

Enclosure No:	1/AWMSG/0524
Agenda Item No:	1 – Minutes of previous meeting
Author:	Chair, AWMSG
Contact:	Tel: 029 218 26900 E-Mail: awttc@wales.nhs.uk

All Wales Medicines Strategy Group (AWMSG)

Draft minutes of the AWMSG meeting held at 9.30 am on Wednesday, 17th April 2024 at Cardiff Metropolitan University, Cyncoed Campus, CF23 6XD

Voting members present:

**Did not
participate in
agenda item:**

- | | |
|---------------------------------|---|
| 1. Prof Iolo Doull | Chairman |
| 2. Prof Stephen Monaghan | Consultant in Public Health Medicine |
| 3. Mrs Eleri Schiavone | NHS Wales Joint Commissioning
Committee |
| 4. Prof Dyfrig Hughes | Health Economist |
| 5. Mr Farhan Mughal | ABPI (Wales) |
| 6. Mrs Claire James | Lay Representative |
| 7. Mrs Pam James | Lay Representative |
| 8. Mr Dylan Jones | Community Pharmacist |
| 9. Dr Jeremy Black | GP with prescribing lead role |
| 10. Ms Alison Hughes | Senior Primary Care Pharmacist |
| 11. Mr Hywel Pullen | Director of Finance |
| 12. Mr David Fox | Senior Hospital Pharmacist |
| 13. Ms Katherine White | Senior Nurse |
| 14. Ms Cathy Wynne | Other healthcare professions eligible to
prescribe |
| 15. Dr Alison Thomas | Clinical Pharmacologist |
| 16. Dr Manjeet Singh | Hospital Consultant |
| 17. Mr Chris Brown | Chief Pharmacist |

Welsh Government:
Mr Andrew Evans

Medicines value unit:

Mr Mark Francis

AWTTC staff:

Mrs Helen Adams, Senior Pharmacist
Ms Shaila Ahmed, Senior Pharmacist
Mr Richard Boldero, Senior Pharmacist
Dr Andy Champion, Programme Director
Dr Thomas Curran, Principal Scientist
Dr Clare Elliott, Senior Scientist
Dr Stephanie Francis, Principal Scientist
Mrs Sian Harbon, Medical Writer
Bridget-Ann Kenny, Senior Scientist
Mrs Claire Thomas, Head of WAPSU
Mrs Gail Woodland, Senior Pharmacist

List of abbreviations:

ABPI	Association of the British Pharmaceutical Industry
AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
AWTTC	All Wales Therapeutics and Toxicology Centre
IR	Independent review
WHSSC	Welsh Health Specialised Services Committee
OWMAG	One Wales Medicines Access Group
NHS Wales JCC	NHS Wales Joint Commissioning Committee
NPGG	National Pharmacogenomics Group
NPIs	National Prescribing Indicators
DHCW	Digital Health and Care Wales
GPW	Good Practice Wales

1. Welcome and introduction

The Chair opened the meeting, welcomed members and observers, and explained the meeting protocol. He sought clarification of the members attending online and confirmed that the quorum had been met.

2. Apologies:

Dr Richard Skone, Medical Director
Dr Sam Cox, Hospital Consultant
Prof James Coulson, Chairman NMG

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 7 February 2024 were checked for accuracy and approved. There were no matters arising.

5. Chairman's report (verbal update)

The Chair informed members that the AWMSG Medicines Strategy 2024-2029 has been launched and is now available on the AWTTC website. Members were thanked for working to ensure that the strategy meets the

needs of the people of Wales and aligns to the priorities of both NHS Wales and Welsh Government.

Members were informed that a document entitled “Back-up antibiotic prescribing: Good practice guide” went out for consultation on 10 April and will close on 3 May 2024. Members were asked to submit comments to AWTTTC.

The Chair announced that following a 12-month review, the One Wales Medicines Assessment Group agreed the starting criteria for abiraterone for treatment of non-metastatic hormone sensitive prostate cancer will include high risk, relapsing patients. This brings the advice in line with proposed NHS England commissioning advice and the change is not expected to increase the budget impact to above the original estimate.

The Chair confirmed the launch of the new NHS Wales Joint Commissioning Committee on 1 April 2024.

The Chair announced that AWTTTC will be hosting a Learning at Lunch session via Teams on Tuesday 21 May 2024 from 1.15 pm -2.15 pm and invited all members to attend and to share the invitation with colleagues.

6. Feedback on AWTTTC Activity:

AWMSG Medicines Access Review (verbal update)

Dr Stephanie Francis advised members that consultation on the review of AWMSG’s Medicines Access processes will finish on Friday 19 April 2024. The next stage will be to work through some examples and update the AWTTTC website to provide clarification of the changes in process. Dr Francis reassured members that AWTTTC will continue to monitor the NICE work program and topic selection. A suggested was made to refer to ‘off label rather than unlicensed medicines’ and to include a section on repurposing medicines. Dr Francis agreed to take on board the comments and re-circulate the consultation document.

Review of NICE terminated appraisals

Dr Clare Elliott presented the NICE terminated appraisal review. The report included a list of terminated appraisals issued by NICE between 1 January 2020 and 31 October 2023 and outlined the reason for termination and whether the treatment in question is routinely available in NHS England and/or NHS Scotland for the stated indication via alternative routes of access. Dr Elliot also gave a verbal update on NICE terminated appraisals issued since 1 November 2023 to date. Dr Elliot confirmed that none of treatments which have a NICE terminated status are routinely available to patients in England via alternative routes of access such as NHS England commissioning. Dr Elliot assured members there is no evidence to suggest that medicines which have been excluded from appraisal by AWMSG due to assessment by NICE, and which have subsequently been terminated by NICE due to non-submission, are being routinely offered to patients in England via other national access routes. Dr Elliott made the point that in considering the wider medicines access landscape there does not appear to

be a gap in advice specific to NHS Wales in respect of NICE terminated appraisals.

Members were informed that AWTTTC will continue to monitor NICE terminated appraisals and will highlight any instances where inequity of access may exist, where there is an identified clinical need for advice within Wales or where alternative assessment by AWMSG may be appropriate.

7. Appraisal 1: Limited Submission

Trifarotene (Akliel[®]▼) 50 microgram/g cream

50 microgram/g cream for the cutaneous treatment of Acne Vulgaris of the face and/or the trunk in patients from 12 years of age and older, when many comedones, papules and pustules are present.

Limited submission by Galderma (UK) Limited

The Chair welcomed delegates from Galderma (UK) Limited

The Chair set the context of the appraisal and asked members to declare any interests. There were none.

Mrs Helen Adams provided an overview of the ASAR and advised members that whilst this submission meets the criteria for a full submission a limited submission had been supplied and accepted. It was noted that clinical experts welcomed the addition of trifarotene as a treatment option. Mrs Adams relayed the NMG preliminary recommendation which supported use of this medicine for the indication under consideration.

The Chair invited comment. It was noted that a limited submission can be considered even when no evidence of cost-effectiveness has been presented. Members were guided by the Chair to consider the budget impact estimates. The lay members expressed disappointment that no patient groups had responded to the request for input. There was a brief discussion. The applicant company delegates confirmed that all the issues raised had been adequately addressed and the process had been fair and transparent.

The Chair thanked the company delegates for attending and closed the meeting to the public. Members voted in private and agreed the recommendation to Welsh Government which was subsequently announced when the meeting re-convened.

Trifarotene (Akliel[®]▼) 50 microgram/g cream

Trifarotene (Akliel[®]▼) is recommended as an option for use within NHS Wales for the cutaneous treatment of Acne Vulgaris of the face and/or the trunk in patients from 12 years of age and older, when many comedones, papules and pustules are present.

8. National Prescribing Indicators 2023-24. Analysis of prescribing data to September 2023

Miss Shaila Ahmed and Mr Richard Boldero presented the data relating to the NPIs for the second quarter of 2023–2024 and the Chair invited members

to comment.

There was discussion regarding the support provided to GP practices to help with their performance. It was noted that AWTTTC's annual Best Practice Day provides opportunity to share good practice and AWTTTC agreed to announce the date of the 2024 event. A member commented that the NPI quarterly report is very useful for comparative benchmarking. AWTTTC was asked to explore whether practice level data could be accessed for prescribing safety NPIs.

9. NHS Wales inhaler carbon footprint report – Data to December 2023

Mr Richard Boldero presented an overview of the report which includes secondary care data. Mr Boldero reported a mixed picture for the three-month period October to December 2023 compared to the previous three-month period July to September 2023. A more positive picture was seen comparing December 2023 to December 2022. Members were informed the January 2024 report is available on the AWTTTC website.

The improvement in the 12-month data was welcomed; however, concern was expressed that the indicative carbon footprint of inhalers had increased in the latest three-month period. Mr Boldero suggested this could be due to seasonal trends as this period runs into winter months. One consideration was that patients who were easier to move to lower global warming inhalers have been, and health boards are now encountering more complicated patients. Clarification was sought as to how Wales compares to other UK nations. Mr Boldero informed members that this is a workstream of the Inhaler Task and Finish Group which has been established to deliver the recommendations of the AWMSG-endorsed Inhaler Strategy.

10. Update report: National Pharmacogenomics Group

Professor Dyfrig Hughes provided an update on the activities and achievements of the NPGG since the last report to the AWMSG in June 2023. A sub-group of the NPGG has been established to scope *CYP2C19* testing for patients being prescribed clopidogrel in anticipation of the publication of NICE guidance on clopidogrel genotype testing after ischaemic stroke or transient ischaemic attack (GID-DG10054). A short-term pilot project within a single health board is being proposed to inform the development of a guidance document that will ensure equity of testing across Wales.

The NPGG has a preference that its guidance, following acknowledgement by the AWMSG, is made available to prescribers via the AWTTTC website and discussions are currently ongoing to agree a way forward.

The All Wales Medical Genomics Service (AWMGS) has designed a custom pharmacogenomics panel with Agena using the Veridose core kit on the MassArray system. This includes 80 variants across 18 genes, including *DPYD* and is currently being validated. AWMGS has purchased a second instrument in anticipation of the volumes required for testing, and to ensure sustainability of new services in the future. Discussions are ongoing with the lead investigators of the PROGRESS programme (Pharmacogenetics Roll Out – Gauging Response to Service) at the Manchester Centre for Genomic

Medicine and with Health and Care Research Wales, with the aim for Wales to become a study site. The PROGRESS programme seeks to establish the feasibility of providing a primary care diagnostic service to identify genetic changes associated with commonly prescribed medicines.

It was noted that one-year funding has been secured for a national pharmacogenomics consultant pharmacist lead. Funding for this post beyond one year is currently uncertain.

Clarification was sought with regards to the funding of genomic testing. Professor Hughes confirmed that the testing will be a commissioned service, but the pathway responsibility would lie with the health boards. The lay member made the point that it is not solely new tests for new medicines but new tests for existing medicines.

It was noted that AWTTTC is providing horizon scanning information on medicines that require a genomic test in order to determine eligibility.

Mrs Thomas asked Professor Hughes to amend wording within the document to clarify that the white paper did not go through the AWMSG endorsement process and this was agreed.

11. Cancer Network – Prevention and Management of Tumour Lysis Syndrome for acknowledgement

Dr Thomas Curran presented this second document from the Cancer Network to members for acknowledgement.

The lay member raised concerns that the contraindications could be made more prominent and that the 'Dose banding schedule' should be amended to avoid any overlaps between patient weight boundaries.

The Chair confirmed AWMSG's agreement to acknowledge the document and asked for the suggestions to be shared with the Cancer Network.

12. SBAR: Medicines optimisation resources – process for consideration of resources for review

Dr Thomas Curran confirmed that following discussion at the AWMSG meeting held in September 2023 the document had been amended and discussed further at the March 2024 meeting of AWPAG. It was noted the term 'retirement' has been adopted. Mr Curran explained that documents will not be removed from the website at the point of retirement. A structured decision-making form has been provided so all decisions around review and retirement can be recorded.

Members supported the process and Dr Curran confirmed that it will be put into practice at the next AWPAG meeting in June.

13. One Wales - Nivolumab monotherapy as a first-line treatment for patients with metastatic deficient mismatch repair (dMMR) / high microsatellite instability (MSI-H) oesophageal and gastric cancer (OW28)

Dr Rosie Spears, the One Wales assessment lead, gave a summary of the

One Wales Medicines Assessment Group (OWMAG) decision rationale and relayed the OWMAG recommendation:

OWMAG recommends the use of nivolumab monotherapy as a first-line treatment for patients with metastatic deficient mismatch repair (dMMR) / high microsatellite instability (MSI-H) oesophageal and gastric adenocarcinoma where the programmed death ligand-1 (PD-L1) combined positive score (CPS) is less than 5. This recommendation is subject to the development of appropriate start/stop criteria.

The Chair sought clarification of the process for endorsement of OWMAG recommendations. Mrs Gail Woodland, Senior AWTTTC Pharmacist, explained that questions can be raised at AWMSG meetings but it would be preferable to have them in advance to allow OWMAG time to respond appropriately. Mrs Woodland highlighted the process for seeking AWMSG endorsement is relatively new and prior to the implementation of this process the Chief Executive Management Team had the responsibility for approval of OWMAG recommendations.

Mr Hywel Pullen highlighted a conflict of interest in that he had been the Finance Director representative at the OWMAG meeting and a voting member. He agreed to tender his resignation from OWMAG with immediate effect.

The Welsh Government official confirmed that AWMSG endorsement of One Wales advice provides a timely and appropriate process for Welsh Government ratification of medicines that fall outside of the HTA process.

The general consensus view of members was that they could not endorse the OWMAG recommendation on the grounds of lack of evidence of clinical and cost effectiveness and Mrs Woodland agreed to relay AWMSG's comments to OWMAG. The Chair asked whether additional information could be provided to AWMSG for consideration in circumstances where the evidence is weak. Mrs Woodland invited the Chair and members to observe an OWMAG meeting and reminded members that AWMSG's medicines access processes are being reviewed. The Chair thanked AWTTTC and closed the discussion.

14. One Wales - Dabrafenib and trametinib for the treatment of inoperable BRAF V600E variant anaplastic thyroid cancer (OW27)

Dr Clare Elliott, the One Wales assessment lead, gave a summary of the One Wales Medicines Assessment Group (OWMAG) decision rationale and relayed the OWMAG recommendation:

Using the agreed starting and stopping criteria dabrafenib (Tafinlar®) and trametinib (Mekinist®) in combination can be made available within NHS Wales for the treatment of inoperable anaplastic thyroid cancer with the BRAF V600E variant.

The risks and benefits of the off-label use of dabrafenib (Tafinlar®) and trametinib (Mekinist®) for this indication should be clearly stated and

discussed with the patient to allow informed consent.

Providers should consult the relevant guidelines on prescribing unlicensed medicines before any off-label medicines are prescribed. This advice will be reviewed after 12 months or earlier if new evidence becomes available. Clinicians will be obliged to collect and monitor patient outcomes.

Dr Elliot confirmed that no queries had been raised prior to the meeting by AWMSG members. The Chair sought confirmation from members that there were no outstanding issues and the rationale for the OWMAG decision is acceptable.

The Chair confirmed AWMSG's endorsement and informed members that the recommendation would go to Welsh Government for ratification prior to publication.

15. Any other business

The lay member reminded members of the importance of social prescribing and highlighted the benefits of physical activity to be used alongside and in place of medication in some health conditions. The Chair thanked the lay member for this comment.

The Chair confirmed the date of the next meeting on Tuesday 14th May 2024