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Regulatory Developments in Medical Devices: A Review of Recent Legislation

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About The Author

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Prior to joining Compliance & Risks, Denise worked in the medical device industry for 13 years across a number of areas including regulatory affairs, post-market surveillance, customer complaints, quality, and technical support.

She has experience in several areas including IVDR, CE marking, labelling, legal documentation, customer and quality technical communications and regulatory risk assessments.

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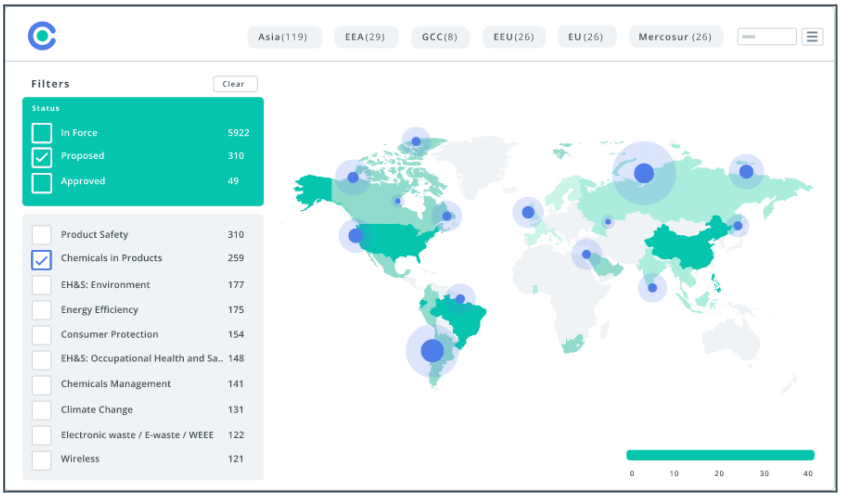

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1. Introduction To Recent Medical Device Regulatory Updates

The medical device regulatory landscape is continuing to evolve, and 2022 saw several important changes introduced.

In the USA, the proposed Protecting and Transforming Cyber Healthcare[1] Act was introduced to address device cybersecurity concerns and if enacted, would amend the Federal Food, Drug, and Cosmetic Act to ensure inclusion of evidence of conformance to cybersecurity requirements in all premarket submissions for cyber devices.

The application date for the European Union (EU) In Vitro Diagnostic Regulation (EU IVDR)[2] on 26 May 2022 had a significant impact on the regulation of in vitro diagnostic medical devices (IVDs).

This year we also saw the publication of a long awaited Drugs, Medical Devices, And Cosmetics Draft Bill[3] in India, which will regulate medical devices as a separate item, and aims to replace the existing Drugs and Cosmetics Act 1940.

In the United Kingdom (UK), the Government recently announced a 12-month extension to the implementation of the future medical device regulations, with an aim to bring the new regulations into force in 2024, allowing manufacturers to continue to place CE (Conformité Européenne) marked devices on the UK market for some time longer.

In November 2022, the Medical Device Authority (MDA) in Malaysia published the sixth edition of the medical device guidance document on Requirements for labelling of medical devices[4].

Overall, this whitepaper provides information on several of these recent key medical device regulatory changes.

[1] USA Protecting and Transforming Cyber Health Care Act of 2022 or the PATCH Act of 2022
[2] Regulation (EU) 2017/746 of the European Parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices.
[3] Ministry of Health & Family Welfare, Draft of New Drugs, Medical Devices and Cosmetics Bill 2022, July 2022.
[4] MDA/GD/0026, 21 November 2022, Sixth Edition, Medical device guidance document requirements for labelling of medical devices

2. UK

The UK left the EU on 31st January 2020 and as a consequence, new rules govern how medical devices are placed on the market in Great Britain (England, Wales and Scotland). Moreover, the UK now intends to strengthen the medical device regulations in Great Britain.
As a result, between September and November 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) published a consultation document on proposed changes to the regulatory framework for medical devices in the UK.

In June 2022, the MHRA published the government response to that consultation on the future regulation of medical devices in the UK[5].
The response highlighted certain areas of change including those aimed at improving patient safety and increasing innovation. There was also support for the use of unique device identification (UDI).
In more detail, the proposals include reclassification of certain products, strengthening of post-market surveillance, expansion of the scope of the regime to cover non-medical products which have a similar risk profile to medical devices. Furthermore, proposals on regulations which are aimed at increasing innovation include those surrounding updates to the rules covering software and artificial intelligence (AI) as medical devices.

It also includes the introduction of alternative routes to market, for example, an innovative MedTech route to market, which would allow the MHRA to authorise initial market approval. The response detailed transitional arrangements for the new framework, which was planned to be adopted in 2023, however in October 2022, the UK Government announced a 12-month extension to the implementation of the future medical device regulations, with an aim to bring the new regulations into force by July 2024.

[5] Medicines and Healthcare products Regulatory Agency (MHRA) Government response to consultation on the future regulation of medical devices in the United Kingdom, 26 June 2022.

The extension of the UKCA implementation to July 2024 means that manufacturers of medical devices will be able to continue to place CE marked devices on the Great Britain market after July 2023 and from July 2024, transitional arrangements will apply. Further updates, guidance and legislation will be issued from the MHRA and will be published on their website.

In September 2022, the MHRA updated its guidance on Medical devices: software applications, which explains when software applications are considered medical devices, and describes how they are regulated. The guidance is applicable to standalone software and apps placed on the Great Britain market. Overall, the guidance gives examples of software and apps which meet the definition of a medical device and it outlines requirements for UKCA marking of medical devices.

3. USA

The proposed Protecting and Transforming Cyber Health Care Act of 2022, or the PATCH Act[6] was introduced in March 2022.
If enacted, the PATCH Act would amend the Federal Food, Drug, and Cosmetic Act to ensure that all premarket submissions for cyber devices include information that demonstrates conformance to cybersecurity requirements.

The bill sets out several minimum cybersecurity requirements for medical device manufacturers including the processes and procedures for updates and patches to the cyber device throughout its lifecycle, as well as establishment of a software bill of materials (SBOM). The SBOM provides a detailed list of the components used in a software application and can help ensure vulnerabilities are detected during design, and easily identifiable post market.
Overall, the bill will oblige medical device manufacturers to address cybersecurity going forward.

The FDA Intends to publish its final guide on 'Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions[7]' in 2023.
The guidance document applies to devices that contain software or programmable logic, and software as a medical device (SaMD).
The draft guidance applies to devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and lays down recommendations surrounding the information to be submitted for devices under certain premarket submission types to demonstrate safety and effectiveness.

Importantly, this guidance document refers to the term "medical device system" indicating the need to consider medical devices as part of a larger overall system. The FDA states that; "For the purposes of this guidance, the term 'medical device system' includes the device and systems such as health care facility networks, other devices, and software update servers to which it is connected."

[6] USA Protecting and Transforming Cyber Health Care Act of 2022 or the PATCH Act of 2022
[7] Draft guidance on Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.

The FDA guidance document focuses on four important principles for cybersecurity in medical devices, these being; A. Cybersecurity is Part of Device Safety and the Quality System Regulations; B. Designing for Security; C. Transparency and D. Submission Documentation. Taken together, the recommendations within this guidance can facilitate an efficient premarket review process, and help ensure that medical devices are resilient to cybersecurity threats.

4. EU

The date of application of the new EU In Vitro Diagnostics Regulation (EU) 2017/746 (IVDR)[8] was 26 May 2022. The IVDR brought about important changes in the regulation of in vitro diagnostic medical devices (IVDs) including more stringent rules on clinical evidence and post-market surveillance as well as clear obligations for economic operators.
Several guidance documents were released by the Medical Device Coordination Group (MDCG) this year to provide clarification on the application of IVDR requirements.

In January 2022, MDCG 2022-2 Guidance on General Principles of Clinical Evidence for IVDs[9] was published.
It provides guidance on general principles of clinical evidence, performance evaluation process, the role of risk management in performance evaluation, performance evaluation plan (PEP), scientific validity, analytical performance and clinical performance, performance evaluation report (PER), and continuous update of the performance evaluation.
The guidance describes collection, generation and documentation of the supporting data required and provides informative appendices on methodological principles for generation of clinical evidence and the required frequency for updates of reports.

In May 2022, MDCG 2022-8, on Regulation (EU) 2017/746 - the application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022[10], was published.
It provides information on the application of the IVDR requirements to both legacy devices and old devices, as well as associated transition periods.

[8] Regulation (EU) 2017/746 of the European Parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices.
[9] MDCG 2022-2 - Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs).
[10] MDCG 2022-8: Regulation (EU) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC.

Legacy devices are defined as “devices referred to in the 2nd or 3rd subparagraph of Article 110(3) IVDR, which are placed on the market or put into service after 26 May 2022 and until the end of the respective transition period set out in the 2nd or 3 rd subparagraph of Article 110(3), if the conditions laid down in the 1st subparagraph of Article 110(3)3 are fulfilled.”

As per MDCG 2022-8, such legacy devices can be devices “covered by a valid EC certificate issued by a notified body in accordance with Directive 98/79/EC prior to 26 May 2022” or devices for which “a declaration of conformity was drawn up prior to 26 May 2022 in accordance with the IVDD and for which the conformity assessment procedure pursuant to the IVDR (contrary to the IVDD) requires the involvement of a notified body.” The Annex of MDCG 2022-8 also provides a useful table illustrating IVDR requirements applicable or not applicable to legacy devices.

Common Specifications for Certain Class D In Vitro Diagnostic Medical Devices in Accordance with Regulation (EU) 2017/746, Regulation (EU) 2022/1107[11] was published in July 2022.
For certain class D IVDs, there are no harmonised standards, which are required to respond to some requirements in Annex I of the IVDR, therefore common specifications can be adopted for those devices in these instances. According to this regulation, “The common technical specifications set out in Commission Decision 2002/364/EC for certain devices covered by Directive 98/79/EC remain relevant.” Compliance with the common specifications laid down in this Regulation will be on a voluntary basis before its date of application.

As per the regulation, “devices that are in conformity with Decision 2002/364/EC are to be presumed to be in conformity with the requirements for certain performance characteristics set out in Annex I to Regulation (EU) 2017/746 until the date of application of this Regulation.”
This Regulation shall apply from 25 July 2024, and article 3 shall apply from 25 July 2022.

[11] Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council.

The Proposed amendment to Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Regulation (EC) 1907/2006 on adding synthetic polymer microparticles to Annex XVII[12] was published in September 2022.
In order to prevent an accumulation of microplastics in the environment, the draft regulation aims to prohibit the placing on the market of microplastics intentionally added to products in concentrations above 0.01% by weight.
For medical devices covered by Regulation (EU) 2017/745, six years were considered necessary for reformulation and transition to suitable alternatives. A first discussion on the proposal took place on 23 September 2022 in the REACH Committee, which is a committee composed of Member State representatives that supports the European Commission on its work under the REACH Regulation. Member States sitting in the REACH Committee will vote on the proposal before the proposal is sent to the European Parliament and the Council for a 3-month scrutiny period before adoption is considered.

In October 2022, a proposed amendment to Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Regulation (EC) 1907/2006 on adding CMR substances to Annex XVII[13] was published. The purpose of this amendment is to incorporate substances classified by Regulation (EU) 2022/692 as CMR category 1A or 1B within the scope of Annex XVII to Regulation (EC) No 1907/2006. The final date for comments is 04 December 2022.

In Ireland, the In Vitro Diagnostic Regulations 2022 (S.I. 256 of 2022)[14], and the European Union (National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices) Regulations 2022 (S.I. 257 of 2022)[15] came into force on 26 May 2022 to further implement the IVDR. Specifically, the In Vitro Diagnostic Regulations 2022 (S.I. 256 of 2022) confer enforcement powers on the Health Products Regulatory Authority (HPRA). The regulation also describes a range of offences for breaches of the requirements of IVDR.

[12] EU: Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Regulation (EC) 1907/2006 – Proposed Amendment – (on adding synthetic polymer microparticles to Annex XVII) Draft Regulation, September 2022.
[13] EU: Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Regulation (EC) 1907/2006 - Proposed Amendment - (on adding CMR substances to Annex XVII) Draft Regulation, October 2022.
[14] S.I. No. 256/2022 - In Vitro Diagnostic Medical Devices Regulations 2022.
[15] S.I. No. 257/2022 - European Union (National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices) Regulations 2022.

The European Union (National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices) Regulations 2022 (S.I. 257 of 2022) provide for the establishment of a national body responsible for ethical standards in the management of performance studies required under the IVDR, and for a National Office to administratively support the work of those committees.

This regulation also describes various offences relating to performance studies.

5. India

The long awaited Bill from India on Drugs, Medical Devices and Cosmetics[16] was published in July 2022 by the Ministry of Health and Family Welfare. The draft Bill is intended to regulate drugs, medical devices, cosmetics, clinical trials, homoeopathic drugs and online pharmacies and will modernise and replace the Drugs and Cosmetics Act, 1940.

The Bill is significant in that it establishes a distinct definition for medical devices and allows for medical devices to be regulated as a distinct entity. As per Chapter II, the Bill also proposes to create a Medical Devices Technical Advisory Board to advise the government on technical matters, and proposes the establishment of central and state medical devices testing centres for testing and evaluation of medical devices. Chapter VI deals with the import, manufacture, sale, distribution and clinical investigation of medical devices.
As per section 125(2) on the regulation of medical devices; "An importer or manufacturer who has received license in respect of medical device shall, after the device has been made available on the market, submit the adverse event reports and periodic safety update reports in respect of the device in such form, at such frequency, and for such duration, as may be prescribed, Provided that for different medical devices, different requirements related to post market surveillance may be imposed depending on the risk to health or safety presented by the device."

The draft bill also makes it mandatory to obtain permission from the Central Licensing Authority when carrying out any clinical investigation of medical devices and medical devices officers will be appointed to carry out inspections.

Overall, the implementation of the Bill is long overdue, and is a positive step for the medical device industry in India. The Drugs, Medical Devices and Cosmetics Act, 2022 shall come into force on a future date appointed by the Central Government.

[16] Ministry of Health & Family Welfare, Draft of New Drugs, Medical Devices and Cosmetics Bill 2022, July 2022.

6. Australia

The Therapeutics Good Administration (TGA) under the Australian Government Department of Health and Aging published consultation document No. 3 in August 2022 on Implementing the Proposed Australian Medical Device Unique Device Identification (UDI) Regulatory Framework[17], as part of their program of reform to the regulation of therapeutic goods.

This is the third consultation paper published by the TGA regarding the implementation of a UDI system for medical devices. There were two earlier papers, the first on a Proposal to introduce a Unique Device Identification system for medical devices in Australia, and the second on Exploring options for the introduction of an Australian Unique Device Identification System.

This third consultation seeks feedback on the impact of accepting both European and USA compliant labels, scope and exemptions in applying the UDI, maintaining data over the full life of the device, UDI related fees and charges, UDI labelling and supporting documentation and adoption and use in the broader healthcare setting.

The TGA accepted comments until 11 October 2022 which will be reviewed by the TGA and outcomes from the consultation will be provided to the Australian Government for consideration.

[17] Therapeutics Good Administration (TGA) under the Australian Government Department of Health and Aging Consultation: Detailed considerations for implementing the proposed Australian medical device UDI regulatory framework.

7. Brazil

In March 2022, the Brazilian Agency for Sanitary Surveillance, ANVISA published Resolution RDC No. 657[18] to regulate Software as a Medical Device (SaMD). Effective from July 2022, this Resolution establishes the requirements for the regularisation of software as a medical device. This resolution does not apply to wellness devices or software used exclusively for administrative and financial management in health services.
In more detail, the Resolution describes labelling requirements, and states that the information on the label and instructions for use may be made available on the software itself, in an easily accessible place. This resolution also contains detail on traceability, audits, market monitoring and inspection by the competent authority, and entered into force on 1 July 2022.

On 8 September 2022, the Brazilian Agency for Sanitary Surveillance, ANVISA published a draft Resolution which describes the essential safety and performance requirements applicable to medical devices and in vitro diagnostic (IVD) medical devices.[19]
This Resolution applies to all medical devices and IVDs and describes the essential principles of safety and performance that must be taken into account during design and manufacturing. According to ANVISA, the draft Resolution proposes that the essential safety and efficacy requirements provided for in RDC 546/2021 (RDC 56/2001) must be updated to reflect new technologies.

The comments period of this draft Resolution closed on 15 November 2022, with an expected entry into force date of 1 March 2023. It will repeal the existing Resolution RDC No. 546 once approved.

[18] ANVISA Resolução de diretoria colegiada - RDC Nº 657, 2022
[19] National Health Surveillance Agency, Public Consultation No. 1112, of September 6, 2022

8. Malaysia

The Medical Device Authority (MDA) in Malaysia published the sixth edition of the medical device guidance document on Requirements for labelling of medical devices on 21 November 2022.
The document applies to all products that fall within the definition of medical device, as defined in Section 2 of the Medical Device Act 2012 (Act 737) and MDA/GD/0006: Definition of Medical Device, including in vitro diagnostic (IVD) medical devices.
This document applies to all medical devices, except those that are exempted from registration as per Medical Device (Exemptions) Order 2016, and Circular Letter No. 4/2018 Exemption from Registration Requirement for Export Only Medical Device. Furthermore, promotional materials and product brochures are not within the scope of this document.

This Guidance Document should be read in parallel with the Medical Device Act 2012 (Act 737); Medical Device Regulations 2012; Medical Device (Duties and Obligations of Establishments) Regulations 2019; and Medical Device (Advertising) Regulations 2019.

9. Conclusion

A high level of regulatory activity was observed across the globe in 2022. The European Union's new In Vitro Diagnostic Medical Device Regulation 2017/746 (IVDR) is now in effect, and while its implementation is an important step in guaranteeing safe and effective IVDs, it has also highlighted certain challenges for all involved.

Concerns remain about notified body capacity and the potential future lack of availability of IVDs on the European market.
The future of medical device regulation in the UK is yet to be finalised, as is the new Drugs, Cosmetics and Medical device Bill in India, and therefore 2023 looks set to be another busy year in terms of medical device regulatory developments.