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A Wide – Angle View of ACTD Regulation: A Criticism

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ABSTRACT

The Aim of the current melancholic approach occupies a major part in requirements for the compilation of drug dossier to ASEAN countries as per ACTD/ACTR regulatory guidelines along with this it talks about the research investments, import of pharmaceuticals, policies and its implementations in ASEAN countries. Dossier is an integral Part of any registration application for Marketing Authorization. A Dossier is submitted to Drug Authority or Ministry of health or any other equivalent authority. The organization of ACTD dossier comprises of four parts which includes Administrative data, Quality Document Non-Clinical Document, and clinical Document report. The regulatory status of pharma in ASEAN countries such as Cambodia, Indonesia, Laos, Malaysia, Philippines, Singapore, Thailand and Vietnam depends on its market potential and it's share value with respective regulatory authority in country specific is updated with general advantages. The ACTR is a written document intended to guide the applicants in preparing application to the expectations of ASEAN regulatory authority.

Key words: *ASEAN countries, ACTD, ACTR, Ministry of Health, Regulatory Authorities.*

INTRODUCTION

1. Association of Southeast Asian Nations (ASEAN):

The Association of Southeast Asian Nations (ASEAN) was created in 1967 with the signing of the ASEAN Declaration by Indonesia, Malaysia, Philippines, Singapore and Thailand. Brunei Darussalam then joined in 1984, Vietnam in 1995, Lao PDR and Cambodia in 1999, arriving at the current number of ten Member States. These ten countries with a total land area of 4.4 million sq. km. are home to 600 million. In 2003, ASEAN Heads of State agreed to establish an ASEAN Community by 2020, a community of nations that is outward looking, living in peace, stability and prosperity, bonded together in partnership in dynamic development and in a community of caring societies.

Goal of Association of Southeast Asian Nations:

The goal is to create common regulations for pharmaceuticals in the region, reduce barriers to trade and to ensure that pharmaceutical products penetrating the ASEAN markets show sufficient safety quality and efficacy [1].

ASEAN Countries:

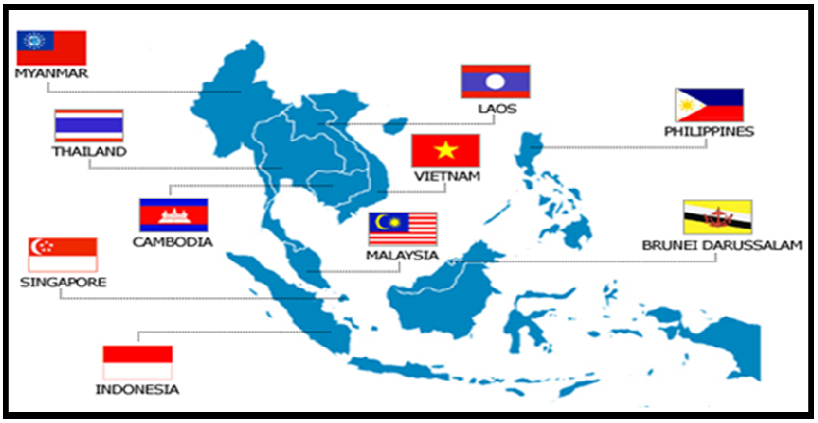

Fig. 1: ASEAN Member States [2]

Accordingly PPWG had it first meeting in September 1999 with Malaysia as chair and Thailand as co-chair. After the subsequent meetings PPWG had developed the ACTD, ACTR and its guidelines [3].

2. Registration Dossier:

Registration Dossier of the pharmaceutical product is a document that contains all the technical data (administrative, quality, nonclinical and clinical) of a pharmaceutical product to be approved / registered / marketed in a country. It is more commonly called as the New Drug Application (NDA) in the USA or Marketing Authorization Application (MAA) in the European Union (EU) and other countries, or simply Registration Dossier. Basically, this consists of data proving that the drug has quality, efficacy and safety properties suitable for the intended use, additional administrative documents, samples of finished product or related substances and reagents necessary to perform analyzes

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of finished product. Therefore, they are the vehicle in a country through which drug sponsors formally propose that the Regulatory Agencies approve a new pharmaceutical for sale and marketing [2].

The registration procedure is different in every region. Some will follow the ICH guidelines, WHO guidelines for the registration of the drug product .But some region have the country specific guidelines for the registration of the FPP. Drug regulatory affairs in pharma industries have mandated two types of dossier namely CTD (Common Technical Dossier) and ACTD (Asean Common Technical Dossier).

Regulated pharma markets (eg.USA, Europe) markets require submission of dossier in CTD format which has to provide clinical trial and bioequivalence studies. As against this, semi-regulated pharma markets (South East Asian) require ACTD format which does not require exhaustive details like CTD. All of these guidelines will be considered the safety, quality and efficacy of the FP product [4].

Table No. 1: Drug Regulatory Authorities following ACTD: [3]

S. No.	Country	Drug Regulatory Authority
1	Singapore	Ministry of health
2	Malaysia	National Pharmaceutical Health Bureau (Ministry of Health) and Drug Control Authority
3	Philippines	Department of Health
4	Lao's	Ministry of Health
5	Cambodia	Ministry of Health
6	Brunei Darussalam	Ministry of Health
7	Indonesia	Ministry of Health
8	Thailand	Food and Drug Administration
9	Vietnam	Drug Administration of Vietnam
10	Myanmar	Union of Myanmar (Ministry Of Health and Department Of Health)

3. ASEAN Common Technical Dossier (ACTD):

The ASEAN Common Technical Document is organized into four parts. The ACTD consists of Parts I to IV whereas ICH – CTD has 5 Modules. The administrative data of Part I is part of ACTD whereas Module 1 of ICH – CTD is purely country specific. The summaries of the quality (Part II), nonclinical (Part III) and clinical (Part IV) are located at the beginning of each part of the ACTD. The ICH – CTD dedicates these summaries in a separate Module 2. As the ACTD does not have such summary part, it consists of only 4 Parts and not 5 [2].

Contents wise ACTD is similar to the ICH CTD. But Module wise it is different. 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 less compared to the ICH countries, e.g. most study reports are not required to be submitted [1].

ACTD Format:

The ASEAN Common Technical Document is organized into four parts: [5]

Part I: Table of Content Administrative Information and Prescribing Information:

Section A: Introduction
Section B: Overall ASEAN Common Technical Dossier Table of Contents
Section C: Documents required for registration (for example, application forms, labeling, Product Data Sheet, prescribing information)

Part II: Quality Document:

Section A: Table of Contents
Section B: Quality Overall Summary
Section C: Body of Data

Part III: Nonclinical Document:

Section A: Table of Contents
Section B: Nonclinical Overview
Section C: Nonclinical Written and Tabulated Summaries

1. Table of Contents
2. Pharmacology
3. Pharmacokinetics
4. Toxicology

Section D: Nonclinical Study Reports

1. Table of Contents
2. Pharmacology
3. Pharmacokinetics
4. Toxicology

Part IV: Clinical Document:

Section A: Table of Contents
Section B: Clinical Overview
Section C: Clinical Summary

1. Summary of Biopharmaceutics and Associated Analytical Methods
2. Summary of Clinical Pharmacology Studies
3. Summary of Clinical Efficacy
4. Summary of Clinical Safety
5. Synopses of Individual Studies

Section D: Tabular Listing of All Clinical Studies
Section E: Clinical Study Reports
Section F: List of Key Literature References

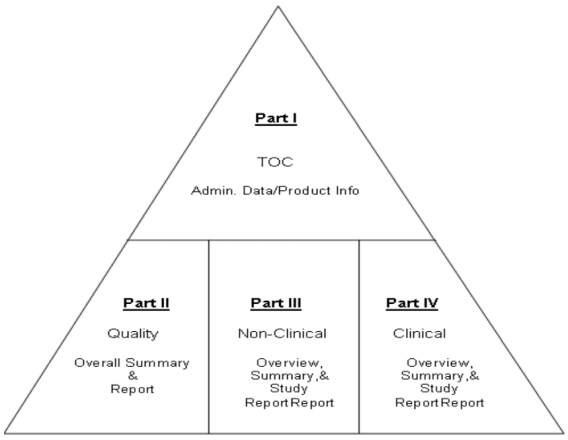

Fig. 2: ACTD [6]

ASEAN common technical requirements (ACTR):

The ACTR is as set of written material intended to guide applicants to prepare an application in a way that is consistent with the expectations of all ASEAN Drug Regulatory Authorities. The ACTD check-lists give recommendations to which extend documentation has to be provided for the different product classifications. The different ASEAN product classifications are namely a New Chemical Entity; Biotechnology derived products, Major/ Minor Variations or Generic Products. Until now these classifications are not clearly defined. The applicant therefore has to apply the regulations of each national regulatory authority and consult them for advice, e.g. pre-submission meetings [1].

Table No. 2: Overview of CTD and ACTD [2]

S.NO	DOCUMENTS	ICH - CTD	ACTD
1	Administrative Documents and Product Information	Module 1	Part I
2	CTD Overview and Summaries	Module 2	Incorporated in parts II, III & IV
3	Quality Documents	Module 3	Part II
4	Non – clinical Documents	Module 4	Part III
5	Clinical Documents	Module 5	Part IV

The ACTD gives information on the format and structure of the dossier that shall be commonly used for applications in the ASEAN region. The ACTD should serve as a locator for documentation that has been compiled for a marketing authorization application.

Advantages of the ACTD:

The advantage of the ACTD is that

1. One dossier can be used for the whole region rather than generating different registration dossiers.
2. ACTD should therefore significantly reduce time and resources needed to compile applications.
3. The harmonized format should also facilitate the regulatory review [1].

4. Regulatory Status of Pharma in ASEAN Countries:

i) Cambodia:

The Cambodian pharmaceutical market is currently quite small, with per capita expenditure on medicine and pharmaceutical products much lower compared to other countries. Cambodia, however, has a high growth potential over the next decade. IBM forecasts that the demand for drugs and drug consumption in Cambodia is expected to increase at a rate of 11.6% and will Reach a level of $302 million by 2014. By 2019, the market will have expanded to $516 million (Research and Markets, 2010). As such Cambodia is increasingly becoming a target country for drug makers. While the national health care budget in Cambodia is increasing, it is mostly an effect of higher foreign contribution levels. Such reliance on foreign money, however, leads to instability in the health care market because programs and agendas are pushed and are then abruptly curtailed when funds are no longer available. While policies have been constructed on paper to address this issue, there is no evidence of implementing these checks in order to prevent the situation from occurring (Park, 2010).

In A survey conducted by C.T. Lon and associates found that 79% of the drugs were not registered (Lon, et al. 2006). Most troubling, however, is that the World Health Organization estimates that Cambodia has close to 2800 illegal medicines sellers and 1000 unregistered medical products (WHO, 2003) [7].

ii) Indonesia:

Indonesia is the largest country in ASEAN in terms of population. The size of the Indonesian pharmaceutical market is about $350 million in 1998. Similarly to other ASEAN countries, Indonesian pharmaceutical industry produces drugs under license from foreign drug firms or more commonly manufacture generic products. These manufacturers generally lack the financial resources and technical experience to carryout original research and to create new compounds. Indonesia shares the same problem as other ASEAN members in its weak enforcement of law, which led to reports that the problem of counterfeit drugs circulating in the country [8].

The Indonesian government believes that due to the lower price and relatively equal effectiveness and safety of generics over name brands, more citizens will have access to medicines that they would not normally be able to afford. The push for generics has gone so far as to require all branded pharmaceutical products to print the generic name at least 80% as big as and directly below the trade name of the product [7].

iii) Laos:

The Ministry of Health is the lead regulator in Lao PDR. Unfortunately, they do not view pharmaceuticals, vaccines, or medical devices as a priority. Moreover, they do not see a high importance on Intellectual Property, parallel importation, counterfeits, or other issues of ASEAN harmonization [7].

In Laos About 70 % of the 3000 pharmaceutical products were imported by 30 licensed pharmaceutical import companies, the remaining was locally produced. These pharmaceutical products are dispersed into more than 2000 licensed private pharmacies. Because of inadequate law enforcement, approximately 60% of drug sellers have also brought from illegal sources [8].

iv) Malaysia:

The Malaysian pharmaceutical sector is mainly made up of the generic pharmaceutical (including branded generics) manufacturers engaged in the formulation and packaging, and a very limited extent the production of pharmaceutical active ingredients. Malaysia is heavily reliant on imports of both raw materials and finished products. About 65% of its pharmaceutical market is accounted for by imports. At the end of 2001, there were 72 licensed pharmaceutical manufacturers, 364 licensed importers and 795 licensed wholesalers. A total of 8,993 scheduled poisons and 6,696 OTC products registered [8].

The manufacturing and marketing of pharmaceutical products in Malaysia are heavily regulated as in most developed countries. Medicines marketed in Malaysia are required to be registered by the Drug Control Authority (DCA) of the Ministry of Health. All manufacturers, importers and wholesalers are required to be licensed by the DCA. The registrations of prescription and OTC medicines require proof of efficacy, quality and safety, and are subjected to stringent screening and testing as well as regular and random post-marketing surveillance and testing. All manufacturers in Malaysia are subjected to regular and random inspection by DCA inspectors. Medicines are regulated under several acts such as: the Poisons Act, the Dangerous Drugs Act and the Drugs Act. Medicine advertisements require prior approval by the Medicines Advertisement Board. Malaysia is a member of the WTO and has acceded to the TRIPS agreement. Patents are registered and copyrights are protected (BMI, 2010) [7].

v) Myanmar:

A 1999 WHO study shows that Myanmar had 1 state-owned pharmaceutical firm, about 60 private small scale pharmaceutical plants, 20 importers, and 275 wholesalers. The public sector offered 144 drug outlets and the private pharmacies numbered about 8500. The total public sector drug expenditure was US$ 6.5 million. The total value of drug imports during the same period was US$ 0.9 million.

The production, trade and use of pharmaceutical come under the jurisdiction of three Ministries–Health, Trade and Commerce, and Industry. The Central Medical Stores Depot (CSMD) of Ministry of Health (MOH) imports drugs and distributes them to government hospitals and health care facilities. Most of the drug supplies from CSMD are purchased from the sole state-owned pharmaceutical company-the Myanmar Pharmaceutical Factory, which is under the Ministry of Industry. The Medicines and Medical Equipment Trading (MMET), under the Ministry of Trade and Commerce, imports drugs and distributes them to the public and to private clinics. Registration is required for imported and locally manufactured products for both the public and the private sectors. Registration is valid for a period of five years. Once a drug is registered, it can be imported into the country by anyone who has a license to import pharmaceuticals. As of 1995, there were a total of 1600 registered products. However, it was also found that more than 50% of the drugs in the market, including those domestically produced, were not registered by the authority.

vi) Philippines:

Medicaments containing antibiotics or their derivates are 73 out of the top 93 imports into the Philippines. However, pharmaceuticals cost more relative to drug prices in other Asian countries. Furthermore, pharmaceutical consumption per head in the Philippines is still relatively low. In 2009, spending on generics has reached US$361 million and the market share increased to about 14% from 12% in 2008. Key drivers of the generics sector are the increasing need for low-cost drugs, budgetary increases, new legislation, patent expirations and the push to increase compliance with public-sector generic prescribing and substitution (Philippines Pharmaceuticals, 2010) [7].

vii) Singapore:

Singapore's pharmaceutical industry remains one of the country's strongest components of its biomedical sciences sector since 1997 .It is the fourth pillar of manufacturing in Singapore, including electronics, chemicals and engineering (Yeo). The rapidly growing city state has developed into one of Asia's fastest growing bio-clusters to develop new medicines for regional and global markets. Today, Singapore is leading the way in the global manufacturing of innovative medicines and is now home to over 4,300 researchers, more than 50 companies and 30 public sector institutes with more than a billion dollars per year dedicated to research and development (SEDB, 2010).

The Centre for Drug Administration (CDA), under the Ministry of Health and Health Sciences Authority, is the main regulatory committee which monitors the quality and safety of all pharmaceutical production and imports. CDA also evaluates the applications and decides on product license approvals (Exhibit 12). Despite its relatively small – in regional terms – pharmaceutical market of US$560 million, Singapore still remains an attraction for multinational companies due to its well-developed economy and high per capita spending (BMI, 2010). Pharmaceutical market forecasts indicate the pharmaceutical market will reach US$601 million and have a compound annual growth rate of 3.26% by 2014 [7].

viii) Thailand:

As of the fourth quarter of 2010, nearly 80 of the 200 registered pharmaceutical firms in Thailand are multinational companies (BMI Thailand, 2010). Accounting for 40% of the overall industry, these multinational companies are increasingly concerned with the progression of the generic drug market in the country. Currently, generic medicines accounts\ for approximately 50% of market share value, and this percentage is expected to increase over the next five years with greater technology and development capabilities (BMI Thailand, 2010). Multinationals have expressed concern about the Thai government's support of the generic market through biased pricing towards local firms, reimbursement, and disadvantageous Intellectual Property environments. Despite these setbacks, there have been some positive signs of intergovernmental acceptance of testing methods with the resumption of free trade agreement (FTA) negotiations with the United States. These talks have the potential to decrease the number of generic drugs on the Thai market and keep the demand of prescription and patented drugs high, especially since physicians and hospitals will continue to prescribe specialized medicines and are the main gatekeepers of the healthcare system [7]. In 2002, the total value of production and import amounted to 44,012.51baht (about US$1143.18 million). Finished products locally manufactured took up 24,144.56 million Baht or 54.9% share of the market. From 1992 when the new Patent Act went into effect, rate of growth in the share of the original drugs in the Thai market increased 14 to 23% between 1993 and 1997 [8].

ix) Vietnam:

The drug supply in Viet Nam is run by two different groups. The first group is the state-owned manufacturing industries that fall under the General Pharmaceutical Company, where the Ministry of Health is the supervisory body. The second group is the manufacturing plants that are managed by the People's Committee for each respective province/city (Wondemagegnehu, 1991) [7]. from 1995, the domestic production outputs increased by an average of 15% per year, and reached US$ 251 million in 2003. This was accounted for 35% of the Vietnam market share, the rest was covered by imports. The products were distributed through hospitals and 10,500 retail pharmacies. The pharmaceutical industry is made up of public and private manufacturing facilities. At the end of 2003, there were 20 state firms, 590 private firms, and 28 projects with foreign investment capital in the pharmaceutical business. The number of GMP-certified firms increased greatly from 2 in 1997 to 41 in 2003 [8].

x) Brunei Darussalam:

There is separate cell for Pharmaceutical services and the Department of Pharmaceutical service is mainly responsible for executing the control of drugs. There are more than 3500 Pharmaceutical products are registered [9]. All medicinal products in Brunei Darussalam are controlled under the Medicines Order 2007 & Poisons Act 1956. As a preliminary step, the Department of Pharmaceutical Services (DPS) issues provisional registration of all medicinal products for human use prior to their use in Brunei Darussalam. All local manufacturers, wholesalers and importers of medicinal products must be licensed before they can conduct their businesses [10].

4. Contrasting the two extremes in drug regulation in ASEAN:

Brunei Darusalam and Singapore are the two ASEAN members with highest GDP per capita in this region. While Brunei does not have a system for drug registration, Singapore has one that is considered the most systematic and strongest regime. While Brunei does not have a pharmaceutical industry and it relies on imports for all its consumption needs, Singapore has the most advanced pharmaceutical industry in this region with the highest revealed comparative advantage value and highest investments in research and development among ASEAN members. With strong government policies on industry development and intellectual property protection, Singapore is able to attract significant investment in R&D from top multi-national pharmaceutical firms. The high level of R&D activities in Singapore is a result of its investment and research environment, not a result of a compromised and weak drug regulation system [8].

Table No. 3: Comparing the Pharmaceutical industry and regulation in Brunei and Singapore [8]

S. No.	Regulation	Brunei	Singapore
1	System of drug regulation: market Authorization	none	Strong
2	Local pharmaceutical manufacturing	none	high
3	Investment in pharmaceutical R&D	-	highest in ASEAN
4	Capability for new drug development and commercialization	none	high

5. ASEAN: Drug Regulation, Research, and Environment:

i) R&D Investments:

The level of investment in research and development in ASEAN is low, compared to North America, Western Europe and Japan. Worse, data on these investments are usually difficult to obtain, and data definitions might differ. From available data, Singapore stands out as the only country in this region with significant R&D investment in science and technology as shown below.

Table No. 4: R&D investment in science and technology

S. No.	Country	GDP/ capita 2003	R&D expenditure (%GDP)	Patents granted (per million people)	Researchers in R&D (per million people)
	Year		1996-2002	2000	1990-2001
1	Brunei	12,971	-	-	-
2	Cambodia	310	-	-	-
3	Indonesia	973	-	0	130
4	Lao, PDR	362	-	-	-
5	Malaysia	4,198	0.4	-	160
6	Myanmar	179	-	-	-
7	Philippines	973	-	-	156

8	Singapore	20,987	2.1	27	4052
9	Thailand	2,291	0.1	3	74
10	Viet Nam	481	-	-	274
11	ASEAN	1,266	-	-	-

ii) Pharmaceutical Sector:

All ASEAN member countries are net importers of pharmaceutical. With the exception of Brunei and Singapore, most have a pharmaceutical industry that remains at a formulation stage. This means that these countries import most raw materials to produce finished drug preparations locally. All countries also import finished products to fill domestic demand. In addition, some member countries manufacture finished drug products for export as well. ASEAN's main sources of pharmaceutical imports are Europe, US, Japan, and India. Imports of pharmaceuticals ranks as one of the top 10 commodities between ASEAN and Europe, and the share has grown continuously, as shown in **Table 5**. Pharmaceutical trade with India is also substantial, and ranked among the top 20 commodities in terms of ASEAN 6 imports from India. India is a key source of raw materials for the generic industry in the region. Per capita consumption of pharmaceuticals among ASEAN members vary greatly. Among the ASEAN 6 where data are available, the consumption ranged from US$ 3 in Indonesia to US$ 42 for Brunei [8].

Table No. 5: Imports of pharmaceuticals from EU by ASEAN 6 [8]

S. No.	Year	2000	2001	2002	2003
1	Value (US$ in millions)	647.5	716.1	829.8	1,013.5
2	Share of total imports (%)	1.7	1.8	2.1	2.4

In an effort to harmonise the pharma regulations through the ASEAN Common Technology Dossier (ACTD), the Association of Southeast Asian Nations (ASEAN) will mandate filing of the dossier as the only regulatory filing for the pharma industry to get approval for business in the 10-member states from 2012. The move will help the Indian generic pharma to grab the US$ 1.4 billion ASEAN market through a single window registration. However, it would also pose a threat for the country's drug research and clinical trial industry in near future, if the government of India is to neglect the need for change in regulations in tandem with the global requirements. With more than 60 per cent of the total market consisting of generic drugs, the Indian pharma firms can grab the opportunity to market their generic products in all the member countries through a single approval. The harmonization project, along with the new India-ASEAN Foreign Trade Agreement (FTA) offers a better opportunity for the Indian pharma exporters. The association expects that the harmonization of standards will help the member countries to lower the cost and increase the quality and availability of medicines in the region. It also aims to formulate rules for importing medicines, to ensure that the region will only have high quality drugs in the market. Rejection or alert on a product in one country will be applicable for all the member countries [11].

The Asia Pacific market is expected to grow from USD 187 billion in 2009 to nearly USD 275 billion in 2013, at a CAGR of 13%. This is mainly due to low cost availability of generic medicines, rising income, growth of business and health insurance schemes [12].

As part of the agreement signed by all the ASEAN countries, the Philippines will begin to only accept dossiers submitted under the ACTD (ASEAN Common Technical Dossier) Guidelines. While submitting guidelines under ACTD has been allowed since 2007, most companies opted to register under the local Philippine guidelines as the number of examiners for the ACTD was few in number, resulting in delayed registration. This step to only allow ACTD is in line with the other proposed changes in the Philippine FDA, including the recent decision to increase FDA fees in some areas by more than 1,000 %. The ACTD was scheduled along with the increase of fees to be implemented by July 1, 2013; however, with the recent resignation of Dr. Go the director of the FDA, the implementation of the ACTD and the fees has been delayed [13].

6. Experiences of ASEAN on Issues Related to Drug Regulation and Research:

ASEAN member countries share a number of common characteristics with regards to their pharmaceutical sector and regulation. Some of these characteristics can be said to reflect what found in developing countries in general. Key relevant characteristics are:

1. Drug regulatory frameworks in ASEAN member countries do not appear to discourage research and development of drugs and vaccines.
2. Drug regulatory capacities in the majority of ASEAN members are constrained by limited human and financial resources.
3. Gaps exist between written regulation and actual enforcement in a number of ASEAN member countries.
4. Among the member countries, only Singapore–which has the most advanced R&D and regulatory capability in the group–adopts a registration system that relies on product assessment and approval of other competent DRAs.
5. All ASEAN countries are net importers of pharmaceuticals. All except Singapore do not have capability for new drug development.
6. Evidence from some ASEAN members shows that R&D capability is a result of a country's investment and research environment, not a result of a compromised and weak drug regulation system.
7. The process of development and implementation of ASEAN harmonized registration standards follows the traditional ASEAN culture of consensus building and flexibility.
8. Levels of health insurance coverage among the populations of ASEAN members vary. In many countries, the majority of the population pays out-of-pocket for drugs. Consequently, even when drugs are available, affordability is a significant issue for access to necessary drugs. For countries with health insurance systems, high drug price affects system sustainability and service quality [8].

CONCLUSION

To develop harmonization scheme of pharmaceuticals regulations of the ASEAN member countries, to complement and facilitate the objective of AFTA, particularly, the elimination of technical barriers to trade posed by the regulations, without compromising on drug quality, efficacy, and safety depends on ASIAN PPWG regulations. A great number of new ideas and new developments have taken place worldwide which will evolve into different policy models. It is important for the international community to be able to learn from these models lessons of success and failure, to identify with what features and under what conditions one model works while another does not.

REFERENCES:

1. Naveen Kadian, Mohit Saini, Manas Tandon, Indo American Journal of Pharmaceutical Research, **2013**; 3(12): pp 1413-1423.
2. Apeksha Gupta, www.pharmatutor.org/articles/registration-dossier pharmaceutic--als.
3. Naveen Kadian, Mohit Saini, Manas Tandon, Indo American Journal of Pharmaceutical Research, **2013**; 3(12): pp 1413-1423.
4. Sneh lata, Rajendra songara, Asian Journal of Pharmaceutical Sciences and Research, **2012**; 2(6): pp 9-43.
5. http://www.hsa.gov.sg/content/dam/HSA/HPRG/Western_Medicine/Overview_Framework_Policies/Guidelines_on_Drug_Registration/ACTD_OrganizationofDossier.pdf
6. Mimansha Patel, Kunjal Patel, Indo American Journal of Pharmaceutical Research, **2013**; 3(2): pp 1746- 1751.
7. Hutagalung, Martin, and US-ASEAN Business Council, Harmonization and Standardization of the ASEAN Medical Industry.
8. Ratanawijitrasin, Sauwakon. Drug Regulation and Incentives for Innovation: The Case of ASEAN, No. id: 2248, 2009.
9. Guide to Application for Registration of Medicinal Products, 2nd ed., Brunei Darussalam; **2008**; p 117.

10. http://www.scribd.com/doc/104779057/Drug-Registration-in-ASEAN-Countries
11. Gireesh Babu, ASEAN harmonises drug registration norms, CTD filing to be mandatory from 2012, leave freedom, last accessed Saturday, January 23, **2010**.
12. Jitendra Kumar Badjatya, Journal of Drug Delivery & Therapeutics, **2013**; 3(2): pp 227-232.
13. Judah Z Hirsch, FDA philippines delays introduction of ACTD guidelines, www.tripleiconsulting.com, last accessed june 28, **2013**.

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