

Enclosure No:	1/AWMSG/0321
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, 9th February 2021 (via Zoom)

VOTING MEMBERS PRESENT:

Did not
participate in

- | | | |
|-----|------------------------------|---|
| 1. | Prof Ceri Phillips | Chair |
| 2. | Prof Stephen Monaghan | Consultant in Public Health Medicine |
| 3. | Prof Iolo Doull | Welsh Health Specialised Services Commission |
| 4. | Prof Dyfrig Hughes | Health Economist |
| 5. | Ms Kate Parrish | ABPI (Wales) |
| 6. | Mr Cliff Jones | Lay Member |
| 7. | Mr Stefan Fec | Community Pharmacist |
| 8. | Dr Jeremy Black | GP with Prescribing Lead role |
| 9. | Mrs Alison Hughes | Senior Primary Care Pharmacist |
| 10. | Mr Hywel Pullen | Finance Director |
| 11. | Mr John Terry | Managed Sector Secondary Care Pharmacist |
| 12. | Mrs Louise Williams | Senior Nurse |

Welsh Government:

No representation present at the meeting

AWTTC staff:

Mr Richard Boldero, Senior Pharmacist
Mr Trevor Brooking, Administration Manager
Mr Thomas Curran, Senior Scientist
Dr Jessica Davis, Senior Scientist
Mr Paul Deslandes, Senior Pharmacist
Dr Stephanie Francis, Senior Scientist
Dr Laurence Gray, AWPAG Chairman
Ms Kath Haines, Head of WAPSU
Mrs Ruth Lang, Senior Liaison Manager
Miss Laura Phillips, Administration Supervisor

Mrs Karen Samuels, Programme Director
Ms Rosie Spears, Senior Scientist
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
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
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.

The Chair 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:

Dr Balwinder Bajaj - Clinical Pharmacologist
Mr Alex Falvey - Other healthcare professions eligible to prescribe not already represented
Dr Jim McGuigan - Medical Director
Mr Andrew Evans, Chief Pharmaceutical Officer
Mrs Lynne Schofield, Head of Pharmacy & Prescribing, Welsh Government

3. Declarations of interest

Ms Kate Parrish confirmed a business interest in agenda item 11 and 12 and it was noted that these agenda items are for information only.

4. Minutes of previous meeting

The draft minutes of the previous meeting held on 8th December 2020 were checked for accuracy and approved as a true record of the meeting.

5. Chairman's report (verbal update)

The Chair confirmed there had been considerable activity since the AWMSG meeting held in December. The first virtual AWMSG Open Day for the pharmaceutical industry held on 15th December provided opportunity to update on the work of AWMSG and share the vision for future collaborative working. Members were informed that a programme of events for the pharmaceutical industry had been arranged throughout the year to enable regular communication, dialogue and collaboration and this had been shared with members of the TDA Partnership Group last week. The Chair confirmed the terms of reference for the TDA Partnership Group are under review.

The Chair informed members that a document reviewing engagement by the pharmaceutical industry in the appraisal process had been taken to the AWMSG Steering Committee in January following concerns raised by Welsh Government officials regarding the number of statements of advice being published. The Chair had requested that it be presented to AWMSG so that members could discuss and understand the reasons why some companies decide not to engage in the appraisal process. The paper will be presented by Rosie Spears.

Members were informed that SMC had announced its involvement in a collaboration with NICE, MHRA, NHSE and NHS Improvement (NHSE&E) for a new Innovative Licensing and Access Pathway (ILAP) – from 1st January 2021 companies were able submit new medicines to this streamlined licensing and patient access process. It was noted that AWMSG and AWTTTC had not had involvement in this collaboration. The Chair confirmed that a meeting has been arranged on 16th February with representatives from MHRA and NICE to seek clarification of the potential impact of this new process in Wales.

The Chair informed members a meeting held in December explored opportunities for closer working with HealthWise Wales to increase the involvement of patients and the public in the work of AWMSG. Two projects undertaken by HealthWise Wales in 2019 aimed to improve public awareness of the Yellow Card Scheme and AWMSG. Of the 1300 participants that responded to the questionnaire, only 7% had heard of AWMSG. Participants were asked to watch a patient information film after which 92% reported having a better understanding of how new medicines are made available in Wales. The Chair highlighted the importance of reporting adverse reactions and the role of information films in raising awareness of the Yellow Card Scheme and work of AWMSG. The Chair agreed to explore with Welsh Government officials the increased use of the AWMSG and YCC patient information videos and confirmed that dialogue with HealthWise Wales will continue.

The Chair drew attention to the NICE consultation paper published on 4th February on proposals for change in the following areas.

- Alignment of the current guidance development processes
- Opportunities for new process improvements and ways of working
- Commercial and Managed Access processes
- Highly Specialised Technologies - vision and principles

The Chair confirmed the response deadline of 15th April and invited members to submit any comments to AWTTTC by Friday, 12th March for incorporation into a joint response.

The Chair drew attention to the consultation currently on-going with regard to the Management of Adult Smokers in Secondary Care and asked members to be aware of up-coming consultations which will include the AWMSG work programme, the communication and engagement strategy and the medicines optimisation framework. The Chair reiterated the importance of taking opportunity to comment on documents early in the development of the documents.

The Chair confirmed that work has started on the merger of the AWTTTC website with the AWMSG website with the aim of having a 'one stop shop' for information on medicines. He highlighted the importance of retaining the individual identities and invited comments and/or suggestions from members

Members were informed that the National Standards for Medication Reviews had been published on the AWMSG website and disseminated, with a request for volunteer practices to participate in the pilot.

The Chair confirmed that work is ongoing within AWTTTC to operationalise the Resource Reallocation project presented by Bangor and Swansea Universities in December.

The Chair drew attention to the Chief Medical Officer for Wales's Special Report on the response in Wales to the first phase of the COVID-19 pandemic, which is available on the Welsh Government website.

The appraisal scheduled for the next AWMSG virtual meeting on Wednesday 10th March 2021 was announced:

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

This will be a full submission with a WPAS by Chiesi 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 AWTTTC for further information on the appraisal process and future work programme.

6. AWMSG Work Programme

AWMSG Statements of Advice: review of process and engagement

Ms Rosie Spears presented the enclosure and highlighted the key issues. The review demonstrated an overall reduction in the number of statements of advice being published. It was evident that despite several attempts to encourage engagement some companies have concluded that it is not commercially viable to submit for appraisal of a medicine to treat a small patient group. One member asked what steps could be taken if this scenario presented

itself and the committee was reminded of the option to appraise a medicine using publicly available information. Mrs Samuels explained some of the differences in the HTA processes in Wales and Scotland. Ms Spears confirmed that further work would be undertaken to look at expenditure on medicines that have not been subject to an appraisal.

**Published article in Bio Drugs - A Look at the History of Biosimilar Adoption
Mixed methods study. AWTTC contributed on behalf of NHS Wales by providing the data and reviewing the manuscript prior to submission.**

Mr Richard Boldero presented an overview of this work and explained the contribution of AWTTC was to provide data, partake in a semi-structured interview and to critically review the paper prior to submission for publication. Members were reminded of the dashboard developed by WAPSU for NHS Wales to interrogate and monitor local and national data. The Chair reiterated the importance of this information to maximise and drive efficiencies.

7. Feedback from AWPAG meeting held 2nd December 2020

Dr Laurence Gray presented the draft minutes of the AWPAG meeting held in December. He confirmed the appointment of Claire Clement as Vice Chair and announced the date of the Best Practice Day 2021 on Tuesday, 13th April. He confirmed the intention to hold a 2 hour virtual seminar sharing real life examples of good practice and prescription management. AWMSG members were invited to attend.

8. Best Practice Reminder - Avoid Nitrofurantoin in the Treatment of Pyelonephritis

The Chair welcomed Dr Tessa Lewis and invited her to present the paper. Dr Lewis explained that the document had evolved due to concerns that key prescribing messages may not be reaching all prescribers. Members were informed that following wide consultation and iteration, AWPAG are seeking endorsement by AWMSG. The Chair opened discussion.

Dr Black noted the discrepancy in NICE and AWMSG advice in relation to the use of cefalexin. Mrs Haines brought Meryl Davies into the discussion and she confirmed that the Antibiotic Guideline Group is looking at primary care guidance and pyelonephritis will be reviewed at the same time. She confirmed the updated Welsh guideline will be brought to AWMSG for endorsement. It was noted that some health boards have updated sections of their local guidance ahead of this review. There was general agreement that there are no negative issues in relation to the paper, the only issue relates to the wider context in that it encourages use of ciprofloxacin. Dr Lewis made the point that the table within the document refers prescribers to local guidance. Dr Gray acknowledged the difficulty in producing national guidance balanced with the intricacies of prescribing at a local level. He agreed that the statement referring prescribers to local guidance should be strengthened. The Chair confirmed AWMSG endorsement subject to highlighting the awareness of the reader to the importance of referring to local guidance.

9. Shared Care Prescribing and Monitoring Guidance

Mrs Claire Thomas presented the updated shared care prescribing and monitoring guidance and sought the endorsement of AWMSG. The Chair opened discussion. Concern was expressed by one member that it was not sufficiently clear that dose adjustments and titration remained the responsibility of the secondary care specialist and that patients should be clear that the GP is not taking over this responsibility. Mrs Thomas agreed to review and update the wording in the document to make it clear that the GP has to agree to taking on shared care, and that it is not an automatic acceptance to do so. The Chair confirmed the endorsement of AWMSG subject to these amendments.

10. Prescribing Dilemmas (2020 Review)

Mr Paul Deslandes presented the Prescribing Dilemmas document that had been discussed by AWMSG in December and updated in light of comments received. Mr Deslandes highlighted the changes to the document. Concern was expressed that the wording in relation to Pelargonium was not consistent with NICE. It stated:

“NICE have suggested that Pelargonium may be used by some adult patients for the self-care of cough, although the quality of evidence is low³³.”

There was agreement that this should be changed to ensure consistency with NICE to: NICE have stated that prescribers should “be aware that some people may wish to try the following self-care treatments, which have limited evidence of some benefit for the relief of cough symptoms Honey (in people aged over 1 year) ... Pelargonium (a herbal medicine; in people aged 12 and over)”.

The Chair confirmed the endorsement of AWMSG subject to the amendment to align the Pelargonium wording with NICE.

11. Safeguarding Users of Opioid Patches by Standardising Patient and Caregiver Counselling – for information

Ms Haines confirmed this document was being presented to AWMSG for information.

12. Persistent pain resources – for information

Ms Haines confirmed this document was being presented to AWMSG for information

The Chair confirmed a 15 minute break and announced the date of the next meeting on 10th March commencing 9.30 am. He confirmed that the meeting would now be closed to the public and locked down to protect commercial confidentiality.

On re-convening the Chair confirmed that only AWMSG members and AW TTC staff remained in the meeting.

**13. Appraisal 1: Full submission (Wales Patient Access Scheme)
Opicapone (Ongentys®) as adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCIs) in adult patients with Parkinson’s disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations**

The Chair welcomed delegates from Bial Pharma 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 confirmed that at the close of the appraisal all observers will leave the meeting and members will vote in private and agreed the wording of the recommendation to Welsh Government. The Chair confirmed the decision of AWMSG will be forwarded to company delegates after the close of the meeting and an acceptance of the recommendation or request for a review is required within ten working days.

The Chair reiterated that members should not repeat the detailed discussions held at NMG. He directed members to consider the recommendation of NMG, seek clarification of any outstanding issues, and take account of any wider societal and budget impact issues. 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 set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR and confirmed the recommendation of NMG.

The Chair opened discussion. There were no outstanding issues of clinical effectiveness.

The Chair invited Professor Hughes to highlight the key aspects of the case for cost-effectiveness. Professor Hughes drew attention to the limitations of the data and construction of the model. Professor Hughes questioned the comparator selected as this is rarely used and suggested that best supportive care would have been more appropriate. The company delegates acknowledged the limitations and explained the difficulties they had in preparing the model. There was discussion in relation to Table 3 in the ASAR – the result of the base-case analysis. Members took account of the feedback from clinicians regarding place in therapy and noted that compliance could be problematic in this patient population. There were no outstanding issues in relation to the budget impact estimates.

Mr Jones relayed information from the questionnaire received from Parkinsons UK Cymru. He alluded to the considerable impact on the quality of life of patients and he relayed the descriptions of symptoms. The view of the patient organisation was that a once a day treatment and the side effect profile may be advantageous. It was noted that some patients had reported improvements in their symptoms. There were no other wider societal issues of note.

The Chair invited the company delegates to offer further insight. Members were informed that this medicine has been approved outside of Wales by some clinical commissioning groups in a second line position. Treatment is monitored and there is strict guidance. Treatment with opicapone (Ongentys®) has been demonstrated to be beneficial with a perceived slow down in disease progression and need for use of more expensive non-oral therapy. The company delegate explained that it is difficult to demonstrate a reduction in the cost burden on Wales. He accepted that the comparator is not regularly used and stated that the company was guided in their comparator selection by the One Wales interim advice. He made the point that NICE encourages a choice of inhibitors and the company is of the view that it offers a choice to prescribers so offers the best option. The company delegates welcomed involvement in the review of this medicine.

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.

Appraisal decision:

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:

Opicapone (Ongentys®) is recommended as an option for restricted use within NHS Wales.

Opicapone (Ongentys®) is licensed for use within NHS Wales as an adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCIs) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations.

Opicapone (Ongentys®) is restricted within the licensed indication for use after failure of entacapone, or in patients who cannot tolerate entacapone.

Opicapone (Ongentys®) is not recommended for use within NHS Wales as a first-line catechol-O-methyltransferase (COMT) inhibitor and should only be used after entacapone.

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.

**14. Appraisal 2: Limited submission (Patient Access Scheme)
Dupilumab (Dupixent®) for the treatment of severe atopic dermatitis in children 6 to 11 years old who are candidates for systemic therapy**

The Chair welcomed delegates from Sanofi.

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 at the close of the appraisal all observers will leave the meeting and members will vote in private and agreed the wording of the recommendation to Welsh Government. The Chair confirmed the decision of AWMSG will be forwarded to company delegates after the close of the meeting and an acceptance of the recommendation or request for a review is required within ten working days.

The Chair reiterated that members should not repeat the detailed discussions held at NMG and reminded members that evidence of cost-effectiveness is not required for a limited submission. He directed members to focus on the evidence of budgetary impact, to take into account the recommendation of NMG and to seek clarification of any outstanding or wider societal issues. 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.

Dr Davis the appraisal lead set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR and confirmed the recommendation of NMG. Dr Davis confirmed that the criteria for a limited submission had been met on the grounds that the application is for a paediatric licence extension for use in children ≥ 6 to < 12 years. She provided an overview of the submission and relayed feedback from clinical experts. She confirmed the recommendation agreed by NMG. The Chair opened discussion.

There were no outstanding issues of clinical-effectiveness. Mr Jones highlighted key points of information from the three patient organisation submissions received from Eczema Outreach Support, National Eczema Society and Nottingham Support Group for Carers of Children with Eczema. There were no questions relating to budget impact or outstanding wider societal issues.

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. The company delegates confirmed they had no further issues to raise and stated that the appraisal summary was resounding. The Chair closed the appraisal and the company delegates left the meeting.

Appraisal decision:

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:

Dupilumab (Dupixent®) is recommended as an option for restricted use within NHS Wales.

Dupilumab (Dupixent®) is licensed for the treatment of severe atopic dermatitis in children 6 to 11 years old who are candidates for systemic therapy.

Dupilumab (Dupixent®) is restricted for the treatment of severe atopic dermatitis in children 6 to 11 years old who are candidates for systemic therapy and where existing systemic therapies are not advisable.

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

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.

15. **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**

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 confirmed that at the close of the appraisal all observers will leave the meeting and members will vote in private and agreed the wording of the recommendation to Welsh Government. The Chair confirmed the decision of AWMSG will be forwarded to company delegates after the close of the meeting and an acceptance of the recommendation or request for a review is required within ten working days.

The Chair reiterated that members should not repeat the detailed discussions held at NMG. He directed members to consider the recommendation of NMG, seek clarification of any outstanding issues, and take account of any wider societal and budget impact issues. 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.

Dr Davis, the appraisal lead, set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR. In her address she summarised key points raised by the clinical experts and confirmed the advice of NMG to recommend use.

The Chair opened discussion in relation to the case for clinical-effectiveness. It was noted that the medicine does not have any particular side effects. One member made comment that he could not identify any significant advantage in efficacy compared to alternative treatments. He asked whether the medicine compared more favourably on price.

Clarification was sought in relation to sleep latency and night time awakenings. The company delegate confirmed that the Slenyto® study demonstrated a meaningful improvement in uninterrupted sleep. The company delegate highlighted the improvements: significantly longer total sleep time and longer sleep episode which impacted on quality of life. It was noted that there were no improvements in the caregiver's quality of life. The company delegate acknowledged the uncertainty and made the point that it was difficult to assess quality of life in this patient population.

One member made the point that melatonin is widely prescribed and Slenyto® is the first licensed product: the importance of having a licensed medicine should be taken into account by AWMSG. He alluded to potential governance issues relating to use of off-label or unlicensed medicines and the significantly high cost of purchasing a solution to address the administration problem in this patient group compared to Slenyto®.

The Chair referred to the patient organisation questionnaire from SMS Foundation UK and asked the lay member to relay the key points for transparency. Mr Jones summarised the issues and highlighted the symptoms and challenges. The importance of sleep hygiene was noted. He confirmed the patient organisation welcomed a licensed version of time-released melatonin for children with SMS as this would be more convenient with access through GP services. Current off-licence prescription is arranged through paediatric or psychiatric services with GP discretion on providing repeat prescriptions. Mr Jones highlighted the point made by the patient organisation that higher dose rates are reported as being used for children with SMS making the introduction of a 5 mg tablet attractive over the current limitation on supply of a 2 mg tablet. For a child requiring 10 mg, this would be the difference of taking two tablets as opposed to five tablets. The importance of having treatment options available was highlighted because of the complex needs of the patients.

Professor Hughes summarised the case for cost-effectiveness highlighting the limitations in the approach taken and the data. The Chair invited questions. Members commented on the limitations in terms of breadth of costs and in relation to ascertaining the utility values in this population. The company delegate acknowledged the methodological challenges and pointed out that of all the scenario analyses there was only one with an ICER over £20,000 and this related to the maximum 10 mg dose. He confirmed the scenario did not assume any greater effectiveness and only acquisition costs were included in the model because there were no significant differences in the non-acquisition costs compared with the comparator. Dr Davis informed members that the focus of discussion at NMG was the cost-effectiveness. The Chair drew members' attention to the budget impact estimates.

No further wider societal issues were raised other than those highlighted in the patient organisation 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 and the Chair closed the discussions. The company delegates left the meeting.

Appraisal decision:

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:

Melatonin (Slenyto®) is not recommended 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.

The cost-effectiveness data presented in the submission were insufficient for AWMSG to recommend its use.

The Chair confirmed the date of the next meeting, on Wednesday, 10th March (via Zoom).
The meeting closed.