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RESEARCH ARTICLE

Regulatory Requirements and Comparing Required Documents for the Drug Registration Process in Indonesia and Vietnam

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ABSTRACT

The regulatory authorities in Indonesia and Vietnam and their procedures for registration of a drug are discussed in this document. The Indonesia and Vietnam comes under ASEAN countries. The drug medication is essential and important in ASEAN region. The process of manufacturing a drug will not vary but the regulatory authorities and requirements will differ. The regulatory authority of any country has to ensure the quality of the product and safety of the patients. As the regulatory requirements differ it will be challenging for the companies to produce drugs which are submitted for approval for various countries. The regulatory documents comparing Indonesia and Vietnam that should be submitted for the drug registration in the respective countries are enclosed in this article.

KEYWORDS

ASEAN, Indonesia, Vietnam, Regulatory Authority

INTRODUCTION

The Indonesia and Vietnam are under ASEAN countries (Association of south East Asian nations). ASEAN countries include the following countries like Indonesia, Philippines, Brunei, Cambodia, Lao People's Democratic Republic, Malaysia, Myanmar, Singapore, and Vietnam. The drug registration permission granted by the relevant state authority to the manufacturer and completes the further process to market the product. The main aim of the manufacturer should be the safety of the products. Indonesia, a country of more than 6000 inhabited islands. The pharmaceutical market in Indonesia is most promising and healthcare market worth is $6.5 billion.

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The Indonesia has 3/4th domestic pharmaceutical manufacturers. The regulatory body of Indonesia is The National Agency of Drug and Food Control. Vietnam is the third largest country by population in Southeast Asia .the health sector has witnessed some dynamic changes during last 20 years, the regulatory body governing of Vietnam is ministry of health and drug administration department of Vietnam.

Dossier Requirements

- The dossier requirements for the ASEAN countries are similar to that of *ICH* guidelines. The ASEAN countries format for drug registration is *ACTD*- Common Technical dossier.
- It is a common application format that is submitted to ASEAN regulatory authorities for the registration of pharmaceutical products for human use. Even though some of the individual ASEAN countries have their

own regulatory registrations formats but they also follows the *ACTD*.

ACTD (ASEAN Common Technical Dossier)

Association of South- East Asian nations (ASEAN) follows *ACTD* along with their respective guidelines framed by their regulatory governing body. The ASEAN region was formed in 1967 consisting of ten countries. The main advantage of *ACTD* is transparency in the regulatory authorities of member countries. Fast review and approval process and significantly reduces the time for the compiling of application. The single filing, single monitoring improves the trust in the public for approved medicines.

I. Flowchart of ACTD (ASEAN Common Technical Dossier)

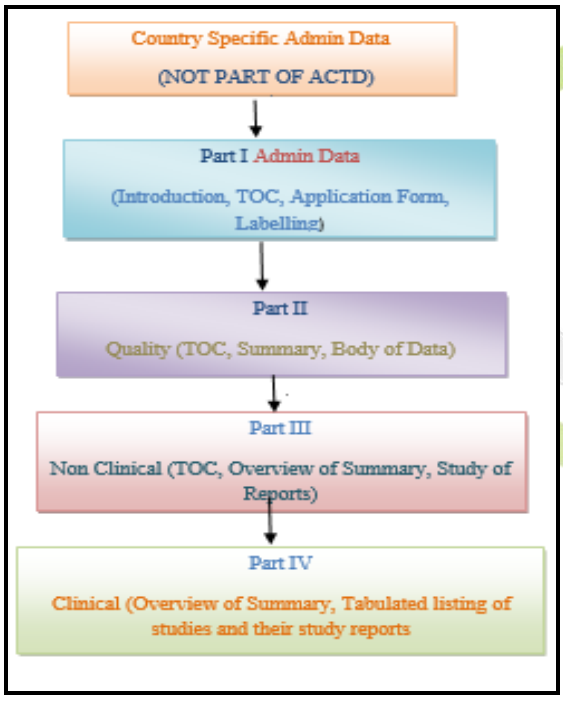


Table 1: General Comparison of Indonesia and Vietnam

S.No	Country	Validity	Format Followed	Format Included
1	Indonesia	5 Yrs	ACTD	ACTD
2	Vietnam	5 Yrs	ACTD	ACTD

Table 2: Comparison of Administrative documents of Indonesia and Vietnam which follow only ACTD

S.No	Administrative Documents	Indonesia	Vietnam
1	Application Form	✓	✓
2	Copy Of Valid Certificate Of Brand Name Clearance	✓	✓
3	Certificate Of Pharmaceutical Product	✓	✓
4	Free Sale Certificate	×	×
5	Good Manufacture Practice	✓	✓
6	License For Pharmaceutical Manufacture	✓	✓
7	Site Master File	✓	✓
8	Permission For Manufacturing & Marketing In Country Of Origin	×	×
9	Letter For Authorization	✓	✓
10	Labelling Documents	✓	✓
11	Patent Information	✓	×
12	Summary Product Characteristics	✓	✓
13	Patent Information Leaflet	×	×
14	Product Information Already Approves In Any State/Country	×	×

Table 3: Technical document comparison in Indonesia and Vietnam

Technical Documents	**Indonesia**	**Vietnam**
Drug Substance	×	×
Quality Overall Summary	✓	✓
General Information	✓	✓
Manufacture Of Drug Substance	✓	✓
Characterization	✓	✓
Quality Control Of Drug Substance	✓	✓
Reference Standards	✓	✓
Container Closure System	✓	✓
Stability	·	·
CEP	×	×
Drug Master File	×	×
Drug Product		
Description & Composition	✓	✓
Pharmaceutical Development	✓	✓
Manufacture	✓	✓
Quality Control Of Excipients	✓	✓
Quality Control Of Finished Products	✓	✓
Reference Standard	✓	✓
Container Closure System/ Packaging	✓	✓
Product Stability	✓	✓
Product Interchange Ability	✓	✓

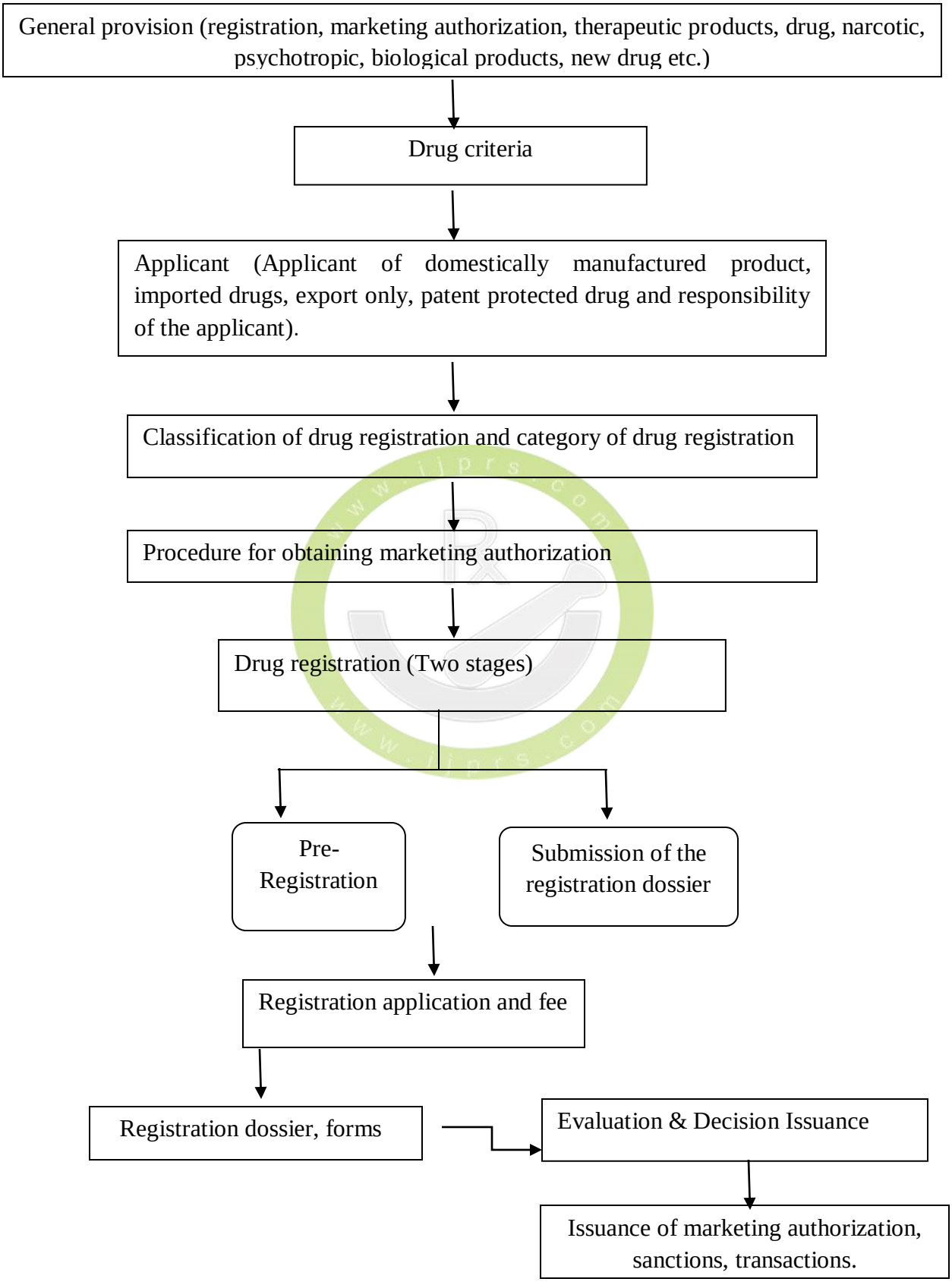
Table 4: Non clinical documents comparison of Indonesia and Vietnam

Non clinical documents	**Indonesia**	**Vietnam**
Non clinical overview	✓	✓
Non clinical written and tabulated summary	×	×
Non clinical study reports	×	×
Literature reference	✓	✓

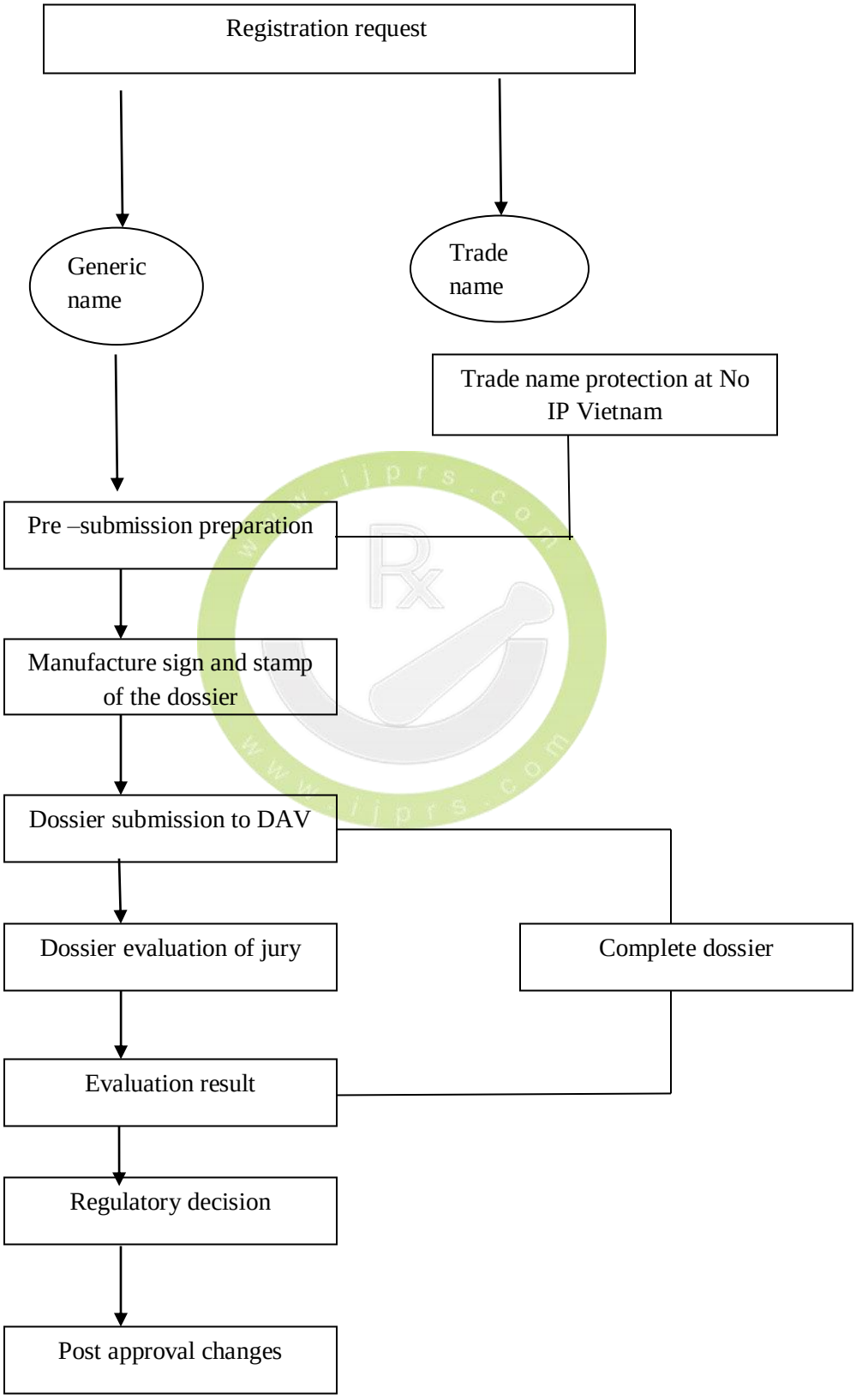
Table 5: Clinical documents comparison of Indonesia and Vietnam

Clinical documents	**Indonesia**	**Vietnam**
Clinical overview	✓	✓
Clinical summary	×	×
Tabular listing of all clinical studies	×	×
Clinical study reports	Only BE	Only BE
List of key literature	✓	✓

II. Flow Chart of Drug Registration Process in Indonesia



III. Flow Chart of Drug Registration in Vietnam



CONCLUSION

This article presents the regulatory requirements for the drug registration in Indonesia and Vietnam and also compared the required documents for the purpose of registration. The importance of presenting the both countries drug registration is because of its high population and on the basis of its pharmaceutical market in ASEAN countries. The main aim of any country should be the safety of the people administrating the drug and the quality of the products and maintaining the GMP, ICH guidelines in every aspect.

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