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Review Article

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Regulatory requirement for the approval of Generic Drug in Vietnam as per ASEAN Common Technical Dossier (ACTD)

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Abstract

Drug approval process differs from one country to another country. The purpose of this study is to give a comparative overview on generic drug market regulation in ASEAN Countries Cambodia and Vietnam. The aim of study is to facilitate proper knowledge regarding main critical issues, differences as well as similarities of related drug regulation. There is a different requirement for registration of generic product in each regulatory system but also comprises of some similar outline that includes some common rules. These are variances and regulatory hurdles such as Number of batches for submission in dossier, stability conditions, registration of product, analysis, bioequivalence and clinical study requirement. ASEAN countries for generic drug product approval ACTD submitted to country specific authority. For solid oral dosage forms as per ASEAN guideline there are 4 parts have to be submitted. Part I contains Administrative requirements which is not a part of common technical document. Part II is Quality contains 3 sections that are a) Table of Content b) Quality overall Summary c) Body of data. Part III contains Non clinical. Part IV contains Clinical data. For the generic drug product Part III and Part IV is not required.

Keywords: ASEAN, Combodia ,Vietnam, ACTD

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1. Introduction

ASEAN Countries

The Association of Southeast Asian Nations or ASEAN was established on 8 August 1967 in Bangkok by the five original Member Countries, namely, Indonesia, Malaysia, Philippines, Singapore, and Thailand. Brunei Darussalam joined on 8 January 1984, Vietnam on 28 July 1995, Lao PDR and Myanmar on 23 July 1997, and Cambodia on 30 April 1999. The ASEAN Declaration states that the aims and purposes of the Association are: (1) to accelerate economic growth, social progress and cultural development in the region and (2) to promote regional peace and stability through abiding respect for justice and the rule of law in the relationship among countries in the region and adherence to the principles of the United Nations Charter.

Cambodia

The drug registration process started in 1994.Department of Drugs and Food (DDF) is the regulatory agency under the Ministry of Health. It is responsible for the efficacy, safety, quality of drug,efficacy of food and cosmetics. (4,5)

Vietnam

The Drug Administration of Vietnam (DAV) is one of the divisions under the Ministry of Health (MoH) and it handles the overall responsibility for the registration of pharmaceutical products to market in Vietnam and issuing legal documents on pharmaceuticals and cosmetics and managing the quality of drugs and cosmetics. (2)

2. Discussion

In this section study of registration requirements for generic pharmaceutical product of selected countries was carried out and compared to understand the critical aspect of generic drug product data requirements. Table 1 shows comparison of registration requirements for generic pharmaceutical product in Cambodia and Vietnam.

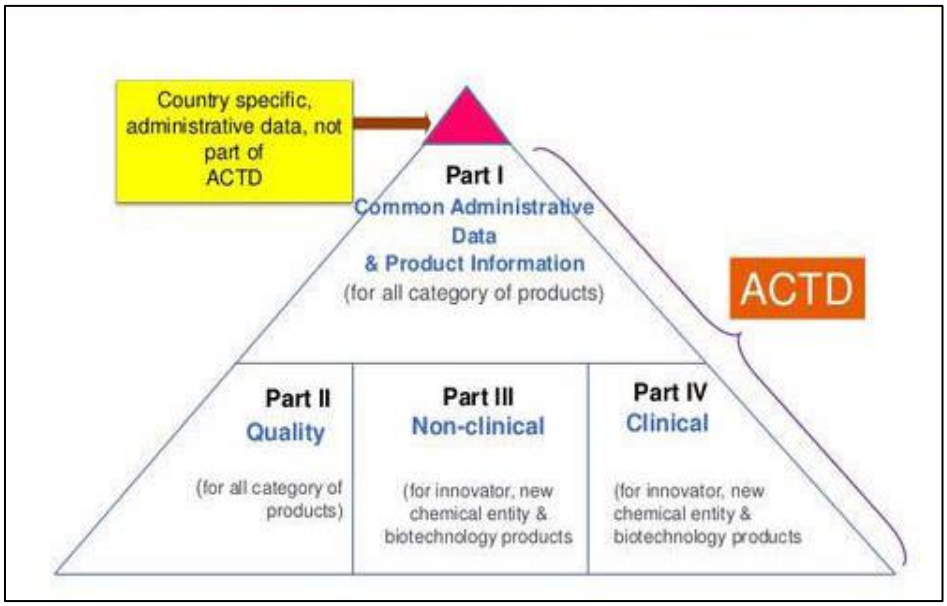

Figure 1. ACTD Triangle

Table 1. Comparison of registration requirements

Parameters	Combodia	Vietnam
Flag		
Regulatory authority	Department of Drugs and Food 	Ministry of health 
Regulatory guidelines	Follows ACTD format	Follows ACTD formats
Cover Letter	Not Required	Required
Application form	Required	Required
Summary of product Characteristics	Required compulsory for self-administered drug it should be in English & Combodian Language (Khmer)	Required and must be in Vietnamese
Label	Required compulsory for self-administered drug it should be in English & Combodian Language (Khmer)	Required and must be in Vietnamese
Fees	Not Required	220-300 USD
Approval Time	6-12 months	14-22 months
GMP certificate	Required as per WHO &GMP guidelines	Required as per WHO &GMP guidelines
Letter of Authorization	Required	Required
Certificate of pharmaceutical product	Not required	Required
Analytical process	Required	Required
Finished Product	Specifications and control tests on the finished product is required	Specifications and control tests on the finished product is required
Batch analysis	Required for 3 pilot batches	Not required
Justification of specification	Required	Required
Container closure system	Required	Required
Reference Standard Material	Required as per ACTD guidelines	Required as per ACTD guidelines
Stability Data	40°C ± 2°C/ 75% ± 5% RH 30°C± 2°C/70% ± 5%RH	40°C ± 2°C/ 75% ± 5% RH 30°C± 2°C/70% ± 5%RH
Climatic Zone	Zone IVb	Zone Ivb

3. Regulatory authority for Generic drugs in Vietnam

Pharmaceutical products in Vietnam are under the management of the Ministry of Health (MOH). The Drug Administration of Vietnam (DAV) is one of the divisions under the Ministry of Health (MoH) and it handles the overall responsibility for the registration of pharmaceutical products to market in Vietnam. (2)

4. Who can apply for registration of Generic drugs in Vietnam (1)

The following entities are allowed to register pharmaceutical products in Vietnam.

- Domestic pharmaceutical manufacturers.
- Foreign companies, having a license to manufacture pharmaceuticals in Vietnam.
- Domestic entities that are allowed to trade in pharmaceuticals.
- Foreign entities that have a trade license.

5. The process to register generic drugs in Vietnam (1)

The process to register generic drugs in Vietnam for the issuance of a marketing registration certificate involves the following steps.

- Step1: Review your product details and understand the regulatory requirements applicable to your product
- Step2: Application dossier submission.
- Step3: Evaluation of application dossier
- Step4: respond to queries and obtain the product registration certificate

Let's discuss each step to understand the entire process to register the generic drug in Vietnam.

Step 1: Review your product details and understand the regulatory requirements applicable to your product

It involves collecting information on the different regulatory aspects concerning generic product registration. For generic drugs, manufacturers need to prepare the application dossier complying with either ASEAN or ICH Common Technical Dossier.

Step 2: Compile and submission of application dossier

The dossier must contain a cover page, the product information sheet, etc. The applicant must arrange these documents in order of the table contents with separation between the sections, and the sections must have numbers for easy reference.

The following documents require separate sections enclosed with product information

- Bioequivalence study report.
- GMP-conformity assessment document regarding foreign manufacturers.

Part 1: The administrative dossier

- The documents in the case of application dossier of foreign drugs.
- GMP inspection application by foreign manufacturers.
- Inspection of documents about the manufacturing conditions.

Part 2: Contents of the Quality Documents includes

Report of bioavailability/bioequivalence study

Step 3: Evaluation of the application dossier

From the date of receipt of the complete registration dossier, the Drug administration will review and send the dossier to expert evaluators. After evaluation, expert evaluators give their opinions to the Drug administration within a specified time.

Step 4: Respond to queries and receive the product registration

After the validation and assessment, if the dossier does not meet the requirements, the DAV usually issues a written response and states the reasons accordingly. DAV requests the applicant for supplementary documents or clarifies issues regarding the application dossier.

The DAV then reviews the supplementation and explanation from the applicant and issue a marketing registration certificate of the drug within the specified time.

The dossier for which the Drug administration seeks opinions from Advisory Council presents them to the council and approves accordingly after the Council's response.

Reasons for pharmaceutical market growth in Vietnam

Several reasons contribute to the pharmaceutical market growth in Vietnam, such as;

- Favorable changes in the government policies and domestic regulations of imported drugs
- Growing demand for quality healthcare with rising incomes in Vietnam
- Higher demand for affordable medicines
- Significant healthcare spending due to the continuous rise of the elderly population over the age of 60 years with changing disease pattern.

6. Approval timeline

Generic drug approval usually takes 14-22 months from the date of submission of the application dossier. Compared to the developed countries, the time taken to evaluate new and generic drug approvals is shorter in Vietnam. However, the application submission process is rigorous. (2)

7. Approval fees

The government Filing fee for marketing Authorization applications in Vietnam ranges between $220-300 USD which depends on the requirements whether the medicinal products have data confidentiality or bioequivalent dossier or clinical dossier requirements. (2)

8. Labelling Requirements in Vietnam

- Product name
- Quantitative, dosage and strength of active ingredients
- Batch number
- Expiration date
- Name of Manufacturer

Package inserts also required and it's contain the product name, active ingredients, indications, instructions for use, including warnings, precautions, adverse drug reaction, and contraindication, dosage and storage information. All labelling requirements must be in Vietnamese. (2)

9. Conclusion

From the study it was found that due to variation in regulatory requirement in various countries it is a major challenge for pharmaceutical companies to register their pharmaceutical products. For pharmaceutical companies in order to develop a drug formulation which can be simultaneously submitted in numerous countries for approval at the same time is difficult. Therefore, continuous process of harmonization is carried out all over the world to overcome this problem. It gives brief information about the regulatory requirements for registration of pharmaceutical Product from the comparison study of Cambodia & Vietnam. It can be concluded that the industry should target on submission or registration of pharmaceutical product at different countries depending on their stability, regional documents and other country specific documents.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article

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