Enclosure No:	**1/AWMSG/0714**
Agenda Item No:	**4** – Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

MINUTES OF THE AWMSG MEETING HELD WEDNESDAY, 11th JUNE 2014 COMMENCING 9.30 AM AT CARDIFF METROPOLITAN UNIVERSITY, LLANDAFF CAMPUS, WESTERN AVENUE, CARDIFF CF5 2YB

VOTING MEMBERS PRESENT:

			Did not participate in
1.	Professor Phil Routledge	Chairman	
2.	Professor David Cohen	Health Economist	
3.	Dr Geoffrey Carroll	Welsh Health Specialised Services Committee	**1-5**
4.	Mrs Debbie Davies	Other professions eligible to prescribe	
5.	Mr Stuart Davies	Finance Director	**9-13**
6.	Mr Stefan Fec	Community Pharmacist	
7.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health	
8.	Dr Emma Mason	Clinical Pharmacologist	
9.	Mrs Susan Murphy	Managed Sector Primary Care Pharmacist	
10.	Mr Christopher Palmer	Lay Member	
11.	Mr Rob Thomas	ABPI Cymru Wales	
12.	Mr Roger Williams	Managed Sector Secondary Care Pharmacist	

IN ATTENDANCE:

13. Mrs Karen Samuels, Head of HTA, AWTTC
14. Mrs Ruth Lang, Head of Liaison & Administration, AWTTC
15. Dr Robert Bracchi, NMG Chairman

AWTTC APPRAISAL LEADS:

16. Mrs Susan Cervetto, Senior Appraisal Pharmacist
17. Mrs Gail Woodland, Senior Appraisal Pharmacist
18. Mrs Helen Adams, Senior Appraisal Pharmacist
19. Dr Caron Jones, Senior Appraisal Scientist
20. Dr Claire Davis, Senior Appraisal Scientist
21. Ms Kelly Wood, 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
CEPP	Clinical Effectiveness Prescribing Programme
CHMP	Committee for Medicinal Products for Human Use
DoH	Department of Health
ECDF	English Cancer Drugs Fund
EMA	European Medicines Agency
FAR	Final Appraisal Recommendation
FDA	US Food and Drug Administration
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Boards
HST	Highly Specialised Technology
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
NSAIDs	Non-steroidal anti-inflammatory drugs
PAR	Preliminary Appraisal Recommendation
PAS	Patient Access Scheme
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

1. Welcome and introduction

The Chairman opened the meeting and confirmed that the first four appraisals would be conducted in private because of their association with a patient access scheme.

2. Apologies

Professor Roger Walker, Chief Pharmaceutical Officer, Welsh Government
Mr Lance Richard, ABPI Cymru Wales
Dr Stuart Linton, Hospital Consultant
Mr Christian Smith, Senior Nurse
Dr Bill Whitehead, GP with Prescribing Lead role
Professor John Watkins, Public Health Wales

3. Declarations of interest

There were no declarations pertinent to the agenda.

4. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy and approved by the Chairman.

5. Appraisal 1 - Full Submission (WPAS)
Insulin degludec (Tresiba®▼) for the treatment of diabetes mellitus in adults

The Chairman welcomed representatives from the applicant company, Novo Nordisk Ltd. The Chairman confirmed that the appraisal would be conducted in private to protect commercial confidentiality due to the association of a WPAS.

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 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, 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 outlined the sequence of events and invited Dr Caron Jones, AWTTC assessment lead, to set the context of the appraisal.

Dr Jones presented an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. Members were informed that three patient organisations had submitted views – Diabetes UK Cymru, the Independent Diabetes Trust and the South Asia Health Foundation.

Dr Rob Bracchi provided a brief overview of the relevant issues identified in the preliminary appraisal and confirmed that NMG had not recommended Insulin degludec (Tresiba®▼) for use within NHS Wales for the treatment of diabetes mellitus in adults. Dr Bracchi stated that NMG members were not convinced that the case presented for clinical and cost-effectiveness supported the use of this medicine. NMG considered that the applicant company had not presented sufficiently relevant clinical and economic analyses to gain approval by NMG as the evidence did not relate directly to the proposed use within the target population within NHS Wales.

The Chairman invited comment in relation to the case for clinical effectiveness. Members questioned the exclusion of hypoglycaemic patients from the trial and sought clarification of the definitions of severe and non-severe. The timing of medication, dosage strength and availability of cardiovascular outcome data were also discussed. The Chairman referred members to the detailed clinical expert summary - Enclosure 2 Appendix 3.

Dr Geoffrey Carroll joined the meeting and the Chairman confirmed that Dr Carroll would not participate in the vote on this application.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen clarified his role as AWMSG Health Economist and explained that he had no involvement in the preparation of the ASAR, neither was he involved in discussions at NMG. He presented a summary of the case for cost-effectiveness and invited the company delegates to respond to his synopsis. The Chairman asked members to consider the budget impact.

The Chairman invited Mr Chris Palmer to highlight the salient issues identified by the patient organisations. Mr Palmer reiterated the treatment's advantages, the main being the potential to reduce nocturnal hypoglycaemia. He conveyed the benefits from a patient perspective.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates to comment. They acknowledged the limitations in

the study programme and focussed on highlighting the innovative nature of the medicine. The delegates offered to work with AWMSG in relation to limiting uptake and monitoring patients. Prior to concluding the appraisal, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Novo Nordisk Ltd 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, the following recommendation would be forwarded to Welsh Government:

Insulin degludec (Tresiba®▼) is not recommended for use within NHS Wales for the treatment of diabetes mellitus in adults.

6. Appraisal 2 - Full Submission (WPAS)
Velaglucerase alfa (VPRIV®) for long-term enzyme replacement therapy in patients with type 1 Gaucher disease

The Chairman welcomed representatives from the applicant company, Shire Pharmaceuticals Ltd. The Chairman confirmed that the appraisal would be conducted in private to protect commercial confidentiality due to the association of a WPAS.

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 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, 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 outlined the sequence of events and invited Mrs Sue Cervetto, AWTTC assessment lead, to set the context of the appraisal.

Mrs Cervetto presented 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 Gauchers Association.

Dr Rob Bracchi provided a brief overview of the relevant issues identified by NMG during the preliminary appraisal. Dr Bracchi confirmed that with the application of the WPAS NMG had supported use of velaglucerase alfa (VPRIV®) as an option within NHS Wales for long-term enzyme replacement therapy in patients with type 1 Gaucher disease.

The Chairman invited comment in relation to the case for clinical effectiveness. Members questioned why children below the age of 2 years had been excluded from the trial. Members expressed disappointment that there was a lack of quality of life data provided. The applicant company delegates confirmed that the programme development had been expedited because of a global medicine shortage of the only other available enzyme replacement therapy, Cerezyme®. There was discussion over treatment efficacy in children compared to adults. Clarification was sought in relation to prevalence and incidence. The Chairman referred to the clinical expert summary. Experts highlighted the need for availability in treatment supply and patient choice.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen highlighted the limitations in undertaking a cost minimisation analysis and

stated that the assumption of therapeutic equivalence across all domains is rarely demonstrated. Professor Cohen asked the delegates to justify their approach and he also explored the issue of waste in relation to vial size. It was confirmed that the model included costs associated with homecare provision.

The Chairman drew member's attention to the detailed patient organisation submission from the Gauchers Association. The Chairman remarked on the high quality of the submission and Mrs Samuels agreed to pass on AWMSG's compliments and thanks to the Gaucher's Association. Mr Palmer highlighted salient aspects of the submission.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates to comment. They thanked AWMSG for their comments particularly for highlighting the potential issues surrounding the vial size available, and also the importance of the quality-of-life data. Prior to concluding the appraisal, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Shire Pharmaceuticals 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, the following recommendation would be forwarded to Welsh Government:

Velaglucerase alfa (VPRIV®) is recommended as an option for use within NHS Wales for long-term enzyme replacement therapy in patients with type 1 Gaucher disease.
This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.

7. Appraisal 3 - Full Submission (PAS)
Eltrombopag (Revolade®) is indicated in adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy

The Chairman welcomed representatives from the applicant company, GlaxoSmithKline Ltd. The Chairman confirmed that the appraisal would be conducted in private to protect commercial confidentiality due to the association of a PAS.

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 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, 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 outlined the sequence of events and invited Ms Kelly Wood, AWTTC assessment lead, to set the context of the appraisal.

Ms Wood presented 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 Waverley Care.

Dr Bracchi provided a brief overview of the relevant issues identified by NMG during the preliminary appraisal. Dr Bracchi confirmed that NMG had supported the use of eltrombopag (Revolade®) in adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy. This recommendation applies only in circumstances where the approved Patient Access Scheme is utilised.

The Chairman invited comment in relation to the case for clinical effectiveness. There was discussion over surrogate end points, outcomes in terms of survival and adverse events. There was also discussion in relation to the alignment of the study design with clinical practice. Clarification was sought in relation to the number of eligible patients in Wales and the Chairman referred members to the clinical expert summary. It was highlighted that no alternative medicines are currently available for patients with HCV infection and with thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy. The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen confirmed that he had not been involved in the preparation of the ASAR, neither had he participated in discussions at NMG. He summarised the case for cost-effectiveness and expressed his views on the submission. Professor Cohen then invited the company delegates to respond to his synopsis, particularly in relation to two key issues he had highlighted. There were no budget impact issues of note.

The Chairman asked members to consider any societal or social value aspects of the submission. Mr Palmer relayed the salient issues highlighted in the patient organisation submission from Waverley Care, a Scottish based organisation. He communicated the organisation's support for the availability of new innovative treatments.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates to comment. They acknowledged the limitations of their submission in relation to the available data. They considered the process had been fair, transparent and the discussion balanced. The Chairman thanked GlaxoSmithKline Limited for engaging in the appraisal process and 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, the following recommendation would be forwarded to Welsh Government:

Eltrombopag (Revolade®) is recommended for use within NHS Wales in adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy. This recommendation applies only in circumstances where the approved Patient Access Scheme is utilised.

8. Appraisal 4 - Full Submission (PAS)
Abiraterone acetate (Zytiga®) in combination with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated

The Chairman welcomed representatives from the applicant company, Janssen-Cilag Ltd. The Chairman confirmed that the appraisal would be conducted in private to protect commercial confidentiality due to the association of a PAS.

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 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, 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 outlined the sequence of events and invited Mrs Gail Woodland, AWTTC assessment lead, to set the context of the appraisal.

Mrs Woodland presented an overview of the submission as detailed in the ASAR and the views of the clinical experts were relayed. It was confirmed that a patient organisation submission had been received from the West Wales Prostate Cancer Group and Prostate Cancer UK, and the views of an individual patient had been submitted and provided to members.

Dr Bracchi provided a brief overview of the relevant issues identified by NMG in the preliminary appraisal. Dr Bracchi confirmed that NMG had not supported the use of abiraterone acetate (Zytiga®▼) with prednisone or prednisolone for the treatment of metastatic castration-resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. NMG considered that the AWMSG criteria for appraising life-extending, end-of-life medicines did not apply to abiraterone acetate (Zytiga®▼) for the indication under consideration as the median overall survival of patients in the control group of study COU-AA-302 was 30.1 months. It was the view of NMG that the case for the cost-effectiveness had not been proven due to uncertainties in the model and uncertainty over life expectancy.

Members were informed that in their response to the preliminary appraisal recommendation, Janssen-Cilag disputed NMG's view with regard to the application of the end of life criteria. In line with AWMSG's appraisal process a meeting had been convened with representatives of Janssen-Cilag. As Chair of the panel, Mrs Samuels confirmed the consensus view and the panel's decision that the grounds for applying the end-of-life criteria review were not upheld, and the NMG preliminary appraisal recommendation to AWMSG should stand. Mrs Samuels informed members that in the absence of any additional information to support the company view the appraisal by AWMSG should continue. The company delegate highlighted an omission from the notes of the panel meeting. Mrs Samuels confirmed that the panel meeting notes had not been shared with AWMSG members as the purpose of that meeting had been to consider the specific issue of the applicability of the end of life criteria. Mrs Samuels informed members that the panel had conveyed that there may be scope for undertaking additional evaluation of evidence for a sub-population, but it would be outside the remit of this appraisal. Mrs Samuels reiterated that AWMSG would take account of the same evidence of clinical effectiveness and cost-effectiveness as that assessed by NMG in undertaking the preliminary appraisal.

The Chairman opened the discussion and invited comment in relation to the case for clinical effectiveness. Clarification was sought in relation to the treatment pathway. There was discussion over monitoring requirements and the shift of treatment in relation to chemotherapy. The Chairman referred to the clinical expert summary. It was noted that experts had expressed frustration over the difference in the management of patients with metastatic castration-resistant prostate cancer in Wales compared to England due to the presence of the Cancer Drugs Fund in England.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen highlighted the strengths and weaknesses of the evidence as outlined in the ASAR. It was confirmed that monitoring costs had been included in the model. The difficulties in assessing quality of life in patients undergoing cytotoxic therapy were acknowledged. The budget impact estimate was noted.

The Chairman invited Mr Palmer to address the meeting. Mr Palmer highlighted salient issues from each of the patient organisation submissions emphasising the advantages of the medication.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates from Janssen-Cilag to comment. The delegate expressed reservation with regard to the applicability of the end of life criteria. Prior to concluding the appraisal, the Chairman sought confirmation from both delegates that the process had been fair and transparent. He thanked Janssen-Cilag Ltd for engaging in the appraisal process and closed the morning appraisal session.

The Chairman confirmed that members would retire to vote in private and recommendations would be announced at the beginning of the afternoon session.

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

Abiraterone acetate (Zytiga®▼) with prednisone or prednisolone is not recommended for use within NHS Wales for the treatment of metastatic castration-resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.

The case for cost-effectiveness has not been proven.

The Chairman announced that confirmation of AWMSG's recommendation would be forwarded to the applicant company within five working days. He informed the delegates that applicant companies have up to ten working days to accept the recommendation or lodge a request for an independent review. It was noted that failure to respond within the deadline would not delay the process.

9. Chairman's report

The Chairman confirmed that he was in the process of preparing a response to a report issued by Welsh Government on 30th April 2014 following the review of AWMSG's process for appraising orphan and ultra-orphan medicines. The Chairman reiterated the approach - to develop and implement a whole-system approach to the identification, appraisal and monitoring of rare diseases where patient numbers are very low; the aim being to ensure that patients with rare diseases have fair and equitable access to appropriate, evidence-based treatments.

The Chairman reported that AWTTC were in the process of preparing a response to the consultation published on 30th April 2014 by Welsh Government following a review into the Individual Patient Funding Request (IPFR) process in Wales. The Chairman confirmed AWTTC would share the response and convene a stakeholder meeting prior to submitting it to Welsh Government.

Members were informed that on 29th April 2014 the Chairman presented at the Annual Meeting of the Antimicrobial Stewardship forum in Cardiff on 'How the All Wales Medicines Strategy Group is contributing to Antimicrobial Stewardship in Wales'. On Wednesday, 4th June, the Chairman met with Professor David Haslam, Chairman of NICE to discuss the collaboration between NICE and AWMSG underpinned by the memorandum of understanding which aims to join up the strategic planning, development and delivery of advice in England and Wales, avoiding duplication and complementing and supporting the work of the NHS in Wales and England.

The Chairman confirmed that ratification of AWMSG's advice which had been forwarded to Welsh Government subsequent to the AWMSG meeting held in May had been received by AWTTC. The relevant pharmaceutical companies and the service had been informed of this.

The Chairman announced the appraisals scheduled for the next meeting to be held in Cardiff on Wednesday, 16th July 2014:

Appraisal 1: Full Submission
Lipegfilgrastim (Lonquex®) for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes)
Applicant Company: TEVA UK Ltd

Appraisal 2: Full Submission
Aripiprazole monohydrate (Abilify Maintena®) for maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole
Applicant Company: Otsuka Pharmaceutical (UK) Ltd

Appraisal 3: Full Submission
Delta-9-tetrahydrocannabinol/cannabidiol (Sativex®) for the treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy
Applicant Company: Bayer Healthcare Pharmaceuticals

Appraisal 4: Full Submission
Fluticasone furoate/vilanterol (as trifenatate) (Relvar® Ellipta®) for the regular treatment of asthma in adults and adolescents aged 12 years old and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate: patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short acting beta2-agonists
Applicant Company: GlaxoSmithKline

Appraisal 5: Limited Submission
Azithromycin (Zedbac®) for the treatment of community-acquired pneumonia due to susceptible microorganisms in adult patients where initial intravenous therapy is required. Treatment of pelvic inflammatory disease due to susceptible microorganisms in patients where initial intravenous therapy is required. Consideration should be given to official guidance regarding the appropriate use of antibacterial agents
Applicant Company: Aspire Pharma Ltd

Appraisal 6: Limited Submission
Linagliptin/metformin (Jentadueto®) for the treatment of adult patients with type 2 diabetes mellitus in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control when insulin and metformin alone do not provide

adequate glycaemic control
Applicant Company: Boehringer Ingelheim Ltd

The Chairman reminded members to declare any interests in relation to this appraisal before the next meeting. The views of patients, patient organisations and patient carers were encouraged

10. National Prescribing Indicators 2013–2014: Analysis of Prescribing Data to December 2013

Mrs Kath Haines presented the analysis of prescribing data to December 2013 highlighting specific areas of interest. Mrs Sue Murphy welcomed the resource and explained how it is used by her on a daily basis to inform discussion within the health board. The Chairman confirmed that AWMSG's national prescribing indicators form the basis of AWTTC's prudent prescribing workshops in 'training the trainers'.

11. Feedback from AWPAG Meeting held 12th March 2014

Mrs Kath Haines presented the draft minutes of the AWPAG meeting held in March and confirmed that the next meeting would be held on 25th June 2014. Mrs Haines highlighted the project work currently on-going in relation to polypharmacy and smoking cessation. She drew attention to the prudent prescribing initiative and respiratory prescribing analysis. The Chairman thanked AWPAG for developing the work and supporting AWMSG's medicines strategy for Wales.

12. Appraisal 5 - Full Submission
Imatinib (Glivec®) as adjuvant treatment, for up to 36 months, of adult patients who are at significant risk of relapse following resection of Kit (CD117)-positive GIST. Patients who have a low or very low risk of recurrence should not receive adjuvant treatment

The Chairman welcomed representatives from the applicant company, Novartis Pharmaceuticals UK Ltd

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 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, 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 confirmed the sequence of events and invited the AWTTC assessment lead, Mrs Helen Adams, to set the context of the appraisal.

Mrs Adams presented an overview of the submission as detailed in the ASAR and the views of the clinical experts were relayed. Members were informed that a patient organisation submission had been received from GIST Support UK and Sarcoma UK.

Dr Bracchi provided a brief overview of the relevant issues identified by NMG during the preliminary appraisal. Dr Bracchi confirmed that NMG had supported the restricted use of imatinib (Glivec®) within its licensed indication for the adjuvant treatment of adult patients who are at significant risk of relapse following resection of KIT (CD117)-positive gastrointestinal stromal tumours. Members were informed that NMG recommended that imatinib (Glivec®) should be restricted for use in patients who are considered to be at high risk of relapse according to the Miettinen criteria. NMG's advice to AWMSG is that imatinib (Glivec®) should not be recommended for use within NHS Wales outside of this subpopulation. Dr Bracchi

highlighted that the evidence supporting this indication was based on treatment duration of 36 months.

The Chairman invited comment in relation to the case for clinical effectiveness. Clarification was sought in relation to the risk stratification criteria. Members explored the clinical elements of high and low risk of relapse. The Chairman referred to the clinical expert summary. Members noted the comment that there is currently no adjuvant treatment available in Wales to reduce the risk of relapse in patients with resected GIST. Relapse, when it occurs, is incurable so there is a need to reduce the frequency with which this happens.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen highlighted some reservation in relation to the uncertainty and commented that the indirect comparison approach was not ideal. The company delegates acknowledged this and stated that there would have been uncertainty with whichever approach the company had taken.

Mr Palmer drew members' attention to the advantages of this therapy from a patient perspective and highlighted the benefit to patients in relation to use of a well understood and tolerated treatment.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates to comment. They acknowledged the balanced approach of AWMSG. Prior to concluding the appraisal, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. The Chairman thanked Novartis Pharmaceuticals UK Ltd 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, the following recommendation would be forwarded to Welsh Government:

Imatinib (Glivec®) is recommended for restricted use within NHS Wales.

Imatinib (Glivec®) should be restricted for use in the following subpopulation within its licensed indication for the adjuvant treatment of adult patients who are at significant risk of relapse following resection of KIT (CD117)-positive gastrointestinal stromal tumours. Patients who have low or very low risk of recurrence should not receive adjuvant treatment.

Imatinib (Glivec®) should be restricted for use in patients who are considered to be at high risk of relapse according to the Miettinen criteria.

Imatinib (Glivec®) is not recommended for use within NHS Wales outside of this subpopulation.

13. Appraisal 6 – Limited Submission
Emtricitabine/rilpivirine/tenofovir disoproxil (Eviplera®▼) for antiretroviral treatment-experienced adults infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with a viral load ≤ 100,000 HIV-1 RNA copies/ml. As with other antiretroviral medicinal products, genotypic resistance testing and/or historical resistance data should guide the use of Eviplera®▼

The Chairman welcomed representatives from the applicant company, Gilead Sciences Ltd and 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 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, 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 Claire Davis, AWTTC assessment lead, to set the context of the appraisal.

Dr Davis presented an overview of the submission as detailed in the ASAR and confirmed that the application had been considered suitable for a limited submission. In line with this process, evidence of budgetary impact compared to the comparator/s is required. The clinical expert highlighted the importance of having treatment options. Members were informed that a patient organisation submission had been received from the Terence Higgins Trust.

Dr Bracchi provided a brief overview of the relevant issues identified in the preliminary appraisal and confirmed that NMG had supported use of emtricitabine/rilpivirine/tenofovir disoproxil (Eviplera®▼) as an option within NHS Wales for the indication under consideration.

The Chairman invited comment in relation to the case for clinical effectiveness. There were no issues of note. He referred members to the clinical expert summary and members noted the comments. Mr Palmer highlighted the benefits of this treatment from a patient perspective and relayed the positive feedback received from patients. The patient view was that emtricitabine/rilpivirine/tenofovir disoproxil (Eviplera®▼) offered significant advances in the treatment of HIV with an improved side effect profile. Additional treatment options were welcomed by patients.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates to comment. They commented that AWTTC had produced a balanced overview of the evidence. Prior to concluding the appraisal, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Gilead Sciences Ltd 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, the following recommendation would be forwarded to Welsh Government:

Emtricitabine/rilpivirine/tenofovir disoproxil (Eviplera®▼) is recommended as an option for use within NHS Wales for antiretroviral treatment-experienced adults infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with a viral load ≤ 100,000 HIV-1 RNA copies/ml. As with other antiretroviral medicinal products, genotypic resistance testing and/or historical resistance data should guide the use of Eviplera®▼.

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded to the applicant companies within five working days. He informed the delegates that companies have up to ten working days to accept the recommendation or lodge a request for an independent review. It was noted that failure to respond within the deadline would not delay the process. The Chairman confirmed the date of the next meeting on Wednesday 16th July 2014 in Cardiff and the meeting closed.