Enclosure No:	**1/AWMSG/0621**
Agenda Item No:	**1** – Minutes of previous meeting
Author:	Chair, AWMSG
Contact:	Tel: 029 2182 6900 E-Mail: awttc@wales.nhs.uk

ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

Draft minutes of the AWMSG meeting held 9.30 am on Wednesday, 19th May 2021 (via Zoom)

VOTING MEMBERS PRESENT:			**Did not participate in**
1.	**Prof Iolo Doull**	**Chair**	
2.	**Prof Stephen Monaghan**	**Consultant in Public Health Medicine**	**1-8**
3.	**Prof Dyfrig Hughes**	**Health Economist**	**1-8**
4.	**Mr Tommy Price**	**ABPI (Wales)**	
5.	**Mr Cliff Jones**	**Lay Member**	
6.	**Ms Claire James**	**Lay Member**	
7.	**Mr Stefan Fec**	**Community Pharmacist**	
8.	**Dr Jim McGuigan**	**Medical Director**	
9.	**Dr Jeremy Black**	**GP with Prescribing Lead role**	
11.	**Miss Alison Hughes**	**Senior Primary Care Pharmacist**	
12.	**Mr Hywel Pullen**	**Finance Director**	
13.	**Mr John Terry**	**Managed Sector Secondary Care Pharmacist**	
14.	**Mrs Louise Williams**	**Senior Nurse**	

Welsh Government:
No representation

AWTTC staff:
Mrs Helen Adams, Senior Pharmacist
Mr Trevor Brooking, Administration Manager
Mrs Susan Cervetto, Senior Pharmacist
Dr James Coulson, NMG Chairman
Dr Paul Deslandes, Senior Pharmacist
Dr Clare Elliott, Senior Scientist
Mrs Claire Ganderton, Senior Pharmacist
Ms Kath Haines, Head of WAPSU
Dr Stuart Keeping, Senior Scientist

Mrs Ruth Lang, Senior Liaison Manager
Mr Anthony Williams, Head of PAMS
Ms Laura Taylor, Administration Supervisor

In attendance:
Victoria Richards-Green, Chronic Conditions Lead Pharmacist, Aneurin Bevan University Health Board for agenda item 7.

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 welcomed members and observers to the meeting. He briefly outlined the protocol for conducting the meeting virtually and confirmed the quorum had been met.

The Chair confirmed that Dr Satish Kumar had been appointed hospital consultant representative and it was confirmed that he was not in attendance.

2. Apologies:

Dr Balwinder Bajaj and Dr Alison Thomas – Clinical Pharmacologist representative
Mr Aled Falvey – representing other healthcare professions eligible to prescribe
Dr Sian Lewis – Welsh Health Specialised Services Committee representative

3. Declarations of interest

The Chair invited declarations of interest. Mr Tommy Price had declared a personal specific interest in relation to agenda item 7 prior to the meeting and it was confirmed that he would be excluded from discussions in relation to the smoking cessation guidance. This was reconfirmed in public at the meeting. The Chair declared he is a Trustee of Ash Cymru and the secretariat confirmed this would not preclude him from chairing agenda item 7.

4. Minutes of previous meeting

The draft minutes of the previous meeting were checked for accuracy. One tracked change was noted within the document. The Chair confirmed that the medicines optimisation framework had been updated to reflect the appointment of an additional lay member. The Chair agreed to discuss the appropriateness of health board medicines and therapeutics committees being the nominating body for GP membership at his next meeting with Welsh Government officials. Members were informed that AWTTC is currently seeking the views on the proposal to establish a GP cluster prescribing forum with the GP cluster co-ordinating group; meetings with GPC Wales and the RCP GP have also been arranged. The Chair confirmed that the Blueteq system has now 'gone live' for WHSSC commissioned medicines and there has been engagement with the Chief Pharmaceutical Officer and the All Wales Chief Pharmacists Group to support the wider use of Blueteq for monitoring the implementation of non-WHSSC commissioned high cost medicines in NHS Wales. The Chair confirmed AWMSG's approval of the minutes as a true record of the meeting.

5. Chairman's verbal report

The Chair confirmed that advice in relation to buprenorphine/naloxone (Suboxone®) sublingual film, recommended for restricted use as substitution treatment for opioid drug dependence at the previous meeting, had been ratified by Welsh Government, disseminated to the service and published on the AWMSG website.

Members were informed that the Steering Committee had met on 27th April and considered issues relating to AWMSG's work programme and other broader medicines-related matters. A meeting of the TDA Partnership Group had been held on 6th May and the proposed change of name to the 'AWTTC Industry Forum' had been agreed to reflect the broadened scope of this group to include the medicines optimisation agenda.

The Chair announced that the second of a series of AWMSG Open Days for the pharmaceutical industry would be held on 10th June and thanked ABPI for technical support in hosting these virtual events.

The Chair announced that AWTTC is reviewing and updating the AWMSG Tramadol Resources and invited comments on the draft paper by 7th June. It was noted that the consultation on SGLT-2 inhibitors in Type 2 diabetes and cardiovascular disease, as reported

at the previous meeting, had closed. The Chair updated members on the Communication and Engagement Strategy and it was confirmed that it would be published on the AWMSG and AWTTC websites when translated from English to Welsh.

The Chair confirmed the appointment of a new Health Minister for NHS Wales and indicated that the direction of travel for AWMSG may change. The Chair announced his recent appointment as WHSSC Medical Director and confirmed that he would continue in the role as Interim AWMSG Chair until such time that Welsh Government appoint to the substantive post. The Chair invited expressions of interest in the role of interim vice chair via email to Ruth at AWTTC. It was confirmed Helen Fardy will join the committee as WHSSC representative. It was noted that no appraisals will be held in June.

The Chair informed members that AWTTC is co-hosting the Health Technology Appraisal International (HTAi) meeting with colleagues in NICE and SMC and the theme is 'Innovation through HTA'. The event will be held over 3 days starting with a welcome reception on the evening of Sunday, 20th June. Due to the pandemic the meeting, originally intended to be held in Manchester, had been moved to a virtual platform. The event will bring together researchers, policy makers, industry, academia, health service providers and patients to debate and discuss the challenges of embedding HTA in health systems. The Chair confirmed that the work of AWMSG will be showcased by AWTTC staff.

The Chair concluded his report and invited Kath Haines to present a paper she authored on '18 years' experience of a National Medicines Optimisation Committee' which has been published in the British Journal of Clinical Pharmacology.

6. AWMSG Work Programme:

The All Wales Medicines Strategy Group: 18 years' experience of a National Medicines Optimisation Committee

Ms Kath Haines confirmed that the aim of the paper published in the British Journal of Clinical Pharmacology had been to celebrate the medicines optimisation achievements of AWMSG since its inception in 2002 and raise awareness of its work in optimising medicines in NHS Wales by promoting best prescribing practice. It was noted, from the outset, pharmacists and clinical pharmacologists collaborated closely and shared their complementary expertise to make a greater contribution to the safe, effective and cost-effective use of medicines than either group could have achieved by working separately. Ms Haines acknowledged the valuable contributions of Professor Philip Routledge, health service colleagues, stakeholders and AWMSG/AWPAG members.

Appraisal of biosimilar medicines (for information)

Mrs Helen Adams reported on the issues surrounding the assessment of biosimilar medicines and the approaches taken in England, Scotland and Northern Ireland which may be used to inform a review of the All Wales Medicines Strategy Group (AWMSG) process. Mrs Adams made the point that the value of biosimilar medicines is well recognised and uptake is actively encouraged in line with national guidelines. Applying the positive HTA recommendation of the reference medicine to the biosimilar medicine is standard practice across the UK. Members were informed that there is a less consistent or well recognised approach in appraising a biosimilar medicine where there is negative advice or an absence of advice for the reference medicine. This is largely owing to the fact that marketing authorisation of the biosimilar medicine is granted based on comparative efficacy to the reference medicine and a lack of primary comparative efficacy data to the current standard of care which is required for HTA. AWMSG noted that NICE may be developing processes to allow for the rapid review of guidance in this area which will be considered in the development of any new processes within Wales. Mrs Adams confirmed that the status report had been brought to AWMSG for information and she would be happy to respond to any questions or queries outside of the meeting.

7. Initial clinical management of adult smokers in secondary care

Ms Vicky Richards Green from Aneurin Bevan UHB presented information and guidance for NHS Wales on the initiation of nicotine replacement therapy (NRT) in secondary care settings for nicotine withdrawal management in adults who smoke. It includes: patients who wish to start a quit attempt; those who do not wish to start a quit attempt but want to have NRT to manage nicotine withdrawal while in hospital; as well as out-patients, patients' families and friends, and hospital staff. The document sets out the roles and responsibilities of healthcare staff (nurses, doctors, pharmacists and smoking cessation practitioners) at admission, during an inpatient stay and at discharge. It covers initial assessment and prescribing of NRT, and prescribing of additional "when required" NRT products; providing additional support and advice to patients, and summarises the training available for healthcare staff. The document provides a guideline for all hospital settings in Wales to support adults who smoke at the point of their admission to hospital. To support secondary care initiated smoking cessation, all sites must have available all forms of NRT and other smoking cessation pharmacotherapies as timely access to these products is vital. The document is intended to be used alongside the AWMSG-endorsed All Wales Guide: Pharmacotherapy for Smoking Cessation, to indicate roles and responsibilities of staff in the patient's smoking cessation journey. The document does not cover the use of Electronic Nicotine Delivery Systems (ENDS). The Chair opened discussion.

Ms Richards Green reassured members that practitioners had been actively involved in the development of the information which complements already existing guidance. The lay member drew attention to easy read guidance for public sector organisations at a local and national level, and also for organisations who produce public information specifically for people with learning disabilities, or anyone involved in commissioning easy read materials. It was suggested that a shortened easy read version may be helpful for patients and busy practitioners as the document presented is lengthy and complex. Ms Richards Green confirmed that Ash Wales is producing patient leaflets and the suggestion would be fed back to the patient support group. Ms Haines confirmed that AWTTC will consider applying the easy read guidance to the wider medicines optimisation work to ensure that AWMSG resources are easier to understand and to help people to make better health choices.

The Chair thanked members for the discussion and confirmed AWMSG's endorsement of the guidance.

Professors Dyfrig Hughes and Professor Stephen Monaghan joined the meeting.

8. Educational pack: Material to support appropriate prescribing of hypnotics and anxiolytics across Wales (2021 update)

Dr Paul Deslandes presented the updated Educational pack: Material to support appropriate prescribing of hypnotics and anxiolytics across Wales document and requested AWMSG's endorsement. He explained that the document provides guidance for health professionals regarding the minimisation of risk associated with the prescribing of benzodiazepines and Z-drugs for the management of insomnia and anxiety. There was agreement that in general practice it is well recognised that the long-term use of these medicines is not appropriate, as they are associated with a range of adverse effects. The information presented to AWMSG was well received and provided a summary of the key issues and suggestions for supporting the management of these medicines. The Chair invited comments from members. There was discussion in relation to the problem of initiation in secondary care and the resultant pressure of on-going management in primary care; the Chair suggested that AWTTC should explore this in more detail with the secondary care psychiatrists. Inconsistencies in the patient information leaflet were noted within the sleep guidelines and will be addressed accordingly. Members discussed different models of care and a suggestion was made that a shared care arrangement might be helpful to ensure that medication reviews are undertaken by the pyschiatrist. Mr Fec highlighted that Community Pharmacy may have an important role in patient education and support. The Chair thanked members for their input, confirmed

AWMSG's endorsement and asked AWTTC to follow up on engagement with psychiatrists.

9. Ulipristal acetate (Esmya®): Review of Final Appraisal Recommendation (FAR) Advice No. 0716 - March 2016

Mrs Sue Cervetto provided the background and explained that in 2016, ulipristal acetate (Esmya®) was recommended as an option for use within NHS Wales for the intermittent treatment or pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. In March 2020, after review of the available data and in particular the 5th cumulative case of serious liver injury leading to liver transplantation, the Pharmacovigilance Risk Assessment Committee (PRAC) recommended, as a temporary measure, the suspension of the marketing authorisations of ulipristal acetate 5 mg medicinal products until a definitive decision could be reached. Esmya® 5 mg tablets were recalled from patients, pharmacies and wholesalers in the UK on 18 March 2020. The temporary suspension has now been lifted, but the indication for ulipristal acetate 5mg has been further restricted (MHRA drug safety update February 2021). The therapeutic indication for ulipristal acetate (Esmya®) now outlined in the SPC is for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women who have not reached menopause when uterine fibroid embolisation and/or surgical treatment options are not suitable or have failed.

Members were informed that due to the drug safety update and the severity of the issue, AWTTC temporarily removed AWMSG's advice for ulipristal acetate (Esmya®) from the website and undertook a review of the evidence. Mrs Cervetto asked members to consider approving an updated FAR and this was displayed on screen. Mrs Cervetto confirmed that if approved, AWTTC would inform the company by email of the amendment, and attach a copy of the revised FAR. The company will have 10 working days to respond, before proceeding to ratification and re-publishing the FAR on the AWMSG website. The Chair opened discussion. There was discussion regarding the use of and/or in the proposed recommendation. The Chair confirmed that AWMSG advice is required to align with the wording in the SPC. The legal standing of the EMA restriction to the licence in light of the UK exit from the EU was clarified. The Chair confirmed AWMSG's approval of the updated recommendation to read:

Ulipristal acetate (Esmya®) is recommended as an option for use within NHS Wales for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women who have not reached menopause when uterine fibroid embolisation and/or surgical treatment options are not suitable or have failed.

10. Appraisal 1: Full Submission

Indacaterol acetate/glycopyrronium bromide/mometasone furoate (Enerzair® Breezhaler®) 114 micrograms/46 micrograms/136 micrograms inhalation powder, hard capsules for maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.

Full Submission by Novartis Pharmaceuticals UK Ltd.

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.

Mrs Lang informed members that information highlighted within the budget impact section is commercially sensitive and should not be disclosed during the discussion. Should members wish to discuss the budget impact in more detail, the meeting would be closed to the public and all observers would be asked to leave the meeting. Members confirmed their understanding and commitment to maintain commercial confidentiality.

The Chair opened the appraisal session and confirmed 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 NMG had explored in detail the clinical and cost effectiveness of the medicine and taken into account the views of clinical experts and patients/patient organisations. He asked members not to repeat NMG's detailed discussions and to focus on the recommendation of NMG, taking into account the rationale for this decision provided by the NMG Chair, and the additional factors that had not been considered by NMG - wider societal issues, the budget impact and equity. The Chair confirmed that the company delegates would be invited to respond to questions and given opportunity to make any concluding remarks.

Dr Stuart Keeping, the AWTTC appraisal lead, set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR. He drew members' attention to an error within Appendix 3 in relation to the medicines acquisition cost and number of inhalations of one of the medicines listed.

The Chair invited Dr James Coulson, NMG Chair, to relay the key factors discussed at NMG. Dr Coulson confirmed that NMG noted the limitations of the cost minimisation analysis, but that on balance, NMG considered the product to be cost effective. Dr Coulson confirmed NMG's recommendation to AWMSG is to support the use of indacaterol acetate/glycopyrronium bromide/mometasone furoate (Enerzair® Breezhaler®) hard capsules for maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.

The Chair opened general discussion relating to clinical effectiveness. The point was made that if recommended by AWMSG the All Wales Asthma Guidance may require updating.

Professor Hughes highlighted the key aspects of the case for cost-effectiveness as outlined in the ASAR and commented on the budget impact section.

Mr Cliff Jones relayed key aspects from the patient organisation submission from Allergy UK and referred to the comments received from clinical experts. The company delegate confirmed the company had no specific data in the elderly population relating to ease of use. Clarification on the definition of exacerbations was provided. There were no other wider societal or other issues of note.

Prior to concluding the appraisal the Chair asked the applicant company delegates to confirm that they were satisfied that the issues raised by AWMSG had been adequately addressed and that the appraisal process had been fair and transparent. This was confirmed.

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 agreed 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 thanked the company delegates for attending and closed the meeting to the public. Members voted in private.

Recommendation to Welsh Government:

Indacaterol acetate/glycopyrronium bromide/mometasone furoate (Enerzair® Breezhaler®) is recommended for the maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long‑acting beta2‑agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.

11. Appraisal 2: Limited Submission (WPAS)
Perampanel (Fycompa®) 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg film-coated tablets, and 0.5 mg/ml oral suspension as adjunctive treatment of partial-onset seizures (POS) with or without secondarily generalised seizures in patients from 4 to < 12 years of age.

Limited submisison by Eisai Ltd.

It was confirmed that all members of the public and observers, apart from AWTTC staff, had left the meeting.

The Chair opened the appraisal session and confirmed 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.

Mrs Claire Ganderton, the AWTTC appraisal lead, 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 by Dr Coulson.

It was confirmed that no patient views had been received. Ms Claire James informed members of the four patient organisations that had been approached by AWTTC. Ms James made reference to the small number of patients and highlighted the emotional and economic impact on families caring for children with difficult to control epilepsy.

The Chair refered members to the budget impact section and invited questions. There were no issues of note.

Prior to concluding the appraisal the Chair asked the applicant company delegates to confirm that they were satisfied that the issues raised by AWMSG had been adequately addressed and that the appraisal process had been fair and transparent. This was confirmed.

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 thanked the company delegates for attending and closed the appraisal and the company delegates left the meeting. Members voted in private.

Recommendation to Welsh Government:

Perampanel (Fycompa®) is recommended as an option for restricted use within NHS Wales.

Perampanel (Fycompa®) should be restricted to treatment of patients whose seizures are still uncontrolled with the first adjunctive therapy, within its licensed indication for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients from 4 to < 12 years of age.

Perampanel (Fycompa®) is not recommended for use within NHS Wales outside of this subpopulation.

This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

12. Appraisal 3: Paediatric licence extension submission (WPAS)
Conestat alfa (Ruconest®) 2,100 U powder and solvent for solution for injection for the treatment of acute angioedema attacks in children (aged 2 years and above) with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.

Submission by Pharming Group NV for a paediatric licence extension where there is existing AWMSG appraisal advice.

It was confirmed that all members of the public and observers, apart from AWTTC staff, had left the meeting.

The Chair opened the appraisal session and confirmed 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.

Dr Clare Elliott, the appraisal lead, confirmed that the draft recommendation and supporting information had been circulated to members prior to the meeting and no outstanding issues had been raised. The Chair asked members if there were any questions with regard to the information provided or in relation to the draft recommendation. No questions were raised.

It was noted that a patient organisation submission had been received from HAE UK.

The Chair asked the company delegate to confirm that they were satisfied with the process for advising Welsh Government on a paediatric licence extension. The applicant company delegate confirmed that the process had been acceptable.

The Chair confirmed the close of the appraisal session. He informed the applicant company delegates 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.

Recommendation to Welsh Government:

Conestat alfa (Ruconest®) is recommended as an option for use within NHS Wales for the treatment of acute angioedema attacks in adults, adolescents, and children (aged 2 years and above) with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.

This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

The Chair confirmed the date of the next meeting on **Tuesday, 15th June commencing 9.30 am** (via Zoom) and closed the meeting.