Enclosure No:	**1/AWMSG/0921**
Agenda Item No:	**1** – Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

Draft minutes of the AWMSG meeting held 9.30 am on Tuesday, 14th September 2021 (via Zoom)

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

Welsh Government:
Mr Andrew Evans, Chief Pharmaceutical Officer

AWTTC staff:
Mrs Helen Adams, Senior Pharmacist
Ms Shaila Ahmed, Advanced Pharmacist
Dr Robert Bracchi, Medical Advisor
Mr Trevor Brooking, Administration Manager
Dr James Coulson, NMG Chairman
Mr Paul Deslandes, Senior Pharmacist
Dr Clare Elliott, Senior Scientist
Dr Stephanie Francis, Senior Scientist

Mrs Claire Ganderton, Senior Pharmacist
Dr Laurence Gray, AWPAG Chairman
Ms Kath Haines, Head of WAPSU
Mrs Rachel Jonas, Medical Writer
Mrs Ruth Lang, Senior Liaison Manager
Mrs Karen Samuels, Programme Director
Mr Anthony Williams, Head of PAMS
Ms Laura Taylor, Administration Supervisor
Mrs Claire Thomas, Senior Pharmacist

List of Abbreviations:

ABPI	Association of the British Pharmaceutical Industry
ASAR	AWMSG Secretariat Assessment Report
AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
AWTTC	All Wales Therapeutics & Toxicology Centre
ATMPs	Advanced Therapy Medicinal Products
BMA	British Medical Association
CAPIG	Clinical and Patient Involvement Group
CEPP	Clinical Effectiveness Prescribing Programme
CHMP	Committee for Medicinal Products for Human Use
DoH	Department of Health
EMA	European Medicines Agency
EMIG	Ethical Medicines Industry Group
EOL	End of life
FAR	Final Appraisal Recommendation
FDA	US Food and Drug Administration
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Board
HEIW	Health Education and Improvement Wales
HST	Highly Specialised Technology
HTA	Health Technology Appraisal
ILAP	Innovative Licensing and Access Pathway
IPCG	Interim Pathway Commissioning Group
IR	Independent Review
MHRA	Medicines and Healthcare products Regulatory Agency
M&TCs	Medicines & Therapeutics Committees
NICE	National Institute for Health and Care Excellence
NMG	New Medicines Group
NPI	National Prescribing Indicator
PAMS	Patient Access to Medicines Service
PAR	Preliminary Appraisal Recommendation
PAS	Patient Access Scheme
PPRS	Prescription Price Regulation Scheme
QAIF	Quality Assurance and Improvement Framework
SMC	Scottish Medicines Consortium
SPC	Summary of Product Characteristics
SPIRA	Server for Prescribing Information Reporting and Analysis
TDAPG	Therapeutic Development Appraisal Partnership Group
T&FG	Task and Finish Group
UHB	University Health Board
WAPSU	Welsh Analytical Prescribing Support Unit
WeMeReC	Welsh Medicines Resource Centre
WG	Welsh Government

WHO	World Health Organization
WHSSC	Welsh Health Specialised Services Committee
WPAS	Wales Patient Access Scheme

1. Welcome and introduction

The Chair opened the meeting, welcomed members and outlined the meeting protocol. It was confirmed that Mr Aled Falvey had resigned from the committee and this will be his final meeting as an AWMSG member. The Chair thanked Mr Falvey for his valuable contribution to the work of AWMSG and confirmed that Ms Cathy Wynn will take over the role representing 'other healthcare professional eligible to prescribe'. The Chair welcomed Dr Helen Fardy to her first meeting as WHSSC representative and Ms Jacqui Seaton representing Powys Teaching Health Board.

2. Apologies:

Ms Claire James – Lay Member
Mrs Mandy James – Senior Nurse
Prof Stephen Monaghan – Consultant in Public Health Medicine
Mrs Louise Williams – Senior Nurse

3. Declarations of interest

Kate Parrish declared an interest in relation to agenda item 15 - her employer, Grunenthal, manufactures a brand of Tramadol. It was confirmed that she would not participate in this agenda item.

4. Minutes of previous meeting

The draft minutes of the previous meeting held on 15th June 2021 were checked for accuracy and approved as a true record of the meeting. There were no matters arising.

5. Appraisal 1: Full Submission (Wales Patient Access Scheme)
Nitisinone (Orfadin®) 10 mg hard capsules for the treatment of adult patients with alkaptonuria

The meeting was closed to observers to protect commercial confidentiality.

The delegate from Swedish Orphan Biovitrum Ltd was welcomed to the meeting. He was joined by Professor Lakshminarayan Ranganath, Honorary Clinical Lecturer at Liverpool University and Mr Nick Sireau, Chief Executive of the AKU Society.

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 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, equity and the CAPIG statement. The Chair confirmed that AWMSG's policy for appraising medicines for rare diseases had been applied. He explained that if a medicine for a rare disease is not recommended by NMG,

the applicant company can request a Clinician and Patient Involvement Group (CAPIG) meeting. Members were reminded that the aim of CAPIG is to identify and discuss in more detail any additional benefits of the medicine from a clinician and patient perspective. The Chair confirmed that the information gathered at the CAPIG meeting will be presented by the CAPIG Chair thus providing members with additional information on which to make a decision.

The Chair confirmed that the company delegates would be invited to respond to questions and given opportunity to make a concluding statement.

Mrs Helen Adams, the AWTTC appraisal lead, set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR.

The Chair invited Dr James Coulson, NMG Chair, to relay the key factors discussed at NMG. Dr Coulson confirmed that the appraisal of nitisinone (Orfadin®) had been undertaken by NMG on 7th July 2021 and, based on the evidence provided and discussions at the meeting, NMG did not recommend nitisinone (Orfadin®) for use within NHS Wales. Dr Coulson stated that in the absence of a health economic model NMG considered the case for cost-effectiveness had not been proven. NMG were satisfied that the results of the pivotal trial provided evidence for clinical effectiveness. NMG agreed that nitisinone (Orfadin®) meets the criteria for appraisal as an ultra-orphan equivalent medicine according to AWMSG's policy. Dr Coulson highlighted the concern of NMG with regard to the inequity of access to nitisinone for people living in Wales as the medicine is available to people living in other parts of the UK.

The Chair invited Dr Robert Bracchi, CAPIG Chair, to relay the key factors discussed at the CAPIG meeting. The impact on patients, their family, carers and wider society were all highlighted. The appraisal lead followed this by confirming the view of clinical experts that there is a substantial unmet need for Welsh patients and the significance of the clinical results in such a rare disease.

The Chair opened general discussion relating to clinical effectivenesss. Clarification was sought regarding the Alkaptonuria Severity Score Index used in the SONIA2 study and results relating to quality of life and the company delegates responded to questions.

Professor Hughes highlighted the limitations of the case for cost-effectiveness and informed members that there was insufficient published evidence to reliably estimate the incremental cost-effectiveness ratio.

Mr Sireau acknowledged the support of Sobi in progressing the medicine through the regulatory process and alluded to the impending loss of the patent and availability of generics. He confirmed that a global registry is in development which will enable the central collection of clinical data and health outcomes.

Clarification was sought with regards to the availability of the medicine in England and Scotland. Mr Evans thanked Sobi, the AKU Society and AWTTC for working together to present a submission for appraisal by AWMSG. He highlighted the important role of AWMSG in advising on medicines for rare diseases where the evidence was limited and the patient population small. He acknowledged the high level of engagement by clinical experts and patients/patient organisation(s). He welcomed the collection of data to audit health outcomes for all medicines.

Mr Jones relayed key aspects from the patient organisation submission from the AKU Society, GP submission, 16 patient submissions and supporting testimonies from patients living in the UK and abroad. He acknowledged the abundance of responses and described the impact on people suffering with this disease and on their families. He highlighted the

unmet clinical need and reiterated that nitisinone (Orfadin®) is the first and only treatment of AKU in adult patients. Mr Jones emphasised the importance of having a licenced treatment routinely available for a small number of patients living in Wales who suffer from this debilitating and devastating disease.

The Chair invited the company delegates to address the committee and they presented brief concluding remarks highlighting the key points of their submission. The delegates welcomed the inclusivity of the appraisal process and appreciated that the views of patients and patient groups had been taken into account. The company acknowledged the lack of cost effectiveness evidence in the submission.

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 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.

The following recommendation was subsequently confirmed:

Nitisinone (Orfadin®) is recommended for use within NHS Wales for the treatment of adult patients with alkaptonuria.

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.

6. Appraisal 2: Full Submission (Patient Access Scheme)
Everolimus (Votubia®) 2 mg, 3 mg and 5 mg dispersible tablet as adjunctive treatment of patients aged 2 years and older whose refractory partial-onset seizures, with or without secondary generalisation, are associated with tuberous sclerosis complex (TSC)

Full Submission by Novartis Pharmaceuticals UK Ltd.

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 reiterated that members should not repeat the detailed discussions held at NMG. He directed members to accept the recommendation of NMG or seek clarification of any issues not taken into account by NMG relevant to wider societal issues, budget impact and issues relating to equity of access. The Chair confirmed that the company delegates would be invited to respond to the issues raised by the committee.

The Chair invited members to declare any interests in either the applicant company or the medicine if they had not already done so.

Dr Clare Elliott, the AWTTC appraisal lead, set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR.

The Chair invited Dr James Coulson, NMG Chair, to relay the key factors discussed at NMG. Dr Coulson confirmed that the appraisal of everolimus (Votubia®) had been undertaken by NMG on 7th July 2021 and, based on the evidence provided and discussions at the meeting, NMG recommended everolimus (Votubia®) for use within NHS Wales where the approved Patient Access Scheme (PAS) is utilised or where the list/contract price is equivalent or lower than the PAS price. NMG agreed everolimus (Votubia®) meets the criteria for appraisal as an orphan medicine according to AWMSG's policy and this process had been applied. Dr Coulson thanked clinical experts for their input. NMG noted that everolimus (Votubia®) is the first licensed medicine for the indication being appraised and it can be considered a disease modifying drug. NMG were satisfied that the results of the pivotal trial provided evidence for clinical effectiveness. Dr Coulson confirmed the view of NMG that the case for cost-effectiveness had been proven.The assessment lead relayed input from clinical experts who supported the use of everolimus (Votubia®) in clinical practice and highlighted the longer term efficacy when compared against anti-epileptic medicines.

Professor Dyfrig Hughes highlighted the key aspects of the case for cost-effectiveness and pointed out the limitations as highlighted in the ASAR. He acknowledged the company had done their best to arrive at some utility estimates given the limitations in the data.

Mr Jones relayed key aspects from the patient organisation submission from the Tuberous Sclerosis Association, Genetic Disorders UK and 3 carer submissions. He described the impact tuberous sclerosis can have on both patients and their families and relayed testimonies from patients with TSC and their carers about the devasting impact refractory seizures have on families, social life, school and employment. He highlighted the unmet clinical need for this indication and the inequity of access for patients in Wales compared to the rest of the UK. Mr Jones emphasised the importance of having a licenced treatment routinely available for the small number of patients living in Wales who have this debilitating and devastating disease.

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 and the Chair closed the appraisal.

The Chair 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.

The following recommendation was subsequently confirmed:

Everolimus (Votubia®) is recommended as an option for use within NHS Wales for the adjunctive treatment of patients aged 2 years and older whose refractory partial-onset seizures, with or without secondary generalisation, are associated with tuberous sclerosis complex (TSC).

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.

7. Appraisal 3: Full Submission (Wales Patient Access Scheme)
Amikacin liposomal (Arikayce®) 590 mg nebuliser dispersion for the treatment of non-tuberculous mycobacterial (NTM) lung infections caused by Mycobacterium avium Complex (MAC) in adults with limited treatment options who do not have cystic fibrosis

Full Submission by Insmed Ltd.

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 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 reiterated that members should not repeat the detailed discussions held at NMG. He directed members to accept the recommendation of NMG or seek clarification of any issues not taken into account by NMG relevant to wider societal issues, budget impact and issues relating to equity of access. The Chair confirmed that the company delegates would be invited to respond to the issues raised by the committee.

The Chair invited members to declare any interests in either the applicant company or the medicine if they had not already done so.

Dr Stephanie Francis, the AWTTC appraisal lead, set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR.

The Chair invited Dr James Coulson, NMG Chair, to relay the key factors discussed at NMG. Dr Coulson confirmed that the appraisal of amikacin liposomal (Arikayce®) had been undertaken by NMG on 7th July 2021 and, based on the evidence provided and discussions at the meeting, NMG supported the use of amikacin liposomal (Arikayce®) within NHS Wales where the approved Welsh Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price. NMG agreed amikacin liposomal (Arikayce®) meets the criteria for appraisal as an ultra-orphan medicine according to AWMSG's policy. Dr James Coulson highlighted the unmet clinical need and limited treatments options highlighted by the clinical experts. Dr Coulson confirmed that NMG considered the case for cost-effectiveness had been made. Key aspects of the views of clinical experts were relayed by the assessment lead. Members were informed that a specialised all Wales MDT group is being established in Wales and treatment will be in accordance with Welsh protocols.

The Chair opened general discussion relating to clinical effectiveness. One member sought clarification as to whether IV amikacin had been considered a comparator in the pivotal study. The company confirmed it was not used directly as a comparator. Clarification was sought regarding potential adverse effects. The assessment lead confirmed that the usual adverse effects seen with aminoglycosides were noted in the SPC. A member asked if NMG had considered the inclusion of a statement with regard to treatment duration. Dr Coulson confirmed that this issue had been discussed and the assessment lead highlighted that treatment duration was captured in the SPC.

Professor Hughes highlighted the key aspects of the case for cost-effectiveness acknowledging the limitations in the approach taken and the data.

Mr Jones relayed key aspects from the patient organisation submission from NTM Patient Care UK. He described the impact on people suffering with this disease and on their families. He highlighted limited treatment availability and the affects this has on quality of life and mental health. He described the symptoms experienced by patients and noted there is limited experience with this nebulised route of administration. It was stated that patients/carers would require training to enable them to use the nebuliser successfully at home, but patients accept this would be a small price to pay for the potential benefits.

The company responded to the patient organisations regarding the use of the nebuliser at home and stated they are offering home care support and the equipment is being provided to patients free of charge.

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 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.

The following recommendation was subsequently confirmed:

Amikacin liposomal (Arikayce®) is recommended as an option for use within NHS Wales for the treatment of nontuberculous mycobacterial (NTM) lung infections caused by Mycobacterium avium Complex (MAC) in adults with limited treatment options who do not have cystic fibrosis.

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.

8. Appraisal 4: Limited Submission (Wales Patient Access Scheme) Dolutegravir (Tivicay®) 5 mg dispersible tablets for the treatment of HIV-1 infected adults, adolescents and children aged at least 4 weeks weighing at least 3 kg, in combination with other antiretrovirals

Limited Submission by ViiV Healthcare UK Ltd.

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 reiterated that members should not repeat the detailed discussions held at NMG. He directed members to accept the recommendation of NMG or seek clarification of any issues not taken into account by NMG relevant to wider societal issues, budget impact and issues relating to equity of access. The Chair confirmed that the company delegates would be invited to respond to the issues raised by the committee.

The Chair invited members to declare any interests in either the applicant company or the medicine if they had not already done so.

Shaila Ahmed, the AWTTC appraisal lead, set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR.

The Chair invited Dr Coulson to relay the key factors discussed at NMG and the recommendation. Dr Coulson confirmed that NMG supported the use of dolutegravir (Tivicay®) within NHS Wales 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 opened general discussion relating to clinical effectiveness.

There was discussion regarding the availability of ODYSSEY trial data and the appraisal lead provided clarification. Dr Coulson confirmed that NMG considered there was sufficient evidence to make a recommendation for this licence extension.

It was confirmed that no patient views had been received and Mr Cliff Jones informed members of the five patient organisations that had been approached by AWTTC.

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 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.

The following recommendation was subsequently confirmed:

Dolutegravir (Tivicay®) is recommended as an option for use within NHS Wales in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults, adolescents and children of at least 4 weeks of age or older and weighing at least 3 kg.

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 meeting opened to the public and the Chair welcomed observers.

9. Appraisal 5: Paediatric licence extension submission

Etravirine (Intelence®) for use in combination with a boosted protease inhibitor and other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced paediatric patients from 2 to <6 years of age

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

The Chair invited members to declare any interests in either the applicant company or the medicine if they had not already done so.

Mrs Claire Ganderton, the appraisal lead, confirmed the draft recommendation had been circulated to members for consideration and comment prior to the meeting and no queries

had been received. The Chair sought confirmation of agreement by members, confirmed AWMSG's acceptance and closed the appraisal session.

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

Etravirine (Intelence®) is recommended as an option for use within NHS Wales, in combination with a boosted protease inhibitor and other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced adults and in antiretroviral treatment-experienced paediatric patients from 2 years of age.

10. Chairman's report (verbal update)

The Chair reported the activity and engagement undertaken by AWTTC since the previous meeting. Members were informed that an Industry Open Day was held on Thursday, 8th July. The focus of this meeting was the evolving appraisal process, in particular, the new process for paediatric licence extensions. There was also a meeting of the AWTTC Industry Forum (formerly the TDA Partnership Group) held on 16th July.

AWMSG's Patient and Public Interest Group re-commenced and the first virtual meeting was held on Friday, 22nd July. As part of this meeting, patients and the public were invited to input into documents currently in development and were informed of future work.

The Chair confirmed that the 2020-2021 AWMSG Annual Report had been published in English and Welsh on the AWMSG website and hard copies are available.

It was reported that a number of meetings have been held with the MHRA and Partners with regards to the new Innovative Licensing and Access Pathway (ILAP) and AWTTC is involved in the development of a process for the introduction of genomics in NHS Wales.

Members were informed of consultations currently in process:

1. All Wales Adult Asthma Management and Prescribing Guidelines
2. All Wales COPD Management and Prescribing Guidelines
   Consultation closed 25th August
3. National Prescribing Indicators 2022–2023 – consultation closed 6th September
4. All Wales Chronic Pain Resources – consultation closed 13th September

Members were informed of consultations due to commence in October:

- Primary care antimicrobial guidelines
- CEPP National Audit - Focus on Antibiotic Prescribing
- Recurrent (Symptomatic) Urinary Tract Infections (Adults)
- Management of Clostridioides difficile Infection in Wales.
- All Wales advice on oral anticoagulation for non-valvular atrial fibrillation

The Chair drew attention to the World Health Organisation World Patient Safety Day on 17th September and confirmed that AWMSG will be joining healthcare professionals across the world to support and promote this important event.

The Chair confirmed that Professor Gillian Leng, Chief Executive of NICE, has announced her retirement.

The Chair informed members that this may be his last meeting as Interim Chair.

11. NPI Quarterly report

Mrs Claire Thomas provided a brief summary of the National Prescribing Indicator report to March 2021 to members for information.

The Chair opened discussion. A member expressed concern that the anticoagulation data implied that 60% of patients have not had a review in the last 12 months. It was suggested that reviews are being undertaken, but not being appropriately coded/recorded. It was agreed that the review codes used for the indicator should be consistently applied across Wales as these codes are also used by the Stop a Stroke project.

The Chair invited Ms Seaton to comment on the report. The variation in performance was highlighted and Ms Seaton asked AWMSG to support the sharing of good practice and to challenge poor performance. The Chair agreed. Ms Haines highlighted the work currently ongoing to promote and share good practice and confirmed that WAPSU is developing a dashboard to show the effects of inequality in prescribing in certain therapeutic areas, with the intention of providing better outcomes.

12. AWMSG Five-Year Medicines Strategy 2018-2023 update report

Dr Robert Bracchi provided a brief summary of progress in delivering the recommendations of the 2018-2023 Medicines Strategy. Members were informed that AWTTC had worked with Healthwise Wales on two modules – one to determine the General public's awareness of AWMSG appraisal process and understanding of how medicines are accessed in Wales, and the second to highlight the Yellow Card Scheme and improve the reporting of suspected adverse drug reactions. Dr Bracchi confirmed that the SPIRA dashboard is now widely used by health boards to show variation in National Prescribing Indicators. Members were informed that AWTTC has identified £3.4m potential savings from Patient Access Schemes offered by the pharmaceutical industry and developed a robust process to monitor patient access schemes within Wales by using the BlueTeq Patient Access Scheme Administration (PASAS) system. It was confirmed that AWTTC is supporting WHSSC with the implementation of advanced therapy medicines products (ATMPs) within NHS Wales by utilising the BlueTeq High Cost Drugs system (HCD). Dr Bracchi informed members that AWTTC's Commercial Medicines Access Team (CMAT) has been working with the National Procurement Lead for Wales and Shared Services to ensure that commercial arrangements offered to NHS England are also available to NHS Wales to enable the implementation of NICE guidance in Wales.

13. Feedback from the AWPAG meeting held 30th June 2021

Ms Haines presented the draft minutes of the AWPAG meeting held on 30th June 2021 and confirmed the date of the next meeting on 22nd September. It was confirmed that Kate Spittle has resigned from the group and new members have been appointed; Sarah Davies, Nurse member; Carol Blount, alternate member for BGMA; and Hazel Hopkins, Pharmacist member for Hywel Dda UHB. It was noted there are still a number of medical member vacancies representing Betsi Cadwaladr UHB, Velindre NHS Trust, Cwm Taf UHB and Powys Teaching Health Board. Ms Haines informed members that in support of the decarbonisation strategy for inhaler use in Wales, Dr Simon Barry had presented an update on the asthma and COPD guidance and this is out for consultation. Ms Haines announced that the date of the next virtual Best Practice Day is 12th October 2021.

14. Wales Advice on SGLT-2i Inhibitors in Type 2 Diabetes and Cardiovascular Disease

Shaila Ahmed provided an overview of the key aspects of the All Wales Advice on SGLT-2 Inhibitors in Type 2 Diabetes and Cardiovascular Disease and confirmed the aim of the guidance is to help support appropriate choice of SGLT-2 inhibitors in patients with type 2 diabetes mellitus and cardiovascular disease. Members were informed the document includes a comprehensive review of the evidence for SGLT-2 inhibitor use in type 2 diabetes mellitus in relation to cardiovascular outcomes, outlines prescribing recommendations on the role of SGLT-2 inhibitors in this patient population and includes an evidence summary for Welsh healthcare practitioners choosing an SGLT-2 inhibitor.

The Chair opened discussion. Members agreed the patient specific characteristics provided in the paper is very useful. It was suggested that the information in the table on page 15 could be simplified and **AWTTC agreed to action** outside of the meeting. It was noted that health boards may wish to produce local guidance based on the summary of evidence provided. The Chair closed discussion and confirmed AWMSG's endorsement.

15. Tramadol Educational Resources (2021 review)

Paul Deslandes presented the updated Tramadol Educational Resources and sought AWMSG's endorsement. Attention was drawn to the consultation responses and resulting actions. Mr Deslandes explained that the resource materials were originally developed in 2013 in response to a request by Welsh Government and he highlighted the changes. The Chair opened discussion and members requested the following actions:

- Include a bilingual patient information leaflet
- Re-insert the legend on Figure 2
- Include MHRA advice relating to end of treatment referenced on page 5
- Separate the referral routes for 'chronic (also known as persistent) pain or dependence on tramadol' (page 6)
- Refer to prescribed medication support services for all health boards if available

With the above changes the Chair confirmed AWMSG's endorsement of the updated Tramadol Educational Resources. It was agreed that AWTTC would update the document in light of the discussion and seek Chair's action before disseminating the document and publishing it on the AWMSG website.

16. Proposal to establish a National Pharmacogenetics Service for Wales

Professor Hughes presented an overview of the proposal that NHS Wales should establish a national pharmacogenetics service that offers timely access to genetic services and clinically relevant information to guide the prescribing of medicines associated with actionable pharmacogenetic variants. The aim of the service would be to improve patient outcomes. The All Wales Medicines Strategy Group's Strategy 2018-23 commits to working with the All Wales Medical Genetics Service as part of the Genomics for Precision Medicines Strategy for Wales with a particular focus on reducing adverse reactions. Professor Hughes briefly outlined how the benefits in terms of improved treatment effectiveness and reduced harms could translate to savings for the NHS.

Mrs Samuels confirmed AWTTC's strong support of the proposal and emphasized the value in a collaborative approach in order for this work to be channelled through AWMSG given its role as Welsh Government's strategy advisory committee on medicines.

The Chair thanked Professor Hughes for the update and confirmed AWMSG's continued support.

17. Any other business

There was no other business

The Chair confirmed the date of the next meeting on Wednesday, 13th October 2021 (via Zoom) and closed the meeting.