

Enclosure No:	1/AWMSG/1220
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 Wednesday, 11th November 2020 (via Zoom)

VOTING MEMBERS PRESENT:

**Did not
participate in**

- | | | |
|------------|------------------------------|---|
| 1. | Prof Ceri Phillips | Chair |
| 2. | Prof Stephen Monaghan | Consultant in Public Health Medicine |
| 3. | Prof Iolo Doull | Welsh Health Specialised Services Commission |
| 4. | Prof Dyfrig Hughes | Health Economist |
| 5. | Mr Tommy Price | ABPI (Wales) |
| 6. | Mr Cliff Jones | Lay Member |
| 7. | Dr Jim McGuigan | Medical Director |
| 8. | Dr Jeremy Black | GP with Prescribing Lead role |
| 9. | Mr Hywel Pullen | Finance Director |
| 10 | Mr John Terry | Managed Sector Secondary Care Pharmacist |
| 11. | Dr Balwinder Bajaj | Clinical Pharmacologist |

Welsh Government:

No representation present at the meeting

AWTTC staff:

Mr Tony 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 Stephanie Francis, Senior Scientist
Ms Karen Jones, Senior Pharmacist
Dr Stuart Keeping, Senior Scientist
Dr Sara Pickett, Principal Health Economist
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. He introduced Dr Sion James, Deputy Medical Director, Mrs Jenny Pugh Jones, Head of Medicines Management and Mr Stuart Rees, Clinical Pharmacy lead for patient services, as the nominated representatives from Hywel Dda Health Board's Executive team.

The Chair confirmed he would pause the meeting at 11 am to remember service men and women who have lost their lives in conflict. He also asked members to remember those who have recently been lost to the coronavirus pandemic.

The Chair welcomed four potential lay members observing the meeting and confirmed that a debrief with representatives of AWTTTC had been arranged later in the day.

The Chair welcomed Joe Ferris representing ABPI Cymru Wales and delegates from Janssen Cilag.

The Chair welcomed Ms Rafia Jamil to her first meeting as Primary Care Pharmacist acting as alternate for Alison Hughes and Dr Laurence Gray for his attendance in the capacity of AWPAG Chair

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:

Mr Stefan Fec and Mr Dylan Jones - Community Pharmacist representatives
Mr Alex Falvey - Other healthcare professions eligible to prescribe not already represented
Mrs Louise Williams, Senior Nurse

Not in attendance:

Ms Rafia Jamil, Primary Care Pharmacist
Dr Cath Bale, Hospital Consultant

3. Declarations of interest

There were no declarations of interest pertinent to the agenda.

4. Minutes of previous meeting

The draft minutes of the previous meeting held on 13th October 2020 were checked for accuracy and approved.

5. Chairman's report (verbal update)

The Chair confirmed the AWMSG Steering Committee had met on 20th October. The membership of AWMSG has been reviewed and the Constitution forwarded to Welsh Government. The Chair informed members that the paper on the alignment of AWMSG with NICE Guidance will not be progressed. Instead, the Memorandum of Understanding will be reviewed - this document formally sets out a collaboration between NICE and AWMSG with the aim of joining up the strategic planning, development and delivery of guidance in England and Wales, avoiding duplication and complementing/supporting the work of NICE and AWMSG.

The following documents have recently been out for consultation:

1. Shared Care Prescribing and Monitoring Guidance
2. Nitrofurantoin in Treatment of Urinary Tract Infection: Common Prescribing Errors

Members were encouraged to submit comments at the consultation stage so that they can be taken into consideration before the documents are presented to AWMSG for endorsement.

The Chair confirmed that following the appraisal of Vaborem[®] at the October meeting, the recommendation to Welsh Government has been ratified, disseminated to the service and is now published on the AWMSG website.

The Chair confirmed that the AWMSG Masterclass will not go ahead this year. Instead, there will be a number of AWMSG/AWTTTC Virtual Open Days – the first is scheduled on 15th December 2020 - these will be short informative meetings held every couple of months to give

the pharmaceutical industry an update on how they can work with us to make the best use of medicines for patients living in Wales.

The Chair confirmed the annual AWMSG members training event will go ahead virtually on Wednesday, 13th January 2021. Members were asked to keep the date free in the calendar and the Chair asked members to suggest topics.

The appraisal scheduled for the next AWMSG virtual meeting on Tuesday, 8th December 2020 at 9.30 am was announced by Mr Tony Williams:

A full submission with a Wales PAS by Chiesi Ltd for the following medicine:

Idebenone (Raxone[®]) for the treatment of visual impairment in adolescent and adult patients with Leber's hereditary optic neuropathy.

It was noted that discussions are on-going with the company to explore the feasibility of a CAPIG meeting following a negative preliminary recommendation made by NMG and prior to the appraisal by AWMSG. Mr Williams confirmed that a CAPIG meeting would impact on the scheduling of this appraisal.

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. AWMSG Work Programme

Mrs Lang provided the background and explained that AWTTTC staff will be providing regular updates on work on-going to ensure that all members and partners are kept fully informed and have opportunity to comment and drive the work programme forward. Mrs Lang confirmed the work programme has to be agile and responsive to the needs of the service and balanced with the aim of delivering the key objectives of AWMSG. Mrs Lang invited Claire Thomas to update members on progress following discussion with representatives from BCUHB at the previous meeting:

Mrs Thomas confirmed that a meeting has been arranged between AWTTTC and BCUHB to take forward some of the discussions held at the previous meeting with regard to improving implementation and supporting best practice with regard to the National Prescribing Indicators and medicines optimisation resources. Mrs Thomas informed members that discussions had been held over the previous twelve months with the software providers ScriptSwitch and OptimiseRX. Members were informed that both suppliers have agreed to work with AWTTTC to ensure that strategic AWMSG prescribing messages can be included in the GP prescribing support systems whilst also enabling local HB formulary management.

Ms Jones introduced herself as the AWTTTC lead for clinician engagement and updated members on work already undertaken and currently ongoing. She also provided an outline of planned work to encourage and improve clinical engagement and raise awareness of the work of AWMSG. Ms Jones confirmed steps to improve communication with clinical networks and specialist groups have already been taken and there are also plans to increase the involvement of medical directors.

Dr Elliott introduced herself as the AWTTTC lead for patient engagement and lay membership and updated members on work currently ongoing. She informed members that a recruitment exercise is underway to increase the pool of lay membership and acknowledged the important role and input of Mr Cliff Jones, the AWMSG lay member. Dr Elliott briefly outlined how AWTTTC is planning to increase support to the lay members. Moving to the broader patient and public engagement, Dr Elliott informed members that with the move to virtual meetings this

may result in increased opportunity for patient and public involvement. Dr Elliott stated that PAPIG meetings will need to be reviewed and reformatted to adapt to the changing work environment caused by the pandemic.

Dr Stephanie Francis introduced herself as the AWTTTC lead for pharmaceutical industry engagement and updated members on work currently ongoing. Dr Francis confirmed that the terms of reference of the TDA Partnership Group will be reviewed and updated to reflect the transition away from health technology appraisal to an increased medicines optimisation agenda. Dr Francis confirmed that the first virtual AWTTTC/AWMSG Open Day will be held on the 15th December 2020 and a schedule of regular events will follow. Topic selection will be based on feedback from the industry and there will be opportunity for questions and informal discussion. Work on improving engagement to inform the horizon scanning and financial forecasting process is on-going, and there has also been significant liaison between AWTTTC and pharmaceutical companies with regard to the implementation of NICE Covid-19 guidance within NHS Wales.

The Chair thanked AWTTTC for sharing the information and reiterated the important role of AWMSG members in communicating this with their constituent organisations and groups.

7. Feedback from AWPAG Meeting held 23rd September 2020

Dr Gray presented the minutes of the AWPAG meeting held on 23rd September 2020 – Enclosure 2. He confirmed the recent appointments and informed members that an expression of interest in the role of AWPAG Vice Chair had been received.

8. Discussions with Hywel Dda University Health Board

The Chair invited Dr Sion James, Deputy Medical Director, Mrs Jenny Pugh Jones, Head of Medicines Management and Mr Stuart Rees, Clinical Pharmacy lead for patient services to comment on what AWMSG could do to support Hywel Dda Health Board deliver the best from medicines for their patients. Due to technical difficulties Mr Rees was unable to participate in the discussion. Mrs Pugh Jones highlighted the need to link to outcomes to measure improvements for patients. Dr James informed members of an initiative within Hywel Dda for regular meetings of GP Prescribing Leads which provided opportunity to compare and benchmark prescribing practices and learn from each other. It was suggested that other areas could adopt the same approach and Dr James informed members that the Committee of Assistant Medical Directors had been exploring the adoption of this across all professionals and on a national basis. It was noted that antibiotic champions had been identified in Hywel Dda HB. Mrs Pugh Jones acknowledged the work currently ongoing by AWTTTC to improve communication and asked AWMSG to help change some of the messaging in relation to the cost pressure of medicines. Mrs Pugh Jones said that the practical support tools were particularly valued by prescribers in the health board. Further support was sought from members to help move forward the digital agenda; there was frustration at the delay of implementing electronic prescribing in Wales. Ms Haines confirmed WAPSU's involvement with this in having representation on relevant committees. Dr James suggested that representation on AWMSG from the Primary Care Assistant Medical Directors Group might be helpful and the Chair confirmed that he would follow this up with Welsh Government officials. Mrs Pugh Jones suggested it might be timely to change the name of the committee from the All Wales Medicines Strategy Group to the Welsh Medicines Strategy Group. She informed the committee that when recruiting pharmacists the candidates were asked a question relating to AWMSG. The Chair invited suggestions for improving engagement and communication with pharmacists and doctors and it was suggested that improving links with the universities and medical schools would ensure that students have a knowledge of the committee and a suggestion was made for a training module for GP appraisals. The Chair thanked Hywel Dda Health Board representatives for their valuable contribution to the meeting.

Action

**Chair to discuss Medical Director representation with Welsh Government officials
Chair to write to the Heads of the School of Pharmacy and Medical Schools in Wales**

9. SBAR – Low Value for Prescribing – paper 3 – suspension of active monitoring

Mr Boldero provided the background to Enclosure 3 and explained that a recommendation had been made at the last AWPAG meeting to suspend the third of a series of papers recommending the active monitoring of low value medicines until the acute pressures in primary care as a result of the COVID-19 pandemic had subsided. The Chair opened discussion. There was general acknowledgement that the service is under pressure. Dr Gray suggested that AWPAG could review the status at their next meeting in March and make the decision as to whether implementation should proceed from April. The Chair confirmed the agreement of the Committee.

Action

AWPAG to review the status in March 2021 for implementation of active monitoring of the low value medicines in paper 3 from April 2021

10. SBAR – The management of vitamin B12 deficiency during the COVID-19 pandemic

Mr Boldero provided the background to Enclosure 4 and explained that following discussion by AWPAG, the views of Welsh Government had been sought in relation to a proposal to remove cyanocobalamin from the Low Value for Prescribing initiative and remove a selected list scheme (SLS) within the Drug Tariff for oral cyanocobalamin. In their reply, Welsh Government officials asked for clarity on the following:

1. Does the evidence support oral treatment being as efficacious as intramuscular in all patients (paying particular reference to the Cochrane review in 2018 which is provided as a separate enclosure for convenience)?
2. If not, are there particular patient groups which on the balance of probabilities would benefit from having oral treatment rather than attend the GP practice for injections?
3. Is this seen as a temporary measure due to COVID-19 related factors rather than something that will be continuing routinely post-COVID-19?

AWPAG members were requested (via email) to provide an initial response to these questions to support discussion by AWMSG members.

The Chair opened discussion and invited Dr Black to outline the issues raised in his response (detailed in Appendix 2). There was agreement that Dr Black's paper set out the issues clearly and members confirmed their support. Members agreed that Welsh Government should pursue the SLS changes. There was a suggestion that educational guidance for Welsh doctors would be helpful. The Chair asked Dr Black to draft a form of words in conjunction with AWTTTC on behalf of the Chair for submitting to Welsh Government.

Action

JB to work with AWTTTC in drafting a recommendation to Welsh Government for the Chair to action

The Chair/AWTTTC to explore the potential for development of guidance for Welsh doctors in conjunction with the haematology specialist network

11. Delivering Value Through Disinvestment: An exploration and analysis of appropriate disinvestment in medicines considered Low Value for Funding by NHS Wales

The Chair invited Professor Deb Fitzsimmons to present Enclosure 5 - Delivering Value Through Disinvestment: an exploration and analysis of appropriate disinvestment in medicines considered low value for funding by NHS Wales, a paper jointly written by the Swansea Centre for Health Economics at Swansea University, and the Centre for Health Economics and Medicines Evaluation at Bangor University. Professor Fitzsimmons confirmed that the project aimed to develop a holistic evidence-based process to support appropriate disinvestment of medicines considered low value in NHS Wales. Professor Hughes and Professor Fitzsimmons jointly presented the output of this collaborative project and explained the work aims to inform AWMSG's recommendation about resource reallocation, under its five-year strategy for 2018–

2023 to support the prudent prescribing of medicines for NHS Wales. It was noted the project focuses on using an evidence-based approach to support appropriate disinvestment (labelled as 'resource reallocation') of medicines considered low priority (later re- termed low value) in NHS Wales. the delivery of AWMSG recommendation 3.6 of AWMSG's Medicines Strategy for Wales.

The Chair invited comment. It was confirmed that the implementation of the process did not fall within the scope of this project. Mr Price confirmed broad support of ABPI Wales in relation to the principles; he made the point that limited time had been given to contribute to the consultation during the summer period. Members sought clarification of the extent of this work. Professor Hughes confirmed that the implementation of such a process would be an international first for AWMSG to have an identified programme for the disinvestment of medicines.

The Chairman suspended discussions and moved on to Agenda item 12 – the limited appraisal. Members were asked to reconvene after a lunch break. Some members confirmed they would be unable to reconvene in the afternoon. The Chairman confirmed he would be unable to extend the morning session due to an alternative commitment.

12. Appraisal session:

Appraisal 1: Limited submission

Darunavir/cobicistat (Rezolsta[®]) 800mg/150mg film-coated tablets in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adolescents 12 to <18 years of age, weighing at least 40 kg

The Chair welcomed the delegates from Janssen-Cilag Ltd.

The Chair confirmed that at the close of the appraisal all observers would be asked to leave the meeting whilst members voted in private and agreed the wording of the advice to Welsh Government. The Chair confirmed the appraisal recommendation will be forwarded to the delegates after the close of the meeting and the company would be allowed ten working days to respond to the recommendation.

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 limited submission as outlined in the ASAR and confirmed the recommendation of 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 issues raised. The company delegates agreed with the recommendation made by NMG and had no issues to raise.

Prior to concluding the appraisal the Chair asked the applicant company delegates to confirmed 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:

Darunavir/cobicistat (Rezolsta[®]) is recommended as an option for use within NHS Wales in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus 1 (HIV 1) infection in adults and in adolescents (aged 12 years and older, weighing at least 40 kg).

Additional note(s):

- This advice incorporates and replaces the existing AWMSG recommendation (Darunavir/cobicistat (Rezolsta[®]) is recommended as an option for use within NHS Wales in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years or older.) (AWTTC reference number 2193, originally published September 2015).

Delivering Value Through Disinvestment: An exploration and analysis of appropriate disinvestment in medicines considered Low Value for Funding by NHS Wales

The following members reconvened for further discussion of this agenda item:

Voting Members:

Professor Ceri Phillips (Chair), Professor Dyfrig Hughes, Mr John Terry, Mr Tommy Price, Dr Balwinder Bajaj, Dr Jim McGuigan

Non voting members:

Ms Kath Haines, Mr Anthony Williams, Mrs Ruth Lang, Mr Richard Boldero, Dr Sara Pickett, Dr Thomas Curran and Professor Debra Fitzsimmons

Observers:

Dr Alice Vernava (AWTTC), Ms Joe Ferris (ABPI Cymru Wales), Prospective lay member/s

Mrs Lang confirmed that the quorum of nine voting members had not been met.

The Chair thanked members for reconvening. He reiterated the importance of this agenda item and stated that the topic required further discussion. Members focused their discussion on Table 7 and the report recommendations which identified a number of aspects of the proposed process that require further consideration and development prior to the process being ready for roll-out. Members agreed that the process as set out was logical and appeared workable. Professor Hughes confirmed the development of criteria for selection, categorisation and prioritisation of medicines for disinvestment was not within the scope of the project.

Based upon the feedback received, the Chair confirmed that AWMSG agreed with the key principles underpinning the paper. He suggested that a recommendation should be drafted which can be presented to the Committee at the next meeting for discussion and formal agreement. Members were requested to submit comments to the Chair via AWTTC by 20th November.

Action

Chair/AWTTC to draft a recommendation for presentation and formal agreement at the next meeting

The Chair confirmed the date of the next meeting, on Tuesday, 8th December (via Zoom).
The meeting closed.