REGULATORY REQUIREMENTS & MARKETING AUTHORIZATION OF GENERIC DRUGS IN SINGAPORE & THAILAND

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REVIEW ARTICLE

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ABSTRACT

The availability of generic medication is an important issue in the ASEAN region. The regulatory requirements of various countries vary from each other. Therefore, it is challenge for the companies to get drug approved for marketing simultaneously in different countries. The role of the regulatory authorities is to ensure the quality, safety, and efficacy of medicines in their country. It not only includes the process of regulating and monitoring the drugs, but also the process of manufacturing, distribution, and promotion. The regulatory environment has similar characteristics, but drug registration requirements and processes differ among the countries. One of the primary challenges for regulatory authority is to ensure that the pharmaceutical products are developed as per the regulatory requirement of that country. This process involves the assessment of critical parameters during product development. In ASEAN region, documentation can be filed in the ACTD format. Even though ACTD format is mandatory from 2009, the member countries have their own requirements for registration process like administrative documents, labeling. The purpose of this paper is to give a comparative overview on the Drug regulatory requirement for generics in two of the ASEAN countries which are Singapore and Thailand.

Keywords: ASEAN, ACTD, Singapore, Thailand.

INTRODUCTION

The ASEAN (Association of Southeast Asian Nations) group of nations, [namely Indonesia, Malaysia, Philippines, Singapore, Thailand, Brunei Darussalam, Vietnam, Laos, Myanmar and Cambodia] are the market of interest for most pharmaceutical companies due to their growing population and attractive pharmaceutical market growth.(1)

ASEAN was established on 8 August 1967 in Bangkok by the five original member countries, Indonesia, Malaysia, Philippines, Singapore and Thailand. On 8 January 1984, Brunei Darussalam joined ASEAN, Vietnam on 28 July 1995, Laos and Myanmar on 23 July 1997, and Cambodia on 30 April 1999. In 1999, a harmonization initiative was started among the 10 ASEAN countries. (2) This was done to harmonize quality guidelines that are valid for all countries in the region and also to extend technical co-operation. Therefore the ASEAN Consultative Committee on Standards and Quality Pharmaceutical Product Working Group (ACCSQ PPWG) was established. The objective of the ACCSQ PPWG is the development of "harmonization schemes of pharmaceuticals' regulations of the ASEAN member countries to complement and facilitate the objective of ASEAN Free Trade Area (AFTA), particularly, the elimination of technical barriers to trade posed by these regulations, without compromising on drug quality, safety and efficacy."

ASEAN established the so called ASEAN Common Technical Document (ACTD) and the ASEAN Common Technical Requirements (ACTR) to create harmonized requirements and a common format for all submissions of dossiers in the ASEAN countries. The ACTD is a common format and content acceptable for an application in the ASEAN member countries. The ACTR are a set of written requirements or guidelines intended to provide guidance to applicants in order to be able to prepare application dossiers in a way that is consistent with the expectations of all ASEAN Drug Regulatory Authorities (DRAs).

The strategy of the ACCSQ PPWG is the "exchange of information on the existing pharmaceutical requirements and regulation

implemented by each ASEAN member countries, to study the harmonized procedures and regulatory systems implemented in the ICH region, development of common technical dossiers with a view of arriving at (Mutual Recognition Arrangements)MRAs".(3)

All regulatory agencies in these 10 ASEAN countries have a relatively weak infrastructure and limited resources. The agencies are structured differently and standards of scientific guidelines are not well established. A big problem of the agencies is the lack of consistency and transparency, especially regarding the evaluation of the dossier. To solve these problems they are constantly improving with more dialogues with the industry. In all ASEAN countries, a Certificate of a Pharmaceutical Product (CPP) from the reference country is required and this builds the basis of the drug approval as the Drug Regulatory Authorities (DRAs) do not have the possibilities, capacities and scientific know-how to make a full evaluation of the submitted dossier (especially with regard to preclinical and clinical data).

Dossier Format –ASEAN CTD (4)

As mentioned before, the ASEAN countries established the ACTD as their format for submissions. It is a standard derived from the ICH CTD. The ASEAN CTD is a guideline of the agreed upon common format for the preparation of a well-structured ACTD application that will be submitted to ASEAN regulatory authorities for the registration of pharmaceuticals for human use.

The ACTD is similar to the ICH CTD. The ICH CTD is divided into 5 modules whereas the ACTD contains of 4 parts. The reason for doing this is the fact that the ASEAN countries normally receive a reference application, which is a dossier which was already approved in other countries in the world (mostly EU and USA) and make the evaluation of the parts mainly based on the overviews and summaries. Based on this, the need for detailed documentation is in most of the ASEAN countries is less compared to the ICH countries, e.g. most study reports are not required to be submitted. The Module 1 of the CTD containing the regional registration and administrative information is still presented as Part 1 of the ACTD. The Module 2 of the CTD does not exist itself for the ACTD. The Quality Overall Summary (QOS) and the overview and summaries of the non-clinical and clinical documentation (similar like the documents in ICH Module 2) are included at the beginning of Part II of ACTD. Part II of the ACTD contains the pharmaceutical –chemical - biological documentation (the quality information), which corresponds to the ICH Module 3.

The non-Clinical information is presented as Part III of the ACTD (equivalent to ICH Module 4) and the clinical documentation is contained in Part IV of the ACTD (to be consistent with ICH Module 5). The differences between ICH-CTD and ACTD are presented in the attached comparison pyramid:

As demonstrated above the ACTD is organized in four parts:

• Part I: Table of contents, Administrative Data and Product Information

• Part II: Quality Document

• Part III: Non-clinical Document

• Part IV: Clinical Document

Dossier Requirements

The requirements for the dossier in the ASEAN countries are in principle very similar to the requirements for the ICH countries.

The non-clinical overview and summary as well as the clinical overview and summary is presented at the beginning of part 3 and 4, followed then by the study reports and literature. For some ASEAN countries these non-clinical and clinical overviews and summaries are sufficient and no additional study reports need to be submitted. In most of the cases, it is sufficient to submit few publications from the mentioned studies in addition to the non-clinical and clinical overviews and summaries.

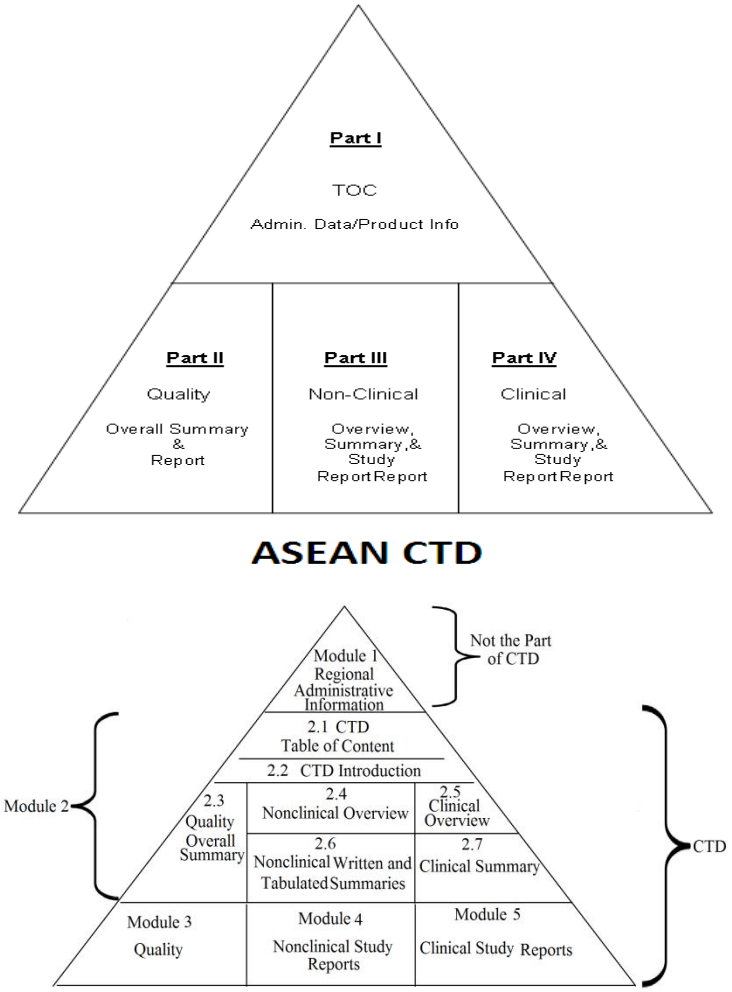

Figure 1: ACTD & ICH Pyramid

SINGAPORE (5)

Legal Framework and Regulations

Singapore's pharmaceutical market is about $500 million. It is also the wealthiest country among ASEAN. Health Sciences Authority (HAS) is the regulatory authority for regulating pharmaceutical products in Singapore.

All pharmaceuticals/drugs require a product license to import or sell in Singapore. In applying for a product license, dossiers must be in either the ICH CTD format or the ACTD format.

For new product licenses, Singapore has a new drug application (NDA) and a generic drug application (GDA). For products already approved by certain regulatory agencies (such as Australia's TGA, the US FDA, etc.), submitting an abridged dossier is possible. Applicants submit an online application through PRISM (Pharmaceutical Regulatory and Information System) and also submit a CTD dossier.

A. Application types

In applying for a new Product Licence for a medicinal product in Singapore, there are two categories of applications: a new drug application (NDA) and a generic drug application (GDA):

GDA-1: For the first strength of a generic chemical product.

GDA-2: For subsequent strength(s) of the generic chemical product that has been registered or has been submitted as a GDA-1. The product name and pharmaceutical dosage form shall be the same as that for the GDA-1.

A generic product is essentially similar to a currently registered product in Singapore (known as the Singapore reference product) but excludes biologics.

Essentially similar is defined as having the same qualitative and quantitative composition in terms of active substances, having the same pharmaceutical form and being bioequivalent. By extension, the concept of essentially similarity also applies to different conventional immediate release oral dosage forms (i.e. tablets and capsules) which contain the same active ingredient(s).

TECHNICAL DOCUMENTS REQUIRED

Administrative documents

- Comprehensive Table of Contents
- Introduction
- Application
- Labeling, Package Insert and Patient Information Leaflet
- Approved Summary Product Characterstics (SPC)/ Patient Information Leaflet (PIL)
- Assessment Report from Reference Agencies
- Description of Batch Numbering System
- Proof of Approval
- Authorization Letters
- GMP Certification/Proof of GMP Compliance
- Patent declaration
- Declaration on rejection, withdrawal and deferral
- Declaration for GDA verification
- Registration status in other countries.

ACTD& ICH CTD overview and summaries

The overview and summary documents are to be inserted into Module 2 of the ICH CTD or into the relevant sections in Part II, III and IV of the ACTD.

A completed Singapore Quality Overall Summary (SQOS) must also be inserted into Module 2, section 2.3 of the ICH CTD or Part II, section B of the ACTD, irrespective of whether an ICH or ACTD QOS has been included in the application dossier. Take note that the SQOS must be named and dated by the applicant prior to submission. The electronic copy of the Singapore QOS should be in Microsoft Word format.

Quality documents

Body of Data

Drug Substance

- Drug Master File (DMF)
- Certificates of Suitability (CEP)
- Control of Drug Substance (3.2.S.4)
- Stability Data of Drug Substance (3.2.S.7)

Body of Data

Drug Product

- Pharmaceutical Development (3.2.P.2)
- Process Validation (3.2.P.3.5)
- Control of Excipients (3.2.P.4)
- Control of Drug Product (3.2.P.5)
- Container Closure System (3.2.P.7)
- Stability Data of Drug Product (3.2.P.8)
- Product Interchangeability (3.2.P.9)
- Blank Production Batch Records

Table 1: Documents Required according to HSA

Primary Reference agency	Documentary requirements
Health Canada and MHRA	• Complete Clinical and quality assessment reports, including assessment on the Question & Answer documents between the Sponsor & Agency and all annexes • Assessment reports and/or documents pertaining to post approval variations, if applicable.
US FDA	• Complete Clinical and quality assessment reports, including assessment on the Question & Answer documents between the Sponsor & Agency and all annexes • Assessment reports and/or documents pertaining to post

	approval variations, if applicable.
EMA	• Complete CHMP Assessment Report, including the following: – Rapporteur's and co-Rapporteur's Day 80 Assessment Reports (non-clinical, clinical, quality, overview and list of question) – CHMP Day 120 list of Questions – Rapporteur's Day 150 Assessment Report (non-clinical, clinical, quality and overview) – Day 180 list of outstanding issues – All other annexes and appendices • Summary of CHMP opinion • Assessment reports and/or documents pertaining to post approval variations if applicable
TGA	• Complete clinical Assessment Reports, including assessment on the question & Agency and all annexes • Complete chemistry and Quality control Assessment Report including assessment on the Question & answer documents between the sponsor & Agency and all annexes. • Assessment reports and/or documents pertaining to post-approval variations, if applicable.

Administrative documents specific to the verification evaluation route that are required at the time of submission include:

i. Proposed PI or PIL should be aligned to the currently-registered Singapore reference product PI or PIL.

ii. Official approval letter, or an equivalent document, from the chosen reference regulatory agency that certify the registration status of the drug product.

iii. Official letter declaring that the application submitted to HSA or similar direction(s) of use, indication(s), dosing regimen(s) and/or patient group(s) have not been rejected, withdrawn, approved via appeal process, or pending deferral by any drug regulatory agency, with reasons in each case if applicable.

iv. Official letter declaring that the Drug Master File provided is the same as that submitted to the chosen reference agency.

v. Official letter declaring that all aspects of the product's quality intended for sale in Singapore are identical as that currently approved by the chosen reference regulatory agency. This includes, but is not limited to, the formulation, site(s) of manufacture, release and shelf life specifications and primary packaging.

Additional technical documents required

Complete quality documents for both drug substance and drug product, which includes:

i. Module 3 dossier as initially submitted to the chosen reference agency;

ii. From Sponsor

a. Question and Answers between the chosen reference agency and sponsor – the Answers should include supporting documents used in response to the Questions;

b. All post-approval variations approved by the chosen reference agency up to the time of submission to HSA, including the application letter for the variation, supporting documents for the variation, questions and answers between the reference agency and sponsor and the approval letter for the variation from the reference agency.

c. Relevant documents required by HSA which have not been submitted to the chosen reference agency, e.g. stability studies in accordance to ASEAN Stability

Guidelines, Singapore Quality Overall Summary, comparative dissolution studies, etc.,

iii. From DMF Holder, if applicable:

- The initial open and closed parts of the DMF submitted to the chosen reference agency from the DMF Holder should be provided to HSA, together with the original Letter of Access;
- Question and Answers between the chosen reference agency and DMF Holder – the Answers should include supporting documents used in response to the Questions; and,
- clinical documents, such as BE studies or justification for biowaiver, as initially submitted to the chosen reference agency with all questions and answers, including supporting documents, between the reference agency and sponsor; and, any additional documents to demonstrate product interchangeability with the Singapore reference product as described in section 17.3.2, where applicable.

❖ **Evaluation routes**

There are three types of evaluation routes for registration of a new product:

1. Abridged evaluation route

Abridged evaluation will apply to a product that has been approved by at least one drug regulatory agency at the time of submission.

2. Verification evaluation route

The verification evaluation route applies to a medicinal product that has been evaluated and approved by at least one of the following HSA's reference drug regulatory agencies:

- Australia Therapeutic Goods Administration
- Health Canada
- US Food and Drug Administration
- European Medicines Agency via the Centralized Procedure;
- UK Medicines and Healthcare Products Regulatory Agency via
  - The national procedure, or
  - As the Reference Member State (RMS) via the Mutual Recognition Procedure or Decentralized Procedure.

The target processing timeline for screening dossiers (NDA, GDA, Major Variation Application (MAV-1), Minor Variation Application (MIV-1) is 25 working days before the first query is issued. The screening timeline begins from the date of the dossier submission, which should be within 2 working days after PRISM submission to prevent delays in processing of the application. The date of submission will be defined as the date when HSA receives the complete dataset for the application.

Table 2: Timelines for drug registration in Singapore

Dossier type	**Target processing time (working days)**	
	Generic Drug Application (GDA)	**Major Variation Application (MAV-1)**
Full	-	270
Abridged	240	180
Verification	-	60

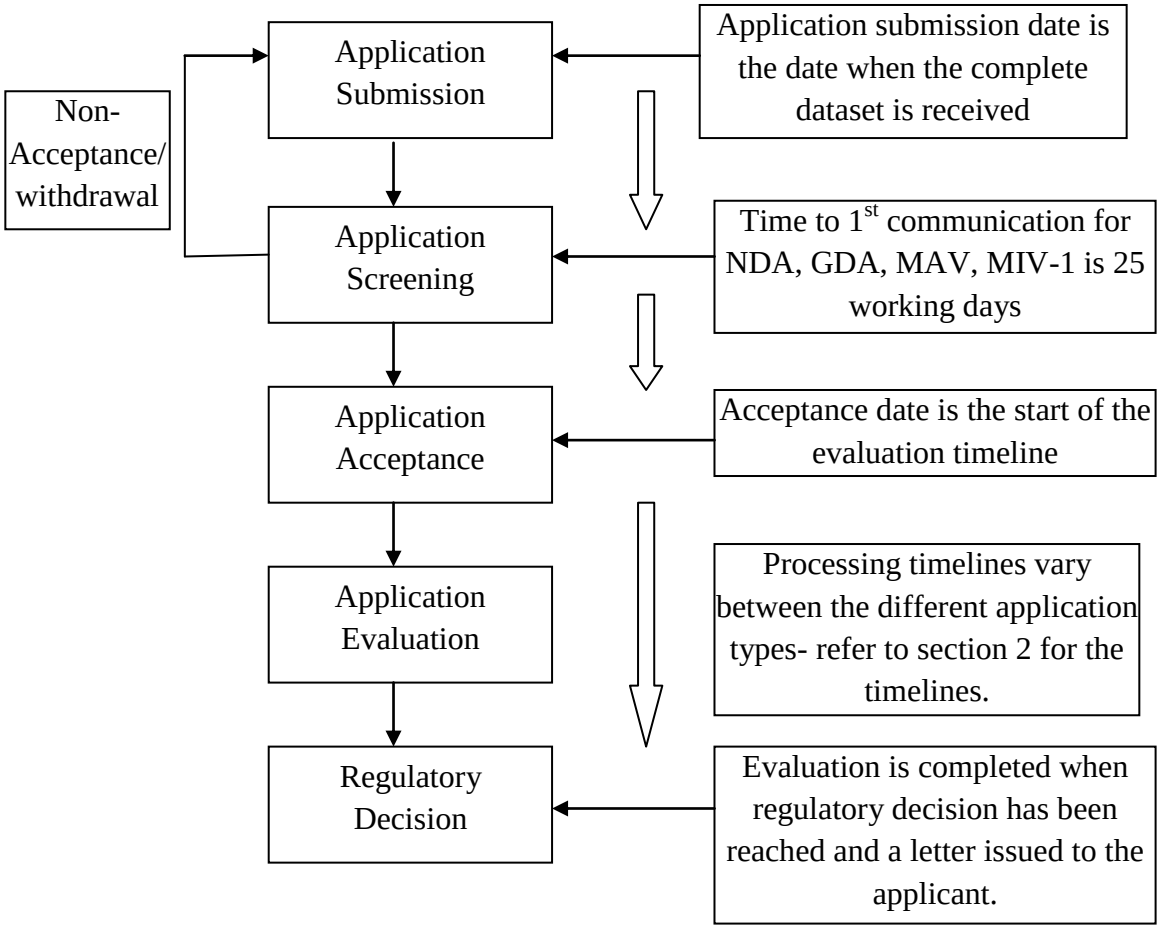

Figure 2: Flowchart of the registration process and processing timelines

Registration dossier

The complete dossier should be submitted within 2 working days after the PRISM application submission to prevent delays in processing of the application. The date of submission will be defined as the date when HSA receives the complete dataset for the application.

THAILAND (6)

Medicines are classified into two major groups: Modern and Traditional drugs.

Modern drug

It means a drug intended for use in the practice of modern medicine.

Modern Drugs are further divided into four categories, namely:

1. Household remedies whose sales require no license;
2. Ready-packed drugs that can be sold in drugstores by nurses or other medical professionals;
3. Dangerous drugs; and
4. Specially controlled drugs.

Dangerous drugs can be bought without a prescription but must be dispensed by pharmacists. Drugs which may possess a potentially harmful effect on health, if misused, will be listed in the last category whose sales require a prescription.

Traditional drugs

Those are intended to be used in indigenous or traditional medical care as monographed in the official pharmacopoeia of traditional medicines or those declared by the Minister of Public Health as traditional medicines or those permitted to be registered as traditional medicines. The control and registration of drugs in this group are less stringent than those for modern drugs.

TYPES OF DRUGS IN THAILAND (6)

- **Generics:** whose registrations require only dossiers on product manufacturing and quality control along with product information
- **New medicines:** whose registrations require a complete set of product dossiers
- **New generics:** whose registrations require dossiers of bioequivalence studies in addition to the required dossiers for generics submission.

Generics mean pharmaceutical products with the same active ingredients and the same dosage forms as those of the original products, but manufactured by different manufacturers.

New medicines include products of new chemicals, new indications, new combinations or new delivery systems and new dosage forms.

New generics are medicines with the same active ingredients, doses and dosage forms as those of the new compounds registered after 1992.

❖ **Format followed for submission**

ACTD format with additional country specific requirements

❖ **PHARMACEUTICAL REGULATIONS IN THAILAND (7, 8)**

Regulatory Procedure

Thailand's national drug control system stems from its Drug Act BE 2510 (1967) and its four amendments. The Ministry of Public Health (MOPH), along with the Drug Control Division of the FDA, is responsible for administering the system. Companies interested in manufacturing or exporting pharmaceutical products must obtain prior approval from the FDA. Both manufacturers and importers are required to get a license to produce, sell or import any pharmaceutical products into Thailand.

The pharmaceutical control system is divided into a pre-marketing and post-marketing phase. In the pre-marketing phase, companies must obtain a license to produce, sell or import any pharmaceuticals into Thailand, as well as register their products in the country. The Bangkok metropolitan area's Drug Control Division and surrounding provincial health offices are in charge of licensing. There are nine categories of licenses, including a license to produce, a license to sell, a license to act as a wholesaler of modern drugs.

DOCUMENTS REQUIRED FOR GENERIC DRUG REGISTRATION

The procedure of generic drugs registration is divided into 2 main steps:

Step1:Application for the permission to import or manufactured drug sample intended to be registered.

The following documents are required

a. Application form to be completely filled by authorized licensee
b. Drug formula [active ingredients(s) only]
c. Drug literature
d. Drug labeling and packaging

Step2:Application for the approval of granted credential certificate .

The following documents are required

a) Application form to be completely filled by authorized licensee
b) Permit to manufacture or import drug sample
c) Drug sample
d) Pharmacological and toxicological study (if any)
e) Clinical trials, safety and efficacy study (if any)
f) Complete drug formula
g) Drug literature
h) Labeling and packaging should consist of name of the drug, registration number, quantity of drug per packaging, formula which shows active ingredient (s) and quantity of strength, lot no. batch control number, name of manufacturer and

address, manufacturing date, the words "dangerous drug"/"specially controlled"/ "for external use"/ "for topical use" written in Thai and in red color if the drug is considered to be one of them, the word "household remedy drug" written in Thai, if the drug is considered to be, the word "for veterinary use" written in Thai if the drug is considered to be, and the expiry date.

i) Certificate of Free sale (in case of imported drug)
j) Manufacturing method
k) In-process control with the relevant acceptable limits
l) Raw material specifications of active(s) and inert ingredients with the corresponding control methods in details
m) Finished product specification with the corresponding control methods in details
n) Certificate of analysis of active ingredient (s) (raw material) [To be required in case of that active substance dose not conform to official pharmacopoeias (USP, NF, BP,etc)
o) Drug analytical control method
p) Packaging
q) Storage condition
r) Stability studies of finished product
s) Certificate of GMP (in case of imported drug)

❖ DRUG REGISTRATION

The registration process is necessary to ensure quality, safety and efficacy of the drugs being marketed in the country. Only authorized licensees are qualified to apply for product registration. Manufacturing plants, in which drug products are manufactured, are subject to inspection for GMP compliance.

➢ The process of drug registration of general medicines is divided into 5 procedures:

- Generic drug registration
- Traditional drug registration
- New drug registration
  - Original New Drug
  - New Generic Drug
- Biological product registration
- Herbal medicine registration

Generic Drug registration involves three steps:

- Application for permission to manufacture or import of drug samples. (at Food and Drug Administration)
- Application for an approval of drug quality control and analytical methods. (at Department of Medical Science)
- Application for granting of a drug registration certificate. (at Food and Drug Administration)

New Generic Drug registration procedure has following steps:

- A protocol on bioequivalence study must be submitted for an approval at the Drug Control Division.
- Application to seek permission for import or manufacture the drug samples.
- Performing the bioequivalence study according to the approved protocol in a specified government institute.
- Submitting an application for registration along with the bioequivalence report and other useful documents.

TIMELINE OF NEW GENERIC DRUG REGISTRATION (10)

In Thailand, drug application for generic can be processed in either of the two track depending on the need by the patients

Track	Review type	Days
Track 1	Standard Review	110 working days
Track 2	Accelerated or Priority Review (Drugs for public health problems / life threatening)	70 working days

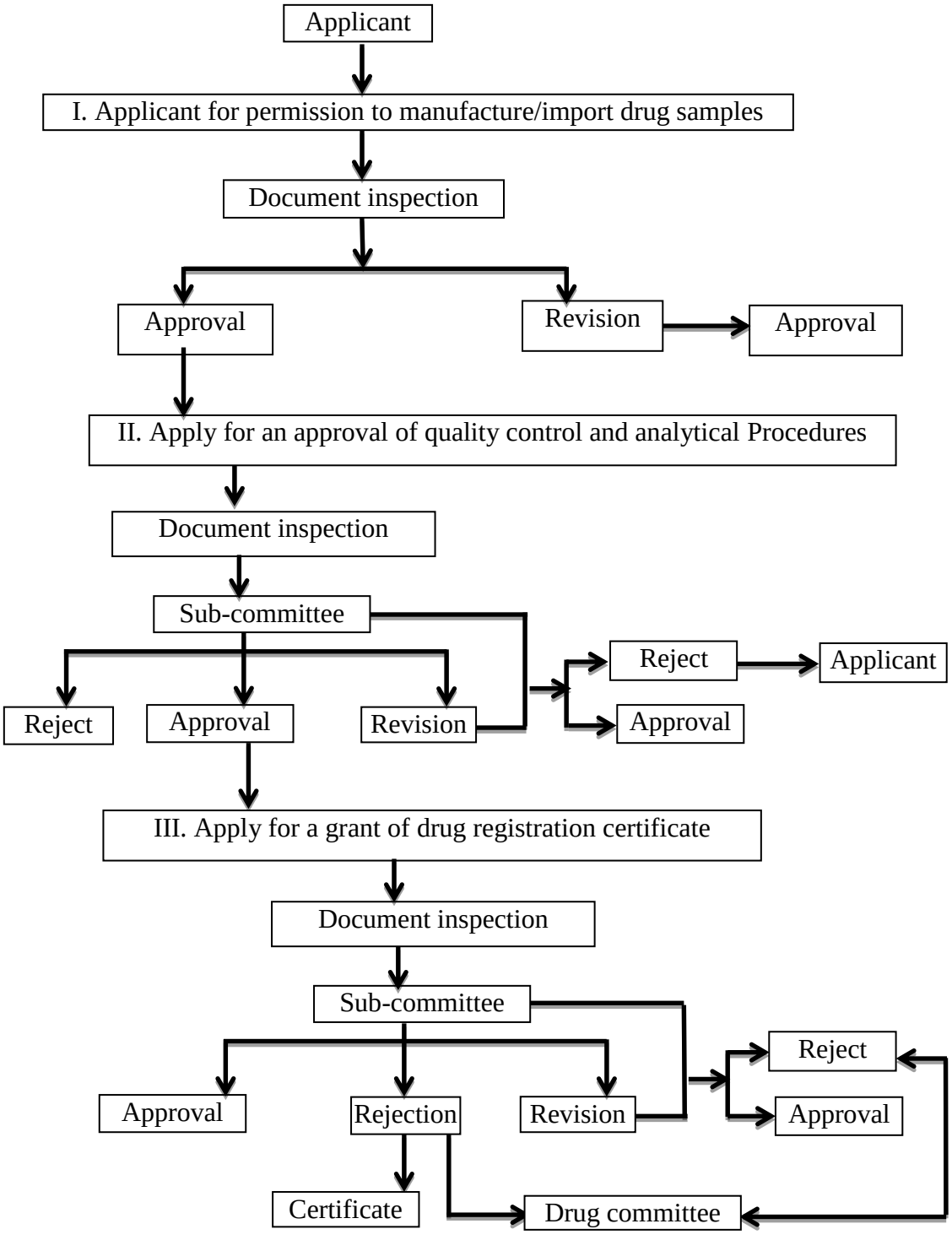

Figure 3: Registration of Generic Drugs in Thailand

FEES FOR APPROVAL (9)

Registration fees = 2,000 TBH (approx 4000 US$)

Table 3: Comparison of requirements in Singapore & Thailand

S. NO	ADMINISTRATIVE DOCUMENTS	THAILAND	SINGAPORE
I.1	Application Form	✓	✓
2	Copy of Valid Certificate of Brand Name Clearance	✓	✓
3	Certificate of pharmaceutical product (COPP)	✓	✓
4	Free sale certificate (FSC)	✗	✗
5	GMP	✓	✓
6	License For Pharmaceutical Manuf.	✓	
7	Site master file (SMF)	✓	✗
8	Permission For Manufacturing & Marketing In Country of Origin	✓	✗
9	Letter of authorization (LOA)	✓	✓
10	Labeling Documents	✓	
11	Patent Information	✓	✓
12	SPC	✓	✓
13	Patient information leaflet (PIL)	✓	✓
14	Mock Up And Specimen	✓	
15	Environmental Risk Assessment	DEPENDS	✗
16	Product Information Already Approved In Any State /country	✗	✓
II.	**DRUG PRODUCT**		
1	Description &Composition	✓	✗
2	Pharmaceutical Development	✓	✓
3	Manufacture	✓	✗
4	QC of Excipients	✓	✓
5	QC of Finished Product	✓	✓
6	Reference Standard	✓	✓
7	Container Closure System / Packing	✓	✓
8	Product Stability	✓	✓
9	Product Interchangeability	✓	✓
III	**NON CLINICAL DOCUMENTS**		
1	Non Clinical Overview	✓	✗

2	Non Clinical Written & Tabulated Summary	✗	✗
3	Non Clinical Study Reports	✗	✗
4	Literature References	✓	✗
IV	**CLINICAL DOCUMENTS**		
1	Clinical Overview	✓	✗
2	Clinical Summary	✗	✗
3	Tabular Listing of All Clinical Studies	✗	✗
4	Clinical Study Reports	Only BE	-

Table 4: Bioequivalence Study Comparison Chart

S. No.	Countries	Bioequivalence Study Acceptable	Other Countries Bioequivalence Study Acceptable
1	**THAILAND**	• Thai Guidelines for the Conduct of Bioavailability and Bioequivalence Studies adopted from "ASEAN Guidelines for The Conduct of Bioavailability and Bioequivalence Studies"	NOT ACCEPTED
2	**SINGAPORE**	• ASEAN Guidelines for the Conduct of Bioavailability and Bioequivalence Studies Also in accordance with Appendix 12 Product Interchangeability and Biowaiver Request for Chemical generic drug applications of the Guidance on Medicinal Product Registration in Singapore 2011	ACCEPTED

CONCLUSION

By looking at the different regulatory environment, it is difficult to get marketing approval at same time and launch in both regions at one go. Hence, it is necessary to understand and define the clear regulatory strategy by looking at the target regions, various application possibilities, data requirements, deadlines for launching products to be marketed in both regions. This eliminates unnecessary studies, minimizes the delay in drug approvals and subsequent launch, and reduces overall cost of research and development.

Singapore and Thailand are well regulated countries in ASEAN, who have well established pharmaceutical regulations and more strict to quality & safety of drugs. Hence by looking at the regulatory requirements of these two countries inline with the ACTD requirement a marketer can enter to the other ASEAN market easily.

ACKNOWLEDGEMENTS

I express my gratitude to my Co authors of this articles who help me in writing this manuscript.

CONFLICT OF INTEREST

Author declares that there are no conflicts of interest.

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