

## **SUMMARY OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON THURSDAY 25 FEBRUARY 2016**

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](mailto: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 manufactured by Silimed. Information of the suspension can be found at: <https://www.gov.uk/government/publications/devices-made-by-silimed>

The Committee was updated with the latest information regarding 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 discussed air embolism from arterial line flushing.

The committee discussed *Mycobacterium chimaera* infection related to heater-coolers.

#### **Educational items/Items for discussion**

The committee were given a presentation on the role of Notified Bodies in medical device regulation.

The committee discussed labelling of medical devices and clinical areas where this may be problematic.

The committee were given a presentation on Borderline products (Those which may fall under regulation of medical devices and/or medicines).

#### **External Advice**

The Committee received updates and discussed:

- Leadless Pacing Expert Advisory Group.
- Metal on Metal Expert Advisory Group.

#### **Procedural Items**

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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 25<sup>th</sup> February, the meeting started at 10:30 and finished at 14:30.

The next meeting will take place on 23 June 2016 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

**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.

**Mrs Mirella Marlow**

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

**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.

**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

**Dr Carl Waldmann** MA MB BChir DA FRCA FFICM EDIC

Consultant in ICM and Anaesthesia at the Royal Berkshire Hospital

**Professor Jeremy Wyatt** DM FRCP ACMI Fellow

Leadership Chair in eHealth Research at the University of Leeds, Clinical Adviser on new information & communication technologies to the Royal College of Physicians in London Royal College of Physicians

**Observer**

**Ms Anna Crossley**

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