

Enclosure No:	1/AWMSG/0923
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
at 10.30 am Tuesday, 11th July 2023 at
the All Nations Centre, Sachville Avenue, Cardiff, CF14 3NY**

Voting members present:

**Did not
participate in
agenda item:**

- | | | |
|------------|------------------------------|--|
| 1. | Prof Iolo Doull | Chairman |
| 2. | Prof Stephen Monaghan | Consultant in Public Health Medicine |
| 3. | Dr Saja Muwaffak | Welsh Health Specialised Services
Committee |
| 4. | Prof Dyfrig Hughes | Health Economist |
| 5. | Ms Kate Parrish | ABPI (Wales) |
| 6. | Mrs Claire James | Lay Representative |
| 7. | Dr Alison Thomas | Clinical Pharmacologist |
| 8. | Mr Dylan Jones | Community Pharmacist |
| 9. | Dr Jeremy Black | GP with prescribing lead role |
| 10. | Mr James Leaves | Director of Finance |
| 11. | Mr David Fox | Senior Hospital Pharmacist |
| 12. | Ms Susan Newport | Senior Nurse |

Welsh Government:

Mr Andrew Evans

AWTTC staff:

Mr Richard Boldero, Senior Pharmacist
 Prof James Coulson, NMG Chairman
 Dr Paul Deslandes, Senior Pharmacist
 Mrs Sian Harbon, Scientist/Medical Writer
 Dr Stuart Keeping, Senior Scientist

Mr Tony Williams, Interim Programme Director
Mrs Gail Woodland, Senior Pharmacist
Mrs Helen Adams, Senior Pharmacist
Dr Laurence Grey, AWPAG Chairman
Mrs Claire Thomas, Head of WAPSU

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.

The Chair welcomed Dr Saja Muwaffat to her first meeting as a voting member in the capacity as WHSSC representative.

2. **Apologies:**

Mr Chris Brown, Chief Pharmacist
 Dr Sam Cox, Hospital Consultant
 Ms Alison Hughes, Senior Primary Care Pharmacist
 Mrs Pam James, Lay Representative
 Mrs Julie Wilson-Thomas, Lay Representative
 Ms Rafia Jamil, Senior Primary Care Pharmacist
 Mr Jonathan Simms, Chief Pharmacist
 Dr Manjeet Singh, Hospital Consultant
 Dr Richard Skone, Medical Director
 Dr Helen Fardy, WHSSC

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 14 June 2023 were checked for accuracy and approved. There were no matters arising.

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

The Chair thanked Dyfrig Hughes for stepping in to chair the end of the meeting on 14th June when he attended a Health and Social Care Committee enquiry into gynaecological cancer treatment at the Senedd. He confirmed the proceedings of this enquiry are available on the Senedd's website.

The Chair informed members that he was pleased to join AWTTTC in celebrating 40 years of Yellow Card reporting at the YCC Wales Medicines Safety Day on Monday, 19 June at the Cardiff City Stadium. The excellent programme included two patient experience presentations which were particularly thought-provoking and highlighted the importance of reporting adverse reactions to medicines.

The One Wales Medicines Assessment Group met in June and reviewed One Wales advice for mepolizumab for the treatment of chronic eosinophilic pneumonia. The Chair asked members to **note** the decision of OWMAG to continue to **not** support use of mepolizumab for this indication. This advice will be reviewed after three years, or sooner should new evidence become available.

The Chair announced the appointment of Dr Andy Champion as the AWTTTC Programme Director and welcomed Claire Thomas to her first meeting as Head of WAPSU and Medicines Optimisation Lead.

The Chair confirmed the next agenda item would be conducted in private to protect commercial confidentiality. Individuals seated in the public gallery left the room.

6. **Emtricitabine/tenofovir alafenamide (Descovy®)** for Pre-exposure prophylaxis (PrEP) of human immunodeficiency virus-1 (HIV-1) infection in at risk men who have sex with men, including adolescents (with a body weight at least 35kg).

The Chair welcomed delegates from Gilead Sciences Ltd and confirmed they would be invited to comment and respond to questions.

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 invited Dr Stuart Keeping, to summarise the evidence. Dr Keeping confirmed the need for advice on Descovy® for this indication has been identified by clinical experts in Wales. Gilead Sciences Ltd did not provide a health technology appraisal submission due to lack of resources. AWTTTC was instructed to prepare a report of the evidence available in the public domain by the AWMSG Steering Committee. It was acknowledged that Gilead Sciences Ltd had provided some supporting information.

Dr Keeping summarised the assessment report and confirmed that no evidence of cost-effectiveness had been submitted. Members were informed that a cost-utility analysis using United States data which compared the costs and effects of Descovy® with generic Truvada had been identified. Members were informed that AWMSG had considered Truvada for PrEP in 2017 and it had not been recommended as the case for cost-effectiveness was not proven. To address the uncertainties raised by AWMSG, Welsh Government funded the PrEPARED study which provided access to Truvada to all those eligible. AWMSG reviewed these data in 2020, noting that generic Truvada was available, and recommended use.

Prof James Coulson summarised the discussion at the NMG meeting and confirmed the NMG recommendation to AWMSG that emtricitabine/tenofovir alafenamide (Descovy®) is not recommended for use within NHS Wales for the indication outlined by Dr Keeping.

Prof Coulson explained the remit of NMG is to consider the evidence of clinical effectiveness and cost effectiveness. NMG noted that clinical experts had expressed an unmet need for patients in cases where Truvada given for PrEP was not suitable in patients presenting with adverse events with existing kidney or bone susceptibilities. Descovy® is the only other licensed option for PrEP.

The Chair raised the issue of the price and asked why Wales may pay a higher price than other parts of the UK. The Gilead Sciences delegate confirmed that confidential conversations were ongoing with NHS Wales procurement and the point was made that tendering processes across the UK varied.

The Chair opened discussion and invited comments relating to clinical effectiveness. Members discussed transmission rates, adherence and prevalence. Clarification was sought as to why two patients discontinued Descovy® in the trial. The company delegate explained it was because of a renal event due to underlying health issues.

The Chair invited Prof Hughes to summarise the evidence of cost-effectiveness. Prof Hughes confirmed that no health economic model had been provided and the absence of any of evidence to demonstrate that Descovy® was cost effective for the patient population identified was noted.

The Chair asked the delegates from Gilead to leave the room for members to discuss the budget impact estimates in private so that commercially sensitive information on price could remain confidential.

The lay member summarised the views and opinions from three individual patient submissions and one from the National Aids Trust. The inequity in access across the UK was noted. The lay representative expressed disappointment that Gilead had not provided any evidence of cost-effectiveness.

Prior to closing the discussion, the Chair asked the company delegates if they wished to comment. They thanked AWMSG members and confirmed that the process had been fair and all the issues had been adequately addressed.

Members retired to vote in private.

The meeting re-convened and the Chair announced AWMSG's recommendation to Welsh Government.

Emtricitabine/tenofovir alafenamide (as fumarate) (Descovy®) is not recommended for use within NHS Wales for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in at-risk men who have sex with men, including adolescents (with body weight at least 35 kg).

The case for cost-effectiveness has not been proven.

The Chair informed the delegates that the recommendation would be emailed to them and they would have ten working days to comment or provide additional information. After this time the recommendation would be forwarded to Welsh Government for ratification.

7. One Wales: Dostarlimab (Jemperli®)

Mrs Gail Woodland, AWTTTC pharmacist, explained that this medicine was taken through the One Wales medicines process for the first line treatment of locally advanced stage II/III deficient mismatch repair (dMMR) / high microsatellite instability (MSI-H) rectal cancer (OW26). Mrs Woodland referred members to the One Wales Medicines Assessment Group (OWMAG) recommendation and accompanying rationale. No comments were raised by members and the Chair confirmed AWMSG's endorsement. The recommendation will be sent to Welsh Government for ratification.

8. Inhaler decarbonisation report

Richard Boldero gave a summary of the report and outlined some changes that had been suggested by the steering committee. The Chair asked to see the direction of travel between primary and secondary care data. In regards to this request Mr Boldero explained that secondary care data could be provided in the reports on a quarterly basis. Claire James made the point that SPIRA data is not accessible to the public. Mr Evans confirmed that Welsh Government is supportive of more accessible data in line with the open data policy.

9. Feedback from the AWPAG meeting held 28 June 2023

Dr Laurence Gray provided verbal feedback from the AWPAG meeting held in June 2023 and drew attention to the key issues of note. He confirmed the draft minutes of the AWPAG June meeting will be shared with members at the next AWMSG meeting in September 'for information only'.

Dr Gray highlighted AWPAG vacancies for doctor members for Cwm Taf Morgannwg University Health Boards, Powys Teaching Health Board and Velindre NHS Trust. Members were asked to forward nominations to AWTTTC.

Dr Gray confirmed the next AWPAG meeting will be held on 20th September 2023.

10. Antidepressant prescribing patterns and adverse events following introduction of a National Prescribing Indicator to monitor dosulepin usage in Wales

Dr Deslandes provided an overview of a paper recently accepted for publication in the British Journal of Clinical Pharmacology. The paper explored patient outcomes following the introduction of the AWMSG NPI monitoring dosulepin usage from 2011 to 2014.

11. Any other business

There was no other business.

The Chair confirmed the date of the next meeting on Wednesday 13th September 2023 Venue: Cardiff Metropolitan University, Cyncoed.

Post meeting date change to Monday, 11th September at 9.00 am