

## SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 13<sup>TH</sup> JANUARY 2026

*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 was updated on the MHRA's current compliance approach for medical devices and how this will develop.
- The Group was presented with the regulatory determination for a Software as a Medical Device. The Group endorsed the MHRA's approach.
- The Group were presented with a high-level summary of one signal concerning medical devices that was assessed by the MHRA in November 2025.
- The Group was provided with a presentation on how the MHRA managed a case concerning a suspected bacterial contamination of a medical device. The presentation focused on actions taken by the MHRA and its stakeholders including case investigation and incident management.
- The Group were invited to review and provide feedback on the draft revision of Managing Medical Devices guidance document.

### **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. No interests were declared.

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 10:03 and finished at 12:09. The next meeting is scheduled to take place on 3<sup>rd</sup> March 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.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
<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 Diagnostics Advisory Committee (DAC), 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> ( <i>apologies</i> )	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)	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>Observer</b>	<b>Dr Sara Davies</b>	Consultant in Public Health Medicine, Scottish Government
<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>Observer</b>	<b>Farhan Ismail</b>	Associate Director, Office for Digital Health and Medtech Topic Intelligence, National Institute for Health and Care Excellence

<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)	Consultant Dermatologist, Oxford University Hospitals NHS Foundation Trust; Honorary Senior Clinical Lecturer, University of Oxford
<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>Observer</b>	<b>Iain Robertson</b> ( <i>apologies</i> )	Medical Advisor Medical Devices and Legislation Unit, Scottish Government
<b>Observer</b>	<b>Freya Rowland</b>	Head of Medical Devices Regulation and Regulatory Policy, Medical Technology Directorate, Department of Health and Social Care
<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>	
<b>Observer</b>	<b>David Wilson</b> ( <i>apologies</i> )	Safety Strategy Unit, Department of Health (NI)