

SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 8TH APRIL 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.

Papers for advice

- The Group considered the evidence presented from the evaluation of risks associated with a gastric balloon. The Group recommended that further risk minimisation measures should be implemented and these actions should be communicated to the relevant stakeholders.

Agency device related internal updates

- The Group were introduced to the new Chair of the Medicines and Healthcare products Regulatory Agency (MHRA). This was followed by a presentation and discussion where several strategic topics were considered. The Group were asked to lend their expertise to help develop future MHRA strategy in relation to the surveillance and safety of medical devices. This topic will continue to be discussed further at future meetings.
- The Group were presented with a high-level summary of signals concerning medical devices that were assessed by the MHRA in February 2025.
- The Group was provided with a short presentation on an assessment the MHRA are undertaking on polyurethane breast implants. An interim paper was drafted to seek advice from PRASEAG on whether precautionary regulatory action should be taken. The interim paper addressed concerns identified from wider literature, international regulators, and from manufacturer technical documentation. This was for information only.

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 10:05 and finished at 12:15.

The next meeting is scheduled to take place on 13th May 2025 at 10:00.

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) <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
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	Professor Sir Andrew F Goddard MA MD FRCP MACP FFOM(Hon) FFSEM(Hon) FRCA(Hon) FRACP(Hon) FAMS FRCPI(Hon)	Consultant Gastroenterologist, Royal Derby Hospital Honorary Professor, University of Nottingham, School of Medicine; Chair of Artificial Intelligence, Software and Apps Expert Advisory Group
Lay Member	Dr Rebecca Harmston	
Member	Mr Michael Hart BSc (Hons) MBChB AHEA PhD FRCSEd (Neuro.surg) FEBNS <i>(apologies)</i>	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 Triton 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 <i>(apologies)</i>	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)	Consultant Dermatologist, Oxford University Hospitals NHS Foundation Trust; Honorary Senior Clinical Lecturer, University of Oxford
Invited Expert	Dr Karen Nugent	Colorectal Surgeon, University of Southampton
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	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