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Research Paper

A Study of Pharmaceutical Product Registration Process in Myanmar – A First Step Towards Developing A Product-Mix

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ABSTRACT: *Myanmar's pharmaceutical market is a very competitive market with high dependence on imported medicines from India, China, Bangladesh, Thailand, Vietnam and Pakistan. India is one of the highest contributors to Myanmar's pharmaceutical imports for several years. In the scenario of a highly competitive market, pharmaceutical companies need to keep adding new products to their product mix. The pharmaceutical market is regulated by the FDA, pharma companies need to focus on and follow the country's regulations for the introduction, distribution and sales of the products. This descriptive qualitative research concentrate on the first step of creating product-mix offerings –i.e. new product registration process. The current Myanmar pharmaceutical product registration guideline takes approximately 18-24 months to register new POM/OTC products, however, the recent shift of process in 2022 will surely help to reduce the timeline to 12-15 months making it easier for companies to offer new products in the market.*

KEYWORDS: *Myanmar, Product Registration, FDA, Pharmaceutical, Dietary supplements, Functional Food supplements, Health supplements, Medical Device, Cosmetics, ACTD, Over the Counter, Drug Registration, Regulations*

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I. INTRODUCTION

Myanmar is a country with very limited own pharmaceutical production. The pharmaceutical market in Myanmar is very competitive, and the country imports 80% of pharmaceutical goods from other nations. The county is dependent on imports for all kind of pharmaceutical products which includes prescription-only medicines, over-the-counter medicines and nutraceutical supplements The pharmaceutical spending is growing at double-digit growth and is expected to reach USD 1.1 billion valuations by 2023.

More than 100 importers and distributors are contributing to the nation's healthcare supply chain. The DKSH & Maxxcare are one of the leading pharmaceutical distributors in the country. Other leading pharmaceutical companies in Myanmar are Sanofi, Pfizer, GSK, Novartis, Roche, Bayer, Cipla, Zydus Cadila healthcare and Torrent pharma. Apart from these pharmaceutical giants', generic brands from India, China, Bangladesh, Thailand, Pakistan and Vietnam operate with significant market shares.

India is a key partner for Myanmar in the pharmaceutical trade. Indian companies like Sun Pharmaceuticals, Dr Reddy's, Wockhardt and Hetro are enjoying significant market share in Myanmar's local pharmaceutical market. Indian generic drug manufacturers are also hugely popular and accepted in Myanmar.

Considering the high growth of the Myanmar pharmaceutical market, foreign manufacturers are keen on selling their products in the local Myanmar market. Introducing new products with convenient dosage forms at economical prices is of prime importance for operating in a highly competitive market like Myanmar. Product registration approval is the first step for introducing a new product in the market. This qualitative study will elaborate on the process of registration of the pharmaceutical products with the Myanmar –FDA

II. OBJECTIVE

This study aims to explore the pharmaceutical product registration process in Myanmar along with the timeline and the cost associated with it.

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III. METHOD

The research objective of the proposed study is complex and hence the qualitative approach has been adopted. Planned one-on-one interviews have been considered the most appropriate method considering the topic's complexity, scope, and depth.

IV. SAMPLING

The volunteer participant has been selected based on the purposeful sampling method. Two subject-matter experts offering the regulatory & product registration service have been interviewed to understand the entire process of pharmaceutical product registration.

V. ANALYSIS & DISCUSSION

5.1 FDA- Myanmar

The Food and Drug Administration is the regulatory body of Myanmar. Established in 1995, FDA ensures the safety and quality of food, drugs, medical devices and cosmetics. It was established under the 1992 National Drug Law headquartered in Nay Pyi Taw.

The FDA has three departments for the registration of pharmaceutical & Food supplement products along with administration & laboratory divisions.

Chart 1 elaborates the responsibilities of the various FDA product registration departments along with the type of dossier required and the approximate timeline for product registration approval.

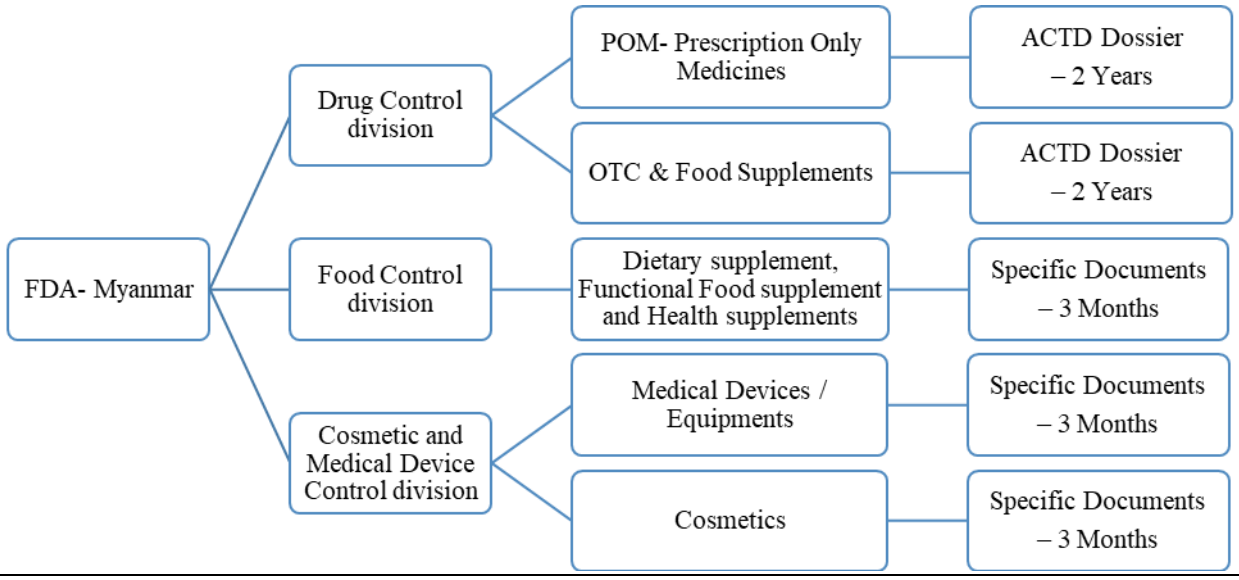

Chart 1: FDA departments & responsibilities

Myanmar FDA does not require manufacturing site registration approval from Myanmar FDA for filing registration applications for pharmaceutical products. Applicants can request directly product registration to FDA in the required format and procedure.

5.2 Prescription-only Medicine Registration

5.2.1 Registration Steps

The Myanmar FDA accepts POM registration applications in their specific format and the ACTD type dossier. The dossiers are filed online on the FDA website as per the guidelines in separated files. FDA has revised product registration submission guidelines recently in February 2022. The steps for the new generic product registration are as below:

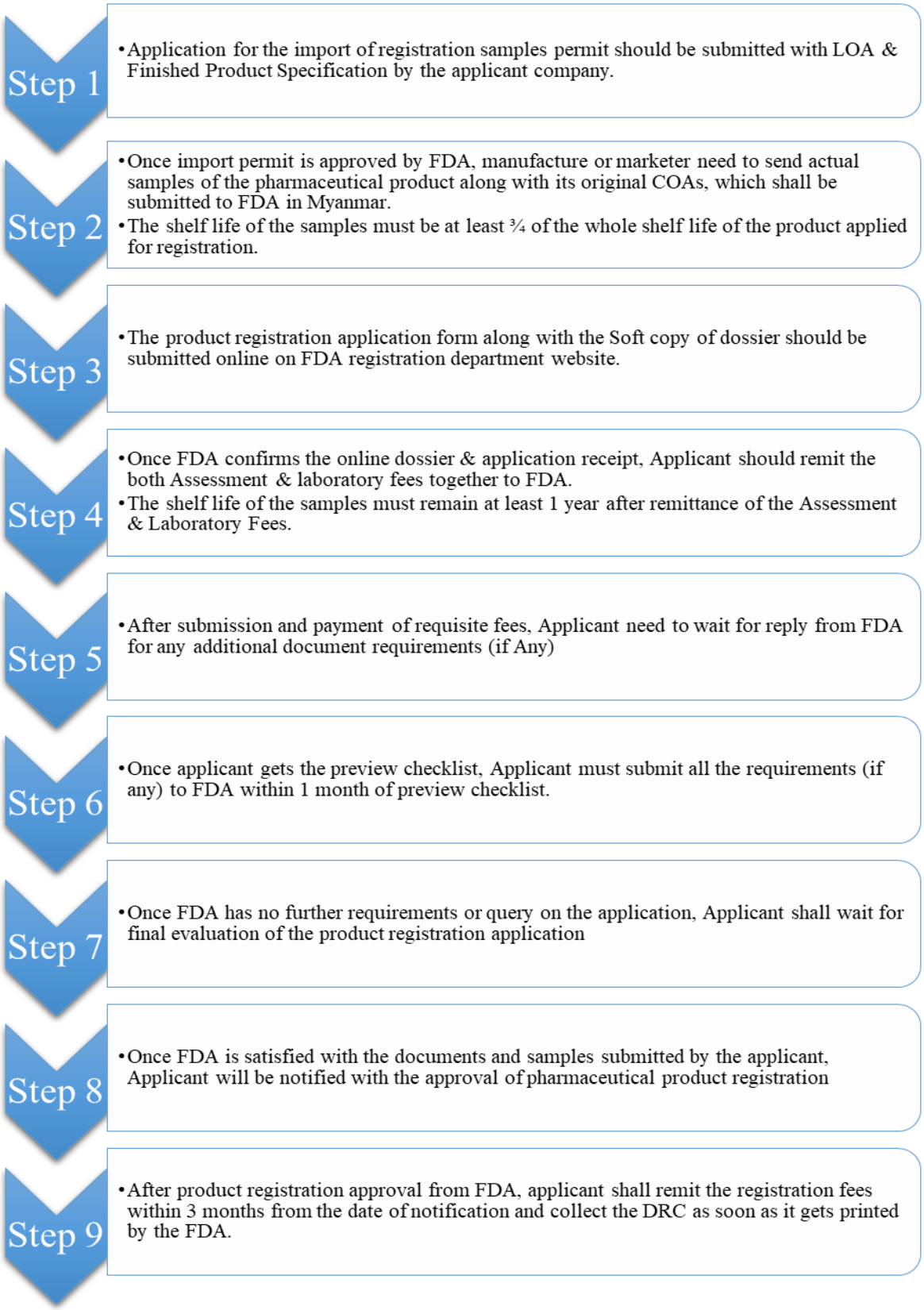

Chart 2: Steps for new generic pharmaceutical product registration

5.2.2 Requirements for Online dossier Submission

The online soft copy dossier for registration has to comply with ASEAN common technical dossier format. Generic drug dossier is submitted in separate files as two parts Administrative Part (Administrative documents and product information) & Quality part (Quality documents for drug substance and drug product)

For online dossiers, FDA can accept only a maximum file size of 3 MB for each file & 100 MB for the whole dossier. PDF files are more convenient to upload.

Administrative Part:

ADM-A1 - Application forms

ADM-A2 - Certificate of Business Registration (for Local company)

ADM-A3 - Attestation by product owner on compliance of manufacturing procedure

ADM-A4 - Product Owner Company Profile

ADM-A5 - A statement describing the duties and responsibilities of each manufacturer

ADM-A6 - Certificate of NRA of the country of origin showing acceptance of more than one manufacturer

ADM-A7 - Manufactures Licenses with conditions, if applicable

ADM-A8 - Manufacture profile including details of manufacturing site and facilities

ADM-A9 - List of countries where the product is authorized for marketing with the date of authorization or last renewal and brand name if different from Myanmar.

ADM-PI2 - Letter of Authorization to represent product owner

ADM-PI3A - COPP

ADM-PI3B - GMP Certificates

ADM-PI3C - Importer License (for Local company)

ADM-PI3D - Site Master file of foreigner Manufacturer

ADM-PI4 - Image of packaging, labelling, primary container & dosage forms

ADM-PI5 - Product Information

ADM-PI51 - Package Insert

ADM-PI52 - Summary of Product Characteristics

ADM-PI525 - Pharmacological Property

ADM-PI526 - Pharmaceutical Particular

ADM-PI53 - Patient Information Leaflet

Quality Part:

PIIP1 - Drug Product Description and Composition

PIIP2 - Pharmaceutical Development

PIIP3 - Drug Product - Manufacture
PIIP4 - Drug Product - Control of Excipients
PIIP5 - Drug Product – Control of Finished Product
PIIP6 - Drug Product – Reference Standards and Materials
PIIP7 - Drug Product – Container Closure System
PIIP8 - Drug Product – Stability Data
PIIP9 - Drug Product – Interchangeability
PIIS1 - Drug Substance – General Information
PIIS2 - Drug Substance - Manufacture

5.2.3 Required Samples for Submission

Dosage Type	No of samples
For all drugs except the Anthelmintic, Anti-neoplastic, Contraceptive, Oral Rehydration Salt Powder, Eye/ Ear Drops	
Tablets/ Capsules/ United Dose	500 Units
Syrup/ Suspension/ Elixir (Up to 120ml)	50 Units
Injection (Ampoules/ Vials/ Bottles)	50 Units
Topical (Tubes/ Bottles)	50 Units
Anthelmintic Drugs	
Single-dose tablets	150 Doses
Multiple doses tablets	500 Doses
Anti-neoplastic Drugs	
Tablets/ Capsules	200 Units
Injection (Ampoules/ Vials & Bottles)	30 Units
Contraceptives	
Tablets/ Capsules	150 Cycles
Oral Rehydration Salt Powder	
One litre pack	200 Sachets
Less than a one-litre pack	400 Sachets
Eye/ Ear Drops	
Topical (Tubes/ Bottles)	100 Units

Table 1: No. of units required as samples for registration

5.2.4 Official Fee Structure – Drug

Fees levied	Amount
Assessment fees :	MMK 300,000
Laboratory fees :	MMK 130.000 – MMK 650,000 (Depending on the product)
Registration fees :	MMK 500,000

5.3 Food Supplement/ Over the Counter Medicine Registration

The food supplements which contain a higher dosage than the recommended daily allowance as per Myanmar FDA notification will be registered under the OTC category along with other notified OTC molecules.

The procedure, timeline and cost of registration for Food Supplement/ OTC are the same as prescription-only medicines (drug Category).

5.3.1 Required Documents

Administrative Data:

- Letter of Authorization
- Free Sale Certificate (Original) issued by the competent authority in the country of origin
- Properly endorsed/ Legalization of Manufacturing License copy
- ISO Certificate (Standard)

Quality:

- Raw Material Specification, Source of raw material
- Raw Material quality control
- Master Formula
- Manufacturing process
- Finished product specification
- Reference Text
- Certificate of Analysis (Finished product)
- Stability test of the finished product

Safety & efficacy data:

- The action of Active Ingredient, if any: (Reference Text)
- Safety data of finished product
- Research Paper/ Literature of Food Supplement (endorsed by a DFDA-Recognized Research Institute)

5.4 Dietary Supplement, Functional Food Supplement and Health Supplement Registration

The product registration application for Dietary Supplement/ Functional Food Supplement/ Health Supplement Registration is accepted, reviewed and approved by the Food control department. Upon approval of registration application for Dietary supplements, Functional Food supplements and Health supplements are issued Import Recommendation letters by FDA.

5.4.1 Required Documents

- Letter of Authorization
- Finished Product Specification
- List of Ingredients / Q and Q Formula
- Free Sale Certificate/ GMP Certificate/ Manufacturing License/ Other Certificates
- Health Certificate or Certificate of Analysis (COA)
- Product Label Artwork

5.4.2 Official Fee Structure – Import Recommendation

Fees levied	Amount
FDA Registration fees :	MMK 500,000

5.5 Medical Device & Cosmetic Registration

Medical devices, Instruments, equipment & cosmetics registration application are evaluated and approved for sale by the Medical device & Cosmetic control department of the FDA.

5.5.1 Required documents for Medical Device

- Letter of Authorization from Manufacturer or owner with a validity date
- Certificate of Analysis or Declaration of Conformity
- ISO Certificate
- GMP Certificate and Free Sale Certificate (If any)
- Labelling Information
- Sterility Certificate (If it is a sterile product)

- Clinical Evaluation Report (If any)
- Risk Management Analysis (If any)
- Copy of Business License of the local Company or Certificate of incorporation

5.5.2 Required documents for Cosmetics

- Letter of Authorization
- Free Sale Certificate
- GMP (if any)
- Detailed Ingredients Lists with % (2 sets)
- Complete packaging art work 2 sets (the ingredients / net weight / C.O & etc. on package)
- Product Label Artwork
- Local Company Registration Copy

5.5.3 Official Fee Structure – Medical Device & Cosmetics

Fees levied	Amount
Notification fees :	MMK 25,600
Laboratory fees :	MMK 100,000 (if lab testing is required)

VI. APPROVAL TIMELINE AND REGISTRATION VALIDITY PERIOD

The table below elaborates on category wise approval timeline, the validity period for registered products and physical product samples required by FDA. The consultancy fee charges can be added separately which will be charged by the regulatory agency for his/his services.

Product Category	No. of samples required	Approval time (Approx.)	Registration Validity
POM / OTC products	As mentioned above	18-24 Months	5 Years
Dietary supplements, Functional Food supplements and Health supplements	Minimum net weight 150gm, if requested by FDA	3 Months	2 years
Medical Device	1 Unit or as requested by FDA	3 Months	2 years
Cosmetics	1 Unit or as requested by FDA	3 Months	2 years

Table 2: Approval Timeline and Registration Validity Period

VII. CONCLUSION

Pharmaceutical product registration in Myanmar does not require manufacturing site approval by Myanmar FDA. Product registrations are processed by three different departments of the FDA as per the product categories. The timeline to get POM & OTC products registration approval is approximately 18-24 months whereas all other category registration can be approved within 3 months. The validity of approval is 2 years whereas it is 5 years in the case of OTC & POMs. Pharmaceutical companies need to plan their product pipeline well in advance to create an appropriate product mix for their customers considering the long timeline for new generic products registration approval. However recent changes in the guideline will certainly help regulators to reduce the overall time for new POM & OTC registrations to around 12-15 months, thereby reducing entry berries for new products and creating a competitive market to offer better values and products to citizens.

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