SAUDI ARABIA PHARMA MARKET & REGULATORY REPORT

Pharmaceuticals Export Promotion Council of India

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

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DEMOGRAPHY

SL. No	Parameter	Description
1	Region	Middle East
2	Country	Saudi Arabia
3	Capital	Riyadh
4	Population	34,173,498(July 2020 est)
5	Population growth rate (%)	1.6%(2020est)
6	GDP (purchasing power parity)	$ 1,775 billion (2017est.)
7	GDP - real growth rate (%)	-0.9% (2017 est.)
8	GDP - per capita (PPP)	$ 54,500(2017 est.)
9	Exchange rates	
10	Population below poverty line	NA
11	Age structure (%)	0-14 years: 24.84%
		15-24 years:15.38 %
		25-54 years 50.2%
		55-64 years 5.95%
		65 years and over:3.63 %

Source: CIA World Fact Book updated to 2020 (Updated in May 2020)

MARKET REPORT

Introduction

Saudi Arabia is among the Middle East's most attractive markets for multinational companies. The Kingdom's diversification plans bode well for local and regional companies, with 'Vision 2030' encouraging the expansion of manufacturing agreements in the country. Major interest to multinationals Key draws like the sheer market size, the sophistication of the demand and the favourable epidemiological trends. Local players will also find a fertile commercial base, given the need to satisfy rising volume demand for the established generic treatments.

However, issues relating to patent approvals and the regulatory system remain a major issue for foreign research based pharmaceutical players.

The market from the present USD 8.3 billion(in 2019) is expected to touch USD 8.8 billion by the end of 2020 with a year on year growth of 5.2%.

Latest Updates

- In March 2020, the Ministry of Health of Saudi Arabia signed a memorandum of understanding with Sanofi to start localising and transferring insulin technology in the kingdom.
- In December 2019, Riga-based Grindex received a certification of Saudi Food and Drug Authority that certifies the compliance of Grindex's final dosage forms, tablets and capsules, with the Saudi Arabia's medicines manufacturing requirements.

STRENGTHES AND WEEKNESSES:-

- The largest pharmaceutical market in the Arabian Peninsula
- Rising government investments in the local drug industry.
- Constant modernization and expansion of health care infrastructure and provisions in the country.
- Rapidly expanding population, with more diseases of 'civilisation' in evidence.
- The market reliance on imports, particularly at the hi-tech end of the scale
- Dominance of patented drugs expected to persists, given the kingdoms wealth. This may soon change.
- Complex nature of the domestic regulatory system restricting the entry of multinationals and drug makers from developing countries.
- Pricing biased in favor of the local industry
- Tight government control on prices resulting in the lowest drug prices in the region.

PHARMACEUTICAL MARKET OF SAUDI ARABIA:

Saudi Arabia's pharmaceutical market was valued at USD 8.3bn in 2019. Forecasts show by 2024 Market will clock $ 10.89 Billion with a CAGR of 5.4%

Sales of patented drug consumption are supported by the population's wealth and the preference for branded drugs among both consumers and prescribers, with patented drug spending accounting for 54.4% of the country's drug market. It is the largest regional pharmaceutical market in overall value, but by drug per capita expenditure with USD242, it ranks seventh in the region.

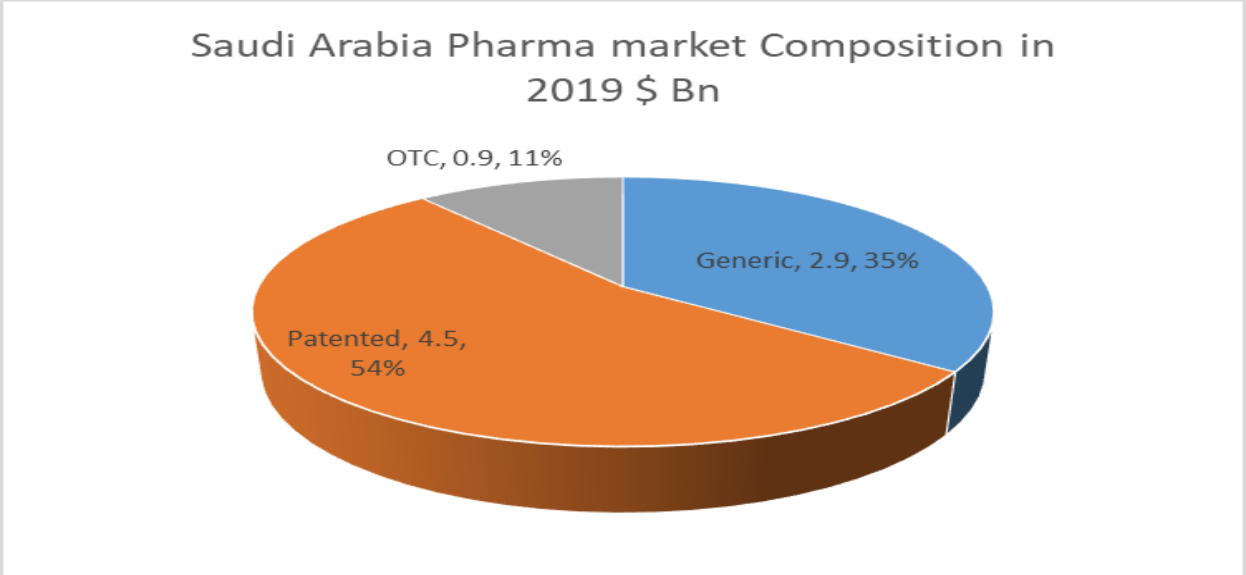
Saudi hospitals are among the best in the Middle East, while specialized tertiary facilities bear comparison with facilities in Western Europe. Large-scale plans for infrastructure developments exist, including new hospitals and health centers.

Saudi Arabia's epidemiological profile represents that of a developed country, with non-communicable diseases accounting for 84% of deaths, according to the WHO. Cardiovascular diseases (49%), ischemic heart disease (24%), and strokes (16%) are the three most prevalent chronic diseases by deaths.

Saudi Arabia's market is dominated by foreign drug makers as a result of the preference for branded drugs, and has a small domestic manufacturing industry. Leading local players include Saudi Pharmaceutical Industries and Medical Appliances Corporation (SPIMACO), Tabuk Pharmaceutical Manufacturing, Jamjoom Pharma and Saudi Arabian Japanese Pharmaceutical (SAJA). The majority of pharmaceuticals are imported from developed countries including Switzerland, Germany, France, the US and the UK. There is an extensive presence of multinationals including Novartis, Pfizer, Bayer, Bristol-Myers Squibb, Roche and Eli Lilly; however, only GlaxoSmithKline and Sanofi manufacture locally. Instead, many multinational companies opt to engage in contract manufacturing with Saudi Arabian drug makers as a means to save costs.

Saudi Arabia imposes strict price controls. The local regulatory authorities are biased and tries to protect the local industry

PHARMACEUTICAL MARKET BY SUB-SECTOR in 2019 US$BN



Generic Market

Saudi Arabia's generic drug market is supported by the government's encouragement of generic substitution as a means to control costs thereby acting as a significant growth driver of this trend. Despite some improvements to regulatory standards in the kingdom, industry bias towards local manufacturers will also support generic drug spending in Saudi Arabia, which is forecasted to grow at a fast rate over the near-and-long term compared with their patented counterparts.

Key obstacles include prescribers' preference for patented drugs and the population's relatively high per capita spending on pharmaceuticals, although this will pave the way for the expansion of branded generic drug

The sector from its present size of $ 2.9(in 2019 constituting 35% of the total Markrt) bn is forecasted to grow at a rate of 8.1% cagr in the next five years and reach $ 4.4by 2024 and may account for 39% of the total market. Country's Local generic industry is driven by Government's encouragement. Local generic drug producers will be aided by plans for closer regional integration and a greater emphasis placed on drugs produced within the GCC. Efforts to wean the region off its overwhelming reliance on imported drugs (primarily in the public sector).

The kingdom's generic drug market will also be supported by the government's encouragement of generic substitution as a means to control costs acting as a significant growth driver of this trend. This is particularly true in light of the Saudi 'Vision 2030' and National Transformation Plan 2020, which has already drawn attention from Merck Sharp & Dohme, Sanofi, and Julphar Pharmaceuticals. Although many multinational companies in Saudi Arabia are primarily branded manufacturers, these firms continue to strengthen their generic activities and it is expected to see more partnerships with local generic drug makers.

Saudi Arabia's target to produce 40% of all drugs domestically in the long term - it is ambitious, but achievable with enough investment. The increased commoditisation of generic drugs and competition from India and China may make this unlikely as these companies will maintain a strong competitive advantage without preferential treatment or moving into the field of hard-to-manufacture pharmaceuticals.

Saudi Arabia depends on imports for its API Requirement.

Pharmaceuticals TRADE

Saudi Arabia's Vision 2030 and National Transformation Plan will encourage the expansion of domestic pharmaceutical manufacturing in the Kingdom. This will reduce the reliance on imported generic medicines, while providing opportunities for exports to neighboring import-reliant states.

Country has imported $ 5.9 bn in 2019. Forecasts see the imports touching $ 6.6 bn through 2023 with a cagr of 4.4%. Import distribution is controlled exclusively by Saudi Arabian firms, led by Banaja Saudi Import Company in the private sector and the government purchasing unit NUPCO.

Local bias towards local and regional producers, regional harmonisation and greater collective bargaining between GCC countries is expected to help stimulate local production and boost exports.

Local Pharmaceutical Industry

Saudi pricing legislation favours local manufacturers. Nevertheless, EU and US companies continue to dominate the region's pharmaceuticals market, given their high-end product offering and are also major suppliers of pharmaceuticals to Saudi Arabia.

However, the restrictive nature of the domestic regulatory system has limited the direct establishment of manufacturing bases in the kingdom. This could improve in line with the government's ambitions to expand the pharmaceutical industry, most notably via enhanced partnerships.

US companies such as, Eli Lilly, Pfizer and Bristol-Myers Squibb are active in the market. GlaxoSmithKline (GSK), Sanofi and more recently Pfizer, manufacture locally - though indirect involvement through contract manufacturing agreements, and local distributors.

Saudi pricing legislation favours local manufacturers, which intensifies competition. The local companies currently produce around one-fifth of domestic pharmaceuticals, and a large proportion of these are not generic drugs, but patented pharmaceuticals produced under licences from multinational drugmakers or through contract manufacturing agreements. We also expect an increase in joint ventures between foreign and Saudi pharmaceutical firms as a means to enter the healthcare market.

In order to encourage local manufacturing, the government is providing incentives to both multinational subsidiaries and domestic companies. These include free property leases, interest-free loans and government subsidies. Further growth of the tender-supplied market is expected in the coming years, supported by demographic and epidemiological trends. To this end, for example, in August 2019, Arab News reported that a new industrial centre lease for the city of Madinah was signed by the Saudi Authority for Industrial Cities and Technology Zones (MODON), with the SAR570mn site to house pharmaceutical research and other facilities.

The Gulf Cooperation Council (GCC) countries are also aiming to develop their domestic manufacturing capabilities, as a means of reducing their dependency on imports. GCC regulations stipulate that producers in member states are not required to obtain registration or licences in order to export to Saudi Arabia, regional producers are effectively given preferential treatment for entry into the Saudi market, particularly in the tendering system. In addition, regulations permit the supply of drugs only through Saudi intermediary agents.

Local Industry-Generic

Local production of generic medicines is handicapped by weak domestic sales and a lack of public awareness of generic drugs, plans for closer regional integration and a greater emphasis placed on drugs produced within the GCC should boost this segment.

Efforts to wean the region off its overwhelming reliance on imported drugs (primarily in the public sector) will encourage the local industry, which mostly produces branded generic products.
Saudi Arabia's target to produce 40% of all drugs domestically in the long term is ambitious, but achievable with enough investment.

Domestic players are becoming increasingly focused on 'branded generics' manufacturing ie, off-patent prescription market. These drugs are deemed to be of a higher quality and as result this improves the overall perception of generic drugs in the country. The government has highlighted the pharmaceutical industry as a focus area for investment. Incentives for establishing new pharmaceutical companies include free property leases, interest-free loans and government subsidies. Furthermore, imports to the GCC have a 5% import tariff and local manufacturers receive preferential treatment during pharmaceutical tenders.

Large Indian drugmakers, that produce generic drugs, are attempting to penetrate the Saudi drug market, with such moves encouraged by local authorities on account of the potential savings of using cheaper generic medicines produced by Indian companies. However, the drug registration system still acts as a significant barrier to entry for most Indian firms, as it requires drugs to have been previously marketed in two 'developed' markets before it can get approval in Saudi Arabia, which virtually allows only the largest Indian players to operate in the country

Statistics:

India Pharma exports to SAUDI ARAB by Category $ Million					
Category	2015-16	2016-17	2017-18	2018-19	Change%
Bulk Drugs & Drug Intermediates	26.87	22.34	26.54	22.30	-15.96
Drug Formulations & Biologicals	8.26	6.07	10.46	27.34	161.36
Ayush	1.42	1.57	1.19	0.72	-39.75
Herbal Products	1.80	1.17	1.63	0.97	-40.06
surgicals	3.44	2.09	2.08	2.58	24.08
Vaccines	0.60	1.05	8.64	22.79	163.96
Total	42.39	34.29	50.53	76.71	51.80

India's Pharma exports to Saudi Arabia During April-March $ Million			
Category	Fy-19	Fy-20	Change%
Bulk Drugs & Drug Intermediates	22.30	17.01	-23.70
Drug formulations & Biologicals	27.27	31.99	17.32
Ayush	0.72	0.90	24.78
Herbal Products	0.97	1.19	22.06
surgicals	2.62	3.12	19.17
Vaccines	22.83	9.73	-57.38
Total	76.71	63.94	-16.64

India exports to Saudi Arabia constitutes 5.81% of its exports to the Middle East.

Imports of Saudi Arabia

Top Ten Importing Partners of Saudi Arabia $ Million						
Rank	Country	2016	2017	2018	Gr% in 2018	Share% of 2018
1	Germany	802.62	930.17	916.09	-1.51	16.51
2	USA	831.96	749.22	878.06	17.20	15.83
3	France	397.88	544.50	630.49	15.79	11.37
4	Switzerland	346.79	388.68	439.21	13.00	7.92
5	Ireland	288.75	394.33	370.65	-6.01	6.68
6	Denmark	292.51	215.56	276.51	28.28	4.98
7	United Kingdom	269.69	282.71	249.38	-11.79	4.50
8	Italy	243	255.16	239.04	-6.32	4.31
9	Sweden	141.14	183.02	190.00	3.81	3.43
10	Jordan	223.04	216.25	182.54	-15.59	3.29
17	India	9	19.50	57.00	192.29	1.03
	World	4837.49	5320.28	5547.03	4.26	100.00
Source: Uncomtrade						

India happens to be 17th st largest importing partner of Saudi Arabia.

REGISTRATION AND REGULATORY REQUIREMENTS

- Regulatory Authority : **Saudi Food And Drug Authority (SFDA)**
- Website of regulatory Authority : https://www.sfda.gov.sa/en/Pages/default.aspx
- Fees for Drug Registration : SAR 40,000
- Normal time taken for registration : 6-18 Months
- Registration Requirement [Dossier Format] : e-CTD
- Whether plant inspection is mandatory : Yes

REGULATORY REGIME

The main regulatory authority in the country is the Ministry of Health (MoH), which requires all pharmaceutical companies to be registered. The registration process takes between six and 18 months to complete, although approval times have been steadily decreasing over the years. Registrations must be renewed every five years.

Local producers or joint ventures are reported to enjoy far shorter product registration times. For imported products, the process often takes years, while for local items the approval time can take as little as three months. Once a product is registered, a price must be approved by the SFDA before it can be sold. Approval for pharmaceuticals new to the market is also undertaken by the SFDA, which follows the US FDA's Good Manufacturing Practice (GMP) guidelines.

According to the World Health Organization (WHO), there were 6,541 pharmaceutical products registered in Saudi Arabia in 2011. Legal provisions exist for the Medicines Regulatory Authority to make the list of registered products available publically and update it regularly. Medicines are registered by their international non-proprietary names (INN) or brand name and INN. There are

no duties imposed on imported active pharmaceutical ingredients (APIs) or on finished dose pharmaceuticals

The SFDA also regulates imported and exported pharmaceuticals and drug manufacturing, advertising and withdrawals. It maintains a list of registered and newly-registered pharmaceutical products, and is responsible for the Saudi National Formulary and over-the-counter (OTC) Formulary.

Products must gain SFDA approval before entering the market. Applications for approval, supported by the required certificates duly legalized by a Saudi Arabian consulate in the applicant's country, are examined and the samples are analyzed by the authorities to ensure that they correspond to the specifications. If the regulatory body is satisfied with the results, a license is then issued to the applicant.

Saudi Food and Drug Authority

The Saudi Food and Drug Authority (SFDA) was established under the Council of Ministers resolution no (1) dated 07/01/1424 H, as an independent body corporate that directly reports to The President of Council of Ministers. The Authority objective is to ensure safety of food and drug for human and animal, and safety of biological and chemical substance as well as electronic products.

Authority's main objectives:

The main purpose of the SFDA establishment is to regulate, oversee, and control food, drug, medical devices, as well as to set mandatory standard specifications thereof, whether they are imported or locally manufactured. The control and/or testing activities can be conducted in the SFDA or other agency's laboratories. Moreover, the SFDA is in charge of consumers awareness on all matters related to food, drug and medical devices and all other products and supplies. The main objectives of SFDA can be outlined as follows:

- Observe the safety, security, and effectiveness of food and drug for humans and animal.
- Observe the safety of complementary biological and chemical substances, cosmetics and pesticides.
- Observe the safety of medical devices and its impact on public health.
- Ensure accuracy and safety of medical and diagnostic devices.
- Launch clear policies and procedures for food and drug, and plan to achieve and implement these policies.
- Conduct research and applied studies to identify health problems, their causes, determine its impact on public, with the consideration of methods for research / studies evaluation. The authority shall establish scientific bases for awareness and consulting services and executive programs in the fields of food and drug. This can be accomplished through the recruitment of experts & specialists or through the partnership with research bodies such as King Abdulaziz City for Science and Technology (KACST) and/or universities research centers.
- Control and supervise licenses procedures for food, drugs and medical devices factories.

- Disseminate and exchange information with local and international scientific and legal agencies and setting up a database for food and drug.

Authority Activities :

- Food
- Drugs
- Medical Equipment

Drugs sector objectives:

The drug sector is responsible for handling some objectives that aims to protect the public health in Saudi Arabia. These objectives include:

- Licensing of the manufacture, import, export, distribution, promotion and advertising of medications.
- Assessing the safety, efficacy and quality of medications, and issuing marketing authorization.
- Inspecting and surveillance of manufacturers, importers, wholesalers and dispensers of medication products.

- Monitoring the quality and safety of marketed medications.
- Monitoring the adverse reactions of medications.
- Provide an independent information on medications to professionals and the public.
- Assuring the safety of cosmetic products.
- Build an affective relationship with the international authorities and scientific societies.
- Enhance the society's pharmaceutical education.
- Set up the suitable rules, specifications and standers before issuing the drugs marketing authorization in the Kingdom.
- Monitor and follow up the marketed drug in order to observe the adverse reaction of it and to prevent of illegal marketing methods.
- address the pharmaceutical and health information to both specialists and public.

REGULATORY FRAMEWORK FOR DRUG APPROVAL

1.NEW MARKETING AUTHORIZATION APPLICATION

The MAA of pharmaceutical product will be subjected to the followings processes:

1.1. Submission

The process of submitting a New MAA consists of two steps:

1.1.1. Online submission

1. The applicant shall apply through SDR system to fill the application form and pay the fees
2. Upload the product file; The components of the file shall follow the requirements and guidelines published on SFDA website

1.1.2. Validation: The product file will be validated in technical and business bases to ensure the applicant fulfills the requirement. The validation involves two steps:

3.1.2.1. Technical validation: The SDR system will validate the submission automatically after the company upload the file on the SDR portal. The validation's result will be sent by email through SDR system to the applicant.

3.1.2.2. Business validation

1. The product file will be validated to ensure that all information provided is according to the requirements and guidelines.

2. If any information is missing or incorrect, an electronic inquiry will be forwarded to the applicant through the SDR system. The applicant will be given an opportunity to complete the file within 30 working days.

3. The completed file will proceed to the next steps for Assessment (section 3.2)

The registration request will be rejected in the following cases:

- No response from the applicant within 30 working days.
- Failure to provide acceptable clarifications after the 4th wave.

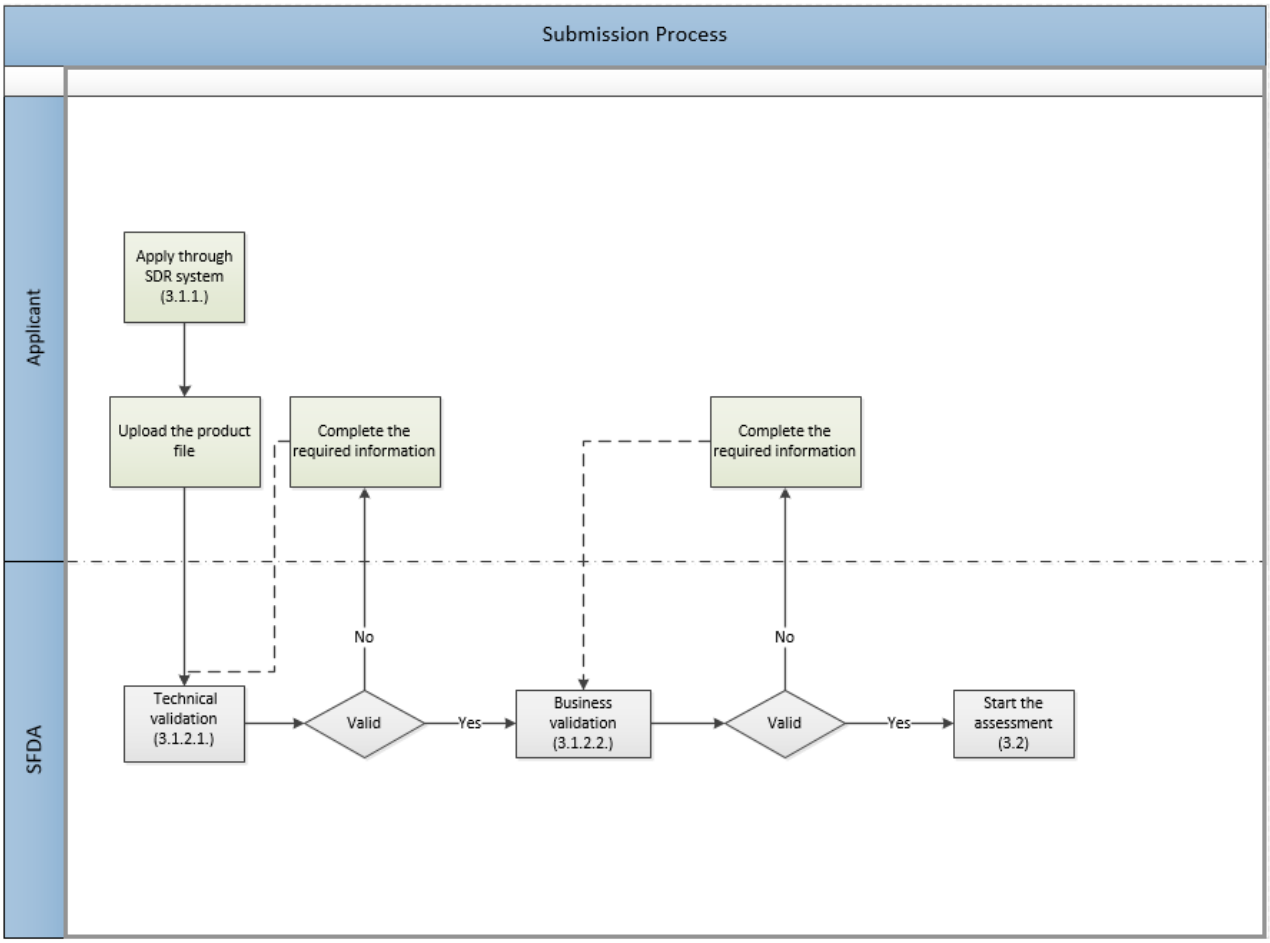


Figure 1: Schematic chart of the submission process

1.2. Assessment: The MAA for different drug submission types subject to the following processes:

1.2.1. Evaluation / Inspection

1. The RA will distribute the registration request to the relevant related departments to assess quality, safety and efficacy.

- For Inspection: the department will check the approval of manufacturing line; if not approved:
- Visit will be scheduled for inspection depending on the time available for both inspectors and the company.

- After the visit, the inspection report will be sent to the company (please, refer to the guidance of Good Manufacturing Practice for Medicinal product).

2. If more information or clarification is required, an electronic inquiry will be posted through SDR system as one wave for evaluation and inspection. A response should be received within 90 working days.

3. Once the evaluation and inspection are completed, the registration request will be forwarded to Pricing

The registration request will be rejected in the following cases:

- No response from the applicant within 90 working days.
- Failure to provide acceptable clarifications after the 4th wave.

3.2.2. Testing:

1. The registration request will be forwarded to the SFDA Central Laboratories.
2. If more information or clarification is required, an electronic inquiry will be posted through SDR system
3. Samples and working standards shall be delivered by the applicant to SFDA Central Laboratories.

Notes:

- Testing will not delay the registration of a product.
- The first batch will not be released if the company did not submit the requirements and inquiries that requested by SFDA Central Laboratories during product registration period

3.3. Pricing

1. The Pricing Department will review product's price according to the "SFDA's pricing rules".

2. If more information or clarification is required, an electronic inquiry will be posted through SDR system. A response should be received within 90 working days.

3. The product's price will be forwarded to Registration Committee

The registration request will be rejected in the following cases:

- No response from the applicant within 90 working days.
- Failure to provide acceptable clarifications after the 4th wave.

3.4. Product licensing

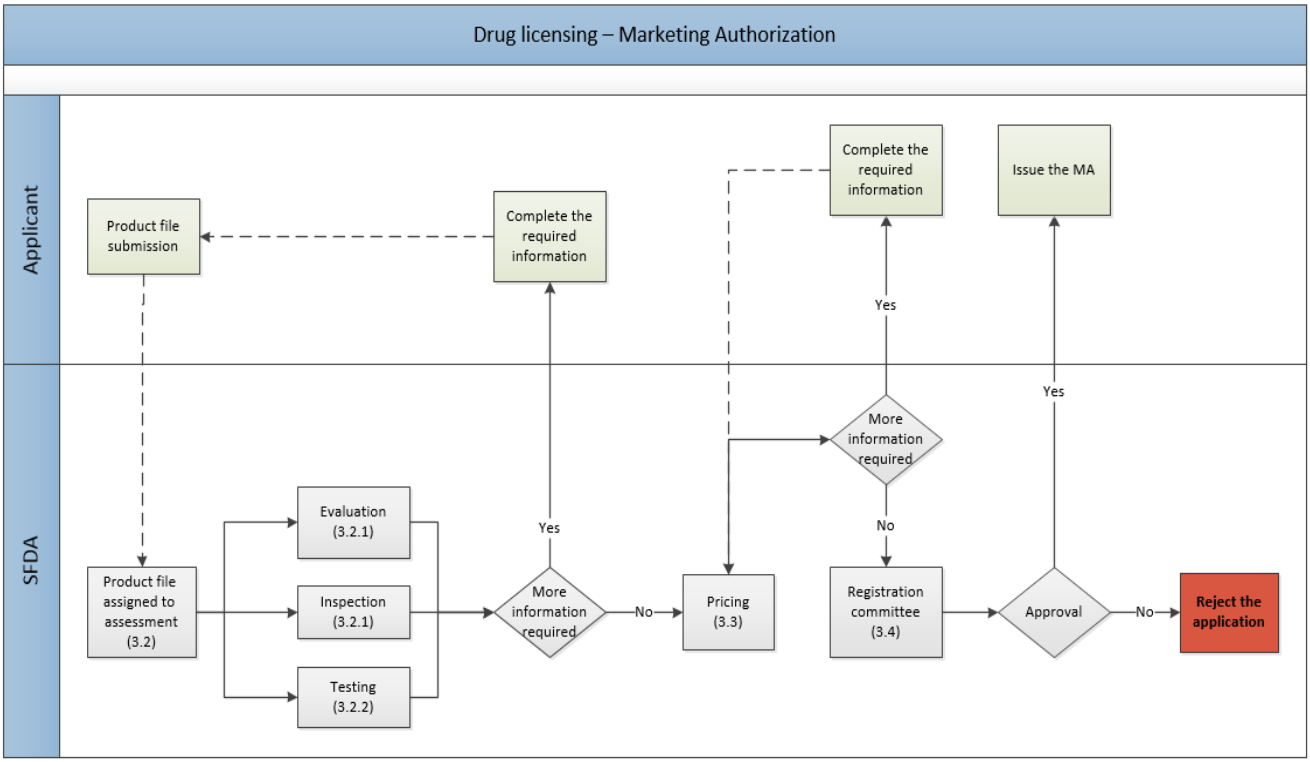
1. The Registration Committee will review the registration request for approval, rejection or ask for further information (if needed).

2. The SFDA CEO will approve the meeting minutes.

3. For approved registration request, the applicant will be notified through SDR system to issue the MA. Otherwise, submit an appeal.

Appeal Process:

The applicant has the right to appeal against any decision within 60 calendar days, for more information refer to Guidance for Submission.



Schematic figure showing the different levels for getting a Marketing Authorization

3.5. Registration performance targets

- The performance target in any step will STOP if a clarification or information is needed from the applicant, and resume after receiving the response.
- All days are considered as working days.
- Total Performance Target calculated without the Business Validation for all pathways

2. VARIATION OF MARKETING AUTHORIZATION

Any changes on a registered product has to be submitted to the SFDA as a Variation of MAA. The variations are classified into two main categories:

A. Minor changes

- Type IA: minor variations that does not require prior approval before implementation **("Do and Tell" procedure)** but require notification submitted by MAH within 60 working days after implementation.
- Type IB: minor variations that must be submitted to the SFDA by MAH before implementation, but do not require a formal approval. However, the MAH must wait a period of 60 working days to ensure that the application is deemed acceptable by the SFDA before implementing the change **("Tell, Wait and Do" procedure).**

B. Major variation

- Type II: major variations in which there might be a significant impact on the Quality, Safety or Efficacy of a pharmaceutical product and require prior approval before implementation.

The variation request subjects to the following process:

2.1. Submission: The process of submitting a variation of MAA consists of two steps:

2.1.1. Online submission

1. The applicant shall apply through SDR system to fill the application form and pay the fees.
2. Upload the product file; The components of the file shall follow the requirements and guidelines published on SFDA website

For applications made via the new SDR system, three parallel variation applications can be submitted at a time, each includes administrative, quality or safety variations. Each category of variations will be assigned to the related departments.

2.1.2. Business Validation

1. The product file will be validated to ensure that all information provided is according to the requirements and/or guidelines.

2. If any information is missing or incorrect, an electronic inquiry will be forwarded to the applicant through the SDR system. The applicant will be given an opportunity to complete the file within 30 working days.

3. The completed file will proceed to the next step for Assessment

The variation request will be rejected in the following cases:

- No response from the applicant within 30 working days.
- Failure to provide acceptable clarifications after the first wave.

2.2. Assessment: Depending on the type of variation, one or more department may review the variation application.

2.2.1. Evaluation / Inspection:

1. The variation request will be distributed to the relevant related department – as needed;

- For the inspection related requests: the department will check the approval of manufacturing line, If not approved:
- Visit will be scheduled for inspection depending on the time available for both inspectors and the company.
- After the visit, the inspection report will be sent to the company (please, refer to the guidance of Good Manufacturing Practice for Medicinal product).

2. If more information or clarification is required, an electronic inquiry will be posted through SDR system. The response should be received within 90 working days.

3. Reports (recommendation for approval or rejection) will be collected by the RA.

4. The reports will be forwarded (if needed) to pricing and registration committee depending on the type of variation.

The variation request will be rejected in the following cases:

- No response from the applicant within 90 working days.
- Failure to provide acceptable clarifications after the first wave.

2.3. Pricing:

1. The Pricing Department handles all variation requests that require pricing review according to "SFDA's pricing rules".

2. If more information or clarification is required, an electronic Inquiry will be posted through SDR system. A response should be received within 90 working days.

3. The approved price will be forwarded to the Registration Committee

The variation request will be rejected in the following cases:

- No response from the applicant within 90 working days.
- Failure to provide acceptable clarifications after the first wave.

2.4. Product Licensing:

For all variation types except variation affecting product price:

1. The RA will approve the final report.
2. Notify the applicant through SDR system.

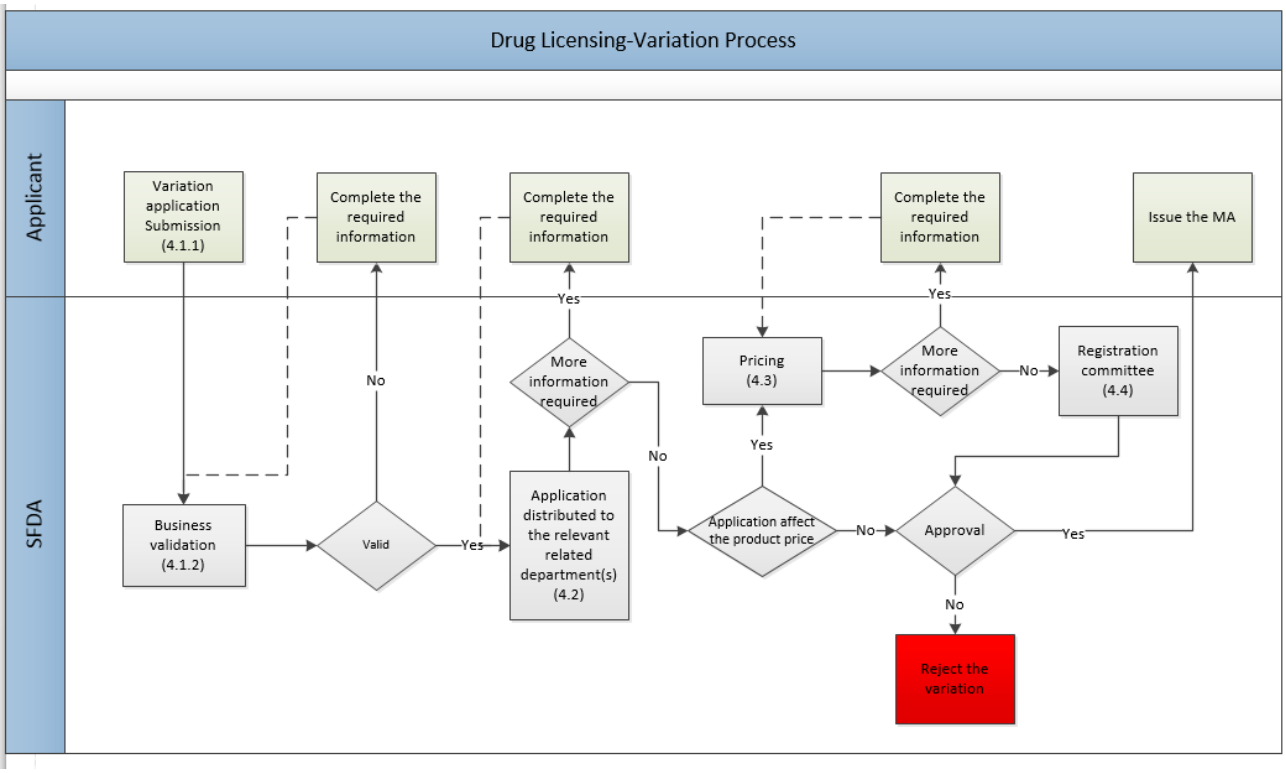
For variation affecting product price:

1. The Registration Committee will review the variation request for approval, rejection or ask for further information (if needed).
2. The SFDA CEO will approve the meeting minutes.
3. For approved variation request, the applicant will be notified through SDR system. Otherwise, submit an appeal.

General variation notes:

- For applications made via the new SDR system; after the completion of an application of a particular category (by approval or rejection), another application of the same category can be submitted.
- For application includes more than one type of variation, the maximum total performance target will be considered. For example: application includes type 1B and type II, the total performance target for the application is 100 working days.

Appeal Process: The applicant has the right to appeal within 60 calendar days of the SFDA's final decision, for more information refer to Guidance for submission.



Schematic figure showing the workflow of Variation

4.5. Variation performance targets:

- The performance target in any step will STOP if a clarification or information is needed from the applicant, and resume after receiving the response.
- All days below are considered as working days.
- Total Performance Target calculated without the Business Validation for all types of variations.

3. RENEWAL OF MARKETING AUTHORIZATION:

An applicant shall submit a renewal request every five years. It is possible to request for renewal within six months of the certificate expiry.

As most of the registered drugs have went through at least one renewal process or have been registered through SDR system; therefore, the renewal process is shorter as follows:

3.1. Submission: The process of submitting a renewal of MA consists of two steps:

3.1.1. Online submission:

- The applicant shall apply through SDR system to fill the application form and pay the fees.
- Upload the renewal file; The components of the file shall follow the requirements and guidelines published on SFDA website.

3.1.2. Business Validation:

1. The product file will be validated to ensure that all information provided are according to the requirements and/or guidelines.
2. If any information is missing or incorrect, an electronic Inquiry will be forwarded to the applicant through SDR system. The applicant will be given an opportunity to complete the file within 30 working days.
3. The completed file will proceed to the Pricing Department

The renewal request will be rejected in the following cases:

- No response from the applicant within 30 working days.
- Failure to provide acceptable clarifications after the first wave.

3.2. Pricing:

1. Pricing Department will review the price according to the "SFDA's pricing rules".
2. If more information or clarification is required, an electronic inquiry will be posted through SDR system. A response should be received within 30 working days.
3. The approved price will be forwarded to the product licensing

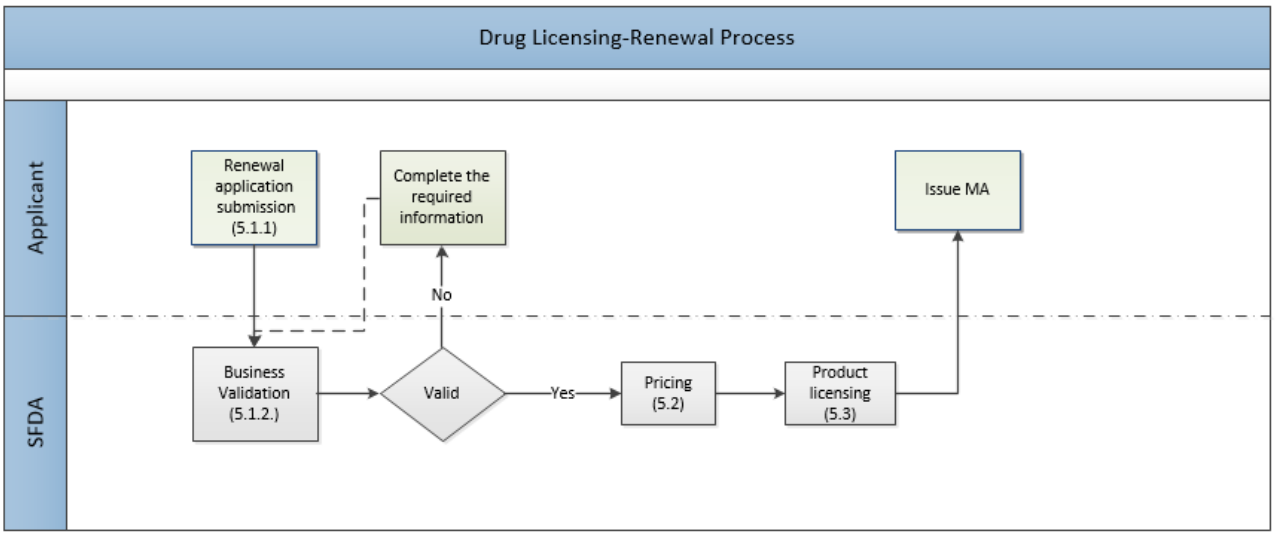
The renewal request will be rejected in the following cases:

- No response from the applicant within 30 working days.
- Failure to provide acceptable clarifications after the first wave.

3.3. Product Licensing

1. The RA will issue the renewal of MA.
2. The applicant will be notified through SDR system. Otherwise, submit an appeal.

Note: The rejected renewal applications obligate the applicant to submit a new one.



Schematic figure showing the renewal process of a Marketing Authorization

3.4. Renewal performance targets:

- The performance target in any step will STOP if a clarification or information is needed from the applicant, and resume after receiving the response.
- All days below are considered as working days.
- Total Performance Target calculated without the Business Validation.

Drug Master File (DMF):

Requirements of the Drug Master File

The content of the submitted DMF shall be composed of the following:

1.1 DMF Form: The following included in the DMF Form: (All fields required)

a) Identification of submission: new, resubmission, renewal or variation
b) Procedure Type: National (SFDA) or Central (GCC-DR) procedure
c) Reference number2
d) Date of submission2
e) Active substance name
f) Pharmacopeial reference
g) Trade name (Specific product covered by the DMF)
h) DMF holder name
i) DMF version number and date (yyyy-mm-dd) for the applicant's part and restricted par.
j) Manufacturer name (if different from DMF holder name)
k) Manufacturer Address
l) Typewritten name and title of the signer

m)Signature of the authorized representative

1.2 Letter of Access: Before SFDA can review DMF information in support of an application, the DMF holder shall submit a letter of authorization permitting SFDA to reference the DMF.

The letter of access should include the following:

a. Identification of submission: new, resubmission, renewal or variation
b. Procedure Type: National (SFDA) or Central (GCC-DR) procedure
c. Registration or Reference number1
d. Active substance name
e. Pharmacopeial reference
f. Trade Name (Specific product covered by the DMF)
g. DMF holder name
h. DMF version number and date (yyyy-mm-dd) for the applicant's part and restricted part.
i. Manufacturer Name (if different from DMF holder name)
j. Manufacturer Address
k. Typewritten name and title of the signer
l. Signature of the authorized representative
m. If no changes were made within the last five years, a letter indicating that the DMF remains current.

Notes:

- A signed statement by the holder certifying that the DMF is current and that the DMF holder will comply with the statements made in it should be submitted
- DMF Form and letter of access must be on company official paper.
- List of all manufacturing sites must be provided.
- An application incorrectly submitted will be rejected

2. Presentation of the DMF: A softcopy (electronic-based) of the DMF including (DMF Application Form and latter of accesses) are only required. No need for Hard copy.

2.1 Language: Information and documents supporting a drug application – such as certificates and approval letters– must be including in Arabic or in English. If documents are neither in Arabic nor in English, a translation to English (from an authorized translation office) must be included.

2.2 Copy Requirements:

2.2.1 Softcopy:

- DMF (pdf)
- DMF application form (word format)
- Letter of access

Each CD or DVD and its hard plastic cover submitted should include the following label information, clearly presented and printed on the submitted CD or DVD with the font of 12 Times New Roman (or equivalent):

- The reference numbers
- The company name
- Trade Name (Specific product covered by the DMF)
- Active substance

2.2.1.1 Number of copies:: Applicants should submit TWO Softcopies. The submission shall be in ONE media only (CD or DVD) i.e. if the submission size is above 750MB then the applicant has to use a DVD.

Fees of Regulatory Services of Pharmaceutical Products

No.	Service type	Fees by Saudi Riyal
New Drugs and Biologicals		
1	Evaluating and analyzing a drug application	95,000
2	Evaluating the addition of a new pharmaceutical dosage form	95,000
3	Evaluating the addition of a new concentration	24,000
4	Evaluating the addition of a new pack type	24,000
5	Evaluating the addition of a new pack size (in a new application)	5,000
6	Evaluating the addition of a new indication	24,000
7	License renewal	30,000
Generic Drugs		
8	Evaluating and analyzing a drug application	40,000
9	Evaluating the addition of a new pharmaceutical dosage form	40,000
10	Evaluating the addition of a new concentration	10,000
11	Evaluating the addition of a new pack type	5,000
12	Evaluating the addition of a new pack size (in a new application)	1,000
13	License renewal	10,000

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Details of importing country embassy in India: **https://samrindia.org/contact-details**

Contact details of Indian Embassy abroad: **https://www.eoiriyadh.gov.in/**

List of Local Pharma Associations:

- National Committee for Pharmaceutical Industries (NCPI)
  King Fahad Branch Rd, Al Mutamarat, Riyadh 12711, Saudi Arabia
  info@ncpi.org.sa
  +966 500 156 785,
  +966 501 928 489