

## SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON TUESDAY 5<sup>TH</sup> SEPTEMBER 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.*

### Paper for advice

#### **Device for the treatment of colic**

The Group considered the benefit and risk profile associated with a device used to treat colic, in particular by non-healthcare professionals. The Group agreed next step actions to further understand the benefit and risk associated with the device.

### Agency updates

#### **Software as a Medical Device – an overview**

The Group were presented with an overview of Software as a Medical Device (SaMD) by a member of the software and AI group within the MHRA. An overview of the upcoming legislative changes and supporting guidance documents was given with a focus on post market surveillance. A review of the key points of recent guidance on post market surveillance of software and AI products was given, highlighting the concept of indirect harm in the reporting and mitigation of risks for software products. The presentation ended with a review of the collaborative projects occurring across government and internationally to ensure safety regulations are in alignment.

#### **DHSC Independent Review Equity in Medical Devices - MHRA response**

The Group were informed of the DHSC sponsored Independent Review on Equity in Medical Devices. The Group heard of the MHRA's responses to key themes in the embargoed report, specifically around pulse oximeters and optical devices, AI and software as a medical device and data collection for medical devices.

The Group noted the extensive, ongoing work by the MHRA to address these issues, and that post-market surveillance will be important in identifying other potential risks of bias. The MHRA will have further powers to address post-marketing surveillance with new regulations coming in 2025.

### 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 held on 5<sup>th</sup> September 2023 started at 10:01 and finished at 12:29.

The next meeting is scheduled to take place on Tuesday 3<sup>rd</sup> October 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 FFICM

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

**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

**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

**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

**Dr Rebecca Harmston**

Lay 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

**Mr Sebastian Janner** MSci MSc

Clinical Scientist, Royal Brompton and Harefield Hospitals

**Professor Tom Joyce** PhD MSc BEng (*apologies*)

Professor of Orthopaedic Engineering, Newcastle University

**Professor Daniel Martin OBE**

Professor of Perioperative and Intensive Care Medicine, Peninsula Medical School, University of Plymouth

**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 Tom Pelly** MBBS BSc (Hons) DCH PGCE FRCP FRCGP

GP Partner, Horfield Health Centre, Bristol; Clinical Director, Phoenix Primary Care Network, Bristol; RCGP Representative

**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 Expert**

**Dr Kathryn Johnson** MBChB FRCPCH

Consultant Neonatologist & Research Lead

Yorkshire & Humber CRN Children's Specialty Lead

Clinical Lead, National Congenital Anomaly and Rare Disease Registration Service, NHSD,  
Leeds General Infirmary

**Observers**

**Vicky Ferguson**

Head of Medical Devices Regulation and Regulatory Policy

Department of Health & Social Care

**Sarah Holt**

Programme Support Officer – Best Start

Chief Public Health Nurse Directorate

Office for Health Improvement and Disparities

Department of Health and Social Care

**Professor Chris Jones**

National Clinical Director, NHS Wales

Deputy Chief Medical Officer, Welsh Government

**Iain Robertson**

Medical Advisor Medical Devices and Legislation Unit

Scottish Government