ALL WALES MEDICINES STRATEGY GROUP

DRAFT MINUTES OF THE AWMSG MEETING HELD ON MONDAY, 2ND OCTOBER 2006 COMMENCING 10.30 AM AT THE BRYN HOWEL HOTEL, TREVOR, LLANGOLLEN, DENBIGHSHIRE LL20 7UW

MEMBERS PRESENT:

1.	Dr Paul Buss	Consultant Physician Gwent Healthcare Trust	
2.	Dr Robert Bracchi	General Practitioner & Prescribing Lead, Abergavenny	
3.	Dr Fraser Campbell	LHB Medical Director Gwynedd LHB	
4.	Mrs Debbie Davies	Other healthcare professionals eligible to prescribe Nurse Prescriber, Gwent Healthcare Trust	
5.	Dr Brian Hawkins	LHB Pharmacist Rhondda Cynon Taf	
6.	Mr Peter Harsant	Industry Representative	
7.	Dr Dyfrig Hughes	Health Economist, Centre for the Economics of Health, University of Wales Bangor	**For item 6**
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 in Health Economics, School of Health Science, University of Wales Swansea	
11.	Prof Philip Routledge	Professor of Clinical Pharmacology, Cardiff University and Acting AWMSG Chairman	
12.	Mr Dave Roberts	Chief Pharmacist Cardiff and Vale NHS Trust	

IN ATTENDANCE:

13.	Mrs Ruth Lang	Liaison Manager, Welsh Medicines Partnership
14.	Mrs Carolyn Poulter	Head of the Pharmaceutical Services Branch Welsh Assembly Government
15.	Mrs Karen Samuels	Programme Manager, Welsh Medicines Partnership

List of Abbreviations:

ABPI	Association of the British Pharmaceutical Industry
ASPB	Assembly Sponsored Public Body
AWMSG	All Wales Medicines Strategy Group
AWDAC	All Wales Dietetic Advisory Committee
AWPAG	All Wales Prescribing Advisory Group
CMO	Chief Medical Officer
CSCG	Cancer Services Co-ordinating Group
DTB	Drug & Therapeutics Bulletin
HCW	Health Commission Wales
HIW	Health Inspectorate 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 of Clinical Excellence
NPHS	National Public Health Service
NSCAG	National Specialist Commissioning Advisory Group
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
WMIC	Welsh Medicines Information Centre
WMP	Welsh Medicines Partnership

17/1 Welcome, introductions and personalia

The Chairman opened the meeting, welcomed those present and confirmed that the quorum for meetings had been met. A welcome was extended to the deputy members, Mrs Debbie Davies (representing Mr Jeff Evans), and Dr Robert Bracchi (representing Dr Tom Lau)

The Chairman informed members that following the June meeting Dr Paul Buss had tendered his resignation as acting chairman of AWMSG and had resumed his role as NHS consultant representative and AWMSG/AWPAG link member. Professor Routledge thanked Dr Buss on behalf of AWMSG and WMP for his leadership and commitment to the role. Professor Routledge confirmed that he has agreed to be acting Chairman until the outcome of the Welsh Assembly Government Consultation on the proposal to place the Statutory Health Professional Advisory Committees with the Wales Centre for Health.

The Chairman congratulated Dr Dyfrig Hughes on his recent appointment to the National Institute of Health and Clinical Excellence's appraisal committee.

17/2 Apologies

Mr Jeff Evans, representing other professions eligible to prescribe
Dr David Gozzard, Medical Director, Conwy & Denbighshire NHS Trust
Dr Thomas Lau, GP with prescribing lead representative
Mr Robert Holcombe, Finance Director representative
Mrs Wendy Warren, Nurse Director
Miss Carwen Wynne-Howells, Chief Pharmaceutical Adviser, Welsh Assembly Government (non voting member)

17/3 Declarations of interest

The Chairman asked members to declare any specific declarations of interest. There were none.

17/4 Minutes of previous meeting

The minutes were checked for accuracy and no changes were made.

Matters arising

14/3 The Chairman confirmed that the AWMSG Steering Committee had noted the recommendations of NHSIF in relation to the House of Commons Health Committee Report on 'The influence of the Pharmaceutical Industry'. The Chairman informed members that the chairs of AWMSG sub-groups will be invited to attend future Steering Committee meetings to improve communication links.

16/6 Mrs Poulter confirmed that following the appraisal of Adalimumab®, HSW had agreed to set up a registry of the drug. Mrs Poulter had informed Dr Sharon Jones of the appropriate contact in HSW but no progress had been made to date.
ACTION – Mrs Poulter to contact Dr Sharon Jones with regard to progressing the setting up of the registry

16/8 Mrs Samuels confirmed that WMP had been awaiting confirmation from WAG in relation to their preferred method of dissemination of the information relating to the prescribing of sip feeds. Mrs Poulter confirmed that the preferred route would be electronic distribution via WMP. Mr Roberts confirmed that he had raised the issue of hospital pharmacists taking responsibility for checking that drug charts had been correctly annotated, and reported the unanimous view of the Chief Pharmacists had been that sip feeds should be written up by the dietitian on the hospital drug chart and endorsed RD (registered dietitian) with no involvement from the hospital pharmacists.
ACTION – WMP to electronically disseminate the information relating to the prescribing of sip feeds

16/2 Dr Hawkins conveyed the disappointment of his HoPMM colleagues at the lack of primary care pharmacist input into the prescribing strategy working groups. Mrs Samuels confirmed that the draft prescribing strategy document would be taken to the two sub-groups for further discussion at their meetings later this month before being presented to AWMSG at a future meeting. It is envisaged that sub-group members will take on the role of link between AWMSG sub-groups and their professional colleagues thus providing opportunity for consultation.

17/5 Chairman's report

Update on broadening the appraisal process:
Mrs Samuels reported that WMP had been formally notified by WAG that their bid to extend the appraisal of medications to include cardiovascular and cancer therapies had been successful. Mrs Poulter confirmed that the Minister for Health & Social Services had agreed to issue a WHC to explain the enhanced process and the responsibilities expected of the NHS. A communication strategy will be developed between AWMSG, the NHS. media and public in order to explain the new process and manage expectations associated with the enhanced appraisal process. Mrs Poulter reported that WMP members will be invited to speak at a future Health & Social Services Committee to explain the changes to the appraisal process. The Chairman confirmed that a discussion paper will be brought to a future AWMSG meeting to allow members opportunity to have input into the proposed changes.

It was reported that Mrs Karen Samuels and Mrs Ruth Lang had met with colleagues in SMC to discuss process issues. The Chairman confirmed that WAG will provide £140,000 to support the broadening of the appraisal process.

The Chairman confirmed that the next AWMSG meeting will be held on 5th December 2006 at The Orangery, Margam Park, Port Talbot. The appraisal of vinorelbine oral (Navelbine®) and sorafenib (Nexavar®) will take place at the March 2007 meeting. Iloprost trometamol (Ventavis®) will be appraised at this meeting. The following appraisals are scheduled:

Appraisal 1: vinorelbine oral (Navelbine® oral)
Manufacturer: Pierre Fabre Ltd
Indication: Treatment of patients with primary pulmonary hypertension, classified as NYHA functional class II, to improve exercise capacity and symptoms.
Scope: An assessment of the cost and clinical effectiveness of vinorelbine oral (Navelbine® oral) in relation to its licensed indication and the place of vinorelbine oral (Navelbine® oral) in relation to current treatment strategies available in NHS Wales.

Appraisal 2: sorafenib (Nexavar®)
Company: Bayer Healthcare
Indication: Treatment of renal cell cancer in patients who have failed prior interferon-alpha or IL-2 based therapy or are considered unsuitable for such therapy.
Scope: An assessment of the cost and clinical effectiveness of sorafenib (Nexavar®) in relation to its licensed indication and the place of sorafenib (Nexavar®) in relation to current treatment strategies available in NHS Wales.

17/6

Appraisal – alglucosidase alfa (Myozyme™)

(Start time 11.30 am)

Professor Routledge announced the start of the appraisal and reminded members to declare any interests pertinent to the appraisal. There were no declarations of interest from any of the Group eligible to vote.

The Chairman welcomed the independent medical expert, Dr Graham Shortland, Consultant Paediatrician at the University Hospital of Wales, with a special interest in metabolic diseases, who had been nominated to provide an expert opinion in relation to alglucosidase alfa (Myozyme™). The Chairman asked Dr Shortland if he any declarations of interest in relation to Genzyme and Dr Shortland confirmed that he had received assistance to independently attend a medical conference three years ago.

The Chairman extended a welcome to Mr Khazal Paradis, Senior Vice President, Clinical Research Europe and Dr Gillies O'Bryan-Tear, Medical Director for the UK & Ireland for Genzyme Limited.

The Chairman introduced the WMP appraisal team:
Dr C Krishna, Consultant Clinical Pharmacologist in Cardiff and Vale NHS Trust, Mrs Gail Woodland, Senior Pharmacist, Welsh Medicines Partnership and Professor Ceri Phillips, Professor in Health Economics, School of Health Science, University of Wales Swansea.

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 to fund accordingly. He confirmed the sequence of events and invited Dr Krishna to present a clinical overview of the WMP assessment report.

Dr Krishna outlined the purpose and scope of the appraisal and summarised the salient points of the clinical aspect of the WMP assessment report (detailed in the WMP assessment report Enc 2/AWMSG/1006).

Mrs Gail Woodland provided an overview of the trials relevant to the submission (detailed in Enc 2/AWMSG/0606). Professor Ceri Phillips summarised the health economic aspect of the WMP assessment report and asked members to note the appendix.

The Chairman invited Dr Shortland to address the Committee and set the clinical scene. Dr Shortland confirmed there is very limited therapy available for patients with Pompe Disease and that enzyme replacement therapy had been proven to be a revolution in the management of such patients. Dr Shortland advised of the need for close supervision, support and reassessment of patients in terms of weight, clinical progress and potential dosage reductions.

Councillor Meurig Hughes was invited by the Chairman to present salient points of the patient interest group submission to the Committee.

The Company representatives were invited to clarify any issues in relation to the WMP assessment report and highlight any salient points of the company submission.

The Chairman confirmed that AWMSG members are only able to assess the evidence provided to the Committee. It was noted that ultra orphan drugs may need to be dealt with by different cost-effectiveness criteria.

The Chairman opened the discussion and provided members with the opportunity to clarify any issues with the company representatives, WMP appraisal team and medical expert. Discussion was structured around clinical effectiveness, then cost-effectiveness.

There was discussion around survival times, the safety of infusions, clarification of initial treatment, patients' willingness to travel in order to receive treatment, infrastructure requirements, clarification of what constitutes a juvenile, insufficient data in late onset patients and patient registries. It was confirmed that this drug is not suitable for shared care.

The Chairman invited Dr Geoffrey Carrol, Medical Director of HCW to address the group from the audience. Dr Carrol confirmed there are special commissioning arrangements for enzyme replacement therapies and informed members that HCW had a rule that HCW would not provide funding until AWMSG had made their recommendation to the Minister for Health & Social Services on the use of the therapy within NHS Wales.

The Chairman closed proceedings at 1.00 pm and voting members retired to meet in camera.

The meeting re-convened at 2.03pm

The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion AWMSG had come to the following decision.

It was agreed (by majority) that the recommendation to the Minister for Health & Social Services with regard to alglucosidase alfa (Myozyme™) is that alglucosidase alfa (Myozyme™) should be endorsed within NHS Wales for the treatment of Pompe disease in accordance with the licensed indication but with the specific restriction.

That there is presently insufficient evidence of clinical effectiveness in late-onset disease and AWMSG does not endorse its use in this group of patients at this stage.

AWMSG recommends that:

1. Patients receiving alglucosidase alfa (Myozyme™) will be entered into the Pompe registry.

2. Treatment will be administered under the supervision of a physician experienced in the management of Pompe disease or other neuromuscular disorders.

3. Treatment will be administered according to agreed guidelines at appropriate centres.

4. The AWMSG recommendation will be reviewed in light of further evidence becoming available.

The appraisal was concluded.

Post meeting note of clarification:
AWMSG endorsed the use of alglucosidase alfa (Myozyme™), but with the specific exclusion of alglucosidase alfa (Myozyme™) in Late-onset Pompe disease of the Adult Onset form (Adult Onset disease) because of insufficient evidence of clinical effectiveness. The Committee was however persuaded that alglucosidase alfa (Myozyme™) should be available for the treatment of Late Onset Pompe disease of the Juvenile Onset form (Juvenile Onset Disease).

17/7 Appraisal – algalsidase beta (Fabrazyme®)

(Start time 2.05 pm)

The Chairman opened the proceedings and reminded members to declare any interests pertinent to the appraisal. There were no declarations of interest from any of the Group eligible to vote.

The Chairman thanked Dr Graham Shortland for agreeing to undertake the role of

independent medical expert for this second appraisal. Dr Shortland reintroduced himself and confirmed he had received assistance to independently attend a medical conference three years ago.

The Chairman extended a welcome to Dr Huub Houben, Director Global Medical Programmes and Dr Gillies O'Bryan-Tear, Medical Director for the UK & Ireland for Genzyme Limited.

The Chairman introduced the WMP appraisal team:
Dr Alison Thomas, Locum Senior Lecturer in Clinical Pharmacology at Cardiff University, Mrs Gail Woodland, Senior Pharmacist, Welsh Medicines Partnership and Dr Dyfrig Hughes, Health Economist, Centre for the Economics of Health, University of Wales Bangor.

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, places an obligation on Trusts and LHBs to fund accordingly. He then invited Dr Thomas to address the Group.

Dr Thomas outlined the purpose and scope of the appraisal and summarised the salient points of the clinical aspect of the WMP assessment report (detailed in the WMP assessment report Enc 3/AWMSG/1006). Mrs Gail Woodland provided a brief overview of the trials relevant to the submission (detailed in Enc 3/AWMSG/0606).

Dr Hughes summarised the health economic aspect of the WMP assessment report (detailed in Enc 2/AWMSG/0606).

Dr Shortland set the clinical scene and provided members with a description of some of the symptoms of the disease. In addition, Dr Shortland addressed lifestyle issues and other treatments required to relieve symptoms of pain.

The Chairman invited Mrs Debbie Davies to present the patient interest perspective. Mrs Davies confirmed that the patient interest group did not wish to submit any further information other than that already provided in their submission which had been circulated to voting members prior to the meeting.

The Chairman invited Dr Houben and Dr O'Bryan-Tear to address the group and asked if they wished to clarify any issues or comment on the WMP assessment report.

The Chairman invited members to clarify any issues with the company representatives, WMP appraisal team and medical expert. The Chairman asked for questions to be structured around those relating to the issues of clinical effectiveness, then cost effectiveness. It was noted that ultra orphan drugs may need to be appraised using different cost-effectiveness criteria to standard appraisals.

There was discussion over NSCAG guidelines with regard to treatment in specialist centres, monitoring, the difference in estimates of UK prevalence, rationale behind decision to treat fortnightly, information regarding for children, the lack of evidence in certain groups of patients, and morbidity and variance of the disease. It was confirmed that this drug is not suitable for shared care.

The Chairman asked AWMSG members, the WMP appraisal team, Dr Shortland and the company representatives if they wished to raise any other issues for discussion.

The Chairman closed proceedings and voting members retired to meet in camera at 3.02pm.

The meeting re-convened at 3.40 pm.

The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion AWMSG had come to the following decision.

It was agreed (by majority) that the recommendation to the Minister for Health & Social Services with regard to algalsidase beta (Fabrazyme®) is that algalsidase beta (Fabrazyme®) should be endorsed within NHS Wales for the treatment of Fabry disease in accordance with the licensed indication with the following restrictions:

AWMSG recommends that:

1. Patients receiving algalsidase beta (Fabrazyme®) will be entered into the Fabry registry.

2. Treatment will be administered under the supervision of a physician experienced in the management of Fabry disease or other inherited metabolic diseases.

3. Treatment will be administered according to agreed guidelines at appropriate centres.

The Chairman confirmed that the use of the drug will be governed by the guidelines agreed and that AWMSG will re-visit the issue of orphan-drugs at a future meeting.

The Chairman reiterated that the AWMSG recommendation in relation to alglucosidase alfa (Myozyme™) and algalsidase beta (Fabrazyme®) will require the ratification of the Minister for Health & Social Services and confirmed that the company have 28 days in which to lodge an appeal, which should be made in writing to the Chairman via the WMP office.

The representatives of Genzyme expressed their thanks and reserved their right to appeal.

The appraisal was concluded.

17/8 Update on independent prescribing

The Chairman asked members to note the report submitted for information.

17/9 Report on AWPAG

The Chairman invited Mrs John to present and overview of the AWPAG meeting held in July 2007. Mrs John confirmed that AWPAG welcomed working with WMP to progress the prescribing strategy. She asked members to note that the Consensus Group on Diabetes had recently issued guidelines. However, the advice on glucose testing had not been included in the document. Mrs John reported that constructive dialogue with Welsh Assembly Government in relation to multi-compartment compliance aids had resulted in the setting up of a meeting in early December to progress this issue. Mrs John confirmed that the views of AWMSG in relation to the national prescribing indicators for 2007/2008 had been considered by AWPAG and that Enc 5 Appendix 1 had been amended to take those views into account. Mrs John reported that further work will be undertaken in relation to the generic prescribing indicator and a new target will be agreed for the following year, 2008/2009. Mrs John informed members that targets had been defined to

ensure a process of encouragement to prescribe towards best practice and the statin indicator had now been included in the document.

The Chairman confirmed that AWMSG endorsed the paper with the above amendments.

The Chairman confirmed he had been invited to attend the Cardiac Reference Group to discuss the updating of the statin template. Mrs John requested administrative and professional support to develop the evidence base and costing information in relation to the AWPAG prescribing reviews. The Chairman invited comment and confirmed that this will be raised at a future AWMSG steering committee. Mrs John reported the on-going work in relation to shared care and there was brief discussion over potential savings in relation to central purchasing of erythropoeitins. It was noted that this could be identified as an issue for the future, although the shared care of tobramycin and dornase alpha had been considered the first priority.

17/10 Report on NHSIF

The Chairman invited Mr David Morgan to present an overview of the NHSIF meeting held in July 2006.

Mr Morgan confirmed that the issue of dissemination and processing of the partnership working questionnaires had now been resolved. Mr Morgan expressed concern that the information requested from HCW in relation to the MS risk sharing scheme had not been made available. Mr Morgan asked members to note the unanimous recommendation of NHSIF that AWMSG should retain its status and remain outside the Wales Centre for Health. Mrs Poulter confirmed that the results of this Welsh Assembly Government consultation should be publicly available and that options on the way forward had been presented to the Minister for Health & Social Services.

Dates of future AWMSG meetings:

Tuesday, 5th December 2006 in Cardiff
Wednesday, 14th March 2007 in Port Talbot