Enclosure No:	**1/AWMSG/0720**
Agenda Item No:	**1** – Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

Minutes of the AWMSG meeting held 9.30 am on Wednesday, 15th July 2020 (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 Dyfrig Hughes	Health Economist	
4.	Mr Farhan Mughal	ABPI (Wales)	
5.	Mr Cliff Jones	Lay Member	
6.	Prof Arpan Guha	Medical Director	
7.	Dr Jeremy Black	GP with Prescribing Lead role	
8.	Mrs Susan Murphy	Primary Care Pharmacist	
9.	Mr Hywel Pullen	Finance Director	
10.	Mr John Terry	Managed Sector Secondary Care Pharmacist	
11.	Mrs Mandy James	Senior Nurse	
12.	Mr Aled Falvey	Other healthcare professions eligible to prescribe not already represented	
13.	Mr Dylan Jones	Community Pharmacist	

Welsh Government in attendance:
Mr Andrew Evans

AWTTC staff in attendance:
Dr James Coulson, NMG Chairman
Mrs Karen Samuels, Programme Director
Ms Kath Haines, Head of WAPSU
Mr Anthony Wiliams, Head of PAMS
Dr Jessica Davis, Senior Scientist
Dr Stephanie Francis, Senior Scientist
Mrs Kelly Wood, Senior Scientist
Ms Laura Taylor, Administration Supervisor

Miss Laura Phillips, Administration Supervisor
Mr Richard Boldero, Senior Pharmacist
Mrs Ruth Lang, Senior Liaison 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
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 members to the second virtual AWMSG meeting.

2. Apologies:

Stefan Fec – Community Pharmacist (Mr Dylan Jones attending)
Dr Balwinder Bajaj, Clinical Pharmacologist

Not in attendance:

Dr Cath Bale, Hospital Consultant
Prof Iolo Doull, Welsh Health Specialised Services Committee

3. Declarations of interest

Members were reminded to declare any interests. No interests were declared.

4. Minutes of previous meeting

The draft minutes of the previous meeting held on 16th June 2020 were checked for accuracy and approved.

5. Chairman's report (verbal update)

The Chair welcomed members and explained that the same protocols and procedures that exist for a 'normal' meeting would be applied to the virtual meeting. All members and observers were asked to ensure that their microphones were muted. The Chair confirmed that members wishing to speak should use the raised hand emoticon and it was confirmed that observers would not be permitted to speak. The Chair thanked members and observers for their feedback from the first Zoom meeting and confirmed that most of the issues highlighted had been taken on board: Some of the problems in terms of internet access can't easily be solved. He confirmed that the feedback had been very positive and acknowledged the difficulties and constraints with virtual meetings. The Chair thanked AWTTC for their support and professionalism.

The Chair reported the following membership issues:

Stuart Davies has served a full term of office as Finance Director representative and Hywel Pullen will step into the full member role. A nomination of a deputy from the Directors of Finance is awaited. Mr Pullen agreed to relay the thanks from the Chair to Mr Davies.

Susan Murphy has served a full term of office as Managed Sector Primary Care Pharmacist. Alison Hughes will step into the main member role and Rafia Jamil has been nominated by the Chief Pharmacists and appointed as a deputy member.

The Chair welcomed Aled Falvey to his first meeting as a full member of AWMSG representing 'other professions eligible to prescribe and confirmed that Cathy Wynne had been appointed as the deputy member.

The Chair confirmed that following discussions at the previous meeting in relation to respiratory guidance, conversations had been had with representatives from the Respiratory Innovation Group and NICE. The Chair confirmed that conversations had been generally positive and he would be putting together a form of wording to explain the rationale for having divergence from NICE guidance in Wales to reflect some differences in terms of clinical context and policy. The Chair confirmed he would be meeting with Welsh Government on Friday and he hoped that the respiratory guidance in relation to pneumonia and COPD would be brought back to AWMSG for endorsement in September.

The Chair informed members that the AWMSG Constitution had been updated to include the

proposed changes highlighted at the previous meeting. He confirmed the document will be taken to the next AWMSG Steering Committee for discussion and sign-off before being forwarded to Welsh Government for approval.

The Chair asked Mrs Karen Samuels to confirm the submissions scheduled for appraisal at the next AWMSG virtual meeting on Tuesday, 15th September 2020 at 9.30 am:

Doravirine (Pifeltro®) in combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class
Applicant company is Merck Sharp & Dohme Ltd (full submission)

Doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo®) for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir
Applicant company is Merck Sharp & Dohme Ltd (limited submission)

Bedaquiline (Sirturo®) for use as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis (MDR-TB) in adolescent patients (12 years to less than 18 years of age and weighing at least 30 kg) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability
Applicant company is Janssen-Cilag Ltd (limited submission)

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

6. National Prescribing Indicator Report (Q3) for information

The Chair confirmed that the National Prescribing Indicator Report was being presented to members for information as part of the regular programme of monitoring work undertaken by WAPSU. Mr Richard Boldero provided the context and drew members attention to areas of improvement. The Chair informed members that represenatives from Cardiff and Vale University Health Board Executive Team had been unable to attend the meeting and he confirmed the continued engagement by AWMSG with executives from every health board to enable opportunity for discussions in relation to prescribing was a priority. Mr Andrew Evans expressed concern in relation to widening inequalities and reiterated the need for improvement. The Chair agreed that AWMSG would explore this further. Mrs Murphy asked whether the targets could be aligned with those in the QAIF and this was supported by Dr Black. It was noted that the current circumstances could impact on the level of antimicrobial prescribing. Dr Black drew attention to the prescribing safety indicator entitled “Number of patients with asthma who have been prescribed a beta-blocker” and queried why the numbers seem to be increasing. Ms Haines confirmed that this will be explored further through the indicator sub-committee, which is in the process of being set up and AWPAG, and will also be raised with the Respiratory Health Implementation Group for their considerations.

ACTION

Indicator working group meeting to be convened

7. All Wales Prescribing Guidelines for Asthma for endorsement as interim guidance in Wales

The Chair confirmed that following consideration by AWMSG at the previous meeting, further discussion had taken place between himself and Dr Katie Pink, representatives from NICE and AWTTC. Mr Boldero confirmed that the suggestion by AWMSG to include recovery and recycling schemes had been included in the guidance and there were no other outstanding issues. It was confirmed that the paper was being presented to AWMSG for endorsement as interim guidance pending publication of joint guidance developed by NICE, the British Thoracic

Society and SIGN. Mr Mughal asked for clarification of updates to the guidance and timelines as he said that there were three inhalers currently going through the regulatory process and which may be relevant to the guidance and associated pathway. The Chair thanked Mr Mughal for his valid question and said that there were no clear timelines and updates would emerge during the proess or as part of the process. Dr Black referred to two safety issues which he said needed to be more prominent within the document and the Chair asked Mr Boldero to relay this request to the author. The Chair asked members to vote and it was confirmed that AWMSG endorsed the implementation of the All Wales Prescribing Guidelines for Asthma as interim guidance in NHS Wales pending publication of NICE/SIGN/BTS guidance.

8. SCHE Collaborative Research – Liothyronine for information and not available on the AWMSG website as 'academic in confidence'

Professor Dyfrig Hughes provided the background to the paper and explained that it would form the basis for a clinical trial and was part of an AWMSG project that had been established to look at a system approach to de-prescribing to achieve greater value through disinvestment. He stated that the project report would be presented to AWMSG once it had gone through the normal medicines optimisation process of initial consideration by AWPAG and wider stakeholder consultation. Professor Hughes said that the purpose of the paper was to identify a potential place in therapy for liothyronine and develop a health economic model to assess the value of the medicine. Professor Hughes answered some questions and there was discussion in relation to the basket of drugs representing the low value indicators. It was confirmed that health boards are responsible for the implementation of the indicators and determining whether the projected savings in relation to liothyronine and any of the indicators is appropriate for their patient population.

9. Appraisal 1: Full submission

Cariprazine (Reagila®) for the treatment of schizophrenia in adult patients.

The Chair welcomed the delegates from Gedeon Richter.

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 appraisal lead set the context of the appraisal and relayed the key aspects of the submission as outlined in the ASAR. It was noted that the company had only provided evidence for the sub-population and not the full licensed indication.

Dr James Coulson relayed the key issues discussed by NMG and confirmed that NMG had not supported use of this medicine in NHS Wales for this indication as the evidence provided was insufficient to recommend use and the level of uncertainty was not acceptable to the committee.

The Chair invited members to raise issues relating to clinical effectiveness and the company delegates responded to questions.

Professor Dyfig Hughes highlighted the uncertainties in the case for cost-effectiveness as outlined in the ASAR. The Chair asked members to note the budget impact estimates.

It was confirmed that no patient views had been received and Mr Cliff Jones informed members of the patient organisations that had been approached by AWTTC. There were no outstanding wider societal issues raised.

The company delegates responded to questions and made the point that the medicine offers a step forward effective antipsychotic treatment for this sub-population and delivers an improvement in functioning which helps the patient journey back to recovery.

Prior to concluding the appraisal the Chair asked the applicant company delegates to confirmed 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 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:

Cariprazine (Reagila®) is not recommended for use within NHS Wales for the treatment of schizophrenia in adults. The clinical and cost-effectiveness data presented in the submission were insufficient for AWMSG to recommend its use in the sub-population highlighted by the applicant company.

The sub-population under consideration was in adults with schizophrenia for use as second-line treatment where predominant negative symptoms have been identified.

The Chair confirmed that the final appraisal recommendation would be forwarded electronically to the applicant company after the meeting and a notice of the outcome of the appraisal would be published on the AWMSG website. The company delegates were informed that they had up to ten working days to accept the recommendation or lodge a request for an independent review the grounds for which should be submitted in accordance with the process for independent review. It was noted that failure to respond within the deadline would not delay the process and the advice would be forwarded to Welsh Government for ratification once the ten day deadline had expired.

10. Appraisal 2: Full submission (orphan-equivalent medicine)
Hydroxycarbamide (Xromi®) for the prevention of vaso-occlusive complications of sickle cell disease in patients over 2 years of age.

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 invited the appraisal lead to highlight the key aspects of the submission as outlined in the ASAR. Dr Davis set the context and provided a summary.

The Chair welcomed representataion from Nova Laboratories Ltd and apologised for not checking their attendance prior to the presentation by the appraisal lead.

The Chair invited Dr Coulson to relay the advice of NMG. Dr Coulson confirmed that NMG considered hydroxycarbamide (Xromi®) to be an orphan-equivalent medicine according to the criteria in the AWMSG appraisal process for a medicine for a rare disease. He confirmed the view of NMG was that hydroxycarbamide (Xromi®) for the prevention of vaso-occlusive complications of sickle cell disease in patients over 2 years of age should be recommended as an option for restricted use.

The Chair opened discussion and asked members to focuss on the case for clinical effectiveness. The company delegates responded to any issues raised. The Chair moved to the case for cost-effectiveness and Professor Dyfrig Hughes re-emphasised some points made earlier by the appraisal lead. It was noted that the CMA assumed bioequivalence. The Chair referred members to the budget impact estimates. Members noted the potential cost-savings.

The Chair confirmed that members had been provided with the questionnaires from three individual patients and a patient organisation submission from Friends of Cardiff Sickle Cell and Thalassaemia. The lay member relayed the key points and described the impact on the lives of children with sickle cell disease. It was noted that there are no other licensed liquid formulations available. The lay member described the pain, loneliness and feeling of isolation felt by children. There were no outstanding wider societal issues of note.

The company delegate input into the discussion and answered questions. Prior to concluding the appraisal the Chair sought and received confirmation that all issues had been adequately disussed and the process had been fair and transparent from a company perspective.

The Chair closed the appraisal and the meeting was closed to observers.

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:

Hydroxycarbamide (Xromi®) is recommended as an option for restricted use within NHS Wales. Hydroxycarbamide (Xromi®) is licensed for the prevention of vaso-occlusive complications of sickle cell disease in patients over two years of age. Hydroxycarbamide (Xromi®) is restricted for use for patients over two years of age who are unable to swallow capsules. Hydroxycarbamide (Xromi®) is not recommended for use within NHS Wales outside of this subpopulation.

The Chair confirmed that the final appraisal recommendation would be forwarded electronically to the applicant company after the meeting and a notice of the outcome of the appraisal would be published on the AWMSG website. The company delegates were informed that they had up to ten working days to accept the recommendation or lodge a request for an independent review, the grounds for which should be submitted in accordance with the process for independent review. It was noted that failure to respond within the deadline would not delay the process and the advice would be forwarded to Welsh Government for ratification once the ten day deadline had expired.

The Chair confirmed that the meeting would be locked down. The Chair allowed a ten minute comfort break before re-convening the meeting.

11. Appraisal 3: Limited Submission (PAS)
Belimumab (Benlysta®) as add-on therapy in patients aged 5 years to < 18 years old with active, autoantibody-positive systemic lupus erythematosus with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy

The Chair welcomed the delegates from GlaxoSmithKline

The Chair invited members to declare any interests in either the applicant company or the medicine if they had not already done so. Dr James Coulson declared an interest and confirmed that he had not participated in the appraisal by NMG. He left the meeting.

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. There was limited discussion and no outstanding issues required clarification. The company delegates were invited to address the committee and they welcomed the advice of NMG. Prior to concluding the appraisal the Chair sought confirmation from the company delegates that the process had been fair and transparent. This was received and the Chair closed the appraisal.

The Chair confirmed that the final appraisal recommendation would be forwarded electronically to the applicant company after the meeting and a notice of the outcome of the appraisal would be published on the AWMSG website. The company delegates were informed that they had up to ten working days to accept the recommendation or lodge a request for an independent review the grounds for which should be submitted in accordance with the process for independent review. It was noted that failure to respond within the deadline would not delay the process and the advice would be forwarded to Welsh Government for ratification once the ten day deadline had expired.

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:

Belimumab (Benlysta®) is recommended as an option for restricted use within NHS Wales.

Belimumab (Benlysta®) is licensed as add-on therapy in patients aged 5 years to < 18 years old with active, autoantibody-positive systemic lupus erythematosus with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy.

Belimumab (Benlysta®) is restricted for the treatment of patients who have serological disease activity (defined as positive anti-double-stranded DNA and low complement) and a Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score greater than or equal to 10 despite standard treatment. Belimumab (Benlysta®) treatment should be continued beyond 24 weeks only if the SELENA-SLEDAI score has improved by 4 points or more.

Belimumab (Benlysta®) 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/WPAS price.

The Chair confirmed the date of the next meeting, **on Tuesday, 15th September (via Zoom)** The Chair thanked AWTTC for making the meeting happen and members/observers for their contributions and attendance. The meeting closed.