

SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 9TH JANUARY 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 IDWG was presented with work undertaken reviewing evidence and outcomes from significant recent published literature regarding the use of paclitaxel devices used to treat patients with PAD (peripheral arterial disease) that includes CLI (critical limb ischemia) and IC (intermittent claudication).

The evidence was reviewed to determine whether current Agency guidance should be updated.

Agency device related internal updates

The IDWG heard a presentation on the MHRA regulatory studyathon (a focussed research event held over multiple days), which took place in the last week of November at the University of Oxford. A summary of initial thoughts and findings on the data and process of analyses was presented, including some headline results and outputs.

The IDWG noted the initial results and commented on the importance of device data recording to enable study of patient outcomes.

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. Dr TC See and Dr Hart declared interests 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 10:04 and finished at 11:56.

The next meeting is scheduled to take place on Tuesday 6th February 2024 at 10am.

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 (*apologies*)

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]

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

Professor Darren Ashcroft BPharm MSc PhD FRPharmS
Professor of Pharmacoepidemiology, Head, Drug Usage and Pharmacy Practice Group,
University of Manchester & Member of the Pharmacovigilance Expert Advisory Group (PEAG)

Professor Robert Morgan FRCR EBIR-ES
Professor of Interventional Radiology and Consultant Radiologist, St George's University
Hospitals NHS Foundation Trust, Molecular and Clinical Sciences Research Institute, St
George's, University of London

Dr Teik Choon (TC) See FRCS FRCR FBIR
Consultant Interventional Radiologist, Affiliated Assistant Professor, University of Cambridge &
Chair of the Paclitaxel Expert Advisory Group

Observers

Peter Barry
Consultant Clinical Advisor, Centre for Guidelines
National Institute for Health and Care Excellence

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