

SUMMARY OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON THURSDAY 4 MAY 2017

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.gsi.gov.uk) and will be considered in accordance with the FOI Act.

The Devices Expert Advisory Committee discussed the following agenda items:

High profile incidents

The committee were briefed on the issue of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Further information can be found at

<https://www.gov.uk/guidance/breast-implants-and-anaplastic-large-cell-lymphoma-alcl>

The committee were updated on the suspension of devices manufactured by Silimed, a large manufacturer of silicone implants in South America. The latest update can be found at:

<https://www.gov.uk/government/publications/devices-made-by-silimed>

The committee were updated on the latest regarding *Mycobacterium chimaera* infection of Heater-cooler devices used in cardiac surgery. *Mycobacterium chimaera* are a group of slow growing environmental organisms that may cause respiratory infections or severe disease in immunocompromised patients. Further information can be found at: <https://www.gov.uk/drug-device-alerts/heater-cooler-devices-used-in-cardiac-surgery-risk-of-infection-with-mycobacterium-species>

Educational items/Items for discussion

The committee discussed the importance of clinical evaluation of Clinical risk algorithms.

The committee discussed plans to further engage with Royal Colleges and Professional Bodies.

External Advice

The committee received updates and discussed:

- Leadless pacemaker Expert Advisory Group
- Orthopaedic Expert Advisory Group
- Labelling Expert Advisory Group
- Plastics and Reconstructive Aesthetic Surgery Expert Advisory Group

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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.
- iii. On Thursday 15th September, the meeting started at 10:30 and finished at 12:20.

The next meeting will take place on 14th September at 10:30.

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ANNEX A

MEMBERS ATTENDED:

Dr Peter Nightingale FRCA FRCP FFICM FRCP (Edin) **(Chairman)**

Consultant in Anaesthesia & Intensive Care Medicine at Wythenshawe Hospital, South Manchester

Ms Anna Crossley

Professional Lead, Acute, Emergency and Critical Care – Royal College of Nursing

Mr Gerard Dean HCPC (Clin.Sci) CEng CSc

Consultant Clinical Engineer; Medical Devices Innovation & Applications Manager, Nottingham University Hospitals NHS Trust

Dr Kathleen Ferguson MBChB FRCA

Consultant Anaesthetist, Aberdeen Royal Infirmary; Member of Royal College of Anaesthetists (RCOA) and Association of Anaesthetist of Great Britain and Ireland (AAGBI)

Dr Peter Groves MBBS MD FRCP **(Vice 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.

Professor Ian Kimber OBE, PhD

Professor of Toxicology at the University of Manchester

Mrs Mirella Marlow

Programme Director of Devices and Diagnostic Systems, Centre for Health Technology Evaluation, National Institute for Health and Clinical Excellence (NICE)

Ms Sara Payne BA CPE LPC

Lay Representative. Solicitor

Dr Iain Robertson MBChB MRCP FRCR EBIR

Chair of Scottish Health Technologies Group; Consultant Interventional Radiologist, NHS Greater Glasgow and Clyde, Past President of the British Society of Interventional Radiologists

Professor Jeremy Wyatt DM FRCP ACMI Fellow

Professor Jeremy Wyatt, Director of Wessex Institute and Professor of Digital Healthcare, Clinical Adviser on new information & communication technologies to the Royal College of Physicians in London