ALL WALES MEDICINES STRATEGY GROUP
MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY, 15th OCTOBER 2008 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY

MEMBERS PRESENT:

			Did not participate in
1.	Dr Paul Buss	NHS Consultant (Vice Chairman)	
2.	Dr Fraser Campbell	LHB Medical Director	
3.	Dr Karen Fitzgerald	National Public Health Service Wales	
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	**10**
8.	Dr Thomas Lau	General Practitioner and prescribing lead	
9.	Prof Ceri Phillips	Health Economist	
10.	Mr Dave Roberts	Chief Pharmacist	**10-14**
11.	Prof Philip Routledge	Clinical Pharmacologist (Chairman)	
12.	Dr Hugo van Woerden	National Public Health Service Wales	

IN ATTENDANCE:

13.	Dr Martin Duerden	NMG Chairman
14.	Miss Sarah O'Sullivan-Adams	Welsh Assembly Government
15.	Miss Carwen Wynne Howells	Welsh Assembly Government)
16.	Mrs Karen Samuels	Welsh Medicines Partnership
17.	Mrs Ruth Lang	Welsh Medicines Partnership
18.	Mrs Kath Haines	Welsh Medicines Partnership

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
BHIVA	British HIV Association
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
NLIAH	National Leadership and Innovation Agency for Healthcare
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 members.

2. Apologies

Dr Geoffrey Carroll, National Public Health Service
Mrs Wendy Warren, Senior Nurse
Dr Bruce Ferguson, Trust Medical Director
Mr Jeff Evans, Other professionals eligible to prescribe

3. Declarations of interest

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

Councillor Meurig Hughes declared a personal non-specific interest in GlaxoSmithKline and the Chairman confirmed he would be unable to participate in the appraisal of. abacavir/lamivudine (Kivexa®).

4. Chairman's report

The Chairman welcomed Dr Hugo van Woerden who was attending in place of Dr Geoffrey Carroll, and Sarah O'Sullivan-Adams, attending in place of Carolyn Poulter as Welsh Assembly representative. Members were informed of the resignation of Peter Harsant as ABPI representative. The Chairman thanked Peter for his contribution to AWMSG and wished him well for the future.

The Chairman announced that Ministerial endorsement had been received for the appraisals held at the August meeting:

Trabectedin (Yondelis®▼)
For advanced soft tissue sarcoma

Tenofovir disoproxil fumarate (Viread®▼)
For the treatment of chronic hepatitis B in adults

Pegfilgrastim (Neulasta®)
For the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy.

It was confirmed that the Final Appraisal Reports had been posted on the AWMSG website and the Service informed.

The Chairman informed members of a meeting held with the Minister for Health and Social Services where it was discussed how AWMSG could influence the prescribing of non-approved medicines and the use of cancer medicines in the last months of life. The Chairman confirmed he had been asked to develop a programme of work to address the terms of reference set out by the Minister and would be canvassing the views of members over the next few weeks.

The Chairman confirmed that representatives from WMP had met with industry colleagues at the TDA Users Group on 6th October to discuss issues relating to the AWMSG appraisal process.

The Chairman announced the appraisals to be held at the next AWMSG meeting on Wednesday, 10th December:

Appraisal 1:	**alemtuzumab (MabCampath®▼)** Treatment of B-cell chronic lymphocytic leukaemia (B-CLL) for whom fludarabine combination chemotherapy is not appropriate.
Appraisal 2:	**atazanavir (Reyataz®▼) experienced adults** Treatment of human immunodeficiency virus (HIV)-1 infected adults, in combination with other antiretroviral medicinal products, for treatment-experienced patients.
Appraisal 3:	**atazanavir (Reyataz®▼) naïve adults** Treatment of human immunodeficiency virus (HIV)-1 infected

adults, in combination with other antiretroviral medicinal products, for treatment naïve patients.

Appraisal 4: **ambrisentan (Volibris®▼)**

Treatment of patients with pulmonary arterial hypertension (PAH) classified as World Health Organisation (WHO) functional Class II and III, to improve exercise capacity

5. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy. No changes were made.

Matters arising:

It was confirmed that the paper on Save a 1000 Lives Campaign would be brought to AWMSG at their next meeting in December 2008.

It was confirmed that the National Prescribing indicators paper for 2009-2010 presented to AWMSG at the meeting in August had been updated in light of discussions and had been posted on the AWMSG website.

6. Appraisal 1 – stiripentol (Diacomit®)

In conjunction with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (SMEI, Dravet's syndrome) whose seizures are not adequately controlled with clobazam and valproate

Start time 10.45 am

It was confirmed that the applicant company, Alan Pharmaceuticals, had declined to attend the appraisal and provide a formal response to the PAR.

Members were asked to confirm any declarations of interest – there were none.

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 and Social Services, places an obligation on Trusts and LHBs in Wales to fund accordingly. He reiterated that AWMSG advice is interim to NICE guidance should it be subsequently published.

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

Dr Duerden set the context of the appraisal and provided an overview of the discussions held at the NMG on 17th September 2008. The relevant issues contained within the PAR, enclosure **2**/AWMSG/1008, were highlighted and he conveyed the views of the medical expert. It was noted that no patient organisation submission had been received. Members were informed there was no attempt by the applicant company to construct a health economic model. In conclusion, he confirmed that, based on the lack of health economic evidence, the preliminary recommendation of NMG was not to support the use of the medicine in Wales. Dr Duerden confirmed there were studies underway which could provide the additional information which could form the basis of a

re-appraisal of this technology. There was no representative of the applicant company to address the issues raised in relation to studies currently underway.

The Chairman opened the discussion and invited members to address issues in relation to clinical effectiveness. Members were informed that the lack of evidence provided had made it difficult for NMG to make a judgement on clinical benefit. The lack of experience in clinical use of this product was noted.

The Chairman asked members to consider the evidence in relation to cost effectiveness and invited Professor Ceri Phillips to bring to members' attention any relevant issues. Professor Phillips confirmed that no health economic model had been provided and no evidence indicating how the company translated the cost savings other than reduced hospitalisation.

The applicant company was not in attendance to provide clarification of issues raised during the appraisal. Disappointment was expressed that the applicant company had not submitted a health economic model and a representative of WMP confirmed that every effort had been made to communicate to the applicant company the importance of providing health economic data. The lay member expressed concern that the applicant company's views were not represented at the meeting and no patient organisation submission had been received.

The Chairman invited members to comment on any societal issues.

The Chairman confirmed that Alan Pharmaceuticals had not wished to provide comment in relation to NMG's preliminary recommendation.

The Chairman closed the discussion at 11.10 am.

Appraisal decision

The recommendation of AWMSG to the Minister for Health and Social Services was announced:

The recommendation of AWMSG is:

Stiripentol (Diacomit®) is not recommended for use within NHS Wales for the treatment of severe myoclonic epilepsy in infancy.

Key factors influencing the recommendation:

- The economic evidence submitted is not sufficient to assess the cost effectiveness of stiripentol (Diacomit®).

7. Appraisal 2 – rufinamide (Inovelon®▼)

As adjunctive therapy in patients four years and older with Lennox-Gastaut syndrome (LGS).

Start time 11.11 am

The Chairman welcomed representatives of the applicant company, Eisai Limited - Dr Amit Patel, Medical Advisor, Dr Lara Verdian, Health Economics & Outcomes Research Manager and Mr Keith Tolley, Director of Health Economics

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 and 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 events and members were asked to confirm any declarations of interest – there were none.

Dr Duerden set the context of the appraisal and provided an overview of the discussions held at the NMG. The relevant issues contained within the PAR, enclosure **3**/AWMSG/1008, were highlighted. Dr Duerden conveyed the views of the medical expert which highlighted the lack of paediatric services in Wales.

Dr Duerden informed members that a submission had been received from the father of a patient who expressed the view that availability of this technology would provide significant benefit and hope to the family in improving the management of patients.

The views of the medical expert were conveyed. Members were informed that a further medical expert submission had been received by WMP after the NMG meeting and the views of this expert were relayed.

After having presented a summary of the issues considered by NMG, the Chairman confirmed NMG's advice to AWMSG was to support the use of rufinamide (Inovelon®) within NHS Wales.

The Chairman opened the discussion and asked members to raise issues relating to the clinical effectiveness of the treatment. The Chairman asked the applicant company to respond to relevant issues raised at the end of members' discussion.

The Chairman asked members to consider issues in relation to the cost effectiveness and invited Professor Phillips to address the Group. Professor Phillips congratulated the applicant company on the quality of the health economic model provided and highlighted the salient issues in relation to cost effectiveness.

The Chairman confirmed that broader societal issues and been considered by the Group, the views of a carer considered, and asked members to raise any other outstanding issues.

The Chairman asked representatives of the applicant company to comment on the general and specific issues, in particular the patient registry. Clarification in relation to drop attacks, clinical markers and health benefits was provided. The issues relating to

cost effectiveness were also clarified.

Prior to closing proceedings, the Chairman sought confirmation that representatives of the applicant company were satisfied that all issues had been adequately discussed and taken into account and the process had been fair and thorough. Confirmation was received.

The Chairman closed proceedings at 11.58 am.

Appraisal decision

The recommendation of AWMSG to the Minister for Health and Social Services was announced:

The recommendation of AWMSG is:

Rufinamide (Inovelon®▼) is recommended for use within NHS Wales as an adjunctive therapy in patients four years and older with Lennox-Gastaut syndrome in patients where other adjunctive treatments have proved sub-optimal or have not been tolerated.

Rufinamide (Inovelon®▼) is not suitable for shared care within NHS Wales.

Additional note:

- AWMSG did not consider that Rufinamide (Inovelon®▼) satisfies their criteria for ultra orphan drug status.

8. Appraisal 3 – raltegravir (Isentress®▼)
In combination with other antiretroviral medicinal products agents for the treatment of Human Immunodeficiency Virus (HIV-1) infection in treatment-experienced adult patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy

Start time 12.10 pm

Members were asked to confirm any declarations of interest – there were none.

The Chairman welcomed Mr Paul Lamba, Medical Affairs Physician and Mr William Dunlop, Outcomes Research Manager from Merck Sharp and Dohme.

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 and 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 Dr Duerden to provide an overview of the discussions held at the NMG. Dr Duerden set the context of the appraisal and highlighted relevant issues contained within the PAR, enclosure **4**/AWMSG/1008. He conveyed the views of the medical experts which were supportive of using tailored regimes within BHIVA guidelines. Dr Duerden drew members' attention to the patient organisation submission from the Terence Higgins Trust which he described as a very well balanced and thorough submission. He concluded his presentation by confirming NMG's advice to AWMSG was to support the use of raltegravir (Isentress®▼) as a treatment option.

The Chairman invited discussion on issues relating to the clinical effectiveness of the treatment and asked representatives of the applicant company to provide clarification of relevant issues raised during the discussion.

The Chairman asked members to consider issues in relation to cost effectiveness, and invited Professor Phillips to address the Group. Professor Phillips highlighted relevant issues relating to cost effectiveness within the submission.

There were no outstanding broader societal or budget impact issues. The Chairman asked members to highlight issues in relation to the patient interest group submission. Speaking on behalf of the patient, the lay member recognised the conciseness of the submission received and welcomed the high standard of this patient organisation submission.

The Chairman asked representatives of the applicant company to comment on general and specific issues in relation to outlining the case for the use of raltegravir (Isentress®▼) in Wales.

Prior to closing proceedings, the Chairman sought confirmation that representatives of the applicant company were satisfied that all issues had been adequately discussed and taken into account and the process had been fair and thorough. Confirmation was received.

The Chairman closed proceedings at 12.45 pm.

Appraisal decision

The recommendation of AWMSG to the Minister for Health and Social Services was announced:

The recommendation of AWMSG is:

Raltegravir (Isentress®▼) is recommended as an option for use within NHS Wales for the treatment of HIV-1 infection in treatment-experienced adults in accordance with British HIV Association (BHIVA) guidance.

Raltegravir (Isentress®▼) is not suitable for shared care within NHS Wales.

Additional note:

- Raltegravir (Isentress®▼) should be used in combination with at least one other active agent to enhance benefit and to reduce the risk of virologic failure and development of resistance to raltegravir (Isentress®▼).

9. Appraisal 4 – icatibant (Firazyr®▼)

Icatibant acetate (Firazyr®▼) is indicated for symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (with C1-esterase-inhibitor deficiency)[1].

Start time 12.46 pm

Members were asked to confirm any declarations of interest – there were none.

The Chairman welcomed Ms Susanne Gellert and Professor Paul Morgan who were representing the views of the applicant company, Jerini AG.

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 and 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 Dr Duerden to provide an overview of the discussions held at the NMG.

Dr Duerden set the context of the appraisal and highlighted relevant issues contained within the PAR, enclosure **5**/AWMSG/1008. He conveyed the views of the medical expert. It was noted that no patient organisation submission had been received. Dr Duerden informed members that NMG had difficultly in understanding how well the technology would work in practice within the currently accepted treatment options in the UK, and that not enough information had been provided to allow NMG to make a cost effectiveness judgement. He concluded his presentation by confirming NMG's advice to AWMSG was not to support the use of icatibant (Firazyr®▼)

The Chairman invited discussion on the clinical effectiveness of the treatment. Issues in relation to prevalence and place in therapy were raised, and the Chairman asked representatives from the applicant company to respond to the issues raised in the discussion.

The Chairman asked members to consider issues in relation to the cost effectiveness and invited Professor Phillips to address the Group. Professor Phillips reiterated the uncertainties in the cost effectiveness and congratulated the company for submitting a health economic model.

The Chairman confirmed that a patient organisation submission had not been submitted. There was discussion in relation to administration, and the Chairman reiterated that AWMSG appraise medicines within their licensed indication. There were no further broader societal or budget impact issues raised by members.

The Chairman asked representatives of the applicant company to comment on the general and specific issues, particularly the prevalence of this disease in Wales and its place in therapy.

Prior to closing proceedings, the Chairman sought confirmation the applicant company were satisfied that all issues had been adequately discussed and taken into account and the process had been fair and thorough. Confirmation was received.

The Chairman closed proceedings at 1.15 pm.

Appraisal decision

The recommendation of AWMSG to the Minister for Health and Social Services was announced:

The recommendation of AWMSG is:

Icatibant acetate (Firazyr®▼) is not recommended for use within NHS Wales for symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (with

C1-esterase-inhibitor deficiency).

Key factors influencing the recommendation:

- The case for cost effectiveness has not been proven.

Additional note:

- There are several uncertainties and limitations within the economic model provided in the company submission.

10. Appraisal 5 – abacavir/lamivudine (Kivexa®)

Kivexa® is a fixed-dose combination of two nucleoside analogues (abacavir and lamivudine). It is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV-1) infection in adults and adolescents from 12 years of age[1].
Start time 2.13 pm

The Chairman confirmed the personal non-specific interest declared by Councillor Meurig Hughes and confirmed that Councillor Hughes would not participate in the appraisal.

The Chairman welcomed Dr Jaydeep Sinha and Mr Anthony Batty from the applicant company, GlaxoSmithKline.

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 and 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 Dr Duerden to provide an overview of the discussions held at the NMG. Dr Duerden set the context of the appraisal and highlighted relevant issues contained within the PAR, enclosure **6**/AWMSG/1008. He conveyed the views of the medical experts and patient organisation, the Terence Higgins Trust. He concluded his presentation by confirming NMG's advice to AWMSG was to recommend the use of fixed dose abacavir/lamivudine (Kivexa®) as an option for use within NHS Wales in antiretroviral combination therapy for the treatment of human immunodeficiency virus (HIV) infection in adults and adolescents from 12 years of age in accordance with BHIVA guidance.

The Chairman opened the discussion on issues relating to the clinical effectiveness of treatment and clarified that the applicant company would be afforded opportunity to respond to the discussion and provide clarification on any issues raised.

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 highlighted salient issues pertaining to cost effectiveness.

The Chairman invited members to identify issues relating to broader societal or budget impact issues. The Chairman asked the applicant company to comment on the general and specific issues, particularly in relation to hypersensitivity reaction, genetic markers, lipid profile and age restrictions. WMP sought clarification with regard to the company

response to the PAR. The Chairman invited the company to raise any outstanding issues.

Prior to closing proceedings, the Chairman sought confirmation that representatives of the applicant company were satisfied that all issues had been adequately discussed and taken into account and the process had been fair and thorough. Confirmation was received.

The Chairman closed proceedings at 2.47 pm.

Appraisal decision

The recommendation of AWMSG to the Minister for Health and Social Services was announced:

The recommendation of AWMSG is:

Fixed dose abacavir and lamivudine (Kivexa®) is recommended as an option for use within NHS Wales in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV-1) infection in adults and adolescents from 12 years of age.

Use should be in accordance with the British HIV Association (BHIVA) guidance.

Fixed dose abacavir and lamivudine (Kivexa®) is not suitable for shared care within NHS Wales.

Additional note:

- Kivexa® should only be used in patients who, upon screening for the HLA-B*5701 allele, are found not to be carriers. As a negative test does not rule out the possibility of a hypersensitivity reaction (HSR) the need for careful counselling and monitoring for abacavir HSR remains.

11. Appraisal 6 – teriparatide (Forsteo®)

Teriparatide (Forsteo®) is indicated for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture[1].

This consideration is limited to the submission for the use of teriparatide in males.

Start time 2.50 pm

Members were asked to declare any interests – there were none.

The Chairman welcomed Giovanni Zanotti, Health Outcomes Advisor and Jessamy Baird, Head of Health Technology Appraisals and Health Economist who were representing the applicant company, Eli Lilly & Co Ltd.

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 and 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 Dr Duerden to provide an overview of the discussions held at the NMG.

Dr Duerden set the context of the appraisal and highlighted relevant issues contained within the PAR, enclosure **7**/AWMSG/1008. He conveyed the views of the medical experts and patient organisation, the National Osteoporosis Society. He concluded his presentation by confirming NMG's advice to AWMSG was not to support the use of teriparatide (Forsteo®) for the treatment of osteoporosis in men at increased risk of fracture and explained the rationale behind this decision.

The Chairman invited comments, observations or issues relating to the clinical effectiveness of the treatment. Following discussion of the clinical effectiveness issues, the Chairman asked members to consider cost effectiveness issues and invited Professor Phillips to highlight any relevant issues. There were no outstanding broader societal or budget impact issues raised by members.

The Chairman asked the applicant company to comment on the general and specific issues raised in the discussion. The issue of equity and Healthcare at Home was noted.

The Chairman reiterated that AWMSG members should appraise the medicine within its licensed indication.

Prior to closing proceedings, the Chairman sought confirmation that the applicant company were satisfied that all issues had been adequately discussed and taken into account and the process had been fair and thorough. Confirmation was received.

The Chairman closed proceedings at 3.23 pm.

Appraisal decision

The recommendation of AWMSG to the Minister for Health and Social Services was announced:

The recommendation of AWMSG is:

Teriparatide (Forsteo®) is not recommended for use within NHS Wales for the treatment of osteoporosis in men at increased risk of fracture.

Key factors influencing the recommendation:

- The case for clinical and cost effectiveness has not been proven.

Additional Notes:

- There are several uncertainties and limitations in the economic model provided.
- AWMSG considered that there is very little evidence for teriparatide (Forsteo®) in relation to clinical fractures in men.
- The only trial with an active comparator was in a relatively small group of subjects who received twice the licensed dose of teriparatide (Forsteo®).

12. Update on NHSIF

The Chairman confirmed that there were no outstanding issues to report and the NHSIF would be meeting on Wednesday, 22nd October. He informed members that a full

update report would be made to AWMSG at the meeting in December.

13. Update on AWPAG

The Chair welcomed Dr Tessa Lewis, Chair of AWPAG, and asked her to update members on work of the AWPAG. Dr Lewis explained that AWPAG had met the previous day and the minutes of that meeting would be presented to AWMSG in December. Dr Lewis informed members that the interface pharmacists group had applied AWMSG's shared care criteria to tenofovir, which had recently been approved for use by AWMSG, as the FAR stated that tenofovir may be suitable for shared care within NHS Wales. The conclusion reached by the Interface Pharmacist Group was that tenofovir would not be suitable for shared care within NHS Wales. Members endorsed this and agreed that a note should be added to the Final Appraisal Report on the AWMSG website informing the Service of this decision.

Unlicensed oral liquid medicines

Mrs Samuels presented a paper, developed by AWPAG, requesting AWMSG to consider the need for consensus guidelines on the use of unlicensed oral liquid medicines across Wales.

AWMSG was asked to review the use of unlicensed oral liquid medicines (specials) prescribed in Wales and to consider measures that can be taken to ensure patients receive the most appropriate and cost effective preparations available. Although the paper presented did not cover unlicensed topical 'special' preparations, AWMSG was asked to consider this area in the future.

During the discussion it was suggested that WMP should contact and consider the views of Dr Julian Smith, All Wales Quality Control Pharmacist. A suggestion was also made to address the issue of unlicensed products with the Editorial Board of the British National Formulary.

The Chairman suggested that WAPSU should collate the intelligence and develop a paper to bring to a future meeting of AWMSG.

14. Verbal update on Welsh Analytical Prescribing Unit (WAPSU)

Mrs Samuels presented a verbal report on the development of the Welsh Analytical Prescribing Unit (WAPSU). She explained that the origins of the unit stemmed back to a recommendation of the Townsend allocation group, that a prescribing support group be set up and resourced within Wales. Following receipt of Ministerial approval, stakeholders had met and agreed details such as the hosting arrangements, and timescales. A task and finish advisory group had been established during the initial period of setting up the unit.

Mrs Samuels outlined the objectives of the unit - to provide the All Wales Medicines Strategy Group (AWMSG) with robust data and analysis of that data in order to help inform advice on prescribing and medicines management to NHS Wales. She explained that it would also aim to provide service users with robust information and tools appropriate to local needs for analysis of prescribing activity.

Mrs Samuels informed members that the objectives of WAPSU were deefined within the AWMSG's Medicines Strategy, to which the Minister had indicated her approval in August 2008.

Mrs Samuels confirmed the first meeting of the operational task and finish group had been held on the 21st May 2008, where milestones for delivery were confirmed as:-

Staffing structure – defined as

- Head of WAPSU
- WAPSU Pharmacist
- Data analyst
- Information scientist e.g. pharmacologist, pharmacy technician
- IT support and communication advice has also been identified as a requirement

Staff employment

- Job descriptions have been agreed.
- The Head post to be advertised shortly. Following successful appointment to this post; the supporting staff to be advertised.
- The post isanticipated to be filled in line with agreed timescales
- The data analyst post to be fulfilled by an SLA with HSW

Communication lines with stakeholders
The main stakeholders were identified as:

- Welsh Assembly Government
- AWMSG
- Health Solutions Wales
- Local Health Boards
- NHS Trusts
- National Public Health Service (Wales)
- Finance Directors
- Medical Directors

Members were informed that expertise, collaborative working and input from all stakeholders had been recognised as vital for the successful functioning of the unit. A monthly update report has been presented to the AWMSG Steering Group, to inform the Welsh Assembly Government representative of progress, along with verbal updates to AWMSG. It was noted that links with key stakeholders would be enhanced with the appointment of staff and prioritisation of the work programme.

In conclusion, Mrs Samuels confirmed the objective - to focus on prescribing and medicines management issues within primary and secondary care relevant to the All Wales Medicines Strategy and stated that WMP were confident that the Unit would be operational by April 2009.

Members were informed that AWMSG had been asked to prioritise the recommendations of the Strategy and a paper would be presented in December 2008, after having been considered by the AWMSG sub-groups.

There were no outstanding issues and the Chairman closed the meeting.

Date of next AWMSG meeting: Wednesday, 10th December 2008 at the Angel Hotel, Abergavenny commencing 10.30 am.