

## SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 2<sup>ND</sup> DECEMBER 2025

*Information is being withheld, under Section 43 of the Freedom of Information Act 2000, on the grounds that information regarding the issue under consideration and advice from the IDWG remains confidential at the date of this summary and will remain so until a final decision has been taken. Any request for future information should be made direct to the MHRA (via [info@mhra.gov.uk](mailto:info@mhra.gov.uk)) and will be considered in accordance with the FOI Act.*

The Group considered and discussed the following:

- The Group were provided with an update on the implementation of the PMS Statutory Instrument (SI) and was presented with a case study to show the impact of the SI.
- The outgoing PRASEAG Chair presented an overview of the PRASEAG committee, including the history and membership.
- The Group received a presentation on the use of mesh devices for rectal prolapse. Key considerations discussed included intended use, governance, patient information, and management of foreseeable use. The recommendations were noted and endorsed, with further work to be taken forward through appropriate MHRA and stakeholder processes.
- The Group reviewed progress toward strengthening the UK's safety and surveillance system for medicines and medical devices. Key priorities include improving data quality, expanding access to real-world evidence, enhancing reporting systems, and developing advanced analytical tools to support timely, proportionate regulatory decisions.
- The Group reviewed progress in improving medical device incident data and introduced the upcoming automated signal-detection system aiming to launch in December 2025. Future plans include strengthening data quality, enhancing methodologies, and expanding tools to support more robust device safety monitoring.
- A roundtable discussion about IDWG between the Group was facilitated by the Chair.
- The Group were provided with an update on the Agency's work on UK regulatory reform for medical devices.

### **Procedural Items**

In addition, the Group completed its usual procedural business including the need to observe the confidentiality of the meeting, to declare interests, apologies, announcements, approval of minutes, and updates on items previously considered. Mr Jonathan Boyle declared an other relevant interest in one or more agenda items and the appropriate action was taken.

A list of members who participated in the meeting is at **Annex A**.

Medicines Healthcare products Regulatory Agency staff may be present for all or part of the meetings or for specific items.

The meeting started at 10:31 and finished at 15:17. The next meeting is scheduled to take place on 13<sup>th</sup> January 2026 at 10:00.

## **Useful website links**

### ***MHRA Website:***

[Medicines and Healthcare products Regulatory Agency - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

### ***MHRA Alerts, recalls and safety information:***

[Alerts, recalls and safety information: drugs and medical devices - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

### ***Yellow Card Website:***

[Yellow Card Scheme - MHRA](http://www.gov.uk)

### ***Drug Safety Update:***

[Drug Safety Update - GOV.UK](http://www.gov.uk)

## MEMBERSHIP OF THE INTERIM DEVICES WORKING GROUP

Post	Name and title	Affiliations
<b>Chair</b>	<b>Professor Tom Clutton-Brock</b> MBE MB ChB FRCP FRCA FFICM	Director, Medical Devices Testing and Evaluation Centre, Clinical Director, NIHR HealthTech Research Centre in Devices, digital and robotics (HRC-DDR), Chair, NICE Interventional Procedures Advisory Committee, Associate Medical Director, University Hospitals Birmingham NHS Foundation Trust, Professor of Anaesthesia & Intensive Care Medicine, University of Birmingham
<b>Observer</b>	<b>Peter Barry</b>	Consultant Clinical Advisor, Centre for Guidelines, National Institute for Health and Care Excellence
<b>Member</b>	<b>Mr Jonathan Boyle</b> MB ChB MD MA (Cantab) FRCSEd FRCSEng FRCS (Gen.Surg)	Consultant Vascular Surgeon and affiliate Assistant Professor, Cambridge University Hospitals NHS Trust
<b>Member</b>	<b>Professor Richard Bulbulia</b> MA MD FRCS FRCS(Gen) <i>(apologies)</i>	Associate Professor, Clinical Trial Service Unit and Epidemiological Studies Unit, Nuffield Department of Population Health, University of Oxford; Medical Research Council Population Health Research Unit at the University of Oxford; Honorary Consultant Vascular Surgeon, Gloucestershire Hospitals NHS Foundation Trust
<b>Member</b>	<b>Professor Alastair Denniston</b> MA MRCP FRCOphth PhD	Chair of Regulatory Science and Innovation , University of Birmingham Hon Consultant Ophthalmologist, University Hospitals Birmingham NHSFT
<b>Lay Member</b>	<b>Dr Rebecca Harmston</b>	
<b>Member</b>	<b>Mr Michael Hart</b> BSc (Hons) MBChB AHEA PhD FRCSEd (Neuro.surg) FEBNS	Senior Lecturer & Honorary Consultant Neurosurgeon, St George's, University of London & St George's University Hospitals NHS Foundation Trust
<b>Member</b>	<b>Professor Chris Hopkins</b> BSc (Hons) FAHCS FIPEM CEng MIET <i>(apologies)</i>	Consultant Clinical Scientist, Honorary Professor and Clinical Director, Assistive Technologies Innovation Centre, University of Wales Trinity Saint David, Head of the Tritech Institute, Hywel Dda University Health Board, Assistant Director of Health Science and AHP's, Betsi Cadwaladr University Health Board, President-Elect of Academy for Healthcare Science
<b>Member</b>	<b>Mr Sebastian Janner</b> MSci MSc	Clinical Scientist, Royal Brompton and Harefield Hospitals
<b>Observer</b>	<b>Sarah Jennings</b>	Patient Safety Clinical Lead - Medical Devices, NHS England
<b>Member</b>	<b>Professor Tom Joyce</b> PhD MSc Beng	Professor of Orthopaedic Engineering, Newcastle University

<b>Member</b>	<b>Professor Daniel Martin</b> OBE BSc MB ChB PhD FRCA FFICM	Professor of Perioperative and Intensive Care Medicine, Peninsula Medical School, University of Plymouth
<b>Member</b>	<b>Dr Rubeta Matin</b> PhD BSc (Hons) MBBS FRCP(Derm) ( <i>apologies</i> )	Consultant Dermatologist, Oxford University Hospitals NHS Foundation Trust; Honorary Senior Clinical Lecturer, University of Oxford
<b>Invited Expert</b>	<b>Mr Nigel Mercer</b>	Consultant Plastic Surgeon; Chair of the Plastics, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG)
<b>Member</b>	<b>Dr Tom Pelly</b> MBBS BSc (Hons) DCH PGCE FRCP FRCGP	GP Partner, Horfield Health Centre, Bristol; Clinical Director, Phoenix Primary Care Network, Bristol; RCGP Representative
<b>Member</b>	<b>Professor Muireann Quigley</b> BSc (Med) BSc (Hons) MBChB MA PhD	Chair in Law, Medicine, and Technology, Birmingham Law School, University of Birmingham
<b>Invited Expert</b>	<b>Dr Baljit Singh</b> BA BM BCh MA DPhil FRCS FACS	Consultant Colorectal Surgeon and Honorary Associate Professor, University Hospitals Leicester NHS Trust
<b>Member</b>	<b>Dr Neil Smart</b> BSc (Hons) MBChB FCAI MBA	Chair of the Scottish Health Technologies Group, Consultant Anaesthetist NHS Greater Glasgow and Clyde and Honorary Clinical Senior Lecturer, University of Glasgow
<b>Lay Member</b>	<b>Ms Josephine Tapper</b>	