

## SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 4<sup>TH</sup> NOVEMBER 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 was provided with a presentation summarising the role of the MHRA's Device Compliance Unit. The presentation covered all aspects including function, enforcement powers and typical breaches encountered by the team.

The Group was presented with MHRA findings and regulatory actions following investigation into continuing reports of discrepant readings of continuous glucose monitors compared to blood glucose monitors.

The Group were presented with a high-level summary of signals concerning medical devices that were assessed by the MHRA in September 2025.

The Group were provided with an overview of the investigation into a Spinal Growing Rod System. The Group were informed that due to regulatory non-compliance, the MHRA issued a suspension notice to prevent further supply of the products to the UK market. A full assessment concluded that the device had not been appropriately CE marked and the MHRA issued a Safety Notice in September 2025.

The Group was provided with a presentation outlining the progress of ongoing investigations of modular neck hip replacements including the development and publication of [DSI/2025/005](#) and current status of ongoing wider investigations.

The Group were presented with an update regarding the investigations into a total knee replacement device with a potential increased risk of revision. The presentation covered a summary of key clinical datasets, a review of the manufacturer's root cause assessment, details of the MHRA's collaboration with stakeholders and potential compliance activities.

### **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 conflicts 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 10:02 and finished at 12:23. The next meeting is scheduled to take place on 2<sup>nd</sup> December 2025.

## **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 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>Chris Bird</b>	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>Observer</b>	<b>Kerry Chalmers</b>	Medical Devices Policy and Legislation Head of Unit, Chief Medical Officer's Policy Division, Scottish Government
<b>Member</b>	<b>Professor Alastair Denniston</b> 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
<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	Consultant Clinical Scientist, Honorary Professor and Clinical Director, Assistive Technologies Innovation Centre, University of Wales Trinity Saint David, Head of the Trittech 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>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>Invited Expert</b>	<b>Dr Ashley Stratton-Powell</b> BSc MSc PhD RAC CEng	Adjunct Assistant Professor in Medical Device Regulatory Affairs, Trinity College Dublin; Compliance and Risk Team Manager (AI), BSI
<b>Lay Member</b>	<b>Ms Josephine Tapper</b> <i>(apologies)</i>	