# SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 7TH NOVEMBER 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) and will be considered in accordance with the FOI Act.***

## Papers for discussion

### Introduction to the benefit risk evaluation review for the use of mesh in rectopexy procedures, in the treatment of rectal prolapse

The IDWG was presented with an introduction to work being undertaken reviewing the use of surgical mesh in the treatment of rectal prolapse.

The IDWG agreed with the Agency's proposed direction of the review and requested updates on the progress. Stakeholder engagement approaches were encouraged as appropriate to support the review.

## Agency device related internal updates

### Pilot study for rectopexy procedures

The IDWG were introduced to the regulatory study-a-thon the MHRA will be running with the University of Oxford, to explore how a federated data network using a common data model might be used to provide regulatory-focused real-world evidence.

The IDWG noted the importance of this work and requested feedback subsequent to the event. They stressed the importance of accessing both primary and secondary healthcare data and ensuring involvement across the devolved nations.

### Summary of MHRA actions for paclitaxel coated stents/balloons

The IDWG were provided with an overview of the actions undertaken by MHRA in response to a potential risk of paclitaxel coated devices for peripheral arterial disease and increased mortality as first suggested in 2018 by Katsanos et al. published data that suggested an increased risk for mortality in patients treated with these devices. The IDWG was informed that this issue will be taken for IDWG discussion in due course following review of the recent evidence.

### Introduction to the MHRA's Innovative Devices Access Pathway (IDAP)

The IDWG were presented with an overview of IDAP which is delivered in partnership by DHSC, Health Technology Wales, the MHRA, NHS England, NICE and the Scottish Health Technologies Group, part of Healthcare Improvement Scotland.

Working together, the consortium aims to develop a new pre-market pathway that will support patient access to innovative medical devices (including diagnostics and digital health technologies) that meet unmet needs in the health and care system that do not have regulatory authorisation in the UK. The programme aims to provide support to organisations to ensure that they generate the evidence required for regulatory approval and health technology assessment and that the work docks into reimbursement pathways.

The IDAP pilot scheme was launched in September 2023, expressions of interest have been received and are currently being assessed by clinicians and partners. A portfolio of 8 projects will be selected to take forward to test and refine the processes and support tools that IDAP will use.

**MHRA safety advice - SteriFeed Colostrum Collection device**

The IDWG were informed of the work completed on colostrum collection devices, the device safety information and press release the MHRA published- SteriFeed Colostrum Collection device and risk of choking due to infant airway occlusion.

## 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 7th November 2023 started at 10:03 and finished at 13:00.

The next meeting is scheduled to take place on 5th December 2023 at 10:30.

## 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

### 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

**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

**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 ***(apologies)***
Clinical Scientist, Royal Brompton and Harefield Hospitals

**Professor Tom Joyce** PhD MSc BEng
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

**Professor Muireann Quigley** BSc (Med) BSc(Hons) MBChB MA PhD
Chair in Law, Medicine, and Technology, Birmingham Law School, University of Birmingham

**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 Baljit Singh** BA BM BCh MA DPhil FRCS FACS
Consultant Colorectal Surgeon and Honorary Associate Professor, University Hospitals Leicester NHS Trust

### Observers

**Vicky Ferguson**
Head of Medical Devices Regulation and Regulatory Policy
Department of Health & Social Care

**Sarah Jennings**
Patient Safety Clinical Lead - Medical Devices
NHS England

**Iain Robertson**
Medical Advisor Medical Devices and Legislation Unit
Scottish Government