Regulatory Affairs Club

1st Club

Friday 20 December 2024

Club Founder
Dr. Mahmoud Bahgat

Co-Founder & Host:
Dr. Zeyad Anany

International RA Regulatory Affairs Club Sharpen your skills

Regulatory Affairs Club

SFDA Drug Registration insights

تسجيل الأدوية فى الهيئة العامة للغذاء والدواء السعودية

Online Zoom

9 pm Egypt - 10 pm KSA - 11 pm UAE

Dr. Amr Makboul
RA Manager
SAJA Pharmaceuticals KSA

SFDA
Drug Registration Insights

Presented by:

Dr. Amr Makboul

RA Manager SAJA Pharmaceutical

Jeddah, KSA

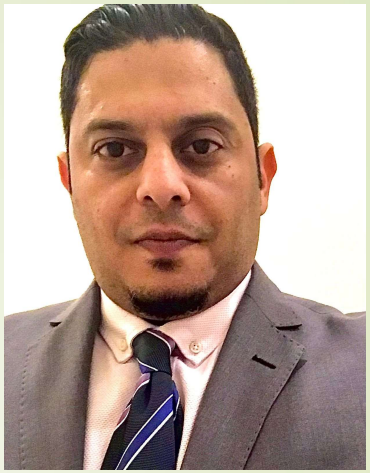
Online Session

15 November 2024

Agenda

- About Me
- Introduction
- Planning for Submission
- Dossier Requirements
- Guidelines
- Drug Application
- Submission
- Validation
- Assessment Process
- Accelerated Approval & Other Routes
- Approval Timelines
- Life Cycle Management

About Me



- I am a pharmacist graduated in 2005 from Asyut University, Egypt.
- +18 years of experience in the pharmaceutical industry including: R&D, analysis, production & RA.
- Since 2011, I have established the RA department from the scratch in SAJA Pharmaceuticals, Jeddah, Saudi Arabia.
- I have enriched the company profile with more than 50 products registered in the SFDA.
- I am dealing with a wide variety of different product types: Brands, Generics, biosimilars, health products.
- During my role in SAJA, I have been managing, training and qualifying colleagues in the department.

Introduction

sssager@sfda.gov.sa

Introduction

. The Saudi Food and Drug Authority (SFDA) was established as a government-independent entity that reports to the President of the Council of Ministers.

. SFDA is responsible for regulating drugs and medical devices in the kingdom, in addition to biological and chemical substances, food, and cosmetic products.

. The submission particulars have significantly transitioned from the paper format to CTD, then NeeS, and finally to the current eCTD dossier. Therefore, to help you prepare the drug file requirements, it is also essential to understand the details of the lengthy registration process.

sssager@sfda.gov.sa

Planning For Submission

- First of all you should set a proper planned date of submission based on business needs.
- Documents/file collection.
- Gap Analysis
- Secure the time consuming steps; ex: DMF RP submission, AWs preparation, patent searches, legalizations , draft application, payments..etc.
- Dossier compiling for submission

Requirements/Guidelines

Dossier Requirements

- **Dossier Files**

- New drug

  These are the innovative drugs equivalent to NDAs, including biosimilars.

  - All five modules are required.

- Generic drug
  - M1: All sections
  - M2: 2.1, 2.2, 2.3, 2.5.2
  - M3: All sections.
  - M4: N/A
  - M5: Only 5.1, 5.2, 5.3.1.2, 5.3.1.3, 5.3.1.4, 5.3.7, and 5.4

- **Dossier Format**
  - Human drug: eCTD.

Dossier Requirements

Module 1 Requirements	
1.0 Cover letter (2), (4), (5)	1.7 Certificates and Documents
1.1 Comprehensive table of content	1.7.1 GMP Certificate (1)
1.2 Application Form (2), (12)	1.7.2 CPP or Free-sales (1)
1.3 Product Information	1.7.3 Certificate of Analysis – Drug Substance / Finished Product (1)
1.3.1 Summary of Product Characteristics (SPC) (8)	1.7.4 Certificate of analysis – Excipients (1)
1.3.2 Labeling (8)	1.7.5 Alcohol-content declaration (1)
1.3.3 Patient information leaflet (PIL) (8)	1.7.6 Pork- content declaration (1)
1.3.3.1 Arabic leaflet (8)	1.7.7 Certificate of Suitability for TSE (1)
1.3.3.2 English leaflet (8)	1.7.8 The diluents and colouring agents in the product formula (1)
1.3.4 Artwork (Mock-ups) (8), (13)	1.7.9 Patent Information (11)
1.3.5 Samples (2), (3)	1.7.10 Letter of access or acknowledgement to DMF (7)
1.4 Information on the experts	1.8 Pricing
1.4.1 Quality (1)	1.8.1 Price list (10)
1.4.2 Non-clinical (1)	1.8.2 Other documents related
1.4.3 Clinical (1)	1.9 Responses to questions
1.5 Environmental Risk Assessment	Additonal data
1.5.1 Non-Genetically Modified Organism (Non-GMO) (1)	1.0 BE summary sheet (14)
1.5.2 GMO	
1.6 Pharmacovigilance	
1.6.1 Pharmacovigilance System (9)	
1.6.2 Risk Management Plan (9)	

Guidelines

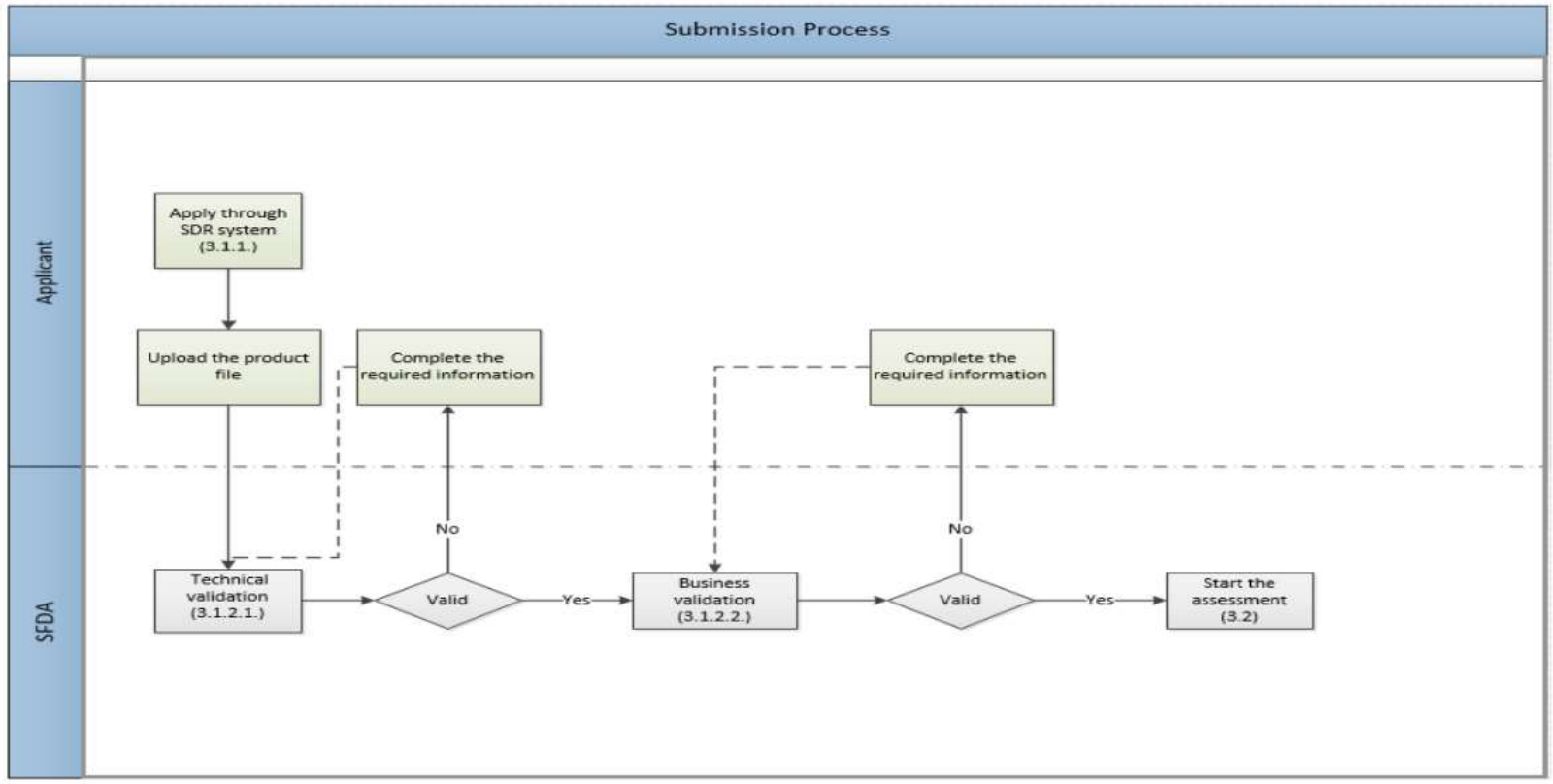
1. Data Requirements for Human Drugs Submission
2. Guidance for Submission
3. Regulatory Framework
4. Guidance for priority review
5. Registration According to Verification and Abridged
6. SFDA Stability Guidelines
7. SFDA guideline for Drug Master File (DMF) Submission
8. SFDA SPC, PIL, and Labeling requirements
9. SFDA PV guidelines
10. SFDA Pricing guideline
11. SFDA Patent guidelines
12. The naming of Medicinal Products
13. Graphic Design of Medication Packaging
14. SFDA Guidelines for Bioequivalence
15. SFDA Biowaiver Guidelines
16. SFDA Product Specific Bioequivalence Guidance
17. SFDA Biosimilars Guidelines

Drug Application

- Applicants must fill out the drug registration application and submit it through the Saudi Drug Registration (eSDR) system. It is a web portal available for local Saudi companies; it enables the applicants to do the following:
  - Fill out the application online.
  - Pay the application fees.
  - Submit the dossier.
  - Receive SFDA inquiries (RFI).
  - Receive SFDA decisions.
  - Print the registration certificate.
  - Submit variations & renewals (life cycle management).

Submission

- The following image shows the application submission process, which involves two layers of validations.



Validation

- **Technical Validation**
  - The SFDA receives the submitted dossier and performs an electronic validation on the compiled eCTD according to the SFDA eCTD Validation Criteria.

- **Business Validation**
  - This evaluation stage is a manual validation performed on the file after passing the electronic validation. It is a step before the initiation of the actual evaluation. It aims to reduce the number of obvious file deficiencies usually discovered during the evaluation process.
  - The SFDA will validate (not evaluate) the presentation and main compliance issues such as:
    - ✓ Application type & fees
    - ✓ MAH and Manufacturer legal status.
    - ✓ M1 Documents
    - ✓ Active Pharmaceutical Ingredient (API)
    - ✓ Finished Pharmaceutical Product (FPP)
    - ✓ Clinical Data

Assessment Process

- The drug approval process consists of multiple parallel evaluation routes within the drug sector. The parallel assessment allows departments to assess the application simultaneously. Below, we will go through each department route in more detail.

- Quality :
  - Active Pharmaceutical Ingredient (API)
  - Finished Pharmaceutical Products (FPP)

- Clinical Efficacy & Safety:
  - Clinical evaluation
  - Bioequivalence (BE)
  - Reference Safety Information (RSI)
    - Summary of Product Characteristics (SPC)
    - Patient Information Leaflet (PIL)

Assessment Process

- **Inspection :**

  - The inspection department is responsible for evaluating, inspecting, and granting the SFDA GMP approval for drug manufacturers. Applicants should expect mandatory GMP licensing for all drug manufacturers. The licensing process includes a physical site inspection by SFDA inspectors and payment of the inspection fees.

- **Testing:**

  - During the SFDA drug registration, you should expect a request for analysis samples and reference standards. Sometimes, you may be able to waive this request until the arrival of the first commercial batch to the Saudi market.

- **Pricing:**

  - The pricing evaluation is the last SFDA drug registration stage. It is not parallel to the other assessments. This department performs a pharmacoeconomic study on the drug and generates a report for the SFDA pricing committee. The committee will set the CIF price and ask the applicant to accept or appeal.

Assessment Process

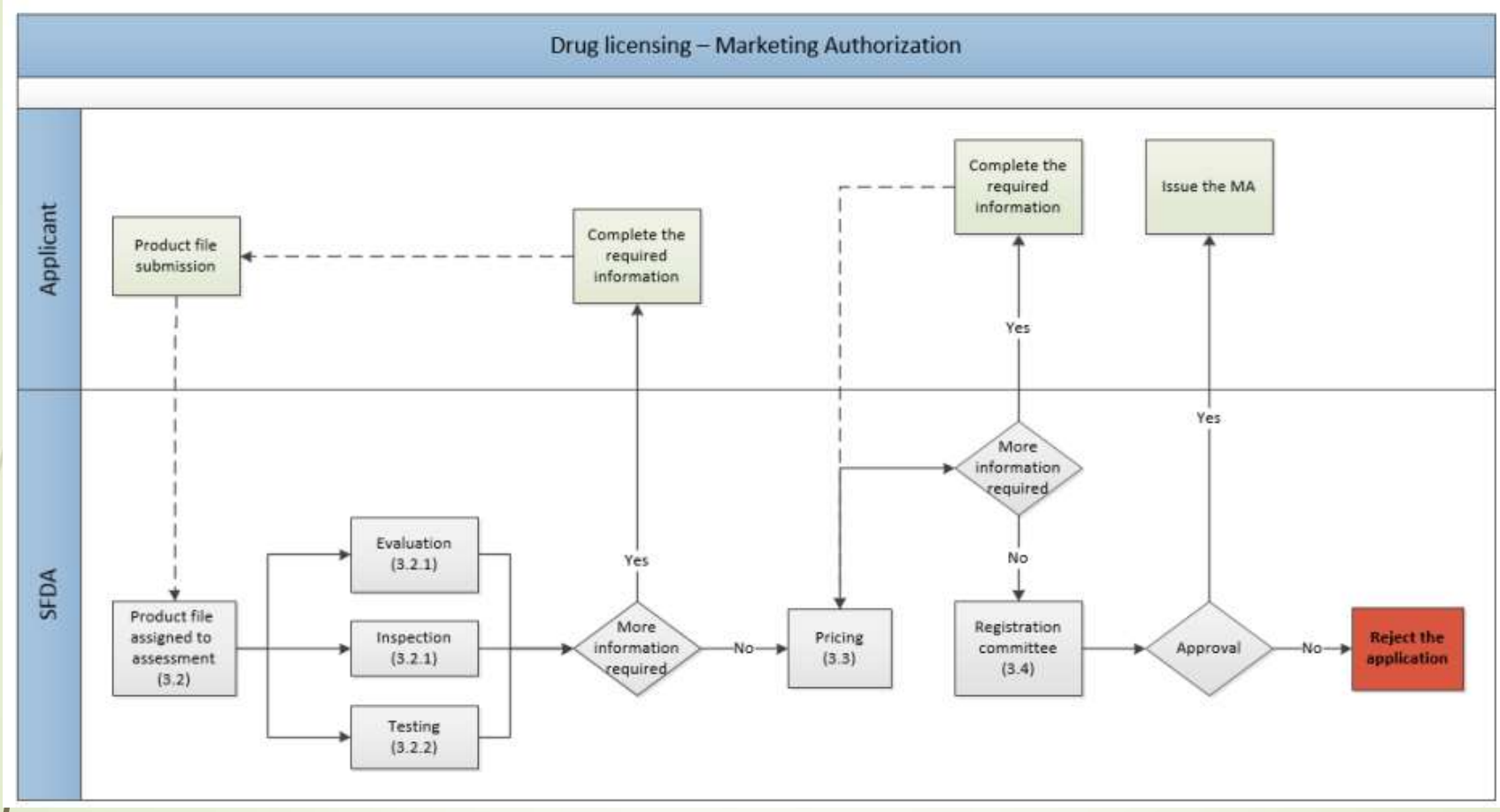
- **Registration Committee Decision/Product Licensing :**

  - The SFDA's registration committee reviews all departments' final comprehensive evaluation report and then issues the formal approval or rejection decision.

- **Registration Certificate:**

  - Approved drug applications will receive a registration certificate that entitles the company to market in Saudi Arabia. The validity of this certificate is five years.

Assessment Process



Accelerated Approval & Other Routes

- **Accelerated Approval Routes**
  - Drug priority review procedure
  - Verification and abridged registration

- **Other Routes and Designations**
  - Orphan Drug Designation (ODD)
  - Conditional Approval
  - Breakthrough Medicines Designation

Approval Timelines

- **Regular review pathway**

Registration phases	Technical Validation	Business Validation	Evaluation / Inspection	Pricing	Product licensing	Total Performance Target
	section 3.1.2.1	section 3.1.2.2	section 3.2.1	section 3.3	section 3.4	
No. of maximum waves	-	3	4		-	
Human Generic	-	10	120	20	15	**155**
Human New Drugs registered in SRA	-	10	245	20	15	**280**
Human New Drugs not registered in SRA	-	10	370	20	15	**405**
Human Biologics registered in SRA	-	10	245	20	15	**280**
Human Biologics not registered in SRA	-	10	370	20	15	**405**

Approval Timelines

- **Priority review pathway**

Registration phases	Technical Validation	Business Validation	Evaluation / Inspection	Pricing	Product licensing	Total Performance target
	section 3.1.2.1	section 3.1.2.2	section 3.2.1	section 3.3	section 3.4	
No. of maximum waves	-	3	4		-	
Human New Drugs registered in SRA	-	10	147	12	9	**168**
Human New Drugs not registered in SRA	-	10	222	12	9	**243**
Human Biologics registered in SRA	-	10	147	12	9	**168**
Human Biologics not registered in SRA	-	10	222	12	9	**243**

Approval Timelines

- **Verification & abridged pathway**

Registration phases	Technical validation	Business validation	Evaluation / Inspection	Pricing	Product licensing	Total Performance target
	section 3.1.2.1	section 3.1.2.2	section 3.2.1	section 3.3	section 3.4	
No. of maximum Waves	-	3	4		-	
Verification	-	5	15	5	10	**30**
Abridged	-	5	40	10	10	**60**

Life Cycle Management

- **Variation**
  - Whether it's an administrative or technical change to the drug file, the SFDA must review and approve (or notified) the variation application before the applicant markets the product.

- **Renewal**
  - Companies must maintain the drug license's validity at all times. When it is nearing expiry, they must submit a renewal application. Submission is allowed six months before the expiration date.

Thank You

شكرا

makboul_m@yahoo.com

+966540883059

Regulatory Affairs Club