

Enclosure No:	1/AWMSG/0223
Agenda Item No:	1 – Minutes of previous meeting
Author:	Chair, AWMSG
Contact:	Tel: 029 218 26900 E-Mail: awttc@wales.nhs.uk

All Wales Medicines Strategy Group (AWMSG)

**Draft minutes of the AWMSG meeting held
Tuesday, 6th December 2022 commencing 10.00 am
at The All Nations Centre, Sachville Avenue, Cardiff, CF14 3NY**

Voting members present:

**Did not
participate in
agenda item:**

- | | | | |
|-----|-------------------------|---------------------------------------|----------------|
| 1. | Prof Iolo Doull | Chair | |
| 2. | Mr Tommy Price | ABPI (Wales) | 7,12,13 |
| 3. | Dr Alison Thomas | Clinical Pharmacologist | |
| 4. | Mrs Claire James | Lay Member | |
| 5. | Dr Jeremy Black | General Practitioner | |
| 6. | Ms Alison Hughes | Senior Primary Care Pharmacist | |
| 7. | Mr Hywel Pullen | Director of Finance | |
| 8. | Mr Stuart Rees | Senior Hospital Pharmacist | |
| 9. | Mrs Mandy James | Senior Nurse | |
| 10. | Dr Sam Cox | Hospital Consultant | |

Welsh Government:

Mr Andrew Evans

AWTTC staff:

Mr Tony Williams, Head of PAMS
Ms Kath Haines, Head of WAPSU
Mrs Helen Adams, Senior Pharmacist
Shaila Ahmed, Senior Pharmacist
Mrs Claire Thomas, Senior Pharmacist
Mr Richard Boldero, Senior Pharmacist
Mr Trevor Brooking, Administration Manager
Dr Clare Elliott, Senior Scientist
Mrs Rachel Jonas, Medical Writer

List of abbreviations:

ABPI	Association of the British Pharmaceutical Industry
ASAR	AWMSG Secretariat Assessment Report
ATMP	Advanced Therapy Medicinal Product
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
DHCW	Digital Health and Care Wales
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 Assessment
ILAP	Innovative Licensing and Access Pathway
IR	Independent Review
MHRA	Medicines and Healthcare products Regulatory Agency
M&TC	Medicines & Therapeutics Committee
NICE	National Institute for Health and Care Excellence
NMG	New Medicines Group
NPI	National Prescribing Indicator
OWMAG	One Wales Medicines Assessment Group
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
RCGP	Royal College of General Practitioners
SABA	Short-acting beta agonist
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 and observers, and explained the meeting protocol.

2. Apologies:

Prof Dyfrig Hughes, Health Economist
Ms Eleri Schiavone, Welsh Health Specialised Services Committee
Mrs Julie Wilson-Thomas, Lay Member
Ms Cathy Wynne, Other healthcare professions
Mr Dylan Jones, Community Pharmacist
Prof Stephen Monaghan, Consultant in Public Health Medicine
Dr Helen Fardy, Welsh Health Specialised Services Committee
Dr Richard Skone, Medical Director

3. Declarations of interest:

The Chair invited declarations of interest. Mr Tommy Price declared a personal non-specific interest in agenda items 7, 12 and 13 and the Chair confirmed that Mr Price would not participate in these agenda items.

4. Minutes of previous meeting

The draft minutes of the previous meeting held on 18th October 2022 were checked for accuracy and approved. There were no matters arising.

5. Chairman's Report

The Chair confirmed that on receipt of Welsh Government ratification the recommendations from the previous meeting on 18th October were published on the AWTTTC website and disseminated to the service. The Chair updated members of meetings held since the previous AWMSG meeting – the Patient and Public Interest Group met on 20th October and the theme of this meeting was Sustainability; the AWTTTC Industry Forum met on 27th October and discussed changes in methods to align with NICE. An Open Day for the Pharmaceutical Industry was held on 24th November. The Chair fed back from AWMSG's 20th Anniversary Conference held on 17th November in Cardiff City Stadium. He thanked all of the speakers and AWTTTC staff for their contribution to the success of this event. The Chair confirmed that the Medicines Strategy for 2023-2028 will be one of the topics discussed at the training session to be held on 11th January. The next formal AWMSG meeting will be held on 8th February and will be Mrs Karen Samuels and Ms Kath Haines final AWMSG meeting before their retirement. The Chair gave his apologies for the February meeting and, in the absence of a Vice Chair, encouraged members to consider stepping in to act as Chair.

6. Biosimilar Medicines Strategy

Ms Kath Haines and Mr Richard Boldero gave an overview of the biosimilar strategy document and highlighted the steps needed to build a strong biologics platform. The collaboration needed between the NHS and pharmaceutical industry to maximise uptake and support a strong competitive biosimilar market for NHS Wales was noted. Mr Andrew Evans thanked all

those who had contributed to the consultation and confirmed that future updates will be brought to AWMSG for consideration as and when required.

7. Provision of everolimus (Votubia®) for tuberous sclerosis complex (TSC) in Wales

Dr Jennifer Gardner joined the meeting

The Chair invited Mrs Helen Adams and Dr Clare Elliott to present the enclosure. Mrs Adams reminded members that everolimus has an associated Patient Access Scheme (PAS) and the confidential information highlighted in the report should not be divulged.

Dr Elliott explained that the unmet clinical need had prompted a request for AW TTC to gather publicly available evidence so that AWMSG could review the provision of everolimus for tuberous sclerosis complex (TSC) within NHS Wales. Dr Elliott confirmed that everolimus is an established treatment which has been included in national and international guidelines. Members were informed that everolimus for TSC is currently not routinely available within NHS Wales because the manufacturer was unable to provide a submission to AWMSG. Dr Elliott highlighted that the patent is due to expire in 2023 and the availability of generic everolimus is expected.

Dr Gardner provided a clinical overview and outlined the burden of disease. Dr Gardner explained the disease pathway, associated complications and discussed treatment with everolimus. Members were informed that the clinical trial evidence from EXIST-2 supports the long-term efficacy and safety of everolimus with tumour growth being stabilised and, in some cases, reduced. The barriers to accessing this treatment currently within Wales were noted and Dr Gardner explained that in order to access this treatment for patients, clinicians are submitting IPFR applications.

Members sought clarification of the process for advising on everolimus for TSC within NHS Wales. Dr Elliott reiterated that the exceptional unmet clinical need had prompted the decision to request AW TTC to collate as much publicly available evidence as possible so that AWMSG could provide advice for NHS Wales. Members were reassured that a positive AWMSG recommendation, if ratified by Welsh Government, would align Wales with the rest of the UK. Although noting caution, members agreed this is a valuable approach and one that may be required for similar scenarios. Members were informed that AW TTC is currently reviewing routes for accessing medicines in Wales to ensure that timely advice can be made available to NHS Wales.

The lay member summarised the individual patient and patient organisation submissions received and commended the high level of responses and pragmatic approach taken. The importance of ensuring that patients living in Wales were not disadvantaged was reiterated.

The Chair referred members to the budget impact estimates. It was noted that the figures will be subject to change as everolimus comes off patent and generic medicines are introduced. Dr Gardner reassured members that the estimated number of eligible patients was reasonable and confirmed that

treatment would be via specialist TSC clinics. The Chair closed the discussion and the audience were asked to leave the room so members could vote in private.

The recommendation was subsequently announced and the Chair confirmed that the advice would be forwarded to Welsh Government for ratification.

Everolimus (Votubia®) is recommended for use within NHS Wales for the treatment of:

- **adult patients with renal angiomyolipoma associated with tuberous sclerosis complex who are at risk of complications (based on factors such as tumour size or presence of aneurysm, or presence of multiple or bilateral tumours) but who do not require immediate surgery, and;**
- **patients with subependymal giant cell astrocytoma associated with tuberous sclerosis complex who require therapeutic intervention but are not amenable to surgery**

This recommendation applies only in circumstances where the approved Patient Access Scheme (PAS) is utilised or where the list/contract price is equivalent to or lower than the PAS price.

Dr Gardner left the meeting

8. NHS Wales inhaler carbon footprint report

Mr Richard Boldero provided an overview of the metrics of the Wales inhaler carbon footprint report for data to August 2022.

It was noted that data for the first 3 years of the report indicates there has not been much improvement in the overall carbon footprint of inhalers. Members were reminded that progress over the last 3 years has been hindered due to COVID-19 and the subsequent drop in primary care face to face consultations. Ms Kath Haines informed members that there are many decarbonisation initiatives being undertaken by Public Health Wales and Health Boards across Wales. Members were reminded that the AWTTTC inhaler decarbonisation dashboard is available to support primary care prescribers in review of inhaler prescribing. The Chair opened discussion. It was suggested a waterfall diagram, similar to that used by cancer research UK for Improving Early Diagnosis of Cancer, could be a useful type of infographic to show prioritisation of decarbonisation initiatives.

9. Inhaler decarbonisation scenarios

Mr Richard Boldero provided an overview of the paper on the inhaler decarbonisation scenarios with each scenario discussed individually. The Chair informed members that there had been previous correspondence with some pharmaceutical companies around this topic and he reiterated that the aim of the paper is to generate discussion. Members were informed that any concerns expressed by individual pharmaceutical companies would be addressed outside of this meeting. Mr Boldero explained that the scenarios were based on historic data which may not always reflect current or future

prices. It was noted that the first scenario presented is likely to bring about the greatest change in the carbon footprint associated with inhaler use. The point was made that the value of switching should be weighed up as low carbon does not always mean low cost and the increase in budget spend may be better invested as an initiative elsewhere in the service. While it does state in the report that staffing costs are not taken into consideration, it was felt this should be considered as patients are known to be reluctant to change medications and this may involve several consultations which increases the use of staff resource. The Chair thanked members for their comments and closed the discussion.

10. Feedback from AWPAG meeting held 28th September 2022

Ms Kath Haines provided feedback from the AWPAG meeting held in September 2022. Ms Haines referred members to the minutes of the meeting and drew attention to the key issues of note.

AWMSG members were reminded that there are currently vacancies for doctor members for Betsi Cadwaladr and Cwm Taf Morgannwg University Health Boards and Powys Teaching Health Board, along with a doctor member from Velindre NHS Trust. Members were asked to forward nominations to AWTTTC.

Ms Haines confirmed the next AWPAG meeting will be 14th December 2022.

11. National Prescribing Indicators – data to June 2022

Mrs Claire Thomas and Mr Richard Boldero provided an overview of the NPI data which was presented to AWMSG for information. A member asked if there was a way to exclude patients who had been reviewed as part of the Prescribing Safety Indicators where treatment was found to be appropriate. It was confirmed that AWTTTC is continuing to work with DHCW to develop a code to exclude patients who have previously been reviewed.

One member asked how the report was used by health boards to improve the service to their patients and whether health boards share initiatives.

Members were informed that the report provides an overview of the NPIs at health board level and the SPIRA platform enabled further interrogation of the data at a more local level. The point was made that the annual AWTTTC Best Practice Day provides opportunity for health boards to share initiatives and relay information.

Members noted significant improvements by some health boards and suggested that the report could be improved by an explanation of what action the health board had taken to achieve the change.

12. AWMSG Policy for appraising a medicine for a very rare disease

Miss Shaila Ahmed presented an overview of the policy which had been updated to align with NICE methods. Members were informed that AWMSG will continue to consider a broad range of considerations when appraising medicines for very rare diseases and the CAPIG process will be retained.

The Chair confirmed AWMSG's endorsement of the updated policy.

13. AWMSG Policy for appraising medicines for severe conditions

Miss Shaila Ahmed presented an overview of the policy. Members heard the introduction of a new severity modifier will benefit a broader range of seriously debilitating conditions and the application of the severity modifier will more accurately reflect social values and preferences.

The Chair confirmed AWMSG's endorsement of the policy.

14. Any other business

There was no other business.

The Chair confirmed the date of the next meeting on Wednesday 8th February 2023 in Cardiff and closed the meeting.