

ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF MEETING HELD ON WEDNESDAY, 8TH JUNE 2005
COMMENCING 10.30 AM AT THE WALES MILLENNIUM CENTRE,
BUTE PLACE, CARDIFF, CF10 5AL

MEMBERS PRESENT:

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|-----|---------------------|---|---|
| 1. | Mrs Kathryn Bourne | Nurse Prescriber, Gwent Healthcare NHS Trust | |
| 2. | Dr Paul Buss | Consultant clinician
Gwent Healthcare Trust | |
| 3. | Dr Bruce Ferguson | Trust Medical Director
Bro Morgannwg NHS Trust | |
| 4. | Dr Richard Greville | Industry Representative, ABPI (Wales)
(deputy member) | |
| 5. | Cllr Meurig Hughes | Lay member
Llangefni, Ynys Mon | Did not
participate in
agenda items
12/13 and 12/14 |
| 6. | Dr Thomas Lau | Local Health Board Prescribing lead
Lliswery Medical Centre, Newport | |
| 7. | Prof Ceri Phillips | Professor in Health Economics, School of Health
Science, University of Wales Swansea | Did not
participate as
member of
AWMSG in
agenda item
12/8 |
| 8. | Mr Mike Pollard | Chief Pharmacist
North East Wales NHS Trust | Did not
participate in
agenda items
12/13 and 12/14 |
| 9. | Mr Jonathan Simms | Local Health Board Pharmacist
(deputy member)
Torfaen Local Health Board | |
| 10. | Dr Paul Tromans | Consultant Public Health Medicine
Regional Director, National Public Health Service,
South East Wales Region
(deputy member) | |
| 11. | Prof Roger Walker | Chairman AWMSG
Consultant in Pharmaceutical Public Health
National Public Health Service, South East Wales
Region | |

IN ATTENDANCE:

- | | | |
|-----|----------------------------|---|
| 12. | Mrs Ruth Lang | Liaison Manager, Welsh Medicines Partnership |
| 13. | Mrs Carolyn Poulter | Pharmaceutical Services Branch
Welsh Assembly Government |
| 14. | Professor Philip Routledge | Medical Director, Welsh Medicines Partnership |
| 15. | Mrs Karen Samuels | Programme Manager, Welsh Medicines Partnership |
| 16. | Mrs Fiona Woods | Director, Welsh Medicines Partnership |
| 17. | Miss Carwen Wynne-Howells | Chief Pharmaceutical Adviser
Welsh Assembly Government |

List of Abbreviations:

AAMW	Ask About Medicines Week
ASPB	Assembly Sponsored Public Body
AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
DSRU	Drug Safety Research Unit
HCW	Health Commission Wales
HSW	Health Solutions Wales
LHB	Local Health Board
MHRA	Medicines and Healthcare Products Regulatory Agency
M&TCs	Medicines & Therapeutics Committees
NAO	National Audit Office
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

12/1 Welcome and Introduction

The Chairman welcomed those present and confirmed that the proceedings were recorded. Members introduced themselves. The Chairman outlined the format of the meeting and reported that the minutes would be posted on the AWMSG website.

12/2 Apologies

Mr Julian Baker (Finance Director) Caerphilly LHB.

Mr Jeff Evans (Other healthcare professionals eligible to prescribe)

Senior Lecturer in Podiatry & Podiatric Surgeon, Wales Centre for Podiatric Studies, UWIC, Cardiff.

Dr David Gozzard (Trust Medical Director) Conwy & Denbighshire NHS Trust.

Mr Peter Harsant (Industry representative) Norgine Limited, Uxbridge, Middlesex.

Mr David Morgan (Consultant in Pharmaceutical Public Health) National Public Health Service, North Wales Region

12/3 Declarations of interest

There were no declarations pertaining to the agenda. The Chairman informed members of an issue relating to Dr Richard Greville, Director of ABPI (Cymru Wales) participating as a voting member in the appraisal of pegvisomant and bortezomib. The Chairman had sought legal advice and confirmed that Dr Greville would not have a vote in these

appraisals. The Chairman agreed to discuss this with Dr Greville outside the meeting to clarify the current decision and explore long term options.

12/4 Minutes of previous meeting

The minutes were checked for accuracy and confirmed.

12/5 Matters arising

9/6 Chairman's report – Ongoing discussions between WMP and HCW

Professor Routledge confirmed that following a meeting with HCW progress had been made with regard to the development of a service level agreement between WMP and HCW.

WMP

9/6 Chairman's report – Nomination for Standing Committee on Resource Allocation sub group

Professor Phillips informed members that the group were looking at a number of different formulae for allocation of resources and had debated the criteria and calculation of population in Wales. Technical difficulties are currently being addressed and Professor Phillips confirmed that the consultation document should be available at the end of July 2005. Professor Phillips agreed to report back to AWMSG at the September meeting.

CP

9/14 Sip Feeds

It was confirmed that the issue of Sip Feeds was being addressed by both sub-groups and WMP had clarified the role and remit of AWPAG and NHSIF. Dr Greville informed the group that the report of the NHSIF sub-group had been prepared and would be passed to AWPAG to be considered at their next meeting in July 2005.

AWPAG

10/6 Chairman's report

Statement of Healthcare Standards for NHS Care and Treatment in Wales – Consultation

The Chairman confirmed that Health Inspectorate Wales will be monitoring the implementation of AWMSG and NICE guidance.

Review of ASPBs

The Chairman reported that he had been in correspondence with Mrs Ann Lloyd, Director of the Health and Social Services Directorate, and had been informed that a public consultation will be held over the summer months.

10/9 Templates for local adaptation

Mrs Poulter confirmed that Ministerial ratification would only be sought for AWMSG appraisal recommendations and any document issued as a Welsh Health Circular.

10/17 Broadening the AWMSG appraisal process

It was reported that a positive endorsement had been received from Mrs Anne Lloyd in relation to a bid by WMP for funding to support the broadening of the AWMSG appraisal process. The bid had been included in the current financial planning round but there was no guarantee that monies would be forthcoming.

11/6 Chairman's report

Mrs Poulter confirmed that following Ministerial ratification, advice from AWMSG

regarding therapeutic drug appraisals would be included in the quarterly newsletter of the Chief Medical Officer.

11/7 GP Out of hours

Mrs Poulter confirmed that a draft questionnaire had been discussed at AWPAG and the final document would be circulated to LHBs. A paper summarising the results would be brought to the September meeting of AWMSG.

11/9 AWMSG future work programme

E1 Patient information leaflets

This item had been referred to the NHSIF. It was agreed that on the advice of NHSIF this be removed from the list of activities on the AWMSG work programme as the opportunity for input was minimal. Regulations on patient information leaflets are governed by European Directives and UK law and are monitored by MHRA.

E11 GP Access to medication e.g. emergency medicine bags

Mrs Poulter confirmed that any issues would be highlighted in the questionnaire on GP out of hours services.

E12 – Use of unlicensed drugs (specials)

A WMP representative confirmed that the All Wales Drugs Contracting Committee would be considering the use of unlicensed drugs (specials) at their meeting on 9th June.

I15 Green Card Scheme

It was reported that the Drug Safety Research Unit in Southampton is liaising directly with HSW with regard to data capture although software compatibility remains an issue. WMP have nominated Mrs Andrea Clark to provide the link between the DSRU and WMP.

11/11 Local prescribing comparators

The Chairman reported that in a letter to Mrs Ann Lloyd he had requested a professional support unit be established to support the work of HCW. He confirmed that this bid for funding had been included in the current financial planning round.

12/6 Chairman's report

AWMSG Constitution

The Chairman invited members to comment on the revised AWMSG Constitution (Enc 2/AWMSG/0605).

It was agreed that two amendments should be made under (3). Membership.

“One Consultant in Public Health Medicine”

“One Nurse prescriber or nurse practitioner (primary or secondary care)”.

It was agreed that an amendment should be made under section (12). Vacancies.

“A member resigns by giving one months notice in writing to the Minister for Health & Social Services, National Assembly for Wales”. It was noted the same statement of resignation should also apply to the Chairman.

The Chairman agreed that Dr Greville could propose wording to clarify 14. Powers of the Committee.

It was confirmed that ratification of the revised constitution would be sought from the Minister.

Membership

The Chairman confirmed that the following members had been re-appointed to 31 July 2008:

Mr Julian Baker
Dr Paul Buss
Mr Jeff Evans
Dr David Gozzard
Councillor Meurig Hughes
Dr Tom Lau
Mr David Morgan
Professor Ceri Phillips
Professor Roger Walker

Applications have been received for the vacant posts and a SIFT panel has been held. Interviews will commence on 4th July and a training day for new members and deputies will be held on 23rd August 2005 in preparation for the September meeting.

The following members have not sought to renew their membership of the committee:

Dr Paul Tromans
Mrs Kathryn Bourne
Mr Mike Pollard

The Chairman expressed his thanks for their contribution to the work of AWMSG and wished them well for the future.

The Chairman congratulated Professor Ceri Phillips on his promotion to a Chair in the University of Swansea.

Cinacalcet (Mimpara®) - Amgen

The Chairman announced that AWMSG would not be appraising Cinacalcet (Mimpara®) at the September 2005 meeting as intended. Amgen had failed to meet the deadlines for submission of documentation, as agreed and set out in the appraisal process. The reason volunteered was a wish to reconsider the robustness of their economic model. The appraisal has been suspended and a statement dated 27 May 2005 issued to the service. The Chairman asked Dr Richard Greville to explore the background to these events and help identify what lessons could be learnt to minimize the risk of a recurrence.

Prescribing Conference – 19/20 January 2006

A conference for all prescribers and advisers will be held at the Cardiff Hilton Hotel on the evening of Thursday, 19th and all day on Friday 20th January 2006. It is proposed that a memorial lecture for Felicity Newton-Savage will be held on the evening of Thursday, 19th January. These dates are subject to the availability of the guest speaker.

12/7 Appraisal: Pegvisomant (Somavert®)

(Start time 11.25 am)

Members were asked to declare any interests. None were reported other than those for Dr Richard Greville. Mrs Fiona Woods and Professor Philip Routledge left the meeting. The WMP appraisal team, Miss Gail Hutchins, Dr John Thompson and Dr Dyfrig Hughes, joined members around the table.

The Chairman welcomed Dr Jonathan Jones, Medical Advisor and Mr Nick Bruce, Health Economist, Pfizer Limited.

The Chairman also welcomed Professor Maurice Scanlon, Professor of Endocrinology, Cardiff and Vale NHS Trust who had been nominated to attend by Dr Alun Rees, President of the Welsh Endocrine and Diabetes Society.

The Chairman invited Professor Scanlon to declare any interests. Professor Scanlon confirmed he had no personal interests although Pfizer has a current commercial relationship with The Department of Endocrinology in the University Hospital of Wales with regard to products other than pegvisomant.

The Chairman reiterated that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation by AWMSG does not impact on the clinical freedom of the prescriber. A positive recommendation by AWMSG that is 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 guidance is interim to NICE guidance should this be subsequently published.

The Chairman invited Professor Scanlon to set the clinical scene. Professor Scanlon concurred with the WMP assessment report but suggested that the numbers may be substantially less than those quoted in the document. He confirmed that most patients residing in North Wales receive treatment in the Cardiff centre and few travel to Liverpool to receive treatment.

Miss Hutchins presented an overview of the WMP assessment report of pegvisomant (Somavert®) and invited Dr Dyfrig Hughes to highlight salient points in relation to the health economic aspect of the WMP report.

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.

The difficulties in assessing orphan drugs was acknowledged. Members sought clarification from the company in relation to patient compliance. Professor Phillips confirmed that no other related costs had been considered in the economic report of WMP. The company representatives outlined details of their process for capping expenditure at £50,000 per patient. Members discussed issues surrounding IGF1 levels and enquired as to availability of mortality/morbidity data.

The Chairman enquired whether Councillor Hughes had made contact with any patient interest group in relation to pegvisomant. Councillor Hughes read out a letter received from Ms Carol Watson, Foundation Manager, The Pituitary Foundation.

The Chairman closed proceedings and voting members retired to meet in camera at 12.29 pm. The meeting re-convened at 1.00 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 (vote: 6-5) that the recommendation to be made to the Minister for Health & Social Services with regard to pegvisomant (Somavert®) was that AWMSG would not support the use of pegvisomant (Somavert®) within NHS Wales.

The Chairman confirmed that the company have 28 days in which to lodge an appeal and this should be made in writing to the Chairman.

The Chairman concluded by thanking Professor Scanlon for his presentation to the Group that assisted AWMSG in formulating the recommendation to the Minister for Health & Social Services. The Chairman also thanked Pfizer Limited for engaging with the AWMSG process and reported that the recommendation would be confirmed in writing. The appraisal was concluded.

12/8 Appraisal: Bortezomib (Velcade®)

(Start time 2.45 pm)

The Chairman asked members around the table to introduce themselves.

Members were asked to declare any interests. The WMP appraisal team, Miss Gail Hutchins, Professor Philip Routledge and Professor Ceri Phillips, joined members around the table. The Chairman confirmed that Dr Dyfrig Hughes was unable to participate in the appraisal as the deputy health economist member as he had a declared a conflict of interest having previously been involved in writing the proposal developed by the Prescribing Research Group to evaluate the cost-effectiveness of the drug. There were no other declarations of interest other than those of Dr Richard Greville.

The Chairman welcomed Miss Angela Christie, Senior Outcomes Research Manager, Janssen-Cilag Limited and Dr Anthony Donovan, Director of Medical Affairs, Ortho Biotech.

The Chairman also welcomed Dr Hamdi Sati, Consultant Haematologist, Singleton Hospital who had been nominated by Glynis Tranter, Director, South West Wales Cancer Network.

The Chairman invited Dr Sati to declare any interests. None were declared.

The Chairman reiterated 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 does not impact on the clinical freedom of the prescriber. A positive recommendation by AWMSG that is 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

guidance is interim to NICE guidance should this be subsequently published.

The Chairman invited Dr Sati to set the clinical scene.

Miss Hutchins presented an overview of the WMP assessment report of bortezomib (Velcade®) and invited Professor Phillips to highlight salient points in relation to the health economic aspect of the WMP report.

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

Members sought clarification of the prediction and monitoring of responsiveness to medication and mechanism for stopping treatment. Dr Donovan highlighted the novel mechanism of action and confirmed that there were 118 different studies currently ongoing in Europe. Dr Sati confirmed the number of cycles and doses that patients could expect to receive and reported the complexity of treatment options available for patients with multiple myeloma. The issue of peripheral neuropathy was discussed and clarification was sought as to current research on managing neuropathy.

The Chairman enquired whether Councillor Hughes had made contact with any patient interest group in relation to bortezomib. Councillor Hughes confirmed he had telephoned the International Myeloma Foundation and had received a letter from Sara Smith, PR & Communications Manager of the International Myeloma Foundation. Councillor Hughes read out the letter.

Dr Donovan confirmed that depending on the outcome of the appraisal Janssen-Cilag would consider submitting bortezomib for appraisal as a second line agent.

The Chairman closed proceedings and voting members retired to meet in camera at 3.45. The meeting re-convened at 4.00 pm.

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

It was agreed (vote: unanimous) that the recommendation to be made to the Minister for Health & Social Services with regard to bortezomib (Velcade®) was that AWMSG would support the use of bortezomib (Velcade®) within NHS Wales for the treatment of multiple myeloma in patients who have received two prior treatments and have demonstrated disease progression. Treatment must be only initiated and administered under the supervision of a physician qualified and experienced both in the use of chemotherapeutic agents and in the management of multiple myeloma.

The Chairman confirmed that the company have 28 days in which to lodge an appeal. The Chairman confirmed the recommendation of AWMSG would not be passed to the Minister until after the expiry of the 28 days unless the company inform him in writing that they do not intend to lodge an appeal. It was noted that AWMSG are unable to identify when Ministerial ratification of the AWMSG recommendation would be received. The Chairman confirmed that the company are asked not to report the AWMSG recommendation to any other party until Ministerial ratification is received and this has been conveyed to NHS Wales by WMP.

The Chairman concluded by thanking Dr Sati for his presentation. to the Group. The Chairman also thanked the company for engaging with the AWMSG process and

reported that the recommendation would be confirmed in writing. The appraisal was concluded.

Dr Donovan thanked AWMSG for the review.

Councillor Meurig Hughes and Mr Michael Pollard left the meeting.

12/9 Shared care

The Chairman invited Dr Tessa Lewis, a general practitioner in Gwent and deputy AWPAG member, to present a brief overview of Enc 5/AWMSG/0605. Members were invited to comment.

Members agreed that in order to progress the paper there was a need to consult with M&TCs. WMP were asked to distribute the draft template and suggested criteria to all Chairs and Secretaries. It was agreed that a consistent and uniform approach should be adopted throughout NHS Wales and a standardised initial template for local adaptation would be recommended. It was noted that the suggested criteria may cause funding issues for some LHBs. It was agreed that the working group should progress to develop shared care protocols for the five drugs stated in the new GMS Contract. The Chairman endorsed the principal of the suggested criteria and asked that comments from M&TCs be considered at the AWPAG meeting in July. Dr Lewis agreed to report back to AWMSG at a future meeting.

WMP

12/10 Report on Task & Finish Group on Supplementary Prescribing

The Chairman invited Mrs Kathryn Bourne to present a brief overview of Enc No. 6/AWMSG/0605. Mrs Bourne informed members that despite early assurances by Astron (the commercial company contracted to provide NHS prescriptions in the UK) that supplementary prescriber prescriptions would be available by September 2004, they failed to deliver. Mrs Bourne assured members that every effort had been made by the Project Manager to avoid this problem. Miss Wynne-Howells confirmed that Welsh Assembly Government representatives would be visiting Astron to investigate the supply difficulties.

Mrs Bourne confirmed that no central monies are currently available to continue the training of supplementary prescribers. Training programmes can be purchased for nurses and pharmacists to become supplementary prescribers in Wales. Multi-professional courses may be available in the future, but would need the approval of the appropriate professional bodies. AWMSG supported the recommendations made in the report and questioned whether a financial statement should accompany the paper.

Miss Wynne-Howells confirmed that the results of the consultation are currently being co-ordinated and, depending on outcome, she would endeavour to move the prescribing agenda forward.

12/11 Prescribing Publications

Members were invited to comment on Enc No 7/AWMSG/0605. The Group identified some omissions and inconsistencies but agreed with the concept of the Access to Knowledge project.

- A need for BNFs to be available on all wards
- A need for BNFs to be available in emergency bags of out of hours providers
- Problems with access to the eBNF
- A need for Consultants to receive an individual copy

WMP was asked to incorporate members' suggestions, redraft the document and bring the issue back to the September AWMSG meeting for further discussion. The Chairman asked if the Access to Knowledge Project Lead could be identified. It was also noted that DrugInfoZone, an electronic based drug alerting resource widely used in primary care, had been assimilated by the Department of Health into the National electronic Library for Medicines. Reassurance was sought by the Chairman that access to this resource in Wales would be maintained.

WMP

12/12 Prescribing trends

Dr Greville requested a more detailed commentary and discussion on prescribing trends at subsequent meetings. It was confirmed that AWPAG had been requested to deliberate the issues around the data and this formed part of their work programme. The WMP representative at the AWPAG meeting held in April confirmed it had been agreed to link with the Heads of Pharmacy and Medicines Management in each LHB and explore the issues in more detail. The Chairman suggested that this information be brought back to the September AWMSG meeting.

**AWPAG/
HOPMMs
/ WMP**

12/13 Report on NHS Industry Forum

Prescribing freedom and formulary development

The Chairman reported that the revised paper had been circulated to AWPAG members, Chief Pharmacists and HoPMMs. The consistent response from these groups was to support the current guidance issued in WHC(2003) 73. It was agreed that AWMSG should not recommend any changes to the current circular or support distribution of the supplementary guidance.

12/14 Report on All Wales Prescribing Advisory Group

The Chairman asked that any comments be forwarded to Mrs Ruth Lang.

Date of next meeting

The next meeting will be held on Tuesday, 13th September 2005 in North Wales. Details will be posted on the website.