

**Approved minutes of the AWMSG meeting held  
Wednesday, 11th September 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 Ceri Phillips  | Chairman                                 |
| 2.  | Dr Balwinder Bajaj  | Clinical Pharmacologist                  |
| 3.  | Mr Hywel Pullen     | Director of Finance                      |
| 4.  | Prof Iolo Doull     | WHSSC                                    |
| 5.  | Mrs Alison Hughes   | Primary Care Pharmacist                  |
| 6.  | Dr Arpan Guha       | Medical Director                         |
| 7.  | Prof Dyfrig Hughes  | Health Economist                         |
| 8.  | Mrs Louise Williams | Senior Nurse                             |
| 9.  | Mr Stefan Fec       | Community Pharmacist                     |
| 10. | Mr John Terry       | Managed Sector Secondary Care Pharmacist |
| 11. | Mr Tommy Price      | ABPI                                     |

**AWTTC staff in attendance:**

Dr James Coulson, Interim Clinical Director & Chairman NMG  
Mrs Karen Samuels, Programme Director  
Mrs Ruth Lang, Senior Liaison Manager  
Ms Sabrina Rind, Senior Pharmacist  
Mr Richard Boldero, Senior Pharmacist  
Mrs Claire Thomas, 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
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
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
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 members. Professor Phillips confirmed his recent appointment as AWMSG Chair and relayed his enthusiasm at the prospect of working with members to contribute to the achievement of the goals of A Healthier Wales. He highlighted the important role that AWMSG will continue to play in providing support to Welsh Government and NHS Wales with regard to the development of the medicines agenda. He acknowledged the achievements of AWMSG since its inception and informed members that he had been one of the founder members of the group and understood the role of members. He shared his vision to make AWMSG more visible and highlighted the importance of it retaining its independence as an All Wales strategic advisory body.

The Chair welcomed new members, Professor Arpan Guha (Medical Director representative) and Mr Tommy Price (ABPI Cymru Wales representative), to their first AWMSG meeting.

**2. Apologies**

Mr Cliff Jones, Lay Member  
Dr Cath Bale, Hospital Consultant  
Dr Jeremy Black, GP  
Mr Aled Falvey, Other professions eligible to prescribe

**3. Declarations of interest**

Members were reminded to declare any interests. Mr Price declared a potential competitor conflict of interest and the Chair confirmed that Mr Price would not be able to participate in the appraisal or vote.

**4. Minutes of previous meeting**

The draft minutes of the previous meeting held on 19<sup>th</sup> June 2019 were checked for accuracy and approved.

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

The Chair informed members that since his appointment he had met with representatives from AWTTTC and officials in Welsh Government and is scheduling appointments with the Health Minister, Director General/Chief Executive NHS Wales and Chief Medical Officer.

The Chair gave recognition to the achievements of AWMSG in developing a highly regarded health technology appraisal process, which has been recognised and accredited by NICE. Professor Phillips highlighted the synergy with NICE and the correlation in previous decision making. The Chair alluded to the changing landscape with regard to health technology appraisal and informed members that an opportunity exists to utilise the multi-disciplinary and multi-professional support network provided by AWTTTC to develop the strategic components of the medicines management agenda. The Chair stated that he had been impressed by the high quality prescribing information held by AWTTTC and stated this must be communicated to the service to ensure the intelligence is fed into the system at the appropriate level.

The Chair paid tribute to Professor John Watkins who had served as Interim Chair and thanked Professor Iolo Doull for acting as Vice Chair during the public appointment process. He also paid tribute to the previous Chairs, Professor Roger Walker, Professor Philip Routledge and Dr Stuart Linton.

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

**Eslicarbazepine acetate (Zebinix®) is recommended** as an option for restricted use within NHS Wales. Eslicarbazepine acetate (Zebinix®) should be restricted to treatment of highly refractory patients who remain uncontrolled with, or are intolerant to, other anti-epileptic medicine combinations, within its licensed indication as adjunctive therapy in adults, adolescents and children aged above six years, with partial onset seizures, with or without secondary generalisation. Eslicarbazepine acetate (Zebinix®) is not recommended for use within NHS Wales outside of this subpopulation.

**Rufinamide (Inovelon®) is recommended** as an option for restricted use within NHS Wales. Rufinamide (Inovelon®) is licensed as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 1 years of age and older. Rufinamide (Inovelon®) is restricted for use where other adjunctive treatments have proved sub-optimal or

have not been tolerated. Rufinamide (Inovelon®) is not recommended for use within NHS Wales outside of this subpopulation.

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 on these medicines or contact AWTTTC for further information on the appraisal process and future work programme.

Mr Tommy Price left the meeting.

## **6. Appraisal 1: Full Submission**

**Buprenorphine (Buvidal®)** for the treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over

The Chair welcomed delegates from Camurus AB Ltd.

The Chair invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

The Chair announced that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an obligation on health boards to fund accordingly. It was confirmed that AWMSG advice is interim to final NICE guidance should this be subsequently published. The Chair set the context and outlined the sequence of events. Members were reminded that NMG had considered the clinical and cost effectiveness issues in detail and there was no expectation that AWMSG would repeat this. The Chair encouraged members to seek clarification of any outstanding issues, particularly in relation to budget impact, and to take into consideration any societal aspects that were not part of the discussion at NMG. The Chair confirmed that delegates from the applicant company would have the opportunity to respond to questions and highlight any salient issues with regard to their submission. The Chair handed over to the AWTTTC appraisal lead.

Mrs Rind presented an overview and relayed the key aspects of the submission as outlined in the ASAR.

The Chair invited Dr James Coulson to relay the recommendation of the NMG. Dr Coulson confirmed the view of NMG that buprenorphine (Buvidal®) should be recommended as an option for use within NHS Wales for the treatment of opioid dependence within a framework of medical, social and psychological treatment. It was noted that treatment is intended for use in adults and adolescents aged 16 years or over. Dr Coulson stated that the input of a clinical expert at NMG had been very useful and helped NMG gain a better understanding how the medicine would be used in practice in Wales. Dr Coulson confirmed that in the absence of any patient organisation views, the lay member at NMG had been fully involved in the discussions. Mrs Rind highlighted the unmet clinical need and stated that clinicians viewed the once weekly/monthly administration was a significant change and allowed patients a more normal lifestyle.

The Chair opened discussion and invited comments or questions with regard to clinical effectiveness. There was discussion over the relevance of the studies to the population in Wales and the company delegates responded. Members enquired about the safety profile and duration of treatment. The point was made that addiction services and treatment of patients is variable across Wales and members asked the company delegates to describe the model outside of Wales. The issue of good communication with regard to shared care arrangements

was highlighted. There was discussion over administration and monitoring arrangements and it was noted that the planning for the process of providing the medicine to patients would only be undertaken following a positive recommendation by AWMSG.

The Chair asked Professor Hughes to present the case for cost-effectiveness. Before presenting a summary of the evidence, Professor Hughes clarified that he had not been involved in producing the assessment report. Professor Hughes highlighted the key aspects of the case for cost-effectiveness and made reference to the ASAR. He brought members' attention to the budget impact estimates. The Chair then opened discussion.

Clarification was sought in relation to the pharmacy costs (page 7 table 1) and there was discussion in relation to dispensing fees and services. Dr Coulson and Mrs Rind confirmed that the clinical expert at NMG had considered the model to be accurate. It was noted that delivery will vary across Wales and the element of uncertainty in cost estimates were acknowledged. Concerns around the consultation, monitoring and nurse time were discussed.

Before concluding the appraisal the Chair sought confirmation from the company delegates that the appraisal process had been fair and transparent. The Chair closed the appraisal and confirmed that members would retire 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:

**Buprenorphine (Buvidal®) is recommended as an option for use within NHS Wales for the treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over.**

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.

Mr Tommy Price rejoined the meeting.

**7. Feedback from AWPAG Meeting held 26<sup>th</sup> June 2019**

Mr Richard Boldero and Mrs Claire Thomas presented an overview of the draft minutes of the AWPAG meeting held on 26<sup>th</sup> June. They highlighted work currently on-going and confirmed the next meeting would be held on Wednesday, 18<sup>th</sup> September 2019. Mr Boldero confirmed that updated guidance from the English Regional Medicines Optimisation Committee on liothyronine would be considered by AWPAG and an update to AWMSG guidance on Medicines Identified as Low Priority for funding in NHS Wales may be required in light of this new information. Members were informed that a third paper was currently being worked on, and the draft will be presented to AWPAG next week. The paper will include vitamins and minerals as well as a number of other medicines identified as being of low priority for funding in NHS Wales.

**8. National Prescribing Indicators 2018-19: Analysis of Prescribing Data to March 2019**

Mr Boldero and Mrs Thomas presented a summary of the analysis of NPI data to March 2019. It was noted that comparison of biosimilar prescribing in Wales and England was problematic due to the different units of measure used. Mr Boldero informed members that on previous examination of the data from Wales, when biosimilar versions had become available, the spend on specific biological medicines had been seen to decrease whilst the number of items issued had increased. Members acknowledged the drive to move to biosimilars is due to

financial savings. It was confirmed that individual health board annual prescribing reports would be made available over the next few weeks. The Chair commented that the report needs more exposure as there is learning from good and bad experiences and contextualization would be required to help to inform the aims of A Healthier Wales. A member enquired what AWTTTC is doing to promote good prescribing and share experiences. Mrs Thomas confirmed that the SHARE communication platform had been developed by AWTTTC so that NHS Wales had an online platform to discuss issues relating to medicines/prescribing and enable the sharing of good and bad experiences. Mrs Thomas made the point that the indicator prescribing dashboards are available to all health boards to enable comparison, and the annual best practice day event which is hosted by AWTTTC for health boards.

#### **9. Review of AWMSG – Final Report for Welsh Government**

The Chair referred members to the Review of The All Wales Medicines Strategy Group Report for Welsh Government produced by the Welsh Institute for Health and Social Care – University of South Wales. Dr Coulson provided the background and the Chair invited comments.

There was disappointment at the lack of an executive summary and recommendations. There was an acknowledgement that the lines of accountability and direction appeared to be unclear to those outside of AWMSG/AWTTTC and members agreed this needs to be addressed. Clarity in relation to the interaction with the medical directors was sought. Dr Coulson provided feedback from his recent meeting with Welsh Government officials and stated that the high quality work undertaken by AWTTTC and AWMSG is valued. There was agreement that the work of AWMSG needs to be more visible and extended to capture outcome data. Supporting the clinical effectiveness agenda in health boards was agreed to be a priority. The Chair reiterated the need for AWMSG/AWTTTC to retain its multi-disciplinary and multi-professional standing and independence so that it can provide the 'grit in the system' and serve the whole of NHS Wales. The Chair shared his vision to move towards more dependency on AWMSG and AWTTTC to inform policy and decision-making. The Chair announced he has a meeting with Welsh Government officials tomorrow.

**The Chair confirmed the date of the next meeting on Wednesday 16<sup>th</sup> October 2019 in Cardiff and the meeting closed.**