**MINUTES OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON 19TH NOVEMBER 2020**

*Meeting held remotely via Zoom videoconference from 10:04 to 13:07*

**Background**

The Devices Expert Advisory Committee (DEAC) is responsible for providing the Medicines and Healthcare products Regulatory Agency (MHRA) with independent, external, expert clinical and scientific input and advice on a wide range of aspects relating to the introduction and safe use of medical devices. The Committee meets approximately four times per year.

DEAC was formed following an independent review on MHRA access to clinical advice and engagement with the clinical community. DEAC also aims to support the MHRA in developing and maintaining collaborative relationships with clinical professional bodies. Full details of the composition of the Committee, including qualifications and affiliations of members, can be seen in Annex A.

The role of DEAC is to provide advice to the MHRA on the 'core' areas of: Strategic, Communication, Professional Networking, Quality Assurance, Professional Advice and e-Health. The Committee reviews their performance against these core activities on an annual basis.

*Please note that regulatory terms in this document are summarised in a glossary at the end of the document. Click on the underlined term to be taken to the definition. This publication summarises the discussions of the meeting held on 19th November 2020.*

**Paclitaxel coated balloons and stents**

Paclitaxel coated balloons and eluting stents are used to treat patients who have a build-up of fatty deposits in their arteries which restricts blood supply to leg muscles, also known as peripheral arterial disease (PAD). This can cause exercise-induced pain in the muscles (intermittent claudication) or a dangerous restriction in blood flow at rest (critical limb ischaemia). The drug paclitaxel is released into the wall of arteries when they are opened using Drug Coated Balloons (DCBs) and Drug-eluting stents (DESs). This drug helps to prevent the growth of excessive scar tissue inside the artery, which can sometimes cause re-narrowing and a return of leg symptoms.

The MHRA conducts safety and surveillance over medical devices once they are on the UK market and draws on a range of data sources as part of its surveillance activities, including published literature which is scanned for potential safety signals. The MHRA [established an expert advisory group](https://www.gov.uk/government/news/expert-advisory-group-set-up-to-review-paclitaxel-drug-coated-balloon-catheters-and-drug-eluting-stents) (EAG) in March 2019 following findings by [Katsanos et al](https://www.ahajournals.org/doi/10.1161/JAHA.118.011245) that raised concerns about the use of paclitaxel eluting balloons and stents in the treatment of patients with peripheral arterial disease (PAD), which suggested increased mortality rates from their use. You can find the findings and recommendations of the EAG [here](https://www.gov.uk/government/publications/recommendations-from-the-independent-expert-advisory-group-on-the-use-of-paclitaxel-drug-coated-balloons-dcbs-and-drug-eluting-stents-dess-to-the). The recommendations of the EAG led to the issuing of a [Medical Device Alert](https://www.gov.uk/drug-device-alerts/recommendations-for-ongoing-use-of-paclitaxel-drug-coated-balloons-dcbs-and-implantable-drug-eluting-stents-dess-in-the-treatment-of-patients-with-peripheral-artery-disease-pad-mda-2019-023) (MDA) in June 2019 to limit the of these devices for routine treatment of patients with intermittent claudication. Paclitaxel has been previously discussed by DEAC, most recently at the 17 September 2020 DEAC meeting.

The discussion in this meeting focused on the use of Paclitaxel-coated devices for the treatment of critical limb ischaemia. The Chair summarised discussions so far and introduced Dr Teik Choon See, the Chair of the Paclitaxel EAG, to present an overview of its review and conclusions on the use of these devices for this specific indication.

The Committee were informed about concerns that the use of Paclitaxel-coated devices may be associated with an increase in mortality and limb amputation. The EAG had concluded that the evidence to support this concern was inconsistent and a recommendation had been made not to restrict the use of these technologies for this indication. DEAC also reviewed the evidence and agreed with this conclusion. It was concluded that this topic should be kept under careful surveillance and that enhanced information sharing and communication were needed, emphasizing the importance of multi-disciplinary clinical decision-making and the need to discuss treatment choices appropriately with patients.

Readers can send incident reports relating to medical devices, including paclitaxel coated stents and balloons, to the MHRA through the [Yellow Card Scheme](https://www.gov.uk/report-problem-medicine-medical-device).

**Breast Implant Associated- Anaplastic Large Cell Lymphoma (BIA ALCL) and patient involvement: an update**

There is an estimated 10 to 35 million women who have received breast implants world-wide, with over a million sold in the UK. Breast Implant Associated - Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare sub-type of ALCL which is a form of Non-Hodgkin’s Lymphoma. Since 2012, the MHRA has been investigating risks associated with breast implants and BIA-ALCL. The Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG) was formed to continue to review the issue and BIA-ALCL information, as well as the UK cases, to assess whether the UK position should be updated. DEAC advice is sought as part of this work.

The Committee were presented with a paper summarising evidence and regulatory activity on BIA-ALCL. They were presented with an update on the MHRA’s action on patient involvement in the assessment of risk.

The Committee were informed about planned research to gauge public perception of acceptable levels of risk regarding the development of ALCL after breast implant and to determine how attitudes to risk may vary amongst different groups. Target groups include the general population, as well as patients who have had reconstructive surgery and breast augmentation (including trans-gender breast augmentation). The research team includes colleagues from Devices and the MHRA communications teams. The project team provided information on its strategy for involving patients in its work. The Committee commended the decisions on progress so far, and one member highlighted the need to approach a variety of organisations who can represent the transgender community.

**Inguinal Hernia Mesh discussion and next steps**

An inguinal hernia is the most common type of hernia, which can appear as a swelling or lump in the groin, or as an enlarged scrotum. Inguinal hernias can be repaired using surgery to push the bulge back into place and strengthen the weakness in the abdominal wall. This involves placing the lump of fatty tissue or loop of bowel back into the abdomen, and placement of mesh in the abdominal wall, to strengthen it.

The MHRA has been made aware of increasing concerns about complications following inguinal hernia mesh procedures. The MHRA summarised the evidence in a paper, that was shared with DEAC members in February 2020, on which members had provided feedback to the MHRA to inform its regulatory decision-making. On this occasion, the topic was brought to open committee for further consideration. DEAC concluded that the evidence currently shows that mesh procedures for inguinal hernia repair do benefit the majority of patients, however there was acknowledgement that complications do occur, although these tend to be minor. It was concluded by the committee that restriction on the use of hernia mesh devices for inguinal hernia repair was currently not required and that instead a registry to effectively monitor the safety and performance of these devices needs to be established. The MHRA will continue to work with partners to agree the next steps in progressing this.

**Future direction of DEAC and its Expert Advisory Groups (EAGs)**

MHRA Senior Management Team provided the Committee with an overview of plans to evolve the operations of DEAC, including its role in peer reviews and providing of professional input. A summary of the strategic direction of the MHRA Devices Division regarding signal detection management and the renewed emphasis on using expert advisory groups to support data driven decision making was provided.

The MHRA confirmed that a plan for development is underway, in part focusing on relationships with DEAC and EAGs, and that DEAC will be given the opportunity to assess these proposals. These developments also intend to increase transparency in operations, including providing clarity on membership appointments, establishment of groups and influence on decision making.

The MHRA outlined its aim to establish clarity around clear lines of responsibility and advisory roles in the decision-making process between MHRA, EAGs and DEAC. The MHRA also highlighted that there were ongoing projects on increasing patient voice and the use of patient panels which are relevant to these efforts.

**Procedural Items**

The Group completed its usual procedural business including the need to observe the confidentiality of the meeting and to declare interests, announcements, apologies, and approval of minutes:

* A list of members who attended the meeting is in Annex A.
* Apologies were given by Professor Haray and Mr Morris.
* All members attended the meeting via Zoom videoconference.
* The meeting started 10:04 and lasted until 13:07.
* The next meeting of DEAC is due to take place on 25th February 2021.

**To note:**

*Information can be withheld, under Section 43 of the Freedom of Information (FOI) Act 2000. Information regarding the issue under consideration and advice from Devices Expert Advisory remain confidential at the date of this summary and will remain so until a final decision has been taken. There is normally no overriding public interest in releasing 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.gov.uk*](mailto:info@mhra.gov.uk)*) and will be considered in accordance with the FOI Act.*

**ANNEX A**

**ATTENDING MEMBERS OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING 19TH NOVEMBER 2020**

**Chair**

Professor Peter Groves MBBS MD FRCP (Chair)

*Consultant Interventional Cardiologist, Cardiff and Vale UHB*

*Chair, Health Technology Wales; Chair, Medical Technologies Advisory Committee, NICE*

**Royal College of Nursing**

Ms Christine Callender MBA MSc RHV RM RGN

*Head of Nursing (Quality & Regulation) Royal College of Nursing*

**NHS Wales and Royal College of Surgeons**

Professor Puthucode Haray MS DNB FRCS FFST(Ed) ***(apologies)***

*Consultant Colorectal Surgeon, Cwm Taf Morgannwg Health Board*

*Professor of Coloproctology, University of South Wales*

**NICE**

Professor Kevin Harris MB BS MA MD FRCP

*Programme Director and Clinical Advisor – Interventional Procedures Programme National Institute for Health and Care Excellence*

**Royal College of Paediatrics and Child Health**

Professor Peter C Hindmarsh

*Professor of Paediatric Endocrinology, University College London*

**British Toxicology Society**

Professor Ian Kimber OBE PhD FRSB

*Emeritus Professor of Toxicology, University of Manchester*

**Royal College of Obstetricians and Gynaecologists**

Mr Edward Morris MBBS BSc MD MRCOG ***(apologies)***

*Consultant in Obstetrics & Gynaecology at the Norfolk & Norwich University Hospital; Honorary School Senior Lecturer, University of East Anglia*

**Royal College of Pathologists**

Dr Martin Myers MBE PhD FRCPath EuSpLM

*Royal Preston Hospital*

**Institute of Physics and Engineering in Medicine**

Professor Stephen A O’Connor DSc CEng CPhys FIPEM FInstP Hon FRCP

*President of Institute of Physics and Engineering in Medicine*

**Lay Representative**

Ms Sara Payne BA CPE LPC

*Lay Representative. Solicitor*

**Royal College of General Practitioners**

Dr Tom Pelly BSc MB BS (Hons) PGCE DCH MRCGP FRCP

*GP Partner, Horfield Health Centre, Bristol; Clinical Director*

*Phoenix Primary Care Network, Bristol; Associate Postgraduate Dean for Foundation and Excellence, Severn GP School, Health Education England (South West)*

**NHS Scotland and Royal College of Radiologists**

Dr Iain Robertson MBChB MRCP FRCR EBIR

*Chair of Scottish Health Technologies Group; Consultant Interventional Radiologist, NHS Greater Glasgow and Clyde*

**Faculty of Intensive Care Medicine and Royal College of Anaesthetists**

Dr Carl Waldmann MA MB BChir DA FRCA FFICM EDIC

*Chair Critical Care Leadership Forum; Immediate ex Dean Faculty of Intensive Care Medicine*

**Royal College of Physicians**

Professor Jeremy Wyatt DM FRCP ACMI Fellow

*Emeritus Professor of Digital Healthcare, University of Southampton; Chair, Faculty of Clinical Informatics AI Special Interest Group and the UK Steering Group on Mobilising Computable Biomedical Knowledge*

**Invited Expert**

Dr Teik Choon (TC) See

*Paclitaxel EAG Chair; BSIR Safety & Quality Committee/Consultant IR Cambridge*

**Glossary of terms, abbreviations and acronyms**

* **Clinical community:** Qualified healthcare professionals, including those who are registered with the [Health and Care Professions Council.](https://www.hcpc-uk.org/)
* **Declaration of interests:** The Chairman and Members are required to declare any interests that they hold in the pharmaceutical companies concerned with any of the agenda items.
* **Expert Advisory Group:** An expert advisory group, comprised of the following experts nominated by member governments and other selected governments, has provided advice and feedback on the plan, performance and outputs of the Innovation Strategy.
* **Freedom of Information (FOI) Act:** An act to make provision for the disclosure of information held by public authorities or by persons providing services for them. For further information, see [here](http://www.legislation.gov.uk/ukpga/2000/36/contents#pt2-l1g43).
* **Medical Device:** A medical device is any device intended to be used for medical purposes. Medical devices benefit patients by helping health care providers diagnose and treat patients and helping patients overcome sickness or disease, improving their quality of life
* **Medical Device Alert (MDA):** the prime means of communicating safety information to health and social care organisations and the wider healthcare environment on medical devices. They are prepared by the MHRA and may come about as a result investigation by any of the UK administrations where the manufacturer cannot demonstrate they have taken appropriate action. Alternatively, they can result through other information received by the MHRA from legally delegated competent authorities around the world.
* **Medicines and Health products Regulatory Agency (MHRA):** the government agency that regulates medicines, medical devices and blood components for transfusion in the UK and ensure patient safety. MHRA is an executive agency, sponsored by the Department of Health and Social Care.
* **National Institute for Health and Care Excellence:** an executive non-departmental public body of the Department of Health in England which produces evidence-based guidance and advice for health, public health and social care practitioners and publishes guidelines to improve outcomes for people using the NHS and other public health and social care services.
* **Patient Panels:** groups of local people who have recent experience of being a patient or carer, who volunteer their time and skills to provide a patient's perspective.
* **Safety Signal:** Information on a new or known adverse event that is potentially caused by a medicine or medical device and that warrants further investigation. Signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature.
* **Signal detection management:** Signal detection is the process of identifying, as soon as possible, any safety signal. Several data sources are used for signal detection- information from spontaneous reporting systems, clinical trials, the scientific literature or health care databases. Detected signals are further evaluated to determine whether the signal actually does represent a real risk and requires further assessment, communication or risk minimisation actions in accordance with the medical importance of the signal.