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Pathway for Harmonizing the Medical Devices Registration Process in Sri Lanka

An APACMed RA India CoE Initiative

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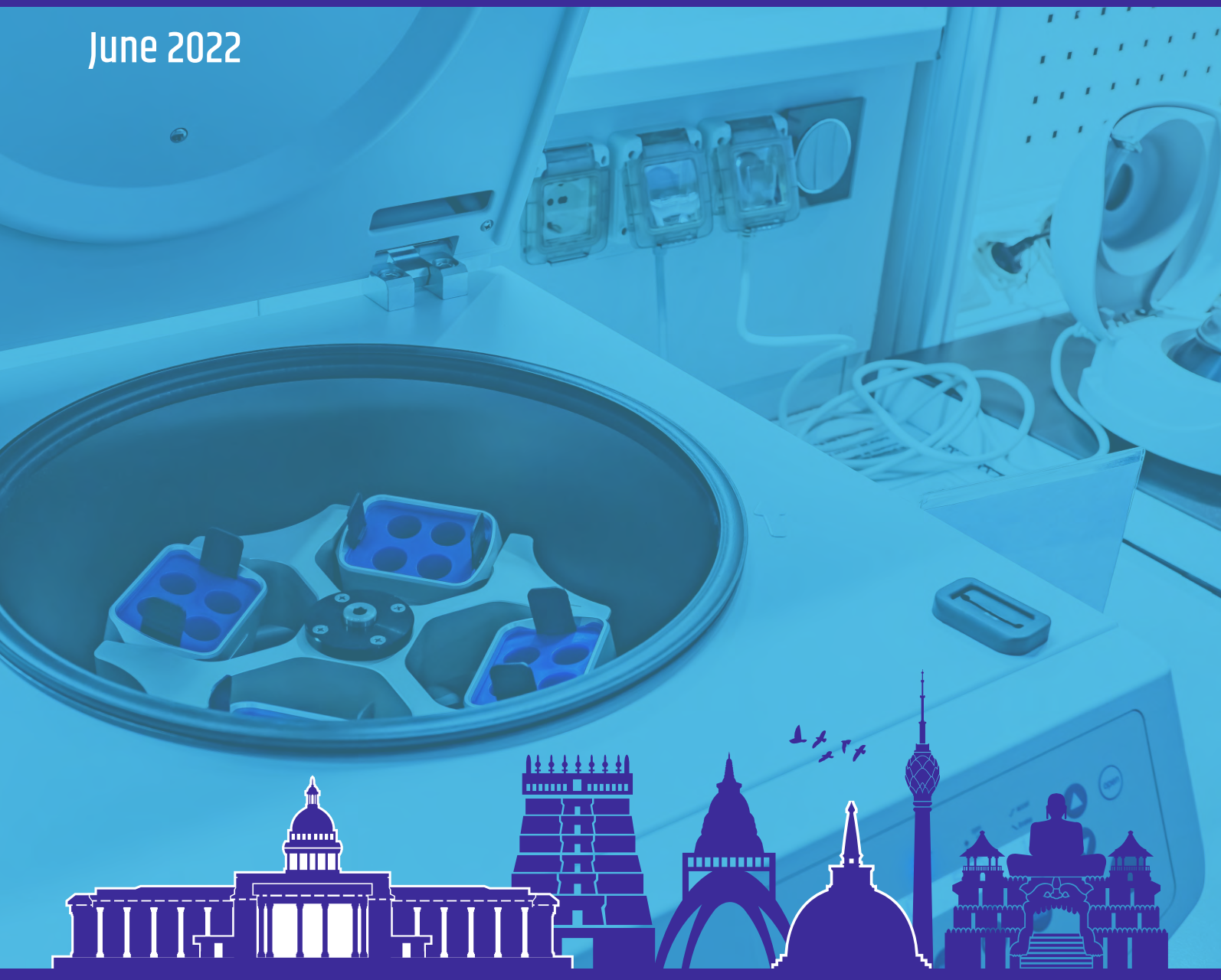

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1 Introduction

In Sri Lanka, National Medicines Regulatory Authority (NMRA) is responsible for the regulation and control of registration, licensing, manufacture, importation and all other aspects pertaining to medical devices and In-vitro diagnostics (IVDs) in a manner compatible with the National Medicines Policy as per the National Medicines Regulatory Authority Act No. 05 of 2015."The Cosmetics Devices and Drug Act No.27 of 1980 and its subsequent amendments are the legislative framework to regulate Cosmetics, Devices and Drugs.

All medical devices/IVDs to be sold in Sri Lanka are regulated and require prior approval from Sri Lanka's regulatory authority i.e. National Medicines Regulatory Authority (NMRA). NMRA follows multi step sequential process to grant approval to a medical device/IVDs. Various steps in the entire registration cycle along with the regulatory review timelines are as follows:¢ Distributor submits the application for site registration

- Site registration approval granted by NMRA
- Submission of sample import license application
- Sample Import license granted by NMRA
- Full Registration dossier submitted to SL MoH
- Registration Approval and Import License granted by MoH

Indicative Timelines for each registration step based upon industry experience are provided below:

- Manufacturing site registration - 7-8 Months
- Sample import license - 3-4 Months
- Registration certificate - 10-12 months
- Import license - 1 month

Therefore, it takes around 20-24 months to completely register a medical devices/IVDs in Sri Lanka. This lengthy approval timeline is a big concern for all stakeholders who wish to register and sell their medical devices/IVDs in Sri Lanka as this could lead in delay access of some lifesaving medical devices and diagnostic tests to Sri Lankan populations. The medical technologies undergo changes at a highly rapid pace. Many times, the medical devices/IVDs

under registration might get obsolete globally or a newer version of the same might get available by the time product is approved by NMRA.

Because of longer approval time and multistep process, many companies are weary of introducing their medical devices/IVDs in Sri Lanka. This ultimately impacts the patients in Sri Lanka who could have got access to latest technology.

A few probable areas which are contributing to lengthy approval timelines and unique process adopted by NMRA are:

- Non-Standardized/Harmonized registration process with other countries
- No defined timelines for approvals
- Multi step sequential registration process
- Sample evaluation
- Capacity & Capability limitation
- Involvement of KOLs in the entire registration process

2 Objective

In view of the above, the position paper aims to compare the regulatory approval process for medical devices/IVDs in Sri Lanka with some of the emerging markets and other economies and propose recommendations to harmonize the regulatory process and requirements to address the issue of lengthy approval timelines and gaps in existing regulatory process. In addition, the purpose of this paper is to promote regulatory reliance as an effective tool to accelerate patient access to medical devices in Sri Lanka without compromising on the safety, and performance of the products.

Regulatory Reliance

Regulatory reliance is a potential tool to help Authorities to expedite the review and approval process to allow for the acceptance of decisions made by another Regulatory Authority and the Relying Authority retains the responsibility in making its own decisions.

The most basic form of regulatory reliance is to leverage the work that has been performed by another Regulatory Authority to support the decision-making process and retain independence in the approval of a medical product by the country regulator. The more advanced form of reliance is to formally accept decisions made by another Regulatory Authority based on agreements such as treaties or mutual recognition, without duplicating any assessment.

3

Comparison of Registration Processes: APAC Geographies

With the new technologies launches across the world, it is important to converge the regulatory requirements across the countries for the timely launch of the safe, effective, and innovative products in a country for the benefit of the patient along with the manufacturers.

The below section is the comparative representation of the registration pathway, including the Registration Process, Classifications of medical devices/IVDs, timelines, sequential or parallel steps and documentation requirements.

Table 1: Registration Process

	Sri Lanka	Singapore	India	Malaysia
Registration Process	▪ Multiple sequential step registration (manufacturing site registration, sample import license, sample testing, registration and import license) ▪ No regulatory reliance on other countries ▪ No risk-based classification	▪ Single step registration ▪ Strong regulatory reliance on GHTF country approvals. ▪ Different registration routes available as per device class: • Class A - Exempt • Class B, C, D - Full evaluation, Abridged evaluation, Immediate registration evaluation • Class and D has additional Expedited evaluation route • Also, Priority Review Scheme (PRS) available within Full Evaluation route for Class B, C and D	▪ Single Step Registration where site and the product manufactured at the site is registered ▪ Strong regulatory reliance on GHTF country approvals. ▪ Different registration documents required available as per device class in line with IMDRF requirements	▪ No Site registration for imported products ▪ Single step registration. ▪ Strong regulatory reliance on GHTF country approvals.

Table 2: Timelines

Classification of products	Sri Lanka	Singapore	India	Malaysia
A	Not defined	NA	9 months	3 – 5 months
B	(No Risk based classification available)	**Full Evaluation Route** 160 Working Days (Normal) 120 Working Days (Priority Review Scheme Route) **Abridged Evaluation Route** 100 Working days **Immediate Class B Registration (IBR) Evaluation Route** Immediate upon submission	9 months	9 months- 1 Year
C		**Full Evaluation Route** 220 Working Days (Normal) 165 Working Days (Priority Review Scheme Route) **Abridged Evaluation Route** 160 Working Days **Expedited Evaluation Route** 120 Working Days **Immediate Class C Registration Evaluation Route** (Solely for standalone medical mobile application) Immediate upon submission	9 months	9 months- 1 Year
D		**Full Evaluation Route** 310 Working Days (Normal) 235 Working Days (Priority Review Scheme Route) **Abridged Evaluation Route, (with or without registrable drug)** 220 Working Days **Expedited Evaluation Route** 180 Working Days Class D with registrable drug – Not Applicable	9 months	9 months- 1 Year

Table 3: Renewal Process

	Sri Lanka	Singapore	India	Malaysia
Renewal Process	▪ Different renewal requirements for Provisional registration and full registration. ▪ Documentation requirement for renewal varies basis the NMRA feedback.	▪ No renewal required. ▪ Only retention fees need to be paid annually	▪ Auto renewal on payment of fees ▪ Only retention fees need to be paid after five years.	▪ Yes- Documents requirements are like the new registration

Table 4: Documentation Requirement

	Sri Lanka	Singapore	India	Malaysia
Documentation Requirement	▪ Standard list of documents published by NMRA, however, certain times there are out of list requests by NMRA depending on the type of product submitted. ▪ Non harmonized document requirements.	▪ Standard checklist of documents as per ASEAN Common Submission Dossier Template (CSDT) are required to be submitted to HSA ▪ Documentation list varies by class of medical device.	▪ Regulatory certificates ▪ Standard document checklist ▪ Harmonized STED (Summary of Technical documents) requirements ▪ Documentation list minimal for lower risk class like Class A devices.	▪ Standard document checklist, ▪ harmonized STED (Summary of Technical documents) requirements

Conclusion

After comparing the different countries regulatory pathway, it is inferredthat most of the countries, compared above, have the mandatory requirement of approval in either one of countries (USA, EU, Canada, Australia, or Japan) and are not having the mandatory requirement of approval in the Country of Origin.

Most of geographiesare following the regulatory reliance approach, by recognizing approvals from the stringent regulators and providing expedited regulatory approval pathway,so that the patients get the early access to new technologies without compromising Patient Safety and Product Quality. Countries have clearly defined classifications and timelines giving more clarity to the manufacturers and the applicants on the launch of the products in their respective countries.

4 Way Forward

Based on the comparative analysis of the registration pathways available in Sri Lanka with major countries like Singapore, Malaysia and India, it can be inferred that there is a scope for Sri Lanka to harmonize its regulatory practices with other major geographies and provide accelerated regulatory pathways for products approved in stringent regulatory geographies. Below table summarizes the comparative analysis between various geographies:

Summary Table

Suggestions	Acceptance of GHTF country approvals	Parallel steps for registration process	Defined Approval timelines for each registration step	Requirement of sample evaluation process
Sri Lanka	X	X	X	✓
Singapore	✓	✓	✓	X
India	✓	✓	✓	X
Malaysia	✓	✓	✓	✓

As evident from the above summary table, Sri Lanka distinguishes itself in majority of the factors as compared to major geographies in the APAC countries and neighboring countries and hence it is recommended that Sri Lanka, in order to make available latest technologies to the Sri Lankan population:

1) Adopt Regulatory Reliance

- All the countries listed above (except Sri Lanka) relies on the regulatory approvals granted by the any one or more erstwhile GHTF countries (i.e., USA, EU, Japan, Canada and Australia) whereas Sri Lanka focusses only on the country-of-origin approval.
- For a harmonized approach, it would be beneficial if NMRA can accept the Free Sale Certificates from any of the erstwhile GHTF countries.
- Regulatory reliance will provide an opportunity to Regulators for capacity building as the exchange of information between Regulatory Authorities will allow Regulators to build on their expertise.

- APACMed can explore working with NMRA and HSA Singapore for regulatory reliance process similar to the one set up between Thai FDA and HSA Singapore.

2) Have a single step registration process

- NMRA has multiple registration steps and this need to be reduced to a single step.
- NMRA does not have published timelines for review of applications at various stages. Having the clearly defined timelines gives the visibility and accountability to all stakeholders and ensures the applications are being processed as per the stipulated timelines.

3) Waive sample evaluation step

- The products being imported in Sri Lanka and manufactured in major geographies like USA, EU, etc. undergo stringent quality checks and follow highest international standards. Majority of the countries accept the same standards and does not perform in-country product testing.
- Sample evaluation process in Sri Lanka consumes a lot of time and does not add value to the entire registration process. This ultimately delays the overall registration process.

4) Allow Multiple Distributors to hold registration for same product

- Better accessibility of products to patients
- Current legal framework within NMRA for change in distributor requires No Objection Certificate (NOC) from previous distributor which is sometime practically challenging and time consuming.

Through this document, APACMed wanted to share the regulatory practices being followed in the major geographies including Singapore, Malaysia and India vis-à-vis Sri Lankan regulations. As highlighted above, there are various factors which makes the registration process in Sri Lanka lengthy. Due to the lengthy approval timelines and complex regulatory environment, introduction of latest technologies in Sri Lanka is delayed and Sri Lankan patient population is devoid of the same. To enable early launch of latest technologies which would benefit Sri Lanka patients, **there is a strong need to reduce registration timeline and adopt regulatory reliance** and harmonizing the regulatory practices with major economies without compromising on patient safety and product quality.

5 References

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About Asia Pacific Medical Technology Association (APACMed)

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed) is the only regional association to provide a unified voice for the medical technology industry in Asia Pacific, representing both multinational corporations as well as small and medium enterprises, together with several local industry associations across the region. Headquartered in Singapore, APACMed's mission is patient-centric, and we strive to continuously improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific.

We are committed to working with governments and other stakeholders to facilitate patient access to innovative and life-saving medical technologies, supporting strong and thriving healthcare systems across the region, and promoting a robust and sustainable regional ecosystem that encourages investment, trade and innovation.

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