Enclosure No:	**1/AWMSG/0222**
Agenda Item No:	**1** – Minutes of previous meeting
Author:	Chair, AWMSG
Contact:	Tel: 029 20716900 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, 8 December 2021 (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.	**Dr Helen Fardy**	**Welsh Health Specialised Services Commission**	9, 10, 12
4.	**Prof Dyfrig Hughes**	**Health Economist**	9, 10, 12
5.	**Dr Alison Thomas**	**Clinical Pharmacologist**	11
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**	**General Practitioner**	
11.	**Mrs Alison Hughes**	**Senior Primary Care Pharmacist**	
12.	**Mr Hywel Pullen**	**Finance Director**	
13.	**Mr John Terry**	**Managed Sector Secondary Care Pharmacist**	
14.	**Ms Cathy Wynne**	**Other Healthcare professions**	
15.	**Mr Farhan Mughal**	**ABPI Cymru Wales**	9, 10

AWTTC staff:

Mr Richard Boldero, Senior Pharmacist
Mr Trevor Brooking, Administration Manager
Dr Katherine Chaplin, Senior Scientist
Dr James Coulson, Chair of New Medicines Group
Dr Clare Elliott, Senior Scientist
Ms Kath Haines, Head of WAPSU
Dr Carolyn Hughes, Medical Writer (Minutes)
Mrs Ruth Lang, Liaison Manager
Mrs Karen Samuels, Programme Director
Ms Kelly Wood, Senior Scientist

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
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
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:

Voting members:
Dr Balwinder Bajaj – Clinical Pharmacologist
Mrs Louise Williams and Mrs Mandy James – Senior 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.

Mr Farhan Mughal declared a conflict of interest for appraisals of rivaroxaban (Xarelto®) and dabigatran etexilate (Pradaxa®); he is employed by a company that manufactures a direct competitor product. The Chair confirmed that Mr Mughal will be required to leave the meeting during the appraisal of these two medicines.

Dr Alison Thomas declared a personal family non-specific conflict of interest with regards to the appraisal of cannabidiol (Epidyolex®). The Chair confirmed that she would not participate in the discussion or vote.

4 Minutes of previous meeting

The draft minutes of the previous meeting held on 9 November 2021 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 announced that the guidelines for the management and prescribing of inhalers to treat asthma and chronic obstructive airways disease in adults have been published on the AWMSG website and disseminated to the service. He stated the guidelines aim to reduce variation in inhaler prescribing and encourage consideration of the decarbonisation

agenda of NHS Wales by recommending the use of dry power inhalers rather than metered dose inhalers because of the significantly lower carbon emissions. The Chair confirmed that AWMSG is playing its part in supporting the target to reduce the use of metered dose inhalers from 70% to less than 20% by 2025. The Chair encouraged members to raise awareness of these guidelines amongst colleagues.

The Chair announced that AWTTC will be launching the respiratory inhaler dashboard, which aims to inform on the carbon footprint of inhaler usage in Wales, at the AWMSG Training Day on 12 January 2022.

The Chair confirmed there no consultations currently ongoing. The Care Homes Medicines Optimisation Toolkit will be going out for consultation shortly. The Chair reminded members to flag any issues before the close of the consultation so comments can be taken on board as early in the process as possible.

The Chair confirmed Welsh Government ratification had been received for the recommendations announced at the previous meeting in November 2021 for ustekinumab (Stelara®) and glecaprevir/pibrentasvir (Maviret®). The final appraisal recommendations have been disseminated to the service and published on the AWMSG website.

The Chair invited Mrs Karen Samuels, AWTTC Programme Director, to announce the appraisals scheduled for the next virtual AWMSG meeting on 9 February 2022:

Full submission:

- Tirbanibulin (Klisyri®) for the field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults.
  Almirall Ltd

Full submissions with a Wales Patient Access Scheme:

- Inclisiran (Leqvio®) in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or; alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.
  Novartis Pharmaceuticals UK Ltd

- Buprenorphine (Sixmo®) substitution treatment for opioid dependence in clinically stable adult patients who require no more than 8 mg/day of sublingual buprenorphine, within a framework of medical, social and psychological treatment.
  L. Molteni & C. dei Fratelli Alitti Società di Esercizio S.p.A.

Paediatric licence extension with a Patient Access Scheme:

- Clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) for symptomatic treatment of focal spasticity of upper limbs in paediatric cerebral palsy patients, two years of age or older.
  Ipsen Ltd

Paediatric licence extension:

- Ravulizumab (Ultomiris®) for the treatment of paediatric patients with a body weight of 10 kg or above with paroxysmal nocturnal haemoglobinuria (PNH):
  - in patients with haemolysis with clinical symptom(s) indicative of high disease activity.
  - in patients who are clinically stable after having been treated with eculizumab for at least the past 6 months.

  Alexion Pharma UK Ltd

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 Heart failure in Wales in 2021 – a parallel approach

The Chair invited Dr Geraint Jenkins, Cardiologist at Morriston Hospital, and Dr Jonathan Goodfellow, to present a new guideline for optimising the treatment of heart failure in Wales. The guideline focuses on the latest available evidence to change the sequencing of treatment and promote the initiation of four medicine groups in parallel, which has shown significant benefits on mortality and morbidity. Dr Jenkins summarised the guideline and explained that it encourages the quick optimisation of medicine doses resulting in minimal hospital visits for patients, and so aims to provide better value for patients and NHS Wales through improved outcomes and efficiencies. AWMSG was asked to consider, discuss and acknowledge the resource.

The Chair opened the discussion and invited comments or questions. Clarification was sought with regards to who the guidance is aimed at. Dr Jenkins confirmed the guidance is aimed at secondary care specialists and general practitioners with expertise in treating patients with heart failure. There was discussion over the variation in cardiology services across NHS Wales and it was acknowledged that the availability of rapid diagnostic systems is more limited in some areas. Dr Goodfellow confirmed that the guidance is already in widespread use within NHS Wales as it was published by the Cardiac Network in June 2021. It was noted that the guidance is aligned to the recently published European Society of Cardiology guidance. Dr Goodfellow reiterated that the guidance makes better use of NHS Wales resources, and he reassured members that morbidity and mortality benefits have been shown.

Concerns were expressed over the lack of evidence of cost-effectiveness and assessment of the resource impact of the guidance.

The Chair thanked Dr Jenkins and Dr Goodfellow for presenting the guidance and they left the meeting.

The Chair asked members if they could support the acknowledgement of this guidance a best practice for NHS Wales. Members agreed.

The Chair asked members if they could support the publication of the new NPI indicator that had been developed to underpin this guidance. Some members expressed a view that they could not support the NPI on the basis of lack of evidence of cost-effectiveness and the lack of data. It was agreed that the publication of this indicator would be deferred. The Chair closed discussion.

7 Antimicrobial wound dressings (AWDs): statement, recommendations and guidance

The Chair invited Mr Peter Phillips, Director of Surgical Materials Testing Laboratory, NHS Wales Shared Services Partnership (NWSSP), to talk about this guidance, which was presented to AWMSG for their acknowledgement.

The document aims to advise NHS Wales on the use of antimicrobial wound dressings on acute or chronic wounds, and is designed to be used by the NWSSP procurement wound management group.

The Chair thanked Mr Phillips for presenting the statement and confirmed AWMSG's acknowledgement.

8 NPI Quarterly Report

The Chair invited Mr Richard Boldero to present the National Prescribing Indicators 2021-2022 Analysis of Prescribing Data to June 2021, provided for their information.

Mrs Hughes enquired if for the analgesia indicators there could be some correlation made to increased operation waiting times. Mr Boldero informed that if there was a data set available this could be explored. Dr McGuigan offered to provide information that Betsi Cadwaladr UHB has access to which could be investigated for use across all health boards. Mr Boldero offered to follow-up with Dr McGuigan outside of the meeting.

Dr Black enquired whether the NSAID basket for the prescribing safety indicator number 7 included the 'coxibs' group of medicines. Mr Boldero later informed members that it did not.

9 Appraisal 1: Full submission (with a PAS)

Cannabidiol (Epidyolex®) for adjunctive therapy of seizures associated with tuberous sclerosis complex (TSC) for patients 2 years of age and older.

The Chair set the context of the appraisal and confirmed that proceedings would be conducted in private to protect commercial confidentiality.

The Chair sought confirmation that the policy for appraising medicines for rare diseases had been made available to members. This was confirmed.

Submission by GW Research Limited. 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. The Chair confirmed that Dr Alison Thomas would be excluded from the appraisal as she had declared a conflict of interest. The Chair welcomed two representatives from GW Research to the meeting.

The Chair invited the appraisal lead, Dr Clare Elliott, to give an overview of the submission. Dr Elliott summarised the key points of the submission, and pointed out that it is being appraised ahead of a NICE appraisal because of requests from clinicians in Wales. A decision from NICE is expected in November 2022. The Chair of the New Medicines Group (NMG), Dr James Coulson, summarised the key points of discussion about this appraisal from the NMG meeting and confirmed that NMG supported the use of cannabidiol (Epidyolex®) within NHS Wales where the PAS is used (or list/contract price is the same or lower than the PAS price).

Dr Elliott outlined feedback from clinical experts about the medicine. Professor Dyfrig Hughes highlighted key aspects of the case for cost-effectiveness and questioned whether some information about the quality-adjusted life years was correct. The company confirmed that the figures were given in an incorrect order and Dr Elliott said that this error would be corrected in the ASAR. AWMSG's lay member, Mr Clifford Jones, summarised the issues highlighted in submissions received from patients and carers.

The Chair informed the company representatives that the final appraisal recommendation would be forwarded by email after the meeting and, for transparency, a notice uploaded to the AWMSG website. He 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:

Cannabidiol (Epidyolex®) is recommended as an option for use within NHS Wales for adjunctive therapy of seizures associated with tuberous sclerosis complex (TSC) for patients 2 years of age and older.

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.

10 Appraisal 2: paediatric licence extension (with a PAS)

Clostridium botulinum neurotoxin type A (Xeomin®) for the symptomatic treatment in children and adolescents aged 2 to 17 years and weighing

≥ 12 kg of chronic sialorrhea due to neurological/neurodevelopmental disorders.

Submission by Merz Pharma UK for a paediatric licence extension where there is existing NICE 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 Merz Pharma UK to the meeting.

Ms Kelly Wood, the appraisal lead, gave an overview of the submission and draft recommendation. The Chair asked the company representative if the draft recommendation was acceptable to Merz Pharma and they confirmed it was. The Chair asked members to confirm their agreement of 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 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:

Clostridium botulinum neurotoxin type A (Xeomin®) is recommended as an option for use within NHS Wales for the symptomatic treatment in children and adolescents aged 2 to 17 years and weighing ≥ 12 kg of chronic sialorrhoea due to neurological/neurodevelopmental disorders.

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.

11 Appraisal 3: paediatric licence extension

Dabigatran extexilate (Pradaxa®) for the treatment of VTE and prevention of recurrent VTE in paediatric patients from 8 years to less than 18 years of age.

Submission by Boehringer Ingelheim Ltd for a paediatric licence extension where there is existing NICE 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. Mr Farhan Mughal declared an interest and left the meeting. The Chair welcomed two representatives from Boehringer Ingelheim Ltd to the meeting.

Dr Katherine Chaplin, the appraisal lead, gave a brief introductory statement and read the draft recommendation. The Chair asked the company representatives if the draft recommendation was acceptable to Boehringer Ingelheim and they confirmed it was. The Chair asked members to confirm their agreement of the draft recommendation and there was unanimous

support.

The following recommendation was subsequently confirmed:

Dabigatran etexilate (Pradaxa®) hard capsules are recommended as an option for use within NHS Wales, for the treatment of VTE and prevention of recurrent VTE in paediatric patients from 8 years to less than 18 years of age.

12 Appraisal 4: paediatric licence extension

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.

Submission by Bayer Healthcare Pharmaceuticals for a paediatric licence extension where there is existing NICE 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. Mr Farhan Mughal declared an interest and left the meeting. No representatives from Bayer were present at the meeting.

Dr Katherine Chaplin, the appraisal lead, gave a brief introductory statement and read the draft recommendation. The Chair asked Dr Chaplin to confirm that the company had agreed that the draft recommendation was acceptable to them; Dr Chaplin confirmed this. The Chair asked members to confirm their agreement of the draft recommendation and there was unanimous support.

The following recommendation was subsequently confirmed:

Rivaroxaban (Xarelto®) granules for oral suspension and film-coated tablets are recommended as an option for use within NHS Wales, 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.

13 Any other business

The Chair informed members that AWTTC will carry out a poll to find out about their preferences for future days for AWMSG meetings.

The Chair reminded members that AWTTC will be holding a virtual Training Day for AWMSG on 12 January 2022.

The Chair confirmed the date of the next meeting on Wednesday, 9 February 2022 (via Zoom) and closed the meeting.