MINUTES OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON 25th FEBRUARY 2021

Meeting held remotely via Zoom videoconference from 10:00 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 25th February 2021.

Future regulations

The MHRA is working to deliver a robust, world-leading regime for medical devices that prioritises patient safety. The committee was provided with an update on this work–and invited to comment on early considerations for this future regime.

COVID-19 testing & EAG

The MHRA has worked continuously to support the Government in its response to the COVID-19 pandemic since March 2020. In particular, Devices Division has been engaged on work relating to diagnostic test kits by scrutinising devices put into use – including issuing Exceptional Use Authorisations – and developing Target Product Profiles (TPPs). The committee commended the MHRA for its contribution to the pandemic response in the COVID-19 testing space.

The Principal Scientific Advisor for In Vitro Diagnostics (IVDs) provided an overview of activities carried out relating to COVID-19 Lateral Flow Tests, including self-testing. The committee were also informed a Target Product Profile for self-tests was in development. An overview of MHRA activities around emergent mutations was also provided, including the establishment of a Variants of Concern working group in partnership with other entities (e.g. PHE) to proactively manage variants which have the potential to affect test and vaccine efficacy.

The committee were briefed more widely on the Agency's ongoing IVD programme. The MHRA's Principal Scientific Advisor for IVDs informed them of the recently established IVD Expert Advisory Group (EAG), which has been established to bring expertise on IVD technology to MHRA to inform regulations and policy, including the development of Target Product Profiles. DEAC member Martin Myers acts as the current chair of the IVD EAG, and the MHRA outlined plans to have its work feed into and support DEAC. The committee welcomed the establishment of the EAG, and advised that the Terms of Reference *(Annex B)* be updated explicitly to add patient and public engagement to the current list of stakeholders that will be engaged with, which currently includes professional bodies and trade associations. The MHRA agreed to this recommendation.

Device registration and registries

Manufactures who place certain medical devices onto the UK market are required to register them with the MHRA. This is to ensure traceability and product safety through market surveillance, which could show the need for a safety alert to be issued or a product to be recalled. In the context of the patient safety agenda, in particular in relation to recommendations seven and nine of the report of Independent Medicines & Medical Devices Safety Review, 'First Do No Harm', there is ongoing work to develop the new Medical Device Safety Programme (MDSP) which will be developing outcome registries for implants for all relevant specialties.

The Group Manager of the MHRA's Devices Information and Operations Group provided an overview of the MHRA comprehensive UK-wide medical device UDI/Registration system and highlighted the inter-relationship with it and the NHS Digital Medical Device Information System (MDIS) and MDSP. The chair introduced guest speaker Professor Tim Briggs, National Director of Clinical Improvements for the NHS, who provided an overview of the MDSP and how it will utilise data from the national MDIS, Scan4Safety and the MHRA's medical device UDI/Registration system to get detailed reference data about devices using Unique Device Identification (UDI).

The Chair also introduced guest speaker Scott Pryde, Medical Technology and Surveillance Lead at NHS Improvement, who provided more detail on collaboration between Getting It Right First Time (GIRFT), NHS Digital and NHSX which contributed to the inclusion of the requirements for the MHRA UDI/Registration system in the Medicines and Medical Devices Act 2021.

The committee members expressed support for the MDSP and advised that patient groups should be involved in the early stages of the programme's development. Professor Briggs explained that the programme intended to adopt the Beyond Compliance approach which involves patients and lay members in data review processes. DEAC members also asked whether primary care data, contraceptives and artificial intelligence / apps were being included in the programme, and outlined that they felt it important to connect primary care and secondary care data to enable the collection of complete data on outcomes or complications. The GIRFT representatives acknowledged the comments made and confirmed that in the first instance the programme would be established in secondary care and it would then be expanded if deemed necessary.

The committee also asked how MDSP would ensure that prompt action was taken when a safety signal was detected. The invited experts explained that the programme intended to look at best practice from the NJR and Beyond Compliance processes which prompt further investigations and action when a signal is detected.

DEAC development and risk assessments

The MHRA is developing the operations of DEAC to maximise the contributions from experts, in part informed by wider MHRA efforts to respond to themes within the First Do No Harm Report, including to build-in engagement with external advisors in a more systematic way.

The MHRA presented the committee an overview of the Devices Safety and Surveillance Group's risk assessment procedure. Particular focus was given to the purpose and design of the Devices Risk Management Report (RMR), which is completed after detection and validation of high risk/ complex signals and covers confirmed risks, for relevant models or types of devices of interest The RMR is a live document and intended to help organise thinking and aid decision making, being based upon principles of risk/benefit assessment (in particular the international standard on risk management, ISO 14971). One core focus of the report is stakeholder engagement and advice from external experts.

MHRA proposed sending DEAC monthly headline summaries of items which have been added or progressed through the RMR. This would allow DEAC to be sighted of topics in between quarterly meetings, allowing a clear indication of the problems identified for a topic and outline the actions sought from the members of the committee (or alternatively, for information only). Where it is required, the issue would then be included in the agenda of the next DEAC meeting for wider committee consideration. DEAC members welcomed the idea in principle and suggested the system be piloted for future meetings.

The MHRA Senior Management Team also provided the Committee with an update on wider plans to evolve the operations of DEAC, including its role in peer reviews and providing of professional input. A summary of the strategic direction of the MHRA Devices Division regarding signal detection management and the renewed emphasis on using expert advisory groups to support data driven decision making was provided.

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 Ms Christine Callendar and Professor Haray.
- All members attended the meeting via Zoom videoconference.
- The meeting started 10:00 and closed at 13:30.
- The next meeting of DEAC is due to take place on 20th May 2021.

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 Committee 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.

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.

- **'First do no harm':** A Report published by The Independent Medicines and Medical Devices Safety Review published in July 2020. It focuses on people who have suffered avoidable harm', specifically from the use of two medications and one medical device. It examined Primodos which was a hormone pregnancy test (HPT) used between the 1950s and 1978; Sodium Valproate which is an anti-epileptic drug taken by women during pregnancy and pelvic mesh implants used for treating vaginal prolapse. The report contains nine recommendations for the healthcare sector. This report is also referred to as the 'Cumberlege Report' in media.

- **The Independent Medicines and Medical Devices Safety Review:** The Independent Medicines and Medical Devices Safety Review is Chaired by Baroness Julia Cumberlege CBE DL. In February 2018, the Secretary of State for Health and Social Care, the Rt Hon Jeremy Hunt MP, announced a review into how the health system responds to reports from patients about harmful side effects from medicines and medical devices. The announcement in the House of Commons follows patient-led campaigns on the use of the hormone pregnancy test Primodos, anti-epileptic drug sodium valproate and surgical mesh. It published the 'First Do No Harm' report in July 2020.

- **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.

- **Getting It Right First Time (GIRFT):** A national programme designed to improve the treatment and care of patients by reviewing health services. The programme undertakes clinically-led reviews of specialties, combining wide-ranging data analysis with the input and professional knowledge of senior clinicians to examine how things are currently being done and how they could be improved.

- **In Vitro Diagnostics Device (IVD):** IVD medical devices are test kits and instrumentation used to test human samples to assist clinical diagnosis or decisions concerning clinical management. Examples include pregnancy tests, blood sugar monitoring systems for diabetics or receptacles manufactured specifically for medical specimens. All COVID-19 tests are classified as IVDs.

- **Lateral Flow Test:** Lateral flow antigen tests are rapid turnaround virus tests that can process COVID-19 samples on site without the need for laboratory equipment, with most generating easy-to-understand results in under half an hour. Because of this, they can be performed in a laboratory or a point of care setting. In the UK, the MHRA has granted NHS Test & Trace an exceptional use authorisation to use certain lateral flow devices as self-

tests to detect infection in asymptomatic individuals who otherwise would not be tested. For more information, please see Gov.uk guide to COVID-19 tests and testing kits

- **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

- **Medical Device Register:** The Medicines and Medical Devices Act 2021 provides MHRA with the legal powers to require manufacturers in the future to provide comprehensive information about the devices placed on the UK market and used in UK healthcare to the MHRA register; and to make such information publicly available.

- **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.'

- **Medicines and Medical Devices Act (MMDA):** Primary legislation, which received royal assets on 11 February 2021 and provides the government's Secretary of State (SoS) for Health with a range of powers to amend the existing regulatory framework regarding human and veterinary medicines, and medical devices in the UK. The Act also establishes a new Commissioner for Patient Safety. The Bill was first introduced in February 2020 by Secretary of State for Health, Matt Hancock. You can read the Act 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.

- **National Joint Registry (NJR):** set up by the Department of Health and Welsh Government in 2002 to collect information in England and Wales on joint replacement operations and to monitor the performance of implants, hospitals and surgeons. welcomes the report recommendations from the Independent Medicines and Medical Devices Safety Review, chaired by Baroness Julia Cumberlege. The NJR also fully supports the development of a wider implant medical devices registry to ensure greater patient safety.

- **NHSX:** NHSX is a United Kingdom Government unit with responsibility for setting national policy and developing best practice for National Health Service technology, digital and data, including data sharing and transparency.

- **NHS Digital:** NHS Digital is the trading name of the Health and Social Care Information Centre, which is the national provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care in England, particularly those involved with the National Health Service of England.

- **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

- **Scan4Safety:** This was an initiative led by the Department of Health and Social Care (DHSC) intended to enable the delivery of better patient care, improved clinical productivity and supply chain efficiency in the NHS in England. It was intended to improve traceability and efficiency in the NHS through the use of international barcoding standards (GS1 standards) and common ways of doing business (PEPPOL). NHSX holds responsibility for Scan4Safety.

- **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.

- **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. Several TPPs have been developed to assist manufacturers to design and deliver tests that might be useful in support of the UK COIVD-19 testing strategy. More information can be found here.

- **Unique Device Identifier (UDI):** A unique numeric or alphanumeric code related to a medical device. It allows clear and unambiguous identification of specific devices on the market and facilitates their traceability, thus improving patient safety.

ANNEX A

ATTENDING MEMBERS OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING 19TH NOVEMBER 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

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
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 Expert
Professor Time Briggs CBE
National Director of Clinical Improvement for the NHS

Invited Expert
Mr Scott Pryde
Medical Technology Surveillance and Analytics lead at NHS Improvement

Apologies

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

ANNEX B

Terms of reference for the In Vitro Diagnostic Expert Advisory Group (IVDEAG) (dated 12th February)

The In-Vitro Diagnostic Expert Advisory Group (IVD-EAG) has been established to consider the issues and provide advice to the MHRA on:

- The development of IVD related policy and regulations
- The formulation of guidance to the IVD industry, health and care professions and patients, where appropriate.
- The development of Target Product Profiles for IVDs
- Applications for exceptional use authorisation, as required.
- Advise on the format and targeting of MHRA communications with relevant stakeholders
- Align communication between MHRA and relevant Professional Bodies and trade associations.
- Priority areas of work in the IVD area
- Regulatory decision making, vigilance and post market surveillance
- Other matters arising where a view on scientific or clinical evidence, uncertainty and best practice may be required.

Frequency:
The group will meet monthly in the first instance with a view to providing timely support to the ongoing COIVD19 public health emergency. This will be reviewed after a period of three months and the frequency adjusted accordingly.
EAG members may be asked to provide advice by e-mail or video call between scheduled meetings, where timescales require it.

Governance:
The IVDEAG will feed into and support the Devices Expert Advisory Group through the Chair.

Term:
IVDEAG members will be expected to serve a 6 month term, in the first instance.