MINUTES OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON 20TH MAY 2021

Meeting held remotely via videoconference from 10:02 to 13:32

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 20th May 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. Partnership work with NHS Test and Trace was highlighted and MHRA reflected on lessons learned to ensure messages to the health service are clear, coherent and consistent. A Patient Safety and Engagement Committee has also been set up in response to the Independent Medicines and Medical Devices Safety Review and any actions taken will be revisited at future meetings. It was also noted that work is underway to create a new Regulatory framework for Great Britain (GB).

DEAC appointments / statutory body update

Members were provided with an update on the evolution of the DEAC and how it can best provide expert advice and input into decision making for the Devices Division and MHRA more widely. MHRA is reviewing processes should a statutory body be established.

In Vitro Diagnostics Expert Advisory Group (IVD EAG) update / COVID-19 update

The MHRA Principle Scientific Advisor presented two papers to provide the Committee with a general update on ongoing In Vitro Diagnostic programmes including COVID 19 testing (including Target Product Profiles) and the work of the In Vitro Diagnostic Expert Advisory Group (IVD EAG).

The first paper detailed the members of the newly formed IVD EAG. The recent expansion of the membership has been key in filling gaps in skills and expertise. The second meeting of the expanded IVD EAG will agree a role description to inform the recruitment of 2 patient and public representatives to join the group as standing members to help develop a programme of Patient and Public Involvement activity to support the IVD work of the EAG. We are particularly interested in working with people who have lived experience of IVDs, especially people who have experience of self-testing, or testing of others under their care (e.g. blood sugar testing of children).

The second paper was the Target Product Profile (TPP) for IVD self-tests for the detection of SARS-CoV-2 in people without symptoms. It was noted that this is MHRAs most extensive and complete TPP to date. Following extensive stakeholder consultation, The TPP has received sign off by the DHSC Test Validation Group (TVG) and is awaiting publication. It was noted that this TPP has become an influential document to support industry and government policy in determining if a test is fit for purpose.

Artificial Intelligence, Software and Apps Expert Advisory Group (AISA EAG) overview

The MHRA Group Manager for Devices Software and Digital Technologies presented two papers to the committee. One introduced the AI, Software and Apps Expert Advisory Group (AISA EAG) setting out how it would provide advice on problematic devices; current and future regulations; and thematic strategic issues. The second paper set out the high-level plans for the regulation of software and AI medical devices.

The Committee noted the membership of the EAG, including where additional expertise might be required. The patient and public engagement in this sector requires some specific activity which MHRA are looking to address in partnership with other relevant groups. The Committee also noted the need for MHRA to work in partnership with other relevant organisations, to develop a consistent vocabulary and to help to establish the right balance between innovation, regulation and safety. Specific areas of interest noted were in digital imaging, digital pathology and digital cellular pathology.

The Committee noted the specific challenges presented by software and AI as medical devices, the scale of deployment and the speed at which changes can be made to products. The Committee also discussed the need for an increased quality and strength of signal to enable the MHRA to be able to undertake post-market surveillance and to apply an appropriate level of scrutiny depending upon the risk presented by these products. The Committee recognised the need for educating all clinical disciplines, manufacturers and the public about this emerging device sector, particularly around clinical evidence, the role of regulation and post-market surveillance.

Safety, risk and signal detection

MHRA delivered a presentation on the role of the Signals, Risk and Messaging (SRM) committee within the Devices Division. This included an overview of the devices lifecycle approach, the functions of SRM and how this links to safety messaging and regulatory actions.

MHRA delivered a presentation on the Signal Management process within the Devices division. The committee were made aware of the purpose and scope of the project which included a summary of the tools and approaches developed.

The DEAC SRM report summary template was shown to the committee and approved for use in the pilot for the next 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:

- A list of members who attended the meeting is in Annex A.
- Apologies were given by Professor Kevin Harris and Mr Edward Morris.
- All members attended the meeting via videoconference.
- The meeting started 10:02 and finished at 13:32.
- The next meeting of DEAC is due to take place on Thursday 16th September 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
20TH MAY 2021

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 *(apologies)*
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 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
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.