ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF MEETING HELD ON 14TH SEPTEMBER 2004
AT 11.00 AM IN THE MÜLLER HALL, ALL NATIONS CENTRE
SACHVILLE AVENUE, HEATH, CARDIFF, CF13 3NY

MEMBERS PRESENT:

1. Mr Julian Baker  Director of Finance
    Caerphilly Local Health Board

2. Mrs Kathryn Bourne  Nurse Prescriber
    Gwent Healthcare NHS Trust

3. Dr Paul Buss  Consultant
    Gwent Healthcare NHS Trust

4. Mr Jeff Evans  Other healthcare professionals eligible to prescribe
    Senior Lecturer in Podiatry & Podiatric Surgeon
    Wales Centre for Podiatric Studies, UWIC, Cardiff

5. Dr Bruce Ferguson  Trust Medical Director
    Bro Morgannwg NHS Trust

6. Mr Peter Harsant  Industry representative
    Norgine Limited, Uxbridge, Middlesex

7. Cllr Meurig Hughes  Lay member
    Llangefn, 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

11. Mr Mike Pollard  Chief Pharmacist
    North East Wales NHS Trust

12. Mr Jonathan Simms  Local Health Board Pharmacist
    Torfaen Local Health Board

Did not participate as member of AWMSG in agenda item
13. Dr Paul Tromans  Acting Regional Director Public Health  
   South East Wales Region  
14. Prof Roger Walker  Chairman AWMSG  
   Consultant in Pharmaceutical Public Health  
   National Public Health Service, South East Wales Region  

IN ATTENDANCE:  
15. Mr Jamie Hayes  Director, Welsh Medicines Partnership  
16. Mrs Ruth Lang  Administrative Office Manager  
   Welsh Medicines Partnership  
17. Mrs Karen Morgan  Pharmaceutical Services Branch  
   Welsh Assembly Government  
18. Mr Paul Parker  Pharmaceutical Services Branch  
   Welsh Assembly Government  
19. Professor Philip Routledge  Director, Welsh Medicines Partnership  
20. Mrs Karen Samuels  Programme Manager, Welsh Medicines Partnership  
21. Miss Carwen Wynne-Howells  Chief Pharmaceutical Adviser  
   Welsh Assembly Government  
22. Mrs Fiona Woods  Director, Welsh Medicines Partnership  

List of Abbreviations:  
AWMSG  All Wales Medicines Strategy Group  
AWPAG  All Wales Prescribing Advisory Group  
HCW  Health Commission Wales  
LHB  Local Health Board  
M&TCs  Medicines & Therapeutics Committees  
NHSIF  NHS-Industry Forum  
SLA  Service level agreement  
TDA User Group  Therapeutic Development Appraisal User Group  
T&FG  Task and Finish Group  
WICS  Welsh Intensive Care Society  
WMP  Welsh Medicines Partnership  

9/1. Welcome and Introduction  
The Chairman welcomed those present to the ninth meeting of AWMSG and confirmed that the proceedings are recorded and there is simultaneous translation from Welsh to English. The minutes will be posted on the AWMSG website. Members introduced themselves.  

9/2. Apologies  
Mr David Gozzard, Medical Director, Conwy & Denbighshire NHS Trust  

9/3. Declarations of interests  
There were no declarations of interest pertaining to the agenda.  

9/4. Minutes of previous meeting  
The minutes were checked for accuracy and agreed.  

9/5. Matters arising  

8/8 Update on All Wales Prescribing Advisory Group
The Chairman confirmed that the appointment of Dr Mark Daniels as co-opted member of AWPAG had been ratified by Welsh Assembly Government.

8/17 Prescribing indicators
A request was made for an update report to the Group on the prescribing indicators in place for the first quarter of 2004. It was confirmed that Health Solutions Wales were in the process of compiling this information in the required format. The Chairman confirmed that a working group would be meeting on 18th October to address the issue of the inappropriate generic indicator basket.

9/6. Chairman’s report

Teriparatide
The Chairman informed the Group that on 16th June 2004 AWMSG were notified by Eli Lilly that they accepted the recommendation made by AWMSG at its June meeting. The recommendation was then passed to Welsh Assembly Government for onward transmission to the Minister. On 21st July a letter was issued by Eli Lilly to health professionals in NHS Wales prior to the decision being made by the Minister on whether she would accept or reject the recommendation of AWMSG. It was sent without the knowledge of AWMSG, had the potential to mislead the reader on the availability of teriparatide, and was contrary to the spirit of the agreed communication process. This was drawn to the attention of ABPI Wales and an e-mail was issued by the Chairman to the service in Wales clarifying the correct status of the advice.

AWMSG were notified of the Minister’s decision to support the recommendation of AWMSG on the afternoon of Thursday, 2nd September and the service was notified on Friday, 3rd September.

The Chairman sought clarification from Mr Peter Harsant as to what action had been taken by ABPI Wales following the report of the incident and asked for an assurance that this would not recur. Apologies were expressed on behalf of Eli Lilly and the Group was informed that the TDA User Group will explore explicit communication channels with WMP at their next meeting.

Ongoing discussions between WMP and Health Commission Wales
The Chairman confirmed that following a second meeting between WMP and HCW on 23rd August to discuss the assessment of high cost, low volume drugs used by specialised centres, WMP had undertaken to horizon scan, provide ad hoc advice and undertake the assessment of such drugs on behalf of HCW. This work would be undertaken as part of an SLA yet to be agreed, and a paper on the relationship of the work undertaken by WMP for HCW, alongside the work undertaken by WMP for AWMSG, will be presented to AWMSG at the December meeting.

Broadening the AWMSG appraisal process
The Chairman informed the Group that he had met with Jane Hutt on 15th June, and Ann Lloyd and Dr Christine Daws on 13th August. Both meetings had been very productive and extremely positive regarding the work undertaken by AWMSG and its subgroups. The issue of broadening the AWMSG appraisal remit had been discussed. The Chairman reported that during the meeting with Ann Lloyd he had received a request that in addition to the prescribing indicators already approved for 2005, AWMSG should consider building an indicator
around the four generics for which there had been recent price reductions i.e. lisinopril, simvastatin, doxazosin and omeprazole. It was agreed that this issue should be progressed by the AWPAG working group on prescribing indicators.

The Chairman stated that he had communicated with chairs and secretaries of M&TCs to elicit their views on whether AWMSG should broaden its remit and confirmed that the proposal has received overwhelming support. He confirmed the intention to develop the paper presented to the Group at the June meeting and asked WMP to clarify the resource issues required to take forward this proposal. A paper on progress would be prepared for the AWMSG December meeting.

**NHSIF**

The Chairman informed members he had attended the meeting of NHSIF in Mold on 22nd July 2004 with the purpose of clarifying the retention of the appeals process by AWMSG. He confirmed that AWMSG had received legal advice that an appeal should be directed at Welsh Assembly not AWMSG and, given the resources involved, clarification as to whether AWMSG should retain an appeal process was sought from the Minister. The Chairman confirmed that following the meeting with the Minister on 15th June it was agreed that AWMSG should retain their appeal process. He had taken the first opportunity to make colleagues in the industry aware of the outcome. The Chairman also reported that the NHSIF meeting had provided an opportunity to discuss the intention to formalise meetings between WMP and the TDA User Group of the pharmaceutical industry and post details of the agenda, membership and diary of meetings on the AWMSG website for information.

With regard to the appeals the Chairman informed NHSIF that the Minister supported the decisions reached by the Appeals Panels and thereby rejected the appeals of Ortho Biotech, Amgen and Roche with respect to erythropoietins. The original decision made by AWMSG therefore stands.

The appeal of Genzyme against the decision of AWMSG not to support Laronidase was also rejected by the Appeal Panel and this was supported by the Minister. The original decision made by AWMSG therefore stands.

**Membership and constitution of AWMSG**

The Chairman confirmed the term of office for all members of the Group expires summer 2005 and called for a rolling programme to be introduced to replace members. A paper would be prepared by Assembly officials for the December meeting of AWMSG.

**Nomination for Standing Committee on Resource Allocation sub group**

The Chairman informed members he had received a request for nominations from WMP and AWMSG for members to serve on the prescribing allocation T&FG to develop a direct needs formula for the allocation of prescribing budgets. Dr Ceri Phillips was nominated as the AWMSG representative with Karen Samuels and Jamie Hayes the nominees from WMP.

**Central procurement**

The Chairman requested an update on the issue of central procurement. A Welsh Assembly Government representative informed the group that eleven organizations had expressed an interest in developing a pilot scheme, but the shortlist had been reduced to two. He informed the Group that a steering group
meeting would be held week commencing 20th September and offered to provide a paper to AWMSG for the December meeting.

**Appraisal of laronidase**
The Chairman informed the Group that Genzyme had notified their intent to apply for judicial review against the decision of AWMSG and the Minister not to support the use of laronidase within NHS Wales because of lack of evidence of cost-effectiveness. He confirmed that throughout August there had been on-going dialogue with Genzyme and without prejudice to AWMSG’s principal position in the judicial review, but given that 12 months had elapsed since the original decision, the Chairman has offered Genzyme the opportunity to present any new information/data they consider relevant to the case, to enable a decision to be made on whether the new information/data is sufficient to justify a reappraisal. The Chairman confirmed that on Friday, 10th September a file of approximately 35 articles was received from Genzyme and this information will be considered by the AWMSG Steering Group at a meeting to be held on Thursday, 16th September. He stated that if a decision is made to reappraise laronidase and Genzyme withdraw the judicial review claim the reappraisal will take place at the next meeting of AWMSG on 1st December 2004. If the decision is reached that there is no substantive new information to justify a reappraisal, AWMSG will proceed to defend the judicial review claim.

The Chairman informed the Group that he was not able to make any further comment or take questions on this item.

**Shared Care**
The Chairman confirmed that WMP had previously been tasked with addressing the issue of shared care arrangements. Progress to date had been slow and it was felt that it may be necessary to establish a T&FG for which membership would be sought outside the meeting.

**9/7. Dr Christine Daws, Director of the Resources Directorate, Welsh Assembly Government**
The Chairman welcomed Dr Daws and invited her to address the Group. Dr Daws set out her agenda as one of trying to introduce clarity as to what the Welsh Assembly Government are getting for their investment. The implementation of a financial information strategy and the introduction of programme budgets were central to this. She confirmed that Wales spends 25-30% more per head of population on prescribing than England and underlined the importance of establishing whether this is due to more effective prescribing, or whether resources are being used ineffectively. Dr Daws confirmed that a sub group of the Townsend Standing Committee will address these questions. She stated there should be equitable access to care and a need to look at case mix and understand different patients’ needs.

Members fully supported the development of detailed prescribing analyses and a direct needs formula. Dr Daws positively supported the work of AWMSG and hoped the Welsh Assembly and AWMSG could work together to unravel some of the mysteries of the prescribing budget. The Chairman informed Dr Daws that AWMSG had supported, and were currently monitoring, the development of the Medusa Project as this was a potential resource, not previously available, to help understand prescribing patterns in Wales.

The issue of benchmarking with the North of England was raised by WMP. It was noted that this work could be of value to the sub group although progress
was hampered because the units of measure in Wales and England were not comparable. WMP members confirmed that discussions have been held with the Newcastle centre in an effort to progress this work.

The Chairman raised the issue of the delay in receiving the Ministerial decision after submission of an AWMSG appraisal recommendation. Dr Daws informed the Group that before the Minister could make a decision the impact on the budget of NHS Wales had to be fully considered. It was agreed that representatives from the Pharmaceutical Services Branch should liaise with WMP to facilitate this and ensure the necessary information was available in a clear and concise manner to expedite this process.

The Chairman advised members that a new group had been established to look at healthcare standards for NHS Wales and he had been invited to be a member of the committee.

9/8. Changes to the current appraisal process
Mrs Karen Samuels presented Enclosure 2/AWMSG/0904 and asked members to endorse the proposed advancement of the therapeutic development appraisal process. Mrs Samuels confirmed that the TDA User Group had worked with WMP in developing this process and were currently compiling a question and answer section. Members made minor suggestions to the flow diagram with regard to consistency of wording and clarity. A suggestion was also made that other health professionals may wish to register their views regarding a product during the development of the appraisal documentation and WMP agreed to explore this suggestion. AWMSG agreed to accept the paper with immediate effect.

9/9. Update on Xigris
Professor Philip Routledge presented Enclosure 3/AWMSG/0904 which had been compiled in conjunction with Dr David Hope, WICS Chairman and Dr Chris Thorpe, WICS Audit Co-ordinator. Professor Routledge confirmed there were no comparators and no cross-country comparisons. It was noted that the final NICE guidance document is expected late September 2004. The Chairman expressed his thanks to WICS for meeting their obligation. The Group noted the value of undertaking an audit in this context and suggested it should be considered standard practice as an integral part of the post appraisal process.

9/10. AWMSG work programme – priority 2 items
Mrs Karen Samuels presented Enclosure 4/AWMSG/0904 outlining potential routes for progressing status 2 items on the AWMSG work programme. It was noted that some of the items have already been progressed or may no longer be of high priority.

- Mr Mike Pollard agreed to take (A6) Funding FP(10) HP and (B6) Drug administration training, back to the Chief Pharmacists.
- The Group were informed of a new European directive that would shortly be issued with regard to patient information leaflets.
- It was felt that I11 Watchdog arrangement for sales promotion had been covered by the ABPI Code of Practice and the Guidance for partnership working.
• The Group discussed the issue of (E11) GP access to medication e.g. emergency bags and (F1) Out of hours access to pharmaceutical services. The Welsh Assembly Government representative agreed to resurrect any existing advice on these issues and prepare a status report for the AWMSG December meeting. It was noted there was a degree of urgency relating to this issue.

• Pharmacist remuneration and (E11 GP) access to medication were considered historical. WMP agreed to identify recommendations from other reports and, where there are recommendations that involve AWMSG and its sub-groups, will bring the issues back to the December meeting for consideration.

It was confirmed that AWMSG were not yet in a position to go out for consultation on a new work programme.

9/11. SIP feeds
Mr Jamie Hayes presented Enclosure 5/AWMSG/0904. Mr Hayes confirmed that WeMeReC had previously produced two articles on SIP feeds, the key clinical messages contained therein were still relevant but would benefit from updating. The major concern related to issues around the purchase and supply of SIP feeds from secondary care and whether value for money was being achieved. Members commented that although there was a need to address educational issues around the clinical indications for the prescribing of SIP feeds, a vulnerable group of patients were involved and must be protected. It was unlikely, and possibly not appropriate, that reductions in the use of SIP feeds should be anticipated. It was, however, accepted that the process for product selection and supply should be at least comparable to that for pharmaceuticals. The management of repeat prescribing systems, use of loss leaders and primary/secondary care interface issues all needed to be addressed. WMP were tasked with collating the necessary information and liaising with interested bodies and volunteers from AWPAG to bring a paper back to the Group.

9/12. Report on Supplementary Prescribing
The Chairman invited Miss Anne Hinchliffe to join members at the table and present Enclosure 6/AWMSG/0904. The Chairman thanked Miss Hinchliffe for preparing a comprehensive update report and opened the paper for discussion. It was noted that although a second cohort were currently being recruited no new monies had been released. With the first cohort, it had not been possible to recruit the initial target number and therefore the remaining monies were utilised to recruit a second cohort. It was not envisaged additional monies would be available to run future courses.

The reasons for unsuccessful applications were discussed and the issue of assessing competency to undertake calculations for a supplementary prescriber trained in England but applying for a position within Wales were raised. Regarding prescribing governance, Miss Hinchliffe referred members to the Implementation Guidance on the AWMSG website. The Chairman sought clarification of the future plans of the T&FG and asked that a recommendation be brought back to AWMSG.

9/13. Prescribing Publications
Mr Jamie Hayes presented Enclosure 7/AWMSG/0904 and asked the Group to consider the need for a centrally co-ordinated approach to ensure the evaluation, purchase and distribution of prescribing publications within Wales. The Group
discussed current arrangements regarding availability, and the role of NPHS and LHBs in purchasing and dissemination, and associated clinical governance issues. Members agreed that defined lists of all prescribers irrespective of background should be compiled centrally. The Group also agreed there was a need to identify those who needed hard copy and others for whom electronic access would suffice. The role of LHBs in developing a coordinated approach to the purchase and dissemination of publications remained pivotal. WMP were tasked with evaluating current and future publications, the bodies that should receive the publications and the format in which they should be received.

Dr Tom Lau presented Enclosure 8/AWMSG/0904 and confirmed that the working group tasked with the development of the prescribing incentive scheme would be meeting on Monday, 20th September. An update report from this working group will be made to AWPAG at their meeting in October, and a paper would be prepared for the AWMSG Meeting in December. Following comments received at the June 2004 AWMSG meeting, the antiplatelet guidance was in the process of being amended. With the statin guidance a wide range of comments had been received and the necessary changes had not yet been made. WMP agreed to consider the comments and assist with the production of the guidance. Both sets of guidance would need to come back to the December meeting of AWMSG.

The Chairman requested AWPAG produce their first annual report.

Mr David Morgan presented the Minutes of the NHSIF meeting held in July 2004. He informed the Group that he was currently in discussion with Welsh Assembly Government to establish a full complement of members and deputies. Mr Morgan also confirmed that the guidance document on partnership working had been amended, following the previous AWMSG meeting, and had been forwarded to Welsh Assembly in August for onward transmission to the Minister.

9/16. Ask about Medicines Week (for information)
The Chairman invited Miss Anne Hinchcliffe to rejoin members at the table. Miss Hinchcliffe informed members that NHS Direct Wales had assisted the campaign by displaying and promoting their message at the National Eisteddfod. The Group were informed that changes had been made to the prompt cards issued the previous year. It was noted that the development of an electronic format of the card was currently being considered and WMP agreed to disseminate this to LHBs in Wales for local promotion should one become available.

9/17. Shipman report (for information)
It was reported there were significant developments in the NHS across the UK on this issue. The fifth Shipman report is currently underway and is likely to be published in December 2004. The Group were informed that working groups had already been established to consider the implications of the recommendations. Representatives of Welsh Assembly Government were involved in discussions with representatives of the other home countries. The Group were assured that members would be informed of any developments as and when it became available. It was noted that in the interim all existing rules and regulations regarding the use of Controlled Drugs should be adhered to and where there are any concerns over who is an authorised person to carry out destruction, contact should be made with Welsh Assembly Government.
Date of next meeting.
The next meeting will be held in Wrexham on Wednesday, 1st December 2004. Details will be posted on the website.