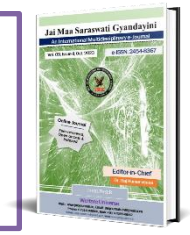
Jai Maa Saraswati Gyandayini
An International Multidisciplinary e-Journal
(Peer-reviewed, Open Access & Indexed)
Journal home page: www.jmsjournals.in, **ISSN: 2454-8367**
Vol. 09, Issue-II, Oct. 2023



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

Dr. Nikunj Patel [a,*]
[a] *Research Scholar (Commerce and Management), Sabarmati University, Ahmedabad (Gujrat), India.*

KEYWORDS
Cambodia, Product Registration, MOH, FDA, Pharmaceutical, Food supplements, Health supplements, ACTD, Drug Registration.

ABSTRACT
The Pharmaceutical market in Cambodia attracts high competition due to the less entry barriers in the market. The Cambodian medicine requirements are highly dependent on the import of medicines from countries like India, China, Bangladesh, Thailand, Vietnam and some European countries. India is one of the leading supplier and contributor to the medicine imports in Cambodia due to its cost-effective generic products. In such a competitive market pharmaceutical companies need to constantly introduce new products and dosage forms to be ahead in the competition and capture market share. Any pharmaceutical product imported in Cambodia must require to be registered at MOH – Cambodia before entering in the country. Hence pharmaceutical companies need to focus on product registration process first, to introduce new product in the market. This descriptive qualitative research concentrates on the first step of creating product-mix offerings –i.e., new product registration process. The data collected from one-to-one personal written interview of the field experts. The current pharmaceutical product registration guideline in Cambodia takes approximately 7 months to register new POM product. However, companies can opt for fast-track approval by paying an additional official fee determined by the regulators.

Introduction

Spending on healthcare in Cambodia has increased as the country's economy grows. The life expectancy of Cambodian men and women has increased to 66.7 and 70.8 years respectively as per reports in 2015. Pharmaceuticals accounted for approx. $ 210 million in Cambodia's healthcare sector in 2015 and expanding at double-digit rates. With a population of over 17 million, Average Cambodian citizen is spending on an average $60 from there out of pocket annually. These expenses are largely in the form of direct purchases from retail pharmacy. Currently, there are no regulations or reimbursement mechanisms in place for prescription medications.

The process of registering a pharmaceutical product follows ASEAN guidelines, costs minimal amount, and takes a less time comparatively. Importing medications, medical supplies, or medical equipment is restricted to firms licenced by the Ministry of Health. Cambodia has 2,516 registered pharmacies, 405 medication import/export firms and branches, and 19 medical manufacturing institutes as of June 2018. In addition to the legitimate or legal distribution and importation market, there is a grey market of

Corresponding author
***E-mail:** nikunj02patel@gmail.com (Dr. Nikunj Patel). https://orcid.org/0009-0003-1004-0460
DOI: https://doi.org/10.53724/jmsg/v9n2.04
Received 09th August 2023; Accepted 20th Sep. 2023; Available online 30th Oct. 2023

smuggled and frequently counterfeit drugs.

France is Cambodia top pharmaceutical product supplier followed by India grabbing the second position. India is Cambodia's largest Asian pharmaceutical supplier. It is very easy to distribute medicines in Cambodia since Phnom Penh as well as the surrounding area accounts for over 80% of all pharmaceutical sales. There is a strong preference in the local market for imported drugs, which account for 55% of the pharmaceutical market. An increasing number of foreign institutions have begun to pay attention.

Considering the low entry barrier in the Cambodian pharmaceutical market, foreign manufacturers are keen on selling their products in the local Cambodian market. Introducing new products with convenient dosage forms at economical prices is of prime importance for operating in a highly competitive market like Cambodia. 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 Cambodia -DDF

Objective

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

Method

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

Analysis & Discussion

FDA- Cambodia

The Department of Drugs & Foods under the Ministry of Health (MOH), Cambodia is responsible for the regulation of pharmaceutical products, food and cosmetics. There are 5 (Five) bureaus or subdivisions under the DDF- Cambodia which are responsible for the entire management and regulation.

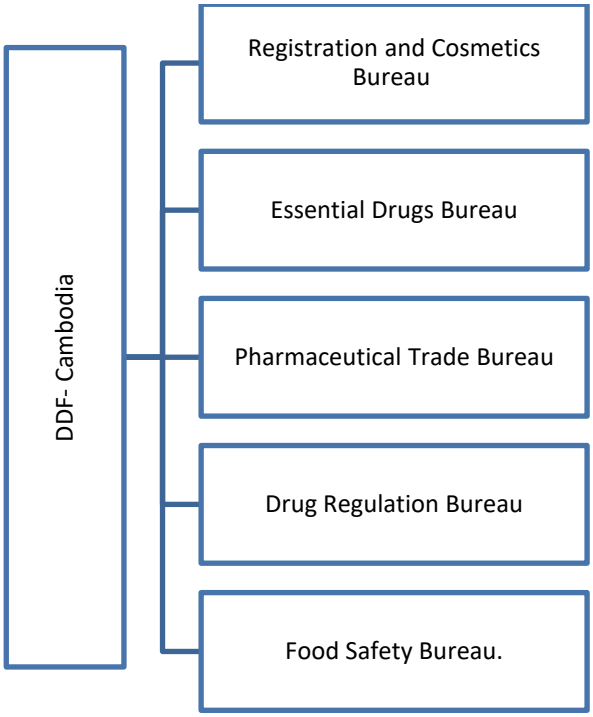


Figure 1: FDA departments

Manufacturer Registration:

Before applying for product registration in DDF-Cambodia, Company needs to apply for manufacturing site approval.

Pharmaceutical products manufacturer or marketer needs to submit the application form to DDF-Cambodia along with supporting information and documents in two parts.

A- Administrative dossier:

- Information on the applicant & the Manufacturer
- G.M.P. Certificate
- Other country registration (If any)
- License to operate in the Country of Origin
- Representative Office in Cambodia or Local representative (If available)
- Business Information
- Organization chart and list of the qualified employees
- Annual sales turnover in the previous three years

B- Technical dossier:

- **Manufacturing information**
  - Master plan of factory
  - Organization chart and list of the qualify employees
  - List of the products manufactured or repacked
  - List of Equipment used at each production site
  - Maintenance and Inspection
- **Quality information**
  - Organization chart and list of the qualified employees
  - Quality certificate or accreditation of Lab
  - Maintenance
  - Stability
  - Storage
- **Quality Assurance**
  - Organization chart and list of the qualified employees
  - List of products subject to customer complaints
  - List of Recalled products

Once the Applicant files the application for manufacturing site approval, the applicant can proceed with the application of products for registration in Cambodia. Applicants need not wait for DDF's approval on manufacture before filing the product registration application. However, the manufacturer should receive approval from DDF for the site before the registration bureau approves the product registration application.

The official fee for the manufacturer registration at DDF- Cambodia is USD 1200 per manufacturer site.

Generic Medicine Registration

Registration Steps

The Department of Drugs & Foods Cambodia, accepts generic medicine registration applications with the ACTD type dossier.

Below are the parts included in the ACTD type dossier accepted in Cambodia. The dossiers are filed online on the FDA website as per the guidelines

- Part I: Administrative Data & Product Information
- Part II: Quality: Overall summary & reports
- Part III: Non-Clinical: Overview, Summary & reports
- Part IV: Clinical: Overview, Summary & reports

The steps for the new generic product registration are as below:

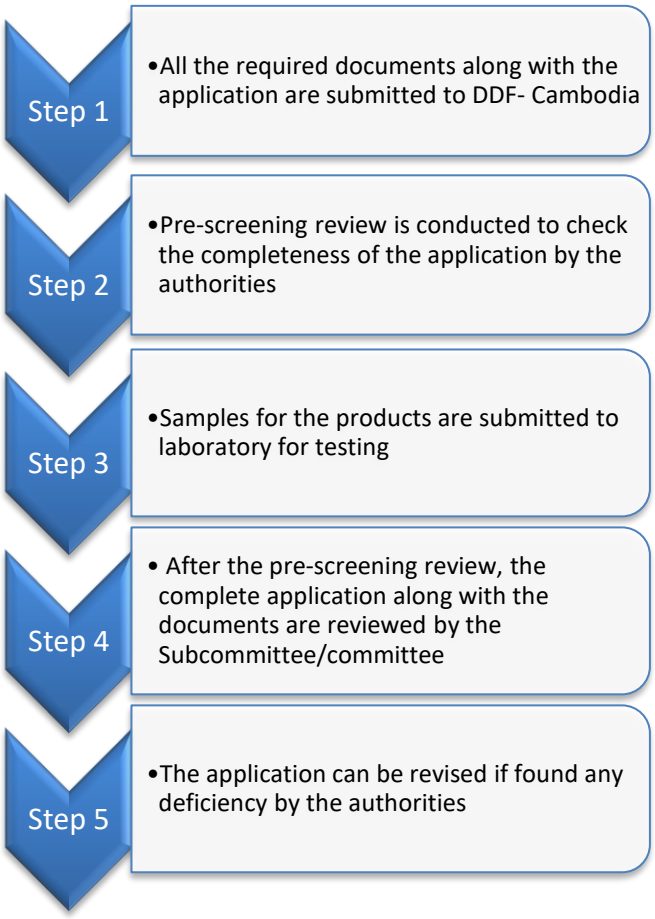


Figure 2: Step by step process of the registration process in Cambodia

Required Samples for Submission

Dosage Form	Samples QTY for NCL	Samples QTY for FDA
I.ORAL FORMS:		
Tablets, Sachets, Capsules	200 Units	2 Boxes
Syrups, Oral Solutions, Elixirs	10 Vials	2 Boxes
Oral Drops	If Sample < 5ml = 60 bottle	2 Boxes
	If Sample < 30ml (10ml-20ml)=30bottles	
	If Sample < 50ml (Ex:30ml) 20bottles	
Ampoules	50 Ampoules	2 Boxes
II. PARENTERAL FORMS:		
Ampoules for Injection	120 Ampoules	2 Boxes
Perfusion	If Sample > 100ml = 10 bottle	2 Boxes
	If Sample < 100ml = 20 bottle	
Freeze, Dried Drug, Powder for Injection	60 Vials	2 Boxes
Serums, Vaccines	10 Vials	2 Boxes
III. LOCAL FORMS:		
1-EXTERNAL USE		
Lotions, Gels, Creams, Ointments, Liniments, Powder	If Sample: 1g-5g =20 Units	2 Boxes
	If Sample: 6g-9g = 15 Units	
	If Sample 10g or more = 10Units	
2-TRANSMUCOSA		
Eye drops, Ophthalmic Ointments, Nasal Drops, Ear Drops, Aerosols, Spray, Inhalation	If Sample: 2,5ml = 30 box	2 Boxes
	If Sample: 5ml-10ml = 20 Vials	
Suppositories, Ovules, Gynaecologic tablets	200 Units	2 Boxes

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

Official Fee Structure – Drug

Fees for Tablet/ Capsule/ Syrup/ Cream/ Ointment/Eye/EarDrops/Nasal Spray/Suppository:

Products containing no. of active pharmaceuticals ingredients	**New dossier filing fees (Government fee)***	Dissolution Test for Tablets/ Capsules	Sterility Test for Eye/Ear Drops	Fast Track
1 API	$ 470/dossier	$50	$100	$300
2 APIs	$620/dossier	$100	$100	$300

Table 2: Official fees for OSD, Topical products

Fees for Injectable:

Products containing no. of active pharmaceuticals ingredients	**New dossier filing fees (Government fee)***	Fast Track
1 API	$ 770/dossier	$300
2 APIs	$ 920/dossier	$300

Table 3: Official fees for Injectable products

Food Supplement/ Health Supplements

The products containing daily supplements having dosages below recommended dosage allowance are registered under the category of health supplements. The Health/food supplement products are easy to register and required less documents compared to regular Drug or generic products.

Required Documents

Administrative Documents:

- Application form
- Free Sale certificate (Letter Head of Drug Regulatory Authority: DRA)
- GMP or ISO Certificate
- Hygienic certificate
- Product Information

Technical Documents:

- Unit Formula and Batch Formula
  (If the active ingredient come from herb or plant, need to provide color picture of the herb or plant with Latin name and Species, part of the herb/plant used and used for)
- Manufacturing Process –in process control
- Control Procedure of Raw Materials
- Control Procedure of the finished product
- Storage condition of the finished product and its predicted expiry date.
- Stability study

Labelling for Unit Cartoon:

- Product Name
- Dosage Form
- Name and Strength of Active Ingredient(s)
- Batch Number
- Manufacturing Date
- Expiration Date
- Storage Condition
- Name and Address of Manufacturer
- Pack sizes (Unit/Volume)

Required Samples for Submission

Dosage Form	Samples QTY for NCL	Samples QTY for FDA
Tablets	200 Tablets	02 Boxes
Sachets	200 Sachets	02 Boxes
Syrups	10 Bottles	02 Boxes
Oral Solutions		
Elixirs		
Oral Drops	20 Bottles	02 Boxes

Table 4: Required samples for registration application

Official Fee Structure – Heath Supplements

Fees levied	Amount
FDA Registration fees:	USD 470

Approval timeline and registration validity period

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

Product Category	Approval time (Approx.)	Registration Validity
Manufacturer Registration	4 Months	5 Years
Generic Medicine products	7 Months	5 Years
Food supplements and Health supplements	3 Months	3 years

Table 5: Summary – Cambodia

Conclusion

Manufacturing site or facility registration is the must prerequisite before registering pharmaceutical product in Cambodia. However,

MOH allows to file applications for both facility GMP registration as well as product registrations simultaneously. While organization can file product registration along with facility approval application, MOH ensures that facility must receive an approval certificate before it gets the product approval certificate (product VISA).

The product approval timeline for drug or prescription only medicine is around 7 months in a normal application however applicant has an opportunity to apply in a fast-track mode which attracts additional official fees of USD 300 per product. Fast track mode applications get approval in 3-4 months' timeline. Product registration approval for food supplement category products is easy and relatively less time consuming.

Plant GMP certificate as well as product registration certificate (VISA) is valid for 5 years from the date of approval. The validity for food supplement product visa is 3 years. Organization needs to apply for registration renewal before 6 months of expiry.

In recent times Cambodia has also adopted online system of products registration application filing. The regulatory guidelines in Cambodia are flexible compared to other ASEAN countries hence the registration approvals are easy comparatively. The less entry barrier for the market attracts more pharmaceutical companies to enter the market hence creating much competitive market.

References:

1. U.S. Embassies abroad. (n.d.). Cambodia - Pharmaceuticals, Medical Supplies, and Medical Equipment. Retrieved from https://www.privacyshield.gov/: https://www.privacyshield.gov/article?id=Cambodia-pharmaceuticals-medical-supplies-and-medical-equipment
2. Real-time Data Solutions. (2019). The Pharmaceutical Market & Healthcare infrastructure in Cambodia. Phnom Penh: The Embassy of India, Cambodia.
3. Shelke, T. V., Khante, S., Sarda, M. B., Mahadik, K. R., & Gaikwad, V. L. (2020, January). An Overview of the Drug Registration Requirements for Export to Tanzania, Nepal, and Cambodia. Therapeutic Innovation & Regulatory Science, 54(1), 171–176. https://doi.org/10.1007/s43441-019-00042-0
4. Bureau-Point, E., Baxerres, C., & Chheang, S. (2020, April 30). Self-Medication and the Pharmaceutical System in Cambodia. Medical Anthropology, 39(8), 765–781. https://doi.org/10.1080/01459740.2020.1753726
5. Pordié, L. (2021, January 29). Unstable pharmaceutical values: the grey political economy of drug circulation in Cambodia. BioSocieties, 16(3), 342–362. https://doi.org/10.1057/s41292-020-00215-3

****