

ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY, 14TH MARCH 2007 COMMENCING 10.30 AM AT THE ORANGERY, MARGAM PARK, PORT TALBOT

MEMBERS PRESENT:

Did not
participate in
agenda item

1. Dr Paul Buss Consultant Physician
 Gwent Healthcare Trust
2. Dr Fraser Campbell LHB Medical Director
 Gwynedd LHB
3. Mr Jeffrey Evans Other healthcare professionals eligible to prescribe
 Podiatrist, UWIC
4. Dr Bruce Ferguson LHB Medical Director
 Bro-Morgannwg
5. Dr Brian Hawkins LHB Pharmacist
 Rhondda Cynon Taf
6. Mr Peter Harsant Industry Representative
7. Cllr Meurig Hughes Lay member
8. Mr David Morgan Consultant in Pharmaceutical Public Health
 National Public Health Service, North Wales
 Region
9. Prof Ceri Phillips Professor of Health Economics, School of Health
 Science, University of Wales Swansea
10. Prof Philip Routledge Professor of Clinical Pharmacology, Cardiff
 Acting Chairman University and Acting AWMSG Chairman
11. Mr Dave Roberts Chief Pharmacist
 Cardiff and Vale NHS Trust
12. Mrs Wendy Warren Nurse Director
 Gwent Healthcare Trust

IN ATTENDANCE:

- | | | |
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| 13. | Mrs Ruth Lang | Liaison Manager, Welsh Medicines Partnership |
| 14. | Mrs Nicola Miller | Admin Assistant, Welsh Medicines Partnership |
| 15. | Mrs Carolyn Poulter | Head of the Pharmaceutical Services Branch
Welsh Assembly Government |
| 16. | Mrs Karen Samuels | Programme Manager, Welsh Medicines Partnership |
| 17. | Dr John Thompson | Medic, Welsh Medicines Partnership |
| 18. | Miss Carwen Wynne-Howells | Chief Pharmaceutical Adviser, Welsh Assembly
Government |

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 for Health and 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

1 Welcome, introductions and personalia

The Chairman opened the meeting and welcomed those present. He informed members that Mrs Gail Woodland would be unable to attend the meeting and that Dr John Thompson would speak on her behalf for the appraisal of sorafenib (Nexavar[®]).

2 Apologies

Dr David Gozzard, Medical Director, Conwy & Denbighshire NHS Trust
Dr Tom Lau, General Practitioner & Prescribing Lead, Gwent
Dr Rob Holcombe, LHB Finance Director

3 Declarations of interest

The Chairman asked members to declare any specific, non-specific, personal or non-personal declarations of interest. Ceri Phillips confirmed a non-personal non-specific interest - his department had been awarded a grant from Pfizer to support a survey in the area of diabetes.

The Chairman reported that a letter had been sent to Bayer with regard to the declaration of interest of Dr Dyfrig Hughes. He confirmed that after contributing to the WMP assessment of Sorafenib (Nexavar[®]), Dr Dyfrig Hughes recollected that he had previously received funding from Pfizer for advice on the non-drug specific issue of patient compliance. Dr Hughes confirmed that he has had no contact with Pfizer in relation to any aspect of sorafenib (Nexavar[®]) or its appraisal by AWMSG, and has not divulged any information (including commercial in confidence data) in relation to this agent. The representatives from Bayer confirmed that the written statement provided them with the necessary assurance and agreed to continue with the appraisal.

4 Minutes of previous meeting

The minutes were checked for accuracy. No changes were made. The Chairman signed the minutes as a true record of the meeting.

Matters arising

Page 4 – The Chairman confirmed that the Welsh Assembly Government have set up a systems working group to discuss monitored dosage systems. The details were clarified and an update provided by Mrs Carolyn Poulter on joining the meeting-see section 9.

Page 11 – It was noted that the training day for the AWMSG members and newly appointed members of the NMG had been rearranged from 1st February 2007 to 19th March 2007 at the Angel Hotel, Abergavenny.

5 Chairman's report

The Chairman reported that issues surrounding the prescribing strategy had been discussed at a recent meeting between representatives of AWPAG, ABPI and NHSIF. A re-drafted document will be taken to the sub-groups for further discussion in April 2007.

The Chairman confirmed that the Minister had endorsed the recommendation in relation to iloprost trometamol (Ventavis[®]). Confirmation of receipt of ministerial endorsement will be disseminated and posted on the AWMSG website.

The Chairman reported that he had attended a meeting with the ABPI in London to discuss the broadening of the appraisal process. He confirmed that ABPI were open and willing to work with AWMSG. Dr Greville confirmed (from the audience) the positive response from the Industry.

The Chairman confirmed that the prescribing reviews of the BNF Chapters being progressed through AWPAG were on hold. WMP is currently actively pursuing resources to fund the editorial process.

The Chairman announced that the following appraisals will be held on 12th June 2007:

Appraisal 1: parathyroid hormone (Preotact[®])

Manufacturer: Nycomed UK

Indication: Treatment of severe osteoporosis in postmenopausal women. An assessment of the cost and clinical effectiveness of parathyroid hormone (Preotact[®]) in relation to its licensed indication and the place of parathyroid hormone (Preotact[®]) in relation to current treatment strategies available in NHS Wales.

Appraisal 2: clofarabine (Evoltra[®])

Manufacturer: Bioenvision Ltd

Indication: Treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients who

have relapsed or are refractory after receiving at least two prior regimens and where there is no other treatment option anticipated to result in a durable response. An assessment of the cost and clinical effectiveness of clofarabine (Evoltra[®]) in relation to its licensed indication and the place of clofarabine (Evoltra[®]) in relation to current treatment strategies available in NHS Wales.

Appraisal 3: dexrazoxane (Savene[®])

Manufacturer: TopTarget (Denmark)

Indication: Treatment of anthracycline extravasation. An assessment of the cost and clinical effectiveness of dexrazoxane (Savene[®]) in relation to its licensed indication and the place of dexrazoxane (Savene[®]) in relation to current treatment strategies available in NHS Wales.

Appraisal 4: Emtricitabine (Emtriva[®])

Manufacturer: Gilead Sciences Ltd

Indication: Treatment of HIV-1 infected adults and children in combination other antiretroviral agents. An assessment of the cost and clinical effectiveness of emtricitabine (Emtriva[®]) in relation to its licensed indication and the place of emtricitabine (Emtriva[®]) in relation to current treatment strategies available in NHS Wales.

Appraisal 5: Emtricitabine/tenofovir (Truvada[®])

Manufacturer: Gilead Sciences Ltd

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

Mrs Poulter joined the meeting.

6 Appraisal – sorafenib (Nexavar[®])

(10.50 am)

Professor Routledge reminded members to declare any interests pertinent to the appraisal. Ceri Phillips restated his non-personal non-specific interest. There were no other declarations of interest from any members of the Group eligible to vote.

The Chairman welcomed the independent medical expert, Dr Jim Barber, Consultant Oncologist at Velindre Hospital, Cardiff. The Chairman asked Dr Barber to declare any interest in relation to sorafenib. Dr Barber introduced himself and confirmed that he had no interests to declare.

The Chairman extended a welcome to Mr Phillip Ashman, Business Unit Head, Oncology, Bayer PLC and Dr Teng Jin Ong, Medical Science Oncology Lead, Bayer PLC.

The Chairman introduced the WMP appraisal team:

Dr John Thompson, Consultant Clinical Pharmacologist in Cardiff and Vale NHS Trust and Dr Dyfrig Hughes, Health Economist, Bangor University

The Chairman reported that the WMP appeal team were not present at the meeting

The Chairman confirmed that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this, and that a negative recommendation would not impact on the clinical freedom of the prescriber. He explained

that a positive recommendation by AWMSG, subsequently endorsed by the Minister for Health & Social Services, places an obligation on Trusts and LHBs in Wales to fund accordingly. AWMSG advice is interim to NICE should it be subsequently published. He confirmed the sequence of events and invited Dr Thompson to present a clinical overview of the WMP assessment report.

Dr Thompson outlined the purpose and scope of the appraisal and summarised the salient points of the clinical aspect of the WMP assessment report and provided an overview of the trials relevant to the submission (detailed in the WMP assessment report Enc 2/AWMSG/0307).

Dr Dyfrig Hughes summarised the health economic aspects of the WMP assessment report.

The Chairman invited Dr Jim Barber, Oncologist at Velindre Hospital, to address the Committee and set the clinical scene. Dr Barber outlined the current treatment options available to patients in Wales. He discussed the impact of these treatments on patients' quality of life and outlined the potential side effects, problems and difficulties encountered by patients receiving these treatments. He also alluded to the two clinical trials of sorafenib that were stopped early as they were deemed unethical to continue with the placebo group.

The Company representatives were invited to clarify issues in relation to the WMP assessment report and highlight any salient points of the company submission. The Chairman confirmed that the confidential supplementary data provided by the Company had been distributed to members and would be collected in at the end of the meeting. Mr Ashman thanked members for the opportunity to summarise the essence of the company submission and proceeded to put forward the company's perspective. He acknowledged that the clinical case had been well presented by WMP.

The Chairman invited Councillor Meurig Hughes to speak on behalf of the patient perspective. Councillor Hughes confirmed that he had been in contact with Kidney Cancer UK. He drew members attention to an article in the Sunday Times of the 25th February written by Daniel Fogel and Sarah Kate Templeton entitled "Kidney Cancer victims denied 'wonder drug'".

The Chairman opened up the discussion and invited members to structure the discussion around the clinical effectiveness issues in the first instance. Members sought clarification of the ongoing clinical research, average survival rates, side effects of the treatment, clinical markers and the suitability for treatment. Discussion then moved on to address cost-effectiveness issues. Questions were raised in relation to the economic model and cost per QALY.

The Chairman asked Mr Ashman and Dr Ong if they had any further questions or whether there were any outstanding issues that required further discussion. Mr Ashman thanked the Chairman and confirmed there were no outstanding issues.

The Chairman closed proceedings at 12.23 pm and voting members retired to meet *in camera*.

The meeting re-convened at 12.44 pm.

Miss Carwen Wynne-Howells joined the meeting.

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 that the recommendation to the Minister for Health & Social Services with regard to sorafenib (Nexavar®) is

AWMSG recommends that sorafenib (Nexavar®) should not be made available for use within NHS Wales on the grounds of lack of evidence of cost-effectiveness.

The appraisal was concluded. The Chairman confirmed that the company has 28 days in which to lodge an appeal against the AWMSG recommendation.

7 AWMSG – Broadening of appraisal process update

The Chairman invited Mrs Karen Samuels, Welsh Medicines Partnership to update the group on the broadening of the appraisal programme (Enc 3 AWMSG/0307)

Mrs Samuels drew members' attention to the appraisal and appeal process diagrams. She confirmed that the new process would come into effect from 1st April 2007. The diagrams provided a general guide to the process and that when published on the website will contain more information behind some of the boxes, either in the form of Q & A or hidden behind and seen when cursor placed over the box.

With regard to the constitution Mrs Samuels confirmed that the comments from the last meeting had been taken on board and that a nurse and a health economist had been added to the NMG membership. Members sought clarification of whether 6.1 "Vice Chair nominated by AWMSG Steering Committee" was correct as that differed to the constitutions of the other two groups. Mrs Samuels confirmed that the NHSIF and AWPAG constitutions would be amended to fall in line with the NMG constitution. It was requested that the wording of 4.1 be altered to ensure that there was no confusion with regard to where a deputy should be sought. It was also confirmed that the heading of 3.4 "National Assembly Government" should be amended to "Welsh Assembly Government".

Mrs Samuels informed the members that in line with the Welsh Health Circular currently being prepared to inform of the broadening of the appraisal process, WMP would be referred to as the AWMSG secretariat. She also confirmed that the time allowed for manufacturers to accept/reject AWMSG recommendation had been extended to 5/10 days at the request of the TDA Users Group.

The Chairman confirmed that there may be a need to seek health economic expertise outside of Wales for appointment to the appeal team. It was noted that ABPI had requested timelines for the scientific dispute and process flow diagrams.

AWMSG members endorsed the broadening of the appraisal process flow diagram and the process to deal with disputes.

8 AWMSG criteria for appraising drugs

The Chairman invited Dr Dyfrig Hughes to provide an overview of Enc 4/AWMSG/0307. Dr Hughes highlighted salient points from the document confirming that the criteria is in line with NICE and does not relate to ultra-orphan drugs.

Members discussed issues addressed in the paper and also requested that the following amendments be made to the document. "Patients experts" be changed to "patient interest group", the title of the document be changed from "drugs" to "medicines" and the wording regarding affordability be rephrased.

The Chairman confirmed that with the above amendments AMWSG endorsed the document.

Dr Dyfrig Hughes left the meeting.

9 Update on AWPAG

In the absence of Mrs Nicola John the Chairman invited Dr Tessa Lewis to provide an overview of the AWPAG meeting held in January 2007.

Dr Lewis drew members attention to salient points of the draft minutes Enc 5/AWMSG/0307. Dr Lewis confirmed that amiodarone shared care was ongoing and would be brought to the June AWMSG meeting. AWPAG representatives had attended a meeting to discuss guidelines and will be updating AWPAG at their meeting in April. Dr Lewis confirmed that there had been no formal feedback from the Renal Advisory Group.

Members were informed that the provision of the BNF in Wales was being cut by 50%. Mrs Carolyn Poulter informed members that it was a necessary cost-saving move. It was noted that the BNF is freely available on HOWIS, and GP/trusts can purchase copies at a 50% reduction in price.

The Chairman confirmed that AWMSG endorsed the BNF as one of the best guides for prescribing and encouraged that it should be a priority resource especially for junior medical staff.

Mrs Carolyn Poulter informed members that Community Pharmacy Wales would assess patients for eligibility in relation to the supply of multicompartiment compliance aids under the Disability Act. Guidance is expected within the next month.

Cystic Fibrosis drugs – interface issues

Shared care agreement: dornase alfa (Pulmozyme®)

Shared care agreement: tobramycin nebulised solution (Tobi®)

The Chairman invited Dr Tessa Lewis to provide an overview of Enc 6/AWMSG/0307.

Dr Lewis highlighted the salient points from the paper and templates and informed members that the LMC's have had an opportunity to comment and that while there were no dissenters, a couple of LMC's requested reiteration that shared care agreements are voluntary for GP's. She sought AWMSG's endorsement of the templates.

The following issues were raised:

- Consistency of template headings
- View of Directors of Finance
- All-Wales template for local adaptation
- Liaison with English centres

The Chairman thanked Dr Lewis for her presentation and Dr Tessa Lewis left the meeting.

10 Office of Fair Trading – Market Study of the PPRS

The Chairman introduced Mr Simon Perrett from the Office of Fair Trading and invited him to discuss the OFT Market Study of the PPRS (Enc 7/AWMSG/0307).

Mr Perrett drew members' attention to the fact that the report aimed to provide value for money drugs for the NHS and at the same time provide financial incentives to industry to manufacture novel medicines. He highlighted the suggestion that SMC, NICE and AWMSG should work together to set drug prices before the drug is licensed. He confirmed a 120 day consultation is currently underway and invited a formal response.

Members sought clarification on the efficiency of retrospectively pricing medicines. Mr Perrett confirmed that the principles highlighted in the report would be more usefully used prospectively. There was discussion over when the measures would be implemented, the models used, the principals of operation and who would be negotiating with the Companies.

The Chairman requested that all members view the full document on the website, concentrating primarily on Annex's L, M and B and that AWMSG would provide a collated response to Mr Perrett. Mr David Morgan requested that this item be added to the NHSIF agenda for April. Mrs Poulter stated that she would be compiling a Government response to the report and requested a copy of the AWMSG response before the end of April.

11 Update on Independent Prescribing

The Chairman invited Mrs Wendy Warren to update members on independent prescribing.

Mrs Warren reported good progress on this issue. There were 180 applicants and a sifting process was currently taking place. She confirmed that there were places available in five areas in Wales which would ensure good coverage, also that the issues surrounding the prescription pads had been resolved.

It was confirmed that Independent Prescribers would only be able to prescribe within their expertise. Carwen Wynne Howells confirmed that Welsh Assembly Government were in discussion with the Health Professions Council to provide courses for therapists, and that there was a move to providing optometrists with independent prescribing rights.

12 Report on NHS Industry Forum

The Chairman invited Mr David Morgan to provide an overview of the NHS Industry Forum meeting held in January 2007.

Mr Morgan drew members' attention to salient points of the draft minutes Enc 9 AWMSG/0307. He informed members that the deadline for receipt of the Partnership questionnaire had been extended to the end of March and that those who had not responded had been contacted and offered another opportunity to reply.

13 Feedback on citizens jury

The Chairman invited Professor Marcus Longley, Principal Investigator and Iain McCrory, Juror to outline their experiences from the citizens jury. He also noted that Peter Elwood, Cardiff University and Mr Jeremy Felvus, Pfizer who were present in the audience had assisted in the setting up of the citizens jury

Dr Longley confirmed that the jurors were selected using a polling company and that their brief was to find 16 people broadly representative of South East Wales. Dr Longley informed members that the debate had highlighted interesting issues that included the use of low dose aspirin, medicine and the preservation of health and how to introduce the voice of a disinterested lay citizen into this debate.

Mr Iain McCrory then addressed members giving them a brief outline of his career and his perspective as a juror. He confirmed that the standard and level of the briefing was high and complex and that the jurors represented a wide spread of the population.

The Chairman confirmed that AWMSG would ensure that the MHRA has sight of the report and that AWMSG would ask them specifically to address the issue of Yellow Card Scheme at a national level.

The Chairman confirmed the endorsement of AWMSG of the importance of the citizens jury role in public engagement in policy making.

Date of next AWMSG meeting: 12th June 2007 in The Angel Hotel, Abergavenny