MINUTES OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON THURSDAY 16TH SEPTEMBER 2021

Meeting held remotely via videoconference from 10:02 to 13:24

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 16th September 2021.

Director's report

The Director of Devices provided DEAC with an update on the work of the Devices division, to help contextualise and provide perspective on the subsequent DEAC discussions.

The MHRA has launched a 10-week consultation on the future of medical device regulation for feedback and comment: Consultation on the future regulation of medical devices in the United Kingdom - GOV.UK (www.gov.uk)

Safety issues update

NuVasive

The Committee were given an update on the MHRA's MAGEC Spinal Rods investigation.

The MHRA's investigation identified several deficiencies with the technical documentation relating to the devices and NuVasive Specialized Orthopedics, Inc. (NSO) quality management system. The MHRA sent its initial findings to NSO and their EU Notified Body in September 2020.

Following this report, the Notified Body undertook its own review, which resulted in the CE certificate being suspended on 25 March 2021.

If CE certification is reinstated and the MHRA has been able to review the Notified Body's assessment, including the manufacturer's corrective action plan, we will reconsider if the UK suspension will be removed.

The MHRA, in consultation with its independent Spinal Expert Advisory Group, issued a Targeted Device Safety Information in May 2021. This letter provides recommendations for clinicians.

The Committee then had an opportunity to ask questions.

BIA-ALCL

Devices Safety and Surveillance presented two papers to the Committee. The first paper was to give an update on the proposal to commission public research to evaluate perception of risk associated with breast implants and Breast Implant Associated Anaplastic Large Cell Lymphoma known as BIA-ALCL to inform our regulatory decisions. The second related to a proposal to enhance transparency of medical devices as outlined in the agency's Delivery Plan.

In the first paper, the Committee was informed of the purpose and scope of the final research proposal to engage with patients and public, and progress made to date. The Committee noted the next steps in the procurement phase to proceed to notice to tender. It commended the steps the agency was taking and also recommended generic research of perception of risk of all medical devices be undertaken.

In the second paper, the Committee were made aware of the next scheduled update of MHRA's BIA-ALCL webpage with new information including update on figures of confirmed cases to MHRA.

They were also informed of a proposal relating to enhanced data transparency, including steps to engage with patients and public on how the agency should communicate benefit and risk. It recognised the challenges of the proposal and importance of contextualising the issue and offered its support on drafting the messages. The Committee commended the agency's steps to enhanced transparency and approved the proposal.

Paclitaxel coated balloons

The Committee were updated on the work undertaken/planned by MHRA in cooperation with the independent Paclitaxel Expert Advisory Group (EAG).

The MHRA outlined the key discussion points and outcomes from the last EAG meeting that took place in August 2021:

> The EAG favoured close patient engagement within the membership of future EAG meetings
>
> The EAG discussed the prospect of an additional publication that could provide readers with a useful insight into the work and decision-making process undertaken by the EAG.

The MHRA also outlined several new recommendations put forward by the EAG to MHRA:

The EAG supported the upholding of the current MHRA guidance on Paclitaxel coated devices, however, the EAG suggested additional recommendations, these are presently under consideration.

The Committee then had an opportunity to question the work and progress of the MHRA and EAG concerning the ongoing benefit vs risk and continued debate surrounding the use of paclitaxel coated devices.

In-Vitro Diagnostics Expert Advisory Group update

The MHRA delivered an update on the recent activities of the recently established IVD Expert Advisory Group. This included an overview of activities in the COVID-19 testing space, such as Exceptional Use Authorizations for COVID-19 lateral flow tests and Target product Profiles, and challenges faced.

The Committee were made aware of the six recommendations of the Royal Statistical Society regarding IVD learning from the COVID-19 pandemic and how MHRA has been addressing these, in collaboration with IVD EAG.

The MHRA outlined its aim to add patient voice to the IVD EAG, to collaborate and help overcome the issues identified.

MHRA size and shape overview

The Committee was informed of the of the current MHRA transformation which is currently open to staff consultation. Changes to the current structure are proposed due to several reasons including: a reduction in income as a result of exiting the EU and change in trading fund status; changes in the world of life sciences and the outcomes of the Cumberlege review to ensure that patients and public are involved in regulatory decision making and scientific innovation. This requires the Agency to work in a different way, to be a nimble regulator delivering the best values and outcomes for patients and public health. The Agency is currently made up of three centres; MHRA (which carries out the main regulation of medicines and devices), the Clinical Practice Research Datalink (CPRD) and the National Institute for Biological Standards and Control (NIBSC). In order to become more efficient, the new organisation will be built as One Agency - this means an intentional move away from the current structure based around three ‘centres’ to a single, interdisciplinary and agile structure. MHRA will move to a product life cycle model. This will completely change working processes and the current structure to become more outcomes focussed. The new structure will include a new Governance Office which will support DEAC as it moves in to operating as a statutory committee.

DEAC statutory development update

The Committee was updated on the DEAC statutory development that would reflect benefit risk teams within the safety and surveillance groups. As part of our openness and public engagement agenda to increase the confidence that patients and the public have in our regulatory decision making, MHRA will be transparent about our membership on our committees, their expertise and the data and assessment on decisions that have been reached. By January 2022 MHRA aims to recruit 10 core shadow DEAC members (including 2 patients reps) with the launch of statutory DEAC by June 2023. Under the terms of the Medicines and Medical Devices Act, the statutory meetings will continue to be held on a

quarterly basis. Next steps will look at the function, Terms of reference, membership, role descriptions and recruitment procedures.

Procedural Items

The Committee 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 Professors Hindmarsh and Kimber, Mr Morris and Dr Pelly.
- All members attended the meeting via videoconference.
- The meeting started 10:02 and lasted until 13:24.
- The next meeting of DEAC is due to take place on Thursday 18th November 2021.

To note:

Information is being withheld, under Section 43 of the Freedom of Information (FOI) 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. 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

Chair
Professor Peter Groves MBBS MD FRCP (Chair)
Consultant Interventional Cardiologist, Cardiff and Vale UHB
Chair, Health Technology Wales

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)
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 *(apologies)*
Professor of Paediatric Endocrinology, University College London

British Toxicology Society
Professor Ian Kimber OBE PhD FRSB *(apologies)*
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 FREng
Immediate Past 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 MBBS BSc (Hons) DCH PGCE FRCP FRCGP *(apologies)*
GP Partner, Horfield Health Centre, Bristol; Clinical Director, Phoenix Primary Care Network, Bristol; RCGP Representative, AI and Software Expert Advisory Group, Medicines and Healthcare Regulatory Agency, London

NHS Scotland and Royal College of Radiologists
Dr Iain Robertson MBChB MRCP FRCR EBIR
Consultant Interventional Radiologist, Medical Advisor - Medical Devices Unit, CMO Division. SG.

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

Glossary of terms, abbreviations and acronyms

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

- **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.

- **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.