

Enclosure No:	1/AWMSG/0512
Agenda Item No:	5 – Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY 21st MARCH 2012 COMMENCING 10.30 AM AT THE CARDIFF METROPOLITAN UNIVERSITY LLANDAFF CAMPUS, WESTERN AVENUE, CARDIFF CF5 2YB

MEMBERS PRESENT:

**Did not
participate in**

- | | | |
|---------------------------|--|----------|
| 1. Prof Philip Routledge | Chairman | |
| 2. Dr Philip Banfield | Hospital Consultant | |
| 3. Dr Geoffrey Carroll | Welsh Health Specialised Services Committee | |
| 4. Prof David Cohen | Health Economist | |
| 5. Mrs Debbie Davies | Representing other professions eligible to prescribe | |
| 6. Ms Ellen Lanham | Community Pharmacist | |
| 7. Dr Karen Fitzgerald | Consultant in Pharmaceutical Public Health | |
| 8. Dr Brian Hawkins | Senior Primary Care Pharmacist | |
| 9. Dr Emma Mason | Clinical Pharmacologist | |
| 10. Mr Christopher Palmer | Lay member | |
| 11. Mr Christian Smith | Senior Nurse | |
| 12. Dr John Watkins | Consultant in Public Health Medicine | |
| 13. Dr William Whitehead | GP with prescribing lead role | |
| 14. Mr Roger Williams | Senior Hospital Pharmacist | 6 |

IN ATTENDANCE:

15. Mrs Karen Samuels, Welsh Medicines Partnership
16. Mrs Ruth Lang, Welsh Medicines Partnership
17. Dr Robert Bracchi, NMG Chairman

WELSH MEDICINES PARTNERSHIP APPRAISAL LEADS:

18. Mrs Sabrina Rind, Senior Appraisal Pharmacist
19. Mr Anthony Williams, Senior Appraisal Pharmacist

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
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
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
WMP	Welsh Medicines Partnership

1. Welcome and introduction

The Chairman welcomed members.

2. Apologies

Dr Bruce Ferguson, Medical Director
Dr Brendan Lloyd, Deputy Medical Director representative
Dr Fraser Campbell, GP with prescribing lead role
Mrs Rebecca Richards, Director of Finance
Mr Robert Holcombe, Deputy Director of Finance
Professor Roger Walker, Welsh Government
Miss Karen Eveleigh, Welsh Government

3. Declarations of interest

The Chairman asked members to declare any interests pertinent to the agenda. Professor Routledge declared a non-specific non-personal interest in that a post within his University department is partly funded by Astra Zeneca. It was confirmed he would continue his role as Chairman but would not participate in the vote on esomeprazole (Nexium® IV).

4. Chairman's report

The Chairman announced the resignation from AWMSG of Mrs Wendy Warren, Senior Nurse representative. The Chairman thanked Mrs Warren for her contribution to the Group.

It was reported that on 1st March 2012 the AWMSG Steering Committee had considered a request from Boehringer Ingelheim Limited/Eli Lilly and Company Limited for an independent review of AWMSG's advice that linagliptin (Trajenta®▼) should not be recommended for use within NHS Wales for the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as:

Monootherapy:

- in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal

impairment.

Combination therapy:

- in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control.
- in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.

Members were informed the AWMSG Steering Committee considered the grounds for review had not been met and suggested that reappraisal, to include significant new information, would be the most appropriate way forward. The Chairman confirmed AWMSG's recommendation would be forwarded to Welsh Government for ratification following the meeting.

It was reported the service had been informed that Welsh Government ratification had been received in relation to the following recommendations:

Abiraterone (Zytiga^{®▼}) with prednisone or prednisolone is recommended for the treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. This recommendation applies only in circumstances where the approved Wales Patient Scheme for access to medicines is utilised. AWMSG is of the opinion that abiraterone (Zytiga^{®▼}) is suitable for specialist only prescribing within NHS Wales for the above indication.

Capsaicin patch (Qutenza^{®▼}) is not recommended for use alone for the treatment of peripheral neuropathic pain (PNP) in non-diabetic adults. Capsaicin patch (Qutenza^{®▼}) is recommended as an option for restricted use within NHS Wales for the treatment of peripheral neuropathic pain (PNP) in non-diabetic adults in combination with other medicinal products for pain and in patients who have not received adequate benefit from, or are intolerant to, alternative conventional treatments. The company submission provided evidence on the cost effectiveness of capsaicin patch (Qutenza^{®▼}) as an add-on treatment in patients who were refractory to or intolerant of usual first or second line treatments. Capsaicin patches (Qutenza^{®▼}) should be administered by healthcare professionals who have completed the approved training and in a specialist clinic setting. AWMSG is of the opinion that capsaicin patch (Qutenza^{®▼}) is suitable for specialist only prescribing within NHS Wales for the above indication.

Entecavir (Baraclude^{®▼}) is recommended as an option for use within NHS Wales for the treatment of chronic hepatitis B virus infection in adults with decompensated liver disease. Oral solution should only be used in circumstances where the tablet form is not a clinical option. Treatment should normally be initiated following dialogue with a specialist liver unit. AWMSG is of the opinion that entecavir (Baraclude^{®▼}) is suitable for specialist only prescribing within NHS Wales for the above indication.

Icatibant (Firazyr^{®▼}) is recommended as an option for use within NHS Wales for the symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (with C1 esterase inhibitor deficiency). This recommendation applies only in circumstances where the approved Wales patient access scheme is utilised. AWMSG is of the opinion that icatibant (Firazyr^{®▼}) is suitable for specialist only prescribing within NHS Wales for the above indication.

The Chairman confirmed, in the absence of a submission from the holder of the marketing authorisation, the following Statements of Advice had been ratified by Welsh Government:

Eslicarbazepine acetate (Zebinix^{®▼}) cannot be endorsed for use within NHS Wales for adjunctive therapy in adults with partial-onset seizures, with or without secondary generalisation.

Everolimus (Votubia^{®▼}) cannot be endorsed for use within NHS Wales for the treatment of

patients with subependymal giant cell astrocytoma associated with tuberous sclerosis complex who require therapeutic intervention but are not amenable to surgery.

Human normal immunoglobulin (Aragam[®]▼) cannot be endorsed for use within NHS Wales for replacement therapy in primary immunodeficiency syndromes such as: congenital agammaglobulinemia and hypogammaglobulinemia; common variable immunodeficiency; severe combined immunodeficiency and Wiskott Aldrich syndrome; myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinemia and recurrent infections; children with congenital AIDS and recurrent infections; immunomodulation; idiopathic thrombocytopenic purpura; children or adults at high risk of bleeding or prior to surgery to correct the platelet count; Guillain Barré syndrome; Kawasaki disease; allogeneic bone marrow transplantation.

Pemetrexed (Alimta[®]▼) cannot be endorsed for use within NHS Wales as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following induction therapy with pemetrexed in combination with cisplatin.

Colecalciferol (Fultium-D3[®]▼) cannot be endorsed for use within NHS Wales for the prevention and treatment of vitamin D deficiency, or as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.

Hydrocortisone MR (Plenadren[®]▼) cannot be endorsed for use within NHS Wales for the treatment of adrenal insufficiency in adults.

The Chairman confirmed a number of statements of advice were in preparation and statements relating to the following medicines would be forwarded to Welsh Government should a Form B or Form C submission not be received by WMP within the next fourteen days.

Fampridine (Fampyra[®]) for improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS 4-7).

Etanercept (Enbrel[®]) for the treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate.

Etanercept (Enbrel[®]) for the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

Racecadotril (Hidrasec[®]) granules for oral suspension for the complementary symptomatic treatment of acute diarrhoea in infants (older than 3 months), and in children, together with oral rehydration, and the usual support measures, when these measures alone are insufficient to control the clinical condition.

Racecadotril (Hidrasec[®]) capsules for the symptomatic treatment of acute diarrhoea in adults.

Bismuth/metronidazole/tetracycline (Pylera[®]) in combination with omeprazole for the eradication of *Helicobacter pylori* and prevention of relapse of peptic ulcers in patients with active, or a history of, *H. pylori* associated ulcers.

Bupivacaine hydrochloride/fentanyl (Bufyl[®]) for maintaining analgesia post-operatively and for maintaining epidural analgesia during labour.

Nomegestrol acetate/estradiol (IOA[®]) for oral contraception.

Tafamidis (Vyndaqel®) for the treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay neurologic impairment.

Clevidipine (Cleviprex®) for rapid reduction of blood pressure in the perioperative setting.

Eculizumab (Soliris®) for the treatment of patients with atypical haemolytic uraemic syndrome (aHUS).

Vildagliptin (Galvus®) for the treatment of type 2 diabetes in patients with moderate or severe renal impairment.

Triptorelin pamoate (Decapeptyl® SR) 22.5 mg as an adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer.

Fidaxomicin (Dificlor®) for the treatment of adults with *Clostridium difficile* infections, also known as *C. difficile*-associated diarrhoea.

Azilsartan medoxomil (Edarbi®) for the treatment of essential hypertension in adults.

Phentolamine mesylate (OraVerse®) for reversal of soft tissue anaesthesia, and the associated functional deficits, resulting from an intraoral submucosal injection of a local anaesthetic containing a catecholamine vasoconstrictor following a routine dental procedure.

Trastuzumab (Herceptin®) for the treatment of early breast cancer in combination with neoadjuvant chemotherapy followed by adjuvant trastuzumab monotherapy, for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter.

Nepafenac (Nevanac®) for reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.

The Chairman announced the appraisals scheduled for the next meeting on Wednesday, 9th May 2012:

Appraisal 1: Full Submission

Midazolam (Buccolam®) for the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to < 18 years). Buccolam must only be used by parents/carers where the patient has been diagnosed to have epilepsy. For infants between 3-6 months of age treatment should be in a hospital setting where monitoring is possible and resuscitation equipment is available.

Applicant Company: ViroPharma Inc

Appraisal 2: Limited submission

Fluorouracil/salicylic acid (Actikerall®) for topical treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (grade I/II) in immunocompetent adult patients

Applicant Company: Almirall Limited

Appraisal 3: Limited submission

Atorvastatin (Lipitor®) chewable tablets as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate.

- To reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable.

- Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.
Applicant Company: Pfizer Limited

The Chairman reminded members to declare to WMP any interests in relation to the appraisals scheduled. The Chairman invited patients, patient organisations and patient carers to submit their views and contact WMP for further information in relation to the future work programme.

The Chairman concluded his report by confirming an invitation would be circulated to AWMSG members, deputies and representatives of NHS Wales to AWMSG's Conference to be held on Thursday, 24th May at the Wales Millennium Stadium. He announced the following guest speakers would be attending:

Mr Robert Darracott, Chief Executive Officer, Pharmacy Voice
The Felicity Newton-Savage Memorial Lecture: "Supporting Better Use of Medicines: Strategies to Reduce Waste".

Professor Munir Pirmohamed, Professor of Clinical Pharmacology, University of Liverpool
British Pharmacological Society Lecture: "Personalised Medicines – The Challenge Of Individualising Treatments"

Professor Dyfrig Hughes, Professor of Pharmacoeconomics, Bangor University
"New Medicines – Are They Value For Money?"

Miss Madeleine Brindley, Health Editor, Media Wales
"Media and Medicine in Wales"

Dr Sharon Hopkins, All Wales Individual Patient Funding Request Policy Executive Lead
"Access to Medicines in Wales - Individual Patient Funding Requests"

Mr Steve Martin, Managing Director of Influence at Work UK Limited
"The Science of Compliance" - he will be uncovering the hidden science of behaviour change and show how simple and often costless interventions can greatly increase the relevance and effectiveness of vital healthcare messages.

5. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy. No changes were made. The Chairman signed the minutes as a true record of the proceedings.

6. Appraisal 1: Limited submission

Esomeprazole (Nexium® IV) for gastric antisecretory treatment when the oral route is not possible, such as gastro-oesophageal reflux disease (GORD) in patients with erosive reflux oesophagitis and/or severe symptoms of reflux for children and adolescents aged 1-18 years of age.

Mr Anthony Williams, WMP assessment lead, joined members.
The Chairman welcomed the delegate from the applicant company, Astra Zeneca 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.

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 set the context of the appraisal and outlined the sequence of events. He confirmed that the application had been considered eligible for a limited submission. In line with this process, evidence of budgetary impact in comparison to the existing comparator product(s) should be demonstrated. He directed members to consider the evidence and highlight any societal issues, take account of NMG's preliminary recommendation and the company response. He confirmed that clinical expert and patient views would be included, where available. He explained, in the event that AWMSG wished to explore any issues within the submission, then the applicant company delegates would be invited to provide clarification. However, if AWMSG considered there were no outstanding issues, they would retire to vote in private and agree the final recommendation, which would be subsequently announced and forwarded to Welsh Government for ratification. The Chairman reiterated that monitoring of budget impact would be essential and AWMSG reserved the right to request a full submission should the budget impact exceed that estimated in the limited submission.

Mr Williams set the context of the appraisal and confirmed that the submission had met the criteria for a limited submission as it was a minor licence extension, the anticipated usage in NHS Wales was considered to be of minimal budget impact, and the estimated difference in cost compared to the comparator was considered to be small. Mr Williams provided an overview of the submission as detailed in the [ASAR](#) and relayed the views of the [clinical experts](#). He reiterated there was no requirement for the company to provide evidence of cost effectiveness.

Dr Bracchi confirmed NMG's view that esomeprazole (Nexium® IV) should be recommended as an option for use within NHS Wales for gastric antisecretory treatment when the oral route is not possible, such as gastro-oesophageal reflux disease (GORD) in patients with erosive reflux oesophagitis and/or severe symptoms of reflux for children and adolescents aged 1–18 years of age. It was noted NMG were of the opinion that esomeprazole (Nexium® IV) would be suitable for specialist only prescribing within NHS Wales for the above indication.

The Chairman opened the discussion and members sought clarification in relation to aspects of the study and comparative safety data. There were no outstanding budget impact or societal issues raised.

The applicant company delegate responded to the issues highlighted by AWMSG in their discussion and highlighted the societal benefit of supporting access to medicines for children. Members were asked to make a note of their recommendation on their *aide memoire* and the Chairman moved on to the second appraisal.

The Chairman sought confirmation that the process had been fair and transparent and thanked Astra Zeneca 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:

Esomeprazole (Nexium® IV) is recommended as an option for use within NHS Wales for gastric antisecretory treatment when the oral route is not possible, such as gastro-oesophageal reflux disease (GORD) in patients with erosive reflux oesophagitis and/or severe symptoms of reflux for children and adolescents aged 1–18 years of age.

AWMSG is of the opinion that esomeprazole (Nexium® IV) is suitable for specialist only prescribing within NHS Wales for the above indication.

7. Appraisal 2: Limited submission

Adalimumab (Humira®▼) in combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 4 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs. Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

Mrs Sabrina Rind, WMP Appraisal Lead, joined members. The Chairman welcomed delegates from the applicant company, Abbot Laboratories Limited.

The Chairman reminded members to declare any interests. There were none.

He 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 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.

Mrs Rind set the context of the appraisal and highlighted relevant issues within the [ASAR](#). She confirmed that the submission had met the criteria for a limited submission in that it was a minor licence extension and the estimated difference in cost compared to the comparator was considered small. Mrs Rind relayed the views of the [clinical experts](#) and confirmed that evidence of cost effectiveness had not been required.

Dr Bracchi confirmed the view of NMG that adalimumab (Humira®▼) in combination with methotrexate should be recommended as an option for use within NHS Wales for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 4 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs. Adalimumab (Humira®▼) can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. It was noted NMG were of the view that adalimumab (Humira®▼) would be suitable for specialist only prescribing within NHS Wales for the above indication.

The Chairman opened the discussion. Criteria within the DE038 study were discussed; also, the treatment population and mechanism of action of the medicine. The Chairman invited comment in relation to budget impact and clarification was sought of the calculation of incident estimates. It was confirmed there are strict criteria in relation to patient responders.

The applicant company delegates responded to issues identified by AWMSG and were invited to highlight relevant aspects of their submission. The societal benefits to children were highlighted. Prior to concluding the appraisal, the Chairman asked the delegates to confirm that all the outstanding issues had been addressed and they agreed that the process had been fair and transparent. The Chairman thanked Abbott Laboratories Limited for engaging in the appraisal process and closed the 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:

Adalimumab (Humira®▼) in combination with methotrexate is recommended as an option for use within NHS Wales for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 4 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs. Adalimumab

(Humira®) can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

AWMSG is of the opinion that adalimumab (Humira®) is suitable for specialist only prescribing within NHS Wales for the above indication.

8. Update from All Wales Prescribing Advisory Group

The Chairman incited Dr Tessa Lewis, Chair of AWPAG, to update members on the work of AWPAG. She referred members to Enc 4/AWMSG/0312 the [draft minutes](#) of the AWPAG meeting held 26th January 2012.

Dr Lewis provided the background to the next agenda items. She outlined the structure of the Clinical Effectiveness Prescribing Programme (CEPP) and elements within the GP contract through which prescribing initiatives can be progressed. She provided the background - in December 2004 AWMSG had endorsed a non-mandatory All Wales Prescribing Incentive Scheme which provided a recommended framework to health boards. The structure comprised of two equally weighted elements. Firstly, the Prescribing Indicators (national and health board defined) and, secondly, a learning portfolio (audit, WeMeReC educational materials or other LHB defined activity). Dr Lewis reminded members that AWPAG undertook a review of schemes across Wales and the outcomes were considered by AWMSG in August 2008. AWMSG agreed that the scheme should continue to be available as a template for local adaptation - now known as the Clinical Effectiveness Prescribing Programme (CEPP).

Dr Lewis updated members in relation to the Clinical Effectiveness Prescribing Programme 2012/13: This included [AWMSG National Indicators](#).

Dr Lewis confirmed that the local comparators were produced to enable benchmarking across a range of prescribing areas. She reported these were not intended to be fully validated and caution should be exercised in their interpretation. Dr Lewis confirmed they would remain available for both local and national comparative measurement in accordance with local prioritisation. She highlighted the educational component included the following national audits:

Lithium	Subject to AWMSG endorsement
Depression	Subject to AWMSG endorsement
Repeat prescribing	In development (planned AWMSG June 2012)

It was noted the audit Towards Appropriate Non-Steroidal Anti-Inflammatory Drug (NSAID) prescribing 2010-2012 (updated 2011) remains available ([add link](#)).

WeMeReC modules include:

Medicines for type II diabetes	May 2012
Antibiotics	Sept 2012
Eye health	Jan 2013

Members were informed that the GMS contract for primary care provided further opportunity to promote safe and effective prescribing. It was noted the organisational domain included two medicines management indicators:

Medicines 6: The practice meets the PCO prescribing adviser at least annually and agrees up to three actions related to prescribing

Medicines 10: The practice meets the PCO prescribing adviser at least annually, has agreed up to three actions related to prescribing and subsequently provided evidence of change

Dr Lewis reported during 2011/12 there were further measures within the Quality and Outcomes Framework of the GMS contract. These were based on the Quality, Innovation, Productivity and Prevention (QIPP) or AWMSG National Prescribing Indicators - these have not been included in

the 2012/13 contract.

The Chairman was encouraged by the range of issues being developed by AWPAG and thanked members for their significant contribution to the delivery of AWMSG's work programme.

9. CEPP National Audit: Patient Safety – Lithium Prescribing

The Chairman welcomed Ms Fiona Walker and invited her to present the lithium audit, as part of the Clinical Effectiveness Prescribing Programme. She explained the purpose was to ensure the implementation in GP practices of the five recommendations contained in the National Patient Safety Agency (NPSA) alert "Safer lithium therapy".

Mrs Walker informed members that GP practices within the Cardiff and Vale University Health Board (UHB) had participated in a patient safety audit with regards to lithium prescribing. The aim of the audit, carried out during 2010/11, was to ensure the implementation of the five recommendations contained in the NPSA patient safety alert "Safer lithium therapy"¹. GP practices were required to identify all patients currently prescribed lithium by their practice and to audit these patients using the UHB audit pack. She confirmed that audit findings were analysed by the practice and the audit standards summary form completed. The audit was undertaken by all GP practices within Cardiff and Vale UHB patients on lithium during 2010/11. A total of 67/68 GP practices have used this documentation and have undertaken two audit cycles. The first cycle was completed by the end of September 2010 and the second by the end of March 2011. A summary of results was provided to members for consideration.

The Chairman opened the discussion. The significant percentage increase towards target was noted. Members discussed the lithium toxicity and there was a suggestion that the audit could be repeated and data relevant to Recommendation 3 would be useful. Members were impressed with the results and there was general support for the audit.

The Chairman closed the discussion by confirming AWMSG's endorsement and thanked AWPAG for developing this work.

10. CEPP National Audit: - Towards more appropriate management of depression in a primary care setting

The Chairman welcomed Dr Sean Young, General Practitioner, ABMU HB, and invited him to present the depression audit, as part of the Clinical Effectiveness Prescribing Programme. He explained the purpose was to provide more appropriate management of depression in the primary care setting.

Members were informed of the background - in 2009, the National Institute for Health and Clinical Excellence (NICE) released an update of its clinical guidelines (CG) on depression (CG90). The document highlighted the importance of non-drug treatment in the management process. In Wales, there has been a perceived lack of these interventions, which may well impact on prescribing. In 2010, the Welsh Government passed a Mental Health Measure which was given Royal approval in December 2010. Part of the measure sets out the requirements for an effective Primary Mental Health Service which should lead to significant improvements in this area of work. It should enable Welsh general practitioners to be able to follow NICE CG90 much more closely.

Dr Young explained that to enable a diagnosis of depression, symptoms need to persist for at least two weeks and an initial period of "watchful waiting" may be appropriate. Antidepressants, when used in the right patients, have a beneficial impact. NICE does not recommend their use in sub-threshold depressive symptoms or mild depression as they have a poor risk-benefit ratio. Psychosocial intervention should be used in these cases. NICE CG90 "Depression: The treatment and management of depression in adults" makes the following recommendation:

“1.4.4 Drug treatment

1.4.4.1 Do not use antidepressants routinely to treat persistent sub-threshold depressive symptoms or mild depression because the risk–benefit ratio is poor, but consider them for people with:

- *a past history of moderate or severe depression **or***
- *initial presentation of sub-threshold depressive symptoms that have been present for a long period (typically at least 2 years) **or***
- *sub threshold depressive symptoms or mild depression that persist(s) after other interventions.”¹²*

Improved access to psychosocial therapy as envisaged by Part 1 of the Mental Health (Wales) Measure should enable practitioners to follow NICE guidance more effectively and potentially reduce the inappropriate use of antidepressants. Further, with increased access to non-pharmacological intervention, patients with depression are provided with more treatment choices. Increasing psychological intervention to support medication for moderate and severe cases should also reduce antidepressant treatment failure and reduce the need for second or third line drugs (which are potentially more toxic).

The Chairman opened the discussion. Clarification was sought in relation to the wording of some of the targets. It was suggested that the wording relating to ‘alcohol misuse’ be clarified. The issue of linking with other groups was explored. There was general support and agreement that this was a well constructed audit, and recognition that it would need updating/amendment in light of the comments received. The Chairman agreed to take Chairman’s action and consider endorsing the updated paper on behalf of AWMSG outside of the meeting.

11. Guidance on prescribing for erectile dysfunction

The Chairman invited Dr Tessa Lewis to present Enc 7/AWMSG/0312 guidance on prescribing for erectile dysfunction. Dr Lewis explained that drug treatments for erectile dysfunction may only be prescribed on the NHS under certain circumstances. The Department of Health (England) recommended that treatment should be available from specialist services when the condition is causing severe distress. The Welsh Health Circular (WHC) (99) 148 provides guidance for the NHS on the identification and management within specialist services of men diagnosed as suffering severe distress resulting from erectile dysfunction.

Members were informed the All Wales Prescribing Advisory Group (AWPAG) had reviewed this guidance and had developed the following recommendations regarding the prescribing of treatments for erectile dysfunction:

AWMSG were asked to endorse the following recommendations:

- For patients who have been assessed as suffering from severe distress as a result of erectile dysfunction, guidance is amended to remove the restriction of specialist service supply, enabling GPs to prescribe the medication.
- The assessment of severe distress resulting from erectile dysfunction should be undertaken by an experienced clinician with appropriate expertise.
- Once-daily preparations should only be considered in patients who anticipate frequent use of single dose preparations (i.e. at least twice-weekly). This should be based on the clinician’s judgement.

The Chairman opened the discussion. It was suggested that as recommendation 1 conflicted with current regulations, AWMSG endorsement of this recommendation may have legal implications and, as such, would require clarification by Welsh Government. Dr Lewis confirmed that Welsh Government officials were aware of the recommendations. It was agreed that the Chairman would address outside of the meeting.

With regard to recommendation 2, a suggestion was made that a definition of the wording 'experienced clinician' would provide more clarity. Dr Lewis agreed to consider the inclusion of an appropriate definition. AWMSG supported recommendation 3.

The Chairman concluded the discussion by confirming AWMSG's broad support. He asked that the paper be updated in light of the discussion, and confirmed that legal implications would require clarification by Welsh Government before the paper could be formally endorsed by AWMSG. He agreed to take Chairman's action outside of the meeting.

12. Date of next meeting

The Chairman confirmed the date of the next meeting - Wednesday, 9th May 2012.
The meeting closed.