

## SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 19<sup>TH</sup> APRIL 2023

*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.*

### **Papers for advice**

The IDWG considered the serious risk of unexpected loss of function, without an accompanying alarm to alert healthcare professionals and users, for a group of devices used in critical care and high dependency settings. The IDWG considered the effectiveness of the current actions to mitigate the risk and proposed further actions.

Based on the evidence, the IDWG endorsed the conclusions that the risk of using these devices outweighed any potential benefit and recommended their removal from use in the UK.

The IDWG also advised on the MHRA issuing further communication on this topic and recommended that relevant stakeholder engagement should be sought on any communications.

### **Procedural Items**

In addition, the IDWG 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 of interest 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 11:03 and finished at 12:22.

The next meeting is scheduled to take place on 16<sup>th</sup> May 2023 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

### Chair

**Professor Tom Clutton-Brock** MBE MB ChB FRCP FRCA

Director, Medical Devices Testing and Evaluation Centre, Clinical Director, NIHR Trauma Management MedTech Cooperative, Chair, NICE Interventional Procedures Advisory Committee, Associate Medical Director, University Hospitals Birmingham NHS Foundation Trust, Professor of Anaesthesia & Intensive Care Medicine, University of Birmingham

### Members

**Professor Alastair Denniston** MA MRCP FRCOphth PhD (*apologies*)

Consultant Ophthalmologist (Uveitis and Medical Retina), University Hospitals Birmingham NHSFT, Honorary Professor and Deputy Director Centre for Regulatory Science and Innovation, University of Birmingham

**Dr Rubeta Matin** PhD BSc (Hons) MBBS FRCP[Derm]

Consultant Dermatologist, Oxford University Hospitals NHS Foundation Trust; Honorary Senior Clinical Lecturer, University of Oxford

**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

**Ms Josephine Tapper**

Lay member

### Invited Experts

**Dr Martin Allen**

Consultant Physician, University Hospital of North Midlands

**Dr Peter Hersey**

Critical Care Lead, Sunderland Royal Hospital

**Dr Ben Messer**

Consultant Critical Care/Home Ventilation, Newcastle Hospitals NHS Foundation Trust

**Professor S. Ramani Moonesinghe**

National Clinical Director for Critical and Perioperative Care, NHS England  
Director, NIHR Central London Patient Safety Research Collaboration  
Professor and Head of Centre for Perioperative Medicine, Charles Bell House, University College London

Head of Research Department for Targeted Intervention, Division of Surgery and Interventional Science, University College London

Honorary Consultant in Anaesthesia and Perioperative Medicine, University College London Hospitals

### Observers

**Peter Barry**

Consultant Clinical Advisor, Centre for Guidelines  
National Institute for Health and Care Excellence

**Sarah Jennings**

Patient Safety Clinical Lead - Medical Devices  
NHS England

**Iain Robertson**

Medical Advisor Medical Devices and Legislation Unit  
Scottish Government

**David Wilson**

Safety Strategy Unit, Department of Health (NI)