

SUMMARY OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON THURSDAY 15 SEPTEMBER 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) discussed the following agenda items:

High profile incidents

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 issues related to the QRISK2 app and subsequent corrective actions taken. The latest update can be found at: <https://www.gov.uk/government/news/mhra-information-on-tpp-and-qrisk2>.

Educational items/Items for discussion

New MHRA guidance on when software applications are considered to be a medical device and how they are regulated was presented to the committee. The guidance can be found at: <https://www.gov.uk/government/publications/medical-devices-software-applications-apps>.

The committee were briefed on MHRA on plans to organise clinical exchange programs with different NHS trusts for MHRA staff to observe medical device use by end-users.

The committee were informed of MHRA plans for collaboration with Royal colleges and Professional bodies for horizon scanning.

The committee were informed of upcoming divisional educational events, in which external experts will be invited to give talks on a wide-range of healthcare topics to Agency staff.

External Advice

The committee received updates and discussed:

- Leadless pacemaker Expert Advisory Group
- Metal on Metal 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 10:300 and finished at 12:20.

The next meeting will take place on 12th January 2017 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 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