

SUMMARY OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON 14TH NOVEMBER 2019

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 DEAC remains confidential at the date of this summary and will remain so until a final decision has been taken. There is no overriding public interest to release such information in advance of the regulatory process being completed. 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 Devices Expert Advisory Committee (DEAC) discussed the following agenda items:

Matters arising from the minutes

Patient reporting of adverse events with medical devices.

Finance

The Committee were informed on the new changes imposed by HMRC and MHRA.

Communications

The Committee members were informed about articles that will be co-published with professional societies about medical devices.

Devices division policy and strategy

The Committee were updated on the current policies below:

- interim director of Devices on 'The future of the Devices Division and its interactions with DEAC'
- BREXIT
- Introduction to IVDs and IVDR
- Reporting of incidents involving a medical device, Yellow Card.

Ad Hoc Advice

The committee received an update from the DEAC Expert Advisory Groups (EAGs) below:

- Plastic, Reconstructive and Aesthetic Surgery EAG (PRASEAG): Regulatory Issues -Summary of current high-profile issues
 - BIA-ALCL
 - Symptoms related to breast implants

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- Urogynaecological mesh devices
- Aluminium leaching from fluid warmers
- Paclitaxel coating peripheral arterial stents and balloons
- T34 syringe drivers – a Medical Device Alert was issued recently recalling version 3 syringe drivers. This is actively being managed as the device is almost a monopoly supplier for the NHS.

Professional Networking

The committee were updated by the chair on RCPATH collaboration.

Procedural Items

In addition, the Committee completed its usual procedural business including the need to observe the confidentiality of the meeting, to declare interests, apologies and announcements.

- i. A list of Members and invited experts who attended the meeting is at **Annex A**.
- ii. Medicines Healthcare products Regulatory Agency staff may be present for all or part of the meetings or for specific items.

The meeting started at 10.39 and concluded at 14.19.

The next meeting will take place on **27th February 2020** at 10:30.

MEMBERSHIP OF THE DEVICES EXPERT ADVISORY COMMITTEE

Professor Peter Groves MBBS MD FRCP (Chair)

Chair of the NICE Medical Technologies Advisory Committee, past- President of the Welsh Cardiovascular Society and previous Council member of the British Cardiovascular Society

Ms Yinglen Butt RGN MSc (*apologies*)

Associate Director of Nursing (Clinical Standards & Supporting Practice)

Dr Kathleen Ferguson MBChB FRCA

Consultant Anaesthetist, Aberdeen Royal Infirmary

Professor Puthucode Haray MS DNB FRCS FFST(Ed) (*apologies*)

Consultant Colorectal Surgeon, Cwm Taf Morgannwg Health Board
Professor of Coloproctology, University of South Wales

Professor Kevin Harris MB BS MA MD FRCP (*apologies*)

Programme Director and Clinical Advisor – Interventional Procedures Programme
National Institute for Health and Care Excellence

Professor Peter C Hindmarsh

Professor of Paediatric Endocrinology, University College London

Professor Ian Kimber OBE PhD FRSB

Emeritus Professor of Toxicology, University of Manchester

Mr Edward Morris MBBS BSc MD MRCOG (*apologies*)

Consultant in Obstetrics & Gynaecology at the Norfolk & Norwich University Hospital;
Honorary School Senior Lecturer, University of East Anglia

Professor Stephen A O'Connor DSc CEng CPhys FIPEM FInstP Hon FRCP

President of Institute of Physics and Engineering in Medicine

Ms Sara Payne BA CPE LPC

Lay Representative. Solicitor

Dr Tom Pelly BSc MB BS (Hons) PGCE DCH MRCGP FRCP

GP Partner, Horfield Health Centre, Bristol; Clinical Director
Phoenix Primary Care Network, Bristol; Associate Postgraduate Dean for Foundation
and Excellence, Severn GP School, Health Education England (South West)

Dr Iain Robertson MBChB MRCP FRCR EBIR

Chair of Scottish Health Technologies Group; Consultant Interventional Radiologist,
NHS Greater Glasgow and Clyde

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Dr Carl Waldmann MA MB BChir DA FRCA FFICM EDIC

Chair Critical Care Leadership Forum; Immediate ex Dean Faculty of Intensive Care
Medicine

Professor Jeremy Wyatt DM FRCP ACMI Fellow

Emeritus Professor of Digital Healthcare, University of Southampton; Chair,
Faculty of Clinical Informatics AI Special Interest Group and the UK Steering
Group on Mobilising Computable Biomedical Knowledge