EXPORT BUSINESS SETUP

PROJECT REPORT 2023

Client: Drugs and Devices Pharma Ltd

Address:

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1.0 PROJECT INTRODUCTION

Drugs and Devices Pharma Pvt. Ltd.

I.INTRODUCTION:

Drugs and Devices Pharma Private Limited is one of the most trustworthy business entities in the pharmaceutical industry operating its business from Mumbai and Dubai which are financial capitals of India and the world because we offer a quality assured range of quality pharmaceutical products, nutraceutical products, surgical range of product and especially products of sexual wellness products.

With the vision of Marketing and Supplying products in Indian as well as in the global market company has established its operation offices in Mumbai and Gujrat and expanding its business wings globally.

Vision :

Drugs and Devices Pharma is willing to be a Quality Medicine manufacturing and Exporter company to cater to mankind and Humanity

Quality Policy :

The company is bound to business and Quality Ethics and will always engage in fair business practices as well as company is Quality-driven as per global quality Norms

II. PROMOTERS:

Drugs and Devices Pharma is a Partnership Firm. The Partners of the Unit are:
1. Mr. Wasim
2. Mr. Kazi
All the partners are young and dynamic and are already engaged in a similar line of business. Further, all the partners are financially sound and are capable of putting their stake in the business.

III. Project Description:
D&D Pharma is willing to spread its wings all over the world with brand-building quality Pharmaceutical Products. Products will be mostly manufactured in India and some parts of Europe.

Targeting the Regulated Countries D and D Pharma is willing to grow its wings to the rest of the world market also.

UAE is the base for D and D Pharma and has its operations also in UAE in the nutraceuticals and Surgical segment D Pharma has served humanity and mankind during the pandemic, it has launched its Vitamin Supplement products as well as some Pharmaceutical products during the COVID-19 Pandemic situation to serve COVID Patients.

Vision Towards Specialty Segment :

D And D Pharma has the vision to build a portfolio in the specialty segment with brand building in the same.

Vital Nutrition and **Sexual well-being** with a Great brand Building is the focus of D and D Pharma along with this Anticancer, Protein supplements the another segment and then the rest of the medicine supplies

2.0 GLOBAL PHARMA MARKET INTRODUCTION

Industry Scenario

The pharmaceutical industry in India is expected to reach $65 Bn by 2024 and $130 Bn by 2030.

The pharmaceutical industry in India is currently valued at $50 Bn.
India is a major exporter of Pharmaceuticals, with over 200+ countries served by Indian pharma exports. India supplies over 50% of Africa's requirement for generics, ~40% of generic demand in the US, and ~25% of all medicine in the UK.
India also accounts for ~60% of global vaccine demand and is a leading supplier of DPT, BCG, and Measles vaccines. 70% of WHO's vaccines (as per the essential Immunization schedule) are sourced from India.

The pharmaceutical export business is an evergreen and profit-making business. Post covid there are many opportunities available in India's Pharma Export Sector
Pharma export stood at USA $ 2514 Billion in FY 2022-23
New entrants shall start from Non-Register Country and Product where there won't be a huge movement involved

Category-wise exports during the last three year

Product Category	2019-20	2020-21	2021-22	% Growth
Drugs Formulations & Biologicals	15948.83	19042.17	19021.05	-0.11
Bulk Drugs & Drug Intermediates	3867.77	4429.70	4472.05	0.96
Ayush & Herbals	428.07	539.88	612.83	13.51
Surgical	458.79	432.29	512.86	18.64
Grand Total	20703.46	24444.03	24618.78	0.71

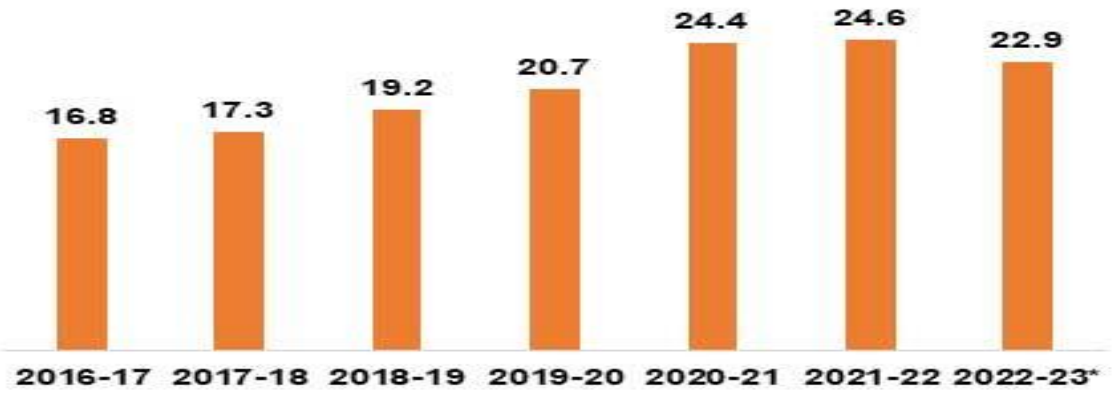
Region-wise exports during the last three years

Top 25 export destinations of India's pharmaceutical products

Region	2019-20	2020-21	2021-22	% Growth
NAFTA	7258.60	8392.84	7820.77	-6.82
EUROPE	3574.36	4234.59	4426.61	4.53
AFRICA	3213.86	3917.90	3856.27	-1.57
LAC	1227.99	1447.66	1710.25	18.14
ASEAN	1292.65	1462.00	1761.01	20.45
WANA	1034.02	1320.44	1335.73	1.16
SOUTH ASIA	1167.69	1238.02	1300.48	5.05
CIS	905.27	1177.96	1097.89	-6.80
NEA	684.07	823.98	803.03	-2.54
OCEANIA	344.94	428.23	466.21	8.87
UNSPECIFIED	0.02	0.41	40.52	9782.93
Grand Total	2070	2444	2461	0.71

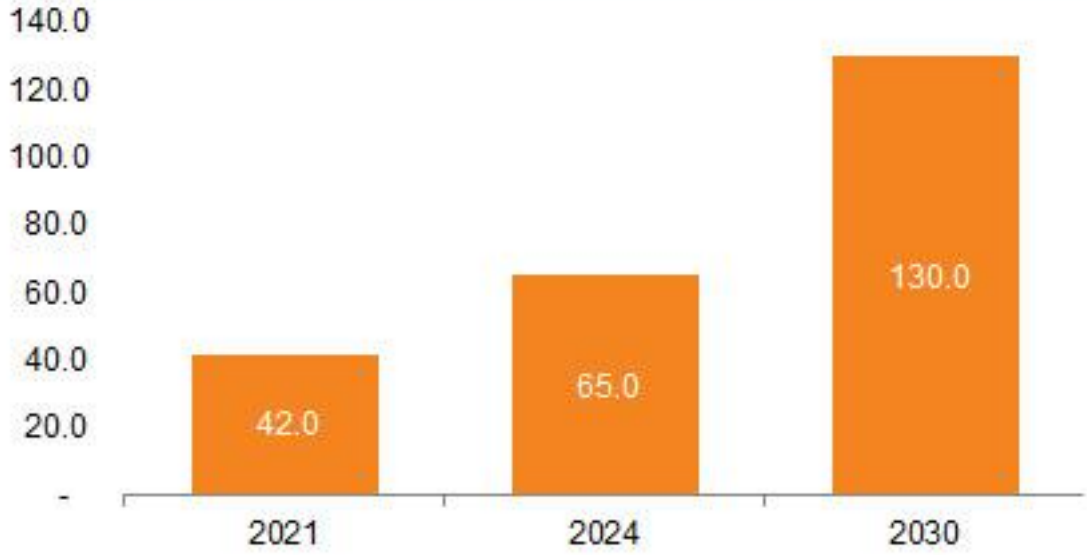
Rank	Country	2019-20	2020-21	2021-22	% Growth
1	U S A	6749.60	7718.80	7101.60	-8.00
2	U K	557.89	716.52	704.51	-1.68
3	SOUTH AFRICA	612.01	833.53	612.30	-26.54
4	RUSSIA	552.41	590.69	597.81	1.21
5	NIGERIA	443.09	573.17	588.59	2.69
6	BRAZIL	473.10	525.28	580.78	10.57
7	GERMANY	504.17	575.47	528.30	-8.20
8	FRANCE	319.50	412.81	512.20	24.08
9	NETHERLAND	321.05	375.18	460.08	22.63
10	BELGIUM	297.18	370.19	449.77	21.50
11	CANADA	334.54	441.77	418.57	-5.25
12	AUSTRALIA	274.10	346.73	386.90	11.58
13	CHINA P RP	287.97	371.31	343.76	-7.42
14	PILLIPIN	263.99	284.40	342.25	20.34
15	KENYA	275.55	282.79	341.37	20.72
16	U ARAB EMTS	203.13	321.64	333.77	3.77
17	MYANMAR	224.75	234.57	329.95	40.66
18	NEPAL	247.26	231.32	320.12	38.39
19	BANGLADESH	250.95	261.43	309.12	18.24
20	MEXICO	159.96	212.43	287.61	35.39
21	TURKEY	216.57	295.24	282.48	-4.32
22	VIETNAM	223.76	243.90	269.05	10.31
23	TANZANIA	218.35	262.62	260.00	-1.00
24	INDONESIA	107.16	158.51	253.32	59.82
25	PAKISTAN	124.71	152.32	243.36	59.77

India's drug and pharmaceutical export trend (US$ billion)



Source: DGCI&S; *Until February 2023

Indian Pharmaceutical Market (US$ billion)



3.0 Export Business Division of D and D Pharma :

This project report is directed towards opening the Export Business division of D and D Pharma.

I . Basic Requirements (Statutory Requirement):

a. Company Registration
b. Wholesale Drug Sales License
c. IEC Code
d. Pharmaxel Registration
e. Shop Act License
f. GST Registration

II . Office Setup:

a. Office Establishment in Mumbai
b. Furniture and basic office requirements with Staff

III. Company Portfolio :

a. Company Boucher
b. Company Website
c. Company Visiting Cards of Concern Staff and Management
d. Product Portfolio
e. Product Moc Photos
f. Company Website
g. Company Email IDs

IV. Manufacturing and Exports

a. Contracts with Manufacturers
b. WHO Manufacturing Units are preferred and mandatory for Export
c. Similar Product presence in India for company Trust and Identity

Requirement for Domestic Marketing :

I . Basic Requirements (Statutory Requirement):

g. Company Registration
h. Wholesale Drug Sales License
i. Shop Act License

j. GST Registration

II . Office Setup:

c. Office Establishment in Mumbai

d. Furniture and basic office requirements with Staff

III. Company Portfolio :

h. Company Boucher

i. Company Website

j. Company Visiting Cards of Concern Staff and Management

k. Product Portfolio

l. Product Moc Photos

m. Company Website

n. Company Email IDs

IV. Manufacturing and Exports

d. Contracts with Manufacturers

Checklist For Ready Reference - For Client Reference

Sr No	Checkpoint	Status
1	Office Establishment in Mumbai	
2	Furniture and basic office requirements with Staff	
3	Company Boucher	
4	Company Website	
5	Company Visiting Cards of Concern Staff and Management	
6	Product Portfolio	
7	Product Moc Photos	
8	Company Website	
9	Company Email IDs	
10	Contracts with Manufacturers	
11	WHO Manufacturing Units are preferred and mandatory for Export	
12	Similar Product presence in India for company Trust and Identity	
13	Distributor Network for Domestic	
14	Logistic Arrangements Export /Domestic	

4.0 Project Budgeting /Finance Plan

Approximate Budget Considering Complete Launch of Project :

Sr. No.	Particulars	Amount
1.	**Office Setup: Furniture /Computers /**	**15,00,000.00**
	Working Expenses :	
2.	**Staff Salaries Approx. Per Month 125000.00 Total Provision for Six Months**	**7,50,000.00**
3.	**Traveling Expenses for Business Per Month 75000.00 (Six Months)**	**4,50,000.00**
4.	**Stationary and Advertisement**	**5,00,000.00**
5.	**Exhibitions and Other Portal Advertisement**	**15,00,000.00**
6.	**Product Launching Cost**	**2,00,000.00**
7.	**Product Manufacturing First Batch Approx. 5000 Strips or Units Per Product Total Average 10 Products**	**15,00000.00**
8.	**Regulatory Dossier Expenses 10 Products Per Product 25000.00**	**2,50,000.00**
9.	**Audit Expenses if Triggered For Semi-Regulated Countries Approx. 3 Countries**	**15,00000.00**
10.	**BA BE Studies as Actual for Approx. 3 Products Per Product Ranging from 2500000 to 4500000 Per Product**	**1,20,00,000.00**
	Total Approximate Project Cost Cost For Six Months Projection After that Business Must be Self-Sustained	2,01,50,000.00
	Without BA BE Studies Consideration	81,50,000.00

5.0 Detailed Business Plan with Requirements :

1. **Business Plan :**
   a. Objective :
      i. To establish an export division of D&D Pharma and spread product marketing To Different countries
      ii. To establish a company brand in UAE and surrounding countries with a vision of financial growth and a stable product portfolio

   b. **Targeted Market Product Segments:**

      a. **First Phase:**

      1.1. **Allopathy brand-building products**

      1.1.1 Erectile dysfunction products.

      a) Sildenafil Citrate Tablet all strengths
      b) Sildenafil Gel all flavors.
      c) Tadalafil Tablet
      d) Tadalafil Gel.

2. Nutraceuticals Product Segments

This is the easiest way to start a business as this product does not require a strong registration process. The Nutra segment is nowadays the most trending segment because the major population is shifting towards natural remedies and so on, the products are in high demand. Especially the diabetic and weight loss segments are more popular in the world market.

Margins and profit are more in the Nutra segment as compared to the other Pharmaceuticals. It does not require a major licensing process or it has simple licensing requirements and world wide countries worldwide have very simple documentation.

As nutraceuticals are being considered as high value and non-decided-cost products, because these products are proprietary brands and do not have any price prediction, according to our advertisements we can convenience clients for any to, as per our quality.

3. Other Medicines -

Other segments can be penetrated according to the requirements of clients, but the medicine sector needs to have registration in almost all countries. It is divided into:

Non-regulated (non-audited) countries

1) Semi-regulated countries
2) Regulated countries

Non Regulated Market

Non-regulated countries' rates are comparatively low but the company can achieve volume. Comparatively semi-regulated and regulated countries have good profit margins and significant product prices are there.

These markets are where it is easy to register any product or there is no registration required. But comparatively, non-developed or under-developed countries have lower margins available as the income or paying capacity of the public is less. Mostly, in such countries, the government is only responsible for the fulfillment of medical needs and so most needs of such countries' imports are through a government tendering system. A lower profit with high-volume business strategies will always work for this market.

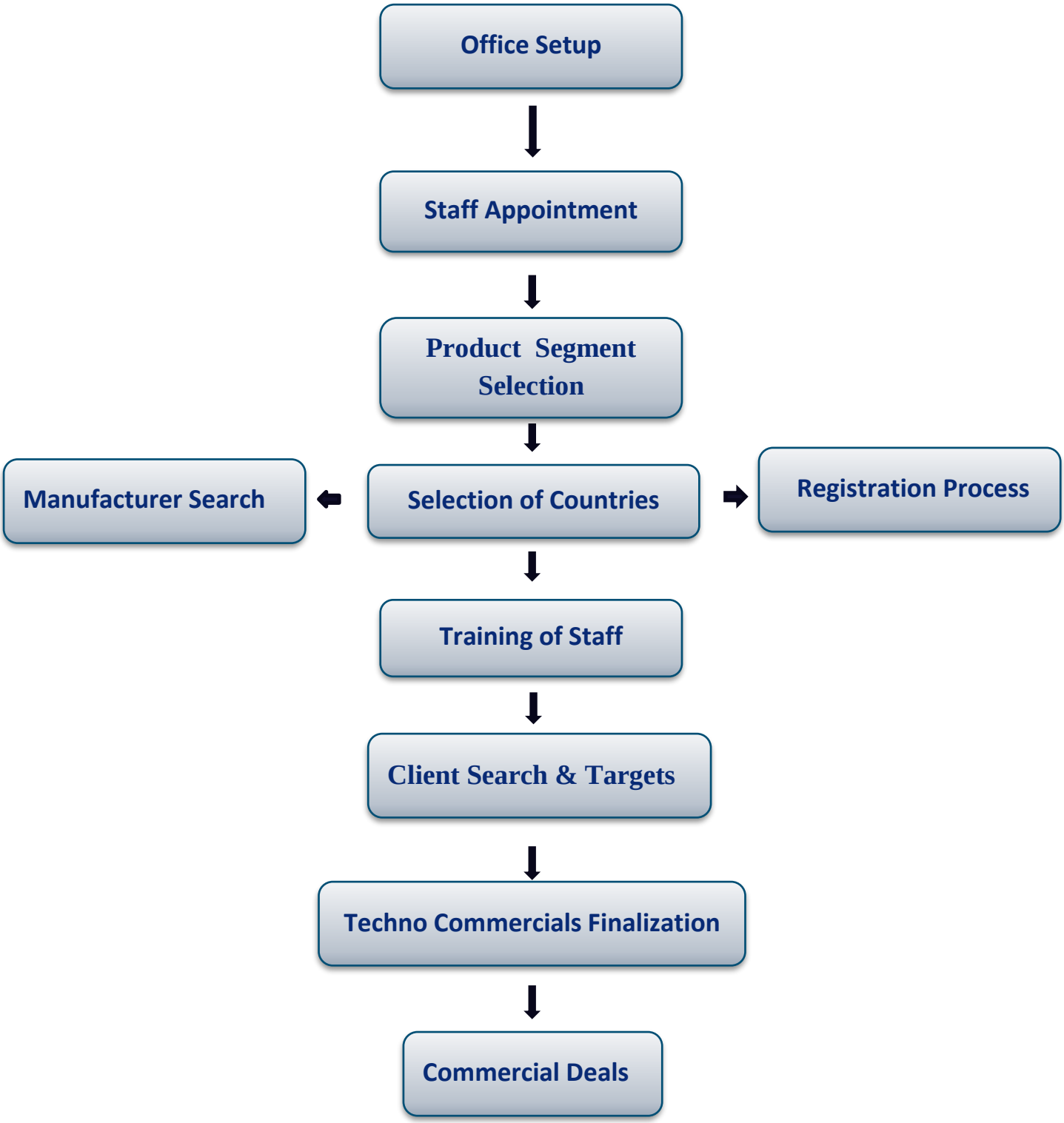
Requirements-:

Basic documentation and only WHO-approved manufacturers can
export to these countries

Semi Regulated Market-

These markets are comparatively stringent market specials where product registration Criteria are applicable and they require extensive and lengthy documents.

6.0 HOW TO START (FLOW CHART)



6.1 Office Setup:

Need to set up an office with the business development team and accessible From the nearby airport or public transport for pharma business physical address Is necessary.

This is not mandatory that the office be in Mumbai or India it can be anywhere in the world. Preferable locations are near to pharma manufacturing hub.

6.2 Selection of Staff :

One or two preferably ladies/female staff shall be appointed with good Communication, good personality, dynamic presentation approach preferred Pharma background will have drug knowledge.

6.3 Staff Training:

Staff training shall be done on bellow topics by professional trainers.

1) Searching pharmaceutical/ medicine or distributors in different countries of the world.
2) Reaching to different importers.
3) Preparing and launching different portals like LinkedIn and others for product and company promotion.
4) Reminder to different clients and importers.
5) Organizing meetings, presenting company.
6) Attending different pharma meets and pharma exhibitions around the world.

6.4 Job profile or job description for business development staff

Skill requirement:

- Good communication skill
- Good presentation skill
- Good personality
- Positive attitude
- Basic knowledge of the pharma industry

Job Description:

- Searching emails and contact details of importers of different countries.

- Promote the company and company brand in different parts of the world.
- Communication with clients.
- Follow-up for orders.
- Discussion and posting of company portfolio on different portals.

6.5 **Hiring of technical staff:**

6.5.1 Pharmaceutical export required to have thorough product knowledge and technical aspects, pharmaceutical aspect of the product which is the most important part.

6.5.2. For the above purpose company needs to hire technical staff who knows

6.5.3. Pharma and regulatory basics.

6.5.4 Understanding regulatory aspects, and guidelines of all countries where we

6.4.5 Promotes our product is again an important part of the export business.

6.4.6 Technical and regulatory co-ordination must know about the formats an

6.5 HOW TO START:

Domestic Existence:

This is most important to build a domestic existence in the Indian market, building a brand in the Indian market always supports revenue generation and also builds trust in the overseas client about the company.

Easy way to start:

1) Nutraceutical product-

Nutra is the easiest way to start operations because the manufacturing cost is less and it is always supportive to have some brands in our hand for sampling or showcasing purposes.

Features of Nutra products:

1) Less manufacturing cost
2) High MRP or rates as there is no price cap.
3) Some products can be launched in the export market as well.

Product segments to launch in Nutra:

1) Weight loss
2) Diabetes
3) Hair loss products
4) Skin glow products

2) Cosmetics product:

Cosmetic is another segment that can be manufactured and exported without major formalities. The cosmetic sector is easy to launch in any country and does not have major registration drawbacks; if a company does not have a public advertising network the cosmetic market can not generate big orders and may fail, but for brand-building purposes cosmetics is a good segment.

3) Drug Products :

The company can start its Export Business with the drug Product segment. All formulations in different drug categories can be launched and can be exported to different countries. This segment requires registration of every product in every country as well as there shall be proper marketing partners, importers, or distributors to sell these products

4.0 Immediate Starting Advice :

D and D Pharma can start bellow product segments with immediate effect:

4.1.0 Domestic Market segment :

This is advised to launch a domestic division for company survival and company working expenses compensation

As discussed and as per the management vision of D& D Company is willing to go ahead with the Sexual wellness sector as a brand-building activity

4.1.1 Scenario of Indian Market :

In India, there is huge competition and the business of pharma especially for public demand or counter-sale products.

Launching with the following Portfolio is helpful for expected recovery and for brand-building purposes.

1. Sildenafil Tablet 50/100 mg Packing 1 x4 Design shall be attractive Approx. Profit Earning ratio will be 20-25%
2. Tadalafil 10/20 mf Packing 1 x 4 Similar to Pfizer Packing Approx. Profit Earning ratio will be 20-25%
3. Protein Powders for Children and Adults as Meal Replacements Approx. Profit Earning ratio will be 30-45%

7.0 Product Portfolio (Trending Product for Export Business)

FINISHED FORMULATION

Product	Strength
GASTROLOGY	
Omeprazole + Domperidone Capsule	20/40 mg
Ondansetron Tablet	4/8 mg
Pantoprazole –Tablet	40
Rabeprazole Sodium Tablet	10/ 20/ 40 mg
Magnesium Tablet	400 mg
Fexofenadine HCl Tablet	8.4/5/10
Loratadine Tablet	5/10 mg
ANALGESIC & ANTISPASMODICS	
Albendazol Tablet	400 mg
Itraconazole Tablet	100/200 mg
ANTI DIABETICS	
Dapagliflozin Tablet	10 mg
Metformin Tablet	500/850/1000 mg
Pioglitazone HCL Tablet	15/30 mg
ANTI-BACTERIAL	
Azithromycin Tablet	100/250/500 mg
Azithromycin dry sup Suspension	200/ 5ml
Clarithromycin Tablet	250/500mg
Clindamycin Capsule	150 /300 /600 mg
Doxycycline Tablet	100 mg
Erythromycin Stearate Tablet	200 mg/500 mg
Gatifloxacin Tablet	200/400 mg
Levofloxacin Tablet	200/500 mg

CARDIOVASCULAR DRUGS	
Amlodipine Tablet	5/10 mg
Atrovastatin Tablet	10/20 mg
Clopidogrel Tablet	75mg
Clopidogrel+ Aspirin Tablet	75+75 mg
Fenofibrate Tablet	145/160/200mg
Irbensartan Tablet	150/300 mg
Lisinopril Tablet	5/10 mg
Irbensartan+Hydrochlorothiazide Tablet	125 mg
Ivabradine Tablet	5/7.5 mg
Lisinopril Tablet	50+12.5 mg
Losartan Potassium Tablet	25/50mg
Rosuvastatin Tablet	20/40 mg
Simvastatin Tablet	5/10/20 mg
Telmisartan Tablet	20/40/80 mg
Valsartan Tablet	80/160/320mg
CNS ANTIPSYCOTIC	
Betahistine HCL - Tablet	8/16/24 mg
Citicoline - Tablet	500 mg
Escitalopram - Tablet	10/20 mg
Gabapenti – Tablet	300/600 mg
Paroxetine – Tablet	250/500mg
Vigabatrin – Tablet	50 mg
ANTI MALARIAL	

Artemether + Lumefantrine Suspension	20+120/40+240/ 80+480mg 60 ml
Artemether + Limefantrine Dry Sus Tablet	60 ml
Combipack of Artesunate & Amodiaquine Tablet	160+320 mg
Dihydroartemisinin+ Piperaquin oral suspension	40+320
Dihydroartemisinin + Piperaquine Dry sus Tablet	80
Primaquine Tablet	7.5/15mg
Artemether+ Mefloquine Tablet	300+375/600+750
NEPHROLOGY & UROLOGY	
Deferasirox – Tablet	100/400/250/500mg
Febuxostat - Tablet	40/80 mg
Finasteride - Tablet	1/5 mg
Sevelamer Hydrochloride – Tablet	400/800 mg
Tamsulosin + Dutasteride – Capsule	400/500 mg
Tamsulosin + HCL – Tablet	400 mg
EFFERVESCENT	
Vitamin C effervescent tablets	500/1000 mg
Paracetamol Effervescent Tablet	500/1000 mg
Paracetamol & Caffeine Tablet	500/65 mg
Sildenafil – Tablet	50/100 mg
Calcium Carbonate - Tablet	500/1000 mg
ERECTILE DYSFUNCTION	
Sildenafil citrate-Tablet	50/100 mg
Sildenafil + Dapoxetine – Tablet	50+60 mg
Vardenafil - Tablet	10/20 mg

Sildenafil - Tablet	100 mg
Sildenafil – Jelly	100 mg
Sildenafil - Dispersible	100 mg
Sildenafil - Chocolate	100 mg

8.0 Erectile Dysfunction Drugs Market Trends

Erectile Dysfunction (ED) Drugs Market 2024-2028

The global erectile dysfunction (ED) drugs market size is estimated to grow by **USD 1.44 billion** at a **CAGR of 6.67%** between 2023 and 2028.

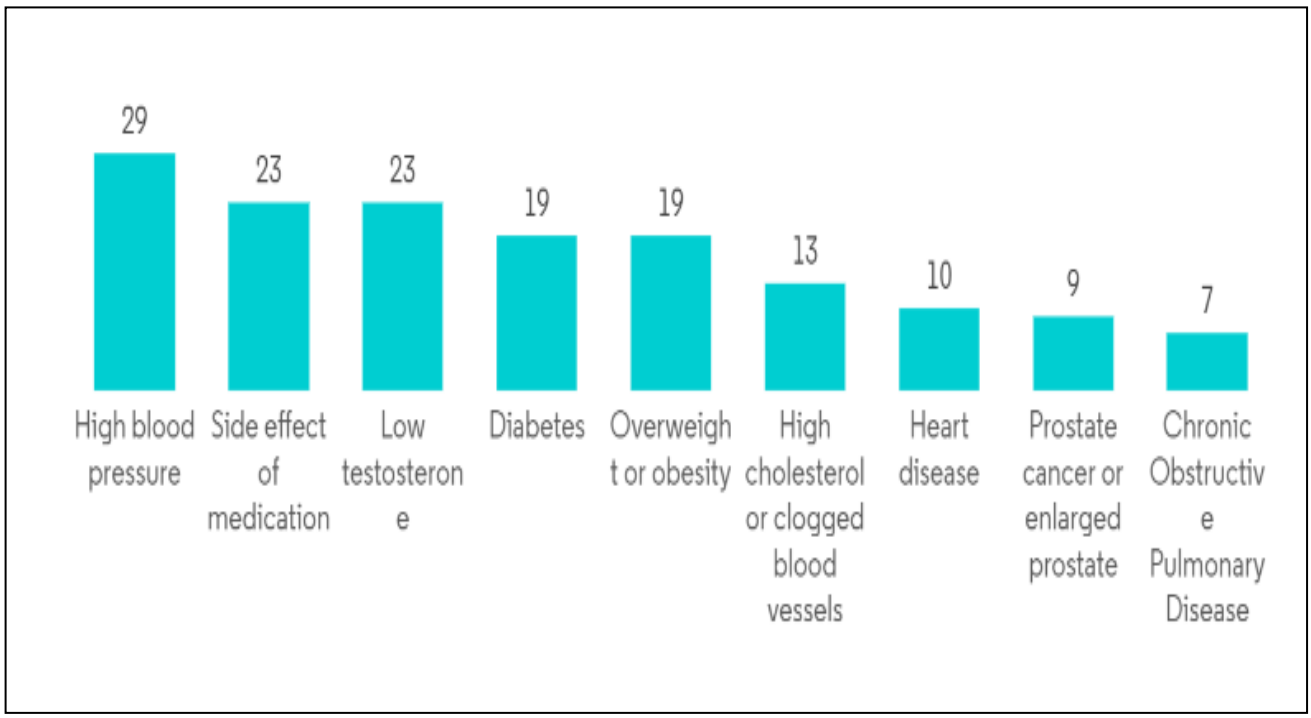
The awareness of erectile dysfunction is growing across the world as it is an underdiagnosed and undertreated disorder. To overcome the lack of awareness regarding the conditions that lead to ED, several organizations, healthcare agencies, and government bodies are focusing on improving the quality of life of the patients. Furthermore, there are several erectile dysfunction support groups, under which patients are provided with information on personal experiences, the side effects of drugs, the dosage forms to be taken, information on the mechanism of action, and the half-life of the drugs used for the treatment of ED. Hence, the rising awareness of ED will fuel the growth of the market during the forecast period.

The Viagra (Sidenafil citrate) Segment is Expected to Dominate the Market

Erectile dysfunction is treated with the drug sildenafil. It helps men get an erection by increasing blood flow to the penis. Viagra is the most common drug used as first-line therapy in the treatment of erectile dysfunction. Viagra is also used to treat pulmonary arterial hypertension, which causes ED. According to an article published by Hims & Hers Health, Inc., in June 2021, more than 95% of erectile dysfunctional males who used sildenafil said they were satisfied with the way it affected their erections.
Furthermore, according to an article published by Inverse, in February 2020, Sildenafil is a popular option for men seeking to treat erectile dysfunction as it helps erections last for three to five hours after taking the medication. Sildenafil is sold under the trade name Viagra, which is highly well-known and earns its parent company, Pfizer, an estimated USD 1.8 billion annually.

Therefore, the above-mentioned factors are expected to drive segmental growth in the market during the forecast period.

Physical Cause of Erectile Dysfunction (in Percentage), United States, 2021



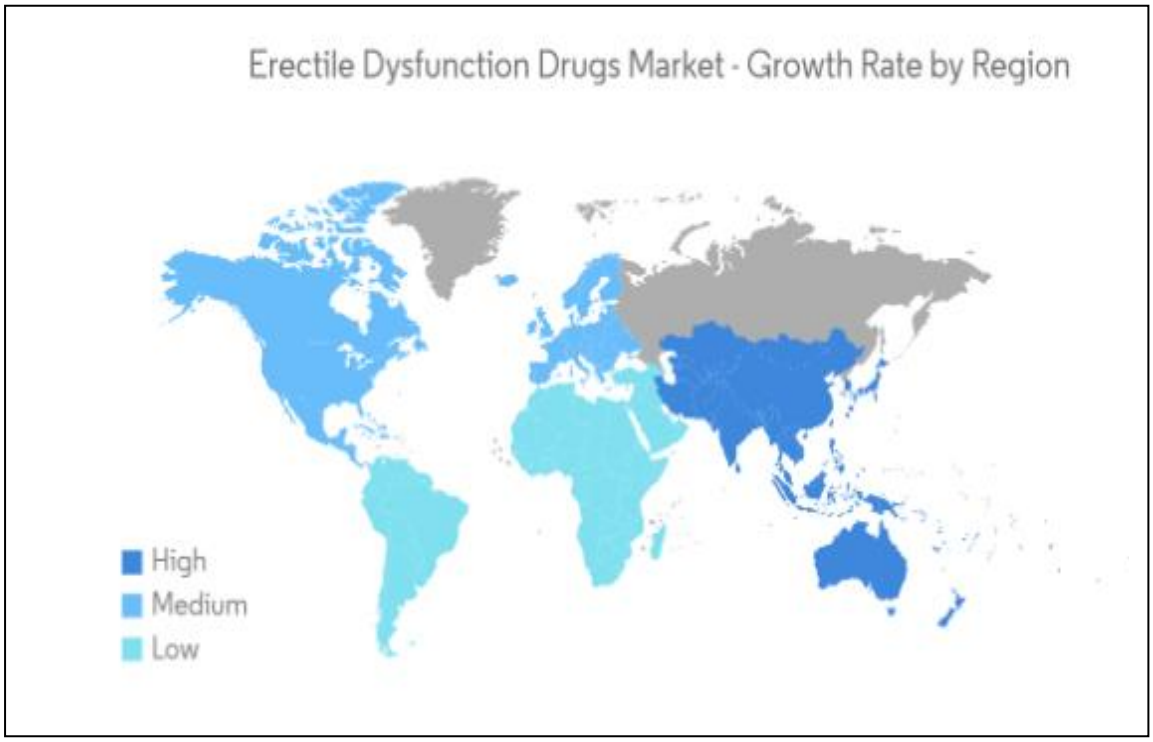
North America is Expected to Dominate the Market over the Forecast Period

North America is expected to dominate the erectile dysfunction drugs market, owing to the rising geriatric population, increase in cases of ED, and the presence of better healthcare infrastructure. According to the September 2022 published article by MSD Manuals, in the United States, about 50% of men 40 to 70 years of age are somewhat affected by ED, and the percentage increases with aging.

Furthermore, as per an article published by the National Institute of Diabetes and Digestive and Kidney Diseases, in 2021, ED affected approximately 30 million men in the United States. Besides, the country has the highest rate of self-reported ED which is expected to drive market growth over the forecast period.

Furthermore, key drugs for ED, including VIAGRA and CIALIS, have faced patent expiration in countries such as the US and Canada. In addition, the US is a developed country, and the economic status of the population is favorable. Thus, they opt for such expensive alternative modes of treatment. The genericization and the increased adoption of alternative treatments are leading to the decelerating growth of the erectile dysfunction drugs market in North America during the forecast period.

Moreover, studies and product launches for the effective treatment of ED are also contributing to the market growth. For instance, in January 2022, Petros Pharmaceuticals, Inc., initiated two self-selection studies for its erectile dysfunction (ED) drug STENDRA (avanafil). Furthermore, in September 2022, Lupin Limited launched Sildenafil for oral suspension, 10 mg/mL, having received approval from the US FDA. Such advancements are driving the market.



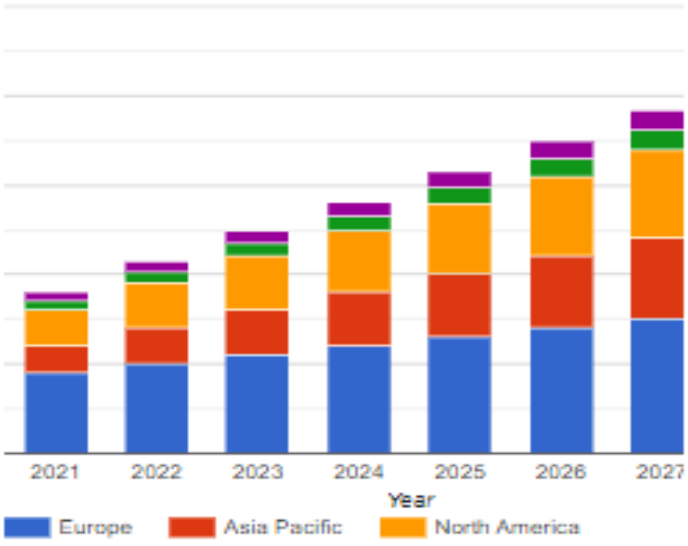
The market for erectile dysfunction treatments is expanding as a result of an increase in the number of individual with erectile dysfunction. Throughout the projection period, market participates are anticipated to become more knowledgeable about erectile dysfunction treatment. Nevertheless, one of the primary issues projected to limit the growth of the erectile dysfunction market is the high cost of penile implants.

US Erectile Dysfunction Market is poised to grow at a sustainable CAGR for the next forecast year.

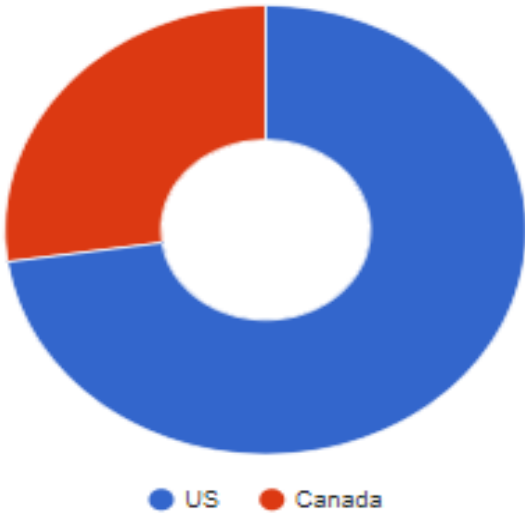
Market Snapshot- 2023-2030

Global Market Size	Largest Segment	Fastest Growth	Growth Rate
USD 2.3 billion	Cialis	Cialis	8.5% CAGR

Global Erectile Dysfunction Market 2021-2028 ($ Bn)

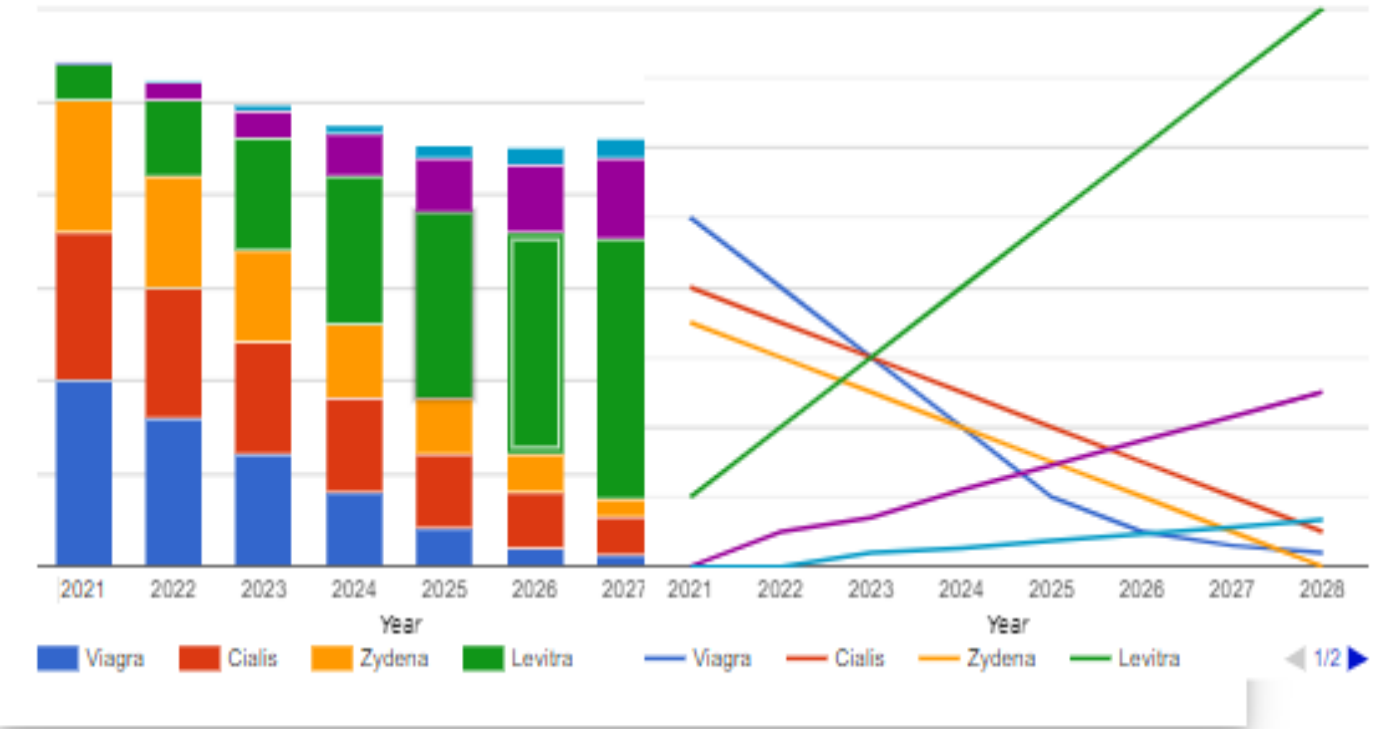


Country Share For North America Region- 2021 (%)



Global Erectile Dysfunction Market Size By Grade Product, 2021-2028 ($ Bn)

Global Erectile Dysfunction Market Size By Grade Product, 2021-2028 (%)



Global Erectile Dysfunction Market Segmental Analysis

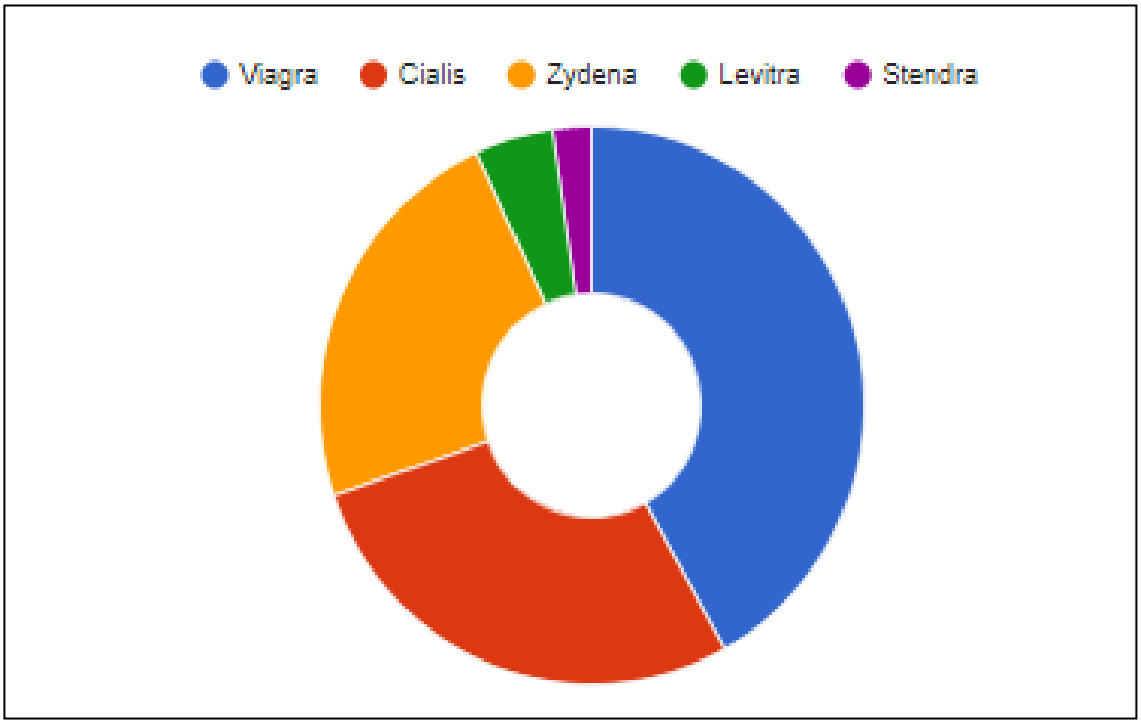
The global erectile dysfunction market segmentation is based on product, and region. Based on product the Erectile Dysfunction Market is segmented into Viagra, Cialis, Zydena, Levitra, Stendra, and others. Based on region the global erectile dysfunction market is segmented into North America, Europe, Asia-Pacific, Latin America, and the Middle East and Africa.

Erectile Dysfunction Market Analysis by Product

In 2021, the category selling Viagra had the biggest revenue share at 57.8%. Many business are currently engaging in a variety of strategic activities to grow their market share, including research alliances, agreements, and partnerships.

Due to the wide application base and accessibility of ED medications like Helleva (lodenafil carbonate), Mvix (mirodenafil), and others that are also used to treat adult patients with erectile dysfunction, the other segment is also anticipated to experience profitable market growth over the forecast period. Increased acceptable of over-the-counter ED medications gives patients easy access. Therefore, the release of such goods could increase the use of ED medications.

Global Erectile Dysfunction Market Share by Grade Product, 2021 (%), 2021 (%)



Global Erectile Dysfunction Market Competitive Landscape

Key market participants in the erectile dysfunction (ED) drugs market are strengthening their market positions by implementing a variety of strategies, including mergers and acquisitions and research partnerships with other business, to introduce novel products and solidify their market positions globally. For instance, due to a production error, Sun Pharmaceutical Industries Ltd. announced the recall of their generic medicine Tadalafil in November 2021. A small gap in the availability of generic ED medications used to treat erectile dysfunction patients may result from this recall.

Erectile Dysfunction Market Top Players Company Profiles

- Pfizer Inc.
- Eli Lilly and Company
- Bayer AG
- VIVUS, Inc.
- Dong-A ST Co. Ltd.
- Meda Pharmaceuticals Inc.
- S.K.Chemicals Co.Ltd.
- Teva Pharmaceutical Industries Ltd.
- Endo International plc
- Futura Medical plc
- Apricus Biosciences, Inc.
- Medtropic plc
- Coloplast Corp.
- Boston Scientific Corporation
- Zephyr Surgical Implants
- Urologix, LLC
- American Medical Systems, LLC
- Pos-T-Vac Medical

Erectile Dysfunction Market Recent Development

- In August 2022, Lupin launched an oral drug named sildenafil for erectile dysfunction in the United States.
- In May 2022, Aspargo Laboratories, Inc. purchased the prescription brand Bandol from the Spanish speciality pharmaceutical company Laboratories Rubio S.A. Bandol is used to treat patients with ED problems.
- In March 2022, the US FDA permitted Lupin to commercialize a generic version of Revation from Viatris Specialty LLC. Lupin's ANDA for sildenafil (10 mg/mL oral suspension) gained this approval.
- In February 2022, Tadalafil MAXON was first approved for marketing authorization by a Polish business, Adamed, under the OTC (over-the-counter) category.
- In January 2022, for its STENDRA erectile dysfunction (ED) medication, Petros Pharmaceuticals Inc., a provider of pharmaceuticals for men's health, started two self-selection trails (avanafil).

Erectile Dysfunction (ED) Drugs Market: Key Drivers, Trends, Challenges, and Customer Landscape

There are multiple factors influencing market growth. Our researchers analyzed the data with 2023 as the base year, along with the key drivers, trends, and challenges.

Key Erectile Dysfunction (ED) Drugs Market Drivers

Rising demand for ED drugs is the key factor driving market growth. With the rising health consciousness across the world, there has been a significant increase in healthcare spending for sexual wellness. As a result of this, there has been a surge in the demand for drugs for the treatment of disorders such as ED. This demand is arising not only due to the OTC availability of drugs but also because of the increase in the number of prescriptions for ED. Owing to the availability of treatment guidelines, physicians are using drug therapies for the treatment of ED. Furthermore, the therapeutic benefits of drugs, such as a longer half-life in the body and the ease of administration even via the sublingual route, are expected to drive the adoption of ED drugs. The rising cyberpornography and the increasing number of advertisements for the treatment of ED are also expected to drive the growth of the global erectile dysfunction (ED) market during the forecast period.

Significant Erectile Dysfunction (ED) Drugs Market Trends

The presence of novel drug formulations in late stages of development is the primary trend shaping market growth. The market is dominated by the oral formulations of the drugs used for the treatment of ED. However, in the next five years, several novel formulations of ED drugs, such as topical gels, injectables, and suppositories, are expected to emerge in the market. These novel formulations will attract a large number of patients owing to their therapeutic benefits. They are also expected to widen the scope of treatment for ED.

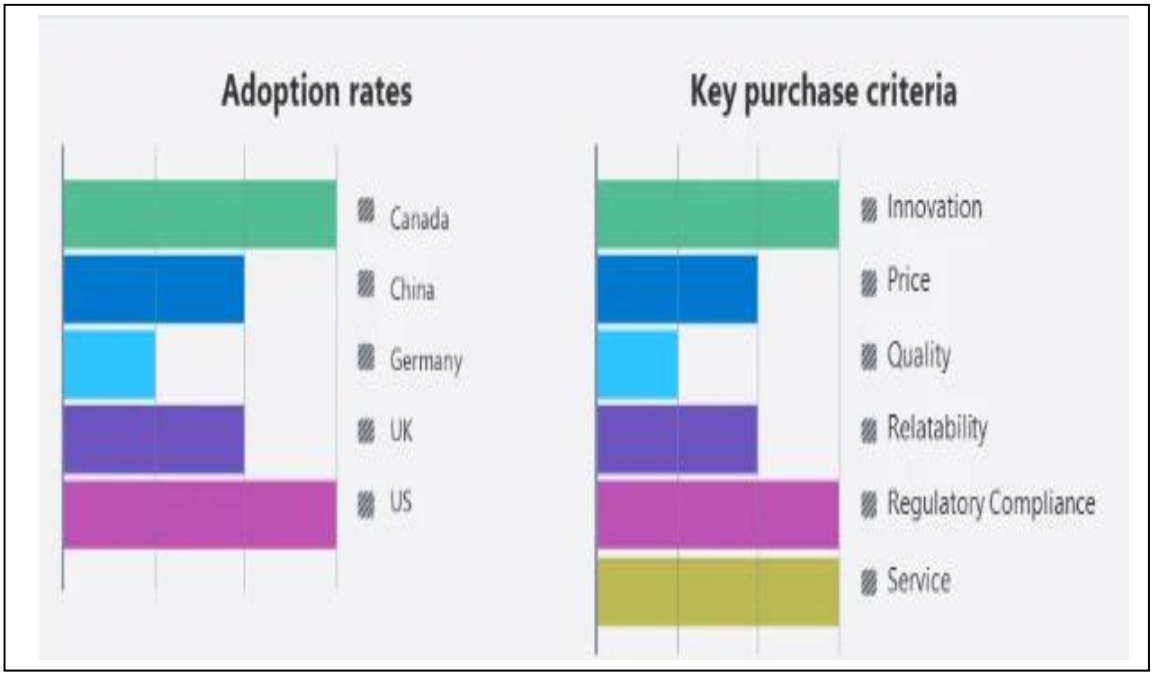
Moreover, for instance, the MonoSol Rx tadalafil oral soluble film by Adamis Pharmaceuticals is currently in the pre-registration stage of evaluation for the treatment of ED. The drug is the first sublingual formulation and is the first film alternative to the oral tablets available for the treatment of ED. Thus, such developments are expected to propel the growth of the global erectile dysfunction (ED) market in focus during the forecast period.

Major Erectile Dysfunction (ED) Drugs Market Challenges

Availability of generics is a challenge that affects market growth. The entry of generic drugs has resulted in hampering the revenue growth of the global ED drugs market. For example, the generic version of VIAGRA, such as sildenafil citrate, is approved by the FDA. Other generic drugs for erectile dysfunction include Avanafil, Tadalafil, and Vardenafil, which is also commercially available. The sales of Viagra have declined in recent years.
Moreover, the decline in sales of Viagra led to a decline in the market share of Pfizer, which impacted the revenue generation for the company. Also, the low cost of generics is the second major cause of the decline of the market. Generic versions of Ed drugs can be obtained at a minimal price. Hence, the availability of generics in the market will act as a challenge to the growth of the global erectile dysfunction (ED) market during the forecast period.

Key Erectile Dysfunction (ED) Drugs Market Customer Landscape

The market report includes the adoption lifecycle of the market, covering from the innovator's stage to the laggard's stage. It focuses on adoption rates in different regions based on penetration. Furthermore, the report also includes key purchase criteria and drivers of price sensitivity to help companies evaluate and develop their growth strategies.



Global Erectile Dysfunction Market Dynamics

- Diabetes, obesity, and cardiovascular disease are on the rise due to the rise in the adoption of an unhealthy lifestyle, which in turn causes issues like ED as people age. Young people's current lifestyles are particularly stressful in many emerging nations, which has led to an increase in fast food and ready-to-eat food consumption as well as drinking and smoking. These variables are compromising general health and fitness, which in turn raises the risk of ED. Additionally, the number of ED patients increases along with continues to be a major driver of the worldwide erectile dysfunction medications market during the projection period.
- Major and growing pharmaceutical brands have boosted their investments in developing nations like India, China, Africa, and important Middle Eastern nations during the past couple of years. This has had a huge impact on the cost of medicine as well as the availability and distribution of medicines within the nations, both of which are anticipated to be important. The global market for erectile dysfunction medications is also anticipated to grow dramatically as a result of increased advertising investments.
- Increasing research and development activities by the market players to provide new treatments for erectile dysfunction is expected to drive the growth of the market.

Erectile Dysfunction Market Restraint

- Drugs for erectile dysfunction are primarily sold in developed and emerging economies; but, now- and middle-income countries account for a smaller portion of their sales. This is primarily a result of people's lack of understanding of these types of treatments, their limited purchasing power, and their unwillingness to incorporate them into their daily lives. The slow growth of the market is partly attributed to the negative side effects of these medications, which include headache, upset stomach, flushing, nasal congestion, visual issues, dizziness, diarrhea, and rash.
- Two significant market challenges are the increased production of generic erectile dysfunction medications and the rising accessibility of fake erectile dysfunction medications. Due to the lucrative marketing of counterfeit erectile dysfunction medications at noticeably lower prices than either patented or generic pharmaceuticals, consumers frequently opt for less expensive generic erectile dysfunction pills over more expensive blockbuster varieties.

Segment Overview

The erectile dysfunction (ED) drugs market report forecasts market growth by revenue at global, regional and country levels and provides an analysis of the latest trends and growth opportunities from 2018 to 2028.

- Region Outlook
  - North America
    - The U.S
    - Canada
  - Europe
    - The U.K
    - Germany
    - France
    - Rest of Europe
  - Asia
    - China
    - India
  - Rest of the World (ROW)
    - Argentina
    - Brazil
    - Australia

Region- North America

Country Name	U.S.
Population	33.19 crores (2021)
Economy	Real gross domestic product (GDP) increased at an annual rate of 4.9 percent in the third quarter of 2023.
War Zone Area	No
Potential for ED Product	Yes
Justification	• By utilizing ED prevalence based on administrative claims, an estimated 8.3% of insured men (10,302,540 estimated men [8,882,548 aged 18-64 years and 1,419,992 aged ≥65 years]) had a diagnosis of ED and sought ED care, out of 124,318,519 eligible US men aged ≥18 years in 2022. • An estimated 17.1% of men with an ED diagnosis claim could benefit from PPI in 2022 (1,759,248 men aged ≥18 years).

Country Name	Canada
Population	3.82 Crores (2021)
Economy	GDP - $ 2.0 Trillion
War Zone Area	No
Potential for ED Product	Yes

Region- Europe

Country Name	U.K
Population	6.73 crores (2021)
Economy	6.3 % in Q3 2023
War Zone Area	No
Potential for ED Product	Yes

Country Name	Germany
Population	8.23 crores (2021)
Economy	GDP - $ 4.4 Trillion (nominal: 2023) $ 5.5 trillion (PPP 2023)
War Zone Area	Yes
Potential for ED Product	Yes

Region- Asia

Country Name	China
Population	141.24 crores (2021)
Economy	GDP growth rate: 8.1% annual change (2021), GDP per capita: 12,556.33 USD (2021)
War Zone Area	Yes
Potential for ED Product	Yes

Country Name	India
Population	140.76 crores (2021)
Economy	₹67.676 lakh crore (US 850 billion): (2022-23)
War Zone Area	No
Potential for ED Product	Yes

Region- Rest of the World (ROW)

- Brazil
- Australia

Country Name	Brazil
Population	21.43 crores (2021)
Economy	GDP per capita: 7,507.16 USD (2021) GDP growth rate: 4.6 % annual change (2021)
War Zone Area	Yes
Potential for ED Product	Yes

Country Name	Australia
Population	2.57 crores (2021)
Economy	GDP per capita: 60,443.11 USD (2021)
War Zone Area	No
Potential for ED Product	Yes

9.0 REGULATION REQUIREMENTS IN DIFFERENT COUNTRIES

Countries with No Formal Regulatory Approval Process

1. Albania	13. Burkina Faso	25. Haiti	38. Saint Kitts and Nevis
2. Anguilla	14. Burundi	26. Kiribati	39. Saint Lucia
3. Antigua and Barbuda	15. Cayman Islands	27. Central African Republic	40. Saint Vincent and the Grenadines
4. Aruba	16. Chad	28. Marshall Islands	41. Sao Tome and Principe
5. Azerbaijan	17. Comoros	29. Mauritius	42. Seychelles
6. Bahamas	18. Timor-Leste	30. Federated States of Micronesia	43. Solomon Islands
7. Barbados	19. Dominica	31. Montserrat	44. Somalia (pending regulations)
8. Belize	20. Gabon	32. Mozambique	45. Suriname
9. Bhutan	21. The Gambia	33. Netherlands Antilles	46. Tonga
10. Botswana	22. Grenada	34. Nauru	47. Trinidad and Tobago
11. The British Virgin Islands	23. Guinea-Bissau	35. Niger	48. Turks and Caicos
12. Brunei Darussalam (regulations for devices are pending in the coming year, per ASEAN membership requirements)	22. Grenada 23. Guinea-Bissau 24. Guyana	36. Palestine 37. Paraguay (not yet harmonized, a member of Mercosur)	49. Vanuatu

Semi-regulated Market: (ROW Countries):

(a) Asia (Sri Lanka, India, Bangladesh, ASEAN: 10 Countries Group -

1 . Philippines	**AUDITED**
2. Vietnam	**AUDITED**
3. Singapore	**AUDITED**
4. Malaysia	**AUDITED**
5. Thailand	**NON AUDITED**
6. Indonesia	**NON AUDITED**
7. Laos	**NON AUDITED**
8. Cambodia	**NON AUDITED**
9. Brunei Darussalam	**NON AUDITED**
10. Myanmar	**NON AUDITED**

(b) African countries

1. Algeria	**NON AUDITED**
2. Zambia	**NON AUDITED**
3. Ethiopia	**AUDITED**
4. Ghana, Kenya	**AUDITED**
5. Malawi	**AUDITED**
6. Mozambique	**NON AUDITED**
7. Namibia	**NON AUDITED**
8. Nigeria	**AUDITED**
9. Sierra Leone	**NON AUDITED**
10. Tanzania	**AUDITED**
11. Zimbabwe etc.	**AUDITED**

(c) Middle East countries (Gulf Co-operation Council countries)

1. Bahrain	**AUDITED**
2. Kuwait	**AUDITED**
3. Oman	**AUDITED**
4. Qatar	**AUDITED**
5. Saudi Arabia	**AUDITED**
6. UAE	**AUDITED**

(d) Latin America

1. Mexico	**AUDITED**
2. Brazil	**AUDITED**
3. Panama	**AUDITED**
4. Peru	**AUDITED**
5. Guatemala	**AUDITED**
6. Argentina	**AUDITED**
7. Chile	**AUDITED**
8. Dominican Republic	**AUDITED**

(e) CIS (commonwealth of independent states):

1. Russia	**AUDITED**
2. Ukraine	**NON AUDITED**
3. Armenia	**NON AUDITED**
4. Azerbaijan	**AUDITED**
5. Belarus	**AUDITED**
6. Georgia	**AUDITED**
7. Kazakhstan	**AUDITED**

8. Kirghizstan	**AUDITED**
9. Moldova	**AUDITED**
10. Tajikistan	**NON AUDITED**
11. Turkmenistan	**NON AUDITED**
12. Uzbekistan	**NON AUDITED**

Regulated Market:

1	**USA**
2	**EU (UK, Germany, France, Ireland, Sweden etc.)**
3	**Japan,**
4	**Canada**
5	**Australia**
6	**New Zealand**
7	**South Africa**

10.0 National Health Authorities/ Regulatory Bodies:

Country	Australia	
Regulatory Body	Therapeutic Goods Administration (TGA)	
Email ID	info@tga.gov.au.	
Website	www.tga.gov.au	
Registration Document	ICH-CTD Format	
Approx. Fee	Type	Application Fee
	New Chemical Entity	$51,608
	New generic product	$19,904
BA BE Study Requirements	Adopted European guidelines for biopharmaceutics studies	
Registration TimeLine	150 Working Days	
Other Information:-		
Audit Fee	a. Application audits assessment fees- IVD medical devices-Class 1 and Class 2 IVDs = $7,387, Class 3 IVDs = $22,387, Class IV= $22,387 b. Application audit assessment fees for medical devices- $4,350	
Guidelines	1. ICH Harmonised Guideline and Nees guideline	

Country	Brunei	
Regulatory Body	Ministry of Health	
Email ID	corp.comms@moh.gov.bn	
Website	www.moh.gov.bn	
Registration Document	ASEAN Common Technical Dossier (ACTD)	
Approx. Fee	Processing Fee	B$200
	Product License Fee	B$50
	Amendment Fee	Major Amendement- B$150 Minor Amendement- B$50
	Renewal Fee	B$250
Data Requirements		
	Product Type	**Data Requirements**
	i) New Chemical Entity (NCE) and Biotechnological Product	
	Registered for less than 5 years in at least one benchmark country	Parts I, II, III and IV
	Registered for less than 5 years in at least one benchmark country containing existing chemical/biological entity(s) in a new dosage form	Part I, Part II, and Pharmacokinetic Data
	Registered for more than 5 years in three benchmark countries	Parts I and II
	ii) Biosimilar Product*	Parts I, II, III and IV
	iii) Generic Product	Parts I and II
	iv) Medicinal Product Evaluated via Abridged Route	Part I, Certificate of Analysis (COA) of Finished Product and Stability Study Report of Finished Product
BA BE Study Requirements	As per ASEAN guidelines for Bioavailability and Bioequivalence studies	
Registration TimeLine	**Product Type**	**Days**
	NCE / Biotech / Biosimilar Products registered < 5 years	336 working days
	NCE / Biotech / Biosimilar Products registered > 5 years	286 working days
	Generic Products	286 working days
Other Information:-		
Audit Fee	Fee= 100 (BND)	
Guidelines	ASEAN Guidelines	

Country	Brazil	
Regulatory Body	ANVISA	
Email ID	-	
Website	www.gov.br	
Registration Document	Dossier	
Approx. Fee	New Drugs	585,72-157,416 beais
	Medical device	702,86 to 49,641.20 beais
BA BE Study Requirements	ANVISA mandates that clinical sites and analytical labs involved in bioequivalence studies must undergo certification by the agency per their RDC 620-2022 guidelines for certification.	
Registration TimeLine	Priority Review	
	Registration- 120 days, Post-Approval Changes-60 days	
	Standard Review	
	Registration-365 days, Post-Approval Changes-180 days	
Other Information:-		
Audit Fee	20,000 USD	
Guidelines	RDC 620-2022 ANVISA guidelines, Brazil is an official member of the ICH and follows the ICH Guideline.	

Country	Canada	
Regulatory Body	Health Canada	
Email ID	**hcinfo.infosc@canada.ca**	
Website	www.canada.ca	
Registration Document	eCTD (Dossier Format)	
Approx. Fees	for Drug Registration	CAD $ 49,811-176,569
	for the Examination of a submission-Drugs for Human Use	
	New active substance	CAD $ 565,465
	Clinical or non-clinical data and chemistry and manufacturing data	CAD $ 292,806
	Comparative study	CAD $ 65,985
	Administrative submission	CAD $ 933
	New Drug Submission- Efficacy and safety data	CAD $ 41,917
	Abbreviated New Drug submission and supplement to an Abbreviated new drug submission	CAD $ 7,610
BA BE Study Requirements	Clinical or non-clinical data only	CAD $ 117,080
	Comparative studies	CAD $ 65,985
Registration TimeLine	Normal time taken for registration: 06-24 Months	
	Whether plant inspection is mandatory - Yes	
Other Information:-		
Audit Fee	Facilities = API	CAD $ 77,111
	Finished Dosage Forms	CAD $ 281,363
	Contract manufacturing organization	CAD $ 107,185
Guidelines	ICH Harmonised Guideline- M4 R4 (CTD)	

Country	Estonia	
Regulatory Body	Republic of Estonia Agency of Medicines	
Email ID	info@ravimiamet.ee	
Website	www.ravimiamet.ee	
Registration Document	eCTD Format	
Approx. Fee	**Marketing authorization applications**	
	Applications	State Fee (€)
	Issue or renewal of marketing authorization application (Human Medicinal Product)	32.00
	Application for variation of both type I and II to a marketing authorization (human medicinal product)	16.00
	Issue of marketing authorization application (veterinary medicinal product)	32.00
	Application for variation requiring assessment - VRA (veterinary medicinal product)	16.00
BA BE Study Requirements	As per emea guidelines	
Registration TimeLine	180 days	
Other Information:-		
Assessment Fees	**Assessment fees of Marketing Authorisation Applications for medicines for national, mutual recognition, and decentralized procedures**	
	1. Stand-alone application (based on original data)	6000 €
	2. Bibliographic application (well-established medicinal use supported by bibliographic literature)	6000 €
	3. Fixed combination application (new medicinal product made of at least two active substances not previously authorized as a fixed combination medicinal product)	6000 €
	4. Generic application	4500 €
	5. Hybrid Application	4500 €

	6. A similar biological medicinal product	4500 €
	7. Application for traditional herbal medicinal product	4500 €
	8. Homeopathic medicinal product	4500 €
	9. Application for parallel import (per source Member State)	1000 €
	10. Informed consent application	3000 €
	11. Subsequent pharmaceutical form or strength containing the same active ingredient of the same future marketing authorization holder	3000 €
	Veterinary Medicinal Products	
	1. Application for marketing authorization: full dossier	6000 €
	2. Application based on bibliographic data	6000 €
	3. Application for combination veterinary medicinal product	6000 €
	4. Application for generic veterinary medicinal product	4500 €
	5. Application for the hybrid veterinary medicinal product	4500 €
	6. Application for homeopathic veterinary medicinal product	4500 €
	7. Application for parallel trade (per source Member State)	1000 €
	Medicinal products for human use or veterinary medicinal products: assessment fees for marketing authorization applications of decentralized procedures and mutual (and subsequent) recognition procedures	

	where Estonia is participating as the Member State concerned (CMS):	
	1. Marketing authorization application	1500 €
	2. Subsequent pharmaceutical form or strength containing the same active ingredient, change or addition of the route of administration of the same future marketing authorization holder	1000 €
	3. Application for subsequent food-producing animal	1000 €
	Assessment fees for the renewal of marketing authorization	
	1. Renewal of the Marketing Authorisation for national, mutual recognition and decentralized procedure (fee per one medicinal product)	1000 €
	2. Subsequent pharmaceutical form or strength containing the same active ingredient of the same future marketing authorization holder	500 €
Guidelines	EMEA Guidelines	

Country	India		
Regulatory Body	Central Drugs Standard Control Organization		
Email ID	dci@nic.in		
Website	Cdsco.gov.in		
Registration Document	CTD Dossier		
Approx. Fee	**Division Name**	**Purpose Name**	**Fee Paid**
	Biologicals	Registration of Site (Form 40)	1500 USD for each site
	Biologicals	Registration of Product (Form 40)	1000 US
	Biologicals	Endorsement (Form 40)	1000 USD for each product
	Biologicals	Import License (Form 8)	Rs 1000 for each product and
	Cosmetics	Fresh (Form 42)	250 USD for each applied category
	Import & Registration	Registration Certificate (Form 40)	Foreign Manufacturing premises Fee – 1500 USD Registration Fee for single drug and 1000 USD
	Import & Registration	Inspection or visit of the manufacturing premises	USD 5000/- Expenditure as may be required for inspection or visit of the manufacturing premises
BA BE Study Requirements	**Fee Payable For Licence, Permission, and Registration Certificate**		
	Rule	**Subject**	**In rupees Indian National Rupee (INR) except where specified in dollars ($)**

	21	Application for permission to conduct clinical trial	
		(i) Phase I	3,00,000
		(ii) Phase II	2,00,000
		(iii) Phase III	2,00,000
		(iv) Phase IV	2,00,000
	22	Reconsideration of application for permission to conduct clinical trial	50,000
	33	Application for permission to conduct bioavailability or bioequivalence study	2,00,000
	34	Reconsideration of application of permission to conduct bioavailability or bioequivalence study	50,000
	45	Application for registration of Bioavailability and Bioequivalence study centre	5,00,000
	47	Reconsideration of application for registration of bioavailability and bio-equivalence study centre	1,00,000
	52	Application for permission to manufacture new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study	5000 per product
	53	Reconsideration of application to manufacture new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study	2000 per product

	59	Application for permission to manufacture unapproved active pharmaceutical ingredient for the development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study	5000 per product
	60	Reconsideration of permission to manufacture unapproved active pharmaceutical ingredient for the development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study	2000
	67	Application for import of new drugs or investigational new drugs for a clinical trial or bioavailability or bioequivalence study or for examination, test, and analysis	5000 per product
	68	Reconsideration of application for Import of new drugs or investigational new drugs for a clinical trial or bioavailability or bioequivalence study or for examination, test, and analysis	1000
	Requirements for BE study of a new molecule not approved in India but approved in other countries		
	1) Application in Form-44 duly signed, by the competent authority with name and designation.		
	2) Treasury Challan of Rs. 25000/- as per Drugs & Cosmetic Rules.		

	3) Undertaking by the Principal Investigator (PI) as per Appendix VII of schedule "Y" of Drugs and Cosmetic Rules.		
	4) A copy of the approval granted to the BE study centre by CDSCO.		
	5) Sponsor's Authorization letter duly signed by the competent authority on their letterhead.		
	6) The study protocols.		
	7) The study synopsis		
	8) Pre-clinical single dose data and repeated dose toxicity data.		
	9) Clinical study data and published reports of pharmacokinetic and pharmacodynamic study carried out in healthy volunteers/patients data published in reputed journals.		
	10) Regulatory status of the drug.		
	11) Names of the countries where the drug is currently being marketed (to be mentioned in the covering letter also).		
	12) Package literature on the international product		
	13) Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study.		
	14) In the case of multiple dose BE study adequate supporting safety data should be submitted.		
	15) In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.		
	16) Depending on the nature of the drug like cytoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.		
Registration TimeLine	**S. No**	**Type of Application**	**Timelines in days**
	1a.	New Drug including Biological, Medical Devices/Clinical Trials/Global Trials/New Claims in consultation with NDAC/MDAC	180
	1b.	IND Applications in consultation with IND committee	180
	1c.	Subsequent New Drug	120
	1d.	Clinical Trial Protocol Amendments (if consultation of NDAC is not required)	60
	2	Fixed Dose Combination in consultation with NDAC	180

	3	Import Registration of Drugs and Medical Devices	270
	4	Endorsement of Additional Product in Registration Certificate	120
	5	Rule 37 & Neutral Code	60
	6	NOC for from 29 (Biological and Medical Device)	60
	7	CLAA in form 28/28-D/28-E/27-C etc	60
	8	Import License in Form 10	45
	9	Test License in Form 11	45
	10	Bioavailability / Bioequivalence (BA/BE) Study	45
	11	Extension of Shelf Life for Export	45
	12	Export of Biological samples	45
	13	Registration of Cosmetics	90
	14	Registration of Ethics Committee	100
	15	Post Approval Changes (major) in consultation with CDL, NDAC	180
	16	Post Approval Changes (minor)	90
	17	BA/Be Site Approval (after receipt of Joint Inspection Report)	60
	18	Written confirmation of per EU Directives	30
Other Information:-			
Audit Fee (Medical Devices)	**As per the provisions of Rule 16 of Medical Devices Rules, 2017, the fee chargeable by notified bodies, as approved by competent authority of Ministry of Health & Family Welfare in the Central Government, are as under:**		
	1. Rs. 20,000 per man-day for audit of manufacturing site including product assessment (on site/offside)		
	2. Rs. 12,500 per man-day with package of Rs. 25000 requiring 2 man-days. In case, if more man-day required, it would be charged other than this fee.		
	3. Above fee are excluding travel cost which shall not normally be more than Rs. 12,000 per auditor/Visit.		
Guidelines	Drugs and Cosmetic act 1940 and rules 1945.		

Country	Korea				
Regulatory Body	Ministry of Food and Drug Safety				
Email ID	-				
Website	www.mfds.go.kr				
	Medical Devices				
Approx. Fee (Medical Devices and IVDs)	Item	Class	Service Fee	Legal timeframe	Practical Timeframe
	1st device registration	Standard Class 1	US$2,000	5 working days	1 week
		Standard Class 2	US$8,000	30 working days	3 months
		Standard Class 3	US$10,000	65 working days	5 months
		Standard Class 4	US$12,000		
	Re-registration	All	US$1,200/application	20 working days	1-2 month
BA BE Study Requirements	-				
Audit Fee	US $2500- US $10,000				
Guidelines	USFDA Guidelines				

<table>
<tr><td>Country</td><td colspan="4">Malaysia</td></tr>
<tr><td>Regulatory Body</td><td colspan="4">National Pharmaceutical Regulatory Agency (NPRA)</td></tr>
<tr><td>Email ID</td><td colspan="4">evisa@npra.gov.bh</td></tr>
<tr><td>Website</td><td colspan="4">www.npra.gov.my</td></tr>
<tr><td>Registration Document</td><td colspan="4">ASEAN CTD/ ACTR</td></tr>
<tr><td>Approx. Fee</td><td>Category of product</td><td>Processing Fees</td><td>Lab Fees</td><td>Certifications Fee</td></tr>
<tr><td rowspan="4"></td><td rowspan="2">Pharmaceutical
a) New Drug Products

b) Biologics</td><td rowspan="2">RM 1,000.00</td><td>Single active ingredient: RM 3,000.00</td><td>RM 4,000.00</td></tr>
<tr><td>Two or more active ingredients: RM 4,000.00</td><td>RM 5,000.00</td></tr>
<tr><td rowspan="2">Pharmaceutical

a) Generic (Scheduled poison)
b) Generic (Non-scheduled poison)</td><td rowspan="2">RM 1000,00</td><td>Single active ingredient: RM 1,200.00</td><td>RM 2,200.00</td></tr>
<tr><td>Two or more active ingredients: RM 2,000.00</td><td>RM 3,000.00</td></tr>
<tr><td>Natural Product</td><td>RM 500.00</td><td>RM 700.00</td><td>RM 1,200.00</td></tr>
<tr><td></td><td colspan="4"></td></tr>
<tr><td>BA BE Study Requirements</td><td colspan="4">Ref: ASEAN Guideline for the conduct of Bioequivalence Studies</td></tr>
<tr><td>Registration TimeLine</td><td colspan="3">Types of Pharmaceutical</td><td>Timeline</td></tr>
<tr><td rowspan="6"></td><td colspan="3">New drugs and biologics</td><td>245 working days</td></tr>
<tr><td colspan="3">Scheduled & Non-Scheduled Poison generic drugs</td><td>210 working days</td></tr>
<tr><td colspan="3">Generic drugs- Non-scheduled poison * Single active ingredient * Two or more active ingredients</td><td>116 working days
136 working days</td></tr>
<tr><td colspan="3">Generic (non- Scheduled Poison)</td><td>80 working days</td></tr>
<tr><td colspan="3">Natural Products
a) Single active ingredient
b) Two or more active ingredients</td><td>a) 116 working days
b) 136 working days</td></tr>
<tr><td colspan="3">Health Supplements
a) Single active ingredient
b) Two or more active ingredients</td><td>a) 116 working days</td></tr>
</table>

	c) Disease Risk Reduction Claims	b) 136 working days c) 245 working days
Other Information:-		
Audit Fee	1. Processing Fee: a) Payment of a processing fee of RM 5,000.00 upon application. b) The processing fee is non-refundable 2. Inspection Fee: a) Payment of an inspection fee of RM 20,000.00 upon issuance of invoice by NPRA.	
Guidelines	Drug Registration Guideline Document (DRGD), Guidelines for Application for Registration of Pharmaceutical Products	

Country	Mexico		
Regulatory Body	Ministry of Health (COBIERNO DE MEXICO)		
Email ID	peptitionsciudadanas@salud.gob.mx		
Website	www.gob.mx		
Registration Document	Dossier		
Approx. Fee	**Classification**	**Fees (Mexican Pesos)**	
	Generic	$82,011.99	
	New Molecule	$146,641.88	
	GMP Inspection	$96,666.39	
BA BE Study Requirements			
Registration TimeLine	**Classification**	**Time of Response (Natural Days)**	
	Generic	180 Days	
	New Molecule	180 Days	
	GMP Inspection	Timelines Vary	
	Request meeting with the COFEPRIS New Molecules Committee	60 Days	
	Receive New molecule committee conclusions after meeting	20-40 Days	
Other Information:-			
Audit Fee	**Additional Fees**	**Time of Response (Business day)**	**Fees (Mexican Pesos)**
	GMP Inspection	Timelines vary	$96,666.39
	Request meeting with the COFEPRIS New Molecules Committee	60 Days	NA
	Receive New molecule committee conclusions after meeting	20-40 Days	NA
Guidelines	ICH Harmonised Guidelines		

Country	New Zealand	
Regulatory Body	Medicines and Medical Devices Safety Authority (MEDSAFE)	
Email ID	**medclearance@health.govt.nz**	
Website	**www.medsafe.govt.nz**	
Registration Document	CTD Format Dossier	
Approx. Fee	**New Medicines Application (NMA) Fees**	
	Types of application	**New Fee ($)**
	New higher-risk medicine containing one or more new active substances (NCE)	106,503
	New intermediate-risk medicine – prescription medicine	53,251
	Any other new higher-risk medicine, including biosimilar	79,877
	New intermediate-risk medicine – non-prescription medicine	26,626
	New lower-risk medicine	10,649
	Additional dose form – higher-risk medicine – Grade 1 or 2	53,252
	Additional dose form – intermediate-risk prescription medicine – Grade 1 or 2	53,252
	Additional dose form – intermediate-risk non-prescription medicine – Grade 1 or 2	26,626
	Additional dose form – lower-risk medicine – Grade 1 or 2	10,649
	New combination product – novel combination of approved active ingredients	70,292
	New combination pack containing two or more currently approved products	3,835
	New Medicines Application (Abbreviated Evaluation Process) Fees	
	Types of Application	**New Fee ($)**
	New higher-risk medicine containing one or more new active substances (NCE)	53,251
	Any other new higher-risk medicine	39,939
	New intermediate-risk medicine – prescription medicine	26,626
	New Related Product Application (NRPA) Fees	
	Types of Application	New Fee ($)
	New related product	5,731
	New Medicine Application Provisional Consent Fees	
	Types of Application	**New Fee ($)**
	Provisional consent to distribute a new medicine (clinical need) High risk NCE	70,292

	Provisional consent to distribute a new medicine (clinical need) High risk other	52,719
	Provisional consent to distribute a new medicine (stock shortage) High risk other	15,975
	Provisional consent to distribute a new medicine (stock shortage) Intermediate risk	10,650
	Provisional consent to distribute a new medicine (stock shortage) Low risk	2,130

BA BE Study Requirements	As Per International Conference on Harmonisation (ICH), Guidance on Good Clinical Practice (E6), and the principles of Good Manufacturing Practice and Good Laboratory Practice guideline			
Evaluation TimeLine	**Target Evaluation Times for NMAs and CMNs**			
	Intermediate and Higher Risk Medicines			
		INE Medsafe	RFI response requested by Applicant	EAI Medsafe
	NMAs (full)	200 days	200 days[1]	120 days[2]
	NMAs (abbreviated)	100 days	200 days[1]	120 days[2]
	Lower Risk Medicines			
		INE Medsafe	RFI response requested by applicant	EAI Medsafe
	L1	50 days	50 days	30 days
	L2	100 days	100 days	60 days
	L3	150 days	150 days	90 days
Other Information:-				
Audit Fee	New Zealand Based- Auditing of Non-Licensed Manufacturers – per hour, plus administration fee, plus disbursements = 186 USD per hour			
Guidelines	Country Specific Guidelines			

Country	Russia	
Regulatory Body	State Institute of Drugs and Good Practices	
Email ID	info@gilsinp.ru	
Website	Gilsinp.ru	
Registration Document	CTD Format (Country specific resemble to CTD)	
Approx. Fee	**For Drugs and Biologicals**	
	For issuing of marketing authorization	Around USD 135 (RUB 10000)
	For examination of a drug at its registration	Around USD 4370 (RUB 325 000)
	For Medical Devices	
	For issuing of marketing authorization	Around USD 95 (RUB 7000)
	For quality, efficiency, and safety examination of a medical device at its state registration (dependent on the class of potential risk)	
	Class 1	Around USD 605 (RUB 45000)
	Class 2a	Around USD 875 (RUB 65000)
	Class 2b	Around USD 1145 (RUB 85000)
	Class 3	Around USD 1550 (RUB 115000)
BA BE Study Requirements	As per country specific	
Registration TimeLine	**Mutual Recognition registration Procedure**	
	Registration of a drug	
	For Reference State	210 Calendar Days
	Decentralized Registration Procedure	
	Registration of a drug	
	For Reference State	210 calendar Days
Registration TimeLine (Medical Devices)	Registration of medical devices (stage 1 & stage 2) shall be 88 business days (58 days for registration activity exercised by RZN and 30 business days for examination conducted by budgetary institution reported to RZN)	
Other Information:-		
Audit Fee	-	
Guidelines	ICH CTD Guideline	

Country	Ireland	
Regulatory Body	Health Product Regulatory Authority	
Email ID	info@hpra.in	
Website	www.hpra.ie	
Registration Document	Dossier	
Approx. Fee	Type	Price in €
	New Application	
	Complex Dossier- New active substance	
	National application	22,235
	National application - each additional form (at same time)	7,785
	National application - each additional strength (at same time)	1,110
	Mutual Recognition - CMS	15,565
	Mutual Recognition - CMS - each additional form (at same time)	5,560
	Mutual Recognition - CMS - each additional strength (at same time)	1,110
	Mutual Recognition - RMS Supplement	16,675
	Outgoing MR Supplement - MRP applied for within 12 months of the national procedure ending	16,675
	Additional Drug Master File submitted	4,445
	Decentralised application – CMS	22,235
	Decentralised application – RMS	55,590
	Decentralised application CMS/RMS - each additional form (at same time)	7,785
	Decentralised application CMS/RMS - each additional strength (at same time)	1,110
	Decentralised/MR - additional RMS supplement	1,670

	where there are 15 or more concerned Member States	
	Reduced Dossier- Complex	
	National application	16,675
	National application - each additional form (at same time)	7,785
	National application - each additional strength (at same time)	1,110
	Mutual Recognition – CMS	11,120
	Mutual Recognition - CMS - each additional form (at same time)	5,560
	Mutual Recognition - CMS - each additional strength (at same time)	1,110
	Mutual Recognition - RMS supplement	16,675
	Outgoing MR Supplement - MRP applied for within 12 months of the national procedure ending	11,120
	Additional Drug Master File submitted	4,445
	Decentralised – CMS	16,675
	Decentralised – RMS	44,470
	Decentralised application CMS/RMS - each additional form (at same time)	7,785
	Decentralised application CMS/RMS - each additional strength (at same time)	1,110
	Decentralised/MR - additional RMS supplement where there are 15 or more concerned member states	1,670
	Reduced Dossier- Standard	
	National application	11,120
	National application - each additional form (at same time)	7,785

	National application - each additional strength (at same time)	1,110
	Mutual Recognition - CMS	7,785
	Mutual Recognition - CMS - each additional form (at same time)	4,445
	Mutual Recognition - CMS - each additional strength (at same time)	1,110
	Mutual Recognition - RMS Supplement	11,120
	Outgoing MR Supplement - MRP applied for within 12 months of the national procedure ending	6,670
	Additional Drug Master File submitted	4,445
	Decentralised application - CMS	11,120
	Decentralised application - RMS	28,905
	Decentralised application CMS/RMS - each additional form (at same time)	7,785
	Decentralised application CMS/RMS - each additional strength (at same time)	1,110
	Decentralised/MR - additional RMS supplement where there are 15 or more concerned member states	1,670
BA BE Study Requirements	As per country specific	
Registration TimeLine	150 Days	
Other Information:-		
Audit Fee	**Type**	**Fees**
	Per day, per member of the inspection team (expenses may be billed additionally in certain circumstances)	1,825
	Part of day (per hour, per member of the inspection team)	260

	Inspection cancellation/rescheduling fee	500
	Cosmetics	
	Inspections of cosmetic product responsible person, manufacturers and distributors	
	Per day, per member of the inspection team (expenses may be billed additionally in certain circumstances)	1,825
	Part of day (per hour, per member of the inspection team)	260
	Audits/ Inspections of Notified Bodies, Medical Device Manufacturers and Distributors	
	Audits (including Notified Body) per day, per member of the audit team	1,825
	Audits (including notified body) per hour, per member of the audit team	260
Guidelines	ICT CTD Guideline	

Country	USA	
Regulatory Body	US-FDA	
Email ID	FDAImportsInquiry@fda.hhs.gov	
Website	www.fda.gov	
Registration Document	Dossier	
Approx. Fee	FDA User Fee FY2022	
	Prescription Drug User Fee Act (PDUFA VI)	
	Applications	FY2022
	Requiring clinical data	$3,117,218
	Not requiring clinical data	$1,558,609
	Program fee	$369,413
	Generic Drug User Fee Amendments (GDUFA II)	
	Applications	FY2022
	Abbreviated new drug application (ANDA)	$225,712
	Drug master File (DMF)	$74,952
	Biosimilar User Fee Amendments (BSUFA)	
	Initial biological product development (BPD)	$57,184
	Annual BPD	$57,184
	Reactivation	$114,368
	Requiring clinical data	$1,746,745
	Not requiring clinical data	$873,373
BA BE Study Requirements	-	
Registration TimeLine	After NDA is received, FDA has 60 days to decide whether to file it so it can be reviewed.	
Other Information:-		
Audit Fee	Domestic FDF Facility	$175,389
	Foreign FDF Facility (i.e. Manufacture in Europe or Asia)	$ 190,389
	Domestic API Facility	$ 26,458
	Foreign API Facility (i.e. manufacture in Europe or Asia)	$ 41,458
Guidelines	ICH CTD Guideline	

<table>
<tr><th>Country</th><th colspan="3">UK</th></tr>
<tr><td>Regulatory Body</td><td colspan="3">Medicines & Healthcare Products Regulatory Agency (MHRA)</td></tr>
<tr><td>Email ID</td><td colspan="3">info@mhra.gov.uk</td></tr>
<tr><td>Website</td><td colspan="3">www.gov.uk</td></tr>
<tr><td>Registration Document</td><td colspan="3">eCTD/ Dossier</td></tr>
<tr><td>Approx. Fee</td><td colspan="3">Fees for registration of active substance manufactures</td></tr>
<tr><td></td><td>New application</td><td>Fees</td><td>Notes</td></tr>
<tr><td></td><td>New application for registration as a manufacturer of active substances</td><td>£6,019</td><td>£3,457 application fee plus £2,562 assessment fee</td></tr>
<tr><td></td><td colspan="3">Fees for registration of active substance importer or distributor</td></tr>
<tr><td></td><td>New Application</td><td>Fees</td><td>Notes</td></tr>
<tr><td></td><td>New application for registration as an importer or distributor of active substances</td><td>£3,845</td><td>£1,983 application fee plus £1,862 assessment fee</td></tr>
<tr><td></td><td>Additional fee if the risk assessment of the initial application triggers an inspection</td><td colspan="2">£640</td></tr>
<tr><td></td><td colspan="3">Variations</td></tr>
<tr><td></td><td>Notification of changes (variation)</td><td colspan="2">£283</td></tr>
<tr><td></td><td>Inspection fee (per site if required)</td><td colspan="2">£ 2,662</td></tr>
<tr><td></td><td></td><td colspan="2"></td></tr>
<tr><td></td><td colspan="3">Active substance importers or distributors fees</td></tr>
</table>

	Application for registration	£1,983
	Assessment of initial application: active substance importer / distributor	£1,862
	Additional fee for the first day of inspection if triggered following risk-assessment of the application	£640
	Active substance manufacturers fees	
	Application for registration	£ 3,457
	Assessment of initial application	£ 2,562
	Additional fee for the first day of an inspection if triggered following risk-assessment of the application	£ 871
	Assessment of the Annual compliance report	£ 283
	Notification of changes	£ 283

Clinical Trials: application fees	**Fee description**	**Types of fee**	**Fee**
	Applications with an IMP dossier	Higher fee (Phase 1, Full and Simplified IMPD)	£ 3,366
	Applications without an IMP dossier	Lower fee (Phase IV, Cross referral, Additional protocol	£248
	CT variations/ amendments		£248

	Assessment of annual safety reports		£248
Clinical investigations for devices: Fees	Notification of a clinical investigation		Fee
	Class I, IIa, or other than implantable or long-term invasive devices		£ 7,472
	Class IIb implantable or long-term invasive, class III, and active implantable devices		£15,627
Registration TimeLine	New active substances and biosimilar products – The assessment process will run in two phases totalling 150 days with an intervening clock-off period between phase 1 and phase 2, if required.		
	Existing Active Substances Applications – The assessment process will run in two phases totalling 150 days with an intervening clock-off period between phase I and Phase II, If required.		
Other Information:-			
Audit Fee	**Fees for registration of active substance importer or distributor**		
	Inspection fee (per site if required)	£2,662	
	Active substance importers or distributors: fees		
	Standard daily rate for inspection	£ 2,662	
	Active substance manufacturers: fees		
	Inspection	£3,651	
	Inspection: fees		
	Type of inspection	**Daily Rate £**	
	All GMP, GCP and Pharmacovigilance inspections including: Intermediate biological sites, manufacturers of active pharmaceutical ingredients (API), sterile, non-sterile and assembly sites, non-routine inspections, pharmacovigilance inspection, clinical trials, contract laboratories, homeopathic manufactures	£3,651	
	Office based evaluation and risk assessments	£2,562	

	GDP (wholesale dealers including homeopathic wholesalers)	
	Full day rate	£2,662
	Reduced rate	£ 1,331
Guidelines	Country specific guideline	

Country	South Africa	
Regulatory Body	South African Health Products Regulatory Authority	
Email ID	enquiries@sahpra.org.za	
Website	www.sahpra.org.za	
Registration Document	eCTD	
Approx. Fee	**Category- Human medicines, including biologicals**	
	In respect of the submission of an application for registration of-	
	(i) New chemical entities, including highly technological products, which have been processed by the abbreviated registration process (AMRP) (first strength, first dosage form)	R111 000 per application
	(ii) Strengths and dosage forms other than those referred to in sub-paragraph (i):	R 44 000 per application
	(iii) New chemical entities, new bio therapeutics other than vaccines (first strength, first dosage form)	R 208 400 per application
	(iv) Strengths and dosage forms other than those referred to in sub-paragraph (iii)	R 82 000 per application
	(v) Biological products e.g. vaccines (excluding new bio-therapeutics)	R 177 000 per application
	(vi) Biological products e.g. biosimilar (excluding new bio-therapeutics)	R 173 000 per application
	(vii) Strengths and dosage forms other than "those referred to in sub-paragraph (vi)	R 55 000 per application
	(viii) Generic products (pharmaceutical, analytical and bioavailability evaluated) including generic dental and radio-pharmaceutical products (first strength, first dosage form)	R 84 000 per application

	(ix) Strengths and dosage forms other than those referred in sub-paragraph (vii)	R 27 000 per application
	(x) Generic products with clinical data	R 84 000 per application
	(xi) Strengths and dosage forms other than those referred to in sub-paragraph (x)	R 27 000 per application
	(xii) Evaluation of additional submitted clinical data (pre-registration)	R 5000 and
	(xiii) An application in terms of section 15c of the Act	R 37 800
	Category Veterinary medicines, including biologicals	
	In respect of the submission of an application for registration of-	
	(i) New chemical entities, including highly technological products, (first strength, first dosage form)	R 13 900 per application
	(ii) Generic products (pharmaceutical, analytical and bioavailability evaluated)	R 12 700 per application
	(iii) Generic products with clinical data	R 13 900
	(iv) Strengths and dosage forms other than those referred to in sub-paragraphs (i), (ii), (iii)	R 4 400
	(v) Screening fee on receipt of the application	R 1 800
	(vi) Evaluation of additional submitted clinical data (pre-registration)	R2 800
	Category Human medicines for which an application for registration has been submitted as counterploted in section 15 of the act	
	In respect of the submission of an application for registration of-	
	(i) Product submitted with clinical and or toxicological data (first strength, first dosage form)	R 14 300 per application
	(ii) Strengths and dosage forms other than those referred to in sub-paragraph (i)	R 4 500 per application

	(iii) Products submitted with no clinical or toxicology data (first strength, first dosage form)	R 6 400 per application
	(iv) Strengths and dosage forms other than those referred to in sub-paragraph (iii)	R 2 100 per application
	(v) Screening fee on receipt of an application:	R 1 800
	(vi) Evaluation of additional submitted clinical data (pre-registration):	R2 900; and
	(vii) An application in terms of Section 15C of the Act:	R34 700
Fees for Clinical Trials	(a) In respect of the submission of an application for the authorization of the use of an unregistered medicine for clinical trials:	
	(i) Clinical trial application (safety and efficacy)	R32 400
	(ii) Clinical trial application (Bioequivalence study)	R30 400
	(iii) Clinical trial application (Postgraduate study)	R10 800
	(iv) Any other clinical trial application	R5 000
	(b) In respect of clinical trials amendments	
	(i) Fees in respect of an application for technical amendments:	R7 000 per amendment
	(ii) Fees in respect of an application for administrative amendment:	R4 100 per amendment; and
	(iii) Any other application except for the purpose of performing a clinical trial	R350
Registration TimeLine	Approx.. 24 months for innovative products and 12 months for generic medicines.	
Other Information:-		
Audit Fee	Fees for inspections to assess the Quality, Safety and Efficacy of Medicines or Scheduled Substances	
	(a) Local manufacturing site	R 600/h (Travel time to be changed)

	(b) International manufacturing sites	R1 600/h (Travel time to be charged)
	(c) Wholesale sites	R1 600/h
	(d) Distributor sites, Local	R1 600/h
	(e) Clinical trial site, Local	R1 600/h
	(f) International clinical trial site	R1 600/h
	(g) Local pharmacovigilance inspection	R1 600/h
	(h) International pharmacovigilance inspection	R1 600/h
	(i) Desktop inspection to assess quality, safety and efficacy of medicines or scheduled substances:	R2 100
Guidelines	ICH CTD guideline	

Country	Myanmar	
Regulatory Body	Food and Drug Administration (FDA)	
Email ID	fda@mohs.gov.mm	
Website	www.fdamyanmar.gov	
Registration Document	ACTD (Dossier Format)	
Approx. Fee	Registration Assessment Fees	300,000 (In Kyats) + Fees (in kyats) for Lab analysis
	Registration Fees	500,000 (In Kyats)
	Variation of Registration	100,000 (In Kyats) for each variation
BA BE Study Requirements	1. required for the registration of generics	
	2. Categories of product for which BE study required -prescription only oral solid dosage forms	
	3. Comparator product – Implement ASEAN selection criteria for comparator product – (innovator product registered in the country, if innovator can't be identified, choice of comparator in order of preference are approval in ICH and associated countries, pre-qualified by WHO	
	4. Condition in which comparator product used in BE study is different from DRA's selection criteria - Considered acceptable if sufficient justification is provided	
	5. Reference guideline when evaluating BE studies for – Conventional oral immediate release solid dosage form – Modified release oral solid dosage forms	
	6. Guideline to evaluate bioanalytical method validation report	
	7. Criteria for evaluate bioanalytical method validation report	

	8. Criteria for accepting oversea BE studies - Study conducted at nationally accredited BE centre - Product approved by reference country (e.g. US, EU, Australia)	
Registration TimeLine	06-12 Months	
	Application for renewal of registration shall be submitted 90 days before the validity of the registration terminates.	
Validity of Registration	05 Years	
Other Information:-		
Audit Fee	a) Assessment Fees	300000 Kyats
	b) Registration Fees	500000 Kyats
	c) Variation Fees	100000 Kyats
Guidelines	ACTD Guidelines	

Country	Philippines			
Regulatory Body	Food and Drug Administration Philippines			
Email ID	fdac@fda.gov.ph			
Website	www.fda.gov.ph			
Registration Document	ASEAN Common Technical Dossier (ACTD)			
Approx. Fee	**Product Type**	**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. Generic			
	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	-
	Medical Device Products			

	Risk Class	Application Fee (Per Device)	Evaluation Fee (Per Device)	Annual Fee (Per Device)
	Class A	5,000	10,000	2,000
	Class B	10,000	20,000	5,000
	Class C	15,000	45,000	9,000
	Class D (Includes devices incorporating medicinal/therapeutic products)	30,000	60,000	12,000
BA BE Study Requirements	As per ASEAN Guideline for the Conduct of Bioavailability and Bioequivalence Studies (July 2004)			
Registration TimeLine	**Type of Application/ Pathway**		**Timeline**	
	Abridged Review		Not more than 45 working days	
	Verification Review		Not more than 30 working days	
	Post-approval changes/s			
Other Information:-				
Assessment Fee	**Assessment Type**	**Fee**	**Note**	
	1. Verification of GMP Standard (EMP 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	
	GMP conformity Assessment Local/Domestic Manufactures of Drug Product			

	Assessment Type	Fee
	Application for GMP Certificate	50,000
	Domestic Manufacturing Inspection	60,000
Guidelines	ASEAN Common Technical Requirements (ACTR)	

Country	Singapore				
Regulatory Body	Health Sciences Authority (HAS)				
Email ID	HSA-CML@hsa.gov.sg				
Website	www.hsa.gov.sg				
Registration Document	ASEAN Common Technical Dossier (ACTD)				
Approx. Fee	Fees for Product Registration				
(Medical Devices)	Fees	Class B	Class C	Class D	Class D with a registrable drug
	Application Fee	$530	$530	$530	$530
	Immediate route Fee	$950	$ 3,180	N.A.	N.A.
	Expedited Route Fee	N.A.	$ 3,180	$ 5,730	N.A.
	Abridged Route Fee	$1,910	$3,710	$6,050	$10,400
	Full route Fee	$3,710	$6,050	$11,800	$75,400
	Full route (Priority Review Scheme Route 1)	$4,220	$6,800	$13,400	$N.A.
	Full route (Priority Review Scheme Route 2)	$5,460	$8,800	$17,300	N.A.
	Annual Retention Fee for SMDR listing	$37	$64	$128	$128
(New Drug)					
	Application Type	Screening Fee	Evaluation fee NDA-1	Evaluation Fee NDA-2	Evaluation Fee NDA-3

	Verification evaluation route	$580	$16,900	$16,900	$5,830
	Abridged evaluation route	$580	$11,400	$11,400	$5,830
	Full evaluation route	$2,910	$82,900	$82,900	$82,900

(Generic Drug)				
	Application Type	**Screening Fee**	**Evaluation Fee GDA-1**	**Evaluation Fee GDA-2**
	• Verification evaluation route • Verification evaluation route (CECA scheme)	$580	$10,400	$5,300
	Abridged Evaluation Route	$580	$4,080	$2,330
Biosimilar Product	**Application Type**	**Screening Fee**	**Evaluation Fee NDA-2**	**Evaluation Fee NDA-3**
	Verification evaluation route	$580	$16,900	$5,830
	Abridged Evaluation Route	$580	$11,400	$5,830
BA BE Study Requirements	-			
Registration TimeLine	Turnaround Time (in working days)			

(Medical Device)	**Registration Route**	**Class B**	**Class C**	**Class D**	**Class D with a registration Drug**
	Immediate Route	Immediate upon submission	Immediate upon submission	N.A.	N.A.
	Expedited route	N.A.	120	180	N.A.
	Abridged route	100	160	220	220
	Full route	160	220	310	310

	Full route (Priority Review Scheme Route 1)	120	165	235	N.A.
	Full Route (Priority Review Scheme Route 2)	120	165	235	N.A.
(New Drug)	**Turnaround Time**				
	Application Type	**Screening (in working days)**		**Evaluation (in working days)**	
	Verification evaluation route	50		60	
	Abridged evaluation route	50		180	
	Full evaluation route	50		270	
(Generic Drug)	Turnaround Time				
	Application Type	**Screening (in working days)**	**First communication (in working days)**	**Evaluation (in working days)**	
	Verification evaluation route	50	N.A.	120	
	Verification evaluation route (CECA Scheme)	50	14	90	
	Abridged Evaluation route	50	N.A.	240	
Biosimilar Product	**Application Type**	**Screening (in working days)**		**Evaluation (in working days)**	
	Verification evaluation route	50		60	
	Abridged evaluation route	50		180	
Other Information:-					
Audit Fee	GMP Conformity Assessment for Therapeutic Products				
	good manufacturing practice (GMP) conformity assessment of overseas manufacturers of therapeutic products		Revised Fees (effective 1 July 2022)		

	GMP Evidence Evaluation (per manufacturing site)	$630
	Quality System Dossier (QSD) Evaluation (per manufacturing site)	$4,770
	On-site GMP audit of a manufacturer located in:	
	(a) An ASEAN country (per manufacturing site) (b) an Asian country (outside of ASEAN) (per manufacturing site) (c) a country outside of Asia (per manufacturing site)	$18,400 $20,400 $24,400
Guidelines	ASEAN Common Technical Requirements (ACTR)	

Country	Vietnam		
Regulatory Body	Ministry of Health- Drug Administration of Vietnam		
Email ID	**cqldvn@moh.gov.vn**		
Website	dav.gov.vn		
Registration Document	ACTD-format		
Approx. Fee	**Drug Authorization Fees**		
	Types of Authorization	**Applicable Fee**	**Applicable Fee in USD**
	Drugs (new)	VND 5.5 million	USD 237 approx.
	Drugs (renewal)	VND 3 million	USD 130 approx.
BA BE Study Requirements	As per "Asian Guidelines For The Conduct of Bioavailability and Bioequivalence Studies"		
	Other Countries Bioequivalence Study Acceptable- Accepted		
	International BE- Accepted		
Registration TimeLine	Under the Vietnamese legal regulation, it takes 06 months, but in reality, it may take up to 08-12 months to complete the renewal		
Other Information:-			
Audit Duration	**The average duration of the review:**		
	- large audit firm: 5 days		
	- Average audit firm: 3 days		
	- Small audit firm: 2 days		
Guidelines	ASEAN CTD Guideline		

Country	Namibia	
Regulatory Body	Ministry of Health and Social Service	
Email ID	**info@nmrc.com.nail**	
Website	**nmrc.gov.na**	
Registration Document	**CTD Format**	
Approx. Fee	1. In respect of an application for registration of a category A medicine-	
	(a) In respect of a medicine compounded in its entirety in Namibia	
	(i) For new chemical entity, including novel dosage forms or delivery systems-	
	(a) per application	N$ 3,000-00;
	) For registration	N$ 1,000-00;
	(ii) For an interchangeable multi-source medicine -	
	(a) Per application	N$ 1,000-00;
	(b) For registration	N$ 500-00;
	(iii) For a line extension of a medicine-	
	(a) Per application	N$ 1,000-00;
	(b) For registration	N$ 500-00;
	(iv) For a medicine not referred to in subparagraphs (i), (ii), or (iii)	
	(a) per application	N$ 1,000-00
	(b) for registration	N$ 500-00;
	(b) in respect of a medicine, not compounded in its entirety in Namibia -	
	(i) for a new chemical entity, including novel dosage forms or delivery systems-	
	(a) per application	N$ 3,500-00;
	(b) for registration	N$ 1,050-00;
	(ii) for an interchangeable multi-source medicine-	
	(a) per application	N$ 1,750-00;
	(b) for registration	N$ 700-00
	(iii) For a line extension of a medicine-	
	(a) per application	N$ 1,750-00;
	(b) for registration	N$ 700-00;
	(iv) for a medicine not referred to in subparagraphs (i), (ii), or (iii)-	
	(a) per application	N$ 1,750-00;
	(b) for registration	N$ 700-00
	2. In respect of an application for registration of a category C medicine-	

	(a) in respect of a medicine compounded in its entirely in Namibia-	
	(i) for a new chemical entity, including novel dosage forms or delivery systems -	
	(a) per application	N$ 1500-00;
	(b) for registration	N$ 500-00;
	(ii) for an interchangeable multi-source medicine -	
	(a) per application	N$ 500-00;
	(b) per registration	N$ 250-00;
	(iii) for a extension of a medicine-	
	(a) per application	N$ 500-00;
	(b) per registration	N$ 250-00;
	(iv) for a medicine not referred to in subparagraphs (i), (ii), or (iii)-	
	(a) per application	N$ 500-00;
	(b) per registration	N$ 250-00;
	(b) in respect of a medicine, not compounded in its entirely in Namibia-	
	(i) for a new chemical entity, including novel dosage forms or delivery systems-	
	(a) per application	N$ 2,100-00;
	(b) for registration	N$ 7,100-00
	(ii) for an interchangeable multi-source medicine-	
	(a) per application	N$ 875-00;
	(b) per registration	N$ 350-00
	(iii) for a line extension of a medicine-	
	(a) per application	N$ 875-00;
	(b) per registration	N$ 350-00;
	(iv) for a medicine not referred to in subparagraphs (i), (ii), or (iii)-	
	(a) per application	N$ 875-00
	(b) per registration	N$ 350-00
BA BE Study Requirements		
Registration TimeLine	170 days	
Other Information:-		
Audit Fee	**For the performance of an inspection to determine whether a premises referred to in item 5 are suitable to be registered as such -**	
	(a) In respect of the premises of a manufacturer of medicines in	N$ 400-00 per hour

	(b) In respect of the premises of a manufacturer of medicines outside Namibia	N$ 9,000-00 per site, plus travelling and accommodation costs for two inspectors.
	1. In respect of an application for registration of a Category A medicine -	
	(i) Screening Fee	N$ 1 000-00;
	(ii) Application fee:	N$ 5 000-00;
	(iii) Expedited registration fee	N$ 15 000-00;
	(v) For a line extension of a medicine:	N$ 2 500-00;
	(vi) Any post-registration amendment submission (whether approved or not):	N$ 1 500-00;
	(vii) Transfer of a certificate of registration (whether approved or not):	N$ 700-00.
	2. In respect of an application for registration of a category C medicine-	
	(i) Screening Fee	N$ 1 000-00;
	(ii) Application Fee	N$ 2 500-00;
	(iii) Expedited registration fee	N$ 7 500-00;
	(iv) For a line extension of a medicine:	N$ 1 500-00;
	(v) Any post-registration amendment submission (whether approved or not):	N$ 1 500-00;
	(vi) Transfer of a certificate of registration (whether approved or not):	N$ 125-00;
	3. In respect of any license issued in terms of section 31 of the act	N$ 1000-00;
	4. In respect of an authorisation granted for the use or sale of an unregistered medicine -	

	(a) registered outside Namibia but not registered in Namibia	N$ 4 000-00;
	(b) not registered at all	N$ 6 000-00;
	(c) not registered at all, but forming part of a clinical trial	N$ 6 000-00
	(d) registered in Namibia, but forming part of a clinical trial for purposes of other indications	N$ 2 000-00;
	(e) prescribed for a specific patient	N$ 50-00;
	5. In respect of an application for the registration of a premises used for the manufacturing of medicines:	N$ 1 000-00;
	6. For the performance of an inspection to determine whether a premises comply with current good manufacturing practices -	
	(a) in respect of the premises of a manufacturer of medicines in Namibia	N$ 10 000-00 per site;
	(b) in respect of the premises of a manufacturer of medicines outside Namibia	N$ 30 000-00 per site;
	7. For the performance of an expedited inspection to determine whether a premises comply with current good manufacturing practices -	
	(a) in respect of the premises of a manufacturer of medicines in Namibia	N$ 20 000-00 per site;
	(b) in respect of the premises of a manufacturer of medicines outside Namibia	N$ 100 000-00 per site;
Guidelines	Guidelines of Registration of Medicines- Own guideline	

Country	Tanzania			
Regulatory Body	Tanzania Medicines & Medical Devices Authority (TMDA)			
Email ID	medicines@tmda.go.tz			
Website	www.tmda.go.tz			
Registration Document	**Product Dossier**			
Approx. Fee	**S/N**	**Service**	**Currency**	**Fee**
	Marketing Authorisation of Human and Veterinary Medicines (Domestic)			
	1	New or renewal application	TZS	1,000,000
	2	Variation – Major	TZS	200,000
	3	Variation – Minor	TZS	100,000
	Marketing Authorisation of Human, Veterinary Medicines and Biological Products (Imported)			
	4	New or renewal application – Non-biologicals	USD	2,000
	5	New or renewal application – Biologicals	USD	3,000
	6	Retention	USD	300
	7	Variation – Major	USD	1,000
	8	Variation- Minor	USD	300
	9	Fast track registration	USD	Double the respective fee
		Pricing of innovator medicinal products		
	10	New or renewal application for pricing	USD	200
	MEDICAL DEVICES			
	Marketing Authorisation of Medical Devices (Domestic)			
	11	Class A for notification (Non –Registrable)	TZS	50,000
	12	Class A (Registrable)	TZS	100,000
	13	Class B	TZS	200,000
	14	Class C	TZS	500,000
	15	Class D	TZS	500,000
	16	Variation- Major	TZS	150,000
	17	Variation-Minor	TZS	100,000

	Marketing Authorisation of Medical Devices (Imported)			
	18	Class A for notification (Non –Registrable)	USD	100
	19	Class A (Registrable)	USD	500
	20	Class B	USD	2,500
	21	Class C	USD	2,500
	22	Class D	USD	2,500
	23	Spare parts and Accessories	USD	500
	24	Variation – Major	USD	300
	25	Variation – Minor	USD	150
	26	Retention (Registered devices)	USD	200
	27	Retention (Notified devices)	USD	50
BA BE Study Requirements	As per Country Specific			
Registration TimeLine	180 days for a drug to get approval for marketing authorization			
Other Information:-				
	GMP Inspection and Quality Audit			
Audit Fee	**S/N**	**Service**	**Currency**	**Fee**
		GMP Inspection and Quality Audit		
		GMP inspection and Quality Audit fee for medicines and medical device facilities per block (Foreign)		
	1.	East Africa	USD	4,000
	2.	Southern Africa Development Community (SADC) Countries	USD	4,500
	3.	Rest of Africa	USD	5,000
	4.	Asia	USD	6,000
	5.	Europe	USD	6,500
	6.	America	USD	7,500
	7.	Australia and New Zealand	USD	7,500
Guidelines	Country Specific Guidelines			

Country	Taiwan		
Regulatory Body	Ministry of Health and Welfare /TFDA		
Email ID	TFDAmethod@fda.gov.tw		
Website	www.mohw.gov.tw		
Registration Document	Dossier		
Dossier Requirement			
Evaluation	NDA	ANDA	OTC Monograph Drug Application
Reference Drug	Not Required	Required	Compiled with monograph
Safety Efficacy	• Pharm/Tox • PK/PD/BA/BE • Clinical trials	Bioequivalence (BE) as a surrogate to clinical trial	Not required
Quality	• Chemistry, Manufacturing and cosmetic (CMC) • PIC/S GMP • GLP,GCP		
Labeling	Labeling (direction of use)		
Approx. Fee for Medical Devices	**Registration Application Fee**		
	Class I	NT $ 3,000 (US $ 97)	
	Class II	NT $ 6,000 (US $ 194)	
	Class III	NT $ 12,000 (US $ 388)	
	Class IV	NT $ 24,000 (US $ 776)	
	Priority review date		
	Class I	NT $ 15,000 (US $ 1521)	
	Class II	NT $ 30,000 (US $ 1,042)	
	Annual Retention Fee		
	Class I	NT $ 1,000 (US $ 32)	
	Class II	NT $ 2,000 (US $ 64)	
	Class III	NT $ 4,000 (US $ 128)	
	Class IV	NT $ 8,000 (US $ 256)	
BA BE Study Requirements	As per regulation of Bioavailability and Bioequivalence Studies		
Registration TimeLine	**Registration of Generic Drugs Review Timeline**		
	Generic Drug (Non-pharmacovigilance)	180 days	

	Generic Drug (Pharmacovigilance)	210 days
	Active Pharmaceutical Ingredients	180 days
	Drug Master File (DMF)	180 days
	Review Process and Timeline for NDAs/BLAs	
	NCE/BLA standard Review	360 days
	Priority Review	240 days
	Abbreviated Review	180 days
	Non-NCE (with clinical data)	300 days
	Non-NCE (without clinical data)	200 days
Other Information:-		
Audit Fee	The fee of the on-site inspection is NT$600,000, including document review (NT$60,000) and on-site inspection (NT$540,000) Each application for on-site inspection shall be limited to 2 items. For those who intend to apply for more than 2 items, an additional NT$35,000 will be charged for each additional inspection item in the same factory, and an additional NT$105,000 will be charged for each additional inspection item in a different factory.	
Guidelines	TFDA Regulations	

Country	Hong Kong	
Regulatory Body	Department of Health	
Email ID	pharmageneral@dh.gov.hk	
Website	www.drugoffice.gov.hk	
Registration Document	Dossier	
Approx. Fee	Fees of New Registration	
	Type	Fees
	Application Fee	HK$ 1,100
	Registration Certificate	HK$ 1,370
	Renewal of Product Registration	
	Renewal of Certificate	HK$ 575
BA BE Study Requirements	The BE studies should be conducted in accordance with the WHO guidance document. "Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability", Or other international guidelines.	
Registration TimeLine	3-6 Months	
Other Information:-	All drugs must be registered with the pharmacy and poisons Board prior to being sold in Hong Kong.	
Audit Fee	-	
Guidelines	ICH CTD	

Country	UAE	
Regulatory Body	Ministry of Health & Prevention	
Email ID	info@mohap.gov.ae	
Website	www.Mohap.gov.ae	
Registration Document	E-CTD Dossier	
Approx. Fee	**Type**	**Fees**
(Medical Device)	Application	AED 100
	Registration of a medical Device	AED 5,000
(Conventional Pharmaceutical Product)	**Service Fees**	
	Types	**Fees**
	Application	AED 100
	Registration of a conventional pharmaceutical product	AED 7,000
	Analysis or re-analysis of a medical product	AED 3,500
	Pricing certificate after committee approval	AED 500
	For PV plan evaluation	AED 1000
BA BE Study Requirements	AED 4000-8000	
Registration TimeLine	**Type**	**Working Days**
(Medical Device)	Registration of Medical Device	45 working days
(Conventional Pharmaceutical Product)	45 Working days	
Other Information:-		
Audit Fee	**Service Fees**	
	Application Fee	**AED 100**
	Fees for initial inspection, according to the type of facility:	
	Warehouses, pharmacies and scientific offices:	AED 1,000 per inspection
	Drug manufacturers and medical devices	AED 3,000 per inspection
	Final inspection fees, according to the type of facility:	
	Warehouses, pharmacies and scientific offices	AED 1,000 per inspection

	Drug manufacturers and medical devices	AED 3,000 per inspection
	Fees for accrediting the geometric plans for factories of medicines and medical devices	AED 2,000
	Final license fees, according to the type of facility:	
	Pharmacies and warehouse	AED 7,500
	Factories of medicines and medical devices	AED 50,000
Guidelines	ICH CTD	

Country	Zimbabwe		
Regulatory Body	Medicines Control Authority of Zimbabwe (MCAZ)		
Email ID	mcaz@mcaz.co.zw		
Website	www.mcaz.co.zw		
Registration Document	CTD Format		
Approx. Fee	**Application for a registration of medicine**		
	(a) in case of a medicine imported into Zimbabwe as a finished product for-		
	Sr. No.		**USD**
	(i)	a new chemical entity including dosage form or delivery system (human)	3,000
	(ii)	a new chemical entity including dosage form or delivery system (veterinary)	2,000
	(iii)	a generic medicine (human)	2,500
	(iv)	a generic medicine (veterinary)	1,500
	(v)	a line extension of medicine (human)	
	(vi)	a line extension of medicine (veterinary)	1,000
	(vii)	Orphan medicine	750
	(viii	a previously registered medicine	750
	(ix)	Submission of an application	600
	(b) In case of a medicine imported into Zimbabwe and which is re-labelled or repacked before being sold as finished product-		
	(i)	Human medicine	1,500
	(ii)	New chemical entity	1,500
	(iii)	Veterinary medicine	900
	(iv)	a previously registered medicine	750
	(v)	Resubmission of an application	600
	(c) In any other case-		
	(i)	Human medicine	1,500
	(ii)	New chemical entity	1,500
	(iii)	Veterinary medicine	900
	(iv)	A previously registered medicine	750
	(v)	Resubmission of an application	600

	(d) In case of expedited review of-		
	(i)	A new chemical	4,500
	(ii)	a generic medicine	4,000
	(iii)	A line of extension of a medicine	3,000
	Retention of registered medicine, annually		
	In case of a medicine for human use imported into Zimbabwe as a finished product		500
	In case of a veterinary medicine imported into Zimbabwe as a finished product		300
	Repacked before being sold as finished product-		
	(i)	Human medicine	300
	(ii)	Veterinary medicine	200
BA BE Study Requirements	**In case of a medicine imported into Zimbabwe as a finished product**		
	(a)	Bioavailability/Bioequivalence	300 USD
	In case of a medicine imported into Zimbabwe and which is re-labelled or repacked before being sold as a human or veterinary medicine		
	(i)	Bioavailability/Bioequivalence	200 USD
	Any other case-		
	(i)	Bioavailability/Bioequivalence	75 USD

Registration TimeLine	**No.**	**Pathway**	**Time (months)**
	1	WHO Collaborative Registration Procedure	3*
	2	Expedited registration pathway	6*
	3	Zazibona (SDAC) Joint Review Pathway + Country level approval	12 (9+3)
	4	Complementary medicines	12
	5	Veterinary medicines	15
	6	0ther products	18-24
Other Information:-			

Audit Fee	**Inspection of premises-**		**USD**
	(a)	Pharmaceutical manufacture's premises	1,000
	(b)	Other premises	200

	(c)	Other premises, expedited inspection	400 plus costs of the re-inspection
Guidelines	**ICH CTD- Guidelines**		

Country	Armenia				
Regulatory Body	The Scientific Canter of Drug and Medical Technologies Expertise (SCDMTE)				
Email ID	admin@pharm.am				
Website	www.pharm.am				
Registration Document	Dossier				
Approx. Fee	**Type of Application**	**Registration under the standard procedure or EAEU regulations valid only for the RA**	**Registration under the simplified procedure**	**Registration under the EAEU regulations (reference country)**	**Re-Reregistration under the EAEU regulations**
	I.A. Generic medicinal product	1 100 000	500 000	2 100 000	1 000 000
	I.A.1 Each subsequent pharmaceutical form and flavouring variety	1 100 000	500 000	2 100 000	1 000 000
	I.A.2 Each subsequent strength	500 000	250 000	1 100000	500 000
	I.A.3 Each subsequent manufacturing site/variation	1 100 000	500 000	2 100000	1 000 000
	Generic medicinal product with well-established use	800 000	500 000	1 500 000	500 000
	Each subsequent pharmaceutical form and	800 000	800 000	1 500 000	500 000

	flavouring variety				
	2. Original medicinal product, immunological medicinal product or new combinations	2 400 000	1 000 000	3 500 000	1 500 000
	2.1 Each subsequent pharmaceutical form and flavoring variety	2 400 000	1 000 000	3 500 000	1 500 000
	2.2 Each subsequent strength	1 200 000	500 000	1 750 000	750 000
	2.3 Each subsequent manufacturing site/variation	2 400 000	1 000 000	3 500 000	1 500 000
	2.4 Each subsequent presentation form	50 000	50 000	80 000	80 000
	3. Biosimilar, blood product, new combinations of well-known medicinal products or hybrid medicinal product	2 100 000	900 000	3 100 000	1 500 000
	4. Veterinary medicinal product	800 000	500 000	1 500 000	500 000
	5. Herbal medicinal product	800 000	500 000	1 500 000	500 000
	6. Homeopathic	800 000	500 000	1 500 000	500 000

	medicinal product				

Expertise fee for clinical trials (studies) authorization in the Republic of Armenia		
	Type of assessment	**Assessment fee, including VAT (Armenian drams)**
	Expertise for clinical trials authorisation in the Republic of Armenia	500 000
	Expertise of bioequivalence studies and in cases when the investigational pharmaceutical product is registered in the Republic of Armenia or has a clinical trial or compassionate use authorisation given by the competent authority of ICH member country	250 000
	Expertise of changes in documents after obtaining clinical trial authorisation	100 000
	Annual fee that must be paid started from next year	100 000

Registration TimeLine	180 days
Other Information: -	

Audit Fee	**Types of Assessment**	**Assessment Fee, including VAT (Armenian drams)**
	Medicinal product manufacturing pre-licensing inspection	280 000
Guidelines	ICH CTD Guideline	

Country	Latvia	
Regulatory Body	State Agency of Medicines Republic of Latvia	
Email ID	info@zva.gov.lv	
Website	www.zva.gov.lv	
Registration Document	eCTD Dossier/ Application Dossier	
Approx. Fee	Type	Fees
	- Application for a new active substance	4000,00 EUR
	-Application for a medicinal product with well-established use	4000,00 EUR
	-Application for marketing authorization of a medicinal product containing an active substance used in an authorized medicinal product, but not in this combination (application for a fixed combination)	4000,00 EUR
	- Application for marketing authorisation where the marketing authorisation holder of the original medicinal product has given their approval for the marketing authorisation applicant to use pharmaceutical, non-clinical and clinical documentation included in the marketing authorisation documentation of the original medicinal product with an identical qualitative and quantitative active substance content and pharmaceutical form (Application with approval)	4000,00 EUR
	-Application for a generic medicinal product	2500,00 EUR
	-Mixed marketing authorisation application	2500,00 EUR
	- Application for expansion of marketing authorisation in accordance with Annex 1 of the European Commission Regulation (EC) No. 1234/2008 of 24 November 2008 concerning the examination of	1500,00 EUR

	variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products	
	-Application for a homeopathic or anthroposophic medicinal product, 1 pharmaceutical form or 1 strength	560,00 EUR
	-Application for a medicinal product with identical marketing authorisation documentation, but different names and one and the same or different marketing authorisation holder (repeat application, submitted simultaneously	1500,00 EUR
	-Application for a homeopathic or anthroposophic medicinal product, 1 pharmaceutical form or 1 strength	560,00 EUR
	-Application for a traditional-use herbal medicinal product (for herbal medicinal products to be authorised via the simplified marketing authorisation procedure), 1 pharmaceutical form or 1 strength	560,00 EUR
	Additional fee for each additional medicinal product strength and/or pharmaceutical form, if submitted together with the initial marketing authorisation application	
	-Marketing authorisation	1000,00 EUR
	Additional fee for performing tasks for Latvia as a reference member state in a mutual recognition or decentralised procedure	
	-For marketing authorisation	8500,00 EUR
	- For repeat use mutual recognition procedure (RUP procedure)	2500,00 EUR
BA BE Study Requirements	2000- 4000 Euros	
Registration TimeLine	120 working days	
Other Information:-		
Audit Fee	- First day of Inspection – EUR 1000,00	
	- The next day of each inspection- EUR 500,00	
Guidelines	ICH CTD Guideline	

Country	Norway	
Regulatory Body	Norwegian Medicines Agency	
Email ID	post@noma.no	
Website	www.legemiddelverket.no	
Registration Document	eCTD Dossier	
Approx. Fee	**National**	
	1.1 Marketing Authorisation application (national)	
	Complete dossier/well established use(WEU)/fixed combinations,	456 089
	Hybrid/Generic/Biosimilar/Informed consent	171 033
	Additional formulations and strengths applied at the same time	17 104
	Annex I: applications except new formulations/strengths	102 620
	Annex I (Line extension): new formulations and strengths	114 023
	Duplicate application (applied at the same time)	34 206
	Application for registration of a traditional herbal medicinal product, with HMPC-monography	171 033
	Application for registration of a traditional herbal medicinal product, without HMPC-monography (upon agreement)	228 045
	Marketing authorisation application for natural remedies	228 045
	Withdrawal of application before procedure start – administrative fee	22 804
	Variation applications and applications for renewal (national)	
	Type IB variation which leads to changes in the SmPC, PL and labeling	9 692
	Type II variation: change in therapeutic indication	85 518
	Type II variation: change in legal status	85 518
	Other type II variations	14 253
	Renewal	45 609
	Traditional herbal medicinal products: type II variation – change in traditional use indication	25 654

	Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling	9 692
	Traditional herbal medicinal products: other type II variations	14 253
	Traditional herbal medicinal products: renewal	22 804
	Parallel import (national)	
	Application for marketing authorisation	18 243
	Renewal	5 701
	MRP- Norway as the RMS	
	Marketing authorisation application (MRP-RMS)	
	Agreement on RMS-ship	57 011
	Initiating MRP, regardless of legal basis	114 023
	Repeat use, regardless of legal basis	114 023
	Annex I: applications except new formulations and strengths	102 620
	Annex I (line extension): new formulations and strengths	142 527
	Variation applications and applications for renewal (MRP-RMS)	
	Type IB variation which leads to changes in the SmPC, PL and labeling	12 541
	Type II variation: change in therapeutic indication	85 518
	Other type II variations	13 683
	Worksharing: change in therapeutic indication	85 518
	Worksharing: type IB variation which leads to changes in the SmPC, PL and labeling	11 403
	Renewal	45 609
	Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling	9 122
	Traditional herbal medicinal products: type II variations	13 683
	Traditional herbal medicinal products: renewal	22 804
	MRP- Norway as CMS	
	Marketing authorisation application (MRP-CMS)	

	Complete dossier/well established use(WEU)/fixed combinations,	114 023
	Hybrid/Generic/Biosimilar/Informed consent,	85 518
	Additional formulations and strengths applied at the same time	17 104
	Annex I: applications except new formulations and strengths	57 011
	Annex I (Line extension): New formulations and strengths	57 011
	Application for registration of a traditional herbal medicinal products, with HMPC monography	85 518
	Application for registration of a traditional herbal medicinal products, without HMPC monography (upon agreement)	114 023
	Withdrawal of application before procedure start – administrative fee	22 804
BA BE Study Requirements	-	
Registration TimeLine	120 Working Days	
Other Information:-		
Audit Fee	-	
Guidelines	ICH CTD Guideline	

Country	Denmark			
Regulatory Body	Danish Medicines Agency			
Email ID	dkma@dkma.dk			
Website	Laegemiddelstyrelsen.dk			
Registration Document	eCTD Dossier			
Approx. Fee	**Application Type**	**Drug Type**	**Boundary**	**Fee**
	new market driving permit and extensions	Ordinary medicines and vitamin/ mineral preparations	Fully documented application	DKK 327,176
			Fixed combination of medicines	DKK 327,176
			Bibliographical applications	DKK 287,447
			Hybrid application with clinical studies regarding efficacy and /or safety	DKK 287,447
			Application concerning biologically medicine that corresponds to already approved medicines	DKK 287,447
			Application concerning vitamin and mineral preparations,	DKK 287,447
		Procedure Denmark's role- National	Hybrid application without clinical studies regarding effect and/ or security	DKK 190,538
			Generics for animals, antiotics	DKK 190,538
			Generic for humans	DKK 189,534
			Generics for animals, not antibiotics	DKK 189,534
			Duplicate with same schedule as an application, where payment is made full fee	DKK 57,430
			Parallel registration	DKK 66,960

			Addition to required assessment beyond standard course due to complexity or of the submitted documentation	DKK 42,648
			Later expansion of marketing permission	DKK 181,400
		Procedure Denmark's role- DCP, RMS	Fully documented application	DKK 378,989
			Fixed combination of medicines	DKK 378,989
			Bibliographical application	DKK 372,689
			Hybrid application with clinical studies regarding effect and/ or security	DKK 372,689
			Application concerning biologically medicine that corresponds to already approved medicines	DKK 372,689
			Hybrid application without clinical studies regarding effect and/ or security	DKK 243,477
			Generics for animals, antibiotics	DKK 242,602
			Generic for humans	DKK 241,347
			Generics for animals, not antibiotics	DKK 241,347
			Duplicate with same schedule as an application, where payment is made full fee	DKK 75,633
			Parallel registration	DKK 74,103
			Addition to required assessment beyond std. course due to complexity or of the submitted documentation	DKK 50,046
			Later expansion of marketing permission	DKK 207,538

		Procedure Denmark's role DCP/MRP, RMS	Evaluation of periodic the security update gs report (PSUR) a fee per D.sp.no.	DKK 8,007
		Procedure Denmark's role DCP/MRP, CMS	All applications about new marketing permission	DKK 33,766
			Addition to required assessment beyond standard course due to complexity or of the submitted documentation	DKK 4,691
			Later expansion of marketing permission	DKK 20,184
	New market driving license, registration and expansion	**Nature-medicines, traditional plant medicines or homeopathic medicines**		
		Procedure Denmark's role- National	-	DKK 116,789
		DCP,RMS	-	DKK 110,425
		DCP/MRP, CMS	-	DKK 32,501
		All procedures	Assessment of periodic security update report (PSUR). A fee per D.sp. no.	DKK 8,007
		All procedures	Addition to required assessment beyond std. course due to complexity or of the submitted documentation	DKK 42,648
	new market driving license,	All types MRP/DCP/, national,	Rejection of new application for marketing permission according to regulatory validation	DKK 24,911

	registration and expansion	everyone roles		
	New marketing authorisation	All types parallel import and parallel trade	Per export country	DKK 9,907
	New Mutual recognition procedure, MRP	All types MRP, RMS	Full procedure, incl. update	DKK 141,212
			Full procedure, incl. administrative update	DKK 54,858
			Day Zero-procedure	DKK 15,025
	Extension of marketing permission/ registration	Ordinary medicines and vitamin/ mineral-preparations		
		National		DKK 5,906
		MRP, CMS		DKK 1,512
		MRP, RMS		DKK 9,656
		All types Parallel import	A fee per D.sp.no.	DKK 2,335
		Natural medicines, traditional plant medicines and homeopathic medicines		
		National		DKK 9,491
	Annual fee for medicines (general authority assignments, monitoring, control and analysis)	All types All Procedure	A fee per MT number/ drug ID	DKK 18,770

	Special fees when a medicine is manufactured at a company outside the EU/EEA area			
	Surcharge	Description		Fee
	Addition to fee for application for marketing authorisation	Addition to the fee for applying for marketing authorization if the medicine is manufactured outside the EU/EEA area, and the Danish Medicines Agency, according to EU rules, must control the company.		DKK 891
	Addition to fee for application to change marketing authorisation	Supplement to the fee for an application to change the marketing authorization if the manufacturing site for the medicinal product is changed to a company outside the EU/EEA area, and the Danish Medicines Agency, according to EU rules, must control the company.		DKK 891
	Supplement to the annual fee for medicinal products	Supplement to the annual tax for medicinal products manufactured outside the EU/EEA area, if the Danish Medicines Agency has to control the company in accordance with EU regulations.		DKK 1,082
Fee for Clinical Trials	**Fees relating to mono-national clinical trials**			**Amount**
	A	For an application for approval of a clinical trial with a medicinal product for which a marketing authorization has been issued in an EU or ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) country:		DKK 25,557
	B	For an application for approval of a clinical trial, where documentation is submitted for the manufacture and quality of the investigational medicinal product in the form of an Investigational Medicinal Product Dossier (IMPD): If the following is met, however, the fee is the same as for marketed medicinal products (A): - The submitted IMPD is significantly simplified.		DKK 50,740

		- The investigational medicinal product is a modification of a medicinal product for which a marketing authorization has been issued, the modification only concerns the medicinal product's packaging, labelling, shape or appearance.	
	C	Application for amendment of a clinical trial (substantial amendment), which the Danish Medicines Agency has approved. Fee for each application:	DKK 5,292
	D	Annual fee for clinical trials: The annual fee is paid per year started and until national completion, but not the first year after the approval of the trial.	DKK 14,263

Registration TimeLine		**Maximum assessment time**	**Check stop periods for applicant**
	New national applications (complete/generic and line extensions)	240 days	6-12 months
	National variation application type IA	30 days	-
	National variation application type IB	60 days	2 months
	National variation application type II	150 days	2 months
	Parallel import application	60 days	24 weeks (clock stop periods for export country) and possibly 30 days for applicant
Other Information:-			

Audit Fee	**Corporation**	**Explanation**	**Application fee**	**Annual Fee**
	API inspection outside the EU	Inspection of companies with APIs outside the EU	DKK 151,181	DKK 151,181

	Inspection of the manufacture of products or data for which import authorities require a GMP or GLP declaration	Inspection of a company in Denmark, where the company is not covered by a license or registration	Calculated individually based on the Danish Medicines Agency's time consumption (per started hour) and hourly price as well as other direct costs incurred by the Danish Medicines Agency as part of the inspection. Hourly price: DKK 1,267	
Guidelines	EU Guideline			

Country	Bahrain			
Regulatory Body	National Health Regulatory Authority (NHRA)			
Email ID	info@nhra.bh			
Website	www.nhra.bh			
Registration Document	eCTD Format			
Approx. Fee	New Product Registration & Re-registration		BD.5/- 5 yrs	
(Medical Device)	Item	Type	Fees (Dinar Bahraini)	Norm
	Request to submit a registration request		5	Each New device
	Low risk	First registration	150	Annual per license
		Registration renewal	100	Annual per license
	Medium Risk	First registration	300	Annual per license
		Registration renewal	200	Annual per license
		First registration	1,000	Annual per license
		Registration renewal	700	Annual per license
	Update medical device registration data		20	Each device
BA BE Study Requirements	300-400 Bahraini Dinar			
Registration TimeLine	45 working days			
Other Information:-				
Audit Fee	Services			
	Application Fee	BHD 100		
	Fees for initial inspection, according to the type of facility:			
	Warehouses, pharmacies and scientific offices:	BHD 100-200 per inspection		
	Drug manufacturers and medical devices	BHD 200-300 per inspection		
Guidelines	CTD Guideline			

Country	Poland					
Regulatory Body	Office for Registration of medical products, Medical Device and Biocidal Products					
Email ID	urpl@urpl.gov.pl					
Website	www.urpl.gov.in					
Registration Document	CTD Dossier					
Approx. Fee	Application for marketing Authorization					
				RMS – MRP, DCP		
	Application for marketing Authorization	Procedure national	CMS – MRP, DCP (100%)	MRP		DCP (150%)
				Preparation report evaluator (75%)	Update report evaluator (50%)	
	full application: - original medicinal product - mixtures of known active substances in a composition not previously used	84,000	84,000	63,000	42,000	126,000
	substances with well-established medical use	67,200	67,200	50,400	33,600	100,800
	equivalent of the original medicinal product ("generic" application)	27,300	27,300	20,475	13,650	40,950
	- biological equivalent of the reference product - the medicinal product referred to in	43,680	43,680	32,760	21,840	65,520

	Art. 15 section 12 ("hybrid" application) - informed consent					
	herbal medicinal products other than those referred to in Article 20a of the Act	30,576	30,576	32,760	21,840	45,864
	herbal medicinal products other than those referred to in Article 20a of the Act for which it was developed community monograph	3,024	3,024	7,560	5,040	4,536
	traditional herbal medicinal products	10,080	10,080	7,560	5,040	15,120
	homeopathic medicinal products other than those referred to in Article 21 of the Act	27,300	Not applicable			
	Homeopathic medicinal products referred to in Art. 21 of the Act: - for a list containing less than 50 products - for a list containing 50					

	to 100 products - for a list containing more than 100 products		

Annual Fee	Annual Fee	Procedure national	CMS	RMS
	Herbal medicinal products referred to in Art. 10 and in Art. 16 section 1 of the Act, other than those referred to in Art. 20a of the Act, or homeopathic medicinal products referred to in Art. 10 and in Art. 16 section 1 of the Act, other than those referred to in Art. 21 of the Act	2,100	2,100	2,730
	Traditional herbal medicinal products referred to in Art. 20a of the Act, and herbal medicinal products other than those referred to in Art. 20a of the Act, for which a Community monograph has been prepared	840	840	1,092
	Herbal medicinal products other than those referred to in Article 10, art. 16 section 1, art. 20 ai art. 21 of the Act	840	840	1,092
	Homeopathic medicinal products referred to in Art. 21 of the Act - for a list containing less than 50 products - for a list containing 50 to 100 products - for a list containing more than 100 products	 621.60 1226.40 1898.40	 621.60 1226.40 1898.40	 808 1594.40 2468

GCP Fees	**Scenario 1:** GCP inspection request for Product A marketing authorisation application and the conduct of clinical trial protocol A at Site A (investigator site) for one clinical trial activity (Activity Group I) and at site B (sponsor site) for two clinical trial activities (Activity Group III and Activity Group IV). GCP inspection of clinical trial protocol B conducted at site C (Central laboratory) for one activity group (Activity group II); Fee payable: 4 basic fees, i.e. 22 400 EURO + 22 400 EURO + 22 400 EURO + 22 400 EURO = 89 600 EURO;		
	Scenario 2: GCP inspection request for Product A marketing authorisation application and the conduct of clinical trial protocol B at Site C (i.e. CRO site including clinical and bioanalytical facility) for two clinical trial activities (Activity Group I) and (Activity Group II). Fee payable: 2 basic fees, i.e. 22 400 EURO + 22 400 EURO = 44 800 EURO		
Registration TimeLine	180 working days		
Other Information:-			
Audit Fee	Basic Fee (Level I)	For each inspection inside or outside the European Union; for inspections outside the European Union, travel expenses shall be charged extra on the basis of actual cost.	22 400 EURO
	Basic fee (Level II)	For each consecutive distinct plasma master file (PMF) inspection performed in conjunction with an inspection that attracts the level I fee, provided that such consecutive inspection concerns the same PMF application, the same inspection team and is conducted in the same PMF inspection tour.	11 200 EURO
	Basic fee (Level III)	For each inspection inside or outside the European Union cancelled due to the withdrawal of the application; or changes to the manufacturing arrangements made by the manufacturer or changes made by the applicant/MAH that necessitate a cancellation of the inspection before the inspection is carried out.	11 200 EURO
Guidelines	EMA Guideline		

Country	Romania	
Regulatory Body	National Agency for Medicines and Medical Devices for Romania	
Email ID	**mdevice@anm.ro**	
Website	**www.anm.ro**	
Registration Document	**Product Dossier**	
Approx. Fee	Medical Products (Including Biologicals)	
	The administrative fees for the marketing authorization of a medicinal product under the national procedure	EUR 5,000 (Paid when the marketing authorization dossier is submitted with NAMMD)
	due for the evaluation of the marketing authorization dossier	EUR 9,500
	The fees are generally lower for the evaluation of generic medicines	EUR 5,700
	for biosimilars	EUR 6,650
Medical Device	There is no administrative fee for the registration of medical devices by NAMMD in the National Database of Medical Devices.	
BA BE study Requirements	As per European Guideline for Bioavailability and Bioequivalence	
Registration TimeLine	120 Days	
Other Information:-		
Audit Fee	1. Stand-alone application (based on original data)	20000-30000 Romanian Leu
	2.Bibliographic application (well-established medicinal use supported by bibliographic literature)	20000-30000 Romanian Leu
	3.Fixed combination application (new medicinal product made of at least two active	18000 – 20000 Romanian Leu

	substances not previously authorised as a fixed combination medicinal product)	
	4.Generic application	22000-25000 Romanian Leu
	5.Hybrid Application	22000-25000 Romanian Leu
	6.Similar biological medicinal product	22000-25000 Romanian Leu
	7.Stand-alone application (based on original data)	20000-30000 Romanian Leu
	8.Bibliographic application (well-established medicinal use supported by bibliographic literature)	20000-30000 Romanian Leu
	9.Fixed combination application (new medicinal product made of at least two active substances not previously authorised as a fixed combination medicinal product)	18000 – 20000 Romanian Leu
	10. Generic application	22000-25000 Romanian Leu
	11. Hybrid Application	22000-25000 Romanian Leu
	12. Similar biological medicinal product	22000-25000 Romanian Leu
Guidelines	EMA Guideline	

Country	Finland		
Regulatory Body	Finnish Medicines Agency (Fimea)		
Email ID	registry@fimea.fi		
Website	https://fimea.fi		
Registration Document	eCTD or NeeS		
Approx. Fee	Fees for marketing authorisations		
	Fee type	Human medicines	Veterinary medicines
	Marketing – authorisation application (single strength, one pharmaceutical form, one presentation	From €345,800	From €173,00
	Extension of marketing authorisation (level I)	€103,800	-
	Type-II variation (major variation)	€103,800	-
	Variations requiring assessment	-	From €8,600
	Scientific advice	From €51,800 to €103,800	From €17,000 to 51,800
	Annual fee (level I)	€123,900	€41,500
	Establishment of MRLs	-	€86,000
BA BE Study Requirements	-		
Registration TimeLine	Processing Times		
	The processing times for marketing authorisation applications are as follows:		
	• National Procedure	210 days	
	• Mutual recognition procedure	90 days + 30 days for the review of translations	

	• Decentralised procedure	210 says + 30 days for the review of translations
	• Centralised Procedure	210 days + the time required by the decision process of the European Commission.
Other Information:-		
Audit Fee	-	
Guidelines	EMA guideline/ European Commission Guideline	

Country	Butan
Regulatory Body	Drug Regulatory Authority
Email ID	registration@dra.gov.bt
Website	https://dra.gov.bt
Registration Document	ASEAN Common Technical Dossier
Approx. Fee	An initial application fee of BTN 500/- per product is levied. Once the assessment of the document is completed, a registration fee of BTN 1500/- per product will be charged. The fees may be however revised from time to time.
	Authorisation for Sale, and export
	1. Application fee for technical authorization for sale- Nu. 900.00 (Nine hundred) 2. Late renewal of Technical Authorization for sale and distribution per day- Nu. 100.00 per day (One hundred) per day 3. Application fee for renewal of technical authorization for sale- Nu. 900.00 (Nine hundred)
	Technical Authorization for Manufacture
	1. Application fee for provisional manufacturing authorization per application – Nu. 5000.00 (five thousand) 2. Application fee for final approval for manufacturing- Nu. 5000 (Five Thousand) 3. Fee for renewal of approval for manufacturing- Nu. 500.00(Five hundred)
Renewal of Registration	Application for renewal shall be submitted within 90 calendar days before the expiry date of registration along with the processing fee
BA BE Study Requirements	-

Registration TimeLine	If all the required documents are submitted during the time of application, a medicinal product can be registered within 2-3 months.
Other Information:-	
Inspection of Clinical Trial	1) The Authority will conduct on-site inspections of the clinical trials to verify compliance to CTA. 2) Member of the EC may be invited during the inspections as and when required.
Guidelines	Country Specific Guideline

<table>
<tr><th>Country</th><th colspan="3">Europe</th></tr>
<tr><td>Regulatory Body</td><td colspan="3">European Medicines Agency</td></tr>
<tr><td>Email ID</td><td colspan="3">noncompliancre@ema.europa.u</td></tr>
<tr><td>Website</td><td colspan="3">www.ema.europa.eu</td></tr>
<tr><td>Registration Document</td><td colspan="3">Dossier</td></tr>
<tr><td>Approx. Fee</td><td colspan="3">Fees for Marketing Authorisations</td></tr>
<tr><td></td><td>Fee Type</td><td>Human Medicines</td><td>Veterinary Medicines</td></tr>
<tr><td rowspan="8"></td><td>Marketing – authorisation application (single strength, one pharmaceutical form, one presentation)</td><td>From €345,800</td><td>From €173,00</td></tr>
<tr><td>Extension of marketing authorisation (level I)</td><td>€103,800</td><td>-</td></tr>
<tr><td>Type-II validation (major validation)</td><td>€103,800</td><td>-</td></tr>
<tr><td>Scientific advice</td><td>From €51,800 to €103,800</td><td>€17,000 to €51,800</td></tr>
<tr><td>Annual fee (level I)</td><td>€123,900</td><td>€41,500</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3">Scenario 1: Full dossier application for a medicinal product having one pharmaceutical form with one strength and X presentations</td></tr>
<tr><td>Basic Fee</td><td colspan="2">296 500 Euro
– Includes one pharmaceutical form and one presentation</td></tr>
<tr><td>Additional Fee</td><td colspan="2">7 400 Euro
- For additional presentations associated with the single strength.</td></tr>
<tr><td rowspan="3"></td><td colspan="3">Scenario 2: Full dossier application for a medicinal product having two pharmaceutical forms with two strengths and X presentations/ strength associated with the first form and one strength and Y presentations associated with the second form</td></tr>
<tr><td>Basic Fee</td><td colspan="2">296 500 EURO
- Includes one pharmaceutical form and one associated strength and one presentation.</td></tr>
<tr><td>Additional fee</td><td colspan="2">+7 400 EURO</td></tr>
</table>

		For additional presentations associated with the first form and strength.
	Additional fee	+29 800 EURO Second strength associated with the first form including one presentation.
	Additional Fee	+7 400 EURO For additional presentations associated with the first form and second strength.
	Additional fee	+29 800 EURO Second form including its associated strength and one presentation.
	Additional fee	+ 7 400 EURO For additional presentations associated with the second form and its strength.
	Scenario 3: Full dossier application for an insulin product having two pharmaceutical forms with six strengths (consisting of two sets of one uncombined preparation and two combination preparations (having different proportions of insulin) with insulin amounts corresponding to A I.U. and B I.U.) and X presentations/strength associated with the first form; and two strengths (of un-combined preparations with insulin amounts corresponding to A I.U. and B I.U.) and Y presentations/strength associated with the second form	
	Basic Fee	296 500 EURO - Includes one pharmaceutical form and one associated strength and one presentation.
	Additional Fee	+ 7 400 EURO - For additional presentations associated with the first form and strength.
	Additional fee	+ 29 800 EURO - For second to sixth strengths associated with the first form including one presentation for each strength.
	Additional fee	+ 7 400 EURO - Additional presentations associated with the second to sixth strengths of the first form.

	Additional fee	+ 29 800 EURO Second form including one associated strength and one presentation.
	Additional fee	+ 7 400 EURO For additional presentations associated with the second form and first strength.
	Additional fee	+ 29 800 EURO -Second strength associated with the second form including one presentation.
	Additional fee	+ 7 400 EURO For additional presentations associated with the second form and second strength.
	Scenario 4: Full dossier application with 3 strengths, e.g. 100mg, 200mg and 300mg. The 100 and 200mg strengths will be packaged together in a starter pack and the 300mg strength will have two presentations. The 100 and 200mg strengths do not have additional presentations.	
	Basic Fee	296 500 EURO Includes one pharmaceutical form and one associated strength and the starter pack presentation.
	Additional Fee	+ 29 800 EURO For second and third strengths associated with the first form including presentation 1 for the 3rd strength.
	Additional Fee	+7 400 Additional presentation 2 associated with the third strength of the first form.
	Examples of the determination of fees for extensions of marketing authorisation	
	Scenario 1: New pharmaceutical form with two strengths and X presentations/strength, for authorised or new route of administration (with submitted/cross-referenced clinical data)	
	Extension Application: • One pharmaceutical form, first strength and X presentations • Second strength (of same new pharmaceutical form) and X presentations	

	Basic Fee	89 900 EURO For extension
	Additional fee	+ 7 400 EURO For additional presentation fees.
	Additional fee	+ 22 400 EURO For additional strength fee.
	Additional Fee	+ 7 400 EURO For additional strength fee
	Scenario 2: New route of administration for authorised pharmaceutical form with two authorised strengths and X presentations/strength (with submitted/cross-referenced clinical data)	
	Extension application: • Route of administration for authorised pharmaceutical form, first strength and X presentations • Second strength (same new route of administration for same authorised pharmaceutical form) and X presentations	
	Basic Fee	89 000 EURO For Extension
	Additional Fee	+ 7 400 EURO For additional presentation fees.
	Additional Fee	+ 22 400 EURO For additional strength fee.
	Additional Fee	+ 7 400 EURO For additional presentation fees.
	Scenario 3: Two new strengths of same authorised pharmaceutical form and X presentations/strength (without submitted/cross-referenced clinical data)	
	Extension Application : • First new strength and X presentations • Second new strength (of same authorised pharmaceutical form) and X presentations	
	Basic Fee	66 800 EURO For extension
	Additional Fee	+ 7 400 EURO For additional presentation fees
	Additional Fee	+ 22 400 EURO For additional strength fee.
	Additional Fee	+ 7 400 EURO For additional presentation fees.
	Scenario 4: One new strength of each of two authorised pharmaceutical forms and X presentations/strength (without submitted/cross-referenced clinical data)	

	THESE SHOULD BE SUBMITTED AS TWO EXTENSION APPLICATIONS:	
	Extension application 1: • New strength (of first authorised pharmaceutical form) and x presentations	
	Basic fee	66 800 EURO For extension
	Additional fee	+ 7 400 EURO For additional presentation fees.
	Extension application 2: • New strength (of second authorised pharmaceutical form) and x presentations	
	Basic Fee	66 800 EURO For extension
	Additional fee	+ 7 400 EURO For additional presentation fees
	Examples of the determination of fees for renewals of marketing authorisation	
	Scenario 1: Full dossier application for a medicinal product having one pharmaceutical form with one strength and X presentations Strengths associated with a pharmaceutical form: • One strength associated with one pharmaceutical form	
	Basic Fee	14 600 EURO For renewal
	Scenario 2: Full dossier application for a medicinal product having two pharmaceutical forms with two strengths and X presentations/strength associated with the first form and one strength and Y presentations associated with the second form. Strengths associated with a pharmaceutical form: • Two strengths associated with first pharmaceutical form • One strength associated with second pharmaceutical form	
	Basic fee	14 600 EURO For renewal
	Additional fee	+14 600 EURO For renewal
	Scenario 3: Full dossier application for an insulin product having two pharmaceutical forms with six strengths (consisting of two sets of one un-combined preparation and two combination preparations (having different proportions of insulin) with insulin	

	amounts corresponding to A I.U. and B I.U.) and X presentations/ strength associated with the first form; and two strengths (of un-combined preparations with insulin amounts corresponding to A I.U. and B I.U.) and Y presentations/strength associated with the second form Strengths associated with a pharmaceutical form: • Six strengths associated with first pharmaceutical form • Two strengths associated with second pharmaceutical form	
	Basic Fee	14 600 EURO For renewal
	Additional Fee	+ 14 600 EURO For renewal
BA BE Study Requirements	As per EMEA Guideline	
Registration TimeLine	**Procedure**	**Days**
	Centralized Procedure	210 Days
	Decentralised Procedure	120 Days
	National Procedure	210 Days
	Mutual Recognition Procedure	90 Days
Other Information:-		
Audit Fee	**Examples of the determination of fees for GMP inspections**	
	Scenario 1: GMP inspection of manufacturing site 1 for one medicinal product A and involving two pharmaceutical forms: capsules (non-sterile) and solution for injection (sterile). The manufacturing activity for the two pharmaceutical forms is the same, i.e. manufacture of the finished product. Fee payable: 2 basic fees (level I), i.e. 22 400 EURO + 22 400 EURO = 44 800 EURO Rationale: there are two types of dosages forms (sterile and non-sterile) and each one attracts a basic fee (Level I).	
	Scenario 2: GMP inspection of manufacturing site 1 for two medicinal products (A and B). Product A involves only one pharmaceutical form (capsules) and one pharmaceutical activity (primary packaging). Product B also involves one pharmaceutical form	

	(tablets) and four manufacturing activities (manufacture of the active substance, quality control of the active substance, manufacture of the finished product and primary packaging). Fee payable: 3 basic fees (Level I), i.e. 22 400 EURO + 22 400 EURO + 22 400 EURO = 67 200 EURO
	Examples of the determination of fees for GCP inspections
	Scenario 1: GCP inspection request for Product A marketing authorisation application and the conduct of clinical trial protocol A at Site A (investigator site) for one clinical trial activity (Activity Group I) and at site B (sponsor site) for two clinical trial activities (Activity Group III and Activity Group IV). GCP inspection of clinical trial protocol B conducted at site C (Central laboratory) for one activity group (Activity group II); Fee payable: 4 basic fees, i.e. 22 400 EURO + 22 400 EURO + 22 400 EURO + 22 400 EURO = 89 600 EURO;
	Scenario 2: GCP inspection request for Product A marketing authorisation application and the conduct of clinical trial protocol B at Site C (i.e. CRO site including clinical and bioanalytical facility) for two clinical trial activities (Activity Group I) and (Activity Group II). Fee payable: 2 basic fees, i.e. 22 400 EURO + 22 400 EURO = 44 800 EURO
Guidelines	EMA Guideline

Country	Croatia	
Regulatory Body	Agency for Medical Products and Medical Devices of Croatia HALMED- Agencija za lijekove I medicinske proizvode	
Email ID	**pisarnica@halmed.hr**	
Website	www.halmed.hr	
Registration Document	Medical Product Dossier: eCTD	
Approx. Fee	**National Procedures**	
	1. For one strength and pharmaceutical form	30.000,00 HRK
	2. For an additional pharmaceutical form	24.000,00 HRK
	3. Issuing of Plasma Master File certificate	20.000,00 HRK
	MRP/DCP Procedures	
	When Croatia acts as a Reference Member states (RMS)	
	1. For one strength and pharmaceutical form	200.000,00 HRK
	2. For one strength and pharmaceutical form	150.000,00 HRK
	3. For one strength and pharmaceutical form - medicinal product with well-established medicinal use	185.000,00 HRK
	4. For one strength and pharmaceutical form - hybrid, biosimilar medicinal product	185.000,00 HRK
	5. For one strength and pharmaceutical form - with the consent to use the dossier of a reference medicinal product	75.000,00 HRK
	6. For one strength and pharmaceutical form - new combination of known active substances	185.000,00 HRK
	7. For an additional pharmaceutical form (at the same time)	100.000,00 HRK

	8. For an additional pharmaceutical form (subsequently)	120.000,00 HRK
	9. For an additional strength (at the same time)	75.000,00 HRK
	10. For an additional strength (subsequently)	85.000,00 HRK
	Croatia is a Concerned Member State (CMS)	
	1. For one strength and pharmaceutical form	30.000,00 HRK
	2. For one strength and pharmaceutical form - generic medicinal product	30.000,00 HRK
	3. For one strength and pharmaceutical form - hybrid, biosimilar medicinal product	30.000,00 HRK
	4. For one strength and pharmaceutical form - with the consent to use the dossier of a reference medicinal product	30.000,00 HRK
	5. For one strength and pharmaceutical form - new combination of known active substances	30.000,00 HRK
	6. For an additional pharmaceutical form (submitted at the same time)	24.000,00 HRK
	7. For an additional pharmaceutical form (submitted subsequently)	30.000,00 HRK
	8. For an additional strength (submitted at the same time)	14.000,00 HRK
	9. For an additional strength (submitted subsequently)	16.000,00 HRK
	Repeat use procedure	
	1. For one strength and pharmaceutical form	30.000,00 HRK
	2. For an additional pharmaceutical form (submitted at the same time)	24.000,00 HRK

	3. For an additional pharmaceutical form (submitted subsequently)	30.000,00 HRK
	4. For an additional strength (submitted at the same time)	14.000,00 HRK
	5. For an additional strength (submitted subsequently)	16.000,00 HRK
	Registration/refusal of registration of a traditional herbal medicinal product	
	In a national procedure	
	For one strength and pharmaceutical form - traditional herbal medicinal product (based on an EU monograph)	11.000,00 HRK
	For one strength and pharmaceutical form - (when there is no EU monograph)	18.000,00 HRK
	For an additional pharmaceutical form of a traditional herbal medicinal product (submitted at the same time)	9.000,00 HRK
	For an additional pharmaceutical form based on an EU monograph (submitted subsequently)	11.000,00 HRK
	For an additional pharmaceutical form when there is no EU monograph (submitted subsequently)	18.000,00 HRK
	For an additional strength of a traditional herbal medicinal product (submitted at the same time)	7.000,00 HRK
	For an additional strength of a traditional herbal medicinal product (submitted subsequently)	8.000,00 HRK

	In a Mutual Recognition or Decentralization Procedure when Croatia acts as a Reference Member State (RMS)	
	For one strength and pharmaceutical form - traditional herbal medicinal product	40.000,00 HRK
	For an additional pharmaceutical form of a traditional herbal medicinal product (submitted at the same time)	32.000,00 HRK
	For an additional pharmaceutical form of a traditional herbal medicinal product (submitted subsequently)	40.000,00 HRK
	For an additional strength of a traditional herbal medicinal product (submitted at the same time)	19.000,00 HRK
	For an additional strength of a traditional herbal medicinal product (submitted subsequently)	21.000,00 HRK
	In a Mutual Recognition or Decentralization Procedure when Croatia is a Concerned Member State	
	For one strength and pharmaceutical form - traditional herbal medicinal product	18.000,00 HRK
	For an additional pharmaceutical form of a traditional herbal medicinal product (submitted at the same time)	9.000,00 HRK
	For an additional pharmaceutical form of a traditional herbal medicinal product (submitted subsequently	18.000,00 HRK

	For an additional strength of a traditional herbal medicinal product (submitted at the same time)	7.000,00 HRK
	For an additional strength of a traditional herbal medicinal product (submitted subsequently)	8.000,00 HRK
	Clinical trial of unauthorised medicinal product	
	Service	**Price**
	Mono-national trial - Part I	15.000,00 HRK
	Mono-national trial - Part II	8.000,00 HRK
	Multinational trial - Croatia RMS - Part I	40.000,00 HRK
	Multinational trial - Croatia RMS - Part II	8.000,00 HRK
	Non-commercial clinical trials	Free of Charge
	Clinical trial of authorized medicinal product	
	Mono-national trial - Part I	10.000,00 HRK
	Mono-national trial - Part II	5.000,00 HRK
	Multinational trial - Croatia RMS - Part I	35.000,00 HRK
	Multinational trial - Croatia RMS - Part II	5.000,00 HRK
Registration TimeLine	Centralized Procedure – 210 Days	
	Mutual Recognition Procedure- 390 Days	
	National Procedures- 210 Days	
	Decentralized Procedure- 210 Days	
Other Information:-		
Audit Fee	**Manufacturing and Inspection**	
	Service	**Price**
	1. Granting/refusal of a manufacturing licence	5.000,00 HRK
	2. Variation of a manufacturing licence	2.000,00 HRK
	3. Revocation of a manufacturing licence	2.000,00 HRK
	4. Good Manufacturing Practice (GMP) certificate,	5.000,00 HRK

	for manufacturers outside of Croatia	
	5. Good Manufacturing Practice (GMP) certificate	1.000,00 HRK
	6. Good Manufacturing Practice inspection and Good Pharmacovigilance inspection	7.000,00 HRK
	Medical Product Marketing	
	Service	**Price**
	1. Approval for an import of an active substance	1.000,00 HRK
	2. Approval for the exemption to the labelling and/or package leaflet obligation	2.000,00 HRK
	Annual Fees	
	Service	**Price**
	1. Annual fee for a medicinal product	4.800,00 HRK
	2. Annual fee for a homeopathic medicinal product/device	500,00 HRK
	3. Annual fee for registration in the register of custom made medical device manufacturers	300,00 HRK
	Medical Devices	
	Service	**Price**
	1. Registration/refusal of registration in the register of manufacturers or manufacturer representatives	5.000,00 HRK
	2. Variation/refusal of variation of registration in the register of manufacturers or authorized manufacturer representatives	1.000,00 HRK
	3. Registration/refusal of registration in the register of medical devices (1 to 5 devices)	6.000,00 HRK
	4. Registration/refusal of registration in the register	6.500,00 HRK

	of medical devices (6 to 30 devices)	
	5. Registration/refusal of registration in the register of medical devices for over 30 medical devices	7.000,00 HRK
Guidelines	ICH Guidelines	

Country	Cambodia			
Regulatory Body	Department of Drug, Food and Cosmetics			
Email ID	Info.campor@moh.gov.kh			
Website	www.ddfcambodia.com			
Registration Document	ASEAN Common Technical Dossier (ACTD)			
Approx. Fee	Types of Authorization	Applicable Fee	Applicable Fee in USD	
	Drugs (new)	900000 Cambodian riel	USD 220 approx.	
	Drugs (renewal)	505000 Cambodian riel	USD 120 approx.	
BA BE Study Requirements	As Per ASEAN GUIDELINE FOR THE CONDUCT OF BIOEQUIVALENCE STUDIES			
Registration TimeLine	Application submission	Screening Process	Evaluation Process	Regulatory Decision
	New Chemical Entity	2 days	4 Months	2 month (Decided by committee meeting every 2 months
	Generic product	2 days	3 Months	2 Months (committee meeting)
	Minor Variation	2 days	2 weeks	2 weeks
	Major Variation	2 days	1 Months	2 weeks
	Renewal	2 days	6 weeks	2 Months (Committee meeting)
Other Information:-				
Audit Fee	200,000 Khmer Reils			
Guidelines	ICH CTD Guideline			

Country	Czech Republic	
Regulatory Body	Ministry of Health / Státní ústav pro kontrolu léčiv	
Email ID	posta@sukl.cz	
Website	www.sukl.cz	
Registration Document	**eCTD Format**	
Approx. Fee	**Application for Marketing Authorisation, National Procedure**	
	Activity	**Fees**
	Article 8(3) application - new active substance	9 600,00 €
	Article 8(3) application - known active substance	8 000,00 €
	Article 10a well established use application	6 400,00 €
	Article 10(1) generic application	8 000,00 €
	Article 10(3) hybrid application	8 500,00 €
	Article 10b fixed combination application	8 000,00 €
	Application for Marketing Authorisation, MRP/DCP-CMS	
	Article 8(3) application - new active substance	6 000,00 €
	Article 8(3) application - known active substance	5 000,00 €
	Article 10(1) generic application	5 000,00 €
	Article 10(3) hybrid application	5 500,00 €
	Article 10b fixed combination application	5 000,00 €

BA BE Study Requirements	As per European Guideline	
Registration TimeLine	Centralized Procedure – 210 Working Days	
	Mutual Recognition Procedure- 390 Working Days	
	National Procedures- 210 Working Days	
	Decentralized Procedure- 210 Working Days	
Other Information:-		
Annual Maintenance Fee	**Sub-category or specification**	**Amount of cost reimbursement**
	Performance of expert activities associated with the maintenance of a medicinal product marketing authorisation, except for cases listed under codes U-002, U-003, U-004, and U-005	19,500 CZK
	Performance of expert activities associated with the maintenance of a medicinal product marketing authorisation where the Czech Republic is the Reference Member State	39,100 CZK
	Performance of expert activities associated with the maintenance of a marketing authorisation of a homeopathic product	3,000 CZK
	Performance of expert activities associated with the maintenance of a medicinal product marketing authorisation where the MA holder is a micro-enterprise	5,000 CZK
	Performance of expert activities associated with the maintenance of a medicinal product marketing authorisation where the MA holder is a small company and it	9,500 CZK

	does not involve homeopathic products	
Guidelines	EMA,EC,CMD and HMA guidelines	

Country	Nigeria		
Regulatory Body	National Agency for Food & Drug Administration (NAFDAC)		
Email ID	nafdac@nafdac.gov.ng		
Website	www.nafdac.gov.ng		
Registration Document	CTD Dossier		
Approx. Fee	Registration		
	Herbal and Nutraceuticals/Alternative Medicines (per product)	Full Registration: $1,252.00 Listing: $ 612.63	
	Description	Local	Foreign
	Medical Devices 1*	20,000	$ 750.00
	Medical Devices 2*	20,000	$ 874.00
	Over the Counter Medicines (OTC)	80,000	$ 967.00
	Orphan Drugs	80,000	$ 967.00
	Prescription Only Medicines (POM) 1*	80,000	$ 1,280.00
	Prescription Only Medicines (POM) 2*	80,000	$ 1,200.00
	Vaccines/Biologicals	80,000	$ 1,200.00
	Veterinary Medicines and Supplements	80,000	$ 1,200.00
	Registration Renewal		
	Registration Renewal	80 % of New registration Cost	

Fees for Clinical Trials	**Description**	**Industry-Sponsored / Locally-developed IMP**	**Industry-Sponsored / Imported IMP**
	Application	250,000	$2,747.25
	1. Individual	NA	
	2. Research Institution	NA	
	3. Dossier/Clinical data review	NA	50,000
	4. Extension of study	50,000	$2,747.25

<table>
<tr><td></td><td>Inspection</td><td>350,000.00</td><td>$5,494.51</td></tr>
<tr><td></td><td>Routine Inspection</td><td>350,000</td><td>$2,747.25</td></tr>
<tr><td>Registration TimeLine</td><td colspan="3">1. Registration of food product not more than 90 days from acceptance of application.</td></tr>
<tr><td></td><td colspan="3">2. Registration of food product not more than 120 days from acceptance of application.</td></tr>
<tr><td></td><td colspan="3">3. Variation of product registration takes not more than 60 days</td></tr>
<tr><td></td><td colspan="3">Summary of Registration Process with Timelines</td></tr>
<tr><td></td><td colspan="2">Submission of Application</td><td>0 days</td></tr>
<tr><td></td><td colspan="2">Document Verification</td><td>10 days</td></tr>
<tr><td></td><td colspan="2">Facility Inspection/ Sampling</td><td>20 days for drugs and 10 days for drug</td></tr>
<tr><td></td><td colspan="2">Laboratory Analysis</td><td>30 days for food, 40 days for drugs</td></tr>
<tr><td></td><td colspan="2">Final Vetting</td><td>10 days</td></tr>
<tr><td></td><td colspan="2">Approval Meeting/Issuance of NAFDAC registration Number (Certificate of registration)</td><td>20 days</td></tr>
<tr><td></td><td colspan="3">Total number of days: 90 days for Food, 120 days for Drugs</td></tr>
<tr><td></td><td colspan="3"></td></tr>
<tr><td>Other Information:-</td><td colspan="3"></td></tr>
<tr><td>Audit Fee</td><td colspan="3">Pharmaceuticals: (Per Line for Local; Per Site for Foreign)</td></tr>
<tr><td></td><td>Description</td><td>Local</td><td>Foreign</td></tr>
<tr><td></td><td>Pre-Production: Small Scale</td><td>50,000</td><td rowspan="3">NA</td></tr>
<tr><td></td><td>Pre-Production: Medium/ Large Scale</td><td>70,000</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td>Production: Medium/Large Scale (Renewable yearly)</td><td>170,000</td><td></td></tr>
<tr><td></td><td colspan="3">Veterinary Cosmetic, Cosmetics and Herbal Products (Per Line for Local; Per Site for Foreign)</td></tr>
<tr><td></td><td>Production: Micro Enterprise (Renewable yearly)</td><td>15,000</td><td rowspan="3">NA</td></tr>
<tr><td></td><td>Production: Small Scale (Renewable yearly)</td><td>30,000</td></tr>
<tr><td></td><td>Production: Medium/Large Scale (Renewable yearly)</td><td>40,000</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Guidelines</td><td colspan="3">ICH CTD Guideline</td></tr>
<tr><td></td><td colspan="3"></td></tr>
</table>

Regulatory Consultancy Charges and Fees

Per Product Charges Approx. For Consultants			
Regulatory Dossier eCTD	**B.A-B.E**	**Dossier Preparations**	**Registration**
Regulated	USD $ 28,849.15- USD $ 48081.92	USD $ 2400- USD $ 6000	USD $ 3600
Semi-Regulated	USD $ 21000- USD $ 24000	USD $ 960	USD $ 1000
ROW (Rest of Other World)	USD $ 7200- USD $ 12000	USD $ 500	USD $ 500

11.0 Example of Sales Profit Calculations Against Investment :

(Excluding Expenses)

Product	Strength	Mfg Rate	Batch Qty	Investment	Sale Rate Domestic	Sale Rate Export	Approx Profit Domestic	Export Profit
Sildenafil Tablet	100	7.5	5000	37500	9.375	11.25	9375	18750
Sildenafil Tablet	50	9.5	5000	47500	11.875	14.25	11875	23750
Tadalafil	10	10	5000	50000	12.5	15	12500	25000
Tadalafil	20	13	5000	65000	16.25	19.5	16250	32500
Sildenafil Gel	100 mg	6.75	150000	1012500	8.4375	10.125	253125	506250
Tadalafil Gel	20 mg	6	150000	900000	7.5	9	225000	450000
Protein Powder	Nutra	55	1000	55000	145	200	90000	145000
Protein Powder -plant	200 gm	165	1000	165000	999	499.5	834000	334500
Protein Powder whey	1 Kg	1650	1000	1650000	2999	1499.5	1349000	-150500
Piles Tablet	60 Tab	175	1000	175000	999	499.5	824000	324500
Vitmine Tablets	60Tab	185	1000	185000	999	499.5	814000	314500
Diabetes Tablet	60 Tab	210	1000	210000	999	499.5	789000	289500
Sex Enhancement Tablets	60Tab	210	1000	210000	999	499.5	789000	289500
				4762500			**6017125**	**2603250**

*Rates May Change from manufacturer to manufacturer

*Except for Drug Products all Nutra MRP and SALE RATE is open and not having any restrictions

*Nutra Domestic SALE RATES ARE FOR customers IT MAY VARY OF SELLING TO DISTRIBUTORS

**Interpretation: In the Investment of 4762500.00 Company Can Earn around 2603250 (50%) Profit On An Average

12.0 Steps To Start: Generating Leads

Sr.No.	Particulars
01	Open an Office In Mumbai or Anywhere else
02	Website finalization
03	Product Portfolio Display On the Website with Photo
04	Company Boucher in Print or Digital
05	Email Ids
06	Staff Appointment
07	Email communication and Data searching By Staff for Domestic as well as Overseas Business
08	If Enquiry generated Sourcing of Products and Making Agreements with Manufacturers

13.0 Advertisement and Marketing

There are many ways to advertise and market pharmaceutical products:

Domestic Market:

1. Generic Market :
    a. This is a direct retail or distributor market that has very Fewer margins and does not require much marketing
    b. This is channel marketing through distributors
2. Ethical Marketing /Prescription Market :
    a. If a company is willing to enter into an ethical market margins and profit ratio is more
    b. Huge manpower and marketing expenses so require more investment
    c. Risk of bad debts
3. Advertisement :
    a. Through Marketing Representatives for Ethical market and Generic through Distributors Network

Export Market :

1. Searching Clients on various Portals
2. Searching overseas Distributors or Importers through emails LinkedIn and different portal
3. One to One to One Telephonic Communication with clients

Direct Customer :

1. Launching Products on different portals
2. Social Media Advertisement
3. Setting up a Delivery channel
4. MLM Marketing Concept

14.0 Manufacturer Selection

1. Pharma Manufacturing :

D AND D Pharma team shall be very careful while selecting a manufacturer :

1. Check what certifications manufacturers are having generally for exports basic is WHO Approval
2. Check the Quality background of the manufacturer
3. Check-in which courtiers manufacturer is supplying already, the manufacturer who is supplying most of the countries or many countries is not a good choice for doing business with such manufacturers as they already have connections and suppliers in that country which may conflict with our or their business interest
4. The capacity of the Manufacturer must be checked
5. Visit to every unit is a must

Checklist for Selection of Manufacturers:

Sr No	Particulars
01	Manufactures all Manufacturing License must be checked
02	Do these manufacturers have WHO Certification?
03	If these manufacturers have any other countries' certification
04	How many countries manufacturers are catering and how many are registered? Is there any country where registration is done but Business has not started

05	Has this manufacturer received any warning from the FDA for any quality failure?
06	What is factory size Small scale Middle scale or Large scale?

15.0 Other Pharma Business which can be Initiated

1. Pharma API and Intermediate Business:

Export of API and Intermediate to Pharmaceutical companies and herbal premixes for Nutraceutical Companies is also a huge business to do from India

2. Essential Oils and Perfume natural extracts:

Middle East and all Arabic countries are importing Essential Floral oils or natural essences from India which is a valuable market these oils are being used in Perfumes which have major consumption in Arabic countries

16.0 Risk Analysis :

Probable Risks while doing Pharma Business :

1. Misguidance and Miscommunication with staff :

   Promotors of Business must have a close watch and must learn all the concepts of pharma business on a Micro level, dependencies on staff and employees may put the business in danger.

2. proper arrangement of Funding :

It is necessary to arrange funding for supplies, timely supplies will maintain business consistency. You can not depend on credit and loans for this business.

3. Quality of Product :

The quality of the Product is the most important part and promotors must ensure the quality of the product before launching it in the market

4. Over Qualified Materials :

If the requirement is of WHO Approved factory and if we are delivering material from EU Approved factory this does not make sense as it won't give more profit, the production cost is and in this case, a business may be in a financial crunch we can send materials which are overqualified to any non-regulated markets as there is three times rate difference for regulated material, need to identified the same with country to country distributors

15. Procedure to be Followed after receiving Enquiry :

When D and D Pharma will receive any global enquiry first need to check with manufacturers about availability of Registration in the buyer country.

If a company is registered with the Country then ask for the dossier of the products and if the dossier is not available check the availability of documents for dossier compilation

If the company does not have documents for the product then change the manufacturer.

What Documents shall we ask to manufacturer:

1. Product License /FSC /GMP /COPP
2. WHO Certificate
3. Country Registration certificate
4. COA of Product (For sending to the client immediately to gain trust)
5. Dossier or Dossier registration certificate
6. Product samples
7. Rates

General Terms of Agreement :

The company CAN CHARGE Around 15000 INR To 30000 INR for the dossier and in the first consignment it can be refunded to the manufacturer

Audit charges shall be contributed as 50-50%

If the new country is there audit charges shall be put in the buyer's account.

Carefully discuss BA BE CHARGES if the manufacturer is asking for the same then it has to be on an exclusivity basis.

17.0 Investor Presentation Content

Sr No	Content
01	Heading Slide
02	Company Introduction
03	Vision Mission Quality Policy
04	Management
05	Project Vision: Brand Building
06	Financial
07	Product Portfolio and brand description
08	Targeted Countries: Not more than 10
09	Manufacturers Support
10.	Agreements Finalized with manufacturers
11	Advertisement Policy if a Consumer product
12	Closing Statement and Future Growth

18.0 Global Reports:

SILDENAFIL

Global Sildenafil Market, By Product Type (Branded and Generics), Application (Peripheral Vasodilator and Erectile Dysfunction), End-Users (Clinics, Hospitals, and Others), Distribution Channel (Hospital Pharmacy, Retail Pharmacy, Online Pharmacy, Others), Country (U.S., Canada, Mexico, Brazil, Argentina, Peru, Rest of South America, Germany, France, U.K., Netherlands, Switzerland, Belgium, Russia, Italy, Spain, Turkey, Hungary, Lithuania, Austria, Ireland, Norway, Poland, Rest of Europe, China, Japan, India, South Korea, Singapore, Malaysia, Australia, Thailand, Indonesia, Philippines, Vietnam, Rest of Asia-Pacific, Saudi Arabia, U.A.E, Egypt, Israel, Kuwait, South Africa, Rest of Middle East and Africa) Industry Trends and Forecast to 2028

Market Analysis and Insights: Global Sildenafil Market

The sildenafil market is expected to gain market growth in the forecast period of 2021 to 2028. Data Bridge Market Research analyses the market is growing at a CAGR of 4.80% and is expected to reach USD 2,096.19 million by 2028 in the above-mentioned research forecast period. Presence of branded drugs and increasing prevalence of erectile dysfunction worldwide.

Moreover, rising awareness and increasing prevalence of diabetes and obesity also boost the market growth. The growing geriatric population and rising healthcare expenditure act as an opportunity for market growth. However, side effects caused by drugs and a strict regulatory framework may hamper the global sildenafil market.

Sildenafil is a phosphodiesterase inhibitor and is indicated for the treatment of erectile dysfunction in men. This medicine improves the exercise ability in adults suffering from pulmonary arterial hypertension. It treats erectile dysfunction by enhancing the blood flow to the penis during sexual stimulation. This increase in blood flow leads to an erection. Sildenafil works by relaxing the blood vessels of the lungs, which allows easy blood flow.

As per the studies conducted, this has been reported that erectile dysfunction is highly prevalent with a 3-76.5% prevalence rate and it increases with an increase in age. This affected population is hugely dependent upon sildenafil to achieve better treatment, hence providing lucrative growth.

This sildenafil market provides details of market share, new developments, and product pipeline analysis, the impact of domestic and localized market players, analyses opportunities in terms of emerging revenue pockets, changes in market regulations, product approvals, strategic decisions,

product launches, geographic expansions, and technological innovations in the market. To understand the analysis and the market scenario contact us for an Analyst Brief, our team will help you create a revenue impact solution to achieve your desired goal.

Global Sildenafil Market Scope and Market Size

The sildenafil market is segmented based on product type, application, end-users, and distribution channel. The growth among segments helps you analyze niche pockets of growth and strategies to approach the market and determine your core application areas and the differences in your target markets.

- **Based on product type, the sildenafil market is segmented into branded and generics.**
- **Based on application, the sildenafil market is segmented into peripheral vasodilator and erectile dysfunction.**

- **Based on end-users, the sildenafil market is segmented into clinics, hospitals, and others.**
- **Based on distribution channels, the sildenafil market is segmented into hospital pharmacies, retail pharmacies, online pharmacies, and others.**

Sildenafil Market Country-Level Analysis

The sildenafil market is analyzed and market size information is provided by country, product type, application, end-users, and distribution channel as referenced above.

The countries covered in the sildenafil market report are U.S., Canada, Mexico in North America, Brazil, Argentina, Peru, Rest of South America, as part of South America, Germany, France, U.K., Netherlands, Switzerland, Belgium, Russia, Italy, Spain, Turkey, Hungary, Lithuania, Austria, Ireland, Norway, Poland, Rest of Europe in Europe, China, Japan, India, South Korea, Singapore, Malaysia, Australia, Thailand, Indonesia, Philippines, Vietnam, Rest of Asia-Pacific, Saudi Arabia, U.A.E, Egypt, Israel, Kuwait, South Africa, Rest of Middle East and Africa, as a part of Middle East and Africa.

On geographical estimation, North America accounts for the largest market share due to branded drugs and the high acceptance of well-recognized drugs. Europe is also expected to grow exponentially due to established healthcare and research and development activities. Asia-Pacific is expected to account for the largest market share due to the rising prevalence of erectile dysfunction-causing infections, the growing geriatric population, and increasing government initiatives for the growth of pharmaceutical industries.

The country section of the report also provides individual market-impacting factors and changes in regulations in the market domestically that impact the current and future trends of the market. Data points such as new sales, replacement sales, country demographics, disease epidemiology, and import-export tariffs are some of the major pointers used to forecast the market scenario for individual countries. Also, the presence and availability of global brands and their challenges faced due to large or scarce competition from local and domestic brands and, the impact of sales channels are considered while providing forecast analysis of the country data.

Patient Epidemiology Analysis

Sildenafil market also provides you with detailed market analysis for patient analysis, prognosis, and cures. Prevalence, incidence, mortality, and adherence rates are some of the data variables that are available in the report. Direct or indirect impact analysis of epidemiology to the market

growth is analyzed to create a more robust and cohort multivariate statistical model for forecasting the market in the growth period.

Competitive Landscape and Sildenafil Market Share Analysis

Sildenafil market competitive landscape provides details by competitor details including are company overview, company financials, revenue generated, market potential, investment in research and development, new market initiatives, global presence, production sites and facilities, company strengths and weaknesses, product launch, clinical trials pipelines, product approvals, patents, product width and breadth, application dominance, technology lifeline curve. The above data points provided are only related to the companies' focus related to the Sildenafil market.

The major players covered in the sildenafil market are Pfizer Inc., Century Pharmaceuticals Ltd., Polpharma, Deva Holdings, Actavis, Inc., Accord-UK Ltd., Mantra Pharma, ANGITA, Apotex Inc., Bayer AG, Ritz Formulations Pvt. Ltd., Cipla, Abbott, Viatris Inc., Sandoz, Hetero Healthcare Limited, Delphis Pharma, Teva Pharmaceuticals USA, Inc., Lupin Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC., Umang Pharmaceuticals among other domestic and global players. DBMR analysts understand competitive strengths and provide competitive analysis for each competitor separately.

TADALAFIL MARKET

The global tadalafil market is expected to grow at a considerable CAGR during the forecast period (2022-2028). Male sexual function disorders including impotence or erectile dysfunction-ED are treated with tadalafil when used in conjunction with sexual stimulation, enabling a man to get and maintain an erection by boosting blood flow to the penis. Additionally, tadalafil is a drug that is used to treat the signs and symptoms of prostate enlargement (benign prostatic hyperplasia-BPH). It helps to relieve BPH symptoms including having problems initiating a pee stream, having a weak stream, and needing to urinate frequently or urgently (including during the middle of the night). When tadalafil is taken, the smooth muscle in the prostate and bladder is thought to relax.

Various growth methods, including partnerships and collaborations, mergers and acquisitions, geographical development, and new product releases, are significantly adopted by the leading companies in the field to stay competitive in the marketplace. For instance, in March 2020, the launch dates for Tadalafil tablets (the branded product: Cialis) were announced by Sawai Pharmaceutical Co., Ltd. The company launched tadalafil tablets 10 mg CI, and tadalafil tablets 20 mg CI in March 2020.

Additionally, the growing use of drugs such as Sildenafil (Viagra), Vardenafil (Levitra, Staxyn), and Avanafil (Stendra), among others restrain the growth of the tadalafil market. The rising prevalence of erectile dysfunction mainly in Japan is a major element driving market growth.

Impact of COVID-19 on Global Tadalafil Market.

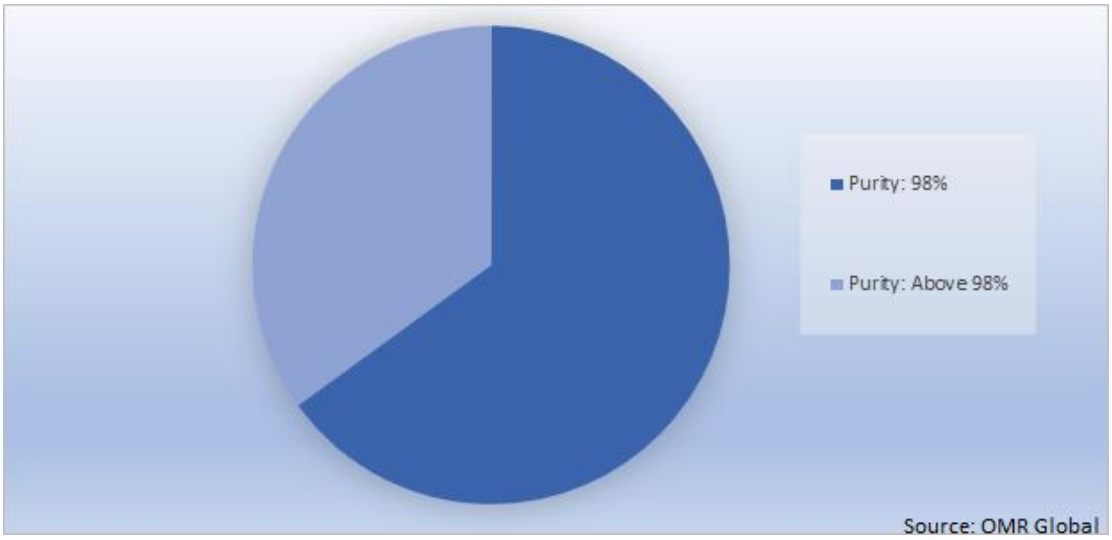
The COVID-19 has benefited the tadalafil market. The COVID-19-infected persons were more than 5 times more likely to acquire ED (erectile dysfunction). Stress, worry, and sadness caused by COVID-19 can affect sexual health and contribute to ED. ED might be an indication of heart disease in its early stages. COVID-19 can affect heart health. This is because it might create inflammation in many places of your body. This includes the heart and, additionally, the adjacent blood capillaries and veins. These factors have increased the demand for tadalafil hence raising the growth of the tadalafil market globally.

Segmental Outlook

The global tadalafil market is segmented based on type and application. Based on type, the market is sub-segmented into Purity: 98% and Purity: above 98%. Based on application the market is sub-segmented into erectile dysfunction, benign prostatic hyperplasia, and others.

**The above-mentioned segments can be customized as per the requirements.

Global Tadalafil Market Share by Product, 2021(%)



Purity: 98% Segment is holding a Prominent Share in the Global Tadalafil Market.

Based on type, purity: 98% is anticipated to hold a prominent share in the market. Further, Maiden Pharmaceutical Ltd. has made Tadalafil (Adcirca) a phosphodiesterase (PDE) inhibitor used to treat erectile dysfunction in men. During stimulation, it increases blood flow to the penis.

Regional Outlooks

The global tadalafil market is further segmented based on geography Including North America (the US, and Canada), Europe (Italy, Spain, Germany, France, and Others), Asia-Pacific (India, China, Japan, South Korea, and Others), and the Rest of the World (the Middle East and Africa, and Latin America). North America is anticipated to hold a lucrative share in the market owing to the presence of market players coupled with increasing healthcare expenditure in the region.

Global Tadalafil Market Growth, by Region 2022-2028

The Asia-Pacific is expected to witness the highest growth rate in the Global Tadalafil Market.

The global tadalafil market is anticipated to be dominated by the Asia-Pacific, and this trend is expected to continue during the forecast period. Japan has the highest percentage of erectile dysfunction followed by China and US and Brazil having the lowest. According to data at the sixth Asian Congress of Sexology in Kobe, one in three Japanese men indicated they suffer from erectile dysfunction in a recent poll. With age, ED becomes more common: roughly 40% of men are affected at age 40, and over 70% of men are impacted at age 70.

Market Players Outlook

The major companies serving the global tadalafil market include Glenmark Pharmaceuticals Ltd., Teva Pharmaceutical Industries Ltd., Eli Lilly and Co. Pvt. Ltd., Cadila Pharmaceuticals Ltd., Cipla Ltd., and others. To enhance their market share, industry participants are adopting various strategies including mergers and acquisitions, new launches, collaborations, and partnerships. For instance, the US Food and Drug Administration has given Alembic Pharmaceuticals NSE -0.06% approval for tadalafil pills, that are used to treat erectile dysfunction. The company's abbreviated new drug application (ANDA) for tadalafil tablets USP in the strengths of 2.5 mg, 5 mg, 10 mg, and 20 mg has been approved by the US Food and Drug Administration (USFDA)

End of Project