

SUMMARY OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON 16TH JULY 2020

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:

Expert advice on regulatory actions

The Committee considered an item on **Paclitaxel-coated balloon and stents**. The Committee were informed of the work of the Expert Advisory Group in considering the potential risk of using these devices for the treatment of patients with peripheral vascular disease and critical limb ischaemia. This work had been informed by additional statistical and toxicological analysis from the Devices Division. Further patient-level analysis is ongoing, and a discussion paper will be brought to the next DEAC meeting to consider regulatory options further.

BIA-ALCL

The Committee were informed that there have now been 102 confirmed cases of BIA-ALCL. The PRASEAG webpages have been updated to include the names of the Chair and deputy Chair. PRASEAG have written an open letter in response to the publication of the Medicines and Medical Devices Safety Review, calling for the adequate funding of the Breast Implant Registry. PRASEAG are working with patient groups and other stakeholders to prepare clinical guidelines for the management of BIA-ALCL as well as to improve information to patients about the risk of this condition after breast implant surgery. The Committee recommended that a better understanding is needed from patients and members of the public about their perceptions of the risks associated with BIA-ALCL following breast implant surgery for cosmetic and reconstructive indications and that this information is essential to add to the work of PRASEAG in arriving at the most appropriate regulatory decisions.

Items of Strategy and Policy

The Committee received an overview of the **Medicines and Medical Devices Bill** and its movement through the Parliamentary process towards receiving Royal Assent.

The Independent Medicines and Medical Devices Safety Review (IMMDSR)

The Committee gave their reflections on the review and the harrowing patient stories that were described in the report. The Committee expressed sympathy and regret for the suffering that had been experienced by patients as well as their full support for the recommendations. The Committee welcomed the emphasis of the report on the importance of involving patients and public more in regulatory decision-making. DEAC members expressed their eagerness to develop further with colleagues in the Devices

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Division the recommendations and actions that have already been initiated to implement the wider recommendations of this report.

COVID-19 Update

The Committee heard an update of the activity of the Devices Division to support the Government in its response to the Covid-19 pandemic. This includes the development of Target Product Profiles (TPPs) for diagnostic tests, cross government working on PPE and the publication on the MHRA webpages of a list of medical devices in receipt of derogations for exceptional use.

Any other business

Additional items that were discussed included an update on the issuing of an MDA on the use of home nebulizers as well as a media campaign to raise awareness about fire risks associated with the use of emollients which will be launched on 29 July 2020.

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 10:00 and concluded at 12:00.

The next meeting will take place on Thursday 17th September 2020.

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ANNEX A

MEMBERSHIP OF THE DEVICES EXPERT ADVISORY COMMITTEE

Chair

Professor Peter Groves MBBS MD FRCP (Chair)

Consultant Interventional Cardiologist, Cardiff and Vale UHB
Chair, Health Technology Wales; Chair, Medical Technologies Advisory Committee, NICE

Royal College of Nursing

Ms Christine Callender MBA MSc RHV RM RGN

Head of Nursing (Quality & Regulation) Royal College of Nursing

Royal College of Anaesthetists

Dr Kathleen Ferguson MBChB FRCA

Consultant Anaesthetist, Aberdeen Royal Infirmary

NHS Wales and Royal College of Surgeons

Professor Puthucode Haray MS DNB FRCS FFST(Ed)

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

NICE

Professor Kevin Harris MB BS MA MD FRCP

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

Royal College of Paediatrics and Child Health

Professor Peter C Hindmarsh

Professor of Paediatric Endocrinology, University College London

British Toxicology Society

Professor Ian Kimber OBE PhD FRSB

Emeritus Professor of Toxicology, University of Manchester

Royal College of Obstetricians and Gynaecologists

Mr Edward Morris MBBS BSc MD MRCOG

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

Institute of Physics and Engineering in Medicine

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

President of Institute of Physics and Engineering in Medicine (*apologies*)

Lay Representative

Ms Sara Payne BA CPE LPC

Lay Representative. Solicitor

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Royal College of General Practitioners

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)

NHS Scotland and Royal College of Radiologists

Dr Iain Robertson MBChB MRCP FRCR EBIR

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

Faculty of Intensive Care Medicine and Royal College of Anaesthetists

Dr Carl Waldmann MA MB BChir DA FRCA FFICM EDIC

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

Royal College of Physicians

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