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COMPARISON STUDY OF REGULATORY APPROACHES OF SOME ASIAN COUNTRIES FOR APPROVED FOR GENERIC PRODUCTS

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The work is focused on demonstrating the current scenario of global countries for approval of generic products. The regulatory framework and ASEAN countries, providing an overview of critical regulations as well as procedures that need to be followed in each country. It Provides post-approval submission in USA, illustrating industrial practices with regards to post-approval management procedure and it includes information regarding post-approval submission within EU and its implications across various categories of variation procedure. The regulatory submissions required for Australia along with general requirements which are applicable here while compares bridging approaches between Australia, Canada, Europe, Russia and ASEAN countries using relevant case studies from industry level so that common development can be achieved at cost effective rates by developing appropriate strategies accordingly. The development of a common drug product that can be filed across the globe is an important step in modern medicine. This process requires collaboration between countries and regulatory bodies to ensure that each country's regulations are taken into account when developing the product. A comprehensive regulatory strategy must also be developed to guide this process, ensuring timely launch of products while meeting existing regulations. The pharmaceutical industry is facing a period of rapid change and evolution, with new regulations being implemented in both the European Union (EU) and United States (US).Understanding what requirements exist across different countries will help provide companies with greater flexibility moving forward, allowing them access larger markets which could ultimately lead higher profits over time. Therefore, by reading these four pieces combined together one can gain an invaluable knowledge base regarding current trends within pharma industry today.One challenge in developing a global drug product is understanding the different requirements for each country's regulation system, as well as how these systems interact with one another. To overcome this challenge, it is necessary to draft regulatory strategy which outline what needs to be included when submitting a regulatory submission for approval within any given country or region. Additionally, they should include information about potential differences between local laws governing safety and efficacy standards so companies know exactly what needs to be done before launching their products globally. Furthermore, establishing clear timelines help to submit pre-submission and post submission in timely manner across the global market. Ultimately, successful implementation of these strategies will enable companies and governments alike achieve their goals regarding international drug approvals faster than ever before.

Key words: ASIAN Countries, Post approval Submissions, Post Approval Managemment, Pharmaceutical Industries.

II.INTRODUCTION

The pharmaceutical landscape across Asia is rapidly evolving, driven by growing healthcare demands, economic development, and the need for affordable medicines. Generic drugs—cost-effective alternatives to branded medications—play a vital role in expanding access to essential treatments. However, the regulatory frameworks governing the approval of generic products vary significantly across Asian countries, reflecting differences in legal structures, public health priorities, and market maturity.

This comparative study explores the regulatory approaches adopted by key Asian nations—such as India, China, Japan, South Korea, and ASEAN member states—for the approval of generic pharmaceuticals. It examines the similarities and divergences in dossier requirements, bioequivalence standards, timelines, and post-marketing surveillance mechanisms. By analyzing these frameworks, the study aims to identify best practices, regulatory bottlenecks, and opportunities for harmonization that could facilitate cross-border collaboration and improve access to quality generics across the region.

REGULATORY FRAME WORK AND COMPARISON OF REGULATORY APPROACHES OF ASEAN COUNTRIES

ASEAN Pharmaceutical Regulatory Policy

The Association of Southeast Asian Nations (ASEAN), comprised of Indonesia, Malaysia, the Philippines, Singapore, Thailand, Vietnam, Brunei, Laos, Myanmar, and Cambodia, was established in 1967 to promote regional peace and stability, facilitate collaboration and mutual assistance among member states, and accelerate regional economic growth, social progress, and cultural development.To that aim, member countries are trying to develop harmonised standards in order to eliminate technical trade obstacles and facilitate the formation of an integrated market. One of the key industries considered for economic integration is healthcare.To establish a single Production Base and a single market all over the ASEAN countries, was decided by ASEAN leaders. Among all over the products Pharmaceutical products are one of the important element of this vision due to their implications in social economic way.

Objectives of ASEAN Pharmaceutical Regulatory Policies:

To offer ASEAN Member States and ASEAN National Regulatory Authorities with a foundation, direction, and policy framework to support the creation of harmonised strategies that facilitate the advancement of national regulatory systems and market integration activities.

III.METHODOLOGY

Registration process of various countries Like Thailand And Singapore

THAILAND: The regulatory agency for Thailand is Thailand Food and Drugs Administration.The main role of Thailand FDA is to protect consumers' health, especially to ensure safety, efficacy and quality of health products in its region. These include foods, drugs, narcotic substances, psychotropic substances, medical devices, cosmetics and other hazardous substances available in the country.

Current Laws and Regulations:

1. Drug Act B.E. 2510 (1967)
2. Drug Act (2nd Revision) B.E. 2518 (1975)
3. Drug Act (3rd Revision) B.E. 2522 (1979)
4. Drug Act (4th Revision) B.E. 2527 (1984)
5. Drug Act (5th Revision) B.E. 2530 (1987)
6. Ministerial Regulation on Drug Registration B.E. 2555 (2012)

Pre-Marketing: Licensing

1. The drug Act requires that persons who wish to sell, produce or import drugs into Thailand have to obtain a license from the Thai FDA,

License to manufacture License to sell

License to import

Post-Marketing

1. Marketed products regularly sampled for testing at the drug analysis

Laboratory of the Department of Medical Sciences

Inspection of manufacturing sites and pharmacy stores

GMP Clearance of Overseas Pharmaceutical Manufacturers – PIC/S

Drug Registration Process

Step-1- The permission to import/manufacture drug samples.

Step-2- Application for product registration approval

Documents:

2. Application form- Manufacturer drug product, Importer drug product, Manufacturer Thai Traditional drug
3. Manufacturer/Importer Name and Address
4. License to manufacture/import Number
5. Product Name and Description
6. Drug Formula (active ingredient(s) only)
7. Packaging
8. Quantity of drug sample to manufacture/import
9. Labels

Leaflets

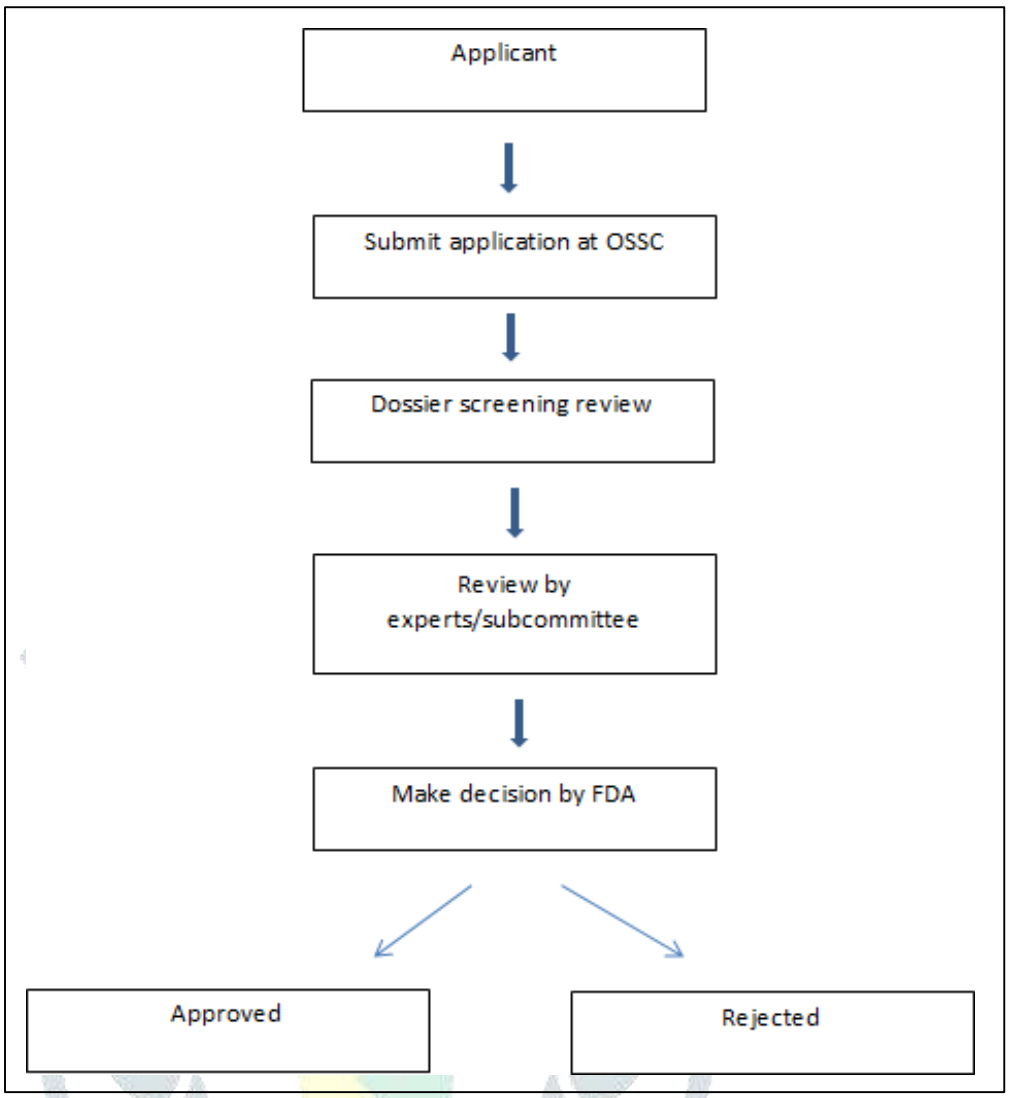

Figure 1: Flowchart of Drug Review ProcesS

Singapore: The regulatory agency for Singapore is Health Sciences Authority. It provides guidelines for the regulatory processes and requirements for therapeutic product registration in Singapore. The Health Products Act (HPA) provides for the legislative basis for regulating the manufacture, import, supply, presentation and advertisement of therapeutic products, one of the health products categories regulated under the Act.

Drug registration process

6.1 A company seeking to market a therapeutic product in Singapore must obtain marketing approval from HSA through making an application for product registration. The registration process involves a series of steps, as shown below-

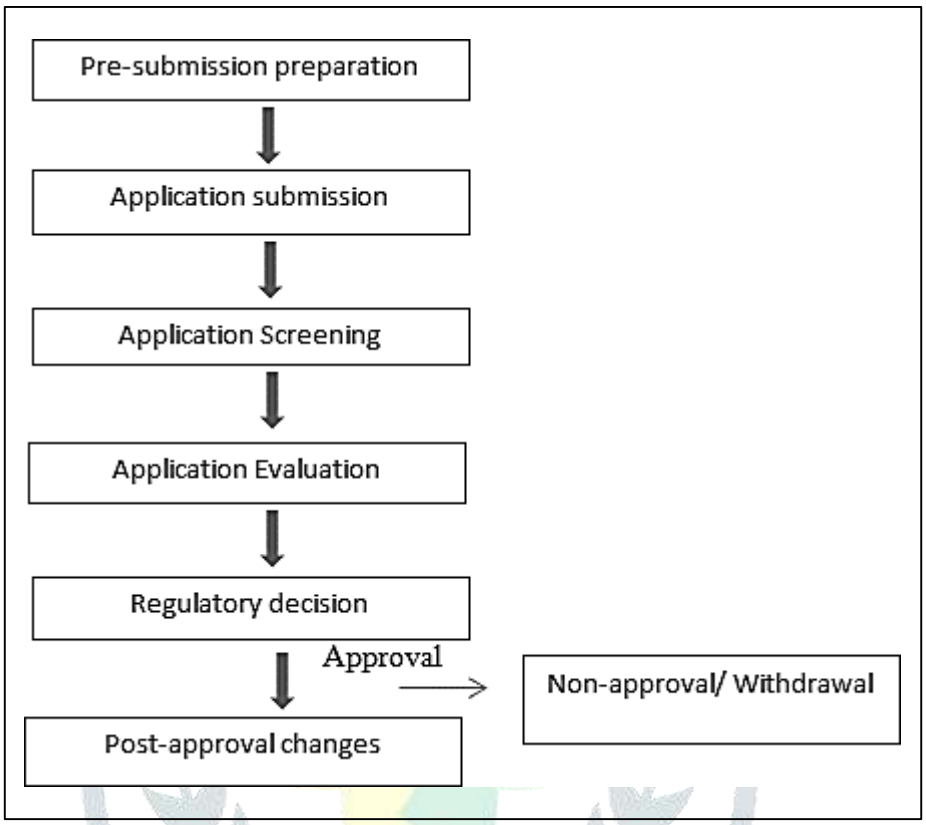

Figure 2: Overview of drug registration process for Singapore

Pre-submission preparation

The following are important considerations for an applicant to register a therapeutic product:

1. Knowing which type of application to apply for;
2. Knowing which evaluation route to choose; and
3. Arranging for a pre-submission consultation with HSA for advice, if required.

Product types

Application types

1. New Drug Application
2. Generic Drug Application

Evaluation routes

1. Full route
2. Abridged route
3. Verification route
4. Verification-CECA route

1. The submission of an application comprises two key steps – (i) online submission of the application form via PRISM and (ii) submission of the technical dossier.

2. Submission Requirements

3. The complete application dossier – i.e. Modules 1 to 5 of the ICH CTD or Parts I to IV of the ACTD – must be submitted in an electronic format.
4. All documents required under Module 1/Part I must be submitted in softcopy in PRISM. Colour scanned copy of the original documents should be submitted and original hardcopy of documents are not required.

Stages of Notification to Applicant		1st Stage	2nd Stage	3rd Stage	4th Stage
Application Type	**Evaluation Route**	Acceptance for Evaluation	Active Evaluation in Progress	Evaluation at Midway	Completed Evaluation
NDA-1 NDA-2 NDA-3	Full or Abridged	Application is accepted for evaluation. This marks the start of the evaluation timeline.	When active evaluation is in progress for the application	Application is approximately midway through the evaluation (Provided that there were no prior stop-clocks which may affect the evaluation progress). Applicants can expect to receive the first set of queries from HSA during this stage.	Evaluation is completed for the application. Application is now undergoing the regulatory decision phase, after which a regulatory decision will be issued. Applicants can still expect further queries from HSA during this stage.
GDA-1 GDA-2	Abridged, Verification, or Verification- CECA				

Table 1: Summary of stages of Product Applications during Evaluation

	Location in	**Module/Part required for**

Documents	ICH CTD	ACTD	Full NDA	Abridged NDA	Verification NDA
Administrative Documents	Module 1	Part I	Yes	Yes	Yes
Common Technical Document Overview and Summaries	Module 2	Incorporated in Parts II, III and IV	Yes	Yes	Yes
Quality documents	Module 3	Part II	Yes	Yes	Yes
Non-clinical documents	Module 4	Part III	Yes	ICH: No ACTD: Overview only	ICH: No ACTD: Overview only
Clinical documents	Module 5	Part IV	Yes	Study report(s) of pivotal studies and synopses of all studies (phase I-IV) relevant to requested indication, dosing and/or patient Group	Study report(s) of pivotal studies and synopses of all studies (phase I-IV) relevant to requested indication, dosing and/or patient group

Table 2: Dossier Submission Requirements for NDAs

CONCLUSION:

ASEAN is an example of a regional integration movement that is evolving and changing.

In the face of more international rivalry and economic upheavals, it has become one of the most effective regional groupings of developing nations in promoting collaboration and commerce.

ASEAN has come a long way since its establishment four decades ago, and it is now at a critical juncture in its evolution from a regional organisation to a vibrant, connected economic community.

For pharmaceutical export, the Association of Southeast Asian Nations (ASEAN) and Gulf Cooperation Council (GCC) territories are classified as "Emerging markets." The ASEAN and Gulf nations' drug product policies encourage the import of high-quality generic medicines from other countries. ASEAN nations utilised the standard ACTD format for drug product submissions in order to register the product in the reference country. In both locations, the climatic zone stability criteria are $30^{o}C$ $2^{o}C$ and 65 percent 5 percent RH.

ASEAN's drug regulatory agencies and industry have collaborated closely not just regionally, but also increasingly with worldwide organisations, to create a number of standardised papers.

These are the ASEAN Common Technical Dossier and the ASEAN Common Technical Requirements, both of which are constantly growing.

They have already been realised to a large extent; the next stage will be to focus on mutual recognition of pharmaceutical registrations and the implementation of a harmonised placement system.

There is still a lot of work to be done in terms of implementation.

Already, ASEAN might be used as an example of a successful pharmaceutical harmonisation strategy. ASEAN is becoming increasingly important in the pharmaceutical sector.

Generic approved products assessment is an important process for many countries, including Malaysia, Indonesia and Thailand. This assessment involves assessing the safety and efficacy of generic drugs in order to ensure they are safe for use by consumers. The purpose of this essay is to discuss the findings from a recent evaluation that was conducted on 25 products in these three countries.

The results showed that most queries were received from Malaysia regarding stability data and COPP – Samples requirement. Vietnam’s Ministry Of Health (MOH) had raised more questions about dissolution tests as well as translated labels compared to other markets surveyed during this study period. In addition, it was found that both Indonesia and Thailand were more likely than other markets surveyed to raise questions about BE studies which ask about methods/validations plus DMF starting material requirements along with stability data requests.

Overall, these findings demonstrate how important it is for pharmaceutical companies producing generic drugs in Southeast Asia must be aware of all local regulations when submitting their applications or responding any query related issues such as those discussed above before releasing their product into the market place. It also

shows why conducting comprehensive assessments like this one can help identify potential problems early on so they can be addressed quickly before reaching consumers who may otherwise unknowingly ingest unsafe medications due to inadequate testing procedures or lack thereof altogether.

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