Pharmaceuticals Export Promotion Council of India

(Set up by Ministry of Commerce & Industry, Government of India)

REGULATORY & MARKET PROFILE OF MYANMAR

DEMOGRAPHY

SL. No	Parameter	Description
1	Region	ASEAN
2	Country	Myanmar
3	Capital	Yangon
4	Population	55,622,506 (July 2018 est.)
5	Population growth rate (%)	0.89% (2018 est.)
6	GDP (purchasing power parity)	$ 329.8 billion (2017 est.)
7	GDP - real growth rate (%)	6.8% (2017 est.)
8	GDP - per capita (PPP)	$6,300 (2017 est.)
9	Epidemiology	Diabetes, Cancer, CVS diseases, HIV
10	Population below poverty line	25.6% 2016 est
11	Age structure (%)	0-14 years: 26.56%
		15-24 years: 17.51%
		25-54 years: 43.51%
		55-64 years: 7.75%
		65 years $ above:5.67%
Source: CIA World Fact Book updated to July 2018		

Introduction:

Myanmar is a growing economy and is continuously supported by Government reforms. In the years to come it's manufacturing and construction sectors which would drive the economy. Its healthcare infrastructure is gradually growing. Its Pharmaceutical **market size was $ 456 million in 2017,** and it is expected to touch $ 492 million by the end of 2018 with a growth of 7%. **Percapita pharma expenditure was $ 8.5 in 2017**

Latest Updates

- In August 2018, the Myanmar Pharmaceutical Industrial Enterprise revealed that Myanmar imports pharmaceuticals and medical equipment worth USD400mn, with local production now meeting approximately10% domestic demand.

- In September 2018, the government called on countries in the Mekong basin to cooperate in combating the rising problem of antimicrobial resistance (AMR) through a regional health security project.

Market Overview

Country's pharmaceutical market is valued at USD 456 Million in 2017. This value is lower than that of most of the ASEAN countries, placing Myanmar below even Singapore in terms of absolute pharmaceutical market size, despite its much larger population (60mn versus 5mn). Looking ahead to 2022 the market is forecasted to touch $ 656 million.

There has been no proper audit of the market and the rough estimates put the market share of OTC to be the highest and the prescription market is accessed only by the rich and top Government official of all the departments.

Myanmar's government has begun to introduce private health insurance programmes to the country that bode well for the healthcare sector.

Currently MNCs interest in this market is of lukewarm nature. It is hoped that passing of the new Myanmar Companies Act will open up previously closed sections of Myanmar's economy to foreign investment including the industrial equipment and pharmaceuticals sector. The new law might bode well for foreign direct investment inflows. Investment in the localized production of medicines by multinational pharmaceutical companies is likely to increase.

In June 2017, the Ministry of Commerce's Notification 36/2017announced that it had relaxed the prohibition on foreign trading, allowing 100% foreign-owned companies to distribute and retail certain limited categories of products (including hospital equipment) to the domestic market and obtain import licenses.

Rural markets of the country is dominated by the traditional medicines. India's exporters are to be encouraged to visit rural markets of the country especially of Ayush products.

Epidemiology

Currently both communicable & non communicable diseases more or less equally balanced. Diabetes, cancer, CVS diseases along with HIV are predominant.

Novo nordisk of Denmark has invested over $1.2 million in Diabetes care program setting up a diabetes excellence care unit, specialized program for diabetes care in Children and training of doctors and Paramedic staff in diabetes care over a period of Four years.

Pharmaceutical Trade:

Country is very reliant on imported pharmaceutical products. This trend is expected to continue in the long term, bringing opportunities particularly to overseas generic drugs producers.

As of 2017, data from UN Comtrade notes that total imports amounted to USD349mn and is expected to rise to USD511mn by 2022. This is a compound annual growth rate of 7.9%.

India's is one of Myanmar's key trading partners. India (USD181.5mn) was the main import source of pharmaceutical products in 2017, followed by Thailand (USD46.8mn), Indonesia (USD32.9mn), Singapore (USD5.2mn)and China (USD26.5mn). The country also exports pharmaceuticals to a few countries. In 2017its top export markets were Malaysia (USD66,331), Pakistan (USD25,200), and Japan (USD16,848).

In September 2017, India and Myanmar formed a chamber of commerce (IMCC) in Yangon represented by large Indian corporations, small and medium enterprises, and entrepreneurs based in Myanmar to boost trade and forge closer economic ties between the countries

Myanmar is also gradually stepping up efforts to increase bilateral trade with its ASEAN partners. In line with this outlook, Indonesia based conglomerate, Lippo Group, opened its first hospital in Myanmar in June 2015. According to its Chief Executive Officer James Riady, the company intends to maintain the rapid expansion of facilities with the aim of having 20 hospitals in Myanmar within the next three to five years. Additionally, bilateral trade between Myanmar and Vietnam hit USD538mn as of December for the 2017-2018 fiscal year, already up 9% over the entire 2016-2017 fiscal year trade of USD494mn. In January 2018, Indonesia-based pharmaceutical company PTPhapros Tbkand Myanmar-basedMedi Myanmar Group established a joint venture to further develop the pharmaceutical and medical devices industries in both countries.

Local Industry

As of 2018, local pharmaceutical production meets 10% of domestic demand, according to the Myanmar Pharmaceutical Industrial Enterprise (MPIE).

Indian generic firms are the main foreign companies operating in Myanmar. Companies with branches in the country include Ranbaxy, Wockhardt and Cipla. Majority of multinational pharmaceutical firms do not have operations in the country. It is hoped that the situation will improve as the country undergoes economic reform that will lead to a growing appreciation of better healthcare provision. Given the highly risky operating environment, poor quality of infrastructure in the country and fragmented nature of the industry, foreign pharmaceutical firms are likely to leverage pharmaceutical distributors. Leading distributors are DKSH, SeaLion and Mega Lifesciences. According to local media, Myanmar Times, as of May 2015, six foreign direct investment proposals to build pharmaceutical manufacturing firms were approved but only two are in operation.
They are - FAME pharmaceuticals and AA Medical Products.

New Companies Act:

The New Companies Act passed in late December 2017 will enable foreign companies to acquire a stake of up to 35% in local companies (compared with none previously) and stipulates that businesses with foreign stakes of more than 35% will be considered foreign rather than domestic. Under the Companies Act of 1914, any company with even as little as a 1% foreign stake was classified a foreign company; however, under the new law, foreign-domestic partnerships will be considered local companies as long as the foreign share does not exceed 35%. This move could encourage foreign-domestic partnerships and joint ventures, resulting in a greater transfer of skills and capital into the Myanmar economy. The Asian Development Bank (ADB) hailed the act as 'an important foundation for the creating of the business environment in Myanmar'.

Statistics:

A rough estimate shows that 12- 15% of India's formulation exports are to Governmental organizations and International NGO's.

India's Pharmaceutical exports to MYANMAR $ Million						
Category	**2015-16**	**2016-17**	**2017-18**	**GR%**	**Contbn %**	**Contbn to Region**
Bulk Drugs and Drug Intermediates	0.61	1.05	1.43	36.22	0.78	0.47
Drug Formulations and Biologicals	141.08	177.27	172.65	-2.61	94.87	23.62
Ayush	0.56	0.70	0.66	-4.83	0.36	8.13
Herbal Products	0.28	0.43	0.50	15.49	0.27	1.71
Surgicals	0.92	1.33	1.62	21.66	0.89	7.47
Vaccines	10.51	5.58	5.13	-8.13	2.82	5.96
Total	153.96	186.36	181.98	-2.35	100.00	15.41

Imports

Myanmar ' Top ten formulation Importing partners $ Million						
Rank	**Country**	**2015**	**2016**	**2017**	**Gr%**	**Share%**
1	India	65.29	89.34	181.16	102.77	34.44
2	Thailand	38.12	39.04	46.69	19.59	8.88
3	Indonesia	20.76	29.07	32.79	12.79	6.23
4	China	23.27	25.22	27.50	9.05	5.23
5	Rep. of Korea	11.55	12.03	26.92	123.77	5.12
6	France	2.92	6.58	24.31	269.61	4.62
7	Germany	4.74	6.25	20.23	223.66	3.85
8	Bangladesh	6.81	9.82	18.63	89.79	3.54
9	USA	1.65	20.34	18.46	-9.23	3.51
10	Viet Nam	8.41	10.05	15.34	52.65	2.92
	World	280.54	345.00	525.93	52.44	100.00
Source:UN comtrade						

Conclusions:

Myanmar is considered as an LDC and is absolved from TRIPPS agreement till 2033. Two of the most important diseases it is manifested with is diabetes and Cancer. It is said that more than 50% of the cases of diabetes are undetected in the country. Only 25% of the detected cases opt for Modern medicine for the management of diabetes. Rest still go in for traditional medicines of Myanmar.

Myanmar is the second largest exporting partner of India in Asean region next to Philippines. As a generics exporting partner it is 12th largest of India as a whole. Most of the exports of India is affected by MSME companies.

India's exporters, planning investments in Myanmar may have an edge, if involved in the social cause of helping detection of Diabetes and educating the patients of the risk of diabetes management with the traditional medicines which are not documented and benefits of managing diabetes with modern medicine. Potential in diabetology and Cancer are immense.

An entrepreneur looking at opportunities (manufacturing) in Myanmar would be better off planning a balanced product portfolio with some aiming at short term objectives like mild to moderate antibiotics Anti-hypertensives one or two Prazoles could also be planned. Therapy of diabetology starting with oral solids could be ideal and as India's long acting insulins are now being exported advanced regulated markets, these products could fetch good share in Myanmar.

REGISTRATION AND LICENSING REQUIREMENTS

➢ Regulatory Authority	:	**The Food and Drug Administration (FDA) , Myanmar**
➢ Website of regulatory Authority	:	http://www.fdamyanmar.gov.mm/
➢ Fees for Drug Registration	:	USD 830 approximately 1.Registration Assessment Fees 300,000Kyats + Fees for Laboratory analysis 2. Registration Fees 500,000 Kyats
➢ Normal time taken for registration	:	06-12 Months
➢ Registration Requirement [Dossier Format]	:	ACTD
➢ Whether plant inspection is mandatory	:	No
➢ Validity of Registration		05 Yrs

FDA, Myanmar:

The Food and Drug Administration (FDA) was established in 1995 as one of the divisions under the Department of Health. The FDA division was upgraded to a separate department in April, 2013.

The aim of the department is to ensure the safety and quality of

- Food,
- Drugs,
- Medical Devices and
- Cosmetics in the country.

FDA Headquarter is located in Nay Pyi Taw, the capital city of Myanmar, with five major divisions:

- Administrative division,
- Drug Control division,
- Food Control division,
- Cosmetic and Medical Device Control division and
- Laboratory division

Administrative Committee: MFDBA (Myanmar Food & Drug Board of Authority) & CFDSC (Central Food and Drug Supervisory Committee)

Technical Committee: DAC (Drug Advisory Committee)

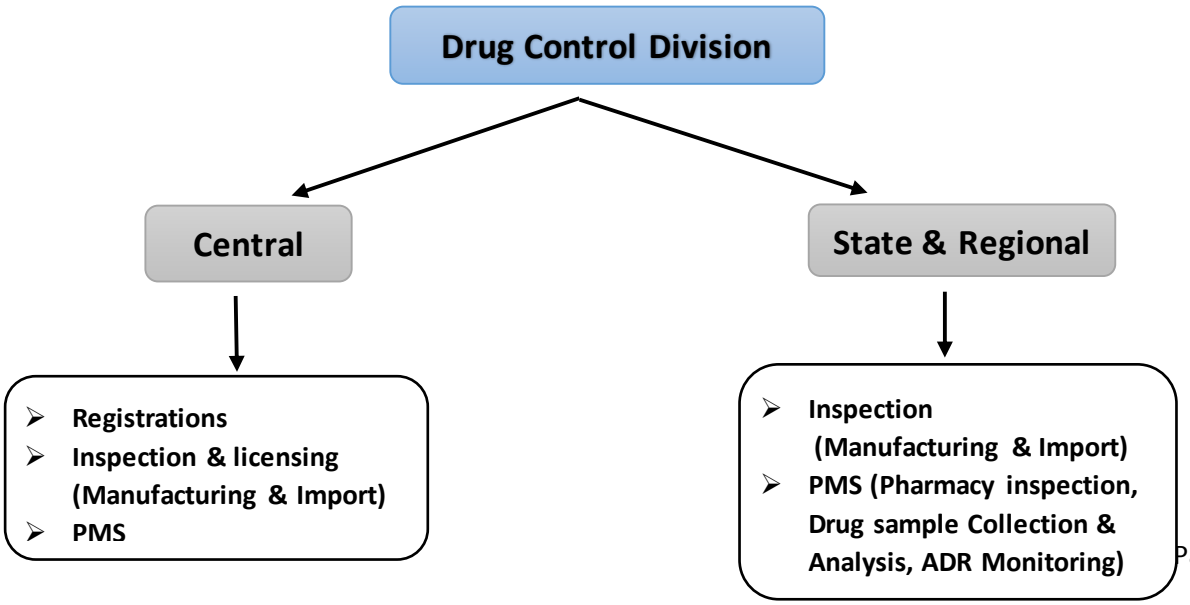
MFDBA, chaired by Minister for Health. The authority is vested power by the law to lay down policy, guidance on production, distribution, importation, exportation, quality assurance, standard setting, classifying controlled food, food additives and substandard foods, labelling and advertisement.

FDSC (Food and Drug Supervisory Committees):
The Food and Drug Supervisory Committees are formed as Central, State and Division, District and Township Food and Drug Supervisory Committees respectively.

Central FDSC (CFDSC), chaired by the Director General of Department of Health, licenses local drug manufacturers and gives drug importation approval certificates to the importers.

The State/Division FDSC, licenses drug wholesalers and retailers.

At township level the FDSCs are managed by the Township Medical Officers. The committees consist of the Township Medical Officer, the Commander of the Police, and the representatives of the City Development Committee and the General Administration Committee.



Asian Common Technical Documents (ACTD)

The Common Technical Document is organized into four parts as follows:

Part I. Table of Contents, Administrative Data and Product Information
Part II. Quality Document
Part III. Nonclinical Document
Part IV. Clinical Document

Part I: Table of Content Administrative Information and Prescribing Information

Part I contains initially the overall Table of Contents of the whole ACTD to provide basically the information's that could be looked through respectively. Secondly, the next content is the Administrative Data where required specific documentation in details is put together such as application forms, label, package insert etc. The last section of this part is Product Information where necessary information includes prescribed information, mode of action, side effects etc.

A general introduction to the pharmaceutical, including its pharmacologic class and mode of action should be included.

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

Part II. Quality Document

Part II should provide the Overall Summary followed by the Study Reports. The quality control document should be described in details as much as possible.

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

Part III. Nonclinical Document

Part III should provide the **Nonclinical Overview**, followed by the Nonclinical Written Summaries and the Nonclinical Tabulated Summaries. The document of this part is not required for Generic Products, Minor Variation Products and some Major Variation Products. For ASEAN member countries, the Study Reports of this part may not be required for NCE, Biotechnological Products and other Major Variation Products if the Original Products are already registered and approved for market authorization in Reference Countries. Therefore, the authority who requires specific Study Reports should ask for the necessary documents.

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

Part IV should provide the Clinical Overview and the Clinical Summary. The document of this part is not required for Generic Products, Minor Variation Products and some Major Variation Products. For ASEAN member countries, the Study Reports of this part may not be required for NCE, Biotechnological Products and other Major Variation Products if the Original Products are already registered and approved for market authorization in Reference Countries. Therefore, the authority who requires specific Study Reports should ask for the necessary documents.

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

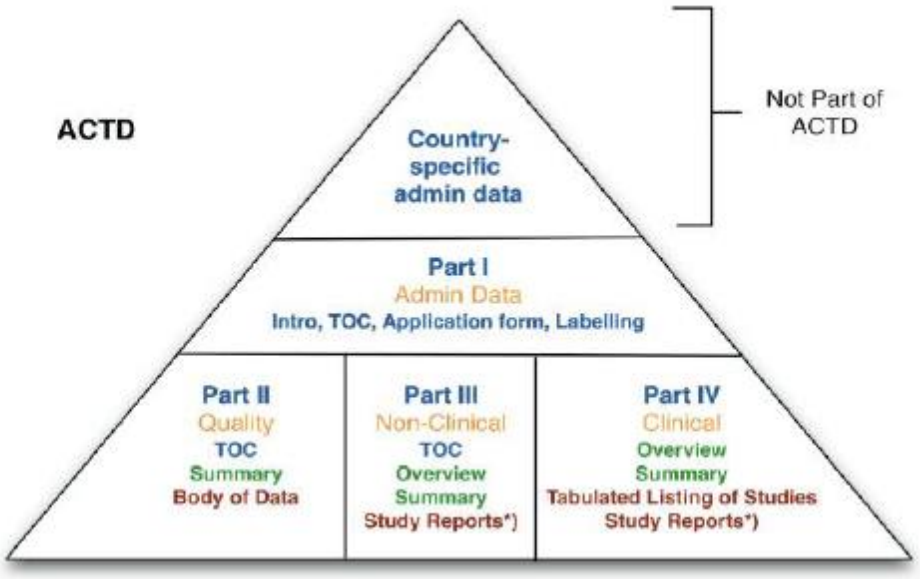


Table 1: Difference of ACTD & ICH CTD

DOCUMENTS	LOCATION IN	
	ICH CTD	ACTD
Administrative Documents and Product Information	Module 1	Part I
Common Technical Document Overviewand Summaries Quality documents	Module 2	Incorporated in Parts II, III & IV
Quality documents	Module 3	Part II
Non-clinical documents	Module 4	Part III
Clinical documents	Module 5	Part IV

Registration Procedure in Myanmar:

Applicant:

- Authorized representative of product license holder at country of Origin
- Resident in Myanmar
- Local Company Representative- Company Employee technical competent person authorized to serve as a contact person

LOA- Letter of Authorisation: Manufacturer to Local Party

- Online submission of application in Form-I
- Verification by FDA and if acceptable, get a letter of intimation for remittance of Assessment of Fee
- Remit Registration Assessment Fee-300,000 Kyats
- Get DFDA Approval for Importation of Sample Drugs
- Submit Physical dossier (ACTD) Form-I within 60 days and samples accompanied with COA
- DFDA conducts Sample analysis and Document verification and submits report to DAC for approval or rejection.
- In case of approved drug, DFDA issue letter of intimation to remit Registration fee
- Remit Registration fee-500,000 Kyats within 90 Days from Dt of intimation
- Issue of Registration Certificate by FDA.

Guideline on Drug Registration Application, Date: 15-2-2018

Government of the Republic of the Union of Myanmar, Ministry of Health and Sports Department of Food and Drug Administration issued guidelines on Drug Registration Application Ref: FDA/ (D)2018/149, Date :15-2-2018.

Initial application for Registration:

1. An application for registration of drug must be submitted to the Department of Food and Drug Administration in the original prescribed form **(Form I Registration).** As of 26 February 2018 applications for new drug products and for renewals will have to be submitted using the online facility at https://user.dcdfdamm.online. Applications that have not been submitted through the online facility will no longer be accepted. In case of online applications, Form I will have to be printed by applicants using the appropriate system facility.

2. A separate registration application has to be submitted for pharmaceutical preparations of different strength, different dosage form or different pack size. Provisions have been made to avoid duplications in printing physical dossiers.

3. Online submissions are first screened by FDA and, if found to be receivable, applicants will be requested to submit a physical dossier consisting of Form (I) accompanied by one set of documentation. One additional copy of the dossier must be kept at company premises. Documents have to be submitted in file in an order as listed in "Documents Required for Registration of Drugs". A list of documents submitted should be shown on the first sheet of the file. Physical dossiers must be submitted within 60 days of being notified by FDA that application is receivable. Failure to meet the 60-day deadline will constitute forgoing of an application by an applicant. If so happens, neither the Registration Assessment Fees remitted nor any documents and drug samples will be returned.

4. A dossier with incomplete documentation or documentation that does not bear the printed security makings cannot be received. Submission of non-receivable dossiers does not affect the 60-day deadline. As a result, an application will be assumed to be forgone by the applicant if no receivable dossier is submitted within the 60-day deadline.

5. (a) An application must be submitted in person by an authorised representative of product owner. Any application made by mail or any means other than in person, will not be accepted. An authorised representative has to be a resident of Myanmar.

   (b) Should an authorisation for representation be granted to a local company, the representative shall be a company employee technical competent person authorised to act as a contact person.

6. **Registration assessment fees; 300000 Kyats** must have been remitted to Department of Food & Drug Administration's bank account MD-012456 at MEB before submission of the application form. The submission must be made within 183 days from the date of payment. A new payment will have to be made in order to submit an application after the payment validity deadline is passed.

7. Applications containing active substances or fixed-dose combinations never marketed in Myanmar can be received only if they have been already authorized for marketing in at least two the following regulatory authorities: TGA, Australia: Health Canada; European Medicines Agency; MHRA,

United Kingdom; FDA, United States. Alternatively, they should have been prequalified by WHO or concern indications that are of specific relevance to Myanmar

8. If it is an application for registration of drugs manufactured outside Myanmar, the Food and Drug Administration will issue **"Approval for importation of Drug Samples"** after receiving an application for it. The drug samples as specified in the approval letter shall then be imported into the country. The holder of the approval letter shall comply not only with the conditions stipulated in the letter but also with the regulations of Trade and Customs Department.

9. As per Ministry of Health Notification 3/93 dated 5-8-93 paragraph 5, prior approval shall be obtained from Food and Drug Administration for the importation of drug registration samples. The FDA

10. A) The following kinds of drug samples are normally required:
    - ✓ Samples for laboratory analysis
    - ✓ Samples for retention
    - ✓ Samples for clinical trials, only for new products of Myanmar that need to undergo clinical trial.

    B) For the total numbers of sample drugs to be submitted, please refer to "Required quantities of samples for registration" (Annex III) of the guideline.

    C) All drug samples must be accompanied by the information described in annex VII of the guideline as well as their respective analytical report (certificate of analysis). The name and designation of an official who signs the report must be stated. A photocopy of the analytical report is not acceptable.

11. The evaluation process for registration will be started only when all the requirements for registration application have been met; viz.:

    (a) Remittance of Registration Assessment Fees,
    (b) Complete set of documents,
    (c) Sufficient quantity of good shelf-life (at least two thirds of shelf-life at lot release) drug samples.

12.
    (a) When the drug is approved for registration, the applicant will be notified to remit **500,000 Kyats as Registration Fee**. The notification will be made only on the notice board of FDA or through the online system, where applicable.
    (b) Failure to remit Registration Fees within 90 days from the date of intimation will constitute forgoing of an application by an applicant. If so happens, neither the Registration Assessment Fees remitted nor registration documents and drug samples will be returned.

13. Failure to make a follow-up of an application by an applicant for more than six months from the date of remittance of assessment fees, will be taken as forgoing of an application.

14. The Drug Registration Certificate will be issued only after the acknowledgement of receipt of payments issued to FDA is submitted.

15. The submitted dossiers and fees are not reclaimable in case of rejection or forgoing of application.

Renewal of Registration

1. Application for renewal of registration shall be submitted 90 days before the validity of the registration terminates. Failure to adhere to the 90 days requirement may result in disruption of continued validity of registration.

2. Application shall be submitted in the same manner as prescribed for application for new registration of a drug product.

3. The drug samples for clinical trial are normally not required. The samples for laboratory analysis and for retention are still required. Please refer to "Required quantities of sample drug for analysis and retention" (Annex III) of the guideline

4. For renewal of validity of marketing authorizations issued after 31 December 2014, the documentary requirement is the same as that of an initial application (See Type of documents required for registration Annex I). Information provided, however, has to be updated. For renewal of validity of marketing authorisations issued before 1 January 2015 the documentary requirement is provided in Annex V. New findings which had not been submitted in an initial application have to be submitted too, especially concerning drug safety profile.

5. Registration Assessment fees must have been remitted to FDA at the time of application of renewal of registration. When the renewal of registration is approved of, 500,000 Kyats must be remitted as Registration Fees.

6. Upon approval of renewal, a new Registration Number will be designated, which shall make the Old Registration Number null and void.

7. Failure to apply for renewal of registration shall result in invalidation of registration with effect from the date of expiry of the certificate.

Updating Changes to Registered Drugs (Variations)

1. Updating changes to registered drugs shall be made only with the approval of Department of Food and Drug Administration.

2. For this purpose, the holder of Registration Certificate shall apply for variation of Registration to FDA, stating

   (a) Reason for change.
   (b) Relevant data or findings from studies on which is based the justification of change.
   (c) Significant effect of changes to the specifications of the drug product.

3. The following shall be submitted together with the application:

(a) An attestation by the country's drug regulatory authority approving such changes. If the regulatory authority's attestation cannot be provided, explain the reason for it.

(b) A photocopy of the Drug Registration Certificate.

4. (a) When it is decided to approve the variation, **100,000 Kyats (per each variation) fee** will be levied on an applicant. The Drug Advisory Committee may waive the fee requirement if it believes that the variation is of benefit to public as regards quality, safety and efficacy of drugs.

(b) An original Registration Certificate must then be submitted to make approved amendments on the certificate or print a new one.

Fees Levied:

1. Registration Assessment Fees 300,000Kyats + Fees for Laboratory analysis
2. Registration Fees 500,000 Kyats
3. Variation of Registration 100,000 Kyats for each variation

Note: (1) & (2) are levied either for new registration or renewal of registration.

THE ASEAN COMMON TECHNICAL DOSSIER (ACTD) FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

PART I: ADMINISTRATIVE DATA AND PRODUCT INFORMATION

1. Application Form
2. Letter of Authorisation
3. Certification

3.1 For contract manufacturing
- (a) License of pharmaceutical industries and contract manufacturer
- (b) Contract manufacturing agreement
- (c) GMP certificate of contract manufacturer

3.2 For manufacturing "under- licence"(country specific)
- (a) License of pharmaceutical industries
- (b) GMP certificate of manufacturer
- (c) Copy of" under-license"agreement

3.3 For imported products
- (a) Licence of pharmaceutical industries/importer/wholesaler (country specific)
- (b) Certificate of Pharmaceutical Product issued by the competent authority in the country of origin according to the current WHO format.
- (c) Site master file of manufacturer (unless previously submitted within the last 2years) (country specific)

4. Labelling

4.1 Unit Carton

4.2 Inner Label

4.3 Blister/Strips

5. Product Information

5 .1 Package insert (package insert is required for generic products)

5.2 Summary of Product Characteristic (Product Data Sheet) (required for NCE & Biotechnology products)

5.2. l Name of the Medicinal Product

(a) Product Name

(b), Strength

(c) Pharmaceutical Dosage Form

5.2.2 Quality and Quantitative Composition

(a) Qualitative Declaration, the active substance should be declared by its recommended INN. Accompanied by its salt or hydrate form if relevant.

(b) Quantitative Declaration The quantity of the active substance must be expressed per dosage unit

5.2.3 Pharmaceutical Form Image clearly showing colour, markings, etc.

5.2.4 Clinical Particulars

(a) Therapeutic indications

(b) Posology and method of administration

(c) Contraindications

(d) Special warning and precautions for use

(e) Interaction with other medicinal products and other forms of interactions

(f) Pregnancy and lactation

(g) Effects on ability to drive and use machine

(h) Undesirable effects

(i) Management of overdose

5.2.5 Pharmacological Properties.

(a) Pharmacodynamic Properties

(b) Pharmacokinetic Properties

(c) Preclinical safety Data

5.2.6 Phannaceutical Particulars

(a) List of excipients

(b) Incompatibilities

(c) Shelf-life. Shelf-life of the medicinal product as packaged for sale. Shelf-life after dilution or reconstitution according to directions. Shelf-life after first opening of the container

(d) Special precautions for storage

(e) Nature and contents of container

5.2.7 Marketing Authorization Holder

5.2.8 Marketing Authorization Numbers

5.2.9 Date of first authorization/ renewal of the authorization

5.2.10 Date of revision of the text

5.3 Patient Information Leaflet (PIL)

Part II: QUALITY

S Drug Substance

S1 General Information

S1.1 Nomenclature

- Information from the SI

S1.2 Structure

- Structural formula, including relative and absolute stereochemistry, the molecular formula, and the relative molecular mass.

S1.3 General Properties

- Physico-chemical characteristics and other relevant properties including biological activity for biotech.
- Schematic amino acid sequence indicating glycosylation sites or the post-translational modifications and relative molecular mass, as appropriate.

S2 Manufacture

S2.1 Manufacturer (s)

- Name and address of the manufacturer (s).

S2.2 Description of Manufacturing Process and Process Controls.*

S2.3 Control of Materials. *

- Starting materials, solvents, reagents, catalysts and any other materials used in the manufacture of the drugs substance indicating where each material is used in the process, Tests and acceptance criteria of these materials.
- Control of source and starting materials of biological origin.
- Source, history and generation of the cell substrate
- Cell banking system, characterization and testing.
- Viral safety evaluation.

S2.4 Controls of Critical Steps and Intermediates

- Critical steps: Test and acceptance criteria, with justification including experimental data, performed at critical steps of the manufacturing process to ensure that the process is controlled. *
- Intermediates: Specifications and analytical procedure, if any, for intermediates isolated during the process. *
- Stability data supporting storage conditions. *

S2.5 Process Validation and/or Evaluation. *

- process validation and/or evaluation studies for aseptic processing and sterilization.

S2.6 Manufacturing Process Development. *

- Description and discussion of significant changes made to the manufacturing process and/or manufacturing site of the drug substance used in producing non-clinical, clinical, scale-up pilot and if available, production scale batches.
- The development history of the manufacturing process as described in S2.2

S3 Characterisation. *

S3.1 Elucidation of Structure and other characteristics

- Confirmation of structure based on e.g. synthetic route and spectral analyses.
- Compendial requirement or appropriate information from the manufacturer.

- Details on primary, secondary and higher-order structure and information on biological activity, purity and immunochemical properties (when relevant).

S3.2 Impurities *

- Summary of impurities monitored or tested for during and after manufacture of drug substance.
- Compendial requirements or appropriate information from the manufacturer.

S4. Control of Drug Substance

S4. l Specification *

- Detailed specification, test and acceptance criteria.
- Compendial specification or appropriate information from the manufacturer
- Specify source, including as appropriate species of animal, type of microorganism etc.

S4.2 Analytical Procedures*

- The analytical procedures used for testing of drug substance.
- Compendial methods or appropriate information from the manufacturer.

S4.3 Validation of Analytical Procedures *

- The analytical information, including experimental data for the analytical procedures used for testing the drug substance.
- Non-compendial methods.

S4.4 Batch Analyses *

- Description of batches and results of the analysis to establish the specification.

S4.5 Justification of Specification *

- Justification for drug substance specification. *

S5 Reference Standard or Materials. *

- Information on the reference standards of reference materials used for testing the drug substance *
- Compendial reference standards.

S6 Container Closure System *

- Descriptions of the container closure systems.

S7 Stability

- Stability report. *
- Literature data

P - DRUG PRODUCT

P1 - Description and Composition

Description

- Dosage form and characteristics
- Accompanying reconstitution diluent (s) if any.
- Type of container and closure used for the dosage form and reconstitution diluent, if applicable.

Composition

- Name quantity stated in metric weight or measures, function and quality

P2.1 Information on Development Studies. *

- Data on the development studies conducted to establish dosage form, formulation, manufacturing process, container closure system.

P2.2 Components of the Drug Product

P2.2.1 Active ingredient

- Justification of the compatibility of the active ingredient with excipients listed in Pl. In case of combination products, justification of the compatibility of active ingredient with each other. *
- Literature data.

P2.2.2 Excipients *

Justification of the choice of excipients mentioned in Pl. which may influence the drug product performance.

P2.3 Finished Product

P2.3.1 Formulation Development

- A brief summary describing the development of the finished product (taking into consideration the proposed route of administration and usage for NCE and Biotech)

P2.3.2 Overages

- Justification of any overage in the formulation(s) described in Pl.
- Physicochemical and Biological Properties.

Parameters relevant to the performance of the finished product e.g. pH, dissolution.

P2.4 Manufacturing Process Development

- Selection and optimisation of the manufacturing process.
- Differences between the manufacturing process(es) used to produce pivotal clinical batches and the process described in P.3.2, if applicable. *

P2.5 - Container Closure System

- Suitability of the container closure system used for the storage, transportation (shipping) and use of the finished product.

P2.6 - Microbiological Attributes

- Microbiological attributes of the dosage form, where appropriate.

P2.7 - Compatibility

- Compatibility of the finished product with reconstitution diluent(s) or dosage devices.

Literature data. *

P3 Manufacture

P3.1 Batch Formula

- Name and quantities of all ingredients.

P3.2 Manufacturing Process and Process Control.

- Description of manufacturing process and process control.

P3.3 Control of Critical Steps and Intermediates

- Tests and acceptance criteria

P3.4 Process Validation and/or Evaluation

- Description documentation and results of the validation and evaluation studies for critical steps or critical assays used in the manufacturing process.

P4 Control of excipients

P4.1- Specifications for excipients *

- Compendial requirement or appropriate information from the manufacturer.

P4.2 Analytical Procedures used for testing excipients where appropriate.

- Compendial requirements or appropriate information from the manufacturer

P4.3 Excipient of Human or Animal Origin: information regarding sources and or adventitious agents*.

- Compendial requirements or appropriate information from the manufacturer.

P4.4 Novel Excipients *

- For excipient(s) used for the first time in a finished product or by a new route of administration, full details of manufacture, characterization.

P5 Control of Finished Product

P5. l. Specification

- The specification(s) for the finished product.

P5.2. Analytical Procedures

- Analytical procedures used for testing the finished product.

P5.3. Validation of Analytical Procedures

- Information including experimental data for the analytical procedure used for testing the finished product. *
- Non compendial method(s).
- Verification of compendial method applicability - precision & accuracy.

P5.4 Batch Analyses

- Description and test results of all relevant batches.

P5.5 Characterisation of Impurities

- Information on the characterisation of impurities. *
- Compendial requirements or appropriate information from the manufacturer

P5.6 Justification of Specification(s)

- Justification of the Proposed finished product specification.

P6. Container Closure System

- Specification and control of primary and secondary packaging material, type of packaging & the package size, details of packaging inclusion (e. g. desiccant, etc.)

P8. Stability

- Stability report: data demonstrating that product is stable through its proposed shelf life.
- Commitment on post approval stability monitoring.

P9 Product Interchangeability (Generic only)

Equivalence evidence

- In Vitro

Comparative dissolution study as required.

- In Vivo

Bioequivalence study as required.

** Required for NCE (New Chemical Entity)/New product for Myanmar*

Steps to be followed in submitting dossier and samples for new drug registration

Step	Applicant action	FDA action
1	Carefully study Guideline for Submission of Application for Drug Registration	
2	Submit list of drug products for which applicant intends to apply for drug registration.	
3	Obtain FDA letter to remit assessment fees.	Issue letter for remittance of assessment fees.
4	Pay assessment fees to FDA's account MD-012456 at MEB.	
5	Request DFDA approval for importation of samples. The following shall be submitted to Drug Control Section: - Receipt issued by MEB upon remittance of assessment fees; - letter, in a format prescribed by DFDA, informing DFDA that payment for the drugs has been made; - List of sample drugs to be imported, specifying name of drug (trade name, generic name), dosage form, presentations, contents of each unit dose, pack size (accounting unit), quantities. (For the convenience sake, a form has been prepared by DFDA); - For samples already at port/airport, in addition to the above, airway bill, signed invoice and packing list of samples. No approval for importation will be issued for samples shipped before obtaining FDA letter for remittance of fees (Step3). Ensure to comply with Trade and Customs Departments' regulations for importation procedures.	Check documents. Verify and then return originals. Issue approval for importation of samples.
6	Submit samples to FDA within one week from the date of clearance from point of entry.	Check and accept (or reject) samples. Issue receipt with reception number and date.

7	Start entering data in online application system https://user.dcdfdamm.online System will not permit to submit applications with incomplete information and without correct sample reception number. Submit complete application online. Application number is generated by computer.	Issue receipt of online application. Check application. Request applicant to correct inaccuracies, if any. Request applicant to print and submit physical dossier, if application meets completion requirements. Reject application if inaccuracies are not addressed by applicant with specified deadline.
8	Submit, in person, computer-generated form I plus all accompanying documentation as required for each type of application within 60 days of being notified by FDA to submit physical dossier. All documentation must be printed using the online application facility. Documentation that does not carry the printed security markings will not be accepted.	Receive and check physical dossier. Issue note acknowledging receipt of physical dossier, if all documentation carried security markings. Reject dossier if documentation does not carry security markings. Assign dossier to specific assessment procedure and determine estimated duration.
9		Request applicant to submit complementary information if found necessary during assessment.
10	Provide requested complementary information through online system within established deadlines.	Acknowledge receipt of complementary information and continue assessment.
11		Complete assessment. If outcome entails issuance of drug registration certificate, issue letter for applicant to remit registration fees. If outcome is denial of approval, issue letter informing of denial. All communications are sent via the online system using the email address provided by the applicant.
12	Remit registration fees within 90 days from the date of intimation. Upload payment receipt using online facility. Original to be submitted when visiting FDA to collect drug registration certificate.	
13	Within 60 days of payment, request appointment for collecting drug registration certificate at FDA premises.	Issue drug registration certificate. Certificate will be delivered in person only to duly authorized company representative.

Local Pharma Associations:

- Myanmar Pharmaceutical & Medical Equipment Entrepreneurs Association. http://www.mpmeea.org/