

IN ATTENDANCE:

15.	Mr Jamie Hayes	Director, Welsh Medicines Partnership
16.	Mrs Ruth Lang	Liaison Manager, Welsh Medicines Partnership
17.	Mr Paul Parker	Acting Head of the Pharmaceutical Services Branch Welsh Assembly Government
18.	Professor Philip Routledge	Medical Director, Welsh Medicines Partnership
19.	Mrs Karen Samuels	Programme Manager, Welsh Medicines Partnership
20.	Mrs Fiona Woods	Director, 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
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
WMP	Welsh Medicines Partnership

Action

14/1 Welcome and introduction

The Chairman welcomed those present and invited members to introduce themselves. He confirmed that the proceedings are recorded and that, by agreement with members, there will be no simultaneous translation from Welsh to English. The Chairman outlined the intention to deal with the issue of trastuzumab under the Chairman's report as the first agenda item and the appraisal of cytarabine at 2.00 pm.

14/2 Apologies

Dr David Gozzard, Medical Director, Conwy & Denbighshire NHS Trust
Dr Fraser Campbell, Medical Director, Gwynedd LHB

14/3 Declarations of interest

There were no declarations of interest pertaining to the agenda.

14/4 Minutes of previous meeting

Page 4 – omission of the word “of” in the first line of the final paragraph

Page 5 – NHISF to be amended to NHSIF

Page 6 – 13/11 Mr David Morgan commented that the recommendation for a re-audit of prescribing structures in Wales had not been recorded and wording would be provided to WMP outside of the meeting.

Post meeting: the following wording was provided - "The NHSIF recommended that AWMSG re-audit the prescribing structures in Wales. It was agreed that WMP would carry out the audit."

Page 8 – 13/15 Mr Peter Harsant commented that it was not clear that the Task & Finish Group to consider supporting the whole health economy – interface engagement would be the same group that considered the prescribing strategy and agreed to provide the appropriate wording outside of the meeting.

14/5 Matters arising

10/17 Broadening the AWMSG appraisal process

No progress to date.

115 Green Card Scheme

No progress to date.

12/11 Prescribing publications

The Welsh Assembly Government representative confirmed this publication would not be funded within Wales because it was only relevant to the work of extended nurse prescribers, a development not supported in Wales. Mrs Wendy Warren agreed to ascertain the strength of demand for the publication.

WW

WMP reported no progress with regard to the commissioning of a cost-assessment exercise.

WMP

13/6 Chairman's report

WMP agreed to contact Welsh Assembly Government and ensure AWMSG members and WMP are added to the circulation list for the Chief Medical Officers newsletter. It was unclear whether or not the recommendation made by AWMSG in relation to the appraisal of pegvisomant (Somavert®) and bortezomib (Velcade®) had been included in the October/November 2005 newsletter.

WMP

Appraisal of cetuximab (Erbix®) – The Chairman confirmed that the AWMSG Steering Committee had deferred the appraisal of this drug as the company had submitted a cost-sharing programme at a very late stage in the process. Additional time had been required to consider and reflect upon the issues raised. The appraisal has been rescheduled for March 2006.

13/14 Sip feeds

Mrs Karen Samuels reported that feedback from AWDAC to the recommendations contained in the AWMSG paper on sip feeds had been positive. She confirmed that WMP had been in contact with AWDAC with regard to taking forward the recommendations but were seeking clarity from AWMSG in relation to the impending NICE guidance before proceeding. It was agreed that AWMSG support this work and that WMP should proceed with identifying individuals for the joint working group.

WMP

13/18 Draft clinical guidelines from the Cancer Services Co-ordinating Group

Professor Routledge confirmed that WMP had offered to undertake independent literature searches in relation to future guideline generation.

14/6 Chairman's report

The Chairman confirmed that Mr Julian Baker had taken up a new role within a Trust and is, therefore, not eligible to serve as LHB Finance Director. No nomination had been received for a deputy LHB Finance Director at the recent appointment process and as a consequence there was no longer a representative of that body on AWMSG. Mr Paul Parker confirmed that an advertisement for vacant posts on AWMSG would be placed in February/March 2006. The Chairman reported that at the meeting of the Steering Committee on 16th November 2005 Welsh Assembly Government representatives had confirmed it was not their intention to progress with the appointment of a new Chairman until the issues around the status of the group in relation to ASPBs had been resolved.

WAG

Nominations for a Vice Chairman were currently being sought (closing date Monday 12th December with the intention that the person appointed would chair meetings of AWMSG for the following twelve month period.

Professor Walker confirmed he had accepted an appointment to serve on the Commission on Human Medicines.

The Chairman reported he had attended a meeting of the Directors of Finance in November 2005, and in October had run a workshop in Prague with a senior representative of NICE on the technology appraisal processes in England and Wales. The meeting was organised by staff at Charles University and presented to representatives from the Czech health ministry and private health insurance funding bodies.

The Chairman reported that AWMSG Steering Committee meetings had been held in September, October and November and it was anticipated that the second report of AWMSG up to June 2005 will be circulated in early January 2006.

Following the announcement of the new NICE single track appraisal (STA) process the Chairman had made a statement to the service and the AWMSG appraisal programme had been revised accordingly to avoid unnecessary duplication.

The Chairman announced the following appraisals will be held in March 2006:

Drug: Mycophenolic acid as the sodium salt (Myfortic®)

Company: Novartis

Indication: In combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection in adult patients receiving allogeneic renal transplants.

Scope: the appraisal will be confined to considering its use in patients who are intolerant to mycophenolate mofetil.

Drug: Cetuximab (Erbix®)

Company: Merck

Indication: In combination with irinotecan for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer after failure of irinotecan-including cytotoxic therapy.

The Chairman reported that a copy of Napp Pharmaceutical's Form B submission for cytarabine (DepoCyte®) had not been circulated to members ten days prior to the meeting as required by the appraisal process. The Chairman informed members that he had spoken to a representative of Napp Pharmaceuticals (Mr Steve Tuplin) prior to the start of the meeting and asked whether or not the company wished to postpone the appraisal of cytarabine. During the morning recess the company subsequently confirmed their intention to proceed with the appraisal.

Prescribing Conference

Professor Routledge confirmed that Professor Sir Michael Rawlins will be presenting the Memorial Lecture for Felicity Newton-Savage on the evening of Thursday, 19th January. The prescribing conference on Friday, 20th January will consist of presentations (including issues around orphan drugs and GP prescribing leads), discussion forums with the cardiac and cancer networks and demonstrations from HSW of CASPA and MEDUSA. The conference is available to all prescribers.

Trastuzumab (Herceptin®)

The Chairman confirmed that AWMSG had been asked by the Welsh Assembly to provide a response to an information note produced jointly by NPHS and the CSCG to give a consistent view on the managed introduction of trastuzumab within NHS Wales. The Chairman reiterated that this would not be an appraisal, but that AWMSG should consider the issues and provide advice to the Minister.

The following individuals had been invited to attend the meeting and participate in the discussion.

Anne Hinchliffe, Principal Pharmacist in Public Health, NPHS

Dr Jane Hanson, Director of Cancer Services for Welsh Assembly Government and Director, CSCG

Professor Bharat Jasani, Pathology Department, Cardiff and Vale NHS Trust (responsible for HER2 testing)

Professor Robert Leonard, Medical Oncologist, Swansea NHS Trust, Clinical Director of Cancer Services and Director of the South West Wales Cancer Institute

The Chairman extended his thanks for attending the meeting at short notice and invited each individual to present a brief outline of their perspective.

It was reported that WMP had been tasked by the Steering Committee to prepare a discussion document setting out points for consideration by AWMSG and this document had been posted on the AWMSG website along with the draft information note jointly prepared by CSCG and NPHS.

Anne Hinchliffe confirmed that NPHS had been requested by Paul Miller, Chief Executive of Velindre NHS Trust, to prepare a briefing note to highlight issues around the use of trastuzumab. At the same time CSCG were compiling planning advice for commissioners on the basis that the license for trastuzumab would be extended to include use in early breast cancer and the indication would be supported by a timely NICE appraisal. It had therefore been agreed that the two bodies would produce a joint note.

Professor Leonard provided a clinical overview and Professor Jasani addressed the issue of HER2 testing.

The Chairman invited members to comment and the discussion included the following issues:

The availability of validated HER2 testing facilities in Wales and testing capacity
Capacity for additional echocardiography

The evidence base for figures quoted in the draft information note

Coping with the anticipated initial surge in demand for testing and treatment from the backlog of potentially eligible women

Use of trastuzumab in relation to surgery and chemotherapy

Weight of evidence produced by US trials

Need for sequential treatment

Testing and use in the over 70's

Need for full economic appraisal

Need to respect planning cycles and established process for the managed introduction of new drugs

It was confirmed that the current Welsh Assembly advice in relation to the use of trastuzumab outside its current licensed indication is that appropriateness should be addressed on a case-by-case basis. Mrs Hanson confirmed there is no formal CSCG stance.

The Chairman confirmed that it is outside the remit of AWMSG to provide advice on the use of an unlicensed indication although there was an apparent need to develop consistent clinical criteria for patient selection where off label use was being considered. It was also noted that various bodies were trying to exert pressure to bypass established processes and planning cycles for the managed entry of new drugs into NHS Wales. It was therefore suggested there should be a review of the entire process with a need to engage all parties to prevent a recurrence of events.

AWMSG were concerned to note the range of issues involved with HER2 testing such as capacity and reliability that needed to be addressed. Capacity issues for echocardiography were also noted.

It was agreed to recommend that NHS Wales should await the outcome of the licensing process and advice from NICE. In the interim WMP should work with the individual partners present to develop criteria for patient selection on a case-by-case basis with the work being undertaken in a timely fashion. Dr Paul Buss and Professor Ceri Phillips offered to work with this group. It was also agreed a review of the process for the managed introduction of new drugs should be undertaken in the near future. AWMSG also recommended that Welsh Assembly Government should ensure the necessary review, planning and development is undertaken to ensure there is capacity to deal with projected requirements for HER2 testing and echocardiography.

14/7 AWMSG / AWPAG and NHSIF Constitutions

The Chairman informed members that minor amendments had been made to the AWMSG constitution following consultation with the Assembly's legal advisers. He confirmed that the constitutions of AWPAG and NHSIF had been developed to mirror each other and the requirement for sub-groups to produce an annual report had been removed. Mr Harsant proposed that the Chairs and Vice Chairs of both sub-groups be invited to attend each others meetings. It was agreed that this was not part of the AWMSG constitution and that the proposal should be taken to the sub-groups for consideration. Mr Morgan

queried the term of office of 1-5 years, and the Chairman confirmed that this had been incorporated following legal advice from Welsh Assembly. AWMSG members approved the updated constitutions and noted the comments.

14/8 National Prescribing Indicators 2006/2007

Mrs Samuels informed members that concern had been expressed by colleagues over the revised wording of the targets prior to the AWMSG meeting. As a consequence of this Enc 3/AWMSG/1205 would be amended to revert back to the original wording "reduction to 25th percentile or below". Clarity in relation to the wording used in the SAFF round will be sought by WMP with Welsh Assembly Government representatives outside of the meeting. The Chairman confirmed that the AWPAG Indicator Working Group had drafted a timetable, so that their recommendations relating to the national prescribing indicators for 2007/2008 would be available for the AWMSG September 2006 meeting ensuring timely inclusion into the SAFF round. Members reiterated the need for clarity over the inappropriate generic indicator and provision of a rationale behind the decision making as part of an educational initiative. Members noted that there was no recommendation from the Indicator Working Group to replace the co-proxamol indicator. It was confirmed that the development of new indicators had been explored but the availability of data against which they could be monitored was not routinely available nor of the required quality. . It was also noted that the antibiotic indicator, remains available for continued use as a local comparator. AWMSG endorsed Enc 3/AWMSG/1205.

14/9 Patient safety issues involving generic prescribing

The Chairman asked Mrs Fiona Woods to provide the background to the recommendation to remove anticonvulsants from the inappropriate generic basket.

Mrs Woods confirmed that oral contraceptives had not been considered by the Inappropriate Generic Working Group and that Mrs Vincent was exploring the recommendation in relation to hyoscine that GP and hospital pharmacy computer systems should be set to default to Buscopan.

The Chairman requested that AWPAG should consider and identify how best to implement and minimise related patient safety issues. Mrs Woods confirmed the group would be willing to reconvene if it was felt necessary and would be happy to consult with other groups if appropriate. It was agreed that AWPAG would be tasked with advising on dissemination and implementation of this document and bring comments back to AWMSG in March 2006.

AWPAG

14/10 Appraisal: Cytarabine (DepoCyte®)

(Start time 2.05 pm)

The Chairman asked representatives of Napp Pharmaceuticals whether or not they wished to proceed with the appraisal of cytarabine (DepoCyte®) given the delay in the distribution of Form B. Mr Tuplin confirmed they wished to proceed and the Chairman commenced proceedings.

The Chairman welcomed the medical expert, Dr David Edwards, Consultant Haematologist at Conwy & Denbighshire NHS Trust who had been nominated to attend by the North Wales Cancer Network. Dr Edwards confirmed he had no personal interests in relation to Napp Pharmaceuticals.

The Chairman also welcomed the representatives of Napp Pharmaceuticals:
Ms Pamela Berry, Senior Health Economist
Mr Steve Tuplin, European Product Manager

The Chairman introduced WMP appraisal team:
Mrs Gail Woodland, Senior Appraisal Pharmacist
Dr C V Krishna, Consultant in Clinical Pharmacology,
Dr Rhiannon Tudor-Edwards, Health Economist, University of Bangor

Dr Dyfrig Hughes replaced Professor Ceri Phillips as AWMSG Health Economist. Mrs Fiona Woods left the meeting. Members were asked to declare any interests.

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 that is subsequently endorsed by the Minister does, however, place an obligation on Trusts and LHBs to fund accordingly. The Chairman outlined the sequence of events and confirmed that all discussion would take place in public, but members would adjourn to vote in private. The Chairman reiterated that AWMSG advice is interim to NICE guidance should this be subsequently published.

The Chairman invited Dr Edwards to set the clinical scene.

Mrs Woodland presented an overview of the WMP assessment report of cytarabine (DepoCyte®) and invited Dr Rhiannon Tudor-Edwards to highlight salient points in relation to the health economic aspects. . Dr Tudor-Edwards commented that consideration of the reduction of invasive therapy could have supported the appraisal submission.

The company representatives were asked if they wished to clarify any aspect of the WMP report or highlight any salient points. The Chairman opened the discussion to members.

Members asked Dr Edwards for clarification on the use of ommaya reservoirs and the availability of specialist centres within Wales. Members sought clarification from the company representatives in relation to the drug acquisition costs, and it was confirmed that the costs quoted exclude VAT. The Chairman confirmed that discounted costs should not be taken into consideration. Dr Edwards confirmed that the disease was more common in HIV patients. It was noted that the incidence of the disease is increasing in Wales and the explanation offered by Mr Tuplin was that this was due to improved diagnosis and increased incidence worldwide. There was discussion around the exclusion criteria and frequency and nature of side effects. The rare nature of the disease and inherent difficulties in clinical trial recruitment was noted.

The Chairman invited Councillor Meurig Hughes to speak on behalf of the patient interest group. Councillor Hughes read a letter he had received from the Lymphoma Association and members were referred to the patient interest group submission contained within their documentation but not made available publicly.

The Chairman closed proceedings and voting members retired to meet in camera at 3.30 pm (approx). The meeting re-convened at 3.45 pm (approx).

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 (vote: 5-8) that the recommendation to the Minister for Health & Social Services with regard to cytarabine (DepoCyte®) is that AWMSG would not support the use of cytarabine (DepoCyte®) within NHS Wales. Whilst liposomal cytarabine offers a more convenient dosing schedule for lymphomatous meningitis there is insufficient clinical evidence to support a claim of superior efficacy over free cytarabine. Effects on symptom improvement were not well defined and there is no robust quality of life data to draw meaningful conclusions. The cost-effectiveness of liposomal cytarabine compared with free cytarabine has not been demonstrated. Overall, there is insufficient clinical and cost-effective evidence to recommend liposomal cytarabine for the treatment of lymphomatous meningitis. The Chairman confirmed that the company would normally have 28 days in which to lodge an appeal, but in view of the seasonal holidays, this would be extended until 6th January 2006.

The Chairman concluded by thanking Dr Edwards for his presentation to the Group and Napp Pharmaceuticals for engaging with the AWMSG process.

The appraisal was concluded. Dr Dyfrig Hughes retired from the meeting as AWMSG Health Economic member. Professor Ceri Phillips and Mrs Fiona Woods re-joined the meeting.

14/11 Prescribing trends

Mrs Samuels reported that the graphs in Enclosure 6/AWMSG/1205 reflect the data from the first quarter of 2005/2006 (April, May and June 2005). The Chairman invited comment. There were no specific issues apart from concern that co-proxamol should be reducing more rapidly to zero. It was agreed that the recommendation note to the Minister should state that co-proxamol should reduce to zero by 31st March 2006 and that the service should be informed. The Chairman asked that this be taken to AWPAG in January 2006 for their advice on action required.

14/12 Prescribing strategy timetable

Professor Routledge confirmed that nominations were currently being sought by WMP for this working group. Mr David Roberts nominated Ms Ffion Johnstone to represent the Chief Pharmacists. Dr Martin Duerden and Professor Ceri Phillips agreed to participate. Dr Brian Hawkins agreed to seek a nomination from the HoPMMs.

**WMP /
BH**

14/13 Report on NHS Industry Forum

Mr David Morgan informed members that he had been unanimously re-elected as NHSIF Chairman. The Chairman confirmed that AWMSG would support the informal arrangement that should the elected Chairman be an NHS representative the Vice Chairman be elected from the industry representatives. The Chairman asked that reference to an applicant be removed from the draft minutes of the NHSIF meeting held in October 2005. It was confirmed that no resources are available for payment of an honorarium to lay members. Mr Paul Parker agreed to explore the possibility of collection of Welsh data at Ministerial

WMP

WAG

level. NHSIF recommended that AWMSG consider the wider nutritional needs of all patients and it was agreed that this should be considered by the joint working group. NHSIF supported the new report on patient information leaflets and implementation of guidance.

**Working
Group**

14/14 Report on All Wales Prescribing Advisory Group

Dr Paul Buss reiterated the need for consistency in relation to glucose testing and confirmed that AWPAG will be considering the minutes of the final meeting of the Welsh Assembly Government Consensus Group. It was reported that AWPAG had been invited by the publishers to discuss the future development of the Paediatric BNF including electronic access.

Feedback on incentive scheme

Mrs Samuels reported a 73% response rate to the WMP feedback questionnaire in relation to the national prescribing incentive scheme. Of those responses, 44% (n=?) had adopted the scheme fully and 50% (n=?) had adopted it partly. Mrs Samuels confirmed the intention to repeat the survey in two years time. The Chairman commented that monitoring the LHBs who had not taken up the scheme could be an interesting student project. Mr Hayes confirmed a significant increase in the number of returned WeMeReC modules.

Audit of clopidogrel

Mr Hayes confirmed that a national audit had been prepared by WMP and will be approved at the AWPAG meeting in January before it becomes available as a resource to the service. It was noted that most LHBs had conducted their own audit and there is a need to continue to develop the work of prescribing indicators.

**WMP/
AWPAG**

14/15 Relationship between WMP and HCW

The Chairman asked members to note the terms of engagement. Dr Martin Duerden and Mr Jamie Hayes left the meeting.

14/16 Shared care

The Chairman invited Dr Tessa Lewis, GP Torfaen and AWPAG member, to address the issue of shared care. Dr Lewis informed AWMSG that the consistency issues highlighted at the previous AWMSG meeting had been addressed and that both the general and specific templates had undergone wide consultation. Dr Lewis reported that there had been good consensus amongst the Welsh rheumatologists as to what protocols they wished to have available in the future. Dr Lau informed members that Gwent MTC had adopted the templates.

Mr Dave Roberts confirmed that in order to avoid duplication the Chief Pharmacists supported the sharing of the workload with the interface pharmacists and those currently working on developing local shared care agreement, but asked that a work schedule be compiled to ensure clarity.

WMP

AWMSG endorsed the templates and it was agreed that WMP should disseminate the general and specific shared care templates to MTCs as exemplars for local agreement. In order to take forward the issue of shared care and identify a national list, it was agreed that an amber list should be compiled and taken to the AWPAG meeting in January – any funding issues should be ignored as it was felt this was outside the remit of AWMSG. The Chairman requested that AWPAG consider all the issues and report back to AWMSG in March 2006.

AWPAG

14/17 GP out of hours

The Chairman informed members that he had approached Community Pharmacy Wales for comment on the Welsh Assembly Government questionnaire on out of hours pharmaceutical provision. Mr Dave Roberts agreed to seek comments from the Chief Pharmacists. The Chairman asked that the questionnaire responses along with feedback from the Chief Pharmacists be considered at the AWPAG meeting in January 2006. AWPAG are requested to highlight any areas of concern that need to be addressed. Councillor Meurig Hughes left the meeting.

AWPAG

14/18 Process for reviewing decisions

Professor Routledge confirmed that during on-going dialogue with the TDA User Group the move from a process to a scientific review had been agreed in principle. It was agreed that WMP would bring this paper back to the next AWMSG meeting and incorporate additional information requested by the TDA Users Group.

WMP

Prior to the close of the meeting at approx 5.20pm, Professor Routledge, Mr David Morgan and Dr Paul Buss congratulated and thanked Professor Roger Walker for his excellent contribution as AWMSG Chairman.