Enclosure No:	**1/AWMSG/1119**
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)

Minutes of the AWMSG meeting held Wednesday, 16th October 2019 commencing 10.30 am at the Copthorne Hotel, Copthorne Way Culverhouse Cross, Cardiff, CF5 6DH

VOTING MEMBERS PRESENT:

Did not participate in

1.	Prof Ceri Phillips	Chair
2.	Dr Cath Bale	Hospital Consultant
3.	Dr Jeremy Black	General Practitioner
4.	Mr Stuart Davies	Director of Finance
5.	Mr Cliff Jones	Lay Member
6.	Mrs Alison Hughes	Primary Care Pharmacist
7.	Mr Farhan Mughal	ABPI Cymru Wales
8.	Prof Dyfrig Hughes	Health Economist
9.	Mrs Mandy James	Senior Nurse
10.	Mr Stefan Fec	Community Pharmacist
11.	Mr John Terry	Managed Sector Secondary Care Pharmacist
12.	Ms Cathy Wynne	Other professions eligible to prescribe

NON-VOTING MEMBERS PRESENT:

13.	Mr Andrew Evans	Chief Pharmaceutical Officer, Welsh Government

AWTTC staff in attendance:
Dr James Coulson, Interim Clinical Director & NMG Chair
Mrs Karen Samuels, Programme Director
Mrs Ruth Lang, Senior Liaison Manager
Mrs Susan Cervetto, Senior Pharmacist
Mr Richard Boldero, Senior Pharmacist
Ms Karen Jones, Senior Pharmacist
Dr Thomas Curran, Senior Scientist

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
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
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
SMC	Scottish Medicines Consortium
SPC	Summary of Product Characteristics
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 and welcomed members. Professor Phillips confirmed this is his second AWMSG meeting since his recent appointment as AWMSG Chair.

2. Apologies

Professor Arpan Guha. Medical Director
Dr Balwinder Bajaj, Clinical Pharmacologist
Professor Stephen Monaghan, Public Health Wales

3. Declarations of interest

Members were reminded to declare any interests. There were none.

4. Minutes of previous meeting

The draft minutes of the previous meeting held on 16th October 2019 were checked for accuracy. The following amendments were noted:
Page 1 – Mrs Louise Williams
Page 2 – make a note that Mr Tommy Price rejoined the meeting for item 7
With these amendments, the draft minutes were agreed.

5. Chair's report (verbal update)

The Chair updated members on conversations he was having with a number of key stakeholders. He confirmed he had been encouraged by the support and level of engagement of Cardiff and Vale University Health Board. He informed members that he had received a letter from the Minister for Health and Social Services setting out the key priorities for AWMSG and the outcomes expected. The following strategic priorities were highlighted:

- Delivering better outcomes for patients
- Reducing harm/improving medication safety
- Supporting the delivery of value based healthcare

The Chair expressed his view that AWMSG needs to be more relevant and play a more prominent role in delivering 'A Healthier Wales'. The Chair called for more ownership by members and said that the organisations represented are key to the delivery of AWMSG's agenda. The Chair confirmed that he was excited by the challenge and will be contacting individual members before Christmas to encourage more involvement in delivering AWMSG's aims and objectives.

The Chair confirmed Welsh Government ratification of AWMSG's recommendation in relation to buprenorphine announced at the meeting held in October. It was confirmed that the applicant companies had been informed and the advice published on the AWMSG website:

Buprenorphine (Buvidal®) is recommended as an option for use within NHS Wales for the treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over.

The Chair informed members that in the absence of a submission from the holder of the marketing authorisation, a number of statements of advice had been ratified by Welsh Government and published on the AWMSG website. It was noted that these medicines for the indication specified cannot be endorsed for use within NHS Wales and should not be prescribed routinely within NHS Wales:

Abatacept (Orencia®) cannot be endorsed for use within NHS Wales in combination with methotrexate for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis in paediatric patients from 2 years of age to < 6 years of age and older who have had an insufficient response to other disease-modifying anti-rheumatic drugs (DMARDs) including at least one tumour necrosis factor (TNF) inhibitor

Olaparib (Lynparza®) cannot be endorsed for use within NHS Wales as monotherapy for the treatment of adult patients with germline BRCA1/2-mutations, who have HER2 negative locally advanced or metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxane in the (neo) adjuvant or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor (HR)-positive breast cancer should also have progressed on or after prior endocrine therapy, or be considered unsuitable for endocrine therapy

Rituximab (MabThera®) cannot be endorsed for use within NHS Wales for the treatment of patients with moderate to severe pemphigus vulgaris

Tenofovir disoproxil fumarate (Viread®) cannot be endorsed for use within NHS Wales for the treatment of hepatitis B in paediatric patients aged 6 to < 12 years with compensated liver disease and evidence of immune active disease, i.e. active viral replication and persistently elevated serum ALT levels or histological evidence of moderate to severe inflammation and/or fibrosis

Lenalidomide (Revlimid®) cannot be endorsed for use within NHS Wales as combination therapy with dexamethasone, or bortezomib and dexamethasone, or melphalan and prednisone for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant

Melatonin cannot be endorsed for use within NHS Wales for the short-term treatment of jet lag in adults

Pegvaliase (Palynziq®) cannot be endorsed for use within NHS Wales for the treatment of patients with phenylketonuria (PKU) aged 16 years and older who have inadequate blood phenylalanine control (blood phenylalanine levels greater than 600 micromol/l) despite prior management with available treatment options.

Pomalidomide (Imnovid®) cannot be endorsed for use within NHS Wales in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide

The Chair announced the next meeting to held on 13th November 2019 at the Copthorne Hotel, Cardiff and the appraisals scheduled:

Limited Submission (PAS)
Dupilumab (Dupixent®) for the treatment of moderate-to-severe atopic dermatitis in adolescents ≥12 to <18 years who are candidates for systemic therapy
Applicant Company: Sanofi

Full Submission
Melatonin (Slenyto®) for the treatment of insomnia in children and adolescents aged 2-18 with autism spectrum disorder (ASD) and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient
Applicant Company: Flynn Pharma Ltd

Limited Submission
Cefepime (Renapime®) for the treatment of infections caused by bacteria that are cefepime-sensitive including lower respiratory tract infections, including nosocomial pneumonia and community acquired pneumonia, acute bacterial exacerbation of chronic bronchitis and secondary bacterial infection of acute bronchitis; uncomplicated and complicated urinary tract infections, including pyelonephritis; skin and subcutaneous infections; intra-abdominal infections, including peritonitis and biliary tract infections; gynaecological infections; bacterial meningitis in infants and children; in combination with other antibacterial agents in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection; treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Consideration should be given to official guidance on the appropriate use of antibacterial agents
Applicant Company: Renascience Pharma Ltd

Limited Submission
Diamorphine hydrochloride (Ayendi®) for the treatment of acute severe nociceptive pain in children and adolescents 2 to 15 years of age in a hospital setting. Diamorphine hydrochloride nasal spray should be administered in the emergency setting by practitioners experienced in the administration of opioids in children and with appropriate monitoring
Applicant Company: Wockhardt UK Ltd

Members were reminded to declare any personal or non-personal interests ahead of the next meeting. Patients, patient organisations and patient carers were invited to submit their views or contact Ruth Lang at AWTTC for further information on the appraisal process and future work programme.

6. Appraisal 1: Limited Submission

Zanamivir (Dectova®) for the treatment of complicated and potentially life-threatening influenza A or B virus infection in adult and paediatric patients (aged ≥6 months) when: The patient's influenza virus is known or suspected to be resistant to anti-influenza medicinal products other than zanamivir, and/or other anti-viral medicinal products for treatment of influenza, including inhaled zanamivir, are not suitable for the individual patient. Dectova should be used in accordance with official guidance

The Chair welcomed delegates from GlaxoSmithKline Limited

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 announced that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an obligation on health boards to fund accordingly. It was confirmed that AWMSG advice is interim to final NICE guidance should this be subsequently published. The Chair set the context of the limited submission and confirmed that evidence of clinical effectiveness and budgetary impact in comparison to any comparator product(s) should be demonstrated. It was confirmed that monitoring of budget impact would be essential and AWMSG reserved the right to request a full submission if the budget impact exceeded that estimated in the submission.

The appraisal lead set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR. It was confirmed that a limited submission had been considered appropriate for a medicine with an anticipated minimal budgetary impact. It was noted that no comparator treatments are available and that intravenous zanamivir is the last treatment option for patients with complicated influenza when all other treatment options have been exhausted or are not appropriate. Ms Jones confirmed that the product supply and launch is anticipated in November 2019 and she highlighted the unmet clinical need due to lack of additional treatments for influenza in critically ill hospitalised patients and at risk groups.

Dr Coulson confirmed that NMG advice to AWMSG is to recommend use of this medicine in NHS Wales for the indication stated. No issues had been highlighted by NMG. The Chair confirmed that no patient submissions had been received. The Committee's lay member, Mr Cliff Jones, listed the patient organisations contacted by AWTTC.

The Chair invited questions or comments from the Committee and asked members to focus on the budget impact estimates. The company delegates confirmed that data on effectiveness and safety would be collected in the post-authorisation setting as agreed with the EMA. Clarification was sought in relation to availability and stock levels. There were no other wider societal issues of note.

The Chair closed the appraisal and confirmed that members would retire to vote in private.

The Chair announced the appraisal recommendation.

Appraisal decision subsequently announced in public:
The Chair confirmed that having read the evidence and considered the various issues that arose during the discussion, the following recommendation would be forwarded to Welsh Government:

Zanamivir (Dectova®) is recommended as an option for use within NHS Wales for the treatment of complicated and potentially life-threatening influenza A or B virus infection in adult and paediatric patients (aged ≥ 6 months) when: the patient's influenza virus is known or suspected to be resistant to anti-influenza medicinal products other than zanamivir, and/or other anti-viral medicinal products for treatment of influenza, including inhaled zanamivir, are not suitable for the individual patient. Zanamivir (Dectova®) should be used in accordance with official guidance.

The Chair announced that confirmation of AWMSG's recommendations would be forwarded within five working days to the applicant company, who have up to ten working days to accept the recommendation or lodge a request for an independent review. It was noted that failure to respond within the deadline would not delay the process.

The Chair confirmed that the next appraisal would be held in private because of an associated Wales patient access scheme. Members sitting in the public gallery left the room and the Chair sought confirmation that the individuals remaining were part of AWTTC.

7. Appraisal 2: Limited Submission
Glecaprevir/pibrentasvir (Maviret®) for the treatment of chronic hepatitis C virus infection in adolescents aged 12 to < 18 years

The Chair welcomed delegates from AbbVie Limited

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 announced that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an obligation on health boards to fund accordingly. It was confirmed that AWMSG advice is interim to final NICE guidance should this be subsequently published. The Chair set the context of the limited submission and confirmed that evidence of clinical effectiveness and budgetary impact in comparison to any comparator product(s) should be demonstrated. It was confirmed that monitoring of budget impact would be essential and AWMSG reserved the right to request a full submission if the budget impact exceeded that estimated in the submission.

The appraisal lead set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR. It was confirmed that a limited submission had been considered appropriate for a minor licence extension with an anticipated minimal budgetary impact. Mrs Cervetto confirmed that AWMSG had appraised and recommended Maviret® for use in aduts in October 2017 and this had been superseded in December by NICE TA449. Mrs Cervetto informed members that the comparator medicine, Harvoni®, is not routinely available within NHS Wales as the manufacturer had not engaged in the AWMSG appraisal process. It was confirmed that the Wales patient access scheme price, submitted in 2017, would be applied to this indication. Mrs Cervetto highlighted the additional monitoring requirements for a black triangle medicine. It was noted that the CHMP concluded that the

safety profile of glecaprevir/pibrentasvir in adolescents is comparable to that seen in adults. No new safety concerns or serious adverse events were reported in the DORA and expanded safety study.

Dr Coulson confirmed that NMG had appraised this medicine on 4th September 2019 and supprted its use as an option within NHS Wales for the treatment of chronic hepatitis C virus (HCV) infection in adolescents in circumstances where the approved WPAS is utilised, or when the contract price is equivalent or lower than the WPAS price.

The Committee's lay member, Mr Jones, confirmed that no patient submissions had been received and he listed the patient organisations contacted by AWTTC.

The Chair invited questions or comments from the Committee. Clinical expert feedback indicated that pegylated interferon and ribavirin for the treatment of children over 12 years of age is no longer used in adults due to its relative lack of efficacy and potential servere side-effects and this sentiment can be reasonably extrapolated to adolscents. The pill burden was noted. There were no other issues of note.

Before concluding the appraisal, the Chair sought confirmation from the company delegates that the appraisal process had been fair and transparent. The Chair closed the appraisal and confirmed that members would retire to vote in private.

The meeting re-opened to the public and the Chair announced the appraisal recommendation.

Appraisal decision subsequently announced in public:
The Chair confirmed that having read the evidence and considered the various issues that arose during the discussion, the following recommendation would be forwarded to Welsh Government:

Glecaprevir/pibrentasvir (Maviret®) is recommended as an option for use within NHS Wales for the treatment of chronic hepatitis C virus (HCV) infection in adolescents aged 12 to < 18 years.

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 announced that confirmation of AWMSG's recommendations would be forwarded within five working days to the applicant company, who have up to ten working days to accept the recommendation or lodge a request for an independent review. It was noted that failure to respond within the deadline would not delay the process.

8. Endocrine management of gender dysphoria in adults: prescribing guidance for non-specialist practitioners

The Chair invited Dr Sophie Quinney, the project lead, and Dr Tom Curran from AWTTC to join the meeting and summarise Enclosure 4 - Endocrine Management of Gender Dysphoria in Adults: Prescribing Guidance for Non-specialist Practitioners which was being presented to AWMSG for endorsement.

Dr Quinney explained that the guidance had been developed for use by healthcare professionals who support prescribing for people who have been psychologically assessed and diagnosed with gender dysphoria and have been initiated on these therapies by an NHS gender clinic. It is based on the current shared care request issued by the Charing Cross Gender Identity Clinic and the upcoming NHS England Prescribing Recommendations for Gender Dysphoria document. The document is intended for non-specialist practitioners

engaged in the monitoring of patients and prescribing of medical therapies used in the management of gender dysphoria, and would be unique guidance for Wales. Dr Quinney took members through the detail and the Chair subsequently opened discussion.

Clarification was sought in relation to the payments and monitoring requirements associated with the directed enhanced service. It was agreed that a statement should be added to clarify who is expected to interpret ultrasound scans. It was suggested that the non-specialist practitioner should liaise with the local community pharmacy to ensure availability of treatment, and Dr Quinney agreed to add a statement within the guideline to this effect. There was discussion in relation to 'bridging prescriptions' and Dr Quinney confirmed that this had specifically not been included in the document. However, it was agreed to include some carefully constructed wording with regard to safety and patients self-treating. A point was made that the guidance should not be published in isolation and links to other supportive services would be useful. Dr Curran briefly confirmed the process for development of the paper which had included wide consultation. It was also confirmed that the consent forms would not form part of the guidance and had been provided for information only. The Chair closed discussion and thanked Dr Quinney and AWTTC for developing the treatment guidance document. With the required changes noted, the Chair confirmed AWMSG's endorsement and asked that it be published alongside links to other supportive services and resources.

9. Medicine Identified as a Low Priority for Funding in NHS Wales – Paper 1 (Update to section on liothyronine)

The Chair invited Mr Richard Boldero to present Enclosure 5 - an update to Medicines Identified as Low Priority for Funding in NHS Wales – Paper 1. Mr Boldero confirmed that the paper includes an update to recommendations for liothyronine following the publication of the Regional Medicines Optimisation Committee (RMOC) publications: 'Guidance – Prescribing of Liothyronine', in June 2019. Mr Boldero informed members that a similar update was provided in 2018. Mr Boldero asked for AWMSG endorsement of the update to this paper. The Chair opened discussion.

Members suggested the inclusion of up to date NHS Wales expenditure for the included medicines. Mr Boldero agreed that more recent data could be reported within the paper. He also confirmed that NHS Wales has access to the AWTTC Low Priority for Funding dashboard which provides the most up to date information and allows greater depth for comparison than that possible for inclusion within the paper. Members requested that a sentence was added to explain the availability of this dashboard.

Professor Hughes informed that a NICE guideline on thyroid disease is likely to be published in November. Mr Boldero acknowledged that the paper may require a further update in light of this, and if required, an amended version can be taken to the December AWPAG meeting for discussion.

The Chair confirmed that AWMSG would give AWPAG the autonomy to approve further updates and present the document to AWMSG for information or discussion if considered appropriate. The Chair asked AWTTC to update the 2016/2017 expenditure data and undertake further work to extrapolate the data so that the impact of implementation can be fully understood. This may be in the form of bringing regular updates to the meeting so that the benefits of this work can be more widely shared with health boards. With the undertaking of the changes suggested, the Chair confirmed AWMSG's endorsement.

10. NICE in Wales – Dr Julie Vile, Implementation Facilitator, NICE Field Team (Wales)

The Chair invited Dr Julie Vile to introduce herself and to tell AWMSG about her role. Julie explained that, as the NICE Implementation Facilitator for Wales, she is responsible for supporting and facilitating the implementation of NICE guidance in Wales across the health, public health and social care sectors. She alluded to the extended service level agreement between NICE and Welsh Government. In this role, Julie provides advice at both national and

local levels to help senior management teams work with NICE guidance effectively and overcome any implementation issues. Julie plays an important role in the promotion and dissemination of the entire range of NICE products. She identifies challenges and opportunities, shares the learning and collates feedback on NICE products from a wide range of stakeholders. Julie confirmed that she works with organisations to help put NICE guidance into practice. She confirmed NICE's commitment to Wales and encouraged members to get more involved in the work of NICE to increase formal representation on NICE committees and provide a balance across England and Wales in the development of guidance. The Chair opened discussion and Andrew Evans from Welsh Government confirmed that NICE is receptive to engaging with Wales. It was noted that some health boards have appointed NICE leads to champion NICE guidelines; however, this approach is not consistent across Wales. Dr Bale suggested engagement with specialist networks. Mrs Samuels asked whether there is scope for more formal representation from Wales on NICE committees and Julie agreed to explore this.The Chair thanked Dr Vile for attending the meeting and closed discussions.

The Chair confirmed the date of the next meeting on Wednesday, 13th November 2019 in Cardiff and the meeting closed