PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA

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

REGULATORY & MARKET PROFILE OF PHILIPPINES

DEMOGRAPHY

SL. No	Parameter	Description
1	Region	ASEAN
2	Country	Philippines
3	Capital	Manila
4	Population	105,893,381 (July 2018 est.)
5	Population growth rate (%)	1.55% (2018 est.)
6	GDP (purchasing power parity)	$877.2 billion (2017 est.)
7	GDP - real growth rate (%)	6.7% (2017 est.)
8	GDP - per capita (PPP)	$8,400 (2017 est.)
9	Epidemiology	HIV Ischemic Heart disease, CVS diseases, Respiratory Tract Infections, Kidney diseases
10	Population below poverty line	21.6% (2017 est.)
11	Age structure (%)	0-14 years: 33.07%
		15-24 years: 19.17%
		25-54 years: 37.11%
		55-64 years: 6.04%
		65 years $ above:4.61%
Source: CIA World Fact Book updated to July 2018		

Introduction

Expansion of PhilHealth coverage, with the aim of achieving universal coverage, will be an important driver of pharmaceuticals and healthcare market growth. The country's disease profile typical of its economic and demographic trends will provide a number of revenue earning opportunities for pharmaceutical firms, especially for Generic drug makers.

Pharma expenditure in 2017 is estimated at $ 3.23 billion. Percapita consumption of medicines stands at $ 30.8 in the year 2017.

Latest Updates

- In October 2017, Novartis announced that it will partner with the Philippines College of Chest Physicians (PCCP) to promote chronic obstructive pulmonary disease (COPD) awareness in the country.
- In end October 2017, the Food and Drug Administration (FDA) penalised the French drugmaker Sanofi Pasteur and drug and beauty products chain Watsons Personal Care Philippines for illegally promoting and advertising the dengue vaccine, Dengvaxia.
- In October, according to the latest data released by the Department of Tourism, the Department of Health, the Department of Trade and Industry and Board of Investments, 62 hospitals around the Philippines were internationally accredited, resulting in the country's status as a growing global medical tourism destination.

Strengths

- The outlook for healthcare access in the Philippines will continue to improve as the government's remains committed to expanding universal healthcare coverage.
- Significant pharmaceutical market growth potential, highly reliant on government's interest in developing the pharmaceutical sector.

Weaknesses

- Financial sustainability of the healthcare system remains a challenge given the growing disease burden.
- Tough pricing regime.
- Vast regional disparities in healthcare coverage and access, in particular between urban and rural areas in the country.
- Uncertain pricing regulation and low levels of intellectual property protection. Government pharmacies are unevenly distributed across the country and suffer from operational issues, such as limited number of available medicines and inadequate professional support.

Market Overview

The Philippines is a lower/middle income country, where only a minority of the population has access to adequate healthcare. Philippines has a strong local drug industry and has clocked $ 3.23 billion in 2017. It is expected to touch $ 3.82 bn by 2021 with a Cagr of 2.5%.The generic drug subsector forms the largest portion of the market (44.7%), valued at USD1.51bn in 2016. Unusually for a lower/middle income country, branded medicines account for a relatively large share of the market. This is a result of strong traditional preferences, the dubious quality of

copy products, intensive advertising and the availability of parallel imports. Patented drug sales and OTC sales were roughly equal in value terms, representing 27.6% and 27.5% of total pharmaceutical sales respectively.

The country aims to implement universal healthcare, similar to other Association of South East Asia Nation (ASEAN) members such as Indonesia, Vietnam, Laos and Myanmar. This plan will require the government to rein in high drug prices in order to keep healthcare affordable for residents. Therefore, over the long term, profit margins for pharmaceutical firms will be narrowed, but they will be able to grow based on volume sales.

In January 2017, Health Secretary PaulynUbial stated that universal health insurance coverage and the lowering of medicine prices would be the Department of Health's main focus for 2017. The operating climate for pharmaceutical manufacturers is positive, reflecting strong economic growth prospects, an improving regulatory landscape, an evolving retail sector and a new government.

The Philippines is considered as an example for intellectual property rights (IPR) enforcement under the Association of South East Asian Nations (ASEAN) IPR Strategic Action Plan for 2016-2025. The government plans to continue implementing an action plan for IPR protection, which aims to facilitate the rapid, effective resolution of IPR disputes, strengthen the IPR framework and enhance interagency coordination and enforcement in the sector. The announcement of establishing a maximum drug retail price (MDRP) regulation for an updated list of essential medicines has been proposed, which would add to the pricing pressures in the short to medium term, if implemented.

The country is reliant on foreign drugs, especially with regards to modern and high-tech treatments, despite counterfeiting being a significant problem. Pfizer, Novartis and GlaxoSmithKline are the leading multinational drugmakers. However, international firms are scrutinised by the public and politicians alike for high retail drug prices. As a result, the outlook for leading local generic manufacturers is positive. The indigenous industry primarily manufactures generic drugs. Leading domestic firm United Laboratories (Unilab) controls about 80% of the local generic drug market.

Epidemiology

WHO figures suggest the Philippines has the fastest growing HIV epidemic in the world, although the current prevalence is still considered to be low. The country posted a record 841 new cases in June 2016.

75% of the disease incidences are of non-communicable in nature, which is unusually high for economy of that nature. It also indicates high sanitation and strong immunization schedules are implemented. CVS is the predominant incidence among the non-communicable type. Ischemia is a major cause of death.

Generic Market

Generic drugmakers will be the primary beneficiaries of the Philippine government's investment into healthcare. While the expansion of universal healthcare is positive for the broader pharmaceutical sector, the specific target of the 2017 budget is to expand healthcare access to low-income Filipinos.
Moreover, the constraints on affordability and the demand for low-cost pharmaceuticals will spur greater investment from drugmakers with strong generic drug portfolios.

Generic drug expenditure reached USD1.51bn) in 2016, representing 61.78% of prescription sales and 44.76% of the total market. In 2017, it is expected the subsector has negatively grown to reach $ USD1.47bn (Mostly due to price cuts and partially due to fillipini currency devaluation). By 2021, forecasts say generic drug sales to grow at a CAGr of 4% to reach $ 1.84 bn.

The major driver of the generic drug sector is the Universally Accessible Cheaper and Quality Medicines Act of 2008, which aims to increase the use of affordable generic medicines while simultaneously reducing reliance on foreign-patented medicines. The discussion to set up a 'pharma zone' with an aim to attract Indian pharmaceutical firms to set up manufacturing operations in the Philippines, in order to cater to the generic drug market, emphasises this trend.

Legislation states that public hospitals are to prescribe generic medicines wherever available.
The government aims to strengthen the generic industry in the Philippines through pharmaceutical economic zones, as well as facilitating the importation of generic products and raw materials for manufacture. As such, local production will be stimulated by the intensification of cost containment pressures and compulsory licensing. For example, local news sources reported in March 2017 that Philippines-based United Laboratories is investing in a new manufacturing plant, its seventh plant in the Philippines, to serve the growing domestic demand for generic medicines.

Pharma trade

In 2016, pharmaceutical imports reached a value of USD1.18bn with exports reaching USD37.2mn. Imports are forecasted to grow at a Cagr of 2.5% in the next five years and reach $ 1.4 bn.

According to UN Comtrade data, India was the Philippines' leading pharmaceutical importer in 2016 with a trade value of USD177mn (12% of total pharmaceutical imports), followed by France (9%), Germany (9%), the US (8%) and Switzerland (8%).

Local Drug Industry

The Philippines has a domestic industry comprising 225 manufacturers and 400 'drug traders' (producers of semi-finished drugs only). Multinationals account for the majority of manufacturing output - in terms of volumes and values - although their dominance is waning.

Unilab (United Laboratories) is the Philippines' largest pharmaceutical manufacturer, which produces over

350 branded prescription, consumer healthcare and personal care products. The company has five manufacturing facilities operating to Good Manufacturing Practice (GMP) standards; however only one -Amherst Laboratories - is EU-GMP certified.

Currently India companies are engaged in Trading in Philippines and are yet to set up units.

Statistics

India's Pharmaceutical exports to PHILIPPINES $ Million						
Category	**2015-16**	**2016-17**	**2017-18**	**GR%**	**contbn% of the category**	**Contbn to Region**
BULK DRUGS AND DRUG INTERMEDIATES	15.49	17.23	19.89	15.47	9.18	6.46
DRUG FORMULATIONS AND BIOLOGICALS	149.47	153.59	172.32	12.19	79.51	23.65
AYUSH	0.81	1.42	1.26	-11.33	0.58	15.40
Herbal Products	2.13	1.25	1.26	1.01	0.58	4.36
Surgicals	2.78	2.35	2.57	9.22	1.19	11.87
Vaccines	22.08	32.54	19.42	-40.33	8.96	22.56
Total	192.76	208.38	216.72	4.00	100.00	18.35

Philippines 's Top ten formulation Importing partners $ Million						
Rank	**Country**	**2015**	**2016**	**2017**	**Gr%**	**Share%**
1	India	146.32	177.49	202.25	13.95	11.80
2	Germany	120.26	126.28	160.92	27.43	9.39
3	Switzerland	101.40	112.20	140.47	25.20	8.19
4	France	107.57	132.23	130.56	-1.26	7.62
5	Indonesia	102.95	111.59	127.39	14.16	7.43
6	USA	111.21	115.81	124.97	7.91	7.29
7	Netherlands	43.94	59.86	108.71	81.62	6.34
8	Belgium	40.52	57.87	98.46	70.14	5.74
9	China	60.09	80.95	90.97	12.37	5.31
10	Thailand	46.23	56.42	60.96	8.04	3.56
	World	1234.78	1455.56	1714.24	17.77	100.00

REGISTRATION AND LICENSING REQUIREMENTS

- Regulatory Authority : **Food and Drug Administration (FDA) , Philippines**
- Website of regulatory Authority : https://www.fda.gov.ph/
- Fees for Drug Registration : Generic drug Application:
  CPR Application Fee: 10,000 ₱
  Evaluation Fee: 75,000 ₱
  Annual Fee:15,000₱
  LOT License Fee: 60,000 ₱
  Annual fee: 12,000₱
- Normal time taken for registration : 18 Months
- Registration Requirement [Dossier Format] : ACTD
- Whether plant inspection is mandatory : No
- Validity of Registration 05 Yrs

FDA, Philippines:

The Food and Drug Administration (FDA) is the national health product regulatory agency created by Republic Act (RA3720), as amended by Executive Order No. 175 and RA 9711. FDA regulates the drugs, medical devices, food, cosmetics and toys, and Household/Urban Hazardous substances.

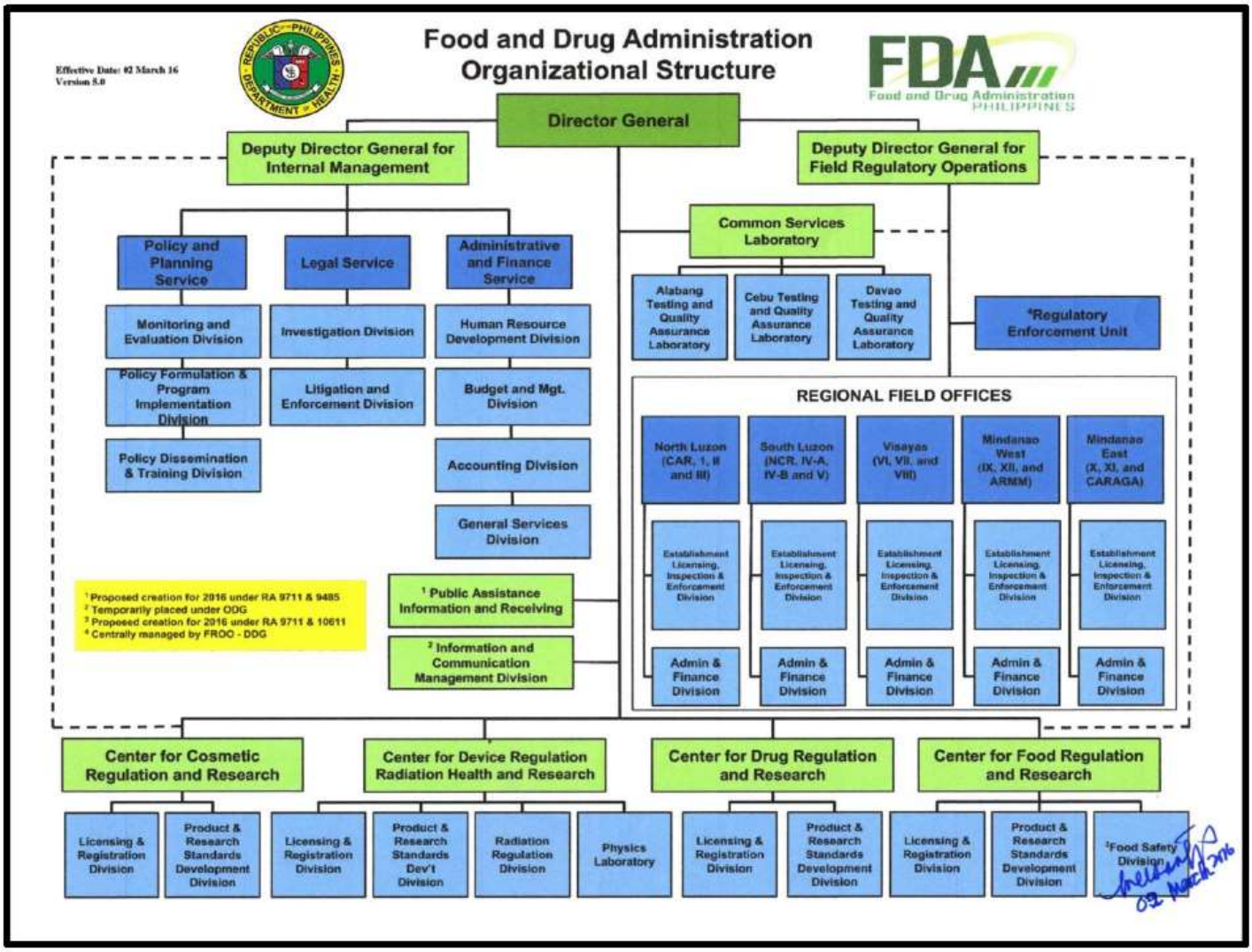
Mission: To guarantee the safety, quality, purity, efficacy of products in order to protect and promote the right to health of the general public.

Vision: The Food and Drug Administration to be an internationally recognized center of excellence in health product regulation by 2026.

Centers:

- CDRR (Center for Drug Regulation & Research)
- CFRR (Center for Food Regulation & Research)
- CCRR (Center for Cosmetic Regulation & Research)
- CDRRHR (Center for Device Radiation Health & Research)
- AFS (Administration & Finances Services)
- FROO (Field Regulatory Operations Office)
- PPS (Policy Planning Service)
- REU (Regulatory Enforcement Unit)
- CSL (Common Services Laboratory)

Organization of Food and Drugs Administration



In the Philippines, drug products are classified into the following:

1) New Drugs or New Chemical Entities
2) Biological Products
3) Generic Drugs
4) Traditionally-Used Herbal Products
5) Herbal Medicines
6) Household Remedies
7) Over-the-Counter Preparations
8) Veterinary Drugs
9) Medical Gases
10) Stem Cell Products

Regulatory Overview

The Food, Drugs and Cosmetics Act, originally introduced in 1963 and heavily revised in subsequent years (most significantly after the 1986 fall of the Marcos dictatorship), provides the main regulatory framework. Although the Generics Act stipulating mandatory generic prescription was passed in 1988, legislation is not uniformly implemented.

The government's administrative order (AO) No.85 permits the state-run Philippine International Trading Corporation (PITC) to parallel import (PI) branded, off-patent pharmaceuticals from India. Pakistan was also approved as a PI source in 2006. The AO exempts the PITC from complying with standard regulatory requirements while also allowing a faster review of the product's registration, which amounts to unfair advantage for the corporation.

In July 2013, the Philippines announced that it will formally adopt the Association of South East Asian Nations (ASEAN) common technical dossier (ACTD) and common technical requirements (ACTR) for the registration of pharmaceutical products for human use, under Administrative Order No. 2013-0021.

The harmonisation process aims to eliminate technical barriers to trade without compromising drug quality, safety and efficacy. Brunei, Indonesia, Malaysia, Singapore, the Philippines, Thailand and Vietnam have fully implemented the ACTD. Cambodia and Laos have achieved partial implementation, while there has been no meaningful update from Myanmar.

The DOH published the fourth annual edition of the Drug Price Reference Index (DPRI) in November 2016, which sets the ceiling prices that all government healthcare facilities should pay for essential drugs. The revised list, which includes 722 medicines, points out that international reference prices may be used to establish the ceiling price for innovative drugs approved for listing in the PNDF, and that for single-source products, cost-effectiveness evaluations conducted in the Philippines may also be used.

Drug Application and Registration

For a company to be able to market a drug product in the Philippines, securing a marketing authorization in the form of a Certificate of Product Registration (CPR) is necessary. A CPR covering a particular drug product shall be a *prima facie*evidence of the registrant's marketing authority for the said drug product in connection with the activities permitted pursuant to the issuance of a LTO (License to Operate).

The process begins with the submission of an electronic copy application using the Integrated Application Form at the Public Assistance, Information, and Receiving (PAIR), by appointment scheduleof an applicant company (which may be a licensed manufacturer, trader, or distributor).

Once an applicant submits the dossier, CDRR evaluates the documents and determines if the product meets the standards of safety, efficacy, and quality. If the product meets these standards, a CPR is issued valid for five (5) years. Should deficiencies be noted, depending on the criticality, a Notice of Deficiency (NOD) or Letter of Disapproval (LOD) may be issued.

The FDA disapproves products based on the following grounds:

- The application requirements submitted show that the drug product does not meet the required technical requirementsor appropriate standards;
- The applicant made misrepresentations, false entries, or withheld any relevant data;
- Major inconsistencies in the information provided in the registration dossier;
- Major queries that were not clarified or addressed satisfactorilyby the applicant company in the compliance for NOD; and
- Major inconsistencies in the compliance for NOD and the registration dossier.

Dept of Health Republic of Philippines adopted the Association of South East Asian Nations (ASEAN) Common Technical Dossier (ACTD) and Common Technical Requirements (ACTR) for the Registration of Pharmaceutical Products for Human Use vide A.O.No:2013-0021 dt:Jul 01 2013

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, packageinsert 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

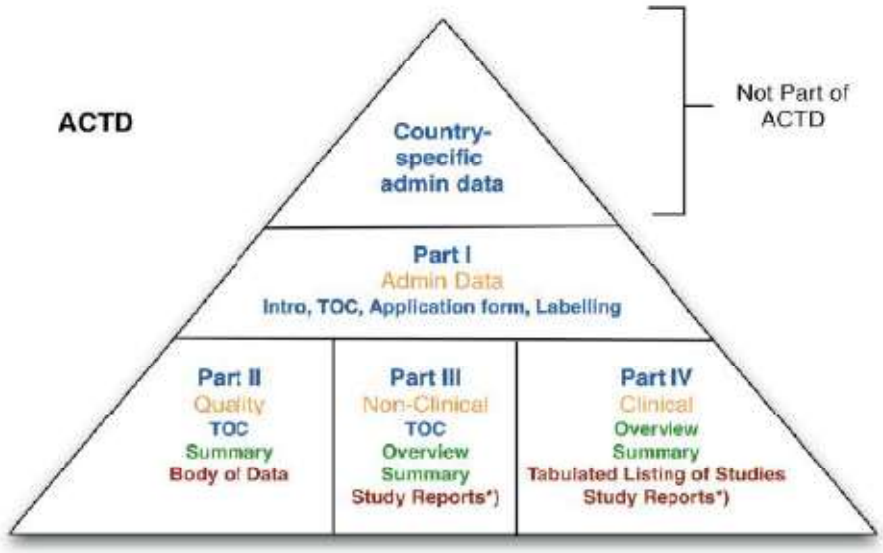
Part IV. Clinical Document

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 AssociatedAnalytical 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



Generic Drug approval application

List of requirements for registration of generic prescription drug products

A. Initial Application

Part I:Administrative Data and Product Information
Sec. A. Introduction
Sec. BTable of Contents
1. Integrated Application Form
2. Letter of Authorization (where applicable)
3. Certifications
4. Labeling

5. Product Information

Sec. C Guidance on the Administrative Data and Product Information

1. Application Form
2. Letter of Authorization (where applicable)
3. Certifications

For contract manufacturing:

a. License of pharmaceutical industries and contract manufacturer
b. Contract manufacturing agreement
c. GMP certificate of contract manufacturer

For manufacturing "under-license"

a. License of pharmaceutical industries
b. GMP certificate of the manufacturer
c. Copy of "under-license" agreement

For locally manufactured

a. License of pharmaceutical industries
b. GMP certificate (country specific)

For imported products

a. License 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

4. Labeling
5. Product Information

5.1.Package Insert

Part II: Quality

Sec. ATable of Contents

Sec. B Quality Overall Summary

Sec. C Body of Data

Drug Substance (S)

S 1 General Information

S 1.1.Nomenclature
S 1.2. Structural Formula
S 1.3. General Properties

S 2 Manufacture

S 2.1. Manufacturer(s)

S 3 Characterization

S 3.1. Elucidation of Structure and Characteristics
S 3.2. Impurities
S 4 Control of Drug Substance
S 4.1. Specifications
S 4.2. Analytical Procedures
S 4.3. Validation of Analytical Procedures
S 5 Reference Standards or Materials
S 7 Stability

Drug Product (P)
P 1 Description and Composition
P 2 Pharmaceutical Development
P 2.2. Components of the Drug Product
P 2.2.1. Active Ingredients
P 2.2.2. Excipients
P 2.3. Finished Product
P 2.3.1. Formulation Development
P 2.3.2. Overages
P 2.3.3. Physicochemical and Biological Properties
P 2.5. Container Closure System
P 2.6. Microbiological Attributes
P 2.7. Compatibility
P 3Manufacture
P 3.1. Batch Formula
P 3.2. Manufacturing Process and Process Control
P 3.3. Controls of Critical Steps and Intermediates
P 3.4. Process Validation and/or Evaluation
P 4Control of Excipients
P 4.1. Specifications
P 4.2.Analytical Procedures
P 4.3. Excipients of Human and Animal Origin
P 5 Control of Finished Product
P 5.1. Specifications
P 5.2. Analytical Procedures
P 5.3. Validation of Analytical Procedures
P 5.5. Characterization of Impurities
P 5.6. Justification of Specifications
P 6 Reference Standards or Materials
P 7 Container Closure System
P 8 Product Stability
P 9 Product Interchangeability

Additional Requirements:

1) Representative Sample with corresponding Certificate of Analysis
2) For imported products:
   (a) Foreign GMP Clearance
3) For single component Vitamin A products and drug products containing non-vitamin/non-mineral APIs combined with vitamins and/or minerals (e.g. Isoniazid + Vitamin B6):
   (a) Proof of interchangeability
4) MR/E to Initial:
   (a) Risk Management Plan (RMP)
   (b) Periodic Safety Update Report (PSUR)

B. Regular Renewal Application

1) Integrated Application Form
2) Unit Dose and Batch Formulation
3) Technical Specifications of Finished Product
4) Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)
5) Assay and Other Test Procedures including Assay with Data Analysis
6) Stability Studies
7) Labeling Materials (actual/commercial label)
8) Actual commercial sample

Additional Requirements:

1) Post-marketing commitments (if any)

C. Automatic Renewal Application

1) Integrated Application Form
2) Copy of Certifications issued as a result of post-approval change(s)
3) Labeling materials (actual/commercial labels)
4) Actual commercial sample

Additional Requirements:

1) Post-marketing commitments (if any)

Processing Timelines

A maximum of 254 calendar days is given by the FDA in the processing of initial applications for generic drug products, excluding stop-clocks due to noted deficiencies.

Renewal of Drug Registration

CPRs issued by the FDA are given 5 year validity. For continuous marketing authorization after the validity, the MAHshall apply for renewal of registration. Submission of the application for renewal shall be on or 120 days before the expiration date of the CPR.Renewal shall be accepted unless the prescribed renewal fee is paid.

There shall be automatic renewal of the CPR when the following conditions are satisfied:

- The application is filed before the expiration date of the registration;
- The prescribed renewal fee is paid upon filing of the application; and

- A sworn statement indicating no change or variation whatsoever in the product is attached to the application.

For applications filed from within 120 days from its original expiry, the CPR shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal.

Failure to market a pharmaceutical product, without legitimate reason, during an uninterrupted period of at least 3 years from the date of issuance or renewal of the registration or the last date of operation or marketing shall be a ground for cancellationof CPR.

Failure to apply for renewal registration shall mean cancellation of the CPR. If the company wishes to reapply for renewal, then the corresponding surcharge will apply.

Post-approval Changes

It is understood that throughout the life cycle of a drugproduct, changesmay occur on the administrativeandtechnical details in the registration dossierwhich may affect the safety, efficacy, and quality of the product. In line with this, the product owner must seek approval from the FDA to implement thechange or provide notification depending on the type of variation being proposed.

In the post-approval change (PAC) scheme of the FDA[35], changes are classified either as those falling under the ASEAN Variation Guidelinesfor Pharmaceutical Products, or those falling under country specific requirements. PACs are also classified according to the risk associated with the product:

Major Variation:

This refers to a variation to a registered pharmaceutical finished product that may affect significantly and/or directly the aspects of quality, safety and efficacy and it does not fall within the definition of minor variation and new registration.

Minor Variation –Prior Approval (MiV-PA) and Minor Variation –Notification (MiV-N)

This refers to a variation to a registered pharmaceutical finished product in terms of administrative data and/or changes with minimal/no significant impact on the aspects of efficacy, quality, and safety.

New Schedule of Fees and Charges of the Food and Drug Administration for Licensing, Registration, and Other Authorizations and Regulatory Services

Fee structure for various kinds of application can be identified at https://ww2.fda.gov.ph/attachments/article/514522/FINAL%20ANNEXES%20for%20AO%20on%20INCREASE%20OF%20FEES.pdf

LICENSE TO OPERATE

	INITIAL	RENEWAL
VALIDITY PERIOD	3 YEARS	5 YEARS

* Renewal Fee is equivalent to Seventy Percent (70%) of the Initial License Fee for each application
** Annual Fees apply to both Initial and Renewal LTO

. CENTER FOR DRUG REGULATION AND RESEARCH

	LICENSE FEE	ANNUAL FEE
Drug Importer	60,000	12,000

CERTIFICATE OF PRODUCT REGISTRATION

VALIDITY PERIOD

TYPE OF AUTHORIZATION	INITIAL	RENEWAL
CERTIFICATE FOR PRODUCT REGISTRATION	3 YEARS	5 YEARS
CERTIFICATE FOR PRODUCT NOTIFICATION	1 YEAR	1 YEAR

* Renewal Fee is equivalent to Seventy Percent (70%) of the Initial Application Fee for each application
** Annual Fees apply to both Initial and Renewal CPR/CPN

II. CENTER FOR DRUG REGULATION AND RESEARCH

A.PRODUCT TYPE

NEW DRUG APPLICATION	APPLICATION FEE	EVALUATION FEE	ANNUAL FEE
1. NEW CHEMICAL ENTITY	100,000	150,000	30,000
2. VACCINES & BIOLOGICALS	100,000	150,000	30,000
3. INNOVATIVE PRODUCTS AND TECHNOLOGIES *	100,000	150,000	30,000
4. GENERICS			
A. PRESCRIPTION			
Imported	10,000	75,000	15,000
Locally Manufactured	5,000	30,000	—
B. NON- PRESCRIPTION			
Imported	7,500	50,000	10,000
Locally Manufactured	3,500	20,000	—
5. TRADITIONAL and HERBAL MEDICINES			
A. PRESCRIPTION			
Imported	10,000	75,000	15,000
Locally Manufactured	5,000	30,000	—
B. NON- PRESCRIPTION			
Imported	7,500	50,000	10,000
Locally Manufactured	3,500	20,000	—

6. OTHER DRUG PRODUCTS**			
Imported	7,500	50,000	10,000
Locally Manufactured	3,500	20,000	—
7. VETERINARY MEDICINES, VACCINES AND BIOLOGICALS			
A. PRESCRIPTION			
Imported	10,000	75,000	15,000
Locally Manufactured	5,000	30,000	—
B. NON- PRESCRIPTION			
Imported	7,500	50,000	10,000
Locally Manufactured	3,500	20,000	—

* e.g. Radio-pharmaceuticals, Blood and Blood Products, Stem Cell, and Human Cell and Tissue-based products
** e.g. Medical Gases

B. VARIATIONS

TYPE OF AUTHORIZATION	MAJOR VARIATION FEE	MINOR VARIATION FEE
CPR of Imported Drug Products	30,000	10,000
CPR for a Locally Manufactured	10,000	5,000

C. OTHER PERMITS

PERMIT/CERTIFICATION	FEE
1. Generic Labelling Exemption	5,000
2. Certificate of Pharmaceutical Product	5,000

GMP conformity assessment of overseas manufacturers of Drug Product

PRODUCT **ASSESSMENT TYPE ***	**FEE**	**NOTE**
1. Verification of GMP Standard (GMP Evidence Evaluation)	50,000	Per manufacturing site
2. Quality System Dossier (QSD) Evaluation	75,000	Per manufacturing site (one-time payment)
3. On-site GMP audit of manufacturer located in:		
A. ASEAN country	USD 7,000	Per manufacturing site
B. Other Asian countries	USD 10,000	Per manufacturing site
C. Any other country	USD 20,000	Per manufacturing site
D. Listed Fee **	USD 12,000	Per manufacturing site

* All new overseas manufacturers who intend to register their drug products in the Philippines will be subjected to GMP Conformity Assessment. The service charge varies according to the geographical location of manufacturer. For the purpose of the application of inspection fees, 'manufacturer' encompasses all types of manufacturing, including: packaging, re-packaging, labeling and re-labeling. A fee is due only when manufacturer is notified that an inspection is being prepared. Listed fees include travel and accommodation costs of the 2- or 3-member inspection team.

** To cover costs and reasonable expenses by each inspector, including costs for travel/transportation fare, accommodation, and per diem/allowance.

LABORATORY FEES FOR CERTIFICATION

CERTIFICATION	**FEE**
A. GENERAL PERMIT AND/OR APPROVAL	
I. Sustainability Evaluation of Food Contact Materials	2,500
II. Evaluation of Test Results from Accredited Laboratories	2,500
B. LOT RELEASE CERTIFICATE	
I. Single Component	3,000
II. Multiple Component	4,500
C. BATCH NOTIFICATION CERTIFICATE	6,500