ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF MEETING HELD THURSDAY, 2ND MARCH 2006 COMMENCING 10.30 AM AT THE ORANGERY, MARGAM PARK NEATH, PORT TALBOT, SA13 2TJ

MEMBERS PRESENT:

1.	Dr Paul Buss	Acting Chairman Consultant Paediatrician Gwent Healthcare Trust	
2.	Dr Fraser Campbell	LHB Medical Director Gwynedd LHB	
3.	Mr Jeff Evans	Other healthcare professionals eligible to prescribe Senior Lecturer in Podiatry & Podiatric Surgeon, Wales Centre for Podiatric Studies, UWIC, Cardiff.	
4.	Mr Peter Harsant	Industry Representative	
5.	Dr Brian Hawkins	LHB Pharmacist Rhondda Cynon Taff	
6.	Mr Robert Holcombe	LHB Finance Director Blaenau Gwent LHB	
7.	Dr Dyfrig Hughes	Health Economist, Centre for the Economics of Health, University of Wales Bangor	**For item 7&9**
8.	Dr Chris James	Consultant Physician Withybush General Hospital	
9.	Dr Thomas Lau	LHB Prescribing Lead Newport, Gwent	
10.	Mr David Morgan	Consultant in Pharmaceutical Public Health National Public Health Service, North Wales Region	
11.	Prof Ceri Phillips	Professor in Health Economics, School of Health Science, University of Wales Swansea	
12.	Mr Dave Roberts	Chief Pharmacist Cardiff and Vale NHS Trust	
13.	Mrs Wendy Warren	Nurse Director Gwent Healthcare NHS Trust	

IN ATTENDANCE:

14.	Mrs Ruth Lang	Liaison Manager, Welsh Medicines Partnership
15.	Mrs Karen Morgan	Pharmaceutical Services Branch Welsh Assembly Government
16.	Professor Philip Routledge	Medical Director, Welsh Medicines Partnership
17.	Mrs Karen Samuels	Programme Manager, Welsh Medicines Partnership
18.	Mrs Fiona Woods	Director WMIC, Welsh Medicines Partnership

List of Abbreviations:

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
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
NHSIF	NHS Industry Forum
NICE	National Institute of Clinical Excellence
NPHS	National Public Health Service
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

Action

15/1 Welcome and introduction
The Chairman welcomed those present. He then reported that Professor Roger Walker had resigned as Chairman and that he had taken on the role of Acting Chairman from 1st January 2006. He invited members to introduce themselves.

15/2 Apologies
Councillor Meurig Hughes, Lay member
Dr David Gozzard, Medical Director, Conwy & Denbighshire NHS Trust

14/3 Declarations of interest
There were no declarations of interest pertaining to the agenda.

14/4 Minutes of previous meeting
Page 9 – omission of the letter m in paragraph three
Page 9 – Ms Ffion Johnson to be changed to Ms Ffion Johnstone
Page 10 – Feedback on incentive scheme (n= numbers should be added)

14/5 Matters arising

13/14 Sip feeds
Mrs Samuels reported that WMP are in the process of receiving nominations for the sip feeds working group. She confirmed that the NICE guidance had recently been issued and the working group would focus on the areas not covered by this guidance.

10/17 Broadening the AWMSG appraisal process
Professor Routledge reported that a meeting arranged between AWMSG/WMP, NICE and the SMC scheduled for 24th February 2006 had been postponed. Professor Routledge confirmed he will be meeting with Professor David Webb of SMC next week to discuss how AWMSG might work with SMC in relation to assessments of new medicines.

12/11 Prescribing publications
Mrs Wendy Warren reported that the Nurse Executive Wales Group meeting had addressed the demand for the Nurse BNF and it was agreed there was no requirement for this publication at the present time provided that nurse prescribers receive a copy of the BNF. Individual requests would be considered on an *ad hoc* basis.

Mrs Samuels reported that WMP had commissioned a cost-assessment of prescribing publications but that no definitive timetable had been agreed.

13/6 Chairman's report – CMO's newsletter
Mrs Lang reported that she had contacted Welsh Assembly Government to request that AWMSG and WMP be added to the circulation list for the Chief Medical Officers newsletter. Mrs Lang confirmed she had forwarded the minutes of the AWMSG December meeting to the publication office so that they could extract the requisite information for inclusion in the next edition.

14/6 Acting Chairman's report

National prescribing indicators
Dr Buss informed the Group that the current national indicators will remain for 2006/2007. He called for constructive thought on how AWMSG might tailor the indicators to improve medicines management across Wales. Dr Buss reported that he had written to the Chair of AWPAG, Mrs Nicola John, to ensure that the indicator working group considers their significant change for 2007/2008 and bring a paper to the AWMSG June meeting for discussion so that the revised national indicators can be signed off at the AWMSG September 2006 meeting. Members agreed that AWMSG need to send a strong message across NHS Wales to encourage the reduction of co-proxamol prescribing to zero.

Trastuzumab (Herceptin®)
Dr Buss reported that the working group had developed the information note on Trastuzumab and had forwarded the updated document to the Minister. Dr Buss confirmed that the information note is intended to assist with the planning for the future introduction of Herceptin should a licence be forthcoming and following a positive recommendation from NICE. Dr Buss informed members that the revised information had been posted on the AWMSG website.

Cytarabine (Depocyte®)
Dr Buss reported that following Ministerial endorsement of the AWMSG recommendation not to approve the use of cytarabine (Depocyte®) for use within NHS Wales, a statement was disseminated to the Service and posted on the AWMSG website.

Clopidogrel audit
Dr Buss confirmed that the audit template had been posted on the AWMSG website (located under the section communication documents / national prescribing incentive scheme).

Meeting of the All Party Group on Cancer Medications
Dr Buss reported that he had attended the above meeting on Tuesday, 28th February 2006 and had received encouragement from Welsh Assembly Government officials with regard to AWMSG's role in ensuring timely advice is made available in relation to cancer drugs. Dr Buss informed members that Professor Peter Littlejohns from NICE had been in attendance and there had been an interesting discussion on collaboration with NICE, whilst maintaining a Welsh dimension. He encouraged AWMSG to rise to the challenge.

AWMSG June Appraisal
Dr Buss announced the following appraisal will be held in June 2006:

Drug: Adalimumab (Humira®)
Company: Abbott Laboratories
Indication: For the treatment of active and progressive psoriatic arthritis in adults when the response for previous disease-modifying anti-rheumatic drug therapy has been inadequate.
Scope: The assessment of the clinical and cost effectiveness of adalimumab (Humira®) in relation to its licensed indications and the place of adalimumab (Humira®) in relation to current treatment strategies available in NHS Wales.

14/7 Appraisal – Mycophenolic acid as the sodium salt (Myfortic®)

(Start time 10.57 am)

Dr Buss requested that any WMP members who may be involved in any appeal in relation to the appraisal should leave the room. The WMP appraisal team joined members at the table.

Dr Buss reminded members to declare any interests pertinent to the appraisal. There were none.

Dr Buss welcomed the medical expert, Dr Kieron Donovan, Consultant Nephrologist at the University Hospital of Wales who had been nominated to attend by the Chair of the Welsh Association of Renal Physicians and Surgeons.

Dr Buss extended a welcome to Dr Derek Wallace, Senior Medical Advisor of Novartis Pharmaceuticals.

Dr John Thompson introduced the WMP appraisal team:
Dr John Thompson, Senior Lecturer in Clinical Pharmacology at Cardiff University.

Mrs Gail Woodland, Senior Pharmacist, Welsh Medicines Partnership
Dr Dyfrig Hughes, Lecturer at the Centre for the Economics of Health, University of Wales, Bangor.

Dr Buss 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 Trust and LHBs to fund accordingly. He then invited Dr John Thompson to address the Group.

Dr Thompson outlined the purpose and scope of the appraisal and summarized the salient points of the clinical aspect of the WMP assessment report (detailed in the WMP assessment report Enc 2/AWMSG/0306). Mrs Gail Woodland provided an overview of the trials on which the company based their submission (detailed in Enc 2/AWMSG/0306). Dr Dyfrig Hughes summarized the health economic aspect of the WMP assessment report and reiterated that based on the results of the data the opinion of the WMP appraisal team is that mycophenolate sodium (Myfortic®) is not cost effective.

Dr Buss asked members if they wished to clarify any aspects of the WMP assessment report. No clarification was sought and he invited Dr Donovan to set the clinical scene.

Dr Donovan said that the believed the WMP assessment report provided a fair and accurate reflection of mycophenolate sodium (Myfortic®) and proceeded to put the cost of the drug into context in relation to the annual spend on transplantation services in NHS Wales. Members were informed of the importance of preserving the length of transplantation and the increasing trend to support transplantation in NHS Wales. He confirmed that the current treatment options do not suit all patients, and that he would wish to try an alternative, if it was available, for use in a small number of patients who cannot tolerate current therapy.

Dr Donovan confirmed he had no declarations of interests in relation to Novartis Pharmaceuticals.

Dr Buss invited Dr Derek Wallace to address the Group.

Dr Wallace commented that he felt the WMP assessment report provided a fair and accurate reflection of the mycophenolage sodium (Myfortic®). Dr Wallace stated that the enteric coating improves the tolerability of the drug and highlighted the improvement in patient quality of life due to the reduction in symptom burden. Dr Wallace highlighted salient points in relation to the available trial data (contained in Form B company submission).

Dr Buss opened the discussion to AWMSG members.

Members discussed the adverse reactions to current therapy, tolerability and the impact on the patients' quality of life. Criteria for switching therapies were discussed.

Dr Buss closed proceedings and voting members retired to meet in camera at 11.50 am. The meeting re-convened at 12.00 noon.

Dr Buss 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 (unanimous) that the recommendation to the Minister for Health & Social Services with regard to mycophenolate sodium (Myfortic®) is that AWMSG would support the use of mycophenolate sodium (Myfortic®) within NHS Wales for the prophylaxis (in combination with ciclosporin and corticosteroids) of acute rejection in adults receiving allogenic renal transplants, and who are intolerant of mycophenolate mofetil. Its use should be under the supervision of a nephrologist.

Dr Buss reiterated that the AWMSG recommendation will require the ratification of the Minister 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.

Dr Buss concluded by thanking Dr Donovan for his presentation to the Group and Novartis Pharmaceuticals for engaging with the AWMSG process.

The appraisal was concluded and the WMP appraisal team retired from the meeting.

14/8 Cost sharing schemes – the principle

Professor Philip Routledge provided an overview of Enc No 3/AWMSG/0306 and asked whether risk sharing schemes may have merit as part of the managed entry of new medicines into NHS Wales. Members were asked to comment on the existing evidence-base for this approach and whether any proposals where risk-sharing might be offered in association with medicines appraised by AWMSG should be considered, when appropriate, as part of AWMSG's appraisal process.

Dr Buss opened this up for discussion. Mr Peter Harsant confirmed that the industry regard the schemes with interest, but that such schemes would require careful consideration of the parameters and monitoring. Some members felt that such schemes may have potential merits to commissioners and industry. However, other members noted the increasing complexity of monitoring, and it was felt that consistent outcome measures would be difficult to achieve. Other comments included:

Administration and monitoring too costly
Difficulties in managing such schemes
Infrastructure not in place to collect full and accurate data
Need to ensure consistency in approach
Difficult to measure QALYs If risk-sharing were used
A practical alternative might be to extend trials within practice
Industry should pick up the cost of monitoring
Implications on patient perspective
This should be a UK-wide issue not solely a Welsh issue
Welsh Assembly Government may have a view – is there a political dimension?
Should seek views of SMC and NICE
Concern over real costs not just drug costs
Schemes should be introduced with high-cost, low-volume drugs

Schemes should not be the norm – and only have a place where cost-effectiveness is unproven
Sub-groups may wish to comment
The Service should work more closely with industry

Dr Buss closed the discussion and confirmed that a summary of the comments will be considered by the AWMSG Steering Committee and a steer will be sought on how to take this issue forward to develop consistency and equity in relation to the appraisal of new medicines in NHS Wales. Dr Buss announced that an information package will be sent to each member within fourteen days and an informed response should expeditiously be returned to him within twenty one days from the meeting. **AWMSGSC**

14/9 Appraisal – Cetuximab (Erbitux®)

(Start time 2.00 pm)

Dr Buss requested that any WMP members who may be involved in any appeal in relation to the appraisal should leave the room. The WMP appraisal team joined members at the table.

Dr Buss reminded members to declare any interests pertinent to the appraisal. There were none. Members introduced themselves to the visitors.

Dr Buss welcomed the medical expert, Professor Tim Maughan, Clinical Oncologist at Velindre Hospital Cardiff who had been nominated by the Chairman of the South East Wales Cancer Network. Professor Maughan confirmed that he had collaborated with Merck Pharmaceuticals in evaluating cetuximab and had attended lectures financed by the company. He is the UKs Chief Investigator in the evaluation of cetuximab.

Dr Buss extended a welcome to Dr Maya Morris, Medical Director and Mr Jeremy White, Market Development Manager of Merck Pharmaceuticals.

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

Dr Thomas outlined the purpose and scope of the appraisal and summarized the salient points of the clinical aspect of the WMP assessment report (detailed in the WMP assessment report Enc 4/AWMSG/0306). Mrs Gail Woodland provided an overview of the trials on which the company based their submission (detailed in Enc 4/AWMSG/0306). Dr Dyfrig Hughes summarized the health economic aspect of the WMP assessment report and reiterated that based on the results of the data the opinion of the WMP appraisal team was that the case for the cost effectiveness of the use of cetuximab (Erbitux®) in NHS Wales has not been made. It was noted that NICE are due to appraise this technology in November 2006. Members were asked to leave the commercial in confidence data provided at the meeting or return it to the WMP office within the next day or so.

Dr Buss asked members if they wished to clarify any aspects of the WMP

assessment report. No clarification was sought and he invited Professor Maughan to set the clinical scene.

Professor Maughan said that the believed the WMP assessment report provided a fair and accurate reflection of cetuximab (Erbitux®) and proceeded to clarify the response rate to cetuximab, which he commented was 55%. Professor Maughan confirmed that it is extremely difficult to assess survival benefit and outlined the inadequacy of current available data. He then discussed EGFR status and adverse reactions to current therapy, and confirmed that treatment with cetuximab would be used in a small number of patients who are in excellent physical condition and where other treatment options have failed. Professor Maughan stated that the drug represents a new mechanism of treatment of action and a CT scan after 6 weeks from commencement of treatment could exclude patients with progressive disease. It was estimated that 50% of patients will fail to respond.

Mr Jeffrey Evans was invited to present the patient's perspective to members and referred to the patient interest group submission from Bowel Cancer UK. He informed members of a patient testimonial – an English lady who reported a twelve month benefit from the therapy.

Dr Buss invited the company representatives to address the Group. Dr Morris commented that it was difficult to interpret survival data and made the point that although there is no ideal data, the license was granted on the data provided. Mr Jeremy Way commented that he felt the WMP assessment report provided a fair and balanced reflection of cetuximab (Erbitux®). Mr Way discussed the issue of utilities. He also pointed out that the literature referred to in the WMP report includes a poster detailing American costs, and felt this was misleading and should not form part of the decision-making process. Mr Way stated that the company would be willing to consider that cetuximab be offered as part of a risk sharing scheme, should AWMSG wish to consider this option.

Prior to opening the discussion, Dr Buss 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 Trust and LHBs to fund accordingly.

Members asked for clarification on the mode and method of EGFR testing. It was confirmed that fitness not age is the critical factor in determining the use of the therapy. Members raised the issue of survival benefit, and Professor Maughan confirmed that, in his opinion, a five month estimate would be reasonable. Other comments included the need for more research in the UK, the emotional need for the patient to have access to the drug, the variation of cost per QUALY, and that the limited dataset and variation in terms of survival rates make it difficult to make a decision. Professor Maughan confirmed that he had prescribed the drug and that the quality of life of the patients who had received the treatment had been variable.

Dr Buss closed proceedings and voting members retired to meet in camera at 3.07 pm. The meeting re-convened at 3.30 pm.

Dr Buss 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 (vote 7-4 with 1 abstention) that the recommendation to the Minister for Health & Social Services with regard to cetuximab (Erbitux®) is that cetuximab, in combination with irinotecan, should be endorsed within NHS Wales, **with specific restrictions applied** for the treatment of EGFR-expressing metastatic colorectal cancer after failure of irinotecan-including cytotoxic therapy. Treatment must only be initiated and administered under the supervision of a physician experienced in the use of chemotherapeutic agents. WMP will set up a working group with the oncologists to agree criteria for the restricted use taking into account the issues discussed during the appraisal.

Dr Buss reiterated that the AWMSG recommendation will require the ratification of the Minister. He then 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.

Dr Buss concluded by thanking Professor Maughan for his presentation to the Group and Merck Pharmaceuticals for engaging with the AWMSG process.

The appraisal was concluded and the WMP appraisal team retired from the meeting.

Post meeting note:

AWMSG's recommendation will not be passed to the Minister for Health & Social Services until the criteria for the restricted usage of cetuximab (Erbitux®) has been agreed by the working group.

14/10 Independent Prescribing

Miss Sian Evans was invited to address the Group in relation to independent prescribing. Miss Evans confirmed that the Minister had announced independent prescribing in January 2006. She outlined the salient points of Enc 5/AWMSG/0306 and asked AWMSG to nominate a representative to be a member of the Task and Finish Group (T&FG) on Independent Prescribing. Mrs Wendy Warren offered to represent AWMSG on the T&FG and report back to the Group. Mrs Ruth Lang offered to post documentation relating to Independent Prescribing on the AWMSG website.

Dr Buss opened the discussion and members sought reassurance that problems relating to the available supply of prescription pads be addressed by the Task & Finish Group as a matter of priority. Also, members asked for information on funding and timetable. Ms Evans reported that the first meeting of the T&FG will be held on 7th Aprill and the timetable will be defined by this group. Ms Evans was not in a position to discuss funding arrangements.

Dr Buss thanked Miss Evans for her report and Mrs Wendy Warren for agreeing to feed back information from the T&FG on a regular basis.

14/11 Patient reporting of adverse drug reactions

Dr Buss invited Professor Philip Routledge to present an overview of Enc 6/AWMSG/0306. Professor Routledge thanked Mrs Jane Houghton, Senior Adverse Drug Reaction Pharmacist at CSM Wales, for her input into the

preparation of the discussion document.

Dr Buss invited members to provide suggestions on how to raise awareness of the importance of reporting adverse drug reactions by all healthcare professional groups and individual patients. The following suggestions were made:-

- Place message on base of repeat prescriptions informing patients of their ability to report
- Introduce a link on clinical IT systems (website prompt by system suppliers)
- Contact postgraduate organizers and ask that a dedicated session on reporting of ADRs be introduced into the training of junior doctors
- Inclusion in one of the public health campaigns as part of the Pharmacy Contract
- Ensure that responsibility to report forms part of nurse training
- Dissemination of information by newsletter by CSM Wales

Dr Buss thanked members for their suggestions and closed the discussion.

14/12 Report from the Medicines Management Collaborative

Mrs Breeda Worthington joined members around the table. The Acting Chairman invited her to give a brief overview of Enc 7/AWMSG/0306. AWMSG members were asked to accept the report and consider what support may be available from/through the group to address the remaining issues of synchronisation and effective discharge communication, whilst supporting the sustaining and further spread of these improvements. Members commented that more detailed information in relation to the health benefit analysis required the consideration of the Group before any suggestions could be forthcoming. Mrs Worthington agreed to provide AWMSG with the published evaluation report when it becomes available.

14/13 Report on the NHS Industry Forum

Mr David Morgan presented an overview of the minutes of the January 2006 meeting of the NHS Industry Forum (Enc 8/AWMSG/0306).

Mr Morgan asked members to note that Dr Richard Greville had been re-elected as Vice-Chairman. Mr Morgan referred members to the minute on page 2 under 'Shortages Group' which stated "a request should be made to Welsh Assembly Government to become involved in ongoing discussions with the Department of Health in relation to handling shortages within the industry". It was reported that examples of partnership working have been posted on the AWMSG website, and the Chairs of the two sub-groups have agreed to exchange minutes in an effort to enhance closer working links. Mr Morgan informed members that a questionnaire on partnership working was being compiled by NHSIF. Mr Morgan reported the comments of NHSIF in relation to the recommendations of the report entitled "The Influence of the Pharmaceutical Industry – House of Commons Health Committee Report recommendation in relation to Wales". It was agreed that the Steering Committee would give the recommendations further consideration.

AWMSG Steering Committee

14/14 Report on the All Wales Prescribing Advisory Group

Dr Buss invited Mrs Nicola John, AWPAG Chair, to join members at the table and present a report of the AWPAG meeting held in January 2006.

Mrs John informed AWMSG that the national indicator in relation to co-proxamol will continue for 2006/2007 as it had been included in the SAFF, but that a process had been established to ensure that the indicators for 2007/2008 will be brought back to AWMSG in a timely fashion.

Mrs John confirmed that the clopidogrel audit had been signed off at the AWPAG meeting and had subsequently been posted on the AWMSG website. It was reported that Welsh Assembly Government had been asked to clarify the legal stance in relation to generic substitution before AWPAG consider any associated wide issues.

Dr Buss closed the proceedings.