Enclosure No:	**1/AWMSG/1112**
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 17th OCTOBER 2012 COMMENCING 10.30 AM AT THE CATRIN FINCH CENTRE, GLYNDWR UNIVERSITY, WREXHAM LL11 2AW

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.	Mr Stuart Davies	Finance Director	
5.	Dr Bruce Ferguson	Medical Director	
6.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health	
7.	Mrs Ellen Lanham	Community Pharmacist	
8.	Mrs Susan Murphy	Managed Sector Primary Care Pharmacist	
9.	Mr Christopher Palmer	Lay member	
10.	Mr Steve Turley	ABPI Wales	**6**
11.	Mr Roger Williams	Senior Hospital Pharmacist	

IN ATTENDANCE:

12. Professor Roger Walker, Chief Pharmaceutical Officer, Welsh Government
13. Dr Robert Bracchi, NMG Chairman
14. Mrs Karen Samuels, Head of HTA & Medicines Management, AWTTC
15. Mrs Ruth Lang, Head of Liaison & Administration, AWTTC

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

16. Mrs Susan Cervetto, Senior Appraisal Pharmacist
17. Dr Claire Davis, Senior Appraisal Scientist
18. Dr Stephanie Francis, Senior Appraisal Scientist
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
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 Appraisals
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 and confirmed the inaugural meeting of AWMSG had been held on 9th October 2002 in the Crispin Lane Library of the North East Wales Institute of Higher Education Wrexham. He announced that AWMSG was officially celebrating its ten year anniversary and expressed his pleasure in visiting Wrexham to celebrate this achievement.

2. Apologies

Dr Philip Banfield (representing hospital consultants)
Mrs Debbie Davies (representing other professions eligible to prescribe)
Dr Geoffrey Carroll (representing Welsh Health Specialised Services Committee)
Mr Christian Smith (representing senior nurses)
Mr John Watkins (representing Public Health Wales)
Dr Emma Mason (representing Clinical Pharmacologist)

3. Declarations of interest

The Chairman reminded members to declare any interests pertinent to the agenda.
Mr Turley declared an interest in relation to the appraisal of paliperidone palmitate (Xeplion®▼) in that his employer is developing a competitor product. The Chairman confirmed that Mr Turley would not participate or vote in the appraisal of this medicine.

4. Chairman's report

The Chairman opened the meeting and read a statement from Dr Philip Banfield:
"I need to offer my resignation from AWMSG to devote time to my new role as Chairman of Welsh Council for the BMA. It is with great sadness that I give up my place on such an interesting and important committee, which has materially improved prescribing habits and the health of patients in Wales. It has been an honour to do my little bit to further this process - I have learnt so much over the years. It is with more than a little regret that I must resign just as I have finally got to grips with health economics, but the experience will serve me well as we face the enormous and immediate challenges for healthcare in Wales.
With best wishes for the future. Philip."

The Chairman thanked Dr Banfield for his contribution to the work of AWMSG and extended his congratulations and best wishes to him as the incoming Chairman of the Welsh Council for the BMA.

The Chairman confirmed that the Minister for Health & Social Services had approved changes to the AWMSG Constitution. He confirmed that the amended version had been uploaded to the AWMSG website and that nominations were being sought for vacant positions on AWMSG and its sub-groups.

The Chairman confirmed that subsequent to the announcement of the AWMSG recommendation not to recommend eplerenone (Inspra®▼) 25 mg and 50 mg film-coated tablets for use within NHS Wales in addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with New York Heart Association (NYHA) class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤ 30), the holder of the marketing authorisation, Pfizer Limited, had requested that the AWMSG Steering Committee consider a review of the decision. The AWMSG Steering Committee considered the grounds for this request and agreed that the detailed additional information contained within the company response to the PAR could have led to some misinterpretation of information. It was agreed that the ASAR should be amended to take account of the additional information, and that it should be reappraised by the New Medicines Group, and, subsequently, AWMSG. The Chairman confirmed that all other recommendations from AWMSG's previous meeting had been accepted by the licence holders and ratification from Welsh Government is awaited.

The Chairman reported that an ABPI Cymru Wales Masterclass had been held at the All Nations Centre on 8th October. He extended thanks to Dr Rick Greville for giving AWTTC an opportunity to update industry colleagues on the details of the appraisal process and other aspects of the work of AWMSG. Members were informed that AWTTC would be updating EMIG, the trade association representing the interests of small to medium-sized pharmaceutical companies, of the appraisal process on 22nd October 2012.

The Chairman announced a Task & Finish Group would be held on Wednesday, 24th October, hosted by the Royal National Institute for the Blind in Cardiff, to explore patient engagement in the work of AWMSG. In partnership with ABPI Wales, representatives from AWTTC will be discussing ways of improving links with patient organisations and support groups.

Members were informed that Welsh Government had approved recent updates to the process for dealing with Welsh Patient Access Schemes. It was announced that the process and guidance notes for submitting a patient access scheme within NHS Wales would be made available on the AWMSG website over the next few days.

It was announced that, in the absence of engagement by the holder of the marketing authorisation within the appropriate timescale, a number of statements of advice were in preparation. Members were informed that should a Form B or Form C not be received within the next fourteen days, then a statement confirming that the following medicines could not be endorsed for use would be forwarded to Welsh Government for ratification.

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

The Chairman announced the appraisals scheduled for the next meeting to be held in Cardiff on Wednesday, 14th November in Abergavenny.

Appraisal 1: Full Submission
Fidaxomicin (Dificlir®▼) for the treatment of adults with Clostridium difficile infections (CDI), also known as C. difficile-associated diarrhoea (CDAD)
Applicant Company: Astellas Pharma Ltd

Appraisal 2: Full Submission (Re-submission)
Degarelix (Firmagon®) for the treatment of adult male patients with advanced hormone-dependent prostate cancer
Applicant Company: Ferring Pharmaceuticals (UK)

Appraisal 3: Full Submission
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
Applicant Company: Novartis Pharmaceuticals UK Ltd

Appraisal 4: Limited Submission
Insulin detemir (Levemir®) for the treatment of diabetes mellitus in children aged 2-5 years
Applicant Company: Novo Nordisk Ltd

The Chairman reminded members to declare to AWTTC any interests in relation to the appraisals scheduled. The Chairman invited patients, patient organisations and patient carers to submit their views and contact 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

Paliperidone palmitate (Xeplion®▼) prolonged release 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 where psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed

The Chairman welcomed representatives from the applicant company: Janssen-Cilag Limited.

Mr Turley joined the audience and 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 Dr Claire Davis, AWTTC 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 that two patient organisation

submissions had been received, one from SANE and the other by Hafal.

Dr Bracchi gave a brief overview of the relevant issues identified in the preliminary appraisal and relayed the view of NMG that paliperidone palmitate (Xeplion®▼) prolonged release suspension for injection should be 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. He confirmed that NMG were of the opinion that paliperidone palmitate (Xeplion®▼) prolonged release suspension for injection would be appropriate for specialist only prescribing within NHS Wales for the indication under consideration.

The Chairman invited comment in relation to the case for clinical effectiveness. Clarification was sought in relation to the confidence intervals in the studies and the high incidence of adverse drug reactions was noted. There was also discussion in relation to regular contact and supervised management of the patients.

Mr Chris Palmer, the lay member, raised several issues highlighted by the patient organisations. Whilst there were some concerns of note, additional choice in treatment options was welcomed by patients.

Professor Cohen commented on the case for cost effectiveness as outlined in the ASAR. Cohen He clarified his role as the AWMSG health economist and confirmed he had not been included in discussions held at NMG. There were no outstanding budget impact issues.

The Chairman drew members' attention to the company response to the preliminary recommendation which supported the NMG view that paliperidone palmitate (Xeplion®▼) should be available as an option within NHS Wales, and invited the company delegates to highlighted any outstanding issues.

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 members retired 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, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

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.

7. Appraisal 2: Full Submission
Eslicarbazepine acetate (Zebinix®▼) as adjunctive therapy in adults with partial-onset seizures, with or without secondary generalisation

The Chairman confirmed that the applicant company: Eisai Limited had declined to participate in the appraisal.

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

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

The Chairman invited Mr Anthony Williams, AWTTC 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 from Epilepsy Action had been received.

Dr Bracchi gave a brief overview of the relevant issues identified in the preliminary appraisal and relayed the view of NMG that eslicarbazepine acetate (Zebinix®▼) should be recommended as an option for restricted use within NHS Wales. NMG suggested that use 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. NMG considered that eslicarbazepine acetate (Zebinix®▼) should not be recommended for use within NHS Wales outside of this subpopulation. Dr Bracchi confirmed NMG was of the opinion that eslicarbazepine acetate (Zebinix®▼) for the indication under consideration may be appropriate for use within NHS Wales prescribed by specialist recommendation and in accordance with NICE guidance.

The Chairman invited comment in relation to the case for clinical effectiveness. It was confirmed there were no monitoring requirements. Members considered the views of the clinical experts who highlighted that eslicarbazepine acetate (Zebinix®▼) may be beneficial in patients who respond to, but cannot tolerate carbamazepine or oxcarbazepine due to adverse reactions. They added that in treatment-resistant epilepsy, patients occasionally find significant benefit through trying a new medication, particularly if there is a new mechanism of action.

The Chairman referred members to the comments received from Epilepsy Action Cymru. Mr Palmer highlighted that Epilepsy Action Cymru considered it crucial that the widest possible range of anti-epileptic medication should be available to Welsh patients with epilepsy. He relayed the patient perspective that the availability of as many safe and effective anti-epileptic medicines with different side effect profiles, would give a greater chance of patients achieving seizure freedom which would increase quality of life.

The Chairman invited Professor David Cohen to clarify any outstanding issues in relation to cost effectiveness. It was noted that four comparators had been requested by AWTTC, but the company had only compared against one. It was highlighted that the company were targeting their submission to a sub-population, but had not included trial data for this group of patients. Professor Cohen suggested the cost effectiveness evidence was not compelling and was subject to several uncertainties.

There were no outstanding societal or budget impact issues of note.

The applicant company, Eisai Limited, had no comments relating to the preliminary appraisal recommendation.

The Chairman closed the discussion.

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:

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.

8. Appraisal 3: Full Submission
Colecalciferol (Fultium-D3®) 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

The Chairman welcomed the representative of the applicant company, Internis Pharmaceuticals Limited.

Dr Stephanie Francis, AWTTC assessment lead, joined members. 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 Francis set the context of the appraisal and highlighted relevant issues within the ASAR. It was confirmed that a patient organisation submission had been received from the National Osteoporosis Society. Dr Francis 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 colecalciferol (Fultium-D_3®) should be 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-D_3® is indicated in adults, the elderly and adolescents. He relayed NMG's opinion that colecalciferol (Fultium-D_3®) may be appropriate for prescribing by all prescribers within NHS Wales for the indication under consideration.

The Chairman invited comment in relation to the case for clinical effectiveness. Clarification from the company delegate was sought in relation to the palatability and tolerability of the tablet. It was noted that use of a licensed preparation would be welcomed.

Mr Chris Palmer, the lay member, referred to the patient organisation submission from the National Osteoporosis Society highlighting that many osteoporosis treatments are difficult for patients to tolerate and often have an unpleasant taste. The issue of poor compliance and adherence to treatment was also noted.

Professor David Cohen confirmed there were no outstanding issues in relation to cost effectiveness. The company delegate confirmed that handling costs of the comparator were not included in the company submission.

There were no other societal or budget impact issues of note.

The Chairman drew members' attention to the company response to the preliminary recommendation and invited the company delegate to highlight any issues from the company's perspective. There were none.

Prior to concluding the discussion, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked Internis 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:

Colecalciferol (Fultium-D_3®) 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-D_3® is indicated in adults, the elderly and adolescents.

9. The Chairman read the statement, pertinent to the limited 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. However a positive recommendation by AWMSG, subsequently endorsed by the Minister for Health and Social Services, would place an obligation on Health Boards to fund accordingly. AWMSG advice is interim to NICE guidance, should this be subsequently published.

The Chairman confirmed the following two applications had been considered eligible for a limited submission and, in line with this process, evidence of budgetary impact in comparison to the existing comparator product(s) should be demonstrated. The Chairman guided AWMSG 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. In the event that AWMSG wished to explore any issues within the submission, then the applicant company delegates would be invited to provide clarification. If AWMSG considered there were no outstanding issues, members 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 if the budget impact exceeded that estimated in the submission.

Appraisal 4: Limited Submission
Bupivacaine hydrochloride/fentanyl (Bufyl®) for maintaining analgesia post-operatively and for maintaining epidural analgesia during labour

The Chairman welcomed the representative from the applicant company, Mercury Pharmaceuticals Limited.

Mrs Susan Cervetto, AWTTC assessment lead, joined members. 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.

Mrs Cervetto set the context of the appraisal and highlighted relevant issues within the ASAR. It was noted the application had been considered eligible for a limited submission. Mrs Cervetto confirmed that a patient organisation submission had not been received. The views of the clinical expert were highlighted.

Dr Bracchi relayed the view of NMG was that bupivacaine hydrochloride/fentanyl (Bufyl®) should be recommended as an option for use within NHS Wales for maintaining analgesia post-operatively and for maintaining epidural analgesia during labour. He confirmed NMG were of the opinion that bupivacaine hydrochloride/fentanyl (Bufyl®) is appropriate for specialist only prescribing within NHS Wales for the indication under consideration.

There were no outstanding issues relating to the appraisal of this medicine. Prior to concluding the appraisal, the Chairman asked the company delegate to confirm that the process had been fair and transparent. The Chairman thanked Mercury Pharmaceuticals 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:

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.

10. Appraisal 5: Limited Submission
Ramipril oral solution for the treatment of hypertension, reduction of cardiovascular morbidity and mortality, treatment of renal disease, treatment of symptomatic heart failure and secondary prevention after acute myocardial infarction

The Chairman confirmed that the applicant company, Rosemont Pharmaceuticals Limited, had declined the invitation to participate in the discussions.

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.

Mrs Cervetto, the AWTTC assessment lead, set the context of the appraisal and highlighted relevant issues within the ASAR. It was noted the application had been considered eligible for a limited submission. Members were informed that clinical expert views had been sought. Expert opinion was that ramipril (in tablet/capsule form) is a well established treatment option for the indication being appraised, and no issues were envisaged with the introduction of ramipril as an oral solution as opposed to tablet/capsules. In light of the perceived lack of any issues, the offer to provide a full formal response to AWMSG had been declined. Mrs Cervetto confirmed that a patient organisation submission had not been received.

Members noted the applicant company had no comments in relation to the preliminary recommendation of NMG.

The Chairman invited comment and the estimated number of patients eligible for treatment in the submission was questioned. A licensed product was welcomed. There were no outstanding issues relating to the appraisal of this medicine.

The Chairman closed appraisal proceedings and members retired 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, AWMSG had agreed the following recommendation would be forwarded to Welsh Government:

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.

AWMSG was of the opinion that ramipril 2.5 mg/5 ml oral solution may be appropriate for prescribing by all prescribers within NHS Wales for the indication under consideration.

The Chairman highlighted that ramipril 2.5 mg/5 ml oral solution should only be considered if the patient can not swallow or tolerate ramipril tablets or capsules.

11. All Wales advice on the role of oral anticoagulants for the prevention of stroke and systemic embolism in people with atrial fibrillation

The Chairman invited Dr Tessa Lewis, AWPAG Chair and co-author of Enc **7**/AWMSG/1012, to highlight relevant issues within the paper. Dr Lewis acknowledged the input of Mr Alan Clatworthy and other health board representatives who formed a multi-professional collaborative group to progress the work. Dr Lewis explained the document had been developed to support the interpretation and implementation of National Institute of Health and Clinical Excellence (NICE) technology appraisals (TA) 249 and 256 on the role of dabigatran etexilate (Pradaxa®▼) and rivaroxaban (Xarelto®▼), respectively, for the prevention of stroke and systemic embolism in people with atrial fibrillation in Wales. Members were informed the document provided interim guidance, pending the update of NICE clinical guideline (CG) 36 "The management of atrial fibrillation". It was noted that CG36 is currently being updated to consider new evidence available for several clinical areas including stroke risk stratification, the role of new antithrombotic agents and ablation strategies variation. Dr Lewis stated that the publication date for this guidance is yet to be confirmed.

The Chairman invited AWMSG members to comment. There was discussion over the appropriateness of the title of the paper. It was agreed that warfarin should be included in the background on page 7. Members agreed the paper served as a valuable tool. Members suggested minor changes to provide further clarity to recommendations 2.1, 2.2 and 3.2. A minor amendment to recommendation 4.3 was suggested, and the Chairman confirmed that AWTTC would seek clarification of the accepted practice from the Nephrology Unit outside of the meeting. Mr Turley welcomed the opportunity for pharmaceutical industry comment as part of the consultation process and suggested it be adopted for similar outputs. There was discussion regarding the dissemination and implementation of the guidance. Mrs Samuels confirmed that communication, dissemination and implementation would be routed via WeMeReC, a constituent organisation within AWTTC. Dr Lewis agreed to update the document in light of discussion and, with the agreement of members, the Chairman agreed to take Chairman's action outside of the meeting.

12. Low molecular weight heparins (LMWH) in pregnancy

Dr Lewis provided the background to Enc **8**/AWMSG/1012 and explained that AWMSG had endorsed the document "Prescribing of Low Molecular Weight Heparin in Wales" at their meeting on 3 March 2010. Recommendation 5 had considered the prescribing of prophylactic doses of LMWH in pregnancy. Members were informed there had been no consensus amongst responders and the conclusion was:

> *"Obstetricians are awaiting national guidance and further discussions with regards to LMWH prophylaxis in pregnant patients for the indication of weight related risk. At the current time, AWMSG is not able to make a national recommendation on the most appropriate place for prescribing for this indication".*

Dr Lewis informed members that the work has been progressed through the auspices of the 1000 Lives Plus programme, the Transforming Maternity Services Mini-Collaborative led by Dr Philip Banfield. It describes the deep vein thrombosis (DVT) risk assessment in pregnancy and applies to all clinicians delivering maternity care in Wales. She confirmed it has already been disseminated to clinical teams in health boards and completes the Welsh low molecular weight heparin (LMWH) prescribing strategy to include pregnancy.

The Chairman opened discussion and members welcomed the paper to provide clarity across NHS Wales. There was a suggestion that the instructions should be separate from the contra-indications and that emphasis should be for secondary care supply not community because of safety issues. A request for educational support was made. With the above caveats the Chairman confirmed AWMSG's support of the approach.

13. All Wales In-Patient Medication Administration Record Charts

The Chairman invited Mr Roger Williams to present Enc **9**/AWMSG/1012 and a draft copy of the in-patient medication administration record was tabled. Mr Williams highlighted that the national standardised in-patient medication administration record charts had been approved by AWMSG in 2010. The process of reviewing the charts and associated supporting material had been delegated to the Patient Quality and Safety sub group of the All Wales Chief Pharmacists' Committee. Previously, the charts had been assessed for compliance with the Standards produced by the Academy of Medical Royal Colleges and other interested parties. Mr Williams confirmed the review had identified that two major changes was considered beneficial for the care of patients in Wales:

1. The inclusion of an oxygen prescription on the chart
2. A requirement to record on the chart that the patient had been assessed for venous thromboembolism prophylaxis (mechanical and/or pharmacological).

Mr Williams reported the previous chart had been re-designed with input from Professors Routledge, Ferro and Jackson representing the Royal College of Physicians and British Pharmacological Society. Dr Simon Barry, representing the "oxygen champions" from around Wales, designed the oxygen section.

Mr Williams asked AWMSG to approve the updated All Wales In-Patient Medication Administration Record Charts for use in Welsh Health Boards, as a template for the following charts:

AWMR03.12 Acute In-Patient Chart
AWMR06.12 Acute In-Patient Chart (discharge version)
AWMR05.12 Long-stay In-Patient Chart
AWMR03STUDENT Acute Students In-Patient chart

AWMSG was asked to recognise the resource implications to sustain the current successful arrangement and to support the on-going development of the medication charts and e-learning package, in collaboration with the Royal College of Physicians, London.

Members were asked to support the recommendation that the e-learning package becomes incorporated as a mandatory element of undergraduate training and hospital induction programmes for all medical, nursing and pharmacy professionals. Mr Williams confirmed that the e-learning package would be available on release of the approved charts in January 2013.

The Chairman opened the discussion. It was suggested that the chart updates should be highlighted to the community hospital doctors. At the close of the discussion the Chairman confirmed that AWMSG supported the developments and endorsed the draft in-patient medical administration record as a template for the subsequent development of the other medication charts. He confirmed that AWMSG supported the collaborative approach with the Royal College of Physicians, London. The recommendation to incorporate the e-learning package as a mandatory element of undergraduate teaching and hospital induction programmes for all medical, nursing and pharmacy professionals was also supported by AWMSG.

Date of next meeting

The Chairman confirmed the date of the next meeting on Wednesday, 14th November 2012 in Abergavenny and the meeting closed.