SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 16TH MAY 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.

Draft Terms of Reference

The proposed terms of reference were presented to the Group and will be further reviewed at the next meeting.

Interim Devices Working Group and EAGs

The IDWG endorsed the continuation of three Expert Advisory Groups (EAGs) that were previously un the Devices Expert Advisory Committee (DEAC). The Artificial Intelligence, Software and Apps EAG, Plastics, Reconstructive and Aesthetic Surgery EAG and In-Vitro Diagnostics EAG.

Effect of darker skin pigmentation on the accuracy of pulse oximeters

The IDWG considered the potential for inaccuracy of pulse oximeter measurements on different skin tones. Evidence considered by the Group included a comprehensive literature review, and the review considered the potential impact of the evidence. The literature review concluded that there was evidence of inaccuracies in different skin tones. The Group heard that although no UK reports of harm associated with inaccuracies related to different skin tone, this may be due to under identification and under reporting of the issue.

The IDWG heard about actions which may address the issue of bias in medical devices, including changes in future regulations. Additionally, the MHRA has previously published guidance on the use and regulation of pulse oximeters on GOV.UK webpages.

The IDWG agreed there was sufficient evidence to conclude there is a risk of inaccuracy with pulse oximeters with different skin tone. The IDWG recommended further appropriate actions to mitigate the risk, including further communication and education about the known limitations of these devices and appropriate use. The IDWG recommended using multiple stakeholders and healthcare partnerships to help raise awareness. The IDWG recommended the MHRA continued to explore regulator options too, working with other bodies where appropriate.

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. Professor Daniel Martin declared an other relevant interest 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 started at 10:32 and finished at 12:40.

The next meeting is scheduled to take place on 6th June 2023 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

Chair

Professor Tom Clutton-Brock MBE MB ChB FRCP FRCA
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]
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

Dr Martin Allen
Consultant Physician, University Hospital of North Midlands

Professor Ian J Douglas BSc MSc PhD
Professor of Pharmacoepidemiology, London School of Hygiene & Tropical Medicine

Professor Daniel Martin OBE
Professor of Perioperative and Intensive Care Medicine, University of Plymouth

Observers

Vicky Ferguson
Head of Medical Devices Regulation and Regulatory Policy
Department of Health & Social Care

Sarah Jennings
Patient Safety Clinical Lead - Medical Devices
NHS England

Professor Chris Jones
National Clinical Director, NHS Wales
Deputy Chief Medical Officer, Welsh Government

Hannah Patrick
Consultant Clinical Advisor, Managed Access
National Institute for Health and Care Excellence

Iain Robertson
Medical Advisor Medical Devices and Legislation Unit
Scottish Government