Enclosure No:	**1/AWMSG/0922**
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 9:30 am on Tuesday, 12th July 2022 at The All Nations Centre, Sachville Avenue, Cardiff, CF14 3NY

Voting members present:			**Did not participate in agenda item:**
1.	**Prof Iolo Doull**	**Chair**	
2.	**Prof Stephen Monaghan**	**Consultant in Public Health Medicine**	
3.	**Ms Eleri Schiavone**	**Welsh Health Specialised Services Commission**	
4.	**Mr Farhan Mughal**	**ABPI (Wales)**	
5.	**Dr Alison Thomas**	**Clinical Pharmacologist**	
6.	**Mr Cliff Jones**	**Lay Member**	
7.	**Ms Claire James**	**Lay Member**	
8.	**Dr Samantha Cox**	**Hospital Consultant**	
9.	**Dr Jeremy Black**	**General Practitioner**	
10.	**Ms Rafia Jamal**	**Senior Primary Care Pharmacist**	
11.	**Mr James Leaves**	**Director of Finance**	
12.	**Ms Katherine White**	**Senior Nurse**	

Welsh Government:
Mr Andrew Evans

AWTTC staff:
Shaila Ahmed, Advanced Pharmacist
Mr Trevor Brooking, Administration Manager
Mr Thomas Curran, Senior Scientist
Ms Kath Haines, Head of WAPSU

Mrs Rachel Jonas, Medical Writer (minutes)
Dr Stuart Keeping, Senior Scientist
Dr Sara Pickett, Principal Health Economist
Mrs Karen Samuels, Programme Director
Mr Tony Williams, Head of PAMS

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
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
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
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:

Dr Pippa Anderson, Health Economist
Mrs Alison Hughes, Senior Primary Care Pharmacist
Prof Dyfrig Hughes, Health Economist
Mr Karl Jackson, Other Healthcare Professions
Mr Dylan Jones, Community Pharmacist
Dr Jim McGuigan, Medical Director
Mr Hywel Pullen, Director of Finance
Mr Stuart Rees, Senior Hospital Pharmacist
Dr Manjeet Singh, Hospital Consultant
Dr Richard Skone, Medical Director
Ms Cathy Wynne, Other Healthcare Professions

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 15 June 2022 were checked for accuracy. There were no matters arising.

5. Chair's verbal report

Audio was played to the members from the recording of the last meeting to inform of John Terry's resignation in case this was missed previously. Stuart Rees from Hywel Dda is the alternate member and will continue to represent Managed Sector Pharmacists on AWMSG. AWTTC will seek a deputy member nomination from the Chief Pharmacists. It was also announced that Mr Cliff Jones will be stepping down temporarily from his role as the lay member.

Members who have offered input into a task and finish group meeting to be held after this meeting were thanked. The focus of the meeting is to identify issues and potential barriers to medicines access and to explore what, if anything, can be done to overcome these barriers and provide advice to Welsh Government. A paper will be presented to AWMSG at some time in the future, all members will have the opportunity to input into discussions.

The Chair, Karen Samuels and Tony Williams attended the HTAi Conference in Utrecht on the weekend of 25th June.

The consultation on the AWTTC Work programme closed on Monday 5th July and AWTTC are in the process of compiling the responses. As part of the consultation process, AWTTC attended a meeting of the Medical Directors to ask for their input and their comments will be incorporated into the consultation response for discussion with Welsh Government.

AWTTC has been working with Welsh Government on the development of strategies for biosimilar medicines, opioids and decarbonisation. All three documents will, at some stage, go out for consultation and members will be asked for their comments.

It was confirmed that the appraisal recommendation for bevacizumab (Avastin®) submitted to Welsh Government following the previous meeting has been ratified. The advice has been disseminated to the Service and published on the website.

The Chair invited Karen Samuels to announce the appraisals scheduled for the next AWMSG meeting on 14 September 2022:

Full Submission using information in the public domain:
Rituximab (MabThera®) for the treatment of patients with moderate to severe pemphigus vulgaris
Roche Products Ltd

Full Submission:
Hydrocortisone MR (Efmody®) for the treatment of congenital adrenal hyperplasia (CAH) in adolescents aged 12 years and over and adults.
Diurnal Limited

Mrs Samuels asked members to contact AWTTC ahead of the next meeting to register any personal or non-personal interests in this medicine.

Patients, patient organisations and patient carers were invited to submit their views via the AWMSG website or contact AWTTC for further information.

6. The wider implementation of the Blueteq high cost drugs system

Kath Haines and Wendy Casey presented a proposal to widen the implementation of the Blueteq High Cost Drugs system to ensure that NHS Wales attains the value from its investment in medicines and strengthens the governance associated with this. The speciality areas suggested to be initially prioritised are rheumatological and haematological medicines, COVID-19 medicines, last line antimicrobials and biologics.

Eleri Schiavone shared the experiences of using the Blueteq HCD system within WHSSC. The benefits of financial and clinical governance were highlighted as well as the ability for audit trails. It allows equality of access to medicines across Wales as all criteria for patient treatment are included on the medicine approval form which is used by NHS England so will also be used for the Welsh patients who have treatment across the border; reporting is subsequently found to be more efficient.

Andrew Evans stated that Welsh Government is supportive of the paper presented to AWMSG. It is important that Blueteq is not seen as an administrative burden and that health boards in Wales will need to be assured of the clinical and financial benefits. It is accepted that the benefits are likely to be subjective, as not all clinical speciality approval forms will be of equivalent use and therefore a balance will be needed going forward.

It was queried if there are any data available with regard to the bullet point *'Provides the ability for clinicians to collect data in a format that is useful to them to support treatment optimisation.'* Welsh data for WHSSC commissioned services is not yet widely available as the system implementation is still in its early stages for Wales. As NHS England have been using the system longer there may be English data available and such data could be helpful with areas such as dose titrations and trend recognitions.

It was confirmed that the responsibility for completing the forms will be tailored for each clinical department depending on capacity; clinicians, nurses and pharmacists are all able to have designated access to the system.

Concerns were raised on the challenges faced by front line services and if this will take them away from providing other services. Reassurance was given that this system would be superseding a paper-based system, so it will be more efficient from a clinical approval perspective with the potential for faster patient access. Each medicine approval form is designed in consultation with the appropriate speciality clinicians and all forms are intended to be user friendly.

Not all high cost medicines will be added to the Blueteq HCD system and there will be de-escalation of applied medicines in future when for example there have been enough data collected or cheaper medicines become available (such as generics).

It was asked where the Blueteq Patient Access Scheme Administration System (PASAS) identified savings mentioned in the paper were being used. It was confirmed that such savings were already expected as part of the commercial arrangements agreed within the cost effectiveness element of the NICE/AWMSG medicine appraisal. The "missed" savings are therefore not new monies and any rebates identified by the Commercial Medicines Access Team will be returned directly to the Health Board or Trust finance department.

The Chair confirmed AWMSG's support of this proposal.

7. AWMSG heath technology evaluation methods & process review

The chair declared an interest in this item as Chair of UK Rare Diseases Framework Board and Forum.

Shaila Ahmed and Sara Pickett presented key proposed changes to AWMSG methods and processes for appraising medicines, following NICE publication of updates to their process and methods manual; this included removal of the

current end-of-life (EOL) modifier and introduction of a new severity modifier. AWTTC also proposed adjustment of the current medicines for rare diseases policy to remove orphan considerations (it was noted that many orphan medicines are likely to be covered by the severity modifier policy), and to fully align the ultra-orphan policy with the NICE Highly Specialised Technologies (HST) policy, in terms of routing criteria. The principal steps required to ensure AWMSG and NICE methods remain aligned were highlighted.

ABPI agreed AWMSG methods have been closely aligned with NICE methods historically but also highlighted some differences, including the flexibilities around AWMSG orphan and ultra-orphan policy. Members were reminded that the additional processes to further assess the benefits of the medicine from the perspective of clinicians and patients were important to retain. It was mentioned removal of the EOL policy may disadvantage end-stage cancer medicines and risk patient access to these important therapies. It was proposed by ABPI that the EOL policy could be kept and used concurrently with the disease severity modifier policy. ABPI also raised concerns regarding the addition of the new NICE HST routing criteria to the AWMSG ultra-orphan policy. It was felt the prevalence of the disease should be sufficient to characterise the medicine as an ultra-orphan medicine and the additional eligibility criterion may impact access to medicines for patients with the very rare conditions.

Members heard that the EOL policy was last used by AWMSG in 2016 and had only been used four times. AWTTC indicated replacing the EOL with the severe disease modifier is evidence based. Application of this new modifier in Wales will improve access to medicines for a broader range of conditions, better reflecting social values/preferences. AWTTC highlighted it is important that AWMSG adopt the same methodological approaches and criteria as NICE where possible, to ensure consistency and promote equity of access to medicines, but are also keen to retain existing processes which have proved valuable in ensuring that the views of clinicians and patients are heard, including the CAPIG process. It was felt that the changes are a positive step-change and are reflective of societal preferences.

ABPI raised concerns regarding the cut offs that NICE has assigned for medicines to benefit from the severity modifier's QALY weighting. It was felt the cut offs implemented under the opportunity cost neutral approach mean conditions which are severely debilitating and life threatening are not considered severe enough to achieve the higher QALY weighting. AWTTC highlighted that NICE has committed to undertaking research to elicit weights and that NICE will monitor the use of the severity modifier in practice. Any amendments by NICE would also be implemented by AWMSG to maintain alignment. AWTTC acknowledge that NICE have taken a pragmatic approach, and welcome the future research.

It was queried, if the ultra-orphan policy was aligned with the NICE HST policy, how the routing criteria would be implemented in Wales. AWTTC highlighted NICE has a committee in place. It is hoped Wales can replicate this approach, including wider stakeholder involvement, which enhances governance. It was highlighted that the current AWMSG medicines for rare

diseases policy already includes similar criteria for consideration of the rarity of the condition as the NICE HST routing criteria, including prevalence, patient numbers for all licensed indications, and considerations of unmet need, innovation, and the availability of alternative treatments. It also allows AWMSG to operate a higher cost-effectiveness threshold, which aligns with NICE HST.

The Chair confirmed AWMSG's support of the changes to the AWMSG methodology as outlined in the paper.

8. Paediatric Licence Extension (PLE)
Grazoprevir/elbasvir (Zepatier®) for the treatment of chronic hepatitis C (CHC) in paediatric patients 12 years of age and older who weigh at least 30 kg

Submission by Merck Sharp & Dohme Ltd for a licence extension for paediatric use where there is existing NICE advice for adults. There were no company delegates in attendance.

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 asked the members if there were any outstanding issues or questions about the appraisal. There were none.

The Chair stated that AWMSG's recommendation will be emailed to the company later today and, for transparency, a notice will be uploaded to the AWMSG website. The company will be asked to confirm acceptance of the final appraisal recommendation within ten working days from this meeting before it is forwarded to Welsh Government for ratification.

9. Paediatric Licence Extension (PLE)
Brivaracetam (Briviact®) as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children from 2 years to < 4 years of age with epilepsy

Submission by UCB Pharma Ltd for a licence extension for paediatric use where there is existing NICE appraisal advice for adults. There were no company delegates in attendance.

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 asked the members if there were any outstanding issues or questions. There were none.

The Chair stated that AWMSG's recommendation will be emailed to the company later today and, for transparency, a notice will be uploaded to the AWMSG website. The company will be asked to confirm acceptance of the

final appraisal recommendation within ten working days from this meeting before it is forwarded to Welsh Government for ratification.

The following recommendations were subsequently confirmed:

Elbasvir/grazoprevir (Zepatier®) is recommended as an option for use within NHS Wales for the treatment of genotype 1 or 4 chronic hepatitis C (CHC) in paediatric patients 12 years of age and older who weigh at least 30 kg.

Brivaracetam (Briviact®) is recommended as an option for restricted use within NHS Wales. Brivaracetam (Briviact®) should be restricted for use in the treatment of patients with refractory epilepsy, who remain uncontrolled with, or are intolerant to, other adjunctive anti-epileptic medicines, within its licensed indication as adjunctive therapy in the treatment of partial-onset seizures (POS) with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy.

10. AWTTC Medicines Optimisation Work Programme

Tom Curran gave an overview of the medicine's optimisation work programme summary. It was noted there have been updates to the antimicrobial guidance since endorsement due to NICE update; these have been published on the AWTTC website and will be presented to members at the next meeting for information.

11. Any other business

There was no other business.

The Chair confirmed the date of the next meeting on Wednesday, 14 September 2022 in Cardiff and closed the meeting.