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Medical Device Regulatory Developments in the EU, UK and China

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1. Introduction

2021 has been a very busy time for the medical device sector around the world. Of particular importance is the EU MDR, due to be implemented in 2020 but postponed until 26 May 2021 due to the COVID-19 pandemic. While the MDR will serve to strengthen the existing regulatory landscape for medical devices in Europe, Brexit has presented a new set of obligations for medical device manufacturers.

Meanwhile in China, Order No. 739 on the Supervision and Administration of Medical Devices became effective on 1 June 2021. The in-vitro diagnostic (IVD) regulation remains at draft stage, and some supplementary regulations have been proposed.

This white paper focuses on the latest regulatory developments for medical devices in the EU, UK and China, providing an overview of key updates between January and June 2021.

2. European Union

Implementation of Medical Devices, Regulation (EU) 2017/745 (MDR)

This regulation repeals the EU Medical Devices Directive 93/42/EEC. Due to the COVID-19 pandemic, the entry into force was postponed until 26 May 2021 and is now in effect. This regulation lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. The regulation also applies to clinical investigations concerning such medical devices and accessories conducted in the Union.

The new regulation contains the following main changes:

- Labeling obligations include marks for reprocessing of single use devices, the Unique Device Identification (UDI) system, and indication of the presence of certain substances that are carcinogenic, mutagenic or toxic to reproduction and endocrine disrupting substances
- Economic operators' role and obligations through the entire life cycle of medical devices

- Stricter rules on the designation of Notified Bodies
- Rules strengthening the market surveillance of medical devices and the establishment of an EU database on medical devices (EUDAMED)
- Stricter rules for substance-based devices and provisions on software as medical devices
- The introduction of "sponsor" as the responsible party for the conduct of a clinical investigation

Decision on Standardization Request as Regards Medical Devices and In Vitro Diagnostic Medical Devices under Regulations (EU) 2017/745 and 2017/746

Commission Implementing Decision C (2021) 2406, issued on 14 April 2021, sets out a standardization request as regards medical devices in support of Regulations (EU) 2017/745 and (EU) 2017/746.

Annex I, table 1 contains a list of 201 existing standards to be revised and Annex I, table 2 contains a list of 27 new standards to be drafted in support of Regulation (EU) 2017/745 for medical devices.

Annex II, table 1 contains a list of 46 existing harmonized standards to be revised and Annex II table 2, contains a list of new harmonized standards to be drafted in support of Regulation (EU) 2017/746 for in vitro diagnostic medical devices.

European Commission Proposed Draft Rules for the Application of Regulation (EU) 2017/745 as Regards Electronic Instructions for Use of Medical Devices in April 2021

This draft aims to facilitate the implementation of the new regulatory framework for devices by allowing manufacturers to provide online manuals instead of paper instructions relating to any of the following devices:

- Implantable and active implantable medical devices and their accessories covered by Regulation (EU) 2017/745
- Fixed installed medical devices covered by Regulation 2017/745
- Medical devices and their accessories covered by Regulation (EU) 2017/745 and fitted with a built-in system visually displaying the instructions for use

Manufacturers may provide online manuals for the said devices under the following conditions:

- The devices and accessories are intended for exclusive use by professional users
- The use by other persons is not reasonably foreseeable

In addition, manufacturers of software covered by Regulation (EU) 2017/745 may also provide instructions for use in electronic form by means of the software itself instead of in paper form.

European Commission Published List of Guidance Documents to Ensure the Smooth Implementation of the New Framework Legislations

1. Factsheet for Class I Medical Devices, February 2021

This factsheet is aimed at manufacturers of Class I medical devices. It covers devices that have already been placed on the market under Directive 93/42/EEC (MDD) and new devices intended to be placed on the market for the first time in accordance with Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 (MDR).

2. Guidance Document on Qualification of Medical Devices, March 2021

This guidance from the European Commission provides decisive steps to assist the qualification of Medical Device Software (MDSW).

3. Implementation Rolling Plan for Regulation (EU) 2017/745 and Regulation (EU) 2017/746, April 2021

This rolling plan contains a list of identified essential implementing acts and other relevant initiatives that the Commission has adopted or intends to adopt in the future. This plan is divided into two sections: implementing acts, and other actions/initiatives. This document is subject to quarterly review in order to provide national authorities and stakeholders with the most updated information.

4. Stronger Rules on Medical Devices, Press Release, May 2021

The European Commission issued a press release to notify stakeholders that, "*As of today, new EU rules on medical devices (MDR) enter into application, establishing a modern and more robust regulatory framework to protect public health and patient safety. The new rules*

start applying after a one-year postponement due to the unprecedented challenges of the coronavirus pandemic, addressing the need for an increased availability of vitally important medical devices across the EU.

The regulation covers medical devices ranging from hip replacements to sticking plasters. It increases transparency and brings EU legislation in line with technological advances and progress in medical science. It improves clinical safety and creates fair market access for manufacturers."

5. Position Paper on Implementation of UDI Requirements for Contact Lenses, Spectacle Frames, Spectacle Lenses & Ready Readers, May 2021

Article 27 of Regulation (EU) 2017/745 on Medical Devices (MDR) introduces a Unique Device Identification (UDI) system, which among other functions aims to improve the identification of devices and enhance the effectiveness of post-market safety-related activities for devices. In the interest of proportional data-entries in EUDAMED for certain highly individualized products, specific UDI assignment solutions are envisaged.

As such, this position paper is intended to provide clarification on the implementation of UDI requirements from 26 May 2021, for contact lenses, spectacle frames, spectacle lenses & ready readers until solutions are finalized. This position paper should be read in conjunction with the relevant provisions of Regulations (EU) 2017/745 (notably Chapter III and Annex VI) and related UDI guidance documents.

6. Q&A Section on Application of Regulation on Medical Devices Questions and Answers, May 2021

The Medical Devices Regulation entered into force in May 2017 and became applicable on 26 May 2021.

This guidance from the European Commission explains the requirements of the amended regulation, addressing questions such as:

- Will medical devices that were certified under the old rules have to reapply?
- What will be the role of Notified Bodies?
- Does the regulation address the use of nanomaterials in medical devices?

7. Guidance on Harmonized Administrative Practices and Technical Solutions Under EUDAMED, MDCG 2021-01

This document provides guidance to Member States and other relevant parties on the application of certain MDR provisions during the absence of EUDAMED. To that end, this guidance intends to describe harmonized administrative practices and alternative technical solutions for the exchange of information until EUDAMED becomes fully functional.

8. Guidance Document on Certification of Class D In Vitro Diagnostic Medical Devices Requirements, MDCG 2021-04

According to Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (the IVDR), as part of conformity assessment of Class D in vitro diagnostic medical devices (IVDs), the manufacturer must submit an application to a Notified Body. In addition to the assessment by the Notified Body, under certain conditions particular elements may be reviewed by an expert panel and/or tested by an EU reference laboratory (EURL).

The establishment of EURLs for a range of Class D devices has been identified as an important priority by the Medical Device Coordination Group. The European Commission is preparing the implementing acts on tasks and criteria of the EURLs and fees they may levy, referred to in Article 100(8) of the IVDR, as well as the first call for applications to be submitted by the Member States.

This document provides indications for how to apply the IVDR provisions related to expert panels and EURLs during the transition period, i.e. before 26 May 2022.

9. Guidance for Standardization of Medical Devices, MDCG 2021-05

This document aims to provide guidance on different aspects related to standards in the medical devices sector in support of the requirements laid down in the applicable EU legislation, considering its specificities.

10. Clinical Investigations of Medical Devices, MDCG 2021-06

This document is intended for sponsors of clinical investigations of medical devices conducted within the scope of the Regulation (EU) 2017/745 (MDR).

11. Guidance Document on Clinical Investigation of Medical Devices Notification Report, MDCG 2021-08

The sponsor of a clinical investigation is required to submit an application/notification1 to the Member State(s) in which a clinical investigation is to be conducted, accompanied by the documentation referred to in Chapter II of Annex XV of Regulation (EU) 2017/745 (MDR).

The application/notification is required to be submitted by means of the electronic system referred to in Article 73 of the MDR. In the absence of the European database on medical devices (EUDAMED), a series of clinical investigation application/notification documents have been created to support clinical investigation procedures with respect to MDR.

12. Guidance Document on Status of Appendixes E-I of IMDRF N48 Under the EU Regulatory Framework for Medical Devices, MDCG 2021-10

This document intends to provide clarifications as to how certain principles and examples outlined in N48 Appendixes E-I apply under the MDR/IVDR. The examples provided within the Appendixes are for informative purposes and should not be interpreted as the sole manner for complying with UDI obligations.

Certain principles and terminology set out within the IMDRF N48 Appendices are not applicable under the MDR/IVDR. The comparison table provided explains the applicable MDR/IVDR principles and terminology that should be applied to comply and is non-exhaustive in its nature.

13. Guidance on Implant Card – 'Device Types', MDCG 2021-11

According to Article 18 (a) of the MDR, the manufacturer of an implantable medical device shall provide, together with the device, information allowing the identification of the device, including the device name, serial number, lot number, the UDI, and the device model, as well as the name, address and the website of the manufacturer.

In accordance with the instructions laid out in MDCG 2019-8, the implant card should also indicate a 'device type' for the implantable medical device in question.

As such, this document provides a non-exhaustive list of implantable medical 'device types' in order to aid manufacturers in allocating an appropriate term for this requested information.

14. European Medical Device Nomenclature, FAQ, MDCG 2021-12

The FAQ section aims to help the industry to gain a better understanding of European Medical Device Nomenclature (EMDN). It addressed the following questions:

- What is the EMDN?
- How was the EMDN created?
- What are the key principles of EMDN?
- How do I gain access to the EMDN?
- How is the EMDN structured?

3. United Kingdom

Publication of Medicines and Medical Devices Act, 2021

The Medicines and Medical Devices Act 2021 (the Act):

- Establishes a Patient Safety Commissioner, with the core duties of promoting patient safety and the importance of the patient voice in relation to the regulation of human medicines and medical devices
- Introduces targeted delegated powers in the fields of human medicines, veterinary medicines, and medical devices to enable the existing regulatory frameworks to be updated following the United Kingdom's departure from the European Union
- Provides information sharing gateways to enable sharing of information with relevant persons (such as regulators and regulatory networks) outside of the UK in order to give effect to international agreements and arrangements concerning the regulation of human medicines, veterinary medicines and medical devices
- Provides a delegated power to establish one or more information systems in relation to medical devices
- Provides a delegated power to establish on a legislative basis a medical device expert advisory committee

- Consolidates the enforcement provisions for medical devices and introduces civil sanctions

Guidance Document on Medical Device Software Applications, January 2021

This guidance provides information on when software applications are considered to be a medical device and how they are regulated. The UKCA (UK Conformity Assessed) mark is used for certain goods, including medical devices, being placed on the Great Britain market.

Please note that CE marked devices will continue to be recognized on the Great Britain market until 30 June 2023.

Draft Medical Devices (Northern Ireland Protocol) Regulations Proposed in June 2021

The draft regulations make provision for the implementation of Regulation (EU) 2017/745 in Northern Ireland. It makes supplementary provisions in relation to placing devices on the market and putting devices into service in Northern Ireland under Regulation (EU) 2017/745.

4. China

Publication and Enforcement of Order No. 739 on the Supervision and Administration of Medical Devices, June 2021

This order is the fundamental framework law that governs medical devices in China. It sets out measures on research and development, manufacture, sale, use and supervision of medical devices. Medical devices are supervised and administered in accordance with risk classifications including low risk, medium risk, and high-risk medical devices. The catalogue of classification and classification rules will be issued by the State Council. Medical devices are required to be registered and relevant information and documents shall be kept in records.

Compared to the previous version, the new Order No. 739 contains the following main changes:

- Establishing a medical device registrant's responsibility system; clarifying registrants' responsibilities on research, design, manufacturing, operation, use and post market surveillance
- Encouraging innovation in the medical device sector; establishing priority approval systems and simplified procedures for innovative medical devices
- Adding provisions regarding emergency response to public emergencies and pandemics; establishing conditional approval for medical devices that are essential for emergency response to speed up the release of the products to the market
- Imposing more severe penalties, particularly in relation to product safety violations

Draft Order on Administrative Measures on Registration of In Vitro Diagnostic Reagent Proposed in March 2021

The draft order proposes the following changes:

- Local authorities will be responsible for local supervision of clinical trial quality control
- In vitro diagnostic reagent that have not been put on the market aboard are not required to submit relevant documents when applying for new product registration
- Products in scope must comply with mandatory standards; companies are encouraged to adopt voluntary standards
- Product inspection reports must be based on product technical requirements
- Conditional approval of products that are used for rare diseases and public health emergencies

Draft Order on Administrative Regulations on Medical Device Clinical Trial Quality Control Proposed in May 2021

The draft order contains 66 Articles in 9 Chapters, including the following main changes:

- Including the in vitro diagnostic reagent to the scope of the regulation
- Setting out obligations on the parties in relation to clinical trials
- Adjusting safety information submission procedures
- Inserting requirements to be in line with international regulatory systems such as IMDRF MDCE WG/N57 FINAL:2019, and ISO 14155:2020

Draft Medical Device Clinical Trial Plan and Further 6 Documents Published for Public Comment in May 2021

The following documents are drafted to be in line with the proposed draft order on Administrative Regulations on Medical Device Clinical Trial Quality Control:

- Medical device clinical trial plan template
- Medical device clinical trial report template
- In vitro diagnostic devices clinical trial plan template
- In vitro diagnostic devices clinical trial report template
- Medical device/in vitro diagnostic devices clinical trial adverse event report template
- Documentation list for medical device clinical trial

Draft Principles on Classification of Artificial Intelligence (AI) Medical Device Software

The draft principles apply to stand alone medical device software which serves its medical purpose using artificial intelligence technologies. It provides rules on classification of said medical device software. According to the draft principles, AI medical device software is classified into the following four categories:

- Diagnostic assistant software
- Image/data processing software
- Analysis/research software
- Medical assistant software

All AI medical device software are Class III medical devices with possible adjustment in the future.

Draft Principles on Registration of Artificial Intelligence (AI) Medical Devices

The draft principles aim to guide the registrants of AI medical devices establishing product lifecycles and preparing for registration applications. It also governs the technical evaluation of AI medical devices.

The draft sets out general requirements for AI medical devices. The registrants shall comply with the parts that are applicable to their products. In terms of the parts that are deemed as

not applicable to the products, the registrants must provide detailed information and reasons.

The draft applies to Class II and Class III standalone AI medical device software and medical devices using AI software. It lays down the following provisions:

- Definitions and scopes on AI medical devices, AI medical device types, and AI algorithm update
- General principles regarding fundamental algorithm, risk assessment, and lifecycle management
- AI medical device lifecycle process needs assessment, data collection, algorithm design, validating and confirmation, and update control
- Technical requirements
- Algorithm research data
- Documentations and instructions for registration applications

5. Conclusion

Across the EU, UK and China, significant changes to the existing medical device regulatory landscape are underway or fast approaching. Although a long list of guidance documents was published to facilitate the implementation of the EU MDR, there are still some uncertainties regarding harmonized standards, limited time to submit notifications and a shortage of Notified Bodies due to the new requirements. Brexit has also created some new challenges. China is in the same situation in terms of how Order No. 739 will be implemented, in particular, the registrants obligation system. As we can see, the IVD regulation is still in the draft stage, as are some supplementary regulations.

Interested in finding out more? Register for our upcoming webinar 'Regulatory Developments in Medical Devices: Your Questions Answered' with expert speakers from Cooley and Compliance & Risks.

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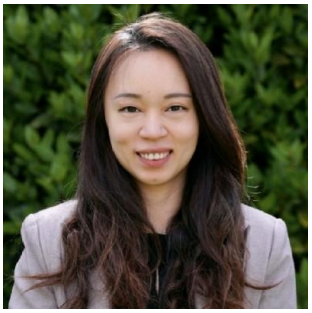

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She helps product manufacturers to identify and understand the regulations in place in the markets to which they sell by helping them to map their obligations with regard to product safety (chemicals, EMC, radio frequency), labeling, energy efficiency, waste and packaging.

Amy is a native Chinese speaker and has a Master of International Commercial Laws from the University of Limerick, and a Bachelor of Law degree from University College Cork.

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