

Enclosure No:	<b>1/AWMSG/0221</b>
Agenda Item No:	<b>1 – Minutes of previous meeting</b>
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## **ALL WALES MEDICINES STRATEGY GROUP (AWMSG)**

### **Minutes of the AWMSG meeting held 9.30 am Tuesday, 8<sup>th</sup> December 2020 (via Zoom)**

#### **VOTING MEMBERS PRESENT:**

Did not  
participate in

- |            |                              |   |
|------------|------------------------------|---|
| <b>1.</b>  | <b>Prof Ceri Phillips</b>    | <b>Chair</b>  |
| <b>2.</b>  | <b>Prof Stephen Monaghan</b> | <b>Consultant in Public Health Medicine</b>                                       |
| <b>3.</b>  | <b>Prof Iolo Doull</b>       | <b>Welsh Health Specialised Services Commission</b>                               |
| <b>4.</b>  | <b>Prof Dyfrig Hughes</b>    | <b>Health Economist</b>   |
| <b>5.</b>  | <b>Ms Kate Parrish</b>       | <b>ABPI (Wales)</b>   |
| <b>6.</b>  | <b>Mr Cliff Jones</b>        | <b>Lay Member</b>   |
| <b>7.</b>  | <b>Mr Stefan Fec</b>         | <b>Community Pharmacist</b>   |
| <b>8.</b>  | <b>Dr Jeremy Black</b>       | <b>GP with Prescribing Lead role</b>  |
| <b>9.</b>  | <b>Mrs Alison Hughes</b>     | <b>Senior Primary Care Pharmacist</b>   |
| <b>10.</b> | <b>Mr Hywel Pullen</b>       | <b>Finance Director</b>   |
| <b>11.</b> | <b>Mr John Terry</b>         | <b>Managed Sector Secondary Care Pharmacist</b>                                   |
| <b>12.</b> | <b>Mrs Mandy James</b>       | <b>Senior Nurse</b>   |
| <b>13.</b> | <b>Mr Aled Falvey</b>        | <b>Other healthcare professions eligible to prescribe not already represented</b> |
| <b>14.</b> | <b>Dr Alison Thomas</b>      | <b>Clinical Pharmacologist</b>  |

#### **Welsh Government:**

Mrs Lynne Schofield

#### **AWTTC staff:**

Ms Kath Haines, Head of WAPSU  
Mrs Karen Samuels, Programme Director  
Mr Richard Boldero, Senior Pharmacist  
Mrs Claire Thomas, Senior Pharmacist  
Mr Paul Deslandes, Senior Pharmacist

Mrs Kelly Wood, Senior Scientist  
 Dr Alice Varnava, Medical Writer  
 Dr Thomas Curran, Senior Scientist  
 Mrs Claire Ganderton, Senior Pharmacist  
 Dr Sara Pickett, Principal Health Economist  
 Professor Deborah Fitzsimmons, Health Economist (Swansea University)  
 Professor Pippa Anderson, Health Economist (Swansea University)  
 Dr Robert Bracchi, Medical Advisor  
 Mrs Ruth Lang, Senior Liaison Manager  
 Ms Laura Taylor, Administration Supervisor

### 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 Assessment 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

**1. Welcome and introduction**

The Chair opened the meeting and welcomed observers and members. He introduced Richard Evans, Executive Medical Director and Judith Vincent, Clinical Director Pharmacy, as the nominated representatives from Swansea Bay UHB Board's Executive team. He acknowledged the severe pressures facing Swansea Bay with the increased number of people testing positive with coronavirus and welcomed the implementation of the Pfizer vaccine programme.

The Chair confirmed the same protocols and procedures that exist for a 'normal' AWMSG meeting would be applied to the 'virtual' meeting and confirmed that nine voting members constituted a quorum.

**2. Apologies:**

Dr Jim McGuigan - Medical Director  
Dr Balwinder Bajaj - Clinical Pharmacologist

**3. Declarations of interest**

There were no declarations of interest pertinent to the agenda.  
No declarations.

**4. Minutes of previous meeting**

The draft minutes of the previous meeting held on 11<sup>th</sup> November 2020 were checked for accuracy. With the amendment of one typographical error, the minutes were approved.

**5. Chairman's report (verbal update)**

The Chair confirmed that the advice announced at the previous meeting following the appraisal of darunavir/cobicistat (Rezolsta<sup>®</sup>) had been ratified by Welsh Government, disseminated to service and published on the AWMSG website.

The Chair confirmed that a consultation on 'Material to Support Appropriate Prescribing of Hypnotics and Anxiolytics' and a NICE methods consultation had been circulated to members for comment.

The Chair announced an AWMSG/AWTTC Open Day to be held on 15<sup>th</sup> December for the pharmaceutical industry. He encouraged ongoing collaboration with the pharmaceutical industry and confirmed he met regularly with representatives of ABPI Cymru Wales. The Chair confirmed that a series of open days and workshops would be available so that the engagement and collaboration between AWMSG/AWTTC and the pharmaceutical industry might be fostered.

The Chair confirmed the annual training event will go ahead in January 2021 and reiterated that it was not too late to get topic suggestions to AWTTTC. He confirmed a session on health economics had been arranged

The Chair confirmed that a meeting of CAPIG will be convened in the New Year to explore, in more detail, the clinical and patient issues in relation to idebenone (Raxone<sup>®</sup>) for the treatment of visual impairment in adolescent and adult patients with Leber's hereditary optic neuropathy, prior to the appraisal by AWMSG.

Mrs Samuels confirmed the appraisals scheduled for the next AWMSG virtual meeting on Tuesday, <sup>th</sup> February 2021 at 9.30 am:

Melatonin (Slenyto<sup>®</sup>) for the treatment of insomnia in children and adolescents aged 2-18

with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome (SMS), where sleep hygiene measures have been insufficient  
A full resubmission with a WPAS by Flynn Pharma Ltd

Dupilumab (Dupixent®) for the treatment of severe atopic dermatitis in children 6 to 11 years old who are candidates for systemic therapy  
A limited submission with a PAS by Sanofi-Aventis

Opicapone (Ongentys®) as adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCIs) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations  
A full submission with a WPAS by Bial - Portela C SA

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

## **6. AWMSG Work Programme**

Mrs Lang invited colleagues to share with members work recently undertaken or currently on-going within AWTTTC.

Dr Alice Varnava introduced herself as a medical writer and the AWTTTC lead for the AWMSG 2019-2020 annual report. Members were informed that AWTTTC had been supported by a newly appointed C&V UHB Communication and Engagement Officer who had introduced more visuals and infographics into the report. Dr Varnava highlighted the move towards a bi-lingual digital-only report and summarised the content. Dr Varnava confirmed that the English and Welsh versions of the report are available on the AWMSG website.

Ms Kelly Wood introduced herself as a senior scientist within AWTTTC and the Welsh Language lead within the organisation. Ms Wood provided an outline of the progress made to date with the implementation of the Welsh language standards and gave a brief overview of the Welsh language objectives for the next 3-6 months. Ms Wood drew attention to the AWTTTC Welsh and English Twitter accounts @AWTTTCymraeg / @AWTTTCcomms and the recently launched bilingual AWMSG website. Members were informed that the Communication and Engagement Strategy currently in development will include bilingual communication.

Dr Tom Curran introduced himself as the AWTTTC's lead for the development of a Medicines Optimisation Framework. He summarised the scope of the project and explained that development of the framework had been prioritised within the AWTTTC work programme as a result of the gradually increasing workload within the AWTTTC Medicines Optimisation workstream, and in order to improve clarity of process and transparency in relation to how resources are developed. It was confirmed that new project submissions would continue to be welcomed from all sources including the pharmaceutical industry and members of the public; all project proposals will be considered on a case-by-case basis and should link with the AWMSG Medicines Strategy for Wales. Clarity was sought on how AWMSG-endorsed resources would be expected to be used when there is existing guidance that has been developed by other national bodies, and whether use of AWMSG-endorsed guidance was going to be enforced in any way. Dr Curran responded by confirming this information will be provided in the framework document.

The Chair made the point that it will be important to maintain the flexibility and reactivity

that AWTTTC has demonstrated during the COVID-19 pandemic. Mrs Samuels reassured the Chair that AWTTTC will continue to be agile in responding to the needs of the service. A suggestion was made to include specific examples of different categories of resources within the Framework document to help the reader differentiate between the different types of resources. Dr Curran confirmed that a full draft of the Framework document is planned to go out for consultation around January–February 2021.

The Chair thanked AWTTTC for developing the paper and for providing clarity in relation to resources that will be developed and utilised by prescribers. The Chair reiterated the importance of All-Wales guidance as it takes into consideration the Welsh perspective and clinical context which might be different to other parts of the UK. The absence of involvement from Wales in the development of NICE prescribing guidance was noted. The Chair sought clarification that the issue of equality was taken into consideration in the development of AWMSG resources and Dr Curran and Ms Wood confirmed that an equality working group had been formed within AWTTTC to take forward the equality agenda.

**7. National Prescribing Indicators 2020-21: Analysis of prescribing data to June 2020**

Mrs Claire Thomas provided a summary of the prescribing data covering the period April to June 2020. The Chair made the point that the document is rich in terms of data and should be used to interrogate and assess prescribing and support health boards in seeking to improve performance. The Chair acknowledged that underlying issues may need to be taken into consideration when scrutinizing the data and called for health boards to work with AWMSG and AWTTTC to ensure that medicines are used more effectively and efficiently going forward. The trend in antibiotic prescribing during the pandemic was noted; the point was made that the report should not be considered in isolation. The Chair acknowledged it was a good starting point for discussion and encouraged health boards to liaise closely with AWMSG/AWTTTC so that appropriate tools and resources can be developed to drive improvement.

**8. Discussions with Swansea Bay University Health Board**

The Chair thanked Dr Richard Evans and Ms Judith Vincent for attending the meeting. He acknowledged the pressures in Swansea Bay and explained that AWMSG wants to work with individual health boards to enhance the health of the Welsh population and consider the inequalities agenda. Dr Evans acknowledged the important work of AWMSG in addressing issues of variation and made the point that prescribing in all its forms is integral to high quality care. He made reference to the increase in infection rates during the coronavirus pandemic and welcomed local information which will enable the health board to start conversations and address the issues. Dr Evans referred to changes in prescribing and informed members that he is keen to understand what is driving the prescribing and take into account a whole system approach. He informed members that Swansea Bay is working with Sally Lewis and the Values Team to develop the whole system approach and link data to health outcomes. Members were informed that a new Chief Executive will be joining Swansea Bay in the New Year and he is interested in population health and the equality agenda. There was agreement that work needs to be done to address inequalities and look at disease prevalence linked to inequalities to ensure that resources are adequately deployed across the health board. The Chair agreed that it is important to make AWMSG members aware of local health board issues and for AWTTTC to continue this dialogue outside of the meeting. The Chair confirmed that the inequalities agenda is a priority for Welsh Government and he is keen to make strides in this direction.

Ms Vincent made the point that the data is the starting point which enables performance to be compared across health boards; she would like to see what interventions had an impact in prescribing in other areas by sharing case studies and working in a mutually involved way.

Ms Vincent said that she would welcome measures across pathways instead of primary and

secondary care; a whole-system measurement to understand the role of medicines across the system. It was noted that some of the information is only available at a local level. Ms Haines made the point that WAPSU is working with Sally Lewis to link values and outcomes to the data and confirmed that AWTTTC is committed to working with the Directors of Finance and All Wales Chief Pharmacists in moving this agenda forward. There was discussion in relation to sharing best practice and Ms Haines confirmed that AWTTTC will be hosting a number of best practice sessions starting in February 2021. Ms Haines informed members that she will be asking health boards to submit examples of best practice to showcase. The point was made that the highest areas of prescribing will be in the highest deprivation areas and traction in the areas of greatest deprivation is required to identify what will change prescribing practice in these areas. Mrs Samuels made the point that the AWTTTC SHARE communication platform is currently under-utilized and needs to be an active space for the function of sharing best practice. The system and technology is in place; the intelligence and case studies from colleagues are invited so that AWMSG and AWTTTC can share and raise awareness.

The Chair wished Swansea Bay HB well in the management of the Covid-19 vaccine roll out and thanked Dr Evans and Ms Vincent again for attending the meeting.

#### **Actions**

**AWTTTC to continue dialogue with Swansea Bay Health Board and follow up the discussion**

**9. Delivering Value Through Disinvestment: An exploration and analysis of appropriate disinvestment in medicines considered Low Value for Funding by NHS Wales (follow-on from previous meeting)**

Mr Boldero provided a brief summary and the Chair thanked members for submitting comments following discussion of this document at the previous AWMSG meeting. A document listing the comments received was provided to members. There was broad support for the proposal to introduce a process for reallocating valuable resources for investing in new clinically-effective and cost-effective medicine. There was an appreciation that it may be difficult for a disinvestment process to be accepted by some patients and there would be a need to provide prescribers with road maps to change prescribing behaviours. The Chair relayed feedback received from Dr Jim McGuigan that the AMDs and MDs were very supportive of the proposed process and put forward a suggestions that the AMDs should work with AWMSG in developing the process. There was support from members and an acknowledgement that there will be significant benefits in adopting a scheme with an evidence-based framework. He made the point that engaging with stakeholders would be crucial.

The Chair confirmed that all questions had been considered and comments taken into account; the proposed process and the research around it has been extensively and thoughtfully reviewed. The Chairman suggested that AWTTTC could consider working through a draft process with two or three examples. The Chair confirmed AWMSG's support to take forward a formal disinvestment process and challenged AWTTTC to establish a process for implementation. The Chair thanked Professors Hughes, Anderson and Fitzsimmons and the AWTTTC team who had worked collectively to develop the proposal. He reminded members of the objective from the Health Minister to release resources to put into areas that generate higher value and stated that AWMSG must subscribe to this.

#### **ACTION**

**AWTTTC to develop a process for the disinvestment of medicines**

**10. Revised AWMSG process for appraising paediatric licence extensions**

The Chair invited Mrs Ganderton to summarise the paper. Mrs Ganderton explained that the process for appraising paediatric licence extensions had been reviewed and simplified to encourage pharmaceutical companies to engage with the AWMSG appraisal process and increase the number of submissions for paediatric licence extensions. Mrs Ganderton

summarised the process undertaken and asked members to endorse the proposal. The Chair opened discussion. Professor Doull confirmed that WHSSC welcomed the paper and asked whether a layer of beaurocracy still remained. Mrs Ganderton reassured Professor Doull that the updated submission form is much less onerous for pharmaceutical companies and a review of the process is planned in 12 months. Mrs Ganderton explained that views from the pharmaceutical industry had been sought. In relation to medicines where the costs remain high, Mrs Ganderton confirmed that an assessment of the budget impact will be undertaken and AWMSG will reserve the right to request a limited submission. Members were informed that if this scenario presents itself then the high impact medicines can be considered in more detail. Professor Doull made the point that a similar process for unlicensed or off label medicines would be welcomed and acknowledged that this is outside the remit of AWMSG.

Chair confirmed AWMSG's endorsement of the proposal and confirmed the new process will be implemented early in the New Year.

#### **11. Welsh National Standards for Medication Review**

Mrs Thomas presented the Welsh National Standards for Medication Review, and confirmed that the processes for developing the standards included wide stakeholder consultation, the comments of which had been taken into consideration. Mrs Thomas relayed the suggestion by AWPAG to develop a competency framework in conjunction with HEIW. Mrs Thomas confirmed that a number of positive responses had been received with an acknowledgement that the paper presented a 'set of gold standards'. Mrs Thomas thanked members of the task and finish group for taking the time to work with AWTTTC in developing the document.

The Chair invited comments. It was confirmed that a Welsh version of the patient information leaflet will be available on the website. It was suggested that 'hospital only' medicines should be included in the list of medications to ensure clarity and avoid potential safety issues. Members commented on the section on adherence and made some suggestions. Dr Black agreed that the document presented 'gold standard targets' and expressed a view that they are not achievable in primary care at the current time. He expressed an opinion that the document does not take into consideration the constraints which exist in primary care and drew attention to the fact that all general practitioners who had responded to the consultation had made the same point. Mrs Thomas reiterated that the standards can be completed over a series of consultations, and the purpose is to have multi-professional medication review standards endorsed by AWMSG.

Mrs Thomas relayed the view of GPC Wales that it would be useful to have a brief document summarising the standards, which was subsequently developed and included within the papers, and reinforce the fact that the standards can be shared and completed over a series of meetings. Mrs Thomas made the point that AWPAG had been involved in several iterations and suggested that it would be good to have something to aim for and work towards with effort and support. Dr Black did not consider the standards were achievable within current practice and made the point that in his practice the pharmacist is given 20 minutes to complete a medication review not 45 minutes. Mrs Thomas informed members that AWTTTC is in discussion with Vision to develop a template to support practices in undertaking medication reviews in line with the document. Dr Black stated that the time and resources to achieve the standards is not available to GP practices currently.

The Chair proposed that AWMSG should endorse the standards and suggested a small scale pilot should be undertaken to identify any issues. The Chair made the point that there is always a trade off between how thoroughly a task is undertaken and the value gained by doing the task. The point was made that the Cumberlege report highlighted the involvement of patients and this would be essential to the success of the standards.

The Chair closed the discussion by endorsing the standards and asking AWTTTC to set up a pilot.

**ACTION**

**Pilot to be undertaken to identify barriers in achieving the standards**

**Prof Hughes to share adherence research with AWTTTC**

**12. Prescribing Dilemmas (2020 Review)**

Dr Bracchi informed members that the Prescribing Dilemmas document had been reviewed and updated based on feedback received following consultation. Dr Bracchi asked AWMSG to endorse the updated document and the Chair opened discussion.

It was noted that reference in the document regarding overseas patients would need to be updated in light of the availability of policy changes and Brexit negotiations. A member considered the off label and unlicensed wording in the first statement to be ambiguous. It was confirmed that the wording in the document had been taken from the GMC definition and clarification is provided within the document. The point was made that it is the MHRA regulations 2012 which is the legal default position. Dr Bracchi agreed to revisit the definition wording. Professor Hughes agreed to provide a copy of the Aronson article.

Dr Black suggested that it might be helpful to include a link to the definitions of 'repeats' and 'repeat prescribing'. There was discussion over the section 'Prescribing where it is considered inappropriate' page 7 4.3 – examples of inappropriate prescribing. Dr Black made the point that GPs should not prescribe medicine if the appropriate authority has not recommended use.

Mrs Samuels confirmed that an AWMSG negative recommendation will not impact on the clinical freedom of the prescriber as a case can be made for exceptionality. She confirmed that a medicine not recommended for use will not be routinely funded by the NHS.

The Chair asked for more work to be done to provide clarification of the issues raised in the discussion and for AWTTTC to bring the document back to the committee for endorsement when these changes have been made.

**ACTION**

**AWTTTC to provide clarity in the document and bring back to AWMSG for endorsement**

The Chair confirmed the date of the next meeting, on Tuesday, 9<sup>th</sup> February 2021 (via Zoom).  
The meeting closed.