

SUMMARY OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON THURSDAY 23 JUNE 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) 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 breast implants manufactured by Silimed, a large manufacturer of silicone implants in South America. 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, a net-like implant, 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 *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>

The committee was updated on issues surrounding the QRISK2 app, which is used for population risk profiling of cardiovascular events.

Educational items/Items for discussion

The committee were given a presentation on MHRA engagement with patients and stakeholders

The committee discussed labelling of medical devices and clinical areas where this may be problematic. Labelling of embolization coils was highlighted as an area for potential improvement.

External Advice

The Committee received updates and discussed:

- Leadless Pacing Expert Advisory Group.
- Metal on Metal 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 23rd June, the meeting started at 10:40 and finished at 13:20.

The next meeting will take place on 15th September 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

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

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

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

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

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 Royal College of Physicians