

SUMMARY OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON THURSDAY 5 NOVEMBER 2015

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 (DEAC) discussed the following agenda items:

High profile incidents

The Committee discussed the suspension of devices manufactures by Silimed. Information of the suspension can be found at: <https://www.gov.uk/government/publications/devices-made-by-silimed>

The Committee received an update on the Metal on Metal Hip Replacements.

The Committee heard a presentation and discussed Transvaginal Mesh Devices, to treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP). Further information can be found at: <https://www.gov.uk/government/publications/vaginal-mesh-implants-summary-of-benefits-and-risks>

The Committee heard a presentation on Heater-cooler devices used in cardiac surgery. 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>

The Committee heard a presentation and discussed Strattice Reconstructive Tissue Matrix.

The Committee discussed air embolism from arterial line flushing.

External Advice

The Committee received updates and discussed:

- Leadless Pacing Expert Advisory Group.
- Ongoing collaborations with BAPRAS (British Association of Plastic, Reconstructive & Aesthetic Surgeons) to provide the agency with external advice.
- AIHO (Association of Independent Healthcare Organisations).
- Collaboration with the Medical Schools Council to address regulatory issues for undergraduates.
- The register of Experts for independent clinical advice.

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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 5 July, the meeting started at 10:30 and finished at 14:05.

The next meeting will take place on 25 February 2016 at 10:30.

ANNEX A

MEMBERS ATTENDED:

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

Consultant in Anaesthesia & Intensive Care Medicine at Wythenshawe Hospital, South Manchester, Trustee of the Intensive Care National Audit & Research Centre (ICNARC)

Professor Derek Alderson MD FRCS

Emeritus Professor of Surgery - University of Birmingham, Vice-President, Royal College of Surgeons of England

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

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 and Associate Dean for Business Development in the Faculty of Life Sciences at the University of Manchester

Mr Edward Morris MBBS BSc MD MRCOG

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

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

Dr Carl Waldmann MA MB BChir DA FRCA FFICM EDIC

Consultant in ICM and Anaesthesia at the Royal Berkshire Hospital