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Actd regulatory requirements for approving an anticancer drug (thioguanine)

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Abstract

This work makes document handling safer and more accessible. It can manage even more complex papers in addition to all the benefits. Using this work, a composite document or papers from several different document sources and formats can be assembled, updated, and published. Each document is treated as a single, identically organized document. BMR, Process Validation Record, Stability Study (including Accelerated & Long Term Stability Study per Myanmar Zone Specification), Anticancer Drug Packing Requirements, and Certificate for Product Permission (covering all aspects from manufacturing to its packing & registration) are among the required documents. It offers reliable scientific methods for determining the effectiveness, safety, and quality of medicinal items. It will assist in comprehending the documentation needs for drug registration in Myanmar.

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INTRODUCTION

Regulatory Affairs is essential to the global protection of public health. By regulating the safety and efficacy of the product, governments in many nations have devised regulations for pharmaceutical, cosmetic, medical device, veterinary, agrochemical, and supplementary medicines. Pharmaceutical firms play a crucial role in community health by offering products that are high-quality, safe, and effective [1]. Companies use product detection, evaluation, formulation, and marketing processes to meet these standards. Government affairs is another name for regulatory affairs (RA). It is a career in one regulated sector,

which includes banking, energy, medical devices, and pharmaceuticals. The primary responsibilities of RAs are to gather, evaluate, and disseminate information regarding the risks, benefits, safety, and effectiveness of medical goods [2].

Additionally, it has a particular meaning in the healthcare industries (pharmaceuticals, medical devices, biologics, nutraceuticals, cosmeceuticals, and functional foods). Regulatory affairs professionals make up most businesses, whether small, inventive biotechnology startups or large, multinational pharmaceutical corporations [3]. The primary approaches in regulatory matters depend on communication, application, and interpretation inside and outside the industry. The discipline of RA focuses on creating new standards and procedures for assessing the performance, quality, safety, and efficacy of medical devices and controlled pharmaceuticals [4].

METHODOLOGY

Dossier Format – ASEAN CTD

The ASEAN nations developed the ACTD as their submission format. This standard was developed using the ICH CTD. The ASEAN CTD serves as a reference for the commonly accepted methodology for creating an organized ACTD application, which is then submitted to ASEAN regulatory bodies to register drugs for human use. The ICH CTD and the ACTD are comparable. While the ACTD comprises four sections, the ICH CTD is divided into five modules. This is done because the ASEAN nations typically receive a reference application—a dossier previously accepted in other countries, primarily the USA and the EU—and base their appraisal of the component components mostly on the overviews and summaries [5]. This means that, compared to ICH countries, most ASEAN countries have less of a requirement for thorough documentation; for example, most study reports are not mandated to be filed. Part 1 of the ACTD is still called Module 1 of the CTD, which contains the administrative and regional registration data [6]. For the ACTD, Module 2 of the CTD does not exist in and of itself. These Parts begin with the Quality Overall Summary (QOS), followed by an overview and summaries of the clinical and nonclinical documentation (comparable to the papers in ICH Module 2). The pharmaceutical-chemical-biological documentation, or quality information, is found in Part II of the ACTD and is in line with ICH Module 3. By ICH Module 5, the clinical documentation is located in Part IV of the ACTD. At the same time, the nonclinical material is supplied in Part III of the document (similar to ICH Module 4) [7].

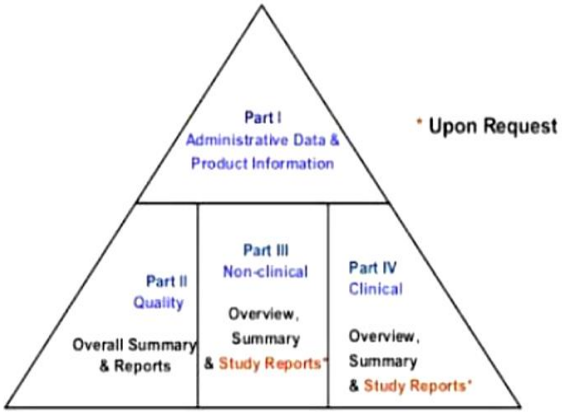

Figure 1 ACTD Organisation

Table 1 The distinction between ICH CTD and ACTD

Documents	Location in	
	ICH CTD	ACTD
Product details and administrative documents	Module 1	Part I
Overview and Summaries of Common Technical Documents	Module 2	Incorporated in Parts II, III & IV
Quality documents	Module 3	Part II
Nonclinical documents	Module 4	Part III
Clinical documents	Module 5	Part IV

Principles

The following principles of ASEAN's foundation are outlined in the Treaty of Amity and Cooperation in Southeast Asia [8]:

- Respect for each other's national identities, territorial integrity, equality, and independence.

- Respect for each other's independence, sovereignty, equality, territorial integrity, and national identity.
- Every State has the right to govern its national life without outside intervention, subversion, or coercion.
- Non-interference in each other's domestic issues.
- Peaceful resolution of disagreements or disputes.
- Refusing to threaten or use physical force.
- Their effective collaboration with one another

Regional Integration

The following tenets of ASEAN's foundation are outlined in the Treaty of Amity and Cooperation in Southeast Asia [9]:

- a region of equal economic growth
- a highly competitive economic region
- a single market and production base
- a territory that is included in the world economy

While low- and semi-skilled labor mobility in ASEAN is controlled by state regulations and bilateral agreements, the AEC advocates for the free flow of skilled labor.

Future

By the AEC, skilled labor, capital, investment, and goods will all be able to flow freely throughout ASEAN. Because of the tremendous economic opportunities the AEC has brought, it is projected that people in the ASEAN region will relocate. A 2007 declaration on the protection and promotion of migrant workers' rights was signed by all ASEAN member states. According to the Declaration, migrant workers shall have adequate access to respectable living and working conditions and fair and suitable employment protection. A consensus on the ASEAN Framework Instrument for the protection and advancement of migrant workers' rights must be reached by Member States by 2020 [10].

Pharmaceuticals

The 1992 National Drug Law of Burma is often known as Myanmar. The production, import, export, storage, distribution, and sale of pharmaceuticals in Myanmar are all subject to strict regulations thanks to this legislation, which is the primary legislation controlling the industry. The writers walk the reader through the complexities of the Act, as well as the organizations and regulatory frameworks it establishes, outlining their functions and issues. In 1992, Myanmar (Burma) passed the National Drug Law, sometimes called the "ND Law." Control and systematic regulation of the production, import, export, storage, distribution, and sale of pharmaceuticals is the fundamental goal of the ND Law[11].

Table 2 General Comparison of ASEAN Countries

Validity format	Country	Followed format	Included in thesis
5 yrs	Singapore	ACTD	ACTD
5 yrs	Malaysia	ACTD	ACTD
5 yrs	Thailand	ACTD	ACTD
5 yrs	Philippines	Country specific & ACTD	Country specific
5 yrs	Indonesia	ACTD	ACTD
5 yrs	Vietnam	ACTD	ACTD
5 yrs	Brunei Darussalam	ACTD	ACTD
5 yrs	Myanmar	Country specific & ACTD	Country specific
5 yrs	Cambodia	ACTD	ACTD
5 yrs	Laos	Country specific & ACTD	Country specific

Technical Documents required

Administrative documents

Comprehensive

Table of Contents

Introduction

Application

Package insert, labeling, and patient information leaflets

Approved patient information leaflet (PIL) and approved summary product characteristics (SPC)

Reference Agencies' Assessment Report

An explanation of the batch numbering system

Proof of Approval

Authorization Letters

GMP Certification/Proof of GMP Compliance

Patent declaration

A statement on denial, withdrawal, and postponement

Declaration for GDA verification

Status of international registration [12].

Quality documents

Drug Substance

Drug Master File (DMF)

Body of Data

Suitability Certificates (CEP)

Control of Substances Used in Drugs

Data on Drug Substance Stability

Product of Drug

Pharmaceutical Development

Process Validation

Control of Excipients

Control of Drug Product

Container Closure System

Stability Information for Medicinal Product

Exchangeability of Products

Recordings of Blank Production Batches [13]

Registration dossier

To avoid application processing delays, the entire dossier must be supplied within two working days of submitting the PRISM application. The moment HAS receives the whole set of application data is when the submission date is determined [14].

Drug Registration procedure and approval system

A drug registration application must be filed in the original required form (Form 1 Registration) to the Ministry of Health of the Republic of the Union. The Department of Food and Drug Administration offices in Yangon, Naypyitaw, and the Department of Food and Drug Administration are where Form (1) can be obtained for one thousand Kyat each. Pharmaceutical compositions with varying dosage forms or strengths require a separate registration application [15]. The documents indicated under "Documents Required for Registration of Drugs" must be filed in the correct sequence. The first page of the file should contain a list of all the papers that have been submitted. Each drug sample must have its corresponding analytical report (the certificate of analysis) attached. The application must be submitted with a sample (20gm). The sample needs to be correctly labeled and packed [16].

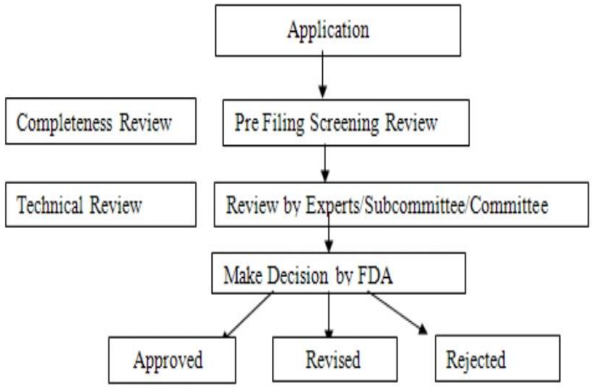

Figure 2 Drug Review Process Flow Chart

RESULTS AND DISCUSSION

Several elements are responsible for this surge in the approval of new drugs:

Increased New Drug Applications

Over the previous ten years, there has been a slight increase in the annual number of New Drug Applications (NDAs) and Biologic Licence Applications (BLAs) filed. An average of 23 approvals were made between 2006 and 2016, increasing to 35 in 2017, 39 in 2018, 45 in 2020, and 46 in 2021. In 2022, 59 new agents received approval. It is possible for an application to be submitted in one year and granted in another. The quantity of new medication applications may

impact the total number of approvals in a particular year. The total number of new medications approved annually is shown in **Figure 1**.

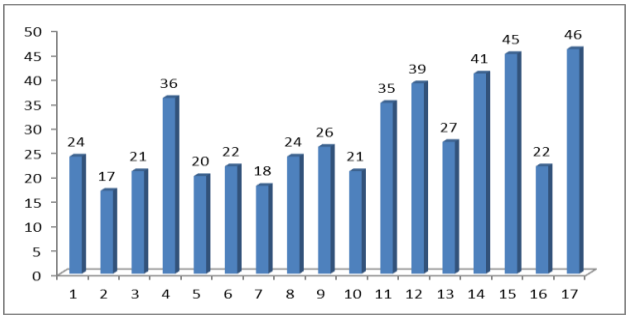

Figure 3 Year-wise new drug approval

First-in-Class and Orphan Approvals

The type of new drugs that are proposed to the FDA for approval has also changed recently: in 2017, CDER approved 20 agents with a unique mechanism of action (first-in-class approvals); in 2020, 21 such approvals were made, and in 2022, 15 approvals were made. While FDA first-in-class approvals ranged from approximately 3 to 15 medicines annually between 1987 and 2015, those are comparatively large numbers (remember that these ranges apply only to new molecular entities (NMEs), not to NMEs and biologics). CDER received five orphan approvals on average between 2006 and 2016, whereas it received eight in 2022, nine in 2021, and twenty-one in 2020. These are some of the most significant numbers in recent history; as a result, since 2000, the total number of FDA orphan approvals has increased consistently. Therefore, the rise in CDER approvals may have been attributed to the unique and novel features of the medications submitted to the FDA in 2015 and 2017. The number of orphan medications approved annually is displayed in **Figure 2**.

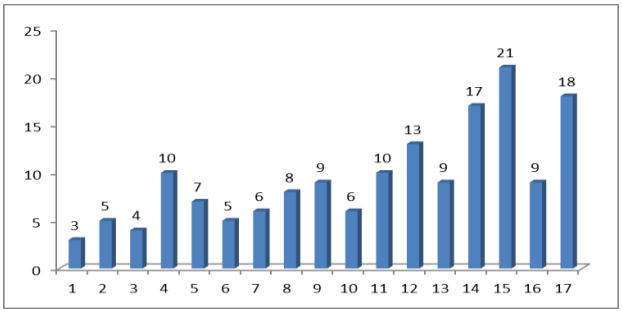

Figure 4 Amount of orphan drugs authorized over several years

Increase in first-cycle approvals

CDER authorized 204 new drugs between 2016 and 2021; 166 (81%) were approved during the first cycle. 39 of the 46 new medicines (85%) were undergoing review during the "first cycle" in 2022. In line with this average is the rate for 2022.

This high percentage of first-cycle approval is a reflection of the lengthy conversations that take place during the medication development process between CDER professionals and drug developers. For this reason, an application must have all the pertinent details the CDER needs to evaluate and understand thoroughly.

Current Programmes for FDA Expedited Approval: The FDA's approach to collaborating with businesses on novel drug development initiatives has changed. Today, the FDA has four pathways for faster development and/or review: fast track, breakthrough therapy, priority review, and accelerated approval. These pathways can be used separately or in combination.

18 of the 46 authorized innovative medications in 2022 (or 39%) received fast-track designations; examples include valbenazine for tardive dyskinesia and ocrelizumab for multiple sclerosis. 28 (61%) received priority review, including dupilumab for atopic dermatitis and midostaurin for acute myeloid leukemia; 6 (13%) received accelerated approval, including benznidazole for Chagas disease. 17 (or 37%) of them were classified as ground-breaking treatments. Since 2000, the number of people using these accelerated programs has been rising consistently.

The breakthrough therapy designation was established in 2017; its effects are now starting to appear. However, the designation is being used more frequently; in 2022, 17 applications were approved, compared to just 3 in 2018.

Stated differently, expedited programs speed up the development and review of new medications, which may account for the rise in CDER approvals in recent years. In the United States, Europe, and Japan, accelerated regulatory paths for new drug development aim to expedite the delivery of innovative treatments to patients.

These have increased recently, presenting developers, patients, regulators, and payers with advantages, disadvantages, and opportunities.

Table 3 List of cancer-preventative drugs authorized in the past 20 years

Year	No	Drug	Indication
2005	2	Triptorelin pamoate Arsenic trioxide	Advanced cancer of the prostate Intense promyelocytic leukemia
2006	1	Imatinib mesylate	CML
2007	2	Oxaliplatin, Fulvestrant	Metastatic colon or rectal cancer Meta breast cancer
2008	3	Gefitinib, Bortezomib, Abarelix	Non-small cell lung cancer in metaphase numerous myeloma, Advanced cancer of the prostate
2009	4	Pemetrexed disodium, Azacitidine, Erlotinib HCl, Clofarabine	Pleural mesothelioma with malignancy Chronic myeloid leukemia (CML) and nonsmall-cell lung cancer, Refractory or relapsed Everyone
2010	2	Nelarabine, Sorafenib tosylate	T-cell ALL, Advanced RCC
2011	4	Sunitinib malate Decitabine, Dasatinib Vorinostat	Gastrointestinal stromal tumor, MDS CML, Cutaneous T-cell lymphoma
2012	4	Lapatinib, Tesirolimus Ixabepilone, Nilotinib	Breast cancer, RCC, Meta breast cancer, CML
2013	3	Bendamustine, Hydrochloride, Iobenuane, Degarelix	CLL, Pheochromocytoma Prostate cancer
2014	4	Everolimus Pralatrexate injection Pazopanib tablet Romidepsin for infusion	Advanced RCC, Relapsed or refractory peripheral T-cell lymphoma Advanced RCC Cutaneous T-cell lymphoma
2015	2	Cabazitaxel eribulin mesylate	Prostate cancer Metastatic breast cancer
2016	6	Brentuximab vedotin Vandetanib Eribulin mesylate Crizotinib Vemurafenib Abiraterone acetate	Both ALCL Meta medullary thyroid carcinoma and Hodgkin's lymphoma Breast cancer that has spread Lung cancer with nonsmall cells Melanoma that spreads Cancer of the prostate
2017	9	Vismodegib, Carfilzomib TBO-filgrastim, Enzalutamide, Bosutinib Regorafenib, Omacetaxine, mepesuccinate, Cabozantinib, Ponatinib	Basal cell carcinoma, Multiple myeloma Cancer chemotherapy-induced severe neutropenia Prostate cancer, CML, Colorectal cancer CML, Medullary thyroid cancer, CML
2018	7	Pomalidomide, Ado- trastuzumab emtansine Dabrafenib, Trametinib Afatinib, Ibrutinib	Several myeloma, Melanoma and metastatic breast cancer, Melanoma Nonsmall cell lung cancer metastases lymphoma with mantle cells
2019	4	Olaparib Idelalisib Belinostat Ceritinib	Advanced ovarian cancer Blood cancer peripheral T-cell lymphoma Nonsmall cell lung cancer

Table 3 List of cancer-preventative drugs authorized in the past 20 years (continued)

Year	No	Drug	Indication
2020	10	Alectinib	Lung cancer with ALK positivity
		Ixazomib	several myeloma
		Osimertinib	Lung cancer with nonsmall cells
		Sonidegib	BCC
		Cobimetinib	Melanoma at advanced stages
		Trabectedin	Sharp tissue tumors
		Trifluridine and tipiracil	advanced colorectal cancer
		Panobinostat	several myeloma
		Lenvatinib	Resistant thyroid cancer
		Palbociclib	Breast cancer with metastases
2021	2	Venetoclax	Lymphocytic leukemia
		Rucaparib	Ovarian cancer
2022	9	Acalabrutinib	lymphoma with mantle cells
		Abemaciclib	breast tumors with metastases
		Enasidenib	Refractory AML
		Copanlisib	Follicle lymphoma relapse
		Neratinib maleate	Lower the chance of recurrent breast cancer.
		Midostaurin	AMY
		Brigatinib	Positive for (ALK) nonsmall cell lung cancer
		Niraparib	fallopian tube, peritoneal, and recurrent
		Ribociclib	epithelial ovarian carcinoma
			advanced carcinoma of the breast

Therapeutic Area

More fast-track, expedited, and priority approvals for cancer drugs were granted between 2000 and 2017 than for any other therapeutic field. This information is especially noteworthy because, as of 2020, oncology accounted for the most significant number of newly authorized treatment areas. 2022 there will be an increase; 12 out of 46 medications are anticancer medicines. Maybe 23 of the 55 medications in 2023 are anticancer ones. The approval rate of cancer medicines in recent years may have been influenced by the ongoing demand for these treatments and their track record of accelerated approval (based on surrogate endpoints). The approved anticancer medication list is highlighted in the table below. The similar pattern is shown in **Figure 5**.

The following are some of the categories in the drug approval process:

First-in-class

First-in-class drug approval refers to a drug with a unique mechanism of action. It is not comparable to any medications currently on the market for a given medical condition. Opelizumab for multiple sclerosis (2022) and palbociclib (2020) for metastatic breast cancer are some of the noteworthy approvals in this category.

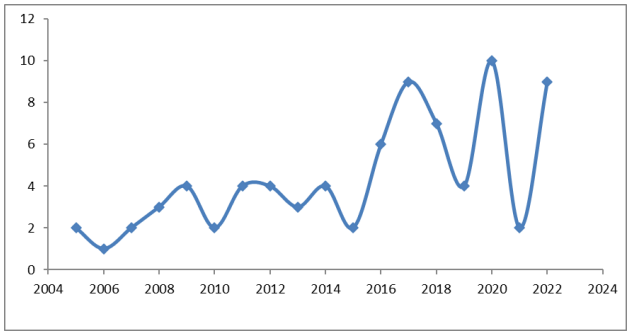

Figure 5 Trend in the approval of anticancer drugs over several years

Drugs for rare diseases (orphan drugs)

Orphan drugs have been approved by fewer than 200,000 patients or a tiny patient group. Patients with rare diseases have extremely few alternatives when it comes to treatment.

First cycle approval

This includes the drug approval process, which consists of a single review cycle. Most medications are approved under this classification;

Table 4 Expedited procedures for drug approval

Fast track approval
Drugs with the capacity to treat insufficient medical needs. By enhancing contact with drug developers or examining parts of a drug application before the complete application is submitted, fast track accelerates the development and review of new drugs.
Breakthrough approval
Drugs with early clinical data suggest they could significantly outperform other treatments for severe illnesses in terms of at least one clinically significant endpoint (i.e., study result). The fast-track program's benefits are included in a breakthrough therapy designation and more thorough FDA instructions on running a successful drug development program. Reduce the time it takes for a possible new therapy to develop.
Priority review
Drugs can significantly improve medical treatment, and established a goal to review the drug in six months as opposed to the usual ten.
Accelerated approval
Early approval of a drug based on a "surrogate endpoint" (e.g., a laboratory measure) or other clinical measure deemed reasonably likely to anticipate a clinical benefit of the medication for a severe or life-threatening illness that offers a benefit above present treatments. However, the medication must undergo more studies after approval to validate that benefit. (Phase IV)

Table 5 Comparing administrative records across ASEAN nations

Administrative Documents	Singapore	Malaysia	Thailand	Indonesia	Vietnam	Brunei	Cambodia
Application Form	✓	✓	✓	✓	✓	✓	✓
Copy of a current clearance certificate for the trademark name	✓	✓	✓	✓	✓	✓	✓
Pharmaceutical Product Certificate	✓	✓	✓	✓	✓	✓	✓
Free Sale Certificate	×	×	×	×	×	×	×
Good Manufacture Practice	✓	×	✓	✓	✓	✓	✓
Pharmaceutical Manufacturer's License	×	×	✓	✓	✓	✓	✓
Site Master File	✓	✓	✓	✓	✓	✓	✓
Authorisation for production and promotion within the nation of origin	×	×	×	×	×	×	×
Letter of Authorization	✓	✓	✓	✓	✓	✓	✓
Labeling Documents	✓	✓	✓	✓	✓	✓	✓
Patent Information	✓	×	✓	✓	×	✓	✓
Overview of Product Features	✓	✓	✓	✓	✓	✓	✓
Patient Information Pamphlet	✓	✓	✓	×	×	×	×
Product details that have been authorized in any state or nation	✓	✓	×	×	×	✓	×

Table 6 Comparing technical documentation among ASEAN nations

Technical Documents	Singapore	Malaysia	Thailand	Indonesia	Vietnam	Brunei	Cambodia
✗	✗	✗	✗	✗	✗	✗	✗
✗	✓	✓	✓	✓	✓	✓	✓
✗	✓	✓	✓	✓	✓	✓	✓
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✓	✓	✓	✓	✓	✓	✓	✓
✓	✓	✓	✓	✓	✓	✓	✓

Table 7 Comparing nonclinical documents across ASEAN nations

Nonclinical Documents	Singapore	Malaysia	Thailand	Indonesia	Vietnam	Brunei	Cambodia
Nonclinical overview	✗	✓	✓	✓	✓	✓	✓
Nonclinical written & Tabulated summary	✗	✗	✗	✗	✗	✗	✗
Nonclinical Study Reports	✗	✗	✗	✗	✗	✗	✗
Literature references	✗	✗	✓	✓	✓	✓	✓

Table 8 Comparing clinical documentation across ASEAN nations

Clinical Documents	Singapore	Malaysia	Thailand	Indonesia	Vietnam	Brunei	Cambodia
Clinical overview	✗	✗	✓	✓	✓	✓	✓
Clinical Summary	✗	✗	✗	✗	✗	✗	✗
Tabular Listing of All Clinical Studies	✗	✗	✗	✗	✗	✗	✗
Clinical Study Reports	✗	✗	Only BE	Only BE	Only BE	Only BE	Only BE
List of Key Literature	✗	✗	✓	✓	✓	✓	✓

examples include evolocumab (2020) for hypercholesteremia and Deflazacort (2022) for Duchenne muscular dystrophy.

Table 9 Myanmar documentation requirements

Documents	Myanmar
Application Form	✓
Certificate Of Pharmaceutical Product	✓
Site Master File	×
Summary of Product Characteristics/PI	×
GMP Certificate of API Mfr	×
Manufacturing License of FPP Mfr	✓
Marketing Authorization In The Country of Origin/ FSC	×
WHO-GMP Certificate	✓
Properties of API (Active Pharmaceutical Ingredient)	✓
Route of Synthesis of API	×
Process Validation of API	×
API Specification	✓
API Certificate of Analysis	✓
Stability Testing	×
Analytical Method Validation	×
Unit Dose & Batch Formula	×
Master Formula	✓
Manufacturing Process	×
In-Process Specifications	✓
Process Validation of FP	×
Monograph- Excipients	✓
COA- Finished Pharmaceutical Product(Certificate of Analysis)	✓
Specifications of Finished Pharmaceutical Product	✓
Monograph of Finished Pharmaceutical Product	✓
Analytical Method Validation	×
Container Closure System	✓
Stability	✓
Labels	✓
Pharmacology, Toxicology	✓
Raw Material Specifications	×
The product has already been approved in other countries.	✓
BE Requirements	✓

Combined expedited approval methods

Innovative regulatory approval techniques, such as breakthrough approval, extended access programs, fast track, rapid approval, and priority review, are used by CDER. NMEs frequently need more than one medication approval procedure from the classifications mentioned above. These accelerate the time lag between research and development and commercial availability.

Examples of medications that are licensed under many categories. The US FDA also unveiled the Regenerative Medicine Advanced Therapy (RMAT) program in March 2017, a new initiative to speed up and simplify the development and review of regenerative medicines.

CONCLUSION

To produce several harmonized papers, the drug regulatory bodies and industry in ASEAN have worked closely together, both within the region and more and more with worldwide organizations.

These are the current evolving ASEAN Common Technical Requirements. Although each member nation has its registration procedures, including labeling and administrative paperwork, the ACTD format became mandatory in 2009.

This work makes document handling safer and more accessible. It can manage even more complex papers in addition to all the benefits. Using this work, a composite document or papers from several different document sources and formats can be assembled, updated, and published. Each document is treated as a single, identically organized document.

BMR, Process Validation Record, Stability Study (including Accelerated & Long Term Stability Study per Myanmar Zone Specification), Anticancer Drug Packing Requirements, and Certificate for Product Permission (covering all aspects from manufacturing to its packing & registration) are among the required documents.

It offers reliable scientific methods for determining the effectiveness, safety, and quality of medicinal items. It will assist in comprehending the documentation needs for product registration in Myanmar.

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Conflict of Interest

The authors declare no conflict of interest, financial or otherwise.

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REFERENCES

[1] J K Badjatya. Overview of drug regulatory affairs and regulatory profession, International Journal of Drug Regulatory Affairs, 1(1):1-4, 2013.

[2] B Brahmaiah, Y Harsha, D Mary, M V Nagabhusanam, D N Reddy, and V S Reddy. Role of regulatory affairs in a pharmaceutical industry volume. International Journal of Pharmaceutical Research and Bioscience, 6(2): 170-177, 2017.

[3] B V Yogesh Kumar. Regulatory Affair: Link between company and Government Authority. Pharma Tutor. | magazine.pharmatutor.org, 2(6);9-20, 2015.

[4] K S Christian, and M Torbjo. The emergence of regulatory science in pharmaceutical medicine. Switzerland: Springer International Publishing; Pharm Med, 27:345–351, 2013.

[5] R Hasumati. Historical Overview of Pharmaceutical Industry and Drug Regulatory Affairs. Kurz, Pharmaceutical Reg Affairs, 002:1-11, 2021.

[6] R Keshari, and A Jha. Role of regulatory affairs in pharmaceutical company: an overview. Global Journal for Research Analysis, 7(1):51-53, 2018.

[7] M Neeti, D Shweta, and K Vrinda. Globalization of Regulatory Affairs in the healthcare industry. Asian Journal of Pharmaceutical Clinical Research, 8(6): 46-49, 2015.

[8] N D Mdege, T Chevo, and P Toner. Perceptions of pharmacists' current and potential public health involvement in developing nations: the case of Zimbabwe. Res Social Adm Pharm, 12(6):876–84, 2016.

[9] M H Khan, M Akazawa, E Dararath, H B Kiet, T Sovannarith, and N Nivanna. Perceptions and practices of pharmaceutical wholesalers surrounding counterfeit medicines in a developing country: a baseline survey. BMC Health Serv Res, 11:306, 2011.

[10] R Rezaie, A M McGahan, S E Frew, A S Daar, and P A Singer. The emergence of biopharmaceutical innovators in China, India, Brazil, and South Africa as global competitors and collaborators. Health Res Policy Syst, 10:18, 2012.

[11] P Nagaraju, N Flary, B M Kumar, D Nagarjuna Reddy, and M V Nagabhushanam. Comparison of generic drug registration requirements in ASEAN countries. IJRPC, 5(1):145-9, 2015.

[12] A Thida and J Finch. Pharmaceuticals in Myanmar - Law and Procedure. Singapore Journal of International and Comparative Law, 4:115-147, 2000.

[13] A. Jain, K T M Pramod, G R M Reddy, and M P Venkatesh. Regulatory requirements & marketing authorization of generic drugs in Singapore & Thailand. International Journal of Drug Regulatory Affairs, 3(1): 62-74, 2015.

[14] P Praneeth. Regulatory Affairs and its Role in Pharmaceutical Industry, SSRG International Journal of Pharmacy and Biomedical Engineering, 3(1):1-2, 2016.

[15] G T K Reddy, and G N K Reddy. Significance of Pharmaceutical Regulatory Bodies - A Review; PharmaTutor, 5(8);15-22, 2017.

[16] P B Dixit and M Dilip. Regulatory Requirement for the Approval of Generic Drugs in Thailand as per ASEAN Common Technical Dossier (ACTD) - A Review. JPSBR, 4(4):243 -51, 2014.