REGULATORY FILING OF A MEDICINAL PRODUCT IN SAUDI ARABIA

& IT'S NAVIGATION PATHWAY

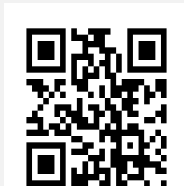## Venkateshwara C. Reddy[1], Abhishek B.V[2],   M P Venkatesh[3]*, Shehnaz Z Khaleeli[4]

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| ARTICLE INFO	ABSTRACT
Key Words SFDA, Navigation, Registration, GCC	Saudi Arabia is one of the significant markets for pharmaceutical organizations in Gulf Cooperation Council and Middle East and North Africa district. As a result of its populace development over a period, ascent of way of life illnesses there is popularity for the medication items. The luxuriousness of the Saudi individuals had prompted higher interest for imported protected medications, now the administration moving the focal point of the general population permitting dynamic private area cooperation, making medical coverage obligatory for exiles and advancing the utilization of non-specific items. Saudi Arabian Food and Drug Authority is the pharmaceutical administrative expert in Kingdom of Saudi Arabia that guarantees the security and adequacy of the therapeutic item promoted in the nation. SFDA gives distinctive assessments pathways to new substance elements (NCEs), generics, home grown and for veterinary medications, for pharmaceutical organizations to showcase their items in Saudi Arabia.The essential point is to encourage the administrative understanding that represents item advancement and guarantee administrative consistence and to know the regulatory requirements to record a Medicinal Products in Saudi Arabia and the route pathways for different applications and entries.

INTRODUCTION

The Kingdom of Saudi Arabia is a nation arranged in Southwest Asia, the largest nation of Arabia, circumscribing the Persian Gulf and the Red Sea, north of Yemen. The Saudi government evaluate is at 22.17 lakh square kilometers, while other respectable appraisals are in the vicinity of 21.49 lakh square kilometers and 22.4 lakh square kilometers. Saudi Arabian Food and Drug Authority (SFDA) is the pharmaceutical administrative agency in Kingdom of Saudi Arabia that guarantees the well-being and viability of the medicinal item advertised in the nation.[1]

Saudi Arabia:

- World's **second largest oil** reserves - accounts for more than 95% of exports and 70% of government revenue.

- World's **sixth largest natural gas** reserves.

- **Area** : 22.5 lakh sq.km (largest among GCC)

- **Capital:** Riyadh

- **Population**: 27 million.

- **Language**: Arabic

- **Currency::** Saudi riyal(1 Saudi Riyal = Rs 12.50)

- The government is absolute monarch.[1]
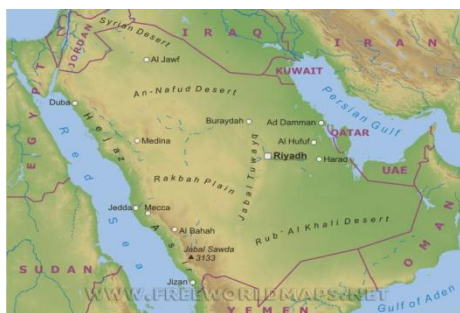
Figure 1: Flowchart to understand a development of a medicinal product

Discussion: Building up a creative human services item from the proof of concept stage to the promoting stage is a costly and complex process. It includes numerous long periods of innovative work. To spare time and cash in offering items for sale to the public, item improvement exercises ought to be led as per the related administrative necessities. Following these necessities can streamline advancement exercises and help you to fabricate an item that meets the administrative benchmarks of focused on authority(s) that is, a quality item that is sheltered and compelling for its proposed utilize.[2,3]. In spite of the fact that data on the administrative prerequisites (e.g., laws, direction archives, universal benchmarks) for social insurance, item advancement is promptly accessible, exploring the administrative framework isn't straightforward, and it gets much more mind boggling when managing

different experts. The Drug Regulatory Authorities are being set up in different nations over the globe. Each nation has its own particular administrative expert, which is mindful to implement the principles and directions and issue the rules to manage tranquilize improvement process, permitting, enrollment, assembling, promoting and naming of pharmaceutical items [2,3].

Administrative expert and associations are mindful in successful medication direction required to guarantee the wellbeing, viability and nature of medications, and also the precision and propriety of the medication data open to general society. For getting to the medication related data one has to know where the directed data i.e., Act/Regulations/Guidance are stopped on the administrative sites. At that point for getting the correct data, one has to know the correct data stopped at specific administrative sites [2,3]. This can be access by the assistance of "route pathway" to get an administrative approval from agency. The real difficulties of administrative specialists and associations around the globe are to guarantee the security, quality and viability of medicinal products, harmonization of lawful methods identified with medicate advancement, observing and guaranteeing consistence with statutory commitments[2,3].

Pharmaceutical Market:

The Saudi pharmaceutical market is the richest in the Gulf area accounts around 65% of Gulf Cooperation Council showcase[3]. **Table 1: Growth of Pharmaceutical market in GCC countries**

Registration Procedure in Saudi Arabia[4]

There are two procedures for registration:

- Centralized Procedure
- Decentralized

Registration Procedure:

- Regardless of the way that there is a unified and extraordinarily fit process for quiet enrollment in GCC nations, the legitimate fundamentals of a few

gigantic nations like Saudi Arabia and UAE are separate[4,5].

- The Saudi Food and Drug Authority [SFDA] is the main drug regulatory body of Saudi Arabia. SFDA prefers the drug dossier submission in electronic format (eCTD)[4,5].

Figure 2: Registration procedure in Saudi Arabia

Registration Rules

Drug segment at SFDA sets the rules for enlisting distinctive kinds of drug products. Such standards are produced by looking at the present and future abilities of its evaluators. These rules will assist the candidates with deciding whether to present their medication applications or not[4].

The following rules/conditions if met, the submitted drug application will be accepted:

1. **New Drug** and **Biological** (either registered in a Stringent Regulatory Authorityornot).

2. Generic Drug that is equal to the enlisted innovator in a SRA (the medication should be enrolled as "New Drug" in light of the fact that the API isn't enrolled in Kingdom of Saudi Arabia).

3. Biosimilar drug only if it is manufacturedlocally.

4. Biosimilar medication if enrolled in a SRA.

5. Combination products (2 or moreAPI):

   a. If the API's are registered in KSA as single drugs (with the **same** strength, dosage form and therapeutic indication); then the application is considered*Generic.*
   b. If one or more of the API's are not registered in KSA, or registered with different strength, dosage form or indication; then the application is considered *NewDrug*[4].

The process of submitting a NEW drug application to the SFDA consists of three majorsteps[5]:

1. Online submission of the APPLICATIONFORM,

2. The PRODUCT FILE delivered inperson,

3. DRUGSAMPLES.

Step by step procedure for Online Submission:

1. Applicant shall visit the Saudi Drug Registration system (SDR) website (http://sdr.sfda.gov.sa/)
2. Login to apply (each applicant should have a user ID and apassword)
3. Choose and complete the appropriate applicationform
4. Then, the applicant has to pay the submission fee (through SADAD Payment System) in order to submit the application form and schedule an appointment to deliver the hard and soft copy of the productfile[5]:

   - *Submission fees are mandatory in order to proceed to the nextstep.*

   - *The applicant can reschedule 3 weeks before the appointment. An automatic reminder will be sent 3 days before theappointment.*

   - *A reference number will be generated, and this number should always be used with regard to any communication with theSFDA.*

5.At the appointment, the applicant will deliver the product file along with the samples.

6.The Regulatory Affairs Pharmacist will validate (Phase I) thefollowing:

   a. The application form
   b. The product file (hard and softcopy)
   c. Thesamples

a. Drug application without deficiencies:
The applicant will be notified of the acceptability by printing an acknowledgement letter. Then, the drug application will be

forwarded to the product manager for further processing and assessment. Once these applications are accepted, they will be assessed in order in which they are received [5].

b. Drug application with deficiencies:

If some of the above are missing or not satisfactory, an affirmation letter will be produced and given to the candidate expressing the lacks. The candidate will have a time of 90 days to finish the prerequisites and the medication application won't be lined. In the event that the candidate neglects to give the asked for data inside 90 days, the medication application will be rejected right away[5].

Figure 3: Submission process in Saudi Arabia

Marketing Authorization Application (MAA)

The Market Authorization Application for the different drug submission types will be subjected to the following processes[4,5]:

A. Validation (PhaseII):

1. The product file will be validated to ensure that all information provided are according to the requirements and/orguidelines:
   a. The completed file will proceed to the next steps in parallel – assessment, testing &inspection.
   b. If any information is missing or incorrect, the applicant will be notified electronically. The applicant will be given an opportunity to complete the file within **90** days. Otherwise, the file will berejected [4,5].

B. Assessment:

1. The product file will be distributed by the product manager to THREE groups: Quality, Safety andEfficacy.
2. **Quality assessment** will be performed by a quality group. Once completed, a report will be forwarded to the productmanager.
3. **Safety assessment** will be performed by a safety group. Once completed, a report will be forwarded to the productmanager.

4. **Efficacy assessment** will be performed by an efficacy group. Once completed, a report will be forwarded to the productmanager.
5. If a clarification is required, an electronic "**Inquiry Form**" will be forwarded to the applicant through the product manager. The response should be received within **90** days. Otherwise, the application will berejected.
6. The reports will be forwarded to the secretary of the RegistrationCommittee[4,5].

C. Testing

1. Samples received by SFDA headquarters will be sent to thelaboratory.
2. If more information, clarification or additional samples are needed, an electronic "**Inquiry Form**" will be forwarded to the applicant through the product manager. A response should be received within **90**days.
3. The results will be written in a report and forwarded to the productmanager.

D. Inspection

1. The product file will be forwarded to the Head of the inspectionunit:
   a. If more information or clarification is required, an electronic "**Inquiry Form**" is forwarded to the applicant through the Inspection unit. A response should be received within **90**days.
2. Inspection department will inspect the manufacturingline:
   a. If the manufacturing line has been approved (valid certificate from KSA MoH, SFDA or GCC-DR), the line would not be inspected and the head of the inspection unit will inform the productmanager.
   b. If the manufacturing line is notapproved:
      i. The head of the inspection unit will schedule a visit for inspection (depending on the

time available for both inspectors and thecompany).

ii. After the visit, the inspection report will be written and forwarded to the Head of inspectionunit.

iii. Head of inspection unit will send the inspection report to the company.

3. The final inspection report will be forwarded to the productmanager[4, 5, 6].

E. Pricing

1. The Pricing department handles pricing requests and ensures that all pricing requirements are met (such as the presence ofa valid, updated and authenticated Price Certificate (Form-30) and a product sample in its final pack form). However, if more information or clarification is required, an electronic "**Inquiry Form**" will be forwarded to the applicant through the product manager. A response should be received within **90**days.

2. The Pricing department will calculate the price of each concentration and/or pack size of different product from a pricing & economic perspective according to the SFDA's pricingrules.

3. If the committee asks for more information or clarification, an electronic "**Inquiry Form**" will be forwarded to the applicant by the pricing department through the product manager. A response should be received within **90**days.

4. The approved price by the committee will be written in a report and forwarded to the productmanager[4,5].

F. Product Licensing

1. Product manager will receive all reports from departments and forward them to the secretary of the "RegistrationCommittee":

   a. The secretary of the Registration Committee will add the product to the agenda of the next availablemeeting.

   b. At the meeting, the Registration Committee will either recommend approval,rejection or ask for further

information – ifneeded[6,7]

Figure 4: Marketing Authorization procedure in Saudi Arabia

Table 2: Marketing Authorization Approval -SAUDI ARABIA

Table 3: Clinical Trial Application -SAUDI ARABIA

Stop Clock

The Stop-clock begins at whatever point SFDA issues an inquiry form. Request might be raised whenever from stage II approval to SFDA choice. The stop-clock closes at whatever point SFDA gets finish and worthy reactions from the candidate. In the event that the candidate faces troubles in reacting to request inside the predefined time, candidate should contact SFDA as quickly as time permits. A medication application will be viewed as rejected if the stop-clock time surpasses the SFDA due date[8].

SFDA Decision

The final decision is made on the outcome of SFDA's assessment, pricing, testing and inspection. The decision can be one of the following[8]:

- Approval
- More information needed
- Rejection

Dossier Format: Structure and Content of Submission

The SFDA will require all candidates to present their applications in understanding to the ICH Common Technical Document (CTD) design. The dossier prerequisites for every application will vary, contingent upon the kind of use[9].

The CTD is organized into five modules.
Module 1: Administrative Information and Prescribing Information
Module 2: CTD Summaries
Module 3: Quality
Module 4: Non Clinical Study Reports
Module 5: Clinical Study Reports

Module 1: Regional Administrative Information

- This Module is required to be submitted. It should contain documents specific to SFDA;

  e.g., application form, proposed labeling, alcohol-content

declaration, pricing, pork- content declaration

Module 2: Common Technical Document Summaries

The following sections are required to be submitted under Module 2:
- 2.1 Table of Contents of Module 2-5.
- 2.2 Introduction:
  This section should begin with a general introduction to the pharmaceutical, including its pharmacologic class, mode of action, and proposed clinical use. In general, the introduction should not exceed one page.
- 2.3 Quality Overall Summary:
  The whole section is required and should reflect the information provided in Module 3.
- 2.4 Non- Clinical Overall Summary:
- 2.5 Clinical Overview:
- 2.5.2"Overview of Biopharmaceutics": The summary of the comparative bioequivalence/bioavailability study reports should be provided under this section.

Module 3: Quality

The whole section is required and the information should be presented

Module 4: Non-Clinical Study Reports

Generally not applicable for generic products

Module 5: Clinical Study Reports
- It is anticipated that only the following relevant sections of Module 5 will normally berequired.
- 5.1 Table of contents for Module 5
- 5.2 Tabular listing of all clinical studies
- 5.3 Clinical study reports
- 5.4 Literature references[9]

Figure 5: eCTD Triangle

Product File

Presentation of Product File

A softcopy of the item record might be presented by the candidate alongside a printed version of Module 1only. The softcopy might be either:

a. eCTD, or
b. An electronic version of the product file in NeeS format the hard copy should be bound into one volume.

The ring binder specifications:
1. A4 D-ring 2-ring binder(box file)
2. Binder approximate dimensions; width 26.5cm, height 34cm and thickness 7.5cm (26.5×34cm× 7.5cm)
3. Label: It should contain the following information
   - Reference number
   - Company Name
   - Product trade name
   - Product generic name
   - Date of submission(DD/MM/YYYY)
   - Type of submission (e.g. initial, renew or variation)

For the soft copy, every CD or DVD and its hard plastic over submitted ought to incorporate the accompanying label information, obviously exhibited and imprinted on the media with the textual style of 12 times new roman.
   - Reference number
   - Company Name
   - Product trade name
   - Product generic name
   - The submission type of each submission contained on CD or DVD
   - The Sequence number of each submission contained on CD or DVD [10].

Number

The candidate ought to submit 3 printed copies of full accommodation and 1 printed version of Module 1. The submitted duplicates ought to be indistinguishable. The accommodation might be done in one media just either CD or DVD. As of now both CD-ROM and DVD ISO 9660 are viewed as a satisfactory media standard [10].

Virus Protection

The applicant is responsible for checking the submission for viruses. Checking must be performed with an up-to-date and well recognized antivirus application. After receipt of the checking at the SFDA, a comparable inside infection check will be performed. On the off chance that an infection is recognized it can

constitute justification for refusal of the electronic accommodation [10].

The list of documents required for Submission

- Latest GMP Certificate
- Proof of Payment
- Letter of approval for correspondence for the benefit of the candidate
- C.V. of the qualified individual for Pharmacovigilance
- Copy of the assembling approval permit
- Copy of Ph. Eur. Endorsement of reasonableness for TSE
- Copy of endorsed Marketing Authorization in different nations
- List of Mock-ups and tests sent with the application, as suitable
- Copy of the Orphan Designation Decision and logical letter
- Copy of the letter of assent from advertising approval holder of the approved item [10]

Stability Requirements

- Thestability of FPP should be on the knowledge of behavior and properties of API and information obtained from the stability studies of API and from pre-formulation studies
- Stability studies ought to be accommodated no less than 3 primary batch of the FPP[11]
- Stability studies should include testing of those attributes of the FPP that are susceptible to change during storage and are likely to influence quality, safety and/or efficacy[11].
- The testing frequency for the long term data should be for every 3 months in the 1st year.
- **Table 4**: Storage Conditions for the drug products
  Table 5: Storage conditions for the drug products stored in refrigerator
  Table 6: Storage condition for the drug products stored in freezer

Labeling

The Labeling guidelines are adopted from EMEA, EudraLex-volume II. The rules mainly focus on how to introduce the required data on SPC, PILS and names. The candidates should code distinctive colors for a similar item with various qualities to separate. The Arabic interpretation for the solution name and capacity conditions ought to be given on all medications with the exception of those utilized as a part of the doctor's facilities[12].

The particulars to appear on the labeling of the outer and immediate package

1. Name of the medicinal product
2. Statement of active substance
3. List of Excipients
   The excipients with some subjective activity should to be given
4. Pharmaceutical form and contents
   Contents by weight, by volume or by number or number of units of administration of the medicinal product
5. Method and route of Administration
   Method of administration: directions per use of the medicinal product.
6. Special warning that the medicinal product must be stored out of the reach and sight of children
7. Manufacturing and expiry dates
8. Storage conditions
9. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate. E.g. radiopharmaceuticals, cytostatics
10. Name of marketing authorization holder
11. Marketing authorization number
12. Batch number
13. General classification for supply, whether medicine is prescription drug or not
14. Price[12].

Minimum requirements to appear on small immediate package units

Small immediate packaging units are defined as containers sized up to and including 10ml.

1. Name of the medicinal product and route of administration
2. Method of administration
3. Batch number , Contents by weight, by volume or by unit
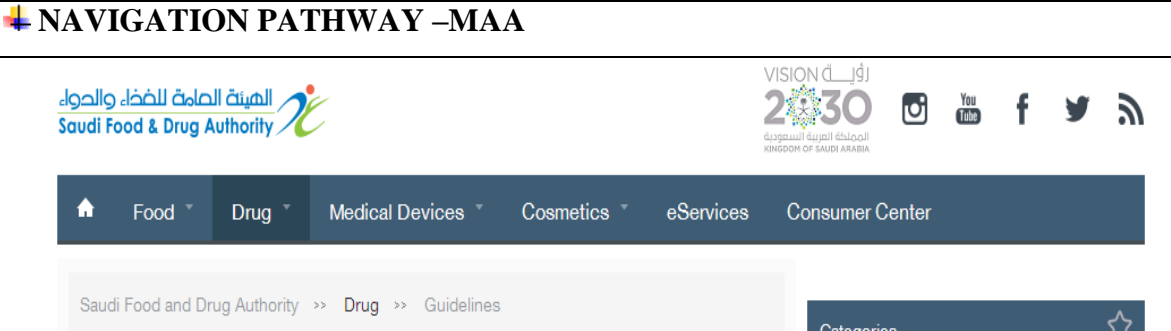4. Special storage conditions[12]

Country	2014	2015	2016
Saudi Arabia	3415	3749	4076
United Arab Emirates	996	1145	1317
Kuwait	311	336	361
Yemen	127	130	134
Qatar	111	119	129
Oman	108	118	129
Bahrain	74	80	84

Table 1: Growth of Pharmaceutical market in GCC countries

Table 2: Marketing Authorization Approval – SAUDI ARABIA

Marketing Authorization Approval – SAUDI ARABIA	
REGULATORY FACTSHEET	
PRODUCT	Medicinal Products
COUNTRY	Saudi Arabia
TYPE OF APPLICATION	Marketing Authorization Application
LIFECYCLE PHASE	MAA
REGULATORY AGENCY	Saudi Food and Drug Administration
REGULATORY CLASSIFICATION	Medicinal Products

➕ **INTRODUCTION**

➢ Marketing Authorization application is an application submitted by a drug manufacturer seeking permission to bring a newly developed medicinal product [7].

➢ According to SFDA, MAA will be subjected to the following process[7]

      1. Validation

      2.Assesment

      3.Pricing

      4.Testing

      5. Inspection

      5.Product licensing

➢ Total Performance target for this all process =295 days

➕ **GUIDANCE DOCUMENTS – Marketing Authorization Approval**

Sl. No	Title	Issued Date
01	Regulatory Framework for Drug Approvals v 5.0	10/11/2015
02	The GCC Data Requirements for Human Drugs Submission	15/07/2014

03	GMP guidelines	15/11/2012
04	Guidance for Submission v 4.0	23/03/2014

➕ NAVIGATION PATHWAY –MAA

SFDA MAA Navigation Pathway

GMP GUIDELINES:

www.sfda.gov.sa/ar/drug/resources/DocLib2/SFDAGMP_2011_v21.pdf

➕ CHECKLIST:
http://www.dhl.nl/content/dam/downloads/g0/express/shipping/customs/sfda_submission_guide_en.pdf

➕ REFERENCE LINK:
http://www.sfda.gov.sa/en/drug/drug_reg/Pages/default.aspx?catid=10&news=Main

Table 3: Clinical Trial Application -SAUDI ARABIA

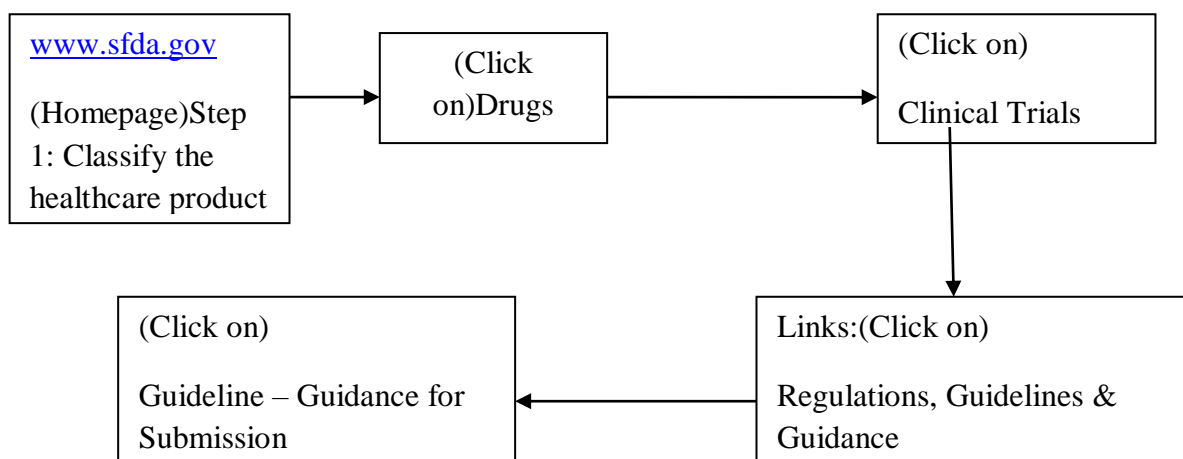| Clinical Trial Application -SAUDI ARABIA	
REGULATORY FACTSHEET	
Product	**Medicinal Products**
Country	Saudi Arabia
Type of application	Clinical Trial Application (CTA)
Lifecycle phase	R&D
Regulatory agency	Saudi Food and Drug Administration
Regulatory classification	Medicinal Products
➕ Introduction	

> ➢ The Clinical Trials administration aims to provide services professionally by evaluation, registration and monitoring the Clinical Trials conducted in Saudi Arabia and contribute to the protection of clinical trial subjects[7]. Also increasing the experience of investigators in the field of clinical research and strengthen the capacity of the regulatory body, legislative and oversight functions[7].

Guidance Documents – Clinical Trial Application[6,7]

Sl. No	Title	Issued Date
01	Regulations and Requirements for Conducting Clinical Trials on Drugs	01/09/2015
02	Clinical Trials Requirement Guideline	27/11/16
03	Regulations and Requirements for Conducting Clinical Trials on Drugs	04/05/2015
04	Guidelines for Investigational New Drugs (IND) Requirements	15/11/2012

Submission Pathway[8]:

```
www.sfda.gov
(Homepage)Step          (Click              (Click on)
1: Classify the   →    on)Drugs      →    Clinical Trials
healthcare product
                                                 ↓
(Click on)                          Links:(Click on)
Guideline – Guidance for    ←     Regulations, Guidelines &
Submission                         Guidance
```

LINK:

http://www.dhl.com/content/dam/downloads/g0/express/shipping/customs/sfda_submission_guide_en.pdf

Navigation Pathway –CTA[8]

SFDA CTA Navigation Pathway

Checklist:
http://www.dhl.com/content/dam/downloads/g0/express/shipping/customs/sfda_submission_guide_en.pdf

Reference Link:
http://www.sfda.gov.sa/en/drug/Clinical_Trials/Pages/Regulations,-Guidelines-and-Guidance.aspx

Type	Study	Storage condition	Minimum time period
General	Long term	30˚C±2˚C/65%±5%RH	12 months
	Accelerated	40˚C±2˚C/75%±5%RH	6 months
Products with semipermeable containers	Long term	30˚C±2˚C/35%±5%RH	12 months
	Accelerated	30˚C±2˚C/ NMT* 25%RH	6 months

Table 4: Storage Conditions for the drug products

Study	Storage condition	Minimum time period
Long term	5˚C±3˚C	12 months
Accelerated	30˚C±2˚C/65%±5%RH	6 months

Table 5: Storage conditions for the drug products stored in refrigerator

Study	Storage condition	Minimum time
Long term	-20˚C±5˚C	12 months

Table 6: Storage condition for the drug products stored in freezer

Step 1: Classify the Health care product	Step 2: Identify the healthcare claim and/or product label	Step 3: Determine the healthcare market

Step 4: Develop the regulatory strategy

Step 5: Establish the product development plan

Step 6: Execute the product development plan

Step 7: Execute the clinical plan	Prepare for a pre-submission meeting to support CTA

Step 8: Collect the data for regulatory submission	Clinical Trial Application

Step 9: Collate the data for regulatory submission	Prepare for a pre-submission meeting to support licensing application

Step 10: Ensure post marketing Surveillance

Figure 1: Flowchart to understand a development of a medicinal product

Once the application is submitted, a reference number is given to the applicant to facilitate communication with SFDA.	The applicant is needed to make an appointment with the SFDA office to hand over the application.	The earliest appointment can be scheduled 1 to 12 weeks in advance. The applicant can reschedule a week before the appointment.

Technical committee for evaluation ← Registration Sector ← File application & enclosure ← Agent

Pending for more information or Approved or Not Approved → Analysis (central laboratory for food and drug analysis) → Technical committee for evaluation

Acceptance or Non Acceptance ← Technical committee for evaluation ← Pricing Section ← Pending for more information or Approved or Not Approved

Final Approval or Rejection

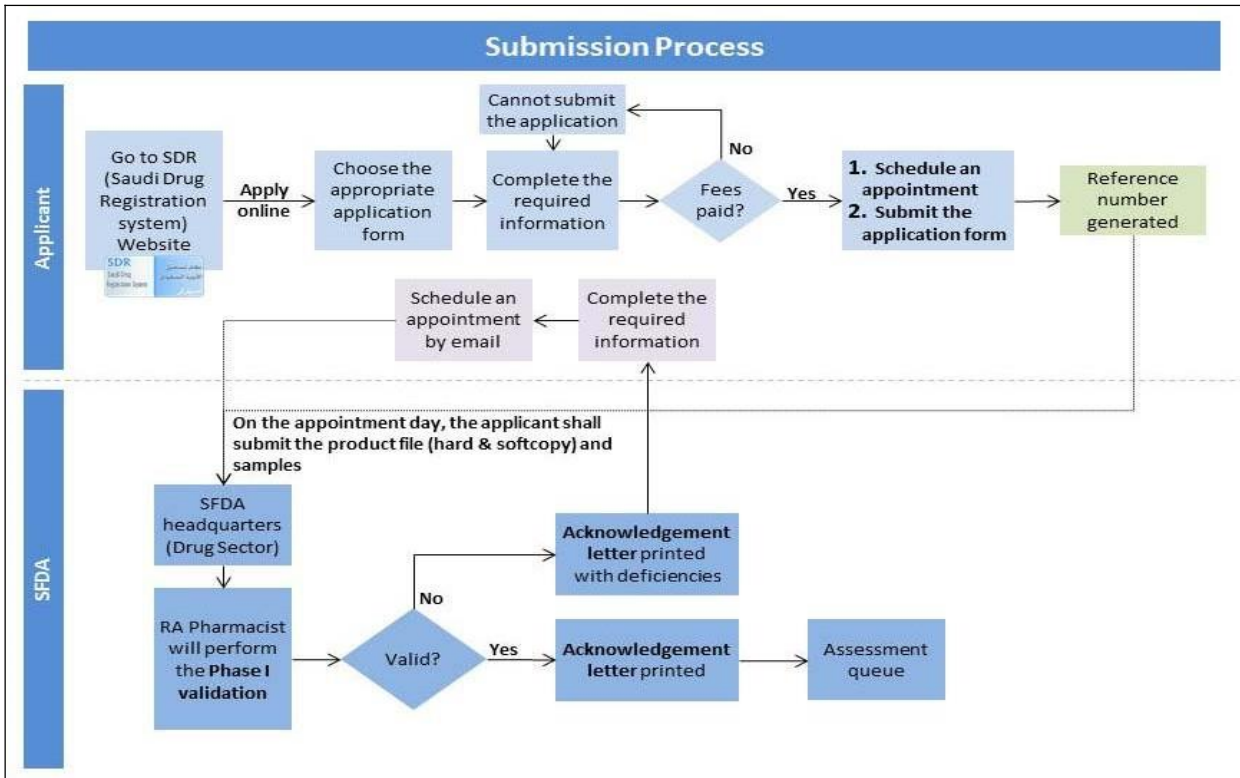**Figure 2: Registration Procedure in Saudi Arabia**

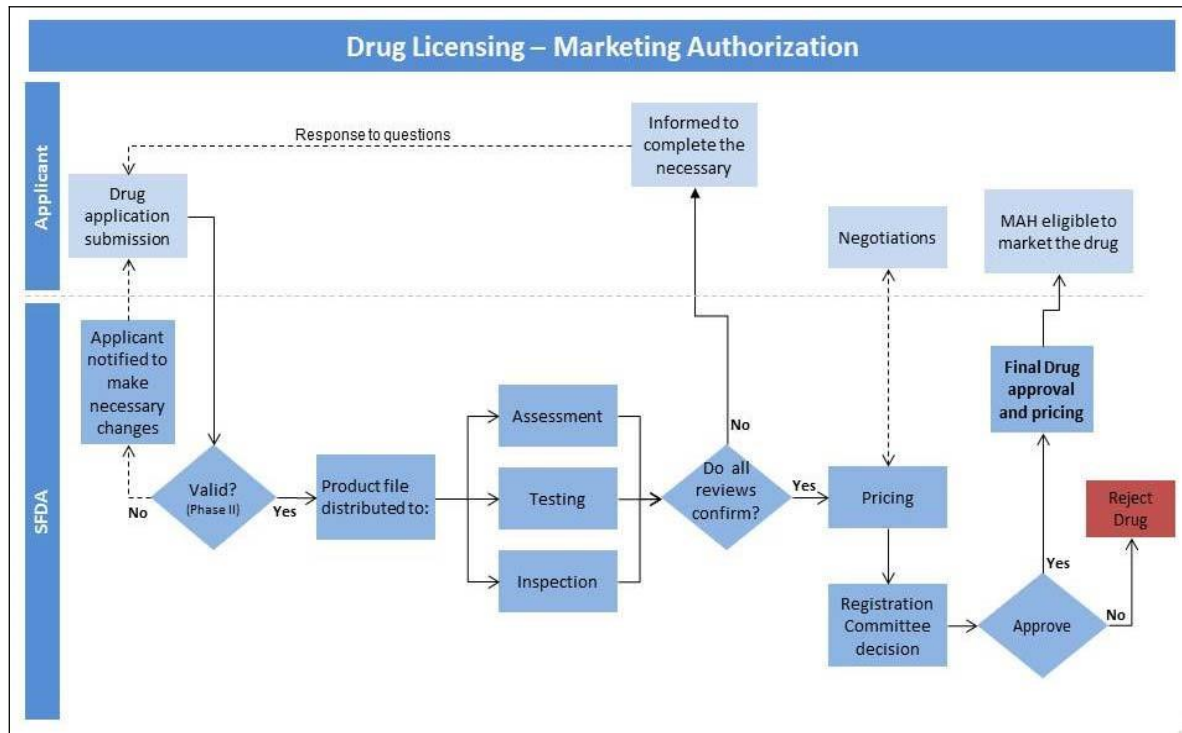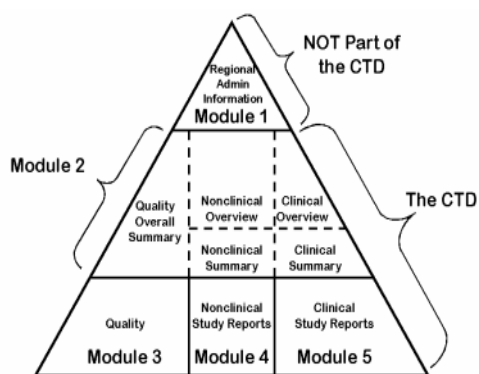**Figure 3: Submission process in Saudi Arabia**

Figure 4: Marketing Authorization procedure in Saudi Arabia

Figure 5: eCTD Triangle

SUMMARY AND CONCLUSION:

In Saudi Arabia, the regulatory body which legalizes medicinal products is the Saudi Food and Drug Administration. The Drug Regulatory Authorities are being set up in different nations over the globe. The administrative body guarantees compliances in different lawful and administrative parts of a medication. Each nation has its own particular administrative expert, which is mindful to implement the principles and directions and issue the rules to manage tranquilize improvement process, permitting, enrollment, assembling, promoting and naming of pharmaceutical items. It guarantees the security and adequacy of the therapeutic item promoted in the nation. SFDA gives distinctive assessments pathways to new substance elements (NCEs), generics, home grown and for veterinary medications, for pharmaceutical organizations to showcase their items in Saudi Arabia. There are different drug submission types under drug section like generics, New drugs, Biologics but all these submission types have common registration process which is explained in detail. Besides the stability and labeling requirements for drug samples on packing is also different. The information that to be submitted under these drugs submission types are based on ICH CTD and the eCTD specifications and the SFDA regulatory framework for drug approval.The fundamental point was to encourage the administrative understanding that represents item advancement and guarantee administrative consistence. The regulatory requirements to record a Medicinal Products in Saudi Arabia and the route pathways for different applications and entries was

studied.Navigation Pathway on how to access key regulatory information for Life-Cycle Management of selected product i.e., Medicinal Products (Drugs) was established and the current study provides a detailed regulatory information management of the act/regulations and guidelines for Saudi Arabia Market.

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