

SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 9TH SEPTEMBER 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) and will be considered in accordance with the FOI Act.

The Group considered and discussed the following:

- The Group considered the evidence presented from the evaluation of risks associated with a renal replacement therapy system.
- The Group considered the evidence presented on the risks and clinical benefits of an infant pillow for the prevention and treatment of plagiocephaly. The Group advised that the device should be recalled.
- The Group considered the evidence in line with a product equivalence and safety associated with a cholic reliver device. Appropriate actions were supported by the Group.
- The Group were presented with a high-level summary of a signal concerning medical devices that were assessed by the MHRA in June and July 2025.
- The Group was informed of a potential safety concern associated with the use of hybrid closed loop systems.

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. Karen Jenkins declared a personal interest in one agenda item 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 10:05 and finished at 12:52. The next meeting is scheduled to take place on 7th October 2025.

Useful website links

MHRA Website:

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

MHRA Alerts, recalls and safety information:

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

Yellow Card Website:

[Yellow Card Scheme - MHRA](https://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
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 (<i>apologies</i>)	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 Fraser Gilmour RCT(Renal) MIET	Renal Technical Manager, Dorset County Hospital NHS Foundation Trust
Lay Member	Dr Rebecca Harmston	
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 (<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
Member	Mr Sebastian Janner MSci MSc	Clinical Scientist, Royal Brompton and Harefield Hospitals
Invited Expert	Karen Jenkins MSc PGDipHE INP RN	UKKA Co-Chair Kidney Patient Safety Committee National Clinical Advisor, Enhanced Supportive Kidney Care; Consultant Nurse, Kent Kidney Care Centre, East Kent Hospitals University NHS Foundation Trust

Member	Professor Tom Joyce PhD MSc BEng <i>(apologies)</i>	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)	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
Invited Expert	Professor Paul Rylance BSc MB BS FRCP CertMedEd	Consultant in General and Renal Medicine, Royal Wolverhampton NHS Trust
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	
Invited Expert	Dr David Tuthill MB BCh FRPCH	Consultant Paediatrician Children's Hospital for Wales, Cardiff
Observer	Peter Barry	Consultant Clinical Advisor, Centre for Guidelines, National Institute for Health and Care Excellence
Observer	Sarah Jennings	Patient Safety Clinical Lead - Medical Devices, NHS England
Observer	Iain Robertson	Medical Advisor Medical Devices and Legislation Unit, Scottish Government