الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Requirements for Formal Meeting between Drug Sector and Applicants

Version 3.1

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Saudi Food & Drug Authority

Drug Sector

For Inquiries *Drug.VP@sfda.gov.sa*

For Comments *Drug.Comments@sfda.gov.sa*

Please visit SFDA's website at
https://www.sfda.gov.sa/en/regulations?tags=2

for the latest update

Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
1.0	Drug Sector	4 December 2014	Final
2.0	Executive Directorate of Regulatory Affairs	11 November 2018	Update section 2 and application form
3.0	Executive Directorate of Regulatory Affairs	20 August 2019	New request form to request meeting with Pricing & Pharmacoeconomics Directorate.
3.1	Executive Directorate of Regulatory Affairs	07 April 2025	Update

Table of Contents

1. Introduction

This document is provided by the drug sector in order to assist applicants in the submission of meeting requests.

For the purposes of this document, formal meeting includes any meeting that is requested by an applicant following the request procedures provided.

2. Information of meeting requests:

To obtain the most efficient information from drug sector resources and before seeking a meeting, we advise the applicant(s) to look for their concern(s) which is probably stated in the SFDA website, drug sector page, under the guidelines section.

If the meeting is still required and to prevent any delay that might occur, the application of meeting request (attached) should be submitted to drug vice president's office via email (drug.vp@sfda.gov.sa). The meeting request should include adequate information in order to assess the potential utility of the meeting and to identify appropriate drug sector member(s) to discuss the proposed issues. The meeting request includes the following:

1. Applicant information: must include name of the contact person, phone number and email address.
2. A brief statement of the purpose and objectives of the meeting, which should include topics that the applicant is planning to discuss with the drug sector during the meeting.
3. A proposed agenda.
4. A list of proposed questions that include an explanation of the context and purpose of the question.
5. A list of all participants in the meeting with their titles who will attend the meeting from the applicant's organization.
6. Select type of meeting:
   - Face to face
   - Face to face and remote (Video / Teleconference)

<u>Important note:</u> If remote connection is needed, connection information **must be** sent in advance.

7. Select the executive directorate requested to attend the meeting.
8. Attach all supported documents, which are related to the request or will be presented in the meeting (including PowerPoint presentation, if any).
9. Suggested date and time of the meeting. The suggested times should be between 09:00 a.m. to 2:00 p.m. from Sunday to Thursday. The requested date and time might be changed later depending on the availability of the staff.

If for any reason, the meeting is requested to meet with Pricing & Pharmacoeconomics Directorate, then the applicant(s) should fill out (B form).

If the meeting for specific product, the applicant(s) should fill out (C form),

3. Assessment of the meeting request:

After the meeting request received, the drug sector will determine to accept or deny the request within five working days, then respond to the applicant via email. The response will be forwarded as soon as the proposed inquiry is studied by the drug sector.

a. Accepting the meeting request:

In case of accepting the request, email response will be sent to the applicant including date, time and place of the meeting. The applicant must send a confirmation email to attend the meeting; otherwise, the meeting will be cancelled.

b. Denying the meeting request:

If the meeting request is denied, email response will be sent to the applicant including justification for the denial.

c. Meeting rescheduling or cancelling:

If the meeting needs to be rescheduled due to any circumstances arise that necessitate the rescheduling, the applicant should send notification as soon as possible to allow preparation a new

appointment. If the meeting is cancelled by the applicant or the applicant does not attend the meeting, a subsequent request will be considered as a new meeting request.

4. Meeting procedure:

The meeting will be managed by the drug sector member and will be based on the meeting request and agenda. During the meeting the applicant has to take into consideration that the drug sector member has the right to cancel the meeting if the applicant does not commit to the meeting request.

Before the end of the meeting, drug sector member and the applicant should summarize the important discussion points, agreements and clarifications.

Appendix: Application of general meeting request:

(A form)

Applicant information	**Full Name**		
	Job title		
	Contact information (Email and phone number)		
	Organization		
Purpose of the Meeting: - A brief description of the reason for the meeting. - Expected goals of the discussions.			
Participants		**Name**	**Title**
Type of meeting		☐ **Physical Meeting**	
		☐ **Virtual Meeting**	
Special Arrangements (Any special arrangements that need to be made (e.g., presentations,..etc).)			
Attachment If there are any documents or materials relevant to the discussions.			
Proposed Department(s)			
Suggested date and time (*Three suggestions should be addressed*)		**Date**	**Time**
Expected time for discussions. (Minutes, hours)			

Pricing & Pharmacoeconomics Directorate

(B form)

☐ New Registration ☐ Price Revision ☐ Pricing Appeal

☐ Renewal ☐ Variation ☐ Other:

Product Name		**Date**	**/ / 14** **/ / 20**	**Letter No.**	
MAH		**Agent**			

1. Product Information:

Registration No.		**Reference No.**	
Active Ingredient		**Strength/ Unit or Conc.**	
Dosage Form		**Route(s) of Administration**	
Pack size		**Therapeutic class**	
Manufacturer		**Country of manufacturer**	

2. Price Information:

Current Price		**Proposed Price by Company**	
CIF		**CIF**	
Public		**Public**	

3. Purpose and Objective(s):

4. Additive information:

☐ Clinical Data ☐ Clinical studies ☐ Case reports ☐ Economic studies ☐ Guidelines	☐ Sample	☐ Others:	

Request for scientific/ regulatory meeting form for specific product

(C form)

Registration Pathway / Designation:

☐ **Regular** ☐ **Priority** ☐ **Breakthrough** ☐ **Conditional Approval**

☐ **Abridge / Verification** ☐ **Orphan** ☐ **Other:**

Product Name		**MAH**	
Manufacture		**Agent**	
Product Type	☐ **Human Product** ☐ **Veterinary Product** ☐ **Herbal/ Health Product**		

1. Product Information:

Name of the active substance (if advice is not product specific please write 'Broader Scope advice')	
Proposed indication(s)	
Is product submitted to SFDA?	☐ Yes, if yes please specify Sub product and request number …… ☐ No
Type of product	☐ Biological ☐ Generic ☐ New ☐ other
Pharmaceutical form(s)	

2. Your development plans

Is the advice connected with a future	☐ Clinical Trial Authorization (CTA) application for a specific study(ies) ☐ Marketing Authorization Application (MAA) ☐ General development advice including both CTA and MAA elements
Key Regulatory procedure in the SFDA on which advice is sought	☐ Clinical Trial Authorization ☐ New Product Authorization ☐ New Therapeutic Indication ☐ Product Variation ☐ Product Renewal ☐ Product Cancellation ☐ appeal to Decision
Specific Advice sought (this will guide which SFDA experts will give advice	☐ Quality ☐ Non-clinical ☐ Clinical ☐ Regulatory ☐ Pharmacovigilance/Risk management plan
Please list the key objectives for the advice sought and provide any additional comments relevant to the request. (Please separately attach a draft of the proposed questions)	

3. Preferences for a meeting/written only advice

Preferred meeting dates		
Unavailable meeting dates		
Do you wish to request written only scientific advice without a meeting?		
Participants	**Name**	**Title**

4. Other procedures related to product

Is this product currently under assessment in any regulatory authorities?	
Has previous SFDA scientific advice been sought on this development programme?	
If 'Yes' please provide details and attach all advice received	
Has scientific advice been sought on this development programme from other agencies?	
If 'Yes' please provide details and attach all advice received	
Has a previous MAA or variation application been made for this product for this indication?	
If 'Yes' please provide the details	