

Enclosure No:	1/AWMSG/1016
Agenda Item No:	1 – Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

Draft minutes of the AWMSG meeting held Wednesday, 21st September 2016 commencing 9.30 am at The Angel Hotel, Abergavenny, NP7 5EN

VOTING MEMBERS PRESENT:

Did not
participate in

- | | | | |
|-----|----------------------|---|---|
| 1. | Prof John Watkins | Chair | |
| 2. | Mr Stephan Fec | Community Pharmacist | |
| 3. | Prof Dyfrig Hughes | Health Economist | |
| 4. | Dr Pushpinder Mangat | Welsh Health Specialised Services Committee | 5 |
| 5. | Dr Cath Bale | Hospital Consultant | |
| 6. | Mrs Alison Hughes | Managed Sector Primary Care Pharmacist | |
| 7. | Mr Chris Palmer | Lay Member | |
| 8. | Mr Rob Thomas | ABPI Cymru Wales | |
| 9. | Dr Anwen Cope | Healthcare Professional eligible to prescribe | |
| 10. | Mr John Terry | Managed Sector Secondary Care Pharmacist | |
| 11. | Dr Jeremy Black | General Practitioner | |
| 12. | Dr Mark Walker | Medical Director | |

WELSH GOVERNMENT:

Ms Karan Edwards

IN ATTENDANCE:

Dr Saad Al-Ismael, NMG Chair (for agenda items 10-18)

Mrs Karen Samuels, Head of Patient Access to Medicines Service, AWTTTC

Mrs Ruth Lang, Head of Liaison & Administration, AWTTTC

AWTTTC APPRAISAL LEADS:

Mrs Sabrina Rind, Senior Appraisal Scientist

Dr David Jarrom, Senior Appraisal Scientist

Dr Caron Jones, Senior Appraisal Scientist

List of Abbreviations:

ABPI	Association of the British Pharmaceutical Industry
ASAR	AWMSG Secretariat Assessment Report
AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
AWTTC	All Wales Therapeutics & Toxicology Centre
BMA	British Medical Association
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
WHO	World Health Organization
WHSSC	Welsh Health Specialised Services Committee
WPAS	Wales Patient Access Scheme

1. Welcome and introduction

The Chairman opened the meeting and welcomed members. The Chairman informed members that the first appraisal would be undertaken in private because of an associated patient access scheme. He confirmed that the meeting would subsequently open to the public at approximately 10:30 am.

2. Apologies

Dr Stuart Linton, Hospital Consultant / AWMSG Chair
Mr Stuart Davies and Mr Rob Holcombe, representing Finance Directors
Dr Emma Mason representing Clinical Pharmacologists
Dr Sian Lewis (Dr Pushpinder Mangat deputising)
Mrs Louise Williams and Mrs Mandy James representing Senior Nurses
Miss Anne Hinchliffe representing Public Health Wales

3. Declarations of interest

Members were reminded to declare any interests. There were none.

4. Minutes of previous meeting

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

5. Appraisal 1: Full Submission (WPAS)

Golimumab (Simponi®) for the treatment of adults with severe, active non radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C reactive protein and/or magnetic resonance imaging evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs

The Chairman welcomed representation from Merck Sharp & Dohme Ltd. The Chairman confirmed that all individuals remaining in the public gallery were part of AWTTTC and asked the company delegates for permission to proceed with the appraisal.

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

Dr Jones highlighted the key aspects of the submission outlined in the ASAR. Dr Jones informed members that SMC had recommended use in Scotland. Members were reminded that the NMG had appraised the medicine on 20th July 2016 and had supported use of golimumab (Simponi®) as an option for use within NHS Wales for the treatment of adults with severe, active non radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs. It was stated that the recommendation should apply only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

The Chairman opened discussion and invited members to seek clarification of any outstanding issues relating to the clinical effectiveness. Members questioned the applicant company delegates on the patient population and asked for clarification of disease duration. There was discussion about adherence and the comparative safety data. Dr Jones referred members to the summary of clinical expert views and highlighted the main issues. She also relayed the views of the clinical expert who attended NMG.

The Chairman invited Professor Hughes to comment on the case for cost-effectiveness. Professor Hughes confirmed his role as the AWMSG health economist informed the company

delegates that he had no involvement in the production of the ASAR but would highlight the relevant aspects of the case for cost-effectiveness. He explained why comparability was not appropriate in this circumstance. When discussing the budget impact, the company delegates informed members that a biosimilar comparator product had not entered the market prior to making the submission. It was noted that when taking into account the Wales Patient Access Scheme there would be no additional financial burden to NHS Wales. It was confirmed that the scheme applied to all indications. Members sought clarification in relation to the projected number of eligible patients.

The Chairman highlighted the role of the lay member in ensuring that patient, carer and public views and experiences inform decision-making. He confirmed that all members have had opportunity to read the individual patient organisation submission from the National Ankylosing Spondylitis Society. For the purposes of transparency he asked Mr Palmer to summarise the issues highlighted in the questionnaire. The Chairman asked members if there were any wider societal issues that required discussion. It was acknowledged that the once monthly administration offered a positive advantage to patients and an additional treatment option for clinicians.

The Chairman invited the pharmaceutical company delegates to comment and asked if they wished to summarise the key points for consideration prior to asking members to vote. The delegates highlighted that the submission was based on comparability, the medicine offered a once monthly simple injection and a homecare service would be provided.

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:

Golimumab (Simponi[®]) is recommended as an option for use within NHS Wales for the treatment of adults with severe, active non radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded within five working days. He informed company 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 meeting was opened to the public.

6. Chairman's Report

The Chairman announced that Dr Pushpinder Mangat had been appointed as deputy for Dr Sian Lewis representing WHSSC. He welcomed Dr Mangat to his first AWMSG meeting.

The Chairman confirmed that Welsh Government ratification of the following AWMSG advice had been received:

Olanzapine (ZypAdhera[®]) is recommended as an option for restricted use within NHS Wales. Olanzapine (ZypAdhera[®]) is licensed for the maintenance treatment of adult patients with schizophrenia sufficiently stabilised during acute treatment with oral olanzapine.

Olanzapine (ZypAdhera[®]) is restricted for use in a subpopulation of patients more appropriately managed with a long acting injection formulation because of difficulties adhering to an oral olanzapine regimen, indicated by recurrent relapse or exacerbation of symptoms. Olanzapine (ZypAdhera[®]) is not recommended for use within NHS Wales outside of this subpopulation.

Evolocumab (Repatha[®]) is recommended as an option for use within NHS Wales for the treatment of adults and adolescents aged 12 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies.

This recommendation applies only in circumstances where the approved Patient Access Scheme (PAS) is utilised or where the list/contract price is equivalent or lower than the PAS price.

Ceftolozane/tazobactam (Zerbaxa[®]) is recommended as an option for restricted use within NHS Wales for the treatment of the following infections in adults: complicated intra-abdominal infections; acute pyelonephritis; and complicated urinary tract infections.

Ceftolozane/tazobactam (Zerbaxa[®]) is recommended only following non responsive first line therapy due to resistance, i.e. where susceptibility has been confirmed and ceftolozane/tazobactam (Zerbaxa[®]) is considered the most clinically appropriate option following Consultant Microbiologist advice. Ceftolozane/tazobactam (Zerbaxa[®]) is not recommended for use within NHS Wales outside of this subgroup of patients. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Aprepitant (EMEND[®]) is recommended as an option for use within NHS Wales for the prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in patients from the age of 6 months to less than 18 years old. Aprepitant is given as part of combination therapy.

Blinatumomab (Blinicyto[®]) is recommended as an option for use within NHS Wales for the treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

Netupitant/palonosetron (Akynzeo[®]) is recommended as an option for restricted use within NHS Wales for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatinbased cancer chemotherapy. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price. Netupitant/palonosetron (Akynzeo[®]) is not recommended for use within NHS Wales for the prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy.

Lenalidomide (Revlimid[®]) is recommended as an option for restricted use within NHS Wales. Lenalidomide (Revlimid[®]) in combination with low-dose dexamethasone should be restricted for use within its licensed indication for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant and are unsuitable for thalidomide-containing regimens.

This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

Lenalidomide (Revlimid[®]) is not recommended for use within NHS Wales outside of this subpopulation.

Elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide (Genvoya[®]) is recommended as an option for use within NHS Wales for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human

immunodeficiency virus 1 (HIV-1) without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

Misoprostol (Mysodelle®) is not recommended for use within NHS Wales for the induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated. The case for cost-effectiveness has not been proven.

The Chairman confirmed that in the absence of a submission from the holder of the marketing authorisation the following statements of advice had been published on the AWMSG website:

Human coagulation factor X (Coagadex®) cannot be endorsed for use within NHS Wales for the treatment and prophylaxis of bleeding episodes and for perioperative management in patients with hereditary factor X deficiency.

Human normal immunoglobulin (Octagam 10%®) cannot be endorsed for use within NHS Wales for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP).

Afatinib (Giotrif®) cannot be endorsed for use within NHS Wales for the treatment of locally advanced or metastatic non-small cell lung cancer of squamous histology progressing on or after platinum-based chemotherapy.

Pitolisant (Wakix®) cannot be endorsed for use within NHS Wales in adults for the treatment of narcolepsy with or without cataplexy.

Ketorolac/phenylephrine (Omidria®) cannot be endorsed for use within NHS Wales for the maintenance of intraoperative mydriasis, prevention of intraoperative miosis and reduction of acute postoperative ocular pain in intraocular lens replacement surgery. This product is currently not marketed in the UK.

The Chairman announced the publication of final NICE Highly Specialised Technology advice in relation to ataluren (Translarna®) for treating children aged 5 and over with Duchenne muscular dystrophy caused by a nonsense mutation and confirmed that Welsh Government had ratified this advice for implementation in NHS Wales.

The Chairman confirmed that the AWMSG Steering Committee had approved the nomination of Dr Susanna Jacks as deputy GP member with an interest in therapeutics. Members were informed that Susanna had served a full term of office on the All Wales Prescribing Advisory Group.

The Chairman informed members that in January 2016, a Genomics Taskforce had been established to ensure Wales capitalises on recent advances in genomics for health and wealth. This led to the production of a Statement of Intent for Genomics and Precision Medicine in Wales which was published in March 2016. The Taskforce is now working to develop a wider Strategy for Genomics and Precision Medicine by Autumn 2016. The aim of the strategy is to create an internationally competitive environment for genomics and precision medicine to support the delivery of prudent healthcare for the population of Wales. The Taskforce is looking to engage with interested parties across Wales and has arranged a series of consultation workshops across Wales. The purpose of the meetings will be:

- To share information about plans for developing a Strategy for Genomics and Precision Medicine in Wales
- To allow stakeholders (including those from the public and patients, Higher Education Institutions, the NHS, Industry and the Third sector) to contribute their opinions and

- voice any concerns
- To capture the opinions of these key stakeholders to inform the development of the Strategy

The Chairman confirmed that workshops would be held in Cardiff, Swansea and North Wales. An AWMSG response had been requested by 5th September and, given the short deadline, it was not possible for AWMSG to submit a response by this date. The Chair indicated that there is likely to be opportunity for further consultation later in the Autumn should the Minister agree to publish the strategy once drafted. The Chair confirmed that a draft response prepared by AWTTTC would be circulated to members for comment and discussed by AWMSG in October.

The Chairman informed members of positive feedback on the AWMSG appraisal process received from a clinician who had recently input into AWMSG's appraisal process.

The Chairman announced the next meeting would be held on Wednesday, 12th October 2016 at the Park Inn, Cardiff and confirmed the appraisal schedule:

Appraisal 1: Full Submission

Insulin degludec (Tresiba[®])

For the treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year
Applicant Company: Novo Nordisk Ltd

Appraisal 2: Limited Submission

Eltrombopag (Revolade[®]) for the treatment of chronic immune (idiopathic) thrombocytopenic purpura patients aged from 1 to < 18 years who are refractory to other treatments (e.g. corticosteroids, immunoglobulins)

Applicant Company: Novartis Pharmaceuticals UK 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 on the medicines scheduled for appraisal.

The Chairman reminded members to sign and return the confidentiality statements to AWTTTC.

7. Appraisal 2: Full Submission

Green tea leaf extract (Catephen[®]) for the cutaneous treatment of external genital and perianal warts (condylomata acuminata) in immunocompetent patients from the age of 18 years

The Chairman welcomed delegates from Kora Healthcare. 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 invited the AWTTTC Appraisal Lead to set the context of the appraisal. Dr Jones highlighted the key aspects of the submission outlined in the ASAR and relayed the relevant issues identified in the appraisal. Dr Jones confirmed that SMC had supported restricted use in Scotland.

The Chairman asked members to highlight any outstanding issues of clinical effectiveness. Clarification was sought in relation to dosage patterns. Members asked the company

delegates to justify why there was no direct comparative data included in their submission. Members explored the side-effect profile. Members questioned the appropriateness of the evidence and Mrs Samuels confirmed that AWTTTC had been in dialogue with the applicant company since 2015 ensuring that the best available evidence was provided to AWMSG. The company delegates confirmed that prescribing will be restricted to specialist genitourinary medicine clinical leads. It was noted that NMG had appraised green tea leaf extract (Catephen[®]) on 20th July 2016 and supported use as an option for restricted use within NHS Wales. Dr Jones confirmed that Green tea leaf extract (Catephen[®]) is licensed for the cutaneous treatment of external genital and perianal warts (condylomata acuminata) in immunocompetent patients from the age of 18 years. Members were informed that NMG recommended that green tea leaf extract (Catephen[®]) should be restricted for use in patients not suitable for podophyllotoxin or who have not responded to treatment with podophyllotoxin and should not be recommended for use within NHS Wales outside of this subpopulation. Clarification was sought in relation to where the company had positioned the medicine in relation to the evidence submitted. Members were referred to the summary of clinical expert views and Dr Jones confirmed that the clinical expert had agreed it had been appropriately placed in the clinical pathway.

The Chairman invited Professor Hughes to comment on the case for cost-effectiveness. Professor Hughes confirmed his role as AWMSG health economist. He summarised the key aspects of the case for cost-effectiveness as outlined in the ASAR. He highlighted that adverse reactions and discontinuation rates had not been taken into account. He commented on the budget impact estimates and highlighted the potential cost savings to NHS Wales over a five year period.

The Chairman confirmed that no patient questionnaires had been received and asked Mr Palmer to inform members which organisations had been approached by AWTTTC. The Chairman asked members whether there were any wider societal issues that required discussion or clarification. The company delegates confirmed there would be cold-chain distribution of supply. Members were cognisant of the psychological effect on patients and the importance of having another treatment option for clinicians. Members took account of the broader public health issue. Members discussed titration of the product and noted the variation in number of tubes used.

The Chairman invited the company delegates if they wished to comment or highlight any further points of discussion. They had no further comment and, 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:

Green tea leaf extract (Catephen[®]) is recommended as an option for restricted use within NHS Wales. Green tea leaf extract (Catephen[®]) is licensed for the cutaneous treatment of external genital and perianal warts (condylomata acuminata) in immunocompetent patients from the age of 18 years. Green tea leaf extract (Catephen[®]) is restricted for use in patients not suitable for podophyllotoxin or who have not responded to treatment with podophyllotoxin. Green tea leaf extract (Catephen[®]) is not recommended for use within NHS Wales outside of this subpopulation.

The Chairman 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.

8. **Appraisal 3: Full Submission**

Brivaracetam (Briviact®) adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy

The Chairman welcomed delegates from UCB Pharma Limited. 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 alluded 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 the AWTTTC Appraisal Lead to set the context of the appraisal.

Dr Jarrom highlighted the key aspects of the submission outlined in the ASAR and relayed issues identified in the preliminary appraisal. He confirmed that NMG had appraised brivaracetam (Briviact®) on 20th July and had not supported use within NHS Wales as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy. The view of NMG was that the case for cost-effectiveness had not been proven. It was considered that the company's submission did not present sufficient evidence to demonstrate that brivaracetam (Briviact®) is cost-effective compared with the range of existing treatment option, and several uncertainties and limitations were highlighted in the economic model provided in the company's submission.

The Chairman opened the discussion in relation to clinical effectiveness. Clarification was sought in relation to the choice of comparators and the company delegates explained the background to the selection. It was noted that UCB anticipate that brivaracetam would be used similarly to these comparators in the treatment pathway and the delegates highlighted that the economic case for its use in clinical practice in NHS Wales had been robustly demonstrated in their submission. The Chairman referred members to the summary of clinical expert views and asked Dr Jarrom to highlight any key issues. Dr Jarrom highlighted the expert view that brivaracetam would be used as an add-on treatment in patients who were resistant to or could not tolerate existing adjunctive epilepsy treatments. Due to its availability as an intravenous formulation and therapeutic effectiveness from day one of administration, one expert had expressed a view that brivaracetam could benefit patients requiring the rapid addition of a second anti-epileptic medicine, such as for the emergency treatment of seizures in patients and those in intensive therapy units. It was suggested that the prescribing of brivaracetam would be infrequent and cautious initially, with increased prescribing in light of clinical experience.

The Chairman invited Professor Hughes to comment on the case for cost-effectiveness. Professor Hughes confirmed his role as AWMSG health economist. Professor Hughes summarised the case for cost-effectiveness as outlined in the ASAR. He commented on the budget impact and highlighted the potential cost-savings. He stated that the lack of titration is the only difference and the medicine was broadly comparable to the alternative treatments. Members explored the seizure-free and retention rates.

The Chairman asked Mr Palmer to relay the views of the patient organisation, Epilepsy Action Cymru. Mr Palmer highlighted that brivaracetam may provide seizure freedom for those people with epilepsy who are not seizure free. As there is no titration period, seizure freedom or a reduction in seizures, could come quicker for some patients, and this would be of particular

benefit to improving a person's quality of life.

The Chairman referred members to the comprehensive response from UCB Pharma and invited further comment from the company delegates. It was highlighted that brivaracetam would be prescribed by clinical specialists in epilepsy in a sub-set of patients and offered an additional treatment option to clinicians and patients in Wales. 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:

Brivaracetam (Briviact[®]▼) is recommended as an option for restricted use within NHS Wales. Brivaracetam (Briviact[®]▼) should be restricted to use in the treatment of patients with refractory epilepsy, who remain uncontrolled with, or are intolerant to, other adjunctive anti-epileptic medicines, within its licensed indication as adjunctive therapy in the treatment of partial-onset seizures (POS) with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy. Brivaracetam (Briviact[®]▼) is not recommended for use within NHS Wales outside of this subpopulation.

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded within five working days. He informed company 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. Feedback from AWPAG Meeting 22nd June 2016

The Chairman invited Mrs Louise Howard-Baker, AWPAG Chair, to present the draft minutes of the AWPAG meeting held on 22nd June. Mrs Howard-Baker highlighted the current and future areas of work of the group and informed members of membership changes. It was noted that representation from 'other professions eligible to prescribe' was vacant.

10. Prescribing of Low Molecular Weight Heparin in Wales

The Chairman invited Dr Robert Bracchi, AWTTTC Medical Adviser, to present Enc 6/AWMSG/0916 – a review of the prescribing of low molecular weight heparin in Wales. Dr Bracchi highlighted the aims of the document:

- To ensure that all patients receive appropriate anticoagulation in a timely manner
- To address prescribers' concerns relating to the safe prescribing of LMWH
- To promote consistent advice to patients via efficient and consistent clinical pathways for the prescribing and supply of LMWH
- To provide interim guidance to prescribers regarding the use of LMWH where the evidence base has yet to be established nationally

Dr Bracchi explained that the project was aligned to the recommendation in AWMSG's Medicines Strategy on Improving Health – Prescribing Guidance, in that AWMSG would work with health boards and other stakeholders to promote the safe, effective and cost-effective use of medicines in Wales. It was noted that an example of good practice for shared care had been included. Members discussed the paper and there was a suggestion that all patients should have a full blood count before initiating treatment. Members welcomed the document as an example of best practice. The Chairman confirmed AWMSG's endorsement of the paper and closed discussion.

11. Prescribing of Amiodarone for Atrial Fibrillation and Atrial Flutter in Wales

The Chairman invited Mrs Louise-Howard Baker to present Enc 7/AWMSG/0916 – an update of AWMSG’s guidance on the prescribing of amiodarone for atrial fibrillation and atrial flutter. Mrs Howard-Baker stated that the paper pertained to the AWMSG Five-Year Strategy 2013-2018 in working with health boards and other stakeholders to promote the safe, effective and cost-effective use of medicines in Wales. She explained the background to the work and confirmed that the best practice guidance had been developed and endorsed by AWMSG in 2010 to assist clinicians when reviewing patients taking amiodarone to establish the need for on-going treatment. The document presented updates the original guidance. The Chairman opened discussion and members shared their experiences and views. A suggestion was made that it should be made clear within the document that initiation by a general practitioner is inappropriate. It was also suggested that a reference to NICE clinical guidelines should be included. With these amendments the Chairman confirmed AWMSG’s endorsement of the updated guidance.

12. Safeguarding users of opioid patches by standardising patient/caregiver counselling

The Chairman invited Mrs Janet Thomas, Patient Safety Pharmacist at Betsi Cadwaladr University Health Board to present Enc 8/AWMSG/0916. Mrs Thomas highlighted the purpose of the project was to implement a counselling checklist that enables healthcare professionals and patients/caregivers to discuss important safety issues regarding the usage and storage of opioid patches, which is a national MHRA requirement. The project aimed to raise awareness of the key issues for healthcare professionals and reduce the risk of avoidable medication-related harm and associated hospital admissions. Members were informed that the checklist would form part of a patient/caregiver/healthcare professional educational programme and questionnaires would be used to evaluate impact and knowledge. Mrs Thomas confirmed that this project pertained to a number of the recommendations in AWMSG’s five-year medicines strategy. The Chairman opened discussion. There was discussion on the counselling of patients and members questioned how this would work in practice and where the responsibility for doing this should lie. There was a suggestion that a general practitioner could endorse the prescription so that it was clear that the responsibility should lie with the individual dispenser. Members welcomed the checklist and suggested that an intelligence gathering exercise be undertaken to establish whether NHS Wales would welcome similar checklists for other medicines. Mrs Thomas agreed to take this suggestion back to AWPAG. The Chairman confirmed AWMSG’s endorsement of the counselling checklist to improve medicines safety for patients in Wales.

13. Appraisal 4: Limited Submission

Rilpivirine (Edurant®) in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive patients from 12 years old to < 18 years old with a viral load ≤ 100,000 HIV-1 RNA copies/ml

The Chairman welcomed representation from Janssen-Cilag Limited. 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 invited the AWTTTC Appraisal Lead to set the context of the appraisal.

The Chairman 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 Chairman reiterated that monitoring of budget impact would be essential and AWMSG reserved to right to request a full submission if the budget impact exceeded that estimated in the submission.

Mrs Sabrina Rind, AWTTTC Appraisal Lead, provided an overview of the ASAR and relayed the view of NMG that use of rilpivirine (Edurant[®]) should be supported as an option within NHS Wales in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive patients from 12 years old to < 18 years old with a viral load \leq 100,000 HIV-1 RNA copies/ml.

The Chairman sought clarification as to whether there were any outstanding issues relating to the case for clinical effectiveness. Members sought clarification in relation to the frequency of depression in adolescents. There were no outstanding issues relating to the budget impact. The Chairman referred members to the patient organisation submission from HIV i-Base and their views that rilpivirine has an important role for people switching from efavirenz due to side effects and as part of the combination tablet Eviplera for people switching from Atripla. The organisation welcomed rilpivirine as an additional treatment option for people aged 12 and older.

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:

Rilpivirine (Edurant[®]▼) is recommended as an option for use within NHS Wales in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive patients from 12 years old to < 18 years old with a viral load \leq 100,000 HIV-1 RNA copies/ml.

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded within five working days. He informed company 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.

14. Appraisal 5: Limited Submissions

Emtricitabine/tenofovir alafenamide (Descovy[®]) in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus type 1 (HIV-1)

The Chairman welcomed delegates from Gilead Sciences Limited.

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 alluded 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 the AWTTTC Appraisal Lead to set the context of the

appraisal.

The Chairman 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 Chairman reiterated that monitoring of budget impact would be essential and AWMSG reserved to right to request a full submission if the budget impact exceeded that estimated in the submission.

Mrs Sabrina Rind, AWTTTC Appraisal Lead, provided an overview of the ASAR and confirmed that NMG had supported use of emtricitabine/tenofovir alafenamide (Descovy[®]) as an option for use within NHS Wales in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus type 1 (HIV-1).

The Chairman sought clarification as to whether there were any outstanding issues relating to the case for clinical effectiveness. Members noted the favourable renal safety profile. It was highlighted that patients did not require monitoring. Clinical experts welcomed a less toxic alternative treatment option which could be prescribed for a wider range of patients, including those with moderate renal impairment. The different strengths of Descovy also offered advantages clinically. The Chairman referred members to the budget impact estimates and members noted it was cost-neutral. There were no outstanding issues of note.

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:

Emtricitabine/tenofovir alafenamide (Descovy[®]) is recommended as an option for use within NHS Wales in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus type 1 (HIV-1).

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded within five working days. He informed company 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.

15. Guidance for partnership working between NHS organisations, primary care contractors, the pharmaceutical industry and the allied commercial sector in Wales

The Chairman invited Ms Kath Haines, Head of WAPSU, to present Enc 11/AWMSG/0916. Ms Haines explained the background and confirmed that guidance for partnership working had been developed through AWMSG in 2004 and disseminated by Welsh Government via a Welsh Health Circular in 2005. She highlighted the aim of the document is to encourage and promote an open and transparent approach to partnership working between NHS Wales, the pharmaceutical industry and the allied commercial sector. Ms Haines confirmed that in line with process the document had been reviewed, updated and, subject to AWMSG endorsement, would replace the previous version which is available on the AWMSG website. Mr Rob Thomas offered to raise awareness of the reviewed document at an ABPI conference in November.

16. All Wales NOAC Alert Card

Mrs Louise Howard-Baker presented Enc 12/AWMSG/0916 a non-vitamin K oral anticoagulant

(NOAC) alert card. She explained that the aim of the document is to improve patient safety by alerting health professionals that the patient is receiving anticoagulation therapy. Mrs Howard-Baker explained that for patients taking NOACs there is a potential high risk of bleeding. It is intended that all patients would be given an alert card containing safety and emergency information for patients and health professionals. The card provides important information to patients and includes signs and symptoms of bleeding. It also provides important information to healthcare professionals including patient details and dosing. It is intended that the alert card would be carried by the patient at all times and shown to every healthcare professional prior to treatment. Mrs Howard-Baker acknowledged the Northern England Strategic Clinical Network for producing the card, which has been adopted and translated into Welsh for use in NHS Wales. The Chair opened discussion. It was suggested that creatinine clearance information on the card did not necessarily reflect all the SPCs for the different agents. There was concern over the wording that antidotes 'may be available'. Mrs Howard-Baker confirmed that there was no opportunity to change the text of the card, as specified by the Northern England Strategic Clinical Network. Mrs Hughes highlighted errors in the Welsh translation. Dr Al-Ismail confirmed that a medicine-specific alert card is provided when the medicine is dispensed. It was suggested that AWPAG consider producing a NHS Wales NOAC alert card with input from Welsh haematologists and patients. The Chair closed discussion and confirmed that in light of the discussion the alert card could not be endorsed by AWMSG for use within NHS Wales.

17. Therapeutic Priorities and Clinical Effectiveness Prescribing Programme Summary 2016–2017

Ms Haines and Dr Louise Howard-Baker presented the Therapeutic Priorities and Clinical Effectiveness Prescribing Programme Summary 2016-2017 to AWMSG. Members were informed that in 2004 AWMSG had endorsed a non-mandatory All Wales Prescribing Incentive Scheme which aimed to encourage a common structure for prescribing incentive schemes across NHS Wales. The framework comprised of two equally weighted elements: prescribing indicators (national and health board defined) and a learning portfolio (National Prescribing Audits, WeMeReC educational material and other health board defined activity). In 2008, AWPAG undertook a review of schemes across Wales and the outcomes were considered by AWMSG. Members agreed that the scheme should continue to be available as a template for local adaptation. The Clinical Effectiveness Prescribing Programme (CEPP) document summarises the priorities which AWMSG were asked to consider and, if appropriate, endorse. The Chairman opened discussion and members shared experiences and provided comment on the document. There was a suggestion to include educationalists in order to change practice and ensure that the interaction between prescriber and patient is the best it can be. Members welcomed the data and agreed that the promotion and sharing of best practice between health boards will be crucial. There was an acknowledgement that the document will form the basis for discussion and would be a valuable tool in order to get the best outcomes for patients. The Chairman thanked AWPAG for developing this work and confirmed AWMSG's endorsement.

18. NPI 2015-2016 Annual Primary Care Prescribing Report

Ms Kath Haines, Head of WAPSU, presented Enc 14/AWMSG/0916 – an annual prescribing report on the AWMSG national indicators for 2015-2016. Ms Haines explained that the thirteen AWMSG national prescribing indicators (NPIs) are a means of promoting safe and cost-effective prescribing. A threshold level of prescribing/reporting is set for twelve out of the thirteen indicators and the report summarises prescribing against the set targets. It was noted that there had been an improvement at an All Wales level for all the NPIs except for proton pump inhibitors and inhaled corticosteroids compared to 2014-2015. Ms Haines highlighted that the launch of SPIRA provides health boards with an interactive application/dashboard which links NPI data to health board, locality, cluster and practice level. The Chairman confirmed AWMSG's endorsement of the report and closed the meeting.

Date of next meeting - Wednesday, 12th October 2016 in The Park Inn, Cardiff