Enclosure No:	**1/AWMSG/1011**
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, 12th OCTOBER 2011 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY

MEMBERS PRESENT:

			Did not participate in
1.	Prof Philip Routledge	Chairman	
2.	Dr Phil Banfield	Hospital Consultant	
3.	Dr Fraser Campbell	GP with prescribing lead role	
4.	Dr Geoffrey Carroll	Welsh Health Specialised Services Committee	
5.	Prof David Cohen	Health Economist	
6.	Mrs Debbie Davies	Representing other professions eligible to prescribe	
7.	Dr Bruce Ferguson	Medical Director	**1-5**
8.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health	
9.	Dr Brian Hawkins	Senior Primary Care Pharmacist	
10.	Ms Ellen Lanham	Community Pharmacist	
11.	Dr Emma Mason	Clinical Pharmacologist	
12.	Mr Christopher Palmer	Lay member	
13.	Mr Christian Smith	Senior Nurse	
14.	Mr Guy Thompson	ABPI (Wales) representative	
15.	Mr Roger Williams	Senior Hospital Pharmacist	

IN ATTENDANCE:

16.	Prof Roger Walker	Welsh Government
17.	Dr Robert Bracchi	NMG Chairman
18.	Mrs Karen Samuels	Welsh Medicines Partnership Board
19.	Mrs Ruth Lang	Welsh Medicines Partnership Board

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. He confirmed that the quorum had been met and opened proceedings.

2. Apologies

Ms Rebecca Richards
Mr Robert Holcombe
Dr John Watkins (no deputy)
Mrs Wendy Warren (Mr Christian Smith deputising)
Professor Ceri Phillips

3. Declarations of interest

The Chairman asked members to declare any interests pertinent to the agenda. There were none.

4. Chairman's report

The Chairman announced that Professor Ceri Phillips had tendered his resignation as the non-voting AWMSG / NMG link member.

The Chairman confirmed that Welsh Government had ratified AWMSG's advice that **sunitinib (Sutent®)** is recommended for use within NHS Wales for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults. Experience with sunitinib as a first-line treatment is limited. AWMSG is of the opinion that sunitinib (Sutent®) is not suitable for shared care within NHS Wales for the above indication.

The Chairman announced that Bristol Myers Squibb had requested an independent review of AWMSG's advice that **dasatinib (Sprycel®▼) should not be recommended for use** within NHS Wales for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia in the chronic phase. AWMSG considered that the case for cost effectiveness had not been proven. Members were informed the grounds for this review would be considered by the AWMSG Steering Committee later this month.

Members were informed that statements of advice reported at the previous meeting had also been ratified and that the draft minutes of this meeting would provide the detail. The draft minutes of the meeting held in September recorded the following statements of advice in preparation:

Bromfenac (Yellox®) cannot be endorsed for use within NHS Wales for the treatment of postoperative ocular inflammation following cataract extraction in adults.

Quetiapine prolonged release (Seroquel XL®) cannot be endorsed for use within NHS Wales for the treatment of major depressive episodes in bipolar disorder.

Temozolomide intravenous solution (Temodal®) cannot be endorsed for use within NHS Wales for the treatment of adult patients with newly-diagnosed glioblastoma multiforme concomitantly with radiotherapy (RT) and subsequently as monotherapy treatment; children from the age of three years, adolescents and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.

Tocofersolan (Vedrop®) cannot be endorsed for use within NHS Wales for the treatment of vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis, from birth (in term newborns) to 16 or 18 years of age, depending on the region..

Latanoprost (Xalatan®) cannot be endorsed for use within NHS Wales for the reduction of elevated intraocular pressure in paediatric patients with elevated intraocular pressure and paediatric glaucoma.

Fentanyl citrate (Breakyl®) cannot be endorsed for use within NHS Wales for the management of breakthrough pain in opioid tolerant adult patients with cancer.

Tapentadol film-coated tablets (Palexia®) cannot be endorsed for use within NHS Wales for the relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics.

Infliximab (Remicade®) cannot be endorsed for use within NHS Wales for the treatment of moderately active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant, or who are intolerant to or have medical contraindications for such therapies.

Methylthioninium chloride (Proveblue®) cannot be endorsed for use within NHS Wales for acute symptomatic treatment of medicinal and chemical products-induced methaemoglobinaemia.

C1 esterase inhibitor (Cinryze®) cannot be endorsed for use within NHS Wales for treatment and pre-procedure prevention of angioedema attacks in adults and adolescents with hereditary angioedema (HAE); or for the routine prevention of angioedema attacks in adults and adolescents with severe and recurrent attacks of HAE, who are intolerant to or insufficiently protected by oral prevention treatments, or patients who are inadequately managed with repeated acute treatment.

Bilastine (Ilaxten®) cannot be endorsed for use within NHS Wales for the symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria.

The Chairman reported that ratification of AWMSG's advice that "**histamine dihydrochloride (Ceplene®▼)** is not be recommended for use within NHS Wales for maintenance therapy for adult patients with acute myeloid leukaemia in accordance with its licensed indication" remained

outstanding.

The Chairman confirmed that at the last meeting it was announced that **rosuvastatin (Crestor®)** for the prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors, would be appraised by AWMSG in October. Members were informed that following appraisal by the New Medicines Group, the applicant Company, AstraZeneca UK Ltd, had been asked to provide further information. At this stage the appraisal process was adjourned. The Chairman confirmed that the process had now resumed, and NMG's preliminary recommendation had been forwarded to AstraZeneca for comment, and appraisal by AWMSG would be undertaken in November.

The Chairman confirmed that, in the absence of a submission from the holder of the marketing authorisation within the appropriate timescales, AWMSG would be advising Welsh Government officials of medicines which could not be endorsed for use within NHS Wales as appraisal by AWMSG had not been undertaken: Members were informed that a number of statements of advice were in preparation, and the draft minutes of the meeting would list the statements which would be forwarded to Welsh Government for ratification as detailed below:

Lapatinib (Tyverb®) for the treatment of patients with breast cancer, whose tumours overexpress HER2 (ErbB2), in combination with capecitabine for patients with advanced or metastatic disease with progression following prior therapy, which must have included anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting.

Abatacept (Orencia®) in combination with methotrexate for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor.

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.

Azithromycin dihydrate (Azyter®) for local antibacterial treatment of conjunctivitis caused by susceptible strains: purulent bacterial conjunctivitis and trachomatous conjunctivitis caused by Chlamydia trachomatis.

Sildenafil (Revatio®) for the treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension.

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

Dexamethasone (Ozurdex®) for the treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis.

Belatacept (Nulojix®) for the prophylaxis of graft rejection in adults receiving a renal transplant, in combination with corticosteroids and a mycophenolic acid.

Mequitazine (Primalan®) for the treatment of allergic conditions such as hay fever, perennial rhinitis, urticaria, pruritis of allergic origin and allergic reactions associated with insect bites and stings.

Fondaparinux sodium (Arixtra®) for the treatment of adult patients with acute symptomatic spontaneous superficial vein thrombosis of the lower limbs without concomitant deep-vein thrombosis.

The Chairman announced the medicines scheduled for appraisal by AWMSG at the next meeting on 9th November 2011:

Tapentadol prolonged release (Palexia SR®) for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics
Applicant Company: Grunenthal Ltd

Paliperidone palmitate (Xeplion®) prolonged release suspension for injection for the maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, it may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed
Applicant Company: Janssen-Cilag Ltd

Collagenase clostridium histolyticum (Xiapex®) for the treatment of Dupuytren's contracture in adult patients with a palpable cord
Applicant Company: Pfizer Ltd

Rosuvastatin (Crestor®) for the prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors
Applicant Company: AstraZeneca UK Ltd

The Chairman reminded members to declare any interest to WMP in relation to these appraisals.

The Chairman invited views from patients, patient organisations and patient carers in relation to the medicines scheduled and those on the future work programme.

5. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy. There were no matters arising.

6. Appraisal 1 - tenofovir disoproxil fumarate (Viread®▼) for the treatment of chronic hepatitis B in adults with decompensated liver disease

The Chairman invited members to declare interests in either the applicant company or the medicine – there were none. Mrs Gail Woodland, WMP Appraisal Lead, joined members.

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 reiterated that NMG had considered the clinical and cost effectiveness issues in detail and had taken account of medical expert and patient organisation views. Members were reminded not to repeat the detailed discussion held at NMG but to seek clarification of any outstanding issues in relation to clinical or cost-effectiveness, consider the company response to the preliminary recommendation and take into account societal and budget impact issues. He confirmed that members would retire to vote in private and agree the recommendation, which would be subsequently announced.

The Chairman welcomed one delegate from the applicant company, Gilead Sciences Limited.

The Chairman invited Dr Robert Bracchi, Chairman of the New Medicines Group, to provide an overview of the discussions held at the preliminary appraisal and set the clinical context of the appraisal. He relayed the views of NMG and the clinical experts, and confirmed that a patient organisation submission had been received from The British Liver Trust and considered by NMG. He concluded his presentation by confirming NMG's recommendation to AWMSG was that tenofovir disoproxil fumarate (Viread®▼) should be recommended as an option for use within NHS Wales for the treatment of chronic hepatitis B (CHB) in adults with decompensated liver disease.

The Chairman opened the discussion and invited members to highlight issues in relation to the case for clinical effectiveness. Members sought clarification of the inclusion criteria of the study, the primary end points and the potential for future efficacy studies.

The Chairman invited Professor David Cohen to provide his views in relation to the case for cost effectiveness. He then asked members to highlight outstanding issues in relation to the case for cost effectiveness. There were no issues of note.

The patient representative drew attention to the main issues highlighted within the patient organisation submission. The Chairman asked Mrs Woodland to provide a summary of the clinical expert opinion.

The company delegate responded to the questions and was offered opportunity to highlight outstanding issues. It was noted that Gilead Sciences Limited had welcomed NMG's positive preliminary recommendation and had confirmed there were no outstanding issues from their perspective.

Prior to concluding the appraisal, the Chairman asked the delegate from Gilead Sciences Limited to confirm that all the outstanding issues had been addressed and she agreed that the process had been fair and transparent. The Chairman thanked Gilead Sciences Limited for engaging in the appraisal process. Members retired to vote.

Appraisal decision
The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had come to the following decision:

Tenofovir disoproxil fumarate (Viread®▼) is recommended as an option for use within NHS Wales for the treatment of chronic hepatitis B (CHB) in adults with decompensated liver disease.

Treatment should normally be initiated following dialogue with a specialist liver unit.

AWMSG is of the opinion that tenofovir disoproxil fumarate (Viread®▼) is not suitable for shared care within NHS Wales for the above indication.

The Chairman announced that confirmation of the AWMSG recommendation would be forwarded by WMP on or before Wednesday, 19th October 2011 and that Gilead Sciences Limited had until Wednesday, 26th October 2011 to accept the recommendation or lodge a request for an independent review, the grounds for which should be submitted to the Chairman in writing. It was confirmed the process would not be delayed if the applicant companies failed to respond to the deadline. It was stated that subject to receiving a request for an independent review within the appropriate timelines, the recommendation would be passed to Welsh Government officials on Thursday, 27th October 2011. The Chairman confirmed that Gilead Sciences Limited would be informed when ratification had been received from Welsh Government.

7. All Wales Prescribing Advisory Group (AWPAG)

The Chairman invited Dr Tessa Lewis to give an overview the AWPAG meeting held on Thursday, 6th October 2011. Dr Lewis confirmed that the draft minutes were in preparation and would be presented to AWMSG at the November AWMSG meeting. She informed members that the following had been considered:

Analgesics leaflet

Dr Lewis confirmed that AWPAG had developed a leaflet to support the prescribing of analgesics. She confirmed the intention to present a paper to AWMSG in November.

Dronedarone

Dr Lewis confirmed that AWPAG had reviewed the prescribing status of dronedarone in light of the EMA statement and recommended that dronedarone should be prescribed and monitored by specialist teams only. Dr Lewis confirmed the intention to present a paper to AWMSG in November.

Monitored Dosage Systems (MDS)

In March 2011 AWMSG endorsed minimum standards for patients admitted on Monitored Dosage Systems (MDS) and requiring one at discharge. This process was proposed as an interim measure where hospitals were unable to provide discharge medication directly, providing a simpler model compared with other models. Subsequently, AWPAG considered the process could be simplified further and undertook two small surveys to allow basic quantification of the problems. Findings from this work had been summarised, key themes developed into standards of good practice, and these were presented to AWPAG for discussion.

Patient information at the point of discharge – Medicine Reminder Charts

Dr Lewis confirmed that AWPAG are proposing measures to promote the provision of patient held medicines reminder charts, to include telephone contact numbers, for use by patients when transferring between care settings and community prescribers. This work will be presented to AWMSG at a future meeting.

National Prescribing Indicators 2012-2013

Dr Lewis informed members that the Indicator Working Group had met on 13th September to review the current national indicators and make recommendations for those to be considered for 2012-2013. The indicators proposed by the working group had been considered by AWPAG. Members were informed that informal consultation on the national indicators proposed for 2012-2013 would be undertaken prior to the AWMSG Steering Committee meeting on 24th November. Several new local comparators were recommended by the Indicator Working Group and these will be considered in detail at AWPAG Jan 2012 meeting.

Feedback from the joint meeting with the Antimicrobial Stewardship Forum

The Chair confirmed that a joint meeting had been held by WMP and the Antimicrobial Stewardship Forum to promote appropriate antimicrobial prescribing within NHS Wales. Key messages were discussed by the group and areas for prioritisation identified. A key outcome from the meeting was that appropriate antimicrobial prescribing guidelines currently exist and there is a need for these guidelines to be promoted and adhered to, and any non-compliance issues identified.

CEPP – National Audits

Dr Lewis confirmed that AWPAG had prioritised areas for development of national audits. AWPAG members had volunteered to undertake pilots.

Erectile dysfunction

AWPAG had reviewed WHC (99) 148 and considered whether the guidance required re-issue in a similar format, or whether it should be changed. Dr Lewis relayed the view of AWPAG that

there is a need for equity, as there is currently variation across Wales in the management of erectile dysfunction. AWPAG had discussed the issue of the most appropriate place for prescribing for the indication of severe distress. Dr Lewis confirmed that the issue will be progressed in discussion with Welsh Government.

Low Molecular Weight Heparin (LMWH) prophylaxis in pregnancy
Dr Lewis informed AWPAG that Dr Phil Banfield, AWMSG Consultant representative and Obstetrician, had attended AWPAG. In March 2010, AWMSG had endorsed five recommendations in relation to the prescribing of low molecular weight heparin (LMWH) in Wales. These had covered the most common scenarios, but there was an outstanding issue in relation to prescribing prophylactic LMWH in pregnant women where high body mass index was a risk factor. A document had been prepared by the Transforming Maternity Services Mini-Collaboration1000 Lives Campaign and brought to AWPAG by Dr Banfield. The aim - to reduce the risk of venous thromboembolism in pregnancy, whilst optimising the number of women being given LMWH prophylaxis, which itself may have direct and indirect adverse consequences. AWPAG had welcomed the clarification and recommendation which included BMI over 45 as part of a DVT risk assessment at booking.

Gluten-free prescribing
Dr Lewis informed members that AWPAG had considered a briefing prepared by a T&FG of the MMPB to address issues relating to the supply of gluten free products on prescription within NHS Wales. AWPAG had supported the recommendations in the briefing and it is intended that this briefing will be presented to AWMSG for endorsement in November.

Non-medical prescribing
Dr Lewis confirmed that AWPAG had endorsed the paper developed by Mr Marc Donovan, Community Pharmacist, to support and promote non-medical prescribing within NHS Wales which would be considered by AWMSG later in the meeting.

Prescribing of warfarin
Dr Lewis confirmed that a T&FG had met to consider issues around the prescribing of warfarin. An update report was in process.

The Chairman was encouraged by the many issues progressed by AWPAG and asked Dr Lewis to relay his thanks to members of her Group.

8. All Wales Student Drug Chart – for information
Professor Routledge informed members that the All Wales Student Drug Chart had been provided to members for information. He confirmed that Helen Day in Swansea University had initiated the development of a chart to assist with the teaching of prescribers in training. The Chairman confirmed that the Welsh Medicines Partnership had provided funding for the printing of paper copies which will be distributed to educational providers, and an electronic version of the student chart would be available to download from the AWMSG website.

9. Patient Access Scheme Wales – update report
The Chairman welcomed Mr Carl Boswell from the NICE Patient Access Scheme Liaison Unit.

Mrs Karen Samuels provided an overview of the discussion paper and invited AWMSG to consider the process for piloting the implementation of patient access schemes (PAS) in NHS Wales. She confirmed that a proposal to establish a Patient Access Scheme Wales Group (PASWG) had been supported by AWMSG at their meeting on 13th July 2011. The remit of PASWG would be to consider the feasibility, workability and acceptability of PAS within NHS Wales. She confirmed that WMP had worked with the Association of the British Pharmaceutical Industry (ABPI) Wales and the National Institute for Health and Clinical Excellence (NICE) Patient Access Support Liaison Unit (PASLU) in developing a process for

dealing with PAS based on the key principles described in the 2009 Pharmaceutical Price Regulation Scheme (PPRS). Mrs Samuels reiterated that the role of PASWG would be to advise the Welsh Government in relation to the feasibility of implementing a PAS within NHS Wales. Based on PASWG advice, Welsh Government would subsequently decide whether or not the PAS could be considered by AWMSG as part of the Health Technology Appraisal process in Wales.

There was discussion in relation to the principles set out in the paper. It was noted that there are currently five companies that have not engaged in the appraisal process in Wales as there is currently no mechanism for considering Wales-specific patient access schemes. Mr Boswell confirmed that patient access schemes approved by the DH once included in a NICE TA are mandatory in Wales and England. The industry member confirmed that the pharmaceutical industry welcomed the proposal. There was discussion over the potential administrative burden of such schemes. The industry representative commented that some of the detail of the proposed pilot required clarification and WMP agreed to liaise further with ABPI Wales outside of the meeting. The Chairman confirmed that no additional nominations for the role of Chair had been received, and that the nomination for Professor Marcus Longley to take on the role as PASWG Chairman would be submitted to Welsh Government officials. It was noted that the Chief Pharmacists Group had nominated a PASWG committee member. It was noted that no other nominations had been received. There was discussion in relation to transparency and duration of schemes, especially fixed term. There was general agreement that the application of such schemes should be the exception rather than the rule. The need for PASWG to work on the same principles as those of PASLU was reiterated. There was discussion regarding the timing of submitting a PAS, and Mr Boswell confirmed that manufacturers had two opportunities to submit a scheme to PASLU – the first before the technology process commences, and the second on publication of NICE's final advice. The Chairman closed the discussion by confirming that once the outstanding issues had been resolved, opportunity would be extended to the five companies not currently engaging in the AWMSG appraisal process to participate in the pilot. It was agreed that a review of the pilot, including a full costing, would subsequently be undertaken.

10. Non Medical Prescribing

The Chairman invited Mr Mark Donovan, Community Pharmacists representative on the MMPB, to present Enc **6/**AWMSG/1011. Mr Donovan informed members that Welsh Government had made a commitment to non medical prescribing which had been supported by a budget allocation to train over 600 nurse and pharmacists as non medical prescribers, and promote non medical prescribing to improve

- patient safety
- choice and access to services without compromising patient safety
- patient care
- use of the skilled healthcare workforce
- more flexible team working across the NHS
- capacity to meet demand of new ways of working

Mr Donovan confirmed that a T&FG had considered whether NHS Wales was utilising and developing the skills of non medical prescribers to deliver on its original policy objectives for improving accessibility of medicines to patients. The group focused efforts in identifying how Health Boards had taken forward the recommendations of the 'Lifting the Lid Symposium', following the letter to Heath Boards from Paul Williams dated June 2010. The Group concluded that the original policy objective of establishing non medical prescribing in Wales was well underway. The feedback from Health Boards was that non medical prescribers are an asset to their organisation and this appeared to be supported by increase in the numbers being trained and in practice.

AWMSG considered the three recommendations of the T&FG:

Recommendation 1 – The on-going use of non medical prescribing be incorporated into AWMSG's Medicines Strategy for Wales.
Recommendation 2 – Commissioning of pilot studies be undertaken to evaluate service redesign
Recommendation 3 – A system for monitoring and surveillance on non medical prescribing should be established

There was general agreement that NHS Wales is facing unprecedented challenges and new ways of working are required to deliver effective services which improve health and make the best use of all available resources.

The Chairman closed the discussion by stating that AWMSG endorsed in principle three recommendations of the paper. He confirmed that non medical prescribing would be incorporated into the Medicines Strategy for Wales which is currently under review.

11. The Chairman announced the date of the next AWMSG meeting - Wednesday, 9h November 2011 at The Angel Hotel, Abergavenny and closed proceedings