

ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF MEETING HELD ON WEDNESDAY, 1st DECEMBER 2004
AT 10.00 AM IN THE CROSS LANES COUNTRY HOUSE HOTEL, WREXHAM

MEMBERS PRESENT:

Did not
participate as
member of
AWMSG in
agenda item

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|-----|--------------------|--|-----------------------------------|
| 1. | Mrs Kathryn Bourne | Nurse Prescriber
Gwent Healthcare NHS Trust | |
| 2. | Mr Jeff Evans | Other healthcare professionals eligible to prescribe
Senior Lecturer in Podiatry & Podiatric Surgeon
Wales Centre for Podiatric Studies, UWIC, Cardiff | |
| 3. | Dr David Gozzard | Trust Medical Director
Conwy & Denbighshire NHS Trust | |
| 4. | Mr Peter Harsant | Industry representative
Norgine Limited, Uxbridge, Middlesex | |
| 5. | Mr Robert Holcombe | Finance Director (deputy member)
Blaenau Gwent LHB | |
| 6. | Dr Dyfrig Hughes | Health Economist (deputy member) | Participated in
appraisal only |
| 7. | Cllr Meurig Hughes | Lay member
Llangefnï, 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 (deputy member)
Torfaen Local Health Board | |

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| 13. Prof Roger Walker | Chairman AWMSG
Consultant in Pharmaceutical Public Health
National Public Health Service, South East Wales Region |
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IN ATTENDANCE:

- | | |
|--------------------------------|--|
| 14. Mr Jamie Hayes | Director, Welsh Medicines Partnership |
| 15. Miss Gail Hutchins | Pharmacist, Welsh Medicines Partnership |
| 16. Mrs Sian James | Pharmaceutical Services Branch
Welsh Assembly Government |
| 17. Mrs Ruth Lang | Administrative Office Manager
Welsh Medicines Partnership |
| 18. Professor Philip Routledge | Director, Welsh Medicines Partnership |
| 19. Mrs Karen Samuels | Programme Manager, Welsh Medicines Partnership |
| 20. Miss Carwen Wynne-Howells | Chief Pharmaceutical Adviser
Welsh Assembly Government |

List of Abbreviations:

ASPB	Advisory Sponsored Public Body
AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
HCW	Health Commission Wales
HSW	Health Solutions 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

Action

10/1. Welcome and Introduction

The Chairman welcomed those present and confirmed that the proceedings are recorded but simultaneous translation from Welsh to English would not be available as the facility had not been used on the previous occasions due to the technical nature of the meetings. The secretariat had contacted The Welsh Language Board and the Welsh Assembly Government to ensure that this action was acceptable, and the Chairman confirmed that the translation service could be reinstated at any time should any members express this wish. The minutes will be posted on the AWMSG website. Members introduced themselves.

10/2. Apologies

Mr Julian Baker, Finance Director, Caerphilly LHB
Dr Paul Buss, Consultant, Gwent Healthcare NHS Trust
Dr Paul Tromans, Acting Regional Director Public Health, South East Wales Region

10/3. Declarations of interests

There were no declarations of interest pertaining to the agenda.

10/4. Minutes of previous meeting

The minutes were checked for accuracy. Page 4 under Membership and constitution of

AWMSG the wording should read, "A paper would be prepared by Assembly official for the December meeting of AWMSG". The alignment of the action points on page 6 should be corrected. Page 8 under Report on All Wales Prescribing Advisory Group – the wording of the final sentence should read, "The Chairman requested AWPAG produce their first annual report".

10/5. Matters arising

9/6 Chairman's report

Ongoing discussions between WMP and HCW

Professor Routledge confirmed that this issue is currently on-going and a resource issue has not allowed the development of a service level agreement. WMP will report back to AWMSG as soon as this issue is resolved.

Nomination for Standing Committee on Resource Allocation sub group

A meeting of this group will be held before the end of December 2004. Dr Ceri Phillips is the nominated AWMSG representative.

Shared Care

Following discussion at the All Wales Prescribing Advisory Group core membership has been agreed and Dr Alison Thomas has agreed to take the lead role on behalf of the Welsh Medicines Partnership.

9/10 AWMSG Work Programme – priority 2 items

Pharmacist remuneration: It was acknowledged that this is an inherited issue. WMP will identify recommendations from other report and, where there are recommendations that involve AWMSG and its sub-groups, will bring the issues back to the March 2005 meeting. Workload pressures had prevented this issue being raised at this December meeting, but the WMP Programme Manager confirmed that WMP would be happy to receive any issues from LHBs in the interim period.

9/12 Report on Supplementary Prescribing

Mrs Bourne confirmed that the issue of assessing competency to undertake calculations for a supplementary prescriber trained in England but who had moved into a post within Wales had been addressed and guidance had been issued to the service. She confirmed the recommendation was that this part of the course would have to be undertaken by the supplementary prescriber to ensure competency for numeracy. A request was made for this guidance to be posted on the AWMSG website. Mrs Bourne confirmed the second cohort would be rolling out within the next couple of months and WMP were currently undertaking the supervisor training workshops.

9.13 Prescribing Publications

Mr Jamie Hayes confirmed he had attended a meeting at NPHS Wales to discuss issues relating to the identifying and dissemination of prescribing publications to healthcare professionals in NHS Wales. Miss Carwen Wynne-Howells confirmed that the responsibility for dissemination lay with the LHBs. Mr Hayes confirmed that he is currently preparing a matrix of publications and would bring this issue back to a future AWMSG meeting. Concern was expressed over the funding of new publications eg NHF for children and Miss Wynne-Howells confirmed that the issue had been raised with the Director of Resources and Director of NHS Wales. A update report will be made at the March 2005 meeting.

9.14 SIP Feeds

It was agreed that WMP would compile the process for progressing this issue. It had

previously been agreed that NHSIF would consider this issue in the first instance and address the process issues, and that AWPAG would develop the paper and concentrate on the clinical issues. The document would then be brought back to AWMSG for consideration at a future meeting.

9/16 Ask about Medicines Week

Miss Wynne-Howells confirmed the First Minister had launched the campaign on 1st November and feedback had been positive. A medicines guide had been distributed through the Welsh Industry Group and ABPI Wales and cards had been distributed to members of the public. The campaign had received good press coverage and a Steering Group would be meeting this week to assess the success of the campaign.

10/6. Chairman's report

AWMSG Training Workshop

The Chairman informed members that a 2-day training working would be held on 23/24 March 2005 for all AWMSG members, AWMSG deputy members and sub-group members. Places were limited to 50 and an invitation would be sent out after the Christmas holidays. The Chairman asked members for prompt confirmation.

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

The Chairman brought attention to the statement that “patients will receive effective treatment and care that conforms to NICE and takes account of NICE clinical guidelines and the recommendation of AWMSG ..” which supports the role of AWMSG within the infrastructure of NHS Wales.

First Minister Statement on ‘Reform of Quangos’

The Chairman confirmed the statement made by Mr Rhodri Morgan that it is the intention that all ASPBs, of which AWMSG is one, will become part of the Welsh Centre for Health. The effect and impact on the work of AWMSG is currently unclear. The Chairman informed the group he would be meeting with Mrs Anne Lloyd within the next couple of weeks to discuss this issue.

Potential appraisal for AWMSG March 2005 meeting

The Chairman stated that in accordance with recent changes to the AWMSG appraisal process an announcement of an appraisal to be held at the proceeding meeting would be made by the Chairman. A submission for appraisal was recently received and although the product met the criteria for AWMSG assessment, it had not at that time received marketing authorisation. We have been informed that the marketing authorisation has been received and we are currently awaiting confirmation from the company that they wish to proceed with the assessment in March. An announcement will therefore be delayed until confirmation is received that the company wish to proceed with the assessment at the March 2005 meeting. The Chairman informed the group that a list of drugs has been identified by LHBs for AWMSG appraisal. All products fall within the AWMSG criteria for appraisal. WMP has contacted the relevant companies to seek their engagement in the AWMSG appraisal process.

10/7. Reappraisal of Aldurazyme (Laronidase®)

(Start time 10.10 am)

All members confirmed they had received and read the appraisal documentation. Members were asked to declare any interests.

The Chairman welcomed Miss Julie Kelly, Senior Director LSD Unit and Dr Gerald Cox, Medical Director of Genzyme Limited, and Mr Edward Perrott from Taylor Vinters Solicitors who was acting as legal adviser to Genzyme.

The Chairman also welcomed Dr Ed Wraith, the independent medical expert and asked Dr Wraith to declare any interests. Dr Wraith confirmed he was principal investigator in a phase III clinical trial on a Hurlers Study sponsored by Genzyme and is currently involved with clinical trial work sponsored by the company. He also confirmed he has acted as a paid and unpaid consultant to Genzyme regarding various aspects of clinical trial work and is involved in similar work for other biotechnology companies developing treatments for patients with lysosomal storage diseases. The Chairman noted the personal specific interest but stated that due to the rarity of the disease this was inevitable, but thanked Dr Wraith for his openness.

The Chairman stated that Laronidase had been appraised by AWMSG in September 2003. On that occasion AWMSG had not supported the use of laronidase and this decision was the subject of a subsequent appeal by Genzyme. The appeal was heard on 8th April 2004 but was unsuccessful. The original decision of AWMSG was upheld and endorsed by the Minister for Health & Social Services. The Chairman confirmed that as part of the on-going dialogue with Genzyme the issue of a reappraisal had emerged and, as, according to the AWMSG criteria, reappraisal may be reconsidered where:

- Significant new information becomes available, and
- At least 12 months has elapsed since the original submission

Since the first appraisal a pivotal paper had been published "Enzyme replacement therapy for mucopolysaccharidosis I: a randomised, double-blinded, placebo-controlled, multinational study of recombinant laronidase" edited by Wraith et al and published in The Journal of Pediatrics, May 2004. Although members of AWMSG had access to the results of the study in September 2003, they did not have access to the full paper, nor were they able to note that it had been published in a peer-reviewed journal. On this basis, a decision to grant a reappraisal was made. The Chairman commented that significant changes had been made in the membership of AWMSG in the interim period.

Dr Wraith confirmed there were currently five patients in Wales with the disease and did not believe there were any undiagnosed pockets of patients in Wales. He confirmed that geographical variation was not uncommon and that the youngest patient in Wales is aged 10 and the oldest patient is in their late 30's.

The Chairman confirmed that as Dr Ceri Phillips was part of the WMP assessment team, Dr Dyfrig Hughes had been invited to attend the appraisal in the capacity of Health Economic deputy member.

The Chairman reiterated that AWMSG guidance is interim to NICE guidance should this be subsequently published. 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 Ed Wraith to address the Group to provide a brief professional and clinical overview. Dr Wraith confirmed his position as Consultant Paediatrician at the Manchester Children's Hospital and had seen over two hundred patients with this rare genetic progressive disease occurring in children and adults. Dr Wraith outlined the different forms of the disease, the treatment options and confirmed that patients would be

subjected to multiple operative procedures. He confirmed that the treatment was relatively safe, with very few adverse reactions, and urged the company to develop home-based treatment of MPS I patients. Dr Wraith suggested that initial treatment infusions could be carried out in hospital, but this could graduate out to a home-care system.

The Chairman invited Prof Philip Routledge to give an overview of Enc 2/AWMSG/1204 the review undertaken by the Welsh Medicines Partnership. Professor Routledge asked members to note the orphan-drug status of the therapy referred to in Form B. Dr Ceri Phillips then addressed the Group from the health economic perspective and indicated there was insufficient evidence on which to base a judgement.

The Chairman invited comments from the company representatives who confirmed that a fair summary of the information had been presented. Dr Cox commented that the value was in the medical benefit to patients.

The Chairman stated that he had asked the AWMSG lay member, Councillor Meurig Hughes, to address the group from the patient perspective. All members had received a copy of the submission from the patient interest group but a decision had been made not to post this information on the website, to protect any patient confidentiality. Councillor Hughes confirmed that he had contacted the Chief Executive of the relevant patient interest group and read out a letter he had received from the Society (see attached).

The Chairman opened the discussion to members and confirmed that the purpose of the questioning was for clarification and that members could only consider the licensed indication.

Members sought clarification on the effectiveness of treatment if commenced at an early stage in the development of the disease. Dr Wraith confirmed that patients absorb a high hospital resource and would not automatically be commenced on treatment. He informed the group that each patient would be individually assessed by a specialist, and clarified how the designated specialist treatment centres eligible to prescribe this product work and share treatments. The issue of offsets was discussed. Dr Wraith informed members of the situation in England and confirmed that the National Designation Circular is only applicable in England and would not apply in Wales. Members questioned Dr Wraith on the follow-up programme for collection of information and sought clarification that all patients would be followed up in an identical way. Dr Wraith confirmed that the independent follow up registry and database was lodged with the MPS Society and that although treatment guidelines were in existence, they were likely to change before 1st April 2005. Dr Cox confirmed that the company held a registry of detailed medical information as part of their post-marketing commitment. The issue of geographical differences in prescribing and rationing by disease prevalence was raised, but the company were advised by their legal adviser that the issue of overall funding could not be addressed and the Chairman accepted this. Dr Perrott suggested that the comment on page 7 of the WMP assessment referring to the funding of gene therapy funding was slightly misleading and confirmed that funding of treatment for AIS is based on classical cost-effectiveness parameters but the conclusion excludes orphan drugs from the assessment.

The Chairman closed proceedings and voting members retired to meet in camera at 11.35 am. The meeting re-convened at 12.25 pm.

The Chairman confirmed that having read the evidence and considered the various issues raised during the discussions that 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 Aldurazyme (laronidase®) is that AWMSG would support the use of Aldurazyme (laronidase®) within NHS Wales subject to the following

restrictions:-

1. Its use must be in accordance with the SPC
2. Treatment of patients from Wales should be made at the specialist centre in Cardiff (University Hospital of Wales) or at one of the six specialist designated centres in England
3. All patients treated should, where appropriate, be entered into an independent MPS I registry and AWMSG should have access to that data as it may be necessary in the future to ensure that treatment is in accordance with the agreed clinical guidelines

Caveat: It is recognized that the use of Aldurazyme (laronidase®) may fall outside the SPC eg bone marrow transplant patients. Where this occurs we would wish to give support to its use where it is part of a clinical trial so that patients from Wales are not disadvantaged.

The Chairman advised the company representatives that they have normally have 28 days to lodge an appeal however, due to the Christmas holidays, the deadline had been extended to Friday, 7th January 2005. The grounds for appeal are set out on the AWMSG website and acceptable grounds for appeal should be lodged through the office of the Welsh Medicines Partnership. The Chairman stated that any decision to accept or reject the appeal would be reached in consultation with those who provide legal advice to AWMSG. The Chairman confirmed that the recommendation of AWMSG would not be passed to the Minister until 7th January had expired unless the company inform the Chairman in writing 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. A summary of the proceedings (not a transcript) will be published on the AWMSG website in approximately 14-21 days.

The Chairman concluded by thanking Dr Wraith for his clear and concise presentation to the group that assisted AWMSG in making a recommendation to the Minister for Health & Social Services. The Chairman thanked Genzyme for engaging with the AWMSG appraisal process in Wales and confirmed that the recommendation would be confirmed in writing. The hearing was concluded.

10/8. All-Wales Prescribing Incentive Scheme

The Chairman welcomed Mrs Nicola John, AWPAG Vice Chair and lead of the All Wales Prescribing Incentive Scheme Working Group. Mrs John presented an overview of Enc 3/AWMSG/1204. She confirmed that the paper had been considered by the LHB Directors of Finance, and suggested that LHB Medical Directors who have responsibility for the LHB prescribing budget should also consider the paper.

The Chairman opened the discussion. Mr Robert Holcombe presented the feedback from the LHB Directors of Finance. He confirmed that his colleagues agreed that the scheme should not be mandatory as LHBs need to have discretion of how they set prescribing budgets to GP practice. The LHB Directors of Finance support the issuing of the guidance as a "Good Practice Prescribing Incentive Scheme framework" and recommend that AWPAG monitor and review both uptake and effectiveness. It was also recommended that the guidance should suggest the capping of potential finance rewards and highlight that the funding of the reward scheme, an assessment of its financial consequences (including affordability) plus benefits should be the responsibility of the LHBs. The LHB Directors of Finance agreed it would be beneficial for AWPAG to receive feedback from the All Wales LHB Medical Directors' Group.

It was agreed that the remuneration level should be set at a sum of £500 per thousand patients and a worked example should be included in the document. Dr Tom Lau, AWPAG Chairman, confirmed that this sum had been agreed by AWPAG at the October 2004 meeting, and it had received the support of the BMA. Mr Harsant applauded the use of audit and education and commented that the 7% reduction in the cost of NHS drugs had not been taken into account. Mr Harsant commented that he felt the reference to industry in the document was disparaging and Mrs John agreed to amend the wording. Dr Lau provided the background to the scheme and asked members to support the scheme that rewards quality and cost effective prescribing. Members raised the issues of double-payments, weighting, flexibility to LHBs and the need for a fair and robust budget setting formula. It was agreed that the scheme should not be mandatory and should allow local flexibility.

The Chairman confirmed there was general support to take the paper forward. Mrs John agreed to address the issue of accumulation of rewards, consistency within the paper with regard to reference to points, percentages and patients.

The Chairman applauded the positive development and confirmed AWMSG's support of a non-mandatory All Wales Prescribing Incentive Scheme. He asked that the refined document be finalized at the January meeting of AWPAG and, following that meeting, re-circulated to AWMSG members. The Chairman confirmed that he would take Chairman's action to progress the document.

Mrs Nicola John and Dr Tom Lau left the meeting.

10/9. Templates for local adaptation

Protocol for use of statins

Protocol for oral antiplatelet therapy

The Chairman welcomed Mr Stuart Evans, Formulary Pharmacist in Swansea NHS Trust and AWPAG member and invited him to address the Group.

Mr Evans informed members that the documents had been circulated widely for comment, which was still being received by the Welsh Medicines Partnership. Mr Harsant asked for clarification as to whether the documents were "guidelines" or "templates", and it was confirmed that the documents are "templates for local adoption and adaptation. WMP agreed to make a minor amendment to the wording (mean/average). It was agreed that AWMSG would recommend that the templates should be disseminated throughout NHS Wales but that the documents should be reviewed on a regular basis and updated in the light of new evidence.

10/10. Central procurement

Mrs Sian James presented an overview of Enc /AWMSG/1204. The Chairman clarified that in September 2003 AWMSG had recommended to the Minister that this issue of central procurement of primary care medicines should not be pursued. Mrs James confirmed that Welsh Assembly Government had been directed by the Audit Commission to pursue the issue and informed the group that the report of the Project Board will be presented to the Minister in January 2005.

10/11. Patient pack dispensing in Community Pharmacy

Mr Michael Pollard presented Enc 6/AWMSG/1204 and asked AWMSG to support a proposal that NHS regulations be amended to allow pharmacists to provide the most appropriate pack size against individual prescriptions. Miss Carwen Wynne-Howells

WAG

confirmed that this currently forms part of the legislation programme and agreed to raise the issue with the appropriate personnel within the Welsh Assembly Government. The Chairman reiterated there are significant advantages by the early adoption and implementation of patient pack dispensing and AWMSG looked forward to its implementation across Wales.

10/12. Membership and constitutional issues of AWMSG and its sub-groups

Mrs Sian James of Welsh Assembly Government presented Enc 7/AWMSG/1204 which addressed membership and constitutional issues of AWMSG and its sub-groups. Mrs James confirmed that all appointments for AWMSG and its sub-groups (NHSIF and AWPAG) would terminate in July 2005, even though AWPAG members would not have served for a full three-year period. On receipt of written confirmation from AWMSG members that they intend to serve a further period, the new term would run for a further 2-5 year period, and the total reappointment membership could be up to ten years. Mrs James confirmed that all AWMSG members who wish to continue their membership would undergo an appraisal by the AWMSG Chairman. Mrs James informed members that the public appointment process undertaken by the Public Appointment Department in Welsh Assembly Government takes approximately six months. The group discussed the appointment of a Trust Director of Finance and Mrs James confirmed that the constitution of AWMSG would need to be changed, and Ministerial agreement would be required. Changes to constitution of sub-group can be made via the AWMSG Steering Group. Members were informed that it is the intention that the Welsh Medicines Partnership would take over responsibility for the sub-group membership, subject to agreement of outstanding resource issues.

10/13. Prescribing trends

Mrs Karen Samuels presented Enc 8/AWMSG/1204 and commended HSW on the presentation of information. It was agreed that AWPAG should identify best prescribing practice and seek an explanation from the appropriate LHBs. The Chairman requested that this prescribing information should be presented to AWMSG on a regular basis for information. Members acknowledged the consistent trend, apart from drugs less suitable for prescribing, and noted that black triangle drugs are reported on a six-monthly basis.

AWPAG

10/14. Update on Task & Finish Group on Supplementary Prescribing

Mrs Kathryn Bourne presented Enc 9/AWMSG/1204 and confirmed that the original task was near completion. She informed members that the remit contains an evaluation element, and evaluation of the second cohort would be undertaken during the Summer of 2005. The viability of centres with low numbers was raised and Mrs Bourne reassured members that the working group had addressed this issue. Members noted the content of the report.

10/15. Report on All Wales Prescribing Advisory Group

The Chairman asked members whether there were any issues that required clarification in Enc 10/AWMSG/1204. WMP confirmed that the overarching work strategy had been posted with the AWPAG meeting documentation on the AWMSG website. The Chairman asked that an amendment be made to the AWPAG minutes under item 9 to read:

"Mrs Stevenson informed the group that Welsh Assembly no longer felt they should be managing nomination and appointment of the sub-groups and that this responsibility should be passed to AWMSG/WMP". Also, he asked that the reference to 'high' and 'low' level indicators in the Chairman's report be amended to 'national' and 'local' indicators. WMP agreed to clarify the role of both groups in relation to the work on SIP feeds.

10/16. Report on NHS-Industry Forum

Mr David Morgan addressed the group and asked the Welsh Assembly Government representative to clarify whether the Guidance for Partnership Working document had

been passed to the Minister. The document had been finalized by NHSIF on 17th August, and forwarded to Welsh Assembly by WMP on 24th August 2004. Mrs James confirmed that other work priorities had taken precedent but stated she hoped to receive a ministerial response by the end of January. The group noted that the document sent to the Minister had not been posted on the AWMSG website in order to avoid any potential confusion. The Chairman raised the issue of presentation of sub-group papers and expressed a need for caution in relation to sensitive issues, particularly in relation to Prescribing freedom and formulary development (5.4) Enclosure 3. Mr Morgan agreed to address the sensitive issues in Enclosure 3 and take the document back to NHSF in January. The Chairman stated that AWMSG should approve meeting documentation and accept the draft minutes prior to any consultation with NHS Wales. AWMSG noted and accepted the annual report.

10/17. Broadening the AWMSG appraisal process - update

Professor Philip Routledge presented Enc 12/AWMSG/1204 and proposed a central process to appraise prospectively all new medicines, significant new indications and formulations for use within NHS Wales. Professor Routledge confirmed the need to use the strengths of service and the industry to streamline the process, and informed members that a business case had been prepared and would be submitted to Welsh Assembly Government very shortly. Professor Routledge also confirmed that the funding of this proposal remained an area of negotiation with the Assembly, and that the TDA User Group would have the opportunity to comment on any process issues.

10/18. GP access to medicines – verbal status report

Miss Wynne-Howells confirmed that an invitation would be extended to Mr Stuart Moncur to address AWMSG at its March 2005 meeting.

10/19. Appraisal process FAQ's & flow diagram

Mrs Karen Samuels asked members to note the content of Enc 13/AWMSG/1204 and the Chairman opened the item for discussion. Mr Harsant asked for consistency with the NICE guidance with regard to wording and asked that a record be made from the industry perspective that the document is encouraging. It was agreed that the wording of the answer to the question:

What implications exist if a company chooses not to submit their product to the AWMSG appraisal process? should be changed to read:

AWMSG would not have opportunity to appraise the product or provide advice to Minister or NHS Wales. This will result in provision of funding being "problematic".

The Chairman confirmed that AWMSG is not in a position to provide guidance to NHS Wales if the product has not been appraised, and if a submission for appraisal is made, advice will subsequently follow. Mrs Samuels confirmed that the FAQ's on Implementation will be presented to AWMSG at a future meeting.

Date of next meeting.

The next meeting will be held in Swansea on Thursday, 3rd March 2005. Details will be posted on the website.