Enclosure No:	**1/AWMSG/1222**
Agenda Item No:	**4** – 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 Tuesday, 18th October 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.	Prof Dyfrig Hughes	Health Economist	
4.	Ms Eleri Schiavone	WHSSC	
5.	Mr Dylan Jones	Community Pharmacist	
6.	Dr Richard Skone	Medical Director	
7.	Mr Tommy Price	ABPI (Wales)	7-10
8.	Dr Alison Thomas	Clinical Pharmacologist	
9.	Mrs Julie Wilson-Thomas	Lay Member	
10.	Mr James Leaves	Director of Finance	
11.	Mr Stuart Rees	Senior Hospital Pharmacist	
12.	Mrs Katherine White	Senior Nurse	
13.	Mr Karl Jackson	Other healthcare professions	
14.	Dr Sam Cox	Hospital Consultant	

AWTTC staff:
Mr Trevor Brooking, Administration Manager
Prof James Coulson, NMG Chairman
Ms Kath Haines, Head of WAPSU
Mrs Rachel Jonas, Medical Writer
Dr Stuart Keeping, Senior Scientist
Mrs Ruth Lang, Senior Liaison Manager
Ms Laura Taylor, Administration Supervisor
Mrs Karen Samuels, Programme Director

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
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
OWMAG	One Wales Medicines Assessment Group
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:

Ms Alison Hughes, Senior Primary Care Pharmacist
Mrs Claire James, Lay Member
Mr Hywel Pullen, Director of Finance
Ms Cathy Wynne, Other healthcare professions
Dr Jeremy Black, General Practitioner
Ms Rafia Jamal, Senior Primary Care Pharmacist

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 14 September 2022 were checked for accuracy. There were no matters arising.

5. Chair's verbal report

The Chair confirmed that following Welsh Government ratification the recommendations announced at the previous AWMSG meeting relating to hydrocortisone MR (Efmody®), dupilumab (Dupixent®), rituximab (MabThera®), lacosamide (Vimpat®) and insulin degladec (Tresiba®) have been published and disseminated.

The Chair informed members that feedback from the AWMSG Training Day held at Cardiff City Stadium on 21st September had been positive and the Leadership presentation by Ian Govier had been extremely well received. A training repository for committee members has been developed by AWTTC. It currently contains training material on health economics and more resources will be added shortly.

The Chair announced that AWTTC will launch its first 'Learning at Lunch' educational event later today which has attracted over 145 delegates – the one-hour online session will focus on three therapeutic areas and will include a round-up of AWMSG activity.

Members were informed that AWMSG's next Patient and Public Interest Group meeting will be held via Zoom on Friday morning, 21st October and the theme for the meeting is The Environmental impact of Medicines. There will be presentations from Swansea Bay UHB on an inhaler recycling in Community Pharmacy Scheme; Steve Hoare from ABPI will talk about the pharmaceutical industry perspective on sustainability in relation to medicines, and Joseph Carter from Asthma and Lung UK will give a patient perspective on sustainability.

It was confirmed that AWTTC will be hosting a virtual Industry Open Day on the morning of Thursday, 24th November which will cover 3 different aspects of AWMSG's work. The event provides opportunity for discussion and questions, with the aim of encouraging pharmaceutical industry engagement.

Members were reminded that all of the events are advertised on the AWTTC website. The AWMSG 20th Anniversary Conference will be held on 17th November and the AWMSG meeting scheduled on the 9th November has been cancelled.

6. Paediatric Licence Extension (PLE)

Ambrisentan (Volibris®) for the treatment of PAH in adolescents and children (aged 8 to less than 18 years) of WHO Functional Class (FC) II to III including use in combination treatment. Efficacy has been shown in IPAH, familial, corrected congenital and in PAH associated with connective tissue disease

Submission by GlaxoSmithKline UK for a licence extension for paediatric use where there is existing AWMSG appraisal advice in adults.

Paediatric Licence Extension (PLE) (PAS)

Migalastat (Galafold®) for long-term treatment of adolescents aged 12 to-16 years with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency) and who have an amenable mutation

Submission by Amicus Therapeutics UK Ltd for a licence extension for paediatric use where there is existing NICE appraisal advice in older adolescents and adults.

Paediatric Licence Extension (PLE)

Bedaquiline (SIRTURO®) as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis (MDR-TB) in paediatric patients (5 to 11 years and weighing at least 15 kg) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability.

Submission by Janssen Cilag Ltd for a licence extension for paediatric use where there is existing AWMSG appraisal advice in adolescents and adults.

Dr Stuart Keeping outlined the process for paediatric licence extension submissions and confirmed that the draft recommendations had been circulated to members prior to the meeting. Dr Stuart Keeping informed members that there is existing AWMSG or NICE advice for all medicines.

For the purposes of transparency, and prior to requesting confirmation of AWMSG's approval, Dr Stuart Keeping read out the recommendations (the paediatric advice is combined with existing AWMSG advice as appropriate):

Ambrisentan (Volibris®) is recommended
as an option for use within NHS Wales for treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III, including use in combination treatment. Efficacy has been shown in idiopathic PAH (IPAH) and in PAH associated with connective tissue.

Ambrisentan (Volibris®) is recommended as an option for use within NHS Wales for the treatment of PAH in adolescents and children (aged 8 to less than 18 years) of WHO Functional Class (FC) II to III including use in combination treatment. Efficacy has been shown in IPAH, familial, corrected congenital and in PAH associated with connective tissue disease

Migalastat (Galafold®) is recommended
as an option for restricted use within NHS Wales.

Migalastat hydrochloride (Galafold®) is licensed for the long-term treatment of adolescents aged 12 to 16 years with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency) and who have an amenable mutation.

Migalastat hydrochloride (Galafold®) is restricted for use for the treatment of Fabry disease in adolescents aged 12 years to 16 years with an amenable mutation, only if enzyme replacement therapy (ERT) would otherwise be offered.

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.

Bedaquiline (SIRTURO®) is recommended
as an option for use within NHS Wales as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis (MDR-TB) in adults and paediatric patients (5 years to less than 18 years of age and weighing at least 15 kg) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability.
The Chair asked the members if there were any outstanding issues or questions relating to the recommendations. There were none. The Chair confirmed AWMSG's approval of the three recommendations.

7. Appraisal 1: Full re-submission

ferric maltol (Feraccru®) for treatment of iron deficiency in adults

Re-submission by Norgine Pharmaceuticals Ltd. The Chair welcomed the company delegates and confirmed they would be invited to comment and respond to questions.

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 invited the appraisal lead, Dr Stuart Keeping, to give an overview of the submission.

Prof James Coulson briefly summarised the discussion at the NMG and confirmed the NMG recommendation to AWMSG that ferric maltol is recommended as an option for use within NHS Wales for indication outlined by Dr Keeping. Prof Coulson explained members of NMG had concerns around the medicine failing the primary end point at 12 weeks in the main trial but noted that ferric maltol and the comparator showed similar results at longer time points Clarity was sought as to whether the whether the trial population reflected the company's proposed place in therapy i.e. if patients would have failed standard oral iron therapy ,the company clarified that patients would be likely to have failed standard treatment. Prof Coulson stated that NMG members considered the clinical expert experience in Wales which confirmed that the use during the Covid-19 pandemic resulted in patients avoiding intravenous infusion. Five out of ten patients were treated successfully with ferric maltol.

The Chair opened discussion and invited comments relating to clinical effectiveness. The company delegates were questioned on the 20% non-inferiority margin in the intention-to-treat population and stated that the margin was selected on the basis of clinical judgement and previous studies of IV iron.

Prof Dyfrig Hughes provided an overview of the case for cost-effectiveness and discussed the key considerations identified in the resubmission as outlined in the ASAR. It was noted that base case results, when compared with the IV comparator, gave a cost saving and an increase in QALYs and ferric maltol dominates as modelled by the CUA. Prof Hughes alluded to a number of limitations including a one-year time horizon and the lack of direct head to head comparative evidence. Professor Coulson was asked to clarify NMG's conclusions from the economic evidence provided. It was noted the small QALY gain is not atypical against active comparators, so should not be dismissed. Prof Hughes stated that given the small and uncertain QALY gain in this case the decision came down to a consideration of comparative costs. The company delegates acknowledged the uncertainty in the evidence presented and agreed that the CMA modelling approach taken previously had been inappropriate.

The Chair referred members to the budget impact estimates, there were no issued raised.

The lay member summarised the views and opinions from the patient perspective. It was pointed out that attendance at a clinic to receive IV treatment may cause stress and inconvenience to patients which may be avoided with an oral treatment. There were no wider societal issues of note. The chair asked members if they were satisfied with the equality impact assessment and to mention if there were any equality issues which had not

been addressed. No equality issues were identified.

The Chair asked the company delegates if they wished to provide any further comments. They thanked AWMSG members and confirmed that the process had been fair and all the issues had been adequately addressed.

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.

8. AWTTC Guide to collaborative working between NHS Wales and the pharmaceutical industry

Mrs Karen Samuels provided a brief overview and confirmed that the document had been reviewed in light of the recent publication of the 2021 ABPI Code of Conduct. AWMSG members were asked to approve the changes to the document. Mrs Samuels acknowledged the input of Joe Ferris from ABPI Wales and Stephanie Francis from AWTTC who jointly worked on the review of this document. Mr Price sought clarification as to whether the NHS organisations included primary care. Mrs Samuels confirmed this to be the case and that it could be addressed outside the meeting. The Chair confirmed AWMSG's approval of the advisory document and stated that he hoped the ethos would be adopted by all NHS organisations.

9. Feedback from the AWPAG meeting held 28th September 2022

Ms Kath Haines gave an overview of the All Wales Prescribing Advisory Group (AWPAG) meetings held virtually on 29th June 2022 with minutes of this meeting provided for information, and a verbal report of the meeting held virtually on 28th September 2022.

10. AWMSG 20th Anniversary Conference programme

Members were reminded to register for the 20th Anniversary Conference on the 17th November 2022.

Any other business

There was none.

The meeting closed to observers and AWMSG members voted in private, Dr Alison Thomas was not present for the vote. The following recommendation was subsequently confirmed:

Ferric maltol (Feraccru®) is recommended as an option for restricted use within NHS Wales.

Ferric maltol (Feraccru®) is licensed for the treatment of iron deficiency in adults.

Ferric maltol (Feraccru®) is restricted for use in adult patients with inflammatory bowel disease (IBD) who have mild to moderate iron deficiency anaemia (IDA) and have failed on, or are intolerant to,

standard oral iron products and are considered suitable for intravenous iron.

Ferric maltol (Feraccru®) is not recommended for use within NHS Wales outside of this subpopulation.

The Chair confirmed the date of the next meeting on Tuesday 6 December at 9:30am in Cardiff and closed the meeting.