation to pre-circulation of papers will be addressed outside of the meeting and timelines will be taken into account to allow opportunity for consultation where appropriate.

It was agreed that in view of the level of comment AWMSG will consider the paper at their meeting in August if timelines permit.
ACTION – Mrs Poulter to confirm timelines
ACTION – Seek comment from NHSIF if timelines permit
ACTION – Bring back to AWMSG in August if timelines permit

Members noted the concern of AWPAG at the lack of engagement with prescribing groups in the development of advice, in particular in relation to blood glucose testing. Members were informed that representatives of AWPAG had been invited to a meeting to discuss the second draft of the Diabetes guidelines prepared by the All Wales Consensus Group. The Chairman reiterated that AWMSG has an important role in ensuring that evidence-base guidelines, consistent with NICE guidance, are available to the Service.

The Chairman confirmed that he had written to the MHRA with regard to ibuprofen prescribing in children. It was confirmed that the MHRA had agreed to report back to the Chairman on this issue.
ACTION – The Chairman to report back to the Committee when MHRA report received

Mrs John confirmed that AWPAG is working with the Renal Advisory Group to address the issues of prescribing of erythropoietins. Members were asked to note the emerging issues in relation to the use of epos and proposed that AWPAG widen the discussion.
ACTION – Mrs John to take comments back to AWPAG

Members were encouraged at the joint working in relation to the prescribing strategy. The Chairman informed members that the appendices are currently being prepared and confirmed the intention to bring the document to the August AWMSG meeting for discussion and endorsement. Members were asked to note the potential strategic problem in relation to age related macular degeneration and it was suggested that the strategy document address the broader issues of budget impact. The Chairman agreed to follow-up the suggestion outside of the meeting.
Members discussed the shared care template and acknowledged the need for robust arrangements in relation to monitoring and follow-up.

The Chairman invited Dr Tessa Lewis, AWPAG Vice Chair and Shared Care Lead. Dr Lewis provided an overview of Enclosure 7 Appendix 2a. Dr Lewis informed members that consultation had been broad and the shared care guidance for the prescribing of amiodarone had been endorsed by the Welsh Council of the Geriatric Society. It was noted that endorsement of the Welsh Cardiac Society had not been received prior to the meeting and remained outstanding. The Chairman and Dr Lewis agreed to follow this up. Minor typographical changes were noted by Dr Lewis.

**AWMSG endorsed the shared care template for the prescribing of amiodarone and asked that Dr Lewis seek endorsement from the Welsh Cardiac Society.**

The Chairman thanked Dr Tessa Lewis for her work in relation to shared care on behalf of AWMSG.

### 12 Report on Independent Prescribing

The Chairman invited Ms Sian Evans to provide an overview of Enc 8/AWMSG/0607 in relation to independent prescribing. Ms Evans confirmed that the final meeting of the Task and Finish Group took place on 8th June 2007 not 11th July as stated in the paper. Ms Evans thanked the Welsh Medicines Partnership for providing the therapeutic element to the course, and the Welsh Medicines Resource Centre for managing and hosting a discussion forum for future independent prescribers in Wales. Ms Evans reassured members in relation to cross-boundary flow and prescription pads. Ms Evans confirmed that plans are in place for supplementary prescribing training of allied professionals with entry criteria being set by the professional society. Members noted the very encouraging progress report. Miss Wynne-Howells thanked Ms Evans for her input into independent prescribing in Wales.

### 13 Report on NHS Industry Forum

The Chairman invited Mr David Morgan to provide an overview Enc 9/AWMSG/0607. Mr Morgan highlighted salient issues in the draft minutes of the NHSIF meeting held on 25th January 2007 and confirmed that he will be responding to the MHRA consultation on pseudoephedrine through the AWMSG Chairman.

**Date of next AWMSG meeting: Wednesday, 15th August 2007 at the Angel Hotel, Abergavenny.**