SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 5TH DECEMBER 2023 AT MHRA, 10 SOUTH COLONNADE, LONDON

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

Forthcoming regulation on post-market surveillance for medical devices

The IDWG was provided with a short presentation on the forthcoming statutory instrument on post-market surveillance for medical device. This covered the reasons for the new regulation, major milestones to date, the latest status, together with a high level summary of the major components of the regulations. This was for information only.

Introduction to Signals

The IDWG were presented with a high-level overview of the medical device signal management process by a member of Patient Safety Monitoring group. It was explained to the IDWG that they will be presented with a high-level summary of devices signals that had been through the signal management process at future meetings.

Devices Registries

A high-level summary was presented outlining the value of registries and their importance to the Agency, how we can interact with Registries, along with the data fields of interest. An example of data quality issues noted the importance of data quality for our purposes, and summarised other initiatives in device data. An overview of the various Registries, current status, challenges, and next steps was also shared with the Committee.

Notified Bodies / Approved Bodies

The IDWG received a presentation on UK Approved Bodies (UKABs). This included an overview of the role of UKABs in assessing the conformity of medical devices, the process by which the MHRA designates UKABs and the surveillance and monitoring undertaken to ensure UKABs fulfil the relevant regulatory requirements.

Med Tech Regulatory Update

The IDWG were provided with an 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 guidance on software and AI. The MHRAs Innovative Devices Access Pilot (IDAP) programme and work related to international collaboration on best practice and avenues for regulatory recognition were discussed.

Safety and Surveillance

The IDWG were provided with an overview of the key challenges encountered by MHRA in relation to evidence generation when determining the benefit risk profile of a medical device issue and the need to support decision making. A summary of the current and emerging critical areas of evidence generation were presented, including clinical investigation data, published literature and the importance of the MDSO (medical device safety officer) network in helping data gathering.

MHRA safety advice

The IDWG were briefed on the issue of DSI/2023/011, that recalled carbomer gels manufactured by Indiana Ophthalmics and advised high risk patients to avoid use of all carbomer containing eye gels. The IDWG were advised of the other actions being taken by MHRA to obtain further evidence.

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 5th December 2023 started at 10:34 and finished at 15:01.

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

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) ***(via Teams)***
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 ***(via Teams)***
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 ***(via Teams)***
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 ***(via Teams)***
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] ***(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

Observers

Sarah Jennings
Patient Safety Clinical Lead - Medical Devices
NHS England

Hannah Patrick ***(via Teams)***
Consultant Clinical Advisor, Managed Access
National Institute for Health and Care Excellence