Enclosure No:	**1/AWMSG/0514**
Agenda Item No:	**4** – Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY, 2nd APRIL 2014 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY, NP7 5EN

VOTING MEMBERS PRESENT:

			Did not participate in
1.	Professor Phil Routledge	Chairman	
2.	Professor David Cohen	Health Economist	
3.	Mr Stuart Davies	Finance Director	
4.	Mr Stefan Fec	Community Pharmacist	
5.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health	
6.	Dr Stuart Linton	Hospital Consultant	
7.	Mrs Susan Murphy	Managed Sector Primary Care Pharmacist	
8.	Mr Christopher Palmer	Lay Member	
9.	Mr Lance Richards	ABPI Cymru Wales	
10.	Mr Christian Smith	Senior Nurse	
11.	Mr John Terry	Managed Sector Secondary Care Pharmacist	
12.	Dr William Whitehead	GP with Prescribing Lead role	

IN ATTENDANCE:

13. Mrs Karen Samuels, Head of HTA, AWTTC
14. Mrs Ruth Lang, Head of Liaison & Administration, AWTTC

AWTTC APPRAISAL LEADS:

15. Mrs Susan Cervetto, 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
CEPP	Clinical Effectiveness Prescribing Programme
CHMP	Committee for Medicinal Products for Human Use
DoH	Department of Health
ECDF	English Cancer Drugs Fund
EMA	European Medicines Agency
FAR	Final Appraisal Recommendation
FDA	US Food and Drug Administration
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Boards
HST	Highly Specialised Technology
HTA	Health Technology Appraisal
IR	Independent Review
MHRA	Medicines and Healthcare products Regulatory Agency
MMPB	Medicines Management Programme Board
M&TCs	Medicines & Therapeutics Committees
NICE	National Institute for Health and Clinical Excellence
NMG	New Medicines Group
NSAIDs	Non-steroidal anti-inflammatory drugs
PAR	Preliminary Appraisal Recommendation
PAS	Patient Access Scheme
SMC	Scottish Medicines Consortium
TDAPG	Therapeutic Development Appraisal Partnership Group
T&FG	Task and Finish Group
WG	Welsh Government
WAPSU	Welsh Analytical Prescribing Support Unit
WPAS	Welsh Patient Access Scheme

1. Welcome and introduction

The Chairman opened the meeting and welcomed members.

2. Apologies

Dr Geoffrey Carroll (representing Welsh Health Specialised Services Committee)
Dr Khesh Sidhu (representing Welsh Health Specialised Services Committee)
Mrs Debbie Davies (representing other professions eligible to prescribe)
Dr Emma Mason (Clinical Pharmacologist)
Mr Roger Williams (Managed Sector Secondary Care Pharmacist)
Mrs Ellen Lanham (Community Pharmacist)

3. Declarations of interest

There were no declarations pertinent to the agenda.

4. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy and approved by the Chairman.

5. Chairman's report

The Chairman informed members that he had been invited to give further evidence to the

Health and Social Care Committee in relation to the enquiry into access to medical technologies on Thursday, 4th April 2014.

The resignation of Dr Brendan Lloyd was announced. The Chairman thanked Dr Lloyd for his support to AWMSG and input into safe and effective prescribing. It was confirmed that AWTTC would be seeking a replacement member and deputy from the Chairman of the Medical Directors Committee.

The Chairman confirmed that the first AWTTC workshop in support of the Prudent Prescribing agenda would be held in North Wales on Wednesday, 9th April.

Members were informed that on 4th March AWTTC hosted a meeting of AWMSG's Patient and Public Interest Group and highlighted the importance of lay people/patients/patient organisations in medicines related issues, particularly in relation to health technology appraisals. The Chairman confirmed that AWTTC were in the process of prioritising the recommendations of the patient strategy which was endorsed by AWMSG in February and is available on the AWMSG website.

It was announced that the outcome of the review of AWMSG's Policy for appraising orphan and ultra orphan medicines is yet to be published and that AWTTC would inform AWMSG members as soon as this became available.

The Chairman confirmed that he would be meeting with the Minister for Health & Social Services on Monday, 7th April to update him on the work of AWMSG.

Members were informed that ratification of AWMSG's advice, which was forwarded to Welsh Government following the meeting held on 19th February 2014 remained outstanding.

The appraisals scheduled for the next meeting to be held in Abergavenny on Wednesday, 7th May 2014 were confirmed.

Appraisal 1: Full Submission
Fluticasone furoate/vilanterol (as trifenatate) (Relvar® Ellipta®) for the symptomatic treatment of adults with chronic obstructive pulmonary disease, with a FEV1 < 70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy
Applicant Company: GlaxoSmithKline

Appraisal 2: Full Submission
Abiraterone acetate (Zytiga®) in combination with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated
Applicant Company: Janssen-Cilag Ltd

The Chairman reminded members to declare any interests in relation to the appraisals before the next meeting. Patients, patient organisations and patient carers were invited to submit their views on the medicines scheduled for appraisal.

6. Appraisal 1 – Limited submission
Darunavir (Prezista®) co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in paediatric patients from the age of 12 years and at least 40 kg body weight who are: antiretroviral therapy (ART)-naive; or ART-experienced with no darunavir resistance associated mutations (DRV-RAMs) and who have plasma HIV-1 RNA < 100,000 copies/ml and CD4+

cell count ≥ 100 cells x 10^6/l. In deciding to initiate treatment with darunavir in such ART-experienced patients, genotypic testing should guide the use of darunavir

The Chairman welcomed representation from the applicant company, Janssen-Cilag Ltd.

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 that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an obligation on Health Boards to fund accordingly. It was confirmed that AWMSG advice is interim to final NICE guidance should this be subsequently published. The Chairman confirmed that the application 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 should be demonstrated. The Chairman reiterated that monitoring of budget impact would be essential and that AWMSG reserved to right to request a full submission if the budget impact exceeded that estimated in this limited submission.

The Chairman invited Mrs Susan Cervetto, AWTTC assessment lead, to set the context of the appraisal. Mrs Cervetto highlighted relevant aspects of the submission as detailed in the ASAR and relayed the views of the clinical experts. In the absence of the NMG Chairman, Mrs Cervetto confirmed NMG's preliminary recommendation that darunavir (Prezista®) should be recommended as an option for use within NHS Wales for the treatment of human immunodeficiency virus-1 (HIV-1) infection in paediatric patients from the age of 12 years and at least 40 kg body weight who are: antiretroviral therapy (ART)-naive; or ART-experienced with no darunavir resistance associated mutations (DRV-RAMs) and who have plasma HIV-1 RNA < 100,000 copies/ml and $CD4^+$ cell count ≥ 100 cells x 10^6/l. In deciding to initiate treatment with darunavir in such ART-experienced patients, genotypic testing should guide the use of darunavir.

The Chairman opened the discussion and invited comment on the case for clinical effectiveness. Clarification was sought in relation to adverse events. The company delegate was unable to respond to the clinical issues raised by AWMSG as he had no medical experience. The Chairman referred members to the clinical expert summary and members considered the views expressed by the clinical experts from within NHS Wales. Members took account of the budget impact and clarification was sought as to whether the genotypic testing was included in the calculation and routinely undertaken. There were no outstanding societal issues.

It was noted that a patient organisation submission had not been received. Mr Palmer informed members of the attempts made by AWTTC to identify a patient organisation submission. Mr Palmer reminded members of the organisation's comments on the importance of having as many treatment options available to patients as possible.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegate to highlight salient issues. There were no further comments. Prior to concluding the discussion, the Chairman sought and received confirmation from the company delegate that the process had been fair and transparent. He thanked Janssen-Cilag for engaging in the appraisal process and concluded appraisal proceedings. Members retired to vote in private and the meeting was opened to the public.

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

Darunavir (Prezista®) is recommended as an option for use within NHS Wales for the treatment of human immunodeficiency virus-1 (HIV-1) infection in paediatric patients from the age of 12 years and at least 40 kg body weight who are: antiretroviral therapy (ART)-naive; or ART-experienced with no darunavir resistance associated mutations (DRV-RAMs) and who have plasma HIV-1 RNA < 100,000 copies/ml and $CD4^+$ cell count ≥ 100 cells x 10^6/l. In deciding to initiate treatment with darunavir in such ART-experienced patients, genotypic testing should guide the use of darunavir.

The Chairman announced that confirmation of AWMSG's recommendation would be forwarded to Janssen-Cilag within five working days; and confirmed that the applicant company had up to ten working days to accept the recommendation or lodge a request for an independent review. It was noted that failure to respond within the deadline would not delay the ratification process.

The appraisal proceedings were concluded.

7. National Prescribing Indicators 2014–2015: Supporting Information for Prescribers
Mrs Kath Haines, Head of WAPSU, joined members around the table. The Chairman asked Mrs Haines to explain the purpose of Enc 3/AWMSG/0414 National Prescribing Indicators 2014-2015: Supporting Information for Prescribers. Mrs Haines explained that the document served as a tool for prescribers in providing a clear, concise summary of the evidence behind AWMSG's National Prescribing Indicators. It was confirmed that the AWMSG lipid guidance would be updated on publication of updated NICE guidance which is anticipated in July. There was discussion in relation to the dissemination of the document within NHS Wales. Professor Walker acknowledged the work involved in producing the information and requested information at local health board and cluster level for monitoring purposes. It was explained that a cluster consisted of a number of general practices working together geographically. Members discussed patient monitoring to audit the effectiveness of medicines. The need to link with Community Pharmacy and all prescribers, including nurses, dentists and optometrists, was highlighted. Dr Fitzgerald suggested linking with patient safety campaigns and patient safety champions. Members welcomed the document and noted the focus on quality rather than cost.

The Chairman thanked members for their comments and confirmed AWMSG's endorsement of the document.

8. National Prescribing Indicators: Analysis of Yellow Card Reporting Data to December 2013
Mrs Haines presented Enc 4/AWMSG/0414 and explained that in addition to the quarterly national prescribing indicator (NPI) reports, WAPSU produces more detailed health board-specific information for selected NPIs on a bi-monthly basis. Members were informed that the number of yellow cards submitted by reporters within Wales has been in decline over the past ten years and, in order to highlight the importance of reporting adverse drug reactions, it had been included as an NPI for 2014–2015. Mrs Haines confirmed that WAPSU had collaborated with the Yellow Card Centre Wales in preparing the document. Mrs Haines referred members to the report; the first part of which included All Wales comparative data relating to yellow card reporting, and the second part which contained data-specific information at health board level. The Chairman opened the discussion and invited comment on ways to improve the reporting of adverse events. It was suggested that all prescribers

should be encouraged to complete and submit at least one yellow card. Other suggestions included auditing adverse drug reactions (ADRs) identified within general practices, use of the medicines use review process to identify ADRs and increase the emphasis on the role of Community Pharmacy in highlighting ADRs. Members supported the move to improve yellow card reporting within NHS Wales and welcomed the inclusion of Yellow Card Reporting within the National Prescribing Indicators.

9. Monitoring of Medicines Appraised by NICE and AWMSG: Summary

The Chairman asked Mrs Haines to take members through Enc 5/AWMSG/0414, a summary report detailing the usage of medicines appraised by the National Institute for Health and Care Excellence (NICE) or AWMSG, or where a statement of advice due to non-submission had been issued by AWMSG. It was noted that the report included all advice issued up to 31 March 2013 and is intended as a working document to support health boards in monitoring prescribing activity. The Industry Representative asked for the full report to be made available to enable fuller discussion and investigation. Mrs Haines confirmed that the decision to provide the summary report had been that of the AWMSG Steering Committee, and the Chairman agreed to relay to the Steering Committee the member's view that the full report be available in the public domain.

10. Mental Health & Medication Wales

In the absence of the author Mrs Haines presented Enc 6/AWMSG/0414 and asked AWMSG to endorse the Mental Health and Medication Wales project and provide support in raising awareness of and publicising the resource amongst health boards, GPs, pharmacies, patient groups and relevant organisations throughout Wales.

The National Centre for Mental Health (NCMH) and Bipolar Education Programme Cymru are providing free access to Mental Health and Medication Wales to support people in Wales to make informed choices. Mrs Haines highlighted that this resource would allow the people of Wales to access evidence-based, hig- quality information regarding medications used to treat mental health conditions. The aim of the paper is to raise awareness of Mental Health and Medication Wales and encourage patients to access the website.

Mental Health and Medication Wales is a website that provides useful and easy to understand information about mental health conditions and the different medications used to help treat these conditions. The area of mental health is one of the largest areas of non-medical prescribing. The website, aimed at patients, carers and professionals in Wales, is endorsed by The College of Mental Health Pharmacy. The independent and quality-assured content is written by specialist mental health pharmacists and based on best available evidence. The website includes answers to commonly asked questions about different mental health conditions and different medications, and provides access to Printable Patient Information Leaflets. These are summaries of the main questions and answers about different medications.

The Chairman confirmed AWMSG's support of this resource and agreed to signpost to it from the AWMSG website. The Chairman offered to meet directly with the author of the paper to relay members' suggestions in relation to potential routes for signposting to the target population.

The Chairman announced the date of the next meeting and closed proceedings.

Date of next meeting:
Wednesday 7th May 2014 in Abergavenny