## **ALL WALES MEDICINES STRATEGY GROUP**

### MINUTES OF MEETING HELD ON THURSDAY, 3<sup>RD</sup> MARCH 2005 COMMENCING 10.30 AM AT THE ORANGERY, MARGAM COUNTRY PARK, NEATH, PORT TALBOT, SA13 2TJ

#### **MEMBERS PRESENT:**

1.	Mr Julian Baker	Finance Director Caerphilly LHB	
2.	Dr Paul Buss	Consultant Gwent Healthcare Trust	
3.	Mr Jeff Evans	Other healthcare professionals eligible to prescribe Senior Lecturer in Podiatry & Podiatric Surgeon Wales Centre for Podiatric Studies, UWIC, Cardiff	1
4.	Dr David Gozzard	Trust Medical Director Conwy & Denbighshire NHS Trust	
5.	Mr Peter Harsant	Industry representative Norgine Limited, Uxbridge, Middlesex	
6.	Dr Dyfrig Hughes	Health Economist (deputy member) Institute of Medical & Social Care Research University of Wales, Bangor	Participated in agenda item 16 only
7.	Cllr Meurig Hughes	Lay member Llangefni, Ynys Mon	
8.	Dr Thomas Lau	LHB prescribing lead Lliswery Medical Centre, Newport	
9.	Mr David Morgan	Consultant in Pharmaceutical Public Health, National Public Health Service, North Wales Region	
10.	Dr Ceri Phillips	Reader in Health Economics, School of Health Science, University of Wales Swansea	Did not participate as member of AWMSG in agenda item 16
11.	Mr Dave Roberts	Chief Pharmacist (deputy member) Cardiff & Vale NHS Trust	

12. Mr Jonathan Simms Local Health Board Pharmacist

(deputy member)

Torfaen Local Health Board

13. Dr Paul Tromans Regional Director, National Public Health

Service, South East Wales Region

(deputy member)

14. Prof Roger Walker Chairman AWMSG

Consultant in Pharmaceutical Public Health National Public Health Service, South East

Wales Region

#### **IN ATTENDANCE:**

16. Mrs Ruth Lang Liaison Manager

Welsh Medicines Partnership

17. Mrs Carolyn Poulter Pharmaceutical Services Branch

Welsh Assembly Government

18. Professor Philip Routledge Director, Welsh Medicines Partnership

19. Mrs Karen Samuels Programme Manager, Welsh Medicines Partnership

20. Mrs Fiona Woods Director, Welsh Medicines Partnership

21. 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
CSM Committee on Safety of Medicines

HCW Health Commission Wales
HSW Health Solutions Wales
LHB Local Health Board

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** 

#### 11/1. Welcome and Introduction

The Chairman welcomed those present and confirmed that the proceedings were recorded. He confirmed that simultaneous translation from Welsh to English would not be available and this decision had been made following consultation with The

Welsh Language Board, Welsh Assembly Government and all AWMSG members. The Chairman confirmed that the translation service could be reinstated at any time should any member express this wish. Members introduced themselves. The Chairman outlined the format of the meeting and reported that the minutes would be posted on the AWMSG website.

#### 11/2 Apologies

Mr Mike Pollard, Chief Pharmacist, North East Wales NHS Trust Mrs Kathryn Bourne, Nurse Prescriber, Gwent Healthcare NHS Trust Miss Carwen Wynne-Howells would not be available for the start of the meeting.

#### 11/3 Declarations of interest

Dr David Gozzard informed members that in his capacity as Consultant Haematologist he had used anagrelide, but had no other interests. Dr Ceri Phillips confirmed he had provided health economic advice to Shire (manufacturers of anagrelide) and would not be participating in agenda item 16. The Chairman confirmed that Dr Phillips had not been involved in any of the appraisal preparatory work.

#### 11/4 Minutes of previous meeting

The minutes were checked for accuracy and confirmed.

#### 11/5 Matters arising

**9/6 Chairman's report – Ongoing discussions between WMP and HCW**Professor Routledge confirmed that due to the outstanding resource issue no further progress had been made with regard to the development of a service level agreement between WMP and HCW.

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

The Chairman reported that this group had met twice and Dr Ceri Phillips had represented AWMSG. Dr Phillips informed the group that a draft consultation document was in the process of being prepared and should be available at the end of July 2005.

#### 9/12 Report on Supplementary Prescribing

Mrs Kathryn Bourne, AWMSG representative on the Task & Finish Group was not in attendance to provide a verbal update. The Chairman reported that the Task & Finish Group would meet on 8<sup>th</sup> March for what would probably be their last meeting. The Group expressed concern that prescription pads would not be available for the first cohort of supplementary prescribers until 31<sup>st</sup> March. This potential problem had been identified at the outset by the Task & Finish Group but had still not been averted. It was reported that the problem lay with Astron and their position of exclusivity with the contract for supply of the pads.

#### 9/13 Prescribing Publications

Professor Routledge informed the group that WMP, were progressing this issue. The Chairman reiterated the original remit of the outstanding work – to provide clarity with regard to who should receive which publications. The issue of funding would not be addressed by WMP. The need to progress this with some degree of urgency was stressed.

**WMP** 

#### **9/14** Sip Feeds

The issue of Sip Feeds was being addressed by both NHSIF and AWPAG. A number of comments had been received from external bodies and these needed to be factored into the progression of this work. Mr Morgan asked WMP to clarify the WMP role and remit of NHSIF in relation to this work. WMP agreed to identify a gastroenterologist willing to participate in the working group set up to address the clinical issues relating to sip feeds.

#### 9/16 Ask About Medicines Week

The Chairman reported that it had been requested that AWMSG retain links with the work of the Welsh Assembly Government on AAMW. The Chairman confirmed a volunteer would be sought outside the meeting to support AAMW.

#### 10/6 Chairman's report

#### **AWMSG Training Workshop**

The Chairman reported that the AWMSG Training Workshop would be held on 23/24 March at the Cardiff Hilton Hotel. A reserve list had been compiled to ensure that all fifty spaces would be fully allocated.

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

The issue of future monitoring of the implementation of guidance of AWMSG and NICE was raised. It was agreed the Chairman would seek clarification from the Welsh Assembly Government on where the responsibilities for this lay.

#### **Review of ASPBs**

The Chairman reported that a preliminary meeting with Mrs Ann Lloyd had taken place but there was no progress to report to date.

#### 10/8 All Wales Prescribing Incentive Scheme

The Chairman reported that the document had been finalised and would be disseminated throughout NHS Wales week commencing 7th March 2005.

<u>10/9</u> Templates for local adaptation
The Chairman confirmed that the title of the documents 'Protocol for use of Statins' and 'Protocol for oral antiplatelet therapy' would be changed to:

'Use of statin therapy in primary and secondary prevention of coronary heart disease', and

'Use of oral antiplatelet therapy'.

The Chairman confirmed the documents would be disseminated to the service week commencing 7th March 2005. It was noted AWPAG had agreed to review the documents on an annual basis.

#### 10/12 Membership and constitution of AWMSG and its sub-groups

The Chairman informed members that the process of reviewing the constitution of AWMSG had commenced and a paper would be brought back to the Group. He confirmed that all appointments would cease at the end of July 2005 and members of AWMSG had been asked to confirm whether or not they wished to serve another term. Each individual wishing to serve an additional term would then be appraised by the Chairman. The Chairman reported that he would like to meet with the Chairmen of the sub-groups in the near future.

#### 10/17 Broadening the AWMSG appraisal process

It was reported that a response had not been received from the Welsh Assembly Government in relation to a bid by WMP for funding to support the broadening of the AWMSG appraisal process. The Welsh Assembly Government representative agreed to follow this up.

WAG

#### 11/6 Chairman's report

The Chairman announced that AWMSG would appraise Pegvisamont (Somavert®) and Bortezomib (Velcade®) at the June 2005 meeting.

It was noted that in future, and following ministerial ratification, advice from AWMSG would not only be communicated by the e-network and posted on the AWMSG website, but would also be included in the newsletter of the Chief Medical Officer.

The Chairman informed the group that ABPI (Wales) had hosted a meeting held on 14<sup>th</sup> February 2005 at The Vale Hotel. The aim had been to raise awareness of the revised AWMSG appraisal process. The Chairman, Dr Ceri Phillips and representatives of WMP had been invited to speak at the meeting. Copies of the presentations would be posted on the ABPI (Wales) and AWMSG websites.

The Chairman informed members that he had also been invited by the Bevan Foundation to give a presentation of the AWMSG appraisal process at a Conference entitled "Health and the Welsh Economy" to be held in The Park Hotel, Cardiff on 25<sup>th</sup> February.

#### 11/7 GP out of hours

Members expressed concern that current arrangements were not working and were having an adverse impact on the workload of accident and emergency departments particularly during holiday periods. The need to improve patient access to medicines out of hours was also highlighted. It was noted LHBs monitored out of hours service provision in their locality although it was unclear if the data was reviewed on an all Wales basis. The Welsh Assembly Government representatives agreed to survey the LHBs to identify if there were any problems and report back at the next meeting. AWMSG members agreed to compile a series of questions that identified their areas of concern and which would be presented to the Welsh Assembly Government.

**WAG** 

AWMSG members

#### 11/8 Blood glucose testing – sharing good practice

The Chairman informed members that this item had been withdrawn from the agenda. He reported a conversation with Professor David Owens, Consultant Diabetologist in Cardiff and Vale NHS Trust who had advised that an All-Wales Consensus Group had been set up by the Welsh Assembly Government to produce a unified set of care pathways for diabetic patients in Wales. As part of their remit the Consensus Group would examine current practice with glucose monitoring. It was their intention to use the work presented in the paper withdrawn. The Chairman recognised the desirability of not promoting conflicting advice and was happy for the Consensus Group to take this issue forward.

#### 11/9 AWMSG future work programme

Miss Wynne-Howells joined the meeting.

Members were asked to comment on Enclosure 4/AWMSG/0305.

#### **D5 All Wales Prescribing Strategy**

Professor Routledge reported that a prescribing strategy was currently being prepared. It would be based upon a draft prescribing strategy that had been discussed at a previous AWPAG meeting. Professor Routledge agreed that WMP would bring the document back to a future AWMSG meeting for discussion.

**WMP** 

#### A6 Funding FP(10)HP

WMP agreed to amend the document to reflect that this is no longer required.

**WMP** 

#### **E1 Patient information leaflets**

This item had been referred to the NHSIF. Mr David Morgan agreed to prepare a paper for the June meeting summarizing the issues.

**NHSIF** 

#### E8/E9/E10 Generic and therapeutic substitution

To be discussed at a future AWPAG meeting

**AWPAG** 

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

It was agreed there was a need to pull available information together. The Welsh Assembly Government representatives agreed to prepare a paper on the out of hours provision of pharmaceuticals for discussion at a future meeting.

WAG

**E12 – Use of unlicensed drugs (specials)** This was referred to the All Wales Drugs Contracting Committee for consideration. WMP agreed to formally write to this committee to ask them to address the issue.

WMP

#### F1 Out of hours access to pharmaceutical services

WMP agreed to formally refer this item to the Chief Pharmacists Committee setting out a clear brief.

WMP/ WAG

#### **G7** Allocation formula

Dr Ceri Phillips, the nominated AWMSG representative, will update and report back to members as appropriate.

CP

#### **I11 Watchdog arrangement for sales promotion**

To be discussed by NHSIF at their meeting in April 2005.

**NHSIF** 

#### **I15 Green Card Scheme**

The Drug Safety Unit in Southampton is liasing directly with HSW with regard to data capture. WMP agreed to follow this issue up

**WMP** 

#### Reduction of medicine waste (new topic)

AWMSG welcomed this initiative being promoted on an all Wales basis and involving the Heads of Pharmacy and Medicines Management in each LHB. WMP agreed to contact Cardiff LHB and offer support on behalf of AWMSG. It was suggested that some aspects associated with attempts to reduce medicine waste may be addressed within the new pharmacy contract.

**WMP** 

It was agreed that there was a need to engage with stakeholders to identify the

needs of the service in the development of the AWMSG work programme. Members agreed to raise this issue with their professional committees and report back at a future meeting. WMP confirmed that the views of Heads of Pharmacy and Medicines Management, representatives of the National Public Health Service and M&TCs had been sought and that communication links with these organisations would be maintained.

#### 11/10 Reducing the harm caused by oral Methotrexate

Members agreed to endorse Enc 5/AWMSG/0305 as good practice and wished to see the same or similar models implemented across Wales.

#### 11/11 Local prescribing comparators

The Chairman invited Mrs Delyth Simons to join members around the table. Mrs Simons introduced herself and presented an overview of Enclosure 6/AWMSG/2005. The Chairman invited comments from members

AWMSG agreed the change in terminology from local prescribing indicators to local comparators. The issue of incentivising prescribing in secondary care was raised and it was agreed that this work should be progressed through AWPAG.

The Group discussed the prescribing comparators, their ongoing development, and the need to work with HSW in producing the data. In the short term AWPAG were the group with the expertise to address this. It had been noted by a number of bodies that HSW required their own professional support to undertake this work and the Chairman agreed to write to Mrs Ann Lloyd to emphasize the need for this. The Welsh Assembly Government representatives also agreed to pursue the provision of this professional support.

AWPAG RW

The request to implement average daily quantities (ADQs) received a cautious welcome from the Group. In principle the move was supported but their was insufficient information presented to identify if their were any resource implications for NHS Wales, whether the current file used in England would be available to HSW, how the file would be updated and the areas where use of ADQs would bring particular benefit. AWPAG were invited to address these issues and advise AWMSG accordingly.

#### 11/12 Prescribing indicator targets 2005/2006

Mrs Samuels asked that members consider the recent advice issued by MHRA and CSM that co-proxamol products should no longer be prescribed and consider the proposal to update the co-proxamol indicator agreed in 13/AWMSG/0604 to a reduction to zero. It was agreed that the advice should read "reduction to zero as soon as possible and before April 2006".

The Chairman invited Mrs Woods, convenor of the inappropriate generic prescribing working group to present a brief overview of their work outlined in Enclosure 7/AWMSG0305.

Mrs Woods reported that the consultation undertaken by the working group had unearthed a number of issues that had practical and educational implications for the patient and prescriber, but which were inappropriate to include in a national indicator. It was suggested that examples be brought together to form an educational" resource for prescribers in Wales. It was felt that this approach would build on the information obtained, allow the working group to be better prepared to

revise the indicator in the future, ensure prescribers are aware of practical prescribing issues and have ongoing dialogue with the industry. It was agreed that individuals with appropriate expertise to review the list on an annual basis and contribute to the ongoing work should be invited to join the working group. Mrs Woods identified the need for more secondary care input.

FW

During the discussion the desirability of prescribing all anti-epileptic drugs by brand name was raised. The Chairman informed members such an approach was not feasible given recent guidance issued by the Department of Health and relating to Lamictal (lamotrigine). This particular guidance identified that the Medicines and Healthcare products Regulatory Agency (MHRA) would ensure bioequivalence between the brand Lamictal and generic alternatives when available in May 2005. This would ensure there was no compelling evidence to suggest switching from the originating brand to a generic alternative would have an adverse clinical outcome. The Chairman suggested this information should be disseminated via the AWMSG e-network and website if Welsh Assembly Government were unable to distribute.

**WMP** 

#### 11/13 Prescribing trends

It was agreed that Enc 8/AWMSG/0305 raised a number of issues that would benefit from discussion by, and feedback from AWPAG. AWPAG were requested to comment on the prescribing patterns observed and identify initiatives that were working to disseminate good practice. There was a particular need to identify the issues behind the increasing use of drugs classified as less suitable for prescribing (BNF classification) and the wish of AWPAG to monitor drugs classified as of limited clinical value (Audit Commission classification).

**AWPAG** 

#### 11/14 Report on NHS-Industry Forum

#### **NAO Report on the Procurement of Primary Care Medicines**

Mrs Poulter confirmed that no progress has been made and the report from the working group had not been sent to the Minister.

#### **Guidance for Partnership Working**

Mr Morgan reported that the Welsh Health Circular (2005) 16 dated 16<sup>th</sup> February 2005 had been issued and expressed concern that the title in the covering letter did not correspond to the title of the document. It was agreed that Mrs Poulter would arrange for an amendment to be issued.

**WAG** 

#### **Ask About Medicines Week**

Mr Morgan confirmed that a letter had been sent to the Welsh Assembly Government suggesting that the campaign not be restricted to one week.

#### **Draft document – Roles and Structures of Prescribing Committees**

Mr Morgan asked members to comment on the draft document prepared by NHSIF on Roles and Structures of Prescribing Committees. Some members expressed concern that the paper appeared to conflict with the advice given in the Welsh Health Circular WHC (2003) 73 and suggested it would cause confusion instead of offering clarity to the service. Professor Routledge confirmed that WMP had submitted a proposal to Welsh Assembly for the funding of a central appraisal process and commented that circulation of the draft document would be untimely.

The Chairman confirmed that any consultation with the service would fall within the

remit of AWMSG and not NHSIF.

The Chairman summarised the discussion and asked that the Welsh Assembly Government provide clarity on the future of a central appraisal process by the next AWMSG meeting in June. It was agreed that in the interim Dr Gozzard would take the paper to the Trust Medical Directors meeting in April, and that AWPAG, the Heads of Pharmacy and Medicines Management, Chief Pharmacists and M&TCs be asked for comments. Mr Morgan agreed to make a number of changes before the draft paper was passed on to these other bodies for comment. Comments received from the professional groups would be fed back to the AWMSG Chairman via the Welsh Medicines Partnership.

DG / WMP

#### 11/15 Report on All Wales Prescribing Advisory Group

The Chairman invited Dr Thomas Lau, AWPAG Chairman to present Enc10/AWMSG/0305. Dr Lau acknowledged the input of members of the subgroup and thanked Mrs Nicola John for chairing the meeting.

#### Membership & constitutional issues

The Chairman clarified that any changes to the constitution of the sub-groups would need to involve the AWMSG Steering Committee and be approved by AWMSG. It was agreed that the wording of the AWPAG minutes should be changed from "It was agreed that" to:

WMP

"It was agreed to recommend that".

#### **All Wales Prescribing Incentive Scheme**

The Chairman confirmed that the document had been finalized and would be distributed week commencing 7<sup>th</sup> March.

It was agreed that the AWPAG working group set up to address incentivising secondary care should consist of an interface <u>or</u> *chief* pharmacist.

**WMP** 

#### 11/16 Appraisal: Anagrelide hydrochloride (Xagrid®)

(Start time 2.00 pm)

All members confirmed they had received and read the appraisal documentation. Members were asked to declare any interests. Mrs Fiona Woods and Mrs Karen Samuels joined the audience. The WMP appraisal team joined members around the table.

The Chairman welcomed Dr Maggie Moss, International Project Leader and Mr Steve Sanderson, Xagrid Marketing Manager, Shire Pharmaceuticals.

The Chairman also welcomed Dr Jonathan Kell, Consultant Haematologist, Cardiff and Vale NHS Trust. WMP had approached the British Haematology Society who, in turn, had contacted Professor Alan Burnett, Head of the Welsh Haematology Forum. Professor Burnett had nominated Dr Jonathan Kell.

The Chairman invited Dr Kell to declare any interests. Dr Kell confirmed he had been part of an Advisory Group for Shire Pharmaceuticals.

The Chairman confirmed that the WMP appraisal team consisted of Miss Gail

Hutchins, Appraisal Pharmacist, Dr Alison Thomas, Acting Senior Lecturer in Clinical Pharmacology and Mrs Shan Davies, Health Economist – Lecturer, School of Health Science, University of Swansea. Dr Ceri Phillips had declared a conflict of interest and was replaced by Dr Dyfrig Hughes, Deputy Health Economist.

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 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 Kell to set the clinical scene. Dr Kell concurred with the WMP assessment report but suggested that the numbers may be less than that quoted in the document. He confirmed that essential thrombocythaemia is often difficult to diagnose, as some patients may be asymptomatic. Dr Kell provided background to the disease, confirmed that anagrelide has a specific action on platelet count and is suitable for small numbers of elderly patients seen at specialized haematology clinics. Dr Kell suggested that the risk of developing acute myeloid leukaemia is more likely to be 9% rather than the 10% quoted in the WMP report, but that the evidence of this is not conclusive. Dr Kell reported that anagrelide has been available for several years on a named patient basis and he would not expect a significant increase in the number of patients taking the drug.

Miss Hutchins presented an overview of the WMP assessment report of anagrelide (Xagrid®). Mrs Shan Davies confirmed that the figures presented by the company in relation to their pharmacoeconomic assessment were logical and correct.

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

It was confirmed that essential thrombocythaemia might not always be clonal. Dr Kell confirmed there are no data available in relation to studies on long-term toxicity. Dr Gozzard confirmed that in his experience the neurological symptoms of his patients had improved following treatment with anagrelide. Members were informed that unpleasant side effects were common with the second line treatment, alpha interferon. It was confirmed that the side effect profile of anagrelide was dose-related and that liver functions tests should be carried out before commencing treatment. It was confirmed that patients with renal and hepatic impairment would commence treatment at reduced doses. Use in patients with severe impairment was contra-indicated, whilst patients with moderate impairment could still receive the drug. It was confirmed that the indication for anagrelide was for use in patients with essential thrombocythaemia resistant to or intolerant of first line therapy.

The chairman closed proceedings and voting members retired to meet in camera at 4.00 pm. The meeting re-convened at 4.15 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 anagrelide (Xagrid®) was that AWMSG would support the use of anagrelide (Xagrid®) within NHS Wales in accordance with its licensed indications subject to the following:-

AWMSG wished to see a uniform pathway for the management of patients with essential thrombocythaemia throughout Wales and would like the appropriate professional group to monitor patients and address concerns with regard to long-term safety issues.

**WMP** 

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 Kell for his concise presentation to the Group that assisted AWMSG in formulating the recommendation to the Minister for Health & Social Services. The Chairman also thanked Shire Pharmaceuticals for engaging with the AWMSG process and reported that the recommendation would be confirmed in writing. The appraisal was concluded.

#### Date of next meeting

The next meeting will be held on Wednesday, 8th June 2005 in Cardiff. Details will be posted on the website.