Enclosure No:	**1/AWMSG/0419**
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 Wednesday, 13th March 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 Iolo Doull	WHSSC & Vice Chair (co-opted)	
2.	Dr Cath Bale	Hospital Consultant	
3.	Dr Jeremy Black	General Practitioner	
4.	Dr Anwen Cope	Other professions eligible to prescribe	
5.	Mr Stuart Davies	Finance Director	
6.	Mr Stefan Fec	Community Pharmacist	
7.	Mr Rob Thomas	ABPI	
8.	Dr Balwinder Bajaj	Clinical Pharmacologist	
9.	Mrs Mandy James	Senior Nurse	
10.	Dr Stephen Monaghan	Public Health Wales	
11.	Mr Cliff Jones	Lay Member	
12.	Mr Stuart Rees	Managed Sector Secondary Care Pharmacist	

In attendance:
Dr James Coulson, NMG Chair
Mrs Karen Samuels, Head of PAMS, AWTTC
Mrs Ruth Lang, Senior Liaison Manager, AWTTC

AWTTC Leads:
Mrs Helen Adams, Senior Pharmacist
Mr Richard Boldero, Senior Pharmacist
Ms Kelly Wood, 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
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
WCPPE	Welsh Centre for Pharmacy Postgraduate Education
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 Stuart Rees to his first meeting.

2. Apologies

Dr Mark Walker, Medical Director
Professor John Watkins, Interim Chair
Mrs Susan Murphy and Mrs Alison Hughes, Senior Primary Care Pharmacist
Professor Dyfrig Hughes, Health Economist

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 were checked for accuracy and approved.

The Chair confirmed that the two appraisals had an associated Patient Access Scheme and would be undertaken in private to protect commercial confidentiality. The Chair confirmed that the meeting would open to the public at the close of the appraisal session.

5. Appraisal 1: Limited Submission (PAS)

Dasatinib (Sprycel®) for the treatment of paediatric patients weighing > 10 kg with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) in chronic phase (Ph+ CML‑CP) or Ph+ CML‑CP resistant or intolerant to prior therapy including imatinib

The Chair welcomed the delegates from Bristol-Myers Squibb Pharmaceuticals Ltd and it was confirmed that individuals remaining seated in the public gallery were staff of AWTTC.

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 minor licence extension to extend in children and anticipated minimal budgetary impact in NHS Wales. Members were informed that dasatinib is available in NHS Wales for adults with an associated Department of Health PAS which would be applied to the paediatric indication. Members were informed that clinical experts highlighted that nilotinib is used infrequently for the treatment of paediatric patients with newly diagnosed Ph+CML-CP and Ph+CML-CP with resistance or intolerance to prior therapy including imatinib. The appraisal lead relayed the view of clinical experts that children presenting in chronic phase CML are currently treated with imatinib first-line; and dasatinib is indicated if patients develop a suboptimal response to imatinib or there is a tyrosine kinase domain mutation.

Dr James Coulson confirmed that NMG supported use of this medicine in NHS Wales for the indication stated. He relayed the view of NMG that the criteria set out in AWMSG's orphan/ultra-orphan/rare disease medicine policy had been met and the medicine had been appraised as an orphan equivalent medicine.

The Chairman referred members to the additional criteria for appraising orphan and ultra-orphan medicines, and medicines developed specifically for rate diseases. He reiterated that where the cost per QALY is above the normal thresholds applied, additional criteria for appraising these medicines would be considered.

The lay members referred members to the two patient organisation submissions from the Chronic Myeloid Leukaemia Support Group and Leukaemia Care. He emphasised the emotional and psychological impact on patients and distress to carers and families. He highlighted the advantage of having a medicine that can be used in both the first and subsequent line of treatment and the tolerable side effect profile. Mr Jones made the point that there is considerable real world and clinical trail data showing the effectiveness of tyrosine kinase inhibitors but some were more manageable to patients than others. Mr Jones stated that patients and clinicians need treatment options which will mitigate emotional and psychological effects and offer hope to patients and families.

The Chair opened discussion in relation to clinical effectiveness. Members discussed the trial data and overall survival and response rates in first line and second line treatment. Members discussed the potential adverse drug reactions. It was noted that the comparator medicine had an associated confidential patient access scheme. The applicant company delegates left the meeting for a short period and AWMSG discussed the budget impact estimates. The applicant company representatives returned and responded to questions posed. Prior to concluding the appraisal the Chair sought confirmation from the company delegates that that the appraisal process had been fair and transparent. The Chair closed the appraisal and confirmed that members would retired to vote in private after the next appraisal.

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:

Dasatinib (Sprycel®) is recommended as an option for use within NHS Wales for the treatment of paediatric patients weighing ≥ 10 kg with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) in chronic phase (Ph+CML-CP) or Ph+CML-CP resistant or intolerant to prior therapy including imatinib.

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. Appraisal 2: Limited Submission (PAS)
Ataluren (Translarna®) for the treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 2 years to 5 years old

The Chair welcomed the representative on behalf of PTC Therapeutics Ltd and it was confirmed that individuals remaining seated in the public gallery were staff of AWTTC.

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. Mrs Adams confirmed that a limited submission had been considered appropriate for a minor paediatric licence extension.

Dr Coulson confirmed that NMG had supported use of Ataluren within NHS Wales for the treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 2 years to less than 5 years and had applied additional criteria to the appraisal of an ultra-orphan medicine in line with AWMSG policy.

The appraisal lead confirmed that the medicine had been recommended by NICE for treating children aged 5 years and older with the nonsense mutation DMD and who can walk and this advice had been adopted in NHS Wales. It was highlighted that the medicine for children aged 5 years and older is currently available in England and Wales under a managed access agreement which includes treatment starting and stopping criteria. The licence extension to include children aged 2 to 5 years had been based on trial resuts which showed a trend favouring treatment compared to historical controls. It was noted that this is the first licensed treatment that targets the underlying disease. Mrs Adams informed members that the EMA had concluded that ataluren offered therapeutic innovation and clinically relevant benefits for a rare disease with high unmet need.

The Chair invited the lay member, Mr Jones, to highlight the issues raised in the patient organisation submissions from the Duchenne Family Support Group and Muscular Dystrophy UK. Mr Jones stated that families struggle to cope and there is a severe emotional impact on children with this disease and members of their family. For children of school age affected by Duchenne muscular dystrophy a significant time is spent attending hospital appointments and children are more likely to have learning and emotional difficulties. Mr Jones highlighted that treatment slows down progression of the disease and keeps a child out of a wheelchair for longer, which is very important for families. Mr Jones drew attention to the strong psychosocial benefits derived from being able to walk for longer, which can impact on interaction with peers, performance at school and overall quality of life and well-being. He reiterated that it is the only treatment which targets the underlying cause, which offers hope for young patients and their family. There was an acknowledged that treatment options are limited and some families opt out of treatment because of serious adverse reactions. The financial burden on the family was also noted.

The Chair opened discussion. Clarification was sought in relation to the collection of data and review to allow for consideration of the outcome data. It was confirmed that the access and exit criteria as set out in the WHSSC policy would be integral to the AWMSG recommendation. Members discussed the key benefits and the variability of the condition was noted. Members considered the adverse reactions and safety information provided and sought clarification of any additional monitoring requirements. It was confirmed that PCT maintains a registry of trial patients and long term data is being captured.

The Chair offered the company represenative opportunity to address the group and it was confirmed the number of patients identified in Wales for this treatment and their current access to ataluren. There were no outstanding issues from the company's perspective. Having received confirmation that the appraisal process had been fair and transparent, the Chair closed the appraisal.

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:

Ataluren (Translarna®) is recommended for use within NHS Wales for the treatment of Duchenne muscular dystrophy (DMD) resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 2 years to less than 5 years.

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.

The meeting opened to the public and announced the two appraisal recommendations.

7. Chair's report (verbal update)
The Chair announced that Welsh Government had ratified AWMSG's recommendations from the meeting held in February. It was confirmed that the applicant companies had been informed and the advice published on the AWMSG website:

Romiplostim (Nplate®) is recommended as an option for use within NHS Wales for the treatment of chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 year to < 18 years who are refractory to other treatments (for example, corticosteroids, immunoglobulins). 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.

Ciclosporin (Verkazia®) is recommended as an option for use within NHS Wales for the treatment of severe vernal keratoconjunctivitis in children from 4 years of age and adolescents (until the age of 18)

The Chair confirmed a number of statements of advice had been published since the previous meeting due to non-engagement by the marketing authorisation holder within the required timescale.

Caplacizumab (Cablivi®) for the treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura, in conjunction with plasma exchange and immunosuppression

Ketotifen (Ketofall®) for the symptomatic treatment of seasonal allergic conjunctivitis

Tocilizumab (RoActemra®) for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 years to < 2 years of age, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. RoActemra can be given as monotherapy (in case of intolerance to methotrexate [MTX] or where treatment with MTX is inappropriate) or in combination with MTX

The appraisals scheduled for the next AWMSG meeting on 10th April 2019 in the Copthorne Hotel, Cardiff were announced:

A limited submission for blinatumomab (Blincyto®) as monotherapy for the treatment of

paediatric patients aged 1 year or older with Philadelphia chromosome negative CD19 positive B-cell precursor ALL which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic haematopoietic stem cell transplantation
Applicant Company: Amgen Ltd

A limited submission for mepolizumab (Nucala®) an add-on treatment for severe refractory eosinophilic asthma in adolescents and children aged 6 years and older
Applicant Company: GlaxoSmithKline

Members were reminded to declare any personal or non-personal interests ahead of the meeting on 13th April 2019.

Patients, patient organisations and patient carers were invited to submit their views on these medicines or contact AWTTC for further information on the appraisal process and future work programme.

8. Therapeutic Priorities and CEPP Summary 2019-2020

The Chair invited Mr Richard Boldero, Senior AWTTC Pharmacist, to present the Therapeutic Priorities and Clinical Effectiveness Prescribing Programme Summary 2019-2020. Mr Boldero explained that the document had been developed by AWTTC to assist Health Boards in the development of their Clinical Effectiveness and Prescribing Programme (CEPP). The document summarises the AWMSG therapeutic priorities for 2019-2020 and highlights opportunities within the CEPP framework where local prescribing initiatives can be undertaken to support these priorities. He informed members that there is an expectation for prescribing initiatives to address a balance of medicines safety, quality and cost-effectiveness. Members were also informed that the CEPP framework consists of two equally weighted elements: prescribing indicators and an educational component. The information provided within the updated document is in a similar format as with previous years, providing additional new resources where relevant. Mr Boldero asked AWMSG members to consider the "Therapeutic Priorities and Clinical Effectiveness Prescribing Programme Summary 2019-2020" for endorsement.

The Chair opened discussion. Mr Stuart Davies asked members how AWMSG could support more rapid implementation of this work to minimise variation in prescribing in health boards and support improvement. Mr Davies asked whether another level of guidance for project work could be considered. One member suggested inclusion of the words "adopt or justify" and acknowledged this approach would require health board chief executive support. A suggestion was made that AWMSG could advise via the minutes and health board executives could pick this up at local level to help drive delivery in these areas. Mr Boldero highlighted the opportunity to share best practice via the AWTTC SHARE communication platform and annual best practice day. The Chair suggested that members feed comments and suggestions into the review of the role and remit of AWMSG.

The Chair confirmed the date of the next meeting on Wednesday, 13th April 2019 in Cardiff