MINUTES OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON 17TH SEPTEMBER 2020

Meeting held remotely via Zoom videoconferencing from 10:30 to 13:00

Minutes by: *Grace Carroll*
Minutes approved by: *DEAC*

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 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 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 17th September 2020.

Phillips Respironics V60 ventilators

A ventilator takes over or supports the body's spontaneous breathing process when disease has caused the lungs to fail. This gives the patient time to be treated and for the lungs to recover. Ventilators have been increasingly used in response to the COVID-19 illness. The Phillips V60 ventilator is a non-invasive ventilator with a mask that fits over the nose and mouth. It can also be used for invasive ventilation if required. You can read the manufacturer page for more information here.

The Committee was informed that it has been discovered that Phillips V60 ventilators can be affected by faulty circuit board soldering which results in sudden switch off of the ventilator. To date, this is thought to have resulted in one reported patient death and three cases of patient harm. The Committee was informed that there are 303 of these ventilators being used in the UK NHS across 80 sites. A timeline of the recognition and responses to this problem was outlined, including the manufacturer's issuance of a Field Safety Notice in March 2020 and a Medical Device Alert issued by the MHRA in June 2020 as well as the discussions that have taken placed between the MHRA and Phillips.

The Committee was informed that the MHRA have communicated with the relevant notified body and are intending to issue a National Patient Safety Alert (NaPSA) to users

of the ventilators, informing them that the ventilators should not be used until components can be replaced, unless there is no alternative. DEAC supported this action.

The Committee emphasised the need to engage with sub-specialists who can support the development of any future alerts and also cooperate with the Care Quality Commission to ensure actions are being taken in response to the alerts.

The Committee recommended that engagement with relevant professional groups should take place as part of the development of Patient Safety Alerts and that consideration should be given to their circulation beyond the current target audience of Healthcare Provider CEOs and Medical Directors to ensure timely responses. The Committee agreed that the impact of the Patient Safety Alert should be reviewed in a future meeting of DEAC.

Paclitaxel Coated Balloons

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 conduct safety and surveillance of medical devices once they are on the UK market and draw 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 (EAG) in March 2019 following findings by Katsanos et al 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. The recommendations of the EAG led to the issuing of a Medical Device Alert in June 2019 that restricted the use of these devices for this indication.

The Committee was presented with newer evidence that raised concerns about a possible increase in mortality and the risk of lower limb amputation in patients treated with paclitaxel eluting balloons and stents for critical limb ischaemia. The EAG recommended that no immediate regulatory action was needed after concluding that there is insufficient certainty from evidence presented to date. DEAC agreed with this conclusion but did express concern about possible clinically significant patient safety issues with these devices and agreed to undertake further discussions with the EAG. This included the provision of additional input of individual experts from within DEAC who will undertake further scrutiny of the evidence in advance of the next meeting. Consideration is underway for the issuing of a Patient Safety alert and it was agreed that a draft of this would be shared with DEAC.

Readers can send incident reports to the MHRA as well through the Yellow Card Scheme.

Other safety issues within devices and surveillance

The MHRA provided the Committee with an overview of current issues in the Devices Safety and Surveillance Group. These included:

- The development of a tender document to commission patient focus groups to better understand attitudes towards tolerance of risk of Anaplastic Large Cell Lymphoma (BIA-ALCL). among people contemplating receiving Breast implants. BIA-ALCL is a rare type of T-cell lymphoma (cancer of the immune system) that can develop in the scar tissue capsule and fluid surrounding a breast implant.

- Cross health system partnerships to address safety concerns with T34 syringe, for which a Medical Device Alert was published in March 2019, stating that a foam pad needs to be added to the battery compartment of all T34TM Ambulatory syringe pumps to ensure that the battery rests securely in the battery compartment.

- Progress on the MHRA investigation into the MAGnetic Expansion Control (MAGEC) rods, for which a Medical Device Alert was issued in April 2020. The initial action instructed that MAGEC rods should not be implanted in the UK and that systems should be put in place to identify and follow-up patients with a device implanted. MHRA's investigation is ongoing.

The Committee was briefed on cooperation with the MHRA communications division to explore a potential safety campaign on oxygen cylinders similar to that launched on emollient skin products and fire risks in July 2020.

The Committee was updated on the MHRA's COVID-19 response and the agency's increased collaboration with the National Institute for Health and Care Excellence (NICE) and its utilisation of Target Product Profiles (TPPs).

Other business

The Committee was provided with a status update on MHRA Expert Advisory Groups (EAGs), confirming that the 'digital' EAG, which was paused during the early part of the COVID-19 outbreak, has restarting work and that the 'aluminum' EAG is no longer meeting since the relevant fluid warming devices have been removed from the market.

The Committee was informed that Polyethylene-glycols (PEG) are increasingly used in medical devices and that there is a perceived under-reporting of adverse incidents. This topic will be explored in more detail at a future meeting.

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:

- Professor Jeremy Wyatt declared an interest in one item; the nature of this interest did not prevent him from taking part in the discussions.
- A list of Members who attended the meeting is in Annex A.
- Apologies were given by Ms Christine Callendar who was unable to attend.
- All members attended the meeting via Zoom teleconference.
- The meeting started 10:04 and lasted until 13:07.
- The next meeting of DEAC is due to take place on 19th November 2020.

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) and will be considered in accordance with the FOI Act.

ANNEX A

ATTENDING MEMBERS OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING 17TH SEPTEMBER 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 (apologies)
Head of Nursing (Quality & Regulation) Royal College of Nursing

Royal College of Anaesthetists
Dr Kathleen Ferguson MBChB FRCA
Consultant Anaesthetist, Aberdeen Royal Infirmary

NHS Wales and Royal College of Surgeons
Professor Puthucode Haray MS DNB FRCS FFST(Ed)
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
Consultant in Obstetrics & Gynaecology at the Norfolk & Norwich University Hospital; Honorary School Senior Lecturer, University of East Anglia

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 Guest
Professor Sir David Spiegelhalter OBE FRS
Winton Professor of the Public Understanding of Risk, University of Cambridge

Glossary of terms, abbreviations and acronyms

- **UK cross health system partnerships:** the cooperative systems between various government departments, agencies and organisations (including the MHRA, NHS English, NHS improvements, DHSC and CQC, Devolved Governments) to deliver high quality patient care and ensure safety.

- **Central Alerting System (CAS):** a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care. See more here.

- **Clinical community:** Qualified healthcare professionals, including those who are registered with the Health and Care Professions Council.

- **Combination medical product (aka 'borderline products'):** Combination devices are unique as they are used as diagnostic or therapeutic products that combine drugs, devices, and/or biological products. For example, a syringe which comes pre-packaged with a medicinal product inside it and cannot then be repurposed. Combination products can be complicated to define and how they are defined affects what regulation can apply to them. You can find guidance on whether a product can be defined as borderline here.

- **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.

- **Field Safety Notice:** A 'field safety notice' (FSN) is an important communication about the safety of a medical device that is sent to customers by a device manufacturer, or their representative. FSNs provide new information and tell you what you need to do to reduce the specified risks of using the medical device. The actions are referred to as 'field safety corrective actions' (FSCAs). If you receive a field safety notice from a manufacturer, always act on it. You can find details of field safety notices here.

- **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.

- **Healthcare Provider CEOs:** Chief Executive Officers of healthcare providing bodies. In England, this includes NHS Foundation trusts, community healthcare providers, mental health trusts. The Devolved Government systems have their equivalent institutions, such as Scotland's health board.

- **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 Patient Safety Alert Committee (NaPSAC):** a committee established in September 2019 to improve the effectiveness of safety critical communications and support providers to better implement required actions derived from them. The committee's leads on the issuance of National Patient Safety Alerts. You can find more details on the committee here.

- **National Patient Safety Alert:** official notices issued by NHS England which give advice or instructions to NHS bodies on how to prevent specific types of incidents which are known to occur in the NHS and cause serious harm or death**.** They are for the most serious, safety critical incidents that require a system-wide response, distributed via the Central Alerting System (CAS). You can find more details about NaPSAs and a list of those which have been issued here.

- **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.

- **Non-invasive ventilator:** breathing support administered through a face mask, nasal mask, or a helmet. Air, usually with added oxygen, is given through the mask under positive pressure. The other main type of ventilator is 'mechanical', which involves a hollow tube (artificial airway) going into the patients mouth and down into their main airway or trachea to help them breathe.

- **Notified Body:** A notified body is an organisation that has been designated by an EU member state (the designating authority) to assess whether manufacturers and their medical devices meet the requirements set out in legislation. The MHRA is the designating and competent authority in the UK. You can see the more information here.

- **Patient Focus groups:** Focus groups comprised of patients who provide opinions and feedback on issues MHRA is focused upon or researching. The MHRA usually commissions organisations to set-up such focus groups, which is why a tender document is being draw up for relevant groups for breast implants BIA-ALC matters. Groups can be comprised of individuals who have undergone relevant treatment or may have an opinion on the matter. involving patients to help with patient public.

- **Safety Campaign:** A campaign lead by the MHRA communications divisions to broadcast messages about device safety, including through the internet and social media.

- **Target Product Profiles:** Outlines the desired ‘profile’ or characteristics of a target product that is aimed at a particular disease or diseases. TPPs state intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics. Such profiles can guide product research and development.

- **Tendering:** An invitation to tender (ITT) is a formal invitation to make an offer for the supply services. The MHRA has issued one for focus groups to feedback on BIA-ALCL.