Enclosure No:	**1/AWMSG/0319**
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 February 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 John Watkins	Interim Chair	
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 Farhan Mughal	ABPI	
8.	Mrs Alison Hughes	Senior Primary Care Pharmacist	
9.	Mrs Louise Williams	Senior Nurse	
10.	Dr Stephen Monaghan	Public Health Wales	
11.	Mr Cliff Jones	Lay Member	
12.	Mr John Terry	Managed Sector Secondary Care Pharmacist	

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

AWTTC Leads:
Mrs Claire Thomas, Senior Pharmacist
Mr Richard Boldero, Senior Pharmacist
Miss Shaila Ahmed, Pharmacist
Mrs Susan Cervetto, Senior Pharmacist

List of Abbreviations:

ABPI	Association of the British Pharmaceutical Industry
ASAR	AWMSG Secretariat Assessment Report
AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
AWTTC	All Wales Therapeutics & Toxicology Centre
BMA	British Medical Association
CAPIG	Clinical and Patient Involvement Group
CEPP	Clinical Effectiveness Prescribing Programme
CHMP	Committee for Medicinal Products for Human Use
DoH	Department of Health
EMA	European Medicines Agency
EMIG	Ethical Medicines Industry Group
EOL	End of life
FAR	Final Appraisal Recommendation
FDA	US Food and Drug Administration
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Board
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 Mr Cliff Jones to his first AWMSG meeting in the capacity of lay member.

2. Apologies

Dr Mark Walker, Medical Director
Dr Balwinder Bajaj, Clinical Pharmacologist
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 first appraisal 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.

5. Appraisal 1: Limited Submission (PAS)

Romiplostim (Nplate®) for the treatment of chronic immune (idiopathic) thrombocytopenic purpura patients aged 1 year to < 18 years who are refractory to other treatments

The Chair welcomed the Senior Medical Adviser from Amgen 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 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 application met the criteria for a limited submission for a paediatric license extension. Members were informed that NICE TA 221 published in April 2011 and updated in October 2018 recommended romiplostim (Nplate®) as an option for treating chronic immune (idiopathic) thrombocytopenic purpura in adults, only if their condition is refractory to standard active treatments and rescue therapies, or they have severe disease and a high risk of bleeding that needs frequent courses of rescue therapies. It was reiterated that this medicine is only available in circumstances when the patient access scheme (PAS) is applied. The applicant company delegate left the meeting whilst the appraisal lead informed members of the cost of the comparator medicine which also had an associated PAS. The company delegate re-joined the meeting after the confidential information had been disclosed to members. It was confirmed that the appraisal would apply to the 125 micrograms powder vial and solvent for solution for sub-cutaneous injection for the paediatric indication. It was noted that SMC had recommended romiplostim (Nplate®) for restricted use within NHS Scotland.

Members were informed that NMG had supported use of romiplostim (Nplate®) 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). NMG advised that a positive recommendation should apply only in circumstances where the approved PAS is utilised or where the list/contract price is equivalent or lower than the PAS price. NMG considered that romiplostim (Nplate®) satisfied the AWMSG criteria for orphan status. The NMG Chair briefly summarised the rationale for the positive recommendation by NMG.

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 Chair reminded members that the criteria for appraising an orphan medicine should be applied and referred to the policy on the meeting table.

The appraisal lead relayed the expert opinion received by AWTTC and confirmed that the estimated number of patients in the submission was similar to that of the experts. Experts indicated that romiplostim (Nplate®) was likely to only be used on children who had failed eltrombobag unless there was a significant drop in price.

The Chair opened discussion in relation to clinical effectiveness. Clarification was sought in relation to the vial sizes and differences in cost. Members noted the different routes of administration of the medicine and the comparator product. The company delegate highlighted the importance of choice of treatment for the clinician and patient. The lay member confirmed that no patient views had been submitted and there were no outstanding societal issues of note.

The Chair offered the company delegate opportunity to address the group. 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 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:

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.

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.

6. Chair's report (verbal update)

The Chair announced that Welsh Government had ratified AWMSG's recommendations from the meeting held in December. It was confirmed that the applicant companies had been informed and the advice published on the AWMSG website:

Brivaracetam (Briviact®) is recommended as an option for restricted use within NHS Wales. Brivaracetam (Briviact®) should be restricted for use in the treatment of patients with refractory epilepsy, who remain uncontrolled with, or are intolerant to, other adjunctive anti-epileptic medicines, within its licensed indication as adjunctive therapy in the treatment of partial-onset seizures (POS) with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy. Brivaracetam (Briviact®) is not recommended for use within NHS Wales outside of this subpopulation.

Dolutegravir/rilpivirine (Juluca®) is recommended as an option for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA < 50 copies/ml) on a stable antiretroviral regimen for at least six months with no history of virological failure and no known or suspected resistance to any nonnucleoside reverse transcriptase inhibitor or integrase inhibitor. 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.

The Chair reported the annual training day for members and deputies of AWMSG and its sub-groups had been held on 16th January in Cardiff City Stadium. The Chair extended his thanks to delegates and organizers, particularly Professor Karl Claxton for his excellent presentation highlighting the implications to decision making. Members were informed that the interactive sessions run by Professor Dyfrig Hughes and his team and Professor Chris Burton had been well received.

The Chair reported that the role of AWMSG in supporting the future delivery of Welsh Government and NHS Wales' priorities would be reviewed. The implications of this in relation to the role of the Chair were noted.

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.

Allopurinol/lesinurad (Duzallo®) for the treatment of hyperuricaemia in gout patients who have not achieved target serum uric acid levels with an adequate dose of allopurinol alone

Brexpiprazole (Rexulti®) for the treatment of schizophrenia in adult patients

Glibenclamide (Amglidia®) for the treatment of neonatal diabetes mellitus, for use in newborns, infants and children

Tocilizumab (RoActemra®) for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and paediatric patients 2 years of age and older

The appraisals scheduled for the next AWMSG meeting on 13th March 2019 in the Copthorne Hotel, Cardiff were announced:

A limited submission for 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
Applicant Company: Bristol-Myers Squibb Pharmaceuticals Ltd

A limited submission for 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 less than 5 years
Applicant Company: PTC Therapeutics Ltd

Members were reminded to declare any personal or non-personal interests.

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.

7. Appraisal 2: Full Submission

Ciclosporin (Verkazia®) for the treatment of severe vernal keratoconjunctivitis in children from 4 years of age and adolescents (until the age of 18)

The Chair welcomed delegates from Santen UK Ltd

The Chair invited members to declare any interests in either the applicant company or the medicine. 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 appraisal and invited the AWTTC appraisal lead to address the group.

The appraisal lead provided an overview of the submission as outlined in the ASAR. Members were informed that ciclosporin (Verkazia®) is the first licensed topical ciclosporin formulation for this indication and the new therapeutic indication was approved under the accelerated EMA assessment scheme. The appraisal lead stated that Verkazia® is licensed for children and adolescents until the age of 18 for the treatment of severe vernal keratoconjunctivitis. Members were informed that Ikervis® 1mg/ml has an identical formulation to Verkazia® and was approved by NICE in 2015 for the treatment of severe keratitis in adults with dry eye disease. It was noted that Ikervis® used as a third line treatment option after topical steroids, is available in NHS England via a commissioning policy. Members were informed that clinical experts highlighted an unmet clinical need. The point was made that in clinical practice, unlicensed and off-label ciclosporin products have been used to treat vernal keratoconjunctivitis for many years. Members were informed that ciclosporin (Verkazia®) was accepted for use by SMC in December 2018 for the indication under appraisal.

Dr Coulson confirmed that following appraisal on Wednesday 9th January 2019, NMG supported ciclosporin (Verkazia®) 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). NMG considered that ciclosporin (Verkazia®) satisfied the AWMSG criteria for orphan status. Dr Coulson confirmed that the CMA approach was not ideal; however the assumed equivalence was accepted by NMG given the absence of well-designed equivalence studies. NMG took into account the importance of having a licensed product available for the indication under consideration.

The Chair reminded members to apply the additional criteria for appraising an orphan medicine and opened up the appraisal discussions.

Clarification was sought in relation to the treatment regimen of Verkazia®. It was noted that the SPC states the dose can be decreased to one drop twice daily once adequate control of signs and symptoms is achieved. CHMP noted that a twice daily regimen would be more convenient for school children. The appraisal lead relayed the view of clinical experts who indicated that off-label Ikervis® is most frequently used in Wales as a steroid sparing agent. She highlighted the dose of Ikervis® would be one or two drops a day which is less than the licensed dose of Verkazia®. It was noted that the company anticipates that Verkazia® would be used in place of off-label and unlicensed ciclosporin. Clarification was sought in relation to post-marketing surveillance.

In the absence of Professor Hughes the Chair invited the AWTTC health economist to highlight the salient aspects of case for cost-effectiveness as outlined in the ASAR. The Chair referred

members to the budget impact estimates. It was noted that clinical experts anticipated that prescribing might increase with the availability of a licensed medicine. The company delegate assured members that their projections had been accurate in other markets.

Mr Jones confirmed that AWTTC had invited views from five patient organisations but no responses had been received. He highlighted the advantages to society in having children attending school and parents attending work and the positive impact on the quality of life of family members. Mr Jones reiterated the importance of having a licensed treatment available to manage this rare and debilitating illness.

The Chair offered the company delegates opportunity to address the group. 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:

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 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 ratification process.

8. All Wales COPD Management and Prescribing Guide

The Chair confirmed that the project lead, Dr Simon Barry, had been unable to attend the meeting to present this work. The Chair invited Mr Rhys Jefferies, Programme Manager for the Respiratory Delivery Plan, and Mr Richard Boldero from AWTTC to present the All Wales COPD Management and Prescribing Guide to AWMSG for endorsement.

Members were informed that the project aims to reduce variation in inhaler prescribing - several health board audits showed that there is wide variation in inhaler prescribing between different practices despite similar prevalence of chronic obstructive pulmonary disease (COPD). Mr Boldero stated that a number of health boards have produced local guidelines for COPD management and it was agreed by the Respiratory Health Implementation Group (RHIG) that an All Wales guideline would be helpful to ensure consistency in approach. An online interactive pathway is also in development and will be available via an app using mobile devices.

Members were informed that the guidelines are pertinent to the following recommendations made in the AWMSG Five-year Strategy 2018–2023:

- 2.1 Workforce development
- 4.2 Nationally available medicines list
- 4.3 Improving prescribing and medicines optimisation within NHS Wales
- 4.8 Using data to improve patient outcomes

Members were provided with the background to the development of the document and it was confirmed that a consultation had been undertaken in October 2018. Mr Boldero confirmed that consultation responses had been passed to the authors for consideration and action.

The Chair opened discussion. The ABPI representative asked for an amendment to the wording in the graphical illustration to "below are examples of options in this category". It was

confirmed that the app will be available for healthcare professionals. Mr Jeffries confirmed that the guideline would be integrated in the Welsh Clinical portal. Members sought clarification as to when the app would be available. Members discussed the need for review, given the rapidly changing clinical landscape. Mr Boldero confirmed that the responsibility for review would lie with the authors and any amendments to the document would require approval from AWPAG and potentially AWMSG, depending on the nature of the amendment. The GP member questioned the introduction of a new classification system as he considered this might cause confusion amongst GPs. The issue of congruence with other guidelines was raised. It was suggested that more information could be provided on the alternative referral pathways prior to prescribing inhaler therapy, and the final stage of annual review. The Chair made the point that the clinical lead was not in attendance to respond to the issues highlighted. The Chair acknowledged there was support amongst members for the consistent approach to reduce variability and improve the care for patients with COPD. The Chair confirmed AWMSG support for a value-based healthcare approach and prudent use of medications. The Chair stated that work needed to be done to address the outstanding issues before he could confirm AWMSG's endorsement of the guidelines. He agreed to take Chairman's action when these issues had been addressed.

9. Feedback from All Wales Prescribing Advisory Group meeting held 5th December 2018

Mrs Louise Howard-Baker presented the draft minutes of the AWMSG meeting held on 5th December 2018. She highlighted work currently on-going and confirmed that a number of projects considered by AWPAG in December were being presented to AWMSG today with more in the pipeline. Mrs Howard-Baker acknowledged the contribution of Dr Sue Jeffs, the AWPAG Vice Chair, who had recently stepped down and resigned from the Group. The Chair opened discussion and clarification was sought in relation to the process for updating documents post endorsement. There were no other issues of note. The Chair expressed his thanks to Dr Jeffs on behalf of AWMSG.

10. National Prescribing Indicators 2018–2019 Analysis of Prescribing Data to Sept 2018

The Chair invited Mr Richard Boldero and Mrs Claire Thomas from WAPSU to present the analysis of the National Prescribing Indicator data to September 2018. Members were informed the report contains data for the second quarter of 2018–2019. Mrs Thomas clarified the report had been categorized in line with the NPIs: Safety, Stewardship or Efficiency. Mrs Thomas summarised the four safety indicators – Prescribing Safety Indicators, prescribing of hypnotics and anxiolytics; analgesics and Yellow Card reporting. It was noted that the Prescribing Safety Indicators are new for 2018–2019 and no targets had been set. Members were informed the data would be used for benchmarking. Mrs Thomas highlighted the key points of note:

- Hypnotic and anxiolytic prescribing, tramadol, and use of opioid patches all showed a reduction in prescribing, compared with the equivalent quarter of 2017–2018, which is in line with the aim of these indicators.
- Prescribing of gabapentin and pregabalin continues to increase with 5.19% increase across Wales, compared with the equivalent quarter of the previous year, despite the aim of the indicator being to reduce prescribing.
- Yellow Card reporting now includes measures and targets for secondary care and member of the public reports, as well as GP and health board reports. The aim of the indicator is to encourage reporting. Across Wales, there was a small increase of 2% in GP practice reports, compared with the equivalent quarter of 2017–2018, which equates to 9 additional reports.
- There was a reduction in reports received from secondary care, members of the public and health boards across Wales, compared with the equivalent quarter of 2017–2018.

Members were informed the stewardship indicators focus on antimicrobial prescribing, with the aim of reducing inappropriate prescribing and variation in primary care, and encouraging appropriate antimicrobial prophylaxis for colorectal surgical patients in secondary care. Mrs

Thomas highlighted the key points of note:

- A specific target has been introduced for total volume of antibacterial prescribing in primary care for health boards. This is a 5% reduction, compared with the equivalent quarter of 2016–2017. Six out of the seven health boards achieved the target.
- Prescribing of co-amoxiclav, cephalosporins, fluoroquinolones and clindamycin, together known as the 4Cs, reduced across Wales, in line with the aim of the indicator.
- For the percentage of elective colorectal surgical patients receiving a single dose antimicrobial for surgical prophylaxis, two health boards achieved the target of 90% or greater, or a proportional increase of 20%, compared with the equivalent quarter of the previous year.

Mr Boldero summarised the efficiency National Prescribing Indicators and highlighted the key points:

- For the proton pump inhibitors (PPI) indicator the unit of measure is defined daily doses (DDDs) per 1000 prescribing units. Across Wales, for the quarter ending September 2018, PPI DDDs per 1,000 prescribing units decreased by 4.32%, compared with the equivalent quarter of the previous year, in line with the aim of this indicator.

- For the insulin NPI, which measures the quantity of long acting insulin analogues as a percentage of the total long-acting and intermediate acting insulin prescribed, when compared to the equivalent quarter of the previous year: In secondary care there was a percentage change decrease of 2.37%, to 74.3%. In primary care there was a decrease of 0.68%, to 87.9%. Both of which are in keeping with the aim of the NPI.

- For the biosimilars NPI the unit of measure is the quantity of biosimilar medicines prescribed as a percentage of the total reference biologic product plus biosimilar product. There are currently three biological medicines being monitored for their biosimilar usage; etanercept, infliximab and rituximab. In comparison to the equivalent quarter of the previous year there were increases to 84%, 94% and 96% respectively, in line with the aim of the NPI.

- For the basket of biological medicines combined, when compared to the equivalent quarter of the previous year, there was an overall increase from 54% to 87% in the use of the biosimilar products.

It was confirmed the next report for the third quarter of 2018–2019 will include data for the trastuzumab and adalimumab biosimilars.

Mrs Thomas confirmed that best practice initiatives to support medicines optimisation can be posted on AWTTC's SHARE online community. Mrs Samuels confirmed that in the future AWTTC would be providing individual health board specific reports on an annual basis.

Dr Cath Bale and Mr Stuart Davies left the meeting.

11. National Prescribing Indicators 2019–2020

12. National Prescribing Indicators 2019–2020: Supporting Information for Prescribers and Healthcare Professionals

The Chair clarified that agenda item 11 and 12 would be considered together and that members were being asked to endorse the National Prescribing Indicators for 2019-2020 and

Supporting Information for Prescribers and Healthcare Professionals.

Members were informed the main document sets out the background, evidence and prescribing data for each indicator. The Supporting Information for Prescribers and Healthcare Professionals document provides a summary, includes links to useful resources and acts as a 'quick reference guide'.

Mrs Thomas confirmed the process by which the National Prescribing Indicators had been developed and highlighted the key changes:

1. The indicator for opioid patches in primary care is proposed for retirement, this will be replaced by an opioid burden indicator which will monitor the average daily quantities of opioids prescribed, per 1,000 patients.
2. The indicator for co-amoxiclav, cephalosporins, fluoroquinolones and clindamycin, together known as the 4Cs, will be reported as items per 1,000 patients only. 4C items as a percentage of total antibacterial items will be retired as it was not providing an accurate reflection of prescribing for very low or very high prescribers of antibiotics overall.
3. The indicator for antimicrobial prophylaxis in colorectal surgery will be retired due to the low patient numbers being reported on and the limited value this provides.
4. Sodium valproate prescribing in females of child bearing age will be included in the suite of Prescribing Safety Indicators, due to the risk of malformations and developmental disorders in babies exposed to sodium valproate in the womb.
5. The indicator for proton pump inhibitors will move from the efficiency section to the safety section, due to the safety concerns regarding long term use.

Mr Boldero confirmed that there are no new proposals for a secondary care based National Prescribing Indicator for 2019–2020 and the main NPI for secondary care will continue to be Biosimilars. Members were informed the same basket of biosimilar medicines will be used in quarters 3 and 4 of 2018–2019; infliximab, etanercept, rituximab, trastuzumab and adalimumab.

The ABPI representative asked if the wording of the biosimilar indicator could be amended and Mrs Samuels asked for him to email the suggested wording to AWTTC for consideration. There were no other issues of note and the Chairman confirmed AWMSG's endorsement.

13. Mental Health Medicines in Older Adults – the ADRe Profile

Mental Health Medicines in Older Adults – the ADRe Profile

Professor Sue Jordan from Swansea University and Dr Alan Willson, Senior Research Officer, Public Health, Policy and Social Sciences at Swansea University introduced themselves and presented Enclosure 9 'Mental health medicines in older adults: the Adverse Drug Reaction (ADRe) Profile to check patients for signs and symptoms of adverse effects'.

Professor Jordan explained that ADRe had been developed in care homes and community mental health teams and a trial of one hundred and twenty before and after observations had been published. The principle aim is to capture data for the attention of carers and health professionals to enable the monitoring of side effects and trigger actions by the carer or health professional. Professor Jordan proposed that the approach could be extended across primary care or to long-stay or rehabilitation units in secondary care. Professor Jordan summarised the potential impact of introducing this approach across other care settings and confirmed the aim of the project is to reduce antipsychotic and sedative prescribing in older adults and comply with recommendations to reduce antipsychotic prescribing in older people set by the Medicines and Healthcare products Regulatory Agency, the Dementia Challenge England, the Older People's Commissioner and the National Assembly for Wales. Professor Jordan asked AWMSG to support the proposal and assist with the dissemination of ADRe information.

The Chair opened discussion. There was discussion in relation to the time required to compile the information and Professor Jordan confirmed than on average this took 10-20 minutes. There were questions in relation to the level of staff completing the form and Professor Jordan confirmed that in some cases an unqualified member of staff would complete the form and it would be checked by a qualified member of staff. There was general acknowledgement amongst members that ADRe was a comprehensive and useful document. A comment was made that it was a good tool for people caring for patients as it would give confidence to carers who monitor side effects. Dr Willson acknowledged that work needed to be done to identify how the model could fit into local processes and procedures. He stated that such conversations regarding the refinement and adjustment of the tool to fit particular settings were currently on-going. The nurse representative suggested that the authors link with the Chief Nursing Officer and Nurse Directors with regard to the electronic collation of documentation and information. A suggestion was made to include the patient perspective to support the principle of joint decision making.

Noting the concerns expressed in relation to data capture and the time taken to complete the form, the Chair confirmed that ADRe was an example of good practice. He stated that bringing a lot of information to the attention of carers, nursing staff and health professionals to effect change is important and is supported by AWMSG. There was general agreement that a pilot of the work outside the care home setting might answer some of the outstanding issues and it was noted that the Assistant Medical Directors Peer Group had offered help and support with this.

The Chairman confirmed AWMSG's support of the tool as an example of good practice and wished Professor Jordan and Dr Willson well with the pilot of ADRe in a real world primary and community care setting. He thanked Professor Jordan and Dr Willson for attending the meeting.

14. Making Choices Together

Dr Bracchi confirmed the final two agenda items were being presented to AWMSG for 'acknowledgement'. He informed members that the new acknowledgement process had been introduced for resources that had already received endorsement or recognition by a national organisation and where the resource has been considered to deliver one or more of the recommendations of the Medicines Strategy and has been supported by AWPAG. This process allows AWMSG to acknowledge and promote the work via the AWMSG website.

Dr Bracchi highlighted recommendation 1.2 of the Medicines Strategy that "involvement of the public and patients is essential in addressing the problem of medicines waste in primary and secondary care". Dr Bracchi confirmed that this project had been presented to PAPIG at a recent meeting, and there had been unanimous support for the campaign. Dr Bracchi had been asked to relay PAPIG's support to AWMSG.

The Chair invited Dr Paul Myres the project lead to provide an overview of the initiative 'Making Choices Together'.

Making Choices Together part of the Choosing Wisely Wales Partnership is the Welsh arm of an international movement promoting wise choices in healthcare with a particular focus on shared decision-making. Making Choices Together aims to:

- Embed a broad culture change in healthcare where clinicians and patients regularly discuss the value of treatments and make shared decisions.
- Ensure reliable and valid information is available for patients and clinicians regarding agreed interventions of low value i.e. where there is a low chance of a beneficial outcome.
- Enable participating professional health organisations, such as the health professional colleges and societies, to produce, with patients, lists of commonly used treatments/interventions whose necessity should be questioned.

- Encourage local clinical teams to use shared decision-making skills in consultations, and adopt or select locally relevant interventions, of low value, to concentrate on when applying shared decision making.
- Reduce harm to patients caused by inappropriate use of tests or interventions.

The Chair confirmed AWMSG's acknowledgement of this project.

15. Your Medicines Your Health (YMYH)

Dr Bracchi reiterated the commitment in AWMSG's medicines strategy to work in partnership with patients and the public. Members were informed that PAPIG supported the ongoing Medicines Waste Campaign and asked that their support be relayed to AWMSG.

The Chair invited Mr Martin Davies, Chief Pharmacist, Community Hospital, Intermediate Care and Mental Health Services at Cwm Taf Health Board and project lead, Clinical Lead, to provide an overview of the 'Your Medicines Your Health' Bevan exemplar project.

Mr Davies informed members that the YMYH team provides a public education programme about the benefits of safe and effective use, storage and disposal of medicines. The campaign centres around advertising and promotional material, personal talks and presentations, using simple messages and giving people easy actions that they can take to improve their medicines management. The key message being "take them if you can, tell us if you can't." It provides an education teaching pack for year 5/6 primary school children delivered by the school nurses in conjunction with the local creative artists. The education programme can be accessed by anyone at any age who lives in Wales or is registered to a Welsh GP practice and it is for individuals, organised groups, schools and voluntary sector organisations.

The Chair confirmed AWMSG's acknowledgement of this project.

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