Medical Device Regulatory Strategy:
Product Development and Product Registration in Asia and Global

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1. Introduction

Regulatory strategy is an important planning that helps the company to understand the regulatory requirement, the required resources and the estimated timeline to register and seek approval from the local authority of the countries of interest.

Regulatory strategy should be prepared whenever the company is developing a new product or modifying a current registered product. It should be discussed early in the product design control process and in the go-to-market strategy so that every stake holder understands the requirements and their responsibilities in achieving the objective of obtaining registration approval and marketing the device on time.

A typical Regulatory strategy consists of the following 10 key information such as:

- Device Name
- Device Description
- Intended Use
- Country of Interest
- Device Classification
- Product Registration or Conformity Assessment route and its Approval timeline
- Technical Documentation
- Quality Management System Requirement
- Clinical Assessment
- Reimbursement Assessment

By understanding of these 10 key points as described in the following sections, the manufacturers will be more prepared for the medical device registration to obtain product approval for placement in the market.

2. Information in Regulatory strategy

2.1 Device Name

A device name or trade name can be found in the product label. It is important for identification purpose and it will distinguish the product from other manufacturers. Also, the device name or trade name is required for registration.

When naming the device, the company should avoid names that

- are confusingly similar to other device names;
- imply unique effectiveness; or
- overstate device efficacy, minimize associated risks, broaden intended use or make unsubstantiated superiority claims.[2]

The company also must ensure that the device name is not used by other competitor as this may lead to infringement issue due to trademark.

2.2 Device Description

Device description depicts useful information to the regulator for understanding the device.

The company should describe how the device function, the basic scientific concepts that form the fundamental for the device, the component materials and accessories used in its principles of operation as well as packaging.

The company should provide a complete description of each functional component, material or ingredient of the device with labelled pictorial representation of the device in the form of diagrams, photographs or drawings, as appropriate.[3, 4, 5]

The company should identify if any legally marketed predicate device and provide detailed comparison in terms of:

- indications for use;
- technology; and
- performance specifications, including any testing

With this, in some countries, the manufacturer can use the safety, effectiveness and clinical data to demonstrate substantial equivalence to predicate device and thus assist regulators in making substantial equivalence determinations which may help in the approval process.

For higher risk devices including implants, stringent safety, effectiveness and clinical data are required by the Authorities.

2.3 Intended Use

Intended use describes the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.[6, 7] Intended use appears in the labelling of the device such as Instruction For Use.

The company should include a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended.

The intended use of the device does have a substantial influence in determining the device classification and thus the company must carefully craft the intended use that suits the device.[8]

2.4 Country of Interest

The company usually target to penetrate potential market with large population. However, there are no one-size-fits-all method in obtaining regulatory approval because each country has its own regulatory requirements.

The company should make the decision based on inputs such as regulatory hurdles, costs and estimated approval timeline.

Some countries have abridged or shorter time application routes for:

- Medical device with approval from the benchmark reference agencies; and/or Medical device with significant clinical benefit for the patient population eg. innovative products, specific clinical diagnosis and treatment products.

With regional[9] and international[6] harmonization efforts, the regulators also discuss and encourage convergence in regulatory requirements, practices and systems to promote safety, effectiveness/performance and quality of medical devices; technological innovation, and international trade. With additional feedback from the industry, the guidelines were finalised from pre-market to post-market regulatory requirements in product lifecycle using risk management approach.

2.5 Device Classification

Device Classification is determined based on company's claims on the device, the device's intended use and risks the device pose to the patient and/or user.

Depending on jurisdiction, the classification scheme is based on recommendations from medical specialty panel of the regulators or rules which were laid by the law of the country.[10]

The company must take note that the device class will define the:

- Product registration or Conformity assessment route;
- Technical Documentation requirement; and
- Quality management system requirement

2.6 Product Registration or Conformity Assessment Route and its Approval Timeline

Each country has its registration route or conformity assessment route for the manufacturer to demonstrate that the product meets the safety and performance requirement before it can be imported and/or placed in the market. The registration route is based on the device classification and any benchmark approval previously obtained, and therefore determining the approval time required for the approval. The higher class the device is, due to its risk, the longer approval timeline is required for the assessment by the regulators.

The company will be able to strategize a plan on which country to penetrate in sequence with inputs from the Regulatory and Sales & Marketing team.

2.7 Technical Documentation Requirement

Regulators will conduct conformity assessment on the company based on the technical documentation[3] prepared for their device.

The technical documentation consists of information on how the medical device was designed, developed and manufactured.

The depth and detail of the information contained in the technical documentation will depend on:

• the classification of the device; and

• the complexity of the device.

The compilation of Technical Documentation is a joint effort amongst all stakeholders and it takes time and effort.

Country-specific requirements should also be considered early in the preparation of the Technical Documentation including technical to labelling requirements.

2.8 Quality Management System Requirement

Quality Management System (QMS) is defined as the organizational structure, responsibilities, procedures, processes and resources needed to implement quality management.

QMS certification is required in the application for Manufacturer Licence and Product Registration.

The company must plan for internal implementation of QMS procedure, documentation and record before seeking external certification from the certification body.

2.9 Clinical Assessment

Clinical evaluation is the assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device. The following are types of clinical data source:[11]

- Literature search;
- Clinical experience; and
- Clinical investigation.

The company should determine the clinical data source to be used and to prepare a Clinical Evaluation Report to document the evaluation process and results.

2.10 Reimbursement Assessment

The purpose of reimbursement assessment is to ensure whether the existing government healthcare payment infrastructure will accommodate to the use of the device and the treatment method. In some countries, there are reimbursement policies where the company is required to obtain both the reimbursement approval and suggested selling price from the reimbursement agency before the products can be placed in the government healthcare facilities.[12]

3. Conclusion

Regulatory strategy planning and preparation is a joint effort amongst all stakeholders and it requires teamwork to achieve the common objective of launching the product timely without regulatory pitfalls.

Continuous observation and awareness on regulatory changes are important to ensure that the latest regulatory strategy is considered and early planning related to the change can be conducted with all the stakeholders from design to supply chain.

Regulatory strategy provides important insights to management which enable them to make informed decision and to direct the company in penetrating markets faster and smartly. Regulatory requirements are to be complied by manufacturers before devices are placed in the market. There are different elements in the requirements and these elements could affect the medical device registration approval and its placements in the market.

4. References

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