Enclosure No:	**1/AWMSG/0613**
Agenda Item No:	**5** – Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY 8th MAY 2013 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY, NP7 5EN

VOTING MEMBERS PRESENT:			**Did not participate in**
1.	Professor Philip Routledge	Chairman	
2.	Dr Fraser Campbell	GP with Prescribing Lead role	**13-18**
3.	Dr Geoffrey Carroll	Welsh Health Specialised Services Committee	
4.	Professor David Cohen	Health Economist	
5.	Mrs Debbie Davies	Healthcare Professional eligible to prescribe	
6.	Mr Stuart Davies	Finance Director	
7.	Mr Stefan Fec	Community Pharmacist	
8.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health	
9.	Dr Stuart Linton	Hospital Consultant	**12-18**
10.	Dr Emma Mason	Clinical Pharmacologist	**12-18**
11.	Mrs Susan Murphy	Managed Sector Primary Care Pharmacist	**13-18**
12.	Mr Christopher Palmer	Lay Member	
13.	Mr Lance Richard	ABPI Cymru Wales	**12**
14.	Mr Roger Williams	Managed Sector Hospital Pharmacist	**12-18**
15	Professor John Watkins	Public Health Wales	**1-7**

IN ATTENDANCE:

16. Professor Roger Walker, Chief Pharmaceutical Officer, Welsh Government
17. Dr Robert Bracchi, NMG Chairman
18. Mrs Karen Samuels, Head of HTA & Medicines Management, AWTTC
19. Mrs Ruth Lang, Head of Liaison & Administration, AWTTC

ALL WALES THERAPEUTICS & TOXICOLOGY CENTRE (AWTTC)
APPRAISAL LEADS:

20. Mrs Sabrina Rind, Senior Appraisal Pharmacist
21. Mr Anthony Williams, Senior Appraisal Pharmacist
22. Mrs Gail Woodland, Senior Appraisal Pharmacist
23. Dr Claire Davis, Senior Appraisal Scientist
24. Dr David Jarrom, 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
CHMP	Committee for Medicinal Products for Human Use
DH	Department of Health
EMA	European Medicines Agency
FAR	Final Appraisal Recommendation
FDA	US Food and Drug Administration
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Boards
HTA	Health Technology Appraisal
IR	Independent Review
MHRA	Medicines and Healthcare products Regulatory Agency
MMPB	Medicines Management Programme Board
M&TCs	Medicines & Therapeutics Committees
NICE	National Institute for Health and Clinical Excellence
NMG	New Medicines Group
PAR	Preliminary Appraisal Recommendation
SMC	Scottish Medicines Consortium
TDAPG	Therapeutic Development Appraisal Partnership Group
T&FG	Task and Finish Group
WG	Welsh Government
WAPSU	Welsh Analytical Prescribing Support Unit
WPAS	Welsh Patient Access Scheme
WMP	Welsh Medicines Partnership

1. Welcome and introduction

The Chairman welcomed AWMSG members and members of the public. The Chairman welcomed Mr Lance Richard to his first AWMSG meeting and confirmed he would be representing ABPI Cymru Wales in relation to appraisal 1-6, and would be representing the applicant company, Eisai Limited, for the appraisal of perampanel (Fycompa®) – appraisal 7. The Chairman confirmed that appraisal 6 and 7 would be held in private, as the submissions contained commercially sensitive information associated with a Wales Patient Access Scheme. It was confirmed that AWMSG's recommendations to Welsh Government would be announced in public.

2. Apologies

Ms Ellen Lanham (Community Pharmacist, Mr Stefan Fec deputising)
Mr Christian Smith (Senior Nurse representative)
Dr Brendan Lloyd (Medical Director representative)

3. Declarations of interest

The Chairman reminded members to declare any interests pertinent to the agenda.

The Chairman confirmed that Mr Lance Richard will be unable to participate as a member in appraisal 7 - perampanel (Fycompa®), and will be joining his colleague to represent the applicant company, Eisai Limited.

Mr Roger Williams declared a personal specific interest in appraisal 4 - linagliptin/metformin (Jentadueto®), and the Chairman confirmed that Mr Williams would be required to leave the room whilst this appraisal was being undertaken.

4. Chairman's report

The Chairman confirmed that appraisal 6 and 7 would be conducted in private, as the submissions were associated with a Wales Patient Access Scheme which included commercially sensitive information.

Members were informed that following the announcement of the final appraisal recommendation in relation to pazopanib (Votrient®▼) on 20th March 2013, a request for an independent review (IR) had been received from GlaxoSmithKline Limited. The Chairman confirmed the AWMSG Steering Committee would be considering the grounds for the review later in the month and, in the interim, the appraisal process would be suspended. With this exception, It was confirmed the recommendations agreed at the March AWMSG meeting were awaiting Welsh Government ratification.

The Chairman announced the launch of a new AWMSG website www.awmsg.org.

The Chairman reported, in the absence of industry engagement, a number of statements of advice were in preparation. It was confirmed that the holders of the licence of these medicines had been informed that unless a Form B or Form C submission is received within the next fourteen days, Welsh Government consent would be sought to issue advice that the medicine could not be endorsed for use. The Chairman reiterated the need for companies to engage in the appraisal process within the appropriate timescales, so that patients in Wales can have timely access to new clinically effective and cost effective medicines.

The Chairman announced the appraisals scheduled for the next AWMSG meeting to be held in Abergavenny on Wednesday, 12th June 2013:

Appraisal 1: Nepafenac (Nevanac®) for the reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients
Applicant Company: Alcon Laboratories (UK) Ltd

Appraisal 2: Adalimumab (Humira®) for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs
Applicant Company: AbbVie Ltd

Appraisal 3: Ceftaroline fosamil (Zinforo®) for the treatment of the following infections: complicated skin and soft-tissue infections (cSSTI) and community-acquired pneumonia (CAP)
Applicant Company: AstraZeneca UK Ltd

Appraisal 4: C1-esterase inhibitor (Berinert®) for the treatment of acute episodes of hereditary angioedema type I and II (HAE)
Applicant Company: CSL Behring UK Ltd

The Chairman reminded members to declare any interests pertinent to the appraisals scheduled. The Chairman invited patients, patient organisations and patient carers to submit their views in relation to medicines scheduled for appraisal, and suggested they contact Ruth Lang at AWTTC for further information in relation to the future work programme.

5. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy. The Chairman signed the minutes as a true record of the meeting.

6. Appraisal 1 – Full submission

Aclidinium bromide (Eklira®Genuair®) for maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease

The Chairman welcomed representatives from the applicant company, Almirall Limited.

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. There were none.

The Chairman announced the statement, pertinent to all appraisals, 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 Mrs Gail Woodland, AWTTC assessment lead, to set the context of the appraisal. Mrs Woodland presented an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. Members were informed that a patient organisation submission had not been received.

The Chairman invited Dr Bracchi, NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Bracchi briefly summarised the issues discussed at NMG and relayed the preliminary recommendation of NMG.

The Chairman invited comment in relation to the case for clinical effectiveness. There was discussion over cardiovascular complications and clarification was sought in relation to the term 'high risk'. The company delegates were asked to explain the scale of symptomatic change and it was confirmed there was no clinical validation of the scale. Other issues highlighted included exercise endurance and the potential for substitution.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen explained the reasons why cost minimisation analysis was not the preferred technique for health economic evaluation. He highlighted the limitations in the case submitted for cost effectiveness. The company representative acknowledged the limitations. There was recognition that with the paucity of data the company had put their best case forward.

The Chairman referred members to the comprehensive clinical expert summary. There were no societal or budget impact issues of note.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates to highlight salient issues. Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Almirall Limited for engaging in the appraisal process and proceeded to the next appraisal.

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:

Aclidinium bromide (Eklira® Genuair®▼) 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.

7. Appraisal 2 – Full submission
Ferumoxytol (Rienso®) for the intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease. The diagnosis of iron deficiency must be based on appropriate laboratory tests

The Chairman welcomed representatives from the applicant company, Takeda UK Limited

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. There were none.

The Chairman invited Dr David Jarrom, AWTTC assessment lead, to set the context of the appraisal. Dr Jarrom presented an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. Dr Jarrom highlighted that the applicant company had only submitted evidence for a sub-population and use outside of this group of patients could not be considered. Members were informed a patient organisation submission had been received from the Kidney Wales Foundation and the National Kidney Federation.

The Chairman invited Dr Bracchi, NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Bracchi briefly summarised the issues discussed at NMG and relayed the preliminary recommendation of NMG that ferumoxytol (Rienso®▼) should be recommended as an option for restricted use within NHS Wales.

Members discussed issues relating to the case for clinical effectiveness. Clarification was sought over the reporting of adverse events and the safety profile. Dr Carroll commented on prevalence and populations and referred to the clinical expert summary. There was discussion over the number of eligible patients in Wales. The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen was critical of the cost minimisation analysis and inability to explore the uncertainties. He clarified the difference between financial analysis and economic analysis. Mr Palmer highlighted the salient issues within the two patient organisation submissions. There were no societal or budget impact issues of note.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates to highlight any additional information. Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Takeda UK Limited for engaging in the appraisal process and proceeded to the next appraisal.

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:

Ferumoxytol (Rienso®▼) is recommended as an option for restricted use within NHS Wales. Ferumoxytol (Rienso®▼) should only be used for the intravenous treatment of iron deficiency anaemia in non-haemodialysis dependent adult chronic kidney disease patients when oral iron is ineffective or cannot be used. Ferumoxytol (Rienso®▼) is not

recommended for use within NHS Wales outside of this subpopulation of patients. The diagnosis of iron deficiency must be based on appropriate laboratory tests.

8. Appraisal 3 – Full submission
Ingenol mebutate (Picato®) for the cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults

The Chairman welcomed the representatives of the applicant company LEO Laboratories Limited. The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. There were none.

The Chairman repeated the statement announced at the commencement of the appraisal session and confirmed it was pertinent to all appraisals.

The Chairman invited Dr David Jarrom, AWTTC assessment lead, to set the context of the appraisal. Dr Jarrom presented an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. Members were informed that a patient organisation submission had been received from Skinship (UK).

The Chairman invited Dr Bracchi, NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Bracchi briefly summarised the issues discussed at NMG and relayed the view of NMG members that ingenol mebutate (Picato®) should be recommended as an option for use within NHS Wales for the indication being considered.

The Chairman invited comment in relation to the case for clinical effectiveness. There was discussion over the application and clarification was sought in relation to re-use. The company delegates were asked to comment on the trial populations attributable to the Welsh population and also recurrence rates. The Chairman referred members to the clinical expert summary and asked members to highlight any outstanding issues. There were none. Mr Chris Palmer highlighted the salient issues within the patient organisation submission from Skinship (UK).

Professor Cohen commented on the case for the cost-effectiveness of the medicine. He alluded to the strong assumptions from the base case, and the company delegates responded acknowledging that the base case was simplistic.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates to highlight any additional information. Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Leo Laboratories Limited for engaging in the appraisal process and proceeded to the next appraisal.

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:

Ingenol mebutate (Picato®▼) is recommended as an option for use within NHS Wales for the cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (AK) in adults.

8. Appraisal 4 – Limited submission
Linagliptin/metformin (Jentadueto®) for the treatment of adult patients with type 2 diabetes mellitus:

- **as an adjunct to diet and exercise to improve glycaemic control in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of linagliptin and metformin;**
- **in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea**

Mr Roger Williams left the meeting. The Chairman welcomed representatives of the applicant company Boehringer Ingelheim Limited/Eli Lilly & Company 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 further declarations were made.

The Chairman confirmed the application made for this medicine had been accepted as a limited submission. He explained that evidence of budgetary impact in comparison to the existing comparator product/s should be demonstrated. The Chairman confirmed that monitoring of the 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. He set the context of the appraisal and confirmed that the company delegates would be invited to respond to any issues raised.

The Chairman invited Dr Claire Davis, AWTTC assessment lead, to set the context of the appraisal. Dr Davis presented an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. Members were informed that a patient organisation submission had been received from Diabetes UK Cymru.

The Chairman invited Dr Bracchi, NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Bracchi briefly summarised the issues discussed at NMG and relayed the view of NMG members that linagliptin/metformin (Jentadueto®) should be available as an option for use within NHS Wales for the indication being considered.

The Chairman invited comment in relation to the case for clinical effectiveness. Clarification was sought in relation to the dosing pattern. The Chairman alluded to the clinical expert summary and invited comment. There were no budget impact or societal issues of note. Mr Palmer highlighted the salient issues within the patient organisation submission received from Diabetes UK Cymru who supported the availability of another treatment option for Welsh patients.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates to highlight any additional information. Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Boehringer Ingelheim Limited/Eli Lilly & Company Limited for engaging in the appraisal process and moved on to the next appraisal.

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:

Linagliptin/metformin (Jentadueto®▼) is recommended as an option for use within NHS Wales for the treatment of adult patients with type 2 diabetes mellitus:

- **as an adjunct to diet and exercise to improve glycaemic control in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of linagliptin and metformin; and**

- **in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea.**

8. Appraisal 5 – Limited submission
Darunavir (Prezista®) co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients, as well as antiretroviral therapy-experienced paediatric patients from the age of 3 years and at least 15 kg body weight

The Chairman welcomed representatives of the applicant company, 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. There were none. Mr Roger Williams re-joined the meeting.

The Chairman confirmed the application made related to a minor licence extension of this medicine which had been considered eligible for a limited submission. He explained that evidence of budgetary impact in comparison to the existing comparator product/s should be demonstrated. The Chairman confirmed that monitoring of the 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. He set the context of the appraisal and confirmed that the company delegates would be invited to respond to any issues raised.

The Chairman invited Mrs Sabrina Rind, AWTTC assessment lead, to set the context of the appraisal. Mrs Rind presented an overview of the submission as detailed in the ASAR and confirmed that clinical experts had declined to submit views in relation to this appraisal. Members were informed that relevant patient organisations had been contacted; however, no submissions had been received.

The Chairman invited Dr Bracchi, NMG Chairman, to provide a brief overview of the issues identified in the preliminary appraisal. Dr Bracchi briefly summarised the issues discussed at NMG and relayed the view of NMG members that darunavir (Prezista®) should be available as an option for use within NHS Wales for the indication being considered.

The Chairman invited comment in relation to the case for clinical effectiveness. There was brief discussion regarding the palatability of the oral solution, and clarification was sought in relation to the cohort study. There were no outstanding societal or budget impact issues of note.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates to highlight any additional information. Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Janssen-Cilag Limited for engaging in the appraisal process and confirmed that members would retire to vote in private.

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:

Darunavir (Prezista®▼) 100 mg/ml oral suspension, co-administered with low dose 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) infection in adult patients, as well as antiretroviral therapy-experienced paediatric patients from the age of 3 years and at least 15 kg body weight.

The Chairman concluded the proceedings of the morning session and confirmed that appraisal 6 and 7 would be conducted in private.

8. Appraisal 6 – Full submission (proceedings held in private)
Ivacaftor (Kalydeco®) for the treatment of cystic fibrosis in patients age 6 years and older who have a G551D mutation in the CFTR gene

The Chairman welcomed the representative of the applicant company Vertex Pharmaceuticals Limited. The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. There were none.

The Chairman announced the statement, pertinent to all appraisals, 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 officials, 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 Mrs Gail Woodland, AWTTC assessment lead, to set the context of the appraisal. Mrs Woodland presented an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. Members were informed that patient organisation submissions had been received from the Ivacaftor Patient Interest Group, the Cystic Fibrosis Trust and Genetic Alliance UK.

The Chairman invited Dr Bracchi, NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Bracchi briefly summarised the issues discussed at NMG. He confirmed that the NMG had considered it appropriate to appraise ivacaftor (Kalydeco®) as an ultra-orphan medicine. He relayed NMG's concern over the limitations of the submission and assumptions made by the applicant company in relation to adherence, utilities and price of generic medicines. It was noted the most plausible ICER exceeded £500,000 per QALY. Dr Bracchi confirmed that after careful consideration of all the relevant issues, including the practical difficulties of interpreting cost-effectiveness data for an ultra-orphan medicine, the preliminary advice of the NMG was that ivacaftor (Kalydeco®) should not be recommended for use within NHS Wales for the treatment of cystic fibrosis in patients age 6 years and older who have a G551D mutation in the CFTR gene.

The Chairman invited comment in relation to the case for clinical effectiveness. Members sought clarification in relation to the availability of follow-up data for pulmonary exacerbation. It was confirmed that this data was not available. There was discussion over the number of eligible patients in Wales and the unmet need. The Chairman drew members' attention to the views of the clinical experts which highlighted that ivacaftor represents a new class of drug which corrects the defect associated with cystic fibrosis in eligible patients, compared to managing the complications which is the current treatment approach. Clarification was sought in relation to the funding of this medicine in other parts of the UK.

The Chairman invited Mr Palmer to relay the views of the patient organisations. Mr Palmer proceeded to read from a letter that had been received from the Cystic Fibrosis Trust in response to the negative preliminary recommendation.

Professor Cohen highlighted the areas of uncertainty and limitations within the company's submission. Members noted the incremental cost effective ratio and assumption of clinical benefit over the lifetime of the patient.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the company delegate to highlight salient aspects of the submission. It was confirmed that all available evidence had been presented and considered by members and there were no aspects of the submission that the company wished to highlight.

Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Vertex Pharmaceuticals Limited for engaging in the appraisal process and proceeded to the next appraisal.

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

Ivacaftor (Kalydeco®) is not recommended for the treatment of cystic fibrosis in patients aged six years and older who have a *G551D* mutation in the *CFTR* gene.

There was a short interruption in proceedings whilst the Chairman and Professor Roger Walker left the meeting to respond to questions from individuals who had been seated in the public gallery during the announcement of AWMSG's recommendation.

Dr Emma Mason, Dr Stuart Linton and Mr Roger Williams left the meeting.

9. Appraisal 7 – Full submission (proceedings held in private)
Perampanel (Fycompa®) for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older

Mr Lance Richard joined his colleague to represent the applicant company, Eisai Limited.
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 further declarations.

The Chairman invited Mr Anthony Williams, AWTTC assessment lead, to set the context of the appraisal. Mr Williams presented an overview of the submission as detailed in the ASAR and relayed the views of the clinical experts. Mr Williams highlighted that in making their submission, Eisai Limited had only provided supporting evidence for a sub-population and this restricted consideration of the medicine for the whole of the licensed indication. Members were informed that a patient organisation submission had been received from Epilepsy Action Cymru.

The Chairman invited Dr Bracchi, NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Bracchi briefly summarised the issues discussed at NMG and relayed the view of NMG members that perampanel (Fycompa®) should be recommended as an option for restricted use within NHS Wales for the indication under consideration. Use outside this restriction could not be recommended.

The Chairman invited comment in relation to the case for clinical effectiveness. Clarification was sought in relation to the nature of the patients identified for treatment. There was discussion over efficacy and response rates. The Chairman drew attention to the clinical expert views which suggested that with the novel mechanism of action this medicine might offer some hope of improvement in patients with epilepsy who continue to experience seizures with current available therapy. Professor Cohen commented on the case for cost-effectiveness and drew members' attention to the salient issues within the submission.

The Chairman invited Mr Palmer to present the views of the patient organisation. He highlighted the treatment gap which suggested that many patients, who may not achieve seizure freedom with the current range of therapies, may go on to do so when prescribed a different medicine with a different mode of action. Epilepsy Action Cymru supported more treatment options for patients.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates to highlight any additional information. Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Eisai Limited for engaging in the appraisal process and closed 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:

Perampanel (Fycompa®▼) is recommended as an option for restricted use within NHS Wales. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.

Perampanel (Fycompa®▼) should be restricted to treatment of patients whose seizures are still uncontrolled with first adjunctive therapy, within its licensed indication as adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older.

Perampanel (Fycompa®▼) is not recommended for use within NHS Wales outside of this subpopulation.

The Chairman confirmed that confirmation of AWMSG's recommendations would be forwarded to the applicant companies within five working days. He confirmed the deadline for lodging a request for an independent review (IR) was fourteen days from the announcement of the recommendation and clarified that in the absence of a request for an IR the recommendations would be passed to Welsh Government for ratification.

The appraisal session was concluded. Mr Lance Richard re-joined members.

13. AWPAG update (draft minutes of March 2013 meeting)
The Chairman invited Dr Tessa Lewis to present the draft minutes of the AWPAG meeting held on 12th March 2013 - Enc **9**/AWMSG/0513. Dr Lewis highlighted the work currently on-going.

14. Recommendations for Homecare Services
The Chairman welcomed Mrs Jenny Pugh-Jones, Chair of the Homecare Sub-group and invited her to present an update on the work of the group. Mrs Pugh-Jones confirmed the Homecare Sub-group aims to strengthen the current governance arrangements and provide tools for health boards to determine a baseline of service provision in order to develop services appropriately according to their local needs. AWMSG was asked to endorse the following recommendations:

1 The Chief Pharmacist in each Health Board/ Trust to be identified as the Responsible Officer for accountability of homecare services relating to medicines. All prescriptions/orders for homecare medicines must be processed through the pharmacy systems.

2. The financial and clinical governance arrangements must be strengthened for both current and future services within each Health Board/Trust with Health Boards/Trust demonstrating a clear option to ensure best possible care and access for all patients.

3. Administration and clinical support must be identified within Health Boards/Trusts to ensure robust mechanisms are in place to review and monitor current and future services.

4. Review and development of an I.T infrastructure and a system that addresses the needs of Health Boards/Trusts in this area of care to be a priority for NWIS.

5. Endorse the use of the self assessment tool kit to assist Health Boards/Trusts to strengthen their own governance arrangements for homecare services.

6. Recommend that a detailed assessment is undertaken of the benefits and risks of the full range of alternative service delivery options.

The Chairman opened discussion and members considered each of the recommendations. It was noted that specialised services had been excluded and it was confirmed that this required further exploration.

There was unanimous support of the recommendations and the Chairman thanked the Homecare Sub-group for setting out clear clinical and financial governance arrangements for the managed delivery of Homecare Services.

15. Dyspepsia and Proton Pump Inhibitor Educational Pack

The Chairman invited Mrs Katherine Jenkins to present the proton pump Inhibitor and dyspepsia resource pack and seek endorsement by AWMSG for its implementation across NHS Wales. Mrs Jenkins explained that long-term use of proton pump inhibitors (PPIs) is associated with adverse effects such as increased risk of pneumonia, clostridium difficile and fractures. Members were informed that PPI use remains high in Wales and continues to increase at around 7% per year. She highlighted to need to tackle inappropriate prescribing. Mrs Jenkins confirmed the purpose of the document is to provide guidance on the management of dyspepsia, thereby addressing concerns in relation to both safety and cost.

The Chairman opened discussion. Mr Fec confirmed that the patient information leaflet had been well received by patients. There was discussion in relation to implementation and clarification that the resource was aimed at general practice. Members welcomed the pack to improve the safe and effective use of PPIs. The Chairman closed discussion and confirmed AWMSG's support of this Invest to Save initiative.

16. Common Ailments Service Formulary

The Chairman invited Mrs Fiona Woods and Dr Tessa Lewis to present Enc/**12**/AWMSG/0513 - The All Wales Common Ailments Service Formulary. Dr Lewis provided the background and confirmed the purpose of the formulary is to promote the use of evidence-based interventions for the management of common minor ailments and support the implementation of the Common Ailments Service pathfinder sites. The Common Ailments Service is intended to encourage patients who would otherwise have visited their GP to visit the pharmacy instead; provide advice and, where appropriate, treatment; promote self care, thereby increasing resilience. It was noted that the formulary was developed via multi-professional discussion and consultation using established resources. Mrs Woods highlighted work outstanding in relation to the development of a review process. Members were informed that an electronic formulary will be

available to the pathfinder sites. There was acknowledgement of the involvement of colleagues across Wales.

The Chairman opened the discussion and invited comment from the Community Pharmacy representative, Mr Fec. Mr Fec welcomed the document and indicated his approval of the content and layout. Members sought clarification in relation to induction and training.

The Chairman closed discussion by confirming AWMSG's unanimous support of the formulary.

17. Quarterly National Indicator report

Mrs Katherine Jenkins presented the Welsh Analytical Prescribing Support Unit's quarterly report on AWMSG's national prescribing indicators. Members were informed the paper reports on the position of each health board against each of the national prescribing indicators as at December 2012. It was noted the threshold for each prescribing indicator is set at the 25th percentile (i.e. reducing or increasing prescribing rates in line with the best performing 25% of practices). Mrs Jenkins confirmed that for the 2012-2013 indicators, the prescribing data for all general practices in Wales for the quarter ending 31 December 2011 had been utilised. All practices within health boards were encouraged to achieve or move toward these thresholds.

The Chairman invited comment. A suggestion was made that percentage change over time might be useful. Mrs Jenkins responded by confirming that this could be reflected in the next report, the final quarter report. There was discussion in over thresholds and targets. Mrs Jenkins suggested that WAPSU were looking at preparing health board specific reports and could provide supporting information. It was suggested that the historical information available via the Public Health Wales surveillance information might be useful. Mrs Jenkins confirmed that the report would be disseminated via AWTTC.

18. Date of next meeting:

The Chairman confirmed the date of the next AWMSG meeting on **Wednesday, 12th June** in **Abergavenny** and closed the meeting.