

Enclosure No:	1/AWMSG/0715
Agenda Item No:	1 – Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

**Minutes of the AWMSG meeting held
Wednesday, 17th June 2015 commencing 9.30
am at [The Angel Hotel](#), Abergavenny, NP7 5EN**

**Did not
participate in**

VOTING MEMBERS PRESENT:

- | | | | |
|-----|------------------------|---|---------|
| 1. | Dr Stuart Linton | Chairman | |
| 2. | Dr Catherine Bale | Hospital Consultant | |
| 3. | Dr Geoffrey Carroll | Welsh Health Specialist Commissioning Service | 1-9 |
| 4. | Mr Scott Cawley | Other professional eligible to prescribe | |
| 5. | Professor David Cohen | Health Economist | |
| 6. | Mr Stuart Davies | Finance Director | 1-5, 12 |
| 7. | Ms Ellen Lanham | Community Pharmacist | |
| 8. | Dr Karen Fitzgerald | Public Health Wales | |
| 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 | 12 |
| 13. | Professor John Watkins | Public Health Wales | |
| 14. | Dr Robert Bracchi | GP with Prescribing Lead role | 9 |

IN ATTENDANCE:

Dr Saad Al-Ismail, NMG Chairman
Mrs Karen Samuels, Head of HTA, AWTTTC
Mrs Ruth Lang, Head of Liaison & Administration, AWTTTC

AWTTC APPRAISAL LEADS:

Dr Claire Davis, Senior Appraisal Scientist
Dr Stephanie Francis, Senior Appraisal Scientist
Dr Caron Jones, Senior Appraisal Scientist
Ms Kelly Wood, Senior Appraisal Scientist

WELSH GOVERNMENT:

No representation

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
CAPIG	Clinical and Patient Involvement Group
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
EOL	End of life
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 Care Excellence
NMG	New Medicines Group
PAR	Preliminary Appraisal Recommendation
PAS	Patient Access Scheme
PPRS	Prescription Price Regulation Scheme
SMC	Scottish Medicines Consortium
SPC	Summary of Product Characteristics
TDAPG	Therapeutic Development Appraisal Partnership Group
T&FG	Task and Finish Group
UHB	University Health Board
WAPSU	Welsh Analytical Prescribing Support Unit
WCPPE	Welsh Centre for Pharmacy Postgraduate Education
WeMeReC	Welsh Medicines Resource Centre
WG	Welsh Government
WHSSC	Welsh Health Specialised Services Committee
WPAS	Wales Patient Access Scheme

Welcome and introduction

1. The Chairman opened the meeting and welcomed members.

AWMSG draft minutes June 2015
Prepared by AWTTC

2. Apologies

Mr Alun Morgan (Other professions eligible to prescribe)
Dr Mark Walker and Dr Brendan Boylan (Medical Director)
Dr Emma Mason (Clinical Pharmacologist)
Mrs Louise Williams (Senior Nurse)

3. Declarations of interest

The Chairman invited declarations of interest pertinent to the agenda. Dr Bracchi declared an interest in Appraisal 4, darunavir (Prezista®), in that he had input into the preparation of the ASAR in his role as AWTTTC Medical Adviser. The Chairman confirmed that Dr Bracchi would not participate in the appraisal or vote.

4. Chairman's report

The Chairman confirmed that the Minister for Health and Social Services had ratified the following AWMSG:

Aflibercept (Zaltrap®) is not recommended for use within NHS Wales in combination with irinotecan/5-fluorouracil/folinic acid (FOLFIRI) chemotherapy for the treatment of adults with metastatic colorectal cancer that is resistant to or has progressed after an oxaliplatin containing regimen. The case for cost-effectiveness has not been proven.

Adalimumab (Humira®) is recommended as an option for use within NHS Wales for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

In the absence of a submission from the holder of the marketing authorisation, **dapagliflozin (Forxgia®) cannot be endorsed for use** within NHS Wales as monotherapy for the treatment of adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance.

Members were informed that the service had been informed and the final appraisal recommendations had been uploaded to the AWMSG website. The Chairman highlighted that AWMSG's recommendation regarding use of ledipasvir/sofosbuvir (Harvoni®) within NHS Wales had not yet been endorsed.

It was reported that Dr William Whitehead, GP representative, had resigned from AWMSG. The Chairman thanked Dr Whitehead for his valuable contribution to AWMSG and wished him well for the future. The Chairman confirmed that Dr Robert Bracchi had agreed to step into the role at short notice – members were informed that Dr Bracchi had previously been a deputy AWMSG member before taking on the role of NMG Chairman. He stepped down as NMG Chairman in March 2015.

The Chairman confirmed that following appraisal by AWMSG in May, and the announcement that AWMSG had not supported the use of enzalutamide (Xtandi®) and pomalidomide (Immovid®) within NHS Wales, the marketing authorisation holder had submitted a request for independent review. An independent review panel will be convened on Wednesday, 24th June to explore the issues highlighted and the findings of the panel would be reported to AWMSG.

The Chairman announced the appraisals scheduled for the next meeting to be held in Cardiff on Wednesday, 15th July 2015:

Full Submission

Brimonidine (Mirvaso®) for the symptomatic treatment of facial erythema of rosacea in adult patients

Applicant Company: Galderma (UK) Ltd

Full Submission

Darunavir/cobicistat (Rezolsta®) in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus 1 (HIV 1) infection in adults aged 18 years or older

Applicant Company: Janssen-Cilag Ltd

Limited Submission

Magnesium aspartate dehydrate (Magnaspartate®) for the treatment and prevention of magnesium deficiency, as diagnosed by a doctor. Magnaspartate is indicated in adults, children and adolescents aged from 2 years

Applicant Company: Kora Corporation Ltd trading as Kora Healthcare

Limited Submission

Tacrolimus (Envarsus®) for prophylaxis of transplant rejection in adult kidney or liver allograft recipients. Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients

Applicant Company: Chiesi Ltd

Members were reminded to declare any interests in relation to these appraisals before the next meeting.

Patients, patient organisations and patient carers were invited to submit their views to AWTTTC in relation to medicines scheduled for appraisal.

5. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy. Mrs Sue Murphy highlighted that reference to 'community pharmacist' under Agenda Item 6 on Page 4, 2nd paragraph, should be amended to read 'community pharmacists'. With this change, the minutes were approved.

6. Appraisal 1: Full Submission

Levonorgestrel (Jaydess®▼) for contraception for up to 3 years

The Chairman welcomed representation from the applicant company Bayer Healthcare Pharmaceuticals

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

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, AWTTTC Appraisal Lead, to set the context of the appraisal.

Mr Stuart Davies joined the meeting.

Ms Wood presented an overview of the submission as detailed in the ASAR and highlighted the key aspects of the clinical expert summary. Members were informed that no patient questionnaires had been received.

The Chairman invited Dr Saad Al-Ismael, the NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Al-Ismael confirmed the view of NMG that levonorgestrel (Jaydess[®]▼) should be recommended as an option for use within NHS Wales for contraception for up to three years.

The Chairman opened the discussion in relation to clinical effectiveness. The device was passed around the table. Clarification was sought in relation to the dynamics of hormone release. The applicant company was asked to comment on the adverse effect profile and comparative safety data. The Chairman drew attention to the clinical expert views Ms Wood drew members' attention to the key aspects of the summary.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen confirmed his role as AWMSG health economist and confirmed he had no involvement in compiling the ASAR or in discussions at NMG. Professor Cohen summarised the case presented, as summarised in the ASAR, and offered the company delegates opportunity to correct or comment on any aspect of his summary. The company delegates accepted that the summary had been fair and had no further comments.

The Chairman drew members' attention to the budget impact evidence in the ASAR. There were no issues of note. Mr Palmer highlighted the steps taken by AWTTTC to seek patient input. A comment from Brook was relayed which highlighted a group of patients who would be likely to benefit from this medicine being available in Wales. There were no outstanding wider societal aspects noted.

The Chairman referred to the applicant company's response and offered further opportunity for the company delegate to comment. Having received confirmation that the appraisal process had been fair and transparent and that all relevant issues had been discussed, the Chairman closed the appraisal.

Appraisal decision subsequently announced in public:

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:

Levonorgestrel (Jaydess[®]▼) is recommended as an option for use within NHS Wales for contraception for up to three years.

7. Appraisal 2 – Full Submission

Peginterferon beta-1a (Plegridy[®]) in adult patients for the treatment of relapsing remitting multiple sclerosis

The Chairman welcomed representation from the applicant company, Biogen Idec Ltd

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

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, 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 the AWTTTC Appraisal Lead, to set the context of the appraisal.

Dr Jones presented an overview of the submission as detailed in the ASAR and confirmed that two patient organisation questionnaires had been received.

The Chairman invited Dr Saad Al-Ismail, the NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Al-Ismail confirmed the view of NMG that peginterferon beta-1a (Plegridy[®]▼) should be recommended as an option for use within NHS Wales in adult patients for the treatment of relapsing remitting multiple sclerosis.

The Chairman opened the discussion in relation to clinical effectiveness. Clarification was sought in relation to the impact of clinical benefit and the company delegate responded. There was discussion over the quality of life outcome scores and statistical significance, and a question was raised regarding the availability of criteria for stopping and starting the medicine.

The Chairman referred members to the clinical expert views. There were no outstanding issues of note.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen confirmed his role as AWMSG health economist and confirmed he had no involvement in compiling the ASAR or in discussions at NMG. Professor Cohen summarised the case presented and offered the company delegates opportunity to correct or comment on any aspect of his summary. He made reference to minor critical comments within the ASAR and stated that he didn't consider these to be major. The company delegate agreed that it had been a fair reflection of the analyses. There were no outstanding issues of note and members noted the potential financial savings highlighted in the budget impact section.

The Chairman invited Mr Chris Palmer, lay member, to provide an overview of the patient organisation submissions. Mr Palmer read extracts from the questionnaires received from the Multiple Sclerosis Trust and Multiple Sclerosis Society highlighting the positive impact the medicine would have on patients and their carers/families.

The Chairman referred to the company response to the preliminary recommendation and invited the company delegates to comment. Prior to concluding the appraisal proceedings he asked the company delegates to confirm they were satisfied that all issues had been adequately addressed and taken into account, and that the process had been fair and transparent. On receipt of this confirmation he concluded the appraisal proceedings.

Appraisal decision subsequently announced in public:

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:

Peginterferon beta-1a (Plegridy[®]▼) is recommended as an option for use within NHS Wales in adult patients for the treatment of relapsing remitting multiple sclerosis.

8. Appraisal 3: Full Submission

Avanafil (Spedra[®]▼) for the treatment of erectile dysfunction in adult men

The Chairman welcomed representation from the applicant company, A. Menarini Farmaceutica Internazionale SRL

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

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, 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 Claire Davis, AWTTC Appraisal Lead, to set the context of the appraisal.

Dr Davis presented an overview of the submission as detailed in the ASAR and confirmed that no patient organisation questionnaires had been received.

The Chairman invited Dr Saad Al-Ismail, the NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Al-Ismail confirmed the view of NMG that avanafil (Spedra[®]▼) should be recommended as an option for use within NHS Wales for the treatment of erectile dysfunction in adult men.

The Chairman opened the discussion in relation to clinical effectiveness. The Chairman referred members to the views of clinical experts and asked Dr Davis to highlight the key aspects of the summary. There were no outstanding clinical issues of note.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen confirmed his role as AWMSG health economist and confirmed he had no involvement in compiling the ASAR or in discussions at NMG. Professor Cohen summarised the case presented, as summarised in the ASAR, and offered the company delegates opportunity to correct or comment on any aspect of his summary. The company delegate responded to Professor Cohen's comment in relation to the prescription cost analysis (Table 4 in the ASAR). There were no outstanding issues relating to the case for cost-effectiveness. Clarification was sought in relation to the adverse event profile. Members noted the budget impact.

Mr Chris Palmer, lay member, highlighted the steps taken by AWMSG to seek input from a patient organisation. Members highlighted that clarification of the regulations in Wales may be required in relation to erectile dysfunction medicines. There were no other wider societal issues of note.

The Chairman referred to the company response to the preliminary recommendation and invited the company delegates to highlight aspects of their response. Prior to concluding the appraisal proceedings he asked the company delegates to confirm they were satisfied that all issues had been adequately addressed and taken into account, and that the process had been fair and transparent. On receipt of this confirmation he concluded the appraisal proceedings and members retired to vote on the three appraisals undertaken.

Appraisal decision subsequently announced in public:

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:

Avanafil (Spedra[®]▼) is recommended as an option for use within NHS Wales for the treatment of erectile dysfunction in adult men.

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded to the applicant company within five working days. He informed the delegates that they had 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. Appraisal 4 - Limited Submission

Darunavir (Prezista®) co-administered with low dose ritonavir is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients from the age of 3 years and at least 15 kg body weight

Dr Bracchi left the meeting. Dr Carroll joined the meeting.

The Chairman welcomed representation from the applicant company, Janssen-Cilag Ltd

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

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. It was noted that the application had been considered eligible for a limited submission. In line with this process, evidence of budgetary impact to the existing comparator products(s) should be demonstrated. The Chairman highlighted that monitoring of budget impact would be essential and AWMSG reserved the right to request a full submission if the budget impact exceeded that estimated in the limited submission.

The Chairman invited Dr Stephanie Francis, AWTTTC Appraisal Lead, to set the context of the appraisal. Dr Francis presented an overview of the limited submission as detailed in the ASAR and confirmed that no patient organisation questionnaires had been received.

The Chairman invited Dr Saad Al-Ismael, the NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Al-Ismael confirmed the view of NMG that darunavir (Prezista®▼) co-administered with low dose ritonavir in combination with other antiretroviral medicinal products should be recommended as an option for use within NHS Wales for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients from the age of three years and at least 15 kg body weight.

The Chairman opened the discussion in relation to clinical effectiveness and there were no outstanding issues of note. The Chairman referred members to the clinical expert views and asked Dr Francis to highlight key aspects of the summary. Dr Francis highlighted the view that the availability of another treatment option would be of great benefit to clinicians. There were no outstanding clinical issues of note. The budget impact was noted.

Mr Chris Palmer, lay member, highlighted the steps taken by AWMSG to seek input from a patient organisation.

The Chairman referred to the company response to the preliminary recommendation and invited the company delegates to comment. Prior to concluding the appraisal proceedings he asked the company delegates to confirm they were satisfied that all issues had been adequately addressed and taken into account, and that the process had been fair and transparent. On receipt of this confirmation he concluded the appraisal proceedings.

Appraisal decision subsequently announced in public:

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:

Darunavir (Prezista[®]) co-administered with low dose ritonavir in combination with other antiretroviral medicinal products is recommended as an option for use within NHS Wales for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients from the age of three years and at least 15 kg body weight.

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 they had 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.

10. National Audit: Focus on Antibiotic Prescribing – Update

The Chairman introduced Ms Kath Haines, Head of WAPSU, AWTTTC, and welcomed her to the meeting. Ms Haines provided an overview of Enc 6/AWMSG/0615, the updated AWMSG National Audit: Focus on Antibiotic Prescribing. Members had supported its uptake and development at the February 2015 meeting and following this, AWPAG and AWTTTC had reviewed and updated the audit based on pilot feedback and Public Health England guidance which underpins the audit. Ms Haines highlighted the changes made to the document and confirmed that AWTTTC are working with Primary Care Quality to utilise Audit Plus to collect the data electronically. The Chairman opened discussion. Members welcomed the audit and reiterated the importance of raising public awareness to the issue of antimicrobial stewardship. Members asked Ms Haines to explore what initiatives have been undertaken in health boards to tackle this issue. Members agreed that there was work to be done in educating the public and highlighting the importance of changing behaviour. Dr Bracchi reminded members of the AWMSG Medicines Strategy recommendation for a Citizens Jury and confirmed that AWTTTC was currently working on a project to develop this to help understand what factors influence public attitudes and behaviour towards antimicrobial stewardship (AMS) in order to encourage and promote more prudent use of these vital therapeutic agents by health professionals, patients and the public. The Chairman reiterated AWMSG's support for the development of this work, and Professor Cohen referred members to his research work with Dr Chris Butler and the paper published in the BMJ. The Chairman suggested that work could be done in identifying pockets of excellence and clinical champions; Mr Rob Thomas offered the support of ABPI Wales and suggested that the pharmaceutical industry would share initiatives. The Chairman concluded the discussion and confirmed AWMSG's commitment to tackling the wider issue of antimicrobial stewardship. He confirmed AWMSG's endorsement of the updated audit as a National audit for 2015-2016.

11. National Audit: Towards Appropriate Non-steroidal Anti-inflammatory Drug (NSAID) Prescribing – Update

Ms Haines asked AWMSG to consider and endorse the updated Clinical Effectiveness Prescribing Programme audit. Members were informed that the audit had been developed by AWPAG with support for read code information provided by Primary Care Quality, part of Public Health Wales. Ms Haines clarified that the document supports review of the prescribing of non-steroidal anti-inflammatory drugs, particularly in patients with a higher risk of side effects. The document includes a practice review section designed to encourage a whole practice response to the audit findings and an evaluation of the quality and usefulness of the audit itself. It was noted that the audit was originally endorsed by AWMSG in March 2010 and the updated version is intended for follow up on the original audit to complete the cycle where possible. It will be available via the AWMSG and Public Health Wales websites.

The Chairman acknowledged this to be a very important area for AWMSG in ensuring safe prescribing, and confirmed AWMSG's endorsement of the updated National Audit: Towards Appropriate Non-steroidal Anti-inflammatory Drug (NSAID) Prescribing.

Mr Roger Williams and Mr Stuart Davies left the meeting.

The meeting was closed to the public. The Chairman confirmed that the last appraisal would be held in private to ensure commercial confidentiality

12. Appraisal 5: Full Submission (WPAS)

Regorafenib (Stivarga®▼) for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumours (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib

Prior to commencing appraisal proceedings, the Chairman asked the applicant company delegates to confirm acceptance that individuals remaining in the public gallery were either employed by AWTTTC or Bayer Healthcare Pharmaceuticals and there were no outstanding issues in relation to confidentiality. Having received confirmation, the appraisal commenced.

The Chairman welcomed representation from the applicant company, Bayer Healthcare Pharmaceuticals.

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

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 Claire Davis, AWTTTC Appraisal Lead, to set the context of the appraisal.

Dr Davis presented an overview of the submission as detailed in the ASAR and confirmed that one patient organisation questionnaire had been received.

The Chairman invited Dr Saad Al-Ismail, the NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Al-Ismail confirmed the view of NMG that regorafenib (Stivarga®▼) should be recommended for use within NHS Wales for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumours (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib. Dr Al-Ismail relayed NMG's view that the recommendation should apply only in circumstances where the approved Wales Patient Access Scheme is utilised. It was noted that NMG did not consider that regorafenib (Stivarga®▼) satisfies the AWMSG criteria for orphan or ultra-orphan drug status. It is licensed for the treatment of diseases (i.e. GIST and metastatic colorectal cancer [mCRC]) with an estimated prevalence of more than 5 in 10,000 persons. NMG acknowledged that the AWMSG criteria for appraising life-extending, end-of-life medicines did not apply to regorafenib (Stivarga®▼) for the indication under consideration. NMG did not consider the cumulative population of both licensed indications of the medicine to be small.

The Chairman opened the discussion in relation to clinical effectiveness and members sought clarity in relation to treatment following disease progression. It was noted that there are no other treatment options licensed for the indication under consideration.

The Chairman referred members to the views of clinical experts and asked Dr Davis to highlight key aspects of the summary. There were no outstanding issues of note.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen confirmed his role as AWMSG health economist and confirmed he had no involvement in compiling the ASAR or in discussions at NMG. Professor Cohen summarised the case presented, as summarised in the ASAR, and offered the company delegates opportunity to correct or comment on any aspect of his summary. The budget impact was noted

Mr Chris Palmer, lay member, provided an overview of the patient organisation submission. He read sections from the questionnaire and highlighted the advantages the new medicine would offer to patients and their families.

The Chairman referred to the company response to the preliminary recommendation and invited the company delegates to highlight aspects of their response. Prior to concluding the appraisal proceedings he asked the company delegates to confirm they were satisfied that all issues had been adequately addressed and taken into account, and that the process had been fair and transparent. On receipt of this confirmation he concluded the appraisal proceedings.

Appraisal decision subsequently announced in public:

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:

Regorafenib (Stivarga[®]▼) is recommended for use within NHS Wales for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumours (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.

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 they had 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, 15th July in Cardiff** and closed proceedings.