

SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 6TH JUNE 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 advice

Plastics, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG) strategy and Terms of Reference 2023

The Group were provided with an overview of the MHRA's PRASEAG strategy and Terms of Reference (ToR) 2023 paper. The paper covered the future direction of travel to evaluate the post market safety evaluation of cosmetic products that fall within the remit of MHRA, the impact of future UK Medical Device Regulations and the new, proposed ToR for PRASEAG.

The Group endorsed the proposals to amend the PRASEAG ToR.

The Group were informed of MHRA's key priorities for cosmetic products that fall within MHRA remit. The Group supported these priorities.

The Group discussed the potential to change the name of PRASEAG to reference the widening of the scope of the EAG. The Group supported the proposal to not change the name of PRASEAG due to its existing recognisable presence.

The Group were in support of broadening the expertise of PRASEAG in line with the new ToR. The Group encouraged the addition of a patient representative.

The Group supported receiving an update of the latest recommendations made by PRASEAG following each EAG meeting.

Continuous Glucose Monitors (CGMs) and reports of erroneous glucose readings, premature sensor detachment and technology issues

The Group considered the potential for premature sensor loss and inaccurate glucose readings associated with CGM devices and associated risks to patient safety. The Group also discussed actions to encourage more reporting of these events to MHRA from manufacturers, patients and healthcare professionals.

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. Dr Neil Smart and Anne-Marie Frohock declared interests in one or more agenda items 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 held on Tuesday 6th June 2023 started at 10:35 and finished at 12:44.

The next meeting is scheduled to take place on 4th July 2023 at 10:00.

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**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 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 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**Anne Marie Frohock**

Children's Dietitians Office, Oxford University Hospitals NHS Foundation Trust;
Lead Paediatric Diabetes Dietitian, Oxfordshire Children's Diabetes Service;
NHSE SE Region Clinical Lead CYP Diabetes;
Thames Valley CYP Diabetes Network Chair

Dr Sufyan Hussain MA MRCP PhD

Consultant Physician in Diabetes & Endocrinology, Guy's & St Thomas' NHS Foundation Trust;
Honorary Senior Clinical Lecturer, Department of Diabetes, School of Cardiovascular, Metabolic Medicine and Sciences, King's College London;
Member, Board of Directors, International Diabetes Federation Europe

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

Iain Robertson

Medical Advisor Medical Devices and Legislation Unit
Scottish Government