ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF MEETING HELD ON 4th SEPTEMBER 2003 COMMENCING 11.00 AM IN THE GLOUCESTER ROOM BRANGWYN HALL, GUILDHALL, SWANSEA, SA1 4PE

MEMBERS PRESENT:

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| 1. | Mr Julian Baker | Director of Finance representative Caerphilly Local Health Board |
| 1. | Mrs Kathryn Bourne | Nurse Prescribing representative |
| | | Gwent Healthcare NHS Trust |
| 2 | Miss Sian Evans | Local Health Board pharmacist representative |
| | | Merthyr Tydfil Local Health Board |
| 3. | Dr David Gozzard | Medical Director representative |
| | | Consultant Haematologist & Medical Director |
| | | Conwy & Denbighshire NH Trust |
| 4. | Mr Peter Harsant | Industry representative |
| | | Norgine Limited, Uxbridge, Middlesex |
| 5. | Mrs Susan Hobbs | NHS Trust Nurse Director representative |
| | | Chief Nurse, Cardiff & Vale NHS Trust |
| 6. | Councillor Meurig Hughes | Lay member representative |
| | | Llangefni, Ynys Mon |
| 7. | Dr Thomas Lau | LHG 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 |
| 10. | Mr Michael Pollard | Chief Pharmacist representative |
| | | Chief Pharmacist, North East Wales NHS Trust |
| 11. | Dr Quentin Sandifer | Consultant in Public Health Medicine representative, |
| | | National Public Health Service, Mid & West Wales Region |
| 12. | Professor Roger Walker | Chairman AWMSG |
| | | Consultant in Pharmaceutical Public Health |
| | | National Public Health Service, South East Wales Region |
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IN ATTENDANCE:

| Mr Jamie Hayes | Welsh Medicines Partnership |
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| Dr Channarayapatna Krishna | Welsh Medicines Partnership |
| Mrs Ruth Lang | Minutes (Welsh Medicines Partnership) |
| Mrs Carolyn Poulter | Head of Pharmaceutical Services Branch |
| • | Welsh Assembly Government, Cardiff |
| Professor Philip Routledge | Welsh Medicines Partnership |
| Mrs Karen Samuels | Welsh Medicines Partnership |
| Mrs Fiona Woods | Welsh Medicines Partnership |
| Miss Carwen Wynne-Howells | Chief Pharmaceutical Adviser |
| • | Welsh Assembly Government, Cardiff |
| | Dr Channarayapatna Krishna Mrs Ruth Lang Mrs Carolyn Poulter Professor Philip Routledge Mrs Karen Samuels Mrs Fiona Woods |

List of Abbreviations:

AWMSG – All Wales Medicines Strategy Group

AWPAG - All Wales Prescribing Advisory Group

DOH - Department of Health

HCW - Health Commission Wales

LHB - Local Health Board

NHSIF - NHS-Industry Forum

PPRS – Pharmaceutical Price Regulation Scheme

WAG – Welsh Assembly Government

WICS - Welsh Intensive Care Society

WMP – Welsh Medicines Partnership

Action

5/1. Welcome and Introduction

The Chairman welcomed Dr Channarayapatna Krishna and Mr Jamie Hayes of WMP, and Mr Julian Baker, Finance Director representative to their first meeting and declared that the role of the Committee is as set out in the constitution, proceedings are recorded and the minutes will be available on the AWMSG website. A simultaneous translation service from Welsh to English was available. The Chairman welcomed attendees to the 5th meeting of AWMSG and members introduced themselves.

5/2. Apologies

Dr Paul Buss Mr Jeffrey Evans

5/3. Declarations of interests

There were no declarations of interest.

5/4. Minutes of previous meeting

The minutes were checked for accuracy.

Page 3, 4/5.4. The Chairman stated that the WAG Finance Director is Dr Christine Daws.

5/5. Matters arising

4.4 Matters arising

A Director of Finance representative, Mr Julian Baker, had been appointed to AWMSG.

4.4 Update on MS Risk Sharing Scheme

It had previously been agreed that the MS Risk Sharing Scheme should remain on the AWMSG agenda for ongoing review. It was agreed that the NHSIF would monitor this issue and developments would be fed back to the parent group.

4/5.4 Prescribing budgets

The question of whether funding would follow an AWMSG appraisal recommendation was raised. The Chairman stated he had recently held discussions with WAG officials on this issue. It had been agreed that following an appraisal that recommended the use of a drug the advice had to be implemented by LHBs/Trusts within six months. The Chairman confirmed that AWMSG guidance was interim to any NICE guidance being published. The financial pressure was recognized and difficulties in planning budgets were acknowledged. The comments were reinforced by Carolyn Poulter who confirmed that SAFF targets were currently being set for the following financial year and assurance was given that the wording would be precise to avoid any confusion regarding implementation. It was confirmed that the Director of Finance at WAG would be invited to address the AWMSG December meeting. The Chairman

confirmed that he hoped AWMSG would have input into the Townsend project when the issue of budget allocations for LHBs is considered.

4/5.4 Update on roles and structures of prescribing committees

Mrs Carolyn Poulter confirmed that a letter reinforcing the AWMSG proposals had been distributed to the service in July 2003. Dr David Gozzard confirmed that this issue had been discussed at the last All Wales Trust Medical Directors meeting. The AWMSG recommendations had been circulated to the Group prior to the meeting. Concern was expressed over the primary/secondary care interface, but the members had agreed to review their present prescribing structures and report back to their next meeting. Dr Gozzard agreed to bring this information back to AWMSG. The Chairman reiterated the AWMSG recommendation to build on existing prescribing committees and review progress in April 2004, and for local committees to adopt and adapt recommendations as appropriate.

4.4.8 Update on drotrecogin alfa

The Chairman reported that outstanding issues had been resolved. A statement was made to the service on 22nd July and is available on the AWMSG website. The Chairman clarified the expectation that WICS will collate the audit data and WMP will bring the information back to the Group.

5/5.1 Update on NHS-Industry Forum

Mr David Morgan, Chairman of NHSIF, presented Enc No. 2/AWMSG/0903 to the group and stated that the minutes were presently unconfirmed. He confirmed that one vacancy exists for a lay member, but efforts were currently being made to appoint a representative from the Community Health Council. The appointment of deputies will be discussed at the next meeting. He also declared that the work programme is currently being reviewed, but will be available at the next NHSIF meeting on 20th October in Hensol and subsequently at the AWMSG meeting on 2nd December in Cardiff.

5/5.2 Update on All Wales Prescribing Advisory Group

Dr Tom Lau, Chairman of AWPAG, presented Enc No 3/AWMSG/0903 and confirmed the first meeting of AWPAG will be held on Wednesday, 22nd October. He confirmed that the group would be looking at prescribing incentive schemes and prescribing indicators. Documentation for the meeting will be available on the AWMSG website. Professor Walker confirmed that the NHSIF would take a lead on the development of the Code of conduct and sponsorship, but AWPAG were also required to have a significant input before it was presented to AWMSG.

5/5.3 Update on Prescribing Indicators

Mrs Karen Samuels presented Enc No 4/AWMSG/0903 to the Group. An acknowledgement was made to HSW for their help and assistance in the preparation of the paper. The Group discussed the content and acknowledged the major step forward in presenting data as defined daily doses (average maintenance dose per day for a drug used for its main indication in adults). A request was made to Mrs Samuels for an explicit statement on how the targets were set. Mrs Samuels confirmed that HSW would disseminate this information to LHBs in the present format. Prescribing Indicators for 2004/2005 will be progressed through AWPAG and brought back to AWMSG for further discussion. There was agreement that the impact of the new GMS contract on prescribing behaviour should also be considered by AWPAG.

At a previous AWMSG meeting it had been agreed that Mr Peter Harsant, Dr Ceri Phillips and Miss Sian Evans would quality assure the prescribing targets set. Due to the late availability of the required prescribing data this had not been possible. It was agreed the group should be involved in evaluating future indicators.

The Group expressed their thanks for the considerable amount of work undertaken by Mrs Samuels. It was agreed that the indicators developed would be extremely helpful in identifying areas of good practice and addressing some of the recommendations in the National Audit Report on the Procurement of Primary Care Medicines.

5/5.4 Update on Supplementary Prescribing

Mrs Kathryn Bourne confirmed that the Task and Finish Group on Supplementary Prescribing had held their first meeting the previous day. A project manager and project support manager have been appointed. The group had agreed in principle the project implementation plan and membership. Minutes of the meeting will be posted on the AWMSG website. The next meeting will be held on 25th September. The Chairman acknowledged this key development within NHS Wales and Mrs Bourne agreed to update AWMSG members at the December meeting.

5/5.5 Update on Horizon Scanning

Mrs Fiona Woods updated members on the three national prescribing documents to be published jointly by UK Medicines Information (UKMI) and the National Prescribing Centre. These documents are confidential to appropriate NHS professionals and will be available on a password-protected basis on the UKMI website. It was agreed Mrs Woods should compile feedback on the appropriateness of the documentation for planning purposes within NHS Wales and requested completed feedback forms should be returned to her at Medicines Information, University Hospital of Wales, Heath, Cardiff. This information would subsequently be fed back to UKMI at National Level. Mrs Woods agreed to follow-up the request by Dr Ceri Phillips for access to confidential information by non-NHS employees who work in partnership with the NHS.

5/6. Therapeutic Assessment - Aldurazyme

Mrs Fiona Woods left the meeting prior to the discussions. The Chairman invited the following to join members at the table.

Dr Michael Badminton, Senior Lecturer/Consultant in Medical Biochemistry (with a specialist interest in inherited metabolic diseases in adults), University of Wales College of Medicine, Cardiff And Vale NHS Trust

Mr Paul Roberts, Clinical Science Associate, Genzyme UK Dr Vincianne Pirard, Medical Manager, Genzyme European Office

The Chairman introduced and welcomed the guests and Dr Michael Badminton confirmed he had no declarations of interest. The Chairman also invited Dr Badminton to clarify the rationale for his invitation to attend. He confirmed that the invitation had originally been extended to Dr Graham Shortland, Consultant Paediatrician at the University Hospital of Wales who has a special interest in patients with metabolic disease and runs a joint clinic with Dr Ed Wraith in Cardiff twice a year for patients in Wales with lysosomal storage disorders. Dr Shortland was unable to attend the AWMSG meeting due to a prior engagement and had asked Dr Badminton to represent him.

Prior to the commencement of the appraisal, 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.

Professor Philip Routledge presented Enc No 5/AWMSG/0903 Appendix I and confirmed that the paper had been independently compiled using the information contained in Form A or available in the public domain. Professor Routledge also

brought to the attention of members a BMJ editorial on the Treatment of lysosomal storage disorders 327: 30 August 2003, 462-463.

Dr Ceri Phillips presented Enc No 5/AWMSG.0803 Appendix II.

The Chairman invited AWMSG members to address the company representatives or Dr Badminton to clarify or query information contained in the appraisal documentation.

Dr Badminton provided his medical opinion and confirmed that a national register was in place to monitor outcomes in patients treated with laronidase. There was a general discussion about the drug and the Group expressed concern over the limited evidence and lack of data. Dr Pirard confirmed that the trials to date had taken place over a short period of time, eg 52 weeks, compared to the lifetime of treatment required by some individuals. Long-term studies are currently being undertaken and the results are eagerly awaited.

The Chairman confirmed that AWMSG had been asked to consider whether Aldurazyme (laronidase) should be available for use within NHS Wales for the treatment of mucopolysaccharidosis type 1 and, were it available, is there a requirement for treatment guidelines concerning its use.

At this point the meeting broke for lunch and the Company representatives left the meeting.

When the meeting reconvened the Chairman stated that AWMSG would not support the use of Aldurazyme (laronidase) within NHS Wales on the grounds of lack of evidence of cost effectiveness.

The Chairman confirmed AWMSG were sympathetic to the plight of patients with mucopolysaccharidosis type 1 and encouraged more clinical trials to be undertaken. The Chairman also stated that AWMSG would be prepared to reconsider the drug should more evidence become available.

5/7. Communication process for therapeutic development assessments

Mrs Karen Samuels presented Enc No 6/AWMSG/0903 and confirmed that WMP had developed the therapeutic development process closely with Dr Richard Greville, Director of ABPI Cymru in an attempt to ensure that as many of the issues involved were considered and pictorially represented. AWMSG members were invited to provide suggestions for improvement and clarity. It was recognized that this is an ongoing process that will require change with experience. WMP extended an invitation to industry representatives to contact and meet with them to alleviate concerns or misunderstandings about the process.

Clarification was sought as to why Form B was not made available to WMP and the health economic assessment teams at the time of the appraisal. The Chairman confirmed the necessity for an independent appraisal to be undertaken. Mrs Samuels agreed to incorporate a definition of the assessment criteria. It was agreed that the document should be displayed on the AWMSG website. The question of mutual recognition between AWMSG and SMC was raised. The Chairman confirmed that dialogue with SMC is ongoing but automatic acceptance of each other's appraisal outcomes was not likely in the immediate future.

5/8. Prescribing trends

Karen Samuels outlined Enc. No. 7/AWMSG/0903 on prescribing trends in Wales. Mrs Samuels stated that the data for Neath Port Talbot had been unintentionally omitted. It was agreed there was a need for further investigation of the trends and changes in prescribing patterns. Dr Ceri Phillips agreed to work with WMP to develop

measures of healthcare improvement linked to prescribing trends. In summary, the Chairman reported that this paper would be progressed through AWPAG, who were tasked with looking at the underlying issues and explanation for prescribing variations, and WMP, who were tasked with continuing to further investigate variation in CVS prescribing patterns and report back to the December meeting.

AWPAG /WMP

5/9. Procurement of Primary Care Medicines

The Chairman outlined the background to Enc No 8/AWMSG/0903 and confirmed receipt of a letter from the Chairman of the British Association of Pharmaceutical Wholesalers which also identified a number of problems with pursuing central purchasing. The Chairman reported that feedback from all parties consulted had been negative. In addition, it was noted that the recent proposals of DOH and WAG to amend the arrangements for the supply and reimbursement of generic medicines, together with ongoing discussions on the PPRS, could create significant instability amongst some manufacturers, wholesalers, community pharmacists and dispensing doctors. This in turn could impact on the feasibility of undertaking a central purchasing pilot. It was therefore agreed that AWMSG felt unable to support the introduction of central procurement at the current time based on the information available and feedback received from those consulted. The Chairman agreed to confirm this decision in writing to WAG and Ann Lloyd, Director NHS Wales.

RW

5/10. Management of Influenza

Mrs Fiona Woods presented Enc No 9/AWMSG/0903 to the Group and the Chairman encouraged all appropriate healthcare professionals to make themselves aware of the available guidance and to ensure it is implemented in practice.

5/11. The Medicines Partnership "Ask about Medicines Week" (for information) Miss Carwen Wynne-Howells presented Enc No 10/AWMSG/0903 and confirmed that the First Minister, Mr Rhodri Morgan, would launch this Medicines Partnership initiative in Wales. She emphasized that the week was all about adopting a cultural shift and not simply about having an opportunity during one week to ask about medicines. An increased workload on practitioners was recognized, but it was felt that NHS Direct would deal with most of the enquiries. AWMSG members were encouraged to respond to requests for media interviews.

5/12. Changes to the AWMSG Constitution (for information)

The Chairman confirmed that changes to the AWMSG constitution had been agreed by the Minister and the amended document will be posted on the AWMSG website.

WMP

5/13. National Patient Safety Agency (for information)

The Chairman requested that members note the work of the National Patient Safety Agency (NPSA) and consider potential opportunities for future collaboration with the NPSA in achieving mutual objectives.

Date of next meeting.

The next meeting will be held in the All Nations Centre, Sachville Avenue, Heath, Cardiff on Tuesday, 2nd December 2003. Details will be posted on the website.