Enclosure No:	**1/AWMSG/0218**
Agenda Item No:	**4** – Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

Minutes of the AWMSG meeting held Wednesday, 6th December 2017 commencing 9.30 am in the Park Inn Hotel, Cardiff North, Circle Way East, Llanedeyrn, Cardiff, CF23 9XF

VOTING MEMBERS PRESENT:

			Did not participate in
1.	Dr Stuart Linton	Chair & Hospital Consultant	
2.	Professor John Watkins	Vice Chair & Consultant in Public Health Medicine	
3.	Dr Catherine Bale	Hospital Consultant	
4.	Dr Jeremy Black	General Practitioner	
5.	Dr Anwen Cope	Healthcare professional eligible to prescribe	
6.	Mr Stuart Davies	Finance Director	
7.	Professor Dyfrig Hughes	Health Economist	
8.	Mrs Ellen Lanham	Community Pharmacist	
9.	Dr Emma Mason	Clinical Pharmacologist	
10.	Mrs Susan Murphy	Managed Sector Primary Care Pharmacist	
11.	Mr Bill Malcolm	ABPI Cymru Wales	
12.	Mr Chris Palmer	Lay Member	
13.	Mr John Terry	Managed Sector Secondary Care Pharmacist	

IN ATTENDANCE:
Mr Anthony Williams, Senior Appraisal Pharmacist, Team Leader, AWTTC
Ms Kath Haines, Head of WAPSU, AWTTC

AWTTC Leads:
Mr Richard Boldero, WAPSU Pharmacist
Dr David Jarrom, Senior Scientist
Mrs Claire Thomas, WAPSU 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
ECDF	English Cancer Drugs Fund
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
MMPB	Medicines Management Programme Board
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 Chairman welcomed members. He confirmed that there was one appraisal to be considered by members.

2. Apologies

Dr Saad Al-Ismail, NMG Chair
Dr Mark Walker, Medical Director
Dr Sian Lewis, WHSSC

3. Declarations of interest

Members were reminded to declare any interests. Professor Dyfrig Hughes declared an interest as a co-investigator in the SYCAMORE trial; the Chairman confirmed that this would not preclude Professor Hughes from participation in appraisal discussion.

4. Minutes of previous meeting

The draft minutes of the previous meeting were checked for accuracy and approved.

5. Chairman's report

The Chairman confirmed Welsh Government ratification of the following AWMSG advice:

Pegvisomant (Somavert) is recommended as an option for use within NHS Wales for the treatment of adult patients with acromegaly who have had an inadequate response to surgery and/or radiation therapy and in whom an appropriate medical treatment with somatostatin analogues did not normalise insulin-like growth factor-1 concentrations or was not tolerated. 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.

Stiripentol (Diacomit) is recommended for use within NHS Wales for use in conjunction with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy whose seizures are not adequately controlled with clobazam and valproate.

In the absence of a submission from the holder of the marketing authorisation, the Chairman confirmed that two statements of advice had been published:

Cariprazine (Reagila) cannot be endorsed for use within NHS Wales for the treatment of schizophrenia in adult patients

Cinacalcet (Mimpara) cannot be endorsed for use within NHS Wales for the treatment of secondary hyperparathyroidism (HPT) in children aged 3 years and older with end stage renal disease (ESRD) on maintenance dialysis therapy in whom secondary HPT is not adequately controlled with standard of care therapy.

The Chairman informed members that a request for an independent review had been received from Abbvie Ltd following the announcement that AWMSG did not recommend the use of levodopa-carbidopa intestinal gel (Duodopa) within NHS Wales for the treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. The Chairman confirmed that a CAPIG meeting would be convened in the New Year.

The Chairman reported that on Tuesday, 23rd January 2018 an independent review panel would be held in relation to the appraisal of afamelanotide (Scenesse) for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria.

The Chairman highlighted a consultation currently ongoing and invited comment on the 'Safe Use of Proton Pump Inhibitors'.

The Chairman reported an AWMSG training day for members and deputies of AWMSG, NMG and AWPAG would be held on 17th January 2018 in Cardiff City Stadium.

The Chairman confirmed that the AWMSG Masterclass held on 22nd November had been well received by pharmaceutical industry delegates.

The appraisals scheduled for the next AWMSG meeting to be held on 14th February 2018 in Cardiff were announced:

Rolapitant (Varuby) 90 mg film-coated tablet for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults. Varuby is given as part of combination therapy.
Applicant Company: TESARO UK Ltd

Lacosamide (Vimpat) 50 mg, 100 mg, 150 mg and 200 mg film-coated tablet for use as an adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in children from ≥ 4 years of age to ≤ 15 years of age with epilepsy.
Applicant Company: UCB Pharma Ltd

Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (Symtuza) 10 mg, 150 mg, 200 mg and 800 mg film-coated tablet for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents (aged 12 years and older with body weight at least 40 kg).
Applicant Company: Janssen-Cilag Ltd

Lopinavir/ritonavir (Kaletra) 20 mg and 80 mg oral solution for use in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected children aged from 14 days to less than 2 years old.
Applicant Company: AbbVie Ltd

The Chairman asked members to contact AWTTC ahead of the next meeting if they had any personal or non-personal interests to declare. Patients, patient organisations and patient carers were invited to submit their views on the medicines to be appraised via the AWMSG website or by contacting Ruth Lang at AWTTC for further information on the appraisal process and future work programme.

6. Appraisal 1: Limited Submission

Adalimumab (Humira) for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate

The Chairman welcomed delegates from Abbvie Ltd.

The Chairman 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 Chairman 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 Chairman informed members that the application had been considered eligible for a limited submission and therefore no cost-effectiveness information is required. He confirmed that for a limited submission the marketing authorisation holder would be expected to provide evidence of budgetary impact in comparison to the existing comparator product/s. The Chairman reiterated 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.

Dr David Jarrom, the AWTTC Appraisal Lead, set the context of the appraisal and relayed the key aspects of the submission. Dr Jarrom highlighted that in October 2016, the One Wales Interim Pathways Commissioning Group recommended off-label adalimumab in Wales for the

treatment of children with severe refractory non-infectious uveitis. As adalimumab now has marketing authorisation to treat children with chronic non-infectious anterior uveitis, this indication is being appraised by AWMSG. Off-label use of adalimumab to treat other types of uveitis will continue to be guided by One Wales advice.

Dr Jarrom confirmed that NMG had appraised adalimumab on Wednesday 1 November 2017, and had recommended adalimumab as an option for use within NHS Wales for the treatment of paediatric chronic non-infectious anterior uveitis in patients from two years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

The Chairman opened discussion in relation to clinical effectiveness. Members sought clarification in relation to the differences between the licensed indications of adalimumab in adults and children, and the implications of AWMSG advice replacing One Wales advice. Dr Jarrom clarified that One Wales advice on adalimumab covers a broader group of patients than the licensed indication; One Wales advice would remain in place for off-label use of adalimumab to treat uveitis.

The Chairman opened discussion in relation to budget impact. It was noted that the budget impact estimates reported in the ASAR do not take into account any current use of adalimumab (due to off-label use in line with One Wales advice) and net budget impact is therefore likely to be lower than that estimated.

The Chairman confirmed that no patient organisation questionnaires had been submitted and Mr Palmer informed members of the organisations that had been approached by AWTTC.

The Chairman referred to the response from Abbvie Ltd to the preliminary recommendation and asked the delegates if they wished to make any closing remarks. The delegates thanked AWMSG for the opportunity to input into the discussion and respond to questions. In concluding, the Chairman thanked the company delegates and, having received confirmation that the appraisal process had been fair and transparent and that all relevant issues had been discussed, the Chairman closed the appraisal.

Appraisal decision subsequently announced in public:
The Chairman 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:

Adalimumab (Humira) is recommended as an option for use within NHS Wales for the treatment of paediatric chronic non-infectious anterior uveitis in patients from two years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

The Chairman 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.

7. AWMSG Five Year Strategy 2018–2023

Dr Rob Bracchi introduced the draft AWMSG Five Year Strategy 2018–2023 and gave an overview of the progress of the document to date. It was stated that the document had undergone a three-week consultation, during which it had received positive feedback from stakeholders and also comments and suggestions, which had been addressed. Dr Bracchi invited comment on the document before it was sent out for a further consultation.

The discussion opened and members thanked Dr Bracchi for his hard work and signalled their

approval of the recommendations made in the strategy.

There was discussion around whether the document should focus on strategic principles or provide a more specific implementation plan; it was felt that a combination of both would be ideal to ensure its delivery. Members highlighted the challenges with producing a five-year document in the changing landscape of the NHS in Wales and aligning it to other organisations' strategies and work streams. The potential change in language from 'prudent healthcare' to a 'value agenda' was raised.

It was noted that ongoing work, such as that for biosimilars and prescribing safety indicators, will feed into a number of the strategic principles. The importance of information sharing in reducing prescribing errors and ADRs was highlighted, and it was suggested that a platform to provide primary and secondary care with access to patients' medical records should be a priority in Wales. Recommendations should align with the 2015 Welsh Government strategy and continue work already underway towards universally accessible information.

The difficulty in separating an adverse event associated with co-morbidity, and an adverse event due to medication was highlighted and it was noted that the intention was to share intelligence rather than apportion blame. Discussion around the effect of working to reduce medication-related admissions highlighted a potential effect on increased coding and subsequent increased visibility over the next five years.

It was agreed that John Terry would supply wording around the appropriate recording of prescribing and administration information, and Dr Bracchi would incorporate wording on significant events and undergraduate teaching.

The Chair thanked members for the valuable discussion and requested that they make suggestions for volunteers to lead on working towards the specific recommendation outcomes.

8. National Prescribing Indicators 2017–2018: Analysis of Prescribing Data to June 2017

Claire Thomas and Richard Boldero presented the June 2017 NPI report for information and highlighted to members the prescribing areas where significant improvements had been made.

Discussion of the biosimilar NPI followed and it was agreed that monitoring of reference and biosimilar costs would continue in order to ensure that the indicator remained fit for purpose.

Kath Haines drew members' attention to the continuing provision of NPI data via SPIRA, and also the forthcoming biosimilar dashboard which is currently being developed. It was stated that a demonstration of SPIRA at a future meeting would be useful.

There was discussion around the increasing use of pregabalin and gabapentin and members commented on some of the drivers for increased prescribing and the lack of options for many patients with pain.

9. Yellow Card Centre (YCC) Wales – 5 year report

Dr Alison Thomas and Alana Adams provided the five-year YCC Wales report to members for information. Members welcomed the report and commented on the significant improvements in reporting over recent years.

There was discussion around variation in reporting between different reporter types and the developments that had contributed to easier reporting.

Members pointed out that receiving feedback from the Yellow Cards submitted had provided additional motivation in the past, and questioned whether there was an option to receive anonymised data on cards submitted to encourage further engagement and reporting, as feedback had ceased since reporting was centralised to the MHRA.

There was discussion of the Yellow Card NPI and it was confirmed that the NPI measure includes reports from the GP practice as a whole.

10. Feedback from AWPAG

Claire Thomas fed back from the AWPAG meeting held on 27 September 2017 outlining the work in progress. There was support for the proposal to produce guidance on glucose monitoring.

The Chairman confirmed the date of the next meeting on Wednesday, 14th February 2018 and closed the meeting.