Enclosure No:	**1/AWMSG/0624**
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 09:30 am on Tuesday, 14th May 2024 at the All Nations Centre, Sachville Avenue, Cardiff, CF14 3NY

Voting members present:			**Did not participate in agenda item:**
1.	**Prof Iolo Doull**	**Chairman**	
2.	**Dr Rachel Gemine**	**NHS Wales Joint Commissioning Committee**	
3.	**Prof Dyfrig Hughes**	**Health Economist**	
4.	**Mr Tommy Price**	**ABPI (Wales)**	
5.	**Mrs Pam James**	**Lay Representative**	
6.	**Mr Dylan Jones**	**Community Pharmacist**	
7.	**Dr Jeremy Black**	**GP with prescribing lead role**	
8.	**Ms Alison Hughes**	**Senior Primary Care Pharmacist**	
9.	**Mr James Leaves**	**Director of Finance**	
10.	**Mr Stuart Rees**	**Senior Hospital Pharmacist**	
11.	**Mrs Susan Newport**	**Senior Nurse**	
12.	**Ms Cathy Wynne**	**Other healthcare professions eligible to prescribe**	
13.	**Dr Sam Cox**	**Hospital Consultant**	
14.	**Mr Jonathan Simms**	**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
Dr Rob Bracchi, Medical Advisor
Dr Thomas Curran, Principal Scientist
Dr Paul Deslandes, Senior Pharmacist
Mrs Rachel Jonas, Medical Writer
Dr Stuart Keeping, Senior Scientist
Dr Bridget-Ann Kenny, Senior Scientist
Mrs Claire Thomas, Head of WAPSU
Mr Anthony Williams, Head of PAMS

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
JCC	NHS Wales Joint Commissioning Committee
OWMAG	One Wales Medicines Access Group
NPIs	National Prescribing Indicators

1. Welcome and introduction

The Chair opened the meeting, welcomed members and observers, and explained the meeting protocol.

2. Apologies:

Prof James Coulson, Chairman NMG
Mrs Claire James, Lay Representative
Prof Stephen Monaghan, Consultant in Public Health Medicine
Mr Hywel Pullen, Director of Finance
Mrs Eleri Schiavone, NHS Wales Joint Commissioning Committee
Dr Richard Skone, Medical Director
Dr Alison Thomas, Clinical Pharmacologist

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

5. Chairman's report (verbal update)

The Chair reminded members of the quarterly meeting of AWMSG's Patient and Public Interest Group, which is being held on Wednesday 22 May and the topics being covered.

The Chair informed members that consultation comments following review of the AWMSG Medicines Access processes are being compiled and will be presented at the June meeting.

The Chair updated members that the One Wales Medicines Assessment Group (OWMAG) took the decision to undertake a reassessment of nivolumab monotherapy for the first line treatment of deficient mismatch repair (dMMR) / high microsatellite instability (MSI-H) oesophageal and gastric cancer which was not endorsed for use by AWMSG in April's meeting. The date of the OWMAG meeting to discuss the reassessment of nivolumab is to be confirmed. OWMAG held a virtual consultation in April 2024 to review One Wales advice for:

- Infliximab for the treatment of refractory pulmonary sarcoidosis
- Vedolizumab (Entyvio®) for the treatment of inflammatory bowel disease in children and young people
- Ustekinumab (Stelara®) for the treatment of inflammatory bowel disease in children and young people
- Infliximab for the treatment of immune checkpoint inhibitor (ICI) induced enterocolitis
- Vedolizumab (Entyvio®) for the treatment of immune checkpoint inhibitor (ICI) induced enterocolitis

AWMSG members were asked to note the decisions of OWMAG:

- Continue to support use of ustekinumab and vedolizumab for inflammatory bowel disease in children and young people. Ustekinumab will be reviewed after 2 years, or sooner should new evidence become available; vedolizumab will be reviewed in three years or sooner.
- Continue to support the use of infliximab for refractory pulmonary sarcoidosis with review after 3 years or sooner should new evidence become available.
- Reassess the evidence for extending the patient groups included for both infliximab and vedolizumab (Entyvio®) for the treatment of ICI induced enterocolitis.

The Chair reminded members of the Learning at Lunch session via Teams on Tuesday 21st May 2024 and the topics being covered.

The Chair announced the 2024 Best Practice Day will be held on 2nd July in Cardiff and encouraged attendance.

6. Retirement of Statements of Advice for specific antiepileptic drugs

Dr Bridget-Ann Kenny and Mrs Helen Adams highlighted a medicines access issue identified by the epilepsy clinical network; specifically, a barrier to routinely prescribe eslicarbazepine acetate for a subpopulation of patients. This is due to the publication of a statement of advice (SOA) for eslicarbazepine acetate's monotherapy indication by AWMSG in 2017, following the decision by the original marketing authorisation (MA) holder not to engage in the AWMSG process. Mrs Adams explained the access routes to the medicine outside of Wales. Options for removal of the SOA in line with existing AWMSG processes are limited.

As part of the ongoing revision of the AWMSG medicines access processes, and to address this issue and future similar cases, AWTTC proposed a set of recommendations including the removal and retirement of SOAs for a small number of specific antiepileptic drugs that now have generic options available. AWTTC propose the introduction of a generic medicine as a trigger for reviewing SOAs on a case by case basis, where the default is that these medicines will most likely be considered by health boards for formulary inclusion.

The Chair confirmed AWMSG's support to retire the eslicarbazepine acetate SOA and revise the current SOAs on the AWTTC website.

7. Appraisal – Limited Submission

Opicapone (Ongentys®) as adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations

Limited submission by Bial - Portela C SA

The Chair welcomed delegates from Bial - Portela C SA:
Dr Glynn Jones - Senior Global HEOR/RWE Manager
Dr Mario Ippolito – Director of Medical Affairs - UK & ROI

The Chair explained 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 confirmed that as this is a limited submission no cost effectiveness information is required. Evidence of budgetary impact in comparison to the existing comparator product(s) should be demonstrated. Monitoring of the budget impact will be essential as AWMSG reserves the right to request a full submission if the budget impact exceeds the estimates.

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 agree 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, Dr Stuart Keeping, set the context of the appraisal and relayed the key aspects of the limited submission as outlined in the ASAR. The recommendation agreed by NMG was relayed.

The Chair invited questions. Clarification was sought in relation to the table of examples of medicine acquisition costs in regards to the number of tablets required. The company clarified the doses taken in clinical practice and Dr Keeping explained the table was more to compare costs of opicapone to the comparator. Dr Keeping agreed to amend wording regarding specialist prescribing for clarity. The company confirmed the pharmacokinetics of the medicine, allowing for once daily dosing.

It was confirmed that a submission from Parkinson's UK Cymru had been received and Mrs Pam James gave an overview of the issues raised by patients and highlighted the potential improvement of quality of life.

There were no wider social or equity issues of note.

It was suggested that this medicine could benefit from monitoring to confirm the projected savings. AWTTC confirmed they would monitor and the company offered their assistance with this.

There were no other issues of note and the Chair invited the company delegates to comment and sought confirmation that 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.

Opicapone (Ongentys®) is recommended as an option for use within NHS Wales as adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations.

8. Update to AWMSG Advice

Alglucosidase alfa (Myozyme®) for long term enzyme replacement therapy in patients with a confirmed diagnosis of Pompe disease (acid α-glucosidase deficiency)

Mrs Helen Adams presented the background and explained AWMSG appraised alglucosidase alfa (Myozyme®) for the above indication in 2006

and recommended it for restricted use in NHS Wales for infantile and juvenile onset Pompe disease. At the time AWMSG concluded there was insufficient evidence of clinical effectiveness for late onset Pompe disease (LOPD) in adults. In 2023, the Welsh Health Specialised Services Committee (WHSSC) contacted AWTTC requesting AWMSG advice is reviewed in line with a recent review of their commissioning policy for lysosomal storage disorders. AWTTC was informed of the unmet need which exists for adult patients with LOPD and since the original appraisal a number of studies conclude that alglucosidase alfa has a beneficial effect in LOPD in adults. Members were told the impact of expanding the indication is likely to be minimal as there are new treatment options available and alglucosidase alfa for LOPD is currently accessed by clinicians applying for IPFR funding.

The industry representative questioned the process for advising on this medicine. Mrs Adams explained that AWMSG will be prioritising medicines where there is an unmet clinical need or where there can be an improvement in value to patients and/or NHS Wales; the process changes are outlined in the consultation on 'AWMSG Medicines Assessment Process for Licensed and Off-label Medicines'.

The Chair invited members to comment. No issues were raised. There was unanimous support to expand the indication for this medicine.

Alglucosidase alfa (Myozyme®) is recommended as an option for use within NHS Wales for long-term enzyme replacement therapy in patients with a confirmed diagnosis of Pompe disease (acid α-glucosidase deficiency).

Myozyme® is indicated in adults and paediatric patients of all ages.

9. All Wales guidance for penicillin allergy de-labelling in adults in secondary care

Shaila Ahmed and Dr Owen Seddon presented the background for the guidance based on the Cardiff and Vale protocol and national standards for setting up a penicillin allergy de-labelling service.

Members requested that patients who are de-labelled based on history alone have a specific GP letter for this situation. This was agreed by AWTTC and will be updated prior to publication. Members discussed the IT logistics of updating a penicillin allergy from a patient's medical history.

Clarification was sought with regards to the responsibility for implementation of this protocol. Dr Seddon explained the current practice within Cardiff and Vale. It was noted some other health boards have started setting up a penicillin allergy de-labelling service. The All Wales guidance advises local implementation will dictate how the direct oral amoxicillin challenge test will be instigated.

The Chair confirmed AWMSG's endorsement.

10. Prescribing Dilemmas: Sharing responsibility for prescribing

between a private clinician and an NHS healthcare professional

Dr Paul Deslandes and Dr Rob Bracchi presented updates to the document to provide advice for NHS prescribers in circumstances where a specialist clinician managing a patient on a private basis has requested that treatment be continued by the NHS under an ongoing shared care agreement. The update followed a request to develop a position statement on this aspect of treatment management. Members were informed that following discussion at the All Wales Prescribing Advisory Group and consultation with Welsh Risk Pool, it became clear that providing definitive recommendations that fit every situation was not feasible. The update to the document includes some considerations to aid the decision of whether to enter into a shared care agreement with a private clinician.

There was extensive discussion around the updates to this document. Members debated whether the document facilitated the decision to enter into a shared care agreement with a private clinician and the comments returned during consultation were noted. There were concerns that GPs may agree to prescribe for a condition on the assumption that there will be ongoing monitoring and review with a private specialist, which would constitute an ongoing episode of private care. There were also concerns that prescriptions may be requested from patients with a diagnosis but GPs would be unable to access the patient records, which would put the prescriber at risk.

It was acknowledged that currently there is delays in opportunity for neurodivergent diagnosis in paediatrics due to long waiting lists, and shared care agreements with private clinicians may be beneficial.

The Chair confirmed that AWMSG is not in a position to endorse the document and requested the concerns raised by members be relayed to AWPAG.

11. Primary care antimicrobial guidelines (minor updates for information)

Dr Thomas Curran highlighted to members the recently published updates to the Primary care antimicrobial guidelines document made following the January 2024 MHRA warning on quinolone use.

12. Feedback from AWPAG meeting held 13th March 2024

Mrs Claire Thomas provided an overview of the AWPAG meeting held on the 13th March 2024.

13. Any other business

There was no other business.

The Chair confirmed the date of the next meeting on Tuesday 11th June 2024
Venue: The All Nations Centre