

## SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 10<sup>TH</sup> SEPTEMBER 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](mailto:info@mhra.gov.uk)) and will be considered in accordance with the FOI Act.*

### **Matters arising**

The IDWG were presented with a summary of the updated IVDEAG Terms of Reference (ToR), highlighting the following key changes:

- Adding recommendations for Coronavirus test device approvals to scope of work.
- Governance updated from the Devices Expert Advisory Committee to the Interim Devices Working Group.
- Enhanced details on governance aspects and membership, to align with IDWG ToR.

There were some minor comments from the IDWG regarding the membership appointment process and handling potential conflicts of interests, however there was general agreement with the updated ToR.

The IDWG was provided with an update concerning an investigation into a defibrillator.

### **Papers for advice/discussion**

The IDWG considered the evidence presented from the evaluation of risks associated with a number of Assisted Reproductive Technology products. Fertility experts were invited to review the scientific evidence available. The IDWG recommended that further communications and follow-up should be carried out for the affected stakeholders.

The IDWG were presented with a high-level summary of signals concerning medical devices that were assessed by the MHRA in June and July 2024.

The IDWG considered Health Institution Exempted devices and shared their recommendations about current published guidance for medical devices as well as considering future proposals.

The IDWG was provided with a presentation on how the MHRA are collaborating with NICE on a 3-year Wellcome funded project to explore the regulation and evaluation of digital mental health technologies (DMHTs) that qualify as Software as a Medical Device (SaMD). The presentation covered all aspects of the project including its completed and proposed work packages and how the work will result in guidance and other information to support a range of stakeholders understand the regulation and evaluation of these technologies.

### **Appointments to Expert Advisory Groups (EAGS)**

The IDWG approved the re-appointments of the following members to the Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRAS EAG) for a period of three years:

**Ms Nora Nugent** FRCSI (Plast)  
Consultant Plastic Surgeon

**Dr Dima El-Sharkawi**  
Haemato-Oncology Consultant

**Mr Stephen Thrush**  
Consultant Breast Surgeon

**Ms Ruth Waters** BM FRCS FRCS (Plast)

Consultant Plastic and Reconstructive Surgeon, Queen Elizabeth Hospital, University Hospitals Birmingham

The IDWG noted the end of appointments of the following PRASEAG members

**Dr Cathy Burton**

Consultant Haematologist

**Mr Stephen Hamilton**

Consultant Plastic and Reconstructive Surgeon

**Mr Mark Henley**

Consultant Plastic Reconstructive and Cleft Surgeon

**Mr Douglas MacMillan**

Consultant Breast Surgeon

**Mr Joe O'Donoghue**

BAPRAS representative

### **Agency device related internal updates**

The MHRA is investigating a spinal system following an anonymous report. A Suspension Notice was issued to halt its sale for six months in the UK. The implanting surgeons have been contacted. The investigation will proceed with a review of the technical documentation, and the Suspension Notice status will be reconsidered based on the review's outcomes. The IDWG fully endorsed the actions taken by the MHRA to date.

The IDWG was presented with a planned user guidance for Yellow Card reporting of diabetes management equipment.

The IDWG were notified that the MHRA issued a Devices Safety Information (DSI) communication informing users of an Increased Risk of Postoperative Periprosthetic Femoral Fracture (PFF) with the CPT Hip System Femoral Stem 12/14 Neck Taper.

The IDWG were informed that the MHRA were notified of the initial results from the unpublished study by the manufacturer and worked closely with them to take appropriate action which included a Field Safety Notice published in July this year which disclosed the risk and notified users of an update to the instructions for use.

The DSI was issued following stakeholder feedback aligning with the advice of a joint statement issued by British Orthopaedic Association (BOA), British Hip Society (BHS) and the National Joint Registry (NJR) to advise against the use of the device except in certain circumstances.

## **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 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 10:04 and finished at 15:10.

The next meeting is scheduled to take place on 8<sup>th</sup> October 2024 at 10:00.

## **Useful website links**

### ***MHRA Website:***

[Medicines and Healthcare products Regulatory Agency - GOV.UK \(www.gov.uk\)](https://www.gov.uk)

### ***MHRA Alerts, recalls and safety information:***

[Alerts, recalls and safety information: drugs and medical devices - GOV.UK \(www.gov.uk\)](https://www.gov.uk)

### ***Yellow Card Website:***

[Yellow Card Scheme - MHRA](https://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
<b>Chair</b>	<b>Professor Tom Clutton-Brock</b> 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
<b>Invited Expert</b>	<b>Dr Virginia Bolton</b> MA PhD	Visiting Senior Lecturer, King's College London
<b>Member</b>	<b>Mr Jonathan Boyle</b> MB ChB MD MA (Cantab) FRCSEd FRCSEng FRCS (Gen.Surg)	Consultant Vascular Surgeon and affiliate Assistant Professor, Cambridge University Hospitals NHS Trust, University Hospital Southampton
<b>Member</b>	<b>Professor Richard Bulbulia</b> 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
<b>Member</b>	<b>Professor Alastair Denniston</b> 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
<b>Observer</b>	<b>Mrs Sharon Fensome-Rimmer</b>	Chief Inspector, Human Fertilisation and Embryology Authority
<b>Lay Member</b>	<b>Dr Rebecca Harmston</b>	
<b>Member</b>	<b>Mr Michael Hart</b> BSc (Hons) MBChB AHEA PhD FRCSEd (Neuro.surg) FEBNS ( <i>apologies</i> )	Senior Lecturer & Honorary Consultant Neurosurgeon, St George's, University of London & St George's University Hospitals NHS Foundation Trust
<b>Member</b>	<b>Professor Chris Hopkins</b> 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
<b>Member</b>	<b>Mr Sebastian Janner</b> MSci MSc	Clinical Scientist, Royal Brompton and Harefield Hospitals

Post	Name and title	Affiliations
Observer	<b>Sarah Jennings</b>	Patient Safety Clinical Lead - Medical Devices, NHS England
Member	<b>Professor Tom Joyce</b> PhD MSc BEng	Professor of Orthopaedic Engineering, Newcastle University
Member	<b>Professor Daniel Martin</b> OBE BSc MB ChB PhD FRCA FFICM	Professor of Perioperative and Intensive Care Medicine, Peninsula Medical School, University of Plymouth
Member	<b>Dr Rubeta Matin</b> PhD BSc (Hons) MBBS FRCP(Derm)	Consultant Dermatologist, Oxford University Hospitals NHS Foundation Trust; Honorary Senior Clinical Lecturer, University of Oxford
Member	<b>Dr Tom Pelly</b> MBBS BSc (Hons) DCH PGCE FRCP FRCGP	GP Partner, Horfield Health Centre, Bristol; Clinical Director, Phoenix Primary Care Network, Bristol; RCGP Representative
Member	<b>Professor Muireann Quigley</b> BSc (Med) BSc(Hons) MBChB MA PhD	Chair in Law, Medicine, and Technology, Birmingham Law School, University of Birmingham
Observer	<b>Iain Robertson</b>	Medical Advisor Medical Devices and Legislation Unit, Scottish Government
Member	<b>Dr Neil Smart</b> 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
Invited Expert	<b>Dr Thomas Tang</b> MD MRCOG	Consultant Gynaecologist and Specialist in Reproductive Medicine, Clinical Lead in the Regional Fertility Centre, Belfast Health and Social Care Trust
Lay Member	<b>Ms Josephine Tapper</b> ( <i>apologies</i> )	