

<b>Enclosure No:</b>	<b>1/AWMSG/0315</b>
<b>Agenda Item No:</b>	<b>4 – Minutes of previous meeting</b>
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## **ALL WALES MEDICINES STRATEGY GROUP (AWMSG)**

**Minutes of the AWMSG meeting held Wednesday, 11<sup>th</sup>  
February 2015 commencing 10.30 am at [The Angel](#)  
[Hotel](#), Abergavenny, NP7 5EN**

**Did not  
participate in**

### **VOTING MEMBERS PRESENT:**

- |     |                        |   |           |
|-----|------------------------|---|-----------|
| 1.  | Dr Stuart Linton       | Chairman                                    |           |
| 2.  | Dr Brendan Boylan      | Medical Director representative             |           |
| 3.  | Dr Geoffrey Carroll    | Welsh Health Specialised Services Committee |           |
| 4.  | Professor David Cohen  | Health Economist                            |           |
| 5.  | Mr Stuart Davies       | Finance Director representative             |           |
| 6.  | Dr Karen Fitzgerald    | Public Health Wales                         |           |
| 7.  | Mrs Ellen Lanham       | Community Pharmacist                        |           |
| 8.  | Mrs Susan Murphy       | Managed Sector Primary Care Pharmacist      |           |
| 9.  | Mr Christopher Palmer  | Lay Member                                  |           |
| 10. | Mr Rob Thomas          | ABPI Cymru Wales                            | <b>12</b> |
| 11. | Professor John Watkins | Vice Chairman                               |           |
| 12. | Mrs Louise Williams    | Nurse representative                        |           |
| 13. | Dr Bill Whitehead      | GP with Prescribing Lead role               |           |
| 14. | Mr Roger Williams      | Managed Sector Secondary Care Pharmacist    |           |

### **IN ATTENDANCE:**

15. Mrs Karen Samuels, Head of HTA, AWTTTC
16. Dr Robert Bracchi, NMG Chairman
17. Ms Ruth Lang, Head of Liaison & Administration, AWTTTC

**AWTTC APPRAISAL LEADS:**

18. Miss Kelly Wood, Senior Appraisal Scientist
19. Mrs Sabrina Rind, Senior Appraisal Pharmacist
20. Mrs Susan Cervetto, Senior Appraisal Pharmacist

**WELSH GOVERNMENT:**

21. Professor Roger Walker, Chief Pharmaceutical Officer

**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
G-CSF	Granulocyte colony-stimulating factor
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
NSAIDs	Non-steroidal anti-inflammatory drugs
PAR	Preliminary Appraisal Recommendation
PAS	Patient Access Scheme
PPRS	Prescription Price Regulation Scheme
SMC	Scottish Medicines Consortium
TDAPG	Therapeutic Development Appraisal Partnership Group
T&FG	Task and Finish Group
UHB	University Health Board
WG	Welsh Government
WAPSU	Welsh Analytical Prescribing Support Unit
WCPPE	Welsh Centre for Pharmacy Postgraduate Education
WeMeReC	Welsh Medicines Resource Centre
WHSSC	Welsh Health Specialised Services Committee
WPAS	Wales Patient Access Scheme

**1. Welcome and introduction**

The Chairman opened the meeting and welcomed Mrs Louise Williams and Dr Brendon Boylan to their first AWMSG Meeting.

## 2. **Apologies**

Mr Alun Morgan and Mr Scott Cawley (other professions eligible to prescribe)  
Dr Emma Mason and Dr Balwinder Bajaj (consultant pharmacologist)  
Dr Mark Walker (deputy medical director in attendance)

## 3. **Declarations of interest**

The Chairman invited declarations of interest pertinent to the agenda. Mr Rob Thomas declared a personal specific interest in relation to appraisal 3 and the Chairman confirmed that he would be required to leave the meeting and would not participate or vote in the appraisal of umeclidinium/vilanterol (as trifenatate) (Anoro<sup>®</sup> Ellipta<sup>®</sup>▼).

## 4. **Minutes of previous meeting**

The minutes of the previous meeting were checked for accuracy and approved by the Chairman. Mrs Samuels drew members' attention to the recommendation on page 8 relating to infliximab (Inflectra<sup>®</sup>▼), and on page 10 relating to Infliximab (Remsima<sup>®</sup>▼). She highlighted that both biosimilar medicines had been recommended by AWMSG as an option for restricted use in December 2014. Members were informed that NICE intend to widen their recommendation for the reference product (Remicade<sup>®</sup>) to include moderately severely active ulcerative colitis in adults and severely active ulcerative colitis in children and young people 6-17 yrs old. Mrs Samuels suggested future-proofing the FAR to take account of the proposed changes to NICE guidance in relation to the reference product. It was agreed that AWMSG would reconsider their recommendation wording in light of this information, as the FARs for Remsima<sup>®</sup>▼ and Inflectra<sup>®</sup>▼ will not be published until after 25<sup>th</sup> February 2015, when the exclusive right to market Remicade<sup>®</sup> is due to expire. The delay in publication of the recommendations would allow sufficient time for the wording to be updated in line with the reference product.

## 5. **Appraisal 1: Full Submission (WPAS)**

**Aflibercept (Zaltrap<sup>®</sup>▼)** in combination with irinotecan/5 fluorouracil/folinic acid (FOLFIRI) chemotherapy is indicated in adults with metastatic colorectal cancer (MCRC) that is resistant to or has progressed after an oxaliplatin containing regimen

The Chairman welcomed delegates from Sanofi-Aventis 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 no interests 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 Miss Kelly Wood, AWTTTC assessment lead, to set the context of the appraisal.

Miss Wood presented an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. She confirmed that two individual patient questionnaires had been received. Members were informed that following a negative recommendation by the New Medicines Group (NMG) in November 2014, the applicant company had requested that the appraisal be suspended pending further discussion regarding the applicability of AWMSG's criteria for appraising life-extending and end-of-life medicines. Mrs Samuels confirmed that following an assessment of the evidence on 19<sup>th</sup> January 2015, the end-of-life panel concluded that there was insufficient evidence that the three month life extension criterion was met.

Dr Bracchi provided a brief overview of the relevant issues identified in the preliminary appraisal and confirmed NMG's decision that aflibercept (Zaltrap®<sup>▼</sup>) in combination with irinotecan/5 fluorouracil/folinic acid (FOLFIRI) chemotherapy is indicated in adults with metastatic colorectal cancer (MCRC) that is resistant to or has progressed after an oxaliplatin containing regimen should not be recommended for use within NHS Wales. NMG considered there was insufficient evidence that the three month life extension criterion had been fulfilled. Dr Bracchi highlighted the limitations highlighted at NMG in relation to the company submission.

The Chairman opened the discussion in relation to clinical effectiveness. There was discussion around the progression-free and survival data; members considered the evaluation of the quality of life evidence. Members explored potential use in sub-groups.

The Chairman drew attention to the clinical expert summary. Clinicians highlighted the limited options available for targeted treatments for patients in Wales, compared to patients living in England who are currently able to access this medicine via alternative commissioning routes.

The Chairman invited Professor Cohen to share his views in relation to the case for cost-effectiveness. Professor Cohen clarified his role as AWMSG health economist and summarised the key aspects of the case for cost-effectiveness outlined in the ASAR. He gave recognition to the strengths and highlighted weaknesses in the company submission. He invited comment. Professor Cohen agreed that a key issue is whether the criteria for end-of-life had been met, and commented that the mean overall survival would be acceptable in this case. The company delegates responded and explained the challenges in fitting curves to the available data. They considered that on balance the majority of the survival is probably 3 months or greater. Clarification was sought in relation to the level of evidence required to prove that the medicine would meet the end of life criteria. Mrs Samuels informed members that the applicant company had been given opportunity to provide further evidence to support their case prior to the appraisal by AWMSG. She explained key factors may have been the high level of uncertainty in the submission, and also the number of patients on which the survival curves were based. It was clarified that an ICER of £20,000 to £30,000 is the norm. The applicant company delegates expressed their disappointment in relation to the end-of-life panel decision. They highlighted the availability of the medicine in Scotland and suggested that the budget impact in Wales would be relatively small. They urged members to consider the significant development in offering patients a targeted agent. Members considered the societal issues and acknowledged the Welsh context in relation to availability of medicines. Members examined the evidence in relation to quality of life and survival, and there was also discussion in relation to opportunity costs.

Members also considered the budget impact. The company delegates confirmed that administration and research costs had been included, and stated that the estimated number of patients eligible in Wales had probably been over-estimated. The Chairman asked Mr Palmer to highlight salient issues from the patient organisation submissions. Mr Palmer relayed the patients' comments.

The Chairman referred to the applicant company's response and offered further opportunity for the company delegates 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 and opened the meeting to the public.

#### **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:

**Aflibercept (Zaltrap<sup>®</sup>▼) 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.**

- There are several uncertainties and limitations in the economic model provided in the company's submission.
- AWMSG acknowledged that the AWMSG criteria for appraising life-extending, end-of-life medicines did not apply to aflibercept (Zaltrap<sup>®</sup>▼) for the indication under consideration. There is insufficient evidence that the three month life extension criterion is fulfilled.
- Patients who are currently being treated with aflibercept (Zaltrap<sup>®</sup>▼) for the indication stated above should have the option to continue their therapy until they and their clinicians consider it appropriate to stop.

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.

## **6. Chairman's report**

The Chairman welcome members to his first meeting as Chairman. He thanked Professor Watkins for chairing the previous meeting in December in his absence, and announced that Professor Watkins had been appointed Vice Chair of AWMSG.

The Chairman reported that the AWMSG Training Day held on 14<sup>th</sup> January 2015 had been well attended and feedback had been positive. He thanked the speakers for their contribution and for making the event a success.

It was confirmed that ratification of AWMSG's recommendations from the meeting held in December had been received (with the exception of the two recommendations in relation to infliximab (Remsima<sup>®</sup>▼) and infliximab (Inflectra<sup>®</sup>▼)). The final appraisal recommendations had been posted on the AWMSG website and the Service informed.

The appraisals scheduled for the next AWMSG meeting on Wednesday, 25<sup>th</sup> March 2015 were announced:

### **Full Submission**

Daclatasvir (Daklinza<sup>®</sup>) in combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults

Applicant Company: Bristol-Myers Squibb Pharmaceuticals Ltd

### **Full Submission**

Bedaquiline (Sirturo<sup>®</sup>) for use as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability. Consideration should be given to official guidance on the appropriate use of antibacterial agents

Applicant Company: Janssen-Cilag Ltd

Full Submission with a Wales Patient Access Scheme

Defibrotide (Defitelio<sup>®</sup>) for the treatment of severe hepatic veno-occlusive disease (VOD) also known as sinusoidal obstructive syndrome (SOS) in haematopoietic stem-cell transplantation (HSCT) therapy in adults, adolescents, children and infants over one month of age

Applicant Company: Jazz Pharmaceuticals plc

Limited Submission with a Wales Patient Access Scheme

Dolutegravir/abacavir/lamivudine (Triumeq<sup>®</sup>) for the treatment of human immunodeficiency virus (HIV) infected adults and adolescents above 12 years of age weighing at least 40 kg.

Applicant Company: ViiV Healthcare UK Ltd

Limited Submission

Entecavir (Baraclude<sup>®</sup>) for the treatment of chronic hepatitis B virus infection in nucleoside naive paediatric patients from 2 to < 18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis

Applicant Company: Bristol-Myers Squibb Pharmaceuticals Ltd

Members were asked 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.

**7. Appraisal 2 - Full Submission**

Lurasidone (Latuda<sup>▼</sup><sup>®</sup>) for the treatment of schizophrenia in adults aged 18 years and over.

The Chairman welcomed delegates representing Sunovion Pharmaceuticals 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 no interests 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 Mrs Sue Cervetto, AWTTTC 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. Experts had highlighted that poor physical health outcomes were well recognised in patients suffering from chronic schizophrenia, with higher morbidity rates of obesity, type 2 diabetes mellitus, metabolic syndrome, and cardiovascular disease. Mortality rates from physical health problems are increased compared with the normal population and patients with schizophrenia have a reduced life expectancy of at least 10 years. Experts agreed that lurasidone appears to have a favourable metabolic profile. They also stated that having other treatment options available is important due to differences between antipsychotics and the need to include choice for patients. Mrs Cervetto confirmed that a patient organisation questionnaire had been received from HAFAL.

Dr Bracchi relayed the view of NMG that the company submission did not present sufficient evidence of comparative cost effectiveness for lurasidone (Latuda<sup>▼</sup><sup>®</sup>) compared to existing treatment options. NMG had concerns regarding the inputs and outcome measures used in the economic model. NMG were not convinced that there was sufficient clinical evidence in the sub-population of patients identified by the applicant company where lurasidone was most

likely to be used, i.e. those at risk of weight gain or other metabolic adverse events. On this basis NMG did not recommend the use of this medicine for the indication under consideration.

The Chairman opened the discussion in relation to clinical effectiveness. It was noted that aripiprazole (Abilify®) had been considered the most appropriate comparator by the applicant company as it has the largest market share among atypical antipsychotic treatments prescribed to patients at risk of weight gain (due to its favourable metabolic profile). The safety profile of lurasidone was discussed. It was noted that comparative data on metabolic outcomes had not been provided and the studies included had not been powered to take account of outcomes relating to metabolic parameters. Members also sought clarification in relation to the discontinuation rates in the studies. The company delegates responded to the issues raised and highlighted the need for another treatment option to be available because of the importance of the metabolic issues, and also because of the idiosyncratic response of patients. The company delegates confirmed that switching patients to lurasidone from other atypical antipsychotics maintained treatment efficacy whilst having the potential to reverse increases in weight and lipid levels. The company delegates commented that they fully recognised the medicine might be used second or third line and reiterated the importance of having another treatment option alongside aripiprazole (Abilify®). They highlighted the importance of compliance in this group of patients. The Chairman confirmed there were no outstanding issues in relation to the clinical expert 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 strengths and key concerns in the case presented, as summarised in the ASAR by the AWTTTC health economist, and offered the company delegates opportunity to correct or comment on any aspect of his summary. The company delegates acknowledged some of the limitations in their submission. The Chairman drew members' attention to the budget impact evidence in the ASAR. The projected uptake and the levels of uncertainty in the estimates were noted.

The Chairman invited Mr Chris Palmer to highlight the salient aspects of the patient organisation questionnaire submitted by HAFAL. The importance of having treatment options available to patients and their clinician was highlighted due to the poor tolerability and adverse effect profile of the treatments. Weight gain and other side effects often lead to patients not taking medication which can result in hospitalisation. The patient organisation highlighted that adherence to medication can often be an issue which can be due to the condition itself or the side effects, some of which include metabolic syndrome, sedation, tardive dyskinesia, extrapyramidal side effects and sexual dysfunction. The patient organisation welcomed an additional treatment option; it was stated that patients need to try a number of medications before they find the one that is both effective in treating their mental health symptoms but also has less side effects than other treatment options. HAFAL expressed disappointment at the high level of side effects associated with mental health medication in general. There were no other 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.

#### **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:

**Lurasidone (Latuda®) is recommended as an option for use within NHS Wales for the treatment of schizophrenia in adults aged 18 years and over.**

8. **National Prescribing Indicators 2014–2015: Analysis of Prescribing Data to September 2014**

Ms Kath Haines presented Enclosure 4, a report produced by WAPSU, summarising the prescribing of medicines associated with a National Prescribing Indicator (NPI) for the second quarter of 2014-2015 (i.e. quarter ending September 2014).

9. **National Prescribing Indicators (NPIs) 2015–2016**

Mrs Kate Jenkins, AWTTTC and Mrs Louise Howard-Baker, AWPAG Chair, presented Enclosure 5, the proposed National Prescribing Indicators (NPIs) for 2015-2016. Members were asked to consider the NPIs in line with the AWMSG Five-year Strategy 2013-2018 'AWMSG will work with health boards and other stakeholders to promote the safe, effective and cost-effective use of medicines in Wales' and endorse the paper. The removal of the indicators monitoring antidepressant and analogue insulin prescribing and the inclusion of two new indicators for proton pump inhibitor and low dose inhaled corticosteroid prescribing were highlighted. It was confirmed that the introduction of the new indicators had been evidence-based and would be reviewed on publication of new evidence. The Chairman confirmed AWMSG's endorsement of the paper.

10. **NPIs 2015–2016 Supporting Information for Prescribers**

A document summarising the NPIs for 2015-2016 with points for consideration and links to supporting materials was presented to AWMSG. It was noted that a slide set will be produced to assist in the implementation of the NPIs. The Chairman confirmed AWMSG's endorsement of the document.

11. **Review of the AWMSG National Audit: Focus on Antibiotic Prescribing 2013–2015**

The Chairman invited Dr Tessa Lewis, AWTTTC Medical Lead, to provide an overview of Enclosure 7. Dr Lewis asked members to support the uptake and development of the [AWMSG National Audit: Focus on Antibiotic Prescribing](#) for 2015-2016. Dr Lewis reminded members of the responsibility of all health boards to reduce the prescribing of antibiotics. In light of this, AWPAG and AWTTTC had reviewed and updated the audit and had investigated the use of electronic templates for the specified conditions, and the on-line completion and submission of audit findings to support feedback to prescribers. AWMSG was asked to continue to promote antimicrobial stewardship. It was explained that this audit is part of a toolkit to reduce antibiotic prescribing and further education initiatives should be implemented to change prescribing practice. The Chairman confirmed AWMSG's unanimous support and endorsed the Antibiotic Prescribing audit as part of a toolkit to reduce antibiotic prescribing.

12. **Appraisal 3: Full Submission**

**Umeclidinium/vilanterol (as trifenate) (Anoro® Ellipta®) for maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease**

Mr Rob Thomas left the meeting.

The Chairman welcomed delegates from GlaxoSmithKline.

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 Mrs Sabrina Rind, AW TTC assessment lead, to set the context of the appraisal.

Mrs Rind presented an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. It was noted that experts highlighted a need for treatment to provide symptom relief and improve quality of life in people with severe chronic obstructive pulmonary disease. An unmet need for patients who experience difficulties with the usage of metered-dose inhalers was also highlighted. Members were informed that clinical experts had raised the issue of inequality in access to in-hospital smoking cessation services and pulmonary rehabilitation within Wales. Mrs Rind confirmed that two patient organisations had been contacted, but no questionnaires had been received.

Dr Bracchi provided a brief overview of the discussion at NMG and relayed the view that having considered the scientific evidence NMG supported the use of umeclidinium/vilanterol (as trifenate) (Anoro<sup>®</sup> Ellipta<sup>®</sup>▼) for maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease as an option within NHS Wales.

The Chairman opened discussion and invited comment in relation to the case for clinical effectiveness. Clarification was sought in relation to where the medicine fits within current NICE guidance. Dr Whitehead expressed slight concern in relation to the dose counting mechanism of the device. The device was tabled and the priming function explained by the company delegates. There was discussion in relation to use in patients with cardiovascular disease. It was confirmed that cardiac patients had been included in the trials. It was noted that no dose adjustment would be required and it was suggested by the applicant company delegates that the simple dosing regimen would improve patient adherence. Members were referred to the clinical expert summary and the views of clinical experts in Wales were noted.

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 highlighted the key aspects of the case for cost-effectiveness identified within the ASAR. The strengths and weaknesses of the submission were highlighted. The company delegates were invited to respond to his synopsis. It was noted that the medicine was dominant over both comparators. Members took account of the projected budget impact.

It was confirmed that no patient or patient organization views had been submitted and there were no wider societal issues of note.

The Chairman referred to the applicant company's response to the preliminary recommendation and offered opportunity to the delegates to provide further comment. The Chairman sought and received confirmation from the applicant company delegates' that the process had been fair and transparent, and all issues had been adequately addressed.

#### **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:

**Umeclidinium/vilanterol (as trifenate) (Anoro<sup>®</sup> Ellipta<sup>®</sup>▼) is recommended as an option for use within NHS Wales as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).**

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

**13. Feedback from AWPAG Meeting 10<sup>th</sup> December 2014**

Mrs Louise Howard-Baker, AWPAG Chair, presented the draft minutes of the AWPAG meeting held on 10<sup>th</sup> December 2014 and highlighted work currently on-going. The Chairman thanked AWPAG for the delivery of AWMSG's work programme.

**14. [Respiratory Prescribing Analysis with Cluster Level Comparators](#)**

The Chairman invited Ms Kath Haines, Head of WAPSU, to present Enclosure 10 – respiratory prescribing analysis with cluster level comparators. Ms Haines explained that the document provides a detailed analysis of respiratory therapeutic area prescribing at national, health board and GP cluster level. The report also incorporates GP cluster level comparators for the respiratory prescribing therapeutic area. This presentation allows prescribing leads in GP clusters and health boards to benchmark their prescribing data against the most similar GP clusters in NHS Wales in terms of specific disease prevalence and socio-economic factors. The Chairman opened the discussion. Members welcomed the availability of this information and acknowledged the valuable role of WAPSU in producing the analysis.

**15. All Wales Advice on the Role of Oral Anticoagulants – Implementation Documents**

The Chairman invited Dr Tessa Lewis, AWTTTC Medical Lead, to present Enclosure 11. Dr Lewis explained that the guidance document, 'All Wales advice on the role of Oral Anticoagulants', was endorsed by AWMSG in September 2014. This document promotes the safe and effective use of oral anticoagulants for the treatment of stroke and systemic embolism in people with non-valvular atrial fibrillation and warfarin for all indications. The paper being presented to members provides a [summary assessment for all people established on oral anticoagulant therapy](#) and [implementation considerations for health boards](#). The Chairman opened the discussion. Members welcomed the document and commented that a template needs to be fully incorporated into the clinical IT systems which would help implementation of AWMSG document. Mrs Sue Murphy agreed to explore this outside of the meeting. It was noted that the evidence-base is changing and a review will be required in twelve months. The Chairman closed the discussion by confirming AWMSG's endorsement of the implementation documents.

**16. Eculizumab for treating atypical haemolytic uraemic syndrome**

Note - this agenda item had been taken during the morning session.

The Chairman welcomed a representative of Alexion Pharmaceuticals, the marketing authorisation holder, who joined the meeting.

The Chairman invited Mrs Samuels to present the background and set the context of the discussion. The Chairman reminded members that AWMSG had committed to the NICE Highly Specialised Technology process in November 2013. He explained the role of AWMSG was to consider the implementation plan proposed by WHSSC in light of the publication of the NICE Final Evaluation Determination in relation to Eculizumab for treating atypical haemolytic uraemic syndrome.

The Chairman invited Dr Geoffrey Carroll to identify issues highlighted by WHSSC in relation to implementation of the NICE HST advice within Wales. Dr Carroll outlined the proposed disciplined approach developed by WHSSC to establish a clear access plan which involved working with the Nationally Designated Centre in Newcastle via an agreed shared care commissioner led clinical access policy. He explained that in order to maximise the benefit to patients in Wales it would be important to set up this collaborative approach between

clinicians in Wales and the treatment centres in England. Dr Carroll expressed concern over the financial risk to WHSSC (based on the list price, 10 patients would cost £3.31 million to treat per annum, cumulative) and highlighted the significant risk of affordability. He explained that implementing this advice in Wales would result in significant displacement activity as WHSSC would be required to disinvest in services in other key areas, for example, cancer, cardiac and mental health. He suggested that an open and transparent process for disinvestment should be adopted, and stakeholders (clinicians and patients) should have the opportunity to be part of the decision process so that they are fully aware of what services will be disinvested in (including the cessation of funding for new services). Dr Carroll highlighted the principles of Prudent Healthcare.

The Chairman thanked Dr Carroll for developing the paper and opened the discussion. Professor Cohen raised the issue of opportunity costs and reminded members that health benefits gained by a very small number of patients would result in health benefits lost for a significantly large number of patients. The Chairman reminded members of their advisory role to Welsh Government and asked members to recognize the full context of their decision to adopt wider societal principles. Members agreed that the implementation of each statement of NICE HST advice needs to be considered on an individual basis so that there is opportunity to highlight areas of concern in relation to implementation. There was general agreement not to diverge from NICE principles and methodology, as there was recognition of its high standing and expertise. A delegate from Alexion confirmed that the NICE HST process was robust and vigorous. He suggested that the implementation costs had been over-estimated and referred to the PPRS which would apply for the next four years. Members agreed to continue to align their position with that of NICE. The patient representative reminded members of the importance of equity of access to this medicine across the UK. There was an understanding that the process developed enabled full disclosure of information, highlighting the practical and financial implications of implementing NICE HST advice. The Chairman asked whether AWMSG could work with WHSSC to identify opportunity costs. The Chairman concluded by thanking AWMSG members and the Alexion delegate for the helpful and healthy debate. He confirmed AWMSG's support to adopt the NICE HST advice.

The Chairman confirmed the date of the next meeting on **Wednesday, 25<sup>th</sup> March 2015** and closed proceedings.