Enclosure No:	**1/AWMSG/0318**
Agenda Item No:	**4** – Minutes of previous meeting
Author:	Chair, AWMSG
Contact:	Tel: 029 20716900 E-Mail: awttc@wales.nhs.uk

ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

Draft minutes of the AWMSG meeting held Wednesday, 14th February 2018 commencing 9.30 am at the Park Inn Hotel, Cardiff North, Circle Way East, Llanedeyrn, Cardiff, CF23 9XF

VOTING MEMBERS PRESENT:			**Did not participate in**
1.	Dr Stuart Linton	Chair & Hospital Consultant	
2.	Professor John Watkins	Vice Chair & Consultant in Public Health Medicine	1-4
3.	Dr Jeremy Black	General Practitioner	
4.	Dr Anwen Cope	Healthcare professional eligible to prescribe	
5.	Mr Stuart Davies	Finance Director	
6.	Professor Dyfrig Hughes	Health Economist	
7.	Mr Stefan Fec	Community Pharmacist	
8.	Dr Sian Lewis	Welsh Health Specialised Services Commission	
9.	Dr Emma Mason	Clinical Pharmacologist	
10.	Mrs Susan Murphy	Managed Sector Primary Care Pharmacist	
11.	Mr Farhan Mughal	ABPI Cymru Wales	
12.	Mr Chris Palmer	Lay Member	
13.	Dr Mark Walker	Medical Director	
14.	Mr John Terry	Managed Sector Secondary Care Pharmacist	
15.	Mrs Louise Williams	Senior Nurse	**1-5**

IN ATTENDANCE:
Dr Saad Al-Ismail, NMG Chair
Mrs Karen Samuels, Head of PAMS, AWTTC
Ms Kath Haines, Head of WAPSU, AWTTC
Mrs Ruth Lang, Liaison Manager, AWTTC

AWTTC Leads:
Mr Richard Boldero, WAPSU Pharmacist
Dr Caron Jones, Senior Scientist, AWTTC
Dr Stuart Keeping, Senior Scientist, AWTTC
Mrs Claire Thomas, WAPSU Pharmacist
Ms Kelly Wood, Senior Scientist, AWTTC

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
EMIG	Ethical Medicines Industry Group
EOL	End of life
FAR	Final Appraisal Recommendation
FDA	US Food and Drug Administration
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Board
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
NPI	National Prescribing Indicator
PAMS	Patient Access to Medicines Service
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
WHO	World Health Organization
WHSSC	Welsh Health Specialised Services Committee
WPAS	Wales Patient Access Scheme

1. Welcome and introduction

The Chair welcomed members.

2. Apologies

Dr Catherine Bale and Dr Sue Jeffs, Hospital Consultant representative
Ms Karen Eveleigh, Welsh Government representative

3. Declarations of interest

Members were reminded to declare any interests.

4. Minutes of previous meeting

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

5. Appraisal 1: Full Submission WPAS

Rolapitant (Varuby®) for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults.

The Chair confirmed that as the appraisal had an associated Wales Patient Access Scheme it would be undertaken in private to protect commercial confidentiality.

The Chair welcomed delegates from Tesaro UK Ltd and it was confirmed that individuals in the public gallery were staff of AWTTC and Welsh Government.

The Chair 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 Chair 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.

Dr Stuart Keeping, the AWTTC Appraisal Lead, set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR. Members were informed that the applicant company proposed that rolapitant should be considered for use in:

- Cisplatin-based highly emetogenic chemotherapy (HEC) as first-line therapy
- Carboplatin-based moderately emetogenic chemotherapy (MEC) in line with international guidelines, where patients currently only received double therapy

Dr Keeping clarified the main comparators included in the company submission – aprepitant (in combination with double therapy) for cisplatin-based HEC and placebo (in combination with double therapy) for carboplatin-based MEC.

Dr Saad Al-Ismail confirmed that NMG had appraised rolapitant on Wednesday 10th January 2018, and that NMGs recommendation was that rolapitant is not recommended for use within NHS Wales for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults. The case for cost-effectiveness had not been proven.

The Chair opened discussion in relation to clinical effectiveness. It was noted that clinical experts had not identified any unmet need in relation to the indication. It was considered that there are currently efficacious antiemetics, with a choice if patients do not tolerate one of the currently available treatments or would prefer a different option. The advantage of a once daily preparation on Day 1 of each treatment cycle was highlighted. One clinical expert had raised a concern in

relation to the governance and education of aprepitant, netupitant/palonosetron (NEPA) and rolapitant as they require different doses of dexamethasone; suggesting this would need to be addressed by the health boards as it could lead to potential errors in prescribing and administration. Clinical experts suggested that aprepitant would be considered for secondary prophylaxis for MEC and not as a first-line treatment. It was noted that the number of patients requiring secondary prophylaxis would be small.

Clarification was sought in relation to the study design for the two patient subgroups. It was noted that the indirect treatment comparison found no significant differences between rolapitant and aprepitant (for HEC) or between rolapitant and placebo (for MEC). The uncertainty around the effectiveness of rolapitant compared to the comparators was highlighted. The company delegates accepted that it was difficult to address the specific differences in the patient populations. The company delegates confirmed that there were no plans to undertake a noninferiority study. The company delegates suggested that one pill at the beginning of each therapy cycle would improve compliance versus three pills of aprepitant per cycle. It was noted that adverse events were manageable and in line with those usually observed with antiemetic therapy. The company delegates confirmed that a study was currently ongoing looking at interactions with analgesics/opioids.

The Chair confirmed that no patient organisation questionnaires had been submitted and Mr Palmer informed members of the organisations that had been approached by AWTTC. There were no further wider societal issues of note.

Professor Dyfrig Hughes provided an overview of the case for cost-effectiveness as outlined in the ASAR. It was noted that two cost utility analyses had been submitted; one comparing rolapitant with aprepitant for the HEC patient population, and the second comparing rolapitant versus double therapy for carboplatin-based MEC patients. Professor Hughes explained that for HEC patients rolapitant was less costly and less effective and for MEC patients it would be more effective and more costly. Members acknowledged that the MEC results generated uncertainty and the company delegates acknowledged the complications and encouraged a simplistic approach. The Chair confirmed that a second comparator medicine, NEPA had an associated patient access scheme and commercial confidentiality was to be respected. The company delegates therefore left the room for a short period whilst members discussed the cost-effectiveness and budget impact of rolapitant compared to NEPA.

The Chair referred to the response from Tesaro UK Ltd to the preliminary recommendation and asked the delegates if they wished to make any closing remarks. The delegates drew members' attention to the additional benefits of rolapitant in clinical practice as outlined in their response to the preliminary recommendation. The delegates thanked AWMSG for the opportunity to input into the discussion and respond to questions. In concluding, the Chair thanked the company delegates and, having received confirmation that the appraisal process had been fair and transparent and that all relevant issues had been discussed, the Chair closed the appraisal.

Appraisal decision subsequently announced in public:
The Chair 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:

Rolapitant (Varuby®) is not recommended for use within NHS Wales for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults. The case for cost-effectiveness has not been proven.

The Chair announced that confirmation of AWMSG's recommendations would be forwarded within five working days to the applicant company, who 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.

6. Chair's report

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

Adalimumab (Humira®) is recommended as an option for use within NHS Wales for the treatment of paediatric chronic non-infectious anterior uveitis in patients from two years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

In the absence of a submission from the holder of the marketing authorisation, Budesonide (Entocort CR®) cannot be endorsed for the induction of remission in patients with active microscopic colitis

In the absence of a submission from the holder of the marketing authorisation, Midostaurin (Rydapt®) cannot be endorsed as monotherapy for the treatment of adult patients with aggressive systemic mastocytosis, systemic mastocytosis with associated haematological neoplasm, or mast cell leukaemia

In the absence of a submission from the holder of the marketing authorisation, Pasireotide (Signifor®) cannot be endorsed for the treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed

In the absence of a submission from the holder of the marketing authorisation, Sofosbuvir (Sovaldi®) in combination with other medicinal products cannot be endorsed for the treatment of chronic hepatitis C in adolescents aged 12 to < 18 years

In the absence of a submission from the holder of the marketing authorisation, Telotristat ethyl (Xermelo®) cannot be endorsed for the treatment of carcinoid syndrome diarrhoea in combination with somatostatin analogue (SSA) therapy in adults inadequately controlled by SSA therapy

The Chair confirmed that an independent review panel (IR) had been convened on 23rd January to explore concerns expressed by the marketing authorisation holder in relation to AWMSG's appraisal of afamelanotide (Scenesse®). The Chair confirmed he would report the outcome of the IR at the next AWMSG meeting.

The Chair confirmed that a Clinician and Patient Involvement Group (CAPIG) meeting had been convened on 24th January to explore the benefits to patients, families/carers and clinicians of levodopa-carbidopa intestinal gel (Duodopa). He confirmed that AWMSG would be asked to reconsider their recommendation to take into account the issues highlighted at the CAPIG meeting.

The Chair thanked members of AWMSG, NMG and AWPAG who had attended the training day held in Cardiff on 17th January. The Chair confirmed that next year's event would take into account the feedback received on the day.

The Chair informed members that Mrs Ellen Lanham would be stepping down as community pharmacist member and would be replaced by Mr Stefan Fec. The Chair thanked Mrs Lanham for her invaluable contribution to AWMSG over a number of years. The Chair confirmed that a nomination for a deputy community pharmacist would be sought from the Royal Pharmaceutical Society in Wales.

The Chair confirmed that Dr Iolo Doull, the newly appointed Deputy Medical Director at WHSSC, had been nominated as WHSSC representative on AWMSG and would be attending his first meeting in March.

The appraisals scheduled for the next AWMSG meeting to be held on 14th March 2018 in Cardiff were announced:

Misprostol (Mysodelle®) for the induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated.
Applicant company: Ferring Pharmaceuticals.

Levodopa-carbidopa intestinal gel (Duodopa®) for the treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.
Applicant company: AbbVie Ltd.

The Chair asked members to contact AWTTC ahead of the next meeting if they had any personal or non-personal interests to declare. Patients, patient organisations and patient carers were invited to submit their views on the medicines to be appraised via the AWMSG website or by contacting Ruth Lang at AWTTC for further information on the appraisal process and future work programme.

7. AWMSG Five Year Strategy 2018–2023

Dr Bracchi introduced the draft AWMSG Five Year Strategy 2018–2023 and gave an overview of the development of the strategy document to date. Dr Bracchi highlighted the main changes to the document following the consultation and having taken members' comments into account. Consultation comments were tabled. Dr Bracchi highlighted the positive feedback received. The Chair opened discussion and invited further comment. He explained that the final version of the document would be brought back to AWMSG in March for endorsement.

Representatives from WHSSC asked AWMSG to develop tools to help with decision-making on new medicines. WHSSC representatives asked AWMSG to review their techniques for appraising medicines for rare diseases and consider what process would be applied to new targeted therapies, such as stem cell treatments. The Chair confirmed that he had met with the Cabinet Secretary on Monday 13th February, this issue had been raised. It was agreed that AWMSG would need an objective approach for these new therapies and would need to consider appropriate techniques and evaluations. There was an acknowledgement that the strategy needs to reflect on the previous strategy and adapt to the ever-changing NHS environment. Members asked Dr Bracchi to strengthen the recommendation on co-production and provide more clarity on the work proposed and outcomes. There was discussion over the work ongoing in relation to resource reallocation and disinvestment. Members agreed that value for money criteria would be helpful. It was noted that the Chief Pharmacists Peer Group were leading on this area and members asked that the stakeholder leads be included in the document. Members discussed the patient safety challenge and it was confirmed that AWTTC were working with Audit Plus to look at safety issues in prescribing. A suggestion was made to clarify the wording in section 3.1 hospital admissions. Dr Bracchi confirmed that a number of workshops would need to be convened to ensure that all stakeholders were involved in further discussions and had full involvement in moving the AWMSG strategy forward.

The Chair closed the discussion and thanked Dr Bracchi for his hard work and signalled AWMSG's approval of the recommendations in the strategy. The Chair thanked members for the valuable discussion and requested that they make suggestions for volunteers to lead on working towards the specific recommendation outcomes and provide Dr Bracchi with any specific wording outside of the meeting.

8. National Prescribing Indicators 2017–2018: Analysis of Prescribing Data to September 2017

Mrs Claire Thomas and Mr Richard Boldero presented the *National Prescribing Indicators 2017–2018: Analysis of Prescribing Data to September 2017* for information and highlighted to members the prescribing areas where significant improvements had been made in both primary and secondary care.

There was discussion around the heat-map showing health board variation in practices achieving the threshold and whether there were lessons that could be learned from the better achieving health boards. Claire Thomas highlighted that the Best Practice Day, due to take place on 10 July 2018, provides an ideal forum for this kind of discussion, as does SHARE, AWTTC's online community.

There was discussion of the increase in pregabalin and gabapentin prescribing, and possible reasons for this were explored.

9/10. National Prescribing Indicators 2018–2019

It was confirmed that agenda items 9 and 10 would be taken in tandem.

National Prescribing Indicators 2018–2019 – Supporting information

Mrs Claire Thomas and Mr Richard Boldero presented the *National Prescribing Indicators (NPIs) 2018–2019* and the *NPIs 2018–2019 Supporting Information for Prescribers*. Members were informed of the new and changed NPIs, and those that will be retired. Members' thoughts on implementation were welcomed.

There was discussion of the biosimilars section, in particular around wording which could encompass use of the best value biological medicine. More clarity was requested around anticipated benefits and it was agreed that the text should be amended to reflect national procurement deals as well as local arrangements. There was the suggestion to replace 'cost effective biological medicines' with 'best value biological medicines' and it was confirmed that this would be considered. It was also confirmed that changes to rituximab information would be made.

The Prescribing Safety Indicators were welcomed and there was discussion of conducting patient review. Susan Murphy will send a link to a British Journal of General Practice article on prescribing safety measures which may be of interest. The measure dealing with number of patients with a peptic ulcer who have been prescribed non-steroidal anti-inflammatory drugs without a proton pump inhibitor (PPI) was discussed and there were questions around the inclusion of PPIs and not histamine 2 receptor antagonists (H2RAs). It was explained that this was to align with pre-determined criteria within Audit+. However, in future years if consultation identifies the requirement for H2RAs to also be included then this could be incorporated within the NPI proposal paper.

Antibacterial items were raised with particular focus on the discrepancy between Wales and England. Claire Thomas offered an explanation based on these having been Commissioning for Quality and Innovation indicators in England. The long-acting insulin analogue trend was also raised and reasons for a relative lack of improvement in primary care were discussed.

Members were directed towards SHARE, AWTTC's online community, as a useful forum for raising questions around the NPIs and for those health boards showing a positive trend in particular indicators to share details of the initiatives that have brought about these improvements.

The Chair closed the discussion and confirmed AWMSG's endorsement of the NPIs for 2018–2019.

11. Feedback from All Wales Prescribing Advisory Group meeting held on 13th December 2017

Ms Kath Haines fed back from the AWPAG meeting held on 13th December 2017 outlining the work in progress. Members were informed that AWPAG had discussed the Best Practice Day to be held on 10 July 2018 and topics had been suggested. It was noted that feedback from the event held this year had been very positive, especially in relation to the patient perspective.

12. Appraisal 2: Limited Submission

Lopinavir/ritonavir (Kaletra®) 80 mg/20 mg oral solution for use in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected children aged from 14 days to less than 2 years old.

The Chair welcomed delegates from Abbvie Ltd.

The Chair 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 Chair 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 Chair informed members that the application had been considered eligible for a limited submission and no cost-effectiveness information is required. He confirmed that for a limited submission the marketing authorisation holder would be expected to provide evidence of budgetary impact in comparison to the existing comparator product(s). The Chair reiterated 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 submission.

Dr Caron Jones, the AWTTC Appraisal Lead, set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR. Dr Jones informed members that this medicine was use in patients aged 2 years and over in the same indication.

Dr Al-Ismail confirmed that NMG had appraised lopinavir/ritonavir on Wednesday 10th January 2018 and NMGs recommendation was that lopinavir/ritonavir is recommended as an option for use within NHS Wales in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected children aged from 14 days to less than 2 years old.

The Chair opened discussion in relation to clinical effectiveness. It was noted that lopinavir/ritonavir is the only ritonavir-boosted protease inhibitor licensed for children aged from 14 days to 2 years old. Clinical experts highlighted that there are very few children in Wales with HIV and the number of patients under 2 years of age eligible for this medicine was expected to be very small. Clinical experts stated that a wide range of unlicensed antiretrovirals are used on an individual patient basis, guided by clinicians with expertise in this area. Clinical experts welcomed an additional treatment option to enable clinicians to construct a treatment regime that is suitable for the majority of patients. One member queried the gap in the licence, i.e. patients younger than 14 days old. The company delegates clarified that the licence only applies at 14 days and above and explained other treatment scenarios depending on the viral load of the mother.

The Chair referred members to the budget impact estimate.

The Chair confirmed that no patient organisation questionnaires had been submitted and Mr Palmer informed members of the organisations that had been approached by AWTTC.

The Chair referred to the response from AbbVie Ltd to the preliminary recommendation and asked the delegates if they wished to make any closing remarks. The delegates thanked AWMSG for the opportunity to input into the discussion and respond to questions. In concluding, the Chair thanked the company delegates and, having received confirmation that the appraisal process had been fair and transparent and that all relevant issues had been discussed, the Chair closed the appraisal.

Appraisal decision subsequently announced in public:
The Chair 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:

Lopinavir/ritonavir (Kaletra®) is recommended as an option for use within NHS Wales in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected children aged from 14 days to less than 2 years old.

The Chair announced that confirmation of AWMSG's recommendations would be forwarded within five working days to the applicant company who 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.

13. Appraisal 3: Limited Submission

Lacosamide (Vimpat®) 50 mg, 100 mg, 150 mg and 200 mg film-coated tablets; 10 mg/ml syrup; 10 mg/ml solution for infusion for use as an adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in children from ≥ 4 years of age to ≤ 15 years of age with epilepsy.

The Chair welcomed delegates from UCB Pharma Ltd.

The Chair 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 Chair 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 Chair informed members that the application had been considered eligible for a limited submission and no cost-effectiveness information is required. He confirmed that for a limited submission the marketing authorisation holder would be expected to provide evidence of budgetary impact in comparison to the existing comparator product(s). The Chair reiterated 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 submission.

Ms Kelly Wood, the AWTTC Appraisal Lead, set the context of the appraisal and relayed the key aspects of the submission as set out in the ASAR. It was noted that the application covered a minor licence extension for use in children.

Dr Al-Ismail confirmed that NMG had appraised lacosamide on Wednesday 10th January 2018, and the recommendation was that lacosamide is recommended as an option for use within NHS Wales as adjunctive therapy in the treatment of partial-onset seizures with or without secondary

generalisation in children from ≥ 4 years of age to ≤ 15 years of age with epilepsy.

The Chair opened discussion in relation to clinical effectiveness. There were no specific outstanding issues of note. Members discussed potential interactions. Experts welcomed an additional treatment option for treating partial epilepsy where other medicines had failed. One expert found it helpful to treat nocturnal frontal seizures. The good side effect profile, high tolerability and efficacy were noted. Clinical expert opinion sought by AWTTC suggested that lacosamide is established treatment in adults as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation.

It was noted that the SMC has recommended restricted use for patients with refractory epilepsy in Scotland. The Chair referred members to the budget impact estimates.

The Chair confirmed that no patient organisation questionnaires had been submitted and Mr Palmer informed members of the organisations that had been approached by AWTTC. There were no wider societal issues of note.

The Chair referred to the response from UCB Pharma Ltd to the preliminary recommendation and asked the delegates if they wished to make any closing remarks. The delegates thanked AWMSG for the opportunity to input into the discussion and respond to questions. In concluding, the Chair thanked the company delegates and, having received confirmation that the appraisal process had been fair and transparent and that all relevant issues had been discussed, the Chair closed the appraisal.

Appraisal decision subsequently announced in public:
The Chair 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:

Lacosamide (Vimpat®) is recommended as an option for use within NHS Wales as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in children from ≥ 4 years of age to ≤ 15 years of age with epilepsy.

The Chair announced that confirmation of AWMSG's recommendations would be forwarded within five working days to the applicant company who 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.

14. Appraisal 4: Limited Submission
Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (Symtuza®) 800 mg/150 mg/200 mg/ 10 mg film-coated tablet for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents (aged 12 years and older with body weight at least 40 kg).
The Chair welcomed delegates from Janssen-Cilag Ltd.

The Chair 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 Chair 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 Chair informed members that the application had been considered eligible for a limited submission and no cost-effectiveness information is required. He confirmed that for a limited submission the marketing authorisation holder would be expected to provide evidence of

budgetary impact in comparison to the existing comparator product(s). The Chair reiterated 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 submission.

Dr Caron Jones the AWTTC Appraisal Lead, set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR.

Dr Al-Ismail confirmed that NMG appraised Symtuza® on Wednesday 10th January 2018, and recommended that Symtuza® should be available in NHS Wales as an option for restricted use in patients currently taking Rezolsta® in combination with Descovy®. It was the view of NMG that Symtuza® should not be recommended outside of this subpopulation.

The Chair opened discussion in relation to clinical effectiveness. It was noted that Symtuza® would only be used in patients currently taking Rezolsta® in combination with Descovy®. Dr Jones informed members that the individual components of Symtuza® had previously been recommended by AWMSG as the fixed dose combinations Rezolsta® (darunavir/cobicistat) and Descovy® (emtricitabine/tenofovir alafenamide). It was highlighted that switching patients from other medications would have additional cost to NHS Wales. Dr Al-Ismail highlighted that the evidence provided by the marketing authorisation holder only supported use in the restricted patient population. Members were reminded of the broader remit of AWMSG and the potential to recommend use in the wider context was noted. The ABPI representative reiterated that SMC had recommended use for the whole licensed indication based on an abbreviated submission. It was suggested that a restricted recommendation would cause a societal issue. Clinical experts reported that as a single, once-daily tablet, Symtuza® would be an attractive option for patients. One expert suggested that protease inhibitors are a preferred treatment choice for patients who may struggle with compliance and a reasonable proportion of patients may choose to switch therapy to Symtuza®. Experts welcomed an additional treatment option.

The Chair confirmed that no patient organisation questionnaires had been submitted and Mr Palmer informed members of the organisations that had been approached by AWTTC.

The Chair referred to the response from Janssen-Cilag Ltd to the preliminary recommendation and asked the delegates if they wished to make any closing remarks. The company delegates drew attention to the key issues outlined in their response to the preliminary recommendation. They expressed their view that a restricted recommendation would be inconsistent with previous AWMSG decisions where other tenofovir alafenamide fumarate (TAF) based therapies were recommended without restrictions and allowed switches for current TAF patients. The delegates thanked AWMSG for the opportunity to input into the discussion and respond to questions. In concluding, the Chair thanked the company delegates and, having received confirmation that the appraisal process had been fair and transparent and that all relevant issues had been discussed, the Chair closed the appraisal.

Appraisal decision subsequently announced in public:
The Chair 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/cobicistat/emtricitabine/tenofovir alafenamide (Symtuza®) is recommended as an option for use within NHS Wales for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents (aged 12 years and older with body weight at least 40 kg).

The Chair announced that confirmation of AWMSG's recommendations would be forwarded within five working days to the applicant company who 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.

15. All Wales Guide: Pharmacotherapy for Smoking Cessation

Mrs Sian Evans, Consultant in Public Health, Public Health Wales, presented the All Wales Guide: Pharmacotherapy for Smoking Cessation. This document has been reviewed by Sian Evans and Rosemary Allgeier as three years have elapsed since its original publication.

Members were informed that amendments to the guide had been made in light of changes to available formulations and to reflect changes in the summaries of product characteristics, in particular that of varenicline. It was noted that a number of responses to the consultation had been received and acted upon. A section on e-cigarettes had been included. The Chair opened the discussion. There was a query regarding the availability of carbon monoxide (CO) testing in GP practices. Sian Evans confirmed that this is considered best practice; all services commissioned to provide specialist behavioural support use CO monitoring to encourage motivation during the quit attempt. Sian Evans confirmed that evidence shows the best outcomes are achieved where there is pharmacotherapy plus specialist behavioural support, which in Wales includes CO monitoring. Members were informed that the guidance is intended to encourage prescribers who are not able to offer their patients 20–30 minutes, or longer, of behavioural support to refer them via Help Me Quit to get the support that will give them the best chance of quitting, rather than supplying pharmacotherapy with limited support. This support may be offered via a range of services such as community pharmacies, hospitals, Stop Smoking Wales and some GP practices. The Chair closed the discussion and confirmed AWMSG's endorsement.

16. Safe Use of Proton Pump Inhibitors

Mr Richard Boldero presented an update of the 2013 Proton Pump Inhibitor (PPI) and Dyspepsia Resource Pack. The Chair invited comment. There was discussion around Table 2 which gives details of medicines which can cause or increase the risk of dyspepsia, gastrointestinal bleeding, or ulceration, and which should be reviewed and either discontinued or continued with gastroprotection in the form of a PPI if it is clinically justified. There was discussion around members' interpretation of this message and whether there was a need clarify this and the algorithm on the deprescribing of PPIs. There was a suggestion that medicines that can cause dyspepsia should be arranged in a hierarchy of risk. The Chair closed the discussion and confirmed AWMSG's endorsement subject to the amendments discussed.

17. Common Ailments Service Formulary

Mrs Gail Woodland, Pharmacist Team Leader – Prudent Prescribing, Welsh Medicines Information Centre, and Mrs Fiona Woods, Director, Welsh Medicines Information Centre, presented the formulary. It was highlighted to members that this is the second update of the formulary which was originally published in 2013 to support the Common Ailments Service. Members were informed that the document had been out to wide consultation and all responses had been actioned. A change to the formulary monograph on bacterial conjunctivitis was also made in light of a response to the consultation on the Patient Information Leaflets, which are being developed to accompany the formulary. The Chair opened discussion.

Members welcomed the document and several specific amendments to individual monographs were suggested. There were several suggestions on possible conditions for future inclusion in the service and it was confirmed that these would be considered at a later stage. It was highlighted that Patient Information Leaflets to accompany the formulary are being developed. The Chair closed the discussion and confirmed AWMSG's endorsement of the formulary subject to the minor amendments discussed.

The Chair confirmed the date of the next meeting on Wednesday, 14th March 2018 and closed the meeting.

.