

# ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF MEETING HELD ON 2<sup>nd</sup> MARCH 2004

AT 11.00 AM IN THE GALLERY ROOM

NORTH EAST WALES INSTITUTE OF HIGHER EDUCATION

MOLD ROAD, WREXHAM, LL11 2AW

## MEMBERS PRESENT:

		Did not participate as member of AWMSG in agenda item
1.	Mrs Kathryn Bourne	Nurse Prescribing representative Gwent Healthcare NHS Trust
2.	Dr Paul Buss	Gwent Healthcare Trust Consultant representative
3.	Dr Bruce Ferguson	Medical Director (deputy member) Bro-Morgannwg NHS Trust
4.	Mr Peter Harsant	Industry representative Norgine Limited, Uxbridge, Middlesex
5.	Dr Dyfrig Hughes	Health Economist (deputy member) Lecturer in Health Economics, University of Liverpool
		7.1 / 7.2 / 7.3 / 7.4 / 7.5 / 7.7 / 7.8 / 7.9 / 7.10 / 7.11 / 7.12 / 7.13
6.	Cllr Meurig Hughes	Lay member representative Llangefni, Ynys Mon
7.	Dr Thomas Lau	LHB prescribing lead representative Lliswery Medical Centre, Newport
8.	Mr David Morgan	Pharmaceutical Public Health representative Consultant in Pharmaceutical Public Health, National Public Health Service, North Wales Region
9.	Dr Ceri Phillips	Health Economics representative Reader in Health Economics, School of Health Science, Swansea University
		7.6 / 7.13
10.	Mr Dave Roberts	Chief Pharmacist (deputy member) Cardiff and Vale NHS Trust
11.	Dr Quentin Sandifer	Consultant in Public Health Medicine representative, National Public Health Service, Mid & West Wales Region
		7.13
12.	Professor Roger Walker	Chairman AWMSG Consultant in Pharmaceutical Public Health National Public Health Service, South East Wales Region

## IN ATTENDANCE:

13.	Mr Jamie Hayes	Welsh Medicines Partnership
14.	Mrs Ruth Lang	Minutes (Welsh Medicines Partnership)
15.	Mr Graham Miles	Senior Partner, Morgan Cole Solicitors
16.	Mrs Carolyn Poulter	Head of Pharmaceutical Services Branch

17.	Professor Philip Routledge	Welsh Assembly Government
18.	Mrs Karen Samuels	Welsh Medicines Partnership
19.	Dr John Thompson	Welsh Medicines Partnership
20.	Mrs Fiona Woods	Welsh Medicines Partnership
21.	Miss Carwen Wynne-Howells	Chief Pharmaceutical Adviser
		Welsh Assembly Government

*List of Abbreviations:*

AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
HCW	Health Commissions Wales
LHB	Local Health Board
M&TCs	Medicines & Therapeutics Committees
NHSIF	NHS-Industry Forum
UCD	Urea Cycle Disorders
WAG	Welsh Assembly Government
WICS	Welsh Intensive Care Society
WMP	Welsh Medicines Partnership

## Action

### 7/1. Welcome and Introduction

The Chairman welcomed those present to the seventh meeting of AWMSG and confirmed that the proceedings are recorded and there is simultaneous translation from Welsh to English. The minutes will be available on the AWMSG website. Members introduced themselves.

### 7/2. Apologies

Mr Julian Baker, Director of Finance representative  
 Mr Jeffrey Evans, representing other healthcare professionals eligible to prescribe  
 Miss Sian Evans, Local Health Board pharmacist representative  
 Dr David Gozzard, Medical Director representative  
 Mrs Susan Hobbs, NHS Trust Nurse Director representative  
 Mr Mike Pollard, Chief Pharmacist representative

### 7/3. Declarations of interests

There were no declarations of interest appertaining to the agenda

### 7/4. Minutes of previous meeting

The minutes were checked for accuracy. It was noted that on page 1 Dr Dyfrig Hughes did not participate in agenda items 6.10 – 6.14 and Dr Quentin Sandifer did not participate in agenda items 6.10-6.14. On page 4 paragraph 9, the sentence should read “Some members expressed concern over the *status of the free* home delivery service”. It was noted there was a spelling error on the penultimate paragraph of page 4 “Restrictions”. On page 5, 6/8, paragraph 9 should read “the feasibility of drawing up a protocol .....”. On page 7, 6/10 the last bullet point should read “impact *of* releasing individuals from their work base”. On page 7, 6/11, there should be a full stop before Mrs Poulter. On page 8, the first paragraph should be amended to read “The Chairman reported that an invitation had been extended to the Chairman of the Scottish Medicines Consortium to attend a meeting in Wales in March 2004 to discuss their mode of *operation*”. The second paragraph on Page 8 should read “.....high level indicators for April 2005/2006 . Page 9, 6/15 should be amended to read “The Chairman asked the Group to note progress with this initiative and its potential as a valuable source of information of secondary care prescribing data”. With these amendments the minutes were then approved.

## **7/5. Matters arising**

### **5/5.3 Update on Prescribing Indicators**

The data presented at the AWMSG September 2003 meeting on defined daily doses had been calculated incorrectly. Professor Philip Routledge confirmed that Mrs Karen Fitzgerald of the National Public Health Service in Wales, who has considerable experience in this area, has agreed to assist and progress the issue of the calculation of DDDs with the Welsh Medicines Partnership.

### **6/6.7 Therapeutic Assessment – Adalimumab (Humira®)**

The Chairman confirmed that the Minister has accepted the recommendations of AWMSG regarding the use of adalimumab within NHS Wales, as stated in the Minutes of the meeting held on 2<sup>nd</sup> December 2003. He informed members that this information had not previously been available, as the decision had not been made on 1<sup>st</sup> March 2004.

### **6/6.9 Therapeutic Assessment – Enfuvirtide (Fuzeon®)**

The Chairman confirmed that the Minister has accepted the recommendations of AWMSG regarding the use of enfuvirtide within NHS Wales, as stated in the Minutes of the meeting held on 2<sup>nd</sup> December 2003. However, he informed members that there were issues outstanding regarding the clarification of the handling of waste, and he was currently in discussion with Roche Products Limited to address these issues.

### **6/15 Update on Medusa Project**

The Chairman requested an update of this project and asked that a paper be prepared for the next meeting.

Mr David Morgan asked for clarification of the current appeals process and the need for timely dissemination of advice to the Service. The Chairman confirmed that the current process was far from ideal and would benefit from clarification. Following appraisal by AWMSG, companies have 28 days in which to appeal against the decision. After this period, but only for drugs that are not the subject of an appeal, the Minister can make a decision on whether or not to accept the recommendation of AWMSG. Once this decision has been reached and no other issues are outstanding, AWMSG can then advise NHS Wales of the outcome. Where a decision of AWMSG is taken to appeal it is not until this process has been completed that the advice can be passed to the Minister and the subsequent decision relayed to NHS Wales.

## **7/6. Therapeutic Assessment – Sodium Phenylbutyrate (Ammonaps®)**

Professor Philip Routledge & Mr Jamie Hayes left the meeting prior to the discussions. Dr Dyfrig Hughes joined members at the table and Dr Ceri Phillips transferred to WMP for this agenda item.

The Chairman invited the following representatives from Orphan Europe to the appraisal table.

Dr Marie-Christine Bielsky, Medical Director  
Mr Nigel Nicholls, Product Affairs Manager

The Chairman introduced and welcomed the guests and explained to members that due to a clinical commitment, the medical expert nominated by the Chairman of the Welsh Paediatric Society, Dr Graham Shortland, had been unable to attend the meeting. Dr Shortland had provided a written statement which, upon receipt by the secretariat, had been circulated to AWMSG members, Orphan Europe and displayed on the AWMSG website. Dr Shortland's report had been compiled after he had had access to the published appraisal documents of WMP and Orphan Europe.

The Chairman reiterated that AWMSG guidance is interim to NICE guidance should this be subsequently published. In addition, AWMSG advice has no impact on the licensing status of the technology and the inherent implications associated with this.

Dr John Thompson gave a brief overview of Enc No 2/AWMSG/0304.

Comments were received from the company representatives and the Chairman opened the debate to AWMSG members.

Concern was expressed over the limited data available on this extremely rare disorder and that support mechanisms for survivors were required within the infrastructure of the NHS in Wales. It was recognized that there would be considerable on-going costs relating to the care of patients with UCD and members sought clarification over the quality of life of these patients. Issues with regard to compliance with treatment and the need for co-operation between the medical teams and parents were acknowledged. The Group discussed difficulties associated with the clarification of the actual number of cases within Wales due to the fact that some patients in North Wales may be treated outside Wales. It was also confirmed by Orphan Europe that when full market approval for the use of the drug had been granted, the Company had been relieved of its obligation to follow-up patients and maintain a database of patient outcomes. It was also noted there were no ongoing trials of sodium phenylbutyrate in UCD. The Group discussed the need for early diagnosis and the possible place of transplantation in disease management.

Members of AWMSG withdrew from the public meeting to reach their decision. Upon re-convening, the Chairman confirmed that AWMSG had reached a unanimous decision.

***It was agreed (vote: unanimous)*** that the following recommendation be made to the Minister for Health & Social Services with regard to sodium phenylbutyrate (Ammonaps®)

- 1. Treatment within NHS Wales should be supported in accordance with appropriate peer-reviewed guidelines.**
- 2. AWMSG were disappointed that Orphan Europe had discontinued maintenance of their patient database and strongly urged the company to reconsider this decision.**

#### **7/7. Welsh Intensive Care Society audit of Xigris**

The Chairman welcomed Dr Chris Thorpe and invited him to join the meeting. Dr Thorpe confirmed he is responsible for the Welsh Intensive Care Society audit of Xigris and had been nominated by the Chairman, Dr David Hope, to address the meeting. The Chairman reminded members that the use of Xigris within NHS Wales had been approved by AWMSG some twelve months previously and at that time AWMSG had recommended WICS be invited back to present feedback on uptake, use and clinical outcomes.

Dr Thorpe confirmed that seven hospitals had returned audit forms representing 50% of the total amount of drug usage. He stated that 44 patients had received treatment with the drug. Figures from Lilly indicated a higher usage. Amongst the 44 patients, there had been 16 deaths, 26 patients had survived and the outcome of 2 patients was uncertain at the time of the presentation.

The Group agreed there was a need to capture data from all patients treated including details of demography, gender and clinical status. Dr Thorpe agreed to collaborate with WMP to produce a robust dataset for re-presentation to AWMSG at a later date.

### **7/8. Update on Task & Finish Group on Supplementary Prescribing**

Mrs Kathryn Bourne confirmed that additional information had come to light since the preparation of Enc 3/AWMSG/0304. She confirmed that locum costs for general practitioners attending the training would be covered. At the time the paper had been written, the Implementation Sub-Group had met once. Mrs Bourne confirmed that the group had now met twice. The Chairman reiterated the need to keep members informed of progress and Mrs Bourne agreed to send a copy of the final minutes of all meetings of both the Implementation Sub Group and the Task & Finish Group, to the secretariat. It was noted that only approved minutes would be posted on the AWMSG web page. The Chairman acknowledged the speed of progress on this issue and requested copies of draft minutes should be made available to the AWMSG secretariat to ensure WMP and AWMSG were aware of developments in a timely manner.

### **7/9. Update on All Wales Prescribing Advisory Group (AWPAG)**

Dr Thomas Lau presented an overview of Enc 4/AWMSG/0304 and asked AWMSG to support the development of a drug budget allocation formula that takes into consideration capitation, morbidity and deprivation. The Chairman supported this approach but suggested this was the remit of the Welsh Assembly Government and not AWMSG. Dr Christine Daws, Director, Resource Directorate had agreed to attend the AWMSG meeting in September 2004. The Chairman asked Dr Lau to convey this information to members of AWPAG and compile questions to aid discussion with Dr Daws.

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The Chairman opened discussion on the remaining issues. The general feeling amongst the group was that AWMSG gave their support to AWPAG to develop a prescribing incentive schemes for use within NHS Wales and supported the proposed, preferred model based on a three element structure to include audit, education & training and a basket of quality and cost effective prescribing indicators. However, it was felt that the issue of whether the scheme should be mandatory or part of a three year rolling programme was not within the powers of AWMSG although a recommendation to this effect could be made. It was agreed that the Prescribing Incentive Scheme Sub-Group should be encouraged to develop guidance for implementation in 2005, and the existing Welsh Assembly Government, Welsh Health Circular relating to prescribing incentive schemes should be brought to the attention of LHBs in the interim period.

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The Chairman endorsed the recommendation that the AWPAG working-group should develop guidance and bring details back to the AWMSG June 2004 meeting.

### **7/10. Update on NHS-Industry Forum (NHSIF)**

Mr David Morgan informed the group that the minutes of the previous meeting of the NHSIF (Enc 5/AWMSG/0304) had been provided for information. Further details relating to page 3, item 7 would be addressed under agenda item 11. Clarification was sought on item 9, page 4 of the NHSIF minutes. Mr Morgan confirmed that discussions on the pharmacy contract had covered the use of parallel imports.

### **7/11. Consultation - Ethical standards for the NHS in Wales. Guidance for partnership working between NHS organisation, primary care contractors, the pharmaceutical industry in Wales and the wider commercial sector**

Mr David Morgan introduced the agenda item and thanked Dr Richard Greville, Vice Chairman of NHSIF, for his support and assistance in preparing the re-draft of the consultation document. Mr Morgan confirmed that legal advice had been sought from Morgan Cole Solicitors and stated he was happy to incorporate the comments made. The Chairman asked for clarity and consistency in the terminology used and agreed to pass his comments to Mr Morgan after the meeting. Mr Morgan agreed that a file

should be kept of examples of partnership working, and a reference to this would be included in the final document. A consultation period of six weeks was agreed. Members considered the accompanying letter and distribution list and additional organizations were suggested. The Chairman requested that any further comments specifically relating to the distribution list, should be passed to the secretariat outside the meeting and before Friday, 5<sup>th</sup> March.

## **7/12. Chairman's report**

### **7/12.1 Appeals hearings**

The Chairman confirmed that appeals against the decisions made by AWMSG had been received from four companies.

On 5<sup>th</sup> April 2004 hearings will be held for Amgen, Roche and Ortho Biotech regarding the use of erythropoietins in the treatment of anaemia in cancer.

On 8<sup>th</sup> April 2004 there will be a hearing for Genzyme Limited with regard to the use of aldurazyme within NHS Wales.

The Chairman confirmed:

- the appeals hearings would be held in the Welsh Assembly Government offices, Cathays Park and would not be open to the public.
- Chairmen of the Appeals Panels had been appointed, but members of the panel have not been finalized until clarification has been received regarding declarations of interest.
- All companies had been informed of the dates of their appeal hearing and the details of the appeals process

### **7/12.2 Health Commissions Wales**

The Chairman informed members that he had met with Dr Geoffrey Carroll, Chairman of Health Commissions Wales (HCW) and Professor Philip Routledge, Director of WMP, to discuss whether or not it was appropriate for AWMSG to appraise drugs which are high cost, low volume and used in highly specialist areas. It was noted that a service level agreement would be drawn up between WMP and HCW to address the assessment of these drugs. The assessment criteria has yet to be defined and further details will be reported in due course to the Group.

### **7/12.3 Appeals**

The Chairman informed the Group that during the process of setting up the appeals hearings legal advice had been received from Morgan Cole Solicitors. The Chairman invited Mr Miles from Morgan Cole to address the Group and present an overview of whether or not AWMSG should have an appeals process in place. The Chairman confirmed that regardless of the outcome of the deliberations the withdrawal of the appeals process would not apply to those companies who have already submitted a request for a therapeutic appraisal and who have not been informed that the appeals process is under review.

The Chairman opened discussion on this issue. Concern was expressed that whilst there is no legal obligation for an appeals process the spirit of AWMSG was to support partnership working and fairness. A comment was made that the document had only been made available to members at short notice. In response, the Chairman reiterated that AWMSG has a policy of openness and transparency, and confirmed the document had been made available to members as soon as it had been prepared by legal advisers to promote discussion within the Group and commence dialogue with the Minister. The Chairman considered it would have been inappropriate to sit on the paper or progress the issue further without members being aware of the advice received.

#### **7/12.4 Meeting in Builth Wells on 19<sup>th</sup> March 2004**

The Chairman confirmed that Professor David Lawson, Chairman of the Scottish Medicines Consortium, had agreed to address a meeting arranged by WMP on 19<sup>th</sup> March 2004. Representatives from M&TCs in Wales, Chief Pharmacists (or nominees), AWMSG members, Chairs and Vice Chairs of AWPAG and NHSIF had been invited to attend and participate in discussions over the appraisal system in Scotland, to feedback on the current situation of M&TCs in Wales and suggest ways of achieving better communication channels and systems within the Principality.

#### **7/12.5 AWMSG Members**

The Chairman confirmed that Mrs Sue Hobbs, AWMSG Chief Nurse representative, would be retiring in the Spring of 2004 and wished her success in her new ventures. This vacancy will be advertised on the AWMSG website.

The Group approved a proposal from the Chairman to request the Minister to change the constitution of AWMSG to permit the appointment of an LHB Medical Director.

The Chairman informed members that Mrs Carolyn Poulter would be absent on maternity leave from April 2004 and thanked her for the continued support she has shown to AWMSG.

#### **7/13. All Wales Drugs Chart**

Mr Dave Roberts presented an overview of Enc 7/AWMSG/0304 and asked members to consider and approve a new all-Wales drug chart for use in acute hospitals. A copy of the chart was circulated to members of AWMSG. Mr Roberts assured members that the design process had been fair and accommodated the views of a wide range of parties. The Group recognized the need to review and update the chart as appropriate. AWMSG also supported the monitoring of implementation.

The Chairman commended the work and it was agreed that AWMSG would support the introduction of the all-Wales drug chart for use in acute hospitals.

#### **Date of next meeting.**

The next meeting will be held in Swansea on Wednesday, 9<sup>th</sup> June 2004. Details will be posted on the website.