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The voice of MedTech

Understanding APAC's LDT regulations - A Strategic Outlook for Healthcare Companies

THU | 20 MAR 2025
2.00 - 3.00 PM SGT
AVAILABLE ON ZOOM

Agenda

1. Opening and Introduction
2. Overview of the LDT white paper
3. Pannel discussion and Q&A
4. Closing

APACMed

The voice of MedTech

Voice

The unifying voice for the medical devices, in-vitro diagnostics and digital health industry in APAC.

Mission

To improve the standards of care for patients in APAC through strategic collaborations with MedTech stakeholders.

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- LEGAL ETHICS AND COMPLIANCE
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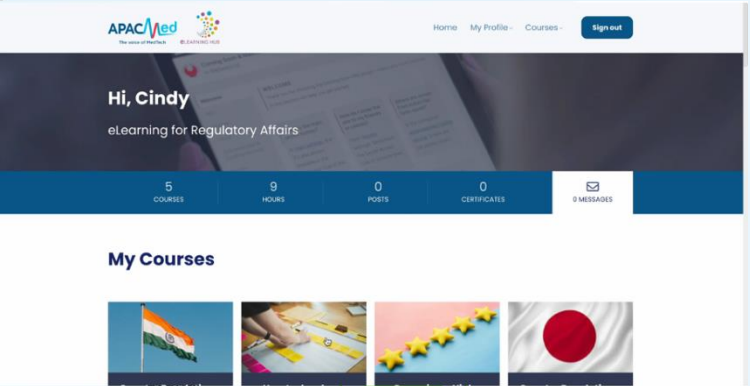

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Katherine Wang
Partner at Ropes & Gray LLP

APACMed White Paper

Regulation of Laboratory Developed Tests (LDTs) in APAC

Katherine Wang, Ropes & Gray

Overview

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- Types of healthcare diagnostic testing
- Regulatory challenges

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LDT Regulation in APAC

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- Singapore

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- European Union

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Risk-Based Regulatory Framework for LDTs

- Elements of a risk-based framework

Types of Diagnostic Testing

In Vitro Diagnostics (IVD)

IVDs are commercially available medical devices that are used for clinical diagnosis.

They are primarily regulated by the Healthcare Products Authority as devices.

Laboratory Developed Test (LDT)

LDTs are developed, manufactured, and used within a single licensed clinical laboratory for purposes of clinical diagnosis. They are generally developed in response to emerging health needs or rare diseases.

Regulation varies, but they are generally co-regulated by the Lab Authority and the Healthcare Products Authority.

Research Use Only (RUO)

RUO products are commercially sold but intended only for research purposes, not for clinical diagnostic use.

Regulatory oversight mostly focuses on labeling and distribution. Pre-market requirements are generally waived.

Regulatory Challenges

- Many rare diseases do not have any cleared IVDs, making it difficult for patients to get diagnosed.
- LDTs are not subject to the same regulatory requirements as IVDs, which disincentivizes the development of IVDs. There is also greater variability in the safety, accuracy, and reliability of LDTs.
- There are a lack of clear and consistent definitions and requirements for LDTs across APAC markets.

APACMed White Paper

- **Outlines LDT regulatory frameworks** across APAC
- **Presents case studies from mature markets** that regulate LDTs (e.g. U.S., Europe, Australia)
- Summarizes **key observations and considerations for regulating LDTs** moving forward

Regulation of LDTs in APAC

LDT Regulation in APAC

The White Paper analyzed:

- The **official definition** of LDTs
- Their **classification** within the regulatory framework
- The roles and functions of the **regulatory authorities**
- The process for obtaining **product market authorization** or registration for LDTs
- Requirements for **post-market surveillance**
- Standards and requirements for **Quality Management Systems** (QMS)

In the following 14 APAC markets:

- Australia
- China
- India
- Indonesia
- Japan
- Malaysia
- Myanmar
- New Zealand
- Philippines
- Singapore
- South Korea
- Taiwan
- Thailand
- Vietnam

Overview

LDTs are not defined in law or regulation	Indonesia, Myanmar, New Zealand, Philippines, Vietnam
LDTs are not defined, but clinical labs are regulated by the government	India, Japan, Malaysia
LDTs are not defined, but chemical substances and raw materials are regulated by the government	South Korea
LDTs are not defined, but if the "intended use" falls under IVDs, it must fulfill IVD requirements	Thailand *(public hospitals and government labs are exempt)*
LDTs are regulated by the health authority through product market authorization, post market surveillance, and quality management systems	Australia, China, Singapore, Taiwan

China

Definition of LDTs: China has implemented an LDT pilot program under which it states that an LDT can only be developed if there is no equivalent commercial IVD reagent on the domestic market. In addition, the LDT must demonstrate technical maturity with clear clinical significance.

Regulatory Authority: The National Medical Products Administration (NMPA) supervises products, including the filing of pilot products and quality management. The National Health Commission (NHC) supervises medical institutions, including the use of pilot products by pilot hospitals.

Product Market Authorization: Pilot medical institutions (as defined by both NMPA and NHC) file an LDT product with their local or provincial NMPA. After getting approval from both NMPA and NHC, the pilot medical institution can begin the LDT process. The LDT's label must clearly indicate that it is an in vitro diagnostic reagent only for use within the specific institution.

Post-Market Surveillance: NMPA will conduct post-filing inspections to ensure that the product meets requirements, matches the filing documents, and is developed and prepared in compliance with Good Manufacturing Practice (GMP). The first onsite inspection is conducted within 3 months after filing, then 6 and 12 months after filing. NHC inspections will checks whether the medical institution meets qualification requirements and uses the LDT appropriately, 6 and 12 months after filing.

Quality Management System: The development and production process for LDTs must follow GMP requirements. Under a unique model, if production is outsourced to a contracted manufacturer, the manufacturer needs to hold a medical device manufacturing license that covers Class II and Class III IVD products and have experience manufacturing similar IVD products.

Australia

Definition of LDTs: LDTs are regulated by the Therapeutic Goods Administration (TGA) under the IVD framework. They are called “in-house IVDs” and are defined as pathology tests that have been developed (or modified) and validated within a laboratory or laboratory network for testing on human samples for purposes of clinical diagnosis or clinical management

Regulatory Authority: The National Association of Testing Authorities (NATA) performs the lab’s quality management system (QMS) accreditation and LDT review. All labs manufacturing Class 1-3 in-house IVDs must comply with the essential principles and conformity assessment procedures, but only Class 4 in-house IVDs must be included on the Australian Register of Therapeutic Goods (ARTG).

Product Market Authorization: Labs that manufacture Class 1-3 in-house IVDs must provide the TGA with an initial notification by July 1st of the next financial year, and must be accredited by NATA either to ISO 15189 or ISO 17025. Labs that manufacture Class 4 in-house IVDs must apply for inclusion in the ARTG and be accredited by NATA to ISO 15189 or obtain a manufacturing license. All in-house IVDs must meet the NPAAC Requirements for the Development and Use of In-House IVDs.

Post-Market Surveillance: Labs must have a post-market system for ongoing monitoring of in-house IVD performance, and notify the TGA of any adverse events or field safety corrective actions (FSCAs).

Quality Management System: Class 1-3 in-house IVDs must be accredited by NATA, meet the NPAAC standard, and establish QMS. Class 4 in-house IVDs must obtain TGA conformity assessment certificates prior to inclusion in ARTG or use existing NATA accreditation or their TGA manufacturing license to apply directly for inclusion in the ARTG.

Singapore

Definition of LDTs: LDTs are defined as IVDs used for clinical diagnostic that are developed and manufactured within a licensed clinical laboratory solely for use in the same laboratory.

Regulatory Authority: The Ministry of Health (MOH) regulates clinical labs, whereas the Health Science Authority (HSA) regulates health products and provides guidance on LDT regulation.

Product Market Authorization: Clinical labs must notify MOH via their licensing portal, Healthcare Application and Licensing Portal (HALP), of the list of LDTs they implement and use in their lab.

Post-Market Surveillance: The HPA and HP (MD) regulations are applicable to clinical labs that manufacture LDTs. They must report adverse events and field safety corrective actions (FSCAs) to HSA, including recalls that are associated with the use of the LDT.

Quality Management System: Clinical labs that develop and use LDTs for clinical diagnostic purposes are considered manufacturers. The labs must be registered with MOH and maintain QMS as stipulated under the Healthcare Services. The clinical labs must document their rationale for using an LDT instead of commercial IVDs using the Objective Checklist (GL-08 Section 3.1.2). In addition, the design and manufacturing process of the LDT should be carried out under QMS (e.g. ISO 13485, ISO 15189).

Case Studies from Mature Markets

Case Study: United States

- In May 2024, the U.S. Food and Drug Administration (FDA) issued a final rule stating that FDA intends to regulate LDTs as a **subcategory of device IVDs**. The rule defined LDTs as **intended for clinical use and designed, manufactured, and used within a single clinical laboratory that meets certain laboratory requirements**.

- Under the new rule, all LDTs would be **subject to pre-market clearance or approval based on risk** as well as **relevant post-market controls** (e.g. establishment registration and device listing requirements, compliance with current Good Manufacturing Practices, labelling and promotion) and **certain quality system requirements** (e.g. design controls, adverse event and medical device reporting).
  - **Some LDTs would still be exempt** from full compliance with the regulations, such as certain types of manual LDTs or those where FDA decides that the cost of compliance outweighs the benefit to public health.

- The **lab must also be certified** under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meet requirements under CLIA to perform high complexity testing. This certification is overseen by the Centers for Medicare and Medicaid Services (CMS).

- Implementation of the final rule would involve a **five-stage phase-out of FDA's enforcement discretion** over four years.

Case Study: European Union

The EU regulates LDTs under EU Regulation 2017/745 (MDR) and EU Regulation 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). An LDT is **defined as a device that is manufactured and used only within a health institution established in the Union**. A "health institution" is an **institution with the primary purpose of care or treatment of patients, or the promotion of public health**.

- RUOs are not regulated by the IVDR and are not considered LDTs so long as they are used for research, not medical, purposes.

LDTs are **exempt from general MDR and IVDR requirements** so long as they **meet the conditions laid out in Article 5(5)**. Among those conditions are the following:

- The exempted device is not transferred to another legal entity;
- There is no equivalent marketed device available to address the specific needs of the target patient groups;
- No industrial-scale manufacture is involved;
- The device is manufactured according to appropriate quality management systems and relevant standards, such as ISO 15189 regarding quality and competence in medical laboratories;
- Manufacture and use of the device is within a health institution;
- For class D IVDs (highest risk), documents must be drawn up on the manufacture, design, and performance of the device, including its intended use.

The **requirements of the IVDR will be phased in** with full compliance expected by May 26, 2028.

Key Elements of a Risk-Based Regulatory Framework

Elements of a Risk-Based Regulatory Framework

- **Clear Definition**: Regulatory authorities should establish **clear and harmonized definitions** for LDTs (as opposed to IVDs and RUOs). This would help facilitate the creation of regulatory pathways based on risk-benefit profiles and clinical needs.

- **Transparency and Accountability**: Different stakeholders (like manufacturers/developers, distributors, medical institutions/laboratories, and healthcare professionals) should be able to **understand their roles and responsibilities** in the lifecycle management of LDTs. There should be **transparency**.

- **Co-Regulation**: It may be appropriate to establish **co-regulation between healthcare product authorities and laboratory authorities** so that their responsibilities complement each other.

- **Scope and Criteria**: Regulatory authorities should **consider local clinical needs and market dynamics** when determining which types of LDTs would best benefit their patients, with the goal of **balancing product availability and patient safety**. This may involve considering testing needs for rare diseases, the commercial supply of IVDs, and public health emergency circumstances.

- **Pre-Market Pathway**: **Risk-based pathways for LDT regulation** are recommended. Regulatory agencies may want to use risk-based classification of medical products consistent with international best practices.

Elements of a Risk-Based Regulatory Framework

- **Product Quality**: In order to produce reliable and effective LDTs, there should be **quality control throughout the development, manufacturing, and testing processes**. International standards such as ISO 15189 for medical laboratories and ISO 13485 for medical devices could be followed.

- **Post-Market Surveillance**: Risk-based post-market requirements, including **adverse event reporting or quality, performance, or safety issue reporting**, should be in place to ensure ongoing monitoring of LDT performance and safety.

- **Pilot Programs**: Markets that do not currently have clear LDT regulations can **start with pilot programs** to evaluate LDT availability and use in the local market. This can enable them to tailor their regulations.

- **Collaboration and Communication**: Collaboration between government agencies, healthcare institutions, laboratories, and manufacturers can help foster innovation, address regulatory challenges, and ensure that patients have access to safe and effective LDTs.

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Closing

Pannel discussion and Q&A

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Charles Lim
Regulatory Affairs Manager at Thermo Fisher Scientific

What's next?

- Join our Advocacy Efforts
- Collaboration and Engagement
- Call to Action
- Stay Connected

Question received during the webinar

Questions	Answers
How about **cross border use of LDT**? example, samples are shipped to a country Lab for LDT testing. Does the country health authority has oversight since patients come from a foreign country? Also, in the **patient point of view**, could they have any legal outlet if anything happens to them?	• The oversight of cross-border LDT testing varies significantly by country and depends on the local regulatory framework. Some countries regulate based on where the test is performed, meaning the foreign lab must comply with local LDT regulations, regardless of where the patient is located. Other jurisdictions focus on where the patient is located, meaning that national health authorities may require additional approvals or impose restrictions on sending patient samples abroad. A key regulatory challenge is that many APAC markets do not yet have clear guidelines for cross-border LDT use, leaving a regulatory gap in oversight and enforcement. • Patients' legal recourse depends on the legal and regulatory frameworks of both the country where the test was performed and the country where the patient is located. If the testing country has strong LDT regulations, patients may have access to legal action under consumer protection or medical negligence laws. If the home country has regulations on cross-border LDT use, the patient may be able to file complaints through their national health authority. However, in markets without clear oversight, patients may face challenges in holding laboratories accountable, especially if there is no legal agreement between the two countries on healthcare liability. Given these legal uncertainties, there is an increasing need for international alignment and patient protection measures in LDT regulations.
When we promote **RUO assays for LDT use**, what would be your recommendation of countries as lower hanging fruit to be focused from regulation perspective?	RUO assays can only be used for research use by its definition. It's not allowed to promote it for clinical diagnosis purpose. LDT is for clinical diagnosis purpose, that's why it should be regulated while RUOs should not have pre-market regulatory requirements
Molecular tests and applications have increased in recent times, and many of these tests are lab-developed without regulatory approvals. At times, it is difficult to differentiate which test results are valid and which tests use approved methods or LDTs. How can patients and clinicians have confidence in test results?	Because LDTs are developed and validated within a single laboratory or laboratory network, patients and clinicians often do not have full visibility into whether a test has undergone regulatory review or follows recognized quality standards. Some markets regulate LDTs by allowing them only when no commercial equivalent (IVD) exists, ensuring that LDTs fill unmet clinical needs rather than competing with approved diagnostic tests. Unlike IVDs, which go through formal regulatory approval processes, LDTs rely on internal validation by laboratories, making it harder to assess their reliability. To build confidence, it is essential that laboratories follow quality management systems (e.g., ISO 15189) and transparent validation processes for LDTs. Improved regulatory oversight and better labelling or disclosure requirements would help patients and clinicians distinguish between regulated and unregulated tests.
What are the recommendations from the panelist to further **influence authorities** using these differences and opportunities identified in a more effective way? seems these awareness have been up in the air for quite a while, but lack for concrete processes.	A major issue is the lack of transparency around LDTs, which makes it difficult for both regulators and stakeholders to build confidence in the regulatory process. One of the key asks in the white paper is improving transparency, including clearer labelling and disclosure on how LDTs are developed and validated. The next step should be turning recommendations into action by engaging authorities and advocating for clearer regulatory pathways, rather than just raising awareness. APACMed encourages stakeholders to use and share the white paper, webinar recording, and findings to engage with regulators, policymakers, and laboratories. Moving forward, we will continue advocacy efforts through capability-building sessions and dialogues, and we invite collaboration to ensure patient access to safe and effective diagnostic tools.

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Thank you.