REGULATORY FRAMEWORK FOR IN-VTRO DIAGNOSTICS IN EU, USA AND INDIA

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ABSTRACT:

Healthcare now includes a variety of practical products and technologies for diagnosis, prevention, treatment, and disease control. In vitro diagnostic medical devices (IVDs) are some of these medical technologies, used alone or in combination, and are used by manufacturers to test laboratory samples of human origin to provide information of diagnosis for monitoring or compliance purposes. CE Mark/Certification is required for in vitro diagnostic medical devices (IVDR) sold in the European Union. IVDR is regulated in a new way by certification bodies and national authorities. The certification body ensures compliance with quality and safety standards and IVD certification with the CE mark, which is a marketing authorization issued by a competent authority of a Member State. IVD regulation in the United States is administered by the CDRH. In order to obtain a marketing permit, strict adherence to the desired principles is required. 510(k) and PMA are the regulatory pathways for obtaining marketing authorization in the United States. In India, CDSCO regulates a small number of IVDs through official news notifications. Some products are classified as drugs in India and devices in other countries. This system does not meet international standards. The existing regime appears to be more traditional than the US and EU regulatory regimes. In this review, we will discuss IVD, MDR, regulation and labeling of Ce.

KEYWORDS: In vitro diagnostic medical device regulation (IVDR), Laboratory-Developed Tests (LDT), IVD regulation, TTIs, Quality Management, Laboratory–development tests,

INTRODUCTION:

Healthcare now includes a variety of practical products and technologies for diagnosis, prevention, treatment, and disease control. In vitro diagnostic medical devices (IVDs) are some of these medical technologies, used alone or in combination, and are used by manufacturers to test laboratory samples of human origin to provide information of diagnosis for the purpose of monitoring or sequencing. The IVD plays an important role in blood transfusion and ensures the safety of blood and blood products by screening for transfusion-transmitted infections (TTI) and determining blood compatibility criteria.

Stability is the ability of an in vitro diagnostic medical device (IVDMD) to maintain its performance characteristics over time. The purpose of stability studies is to investigate the duration and storage conditions for which stable performance characteristics of the IVD can be claimed. One of the key aspects of developing and manufacturing reagents for in vitro diagnostic medical devices (IVD) is to first design the stability of the product and then determines and ensure its stability when the product enters the market. Manufacturers evaluate to determine shelf life, vehicle stability and stability in use. To provide this important information to consumers, manufacturers identify important factors that may affect the stability of IVD reagents and carefully evaluate these characteristics. IVD reagent stability affects device performance and thus patient outcomes. It is the responsibility of the manufacturer to determine and monitor the stability of the IVD product to maintain the product's performance characteristics.

In vitro diagnostic (IVD) medical device: Medical devices, alone or in combination, used by the manufacturer for diagnostic, regulatory or compliance purposes or primarily for laboratory testing of human or animal specimens.

Note: IVD includes reagents, calibrators, control materials, sample containers, devices, instruments, equipment, materials or software or accessories used for testing purposes: for diagnosis, diagnostic equipment, screening, monitoring, prognostic factors, prognosis, prediction, to determine the physical condition.

Table 1: The major differences between the IVDD and the IVDR

Subject	**IVDD**	**IVDR**
IVD definition	• Reagents, calibrators, control materials, instruments, devices, tools, specimen containers, devices or specimens of human origin for laboratory tests, solely for the purpose of determining physiological or pathological, or natural diseases. Monitoring	• Includes tests, software, and accompanying diagnostics for predicting medical conditions and diseases (predicting response and treatment) (Part 2) • Some new definitions are also introduced. A device for "close to patient" testing intended for use by medical professionals outside of the laboratory environment. Devices that are used directly with specific drug therapy (co-

	Abnormalities, Compatibility and Potential Recipients or Treatments (Part 1)	diagnosis).
IVD classification	• Classified into high-risk devices that have been defined (List A) and medium-risk devices (List B) (both in the Annex). Device for self-examination of IVD remnants • certification authorities are mainly interested in A-list devices and less interested in B-list and self-testing devices. Together, they make up about 10% of all devices	IVD classes (a) Class A (personal risk and low health risk). (b) Class B (moderate personal risk, low health risk). (c) Class C (high personal risk, moderate health risk). (d) Class D (high personal risk and high health risk; "high risk" IVD). • CE certification of devices B, C and D (85% of all IVDs) requires increased participation of certifying bodies. • CE certification for Class D equipment requires an EU reference laboratory for performance verification and batch testing.
'High risk' IVDs	It is difficult to extend the markers identified as List A in Annex II with new markers List A: • Viruses: HIV1 and 2, HTLV I and II, HBV, HCV, HDV • Blood compatibility: ABO, Rhesus	Class D Flexibility to add more markers in the future as defined in Annex VIII Regulation 1 or 2. Rule 1: (a) Use of blood, tissue, cellular, and transplant immunity tests (eg, HIV1 and 2, HTLV I and II, HBV, HCV, HDV, HEV, Treponema pallidum, CMV, EBV, Plasmodium spp.) tools for immunoassays, Trypanosama cruzi, Toxoplasma gondii).
Notified Bodies	Conformity assessment procedure, EC declaration of conformity etc. Certain listed positions (Articles 9, 15, 21 and Annexes III-VII)	Improve the control of certification bodies • Designate a certification body: 12 months of work involving assessors from various national and European authorities. • Strong standards for scientific and technical

		assessment capabilities.
Device identification	• There are no special requirements to implement an integrated device identification system.	• Introducing the Unique Device Identifier (UDI) system to improve IVD identification, traceability and post-market security measures (Article 24). • Unique Device Identifier (UDI-DI) Product Identifier (UDI-PI) to identify the model and packaging of the device and place of manufacture.
Manufacturers' obligations	General liabilities are listed • Risk management and quality control systems. • conformity assessment procedure. • Ensure accountability for equipment on the market (appropriate corrective actions, record and report incidents, provide appropriate evidence to authorities).	More detailed and specific instructions on this: (Chapter 10) • Risk management and quality control systems. • more accurate clinical evidence: conducting research and evaluating clinical performance. • Update technical documentation archive. • conformity assessment procedure. • Ensure accountability for devices on the market (appropriate corrective action, record and report incidents, provide appropriate evidence to authorities). • general specifications with additional requirements for special equipment (clause 9). • Appointing a person responsible for legal and regulatory responsibilities for the necessary practices in the IVD sector (chapter 15).

The IVDR will affect assay portfolios of diagnostic laboratories:

The IVDR mainly regulates CE-IVDs, but also covers IH-IVDs manufactured and used in medical facilities. IVDR requirements do not apply to devices other than the General Safety and

Performance Requirements (GSPR) in Annex I (see also the IVDR Requirements section for more information, it is important to know IVDR) availability and use of CE-IVD and IH-IVD in diagnostic laboratories.

More stringent requirements for manufacturers affect the availability of CE-IVD tests:

The IVDR requires classifying existing and new IVDs according to a risk-based classification system. IVD classes vary depending on the intended purpose and the level of risk associated with the patient and the public. Table 1 shows the different categories listed in the IVDR (see also IVDR Annex). The highest risk category, D, includes infectious agents (eg, HIV, hepatitis B, SARS-CoV-2) and, most importantly, blood type testing. Most other tests used in hematology/hematology-oncology are classified as C, such as cancer and genetic tests. IVD categories specify specific requirements and evaluation methods for specific IVDs, as well as the depth of documentation required for review. Confirms that all requirements are met, Class A non-sterile devices are approved by manufacturers after compliance with the IVDR.

All other devices must be evaluated for compliance by the certification authority. In addition, expert committees and EU research laboratories are also involved in the assessment of Class D devices. After certification, manufacturers must update the documentation for C and D devices at least annually. Importantly, as a direct result of the new classification rules, many products that are currently self-certified under the IVDD must now be certified by a certification authority under the IVDR. The proportion of IVDs requiring certification by a certification authority is expected to increase from 15% (or less) for IVDD to 70% for IVDR to 90%. 3 In addition, clinical evidence (focus on clinical performance) and post-marketing surveillance (regular evaluation of IVD use experience for corrective and preventive measures is needed) are becoming more stringent in IVDR.

For IVD manufacturers, these changes require additional trained personnel, increase investment time, and increase costs. Additionally, the fact that many IVDs no longer self-certify means a significant workload for certification bodies. So far, only four notified bodies have been designated as IVDRs, so the total capacity of notified bodies will not be sufficient to evaluate all IVDs by May 2022. As a result, other important infrastructure (such as EU standard laboratories) and formal guidance documents are still lacking. This may result in the company not being able to hire the designated body in time or delaying the compliance assessment, leading to not all IVDs being approved before the IVDR is fully implemented. This suggests that although IVDR (fitness for purpose) is expected to improve the overall quality of CE-IVDs, the availability of CE-IVDs may be affected. Manufacturers have priorities, for example, the most important and profitable products are CE marked, while other products may be temporarily unavailable or even discontinued.

The IVDR specifies the requirements for using the IH-IVD.

As stated in Sections 28 and 29, the objective of the IVDR is to ensure the highest level of health protection by clarifying and strengthening the rules governing intrauterine devices. However, according to the introduction, "it is important that EU health facilities (hospitals, laboratories, health facilities, etc.) are exempted from the use of the IH-IVD, although the purpose of the IVDR is still proportionately fulfilled." For organizations whose main purpose is health promotion, it is used only in the following cases: Certain conditions are met.

From the date of IVDR use, all diagnostic laboratories in the European Union that use IH-IVD for diagnostic treatment of patients require an IVDR medical facility exemption.

What is the Pre-Submission Process for IVDs?

The pre-submission process was established in MDUFA III and modified by the MDUFA IV Directive and the Q submission process.

Submissions include a formal written request for comment from FDA, which may be recorded in the form of a formal written response or, if the submitter so desires, in the form of a comment letter or conference minutes. . A pre-submission meeting is a meeting or conference that provides important feedback prior to FDA submission.

Initial submissions are timely when FDA feedback on specific questions is needed to prepare for product development and submission.

The FDA recommends the use of predelivery in the following situations:

- Equipment that has new technology, new intended use, or a new analyzer, and it will help to familiarize you with the new features before submitting to the FDA.
- Need help identifying potential regulatory pathways.
- Research includes complex data and statistical approaches.
- The specific method or reference is vague or ambiguous. Or
- The new device is a multiplex device that can test several analytes at the same time.

The sponsor must submit a request for FDA comments on the study or proposal before the study begins. The advantages of pre-submission include:

- Initiate dialogue and strengthen understanding with the FDA.
- Reduce research costs by focusing on the information required for FDA approval (or clearance) and eliminating unnecessary or burdensome training.

- Speed up the review process for future marketing applications because the FDA is familiar with the device.

Pre-submission and related meetings are entirely voluntary and comments or suggestions made during protocol review or at these meetings are not binding on the manufacturer or the FDA.

Use of laboratory diagnostic medical equipment in medical facilities:

Medical institutions such as hospitals, pathology laboratories, medical laboratories, and healthcare centers use commercially available IVDs as clients for the diagnostic process chain (CE-IVDs [CE-IVDs], but only for research devices [RUO]. We in-house diagnostic methods and also develop, optimize, implement and validate materials. For example, in a Belgian university hospital study, almost all test results were obtained with CE-marked IVD methods (98%), but only half (47%) of the different IVD devices used. were developed in-house (IH), with no commercial preference (72%).

Various laboratory diagnostic tools can be used in the defined process chain, from the collection or extraction of the sample to the diagnostic result (Figure 1a). Here, two commercially available devices (CE-IVD, RUO device) and IH-IVD are used or combined (Figure 1b). Here, industry can complement or integrate IVD, in-house methods and materials used in public laboratories to find the results they need to provide optimal patient care. It not only regulates, but also provides requirements for IH-IVDs to be produced and used by medical facilities for internal use. This includes the use of RUO tools in diagnostics. The definition of "laboratory diagnostic medical device" is slightly modified by the new IVDR to expressly cover standalone software. However, according to the IVDR definition, the diagnostic method itself is not a laboratory diagnostic tool. New and stricter requirements for manufacturers to obtain IVD approval and not to inherit already approved products could have a direct impact on price cuts. Devices that are important to patients but not cost-effective due to growing needs may be pulled from the market altogether. For example, important but rarely used tests for patients with rare diseases may no longer be available or must be supplemented by tests developed in-house. In July 2021, a survey of 115 manufacturers for the European market conducted by MedTech Europe, a European trade association representing the medical technology industry, found that not all CE-IVD devices are likely to be subject to the new regulations.

This affects approximately one in five CE-IVDs on the market, leaving healthcare organizations unable to use them to treat patients or requiring replacement with advanced IH-IVDs. Approved replacement devices kept by healthcare facilities can be used until they expire. According to Article 29 of the Preamble of the IVDR, the development, production and use of in-house tests by healthcare institutions should remain an option to meet the specific needs of patients. This can still be done without the involvement of the relevant assessment bodies (known as notified bodies) and without the use of CE marked equipment. However, this regulation now aims to clarify and strengthen the rules related to IH-IVD to guarantee "the highest level of health

protection" (Article 28). This explanation is provided in Article 5(5) IVDR. This regulation imposes several conditions on healthcare facilities regarding the manufacture and use of IH-IVDs. It also explains that other requirements of the IVDR do not apply to health facilities when the conditions set in the IVDR are met.

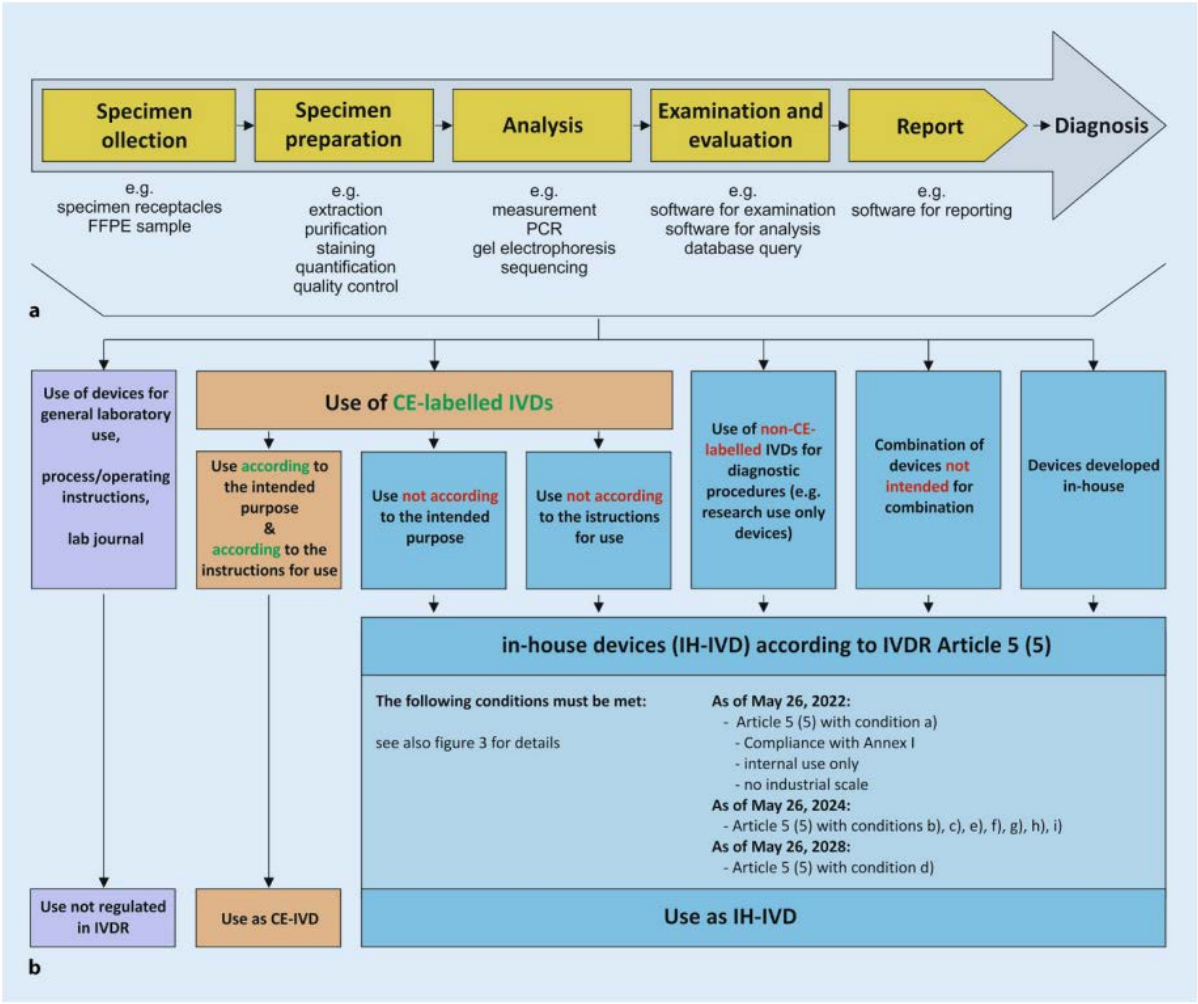

Figure 1: a: Process chain in the analysis of health care organizations. **b**: Each link in the process chain (a) from sampling to diagnostic results, general laboratory use case (purple), equipment in the CE-IVD diagnostic laboratory, orange) is defined internally, noting Advanced IVD

REGULATION OF IVDS IN THE EU – IVD DIRECTIVE (IVDD) AND IVD REGULATION (IVDR):

The European Union Directive on in vitro diagnostic medical devices (98/79/EC), adopted on December 7, 1998, establishes legal requirements that must be followed by all European Union

member states regarding the safety, quality, and performance of IVDs. Should have until 2000, several European Union member states had different national regulations on IVD. For example, in Germany, the Paul Ehrlich Institute (PEI) evaluated and approved IVDs (for HIV, HBV, HCV, cytomegalovirus, rubella, blood group markers) in accordance with the German Medicines Act. However, the transition period after 2000 requires the transposition of IVDD into national law in all member states of the European Union. IVDD compliance became mandatory on December 7, 2003, and since then only compliant IVDs are allowed to be sold and used in the EU. Only these are allowed to carry the "European Commission" (CE) mark. In summary, the IVDD sets, among other regulations, essential safety, quality and performance requirements for all IVDs on the EU market. The IVDD defines the tasks to be carried out by the Notified Body (NB) designated by the individual Member States. For high-risk devices (Annex II lists A and B and self-testing), manufacturers must apply to NB to guarantee their products. NB evaluates according to the established conformity assessment procedure. For "high risk" IVDs (defined as List A in Annex II: HIV, HBV, HCV, blood group markers), each device must undergo a complete Technical Document (TD), including design and evaluation. productivity. The Common Technical Specification (CTS) was developed specifically to define the minimum performance characteristics of this most dangerous IVD, through the general standardization obligation.

After the recent medical device scandal mentioned in the introduction, new rules were approved on April 5, 2017 and entered into force on May 25, 2017. Regulation 2017/746 of the European Parliament and of the Council [15] In April 2017, the In Vitro Diagnostic Medical Devices Act (IVDR) was adopted; repeal IVDD 98/79/EC. These rules prevent different national interpretations and improve coordination between Member States. This is different from the directive, which must be implemented in the national law of the member states and is open to interpretation, given that there may be differences between member states. The IVDR has been implemented since May 2017 and is mandatory after a five-year transition period with a modern and reliable approach to protect public health and patient safety. The objective of the IVDR is to improve the health and safety standards of EU citizens and ensure compliance with EU legislation, with significant technological and scientific progress in this field over the past 20 years. From May 26, 2022, the IVDD will be abolished and this date will be the "use date" of the IVDR, and some regulations (such as NB) will apply earlier.

IVDD and IVDR have similar regulatory processes in terms of impact on producers and products. The IVDR represents significant progress, including a broader and more specific definition of IVD, a new IVD classification system, improved certification body identification criteria, and subsequent regulatory and clinical approval processes for all IVDs, stricter rules to ensure patient safety, stricter treatment and post-marketing surveillance requirements for manufacturers, and a better coordination strategy between EU countries in this area. The new IVD classification system is based on the risk associated with IVDs and uses classification rules to replace the predefined list of IVDs. The regulation differentiates the classification of devices from Class A (low risk) to Class D (high risk) while increasing regulatory requirements. The purpose of an

IVD (eg, diagnosing patients or screening blood donors) can affect its classification and associated regulatory burden. Therefore, for some devices, manufacturers may choose not to require a "blood test" even if the device is suitable for this use. This approach may pose a challenge for blood safety if, for example, a small number of devices are produced at the start of a new or emerging infection. These provisions mainly add new requirements to existing Directive requirements. For example, one of the new components of the IVDR is the inclusion of the European Union Reference Laboratory (EURL) to verify the most important performance requirements in laboratories before high-risk devices (class D) are sold. The IVDR also emphasizes continuous evaluation throughout the product life cycle and requires manufacturers to demonstrate that they have a quality management system in place. We need greater data transparency on IVD devices and specific requirements for performance studies of high-risk devices. The summary must be available to the public. In addition, self-testing devices and near-patient testing devices will be subject to a pre-market validation approach to verify IVD suitability for relevant user groups. The IVDR adopts many of the concepts expressed by the International Medical Devices Regulatory Forum (IMDRF) to achieve global regulatory harmonization and convergence. The IVDR also leaves no room for "ancestor" regulations (for devices that were on the market before the new regulations) and now all IVD devices must comply with the new requirements.

A set of technical and clinical requirements that guide IVD safety and performance are all contained in Common Technical Specifications (CTS for IVDD) or Common Specifications (CS for IVDR) documents. This document outlines general safety and performance requirements and the minimum performance requirements that IVD manufacturers are expected to meet. Compared to the general technical specification (CTS) for IVDD, the general specification (CS) for IVDR adopts requirements for technical documentation (IVDR - Annex II, III), performance tests or performance evaluation (IVDR - Annex XIII); Market surveillance (IVDR - Annex XIII). The latest version of CTS requires the evaluation of the manufacturer (sensitivity, specificity, interference), information materials and regulations for batch release for manufacturers. The CTS blood test also clearly defines the sensitivity, specificity, and sampling requirements for evaluating IVD function. Such IVDs are usually covered and extended in the IVDR, which includes IVDs for blood group testing and compatibility testing with related general specifications. The European Union Reference Laboratory (EURL) requires manufacturers of all Class D devices to verify the required performance and compliance with CS through laboratory tests. The results of this mandatory manufacturer independent test must be used to determine the NB. Further functions of the EURL include batch approval testing of Class D devices and advice to the European Commission, Member States and NB on issues related to IVD. Since Class D devices are diverse, it is expected to have different domains (marker sets) covered by different EURLs and each domain covered by several EURLs to handle the expected workload. The different EURLs should provide common test methods and decision criteria by establishing a network of EURLs. Individual EURLs can use the specific expertise available under the "National Standard Laboratory" subcontract. The functions and standards of the EURL are

summarized in Article 100 of the IVDR and defined by the implementing regulations of the European Commission.

Steps for marketing approval in Europe [14]:

1. Identify the IVDR used in the device.
2. Determine the class using Appendix IX.
3. Select the conformity assessment procedure / route.
4. Appoint an authorized representative located in Europe.
5. Verification of QMS and technical documents by notified bodies.
6. Register the equipment with the competent authorities of the member states.
7. Prepare a declaration of conformity showing that the IVDR complies with the applicable Directives
8. CE mark affix.

REGULATION OF IVDS IN THE UNITED STATE (FDA):

IVDs and other medical devices are subject to general control unless expressly exempted by law or regulation.

General oversight the main provisions of the Medical Device Amendments to the FD&C Act, enacted on May 28, 1976, provide the FDA with the means to regulate devices to ensure safety and efficacy. General regulatory rules apply to all medical devices, including IVDs. This includes situations related to fraud, record and count faulty equipment. Advance market notice of equipment limitations, including maintenance, replacement, returns, music and reports. Limited tools and good manufacturing practices.

What is the Pre-Submission Process for IVDs? [8]

The pre-submission process was established in MDUFA III and modified by the MDUFA IV Directive and the Q submission process.

Submissions include a formal written request for comment from FDA, which may be recorded in the form of a formal written response or, if the submitter so desires, in the form of a comment letter or conference minutes. . A pre-submission meeting is a meeting or conference that provides important feedback prior to FDA submission.

Initial submissions are timely when FDA feedback on specific questions is needed to prepare for product development and submission.

The FDA recommends the use of pre delivery in the following situations:

- Help familiarize with new technology, new intended use, or new analytical tools and new features before FDA submission.
- Need help identifying potential regulatory pathways.
- Research includes complex data and statistical approaches.
- Definition of reference or method is vague or unclear. Or
- The new device is a multiplex device that can test several analytes at the same time.

Sponsors must submit a request to the FDA if they want to know what the FDA thinks about a study or proposal before the study begins. Potential benefits of pre-shipment include:

- Initiate dialogue and strengthen understanding with the FDA.
- Reduce research costs by focusing on information needed for FDA approval (or clearance) and eliminating unnecessary or burdensome studies.
- Speed up the review process for future marketing applications because the FDA is familiar with the device.

Pre-submission and related meetings are entirely voluntary, and any comments or suggestions made during protocol review or at these meetings are not binding on the manufacturer or the FDA.

Premarket Notification [510(k)]:

510(k) Notification (not applicable to PMA) to demonstrate that the marketed device is at least as safe and effective as prior notification of a legally marketed device (SE) required by the FDA [21 CFR 807.92(a)(3)].

There are three types of 510(k) notices that can be submitted to the FDA: standard, special, and abbreviated.

Premarket Approval (PMA):

Premarket Approval (PMA) is the FDA's scientific and regulatory review process to assess the safety and efficacy of a Class III medical device.

For IVDs, there is a unique relationship between security and performance, because device security is typically independent of device-patient communication. Device safety for IVD products concerns the impact of device performance, particularly the impact of false-negative and false-positive results on patient health.

Requirements for IVD Labeling:

Laboratory diagnostic products have additional labeling requirements in 21 CFR 809, subpart B, Laboratory Diagnostic Products for Human Use. Before obtaining a marketing license for an IVD product, the manufacturer must label the product in accordance with labeling regulations.

FDA controls the quality of IVD devices:

Manufacturers who establish materials or quality control methods must refer to 21 CFR 862.1660 and 21 CFR 862.9.

Establishment Registration:

Facilities involved in the manufacture and distribution of medical devices for commercial distribution in the United States (USA) must be registered with the FDA. Registration provides the Food and Drug Administration with the location of facilities and importers of medical devices.

Device registration is not FDA approval of the device or equipment. That is, the FDA does not approve vending machines. Prior approval is required before any device can be commercially distributed in the United States.

Current good manufacturing practices (CGMPs) and Quality System (QS) Regulation requirements:

CGMP requirements are outlined in the Quality System Regulations. The regulation prohibits domestic or foreign manufacturers of medical devices from having quality systems for design, manufacture, packaging, labeling and service, installation and maintenance, unless they are exclusively issued from the QSR. , listed in the special classification regulations in 21 CFR parts 862-892. QS regulations are in 21 CFR 820.

Steps for marketing approval in USA [18]:

1. Classification of a in vitro diagnostic device.
2. Implement a quality management system (GMP requirements).
3. Submission of clinical trial data, if applicable (Investigative Device Exemption (IDE)).
4. Submit a marketing approval application (510(k) Premarket Notice of Premarket Approval Application).
5. FDA 510(k) Clearance Letter or PMA Approval Letter.
6. FDA Quality System Inspection of Manufacturing Facilities.
7. List of IVDR in the FURLS system.
8. FURLS registration mark.

REGULATION OF IVDS IN THE INDIA:

CDSCO announces the publication of a draft guidance document for in vitro diagnostic medical device (IVDMD) stability studies. This guidance is intended for manufacturers preparing pre-market review documents for IVDMD import or production permit applications.

Currently, scientific instruments are regulated as drugs by the Central Drug Control Agency (DCGI). The lack of distinction between drugs and devices poses a challenge for foreign authorities in the IVDR market. Entries are not limited to one time only. An endless list of controlled devices must correspond to specific rules for certain devices, and some devices are not controlled at all [19]. The Indian government is working hard to address this issue with proposed regulations for new clinical facilities and several other reforms. Although these policies and reforms promise to consolidate and accelerate the manufacturing and import of medical devices in India, they pose their own challenges and challenges. CLAA, which is part of CDSCO, participates in the Medical Devices Advisory Committee Conference as the main regulatory framework for scientific devices [19]. CLAA establishes and enforces safety standards, appoints certification bodies and oversees assessment procedures, PMS, warning letters and recalls.

A new legal framework for this review was introduced in 2006. The proposed law is known as the Medical Devices Regulation Act 2006. This new law came into effect on December 31, 2009.

Regulations related to IVD are set by the central and state governments. Depending on the applicable regulatory framework, the manufacture, import, distribution and sale of IVD may be licensed or permitted. The import, manufacture, sale and distribution of IVDs are regulated by the Narcotics and Cosmetics Act 1940. The IVDs listed below are currently regulated under this Act. In addition, the following products are regulated by the Medicines and Cosmetics Act and

are considered "IVD" in their country of origin. These regulations are unclear and do not meet uniform standards for IVD. The manufacture of these products for sale is only regulated by the relevant pharmaceutical authorities.

The Indian government issued guidelines for IVD sales licenses in 2012 through CDSCO. In this document, CDSCO hopes to be granted a license to import and manufacture medical devices.

IVDs / Medical devices approval process in India:

This chart shows the CDSCO approval process for device classification in India and can be downloaded from the Regulatory Affairs Management System (RAMS). Here we provide only a brief description of the main registration steps [24].

- Determine the classification of equipment based on the classification list published by CDSCO.
- Appoint an authorized representative in India to manage device registration and communicate with CDSCO on your behalf.
- Prepare hardware applications and supporting documentation for submission to CDSCO.
- Pay the application fee. CDSCO will review your request and may request additional information.
- License to import equipment after approval by CDSCO.

CONCLUSION:

The regulation of in vitro diagnostic devices (IVDR) is a comprehensive set of regulations that pose significant challenges for all stakeholders: manufacturers, regulatory authorities, importers, distributors and laboratories. Unlike the IVDD, the IVDR not only strengthens the regulatory requirements, but also expands their scope. Products such as in-house IVD (Laboratory Developed Tests, LDT) are also now subject to IVDR.

IVDR is regulated by certification bodies and national authorities in a new way. The certification body ensures compliance with quality and safety standards and certifies the IVD with the CE mark, which a marketing authorization is issued by the competent authority of the member states.

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