

Enclosure No:	1/AWMSG/1219
Agenda Item No:	1 – Minutes of previous meeting
Author:	Chair, AWMSG
Contact:	Tel: 029 20716900 E-Mail: awttc@wales.nhs.uk

ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

**Minutes of the AWMSG meeting held
Wednesday, 13th November 2019 commencing 10.30 am
at the Copthorne Hotel, Copthorne Way
Culverhouse Cross, Cardiff, CF5 6DH**

VOTING MEMBERS PRESENT:

**Did not
participate in**

1.	Prof Ceri Phillips	Chair	
2.	Prof Iolo Doull	WHSSC	
3.	Prof Arpan Guha	Medical Director	
4.	Dr Jeremy Black	General Practitioner	
5.	Mr Stuart Davies	Director of Finance	8-10
6.	Mr Cliff Jones	Lay Member	
7.	Mrs Susan Murphy	Primary Care Pharmacist	
8.	Mr Rob Thomas	ABPI Cymru Wales	
9.	Prof Dyfrig Hughes	Health Economist	
10.	Mrs Louise Williams	Senior Nurse	
11.	Mr Stefan Fec	Community Pharmacist	
12.	Mr John Terry	Managed Sector Secondary Care Pharmacist	
13.	Mr Aled Falvey	Other professions eligible to prescribe	

AWTTC staff in attendance:

Dr James Coulson, Interim Clinical Director & NMG Chair
Mrs Karen Samuels, Programme Director
Mrs Ruth Lang, Senior Liaison Manager
Miss Shaila Ahmed, Advanced Pharmacist
Ms Karen Jones, Senior Pharmacist
Dr Jessica Davis, Senior Scientist
Dr Stuart Keeping, Senior Scientist

List of Abbreviations:

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

1. Welcome and introduction

The Chair opened the meeting and welcomed members. Professor Phillips confirmed the first appraisal would be conducted in private to protect commercial confidentiality.

2. Apologies

Dr Balwinder Bajaj, Clinical Pharmacologist
Professor Stephen Monaghan, Public Health Wales
Dr Cath Bale, Hospital Consultant

3. **Declarations of interest**

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

4. **Minutes of previous meeting**

The draft minutes of the previous meeting held on 16th October 2019 were checked for accuracy and approved.

The meeting closed to the public.

5. **Appraisal 1: Limited Submission (PAS)**

Dupilumab (Dupixent[®]) for the treatment of moderate-to-severe atopic dermatitis in adolescents ≥ 12 to < 18 years who are candidates for systemic therapy

The Chair welcomed delegates from Sanofi.

The Chair confirmed that individuals sitting in the public gallery were part of AWTTTC or Sanofi. The Chair invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

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

The appraisal lead set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR. It was confirmed that a limited submission had been considered appropriate for the licence extension for use in adolescents ≥ 12 to < 18 years who are candidates for systemic therapy. Members were informed that NICE TA534 recommends the use of dupilumab in adults, restricted to disease that has not responded to at least one other systemic therapy, or these are contraindicated or not tolerated. The appraisal lead confirmed that the submission being considered by AWMSG had been restricted by the applicant company to the subpopulation of patients whose disease has not responded to at least one other systemic therapy or these are contraindicated or not tolerated. Dupilumab is available in England for adolescents via the Commissioning Medicines for Children in Specialised Services policy and patients would be eligible for the medicine when specific commissioning conditions had been met.

Dr Coulson confirmed that NMG's advice to AWMSG is to recommend restricted use of dupilumab within NHS Wales for the indication stated. NMG was satisfied the results showed a statistically significant improvement in the extent and severity of skin lesions in adolescent patients who received dupilumab compared to those who received placebo.

The Chair referred to the patient organisation questionnaires and invited Mr Cliff Jones to summarise the patient views. Mr Jones confirmed that AWTTTC had received three submissions: two from patient organisations (Eczema Outreach Support and National Eczema Society) and one from an adult patient with experience of dupilumab. Mr Jones highlighted difficulties experienced by individuals with severe eczema and the serious impact on education, social life and on the family. Reducing the need for time-consuming application of topical steroids would be welcomed by patients and carers. He relayed an anecdote from a patient who had received dupilumab through the Early Access to Medicines Scheme (EAMS)

who stated that their physical, psychological and social health had been transformed since starting dupilumab. Mr Jones highlighted the benefits of this treatment.

The Chair opened discussion and invited comment from members. Clarification was sought in relation to the safety profile and it was noted that no new safety signals specific to the adolescent population had been reported. A member questioned the company delegates about the availability of patient registries and the company referred to a registry at Guys & St Thomas NHS Trust in England. Members were informed that the company intend to extend the licence to lower ages and it was confirmed that studies are underway. One member expressed access of the medicine through EAMS had been positive. The Chair drew members' attention to the budget impact estimates. There were no other wider societal issues of note and, having received confirmation that the process had been fair and transparent, the Chair closed the appraisal and members retired to vote in private.

The meeting was opened to the public.

Appraisal decision subsequently announced in public:

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

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

Dupilumab (Dupixent®) is licensed for the treatment of moderate-to-severe atopic dermatitis in adolescents ≥ 12 to < 18 years who are candidates for systemic therapy.

Dupilumab (Dupixent®) is restricted for the treatment of moderate-to-severe atopic dermatitis in adolescents ≥ 12 to < 18 years who are candidates for systemic therapy, only if the disease has not responded to at least one other systemic therapy, or these are contraindicated or not tolerated.

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.

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

6. Chair's report (verbal update)

The Chair confirmed Welsh Government ratification of AWMSG's recommendation in relation to Glecaprevir/pibrentasvir (Maviret®) and Zanamivir (Dectova®) announced at the meeting held in October. It was confirmed that the applicant companies had been informed and the following advice has been published on the AWMSG website:

Glecaprevir/pibrentasvir (Maviret®) is recommended as an option for use within NHS Wales for the treatment of chronic hepatitis C virus (HCV) infection in adolescents aged 12 to < 18 years. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

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

NOTE: This product is not currently launched in the UK

The Chair informed members the Annual AWMSG Masterclass for the pharmaceutical industry scheduled on 27th November 2019 had been cancelled because of the low uptake. The Chair confirmed the Masterclass may be rescheduled later in the year.

The Chair asked that all members and deputies of AWMSG, AWPAG and NMG attend the Annual Training Day to be held in Cardiff City Stadium on Wednesday, 15th January 2020. The Chair reiterated that attendance by all is essential.

The Chair announced the next meeting to held on 11th December 2019 at the Cophorne Hotel, Cardiff and the appraisals scheduled:

Full Submission (WPAS)

Fampridine (Fampyra®) for the improvement of walking in adult patients with multiple sclerosis with walking disability (Expanded Disability Status Scale 4–7)

Applicant Company: Biogen Idec Ltd

Full Submission (WPAS)

Glycerol phenylbutyrate (Ravicti®) as adjunctive therapy for chronic management of patients with urea cycle disorders including deficiencies of carbamoyl phosphate-synthase-I (CPS), ornithine carbamoyltransferase (OTC), argininosuccinate synthetase (ASS), argininosuccinate lyase (ASL), arginase I (ARG) and ornithine translocase deficiency hyperornithinaemia-hyperammonaemia homocitrullinuria syndrome (HHH) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Ravicti® must be used with dietary protein restriction and, in some cases, dietary supplements (e.g. essential amino acids, arginine, citrulline, protein-free calorie supplements)

Applicant Company: Swedish Orphan Biovitrum 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.

7. **Appraisal 2: Full Submission**

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

The Chair welcomed delegates from Flynn Pharma Limited

The Chair invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

The Chair announced that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an obligation on health boards to fund accordingly. It was confirmed that AWMSG advice is interim

to final NICE guidance should this be subsequently published. The Chair set the context and outlined the sequence of events. Members were reminded that NMG had considered the clinical and cost effectiveness issues in detail and there was no expectation that AWMSG would repeat this. The Chair encouraged members to seek clarification of any outstanding issues, particularly in relation to budget impact, and to take into consideration any societal aspects that were not part of the discussion at NMG. The Chair confirmed that delegates from the applicant company would have the opportunity to respond to questions and highlight any salient issues with regard to their submission.

The Chair invited the AWTTTC appraisal lead to present an overview and relay the key aspects of the submission as outlined in the ASAR. Dr Keeping highlighted that melatonin (Slenyto[®]) is the first licensed melatonin product for the indication under consideration. Members were informed that Welsh clinical experts confirmed the main comparator is Circadin[®] tablets in prolonged release formulation used off-label in this paediatric indication. Circadin[®] is sometimes used crushed and, if children can't be persuaded to eat crushed tablets, melatonin liquid is used. It was noted that the company had selected instantaneous release formulations of melatonin in tablet, capsule and liquid form as the comparators. Dr Keeping relayed the view received from the clinical experts that for patients with problems staying asleep, prolonged-release melatonin is best and for those with problems falling asleep, instantaneous release is best. One expert considered there was no therapeutic difference between the two formulations. Dr Keeping informed members that the SMC had not recommended use in Scotland.

Dr Coulson confirmed the NMG had appraised the medicine in October and did not recommend melatonin (Slenyto[®]) for the treatment of insomnia in children and adolescents aged 2-18 with autism spectrum disorder (ASD) and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient. NMG was of the view that there were limitations and uncertainties in the modelling. NMG had questioned the utility assumptions used and noted structural and parameter uncertainty in the model.

The Chair opened the discussion in relation to clinical effectiveness. Members sought clarification in relation to sleep time and awakenings. Members questioned the measures and clinical significance. The importance of improved parental sleep and quality of life was noted. Clarification was sought in relation to on-going and potential future studies and the company delegates confirmed that no further studies were planned. Members questioned the company delegates on the approach taken in their submission and in relation to the reliability of the evidence. It was noted that adverse drug reactions had not been captured in the model.

The Chair invited Professor Hughes to summarise the case for cost-effectiveness. Prof Hughes clarified his role as health economic member on AWMSG and confirmed he had no involvement in the preparation of the ASAR. He highlighted the limitations and made the point that AWTTTC scenarios using Circadin[®] as opposed to instantaneous release melatonin indicated significantly less cost-effectiveness than the projections presented by the company. Prof Hughes confirmed the budget impact analysis had been based on Slenyto[®] displacing off-label and unlicensed melatonin products, with Circadin[®] being the main medicine displaced in contradiction to the model. It was noted that, if approved, the company estimates that approximately 330 children will receive Slenyto[®] resulting in net acquisition costs of approximately £270,000 per year.

The Chair referred members to the patient organisation submission from The Smith-Magenis Syndrome (SMS) Foundation UK and asked the lay member to highlight the key points. Mr Jones summarised the information within the questionnaire. He referred to a number of quotes from parents and the experiences described. The advantages of the treatment were relayed and the ease of administration was noted. The patient organisation did not anticipate any disadvantages to this treatment. The Chair opened discussion and invited questions in relation to the wider societal issues. The importance of assuring the quality of the unlicensed product

was mentioned by one member. The ethical and legal implications of prescribing an unlicensed treatment were noted and the point was made that governance was a significant issue for AWMSG to take into consideration. The company delegate endorsed these comments. The company delegates reiterated that the EMA does not consider Circadin® to be a child-appropriate profile and they made the point that Slenyto minitables of melatonin were easier for children to swallow (which also benefited parents and carers). The company delegates referred to the anecdotes from parents that sleep improvement can be translated into real behavioural benefits for children and quality of life improvement for parents and carers. Reference was made to the favourable compliance rates with mini-tablet administration.

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

Appraisal decision subsequently announced in public:

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

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 case for cost-effectiveness has not been proven.

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

Mr Stuart Davies left the meeting.

8. Appraisal 3: Limited Submission

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

The Chair confirmed that Renascence Pharma Limited had declined the invitation to attend and participate in discussions.

The Chair invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

The Chair announced that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an

obligation on health boards to fund accordingly. It was confirmed that AWMSG advice is interim to final NICE guidance should this be subsequently published. The Chair set the context of the limited submission and confirmed that evidence of clinical effectiveness and budgetary impact in comparison to any comparator product(s) should be demonstrated. It was confirmed that monitoring of budget impact would be essential and AWMSG reserved the right to request a full submission if the budget impact exceeded that estimated in the submission.

The appraisal lead set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR. It was confirmed that the decision to accept a limited submission had been based on the anticipated minimal budgetary impact. Ms Jones relayed the request of the applicant company that use should be considered in a subgroup of patients within its licensed indication – those who have pseudomas infections where first-line agents are not effective or are contraindicated. It was noted that the MHRA approved cefepime in December 2017 via a generic application as part of a decentralised procedure. Ms Jones confirmed that cefepime has been widely used in Europe and has established efficacy and tolerability. Clinical experts suggested that cefepime is likely to be reserved for use when other antibacterial agents are considered inappropriate or when alternatives have failed to demonstrate efficacy. Ms Jones highlighted concerns in relation to antibacterial resistance across Europe and the need for new and effective treatments.

Dr Coulson confirmed the recommendation of NMG to AWMSG that use in the sub-population of the licensed indication should be supported. NMG acknowledged the difficulty in establishing patient numbers and took into account feedback from clinical experts.

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

The Chair invited questions or comments from the Committee. Clarification was sought in relation to the process for identifying appropriate clinical experts and Ms Jones explained that AWTTTC contact the relevant specialist networks. There were no other issues of note.

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

Appraisal decision subsequently announced in public:

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

Cefepime (Renapime®) is recommended as an option for restricted use within NHS Wales.

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

Cefepime (Renapime®) is restricted for use for resistant pseudomonas infections where first-line agents are not effective or contraindicated.

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

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

9. Appraisal 4: Limited Submission

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

The Chair confirmed that Wockhardt UK Limited had declined the invitation to attend and participate in discussions.

The Chair invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

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

The appraisal lead set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR. It was confirmed that a limited submission had been considered appropriate for a medicine with an anticipated minimal budgetary impact. Miss Ahmed informed members that use of unlicensed intranasal diamorphine is recognised as established practice in Wales as first-line treatment for severe pain in children in the emergency setting and is recommended in the College of Emergency Medicine Guidelines. It was noted that Ayendi® is the first licensed diamorphine nasal spray preparation. No dosing calculations are required for reconstitution and, once made, the product is immediately available for use in multiple patients. This offers quicker access to pain relief for patients in contrast to the unlicensed diamorphine nasal spray which has to be made per patient following dosing charts. Miss Ahmed confirmed that Ayendi® has been recommended for use in Scotland for this indication. Miss Ahmed relayed the views of three clinical experts from within NHS Wales, one of whom stated that the medicine had been used on a trial basis in their paediatric emergency department and confirmed it to be a good choice of treatment for severe pain. The ease of dosing and administration was also confirmed.

Dr Coulson confirmed that NMG appraised diamorphine hydrochloride (Ayendi®) for the above indication and supported its use within NHS Wales as an option. NMG was of the view that diamorphine hydrochloride should be administered in the emergency setting by practitioners experienced in the administration of opioids to children and with the appropriate monitoring.

The Committee's lay member, Mr Jones, confirmed that no patient submissions had been

received and he listed the patient organisations contacted by AWTTTC.

The Chair invited questions or comments from the Committee. There was an acknowledgement that the ease of dosing and administration would improve patient safety and reduce risk. There were no other issues of note.

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

Appraisal decision subsequently announced in public:

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

Diamorphine hydrochloride (Ayendi®) is recommended as an option for use within NHS Wales for the treatment of acute severe nociceptive pain in children and adolescents 2 to 15 years of age in a hospital setting. Ayendi® nasal spray should be administered in the emergency setting by practitioners experienced in the administration of opioids in children and with the appropriate monitoring.

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

10. Any other business

The Chair confirmed that Welsh Government will today issue a statement confirming that agreement in principle has been reached with Vertex Pharmaceuticals to make Orkambi and Symkevi available within NHS Wales. Welsh Government will also allow continued access to Kalydeco for all current and future licensed indications for people living with cystic fibrosis in Wales. The detail of the agreement will be finalised before the end of November to enable access to these medicines for priority patients in December 2019.

The Chair confirmed the date of the next meeting on Wednesday, 11th December 2019 in Cardiff and the meeting closed