

<b>Enclosure No:</b>	1/AWMSG/0904
<b>Agenda Item No:</b>	4 – Minutes of previous meeting
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# ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF MEETING HELD ON 9<sup>TH</sup> JUNE 2004

AT 11.00 AM IN CONFERENCE ROOM 2

THE DYLAN THOMAS CENTRE, SOMERSET PLACE, SWANSEA, SA1 1RR

## MEMBERS PRESENT:

Did not  
participate as  
member of  
AWMSG in  
agenda item

- |    |                    |  |       |
|----|--------------------|--|-------|
| 1. | Mr Julian Baker    | Director of Finance representative<br>Caerphilly Local Health Board  |       |
| 2. | Dr David Gozzard   | Trust Medical Director representative<br>Conwy & Denbighshire NHS Trust  |       |
| 3. | Mr Peter Harsant   | Industry representative<br>Norgine Limited, Uxbridge, Middlesex  |       |
| 4. | Cllr Meurig Hughes | Lay member representative<br>Llangefni, Ynys Mon   |       |
| 5. | Dr Thomas Lau      | LHB prescribing lead representative<br>Lliswery Medical Centre, Newport  |       |
| 6. | Mr David Morgan    | Pharmaceutical Public Health representative<br>Consultant in Pharmaceutical Public Health, National<br>Public Health Service, North Wales Region |       |
| 7. | Dr Ceri Phillips   | Health Economics representative<br>Reader in Health Economics, School of Health Science,<br>Swansea University                                   | 8/11. |
| 8. | Mr Mike Pollard    | Chief Pharmacist<br>North East Wales NHS Trust   |       |

9. Mr Jonathan Simms      Local Health Board Pharmacists representative  
Torfaen Local Health Board
10. Professor Roger Walker      Chairman AWMSG  
Consultant in Pharmaceutical Public Health  
National Public Health Service, South East Wales Region

**IN ATTENDANCE:**

11. Mr Jamie Hayes      Director, Welsh Medicines Partnership
12. Mrs Sian James      Pharmaceutical Services Branch  
Welsh Assembly Government
13. Mrs Ruth Lang      Administrative Office Manager  
Welsh Medicines Partnership
14. Mr Graham Miles      Senior Partner, Morgan Cole Solicitors
15. Mrs Karen Morgan      Pharmaceutical Services Branch  
Welsh Assembly Government
16. Professor Philip Routledge      Director, Welsh Medicines Partnership
17. Mrs Karen Samuels      Programme Manager, Welsh Medicines Partnership
18. Dr Alison Thomas      Acting Senior Lecturer, Welsh Medicines Partnership
19. Mrs Fiona Woods      Director, Welsh Medicines Partnership

*List of Abbreviations:*

AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
LHB	Local Health Board
M&TCs	Medicines & Therapeutics Committees
NHSIF	NHS-Industry Forum
TDA	Therapeutic Development Assessment
WICS	Welsh Intensive Care Society
WIG	Wales Industry Group
WMP	Welsh Medicines Partnership

**8/1. Welcome and Introduction**

The Chairman welcomed those present to the eighth 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. The Chairman confirmed that resignations had been received from Dr Quentin Sandifer and Miss Sian Evans, and AWMSG was seeking nominations to replace the vacant posts.

**8/2. Apologies**

Mrs Kathryn Bourne, Nurse Prescriber representative

Dr Paul Buss, Consultant representative

Mr Jeffrey Evans, representing other healthcare professionals eligible to prescribe

Dr Dyfrig Hughes, deputy Health Economist representative (for agenda item 11)

**8/3. Declarations of interests**

There were no declarations of interest pertaining to the agenda

**8/4. Minutes of previous meeting**

The minutes were checked for accuracy. It was noted that on page 3 5/5.3 Mrs Karen Fitzgerald should be replaced with Dr Karen Fitzgerald. 7/12/2 Mr David Morgan questioned the accuracy of the first sentence and the Chairman confirmed that the wording was correct. 7/12/3 Mr Peter Harsant asked that the following sentence be added "The feelings that were expressed were in favour of the retention of the appeals process". With these amendments the minutes were then approved.

**8/5. Matters arising****6/6.9 Therapeutic Assessment – Enfuvirtide (Fuzeon®)**

The Chairman informed members that agreement had been reached with Roche Products Limited with regard to the clarification of the handling of waste as stated in the Patient Product Information Sheet. He confirmed that AWMSG would like to draw the attention of prescribers in Wales to the following statement which would be added to the recommendation on the website.

***"AWMSG has concerns that reference in the Patient Product Information Sheet of returning vials to the Pharmacy may be misinterpreted by patients and could result in them attempting to return a wider range of clinical waste to the Pharmacy. Pharmacists, doctors and nurses may find it necessary to draw to the attention of patients the correct way to dispose of their clinical waste".***

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

Professor Routledge confirmed that a meeting has been arranged with Dr David Hope of WICS.

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

Dr Tom Lau informed members that a prescribing incentive scheme working group consisting of nominated members from AWPAG had agreed to meet to discuss detailed proposals to bring back to their meeting in October. Comments from that meeting would be incorporated into the document and presented to the AWMSG December 2004 meeting. It was acknowledged there was a workload issue that prevented this document being brought to AWMSG before this time. Dr Lau confirmed that WMP is preparing a statement on his behalf to be issued to LHBs recommending that incentive schemes should be retained until April 2005 and the Welsh Health Circular (WHC (2003) 62)

remains extant. Mr Julian Baker agreed to be party to the discussions of the working group as it was agreed there was need for input from a Finance Director.

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

The Chairman informed members that the issue of the retention of the appeals process had not been progressed but would form part of the agenda for a meeting arranged with the Minister on 15<sup>th</sup> June. The Chairman confirmed he would advise members as soon as further information had been received.

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

Professor Routledge informed the Group of a meeting that had taken place with representatives of M&TCs in Wales with regard to the managed entry of new medicines in Wales. Professor David Lawson, Chairman of the Scottish Medicines Consortium, had shared his experience with the meeting. Professor Routledge also confirmed that WMP had set up regular meetings with the TDA User Group of WIG. A discussion document outlining proposed changes to the current AWMSG appraisal process had been prepared by WMP for discussion under agenda item 13.

#### **8/6. Chairman's report**

The Chairman informed members that the following appeals hearings had been held:  
On 5<sup>th</sup> April 2004 a hearing had been 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 a hearing had been held for Genzyme Limited with regard to the use of aldurazyme in the treatment of mucopolysaccharidosis I. .

The Chairman confirmed that no element of the appeals had been upheld. A further statement would be made once the outcome had been considered by the Minister. **Action**

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

The Chairman reported that Mrs Kathryn Bourne had been taken ill at short notice and was unable to present her report. Members were invited to raise any issues.

Members felt the timescale over which the Task and Finish Group would remain needed to be clarified along with role and lifespan of its subgroup. Members expressed concern over the limited funding available for continuation of the programme.

Professor Routledge informed members that he had been involved with the training of the designated supervising medical practitioners and felt there was enthusiasm and a commitment for supplementary prescribing to work in Wales by both primary and secondary care doctors.

**KB**

Mr Michael Pollard identified the need for advice from the Task and Finish Group on the accreditation of supplementary prescribers trained in England. Individuals trained in Wales had to demonstrate their competency with calculations but this was not the case in England.

The issue of the small number of community pharmacists was also raised and members asked for feedback on the quality and standard of training and the implementation of monitoring of the impact on practice and accreditation of prescribers.

#### **8/8. Update on All Wales Prescribing Advisory Group (AWPAG)**

Dr Lau informed members that the minutes of the previous AWPAG meeting held on 28<sup>th</sup> April 2004 in Wrexham had been provided for information (Enc 3/AWMSG0604). Thanks

were expressed to those who had been involved in the preparation of agenda item 15 – All-Wales antiplatelet prescribing guidance and 18 – National prescribing indicators for 2005/2006 as the items had been developed by members of AWPAG.

Dr Lau reiterated that where a need was identified within an LHB, AWPAG would support the appointment of a GP prescribing lead. Time constraints had prevented a paper on this particular topic being prepared in time for the AWMSG June meeting. However, the proposed job description and associated discussion paper had been posted on the AWMSG website for information and dissemination ([click here to view](#)).

The Chairman enquired whether the constitution of AWPAG allowed the Group the power to co-opt a member. Dr Lau confirmed that approval had been sought from the Welsh Assembly Government representative at the AWPAG meeting prior to the co-option of Dr Mark Daniels. He had been informed that this was permissible. The Chairman was in full support of the appointment but asked representatives from Welsh Assembly Government to confirm it was allowed within the constitution of AWPAG.

Clarification was also sought as to whether there was an intention that AWPAG working group meetings would be minuted to further enhance the spirit of openness and transparency. It was acknowledged there would be considerable financial and workload implications if this were implemented. The Chairman confirmed that recommendations from sub-groups and working-groups would always be brought to the parent group for ratification and at that point would become a matter of public record.

#### **8/9. Update on NHS-Industry Forum (NHSIF)**

Mr David Morgan informed the Group that the minutes of the previous meeting of the NHSIF held in Swansea on 21<sup>st</sup> April 2004 (Enc 4/AWMSG/0604) had been provided for information. Further details relating to the partnership document would be addressed under agenda item 10. Mr Morgan highlighted key issues from the minutes and expressed the Group's disappointment at the difficulties experienced in appointing a lay member to NHSIF. Mr Morgan confirmed that Mrs Jennie Hammond will be attending the next NHSIF meeting as the NHSIF member and Mr Jeremy Felvus, deputy member, will not be required to attend. Mr Morgan informed members that NHSIF would be considering the use of Controlled Drugs in Wales at their meeting in July 2004. The Group agreed this was a priority item and collaborative work with others within NHS Wales would be required.

**Action**

The meeting had also discussed patient pack dispensing and noted anecdotal reports of a significant impact on the reduction of administration and dispensing errors. It was agreed to clarify this issue and request Mr Mike Pollard to bring further information to the attention of AWMSG. It was also pointed out that the policy of the pricing bureau on the reimbursement of chemist contractors could also mitigate against the use of patient packs and required clarification.

**MP**

**WMP**

#### **8/10. 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 allied commercial sector**

Mr Morgan confirmed that forty-seven consultation responses had been received. It was agreed that copies of the responses would be made available by WMP on request, but that only the summary of comments would be posted on the website. Mr Morgan confirmed that a working party consisting of ten members from NHSIF (five from industry and five from the NHS) had met one week following the close of the consultation to consider the comments (Enc 5b/AWMSG/0603). Following the working group meeting, the partnership document had been re-drafted (Enc 5a/AWMSG/0603) and the Chairman invited AWMSG members to comment. The following points were discussed and noted:

*Definition of 'partnership' had been included in the document*  
*Logo removed*  
*Glossary to be finalized outside of the meeting*  
*Repetition of text reduced*  
*No reference to Caldicot (following legal advice)*  
*Some concern expressed over implementation in primary and secondary care*  
*Remove "evaluation" and replace with "assessment" in bullet point 3, point 11 on page 5*  
*Include "independent contractor" in the brackets on page 17*  
*Government policy of partnership working and openness recognized*  
*Remove "reasonable" in paragraph B of Annex 8 on page 21*  
*Remove "representative" in paragraph B of Annex 8 on page 21 and replace with "company" to remove ambiguity*  
*The issue of an amendment to standing orders prior to the release of the guidance should be addressed*  
*Direct sponsorship issue needs to be addressed in a separate document*  
*Ethics approval to be added to the checklist*

The Chairman reiterated that this was the final opportunity for member to raise any outstanding issues before the document was passed to the Minister. He also stated there was no guarantee the document would be issued as a Welsh Health Circular, as this decision was not within the remit of AWMSG. The Group gave their full support to the document and acknowledged the amount of work that had gone into its preparation. The Chairman congratulated NHSIF on the development of this work in an open and transparent manner and stated that he looked forward to its successful implementation.

## Action

### 8/11. Therapeutic Assessment – Teriparatide (Forsteo®)

(Start time 1.30 pm)

Mr Jamie Hayes left the meeting prior to the discussions. Dr Ceri Phillips transferred to WMP for this agenda item and was not permitted to vote.

The Chairman introduced and welcomed Mr Chris Chinn, UK Health Outcomes Manager and Ms Tina Phelan, Osteoporosis Clinical Adviser from Eli Lilly & Co and Dr Pam Brown the NHS Wales medical expert nominated by the Chairman of the Welsh Osteoporosis Advisory Group. The Chairman asked Dr Brown to declare any interests and she confirmed participation in a study that was awaiting publication. It was noted this was a lapsed interest that had expired over a year ago.

The Chairman reiterated that AWMSG guidance is interim to NICE guidance should this be subsequently published. It was noted that WMP had contacted the company to ascertain whether they wished to proceed with the appraisal in the light of the release of interim guidance from NICE. The company had confirmed they wished to proceed. The Chairman stated that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A positive appraisal by AWMSG that is endorsed by the Minister does, however, place an obligation on Trusts and LHBs to fund accordingly.

The Chairman invited Dr Brown to address the Group to provide a clinical overview.

Dr Brown stated that osteoporosis is very common particularly in postmenopausal women and is often undiagnosed or misdiagnosed. Fracture rates are increasing and some patients fail to respond to current medication. Dr Brown indicated the size of the problem in Wales and stated there was a definite role for teriparatide in conjunction with a

programme of extensive education of general practitioners and other healthcare workers. Dr Brown urged the Group not to place an age restriction on access and reiterated that teriparatide was an important advance for patients with severe osteoporosis to reduce the risk of subsequent fractures.

The Chairman invited Dr Alison Thomas to give an overview of Enc 6a/AWMSG/0604 the review undertaken by the Welsh Medicines Partnership. Dr Ceri Phillips then addressed the Group from the health economic perspective and indicated the only data available was from an incomplete study.

The Chairman invited comments from the company representatives. Miss Phelan confirmed that the final NICE appraisal document relating to the secondary prevention of osteoporotic fractures in postmenopausal women was expected in October 2004. The company felt that as further delays could be encountered there may be a benefit for high risk patients in Wales hence the decision to proceed with the appraisal. Miss Phelan asked the Group not to place an age restriction on access as this would not significantly impact on the financial burden of the NHS in Wales. Miss Phelan stated that the projections in Form A are based on assumptions that do not include age. Mr Chinn stated that it would be prudent to take the uncertainty of the NICE model into account as he considered the Sheffield/NICE assessment was flawed.

The Chairman opened the debate to AWMSG members. The Group asked for clarification of the additional information ([click here to view](#)) that had been submitted by Eli Lilly & Co in response to the WMP report.

#### Action

The Group discussed the feasibility of shared care, the current management of fractures and the spectrum of interventions and requisite infrastructure support. The question of availability of services in Wales was raised and Dr Brown confirmed that all specialist centres would have access to DEXA scans. The Group discussed problems in initial assessment, restricted specialist use, the role of the general practitioner, definitions of severity of the disease, T-scores, eligibility for treatment and cycling therapy. The company were questioned about their post marketing surveillance and follow-up programmes.

Members of AWMSG withdrew from the public meeting to consider their decision at 2.55 pm. Upon re-convening at 3.35 pm, the Chairman confirmed that AWMSG had reached the following decision.

***It was agreed (vote: 7 for, 1 against)*** that the following recommendation be made to the Minister for Health & Social Services with regard to Teriparatide (Forsteo®):

- i. **AWMSG support the use of Teriparatide within NHS Wales for the treatment of established severe osteoporosis in post menopausal women at a quadrupled risk for another osteoporotic fragility fracture.**
- ii. **Treatment should be initiated and supplied from secondary care for the full treatment course.**
- iii. **Although not a prerequisite of support, AWMSG would wish to see a register established for long term safety follow up of patients treated with teriparatide (Forsteo®).**

The Chairman advised the company representatives that they have 28 days to lodge an appeal. The grounds for appeal are set out on the AWMSG website. The Chairman

confirmed that the advice of AWMSG will not be passed to the Minister until the 28 days has expired unless the company inform the Chairman in writing they do not intend to lodge an appeal. A summary of the proceedings will be published on the website in approximately fourteen days”.

Dr Brown, Ms Phelan, Mr Chin and Dr Thomas left the meeting.

#### **8/12. AWMSG work programme**

The Chairman invited Mrs Karen Samuels to present Enc 7/AWMSG/0603 on behalf of the Welsh Medicines Partnership. The paper outlined the progress made against the highest priority items in the first eighteen months from the inception of AWMSG. Members were asked to note that seventeen out of the nineteen high priority objectives have been achieved.

A proposal was put forward to consult with professional groups and stakeholders throughout Wales on the work of AWMSG and its priorities in relation to the work programme.

It was agreed that WMP should consider work strategy issues and workforce planning to deliver healthcare as part of a paper to take the work programme forward and seek the views of WAG and the service in Wales.

**WMP**

#### **8/13. Proposed changes to AWMSG appraisal process**

The Chairman invited Professor Philip Routledge to present an overview of Enc 8/AWMSG/0604. Professor Routledge informed the Group that the paper outlined an approach to appraisal and review by AWMSG of all new medicines and significant licence changes in Wales building on the current principles of robustness, openness and transparency. There was general support to develop the proposal although it was acknowledged that this would be on a long-term basis. Concern was expressed over the need for involvement of medical staff across Wales and the resource implications. However, there was general agreement and support for development of the proposal. It was also agreed that there was a need to consult widely within the service to appraise the possible options. The proposal also had the broad support of the industry.

**Action**

It was noted that the proposed appraisal process involved consultation with patient groups. This development received general support along with the suggestion that a similar approach be incorporated within the current process if at all possible.

**WMP**

There was a request by Dr Ceri Phillips for sight of Form B at an earlier stage to assist in the compilation of a more comprehensive WMP report. It was agreed this issue should be clarified and a paper prepared for presentation at the next meeting of AWMSG.

#### **8/14. Update on Medicines & Therapeutics Committees**

The Chairman invited Dr David Gozzard to present Enc 9/AWMSG/0604. The document is a position paper on the present constitution of the local prescribing committees aligned to primary/secondary care. The Group discussed the evolving process and acknowledged many LHBs had not been in a position to adopt WHC(2003)73 when the circular had been disseminated but recognised this was no longer the case. Dr Gozzard confirmed the paper would be discussed at the Welsh Medical Directors meeting to be held later in the month. The Group also suggested the paper be considered at the next AWPAG meeting and examples of good practice identified.

**DG/  
AWPAG**

Mrs Karen Morgan left the meeting.

#### **8/15. All-Wales antiplatelet prescribing guidance**



The Chairman invited Mr Stuart Evans (Interface/Formulary Pharmacist at Swansea NHS Trust/Swansea LHB and member of AWPAG, to join the meeting and present an overview of Enc10/AWMSG/0604. Mr Evans confirmed there was a requirement for minor rewording in parts of the paper, but asked the Group to support the guidance. It was agreed that input from a stroke specialist, vascular surgeon, consultant cardiologist, medical biochemist and cardiac networks would further add to the value of the paper. Mr Evans agreed to work with WMP to progress the guidance to completion.

SE/  
WMP

#### **8/16. Prescribing update – Statins & Clopidogrel**

The Chairman invited Mr Jamie Hayes to present an overview of Enc 11/AWMSG/0603 on behalf of the Welsh Medicines Partnership. The paper was an update of an earlier paper (10/AWMSG/1203) that covered the prescribing of statins and clopidogrel within primary care in Wales.

The Group identified the process adopted by Bridgend LHB as an exemplar of good practice and discussed the identification and dissemination of such information. It was agreed that this should be taken forward through AWPAG.

The Group were asked to ensure that when endorsing a single drug there should be a strong evidence base and cost alone must not be the sole arbiter. It was reiterated that simvastatin 40mg had a very strong evidence-based to support its use.

AWPAG

#### **8/17. Prescribing indicators: report on high level (national) prescribing indicators**

The Chairman invited Mrs Karen Samuels to present Enc 12/AWMSG/0603 on behalf of the Welsh Medicines Partnership. The paper informed AWMSG of changes in prescribing within Wales in relation to the high level (national) prescribing indicators, illustrating prescribing change within each LHB in Wales for the comparative years 2002 to 2003, their relative position and the Welsh National GP average for each of the high level prescribing indicators.

Action

The Group considered the document in detail and acknowledged the benefit of looking at the graphs together. The progress of LHBs across Wales was noted and the Group discussed data dissemination, effective communication and identifying examples of good practice. It was noted that WeMeReC should be involved in the dissemination process. The Chairman commended Mrs Samuels for the report.

#### **8/18. Prescribing Indicators: national prescribing indicators 2005/2006**

The Chairman invited Mrs Judith Vincent, Head of Pharmacy & Medicines Management at Swansea LHB and AWPAG member, to present Enc 13/AWMSG/0603. The paper had been compiled by a working Group of AWPAG and set out the proposed national prescribing indicators to monitor LHB prescribing patterns across Wales for 2005/2006. The methods and principles used to determine the indicators and targets were also set out. Mrs Vincent confirmed the criteria used, that the indicators be evidence-based, easily understood with challenging but achievable targets.

There was discussion over the evidence-base behind the 78% target on the generic indicator.

It was noted that monitoring of the current high level indicators would continue through 2005/2006 but they would no longer be included in the national indicator basket.

There was discussion around the drugs to be included in the basket for inappropriate generic prescribing. It was agreed the evidence base for each drug included should be examined and placed on the AWMSG web page. The Chairman agreed to convene a small group to include Peter Harsant, Fiona Woods and representatives from the AWPAG

working group to examine the evidence base for each drug.

Mr Morgan confirmed that the implementation of NICE guidance in Wales would be on the agenda of the next NHSIF meeting. The Group was asked to note the proposal that high level indicators should become known as national indicators. The Chairman confirmed there would be on-going dialogue with Welsh Assembly to discuss the incorporation of the national indicators into the next SAFF round.

**SJ**

It was agreed the Group would endorse the proposed national indicators for 2005/2006.

At this point the meeting was advised of the need to vacate the premises. The Chairman drew the meeting to a close with the following items outstanding:

8/19. MHRA consultation: Report of an Independent Review of Access to the Yellow Card Scheme

8/20. BANs to INNn (for information)

8/21. Update on Medusa (for information)

**Date of next meeting.**

The next meeting will be held in Cardiff on Tuesday, 14<sup>th</sup> September 2004. Details will be posted on the website.