

SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 12TH NOVEMBER 2024

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) and will be considered in accordance with the FOI Act.

Papers for advice

The IDWG were provided with a brief update on the [draft Post-Market Surveillance statutory instrument \(PMS SI\)](#) which was laid in Parliament on 21 October 2024. This instrument will introduce new PMS requirements for medical devices that prioritise patient safety, while still giving patients access to the safe medical devices they need and ensuring the UK remains an attractive market for medical technology innovators.

The IDWG were provided with an update and presentation concerning an investigation into a defibrillator.

The IDWG was updated on the progress of signal detection, validation, and confirmation in drug-event case studies, with a focus on ADR analysis and causality assessment. Recent developments in signal detection methods were discussed, including the use of disproportionality analysis (DPA) and pattern recognition, alongside new software to optimize EBGM calculations. The group also explored how these data-driven approaches could be adapted for device data, considering differences in reporting structures, data completeness, and types of adverse events between drugs and devices.

The IDWG was provided with a top level overview of 'Software' from the Chair of the Artificial Intelligence, Software and Apps Expert Advisory Group.

The IDWG were presented with a high-level summary of signals concerning medical devices that were assessed by the MHRA in September 2024.

The IDWG considered the evidence presented from the evaluation of risks associated with surgical mesh used for rectopexy. The topic will be brought back to a future meeting for continued discussion.

A general roundtable discussion took place between IDWG members, covering the statutory function update, length of meetings and suggestions for future meetings, before the Chair thanked the Committee and closed the meeting.

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 Thomas Dudding declared personal interests 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 10:25 and finished at 15:04.

The next meeting is scheduled to take place on 10th December 2024.

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.mhra.gov.uk)

Drug Safety Update:

<http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm>

MEMBERSHIP OF THE INTERIM DEVICES WORKING GROUP

Post	Name and title	Affiliations
Chair	Professor Tom Clutton-Brock 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
Member	Mr Jonathan Boyle MB ChB MD MA (Cantab) FRCSEd FRCSEng FRCS (Gen.Surg)	Consultant Vascular Surgeon and affiliate Assistant Professor, Cambridge University Hospitals NHS Trust, University Hospital Southampton
Member	Professor Richard Bulbulia MA MD FRCS FRCS(Gen)	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
Member	Professor Alastair Denniston MA MRCP FRCOphth PhD	Consultant Ophthalmologist (Uveitis and Medical Retina), University Hospitals Birmingham NHSFT, Honorary Professor and Deputy Director Centre for Regulatory Science and Innovation, University of Birmingham
Invited Expert	Mr Thomas Dudding MD FRCS	Consultant Colorectal Surgeon, University Hospital Southampton
Lay Member	Dr Rebecca Harmston (<i>apologies</i>)	
Member	Mr Michael Hart 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
Member	Professor Chris Hopkins BSc (Hons) FAHCS FIPEM CEng MIET	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
Member	Mr Sebastian Janner MSc MSc	Clinical Scientist, Royal Brompton and Harefield Hospitals
Member	Professor Tom Joyce PhD MSc BEng	Professor of Orthopaedic Engineering, Newcastle University
Member	Professor Daniel Martin OBE BSc MB ChB PhD FRCA FFICM	Professor of Perioperative and Intensive Care Medicine, Peninsula Medical School, University of Plymouth

Member	Dr Rubeta Matin PhD BSc (Hons) MBBS FRCP(Derm) <i>(apologies)</i>	Consultant Dermatologist, Oxford University Hospitals NHS Foundation Trust; Honorary Senior Clinical Lecturer, University of Oxford
Member	Dr Tom Pelly MBBS BSc (Hons) DCH PGCE FRCP FRCGP	GP Partner, Horfield Health Centre, Bristol; Clinical Director, Phoenix Primary Care Network, Bristol; RCGP Representative
Member	Professor Muireann Quigley BSc (Med) BSc (Hons) MBChB MA PhD	Chair in Law, Medicine, and Technology, Birmingham Law School, University of Birmingham
Member	Dr Neil Smart 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
Lay Member	Ms Josephine Tapper	
Observer	Sarah Jennings	Patient Safety Clinical Lead - Medical Devices, NHS England
Observer	Iain Robertson	Medical Advisor Medical Devices and Legislation Unit, Scottish Government