

Enclosure No:	1/AWMSG/0620
Agenda Item No:	1 – Minutes of previous meeting
Author:	Chair, AWMSG
Contact:	Tel: 029 20716900 E-Mail: awttc@wales.nhs.uk

ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

Minutes of the AWMSG meeting held Tuesday, 11th February 2020 commencing 10.30 am at the Copthorne Hotel, Copthorne Way Culverhouse Cross, Cardiff, CF5 6DH

VOTING MEMBERS PRESENT:

**Did not
participate in**

- | | | |
|-----|-----------------------|--|
| 1. | Prof Ceri Phillips | Chair |
| 2. | Prof Stephen Monaghan | Consultant in Public Health Medicine |
| 3. | Dr Jeremy Black | General Practitioner |
| 4. | Dr Anwen Cope | Other professions eligible to prescribe |
| 5. | Mr Cliff Jones | Lay Member |
| 6. | Mrs Susan Murphy | Primary Care Pharmacist |
| 7. | Mr Rob Thomas | ABPI Cymru Wales |
| 8. | Prof Dyfrig Hughes | Health Economist |
| 9. | Dr Alison Thomas | Clinical Pharmacologist |
| 10. | Mr Stefan Fec | Community Pharmacist |
| 11. | Mr John Terry | Managed Sector Secondary Care Pharmacist |

AWTTC staff in attendance:

Dr James Coulson, Interim Clinical Director & NMG Chair
Mrs Karen Samuels, Programme Director
Ms Kath Haines, Head of WAPSU
Mrs Ruth Lang, Senior Liaison Manager
Mr Richard Boldero, Senior Pharmacist
Mrs Claire Thomas, Senior Pharmacist
Dr Clare Elliott, Senior Scientist
Dr Jessica Davis, Senior Scientist
Miss Shaila Ahmed, Advanced Pharmacist
Dr Thomas Curran, Senior Scientist

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
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 members. He confirmed that appraisal 2 would be conducted in private to protect commercial confidentiality.

2. **Apologies**

Dr Balwinder Bajaj, Clinical Pharmacologist (Dr Alison Thomas attending)
Professor Arpan Guha, Medical Director representative
Dr Cath Bale, Hospital Consultant representative

Not in attendance:

Mrs Louise Williams/Mrs Mandy James, Senior Nurse representative
Professor Iolo Doull, WHSSC representative
Mr Stuart Davies/Mr Hywel Pullen, Finance Director representative

3. Declarations of interest

Members were reminded to declare any interests. There were none.

4. Minutes of previous meeting

The draft minutes of the previous meeting held on 11th December 2019 were checked for accuracy and approved.

5. Chairman's report (verbal update)

The Chair confirmed Welsh Government ratification of AWMSG's recommendations announced at the meeting held in December had been received. It was confirmed that the applicant companies had been informed and the advice disseminated to the service and published on the AWMSG website.

The Chair confirmed he had written to health boards with regard to the National Prescribing Indicator report and had received several responses.

The Chair informed members that in the absence of a submission from the holder of the marketing authorisation, a number of statements of advice had been ratified by Welsh Government and published on the AWMSG website. It was noted that these medicines for the indication specified cannot be endorsed for use within NHS Wales and should not be prescribed routinely within NHS Wales:

The Chair announced that Mrs Louise Howard-Baker would be stepping down as AWPAG Chair in March having served a full term of office. It was confirmed that expressions of interest in the role of Chair would be invited from AWPAG members and deputies. The Chair relayed the gratitude of the Group and confirmed discussions were ongoing regarding future roles and memberships.

The Chair announced that Mr Scott Peglar had stepped down as NMG Vice-Chair having served a full term of office and nominations would be sought for a replacement. He thanked Mr Peglar for his service and commitment to the work of the NMG.

The Chair announced that future AWMSG meetings would be held in or around each of the health boards in Wales to enable opportunity for two way discussion. He confirmed the intention to start this in April, and confirmed the next meeting would be held on Tuesday, 17th March 2020 at the Copthorne Hotel, Cardiff. 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. Feedback from the AWPAG meeting held 4th December 2019

Mrs Howard-Baker summarised the draft minutes of the AWMSG meeting held in December and highlighted the work currently on-going.

7. National Prescribing Indicators 2020-2021 and National Prescribing Indicators 2020–2021: Supporting Information for Prescribers and Healthcare Professionals

Mrs Claire Thomas and Mr Richard Boldero presented the National Prescribing Indicators 2020–2021 and Supporting Information for Prescribers and Healthcare Professionals, and summarised the main issues within the documents.

The Chair then opened discussion. There was discussion in relation to the appropriate use of gabapentin and pregabalin. The involvement of Audit+ and difficulties in relation to coding for neuropathic pain were highlighted. Concern was expressed over the inability to access the required level of data. There was discussion over the pregabalin indicator – it was suggested that the measure might be too crude for it to deliver the intended change in prescribing. Members agreed that for reasons of safety it should remain and other ways of reducing inappropriate prescribing needed to be considered. The Chair tasked AWPAG with looking at areas of best practice and to identify any local initiatives that had made a positive impact on the prescribing in that area. The Chair called for the barriers in accessing data to be removed so that the performance at a practice level can be monitored. The CPO confirmed on-going discussions with agencies in this respect. Mrs Murphy agreed to share an initiative undertaken in North Wales to identify and support the worst performing practices. The importance of alignment with QAIF was noted. There was discussion regarding the lack of adequate chronic pain services across NHS Wales. The Chair asked AWTTTC to pick up the issues raised in the discussion and confirmed AWMSG's endorsement of the document.

ACTION

AWPAG to identify best practice initiatives to support the NPIs

SM to share the North Wales initiative

AWTTTC to pick up the issues identified in the discussion

AWTTTC to publish National Prescribing Indicators 2020–2021 and associated resources

8. National Prescribing Indicators 2020-2021: Analysis of Prescribing Data to September

A summary of the document was provided and the key priority areas highlighted. There was discussion in relation to the colour and format of the charts within the document, in particular Table 5. Concern was expressed over the level of granularity of the data and Mrs Haines made the point that more detailed analysis is available via the SPIRA dashboard. The Chair encouraged health boards to investigate the information at a cluster/local level. AWTTTC was asked for more tools to assist health boards in changing inappropriate prescribing.

ACTION

AWTTTC to pick up the issues highlighted in the discussion

9. Appraisal 1: Limited Submission (orphan medicine)

Plerixafor (Mozobil®) In combination with granulocyte-colony stimulating factor (G-CSF) to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in children aged 1 to less than 18 years with lymphoma or solid malignant tumours, either: pre-emptively, when circulating stem cell count on the predicted day of collection after adequate mobilization with G-CSF (with or without chemotherapy) is expected to be insufficient with regards to desired hematopoietic stem cells yield; or who previously failed to collect sufficient haematopoietic stem cells.

The Chair welcomed the delegates from Sanofi Aventis

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 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 Chair set the context and outlined the sequence of events. Members were reminded that the application had been considered eligible for a limited submission and cost-effectiveness information is not required. Evidence of budgetary impact compared to the existing comparator product should be demonstrated. The Chair encouraged members to seek clarification of any outstanding issues,

particularly in relation to budget impact, and to take into consideration any societal aspects that were not part of the discussion at NMG. The Chair confirmed that delegates from the applicant company would have the opportunity to respond to questions and highlight any salient issues with regard to their submission. The Chair handed over to the AWTTTC appraisal lead.

The AWTTTC appraisal lead presented an overview and relayed the key aspects of the limited submission as outlined in the ASAR.

Dr Coulson relayed the advice of NMG that plerixafor (Mozobil®) should be supported for restricted use within NHS Wales in combination with granulocyte colony stimulating factor (G-CSF) to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in children aged ≥ 1 to <18 years with lymphoma or solid malignant tumours who previously failed to collect sufficient haematopoietic stem cells. NMG were of the view that plerixafor (Mozobil®) should not be recommended for use within NHS Wales in combination with granulocyte colony stimulating factor (G-CSF) to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in children aged ≥ 1 to <18 years with lymphoma or solid malignant tumours pre-emptively, when circulating stem cell count on the predicted day of collection after adequate mobilization with G-CSF (with or without chemotherapy) is expected to be insufficient with regards to desired hematopoietic stem cells yield. Dr Coulson confirmed the policy for appraising a medicine for a rare disease had been applied.

The lay member confirmed that no patients, carers or support organisations had submitted views on this medicine. Lymphoma Action, LATCH< Kids Cancer Charity, CLIC Sargent, Children's Cancer and Leukaemia Group and the Anthony Nolan Trust had been contacted and invited to submit views. Clinical expert views had been canvassed. No significant unmet need had been identified. The Chair asked members to raise any outstanding issue and clarification was sought in relation to the stage II trial.

The company delegates confirmed they had no further issues to raise in addition to their response to the PAR. Having received confirmation from the company delegates that the appraisal process had been fair and transparent, the Chair closed the appraisal and members retired to vote in private.

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:

Plerixafor (Mozobil®) is recommended for use within NHS Wales in combination with granulocyte colony stimulating factor (G-CSF) to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in children aged ≥ 1 to <18 years with lymphoma or solid malignant tumours either:

- **pre-emptively, when circulating stem cell count on the predicted day of collection after adequate mobilization with G-CSF (with or without chemotherapy) is expected to be insufficient with regards to desired hematopoietic stem cells yield, or**
- **who previously failed to collect sufficient haematopoietic stem cells.**

The Chair announced that confirmation of AWMSG's recommendations would be forwarded within five working days to the applicant company, who 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 meeting closed to the public and individuals in the public gallery left the meeting. The Chair sought confirmation that the individuals remaining in the public gallery were affiliated to either AWTTTC or the applicant company.

The public gallery cleared to protect commercial confidentiality in relation to appraisal 2.

10.

Appraisal 2: Limited Submission (WPAS)

Dolutegravir/lamivudine (Dovato®) for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

The Chair welcomed delegates from ViiV Healthcare UK Limited.

The Chair sought confirmation that individuals remaining seated in the public gallery were part of the AWTTTC team.

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 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 Chair set the context and outlined the sequence of events. Members were reminded that the application had been considered eligible for a limited submission and cost-effectiveness information is not required. Evidence of budgetary impact compared to the existing comparator product should be demonstrated. The Chair encouraged members to seek clarification of any outstanding issues, particularly in relation to budget impact, and to take into consideration any societal aspects that were not part of the discussion at NMG. The Chair confirmed that delegates from the applicant company would have the opportunity to respond to questions and highlight any salient issues with regard to their submission. The Chair handed over to the AWTTTC appraisal lead.

The AWTTTC appraisal lead presented an overview and relayed the key aspects of the submission as outlined in the ASAR.

Dr Coulson relayed the view of NMG that dolutegravir/lamivudine (Dovato®) should be supported for use as an option for use within NHS Wales for the treatment of HIV-1 infection in adults and adolescents above 12 years of age weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

The lay member confirmed that AWTTTC had received one submission from an individual patient from the Children's HIV Association (CHIVA) and he relayed the key points reported by the patient.

The Chair opened discussion and asked members if there were any outstanding issues for discussion. There were no issues of note.

Having received confirmation from the company delegates that the appraisal process had been fair and transparent, the Chair closed the appraisal and members retired to vote in private.

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:

Dolutegravir/lamivudine (Dovato[®]) is recommended as an option for use within NHS Wales for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

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 announced that confirmation of AWMSG's recommendations would be forwarded within five working days to the applicant company, who 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.

11. All Wales Advice on Oral Anticoagulation for Non-valvular Atrial Fibrillation

Miss Shaila Ahmed gave an overview of the document and summarised the process with regard to the development of the All Wales Advice on Oral Anticoagulation for Non-valvular Atrial Fibrillation. She confirmed there had been widespread consultation and subsequent iteration. The Chairman informed members that a letter dated 6th February from Daiichi-Sankyo raised a number of issues and he sought clarification from the AWPAG Chair and the AWTTTC project lead that all the issues had been explored and discussed prior to the document being presented to AWMSG. Confirmation was received that all the issues raised by Daiichi-Sankyo had been addressed. The industry member confirmed his agreement that the issues raised by Daiichi-Sankyo had been adequately addressed and that due process had been followed. The Chair confirmed that in the interests of transparency the letter is available to members and he opened discussion.

It was noted that NICE guidance is expected to be published in September 2020 and realignment of the all-Wales guidance will be necessary. Members welcomed the guidance which would provide valuable support to prescribers in a complicated area. Some minor technical issues were noted. Members discussed the decision aid tool, compliance and Yellow Card reporting. The Chair asked the project lead to note the issues raised in the discussion.

The Chair confirmed AWMSG's endorsement of the paper and confirmed that the document will be updated by AWTTTC to reflect the issues raised by members. The Chair passed the AWPAG Chair authority to approve the amendments to the document in light of AWMSG's discussion and requested final scrutiny by AWPAG in March.

ACTION

AWTTTC to update document, addressing points raised in the meeting

AWPAG Chair to approve the amendments

Updated document to be scrutinised by AWPAG prior to publication

12. Items Identified as Low Priority for Funding in NHS Wales (Paper 3)

Mr Boldero presented the third in a series of papers identifying items considered low value and less suitable for prescribing. The document had been developed to improve primary care prescribing. Mr Boldero reiterated that the driver for the paper was not 'financial saving' but 'limited value'. Members discussed the document and some minor changes were noted. The Chair asked members how the message could be strengthened and awareness raised of the limited value in prescribing these items. It was suggested that Welsh Government ratification of all AWMSG guidance would provide some gravitas. The Chair confirmed that he would explore this further. He confirmed AWMSG's endorsement subject to minor changes.

ACTION

Chair to explore ratification of all AWMSG guidance by Welsh Government

13. National Guiding Principles for Medicines Support in the Domiciliary Care Sector

Mr Emyr Jones, Consultant Pharmacist – Community Healthcare provided the background to the development of National Guiding Principles for Medicines Support in the Domiciliary Care Sector. He confirmed there had been wide consultation and input from health care and social care sectors in developing a person-centred approach. Mr Jones sought endorsement of the principles by AWMSG. The Chair opened discussion.

Members welcomed the document to improve consistency and assist with the adoption of a standardized approach across Wales. It was noted that training would need to follow and clarity of legislation was the first step. The importance of good medicines support in the community was acknowledged. A suggestion was made to include clarification of the responsibility of the pharmacist or dispensing GP to assess the patient within the document. One member highlighted that a robust process for reordering medicines for patients needs to be addressed. Mr Jones responded to members' questions and noted their suggestions. The Chair concluded the discussion by confirming AWMSG's endorsement of the National Guiding Principles for Medicines Support in the Domiciliary Care Sector.

14. Any other business

There was no other business.

Date of the next meeting - Tuesday, 17th March 2020 in Cardiff