Introduction to Regulatory Affairs in Medical Devices

[glossary_exclude] In the last decades, the evolution of new technologies contributed to the development and implementation of the new regulatory framework on which Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) are grounded. The MDR and IVDR have introduced new responsibilities for many organisations in the healthcare sector, including the European Medicines Agency(EMA) and national competent authorities in the assessment of certain classes of medical devices.[/glossary_exclude]

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Exploring the Regulatory Landscape

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[glossary_exclude] US Terrain [/glossary_exclude]

[glossary_exclude]Originating with the Federal Food Drug and Cosmetics Act (FD&C Act) in 1938, subsequent milestones include the 1944 Public Health Service Act addressing laboratories and biologics, and the 1968 Radiation Control Act focusing on radiation-emitting machines. The pivotal 1976 Medical Device Amendments established a three-class system and pathways like Pre-Market Approval (PMA) and premarket notification (510(k)). The Safe Medical Devices Act (SMDA) in 1990 increased reporting and post-market surveillance. The 1997 Food and Drug Administration Modernization Act (FDAMA)

introduced third-party reviews and the De Novo program through which novel low-to-moderate risk devices could be classified into Class I or II instead of automatically classifying them into Class III. Ongoing evolution through acts, like the 2016 “21st Century Cures Act” focusing on how to fasten the patient access, and the 2017 Food and Drug Administration Reauthorization Act (FDARA) requiring the FDA to conduct at least one pilot project to explore how real-world evidence, can improve post-market surveillance [1].[/glossary_exclude]

[glossary_exclude] EU Setting [/glossary_exclude]

[glossary_exclude] The European Medical Device Regulation (EU) 2017/745 (MDR) governs the design, clinical investigations, production, distribution and commercialisation of Medical Devices in Europe. It brings a range of strengthened requirements that collectively raise the bar for Medical Devices placed on the EU market and aims thereby to increase the safety for the patient.

The European in Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) is the new regulation for a specific category of Medical Devices [1] and lays down the rules concerning the placing in the market, making available on the market or putting into service of *in vitro* diagnostic Medical Devices for human use and accessories for such devices in the European Union [2].

The European Commission has published several additions to the MDR and the IVDR and it is expected that more changes/finetuning by the Commission will follow.[/glossary_exclude]

[glossary_exclude] Fragmented Standards: Discrepancies in Market Access and Procurement Processes across the EU [/glossary_exclude]

[glossary_exclude]Market access is the umbrella term for a variety of different routes for a product to reach patients. However, whether the device goes on to be sold and how it is implemented in a Member State is a separate matter, depending on country-specific criteria, including relative clinical effectiveness, comparison between alternatives and price negotiations. Thus, there are many competing frameworks for assessing the value of Medical Devices and in general, this is a space that is **not** harmonised across Europe. Lastly, frameworks regarding procurement of Medical Devices are equally **not** harmonised.[/glossary_exclude]

What about New Technologies?

[glossary_exclude]Medical Device software (MDSW), based for example on Artificial Intelligence and machine learning, and digital health are one of the areas in Medical Devices that are developing rapidly. The FDA has a database of approved AI technologies: Artificial Intelligence and Machine Learning in Software as a Medical Device | FDA (source: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device). The EU and other countries do not have such a database. At the time of writing, the EU institutions are negotiating a proposal for a new EU Artificial Intelligence Regulation (the so-called 'AI Act'), which if adopted would add an additional layer of requirements for AI technologies that comprise (or are found in) Medical Devices.[/glossary_exclude]

Learning Resources

[glossary_exclude]Take your skills to new heights by earning certification in emerging fields like Medical Devices! Explore the EUPATI **Open Classroom** and delve into the module Introduction to Medical Devices and their regulatory framework, Introduction to market access, key elements and patient involvement & Medical Device development, Lifecycle management, New Technologies, Patient involvement to deepen your understanding of the Medical Devices' landscape. Strengthen your expertise, empowering you to advocate for, engage in discussions, and play a pivotal role in implementing key elements that align with your vision for the healthcare system.[/glossary_exclude]

References

[glossary_exclude][1] https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states

[2] Regulation 2017/746 of the European Parliament and the Council: REGULATION (EU) 2017/ 746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL – of 5 April 2017 – on in vitro diagnostic medical devices and repealing Directive 98/ 79/ EC and Commission Decision 2010/ 227/ EU (europa.eu)[/glossary_exclude]