

SUMMARY OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON 14TH MAY 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 planned communication on nebuliser use at home by children with asthma has been delayed in order to update it to be relevant to the current Covid-19 emergency situation. The comments were noted and that the MHRA will consider including further communications in the current context for UK healthcare.

Devices division policy and strategy

The Committee received two papers and a supporting presentation about the Division's response to Covid-19. They were supportive and congratulated the Agency for its rapid and thorough work in response to this emergency.

Expert advice on regulatory actions

The Committee received a paper that included a position statement by the PRASEAG as well as a summarising presentation on BIA-ALCL. The DEAC strongly supported the suggestions for improving the provision of information to patients and the public about the risks of ALCL with breast implants; the strengthening of the consent process; and the improvement in National Registry usage and data sharing for breast implants. The Committee recommended that urgent priority be given to progressing these actions. The Committee suggested that the implications of the differential indication for breast implants, either reconstructive or cosmetic, on patient and clinician risk assessment as well as on the consent process be further elucidated. The Committee recommended that the proposed manufacturer documentation review should be completed as a matter of urgency, notwithstanding the current pressures on the Devices Division team as a result of the Covid-19 pandemic, and that this information be reported back to DEAC as soon as it is available for further consideration.

The Committee receive a paper and a supporting presentation on a spinal implant system. They supported the regulatory actions recently taken by the MHRA Devices Division including the establishment of a spinal EAG to provide further expert advice. The DEAC suggested that membership of the EAG could be extended to include a paediatrician, patient and lay person.

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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 10:01 and concluded at 12:03.

The next meeting will take place on Thursday 16th July 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 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 (apologies)

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

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 (apologies)

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