

SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON TUESDAY 5TH MARCH 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.

Papers for advice

The Group agreed legal advice should be sought to clarify the position of products that have been authorised to be sold in the UK on more than one certification then have one of the certificates withdrawn. The Group considered the safety and performance of a defibrillator and whether and what additional risk mitigation measures should be taken.

The Group was provided with an overview of the paper regarding the potential for early revision with a specific brand of knee arthroplasty system. The Group was presented a summary of the MHRA's proposed strategy to address the current gaps in evidence alongside the performance seen in the UK, compared to other regions, European & Worldwide, where this device is commercialized. Based on the evidence, the IDWG endorsed the MHRA's proposed recommendation for a voluntary suspension to use within the UK. Additionally, members of the Group advised on strategies to ensure patients that are already implanted with this device are followed up as appropriate. The IDWG supported the MHRA issuing further communication on this topic and recommended that relevant stakeholder engagement should be sought on any communications.

Other items

The Group endorsed the appointment of Mrs Dawn Knight, Lay Member to the Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG) for a period of three years.

The Group was presented with a summary of for a field safety corrective action involving sage vitrification kits, manufactured by CooperSurgical and affecting two clinics in the UK. This included the Agency's proposed next steps. The IDWG noted that the corrective action had been in the subject of press interest, due to an investigation being undertaken by the UK fertility regulator HFEA.

The Group was advised that the general guidance published in November 2023 regarding anti-choking devices will be updated following the upcoming publication of the DSI on counterfeit anti-choking devices.

The Group was provided with a short presentation on a review the MHRA are undertaking on a medical device manufacturer. This covered background on the manufacturer, the reasons for conducting this review, case studies, and the aims of the review. This was for information only.

The Group was informed that the Agency is undertaking a review of women's health regulatory inequities, and that their advice on medical advice devices aspects would be sought once the review is complete.

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 10:03 and finished at 13:18.

The next meeting is scheduled to take place on 9th April 2024.

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

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

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) (*apologies*)

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 Experts

Mr Edward Caton
Business Consultant, NEC Software Solutions

Professor Charles Deakin MA MD MB BChir FRCA FRCP FFICM FERC
Honorary Professor of Resuscitation and Pre Hospital Emergency Medicine within Medicine at the University of Southampton

Mr Martin Fagan
National Secretary, The Community Heartbeat Trust

Mr Anthony Hui MA (Cantab) FRCS Ed (Orth)
Orthopaedic Surgeon

Mr Keith Tucker MB BS FRCS
Chair ODEP and the Beyond Compliance Advisory Group

Mr Timothy Wilton MA FRCS
Consultant Orthopaedic Surgeon; President of the British Orthopaedic Association; BASK rep to ODEP; Former member NJR Steering Committee

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

Heather Payne
Senior Medical Officer, Welsh Government

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