Enclosure No:	**1/AWMSG/0313**
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 6th FEBRUARY 2013 COMMENCING 9.30 AM AT CARDIFF METROPOLITAN UNIVERSITY, LLANDAFF CAMPUS, WESTERN AVENUE, CARDIFF CF5 2YB

VOTING MEMBERS PRESENT:			**Did not participate in**
1.	Professor Philip Routledge	Chairman	10-11,13-15
2.	Dr Fraser Campbell	GP with Prescribing Lead role Acting Vice Chairman	Chaired items 10-11,13-15
3.	Professor David Cohen	Health Economist	
4.	Mrs Debbie Davies	Healthcare Professional eligible to prescribe	
5.	Mr Stuart Davies	Finance Director	
6.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health	
7.	Ms Alison Hughes	Managed Sector Primary Care Pharmacist	
8.	Mr Stefan Fec	Community Pharmacist	
9.	Dr Stuart Linton	Hospital Consultant	
10.	Dr Emma Mason	Clinical Pharmacologist	10-11,13-15
11.	Mr Christopher Palmer	Lay Member	
12.	Mr Christian Smith	Senior Nurse	
13.	Mr John Terry	Managed Sector Hospital Pharmacist	
14.	Mr Steve Turley	ABPI Wales	
15.	Dr Philip Webb	Welsh Health Specialised Services Committee	10-11,13-15

IN ATTENDANCE:

16. Professor Roger Walker, Chief Pharmaceutical Officer, Welsh Government
17. Dr Robert Bracchi, NMG Chairman

18. Mrs Karen Samuels, Head of HTA & Medicines Management, AWTTC
19. Mrs Ruth Lang, Head of Liaison & Administration, AWTTC

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

20. Mr Anthony Williams, Senior Appraisal Pharmacist
21. Dr David Jarrom, Senior Appraisal Scientist
21. Dr Stephanie Francis, 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
BMA	British Medical Association
CHMP	Committee for Medicinal Products for Human Use
DH	Department of Health
EMA	European Medicines Agency
FAR	Final Appraisal Recommendation
FDA	US Food and Drug Administration
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Boards
HTA	Health Technology Appraisal
IR	Independent Review
MHRA	Medicines and Healthcare products Regulatory Agency
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
WPAS	Welsh Patient Access Scheme
WMP	Welsh Medicines Partnership

1. Welcome and introduction

The Chairman opened the meeting and welcomed members and those seated in the public gallery.

2. Apologies

Dr Brendon Lloyd, Medical Director (deputy)
Mr Roger Williams (Mr John Terry deputising)
Ms Ellen Lanham (Mr Stefan Fec deputising)
Mrs Susan Murphy (Ms Alison Hughes deputising)
Professor John Watkins (Public Health Wales)
Dr Stephen Monaghan (Public Health Wales)

It was confirmed that Professor Walker would be arriving later.

3. Declarations of interest

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

4. Chairman's report

The Chairman reported that representatives from the Scottish Medicines Consortium had visited AWTTC in January to share experiences and foster links.

Members were informed that a meeting of the All Wales Prescribing Advisory Group had been held on 17th January 2013. He confirmed the minutes of the meeting were in preparation and would be available to AWMSG at the next meeting.

The Chairman confirmed that on Monday 28th January 2013 the NICE Accreditation Programme pages had moved from NHS Evidence to the NICE website. He explained the move underlines the role of the NICE Accreditation Programme as a core NICE service with links to the quality standards programme. To reflect this change, the Chairman confirmed that the NHS Evidence boilerplate would be replaced by the 'NICE Accreditation Statement,' which AWMSG will be entitled to use on final appraisal recommendations issued after 28th January 2013. It was confirmed the accreditation term for the process used by AWMSG to produce final appraisal recommendations will expire in October 2016, not October 2014 as previously communicated. Members were informed that representatives from AWTTC will be meeting with NICE to explore issues such as the use of the Accreditation Mark and its recognition among key audiences, the impact of accreditation on uptake and implementation of AWMSG guidance and any process changes since or as a result of accreditation.

It was reported, at the AWMSG Steering Committee meeting held on 22nd January, there was discussion over the growing market in biosimilar medicines, and potential financial savings that could be made with their appropriate use within NHS Wales. The Chairman took the opportunity to encourage manufacturers of biosimilar medicines to engage in the appraisal process in Wales. The Steering Committee agreed AWTTC's proposal that advice to health boards in relation to the appropriate place for the prescribing a new medicine should be within the AWMSG Secretariat Assessment Report (ASAR), rather than on the final appraisal report (FAR).

The Chairman confirmed Welsh Government ratification of the following AWMSG advice:

Argatroban (Exembol®) is recommended as an option for use within NHS Wales for anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy. The diagnosis should be confirmed by the HIPAA (heparin induced platelet activation assay) or an equivalent test. However, such confirmation must not delay the start of treatment.

Eplerenone (Inspra®▼) is recommended as an option 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%).

Sildenafil (Revatio®▼) 10mg/ml powder for oral suspension is recommended as an option for use within NHS Wales for the treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease.

Bortezomib (Velcade®▼) 3.5 mg subcutaneous injection is recommended as an option for use within NHS Wales:

- for the treatment of adult patients with progressive multiple myeloma who have received at

least 1 prior therapy and who have already undergone or are unsuitable for bone marrow transplantation;

- in combination with melphalan and prednisone for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant.

In the absence of a submission from the holder of the marketing authorisation, the Chairman confirmed the following medicines could not be endorsed for use within NHS Wales:

Zolpidem tartrate (Edluar®) for the short term treatment of insomnia.

Etanercept (Enbrel®) for the treatment of polyarthritis and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate; treatment of psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate; and treatment of enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy.

Imiquimod (Zyclara®) 3.75% cream for the topical treatment of clinically typical, visible or palpable actinic keratoses of the full face or balding scalp in adults when other topical treatment options are contraindicated or less appropriate.

Adalimumab (Humira®) for the treatment of moderately active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.

Teduglutide (Revestive®) for the treatment of adult patients with short-bowel syndrome.

Catridecacog (Novothirteen®) for the long term prophylactic treatment of bleeding in patients 6 years and above with congenital factor XIII A-subunit deficiency.

Lidocaine/tetracaine (Pliaglis®) for local dermal anaesthesia on intact skin prior to dermatological procedures in adults.

Lubiprostone (Amitiza®) for the treatment of chronic idiopathic constipation and associated symptoms in adults.

The Chairman highlighted the medicines for which the holder of the licence had not provided a submission within the appropriate timescale. It was confirmed that unless a Form B or Form C submission is received within the next fourteen days Welsh Government consent would be sought to issue advice that the following medicines could not be endorsed for use:

Budesonide (Budenofalk®) for the induction of remission in patients with active collagenous colitis

Mesalazine (Salofalk®) for the treatment of acute episodes and the maintenance of remission of ulcerative colitis

Ursodeoxycholic acid (Ursofalk®) for the treatment of primary biliary cirrhosis

Vildagliptin/metformin hydrochloride (Eucreas®) for the treatment of type 2 diabetes mellitus in combination with a sulphonylurea as an adjunct to diet and exercise in patients inadequately controlled with metformin and a sulphonylurea; and treatment of type 2 diabetes mellitus as

triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control

Decitabine (Dacogen®) for the treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia who are not candidates for standard induction chemotherapy

Botulinum toxin type A (Botox®) for the management of urinary incontinence in adults with neurogenic detrusor overactivity resulting from neurogenic bladder due to spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are not adequately managed with anticholinergic therapy and who are already catheterising or who are willing to catheterise if required

Crizotinib (Xalkori®) for the treatment of adults with previously treated anaplastic lymphoma kinase positive advanced non-small cell lung cancer

Tadalafil (Cialis®) 5 mg for the treatment of the signs and symptoms of benign prostatic hyperplasia in adult males

Brentuximab vedotin (Adcetris®) for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma following autologous stem cell transplant or following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option; and for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma

Alipogene tiparvovec (Glybera®) for the treatment of adult patients diagnosed with familial lipoprotein lipase deficiency and suffering from severe or multiple pancreatitis attacks despite dietary fat restrictions

Vildagliptin (Galvus®) for the treatment of type 2 diabetes mellitus in adults as triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these agents do not provide adequate glycaemic control; and in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control

The Chairman urged the holders of the licence to engage in the AWMSG appraisal process as early as possible, so that patients in Wales can have timely access to new clinically-effective and cost-effective medicines.

The Chairman announced the appraisals scheduled for the next AWMSG meeting to be held on Wednesday, 20th March 2013 in Abergavenny.

Appraisal 1: Full Submission
Linagliptin (Trajenta®▼) for the treatment of type 2 diabetes mellitus to improve glycaemic control in adults:
<u>as monotherapy</u>

- **in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment;**

<u>as combination therapy</u>

- **in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control;**
- **in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control; and**
- **in combination with insulin with or without metformin, when this regimen alone,**

with diet and exercise, does not provide adequate glycaemic control.

Applicant Company: Boehringer Ingelheim Ltd/Eli Lilly & Co Ltd

Appraisal 2: Full Submission
Pazopanib (Votrient®) for the treatment of adult patients with selective subtypes of advanced soft tissue sarcoma who have received prior chemotherapy for metastatic disease or who have progressed within 12 months after (neo) adjuvant therapy

Applicant Company: GlaxoSmithKline

Appraisal 3: Full Submission
Glycopyrronium bromide (Seebri Breezhaler®) as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease

Applicant Company: Novartis Pharmaceuticals UK Limited

Appraisal 4: Full Submission
Aztreonam lysine (Cayston®) for the suppressive therapy of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis aged 6 years and older

Applicant Company: Gilead Sciences Ltd

The Chairman reminded members to declare any interests pertinent to these appraisals scheduled.

The Chairman invited patients, patient organisations and patient carers to submit their views in relation to medicines scheduled for appraisal, and suggested they contact Ruth Lang at 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
Racecadotril (Hidrasec®▼) granules for oral suspension for the complementary symptomatic treatment of acute diarrhoea in infants (older than 3 months), and in children, together with oral rehydration, and the usual support measures, when these measures alone are insufficient to control the clinical condition

The Chairman welcomed representatives from the applicant company, Abbot Healthcare Products 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 David Jarrom, AWTTC assessment lead, 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 not been received.

The Chairman invited Dr Bracchi, NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Bracchi briefly summarised the issues discussed at NMG and relayed the view of NMG members that racecadotril (Hidrasec®▼) granules for oral suspension should not be recommended for use within NHS Wales for the complementary symptomatic treatment of acute diarrhoea in infants (older than 3 months) and children. Dr Bracchi informed members that NMG were not convinced that the case presented for clinical and cost effectiveness supported the use of this medicine in NHS Wales. Their view was that the applicant company had not presented robust clinical and economic analyses and there were several uncertainties and limitations in the economic model provided in the company's submission.

The Chairman invited comment in relation to the case for clinical effectiveness. Clarification was sought in relation to the place of treatment and it was confirmed that the majority of prescribing was anticipated to be in the primary care setting. There was discussion in relation to trial data and adherence. It was noted there was limited data in children aged over five years. The Chairman referred members to the clinical expert summary of opinion, which did not highlight any areas of unmet need for this condition. The opinion of clinicians in Wales was that the focus of acute diarrhoea treatment in children should be the treatment and prevention of dehydration. It was noted that oral rehydration therapy was considered the most effective and predominant treatment option.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. His role as the AWMSG health economist was clarified and it was confirmed he had not been included in the preliminary discussions held at NMG. Professor Cohen apologised that some of the issued raised in his report to the group had already been highlighted by the AWTTC lead assessor. He drew attention to the uncertainties and limitations within the submission and invited the company delegates to respond to all the issues highlighted in his report.

In response, the company delegates highlighted use of the medicine in vulnerable children at risk of dehydration due to diarrhoea, the reduction of risks associated with this illness and hospital admission.
There were no outstanding budget impact or societal issues. It was noted that AWTTC had approached three patient organisations; however, no patient organisation submission had been received.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates from Abbot Healthcare Products Limited to raise any issues they considered might not have been adequately addressed during the appraisal. Dr Jarrom clarified that the AWMSG appraisal process did not allow for the information offered by the applicant company in their response to the preliminary appraisal report to be accepted by AWTTC. Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Abbot Healthcare Products Limited for engaging in the appraisal process and proceeded to the next 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:

Racecadotril (Hidrasec®▼) granules for oral suspension are not recommended for use within NHS Wales for the complementary symptomatic treatment of acute diarrhoea in infants (older than 3 months) and children.

AWMSG was not convinced that the case presented for clinical and cost effectiveness supported the use of this medicine in NHS Wales.

7. Appraisal 2: Full Submission
Vildagliptin (Galvus®) for the treatment of type 2 diabetes as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance

The Chairman welcomed representatives of 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, and alluded to the statement pertinent to all appraisals.

Professor Roger Walker joined the meeting.

Dr Stephanie Francis, the AWTTC assessment lead, set the context of the appraisal and highlighted relevant issues within the ASAR. It was confirmed that a patient organisation submission had been received from Diabetes UK Cymru. Dr Francis referred to the summary of clinical expert opinion and relayed the views and salient issues highlighted by the clinicians.

Dr Bracchi gave an overview of the relevant issues identified in the preliminary appraisal and confirmed that NMG had considered vildagliptin (Galvus®) should be recommended as an option for use within NHS Wales for the treatment of type 2 diabetes mellitus as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. NMG were of the opinion that vildagliptin (Galvus®) may be appropriate for prescribing by all prescribers within NHS Wales for the above recommendation.

The Chairman opened the discussion and invited members to comment on case for clinical effectiveness. Clarification was sought in relation to the advantages this medicine offered compared to other available treatments. There was discussion over use in patients with hepatic impairment and renal testing in diabetes patients. The requirement for liver function monitoring was highlighted in the discussion. It was confirmed there are no available studies of adherence. The company delegates responded to the issues raised. The Chairman asked members to consider the summary of clinical expert opinion from within NHS Wales. Clinical opinion suggested that vildagliptin would be an alternative to other gliptins in this cohort of patients who were not suitable for metformin.

The Chairman invited Professor Cohen to comment on the case for cost effectiveness. Professor Cohen provided an overview of the evidence submitted by the applicant company and invited response by the industry delegates to the issues highlighted.

Mr Chris Palmer, the lay member, referred members to the patient questionnaire received from Diabetes UK Cymru, and summarised the advantages and disadvantages of the treatment options from the patient perspective. There were no outstanding societal or budget impact issues

The delegates from the applicant company, Novartis Pharmaceuticals UK Limited, responded to the discussion and, prior to closing the appraisal, the Chairman invited concluding remarks. The Chairman sought confirmation from the company delegates that the process had been fair and

transparent. He thanked Novartis Pharmaceuticals UK 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:

Vildagliptin (Galvus®) 50 mg tablets are recommended as an option for use within NHS Wales for the treatment of type 2 diabetes mellitus as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

8. Appraisal 3: Full Submission
C1 inhibitor (Cinryze®▼) for the treatment and pre-procedure prevention of angioedema attacks in adults and adolescents with hereditary angioedema (HAE) and for routine prevention of angioedema attacks in adults and adolescents with severe and recurrent attacks of hereditary angioedema (HAE), who are intolerant to or insufficiently protected by oral prevention treatments, or patients who are inadequately managed with repeated acute treatment

The Chairman welcomed the representatives of the applicant company ViroPharma 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 repeated the statement announced at the commencement of the appraisal session and confirmed it was pertinent to all appraisals.

The Chairman invited Mr Anthony Williams, AWTTC assessment lead, to set the context of the appraisal. Mr Williams provided an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. Mr Williams explained that in light of comments received from the applicant company, and with the agreement of AWMSG, section 5.1.2 of the ASAR would be updated subsequent to the meeting. Members were informed that a patient organisation submission had been received from Hereditary Angioedema UK.

Dr Bracchi provided a brief synopsis of discussion at NMG and relayed the preliminary recommendation that C1 inhibitor (Cinryze®▼) should be recommended as an option for use within NHS Wales for the treatment and pre-procedure prevention of angioedema attacks in adults and adolescents with hereditary angioedema, and routine prevention of angioedema attacks in adults and adolescents with severe and recurrent attacks of hereditary angioedema, who are intolerant to or insufficiently protected by oral prevention treatments, or patients who are inadequately managed with repeated acute treatment. He confirmed that NMG were of the opinion that C1 inhibitor (Cinryze®▼) therapy should be initiated under supervision of a physician experienced in the care of patients with hereditary angioedema. Dr Bracchi highlighted that NMG felt that C1 inhibitor (Cinryze®▼) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance.

The Chairman asked members if there were any outstanding issues in relation to the case for clinical effectiveness. Members considered the summary of clinical expert opinion that there are issues regarding awareness of this rare condition, which often leads to delay in diagnosis and treatment. They highlighted that patients can face a delay in treatment during acute episodes. Clinicians considered that patients would welcome the opportunity to be trained in self-administration at home which would minimise delays and offer additional benefits.

Professor Cohen provided an overview of the health economic evidence submitted by the applicant company and invited the company to respond to the issues highlighted.

The Chairman referred members to the patient organisation questionnaire and invited Mr Chris Palmer to summarise the issues main highlighted by Hereditary Angioedema UK. It was noted the submission provided members with a comprehensive insight into the disease from the patient's perspective. There was discussion in the medicine's storage, delivery, registry and training. There were no other societal or budget impact issue of note.

The Chairman referred to the applicant company response to the preliminary recommendation and asked the delegates if they wished to provide any additional comment. Having responded to the issues raised in the appraisal, the company delegates confirmed they were satisfied that all the issues had been adequately discussed and the process had been fair and transparent.

The Chairman closed the discussion.

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:

C1 inhibitor (Cinryze®▼) is recommended as an option for use within NHS Wales for the treatment and pre-procedure prevention of angioedema attacks in adults and adolescents with hereditary angioedema, and routine prevention of angioedema attacks in adults and adolescents with severe and recurrent attacks of hereditary angioedema, who are intolerant to or insufficiently protected by oral prevention treatments, or patients who are inadequately managed with repeated acute treatment.

9. Appraisal 4: Limited Submission
Insulin glargine (Lantus®) for the treatment of diabetes mellitus in children aged 2 to less than 6 years

The Chairman welcomed delegates from the applicant company Sanofi-Aventis 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 repeated the statement announced at the commencement of the appraisal session and confirmed it was pertinent to all appraisals. He explained the format of appraising a limited submission and highlighted that evidence relating to budgetary impact in comparison to the existing comparator product should be discussed. He reiterated that AWMSG reserved the right to request a full submission, should the budget impact exceed that estimated in the limited submission.

The Chairman invited Dr David Jarrom, AWTTC assessment lead, to set the context of the appraisal. Dr Jarrom provided an overview of the limited submission as detailed in the ASAR and relayed the views of the clinical experts. He explained that AWTTC considered the application met the criteria for a limited submission for a minor licence extension. He confirmed a patient organisation submission had not been received.

Dr Bracchi confirmed NMG's preliminary recommendation that insulin glargine (Lantus®) should be recommended as an option for use within NHS Wales for the treatment of diabetes mellitus in children aged 2 to less than 6 years, prescribed under specialist recommendation.

There were no outstanding issues of note and discussion was limited. The company delegate confirmed the intention to launch a pen unit formulation. It was noted that four patient organisations had been approached; however, none made a submission. Clinical experts highlighted an unmet need in terms of support (education, psychological support and dietetic support) for paediatric T1DM patients and their families.

Prior to concluding the appraisal, and having been afforded opportunity to comment, the company delegate confirmed his satisfaction that any issues had been adequately discussed and the process had been fair and transparent.

The Chairman closed the discussion and members retired to vote in camera.

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:

Insulin glargine (Lantus®) 100 units/ml solution for injection is recommended as an option for use within NHS Wales for the treatment of diabetes mellitus in children aged 2 to less than 6 years.

The Chairman confirmed that confirmation of AWMSG's recommendations would be forwarded to the applicant companies within five working days. He confirmed the deadline for lodging a request for an independent review (IR) was fourteen days from the announcement of the recommendation and clarified that in the absence of a request for an IR the recommendations would be passed to Welsh Government for ratification.

The appraisal session was concluded.

10. Monitoring of medicines appraised by AWMSG / NICE
The Chairman invited Mrs Kath Haines from AWTTC to provide an overview of Enclosure 6 – a report on the monitoring of medicines appraised by AWMSG and NICE. Mrs Haines explained the intention of the paper was to inform AWMSG of progress made in monitoring the usage of medicines appraised by AWMSG and the National Institute for Health and Clinical Excellence (NICE). WAPSU analysed the usage of medicines appraised by AWMSG and NICE from 1 April 2006 to 30 September 2012 and included medicines recommended and not recommended for use in NHS Wales. It was noted that during this period 89 statements of advice had been issued relating to medicines not be endorsed for use, as the holder of the marketing authorisation had declined to engage in the AWMSG appraisal process. There was discussion around the ability to delve further into the data behind the paper, and an offer to work with the pharmaceutical industry in order to triangulate the data was received. Suggestions for measures against projected uptake, formulary status in Health Boards within Wales, patent expiry and the use of a common patient denominator were noted for consideration in future reports.

11. National Prescribing Indicators 2012-2013
Analysis of prescribing data to September 2012
The Chairman invited Mrs Haines to present Enclosure 7. Mrs Haines outlined the purpose of the paper and asked members to note the position of Health Boards within NHS Wales with respect to the National Prescribing Indicators based on the latest available data, September 2012. Members noted that the National Prescribing Indicators, agreed by AWMSG and Welsh Government, are included as part of the Improving Efficiency and Productivity Programme for 2011-131. These are applied at unitary authority level and are reported quarterly. They key issues were highlighted - the indicators are evidence based, are intended to be clear, easily understood and applicable at practice level, and that targets aim to address efficiency as well as quality. It was noted that Welsh Government had confirmed that the measurement of the National Prescribing Indicators, as described in Improving Efficiency and Productivity within NHS Wales, can be aligned with the principles adopted for Quality and Productivity (QP) indicators as specified within the GMS contract2. It was confirmed that the threshold for each prescribing indicator is set at the 25th percentile (i.e. reducing or increasing prescribing rates in line with the best performing 25% of practices). For the 2012–2013 indicators, the prescribing

data for all general practices in Wales for the quarter ending 31 December 2011 had been utilised. It was noted that all practices within Health Boards were encouraged to achieve or move towards these thresholds.

12. Pharmacy teaching in Wales (taken as first item in agenda)

The Chairman invited Mr Robert McArtney, Secretary of the Patient Safety and Quality Subgroup of the All Wales Chief Pharmacists' Committee, to present enclosure 8. Members were informed that the paper had been co-authored with the Chairman of that group, Mr Roger Williams, to support and promote the role of clinical pharmacists in providing work-based teaching in safe and effective prescribing for medical undergraduates in Welsh Health Boards. Mr McArtney provided the background and alluded to recommendation ten of the AWMSG vision for prescribing and medicines management in Wales, 'Getting the Best Outcomes from Medicines for Wales', stating "providers of education and training in therapeutics will ensure the principles of clinically and cost effective, acceptably safe prescribing are included within the undergraduate curriculum of all potential future prescribers. Mr McArtney asked AWMSG to recommend that Health Boards consider providing an allocation of their annual Service Increment for Teaching (SIFT) funding for a pharmacy resource to provide this input. AWMSG members voiced support of the move to foster close working relationships between the two professional groups. The Chairman confirmed AWMSG's unanimous support of the recommendations.

13. All Wales guidance for prescribing gluten free products

The Chairman welcomed Ms Cathryn Roberts, Advanced Specialist Dietician in Gastroenterology, based at Morriston Hospital, Swansea and Mrs Julie Nedin, Manager of Swansea Nutrition & Dietetic Services in Abertawe Bro Morgannwg University Health Board. Mrs Nedin asked members to consider and endorse the updated All Wales guide to prescribing gluten-free products, including the Advisory Committee on Borderline Substances (ACBS)-approved gluten-free products (foods) list for prescribing. Members were informed that the guide to prescribing gluten-free products aims to support general practitioners and other healthcare professionals in the management of patients with coeliac disease.

The Chairman opened discussion. Members welcomed the guidance and agreed the importance of improving efficiency of supply. It was confirmed a pilot is underway within Cardiff & Vale UHB and Professor Roger Walker suggested that a report form Cardiff and Vale would be welcomed at AWMSG. Members agreed that ordering and collection of products should be timely. It was agreed that an assessment of the impact of the document should be undertaken in Summer 2014 and that the product list should be reviewed annually. The Chairman concluded discussion by confirming AWMSG's endorsement of the guidance.

14. All Wales review and guidance for prescribing intervals (28-day prescribing)

The Chairman invited Mr Stefan Fec, Community Pharmacist representative, to provide an overview of Enclosure 10. Mr Fec explained that the paper pertained to recommendation 42 of AWMSG's Medicines Strategy for Wales - AWMSG will initiate an investigation on the scale of medicines wastage within Wales and explore methods that reduce this waste in collaboration with the NHS service and other organisations.

Mr Fec explained that on reviewing the available evidence, there was no agreement to recommend one approach over another. Mr Fec confirmed the following recommendations represented a consensus view of AWPAG members:

A 28-day repeat prescribing interval is broadly recommended; however, discretion should be used for individual patients or medicines. This should be coupled with a rigorous and effective medication review process.

Repeat prescribing systems that promote synchronised, once per month requests for long-term medication should be developed.

People that are stabilised on their medicines and are suitable for longer prescribing intervals can be considered for repeat dispensing (28-day prescriptions for 6–12 months). However, due to low uptake and other issues highlighted in this paper, a robust evaluation of the Repeat Dispensing Scheme in Wales would ensure that resources are being spent appropriately and will guide a decision on the future of the service.

Prescribers should consider a flexible approach when initiating a medicine; a shorter interval (7–14 days) may be appropriate initially to assess tolerability and compliance, or may be recommended by the BNF or regulatory bodies.

The Chairman concluded discussions by endorsing the paper and confirming the strong support voiced by AWMSG members.

15. Date of next meeting

The Chairman confirmed the date of the next meeting on Wednesday, 20th March 2013 in Abergavenny and the meeting closed.