

Enclosure No:	1/AWMSG/1212
Agenda Item No:	5 – Minutes of previous meeting
Author:	Chairman, AWMSG
Contact:	Tel: 029 20716900 E-Mail: awttc@wales.nhs.uk

ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY 14TH NOVEMBER 2012 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
3. Professor David Cohen Health Economist
4. Mrs Debbie Davies Healthcare Professional eligible to prescribe
5. Dr Bruce Ferguson Medical Director
6. Dr Karen Fitzgerald Consultant in Pharmaceutical Public Health
7. Mrs Ellen Lanham Community Pharmacist
8. Dr Stuart Linton Hospital Consultant
9. Mrs Susan Murphy Managed Sector Primary Care Pharmacist
10. Mr Christopher Palmer Lay Member
11. Mr Christian Smith Senior Nurse
12. Mr Rob Thomas ABPI Wales
13. Mr John Watkins Public Health Wales
14. Mr Roger Williams Managed Sector Hospital Pharmacist

9

IN ATTENDANCE:

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

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

19. Mr Anthony Williams, Senior Appraisal Pharmacist
20. Dr Claire Davis, Senior Appraisal Scientist
21. 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
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Boards
HTA	Health Technology Appraisal
IR	Independent Review
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 announced that Dr Stuart Linton, Consultant Rheumatologist, Aneurin Bevan Health Board had stepped into the role recently vacated by Dr Phil Banfield, as Hospital Consultant representative. The Chairman welcomed Dr Linton to his first AWMSG meeting as a full member.

2. Apologies

Dr Geoffrey Carroll, Welsh Health Specialised Services Committee representative
Dr Phil Webb, Welsh Health Specialised Services Committee (deputy member)
Mr Stuart Davies, Finance Director representative
Dr Emma Mason, Clinical Pharmacologist representative

3. Declarations of interest

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

4. Chairman's report

The Chairman reported a Task & Finish Group had been held on Wednesday, 24th October at the Royal National Institute for the Blind, Cardiff to explore ways of improving patient engagement in the work of AWMSG. In partnership with ABPI Wales, representatives from AWTTC had discussed ways of improving links with patient organisations, patient carers and support groups. Members were informed that feedback from this meeting would be considered by the AWMSG Steering Committee and the TDA Partnership Group.

The Chairman announced the postponement of the appraisal of vildagliptin (Galvus[®]▼) for the treatment of type 2 diabetes as monotherapy in patients inadequately controlled by diet and exercise alone, and for whom metformin is inappropriate due to contraindications or intolerance. He informed members that subsequent to the preliminary appraisal by the New Medicines Group, the applicant Company, Novartis Pharmaceuticals UK Limited, had highlighted an error

in their submission. The Chairman confirmed the appraisal by AWMSG had been rescheduled.

It was reported that All Wales advice on the role of oral anticoagulants for the prevention of stroke and systemic embolism in people with atrial fibrillation would shortly be uploaded to the AWMSG website. The document had been amended in light of discussion at the previous AWMSG meeting and the Chairman took action in approving the updated document. The Chairman confirmed the advice would be cascaded to all general practitioners in Wales via WeMeReC – the communication arm of AWTTC – and a WeMeReC bulletin will follow in September 2013. It is intended that the next AWMSG update in the Chief Medical Officer's Newsletter would also make reference to the availability of the advice. The Chairman informed members a workshop had been piloted by AWTTC in North Wales and, with appropriate financial resource; this could be extended to all health boards in Wales.

The Chairman confirmed ratification had been received from Welsh Government in relation to following AWMSG advice:

Paliperidone palmitate (Xeplion[®]▼) prolonged release suspension for injection is recommended as an option for use within NHS Wales for the maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone; and in selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, without prior stabilisation with oral treatment when psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed.

Colecalciferol (Fultium-D₃[®]) is recommended as an option for use within NHS Wales for the prevention and treatment of vitamin D deficiency and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency. Fultium-D₃[®] is indicated in adults, the elderly and adolescents.

Eslicarbazepine acetate (Zebinix[®]) is recommended as an option for restricted use within NHS Wales. Eslicarbazepine acetate (Zebinix[®]) should be restricted to treatment of highly refractory patients who remain uncontrolled with, or are intolerant to, other anti-epileptic medicine combinations, within its licensed indication as adjunctive therapy in adults with partial-onset seizures, with or without secondary generalisation. Eslicarbazepine acetate (Zebinix[®]) is not recommended for use within NHS Wales outside of this subpopulation.

Bupivacaine hydrochloride/fentanyl solution for infusion (Bufyl[®]) is recommended as an option for use within NHS Wales for maintaining analgesia post-operatively and for maintaining epidural analgesia during labour.

Ramipril oral solution is recommended as an option for use within NHS Wales for:

- Treatment of hypertension.
- Cardiovascular prevention: reduction of cardiovascular morbidity and mortality in patients with:
 - manifest atherothrombotic cardiovascular disease (history of coronary heart disease or stroke, or peripheral vascular disease);
 - diabetes with at least one cardiovascular risk factor.
- Treatment of renal disease:
 - incipient glomerular diabetic nephropathy as defined by the presence of macroalbuminuria;
 - manifest glomerular diabetic nephropathy as defined by macroproteinuria in patients with at least one cardiovascular risk factor;
 - manifest glomerular non diabetic nephropathy as defined by macroproteinuria ≥ 3 g/day.
- Treatment of symptomatic heart failure.
- Secondary prevention after acute myocardial infarction: reduction of mortality from the acute phase of myocardial infarction in patients with clinical signs of heart failure when started > 48 hours following acute myocardial infarction.

The Chairman confirmed that Welsh Government had ratified three statements of advice since the previous AWMSG meeting. The Chairman clarified, in the absence of engagement in the AWMSG appraisal process within the required timescale, the following medicines could not be endorsed for use within NHS Wales.

Pasireotide (Signifor[®]▼) for the treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed

Ferumoxytol (Rienso[®]▼) for intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease

Strontium ranelate (Protelos[®]) for the treatment of osteoporosis in men at increased risk of fracture

Members were informed that two statements of advice are in preparation and unless a Form B or Form C submission is received within the next fourteen days statements related to the following medicines would be forwarded to Welsh Government.

Adalimumab (Humira[®]) for the treatment of adults with severe axial spondyloarthritis who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs

Zonisamide (Zonegran[®]) as monotherapy in the treatment of partial seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy

The Chairman announced the appraisals scheduled for the next AWMSG meeting to be held in Abergavenny on Wednesday, 12th December 2012.

Appraisal 1: Full Submission

Argatroban (Exembo[®]) for anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy.

Applicant Company: Mitsubishi Pharma Europe Ltd

Appraisal 2: Limited Submission

Bortezomib (Velcade[®]▼) subcutaneous injection in combination with melphalan and prednisone for the treatment of patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant; and as monotherapy for the treatment of progressive multiple myeloma in patients who have received at least 1 prior therapy and who have already undergone or are unsuitable for bone marrow transplantation

Applicant Company: Janssen Ltd

Appraisal 3: Limited Submission

Sildenafil citrate (Revatio[®]▼) for the treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Applicant Company: Pfizer Ltd

Appraisal 4: Full Submission

Eplerenone (Inspra[®]▼) in addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with NYHA class II (chronic) heart failure and left ventricular systolic dysfunction

Applicant Company: Pfizer Ltd

As previously stated, the Chairman confirmed the appraisal of Vildagliptin (Galvus[®]▼) for the treatment of type 2 diabetes as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance is to be re-scheduled. Applicant Company: Novartis Pharmaceuticals UK Ltd

The Chairman asked members to declare any interest in relation to the appraisals scheduled for

December to AWTTTC prior to the meeting.

The Chairman invited patients, patient organisations and patient carers to submit that their views in relation to medicines scheduled for appraisal, and suggested they contact Ruth Lang at AWTTTC 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

Fidaxomicin (Dificlr[®]▼) for the treatment of adults with *Clostridium difficile* infections (CDI), also known as *C. difficile*-associated diarrhoea (CDAD)

The Chairman welcomed representatives from the applicant company, Astellas 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. 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 Mr Anthony Williams, AWTTTC assessment lead, to set the context of the appraisal. Mr Williams provided 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 National Concern for Healthcare Infection.

The Chairman asked 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 fidaxomicin (Dificlr[®]▼) 200 mg film-coated tablets should be recommended as an option for restricted use within NHS Wales. Dr Bracchi explained why NMG had considered that fidaxomicin (Dificlr[®]▼) 200 mg film-coated tablets should be restricted for use in patients with severe *Clostridium difficile* infections and patients with recurrence of *Clostridium difficile* infections. He confirmed that NMG did not recommend use of fidaxomicin (Dificlr[®]▼) 200 mg film-coated tablets outside of the restricted sub-population. The view of NMG was that it should only be prescribed on the advice of a consultant microbiologist, consistent with Health Protection Agency guidance.

The Chairman invited comment in relation to the case for clinical effectiveness. Members sought clarification in relation to the mode of action, the dosing levels within the study and enquired whether any further trials were ongoing. There was discussion in relation to the definition of 'severe' CDI and the company representatives were asked to comment on the limited evidence in relation to the whole of the licensed indication. The company delegates responded and confirmed that Astellas considered the case for first recurrence demonstrated the most benefit to patients.

Mr Chris Palmer, the lay member, raised several issues highlighted by the patient organisation and referred members to the information provided by National Concern for Healthcare Infection.

Professor Cohen commented on the case for cost effectiveness as outlined in the ASAR. He clarified his role as the AWMSG health economist and confirmed he had not been included in

discussions held at NMG. He provided members with a comprehensive overview of the submission and the company delegates had opportunity to respond to all the issues raised.

There were no outstanding budget impact issues or societal issues.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates from Astellas to raise any issues they considered might not have been adequately addressed during the appraisal. Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Astellas 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:

Fidaxomicin (Dificlr[®]▼) is recommended as an option for restricted use within NHS Wales.

Fidaxomicin (Dificlr[®]▼) should be restricted for use in the following subpopulations within its licensed indication for the treatment of adults with *Clostridium difficile* infections (CDI), also known as *C. difficile*-associated diarrhoea (CDAD):

- Patients with severe CDI
- Patients with recurrence of CDI

Fidaxomicin (Dificlr[®]▼) should be prescribed on the advice of a consultant microbiologist, consistent with Health Protection Agency guidance.

Fidaxomicin (Dificlr[®]▼) is not recommended for use within NHS Wales outside the specified subpopulations

7. Appraisal 2: Limited Submission

Insulin detemir (Levemir[®]) for the treatment of diabetes mellitus in children aged 2–5 years

The Chairman welcomed delegates from the applicant company: Novo Nordisk 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. He explained the format of appraising a limited submission and highlighted that evidence relating to budgetary impact in comparison to the existing comparator product should be discussed.

The Chairman invited Dr Claire Davis, AWTTTC assessment lead, to set the context of the appraisal. Dr Davis provided an overview of the submission as detailed in the [ASAR](#) and relayed the views of the [clinical experts](#). Members were informed of the patient organisations approached by AWTTTC; Dr Davis confirmed that a patient organisation submission had not been received.

The Chairman asked Dr Bracchi to relay the view of NMG. Dr Bracchi confirmed there were no outstanding issues and NMG had agreed that insulin detemir (Levemir[®]) should be recommended as an option for use within NHS Wales for the treatment of diabetes mellitus in

children aged 2–5 years. NMG were of the opinion that insulin detemir (Levemir®) may be appropriate for use within NHS Wales prescribed under specialist recommendation for the indication under consideration.

The Chairman invited comment in relation to the case for clinical effectiveness. The views of the clinical experts were discussed and the company delegates confirmed that the summary of comments was in line with feedback received by Novo Nordisk.

Professor Cohen relayed his views in relation to the submission. There were no outstanding societal issues of note.

The Chairman alluded to the applicant company response to the preliminary recommendation. It was noted that Novo Nordisk Limited had been fully supportive of the preliminary recommendation. Having responded to the issues raised in the appraisal, the company delegates confirmed they were satisfied that all the issues had been adequately discussed and the process had been fair and transparent.

The Chairman closed the discussion and members retired to vote in camera.

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:

Insulin detemir (Levemir®) is recommended as an option for use within NHS Wales for the treatment of diabetes mellitus in children aged 2–5 years.

The Chairman confirmed that confirmation of AWMSG's recommendation 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, subject to receiving a request for an IR; the recommendations would be passed to Welsh Government for ratification.

It was confirmed that the third appraisal would be conducted in private as the submission included a Welsh Patient Access Scheme (WPAS) which contained confidential and commercially sensitive information.

8. Appraisal 3: Full Submission (Resubmission)

Degarelix (Firmagon®) for the treatment of adult male patients with advanced hormone-dependent prostate cancer

The Chairman welcomed the representatives of the applicant company, Ferring Pharmaceuticals Limited, and read out a list of names, that had been provided prior to the meeting, of observers who were in attendance at the expressed wish of Ferring Pharmaceuticals.

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so and alluded to the statement pertinent to all appraisals.

Dr Jarrom, the AWTTTC assessment lead, set the context of the appraisal and highlighted relevant issues within the [ASAR](#). It was confirmed that two patient organisation submissions had been received – one from the Prostate Cancer Cardiff Support Group and one from the Red Sock Campaign. Dr Jarrom relayed the views of the [clinical experts](#).

The Chairman invited Dr Bracchi to give an overview of the relevant issues identified in the preliminary appraisal. Dr Bracchi confirmed that NMG considered degarelix (Firmagon®) 80

mg and 120 mg injection should be recommended as an option for use within NHS Wales for the treatment of adult male patients with advanced hormone-dependent prostate cancer only in circumstances where the approved Wales Patient Access Scheme is utilised. It was noted, NMG were of the opinion that degarelix (Firmagon®) 80 mg and 120 mg injection may be appropriate for use within NHS Wales when prescribed under specialist initiation for the indication under consideration.

Members discussed the case for clinical effectiveness and clarification sought in relation the extrapolation of time-limited information. Members noted the views of clinical experts who expressed they would strongly welcome advice from AWMSG that would allow discretionary use of degarelix for treatment of emergency patients, but they were not convinced that there is sufficient evidence to justify switching all eligible patients to treatment.

Mr Chris Palmer, the lay member, referred to the patient organisation questionnaires included in members' documentation. He summarised the experiences shared by patients and highlighted the view expressed that for patients the main concern is adverse events and the availability of this medicine within NHS Wales would be a welcomed addition to the treatment options for men with advanced hormone-dependent prostate cancer.

Professor David Cohen provided a comprehensive view of the case for cost effectiveness. It was noted that Ferring Pharmaceuticals had no comments in relation to the preliminary recommendation. The delegates responded to the issues raised in the discussion and, prior to closing the appraisal, the Chairman invited them to make any concluding remarks. The Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Ferring Pharmaceuticals Limited for engaging in the appraisal process.

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:

Degarelix (Firmagon®) is recommended as an option for use within NHS Wales for the treatment of adult male patients with advanced hormone-dependent prostate cancer. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.

9. Homecare Services Sub Group

The Chairman invited Ms Kath Haines to present Enc5/AWMSG/1112 – a paper detailing the terms of reference and work programme of the Homecare Services Sub-Group. Ms Haines explained that there has been a rapid development of services which deliver medicines and additional homecare direct to patients' homes. Although the concept fits within the current policy to deliver care closer to home, there has been concern in relation to governance arrangements (both financial and clinical). In response to this, an All Wales Homecare Group has been established as a sub group of the All Wales Medicines Strategy Group (AWMSG). Ms Haines asked that AWMSG approve the amended Terms of Reference and note the key changes to the Terms of Reference which included:

- The addition of the AWMSG exclusion criteria used to determine whether a medicine/product is appropriate for appraisal.
- Membership of the group to include representation from Primary, Community and Mental Health, Nursing and Planning to ensure a wide range of health professionals have opportunity to inform and steer this significant area of health care in the strategic direction of travel for NHS Wales.

Ms Haines informed members that representatives are currently being sought and a full list of members would be available at the next meeting. It was highlighted that in Wales it is estimated that £55-£65 million is spent each year on homecare services and this figure is expected to increase. Ms Haines highlighted the importance of considering all available service delivery options before entering into arrangements with non NHS companies.

Members were informed that the AWMSG Steering Committee had supported the establishment of the All Wales Homecare Group to consider the issue of Homecare Services within Wales and suggest how these can be addressed in a consistent and timely way. The aim is to secure economies of scale, ensuring best value for money in the context of the wider strategic direction of travel for the modernisation of services in NHS Wales.

The Chairman opened the discussion and members were asked to consider the recommendations. There was a suggestion to include a quorum and explanation that voting will be based on a simple majority in the terms of reference. There was discussion in relation to membership of the group, particularly the lack of GP and Community Pharmacy input. Members agreed that terminology should include reference to sustainability. Members discussed the balance in relation to economies of scale and local flexibility. Members discussed the importance of linking with general practice information technology systems. The Chairman confirmed that with changes in the order and wording clarification of section 2.3, there was general support of the recommendations as set out in the paper. Ms Haines made note of the suggestions and agreed to take comments back to the Home Care Group.

Date of next meeting

The Chairman confirmed the date of the next meeting on **Wednesday, 12th December 2012 in Abergavenny** and the meeting closed.