

Enclosure No:	1/AWMSG/1020
Agenda Item No:	1 – Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

Minutes of the AWMSG meeting held 9.30 am on Tuesday, 15th September 2020 (via Zoom)

VOTING MEMBERS PRESENT:

**Did not
participate in**

- | | | |
|------------|---------------------------|---|
| 1. | Prof Ceri Phillips | Chair |
| 2. | Prof Iolo Doull | Welsh Health Specialised Services Commission |
| 3. | Prof Dyfrig Hughes | Health Economist |
| 4. | Ms Kate Parrish | ABPI (Wales) |
| 5. | Mr Cliff Jones | Lay Member |
| 6. | Mr Stefan Fec | Community Pharmacist |
| 7. | Dr Jeremy Black | GP with Prescribing Lead role |
| 8. | Mrs Alison Hughes | Primary Care Pharmacist |
| 9. | Mr Hywel Pullen | Finance Director |
| 10. | Mr John Terry | Managed Sector Secondary Care Pharmacist |

Welsh Government:

Mrs Lynne Schofield, Head of Pharmacy & Prescribing

AWTTC staff:

Mrs Karen Samuels, Programme Director

Mr Anthony Williams, Head of PAMS

Ms Kath Haines, Head of WAPSU

Mr Richard Boldero, Senior Pharmacist

Mrs Claire Thomas, Senior Pharmacist

Dr Clare Elliott, Senior Scientist

Dr Stuart Keeping, Senior Scientist

Mrs Ruth Lang, Senior Liaison Manager

Ms Laura Taylor, Administration Supervisor

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
EMA	European Medicines Agency
EMIG	Ethical Medicines Industry Group
EOL	End of life
FAR	Final Appraisal Recommendation
FDA	US Food and Drug Administration
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Board
HEIW	Health Education and Improvement Wales
HST	Highly Specialised Technology
HTA	Health Technology Appraisal
IR	Independent Review
MHRA	Medicines and Healthcare products Regulatory Agency
M&TCs	Medicines & Therapeutics Committees
NICE	National Institute for Health and Care Excellence
NMG	New Medicines Group
NPI	National Prescribing Indicator
PAMS	Patient Access to Medicines Service
PAR	Preliminary Appraisal Recommendation
PAS	Patient Access Scheme
PPRS	Prescription Price Regulation Scheme
QAIF	Quality Assurance and Improvement Framework
SMC	Scottish Medicines Consortium
SPC	Summary of Product Characteristics
SPIRA	Server for Prescribing Information Reporting and Analysis
TDAPG	Therapeutic Development Appraisal Partnership Group
T&FG	Task and Finish Group
UHB	University Health Board
WAPSU	Welsh Analytical Prescribing Support Unit
WeMeReC	Welsh Medicines Resource Centre
WG	Welsh Government
WHO	World Health Organization
WHSSC	Welsh Health Specialised Services Committee
WPAS	Wales Patient Access Scheme

1. Welcome and introduction

The Chair opened the meeting and welcomed observers and members to the third virtual AWMSG meeting. He introduced Dr Brian Hawkins as the nominated representative from Cwm Taf Health Board's Executive team. The Chair confirmed that an invitation had been sent to each health board's Executive to attend an AWMSG meeting in an effort to make AWMSG more relevant to the service. He confirmed that Dr Hawkins would be invited to join the discussion following the quarterly report on the national prescribing indicators.

The Chair welcomed Mr Hywel Pullen to his first meeting as a full member of AWMSG representing Finance Directors and Mrs Alison Hughes to her first meeting as a full member of

AWMSG representing Primary Care Pharmacists. He welcomed Ms Kate Parrish to her first meeting as representing ABPI Cymru Wales

The Chair confirmed the same protocols and procedures that exist for a 'normal' AWMSG meeting would be applied to the 'virtual' meeting and confirmed that nine voting members constituted a quorum.

2. Apologies:

Dr Balwinder Bajaj and Dr Alison Thomas - Clinical Pharmacologists
Mrs Louise Williams - Nurse representative
Mr Aled Falvey and Cathy Wynne - Healthcare professional eligible to prescribe
Prof Arpan Guha and Dr Jim McGuigan - Medical Director representatives
Dr Cath Bale -Hospital Consultant

Not in attendance:

Professor Stephen Monaghan, Public Health Wales

3. Declarations of interest

Members were reminded to declare any interests. No interests were declared.

4. Minutes of previous meeting

The draft minutes of the previous meeting held on 15th July 2020 were checked for accuracy and approved.

5. Chairman's report (verbal update)

The Chair confirmed that a two week consultation document on the AWMSG work programme had been shared with partners and stakeholders and a number of responses had been received by the deadline of Friday, 11th September. The Chair thanked the responders and confirmed that the final work programme would be submitted to Welsh Government by the end of the month.

The Chair highlighted the World Health Organisation Patient Safety Day on 17th September to promote and increase public awareness of the measures being taken in the interest of patient safety and asked members to promote this annual event.

It was confirmed that the AWMSG Steering Committee meeting had met on 25th August. Members were informed that the AWMSG Constitution would be forwarded to Welsh Government following clarification of some outstanding membership issues.

The Chair confirmed that the prescribing guidance for asthma had been published and disseminated to NHS Wales. Members were informed that the status of the pneumonia and COPD guidance remains unchanged as information requested by AWMSG from the clinical lead remains outstanding. The Chair confirmed he will be drafting a document explaining that differences in terms of clinical context and policy may result in divergence from NICE guidance; he reiterated this scenario will be the exception rather than the rule.

The Chair confirmed that the final appraisal recommendations announced at the meeting in July had been ratified by Welsh Government and published on the AWMSG website.

The appraisal scheduled for the next AWMSG virtual meeting on Tuesday, 13th October 2020 at 9.30 am was announced.

A full submission by Menarini Farmaceutica Internazionale srl for the following medicine:

Meropenem\vaborbactam (Vaborem®) for the treatment of complicated urinary tract infection including pyelonephritis, complicated intra-abdominal infection, hospital-acquired pneumonia

including ventilator associated pneumonia in adults and for the treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Meropenem/vaborbactam is also indicated for the treatment of infections due to Gram-negative organisms in adults with limited treatment options

Members were reminded to declare any personal or non-personal interests ahead of the next meeting. Patients, patient organisations and patient carers were invited to submit their views or contact Ruth Lang at AWTTTC for further information on the appraisal process and future work programme.

6. National Prescribing Indicators – Quarterly report to March 2020

Mr Boldero presented a brief overview of the national prescribing indicator quarterly report (to March 2020). The Chair invited Dr Brian Hawkins to join the conversation. There was general agreement that the data/reports on prescribing by health board need to inform decision-making across the whole of the organisation and more work is required to understand the context. Reference was made to the lack of appropriate pain services in some areas which might explain their higher levels of prescribing, where GPs are treating patients whilst they wait for an appointment with a specialist. The Chair stated that AWMSG needs to act as a receptacle for good practice which can be shared with health boards so that they can learn from each other. All agreed that closer dialogue with health boards and further investigation going forward is needed so that AWMSG can provide any support required. Kath Haines informed members that representatives from AWTTTC had met with Dr Tessa Lewis to discuss a proposal to develop a cluster prescribing leads forum. She confirmed that the annual Best Practice Day serves as a forum to share exemplars of good practice. The Chair drew attention to specific areas for improvement. There was agreement that AWMSG should continue to ask questions of the health boards. The Chair agreed to request a response from each health board with an action plan; also a request to share examples of good practice. A suggestion was made to engage with the Finance Directors and Quality and Safety Committees.

The Chair closed the discussion and thanked members for their comments. He thanked Dr Hawkins for his contribution and asked for his thanks to be extended to the health board executive committee.

7. Royal College of Paediatrics and Child Health and Neonatal and Paediatrics Pharmacist Group position statement - Using Standardised Strengths of Unlicensed Liquid Medicines in Children

Mr Anthony Lewis from the Department of Pharmacy, Cardiff and Vale UHB presented a brief overview of the document. He explained the background and asked AWMSG to acknowledge it as best practice for improving patient safety. There was a brief discussion before the Chair confirmed AWMSG's support.

8. Feedback from AWPAG Meeting held 10th June 2020

Kath Haines presented the minutes of the AWPAG meeting held on 10th June 2020. Following this, the Chair allowed a ten minute comfort break before re-convening the meeting.

9. Appraisal session:

On re-convening, the Chair opened the appraisal session and confirmed that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation will not impact on the clinical freedom of the prescriber. A positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an obligation on Health Boards to fund accordingly. AWMSG advice is **interim** to NICE guidance, should this be subsequently published.

The Chair guided members to seek clarification of any outstanding issues and confirmed that the applicant company delegates would be invited to respond to questions.

The Chair confirmed that the final appraisal recommendations would be forwarded electronically to the applicant company after the meeting closed and a notice published on the AWMSG website. The company delegates were informed that they had up to ten working days to accept the recommendation or lodge a request for an independent review the grounds for which should be submitted in accordance with the process for independent review. It was noted that failure to respond within the deadline would not delay the process and the advice would be forwarded to Welsh Government for ratification once the ten day deadline had expired.

Appraisal 1: Limited submission (Ultra-Orphan)

Bedaquiline (Sirturo®) for use as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis (MDR-TB) in adolescent patients (12 years to less than 18 years of age and weighing at least 30 kg) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability

The Chair welcomed the delegates from Janssen-Cilag Ltd

The Chair 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 appraisal lead set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR and confirmed the recommendation of the NMG.

The Chair drew members' attention to the budget impact estimates on Page 2 of the ASAR and reiterated that the application satisfied AWMSG's criteria for appraising orphan, ultra orphan medicines and medicines developed specifically for rare diseases. The Chair confirmed that additional criteria, which he confirmed had been circulated to members, would be applied when appraising this medicine.

It was confirmed that no patient views had been received and Mr Cliff Jones informed members of the patient organisations that had been approached by AWTTTC. There were no outstanding wider societal issues raised.

One member questioned the rates of hepatotoxicity in adults and the company delegate confirmed that the rates were similar to other treatment options. He stated this is the first medicine for this patient population and there were no specific monitoring requirements. There were no budgetary impact or societal issues raised.

Prior to concluding the appraisal the Chair asked the applicant company delegates to confirm that they were satisfied that the issues raised by AWMSG had been adequately addressed and that the appraisal process had been fair and transparent. This was confirmed and the Chair closed the discussions.

The company delegates left the meeting.

Appraisal decision subsequently announced in public:

The Chair 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:

Bedaquiline (Sirturo®▼) is recommended as an option for use within NHS Wales as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis (MDR-TB) in adults and adolescent patients (12 years to less than 18 years of age and weighing at least 30 kg) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability.

10. Appraisal 2: Full submission (Wales Patient Access Scheme) doravirine (Pifeltro®) in combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class

The Chair welcomed the delegates from Merck Sharp & Dohme Ltd

The Chair 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 appraisal lead set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR and confirmed the recommendation of the NMG.

The Chair invited members to raise issues relating to clinical effectiveness and there were no outstanding issues. To protect commercial confidentiality of the PAS for the comparator medicine, the Chair asked the company representatives to step out of the meeting so that AWMSG could address some of the issues in relation to the case for cost-effectiveness and budget impact.

On their return, it was confirmed that no patient views had been received and Mr Cliff Jones informed members of the patient organisations that had been approached by AWTTTC. There were no outstanding wider societal issues of note.

The company delegates confirmed they had no issues to raise and the process had been fair and transparent. They left the meeting. AWMSG members proceeded to vote on all three appraisals.

Appraisal decision subsequently announced in public:

The Chair 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:

Doravirine (Pifeltro®) is recommended as an option for use within NHS Wales, in combination with other antiretroviral products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

The following additional note was included in the FAR:

Please refer to the Summary of Product Characteristics section 4.4 (special warnings and precautions for use) and 5.1 (pharmacodynamic properties) for further information, as specified in the licenced indication

11. Appraisal 3: Limited submission (Wales Patient Access Scheme) doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo®) for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir

The Chair welcomed the delegates from Janssen-Cilag Ltd

The Chair 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 appraisal lead set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR and confirmed the recommendation of the NMG.

There were no outstanding issues of clinical effectiveness. It was confirmed that no patient views had been received and Mr Cliff Jones informed members of the patient organisations that had been approached by AWTTTC. There were no outstanding wider societal issues raised. No questions were posed to the company delegates and they had no issues to raise.

Prior to concluding the appraisal the Chair asked the applicant company delegates to confirm that they were satisfied that the issues raised by AWMSG had been adequately addressed and that the appraisal process had been fair and transparent. This was confirmed and the Chair closed the discussions.

Appraisal decision subsequently announced in public:

The Chair 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:

Doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo®) is recommended as an option for use within NHS Wales for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, lamivudine, or tenofovir. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

The Chair confirmed the date of the next meeting, **on Tuesday, 13th October (via Zoom)** The Chair thanked AWTTTC for making the meeting happen and members/observers for their contributions and attendance. The meeting closed.