

Enclosure No:	1/AWMSG/0722
Agenda Item No:	1 – Minutes of previous meeting
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All Wales Medicines Strategy Group (AWMSG)

Draft minutes of the AWMSG meeting held at 9:30 am on Wednesday, 15 June 2022 via Zoom

Voting members present:		Did not participate in agenda item:
1. Prof Iolo Doull	Chair	
2. Prof Stephen Monaghan	Consultant in Public Health Medicine	
3. Dr Helen Fardy	Welsh Health Specialised Services Commission	
4. Prof Dyfrig Hughes	Health Economist	
5. Ms Kate Parrish	ABPI (Wales)	
6. Mr Cliff Jones	Lay Member	
7. Ms Claire James	Lay Member	
8. Dr Jim McGuigan	Medical Director	
9. Dr Jeremy Black	General Practitioner	
10. Mrs Alison Hughes	Senior Primary Care Pharmacist	
11. Mr James Leaves	Director of Finance	
12. Mr John Terry	Senior Hospital Pharmacist	
13. Mrs Mandy James	Senior Nurse	
14. Ms Cathy Wynne	Other healthcare professions	
15. Dr Alison Thomas	Clinical Pharmacologist	

Welsh Government:

Mr Andrew Evans

AWTTC staff:

Mrs Helen Adams, Senior Pharmacist
Prof James Coulson, NMG Chairman
Mr Thomas Curran, Senior Scientist
Ms Kath Haines, Head of WAPSU
Mrs Rachel Jonas, Medical Writer
Ms Rosie Spears, Senior Scientist
Mr Anthony Williams, Head of PAMS

List of abbreviations:

ABPI	Association of the British Pharmaceutical Industry
ASAR	AWMSG Secretariat Assessment Report
ATMP	Advanced Therapy Medicinal Product
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
DHCW	Digital Health and Care Wales
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 Assessment
ILAP	Innovative Licensing and Access Pathway
IPCG	Interim Pathway Commissioning Group
IR	Independent Review
MHRA	Medicines and Healthcare products Regulatory Agency
M&TC	Medicines & Therapeutics Committee
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
RCGP	Royal College of General Practitioners
SABA	Short-acting beta agonist

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, welcomed members and observers and explained the meeting protocol.

2. Apologies:

Mr Dylan Jones - Community Pharmacist

Mr Hywel Pullen - Director of Finance

Ms Eleri Schiavone - Welsh Health Specialised Services Commission

3. Declarations of interest:

The Chair invited declarations of interest. There were none.

4. Minutes of previous meeting

The draft minutes of the previous meeting held on 17th May 2022 were checked for accuracy. There were no matters arising.

5. Chair's verbal report

Subsequent to the last meeting, changes were made to the value-based prescribing paper to reflect members' comments, and these were approved by Chair's action. This endorsed document has since been disseminated and published on the website.

Forthcoming events include an Industry Open Day on 23rd June; the HTAi Conference in Utrecht on the weekend of 25th June, AWPAG on the 29th June and the Best Practice Day on 19th July. Arrangements are being made for AWMSG's 20th Anniversary Conference.

Since a meeting held with Welsh Government officials on 28th May, a consultation has been sent out to colleagues and partners inviting comment on planned new areas of work.

The Chair invited Mr Anthony Williams, Head of PAMS, to announce the appraisals scheduled for the next AWMSG meeting on 12th July 2022:

Paediatric license extension:

Grazoprevir/elbasvir (Zepatier®) for the treatment of chronic hepatitis C (CHC) in paediatric patients 12 years of age and older who weigh at least 30 kg

Paediatric license extension:

Brivaracetam (Briviant®) as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children from 2 years to < 4 years of age with epilepsy

Mr Williams asked members to contact AWTTC ahead of the next meeting to register any personal or non-personal interests in this medicine.

6. AWTTC Work Programme consultation

The Chair invited Mr Anthony Williams and Ms Kath Haines to present the AWTTC Work Programme 2022-2023 consultation. A background to the document was provided, and the new proposed work streams were highlighted. Members were asked to consider the consultation document and forward any comments to AWTTC before the deadline of 4th July.

7. Medicines Optimisation Work Programme

Mr Tom Curran gave a summary of the medicine's optimisation work programme. The Chair invited comments and questions.

It was queried what impact the delay of the chronic pain document has had on front line service; it is believed as this is a new document rather than an update, that there should be minimal impact at this stage as guidance will already be in place to follow locally and this is hoping to be a more national guideline.

The importance of the "Safer Prescribing of Sodium Valproate" work was highlighted, as audits from health boards have shown poor documentation is available for contraception review in female patients of child bearing potential. A Task and Finish group is developing a resource hub to ensure guidance will be available to support all health care professionals in this treatment area.

8. Review of AWMSG Statements of Advice

The chair invited Mrs Helen Adams and Mrs Rosie Spears to present a review of AWMSG Statements of Advice (SOAs).

The Chair asked for clarification regarding everolimus as two indications for this medicine are available within England, but have existing SOAs within Wales. It was explained that a number of factors can trigger a review of an SOA including enquiries from patients/patient organisations, demand from clinical experts and a review of IPFR data, and it was noted that everolimus was a good example of this. This medicine has been discussed at AWMSG Steering Committee and communication with the Lead Clinician has been held. Views were expressed that the issuing of some SOAs may lead to difficulty within the Service and may be considered an unacceptable barrier to patients accessing medicines, and that the process would benefit from a

review.

Mrs Adams explained it is hoped that the series of SOA reports can be used as the basis to review the wider remit of AWMSG because the complex issues identified, including the appraisal of biosimilars and antimicrobials, cannot be addressed within the SOA process alone. Mr Williams highlighted this will also form part of the new work programme currently out for consultation.

Examples of reasons why a marketing authorisation holder may not engage in the appraisal process were discussed, including when a product is not going to be launched in the UK.

Mrs Adams thanked members for their comments and highlighted the SOA process was originally implemented to encourage engagement and ensure timely access to new medicines in NHS Wales. Mrs Adams emphasised how much has changed since the SOA process was first introduced and welcomed the support to review the wider remit. The Chair clarified that this SOA paper was provided for information but the committee support taking forward the recommendations with urgency.

9. AWMSG 20 Year Anniversary Conference

The Chair confirmed the conference is 17th November 2022 at Cardiff City stadium. The names of the confirmed speakers were shared and a call was made for an ABPI representative to present.

10. Best Practice Day 2022

Ms Kath Haines gave an overview of the event being held virtually on 19th July 2022. The theme of the meeting is “Environmental Impact of Medicines”.

It was confirmed the recording of the meeting will be available on the AWTTC website as soon as possible following the meeting.

11 Full Submission – (PAS) (Resubmission)

Bevacizumab (Avastin®) in combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix

Resubmission by Roche Products Ltd. There were no company delegates in attendance.

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 Chair asked members not to repeat the detailed discussions held at NMG but to raise any outstanding issues relating to clinical effectiveness and cost-effectiveness. He confirmed the broader remit of AWMSG including consideration of wider societal issues, budget impact and issues relating to equity of access.

The Chair invited the appraisal lead, Mrs Helen Adams, to give an overview of the submission and to detail the comments from clinical experts. Prof James Coulson briefly summarised the discussion at the NMG and confirmed that NMG's recommendation to AWMSG is that bevacizumab (Avastin®) is recommended as an option for restricted use within NHS Wales for use in combination with paclitaxel and cisplatin, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix. Dr Coulson relayed the discussions around the policy for medicines for rare diseases and for life-extending, end-of-life medicines. Dr Coulson highlighted it was acknowledged from clinical experts that, in practice, carboplatin is preferable to cisplatin due to a more favourable side-effect profile and ease of administration.

The Chair invited Prof Dyfrig Hughes to give an overview of the case for cost-effectiveness. Prof Hughes discussed the key considerations identified in the resubmission and noted the range of plausible ICERs. Members discussed the applicability of the policy for rare disease and for life-extending, end-of-life medicines. The Chair referred members to the budget impact estimates, and clarification was sought around the patient numbers and the patient access scheme. It was highlighted that the current HPV vaccination scheme and screening will reduce the incidences of cervical cancers going forward.

The side effect profile was discussed including the associated costs. Although carboplatin may be preferred in clinical practice it was acknowledged that it is not part of this submission or licenced in this indication.

The lay member detailed the comments received via the patient organisation, Jo's cervical cancer trust. The lay member highlighted the importance of access to medicines across all nations. Members noted the additional societal issues as detailed in the ASAR.

The Chair informed the group that AWMSG's recommendation would be forwarded by email to the company after the meeting and, for transparency, a notice uploaded to the website. He confirmed that the recommendation would be forwarded to Welsh Government for ratification unless the company requests a review within ten working days.

The meeting closed and AWMSG members voted in private. The following recommendation was subsequently confirmed:

Bevacizumab (Avastin®) is recommended as an option for restricted use within NHS Wales for use in combination with paclitaxel and cisplatin, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix.

Bevacizumab (Avastin®) is not recommended for use within NHS Wales for use in combination with paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with

persistent, recurrent, or metastatic carcinoma of the cervix.

This recommendation applies only in circumstances where the approved Patient Access Scheme (PAS) is utilised or where the list/contract price is equivalent or lower than the PAS price.

Bevacizumab should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance.

12. Any other business

Mr John Terry informed the meeting that this would be his last meeting due to retirement. The Chair thanked him for his contribution to AWMSG and its sub groups over the past 19 years.

The Chair confirmed the date of the next meeting as Tuesday 12th July 2022 in Cardiff and closed the meeting.