Enclosure No:	**1/AWMSG/1221**
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 9.30 am on Tuesday, 9th November 2021 (via Zoom)

VOTING MEMBERS PRESENT:		**Did not participate in**
1. Prof Iolo Doull	**Chair**	
2. Prof Stephen Monaghan	**Consultant in Public Health Medicine**	
3. Dr Helen Fardy	**Welsh Health Specialised Services Commission**	
4. Prof Dyfrig Hughes	**Health Economist**	
5. Ms Kate Parrish	**ABPI (Wales)**	
6. Mr Cliff Jones	**Lay Member**	
7. Ms Claire James	**Lay Member**	
8. Mr Stefan Fec	**Community Pharmacist**	
9. Dr Jim McGuigan	**Medical Director**	
10. Dr Jeremy Black	**GP with Prescribing Lead role**	
11. Mrs Alison Hughes	**Senior Primary Care Pharmacist**	
12. Mr Hywel Pullen	**Finance Director**	
13. Mr John Terry	**Managed Sector Secondary Care Pharmacist**	
14. Mr Karl Jackson	**Other healthcare professions**	

AWTTC staff:
Mrs Helen Adams, Senior Pharmacist
Mr Richard Boldero, Senior Pharmacist
Ms Kath Haines, Head of WAPSU
Dr Stuart Keeping, Senior Scientist
Mrs Ruth Lang, Liaison Manager
Mrs Karen Samuels, Programme Director
Mr Anthony Williams, Head of PAMS
Mrs Claire Thomas, Senior Pharmacist

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
ATMPs	Advanced Therapy Medicinal Products
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
ILAP	Innovative Licensing and Access Pathway
IPCG	Interim Pathway Commissioning Group
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
QAIF	Quality Assurance and Improvement Framework
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 Mr Karl Jackson to his first AWMSG meeting.

2. Apologies:

Voting members:
Dr Balwinder Bajaj and Dr Alison Thomas – Clinical Pharmacologist
Ms Cathy Wynne – Other healthcare professions
Mrs Louise Williams and Mrs Mandy James – Nurse

Non-voting members:
Mr Andrew Evans – Welsh Government

Did not attend:
Dr Satish Kumar, Hospital Consultant

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 13th October 2021 were checked for accuracy and approved as a true record of the meeting. There were no matters arising.

The Chair asked AWTTC to explore access to everolimus for the indication(s) not yet appraised. Mrs Samuels confirmed she would take this back to AWTTC and update the Committee on this matter at the next meeting.

5. Chairman's verbal report
The Chair informed members that an AWMSG Steering Committee meeting was held on 19th October and Mr Karl Jackson's appointment as the alternate for Cathy Wynne, representing 'other professions eligible to prescribe,' had been confirmed.

The Chair announced four consultations currently ongoing:

- Primary care antimicrobial guidelines
- CEPP National Audit - Focus on Antibiotic Prescribing
- Recurrent (Symptomatic) Urinary Tract Infections (Adults)
- Management of Clostridioides difficile Infection in Wales

Members were encouraged to submit comments to AWTTC before the consultation deadline on 10th November 2021.

The Chair announced the AWMSG Annual Training Day scheduled on 12th January will go ahead as a 'face to face' meeting. Members were invited to submit topic suggestions to AWTTC. The Chair confirmed an invitation will be extended to sub-group members.

The Chair invited Mrs Karen Samuels to announce the appraisals scheduled for the next AWMSG virtual meeting on Wednesday 8th December 2021 commencing at 9:30am:

A full submission with a Patient Access Scheme:
cannabidiol (Epidyolex®) (Orphan/Ultra-Orphan) as adjunctive therapy of seizures associated with tuberous sclerosis complex (TSC) for patients 2 years of age and older
GW Pharmaceuticals

Three paediatric licence extensions:

Rivaroxaban (Xarelto®) for the treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in term neonates, infants and toddlers, children, and adolescents aged less than 18 years after at least 5 days of initial parenteral anticoagulation treatment

Bayer Healthcare Pharmaceuticals

Dabigatran etexilate (Pradaxa®) for the treatment of VTE and prevention of recurrent VTE in paediatric patients from birth to less than 18 years of age
Boehringer Ingelheim Ltd

Clostridium botulinum neurotoxin type A (Xeomin®) for symptomatic treatment in children and adolescents aged 2 to 17 years and weighing ≥ 12 kg of chronic sialorrhea due to neurological/neurodevelopmental disorders
Merz Pharmaceuticals GmbH
It was noted this appraisal has an associated Patient Access Scheme

Mrs Samuels asked members to contact AWTTC 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 AWTTC, for further information on the appraisal process and future work programme.

6. Cellulitis Pathway for People with Lymphoedema or Chronic Oedema in NHS Wales

Ms Joanne Browne from Swansea UHB provided a summary of the pathway and explained that it was more comprehensive and inclusive than the guidance previously produced. She explained the purpose of the document is to aid diagnosis and management of people with lymphoedema or chronic oedema. She highlighted the key points and confirmed there had been wide stakeholder engagement and input. She sought the 'acknowledgement' of AWMSG as best practice. The Chair opened discussion and invited comments or questions.

The point was made that GPs can't prescribe treatment for overseas use and there was brief discussion with regards to rescue packs. Dr McGuigan asked to have a conversation with Ms Browne outside of the meeting with regards to the news score and pointed out it is not validated in Primary Care. A typographical error was noted. Clarification was sought with regards to the licensed dose and the Chair suggested that medicines licensing could be a topic for the Training Day. Members highlighted potential capacity issues for lymphoedema services within NHS Wales. There were suggestions for inclusion in the list of signs and symptoms.

The Chair closed discussion and thanked Ms Browne for presenting the document 'for acknowledgement' by AWMSG.

7. All Wales Adult Asthma Management and Prescribing Guidelines (2021 update)

Dr Simon Barry presented the updated All Wales Adult Asthma Management and Prescribing Guidelines and he explained these had recently been reviewed and updated. Dr Barry highlighted the changes from the previous version. He confirmed the work forms part of national strategic implementation guidance developed in accordance with prudent healthcare principles for people living in Wales. The guidance promotes use of more environmentally friendly inhalers with reduced carbon emissions. The Chair opened discussion.

Suggestions were made to improve formatting and display. A further suggestion was made to change 'concordance' to 'adherence' on page 6. Dr Barry referred to the availability of supporting information for patients to aid in the implementation of the guidance. There was also some discussion with regards to the move towards genotype-based guidance. Clarification was sought with regards to links of one of the manufacturers with the tobacco industry. Members agreed that this issue is complex and should be resolved by politicians as opposed to clinicians. The Chair confirmed he was satisfied the issue had been noted by the committee.

The Chair closed discussion and confirmed AWMSG's endorsement.

8. All Wales COPD Management and Prescribing Guidelines (2021 update)

Dr Barry presented the updated All Wales COPD Management and Prescribing Guidelines and confirmed the format remains the same as the previous version. The key aspects of the guidelines were highlighted. The Chair opened discussion and invited comments.

Dr Barry confirmed that health professionals will work in the community across all parts of Wales to support the implementation of the guidance. Clarification was sought as to whether the guidance could be embedded into primary care computer systems and Dr Barry confirmed this to be the intention. There was discussion in relation to the model for spirometry, use of antibiotics, potential risk of over-prescribing and use of betablockers in asthma patients. At the end of the discussion the Chair confirmed AWMSG's endorsement subject to the changes suggested. Dr Barry confirmed he would list the changes to the document and feedback to the Chair outside of the meeting. The Chair thanked Dr Barry for leading this important work.

9. National Prescribing Indicators 2022 – 2023

The Chair invited Mrs Thomas to present the national prescribing indicators for 2022/2023. Mrs Thomas explained that the indicators had been rolled over from 2020/2021 due to the coronavirus pandemic. During this time, the timelines for developing the national prescribing indicators had been reviewed and the process commenced earlier to allow more time between publication and implementation by health boards. Mrs Thomas described the process for developing the national prescribing indicators and highlighted the proposed changes in for 2022/2023 as outlined in Enclosure 5 of the meeting papers. Mr Boldero highlighted changes to the best value biological medicine basket and explained the focus for reporting will be on those where biosimilar versions had recently become available. Members were informed that the dashboard(s) on SPIRA have the level of detail required for health boards to monitor prescribing and drill down into the data. The Chair opened discussion and the issue of read codes related to the proposed indicator for the pharmacological management of heart failure was raised. A comment was made that to make sense of the data the read codes related to diagnosis need to be correct. A member highlighted that the Welsh Cardiac Network Guideline is not yet publicly available and suggested that endorsement of the national prescribing indicator in heart failure should be deferred until AWMSG has opportunity to consider this document. It was explained that AWTTC was expecting this guidance to be presented to AWMSG for 'acknowledgement' and had been in contact with the National Clinical Lead. Mrs Samuels reiterated the role of the committee in producing the national prescribing indicators and the responsibility of health boards with regards to implementation and monitoring. The Chair agreed that sight of the Welsh Cardiac Network Guideline is necessary in order for AWMSG to endorse the national prescribing indicator that underpins it. This issue aside, AWMSG supported the proposals as outlined in Enclosure 5.

10.. Appraisal 1: Paediatric Licence Extension

Ustekinumab (Stelara®) for the treatment of moderate to severe plaque psoriasis in children from the age of 6 to 11 years, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies

Submission by Janssen-Cilag Ltd for a paediatric licence extension where there is existing AWMSG appraisal advice.

The Chair invited members to declare any interests in either the applicant company or the medicine if they had not already done so. There were none. The Chair welcomed a representative from Janssen-Cilag Ltd to the meeting.

Mrs Helen Adams, the appraisal lead, provided a brief introductory statement and read out the draft recommendation. The Chair asked the company representative whether the draft recommendation is acceptable to Janssen-Cilag and this was confirmed. The Chair sought confirmation that members agreed with the draft recommendation and there was unanimous support. The Chair confirmed AWMSG's agreement and confirmed that the final appraisal

recommendation would be forwarded to the applicant company by email after the meeting and, for transparency, a notice uploaded to the AWMSG website. The Chair confirmed that the recommendation would be forwarded to Welsh Government for ratification unless the company requests a review within ten working days.

The following recommendation was subsequently confirmed:

Ustekinumab (Stelara®) is recommended as an option for restricted use within NHS Wales. Ustekinumab (Stelara®) is licensed for the treatment of moderate to severe plaque psoriasis in children from the age of 6 to 11 years, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. Ustekinumab (Stelara®) is restricted for use for the treatment of severe plaque psoriasis (as defined by a total Psoriasis Area Severity Index [PASI] of 10 or more) in children from the age of 6 to 11 years, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. Ustekinumab (Stelara®) is not recommended for use within NHS Wales outside of this subpopulation.

11. Appraisal 2: Paediatric Licence Extension
Glecaprevir/pibrentasvir (Maviret®) for the treatment of chronic hepatitis C virus (HCV) infection in children aged 3 years to <12 years

Submission by AbbVie Ltd for a paediatric licence extension where there is existing AWMSG appraisal advice.

The Chair invited members to declare any interests in either the applicant company or the medicine if they had not already done so. There were none.

Dr Stuart Keeping, the appraisal lead, provided a brief introductory statement and read out the draft recommendation. The Chair sought confirmation of agreement of the draft recommendation by members and there was unanimous support. The Chair confirmed AWMSG's agreement and confirmed that the final appraisal recommendation would be forwarded to the applicant company by email after the meeting and, for transparency, a notice uploaded to the AWMSG website. The Chair confirmed that the recommendation would be forwarded to Welsh Government for ratification unless the company requests a review within ten working days.

The following recommendation was subsequently confirmed:

Glecaprevir/pibrentasvir (Maviret®) granules are recommended as an option for use within NHS Wales, for the treatment of chronic hepatitis C virus (HCV) infection in children aged 3 years to < 12 years, and glecaprevir/pibrentasvir (Maviret®) tablets are recommended as an option for use within NHS Wales for those aged 12 years to less than 18 years.

12. Any other business
There was no other business.

The Chair confirmed the date of the next meeting on Wednesday, 8th December 2021 (via Zoom) and closed the meeting.