

SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 9TH APRIL 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.

Agency device related internal updates

The Group received an update regarding the safety and performance of a defibrillator. The Group discussed possible actions open to MHRA in a scenario where a manufacturer is unable to provide sufficient evidence regarding the safety and performance a device.

The Group were informed of the MHRA's investigation into the *Ralstonia pickettii* outbreak associated with contaminated 0.9% sodium chloride products intended for irrigation, inhalation and eyewash and the resulting recall of these products. The Group also heard of the communications associated with this action, including the Device safety Information and the news story the MHRA published - [Precautionary recall of some sodium chloride solutions for irrigation, eyewash and inhalation, manufactured between April and November 2023 - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/news/precautionary-recall-of-some-sodium-chloride-solutions-for-irrigation-eyewash-and-inhalation-manufactured-between-april-and-november-2023)

The Group received a summary presentation on the equity in medical devices independent review. This included a summary of the guidance issued because of this review. The presentation and Group focused on and discussed pulse oximeter devices that are in widespread use. The Group discussed the complications associated with categorisation of skin colour including the limitations, inaccuracies, and biases of skin colour charts.

The Group received a brief presentation on medical device counterfeit examples and discussion followed on the similarities and differences between the examples presented.

The Group received a presentation on NIHR HealthTech Research Centres (HRCs) and informed about 14 new HRCs launched in April 2024. There was discussion on the benefits and contributions made by HRCs in bringing medical devices to healthcare.

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 10:02 and finished at 11:25.

The next meeting is scheduled to take place on 14th May 2024 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
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	Consultant Ophthalmologist (Uveitis and Medical Retina), University Hospitals Birmingham NHSFT, Honorary Professor and Deputy Director Centre for Regulatory Science and Innovation, University of Birmingham
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	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 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

Post	Name and title	Affiliations
Member	Professor Daniel Martin OBE	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
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