الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Requirements for Formal Meeting between Drug Sector and Applicants

Version 3.0

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Drug Sector

Saudi Food & Drug Authority

Please visit SFDA's website at http://www.sfda.gov.sa/en/drug/drug_reg/Pages/default.aspx for the latest update

For meeting request	*Drug.VP@sfda.gov.sa*
For Comments	*Drug.Comments@sfda.gov.sa*

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 & Pharamcoeconomics Directorate.

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 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)

   Important note: 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 & Pharamcoeconomics Directorate then the applicant(s) should fill out (B form).

3. Assessment of the meeting request:

After the meeting request received, the drug sector will determine to accept or deny the request 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.

4. 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 applicant or the applicant does not attend the meeting, a subsequent request will be considered as a new meeting request.

5. 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.

6. References:

- The FDA Guidance for Industry Formal Meetings between the FDA and Sponsors or Applicants, May 2009.
- The Swiss agency for therapeutic products.

Appendix: Application of meeting request:

(A form)

1. Applicant information *(Include name of contact person, phone no. and e-mail) address.*		
2. Meeting purpose and objective(s)	• **Purpose**: • **Objective(s)**:	
3. Proposed agenda	**Agenda point(s)**	**Estimated time (Min.)**
	Note: The time should be determined for each point.	**Total Estimated Time:**
4. Proposed question(s)		
5. List of participants from the organization	**Name**	**Title**
6. Type of meeting	☐ **Face to face**	
	☐ **Face to face and remote (Video / Teleconference)** ❖ *Connection information:*	
7. Drug sector executive directorate	☐ **Executive Directorate of Regulatory Affairs**	
	☐ **Executive Directorate of Pharmaceutical Products Evaluation**	
	☐ **Executive Directorate of Pharmacovigilance**	
	☐ **Drug Availability and Tracking Centre**	
8. List of document(s) attached to support the meeting request		
9. Suggested date and time *(Three suggestions should be addressed)*	**Date**	**Time**

You can fill this form by using Adobe Acrobat Reader

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Pricing & Pharamcoeconomics 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: