

SUMMARY OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON 27TH FEBRUARY 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:

Matters arising from the minutes

The minutes of the meeting held on 14th November 2019 were agreed with minor typographical amendments.

The president of the Royal College of Pathologists agreed to nominate a member to join DEAC.

Devices division policy and strategy

Dr Raine introduced herself to the Committee and set out her vision and priorities for the Agency. The Medicines and Medical Devices Bill is now before Parliament.

Mr Tunbridge discussed some elements of the MMD Bill and set out how the Devices Division strategy fits within the overall Agency strategy.

Expert advice on regulatory actions

Symptoms sometimes referred to as Breast Implant Illness – the Committee opined on the difficulty of diagnosis and agreed that further work should be undertaken to understand this. They were supportive of PRASEAG being expanded to include experts in immunology and rheumatology to help with understanding any systemic illness that may arise from breast implants. They opined that no further regulatory action currently is the correct course as there is insufficient information. A well-functioning breast implant registry would help to understand and define the problem further.

ALCL –The Committee were informed that a review of the technical file of breast implants available in the UK was due to be undertaken imminently and agreed that this would provide useful additional information. The Committee expressed their support for this as an urgent undertaking. The conclusions of the PRASEAG are awaited and DEAC proposed a number of additional areas for consideration by the EAG. In the meantime, the Committee concluded that there is currently insufficient information to take regulatory action on textured breast implant in relation to ALCL and that any potential risks to patients while awaiting additional information is likely to be very small.

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Aluminium – The Committee noted that the EnFlow device has been withdrawn from the market and that there is ongoing work to define the exposure of previous patients to aluminium by this and similar devices.

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 10:34 and concluded at 14:54.

The next meeting will take place on Thursday 14th May 2020.

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 and Midwifery

Ms Yinglen Butt RGN MSc (apologies)

Associate Director of Nursing (Clinical Standards & Supporting Practice)

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

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 (apologies)

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

INVITED EXPERT

Chair of Plastics, Reconstructive and Aesthetic Surgery Expert Advisory Group
(PRASEAG)

Mr Nigel Mercer BAPRAS President