ALL WALES MEDICINES STRATEGY GROUP
MINUTES OF THE AWMSG MEETING HELD ON THURSDAY, 14TH FEBRUARY 2008 COMMENCING 10.30 AM AT THE WALES MILLENNIUM STADIUM, CARDIFF

MEMBERS PRESENT:

			Did not participate in
1.	Dr Philip Banfield	NHS Consultant	
2.	Dr Geoffrey Carroll	Health Commission Wales	
3.	Dr Bruce Ferguson	Trust Medical Director	
4.	Mr Peter Harsant	Industry Representative	
5.	Mr Brian Hawkins	LHB Pharmacist	
6.	Mr Robert Holcombe	LHB Finance Director	
7.	Cllr Meurig Hughes	Lay member	**Appraisals 1 & 2**
8.	Dr Thomas Lau	General Practitioner and prescribing lead	
9.	Dr Bendan Lloyd	LHB Medical Director	
10.	Mr David Morgan	National Public Health Service Wales	
11.	Prof Ceri Phillips	Health Economist	
12.	Mr Dave Roberts	Chief Pharmacist	
13.	Prof Philip Routledge	Clinical Pharmacologist (Chairman)	

IN ATTENDANCE:

			Did not participate in
14.	Mrs Ruth Lang	Welsh Medicines Partnership	
15.	Mrs Carolyn Poulter	Welsh Assembly Government	
16.	Mrs Karen Samuels	Welsh Medicines Partnership	
17.	Dr Martin Duerden	NMG Chairman (for appraisals only)	**Appraisal 3**

List of Abbreviations:

ABPI	Association of the British Pharmaceutical Industry
ASAR	AWMSG Secretariat Assessment Report
AWCDG	All Wales Cancer Drugs Group
AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
BMA	British Medical Association
BNF	British National Formulary
CR/ASAR	Company response to the AWMSG Secretariat assessment report
CR/FAR	Company response to the final appraisal report
CR/PAR	Company response to the preliminary appraisal report
CSCG	Cancer Services Co-ordinating Group
CHM	Commission on Human Medicines
DTB	Drug & Therapeutics Bulletin
FAR	Final appraisal report
HCW	Health Commission 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
NMG	New Medicines Group
NPHS	National Public Health Service
PAR	Preliminary appraisal report
PPRS	Prescription Price Regulation Scheme
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
WeMeReC	Welsh Medicines Resource Centre
WMIC	Welsh Medicines Information Centre
WMP	Welsh Medicines Partnership

1. Welcome and introduction

The Chairman opened the meeting and welcomed Dr Brendan Lloyd to his first AWMSG meeting as deputy LHB Medical Director.

2. Apologies

Dr Paul Buss, NHS Consultant
Dr Fraser Campbell, LHB Medical Director
Mr Jeff Evans, representing other professionals eligible to prescribe
Mrs Wendy Warren, Senior Nurse
Miss Carwen Wynne Howells, Welsh Assembly Government

3. Declarations of interest

The Chairman asked members to declare any specific, non-specific, personal or non-personal interests.

Mr Meurig Hughes declared a personal interest in GlaxoSmithKline. The Chairman confirmed Mr Hughes would be unable to participate in Appraisals 1 and 2.

Dr Martin Duerden declared a personal interest in epoetin delta (Dyneo®). The Chairman confirmed that Dr Duerden would be unable to participate in Appraisal 3.

4. Chairman's report

The Chairman thanked those who participated in the Prescribing Strategy Brainstorming meeting held on Monday, 7th January in Abergavenny, which was very constructive and provided opportunity for representatives of NHSIF and AWPAG to work with WMP to progress the document which will be discussed later in the day.

The Chairman confirmed that the TDA User Group had met on Monday, 21st January to discuss issues around the AWMSG appraisal process. All AWMSG sub-groups met in January and a training day in Health Economics was held at Cardiff Rugby Club on Friday, 8th February. The Chairman thanked Dr Dyfrig Hughes, Professor Ceri Phillips, Dr Martin Duerden and Mrs Karen Samuels who all contributed to the day. Representatives from MTCs, the Cardiac and Cancer networks were also in attendance.

Members were informed that WMP had hosted a meeting of Welsh interface pharmacists on Friday, 25th January, led by Dr Tessa Lewis. This group is addressing issues in relation to shared care.

The Chairman confirmed that the appointment of AWMSG Vice Chair will be conducted outside of the meeting. Members will be asked to submit nominations electronically to WMP. It was confirmed that following the December meeting, the revised AWMSG Constitution has been posted on the AWMSG website.

Members were informed that the AWMSG Steering Committee had endorsed the appointment of Mr Jeremy Felvus as deputy Industry Representative for Mr Peter Harsant. Members were asked to support this nomination from ABPI, which will require ratification from the Welsh Assembly.

The Chairman announced that appraisal of tobramycin (Bramitob®) for the management of chronic pulmonary infection due to *Pseudomonas aeruginosa* in patients with cystic fibrosis aged 6 and older, will not be undertaken by AWMSG today as the applicant company had not received the marketing authorisation. The Chairman informed members that WMP are liaising with Trinity-Chiesi Pharmaceuticals.

The Chairman reported that Ministerial ratification of AWMSG recommendations in relation to the appraisals held at the December meeting had been received. The Chairman confirmed that the final appraisal reports (FARs) of dasatinib (Sprycel®) for adults with Philadelphia chromosome positive (PH+) ALL, and lymphoid blast CML with resistance or intolerance to prior therapy and for adults with chronic accelerated or blast phase chronic myeloid leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesilate, had been posted on the AWMSG website. The manufacturers and the Service have been notified.

The Chairman announced that the following appraisals will be undertaken by NMG on 13th March 2007 and AWMSG on Wednesday16th April 2008 in Abergavenny:

Medicine: ziconotide injection (Prialt®)
Manufacturers: Eisai Ltd
Indication: For severe chronic pain

Medicine: fondaparinux sodium (Arixtra®)
Manufacturers: GlaxoSmithKline
Indication: Treatment of unstable angina or non-ST segment elevation myocardial infarction (UA/NSTEMI) in patients for whom urgent (<120 minutes) invasive management (PCI) is not indicated.

Medicine: fondaparinux STEMI (Arixtra®)
Manufacturers: GlaxoSmithKline
Indication: Treatment of STEMI in patients who are managed with thrombolytics or who initially are to receive no other form of reperfusion therapy.

The Chairman confirmed that the AWMSG meeting scheduled for 11th June 2008 had been changed to Friday, 13th June 2008.

The Chairman announced the resignation of Mrs Nicola John as Chair of AWPAG. He confirmed that following receipt of her resignation, members had nominated Dr Tessa Lewis to take up the role of Chair, and the Steering Committee had supported her appointment. Nominations for a Vice Chair will be sought from AWPAG members.

5. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy.

Matters arising:

There were no matters arising outside the agenda.

6. Appraisal 1 – intravenous topotecan hydrochloride (Hycamtin®) SCLC
Manufacturer: GlaxoSmithKline
Indication: Intravenous (IV) topotecan is licensed for use in patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate.

Start time – 10.45 am

The Chairman welcomed representatives from the applicant company, GlaxoSmithKline, Dr Helen Rudge and Dr Stijn Hollemeersch, and confirmed that opportunity would afforded them to comment on the appraisal and raise issues. The Chairman confirmed that Mr Meurig Hughes would not participate in the appraisal as he had declared a personal specific interest.

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. He reiterated that AWMSG advice is interim to NICE should it be subsequently published.

The Chairman confirmed the sequence of the appraisal and invited Dr Martin Duerden, NMG Chairman, to address the Group. Dr Duerden set the context of the appraisal and provided a brief overview of the discussions held at the New Medicines Group. The relevant issues contained within the PAR - Enclosure 2/AWMSG/0208 were highlighted. Dr Duerden confirmed the NMG recommendation and drew members' attention to the key factors influencing the recommendation not to support the use of intravenous (IV) topotecan licensed for use in patients with relapsed small cell lung cancer (SCLC) for

whom re-treatment with the first-line regimen is not considered appropriate as, it was considered that the case for cost-effectiveness had not been proven. It was noted that NMG members had agreed that the economic analysis in the manufacturer's submission had been based on a population that may not be representative of clinical practice.

It was noted that there was one medical expert submission. The Chairman confirmed that several medical experts are approached for their views within the appraisal process to present their views in a structured written questionnaire.

The Chairman opened the discussion and asked members to consider the evidence in relation to the clinical effectiveness of the new medicine within its licensed indication.

There was discussion over clinical improvement, the adverse effect profile, survival rates and quality of life of patients.

The Chairman asked members to consider the evidence in relation to the cost effectiveness and invited Professor Ceri Phillips to bring to the attention of the Committee any relevant issues. Members were asked to note that a probablistic sensitivity analysis undertaken by the applicant company would have been useful in the deliberations.

It was noted that the oral preparation has not received its licence. The Chairman invited comment on the broader societal issues and drew members' attention to the patient interest group submission received from the Roy Castle Lung Foundation. There was discussion over wastage and need for stability data. The Chairman thanked the patient interest group for a very thorough and well presented submission.

The Chairman asked members to consider the issues outlined in the CR/PAR, and invited representatives of the applicant company to comment on general and specific issues.

Dr Rudge clarified the selection criteria in relation to the study population and the cardiovascular risk of the sub-group. Dr Hollemeersch clarified issues around duration of median survival and best supportive care. Dr Rudge confirmed that the omission of probablistic analysis was due to time constraints.

Following the discussion, and prior to closing proceedings, Dr Rudge and Dr Hollemeersch provided confirmation to the Chairman that they were satisfied that all issues had been adequately discussed and taken into account.

In the light of the discussions the Chairman asked members to make note of their initial recommendation on their aide-memoir for reference at a later stage.

The Chairman closed proceedings at 11.35 am and confirmed that the Committee would retire at the end of the appraisal session to vote in private.

7. **Appraisal 2 -** intravenous topotecan hydrochloride (Hycamtin®) Cervical Cancer
Manufacturer: GlaxoSmithKline
Indication: Topotecan in combination with cisplatin for patients with carcinoma of the cervix recurrent after radiotherapy and for patients with Stage IVB disease. Patients with prior exposure to cisplatin require a sustained treatment free interval (TFI) to justify treatment with the combination.

Start time 11.35 am

The Chairman invited Dr Rudge and Dr Hollemeersch to remain at the meeting table and confirmed that Mr Meurig Hughes would not participate in the appraisal.

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. He reiterated that AWMSG advice is interim to NICE should it be subsequently published.

The Chairman confirmed the sequence of the appraisal and invited Dr Martin Duerden in his capacity as NMG Chairman, to address the Group.

Dr Duerden set the context of the appraisal and provided a brief overview of the discussions held at the New Medicines Group. The relevant issues contained within the PAR - Enclosure 3/AWMSG/0208 were highlighted. Dr Duerden confirmed the NMG recommendation to support the use of topotecan in combination with cisplatin for patients with carcinoma of the cervix recurrent after radiotherapy and for patients with Stage IVB. He confirmed the NMG view that it should be restricted for use in patients who are cisplatin-naïve and drew members' attention to the key factors influencing the decision.

The Chairman asked members to consider any outstanding issues in relation to the cost effectiveness and invited Professor Phillips to address the Group. Professor Phillips confirmed that cost-effectiveness had been demonstrated. It was noted that the inclusion of a probabilistic analysis was useful in deliberations.

The Chairman invited members to seek clarification of any outstanding issues in relation to the clinical effectiveness.

The Chairman invited comment on the budget impact and broader society issues and, in particular, the patient interest group submission received from Jo's Trust Fighting Cervical Cancer. The Chairman thanked the patient interest group for their submission which informed both NMG and AWMSG.

The Chairman drew members' attention to the issues raised in the CR/PAR and invited members to comment on the issues raised.

The Chairman asked representatives of the applicant company to comment on the general and specific issues. Dr Rudge clarified the outstanding issues raised during members' discussion.

Prior to closing proceedings, the Chairman invited Dr Rudge and Dr Hollemeersch to confirm they were satisfied that all issues had been adequately discussed and taken into account. Confirmation was received and the Chairman thanked the company for engaging with the AWMSG process.

In the light of the discussions the Chairman asked members to make note of their initial recommendation on their aide-memoir for reference at a later stage. The Chairman closed proceedings at 12.07 pm and confirmed that the Committee would retire at the end of the appraisal session to vote in private.

8. **Appraisal 3** - tacrolimus (Advagraf®)
Manufacturer: Astellas Pharma Ltd
Indication: Prophylaxis of transplant rejection in adult kidney or liver allograft recipients. Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients.

Start time 12.20 pm

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. He reiterated that AWMSG advice is interim to NICE should it be subsequently published.

The Chairman invited members to declare any interests. There were none.

The Chairman welcomed representatives from the applicant company, Astellas Pharma Limited, Philippa Tomlinson and Dr Malcolm Brown, Medical Director.

The Chairman invited Dr Martin Duerden, NMG Chairman, to address the Group. Dr Duerden set the context of the appraisal and provided a brief overview of the discussions held at the New Medicines Group. The relevant issues contained within the PAR - Enclosure 3/AWMSG/0208 were highlighted. Dr Duerden confirmed the NMG recommendation and drew members' attention to the key factors influencing the recommendation not to support the use of tacrolimus (Advagraf®) as the case for cost-effectiveness had not been proven. It was noted that NMG members agreed that the economic analysis in the manufacturer's submission had been based on a population not representative of clinical practice.

The Chairman opened the discussion and asked members to consider the evidence in relation to the clinical effectiveness.

The Chairman confirmed that representatives from the applicant company would have opportunity to comment on issues raised by members in their discussion.

There was discussion over equivalence between oral and intravenous formulations, convenience of dose and minimisation of risk to patients.

The Chairman asked members to consider the evidence in relation to the cost effectiveness. Professor Phillips provided clarification in relation to the health economic case presented.

The Chairman asked member to raise any societal or budget impact issues. It was noted that the patent is due to expire in 2009.

The Chairman invited comment on the broader societal issues and drew members' attention to the patient interest group submission received from the Welsh Kidney Patient Association.

The Chairman invited Ms Tomlinson and Dr Brown to highlight salient points of their response to the preliminary recommendation and clarify issues that were raised during the discussion. There was discussion over dosage and compliance.

Following the discussion, and prior to closing proceedings, Dr Brown provided confirmation to the Chairman that he was satisfied that all issues had been adequately discussed and taken into account.

In light of the discussions the Chairman asked members to make note of their initial recommendation on their aide-memoir for reference at a later stage.

The Chairman closed proceedings at 1.20 pm and confirmed that the Committee would retire for a short break.

9. **Appraisal 4** – epoetin delta (Dynepo®)
Manufacturer: Shire Pharmaceuticals
Indication: Treatment of anaemia in patients with chronic renal failure. Dynepo® may be used in patients on dialysis and patients not on dialysis.

Start time 2.15 pm

The Chairman welcomed representatives from the applicant company, Shire Pharmaceuticals, Mr Michael Gains and Mr Steve Sanderson. The Chairman confirmed that opportunity would be afforded to them to comment on the appraisal and raise any relevant issues.

The Chairman reminded members that Dr Martin Duerden had declared an interest in Shire Pharmaceuticals and would not participate in this appraisal.

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. He reiterated that AWMSG advice is interim to NICE should it be subsequently published.

The Chairman confirmed the sequence of the appraisal and invited Professor Ceri Phillips, as NMG Vice Chairman, to address the Group. Professor Phillips set the context of the appraisal and provided a brief overview of the discussions held at the New Medicines Group. The relevant issues contained within the PAR - Enclosure 4/AWMSG/0208 were highlighted. Professor Phillips confirmed the NMG recommendation and drew members' attention to the key factors influencing the recommendation to support the use of epoetin delta (Dynepo®) for use in patients on dialysis (and in patients not on dialysis) within NHS Wales for the treatment of anaemia in patients with chronic renal failure. It was noted that NMG were of the opinion that epoetin delta (Dynepo®) may be suitable for shared care agreements within NHS Wales and that existing shared care protocols for current ESAs may need to be reconsidered in light of this submission.

The Chairman opened the discussion and asked members to consider the evidence in relation to the clinical effectiveness of the new medicine within its licensed indication.

The Chairman asked members to consider the evidence in relation to the cost effectiveness and to raise any societal or budget impact issues.

The Chairman invited comment on the broader societal issues. It was noted that no patient interest group had made a submission.

The Chairman asked members to consider the issues raised in the CR/PAR, and invited representatives of the applicant company to comment on general and specific issues. Dr Sanderson responded to the discussion on behalf of the applicant company and clarified any outstanding issues.

Following the discussion, and prior to closing proceedings Mr Sanderson provided confirmation to the Chairman that they were satisfied that all issues had been adequately discussed and taken into account.

The Chairman closed this appraisal at 2.45 pm and confirmed that the Committee would retire to vote in private.

Appraisal decisions

At 2.10 pm the Chairman announced the decision of AWMSG for appraisals 1-3.

Appraisal 1 – intravenous topotecan hydrochloride (Hycamtin®) SCLC
Manufacturer: GlaxoSmithKline
Indication: Intravenous (IV) topotecan is licensed for use in patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate.

The recommendation of AWMSG is:

Intravenous topotecan (Hycamtin®) is recommended for use within NHS Wales for the treatment of patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate**.**

Topotecan (Hycamtin®) should only be initiated by specialists experienced in the treatment of SCLC.

Topotecan (Hycamtin®) is not presently recommended for shared care.

Appraisal 2 - intravenous topotecan hydrochloride (Hycamtin®) Cervical Cancer
Manufacturer: GlaxoSmithKline
Indication: Topotecan in combination with cisplatin for patients with carcinoma of the cervix recurrent after radiotherapy and for patients with Stage IVB disease. Patients with prior exposure to cisplatin require a sustained treatment free interval (TFI) to justify treatment with the combination.

The recommendation of AWMSG is:

Intravenous topotecan (Hycamtin®) is recommended for use within NHS Wales in combination with cisplatin, for the treatment of patients with carcinoma of the cervix recurrent after radiotherapy and for patients with Stage IVB disease. It is restricted for use in patients who are cisplatin-naïve.

Topotecan (Hycamtin®) should only be initiated by specialists experienced in the treatment of cervical cancer.

Topotecan (Hycamtin®) is not presently recommended for shared care.

Appraisal 3 - tacrolimus (Advagraf®)
Manufacturer: Astellas Pharma Ltd
Indication: Prophylaxis of transplant rejection in adult kidney or liver allograft recipients. Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients.

The recommendation of AWMSG is:

Tacrolimus (Advagraf®) is not recommended for use within NHS Wales for the prophylaxis of transplant rejection in adult kidney or liver allograft recipients and the treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients.

Appraisal 4 – epoetin delta (Dynepo®)
Manufacturer: Shire Pharmaceuticals
Indication: Treatment of anaemia in patients with chronic renal failure. Dynepo® may be used in patients on dialysis and patients not on dialysis.

The recommendation of AWMSG is:

Epoetin delta (Dynepo®) is recommended for use in patients on dialysis (and in patients not on dialysis) within NHS Wales for the treatment of anaemia in patients with chronic renal failure.

Epoetin delta (Dynepo®) should only be initiated by specialists experienced in the treatment of chronic renal failure.

AWMSG are of the opinion that epoetin delta (Dynepo®) may be suitable for shared care agreements within NHS Wales. Existing shared care protocols for current erythropoietin stimulating agents (ESAs) may need to be reviewed in light of this decision.

The Chairman confirmed that the recommendations would be forwarded to the applicant companies within five working days from the meeting.

10. Report on NHSIF

Mr Morgan, NHSIF Chairman, drew members' attention to the salient issues from the draft minutes of the January 2008 meeting. Mrs Poulter confirmed that the Minister had agreed that an analytical prescribing unit should be established within Wales which will sit within the Welsh Medicines Partnership and feed into the AWMSG reporting mechanisms. It was confirmed that a paper will be presented to AWMSG for information at a future meeting. Mr Harsant suggested that a flow diagram in relation to the editorial process of the prescribing reviews would be helpful. There were no other issues.

11. Update on AWPAG

Mrs John provided an overview of the draft minutes of the AWPAG meeting held in January 2008. Dr Tessa Lewis, AWPAG Vice Chair, provided an update on the amiodarone shared care template and confirmed that endorsement of the template from the Welsh Cardiovascular Society had not been received. Members were informed that WMP is awaiting written confirmation of the concerns of the Welsh Cardiovascular Society and are hoping to attend the Spring meeting of the Society.

Members were informed that AWPAG had suggested a review of methotrexate prescribing in secondary care to determine whether there are any safety issues and agreed to work with Chief Pharmacists to overcome any problems and ensure that the National Patient Safety Agency guidance is adhered to.

Clarification was sought as to whether NICE guidelines supersede AWMSG guidelines in relation to the prescribing of statins. Mr Harsant agreed to discuss this with Mrs Poulter outside of the meeting.

Proposed anticoagulation audit

Dr Lewis provided an overview of the proposed national incentive scheme anticoagulation audit and referred members to the appendix. Dr Lewis confirmed that the scheme proposed by AWPAG is based on NPSA anticoagulation alert and is in line with the All Wales Safety Campaign – Prevent Harm from High-Alert Medications – Anticoagulants that will be launch in April 2008. It was noted there had been collaboration with NLIAH to agree process measures. The aim of the audit is to enable practices in Wales to review their prescribing of warfarin and to assess the extent to which they comply with the guidance issued by the National Patient Safety Agency. Dr Lewis informed the Group that the audit required verification in terms of terminology, usability and sample size, but that it was hoped that the scheme would be available in April 2008. Members endorsed the scheme subject to some minor amendments which were suggested and noted.

The Chairman thanked Dr Lewis and Mrs John, who was presented with a bouquet of flowers as a small token of appreciation of her work as AWPAG Chair.

12. AWMSG Prescribing Strategy

The Chairman provided the background to the document and invited members to comment on the revised version of the strategy document. The Chairman outlined the consultation that had taken place. It was suggested that further informal comment from professional colleagues should be sought. It was agreed that an email should be disseminated to the service with the AWMSG minutes inviting requests for an electronic copy so that professional groups are given another opportunity to comment on the document before it is submitted to the Assembly. The Chairman confirmed that comments should be submitted to the WMP office by the end of the first week of March. Members agreed that AWMSG should offer to assist the Assembly with the prioritisation of the recommendations.

13. The risk management of injectable medicines therapy

The Chairman invited Mr Paul Spark of Cardiff and Vale NHS Trust to address the Group. Mr Spark provided an overview of Enc **9**/AWMSG/0208 and asked members to facilitate the risk management of injectable therapy by supporting the principle of rationalisation and standardisation of clinical practice in the prescribing, preparation and administration of injectable medicines. Members applauded the work and supported the establishment of a mechanism for all Wales collaboration in the provision of a range of ready-to-administer injectable drugs, prioritised using the risk assessment tool recommended by the NPSA. Also, the development of common prescribing and administration protocols, provision of technical information on injectable drug use and training of healthcare staff involved in prescribing, preparation, administration and monitoring of injectable therapy was unanimously supported. The Chairman confirmed AWMSG's endorsement of the paper and closed the discussion.

14. Consultation on rare diseases

The Chairman referred members to the European Commission Public Consultation on Rare Disease and Enc **10**/AWMSG/0208 **-** a draft response prepared by Dr Dyfrig Hughes on behalf of AWMSG - and opened the discussion. It was agreed that "(from pharmaceutical manufacturers and patients groups)" be removed from the text under Question 13. It was also agreed that the final sentence should be removed. Dr Banfield agreed to provide WMP with some minor typographical amendments. With these changes, members confirmed they were comfortable with the proposed wording and endorsed the response. It was noted that NHSIF and AWPAG had been invited to comment.

Any other business:
The Chairman confirmed that the Medicines and Healthcare products Regulatory Agency (MHRA) is preparing a national campaign to increase public awareness of the Yellow Card Scheme, which collects reports of suspected adverse drug reactions, and to re-launch public reporting to the scheme. The MHRA would like to engage all community pharmacists in this campaign as part of their contractual participation in local health promotion campaigns. The Scheme will begin mid February 2008 and the MHRA will provide information leaflets for community pharmacy staff, information cards for patients, posters to be displayed in the pharmacy and paper versions of the patient Yellow Card. Materials will be distributed directly from the MHRA via pharmaceutical wholesalers to all pharmacies. The Yellow Card Centre Wales (YCC Wales) can provide local help and advice about the Yellow Card Scheme in general and also in relation to the national campaign.

Professor Ceri Phillips offered the congratulations of AWMSG to Professor Routledge who was awarded an OBE in the Queen's New Years Honours List.

Date of next AWMSG meeting: Wednesday, 16th April 2008 at the Angel Hotel, Abergavenny commencing 10.30 am.