

Enclosure No:	<b>1/AWMSG/0521</b>
Agenda Item No:	<b>1 – Minutes of previous meeting</b>
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## **ALL WALES MEDICINES STRATEGY GROUP (AWMSG)**

### **Draft minutes of the AWMSG meeting held 9.30 am on Tuesday, 20<sup>th</sup> April 2021 (via Zoom)**

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

Did not  
participate in

- |     |                              |   |
|-----|------------------------------|---|
| 1.  | <b>Prof Iolo Doull</b>       | <b>Chair</b>                                    |
| 2.  | <b>Prof Stephen Monaghan</b> | <b>Consultant in Public Health Medicine</b>     |
| 3.  | <b>Prof Dyfrig Hughes</b>    | <b>Health Economist</b>                         |
| 4.  | <b>Mr Farhan Mughal</b>      | <b>ABPI (Wales)</b>                             |
| 5.  | <b>Mr Cliff Jones</b>        | <b>Lay Member</b>                               |
| 6.  | <b>Ms Claire James</b>       | <b>Lay Member</b>                               |
| 7.  | <b>Mr Dylan Jones</b>        | <b>Community Pharmacist</b>                     |
| 8.  | <b>Dr Jim McGuigan</b>       | <b>Medical Director</b>                         |
| 9.  | <b>Dr Jeremy Black</b>       | <b>GP with Prescribing Lead role</b>            |
| 10. | <b>Mrs Alison Hughes</b>     | <b>Senior Primary Care Pharmacist</b>           |
| 11. | <b>Mr Hywel Pullen</b>       | <b>Finance Director</b>                         |
| 12. | <b>Mr John Terry</b>         | <b>Managed Sector Secondary Care Pharmacist</b> |
| 13. | <b>Dr Balwinder Bajaj</b>    | <b>Clinical Pharmacologist</b>                  |

#### **Welsh Government:**

No Welsh Government officials in attendance

#### **AWTTC staff:**

Dr Robert Bracchi, Medical Advisor  
Mr Trevor Brooking, Administration Manager  
Dr Thomas Curran, Senior Scientist  
Dr Laurence Gray, Chairman AWPAG  
Ms Kath Haines, Head of WAPSU  
Mrs Karen Jones, Senior Pharmacist  
Mrs Ruth Lang, Senior Liaison Manager  
Mrs Karen Samuels, Programme Director  
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
ATMPs	Advanced Therapy Medicinal Products
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
ILAP	Innovative Licensing and Access Pathway
IPCG	Interim Pathway Commissioning Group
IR	Independent Review
MHRA	Medicines and Healthcare products Regulatory Agency
M&TCs	Medicines & Therapeutics Committees
NICE	National Institute for Health and Care Excellence
NMG	New Medicines Group
NPI	National Prescribing Indicator
PAMS	Patient Access to Medicines Service
PAR	Preliminary Appraisal Recommendation
PAS	Patient Access Scheme
PPRS	Prescription Price Regulation Scheme
QAIF	Quality Assurance and Improvement Framework
SMC	Scottish Medicines Consortium
SPC	Summary of Product Characteristics
SPIRA	Server for Prescribing Information Reporting and Analysis
TDAPG	Therapeutic Development Appraisal Partnership Group
T&FG	Task and Finish Group
UHB	University Health Board
WAPSU	Welsh Analytical Prescribing Support Unit
WeMeReC	Welsh Medicines Resource Centre
WG	Welsh Government
WHO	World Health Organization
WHSSC	Welsh Health Specialised Services Committee
WPAS	Wales Patient Access Scheme

**1. Welcome and introduction**

The Chair opened the meeting, welcomed members/observers and outlined the meeting protocol.

**2. Apologies:**

**Voting members:**

Mr Stefan Fec and Mr Dylan Jones - Community Pharmacist

Mr Aled Falvey - Other healthcare professions eligible to prescribe not already represented

**3. Declarations of interest**

The Chair invited declarations of interest - there were none.

**4. Minutes of previous meeting**

The draft minutes of the previous meeting held on 10<sup>th</sup> March 2021 were checked for accuracy and approved as a true record of the meeting. There were no matters arising.

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

The Chair confirmed his appointment as Interim Chair following the resignation of Professor Ceri Phillips who has taken on the role of Vice Chair, Cardiff and Vale University Health Board. The Chair thanked Professor Phillips for his tenure and for his achievement in establishing closer links with health boards despite the challenges of the pandemic.

The Chair invited expressions of interest in the position of Interim Vice Chair and confirmed that a replacement WHSCC representative would be sought.

The Chair confirmed that since taking on the role of Interim Chair he had attended a meeting of the Steering Committee of the new Innovative Licensing and Access Pathway with representatives from MHRA and partners, including SMC and NICE. The Chair highlighted the importance of AWMSG involvement in this new route to access medicines and confirmed that greater clarity with regard to the future of health technology appraisal by AWMSG would be sought when reviewing the Memorandum of Understanding with NICE.

The Chair confirmed that AWTTTC is supporting the implementation of WHSSC-commissioned medicines via the Blueteq system and he stressed the importance of having electronic systems available in Wales to support the prescribing, administration and monitoring of medicines. He confirmed that this would be a priority for him as Interim Chair of AWMSG.

The Chair confirmed that AWMSG's advice in relation to Opicapone (Ongentys®) and Dupilumab (Dupixent®), appraised at the meeting on 8<sup>th</sup> February, and Lurasidone (Latuda®), Idebenone (Raxone®) and Melatonin (Slenyto®) which were appraised at the meeting on 10<sup>th</sup> March, had been ratified by Welsh Government, disseminated to service and published on the AWMSG website.

Mrs Samuels Karen announced the appraisals scheduled for the next AWMSG meeting on Wednesday 19<sup>th</sup> May 2021:

**Appraisal 1: A full submission from Novartis Pharmaceuticals UK Ltd**

**Indacaterol/glycopyrronium/mometasone (Enerzair Breezhaler®)** for maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta<sub>2</sub>-agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year

**Appraisal 2: A limited submission with a Welsh Patient Access Scheme from Eisai Ltd**

**Perampanel (Fycompa®)** as adjunctive treatment of partial-onset seizures (POS) with or without secondarily generalised seizures in patients from 4 to < 12 years of age

**Appraisal 3: A limited appraisal from Pharming Group NV with a Welsh Patient Access Scheme, using the AWMSG process for appraising licence extensions for paediatric use**

**Conestat alfa (Ruconest®)** for the treatment of acute angioedema attacks in children (aged 2 years and above) with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency

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

**6. AWMSG Work Programme:**

**Consultation on the AWTTTC Work Programme update**

Mrs Samuels presented the background and confirmed that a summary of consultation responses on planned new work is being presented to AWMSG for comment and prioritisation. Mrs Samuels explained that the tasks involving other parties may be subject to change in terms of delivery and deadlines. Members were informed that all work is aligned to the strategic aims of AWMSG as set out by the Health Minister. Mrs Samuels thanked consultees for comments received during the consultation process and confirmed that further discussions would need to be had with the Chair and Welsh Government to agree the operational plan going forward. Mrs Samuels confirmed that the operational plan, once agreed with Welsh Government, would be shared with members. The Chair opened discussion.

Mrs James asked what communication and co-ordination exists between AWMSG and Genomic Partnership Wales (GPW) with regard to ATMPs and precision medicines. Mrs James confirmed her involvement as patient representative on the GPW Governance Board. Mrs Samuels confirmed that AWTTTC provided support in terms of horizon scanning and financial forecasting and Mrs James asked for this to be included in the documentation.

A question was raised regarding the impact of the reducing number of appraisals on the role and remit of the New Medicines Group. Mrs Samuels confirmed that a review would be undertaken as part of the operational plan to ensure that the skills of members were utilised appropriately. A suggestion was made that NMG could potentially get involved in the planned new project on resource reallocation and assessment of the value of medicines. The Chair acknowledged the considerable skillset of members and reassured the Group that this would not be lost or diluted going forward.

Mrs Hughes expressed a view that progressing the low value prescribing would be her highest priority. Mrs Hughes sought clarification of the abbreviation of IPCG on page 3 and Mrs Samuels agreed to update the document and include the full name of the Interim Pathway Commissioning Group. The ABPI representative suggested there may be opportunity for work to be done on the implementation of a commercial medicines framework similar to the one published in England. Professor Hughes highlighted the importance of continuing to utilise existing methodology such as the cost per QALY framework and avoid using more flexible and weaker methods. Mrs Samuels assured Professor Hughes of the commitment to maintain the high standards of rigour and acknowledged that practicalities of this would need to be explored in the wider context.

The Chair thanked members for their comments and closed discussion.

### **AWTTC Medicines Optimisation Framework**

Dr Curran presented the medicines optimisation framework and sought the endorsement of AWMSG. He explained that a scope document presented to AWMSG in December had outlined the aim of the document to improve communication and increase transparency and awareness of the medicines optimisation project development process. He referred to comments received during the consultation in February and updated members on feedback from AWPAG members regarding their preference for considering papers before and after consultation. Consultation comments had also highlighted that AWTTC is uniquely placed to facilitate and monitor the implementation of projects and Dr Curran confirmed that AWTTC is looking at how this can be supported. Members were informed the document would be regularly reviewed and updated. The Chair invited comment.

It was suggested that the membership list should be updated to reflect the recent appointment of an additional lay member on AWMSG. Dr Black suggested a change to the nominating body for general practitioners. Mrs Haines confirmed that AWTTC would address these issues outside of the meeting. Mr Pullen expressed his support and thanked AWTTC for producing the framework.

### **NHS Wales GP Cluster Prescribing Leads Forum proposal**

Ms Haines presented a proposal to develop a GP Cluster Prescribing Leads Forum to improve two-way communication with health boards and share best practice. The absence of a national network of GP prescribing leads was highlighted and it was felt that such a forum would improve communication with AWPAG and AWMSG and facilitate exchange of views in relation to medicines and prescribing. The Chair invited Dr Tessa Lewis and Dr Rob Bracchi to comment on the proposal.

Dr Lewis stated that as a practising GP she felt there would be benefit from having a forum and opportunity to exchange views and identify barriers to the implementation of nationally-agreed consensus guidance. Dr Lewis confirmed she would welcome a network of prescribing enthusiasts. Dr Bracchi agreed and highlighted the importance of two-way discussion. Dr Lewis said that GPs are struggling to keep up with the latest information and a forum would massively help with this and help support change in prescribing practices. There was general agreement that the proposal required appropriate consultation with the cluster leads groups. There was a concern that membership from 64 cluster groups would be unmanageable. Members agreed there is likely to be resistance to a top down approach and a more organic approach would be preferred. It was suggested there may be a degree of concern and suspicion regarding the proposal if not approached appropriately. Dr Bracchi reiterated the need for 2-way communication and opportunity for feedback so that AWMSG can understand whether the guidance it produces is relevant and of value to the service. The Chair confirmed that following recent discussions at AWMSG meeting with health board executives, there was general consensus that a forum for sharing best practice and improving engagement would be welcomed. The Chair concluded discussions by agreeing to take the paper to Medical Directors and to seek the views of the Primary Care Assistant Medical Directors Group. Ms Haines, Dr Lewis and Dr Bracchi agreed to attend meetings of the Cluster Group Leads to seek their views on the proposal.

### **AWTTC: Supporting implementation of ATMPs in NHS Wales**

Mrs Samuels confirmed that the paper is being presented for information because the work does not normally come through AWMSG. Mrs Samuels highlighted that the route for assessing ATMPs in Wales is different and not routed via AWMSG currently. It is intended that ATMPs will be appraised by NICE and the guidance will apply within NHS Wales. Mrs Samuels confirmed the role of AWTTC is to provide horizon scanning information to the ATMP Programme Board and highlight potential financial implications of implementing ATMPs in NHS Wales. Mrs Samuels outlined the support provided by AWTTC with regard to the implementation of ATMPs involving the Blueteq system procured by WHSSC. Members were informed that good progress is being made and the system will go live later in the month.

Mrs Samuels highlighted potential scope for involvement beyond that currently provided by AWTTTC, such as a monitoring role and assessment of the financial impact on the service. It was noted the issue of affordability is one for policy and decision-makers. Mrs Samuels suggested there is considerable scope for improved communication in relation to the introduction of ATMPs within NHS Wales.

The Chair concluded discussions and confirmed that he would engage with the CMO and CPO on these issues.

**7. Feedback from the All Wales Prescribing Advisory Group meeting held 17<sup>th</sup> March 2021**

Dr Gray presented the draft minutes of the AWPAG meeting and briefly summarised the topics considered at the meeting held on 17<sup>th</sup> March. Members were informed that attendance was good and Dr Gray updated on the appointment of three new members to the committee.

Dr Gray reported that the Best Practice Day held on 13<sup>th</sup> April had been over-subscribed. A presentation from Neath and Port Talbot Hospital Integrated Medicines Team on medicines review and optimisation in the community and care home setting had been extremely well received. Dr Gray informed members that he presented on a project he is involved with in relation to the de-labelling of penicillin allergy. He highlighted the impact of this work with regard to potential financial savings, reduction in waste and improved antibiotic stewardship. Dr Gray confirmed the next Best Practice Day will be held in the Autumn.

Dr Gray informed members that a consultation has gone out on guidance developed to help support healthcare professionals in the prescribing of SGLT-2 inhibitors in patients with type 2 diabetes mellitus and cardiovascular disease which includes a comprehensive review of the evidence for SGLT-2 inhibitor use in type 2 diabetes mellitus in relation to cardiovascular outcomes and provides recommendations on the role of SGLT-2 inhibitors in this patient population. Dr Gray invited members to comment on the draft paper at an early stage.

Dr Gray confirmed the date of the next AWPAG meeting on 30<sup>th</sup> June. There were no questions and the Chair thanked Dr Gray for the overview.

The Chair suspended the meeting for 10 minutes and encouraged members to take a comfort break.

**8. Appraisal 1: Limited submission**

**Buprenorphine/naloxone (Suboxone<sup>®</sup>) 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg and 12 mg/3 mg sublingual film**

**Limited submission by Indivior UK Ltd.**

The Chair welcomed delegates from Indivior UK Ltd.

The Chair confirmed that at the close of the appraisal all observers would be asked to leave the meeting whilst members voted in private and agreed the wording of the advice to Welsh Government. The Chair confirmed the appraisal recommendation will be forwarded to the delegates after the close of the meeting and the company would be allowed ten working days to respond to the recommendation.

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 limited submission as outlined in the ASAR. The recommendation agreed by NMG was relayed.

The Chair invited questions. Clarification was sought in relation to the indication for Suboxone® in adults and adolescents over 15 years of age who have agreed to be treated for addiction. The company delegate was asked whether this referred to adolescents aged one day over their 15<sup>th</sup> birthday or from the age of 16. The company was unable to provide clarification and agreed to check this outside of the meeting.

Clarification was sought in relation to the unwanted side-effects of naloxone and the company delegate confirmed there is no clinical effect if treatment is administered as directed.

It was confirmed that no patient views had been received and Mr Cliff Jones informed members of the four patient organisations that had been approached by AW TTC.

The importance of having tablet and film treatment options for clinicians and consideration of patient preference and individual assessment of patients was noted. It was acknowledged that decreased administration time could impact on patient preference. The lay members sought clarification of the difference in cost between the film and tablet. The appraisal lead highlighted the restriction in the assessment report for use under specialist recommendation. The potential for other providers to enter the market in Wales was highlighted.

There were no wider social or equity issues of note. The Chair drew attention to the budget impact estimates. The uncertainty in patient numbers and limitations to the estimated savings was noted.

There were no other issues of note and the Chair invited the company delegates to comment. They highlighted the limited treatment options for this patient group and urged AWMSG to take into account the importance of treatment choices for patients. The delegate reminded members of Welsh Government's commitment to increase treatment choices in people with opioid dependence to align with their individual needs and support adherence. Prior to concluding the appraisal the Chair asked the applicant company delegates to confirm they were satisfied that the issues raised by AWMSG had been adequately addressed and that the appraisal process had been fair and transparent; this was confirmed. The Chair reminded the delegates to clarify the age restriction and closed discussion.

The Chair thanked the company delegates for attending and closed the meeting to the public. Members voted in private and agreed the recommendation to Welsh Government.

**Buprenorphine/naloxone (Suboxone®) sublingual film is recommended as an option for restricted use within NHS Wales as substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Suboxone® is indicated in adults and adolescents over 15 years of age who have agreed to be treated for addiction. In accordance with NICE guidance such treatment should be considered in patients who are unsuitable for maintenance treatment with methadone.**

The Chair confirmed the date of the next meeting on **Wednesday, 19<sup>th</sup> May commencing 9.30 am** (via Zoom) and closed the meeting.