Enclosure No:	**1/AWMSG/0614**
Agenda Item No:	**4** – 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, 7th MAY 2014 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY, NP7 5EN

VOTING MEMBERS PRESENT:

			Did not participate in
1.	Professor John Watkins	Chairman	
2.	Professor David Cohen	Health Economist	
3.	Mrs Debbie Davies	Other professions eligible to prescribe	
4.	Mr Stuart Davies	Finance Director	
5.	Mrs Ellen Lanham	Community Pharmacist	
6.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health	
7.	Dr Stuart Linton	Hospital Consultant	
8.	Dr Emma Mason	Clinical Pharmacologist	
9.	Mrs Susan Murphy	Managed Sector Primary Care Pharmacist	
10.	Mr Christopher Palmer	Lay Member	
11.	Dr Stephen Monaghan	Public Health Wales	
12.	Mr Roger Williams	Managed Sector Secondary Care Pharmacist	
13.	Dr William Whitehead	GP with Prescribing Lead role	

IN ATTENDANCE:

14. Mrs Karen Samuels, Head of HTA, AWTTC
15. Mrs Ruth Lang, Head of Liaison & Administration, AWTTC
16. Dr Robert Bracchi, NMG Chairman

AWTTC APPRAISAL LEADS:

17. Mrs Sabrina Rind, Senior Appraisal Pharmacist
18. Mrs Gail Woodland, 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 Dr Stephen Monaghan to his first AWMSG meeting.

2. Apologies

Professor Philip Routledge, AWMSG Chairman
Professor Roger Walker, Chief Pharmaceutical Officer, Welsh Government
Mr Rob Thomas, ABPI Cymru Wales
Mr Lance Richard, ABPI Cymru Wales
Mr Christian Smith, Senior Nurse

Not in attendance

Dr Geoffrey Carroll (representing Welsh Health Specialised Services Committee)

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

Members were informed that a report had been issued by Welsh Government on 30th April 2014 following a review of AWMSG's process for appraising orphan and ultra-orphan medicines. The report and a summary of the consultation responses received are available on the Welsh Government website. The Chairman confirmed that AWMSG had been asked to develop and implement a whole-system approach to the identification, appraisal and monitoring of rare diseases where patient numbers are very low; the aim being to ensure that patients with rare diseases have fair and equitable access to appropriate, evidence-based treatments.

The Chairman reported that the outcome of a review commissioned by Welsh Government into the Individual Patient Funding Request (IPFR) process had been published on 30th April and is available on the Wales.gov.uk website. An 8 week consultation into the group's recommendations would be undertaken.

The Chairman confirmed that ratification of AWMSG's advice, forwarded to Welsh Government subsequent to the meetings held on 19th February and 2nd April, had not been received by AWTTC. He stated that the relevant companies and the service would be informed when confirmation of ratification had been received.

The Chairman announced five appraisals scheduled for the next meeting to be held in Cardiff on Wednesday, 11th June 2014:

Appraisal 1: Full Submission
Insulin degludec (Tresiba®) for the treatment of diabetes mellitus in adults
Applicant Company: Novo Nordisk Ltd

Appraisal 2: Full Submission
Imatinib (Glivec®) as adjuvant treatment, for up to 36 months, of adult patients who are at significant risk of relapse following resection of Kit (CD117)-positive GIST. Patients who have a low or very low risk of recurrence should not receive adjuvant treatment
Applicant Company: Novartis Pharmaceuticals UK Ltd

Appraisal 3: Full Submission
Eltrombopag (Revolade®) is indicated in adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy
Applicant Company: GlaxoSmithKline UK

Appraisal 4: Full Submission
Velaglucerase alfa (VPRIV®) for long-term enzyme replacement therapy in patients with type 1 Gaucher disease
Applicant Company: Shire Pharmaceuticals Ltd

Appraisal 5: Limited Submission
Emtricitabine/rilpivirine/tenofovir disoproxil (Eviplera®) for antiretroviral treatment-experienced adults infected with human immunodeficiency virus type 1 without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with a viral load ≤ 100,000 HIV-1 RNA copies/ml. As with other antiretroviral medicinal products, genotypic resistance testing and/or

historical resistance data should guide the use of Eviplera
Applicant Company: Gilead Sciences Ltd

The Chairman highlighted that three submissions were associated with a patient access scheme and the appraisal would be undertaken in private to protect commercial confidentiality.

The Chairman reminded members to declare any interests in relation to this appraisal before the next meeting. The views of patients, patient organisations and patient carers were encouraged.

6. Appraisal 1

The Chairman announced that the first appraisal had been postponed and asked Mrs Gail Woodland, AWTTC Lead Assessor, to explain the reasons for this.

Mrs Woodland confirmed that on 9th April 2014 NMG undertook the preliminary appraisal of abiraterone acetate (Zytiga®▼) 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. She confirmed NMG's view that abiraterone should not be recommended and the key factor influencing NMG's decision was that the case for cost effectiveness had not been proven. NMG acknowledged that the AWMSG criteria for appraising life-extending, end-of-life medicines did not apply to abiraterone acetate (Zytiga®▼) for the indication under consideration as the median overall survival of patients in the control group of study COU-AA-302 was 30.1 months. Part of the conditions to satisfy end of life is that patients are expected to have a short life expectancy which is normally less than 24 months and therefore NMG considered that the overall survival of patients would exceed this period of time.

Members were informed that in line with the appraisal process the market authorisation holder, Janssen-Cilag Ltd, was provided with the preliminary appraisal recommendation and given an opportunity to respond. In their reply Janssen-Cilag Ltd stated that they considered the life expectancy of patients within the terms of the licence was less than 24 months and submitted additional information to support this view.

Mrs Woodland highlighted that the process for consideration of the applicability of NICE's End of Life Criteria states that if the company does not accept NMG's interpretation, then the company have opportunity to request a meeting be convened to discuss the issues prior to appraisal by AWMSG. Members were informed that AWTTC are in the process of setting up this meeting and the appraisal had been postponed.

7. Appraisal 2 - Full Submission

Fluticasone furoate/vilanterol (as trifenatate) (Relvar® Ellipta®) for the symptomatic treatment of adults with chronic obstructive pulmonary disease, with a FEV_1 < 70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy

The Chairman welcomed representatives from the applicant company, GlaxoSmithKline Limited.

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

The Chairman announced 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 invited Mrs Sabrina Rind, AWTTC assessment lead, to set the context of the appraisal. Mrs Rind presented an overview of the submission as detailed in the ASAR and the views of the clinical experts were relayed. Members were informed that a patient organisation submission had not been received.

The Chairman invited Dr Bracchi, NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Bracchi confirmed that NMG recommended that the medicine should be restricted for use in line with NICE Clinical Guideline on chronic obstructive pulmonary disease for the symptomatic treatment of adults with chronic obstructive pulmonary disease with a FEV_1<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy. NMG wished to highlight their concerns with the similarity of the colour of fluticasone furoate/vilanterol (Relvar® Ellipta®▼) inhaler to a reliever inhaler and the potential risks of steroid overdose.

The Chairman invited comment in relation to the case for clinical effectiveness. Clarification was sought in relation to dose description on the labelling and serious adverse reactions identified in the treatment group were discussed. Members explored the rationale behind the study design. The Chairman referred to the clinical expert summary. Experts highlighted an unmet need in smoking cessation services in relation to the treatment of chronic obstructive pulmonary disease.

The Chairman invited Professor Cohen to comment on the case for cost effectiveness. Professor Cohen highlighted the limitations in undertaking a cost minimisation analysis and stated that assumption of equivalence across all domains is rarely demonstrated.

The Chairman referred to the applicant company response to the preliminary recommendation and offered opportunity to the delegates to comment. The company delegate stated that he agreed with the limitations highlighted by Professor Cohen and provided an explanation for the pragmatic approach taken by the company in demonstrating the cost effectiveness of this medicine. The restriction within the preliminary recommendation was accepted.

Prior to concluding the appraisal, the Chairman sought confirmation from the company delegates that the process had been fair and transparent. He thanked GlaxoSmithKline 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, the following recommendation would be forwarded to Welsh Government:

Fluticasone furoate/vilanterol (as trifenatate) (Relvar® Ellipta®▼) is recommended as an option for use within NHS Wales for the symptomatic treatment of adults with chronic obstructive pulmonary disease with a FEV_1< 70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.

The Chairman announced that confirmation of AWMSG's recommendation would be forwarded to GlaxoSmithKline Limited within five working days. He informed the delegates that applicant companies have 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 process.

The Chairman thanked GlaxoSmithKline Limited for engaging in the process and appraisal proceedings were concluded.

8. One System for Health

The Chairman invited Dr Bracchi to present the background to Enc 4/AWMSG/0514. Dr Bracchi explained the purpose of the document is to update AWMSG on progress against one of the key recommendations and outcomes within the AWMSG Five-year Strategy 2013–2018 and to request support in delivering the outcomes of the recommendations. It was highlighted that the availability of electronic discharge advice letters (DALs) would improve communication about patients' medicines between secondary and primary care. Also, the implementation of electronic prescribing in hospitals would support safer prescribing and management of medicines expenditure across NHS Wales. The Chairman opened discussion and invited comments and suggestions. Members agreed that full electronic prescribing is a priority for NHS Wales and should be supported by all professional forums. There was general agreement that its development should not be fragmented, but should be moved forward in a co-ordinated way. There was a suggestion that a multidisciplinary stakeholder group could be set up to help support and drive the initiative. Mr Stuart Davies agreed to seek the views of the Finance Directors. Members suggested that a presentation to Medical Directors, Nurse Directors and Chief Executives to promote the benefits of electronic prescribing may help progress the implementation of hospital electronic prescribing and medicines administration across Wales. Dr Whitehead highlighted a need for medicine and clinical information to be available to prescribers. The Chairman closed discussion and confirmed AWMSG's wholehearted support of the initiative.

Date of next meeting:
Wednesday 11th June 2014 in Cardiff