MINUTES OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON 18TH NOVEMBER 2021

Meeting held remotely via videoconference from 10:01 to 13:35

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 18th November 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.

Mr Tunbridge informed the committee that the public consultation on the future medical device regulatory framework closed on Friday 19 November 2021. The consultation which was open for 9 weeks received a good level of engagement, receiving around 200 responses which are now being analysed and drafted into policy that will inform the future regulatory framework. The aim is to provide a response by March 2022. MHRA are pleased with how the consultation has landed and the warm reception received.

Mr Tunbridge said that the MHRA was engaging with major regulators globally via a regular safety call. MHRA continues to observe a single audit programme, the international medical device regulators forum and is in early discussions with a smaller network of regulators around a single review programme.

The committee were informed that MHRA had published a paper in collaboration with Health Canada and the Food and Drug Administration (FDA) on good machine learning practice on AI algorithms. There are further plans to publish a similar paper on the key learnings in the diagnostic space looking at testing during the Covid-19 pandemic.

Mr Tunbridge said that work around derogations had slowed down and a further approval for new lateral flow device has been deployed as part of the national testing programme. A

paper is being sent to Committee on Human Medicines (CHM) to look at AI work that overlaps the various EAGs.

There are over 1 million medical device products registered with the MHRA to date, this is expected to double as the end of 2021 deadline approaches.

Mr Tunbridge said that the public engagement around breast implants is beginning to take shape. This will act as a pilot for engaging with the public to inform regulatory decision making. MHRA have also updated their patient facing information on BIA-ALCL and it is expected that as the data becomes richer more information will be published on ALCL as part of the wider transparency work with the ability to breakdown data by manufacturer and other categories.

The Committee were pleased to learn of all the patient engagement events currently going on. Clarification was sought around data captured with regards to breast implants for clinical need vs cosmetic need and the committee was pleased that both will be looked at with a benefit risk lens. The committee welcomed the suggestion for the MHRA Group Manager of Software and Apps to attend a future meeting to provide an update on the new multi-agency advice service which has recently launched.

IDAP update

The MHRA is currently working in partnership with NICE, Health Technology Wales (HTW) and the Scottish Health Technologies Group (SHTG) to establish the Innovative Devices Access Pathway (IDAP). IDAP is a supported access pathway for innovative medical devices, including diagnostic and digital health technologies, focused on bringing innovative devices which provide a solution to an identified critical unmet need within the health and social care system.

For the most innovative technologies, IDAP will facilitate early and safe market access using MHRA's Exceptional Use Authorisation (EUA) powers, as well as providing post-market support. When an application is not deemed appropriate for EUA, IDAP will continue to support the applicant's product development by offering tailored scientific guidance and practical next steps to guide the product to market through alternative routes, or development until EUA is deemed appropriate.

The committee was provided with an update on the development of IDAP, which is about to move to a pilot phase by opening for applications in early 2022. The recent consultation on Future Device Regulation included IDAP in the Routes to Market Chapter, and readers can find more information on the pathway on the Gov.UK webpage here.

IVD EAG update

Dr Martin Myers provided a substantial update on the evolution of the Invitro Diagnostic (IVD) EAG. The EAG work programme includes providing advice on Target Product Profiles (TPP), advice on Exceptional Use Authorisations (EUAs), consideration of Use Case proposals. The EAG is also discussing and advising on a list of national essential tests. This follows from understandings that the new EUIVDR is providing challenges to manufacturers who are then choosing to remove their tests from use. The purpose of this endeavor is to support equality of access to tests, support regulatory decision making and ensure flexibility in the case of emergency situations. For essential tests there will be common specifications with minimal acceptance regarding performance and agreed post-market surveillance. The group is committed to working in partnership including ensuring that the National Pathology

Board is aware of the implications of IVD matters as they arise. Looking to the future the group will have a role in supporting bringing new tests safely to market though such initiatives as the IDAP, ensuring proactive post-market surveillance. A continued partnership with UK Health Security Agency (UKHSA) will be important to ensure arrangements for any future pandemic preparedness. The national testing directory will facilitate a risk based approach to any proactive post-market surveillance The IVD EAG demonstrates how the agency has been able to utilize the expertise within the group and the value such a group adds to the safety of devices in the UK through DEAC.

Update from EAGs

Updates were provided to DEAC from each committee members in regard to the work of other EAGs as well as the relevant areas of collaborations with Royal Colleges, Specialist Societies and Devolved nations represented by the individual committee members.

DEAC statutory development update

Dr Janine Jolly and Mrs Catriona Blake gave an update on DEAC Statutory Development. The new Statutory DEAC committee will be established under the Medicines and Medical Devices Act 2021 section 20 and Implemented by a Statutory Instrument. The future format is restricted to a maximum of 9 members and a Chair who will be recruited by the DHSC public appointments team.

The membership will be drawn from a variety of therapeutic areas, healthcare sectors and patients, the voluntary sector, other relevant representatives and shall reflect the expertise required for the business of the Committee. Additional experts may be invited to attend to advise the committee in considering and interpreting the evidence on individual topics. The committee will have a Chair and deputy Chair and representatives from a range of areas including community health, public health, social care, Ambulance and acute, laboratory services, a statistician or epidemiologist, researcher/academic, and two patent safety partners (patient and public representative).

The functions of DEAC are to advise on matters relating to medical devices including giving advice on the safety and quality of medical devices, assistance with signal validation of issues that lead to MHRA providing national advice; providing advice on communications including the most effective method to disseminate safety advice and transparent decision-making processes to the healthcare community and the public; to create and maintain oversight of specialist Expert Advisory Groups; to consider representations made (either in writing or at a meeting) by a party to resolve matters of dispute; to provide advice on strategic areas and priorities such as emerging issues and 'horizon scanning' for topics that might influence operational activity and MHRA policy; develop open and constructive relationships with key partners including the Commission on Human Medicines and to undertake and support audit of MHRA safety decision-making including the retrospective review of signal decisions.

It is expected that members will serve for an initial period of three years, which can be renewed for 2 further 3-year periods. Members are expected to attend at least 75% of their committee’s meetings during a 12-month period and not to miss more than 2 consecutive committee meetings. The committee normally will meet 4 times a year. All meetings will be held via Microsoft Teams though at least one meeting a year will be a hybrid of in-person and virtual. Extraordinary meetings may be called as required. In addition, there may be off-line correspondence and Chairs actions.

Any Other Busines

There were no items recorded any other business.

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 Callender and Professor Haray.
- All members attended the meeting via videoconference.
- The meeting started 10:01 and lasted until 13:35.
- The next meeting of DEAC is to be confirmed.

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 18TH NOVEMBER 2021

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 *(apologies)*
Head of Nursing (Quality & Regulation)

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
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 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

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.