

Enclosure No:	1/AWMSG/0422
Agenda Item No:	1 – Minutes of previous meeting
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All Wales Medicines Strategy Group (AWMSG)

Minutes of the AWMSG meeting held at 9.30 am on Tuesday, 8 March 2022 (via Zoom)

Voting members present:

**Did not
participate in
agenda item:**

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| 1. | Prof Iolo Doull | Chair |
| 2. | Prof Stephen Monaghan | Consultant in Public Health Medicine |
| 3. | Ms Eleri Schiavone | Welsh Health Specialised Services
Commission |
| 4. | Prof Dyfrig Hughes | Health Economist |
| 5. | Mr Farhan Mughal | ABPI (Wales) |
| 6. | Dr Alison Thomas | Clinical Pharmacologist |
| 7. | Mr Cliff Jones | Lay Member |
| 8. | Ms Claire James | Lay Member |
| 9. | Dr Jim McGuigan | Medical Director |
| 10. | Dr Jeremy Black | General Practitioner |
| 11. | Mrs Alison Hughes | Senior Primary Care Pharmacist |
| 12. | Mr John Terry | Managed Sector Secondary Care
Pharmacist |
| 13. | Dr Sam Cox | Hospital Consultant |
| 14. | Mrs Mandy James | Senior Nurse |

Welsh Government:
Ms Lois Lloyd

AWTTC staff:

Mrs Helen Adams, Senior Pharmacist
Mr Richard Boldero, Senior Pharmacist
Mr Trevor Brooking, Administration Manager
Ms Kath Haines, Head of WAPSU
Dr Carolyn Hughes, Medical Writer (Minutes)
Dr Stuart Keeping, Senior Scientist
Mrs Ruth Lang, Liaison Manager
Mrs Karen Samuels, Programme Director
Mrs Claire Thomas, Senior Pharmacist
Mr Tony Williams, Senior Pharmacist

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
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. The Chair welcomed Dr Samantha Cox, the new Hospital Consultant member of AWMSG attending for the first time, and Ms Lois Lloyd, Wales' Deputy Chief Pharmaceutical Officer, who was representing Welsh Government as a non-voting member.

2. **Apologies:**

Mr Karl Jackson - Other Healthcare professions
 Mr Dylan Jones - Community Pharmacist
 Mr James Leaves - Finance Director
 Mr Hywel Pullen - Finance Director
 Ms Cathy Wynne - Other Healthcare professions

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 9 February 2022 were checked for accuracy and approved as a true record of the meeting. There were no matters arising.

5. **Chair's verbal report**

The Chair informed the meeting that the appraisal of hydrocortisone (Efmody[®]) had been postponed. The applicant company has requested that the committee members consider a restriction to the licensed indication, and NMG will re-appraise the medicine before it will be considered by AWMSG.

The Chair confirmed that Welsh Government ratification had been received for the recommendations announced at the previous meeting in February 2022 for: clostridium botulinum toxin (Dysport[®]), tirbanibulin (Klisyri[®]), inclisiran (Leqvio[®]), ravulizumab (Ultomiris[®]) and buprenorphine (Sixmo[®]). The final appraisal recommendations have been disseminated to the service and published on the AWMSG website.

The Chair reported that the All Wales Advice on Oral Anticoagulation in Non-valvular Atrial Fibrillation, discussed at the previous meeting in February 2022, had been updated to include a statement on trough level measurement

availability at health board level. The document has since been disseminated and published on the AWTTTC website. The National Prescribing Indicator (NPI) Supporting Information had also been disseminated and published on the website, and the antimicrobial guidelines are due to be disseminated and published the week commencing 14 March 2022. An update of the NPI Analysis of Prescribing Data to September 2021 had been published on the website and would be discussed later in the meeting.

The Chair said that he was currently seeking nominations for the role of Vice Chair of AWMSG; members should have received an email inviting them to put themselves forward if they wished to be considered for the role. The Chair also mentioned that we are also seeking to appoint into a number of vacant positions on AWMSG and its two sub-committees: New Medicines Group (NMG) and All Wales Prescribing Advisory Group (AWPAG). Emails have gone out to the service, and members may also nominate a colleague if they wish.

The Chair reported that an AWMSG Steering Committee meeting was held on 15 February, the One Wales Medicines Access Group met on 28 February, and the NMG met on 2 March. AWTTTC held an Open Event for the pharmaceutical industry on 3 March; over 90 delegates registered and AWTTTC staff explained the AWMSG appraisal process and how companies could submit commercial arrangements.

The Chair announced that AWPAG will be meeting on 16 March. The agenda includes:

- the Care Homes Medicines Optimisation toolkit which is due to come to AWMSG in April;
- All Wales Guidance for Prescribing Intervals (the consultation is anticipated at the end of March/early April);
- A review of the Polypharmacy – Guidance for prescribing; and
- A value-based prescribing paper which has been out to consultation and is due to be considered by AWMSG in April.

The Chair announced that AWMSG's Patient and Public Interest Group is holding their next meeting on Friday 18 March. The meeting will focus on the importance of patient engagement and lay representation.

The Chair also reported that the AWMSG Training Day is likely to be scheduled for September 2022. The Chair invited members to suggest topics for the 20th Anniversary Conference, scheduled to take place on 17 November 2022.

The Chair said that AWMSG are looking to hold face-to-face meetings again, and AWTTTC are looking at possible venues over the next few weeks with a view to hosting a 'hybrid' meeting in the first instance.

The Chair asked if anyone had any questions; there were none. The Chair then invited Mrs Karen Samuels, AWTTTC Programme Director, to announce the appraisals scheduled for the next AWMSG meeting on 27 April 2022:

Full submission:

- Oritavancin (Tenkasi[®]) for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults

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Full resubmission:

- Cariprazine (Reagila[®]) for the treatment of schizophrenia in adult patients

Full submission with a Wales Patient Access Scheme:

- Mercaptamine bitartrate (Procysbi[®]) for the treatment of proven nephropathic cystinosis. Mercaptamine reduces cystine accumulation in some cells (e.g. leukocytes, muscle and liver cells) of nephropathic cystinosis patients and, when treatment is started early, it delays the development of renal failure

Paediatric licence extension:

- Bedaquiline (Sirturo[®]) as use as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis (MDR-TB) in paediatric patients (5 years to less than 12 years of age and weighing at least 15 kg) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability

Mrs Samuels asked members to contact AWTTTC ahead of the next meeting to register any personal or non-personal interests in these medicines. Patients, patient organisations and patient carers were invited to submit their views and refer to the AWMSG website, or contact Ruth Lang at AWTTTC, for further information on the appraisal process and future work programme.

6. National Prescribing Indicators Quarterly Report: Analysis of data to September 2021

The Chair invited Mrs Claire Thomas and Mr Richard Boldero to present the NPI Quarterly Report – an analysis of data to September 2021. Mrs Thomas summarised the trends in the data for the priority areas and safety domain and Mr Boldero summarised the data for the efficiency domain.

The increase in use of proton pump inhibitors (PPIs) was raised; Mrs Claire Thomas stated that there were ongoing issues with ranitidine which was likely to be a contributing factor and as a result the indicator will be retired from the 2022-2023 NPIs. A member queried the reduction in Yellow Card reports by healthcare professionals and asked what could be done to reverse this. Dr Alison Thomas highlighted that the work of health board Yellow Card champions had been diverted due to the Covid-19 pandemic. She also discussed plans at Yellow Card Centre Wales to try to increase Yellow Card reporting by healthcare professionals and to raise awareness in Wales. It was suggested that the lay members of AWMSG's committees could help to explore ways to increase Yellow Card reporting. It was noted that although the percentage reductions appear significant, the actual number of reports

should be considered alongside the percentages. The increase in reporting by members of the public was discussed. Dr Alison Thomas pointed out that the public might now be more aware of reporting adverse effects of medicines because of COVID-19 vaccination programmes.

Questions were asked about the granularity of the NPI data; how health boards in Wales use it to plan services; and whether health inequalities are considered. Mrs Claire Thomas informed members that SPIRA, the online interactive dashboard, enables users to drill down to GP practice level to provide granularity. It is well used by health boards; the numbers of hits are monitored and a SPIRA steering committee is in place to ensure it remains fit for purpose. Mrs Claire Thomas explained that it is down to health boards to determine how they use it to service plan. It was highlighted that AWTTTC is developing a dashboard to link health inequalities to prescribing to provide further intelligence.

Questions were asked about the level of depth available to analyse the data, such as postcode level data, and Mr Boldero replied that the AWTTTC team working on the dashboard will be looking into that. The Chair asked when data might be available about health deprivation; Mr Boldero said that by 2023 they might have a more accurate picture of the data on health inequalities. One member mentioned an “additional needs index” coded data for GP practices as a potential source of data. Another member commented that perhaps the SAIL data team in Swansea might be able to provide data needed.

One member asked how the data were collected for one of the anticoagulation in atrial fibrillation indicators. Mrs Thomas replied that the data was extracted via Audit+ and utilised the retired QoF indicator methodology. The member then suggested that because of the way the data were coded, this indicator might not be measuring what we want it to measure and the Chair asked how we could measure it better. Mrs Kath Haines said that AWTTTC will look into this.

7. NHS Wales inhaler carbon footprint report

The Chair invited Mr Richard Boldero to present a report on the progress made in reducing the carbon footprint of inhalers in primary care in Wales. The aim of NHS Wales is to increase the use of inhalers that have low global warming potential to 80% of total inhalers issued by 2025.

A question was asked about how to get prescribers to change what inhalers they prescribe. A member commented that a joined-up approach to change prescribing by primary and secondary care was already in place. Another question was asked about procurement of inhalers by the health boards; Mrs Haines and Mr Boldero said that AWTTTC will look at the secondary care data on what inhalers health boards in Wales are procuring and whether they reflect the decarbonisation agenda.

One member suggested that practice nurses might be influential in driving the changes in inhaler prescribing; another member agreed and said that there is an All Wales Practice Nurses Forum who could be contacted about

this. One member suggested making all prescribers aware of this target; the Chair commented that the approach should also include non-respiratory physicians.

One member commented that the new inhalers were more expensive and asked if AWMSG had looked at the economic aspect of this change in prescribing. The Chair asked about the budget impact of the change in policy. Mr Boldero said that they had tried to look at using the dashboard with regards to costs and were currently working on an update. One member commented that they would welcome a document about the budget impact of the programme to increase the use of inhalers with low global warming potential.

8. **Appraisal 1 – Paediatric Licence Extension**

Adalimumab (Humira®) for treatment of moderately to severely active ulcerative colitis in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies

Submission by AbbVie Ltd for a licence extension for paediatric use where there is existing NICE appraisal advice for adults. There were no company delegates attending the meeting.

The Chair set the context of the appraisal and stated 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 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 sought confirmation that the meeting was quorate; the Secretariat confirmed that the meeting was quorate.

The Chair stated that this appraisal is being considered via the new streamlined process for paediatric licence extensions and, based on the summary of information provided to members prior to the meeting, a draft recommendation is being presented to AWMSG for consideration and approval. The Chair said he was not aware that any issues have been highlighted by members ahead of the meeting, and the assessment lead, Dr Stuart Keeping, confirmed this. The Chair said that, as is the case with limited submissions, monitoring of budget impact will be essential and AWMSG reserves the right to request a full submission if the budget impact exceeds that estimated in this paediatric licence extension submission. The Chair asked Dr Keeping if there were any significant issues that need to be considered by AWMSG. Dr Keeping replied that there were none and confirmed the draft recommendation.

The Chair asked the members if there were any outstanding issues or questions about the appraisal. There were none.

The Chair stated that AWMSG's recommendation will be emailed to the company later today and, for transparency, a notice will be uploaded to the AWMSG website. The company will be asked to confirm acceptance of the final appraisal recommendation within ten working days from this meeting before it is forwarded to Welsh Government for ratification. The meeting closed to observers and AWMSG members voted in private.

The following recommendation was subsequently confirmed:

Adalimumab (Humira®) is recommended as an option for use within NHS Wales for the treatment of moderately to severely active ulcerative colitis in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

9. Any other business

There was no other business.

The Chair confirmed the date of the next meeting on Wednesday 27 April 2022 and closed the meeting.