MINUTES OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON 17TH MARCH 2022

Meeting held remotely via videoconference from 10:03 to 13:30

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 17th March 2022.

MHRA medical devices overview

Transitioning of agency

Two Benefit Risk Evaluation groups with 10 Therapeutic Area Units that will be integrated between medicines and devices colleagues

Safety aspects (for information)

A lateral flow test that is now CE marked will move to normal business approach regarding post market surveillance.

VOC assurance will continue as important element of strategy around maintaining vigilance around potential variants of concern.

A laboratory who was not subject to in house exemption, were not happy with advice as they felt it contradicted advice the agency had provided 17 years ago. They progressed with a judicial review which was rejected.

The MHRA gave an update on work around Field Safety Notice awareness and manufacturer's responsibilities.

Patient and public involvement

Increasing emphasis on work in terms of informing benefit/risk assessments and the MHRA are starting to form partnerships and undertake listening events, as well as a focus on patient engagement.

Regulations

Members were assured that safety and surveillance aspects of proposed regulations has been well discussed with Agency board members

Safety issues update

Roche Accu Check

The Committee considered evidence related to a safety concern of leakages, including cracked cartridges with Accu-Chek Insight insulin pump and NovoRapid PumpCart insulin cartridge. The Committee supported the recommendation to issue a national patient safety alert (NatPSA) and requested engagement to be conducted with the healthcare system and patients and the public to ensure that the content of alert was accessible and feasible to implement.

LifeVac/De-choker

MHRA Devices Safety and Surveillance presented a paper to the Committee proposing the lifting of sales restrictions on two airway clearance devices (LifeVac and DeChoker). The Committee were informed of the original rationale for MHRA Devices Compliance Group imposing the restrictions in 2017. Since then, usage data gathered, and additional evidence reviewed indicates that the benefit risk assessment has changed for the better and the sales restrictions are no longer appropriate. The Committee agreed with the proposal to lift restrictions, noted the next steps planned and recommended that MHRA notify the UK Resuscitation Council (UKRC) before the restrictions were lifted with an explanation of the decision and how it had been reached.

EAG updates

The In-Vitro Diagnostics EAG (IVDEAG) gave an update that included reference to the new IVD Regulations.

The Artificial Intelligence, Software and Apps EAG (AISAEAG) gave an update including work on a software and AI roadmap.

DEAC developments and future direction

The proposals for a statutory expert advisory committee, the Committee on Medical Devices, that were shared at the November meeting have been updated. The role of observers have been introduced and there is greater clarity on how the Expert Advisory Committees would report into the Committee on medical devices. The proposed membership has been updated so that the committee will have a Chair and deputy Chair and representatives from a range of areas including 2 posts from integrated care, public health, laboratory services, a statistician or epidemiologist, researcher/academic and 2 patient partners. The proposals on the Committee of Medical Devices will be subject to a public consultation.

The plans for an interim Committee on Medical Devices are going forward with a view to a first meeting in Summer 2022.

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 Ms Christine Callender and Professors Haray & Kimber.
- All members attended the meeting via videoconference.
- The meeting started 10:03 and lasted until 13:30.
- This iteration of DEAC was formerly closed at the end of the meeting, with sincere thanks to members.

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 17TH MARCH 2022

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

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
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

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
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
Professional Advisor, Medical Devices and Legislation Unit, Scottish Government

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
Professor Amanda Adler MD PhD FRCP
Professor of Diabetic Medicine and Health Policy, University of Oxford
Member of the Commission on Human Medicines

Invited Expert
Professor Partha Kar
Consultant in Diabetes & Endocrinology, Portsmouth Hospitals NHS Trust

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.