

Enclosure No:	1/AWMSG/0421
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
Wednesday, 10th March 2021 (via Zoom)**

VOTING MEMBERS PRESENT:

**Did not
participate in**

- | | | |
|------------|---------------------------|---|
| 1. | Prof Ceri Phillips | Chair |
| 2. | Prof Iolo Doull | Welsh Health Specialised Services Commission |
| 3. | Prof Dyfrig Hughes | Health Economist |
| 4. | Mr Tommy Price | ABPI (Wales) |
| 5. | Mr Cliff Jones | Lay Member |
| 6. | Mr Aled Falvey | Other healthcare professions eligible to
prescribe not already represented |
| 7. | Mr Stefan Fec | Community Pharmacist |
| 8. | Dr Jeremy Black | GP with Prescribing Lead role |
| 9. | Ms Rafia Jamil | Senior Primary Care Pharmacist |
| 10. | Mr Hywel Pullen | Finance Director |
| 11. | Mr John Terry | Managed Sector Secondary Care Pharmacist |
| 12. | Mrs Mandy James | Senior Nurse |

Welsh Government:

No representation present at the meeting

AWTTC staff:

Mrs Karen Samuels, Programme Director
Ms Kath Haines, Head of WAPSU
Mr Richard Boldero, Senior Pharmacist
Mrs Claire Thomas, Senior Pharmacist
Mrs Claire Ganderton, Senior Pharmacist
Dr Jessica Davis, Senior Scientist
Dr Stuart Keeping, Senior Scientist
Dr Carolyn Hughes, Scientist/Medical Writer
Mrs Ruth Lang, Senior Liaison Manager

Ms Laura Taylor, Administration Supervisor
Mr Trevor Brooking, Administration Manager

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
ILAP	Innovative Licensing and Access Pathway
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 and welcomed observers and members. He confirmed that the same protocols and procedures that exist for a 'normal' AWMSG meeting would be applied to the 'virtual' meeting and confirmed that the meeting quorum had been met.

2. Apologies:

Voting members:

Dr Balwinder Bajaj - Clinical Pharmacologist

Dr Jim McGuigan - Medical Director

Prof Stephen Monaghan - Consultant in Public Health Medicine

Non-voting members:

Mr Andrew Evans, Chief Pharmaceutical Officer, Welsh Government

Mrs Lynne Schofield, Head of Pharmacy & Prescribing, Welsh Government

3. Declarations of interest

There were no declarations of interest.

4. Minutes of previous meeting

The draft minutes of the previous meeting held on 11th February 2021 were checked for accuracy. A request was made to amend one section relating to antibiotics on page 5, agenda item 8. With that amendment the minutes were accepted as a true record of the meeting.

5. Chairman's report (verbal update)

The Chair confirmed that the meeting would close to the public after agenda item 8 to protect commercial confidentiality associated with the patient access schemes.

The Chair thanked ABPI Cymru Wales for arranging a presentation by Mr Paul Catchpole after the AWMSG meeting held in February on the development of a process for the evaluation and reimbursement of antibiotic treatments.

The Chair confirmed that a meeting had been held between representatives of the MHRA, NICE and AWTTTC to discuss the new Innovative Licensing and Access Pathway (ILAP) for new medicines introduced on 1st January 2021 and informed members that there would be on-going involvement to ensure that the Welsh perspective is taken into account when developing NICE guidance. The Chair acknowledged this to be a positive step forward.

The Chair informed members that subsequent to the meeting held in February, a request for review of AWMSG's recommendation in relation to melatonin (Slenyto®) on the grounds of 'process' was submitted by Flynn Pharma. The Chair confirmed the complaint had been upheld - Dr James Coulson had been called away from the meeting to attend to an urgent clinical issue. The Chair confirmed that AWMSG would be asked to undertake this appraisal again with the involvement of Dr Coulson, the NMG Chair, who would relay discussions and provide the rationale for NMG's decision to recommend the use of the medicine.

Mrs Samuels announced the appraisal scheduled for the next AWMSG virtual meeting on Tuesday 20th April 2021 commencing 9.30 am:

Buprenorphine/naloxone (Suboxone®) for the treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Suboxone is indicated in adults and adolescents over 15 years of age who have agreed to be treated for addiction

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 AWTTTC for further information on the appraisal process and future work programme.

The Chair confirmed this would be his last AWMSG meeting as he will be stepping down as AWMSG Chair to take up the appointment of Vice Chair, Cardiff and Vale University Health Board. He confirmed that Welsh Government will be making interim arrangements while they identify a successor. The Chair thanked members and AWTTTC for their contributions and support during his tenure.

6. AWMSG Work Programme

Medicines Access for Patients in Wales - document in plain language

Dr Carolyn Hughes introduced the document “Access to medicines for patients in Wales” – a guide that explains the different ways in which licensed medicines reach patients in NHS Wales. She explained the document was developed in collaboration with the TDA Partnership Group and is based on an ABPI document. Dr Hughes informed members that her remit was to produce a plain language version of the document explaining how NICE and AWMSG’s health technology appraisal process works and other medicines pathways. Dr Hughes confirmed that it is a ‘live’ document and will be amended to reflect any changes or new processes; it will be reviewed annually. Dr Hughes confirmed that a glossary is yet to be included which will make it more accessible and easier to understand.

The Chair opened discussion. Mr Price thanked Dr Hughes on behalf of ABPI for her efforts in completing this work and asked whether there would be merit in exploring a regulatory commercial framework within Wales similar to NHS England. The Chair confirmed his agreement that there may be value in this. The Chair thanked Dr Hughes for making a complicated area simple to read and acknowledged these rare skills. The Chair remarked that he hoped this work would translate to improved engagement by pharmaceutical companies in AWMSG’s health technology appraisal process.

AWTTTC Work Programme Consultation 2021/2022

Mrs Karen Samuels confirmed that AWTTTC had published a consultation on planned new work to deliver AWMSG’s strategic objectives with a deadline for responses of Thursday, 18th March. She confirmed the aim of the consultation is to increase engagement and ownership of the service. Mrs Samuels clarified that no routine or core work had been included. A member suggested that the abbreviation IPCG should be in full. The Chair expressed his personal thanks to AWTTTC for taking the agenda forward and stated that the pandemic had demonstrated AWTTTC’s ability to be dynamic in responding to the needs of the service. The Chair confirmed that Welsh Government had contributed to the iterations and asked members to respond to the consultation by the deadline.

AWTTTC Communications and Engagement Strategy

Miss Jessica Rayner presented an overview of the document and confirmed that comments had been received prior to the meeting from Welsh Government officials. Members were informed that the document outlines how AWTTTC and AWMSG will engage with the service, pharmaceutical industry, clinicians and patients through various communication channels and platforms. A list of tasks to deliver the strategy is being compiled and steps have already been taken to action some of these tasks. Miss Rayner confirmed that comments and feedback will be invited and the document will go out for consultation. The Chair opened discussion. Mr Price thanked AWTTTC on behalf of ABPI for their commitment pharmaceutical engagement and confirmed that 74 delegates had enrolled for a workshop for the pharmaceutical industry set up by AWTTTC in collaboration with ABPI. A programme of events for the pharmaceutical industry is planned and Mr Price said this is a good example of how AWTTTC/AWMSG and the pharmaceutical industry can work together to add value. The Chair referred to the importance

of good communication, particularly over the last twelve months, with the limitations imposed by the pandemic, and he congratulated Miss Rayner on the document which had been well received by members.

7. National Prescribing Indicators 2020-21 Q2 Report (for information)

Mrs Claire Thomas and Mr Richard Boldero provided a brief summary of the National Prescribing Indicator report presented to AWMSG for information. It was confirmed that the next report for the period up to December 2020 will be available on 23rd April 2021.

The Chair introduced Mr Darrell Baker, Chief Pharmacist, Cardiff and Vale Health Board and Professor Meriel Jenney, Assistant Medical Director, Cardiff and Vale Health Board. It was subsequently confirmed that Professor Jenney had been unable to attend the meeting. The Chair confirmed that the NPIs had been used as a vehicle for engaging conversations with Executives of Health Boards across NHS Wales with the intention of improving safe and effective prescribing. Mr Baker replied by thanking the Chair for the opportunity of engaging AWMSG in local health board activities.

The Chair opened discussion. One member queried the baseline for the antimicrobial target as it was noted that most targets had been set against the previous year. Mrs Thomas confirmed that the antimicrobial targets are set against a baseline year of 2018-2019 as stated in the NPI document. It was noted that two health boards had seen an increase in the prescribing of antimicrobials, when compared with the previous year, and the Chair asked for this to be queried and monitored.

Mr Baker informed members the the NPI report is discussed at the corporate Medicines Management Group within Cardiff and Vale and comparisons made of performance against other health boards. Mr Baker confirmed that a data analyst and lead pharmacist for antimicrobial stewardship have recently been appointed following a successful business case. Mr Baker shared a presentation so that AWMSG members could understand the level of discussions that are held at health board level. Mr Baker confirmed the focus is on quality and safety primarily, with the financial elements being secondary considerations. Mr Baker highlighted the financial improvements and benefits in relation to the percentage of biosimilar medicines. It was confirmed that Cardiff and Vale Health Board is actively progressing electronic prescribing systems in secondary care. Mr Baker highlighted the importance of shared decision making and patient/public discussions. He stated that a multi-layered approach embeds and reiterates key prescribing messages and all areas of health systems need to be aligned. He emphasized the importance of a value based and educational approach to optimise use of medicines and identify benefits elsewhere in the health system.

The Chair opened discussion. One member asked how general practitioners (GPs) in C&V UHB might input into the medicines management group or link with the GP representatives to feel more connected. Mr Baker agreed to take this back to the GPs on the group. The important role of community pharmacy in supporting GPs was acknowledged. The Finance Representative agreed that the emphasis on quality and safety results in financial gains and asked what could be done to share the good work going on within Cardiff and Vale Health Board. He made the point that high quality services generally cost less because it results in less complications and admissions to hospital and makes better use of available resources.

Ms Haines confirmed that the Best Practice annual event hosted by AWTTTC aims to showcase local initiatives that have worked well and have driven improvements/efficiencies. By sharing these initiatives it is hope that the success can be replicated across NHS Wales.

It was noted in the NPI report that low value medicines show a substantial decrease in all health boards. Mr Boldero confirmed that a more detailed breakdown and data analysis is available via the SPIRA dashboard. The Chair confirmed that AWTTTC is likely to progress a resource releasing project in the area of diabetes. Mr Baker confirmed that a project on heart

failure is being undertaken in Cardiff and Vale and members said they would be interested to see the results of this project to identify whether investment in medicines would reduce hospital admission rates.

The Chair closed discussion and thanked Mr Baker for attending AWMSG.

**8. Appraisal 1: Paediatric licence extension submission
Lurasidone (Latuda®) 18.5 mg, 37 mg and 74 mg film-coated tablets for the treatment of schizophrenia in adolescents aged 13 years to 17 years**

Submission by Sunovion Pharmaceuticals Europe Ltd for a paediatric licence extension where there is existing AWMSG appraisal advice

The Chair welcomed one delegate representing Sunovion Pharmaceuticals.

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.

The Chair confirmed that the application met the criteria for appraisal via the new process for paediatric licence extensions and is the first to be brought to AWMSG. Members were informed that based on the summary of information provided to members prior to the meeting, a draft recommendation had been prepared for consideration/approval by AWMSG. The Chair confirmed the applicant company delegate could respond to any questions posed by members.

The Chair confirmed that as part of the new process he would ask the appraisal lead to confirm the draft recommendation and highlight any issues that required the attention of, or discussion by, AWMSG prior to the vote. It was confirmed that monitoring of budget impact will be essential and AWMSG reserves the right to request a full submission if the budget impact exceeds that estimated in the paediatric licence extension submission.

The appraisal lead confirmed the draft recommendation and that there were no issues raised by members prior to the meeting that required discussion or clarification. The Chair asked members if there were any questions with regard to the information provided or draft recommendation. No questions were raised.

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 stated that the new process had been very straightforward and that the company accepts the recommendation wording as presented to AWMSG.

The Chair confirmed the close of the appraisal session. He informed the applicant company delegate 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 Chair closed the meeting to the public.

The following recommendation was subsequently confirmed:

Lurasidone (Latuda®) is recommended as an option for use within NHS Wales for the treatment of schizophrenia in adults and adolescents aged 13 years and over.

9. Appraisal 2: Full submission (Wales Patient Access Scheme)

Idebenone (Raxone®) for the treatment of visual impairment in adolescent and adult patients with Leber's hereditary optic neuropathy

The Chair sought confirmation that members had received and read AWMSG's policy for appraising medicines for rare diseases with the meeting papers.

The Chair welcomed delegates from Chiesi Limited

The Chair sought confirmation that the meeting had been closed to the public and all observers 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 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 medicine for rare diseases has been applied which involves a meeting of the Clinical and Patient Involvement Group (CAPIG). He explained that if a medicine for a rare disease is not recommended by NMG, the applicant company can request a 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 clinical 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 any concluding remarks.

The appraisal lead set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR.

Dr Coulson confirmed that the appraisal of idebenone (Raxone®) had been undertaken by NMG on 4th November 2020 and, based on the evidence provided and discussions at the meeting, NMG does not recommend idebenone (Raxone®) for use within NHS Wales for the treatment of visual impairment in adolescent and adult patients with Leber's Hereditary Optic Neuropathy (LHON). NMG considered the case for cost-effectiveness had not been proven. Dr Coulson relayed the view of NMG that the company's submission did not present sufficient evidence to demonstrate that idebenone (Raxone®) is clinically effective and cost-effective. NMG agreed that idebenone (Raxone®) meets the criteria for appraisal as an ultra-orphan medicine according to AWMSG's policy and this process had been applied.

Dr Bracchi highlighted the key aspects of the CAPIG report. The appraisal lead followed this by confirming the view of clinical experts that people need to be treated as soon as possible after diagnosis. There was recognition that gathering evidence for this rare disease is a challenge and the end point measurement of visual field would have been more appropriate than the measurement of visual acuity. Even though efficacy was not proven in the pivotal trial there was acknowledgement that it appeared to work in some patients: The reasons for this could not be demonstrated.

The company delegates input into the discussion and clarified the situation regarding the expanded access programme in NHS England. The Chair sought confirmation that members agreed with NMG's decision regarding the ultra orphan status. The uncertainties in the company's submission were acknowledged and the point was made that gaps in data are not unusual when appraising medicines for rare diseases. Professor Hughes summarised the case for cost-effectiveness and highlighted the limitations. The company delegate agreed there is a high level of uncertainty; he reassured members that they had been conservative and transparent in approach. Costs taken from relevant sources had been inflated and validated by Wales clinicians; the company showed the range to be cost-effective. The Chair drew members attention to the budget impact estimates.

Mr Jones relayed key aspects from the patient organisation submission from the LHON Society. He described the impact on people suffering with this disease and on their families. He made the point that rapid and severe loss of sight has a dramatic impact on social life, school and employment and often leads to depression and suicidal thoughts. He highlighted the unmet clinical need and reiterated the fact that idebenone (Raxone®) is the first and only treatment of visual impairment in adolescent and adult patients with Leber's hereditary optic neuropathy. 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 point was made that the budget impact is predictable because of the limited period of treatment and members were asked to take this factor into consideration. 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 close of the appraisal session. He informed the applicant company that the final appraisal recommendation will be forwarded by email after the meeting and, for transparency, a notice uploaded to the AWMSG website. The Chair confirmed that recommendation would be forwarded to Welsh Government for ratification and the company has ten working days to accept the recommendation or request an independent review. The Chair thanked the delegates for engaging in the AWMSG appraisal process and they left the meeting.

The following recommendation was subsequently confirmed:

Idebenone (Raxone®) is recommended for use within NHS Wales for the treatment of visual impairment in adolescent and adult patients with Leber's Hereditary Optic Neuropathy (LHON). 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.

**10. Reappraisal following request for review on the grounds of ‘Process’
Appraisal 3: Full submission (Wales Patient Access Scheme)
Melatonin (Slenyto®) for the treatment of insomnia in children and adolescents aged 2 to 18 years with autism spectrum disorder (ASD) and / or Smith-Magenis syndrome (SMS), where sleep hygiene measures have been insufficient**

It was confirmed that the meeting was closed to observers to protect commercial confidentiality.

The Chair welcomed delegates from Flynn Pharma 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. No interests were declared.

The appraisal lead, Dr Jessica Davis, set the context of the appraisal and relayed the key aspects of the resubmission as outlined in the ASAR. She drew members attention to the fact that a Wales Patient Access Scheme had been submitted to address the issues relating to cost-effectiveness that had been highlighted at the previous appraisal.

The Chair invited Dr James Coulson, NMG Chair, to relay the key factors discussed at NMG and asked him to explain the rationale for their decision to recommend the use of melatonin (Slenyto®) within NHS Wales. Dr Coulson made the point that NMG had been guided by the clinical experts who had attended the NMG meeting who had reinforced the unmet clinical need and highlighted the significance of melatonin (Slenyto®) being the only licensed medicine available. Experts confirmed that the efficacy of the different preparations were comparable. Experts also suggested that one of the secondary end points was perhaps the most significant end point and NMG considered this demonstrated clinical effectiveness. NMG acknowledged there had been an updated cost effectiveness model and the company had submitted a Wales Patient Access Scheme to improve the case for cost-effectiveness.

The Chair opened discussion. Mrs Samuels highlighted the current inequity of access to the medicine in NHS Wales. There was discussion over the clinical trial study design, measures and sleep latency times. Clarification was sought in relation to the clinical significance of the results. The company delegates responded to questions and clarified all the outstanding issues raised in the discussion.

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

Mr Jones relayed information from the questionnaire received from SMS Foundation UK. He gave a comprehensive summary of the information provided by the patient organisation and highlighted some practical problems faced by carers. The importance of having a licenced medicine available was reiterated by Mr Jones as this was considered a key factor from the feedback received. The point was made that the clinicians need treatment options.

The company delegates shared costs associated with purchasing unlicensed preparations. There were no other wider societal issues of note.

The Chair invited the company delegates to address the committee and they presented brief concluding remarks highlighting the key points of their resubmission. They welcomed the opportunity for reappraisal and acknowledged the robustness of the appraisal process. 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 discussions.

The Chair informed the applicant company delegates that the final appraisal recommendation will be forwarded by email after the meeting and, for transparency, a notice uploaded to the AWMSG website. He confirmed that the recommendation will be forwarded to Welsh Government for ratification and the company has ten working days to accept the recommendation or lodge a request for an independent review. The delegates left the meeting and members voted in private.

The following recommendation was subsequently confirmed:

Melatonin (Slenyto®) is recommended as an option for use within NHS Wales for the treatment of insomnia in children and adolescents aged 2 to 18 years with autism spectrum disorder and/or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient. 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, 20th April Wednesday commencing 9.30 am** (via Zoom); he thanked members for their contributions and the meeting closed.