

## **SUMMARY OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON 22<sup>nd</sup> February 2018**

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 were updated on the latest regarding Breast Implant Associated Anaplastic Large Cell Lymphoma. Further information can be found at:

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

The committee were informed about increased levels of histamine found in some batches of the antibiotic gentamicin. Further information can be found at the following link:

<https://www.gov.uk/drug-safety-update/gentamicin-potential-for-histamine-related-adverse-drug-reactions-with-some-batches>

The committee discussed suspension of the CE certificate of the Essure contraceptive device.

Further information can be found at: <https://www.gov.uk/government/news/mhra-statement-on-essure-devices>

The committee discussed the latest developments surrounding Transvaginal Mesh implants.

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

The committee were updated on the MHRA Patient Public Engagement Strategy

The committee were updated on the recent MHRA Health Summit

The committee were updated on the latest regarding burn injuries resulting from some emollient creams. Further information can be found at the following link:

<https://www.gov.uk/drug-safety-update/paraffin-based-skin-emollients-on-dressings-or-clothing-fire-risk>

#### **External Advice**

The Committee received updates and discussed:

- Orthopaedic Expert Advisory Group.
- Labelling Expert Advisory Group
- Plastics and Reconstructive Aesthetic Surgery 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.

The next meeting will take place on 7<sup>th</sup> June 2018 at 10:30.

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**ANNEX A**

**MEMBERS ATTENDED:**

**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.

**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)

**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, Vice President, Clinical Quality, RCOG

**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

**Invited Experts**

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

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

**Mr Suman Shrestha**

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