Enclosure No:	**1/AWMSG/1012**
Agenda Item No:	**5** – Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY 12th SEPTEMBER 2012 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY, NP7 5EN

VOTING MEMBERS PRESENT:

			Did not participate in
1.	Professor Philip Routledge	Chairman	
2.	Dr Balwinder Bajaj	Clinical Pharmacology	
3.	Dr Philip Banfield	Hospital Consultant	
4.	Dr Fraser Campbell	GP with prescribing lead role	
5.	Dr Geoffrey Carroll	Welsh Health Specialised Services Committee	
6.	Professor David Cohen	Health Economist	
7.	Mrs Debbie Davies	Other professions eligible to prescribe	
8.	Mr Stuart Davies	Finance Director	
9.	Mr Stefan Fec	Community Pharmacist	
10.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health	
11.	Mrs Susan Murphy	Managed Sector Primary Care Pharmacist	
12.	Mr Christopher Palmer	Lay member	
13.	Mr Christian Smith	Senior Nurse	**6**
14.	Mr Rob Thomas	ABPI Wales	
15.	Mr John Terry	Senior Hospital Pharmacist	

IN ATTENDANCE:

16. Professor Roger Walker, Chief Pharmaceutical Officer, Welsh Government
17. Mrs Karen Samuels, All Wales Therapeutics & Toxicology Centre
18. Professor Dyfrig Hughes, Bangor University – AWTTC Health Economist
19. Mrs Ruth Lang, All Wales Therapeutics & Toxicology Centre

ALL WALES THERAPEUTICS & TOXICOLOGY CENTRE (AWTTC) APPRAISAL LEADS:

20. Mrs Sabrina Rind, Senior Appraisal Pharmacist
21. Mr Anthony Williams, Senior Appraisal Pharmacist
22. Dr David Jarrom, Senior Appraisal Scientist
23. Dr Claire Davis, Senior Appraisal Scientist

List of Abbreviations:

ABPI	Association of the British Pharmaceutical Industry
ASAR	AWMSG Secretariat Assessment Report
AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
AWTTC	All Wales Therapeutics & Toxicology Centre
CHMP	Committee for Medicinal Products for Human Use
DH	Department of Health
EMA	European Medicines Agency
FAR	Final Appraisal Recommendation
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Boards
MMPB	Medicines Management Programme Board
M&TCs	Medicines & Therapeutics Committees
NICE	National Institute for Health and Clinical Excellence
NMG	New Medicines Group
PAR	Preliminary Appraisal Recommendation
SMC	Scottish Medicines Consortium
TDAPG	Therapeutic Development Appraisal Partnership Group
T&FG	Task and Finish Group
WG	Welsh Government
WAPSU	Welsh Analytical Prescribing Support Unit
WMP	Welsh Medicines Partnership

1. Welcome and introduction

The Chairman thanked Dr Fraser Campbell for stepping into the role of Chairman for the afternoon session of the previous AWMSG meeting, and welcomed Mrs Susan Murphy who had taken over the role of Managed Sector Primary Care Pharmacist. Members were informed that Mr Stuart Davies from Welsh Health Specialised Services Committee had replaced Mrs Rebecca Richards as Finance Director representative. The Chairman thanked Mrs Richards for her contribution to AWMSG and welcomed Mr Davies to his first AWMSG meeting. The Chairman also welcomed Professor Dyfrig Hughes from Bangor University who was attending the meeting in a non-voting capacity as AWTTC's Health Economist.

2. Apologies

Dr Bruce Ferguson
Dr Brendan Lloyd
Dr Emma Mason
Dr John Watkins
Mrs Ellen Lanham
Mr Roger Williams

3. Declarations of interest

The Chairman reminded members to declare any interests pertinent to the agenda. Mr Christian Smith declared a personal specific interest in Pfizer Limited in that he is a member of the Nurse Faculty Board. The Chairman confirmed that Mr Smith would not participate in, or vote on the appraisal of eplerenone (Inspra®▼).

4. Chairman's report

The Chairman announced that ratification of the following recommendations had been received from Welsh Government and that notice of this had been disseminated to the Service.

Belatacept (Nulojix®▼) is not recommended as an option for use within NHS Wales, in combination with corticosteroids and a mycophenolic acid, for prophylaxis of graft rejection in adults receiving a renal transplant. The case for cost effectiveness has not been proven.

Nevirapine (Viramune®) prolonged release tablets are recommended as an option for use within NHS Wales in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus type 1 (HIV-1) infected adults, adolescents, and children three years and above and able to swallow tablets.

Prolonged release tablets are not suitable for the 14-day lead-in phase for patients starting nevirapine. Other nevirapine formulations, such as immediate release tablets or oral suspension should be used.

Most of the experience with Viramune® is in combination with nucleoside reverse transcriptase inhibitors (NRTIs). The choice of a subsequent therapy after Viramune® should be based on clinical experience and resistance testing.

Rifaximin (Xifaxanta®▼) is recommended as an option for use within NHS Wales for the treatment of travellers' diarrhoea that is not associated with any of: fever, bloody diarrhoea, eight or more unformed stools in the previous 24 hours, occult blood or leucocytes in the stool or to shorten the duration of diarrhoea when this is associated with non-invasive strains of E.coli.

Rilpivirine (Edurant®▼) is recommended as an option for use within NHS Wales for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml, in combination with other antiretroviral medicinal products.

Emtricitabine/rilpivirine/tenofovir (Eviplera®▼) is recommended as an option for use within NHS for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml.

Darunavir (Prezista®▼) 800 mg once daily, co-administered with low dose ritonavir, is recommended as an option for use within NHS Wales for the treatment of HIV-1 infection in antiretroviral therapy-experienced adults with no darunavir resistance-associated mutations and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≥100 cells × 10^6/l.

Dihydroartemisinin/piperaquine phosphate (Eurartesim®▼) is recommended as an option for use within NHS Wales for the treatment of uncomplicated *Plasmodium falciparum* malaria in adults, children and infants 6 months and over and weighing 5 kg or more.

Saxagliptin (Onglyza®▼) is recommended as an option for use within NHS Wales for the treatment of adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with insulin (with or without metformin) when this regimen alone with diet and exercise does not provide adequate glycaemic control.

Everolimus (Afinitor®▼) is recommended as an option for use within NHS Wales for the treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumours of pancreatic origin in adults with progressive disease.

Dexmedetomidine (Dexdor®▼) is recommended as an option for use within NHS Wales for the sedation of adult intensive care unit (ICU) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale [RASS] 0 to -3).

It was announced that, in the absence of engagement by the holder of the marketing authorisation within the appropriate timescale, a number of statements of advice were in preparation. Members were informed that the draft minutes of the meeting would list the medicines and their full licensed indications. Members were informed that statements of advice

relating to the following medicines would be forwarded to Welsh Government unless a Form B or Form C submission is received within the next fourteen days.

Granisetron (Sancuso®) transdermal patch
In adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral anti-emetic administration is complicated by factors making swallowing difficult

Pixantrone (Pixuvri®)
Monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive Non-Hodgkin B-cell Lymphomas. The benefit of pixantrone treatment has not been established in patients when used as fifth line or greater chemotherapy in patients who are refractory to last therapy

Colecalciferol (Desunin®)
Prevention and treatment of vitamin D deficiency in adults and adolescents. In addition to specific osteoporosis treatment of patients who are at risk of vitamin D deficiency, supplemental calcium should be considered

Etoricoxib (Arcoxia®▼)
Short-term treatment of moderate pain associated with dental surgery

Insulin glargine (Lantus®)
Treatment of diabetes mellitus in children aged 2 to less than 6 years (licence extension)

The Chairman announced the appraisals scheduled for the next meeting to be held in Wrexham on Wednesday, 17th October.

Appraisal 1: Full Submission
Paliperidone palmitate (Xeplion®▼) prolonged release for the maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone, and in selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, without prior stabilisation with oral treatment where psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed
Applicant Company: Janssen-Cilag Ltd

Appraisal 2: Full Submission
Colecalciferol (Fultium-D3®) for the prevention and treatment of vitamin D deficiency and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency. Fultium-D3 is indicated in adults, the elderly and adolescents
Applicant Company: Internis Pharmaceuticals Ltd

Appraisal 3: Full Submission
Eslicarbazepine acetate (Zebinix®) as adjunctive therapy in adults with partial-onset seizures, with or without secondary generalisation
Applicant Company: Eisai Ltd

Appraisal 4: Full Submission
Lapatinib (Tyverb®▼) for the treatment of patients with breast cancer, whose tumours overexpress HER2 (ErbB2), in combination with capecitabine for patients with advanced or metastatic disease with progression following prior therapy, which must have included anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting
Applicant Company: GlaxoSmithKline

Appraisal 5: Limited Submission
Bupivacaine hydrochloride/fentanyl (Bufyl®) for maintaining analgesia post-operatively and for maintaining epidural analgesia during labour

Applicant Company: Mercury Pharmaceuticals Limited

Appraisal 6: Limited Submission
Ramipril oral solution for the treatment of hypertension, reduction of cardiovascular morbidity and mortality, treatment of renal disease, treatment of symptomatic heart failure and secondary prevention after acute myocardial infarction
Applicant Company: Rosemont Pharmaceuticals Ltd

The Chairman reminded members to declare to AWTTC any interests in relation to the appraisals scheduled. The Chairman invited patients, patient organisations and patient carers to submit their views and contact AWTTC for further information in relation to the future work programme.

5. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy. The Chairman signed the minutes as a true record of the meeting.

6. Appraisal 1: Full Submission

Eplerenone (Inspra®▼) to reduce the risk of cardiovascular mortality and morbidity in adult patients with NYHA class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤ 30%) in addition to standard optimal therapy

Mrs Sabrina Rind, AWTTC assessment lead, joined members. Mr Christian Smith left the meeting. The Chairman welcomed delegates from the applicant company, Pfizer Limited.

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. There were none.

The Chairman announced the statement, pertinent to all appraisals, that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by Welsh Government officials, places an obligation on Health Boards to fund accordingly. It was confirmed that AWMSG advice is interim to final NICE guidance should this be subsequently published.

The Chairman invited Mrs Rind to set the context of the appraisal. Mrs Rind provided an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. Members were informed that a patient organisation submission had been sought but none had been received.

Dr Bracchi gave a brief overview of the relevant issues identified in the preliminary appraisal and relayed the view of NMG that the cost utility data presented in the submission were insufficient for NMG to recommend its use. Members were informed that NMG had considered the case for clinical effectiveness had been proven, but had not been persuaded that the model extrapolation had resulted in reliable estimates of cost effectiveness. NMG had concluded that eplerenone (Inspra®▼) should not be recommended for use within NHS Wales in addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with New York Heart Association (NYHA) class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤ 30).

The Chairman invited Professor David Cohen to clarify the issues in relation to the model extrapolation. Professor Cohen directed this to Professor Hughes and asked him to respond in the first instance.

Professor Hughes informed members that the company had submitted a discrete event simulation model of the cost utility of eplerenone compared with standard care. Based on the

EMPHASIS HF trial, the model generated an ICER estimate of £3,534 per QALY gained.

Professor Hughes highlighted the key issue raised in the ASAR was the extrapolation of benefits beyond the time horizon of EMPHASIS HF. Survival curves indicated continuing divergence from the control group over a lifetime horizon of analysis. Members were informed that in response to this scenario, the applicant company had provided additional scenario analyses. It was confirmed there was no evidence of costs continuing for a lifetime, with variable rates of convergence of survival curves. Professor Hughes noted that a figure in one of the tables provided by the company had been incorrectly labelled. He informed members that the total number of life-years and standard care respectively, could not be replicated from the model submitted. Professor Hughes acknowledged that evidence submitted had supported the model's accuracy in relation to death from cardiovascular causes; however, there appeared to be no such evidence submitted for overall mortality. It was confirmed that the evidence submitted in relation to life years gained could not be verified, and was different from the overall survival data from EMPHASIS-HF.

Professor Hughes concluded by confirming that AWTTC calculations had resulted in ICERs that did not exceed £15,500 per QALY gained

Professor Cohen clarified his role as AWMSG health economist and confirmed he had not been included in discussions held at NMG. He concurred with the overview provided by Professor Hughes. The Chairman confirmed that representatives from Pfizer would have opportunity to comment on the issues raised by Professor Hughes.

The Chairman invited comment in relation to the case for clinical effectiveness. Clarification was sought in relation to follow up of the clinical trial and measurement of outcomes. There were no other issues of note.

The Chairman drew members' attention to the comprehensive company response to the preliminary recommendation. Mrs Samuels confirmed that the appraisal process did not usually allow for additional information to be submitted by an applicant company at such a late stage in the process. However, in order for AWMSG members to fully understand the outstanding issues, it had been considered appropriate and the information had been included in the meeting papers.

The Chairman invited the company delegates to respond to the issues highlighted by AWMSG in their discussion and opportunity was provided to highlight any additional salient issues. The case for clinical effectiveness was highlighted. Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Pfizer Limited for engaging in the appraisal process and members retired to vote in private.

Appraisal decision subsequently announced
The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

Eplerenone (Inspra®▼) 25 mg and 50 mg film-coated tablets are not recommended for use within NHS Wales in addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with New York Heart Association (NYHA) class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤ 30). The data presented were insufficient for AWMSG to recommend its use. The case for clinical effectiveness was proven.

7. Appraisal 2: Limited Submission
Trastuzumab (Herceptin®▼) for the treatment of HER2 positive early breast cancer in combination with neoadjuvant chemotherapy followed by adjuvant trastuzumab therapy for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter

The Chairman welcomed the delegates from the applicant company, Roche Products Limited.

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

The Chairman referred to his previous statement that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by Welsh Government officials, places an obligation on Health Boards to fund accordingly. It was confirmed that AWMSG advice is interim to final NICE guidance should this be subsequently published. The Chairman reiterated that this statement pertained to all the appraisals scheduled.

Mrs Rind set the context of the appraisal and highlighted relevant issues within the ASAR. It was noted the application had been considered eligible for a limited submission - a minor licence extension with a minimal anticipated budget impact to NHS Wales and estimated small difference in cost compared to the comparator.

Mrs Rind relayed the views of the clinical experts, a summary of which had been provided to members.

The Chairman referred members to the patient organisation submission received from Breast Cancer Care and Mr Palmer highlighted the salient issues.

There were no specific outstanding issues of note.

Prior to concluding the appraisal, the Chairman asked the company delegate to confirm that all the issues had been adequately addressed and they agreed that the process had been fair and transparent. The Chairman thanked Roche Products Limited for engaging in the appraisal process and closed the appraisal.

Appraisal decision subsequently announced
The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

Trastuzumab (Herceptin®▼) 150 mg powder for concentrate for solution for infusion is recommended as an option for use within NHS Wales for the treatment of HER2 positive early breast cancer in combination with neoadjuvant chemotherapy followed by adjuvant trastuzumab therapy for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter.

8. Appraisal 3: Limited Submission
Mercaptopurine (Xaluprine®) oral suspension for the treatment of acute lymphoblastic leukaemia in adults, adolescents and children

Dr Claire Davis, AWTTC assessment lead, joined members. The Chairman confirmed that the applicant company, Nova Laboratories Limited, had declined the invitation to attend the appraisal. The Chairman reminded members to declare any interests. There were none.

Dr Davis set the context of the appraisal and highlighted relevant issues within the ASAR. It was noted the application had been considered eligible for a limited submission – a minimal anticipated budget impact to NHS Wales and estimated small difference in cost compared to

the comparators.

Dr Davis relayed the views of the clinical expert summary and confirmed that no patient organisation submissions had been received.

Members noted the preliminary recommendation of NMG and the company response to this.

There were no outstanding issues relating to the appraisal of this medicine and Chairman closed the appraisal proceedings.

Appraisal decision subsequently announced
The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

Mercaptopurine (Xaluprine®) 20 mg/ml oral suspension is recommended as an option for use within NHS Wales for the treatment of acute lymphoblastic leukaemia (ALL) in adults, adolescents and children.

9. Appraisal 4: Limited Submission
Sitagliptin (Januvia®▼) 25 and 50 mg tablets for improvement of glycaemic control in type 2 diabetes mellitus patients with moderate renal impairment (CrCl ≥ 30 to < 50 mL/min), severe renal impairment (CrCl < 30 mL/min) or with end-stage renal disease (ESRD) requiring haemodialysis or peritoneal dialysis

The Chairman welcomed delegates from the applicant company, Merck Sharp & Dohme Limited. Dr David Jarrom, AWTTC assessment lead, joined members. The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. There were none.

Dr Jarrom set the context of the appraisal and highlighted relevant issues within the ASAR. It was noted the application had been considered eligible for a limited submission – a minimal anticipated budget impact to NHS Wales and estimated small difference in cost compared to the comparators.

Dr Jarrom relayed the views of the clinical expert summary and confirmed that no patient organisation submissions had been received.

Members noted the preliminary recommendation of NMG and the company response to this.

There were no outstanding issues relating to the appraisal of this medicine. Prior to concluding the appraisal, the Chairman asked the company delegate to confirm that all the issues had been adequately addressed and they agreed that the process had been fair and transparent. The Chairman thanked Merck Sharp & Dohme Limited for engaging in the appraisal process and closed the appraisal.

Appraisal decision subsequently announced
The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

Sitagliptin (Januvia®▼) 25 and 50 mg tablets are recommended as an option for use within NHS Wales for the improvement of glycaemic control in type 2 diabetes mellitus patients with moderate renal impairment (CrCl ≥ 30 to < 50 ml/min), severe renal impairment (CrCl < 30 ml/min) or with end-stage renal disease (ESRD) requiring haemodialysis or peritoneal dialysis.

10. Appraisal 5: Limited Submission
Vildagliptin (Galvus®▼) for the treatment of type 2 diabetes in patients with moderate or severe renal impairment

The Chairman welcomed delegates from the applicant company, Novartis Pharmaceuticals UK Limited. The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. There were none.

Dr Jarrom set the context of the appraisal and highlighted relevant issues within the ASAR. It was noted the application had been considered eligible for a limited submission – a minimal anticipated budget impact to NHS Wales and estimated small difference in cost compared to the comparators. The clinical expert views were relayed.

Dr Jarrom confirmed that a patient organisation submission had been received from Diabetes Cymru in relation to this medicine. The lay member highlighted the salient issues within this submission.

Members noted the preliminary recommendation of NMG and the company response to this.

There were no outstanding issues relating to the appraisal of this medicine. Prior to concluding the appraisal, the Chairman asked the company delegate to confirm that all the issues had been adequately addressed and they agreed that the process had been fair and transparent. The Chairman thanked Novartis Pharmaceuticals Limited for engaging in the appraisal process and closed the appraisal.

Appraisal decision subsequently announced
The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

Vildagliptin (Galvus®▼) 50 mg tablets are recommended as an option for use within NHS Wales for the treatment of type 2 diabetes in patients with moderate or severe renal impairment.

11. Appraisal 6: Limited Submission
Rufinamide (Inovelon®▼) oral suspension as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 4 years of age and older

Mr Anthony Williams, AWTTC assessment lead, joined members. The Chairman confirmed that the applicant company, Eisai Limited, had declined the invitation to attend the appraisal. The Chairman reminded members to declare any interests. There were none.

Mr Williams set the context of the appraisal and highlighted relevant issues within the ASAR. It was noted the application had been considered eligible for a limited submission - anticipated minimal budget impact to NHS Wales.

Mr Williams confirmed that no clinical expert views or patient organisation submissions had been received.

Members noted the preliminary recommendation of NMG and the company response to this.

There were no outstanding issues relating to the appraisal of this medicine and Chairman closed the appraisal proceedings.

Appraisal decision subsequently announced
The Chairman confirmed that having read the evidence and considered the various issues that

arose during the discussion, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

Rufinamide (Inovelon®▼) 40 mg/ml oral suspension is recommended as an option for use within NHS Wales as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 4 years of age and older where other adjunctive treatments have proved sub-optimal or have not been tolerated.

The Chairman confirmed that the final appraisal recommendations would be forwarded to the relevant companies on or before Wednesday, 19th September 2012. He confirmed that the applicant companies had until Wednesday, 26th September 2012 to accept the recommendation or lodge a request for an independent review, the grounds for which should be submitted in writing to the Chairman via the All Wales Therapeutics & Toxicology Centre. He explained the process would not be delayed if the companies failed to respond by the deadline. Subject to receiving a request for an independent review within the appropriate timelines, the recommendation would be passed to Welsh Government. The Chairman informed the company delegates they would be informed when ratification of AWMSG's recommendation had been received.

The Chairman thanked the applicant companies for engaging with the AWMSG process and confirmed that the appraisal proceedings were concluded.

12. AWPAG update

The Chairman invited Dr Tessa Lewis, Chair of the All Wales Prescribing Advisory Group to present an overview of the proceedings of the AWPAG meeting held in July. Dr Lewis drew members' attention to the draft minutes. Members were informed that the paper entitled – Guidance on prescribing for erectile dysfunction in Wales – endorsed by AWMSG at a previous meeting, had been presented to the Assistant Medical Directors earlier in September. It was confirmed a submission to the Minister for Health & Social Services is in process, and the previous guidance will be retracted.

13. All Wales prescribing guidelines: Initiating contraception in primary care

The Chairman invited Ms Nuala Brennan, Consultant in Pharmaceutical Public Health, Public Health Wales, to present All Wales prescribing guidelines for initiating contraception in primary care. Ms Brenan explained the purpose of developing All Wales contraceptives prescribing guidelines is to reduce variation in contraceptives prescribing across the health boards in NHS Wales, whilst encouraging the provision of safe and cost-effective methods of first contraception, in line with agreed prescribing guidelines. The need to develop relevant prescribing indicators or comparators to aid the promotion of agreed prescribing guidance was highlighted.

Members were informed that the enclosure pertained to Recommendation 19 of the All Wales Medicines Strategy Group (AWMSG) Medicines Strategy for Wales: *"AWMSG will work with clinical networks and specialist groups to ensure that national clinical pathways and guidance include consistent advice on cost-effective and evidence-based prescribing."*

The Chairman opened the discussion - members were complimentary of the paper and warmly welcomed the guidance. There was discussion relating to implementation, and a suggestion was made that it could be included in the next Chief Medical Officer or Chief Pharmaceutical Officer newsletter.

The Chairman closed the discussion by confirming AWMSG's unanimous support and endorsement of the guidance.

14. All Wales paediatric steroid replacement card

The Chairman invited Dr Tessa Lewis to present Enc 10/AWMSG/09/12, the All Wales paediatric steroid replacement card. Dr Lewis acknowledged the lead author, Dr Rebekah

Pryce, Paediatric Consultant at Singleton Hospital, Abertawe Bro Morgannwg, who had been unable to attend the AWMSG meeting to present the work. Dr Lewis informed members that patients that require long-term steroid replacement therapy for adrenal suppression are at risk of adrenal crises at times of illness. It was suggested that the steroid card be carried by at-risk patients to ensure they are treated appropriately with minimisation of adverse events in an emergency situation.

Members were informed that the enclosure pertained to recommendations 7 and 13 of the AWMSG Medicines Strategy for Wales:"*AWMSG will work with all health and social care organisations to provide robust methods of spreading existing good medicines management practice across Wales.*" *"All health care professionals in Wales should have easy access to up to date quality prescribing information*

The Chairman opened the discussion and members raised the issue of implementation. It was suggested that although dissemination and implementation would primarily be via paediatricians, general practitioners should also be notified of the guidance. Collaboration with the Welsh Ambulance Service was confirmed and importance of ambulance triage highlighted. There was general support around the table.

The Chairman closed the discussion by confirming the endorsement of AWMSG to the All Wales Paediatric Steroid Replacement card.

15. Wales Patient Access Scheme Update

The Chairman invited Mr Paul Deslandes, Senior AWTTC Pharmacist, to inform members of updates to the process for considering Wales Patient Access Schemes. Members were informed that following discussion at the July 2012 AWMSG meeting the process guidance for the submission of a Wales Patient Access Scheme (WPAS) had been amended. AWMSG was asked to consider and endorse the updated process guidance. It was noted that following a meeting of the TDA Partnership Group the previous day, minor changes to the wording remained outstanding. In order to progress this as a matter of urgency, it was agreed that, subject to final scrutiny of the updated guidance by AWMSG members outside of the meeting, the Chairman would take action.

16. WAPSU Work Programme Update

The work programme of the Welsh Analytical Prescribing Support Unit was presented to members for information. The outline objective of WAPSU was highlighted – to provide AWMSG and NHS Wales with robust data and analysis to help inform advice on prescribing and medicines management to NHS Wales. Additionally, to provide service users with information and tools for analysis of prescribing activity appropriate to local need. It was noted the work programme had been developed with Welsh Government to reflect current NHS Wales priorities. Mrs Samuels confirmed that following confirmation of the continued funding of the unit in April 2012, there was a need for transparency in relation to the work to be undertaken to inform the Medicines Strategy and NHS Wales, and collaborative working with all stakeholders was recognised as vital for the successful functioning of the unit.

Date of next meeting

The Chairman confirmed the date of the next meeting on Wednesday, 17th October 2012 in Wrexham and the meeting closed.