SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 7TH OCTOBER 2025

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.

The Group considered and discussed the following:

- The Group received an update to the paper presented at September's meeting, involving a renal replacement therapy system with the potential for patient exposure to cobalt and nickel. The update focused on the toxicological risk assessment of the company's worst case simulated use testing to independently determine the risk to exposed patients. A number of specialist invited experts attended the meeting to provide clinical, technical and toxicological expertise.

  The Group reviewed the data and the toxicological risk assessment, and concluded that based on current information, that continued use is considered unlikely to be of clinical concern. The amount of cobalt and nickel available from the device under worst case simulated use were less than parenteral Permissible Daily Exposure (PDE) levels established in ICH Q3D – Elemental Impurities. The amount available was also less than the Toxicological Threshold of Concern (TTC) value established for the contact duration period of > 1 year to 10 years according to ISO/TC 21726. The TTC defines the level of exposure for constituents, below which there would be no appreciable risk to human health and has been developed to be protective for cancer-based effects.

  The Group were also advised that for nickel sensitive patients, there is currently an absence of comprehensive data to fully understand how nickel reactions may manifest through IV exposure. Based on evidence published by the Committee on Toxicology - Statement on potential risks from nickel in the diet of infants aged 0 to 12 months and children aged 1 to 5 years, it appears that patients may experience dermatitis flare-ups when exposed to nickel via routes other than dermal exposure. Systemic effects are not expected. The Group were advised that it will be difficult to differentiate in nickel sensitive patients between true nickel effect reactions and usual dialysis side effects of dermatitis and itching.

  The Group agreed that we have a duty to communicate this new information, ideally through an updated field safety notice published by the manufacturer. The Group agreed that based on the data provided, the risk assessment is acceptable. The Group agreed with the recommendation that a field safety notice (FSN) should be undertaken, with risk management for nickel sensitive patients. Further assessment should be considered for other brands of renal replacement therapies to determine if they are also impacted.

- A paper was brought to the Group of a potential safety concern associated with the use of hybrid closed loop systems.

- The Group considered the evidence presented from the evaluation of risks associated with use of an infusion set instead of a transfusion specific set to deliver a blood transfusion. It was agreed that device manufacturers should make improvements to support correct choice, and that the risks should be communicated to healthcare professionals to raise awareness.

- The Group was provided with an update on a recently published Device Safety Information (DSI) notice. This related to software used for infusion pump management. As the software is not compatible with Windows 11, and there was a delay in the company providing a solution, the DSI was published to provide guidance to relevant device staff and users on how to manage transition to Windows 11, in order to minimise disruption for pump users.

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. Karen Jenkins declared a personal interest in one agenda item and the appropriate action was taken.

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 12:30. The next meeting is scheduled to take place on 4th November 2025 at 10:00.

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 ***(apologies)***	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
Acting Chair	**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
Member	**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
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
Invited Expert	**Dr James Coulson** BSc (Hons) MB BCh (Hons) LLM MD MFPH MRSB FRCP FRCPE	Clinical Reader in Clinical Pharmacology, Therapeutics & Toxicology, Cardiff University. Honorary Professor of Clinical Pharmacology & Toxicology, Cardiff Metropolitan University. (Visiting) Professor of Clinical Pharmacology, University of South Wales. Honorary Consultant Physician, Clinical Pharmacologist & Toxicologist, Cardiff & Vale University Health Board. Interim Clinical Director of the All Wales Therapeutics & Toxicology Centre
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
Invited Expert	**Mr Fraser Gilmour** RCT(Renal) MIET	Renal Technical Manager, Dorset County Hospital NHS Foundation Trust
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, President-Elect of Academy for Healthcare Science

Member	**Mr Sebastian Janner** MSci MSc	Clinical Scientist, Royal Brompton and Harefield Hospitals
Invited Expert	**Karen Jenkins** MSc PGDipHE INP RN	UKKA Co-Chair Kidney Patient Safety Committee National Clinical Advisor, Enhanced Supportive Kidney Care; Consultant Nurse, Kent Kidney Care Centre, East Kent Hospitals University NHS Foundation Trust
Member	**Professor Tom Joyce** PhD MSc BEng	Professor of Orthopaedic Engineering, Newcastle University
Member	**Professor Daniel Martin** OBE BSc MB ChB PhD FRCA FFICM	Professor of Perioperative and Intensive Care Medicine, Peninsula Medical School, University of Plymouth
Member	**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
Invited Expert	**Emma Milser**	SHOT Haemovigilance/Patient Blood Management Specialist, Serious Hazards of Transfusion (SHOT)
Invited Expert	**Shruthi Narayan**	Medical Director, Serious Hazards of Transfusion (SHOT); Consultant in Donor Medicine, NHS Blood and Transplant
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
Invited Expert	**Professor Paul Rylance** BSc MB BS FRCP CertMedEd	Consultant in General and Renal Medicine, Royal Wolverhampton NHS Trust
Invited Expert	**Nicola Swarbrick**	Laboratory Incidents Specialist, Serious Hazards of Transfusion (SHOT)
Lay Member	**Ms Josephine Tapper**	
Invited Expert	**Victoria Tuckley**	Laboratory Incidents Specialist, Serious Hazards of Transfusion (SHOT)
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