

Enclosure No:	1/AWMSG/0515
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 Wednesday,
22nd April 2015 commencing 10.30 am at Cardiff
Metropolitan University (Llandaff Campus) Western
Avenue, Cardiff, CF5 2YB**

**Did not
participate in**

VOTING MEMBERS PRESENT:

1. Dr Stuart Linton Chairman
2. Dr Geoffrey Carroll Welsh Health Specialised Services Committee
3. Professor David Cohen Health Economist
4. Dr Karen Fitzgerald Public Health Wales
5. Mrs Ellen Lanham Community Pharmacist
6. Dr Balwinder Bajaj Clinical Pharmacologist
7. Mrs Alison Hughes Managed Sector Primary Care Pharmacist
8. Mr Alun Morgan Other professions eligible to prescribe
9. Mr Christopher Palmer Lay Member
10. Mr John Terry Managed Sector Secondary Care Pharmacist
11. Mr Bill Malcolm ABPI Cymru Wales
12. Professor John Watkins Public Health Wales
13. Mrs Louise Williams Nurse representative
14. Dr Bill Whitehead GP with Prescribing Lead role

IN ATTENDANCE:

Dr Saad Al-Ismael, NMG Chairman
Mrs Karen Samuels, Head of HTA, AWTTTC
Mrs Ruth Lang, Head of Liaison & Administration, AWTTTC

AWTTC APPRAISAL LEADS:

Dr Caron Jones, Senior Appraisal Scientist
Mrs Gail Woodland Senior Appraisal Pharmacist

WELSH GOVERNMENT:

No representation

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
CAPIG	Clinical and Patient Involvement Group
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
EOL	End of life
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 Care Excellence
NMG	New Medicines Group
PAR	Preliminary Appraisal Recommendation
PAS	Patient Access Scheme
PPRS	Prescription Price Regulation Scheme
SMC	Scottish Medicines Consortium
TDAPG	Therapeutic Development Appraisal Partnership Group
T&FG	Task and Finish Group
UHB	University Health Board
WAPSU	Welsh Analytical Prescribing Support Unit
WCPPE	Welsh Centre for Pharmacy Postgraduate Education
WeMeReC	Welsh Medicines Resource Centre
WG	Welsh Government
WHSSC	Welsh Health Specialised Services Committee
WPAS	Wales Patient Access Scheme

1. Welcome and introduction

The Chairman opened the meeting and welcomed members. He welcomed Dr Saad Al-Ismael to his first AWMSG meeting as NMG Chairman, and Mr Bill Malcolm to his first meeting as ABPI representative.

2. Apologies

Dr Mark Walker & Dr Brendan Boylan (Medical Director representatives)
Dr Emma Mason (Dr Balwinder Bajaj attending)
Mrs Sue Murphy (Mrs Alison Hughes attending)
Dr Catherine Bale (Hospital Consultant representative)
Professor Roger Walker, Chief Pharmaceutical Officer, Welsh Government

Not in attendance:

Mr Stuart Davies (Finance Director representative)

3. Declarations of interest

The Chairman invited declarations of interest pertinent to the agenda. Mr Bill Malcolm declared an interest pertaining to Appraisal 2 - Adalimumab (Humira[®]) in that his employer, Novartis, manufacture a competitor product. It was confirmed that Mr Malcolm would not participate or vote in this appraisal.

4. Chairman's report

The Chairman updated members on the request made by Sanofi-Aventis Limited for an independent review in relation to aflibercept (Zaltrap[®]) in combination with irinotecan/5 fluorouracil/folinic acid (FOLFIRI) chemotherapy for the treatment of adults with metastatic colorectal cancer (MCR) that is resistant to or has progressed after an oxaliplatin containing regimen. The Chairman confirmed that having considered the grounds, he had come to the conclusion that an independent review would not be appropriate and the request was declined. It was confirmed that AWMSG's final appraisal recommendation would be forwarded to Welsh Government for ratification.

The Chairman confirmed that ratification of AWMSG's recommendations from the meeting held in March had not been received.

The Chairman reported that the appraisal of beclometasone dipropionate/formoterol fumarate (Fostair[®]) for the symptomatic treatment of patients with COPD, with a FEV1 < 50% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators has been postponed to the next meeting and would be appraised on 20th May along with the following submissions:

Appraisal 1: Full Submission (DoH PAS)

Enzalutamide (Xtandi[®]) for the treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated

Applicant Company: Astellas Pharma Ltd

Appraisal 2: Full Submission (Welsh PAS)

Pomalidomide (Imnovid[®]) in combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy

Applicant Company: Celgene Ltd

Appraisal 3: Full Submission

Brentuximab vedotin (Adcetris[®]) for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma following autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option; as well as for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL)

Applicant Company: Takeda UK Ltd

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

5. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy. Two typographical errors were noted and, with these corrections, the draft minutes were approved by the Chairman.

6. Appraisal 1: Full Submission

Ledipasvir/sofosbuvir (Harvoni®) for the treatment of chronic hepatitis C in adults

The Chairman welcomed representation from the applicant company Gilead Sciences Ltd

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

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 outlined the sequence of events and invited Mrs Gail Woodland, AWTTTC assessment lead, to set the context of the appraisal.

Mrs Woodland presented an overview of the submission as detailed in the ASAR. Mrs Woodland highlighted the clinical experts' preference for the new pegylated interferon-free regimens, including ledipasvir/sofosbuvir, because they are better tolerated and superior in efficacy. Members were informed that a number of patient questionnaires had been received - two from individual patients, two family member submissions, one patient carer and also one from the British Liver Trust.

The Chairman invited Dr Saad Al-Ismael to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Al-Ismael highlighted that no economic data had been provided for genotype 1 or 4 patients with decompensated cirrhosis, or who are pre-/post liver transplant. Similarly, no economic data were provided for genotype 3 patients with cirrhosis and/or prior treatment failure. It was the view of NMG that the cost effectiveness data presented in the submission were insufficient for NMG to recommend use beyond 12 weeks. Dr Al-Ismael confirmed the NMG decision to support the restricted use of ledipasvir/sofosbuvir (Harvoni®) as an option for the treatment of chronic hepatitis C in adults with hepatitis C virus genotype 1 and 4 without cirrhosis or with compensated cirrhosis for up to 12 weeks. It was the view of NMG that ledipasvir/sofosbuvir (Harvoni®) should not be recommended for use within NHS Wales outside of this subpopulation/these circumstances.

The Chairman opened the discussion in relation to clinical effectiveness. Clarification was sought in relation to virological antigen-free follow-up and the company delegates confirmed that a registry had been established. Clarification was also sought in relation to the effects in genotype 3. The low adverse event profile was noted. There was discussion over the patient populations and provision of homecare. Delegates from the applicant company responded to all the issues raised in the discussion.

The Chairman drew attention to the clinical expert summary. The reduced burden of the hepatitis C virus from an individual and societal perspective was noted. The improvement in tolerability was deemed by the clinicians to be very important since it would allow treatment of

patients with a greater likelihood of liver-related morbidity and mortality, potentially preventing expensive liver transplants as well as providing a potential treatment to patients who are intolerant of existing regimens. Adoption would reduce the pool of infection within the population. It was noted that the new treatments are likely to reduce costs of patient monitoring due to their safety profile.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen confirmed his role as AWMSG health economist and confirmed he had no involvement in compiling the ASAR or in discussions at NMG. Professor Cohen summarised the strengths in the case presented, as summarised in the ASAR by the AWTTTC health economist, and offered the company delegates opportunity to correct or comment on any aspect of his summary. The Chairman drew members' attention to the budget impact evidence in the ASAR. There were no outstanding wider societal aspects noted.

The Chairman asked Mr Palmer to highlight relevant information from the patient organisation submissions. Mr Palmer relayed the organisation's comments and emphasised that the treatment offered the potential to eradicate the hepatitis C virus and effectively cure patients. The significant beneficial impacts on patients were noted.

The Chairman referred to the applicant company's response and offered further opportunity for the company delegate to comment. Having received confirmation that the appraisal process had been fair and transparent and that all relevant issues had been discussed, the Chairman closed the appraisal.

Appraisal decision subsequently announced in public:

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:

Ledipasvir/sofosbuvir (Harvoni[®]) is recommended as an option for restricted use within NHS Wales for the treatment of chronic hepatitis C in adults with hepatitis C virus genotype 1 and 4 without cirrhosis or with compensated cirrhosis for up to 12 weeks.

Ledipasvir/sofosbuvir (Harvoni[®]) is not recommended for use within NHS Wales outside of this subpopulation/these circumstances.

Key factor(s) influencing the recommendation:

- **The cost effectiveness data presented in the submission were insufficient for AWMSG to recommend use beyond 12 weeks.**
- **No economic data were provided for genotype 1 or 4 patients with decompensated cirrhosis or who are pre-/post liver transplant.**
- **Similarly, no economic data were provided for genotype 3 patients with cirrhosis and/or prior treatment failure**

7. Appraisal 2 - Limited Submission

Adalimumab (Humira[®]) for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy

The Chairman welcomed delegates representing AbbVie Ltd.

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No further interests were declared.

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 outlined the sequence of events and invited Dr Caron Jones, AWTTTC assessment lead, to set the context of the appraisal.

Dr Jones confirmed that the application had been considered eligible for a limited submission because it was a minor licence extension and the anticipated usage in NHS Wales was considered to be of minimal budgetary impact due to the small difference in cost compared to the comparator. Dr Jones presented an overview of the submission as detailed in the ASAR and relayed the view of clinical experts that adalimumab may be the preferred treatment option, particularly for children with enthesitis-related arthritis in association with uveitis. Dr Jones confirmed that patient organisation questionnaires had not been received.

The Chairman asked for the view of NMG. Dr Al-Ismaïl provided a brief overview of discussion held at NMG and confirmed the view that adalimumab (Humira[®]) should be recommended as an option for use within NHS Wales for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

The Chairman opened the discussion in relation to clinical effectiveness. There were no outstanding issues of note. The Chairman referred members to the clinical expert summary.

The Chairman reminded members that no evidence of cost-effectiveness was required for a limited submission. The budget impact was noted. There were no societal issues of note.

The Chairman referred to the company response to the preliminary recommendation and invited the company delegates to highlight aspects of their response. Prior to concluding the appraisal proceedings he asked the company delegates to confirm they were satisfied that all issues had been adequately addressed and taken into account, and that the process had been fair and transparent. On receipt of this confirmation he concluded the appraisal proceedings.

Appraisal decision subsequently announced in public:

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:

Adalimumab (Humira[®]) is recommended as an option for use within NHS Wales for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded to the applicant company within five working days. He informed the delegates that they 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 process.

8. Feedback from AWPAG – meeting held 11th March 2015

The Chairman invited Ms Kath Haines, Head of WAPSU, to present the draft minutes of the AWPAG meeting held 11th March 2015. Ms Haines informed members that the polypharmacy document, endorsed by AWMSG at a previous meeting, had been very well received within NHS Wales. Members were informed that Professor John Hindle (BCUHB) is actively promoting the work via the Older Persons Advisory Group. It was reported that an approach had been made from NICE to include the document within the NICE Endorsement Programme and Ms Haines confirmed that AWTTTC would follow this up. Ms Haines highlighted that consultation on the Primary Care Antimicrobial Guidelines is imminent and confirmed that the document will be presented to AWMSG at a future meeting following AWPAG consideration. Ms Haines referred members to the notes of the meeting for an update on the various projects currently being progressed via AWPAG. There were no outstanding issues of note.

The Chairman confirmed the date of the next meeting on **Wednesday, 17th June in Abergavenny** and closed proceedings.