Enclosure No:	**1/AWMSG/0912**
Agenda Item No:	**5** – Minutes of previous meeting
Author:	Chairman, AWMSG
Contact:	Tel: 029 20716900 E-Mail: awttc@wales.nhs.uk

ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY 18th JULY 2012 COMMENCING 10.30 AM AT CARDIFF METROPOLITAN UNIVERSITY, LLANDAFF CAMPUS, WESTERN AVENUE, CARDIFF CF5 2YB

VOTING MEMBERS PRESENT:

			Did not participate in
1.	Professor Philip Routledge	Chairman	**12-14**
2.	Dr Fraser Campbell	GP with prescribing lead role (chaired items 12-14)	
3.	Dr Geoffrey Carroll	Welsh Health Specialised Services Committee	
4.	Prof David Cohen	Health Economist	
5.	Mr Stefan Fec	Community Pharmacist	
6.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health	
7.	Dr Brian Hawkins	Senior Primary Care Pharmacist	
8.	Dr Emma Mason	Clinical Pharmacologist	
9.	Dr Richard Moore	Hospital Consultant	
10.	Mr Christopher Palmer	Lay member	
11.	Mr Paul Robinson	ABPI Wales	**6,10,11**
12.	Mr Christian Smith	Senior Nurse	
13.	Professor Roger Walker	Welsh Government	
14.	Mr Roger Williams	Senior Hospital Pharmacist	

IN ATTENDANCE:

15. Professor Roger Walker, Chief Pharmaceutical Officer, Welsh Government
16. Mrs Karen Samuels, All Wales Therapeutics & Toxicology Centre
17. Mrs Ruth Lang, All Wales Therapeutics & Toxicology Centre

AWTTC APPRAISAL LEADS:

18. Mrs Sabrina Rind, Senior Appraisal Pharmacist
19. Mr Anthony Williams, Senior Appraisal Pharmacist
20. Dr David Jarrom, 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 welcomed members.

2. Apologies

Dr Phil Banfield
Mrs Debbie Davies
Dr Bruce Ferguson
Dr Brendan Lloyd
Mrs Rebecca Richards
Mr Robert Holcombe

3. Declarations of interest

The Chairman reminded members to declare any interests pertinent to the agenda. Mr Paul Robinson declared an interest in that he is employed by the manufacturer of products competing with three medicines being appraised. The Chairman confirmed he would not vote on, or participate in the proceedings of appraisal 1, appraisal 5 and appraisal 6.

4. Chairman's report

The Chairman thanked Dr Bruce Ferguson for Chairing the previous meeting. It was confirmed that Professor Routledge would chair the morning session and members agreed that Dr Fraser Campbell would chair the afternoon session.

The Chairman reported, in March 2012 AWMSG had considered guidance on prescribing for erectile dysfunction. At that time, it was considered by AWMSG that recommendation 1 conflicted with current regulations and endorsement of this recommendation might have legal implications. With regard to recommendation 2, it was suggested that a definition of the wording 'experienced clinician' would provide more clarity. AWMSG supported recommendation 3. The Chairman confirmed the legal implications had subsequently been clarified. In light of the amendments to the paper it had been presented to the AWMSG Steering Committee for consideration in June. The Chairman confirmed, on behalf of AWMSG, he had endorsed the guidance and confirmed it would be forwarded to Welsh Government to inform policy.

It was announced that, following the resignation of Dr Brian Hawkins, the All Wales Chief Pharmacists Group had nominated Mrs Susan Murphy to step into the role of Member and Mrs Alison Hughes as deputy Managed Sector Primary Care Pharmacist. The Chairman confirmed that the AWMSG Steering Committee had approved the nominations. He thanked Dr Hawkins for his invaluable contribution to AWMSG over the last seven years and confirmed that this would be his last AWMSG meeting.

Members were informed that, in line with the appraisal process, recommendations from the previous meeting had been forwarded to Welsh Government for ratification. The Chairman confirmed the relevant companies and the Service would be informed when ratification of AWMSG's recommendations had been received.

It was announced, 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 the following statements would be forwarded to Welsh Government unless a Form B or Form C submission is received within the next fourteen days.

Clonazepam oral solution for the treatment of all clinical forms of epileptic disease and seizures in adults, especially absence seizures (petit mal) including atypical absence; primary or secondarily generalised tonic-clonic (grand mal), tonic or clonic seizures; partial (focal) seizures with elementary or complex symptomatology; various forms of myoclonic seizures, myoclonus and associated abnormal movements.

Alendronic acid (Steovess®) once-weekly 70 mg effervescent tablets for the treatment of postmenopausal osteoporosis

Dapoxetine (Priligy®) for the treatment of premature ejaculation in men aged 18 to 64 years old

Rupatadine (Rupafin®) 1 mg/ml oral solution for the treatment of symptomatic treatment of allergic rhinitis (including persistent allergic rhinitis) in children aged 6 to 11 years

Artemether/lumefantrine (Riamet®) 20 mg/120 mg dispersible tablets for the treatment of acute uncomplicated Plasmodium falciparum malaria in infants and children weighing 5 kg to less than 35 kg. Consideration should be given to official guidance regarding the appropriate use of antimalarial agents

The Chairman confirmed the appraisals scheduled for the next meeting to be held in Abergavenny on Wednesday, 12th September 2012:

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
Applicant Company: Pfizer Limited

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
Applicant Company: Roche Products Limited

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

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
Applicant Company: Merck Sharp & Dohme Limited

Appraisal 5: Limited Submission
Vildagliptin (Galvus®▼) for the treatment of type 2 diabetes in patients with moderate or severe renal impairment
Applicant Company: Novartis Pharmaceuticals UK Limited

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
Applicant Company: Eisai Limited

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. It was noted under 'in attendance' that Mr Phil Webb should read Dr Phil Webb. With that amendment, the Chairman signed the minutes as a true record of the proceedings.

6. Appraisal 1: Full Submission

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

Dr David Jarrom, AWTTC assessment lead, joined members. Mr Paul Robinson left the meeting. The Chairman welcomed delegates from the applicant company, Janssen-Cilag 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 Dr Jarrom to set the context of the appraisal. Dr Jarrom 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 received

from the Terence Higgins Trust.

Dr Bracchi gave a brief overview of the relevant issues indentified in the preliminary appraisal and relayed the view of NMG that darunavir (Prezista®▼) should be 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. It was noted that NMG were of the opinion that darunavir (Prezista®▼) would be appropriate for specialist only prescribing within NHS Wales for the stated indication.

The Chairman opened the discussion and asked members to seek clarification of any outstanding issues relating to the case for clinical effectiveness. Members sought clarification of the criteria for including patients in the study and the relation to the approved license indication. Also, the company delegates were asked to clarify the PI mutations between different regimens as outlined in Table 1.

The Chairman invited comment in relation to the case for cost-effectiveness. Professor Cohen clarified his role as AWMSG health economist and confirmed he had not been included in discussions held at NMG. Professor Cohen elaborated on the health economic issues previously identified by Dr Jarrom. He alluded to the uncertainty in the model, but considered that overall the case for cost effectiveness had been made.

The patient representative highlighted the issues highlighted by the Terence Higgins Trust. It was noted that feedback from patients indicated that the therapy had been well tolerated.

There were no outstanding societal or budget impact issues of note.

The Chairman drew members' attention to the company response to the preliminary recommendation. He invited the company delegates to respond to the issues highlighted by AWMSG in their discussion. The Chairman confirmed the procedure - the applicant company would have the final opportunity to identify any outstanding issues prior to the close of proceedings.

Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Janssen-Cilag Limited for engaging in the appraisal process.

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:

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.

7. Appraisal 2: Full submission
Dexmedetomidine (Dexdor®▼) for sedation of adult ICU (intensive care unit) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale (RASS) 0 to -3)

Mrs Sabrina Rind, AWTTC assessment lead, joined members. Mr Paul Robinson returned to the meeting. The Chairman welcomed the delegate from the applicant company, Orion Pharma UK 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.

Mrs Rind set the context of the appraisal and highlighted relevant issues within the ASAR. She relayed the views of the clinical experts, a summary of which had been made available. It was noted that three patient organisations had been approached. A patient organisation submission had not been received. The common adverse reactions were highlighted.

Dr Bracchi provided a brief overview of the relevant issues indentified in the preliminary appraisal and relayed the view of NMG that dexmedetomidine (Dexdor®▼) should be recommended as an option for use within NHS Wales for the licensed indication being considered. It was noted that NMG were of the opinion that dexmedetomidine (Dexdor®▼) would be appropriate for specialist only prescribing within NHS Wales for the stated indication.

The Chairman invited members to raise issues in relation to the case for clinical effectiveness. There was discussion over the discontinuation rates and regional differences in current practice were noted. There was also discussion relating to use in the induction phase.

Professor Cohen elaborated on issues relating to the case for cost effectiveness identified earlier by Mrs Rind. He confirmed that, after considering the health economic evidence, in his opinion the case had been made by the applicant company.

There were no societal or budget impact issues of note. The Chairman drew members' attention to the clinical expert views. The Chairman alluded to the applicant company's response to the preliminary recommendation and extended an opportunity for the delegate to respond to the discussion and identify any outstanding issues.

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 Orion Pharma UK 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:

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).

8. Appraisal 3: Full submission
Everolimus (Afinitor®▼) for the treatment of unresectable or metastatic, well or moderately-differentiated neuroendocrine tumours of pancreatic origin in adults with progressive disease

Dr David Jarrom, AWTTC assessment lead, joined members. The Chairman welcomed delegates from the applicant company, Novartis Pharmaceuticals UK Limited. The Chairman reminded members to declare any interests. There were none.

Dr Jarrom set the context of the appraisal and highlighted relevant issues within the ASAR. Dr Davies relayed the views of the clinical expert summary and confirmed that two patient organisation submissions had been received from Pancreatic Cancer UK and NET Foundation.

Dr Bracchi provided a brief overview of the relevant issues indentified in the preliminary appraisal and relayed the view of NMG that everolimus (Afinitor®▼) should be 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. It was noted that NMG were of the opinion that everolimus (Afinitor®▼) would be appropriate for specialist only prescribing within NHS Wales for the stated indication.

The Chairman invited members to raise any issues in relation to the case for clinical effectiveness. Clarification was sought in relation to the cardiac complications. The company was asked to elaborate on the survey, particularly the selection and number of patients involved in the survey.

Professor Cohen presented a brief overview of the health economic case and the Chairman opened the discussion. Issues highlighted included the small number of patients in Wales and its place of treatment for this rare disease. Also, it was noted that it was difficult to provide accurate cost implications due to the small numbers of patients involved. There were no outstanding societal or budget impact issues of note.

The company delegates responded to the discussion and were extended the opportunity to comment on the appraisal. Prior to concluding the appraisal, the Chairman asked the company delegates to confirm that all the outstanding issues had been addressed and they agreed that the process had been fair and transparent. The Chairman thanked Novartis Pharmaceutical UK 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:

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.

9. Appraisal 4: Limited Submission
Dihydroartemisinin/piperaquine phosphate (Eurartesim®▼) for the treatment of uncomplicated Plasmodium falciparum malaria in adults, children and infants 6 months and over and weighing 5 kg or more

The Chairman welcomed delegates from the applicant company, Sigma Tau Pharma Limited (UK). 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 invited Dr Jarrom to address members. Dr Jarrom confirmed that the submission had met the criteria for a limited submission. He presented a brief overview of the ASAR and confirmed that no evidence of clinical effectiveness is required within the limited submission. He alluded to the views of the clinical experts.

Dr Bracchi relayed the view of NMG that dihydroartemisinin/piperaquine phosphate (Eurartesim®▼) should be 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. It was noted that NMG were of the opinion that dihydroartemisinin/piperaquine phosphate (Eurartesim®▼) may be appropriate for use within NHS Wales prescribed under specialist recommendation for the stated indication.

Before opening the discussion, the Chairman set the context of the appraisal and outlined the sequence of events. He highlighted that evidence of budgetary impact in comparison to the existing comparator product(s) should be demonstrated. He directed members to consider the evidence and highlight any societal issues, take account of NMG's preliminary recommendation and the company response. He confirmed that clinical expert and patient views would be included, where available. He explained, in the event that AWMSG wished to explore any issues within the submission, then the applicant company delegates would be invited to provide clarification. However, if AWMSG considered there were no outstanding issues, they would retire to vote in private and agree the final recommendation, which would be subsequently announced and forwarded to Welsh Government for ratification. The Chairman reiterated that monitoring of budget impact would be essential and AWMSG reserved the right to request a full submission should the budget impact exceed that estimated in the limited submission.

The Chairman invited members to raise any outstanding issues in relation to the limited submission. Clarification was sought in relation to the monitoring of safety. There were no societal or budget impact issues of note. It was highlighted that there is no requirement for patients to take this medicine with food.

Prior to concluding the appraisal, the Chairman asked the company delegates to confirm that all the outstanding issues had been addressed and they agreed that the process had been fair and transparent. The Chairman thanked Sigma Tau Pharma Limited (UK) 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:

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.

10. Appraisal 5: Limited Submission
Emtricitabine/rilpivirine/tenofovir (Eviplera®▼) 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

Mr Tony Williams, AWTTC assessment lead, joined members. Mr Paul Robinson left the meeting. The Chairman welcomed the delegates from the applicant company, Gilead Sciences Limited. The Chairman reminded members to declare any interests. There were no additional declarations. The Chairman referred to his previous statement regarding the impact on the licensed status of the technology and the associated implications. It was confirmed that this submission met the criteria for a limited submission.

The Chairman invited Mr Williams to set the context of the appraisal. Mr WIlliams provided a brief overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. It was noted that a patient organisation submission had been received from the Terence Higgins Trust.

Dr Bracchi relayed the view of NMG that emtricitabine/rilpivirine/tenofovir (Eviplera®▼) should be available in NHS Wales 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. It was noted that NMG were of the opinion that emtricitabine/rilpivirine/tenofovir (Eviplera®▼) would appropriate for specialist only prescribing within NHS Wales for the indication under consideration.

The Chairman opened the discussion. There were no outstanding issues of note. The patient representative highlighted the feedback received from patients. The advantage for patients in taking one pill a day was acknowledged.

Prior to concluding the appraisal, the Chairman asked the company delegate to confirm that all the outstanding issues had been addressed and they agreed that the process had been fair and transparent. The Chairman thanked Gilead Sciences 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:

Emtricitabine/rilpivirine/tenofovir (Eviplera®▼) 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.

11. Appraisal 6: Limited Submission
Saxagliptin (Onglyza®▼) 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

The Chairman welcomed delegates from the applicant company, Bristol-Myers Squibb Pharmaceuticals Limited and AstraZeneca UK Limited.

The Chairman reminded members to declare any interests. He declared a non-personal non-specific interest in that a post within the Pharmacology Department in Cardiff University is part-funded by Astra Zeneca through the ABPI clinical pharmacology training scheme. Members agreed he could continue to chair the proceedings but would not participate in the vote.

The Chairman referred to his previous statement regarding the impact on the licensed status of the technology and the associated implications. It was confirmed that this submission met the criteria for a limited submission.

The Chairman invited Mr Williams to set the context of the appraisal. Mr WIlliams provided a brief overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. It was confirmed that no patient views had been received.

The Chairman invited Dr Bracchi to relay the view of NMG. It was confirmed that NMG considered saxagliptin (Onglyza®▼) should be available as an option for use within NHS Wales for the above indication. NMG were of the opinion that saxagliptin (Onglyza®▼) may be appropriate for prescribing by all prescribers within NHS Wales for the stated indication.

The Chairman opened the discussion and clarification was sought in relation to the diet and exercise plan, particularly the clinical improvement shown in patients receiving placebo. There were no other outstanding issues of note.

Prior to concluding the appraisal, the Chairman asked the company delegate to confirm that all the outstanding issues had been addressed and they agreed that the process had been fair and transparent. The Chairman thanked Bristol-Myers Squibb Pharmaceuticals Ltd and AstraZeneca UK Ltd 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:

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.

The Chairman confirmed that the final appraisal recommendations would be forwarded to the relevant companies on or before Wednesday, 25th July 2012. He confirmed that the applicant companies had until Wednesday, 1st August 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. Review of AWMSG recommendations
The Chairman invited Mrs Samuels to present Enc **8**/AWMSG/0712, the process for reviewing AWMSG final appraisal recommendations. Mrs Samuels explained that a recommendation had been made when applying for NHS Evidence Accreditation that AWMSG consider a process for reviewing recommendations. In conjunction with the TDA Partnership Group, AWTTC had developed a process for reviewing positive and restricted recommendations three years following ratification of the recommendation by Welsh Government. Mrs Samuels confirmed the review process was in development and comments on the document could be submitted to AWTTC outside of the meeting. It was noted that the process would be implemented in 2014. Professor Walker reiterated that Welsh Government reserves the right to request AWMSG guidance at any time. The Chairman concluded the discussion by confirming acceptance of the process, acknowledging that the process may be updated in light of comments received outside of the meeting.

13. AWMSG Constitution - update
The Chairman invited Mrs Samuels to highlight the updates to the AWMSG Constitution. Mrs Samuels confirmed that the updates reflected organisational changes and included representation from health board Chief Executives. The All Wales Chief Pharmacists had suggested that pharmacist membership be updated to Managed Sector - Primary Care Pharmacist and Managed Sector Hospital Pharmacist. Members supported the amendments and it was confirmed that the updated Constitution would be forwarded to Welsh Government for the approval of the Minister for Health and Social Services. It was noted that nominations would be sought by AWTTC in relation to vacant positions.

13. Proposal – future of the Wales Patient Access Scheme
The Chairman welcomed Mrs Kath Haines and Mr Paul Deslandes and invited them to present Enc **10**/AWMSG/0712 – feedback from the Patient Access scheme Wales pilot and proposal to continue accepting such schemes. Members were informed of issues that had come to light following the processing of four patient access schemes since the introduction of the pilot in November 2011. It was noted there were no substantive changes to the updated process, which had been simplified in light of experience. The Welsh Government representative suggested that slight amendment to some of the wording would be required outside of the meeting. It was noted that Welsh Government favour simple discount schemes.

AWMSG endorsed in principle the updated process and agreed to continue to accept patient schemes within NHS Wales.

14. Date of next meeting

The Chairman confirmed the date of the next meeting on Wednesday, 12th September 2012 in Abergavenny and the meeting closed.