

ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF THE AWMSG MEETING HELD ON TUESDAY, 5th DECEMBER 2006 COMMENCING 10.30 AM AT THE WALES MILLENNIUM CENTRE, CARDIFF BAY

MEMBERS PRESENT:

Did not
participate in
agenda item

- | | | | |
|-----|-----------------------|---|-----|
| 1. | Dr Paul Buss | Consultant Physician
Gwent Healthcare Trust | |
| 2. | Dr Fraser Campbell | LHB Medical Director
Gwynedd LHB | 1-7 |
| 3. | Mr Jeff Evans | Other healthcare professionals eligible to prescribe
Podiatrist, UWIC | |
| 4. | Dr Bruce Ferguson | LHB Medical Director
Bro-Morgannwg | |
| 5. | Dr Brian Hawkins | LHB Pharmacist
Rhondda Cynon Taf | |
| 6. | Mr Peter Harsant | Industry Representative | |
| 7. | Cllr Meurig Hughes | Lay member | |
| 8. | Dr Tom Lau | General Practitioner & Prescribing Lead, Gwent | |
| 9. | Mr David Morgan | Consultant in Pharmaceutical Public Health
National Public Health Service, North Wales
Region | |
| 10. | Prof Ceri Phillips | Professor of Health Economics, School of Health
Science, University of Wales Swansea | |
| 11. | Prof Philip Routledge | Professor of Clinical Pharmacology, Cardiff
University and Acting AWMSG Chairman | |
| 12. | Mr Dave Roberts | Chief Pharmacist
Cardiff and Vale NHS Trust | |
| 13. | Mrs Wendy Warren | Nurse Director | |

IN ATTENDANCE:

- | | | |
|-----|---------------------------|---|
| 14. | Mr Jamie Hayes | Director, Welsh Medicines Partnership |
| 15. | Mrs Ruth Lang | Liaison Manager, Welsh Medicines Partnership |
| 16. | Mrs Carolyn Poulter | Head of the Pharmaceutical Services Branch
Welsh Assembly Government |
| 17. | Mrs Karen Samuels | Programme Manager, Welsh Medicines Partnership |
| 18. | Miss Carwen Wynne-Howells | Chief Pharmaceutical Adviser, Welsh Assembly
Government |

List of Abbreviations:

ABPI	Association of the British Pharmaceutical Industry
ASPB	Assembly Sponsored Public Body
AWMSG	All Wales Medicines Strategy Group
AWDAC	All Wales Dietetic Advisory Committee
AWPAG	All Wales Prescribing Advisory Group
CMO	Chief Medical Officer
CSCG	Cancer Services Co-ordinating Group
DTB	Drug & Therapeutics Bulletin
HCW	Health Commission Wales
HIW	Health Inspectorate Wales
HoPMMs	Heads of Pharmacy and Medicines Management
HSW	Health Solutions Wales
LHB	Local Health Board
M&TCs	Medicines & Therapeutics Committees
MHRA	Medicines & Herbals Regulatory Authority
NHSIF	NHS Industry Forum
NICE	National Institute for Health and Clinical Excellence
NPHS	National Public Health Service
NSCAG	National Specialist Commissioning Advisory Group
SAFF	Service and Financial Framework
SMC	Scottish Medicines Consortium
SPC	Summary of Product Characteristics
TDA User Group	Therapeutic Development Appraisal User Group
T&FG	Task and Finish Group
WMIC	Welsh Medicines Information Centre
WMP	Welsh Medicines Partnership

18/1 Welcome, introductions and personalia

The Chairman opened the meeting and welcomed those present.

18/2 Apologies

Dr David Gozzard, Medical Director, Conwy & Denbighshire NHS Trust
Mr Robert Holcombe, Finance Director representative

The Chairman announced that Miss Carwen Wynne-Howells, Dr Dyfrig Hughes and Dr Fraser Campbell are expected to arrive late, but that he would start the proceedings on time.

18/3 Declarations of interest

The Chairman asked members to declare any specific, non-specific, personal or non-personal declarations of interest. None were declared.

18/4 Minutes of previous meeting

The minutes were checked for accuracy and the following was noted:

The appraisal of vinorelbine oral (Navelbine®) and sorafenib (Nexavar®) will take place at the March 2007 meeting. Iloprost trometamol (Ventavis®) will be appraised at this meeting.

With the above changes, the Chairman signed the minutes as a true record of the meeting.

Matters arising

The Chairman drew members' attention to the post meeting note of clarification in relation to algalisidase beta (Fabrazyme®). The Chairman asked the Welsh Assembly Government representative whether Ministerial endorsement had been received for the AWMSG recommendations relating to alglucosidase alfa (Myozyme®) and algalisidase beta (Fabrazyme®). Mrs Poulter confirmed that the Minister had endorsed the recommendations in relation to alglucosidase alfa (Myozyme®) and algalisidase beta (Fabrazyme®). Confirmation of receipt of ministerial endorsement will be disseminated and posted on the AWMSG website.

The Chairman confirmed that the Welsh Assembly Government consultation on the proposal to place the Statutory Health Professional Advisory Committees with the Wales Centre for Health had endorsed the recommendations of AWMSG and its sub-groups, that it should remain as an independent advisory committee. The outcome of the consultation had been confirmed in a letter from the Chief Medical Officer and it was noted that AWMSG will be subject to review in 2008.

18/5 Chairman's report

The Chairman confirmed there were no major issues to report. Proposed changes with regard to the broadening of the appraisal process will be reported and discussed later in the meeting. The Chairman reported that the draft prescribing strategy document had been disseminated to professional groups for comment via AWMSG sub-group members. The deadline for receipt of comments had now passed and a re-drafted document will be prepared for the sub-group meetings in January for further comment before being presented to AWMSG in March 2007.

The Chairman announced the following appraisals will be held in March 2007:

Appraisal 1: vinorelbine oral (Navelbine® oral)

Manufacturer: Pierre Fabre Ltd

Indication: For treatment of advanced breast cancer stage III and IV relapsing after or refractory to an anthracycline-containing regimen.

Scope: An assessment of the cost and clinical effectiveness of vinorelbine oral (Navelbine® oral) in relation to its licensed indication and the place of vinorelbine oral (Navelbine® oral) in relation to current treatment strategies available in NHS Wales.

Appraisal 2: sorafenib (Nexavar®)

Company: Bayer Healthcare

Indication: Treatment of renal cell cancer in patients who have failed prior interferon-alpha or IL-2 based therapy or are considered unsuitable for such therapy.

Scope: An assessment of the cost and clinical effectiveness of sorafenib (Nexavar®) in relation to its licensed indication and the place of sorafenib (Nexavar®) in relation to current treatment strategies available in NHS Wales.

18/6 Report on AWPAG

The Chairman invited Mrs Nicola John to provide an overview of the AWPAG meeting held in October 2006.

Mrs John invited comments on the draft minutes (Enc 2/AWMSG/1206).

Mr Harsant asked whether the revised wording of the indicators had been incorporated into the document provided to Welsh Assembly Government. Mrs John confirmed that the 2007/2008 targets had not yet been published and the wording would be finalized before the end of December 2006.

Mrs John confirmed that the updating of the statin template will be undertaken by AWPAG and it is hoped that AWPAG will work closely with the Cardiac Network in formulating the revised document to provide consistent advice to the Service.

The Chairman confirmed that the Regional Monitoring Centre for suspected adverse drug reactions, CSM Wales has been re-named the Yellow Card Centre Wales (YCC Wales). He informed members that a new "SENTINEL" system has been developed by MHRA to replace the ADROIT system and since May 2006, all yellow cards from UK reporters are being sent directly to a central scanning facility and then electronically transferred to MHRA. Regional Monitoring Centres are being requested to follow-up selected reports only and are not presently authorised to hold full regional data. Discussions are in hand to obtain suitably anonymised data at an appropriate level of detail for educational purposes. The Chairman confirmed that YCC Wales could not help directly in identifying a safety signal in relation to ibuprofen prescribing in children in Wales.

Mrs Poulter confirmed that Welsh Assembly Government had set up a meeting of interested parties to discuss a range of issues relating to monitored dosage systems. A working group will be formed and will aim to establish a clear way forward before the next financial year. Another meeting has been arranged later this month.

Mrs Lang confirmed that the prescribing audit templates will be posted on the AWMSG website imminently.

Members discussed the collection of audit data in relation to the prescribing incentive scheme. It was noted that individual LHB data was available, and members agreed that work should be undertaken to collate the data at an All Wales level. Mrs John agreed to raise this issue at the next AWPAG meeting in January 2007.

18/7 Shared care

Tobramycin and dornase alfa

The Chairman provided the background and informed members that AWMSG had been requested to advise on interface issues in relation to the prescribing of tobramycin nebulised solution (TOBI[®]) and the enzyme dornase alfa (Pulmozyme[®]) for the treatment of cystic fibrosis in suitable patients. Dr Tessa Lewis, a GP in Blaenavon who is also Vice Chair of AWPAG, agreed to take the lead on behalf of WMP in exploring this issue in more detail. The Chairman invited Dr Lewis to join members at the table and also Dr Ian Ketchell, Consultant Physician and Director of the Adult Cystic Fibrosis Centre and Lucy Philpott, Lead Pharmacist in the Cystic Fibrosis Centre in Llandough.

The Chairman invited Dr Tessa Lewis to provide an overview of Enc 3/AWMSG/1206 in relation to the shared care of tobramycin nebulised solution (TOBI[®]) and the enzyme dornase alfa (Pulmozyme[®]) for the treatment of cystic fibrosis in adult patients. Dr Lewis explained that AWPAG had considered the paper and recommended that tobramycin

nebulised solution (TOBI[®]) and dornase alfa (Pulmozyme[®]) were not suitable for shared care.

Dr Lewis outlined the potential problems if they were prescribed by GP's and highlighted regional variations in agreeing to shared care arrangements. She explained the criteria for developing a shared care protocol which were considered by AWPAG in addressing the clinical aspects of the issue. Dr Lewis confirmed that the recommendation of AWPAG was that the prescribing should be in secondary care of tobramycin nebulised solution (TOBI[®]) and dornase alfa (Pulmozyme[®]).

The Chairman drew members' attention to the statement of interests declared by Dr Ketchell in the enclosure and asked him to address the clinical issues relating to shared care of tobramycin nebulised solution (TOBI[®]) and dornase alfa (Pulmozyme[®]). Ms Philpott had no conflicts of interest to declare.

Dr Ketchell expressed concern over patient care, duplication of treatment and clinical input, access to medication and additional travelling costs for patients. He expressed a personal opinion that it would be a retrograde step to stop GPs prescribing and that neither drugs had been appropriately prescribed within NHS Wales for some time. Dr Ketchell explained that the centre in Llandough is the only adult centre for patients with cystic fibrosis.

AWMSG members expressed concern over patient access to medication and that the criteria for shared care when applied in their view supported shared care arrangements. Members felt that the AWPAG recommendation appeared not to accord with the detail in the paper submitted. It was acknowledged there is a need for consistent decision making and that resource issues should be addressed separately. Members discussed other potential supply mechanisms for patients and sought clarification of the monitoring of treatment responses. Members also sought clarification of any other potential safety issues and reiterated that clinical issues should be separated from cost and commissioning issues.

Members discussed community care in out-reach centres. Dr Ketchell agreed that this would be a model he would like to explore, but alluded to the lack of resources and expertise that would be required to ensure safe prescribing to adult patients. Members agreed that the availability of an out-reach programme should be a priority. A suggestion was made that a specialist respiratory nurse working in the community under the care of a specialist secondary care consultant should be explored.

There was discussion over a unified budget and the need to develop solutions to ensure that care is delivered to patients in the appropriate setting. Mrs Poulter confirmed that a working group has been established under the Townsend Group to discuss this issue and, if a positive recommendation was forthcoming, it will be put into effect in the 2008/2009 financial year.

AWMSG members agreed that the evidence presented to them did not support the recommendation of AWPAG that prescribing could not take place in primary care and there was an unwillingness to endorse the AWPAG recommendation. The Chairman suggested that the working group re-convene to consider the outstanding issues, such as cross-boundary flow, resource allocation and future models. The Chairman confirmed that Mr Rob Holcombe, LHB Finance Director representative, had been able to attend but had expressed by email his concerns regarding resource implications and indicated a willingness to be involved in further discussions of the working group.

The Chairman confirmed that AWMSG did not support the recommendation and

reiterated the need to send a clear message to the service that the sub-group recommendation had not been endorsed by the parent group.

The Chairman thanked Dr Lewis for agreeing to continue to take the lead on shared care on behalf of WMP, and Dr Ketchell and Miss Philpott for their input into the discussions.

Amiodarone

The Chairman invited Dr Lewis to provide an overview of Enc 4/AWMSG/1206. Dr Lewis highlighted salient points of the enclosure and asked AWMSG to endorse the AWPAG recommendation.

There was general discussion on blood monitoring requirements and initial doses. Dr Lewis confirmed that formal consultation with the specialist group had not yet taken place.

Dr Fraser Campbell joined the meeting.

Following the discussion ***the Chairman confirmed that AWMSG supported all three recommendations.***

Dr Lewis agreed she would be willing to take the issue forward and liaise with Welsh Cardiologists on the development of the draft template.

18/8

AWPAG Prescribing reviews

The Chairman invited Mrs Nicola John to address the group.

Mrs John confirmed that AWPAG had agreed the merit of looking at prescribing trends so that issues could be identified at an early stage and prescribing messages shared. Mrs John informed members that representatives from each of the three regions had agreed to address two chapters of the BNF on a rotating basis and bring together prescribing messages for consideration by AWPAG and AWMSG. Mrs John explained that Enclosures 5/AWMS/1206 and 6/AWMSG/1206 were a prototype and invited the views of members on the principle and content.

Members congratulated AWPAG on this important initiative. The principle was fully supported and the need to ensure there is resource available to validate the evidence and edit the information was acknowledged. A suggestion was made that AWPAG could also consider OTC drugs and secondary care prescribing in due course. Mr Dave Roberts agreed to discuss with Mrs John outside of the meeting possible collaborative work with the Welsh Chief Pharmacists Group. Mr Jamie Hayes offered the support of WeMeReC in providing editorial robustness and due process in the development of the papers. Mrs John confirmed AWPAG's support of WeMeReC involvement, although she acknowledged the resource implications. Mr Harsant welcomed the opportunity for industry input into the editorial process and confirmed the support of industry in developing robust and evidence-based prescribing messages.

Members addressed the recommendations. Comments specific to the recommendations included:

All Wales Drug Contracting Committee – there is now an LHB representatives on the Group

Cholesterol targets are to remain unchanged until the end of 2007

The Chairman confirmed the full support of AWMSG in AWPAG developing the prescribing reviews and suggested that WeMeReC involvement in the editorial process and communication be further explored outside of the meeting.

18/9 Sharing good prescribing practice (for information)

The Chairman invited Mr Jonathan Simms to present Enc 7/AWMSG/1206 a paper prepared by Mr Trevor Batt on behalf of the All Wales Prescribing Advisory Group to improve the safety of patients on high doses of inhaled corticosteroids through the provision of comprehensive guidance on when to issue a steroid card with the aim of reducing uncertainty and standardising practice for healthcare professionals across Wales.

Mr Simms highlighted the key issues in the document and the Chairman invited members to comment on the document.

Members supported the work and agreed there was a need to communicate good practice and avoid variation in prescribing. It was felt that the endorsement of the specialist group would strengthen the paper, and a suggestion was made that the document be taken to the Respiratory sub-group of the Royal College of Physicians in Wales for their comment. It was agreed that the mode of dissemination of information would be considered by the Steering Committee outside of the meeting.

The Chairman thanked Mr Simms for presenting, and Mr Batt for preparing the paper and closed the discussion.

18/10 Appraisal – iloprost trometamol (Ventavis®)

(2.15 pm)

The Chairman announced that Mrs Shan Davies, the WMP health economist had been delayed and asked whether the representatives from Schering had any objections to continuing the proceedings in her absence. The Company representatives confirmed they had no objections to proceeding with the AWMSG appraisal of iloprost trometamol (Ventavis®).

Professor Routledge reminded members to declare any interests pertinent to the appraisal. There were no declarations of interest from any of the Group eligible to vote.

The Chairman welcomed the independent medical expert, Dr Ben Hope-Gill who had been nominated by Dr N K Harrison, Consultant Chest Physician.

The Chairman extended a welcome to Dr Jackie Napier, Medical Director of Schering Healthcare and Mr Adam Lloyd, Director, 4th Hurdle Consulting who had been commissioned by the company to prepare the economic model in relation to iloprost trometamol.

The Chairman introduced the WMP appraisal team:

Dr John Thompson, Consultant Clinical Pharmacologist in Cardiff and Vale NHS Trust, Mrs Gail Woodland, Senior Pharmacist, Welsh Medicines Partnership and Mrs Shan Davies from the University of Wales, Swansea.

The Chairman confirmed that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this, and that a negative recommendation would not impact on the clinical freedom of the prescriber. He explained that a positive recommendation by AWMSG, subsequently endorsed by the Minister for Health & Social Services, places an obligation on Trusts and LHBs in Wales to fund accordingly. AWMSG advice is interim to NICE should it be subsequently published. He confirmed the sequence of events and invited Dr Thompson to present a clinical overview of the WMP assessment report.

Dr Thompson outlined the purpose and scope of the appraisal and summarised the salient points of the clinical aspect of the WMP assessment report (detailed in the WMP assessment report Enc 8/AWMSG/1206).

Mrs Shan Davies arrived and joined the WMP appraisal team.

Mrs Gail Woodland provided an overview of the trials relevant to the submission (detailed in Enc 8/AWMSG/1206).

The Chairman asked Mrs Davies to confirm she had no declarations of interest in Schering or in the technology. Mrs Shan Davies confirmed she had no declarations of interest and proceeded to summarise the health economic aspect of the WMP assessment report.

The Chairman invited Dr Ben Hope-Gill, Respiratory Physician at Llandough Hospital, to address the Committee and set the clinical scene. The Chairman asked Dr Hope-Gill if he had any declarations of interest in relation to iloprost trometamol. Dr Hope-Gill introduced himself and confirmed he had no interests to declare. He asked members to note that all decisions made in relation to treatment of patients with pulmonary hypertension are currently made in treatment centres outside Wales. Dr Hope-Gill outlined the current treatment options available to patients in Wales. He confirmed that access to medication is often problematic and impacts on the patient's quality of life. Dr Hope-Gill outlined the different classes of the severity of disease, routes of administration and associated complications. He reported that it was not uncommon for patients to travel for 3 hours to attend a specialist pulmonary hypertension unit outside Wales (usually centres in Sheffield or London). Dr Hope-Gill outlined potential side effects, complaints and difficulties encountered by patients.

The Company representatives were invited to clarify any issues in relation to the WMP assessment report and highlight any salient points of the company submission. Dr Napier thanked members for the opportunity to summarise the essence of the company submission and proceeded to put forward the company's perspective. Dr Napier reiterated the need for the product to be used within its licensed indications, in specialist centres with close monitoring. Dr Napier acknowledged the rarity of the disease and alluded to the problem of recruitment to clinical trials from the very small patient pool. It was noted there are three patients in Wales currently receiving treatment and it is not anticipated that this figure will increase. Mr Lloyd addressed members and provided a brief summary of the health economic aspect of the company submission, confirming that adverse drug reactions had not been included in the model.

The Chairman opened up the discussion and invited members to structure the discussion around clinical effectiveness issues in the first instance. Members sought clarification on improvements in tolerance, efficacy, end points of groups, pathogenic mechanism of treatment, treatments responses and individual responses, screening procedures, referral patterns and patient access to treatment and specialist centres. Dr Napier confirmed she is not aware of any patients receiving combination therapy.

Discussion then moved on to address cost-effectiveness issues. It was noted that the economic model had produced a negative cost per QALY estimate. The question was posed as to whether AWMSG would make appraisal decisions based on potential cost savings, without a cost per QALY estimate. Mr Lloyd confirmed that the normal cost per QALY was not reported because of the non-significant difference in effect and the significant difference in cost in favour of iloprost trometamol, a situation not previously encountered in AWMSG appraisals.

It was confirmed that this product meets the AWMSG criteria for ultra orphan drug status.

The Chairman asked Dr Napier and Mr Lloyd if they had any further questions or whether there were any outstanding issues that required further discussion. Dr Napier thanked the Chairman for a fair hearing and confirmed there were no outstanding issues.

The Chairman closed proceedings at 3.33pm and voting members retired to meet *in camera*.

The meeting re-convened at 4.00 pm

The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion AWMSG had come to the following decision.

It was agreed (by majority) that the recommendation to the Minister for Health & Social Services with regard to iloprost trometamol (Ventavis®) is

AWMSG recommends that iloprost trometamol (Ventavis®) should be made available for use within NHS Wales with the following restrictions:

It is used according to its licensed indications within NHS Wales for the treatment of patients with New York Heart Association Class III primary pulmonary hypertension as a second-line treatment when oral treatments are ineffective or not tolerated.

Iloprost trometamol (Ventavis®) should also be restricted for use only as an alternative in patients receiving other forms of prostacyclin treatment.

Iloprost trometamol (Ventavis®) should be initiated by specialists in centres treating pulmonary hypertension.

The appraisal was concluded. The Chairman confirmed that the company has 28 days in which to lodge an appeal against the AWMSG recommendation.

18/11 Orphan and ultra orphan drugs

The Chairman extended congratulations to Dr Dyfrig Hughes on the recent birth of his son and invited him to provide an overview of 9/AWMSG1206.

Dr Hughes outlined the background to the paper. At a previous meeting AWMSG requested input into the development of a policy for AWMSG appraisal of ultra-orphan drugs. It was confirmed that a policy for orphan drugs will be considered at a future AWMSG meeting as these would be more frequently considered by the Group.

It was agreed that the following statement should be added to provide clarity:

“Orphan drugs will be considered along the same lines as any other AWMSG appraisal.”

It was also agreed that the word “Initially” should be added to the first sentence of the second paragraph under the summary to read:

“Consideration for the approval of ultra-orphan drugs should initially be based on the same criteria of clinical and cost-effectiveness as those applied for other drugs.”

Dr Hughes confirmed he would prepare a paper for the next meeting on assessment of

medicines other than ultra-orphan drugs.

Mr Morgan questioned the feasibility of presenting the appraisal information against the criteria in the document and Mrs Samuels confirmed that this could be included as part of the paperwork submitted to pharmaceutical companies.

With the above changes, AWMSG endorsed the document. The amended document will be posted on the AWMSG website under the Drug Appraisal section.

Miss Carwen Wynne-Howells joined the meeting.

18/12 Update on Independent Prescribing

The Chairman invited Miss Sian Evans, Welsh Assembly Government lead on Independent Prescribing to provide an overview of Enc 10/AWMSG/1206.

Miss Evans confirmed that the application forms for the first cohort are now available and have been circulated to Trusts and LHBs. The deadline for receipt of applications is 31st January 2007. Members sought reassurance that transfer of funding across financial years would not be problematic and that prescription pads would be available in a timely manner. Miss Evans confirmed that neither of these issues would give cause for concern in the future. It was noted that the training will be over-subscribed. Mrs Wendy Warren and Miss Wynne Howells expressed their support.

The Chairman thanked Miss Evans and commented that AWMSG looked forward to future updates.

18/13 Report on NHS Industry Forum

The Chairman invited Mr David Morgan to provide an overview of the NHS industry Forum meeting held in October 2006.

Mr Morgan drew members' attention to salient points of the draft minutes Enc 11/AWMSG/1206. Mr Morgan confirmed that the questionnaire on partnership working had been circulated to Trusts, LHBs and the pharmaceutical industry. Mr Morgan confirmed the deadline for their return to WMP is 28th February 2007 and WMP had been tasked with collating the responses.

18/14 AWMSG – Broadening of appraisal process

The Chairman invited Mrs Samuels to provide an outline of the proposals for moving the broadening of the AWMSG appraisal process forward (Enc 12/AWMSG/1206).

Mrs Samuels drew members' attention to the proposed meeting dates and deadlines for submissions and confirmed that current submissions for appraisal of new high cost medicines will fall under the broadened appraisal process. Members considered the proposed membership of AWMSG and the NMG and it was agreed that a nurse representative should be included on both groups. Mrs Samuels confirmed that the lack of detail in the proposed split of pharmacists and doctors allowed WMP some flexibility in identifying individuals, but a balance of primary and secondary care experience would be sought.

Clarification of the process for identifying individuals was sought. Mrs Samuels confirmed that WMP will be approaching MTCs, AWMSG and its sub-groups for advice on identifying individuals.

It was confirmed that the NMG will be considered as an additional AWMSG sub-group. It was confirmed that a constitution will be developed by WMP in collaboration with the

AWMSG Steering Committee and brought to a future AWMSG meeting for endorsement.

Mr Harsant, the industry representative was encouraged that under the new process the ministerial ratification process will be streamlined, but expressed concern over the resources required, particularly the health economic input.

WMP representatives confirmed their engagement with the TDA Users Group and ABPI (Wales) in developing the process, and expressed their view that the new process will be more interactive but less presentational in order to streamline the process. It was felt that the proposed changes should increase the robustness of the appraisal process.

It was emphasised that in the new process, AWMSG will review the recommendations of the sub-group (NMG) and make the final recommendation to the Minister after consideration of any broader societal and strategic issues.

Members were asked to note that a training day for AWMSG members and newly appointed members of the NMG has been arranged in the Angel Hotel, Abergavenny on Thursday, 1st February 2007 (further details will follow).

Date of next AWMSG meeting: Wednesday, 14th March 2007 in Margam Park, Port Talbot