# SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 14TH MAY 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.***

## Matters arising

The Group was presented with a further update regarding the potential for early revision with a total knee arthroplasty system, that was discussed at the previous meeting. They were notified that after a period of stakeholder consultation, a Device Safety Information page has been published on the MHRA alerts website. Confirmation was given that the manufacturer has currently suspended all further sales and implantations of the device family in the UK and would not be reinstated to the market until the manufacturer has provided sufficient evidence concerning device performance. The Group endorsed the actions taken since the previous meeting.

The Group was updated on matters relating to a defibrillator.

## Device signals

The Group was presented with a high-level summary of any signals concerning medical devices that were assessed by the MHRA in March 2024.

## Agency device related internal updates

The Group were presented with an update on the progress with the Innovative Devices Access Pathway (IDAP) Pilot program which is designed to accelerate the development of innovative medical devices that meet an unmet clinical need in the NHS and support their integration into the UK market. The pilot aims to enable and improve patient access to innovative and transformative medical devices, by providing an integrated and enhanced regulatory and access pathway to developers. The purpose of the IDAP Pilot is to test the main elements of the pathway which includes tools to support manufacturers to develop the evidence base to meet the regulatory requirements (MHRA), Health Technology Assessment (NICE) and access to the NHS.

## Med Tech Regulatory Reform update

The Group were provided with an update and overview of the actions undertaken by MHRA in relation to evolving medical device regulatory reform. The presentation and discussion focused on key milestones and future regulatory framework areas of interest and ongoing work related to the development of current and future Statutory Instruments. Additional information was provided around MHRA work related to stakeholder engagement, the strategic work on Artificial Intelligence, health institution exemption and publication of a new “AI Airlock” webpage to help address novel regulatory challenges across sectors.

The Group were presented with the latest position regarding the guidance document to support the forthcoming GB regulations on the post-market surveillance of medical devices. This covered the purpose and target audience for the guidance, together with its development and structure. The main focus was upon a selection of key areas expanded in the guidance where it was felt more clarity was needed to help understand the details of the regulations.

The Group were presented with an overview of the latest position regarding International Recognition for Medical Devices and IVDs. This outlined the proposed policy, objectives and framework depending on device type, class, and prior approval.

## 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 12:59.

The next meeting is scheduled to take place on Tuesday 11th June 2024 at 10am.

## Useful website links

***MHRA Website:***
Medicines and Healthcare products Regulatory Agency - GOV.UK (www.gov.uk)

***MHRA Alerts, recalls and safety information:***
Alerts, recalls and safety information: drugs and medical devices - GOV.UK (www.gov.uk)

***Yellow Card Website:***
Yellow Card Scheme - MHRA

***Drug Safety Update:***
http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm

**ANNEX A**

## 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) ***(apologies)*** | 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 | 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 ***(apologies)*** | 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 ***(apologies)*** | 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, BSc, MB ChB, PhD, FRCA, FFICM ***(apologies)*** | 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 |