ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF MEETING HELD ON

2nd DECEMBER 2003 COMMENCING 11.00 AM IN THE MŰLLER HALL

ALL NATIONS CENTRE, SACHVILLE AVENUE, HEATH, CARDIFF, CF13 4NY

MEMBERS PRESENT:

			Member did not participate in agenda item
1.	Mr Julian Baker	Director of Finance representative Caerphilly Local Health Board	
2.	Mrs Kathryn Bourne	Nurse Prescribing representative Gwent Healthcare NHS Trust	
3.	Dr Paul Buss	Gwent Healthcare Trust Consultant representative	
4.	Mr Jeffrey Evans	Representing other healthcare professionals eligible to prescribe Senior Lecturer in Podiatry & Podiatric Surgeon Wales Centre for Podiatric Studies, UWIC, Cardiff	
5.	Miss Sian Evans	Local Health Board pharmacist representative Merthyr Tydfil Local Health Board	
6.	Dr David Gozzard	Medical Director representative Consultant Haematologist & Medical Director Conwy & Denbighshire NH Trust	
7.	Mr Peter Harsant	Industry representative Norgine Limited, Uxbridge, Middlesex	
8.	Mrs Susan Hobbs	NHS Trust Nurse Director representative Chief Nurse, Cardiff & Vale NHS Trust	
9.	Dr Dyfrig Hughes	Health Economist deputy Lecturer in Health Economics, University of Liverpool	6.1 / 6.2 / 6.3 / 6.4 / 6.5 / 6.6
10.	Cllr Meurig Hughes	Lay member representative Llangefni, Ynys Mon	
11.	Dr Thomas Lau	LHG prescribing lead representative Lliswery Medical Centre, Newport	
12.	Mr David Morgan	Pharmaceutical Public Health representative Consultant in Pharmaceutical Public Health, National Public Health Service, North Wales Region	
13.	Dr Ceri Phillips	Health Economics representative Reader in Health Economics, School of Health Science, Swansea University	6.7 / 6.8 / 6.9
14.	Mr Dave Roberts	Chief Pharmacist deputy Cardiff and Vale NHS Trust	6.1 / 6.2 / 6.3 / 6.4 / 6.5 / 6.6 / 6.7
15.	Dr Quentin Sandifer	Consultant in Public Health Medicine representative, National Public Health Service, Mid & West Wales Region	6.9
16.	Professor Roger Walker	Chairman AWMSG Consultant in Pharmaceutical Public Health National Public Health Service, South East Wales Region	

IN ATTENDANCE:

17.	Mr Jamie Hayes	Welsh Medicines Partnership
18.	Dr Channarayapatna Krishna	Welsh Medicines Partnership
19.	Mrs Ruth Lang	Minutes (Welsh Medicines Partnership)
20.	Mrs Gemma Nye	Pharmaceutical Services Branch Welsh Assembly Government
21.	Mrs Carolyn Poulter	Head of Pharmaceutical Services Branch Welsh Assembly Government
22.	Professor Philip Routledge	Welsh Medicines Partnership
23.	Mrs Karen Samuels	Welsh Medicines Partnership
24.	Dr John Thompson	Welsh Medicines Partnership
25.	Mrs Fiona Woods	Welsh Medicines Partnership
26.	Miss Carwen Wynne-Howells	Chief Pharmaceutical Adviser Welsh Assembly Government

List of Abbreviations:
AWMSG – All Wales Medicines Strategy Group
AWPAG – All Wales Prescribing Advisory Group
HSW – Health Solutions Wales
LHB – Local Health Board
NHSIF – NHS-Industry Forum
SAFF – Service and Financial Framework
SPC - Summary of Product Characteristics
UKMI – UK Medicines Information
WAG – Welsh Assembly Government
WICS – Welsh Intensive Care Society
WMP – Welsh Medicines Partnership

Action

6/1. Welcome and Introduction
The Chairman welcomed those present to the sixth meeting of the AWMSG and advised those present that the proceedings are recorded and there is simultaneous translation from Welsh to English. The minutes will be available on the AWMSG website. Members introduced themselves.

6/2. Apologies
Mr Mike Pollard, Chief Pharmacist representative

6/3. Declarations of interests
Dr David Gozzard declared an interest in Item 8 – non personal, non specific (has used all erythropoietin products)
Mr Meurig Hughes declared an interest in Item 13 - personal, non specific (small shareholding in Astra Zeneca)
Dr Ceri Phillips declared an interesting Item 7- personal, specific (payment for attendance as speaker at a meeting on adalimumab sponsored by Abbott Laboratories). The Chairman confirmed Dr Hughes would participate in the discussion of this agenda item.
Professor Philip Routledge declared a lapsed interest (3 years previously) – non personal, non specific (training of Roche Pharmaceutical Company staff in monitoring drug safety).

6/4. Minutes of previous meeting
The minutes were checked for accuracy. It was noted that page 5 paragraph 8 should read
"When the meeting reconvened the Chairman stated that AWMSG would not support the use of Aldurazyme (larondiase) within NHS Wales on the grounds of lack of

evidence ***of cost effectiveness."*** With this amendment the minutes were then approved.

6/5. Matters arising

4/5.4 Prescribing budgets
The Chairman confirmed that he and members of WMP had received and accepted an invitation to attend meetings of the Townsend Implementation Group. An invitation had been extended to the Chairman to send a representative to the Wanless Implementation Programme and he confirmed that Mrs Nicola John, Vice Chairman of the All Wales Prescribing Advisory Group had been nominated.

4/4.8 Update on Drotrecogin
Mrs Woods stated that the Chairman of WICS had confirmed he (or a nominated representative) would report back to the AWMSG March 2004 meeting on the audit of drotrecogin use within NHS Wales.

5/5.3 Update on Prescribing Indicators
The data presented at the AWMSG September 2003 meeting on defined daily doses had been calculated incorrectly by HSW. The Chairman confirmed the data has been withdrawn and will be re-presented once the correct information is available.

5/5.5 Update on Horizon Scanning
Mrs Woods confirmed that UKMI had granted Dr Ceri Phillips access to confidential NHS information via their website.

5/5.9 Procurement of Primary Care Medicines
The Chairman stated that he had written to Mrs Ann Lloyd, Director NHS Wales, and confirmed that AWMSG did not support the introduction of central procurement at the present time. A copy of this letter, and the response from Mrs Lloyd, is available on the website. http://www.wales.nhs.uk/sites/page.cfm?orgid=371&pid=3257

6/6. Appointment Process
Mrs Poulter referred members to Enc **2**/AWMSG/1203 and confirmed that designated deputies had been appointed for AWMSG and AWPAG, but it was felt more appropriate that a pool of deputies should be sought for NHSIF. She stated that since preparing the document further appointments had been made and an updated paper will be issued shortly. Members' attention was drawn to the fact that the onus is on the member to contact their deputy in the event of planned absence and inform the Secretariat so that meeting papers can be forwarded to the nominated deputy. The Chairman asked members to note that Mr Dave Roberts had been appointed deputy to Mr Mike Pollard, and Dr Dyfrig Hughes deputy to Dr Ceri Phillips. Mr Julian Baker asked the Group to consider the appointment of an NHS Trust Finance Director. Mr Peter Harsant asked that membership for the AWMSG Steering Committee also be published.

6/7. Therapeutic Assessment – Adalimumab (Humira®)

Dr Krishna & Mrs Karen Samuels left the meeting prior to the discussions. Dr Dyfrig Hughes joined members at the table.

Mr Dave Roberts, Deputy Chief Pharmacist, declared a personal & specific interest (payment for attendance as speaker at a meeting on adalimumab sponsored by Abbott Laboratories) and was therefore unable to participate in this discussion.

The Chairman invited the following to the appraisal table.

Dr Sharon Jones, Consultant Rheumatologist, Cardiff snd Vale NHS Trust as a clinical expert within NHS Wales.
Dr Victoria Gurmin and Dr Francis Pang representing Abbott Laboratories

The Chairman introduced and welcomed the guests and Dr Jones confirmed she had no declarations of interest. The Chairman invited Dr Jones to clarify the rationale for her invitation to attend.

Dr Jones confirmed she had been nominated by Dr Margaret O'Sullivan, Chair of the Welsh Rheumatology Society. She was asked to express her views on the use of adalimumab (Humira®) in adult patients with severely active rheumatoid arthritis. Dr Jones outlined the positive benefits to patients and stated that she saw this drug as an addition not a replacement to existing therapy.

The Chairman reiterated that AWMSG guidance is interim to NICE guidance should this be subsequently published. In addition, AWMSG advice has no impact on the licensing status of the technology and the inherent implications associated with this.

Dr John Thompson gave a brief overview of Enc No 3/AWMSG/1203 Appendix I and confirmed that the paper had been independently compiled using the information contained in Form A or available in the public domain.

Comments were received from the company representatives and the Chairman opened the debate to AWMSG members.

Detailed discussions followed. It was noted that all patients should be monitored and entered into a biologic register unless the patient withholds permission. Dr Jones indicated that data for patients from Wales could be extracted from this database. Some members expressed concern over the status of the free home delivery service.

The Chairman confirmed that AWMSG had been asked to consider whether adalimumab should be available for use within NHS Wales for the treatment of moderate to severe rheumatoid arthritis in adults. Members were asked to vote.

It was agreed(vote: 12-1) that the following recommendation be made to the Minister for Health & Social Services with regard to Adalimumab (Humira®)

Treatment within NHS Wales should be supported with Restrictions

Resctrictions identified included:

- Adalimumab should only be available to physicians in secondary care specialising in rheumatology.
- Adalimumab must be used in accordance with the British Society of Rheumatology guidelines for the use of anti-TNF agents.
- Prescribers should be encouraged to report all suspected adverse reactions to adalimumab using the yellow card scheme.

6/8. Therapeutic Assessment – Erythropoietins

Dr John Thompson and Mrs Fiona Woods left the meeting prior to the discussions. The Chairman invited the following to the appraisal table.

Mr Dave Roberts, Chief Pharmacist deputy, was invited to the table to join the discussions.

Dr Ivor Cavill, Senior Lecturer in Haematology, UWCM, Heath Park, Cardiff as a clinical expert from within NHS Wales.
Dr Tony Donovan and Mr Keith Tolley representing Ortho-Biotech
Dr Martin Bexon and Ms Carole Farina representing Roche Pharmaceuticals
Mr Paul Greenland representing Amgen

Prior to the commencement of the appraisal, the Chairman reiterated that AWMSG guidance is interim to publication of NICE guidance. In addition, AWMSG advice has no impact on the licensing status of the technology and the inherent implications associated with this. AWMSG were aware that the use of erythropoietin in the treatment of anaemia associated with cancer has been referred to NICE for incorporation in their 9th wave of appraisals. Nevertheless, the Minister has requested that AWMSG undertake an appraisal to clarify use in Wales in the interim.

The Chairman introduced and welcomed the guests and Dr Cavill declared interests in the three companies - personal, specific (consultancy and payment for attendance as speaker at meetings on erythropoietins sponsored by Roche, Amgen and Ortho-Biotech).

Dr Cavill confirmed he had been nominated by Professor Tim Maughan, Chairman of the All Wales Cancer Network and has thirty years experience in the treatment of anaemia. He was asked to present his views on the use erythropoietins in patients with cancer related anaemia.

Dr Cavill outlined the positive benefits to patients suffering from cancer related anaemia and these included an improvement in quality of life and a reduction in the level of fatigue often experienced with the treatment of cancer.

Professor Philip Routledge, Mr Jamie Hayes and Dr Ceri Phillips presented an overview of Enc **4**/AWMSG/1203 and confirmed that the paper had been independently compiled using the information contained in Form A or available in the public domain.

Comments were received from the company representatives and the Chairman opened the debate to AWMSG members. Detailed discussion ensued and members asked for further information on the alternative therapies available, targeting treatment, guidance on the use of blood, the feasibility of drawing up of a protocol to make a rational assessment to predict likely response to therapy, the eligible patient population and infrastructure to meet unmet need.

Concern was expressed over the lack of an infrastructure in NHS Wales to assess the quality of life of patients and address the issue of anaemia in cancer patients. The Group raised the issue of whether blood and drug budgets could be linked.

The general feeling was of conflicting evidence on clinical effectiveness and a lack of cost-effectiveness data. There was detailed discussion on the validity and availability of cost per QALY estimates, but it was felt there was no clear evidence that the use of erythropoietins were cost-effective. Discussions revealed shortcomings in existing service provision and indicated a more robust approach to the management of anaemia in malignancy was required.

The Chairman confirmed that AWMSG had been asked to consider whether erythropoietin use in the treatment of anaemia associated with cancer should be supported within NHS Wales.

It was agreed (vote: – 9-5 (no abstentions) that the following recommendation be made to the Minister for Health & Social Services.

Not to support the use of erythropoietin in the treatment of anaemia associated with cancer due to lack of evidence of cost-effectiveness

6/9. Therapeutic Assessment – Enfuvirtide (Fuzeon®)

Professor Philip Routledge and Mr Jamie Hayes left the meeting prior to the discussions. The Chairman invited the following to the appraisal table.

Dr Richard Evans, Consultant in Infectious Diseases, Cardiff and Vale NHS Trust representing clinical expertise within NHS Wales.
Ms Carole Farina and Dr John Drake representing Roche Pharmaceuticals

The Chairman introduced and welcomed the guests and Dr Evans confirmed he had no declarations of interest.

Prior to the commencement of the appraisal, the Chairman reiterated that AWMSG guidance is interim to NICE guidance should this be subsequently published. In addition, AWMSG advice has no impact on the licensing status of the technology and the inherent implications associated with this.

Dr Evans was asked to express his views on the use of enfuvirtide (Fuzeon®) in combination with other antiretroviral medicinal products in HIV-1 patients who previously failed on combination regimens containing one or more drugs from the class of protease inhibitors (PI), non-nucleoside reverse transcriptase inhibitors (NNRTI) and nucleoside reverse transcriptase inhibitors (NRT) or patients intolerant to previous anti-retroviral regimens. He confirmed that guidelines have been produced by HIV associations for the use of HIV drugs, including enfuvirtide.

Mrs Karen Samuels gave a brief overview of Enc No **5**/AWMSG/1203 Appendix I and confirmed the paper had been independently compiled using the information contained in Form A or available in the public domain.

Comments were received from the company representatives and the Chairman opened the debate to AWMSG members.

Detailed discussions followed and members expressed concern over the following:

- Patient non-compliance
- Monitoring
- Variation in baseline information / quality of available Welsh data
- Collection and disposal of waste

The Chairman confirmed that AWMSG had been asked to consider whether enfuvirtide (Fuzeon®) should be available for use within NHS Wales for the treatment of patients with HIV-1. Members were asked to vote.

It was agreed (vote: unanimous) that the following recommendation be made to the Minister for Health & Social Services with regard to enfuvirtide (Fuzeon®)

Treatment within NHS Wales should be supported with restrictions.

Restrictions identified included:

- Enfuvirtide (Fuzeon®) should only be available to physicians in secondary care specialising in the management of patients with HIV
- Enfuvirtide (Fuzeon®) must be used in accordance with criteria defined by the

product SPC and the UK British HIV Association (BHIVA) guidelines.

There was an additional request that Roche clarify collection and disposal of medical waste and sharps associated with the use of enfuvirtide.

The patient instructions state that patients should "throw away the syringe into the sharps container". Further instructions for the patient indicate "you should throw away the vial into the dedicated waste container with a lid or return it to the pharmacy". Neither hospital nor community pharmacies have facilities for disposal of used medical waste of this nature and the reference to pharmacy should therefore be corrected.

6/10. Update on Task & Finish Group on Supplementary Prescribing

Mrs Kath Bourne provided an overview of Enc **6**/AWMSG/1203 and asked members to note that the Education sub-group will present the final training package at the Task & Finish Group's December meeting. Mrs Bourne confirmed that an implementation sub-group would be formed to address specific issues such as the clinical management plan and prescribing in a hospital environment. It is anticipated that Trusts / LHBs would be asked to submit applications at the end of December, early January. Several areas of concern were noted

- Communication (needs to be consistent)
- Targeting (not to be restrictive)
- Willingness and resource implications of independent prescribers contributing to training
- Background of candidate
- Need to monitor implementation for early identification of models of good supplementary prescribing practice
- Impact of releasing individuals from their work base.

The Group were reassured that the T&FG were working to minimize the impact of these areas of concern. Minutes of meetings of the Task & Finish Group on Supplementary Prescribing and all relevant documentation is posted on the AWMSG website. All website enquiries will be directed to Ann Hinchliffe.

6/11. Update on NHS Industry Forum (NHSIF)

Mr David Morgan presented an overview of Enc **7**/AWMSG/1203 and the attached work programme. He confirmed that the NHSIF had responded to the consultation paper on new arrangements for the supply of generic medicines. The vacancy for a lay member remains. Attention was drawn to the disappointment of the Forum that Welsh Assembly Government were progressing with costed models for central procurement. Mrs Poulter confirmed that the Welsh Procurement Initiative Team would be undertaking this work and this was consistent with the advice received by AWMSG.

6/12. Update on All Wales Prescribing Advisory Group (AWPAG)

Dr Thomas Lau presented an overview of Enc **8**/AWMSG/1203 and confirmed that the inaugural meeting of AWPAG had been held on 22nd October 2003. The Group were asked to confirm whether or not AWPAG might explore the issue of an All-Wales Advisory Drug List incorporating key principles for local adoption/adaption. It was generally agreed there was likely to be some commonality between such formularies and there was a need to draw together a non-mandatory advisory drug list. The Chairman confirmed that AWMSG was happy to support the work of AWPAG in drawing together this information and compiling a core list.

AWMSG was asked to consider broadening the criteria for therapeutic drug assessments to consider high volume low cost drugs. The general feeling was that if this development was supported across NHS Wales it should be explored further. It was noted, however, that there were resource implications of such a development.

The Chairman reported that an invitation had been extended to the Chairman of the Scottish Medicines Consortium to attend a meeting in Wales in March 2004 to discuss their mode of operation.

AWPAG sought permission to develop and produce both high and low level indicators for 2004/05. After discussion the Chairman confirmed that AWPAG would be tasked with developing high level indicators for may 2005/06 and these needed to be agreed by June 2004 in preparation for the next SAFF round. High level indicators could be developed by AWPAG for 2005/06.

Dr Lau acknowledged the importance of the pharmaceutical industry in Wales, but confirmed that discussions within AWPAG on the Code of Conduct / Sponsorship paper had revealed tensions with the work of NHSIF on this issue.

The Chairman confirmed that AWMSG was happy to support AWPAG in exploring the need within NHS Wales for national advice or guidelines on the prescribing of antiplatelet drugs. This work should take cognisance of that currently been undertaken by WMP and WeMeReC.

6/13. Ethical standards for the NHS in Wales. Guidance for partnership working between the NHS and the pharmaceutical industry in Wales

Mr David Morgan presented an overview of Enc **9**/AWMSG/1203 and confirmed that the paper had not been drafted by the NHSIF but an employee of Welsh Assembly Government. As Chairman of NHSIF, he confirmed he would continue to ensure fairness in the development of this document. Members were informed that comments received from AWPAG had been welcomed and would be incorporated into the re-draft where appropriate. Mr Morgan confirmed that he and Dr Richard Greville, Vice Chairman NHSIF, had considered each comment individually and would respond in writing to AWPAG. It was noted this is not a mandatory document, but promotes good practice within NHS Wales.

The Chairman opened this item for discussion amongst the Group. Several comments were noted:

- Requirement to reformat document to make it reader-friendly
- Reference sources to be included
- Professional bodies need be identified correctly
- Legal advice from NHS and WAG to be sought before and after the open consultation
- Essential information to be presented as bullet points
- Reconsideration of exemplars
- Reference to GMS contract needs to be more specific

It was agreed that the paper should be redrafted for consideration at the January 2004 meetings of AWPAG and NHSIF.

6/14. Prescribing patterns CVS (for information)

Mrs Samuels presented an overview of Enc **10**/AWMSG/1203 and asked the Group to consider the proposal to develop an all-Wales statin prescribing policy template and audit tool via AWPAG for local medicines and therapeutic committees to tailor and implement. The Group was also asked to consider the proposal to develop an all-Wales guidance for antiplatelet prescribing and audit tool using the initiatives already underway in Wales via AWPAG and promote a distance learning module for prescribers in Wales to encourage evidence-based prescribing of antiplatelet drugs. Following discussion, the Chairman confirmed that AWMSG was happy to agree to AWPAG undertaking the proposed work and looked forward to receiving the various papers for approval in due course.

6/15. Update on the Medusa Project (for information)
The Chairman asked the Group to note progress with this initiative and its potential as a valuable source of information of secondary care prescribing data.

6/16. Taskforce on Medicines Partnership (for information)
The Chairman requested that members note the work of the Medicines Partnership.

Date of next meeting.
The next meeting will be held in Wrexham on Tuesday, 2nd March 2004. Details will be posted on the website.