



Kingdom of Saudi Arabia
Saudi Food & Drug Authority



Manual of the Controls and Procedures of Holding Scientific Lectures directed to Healthcare Practitioners

Version No. 3

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Introduction

We refer to Paragraph (4) of Article (31) of the Implementing Regulations of Law on the Pharmaceutical and Herbal Establishments and Products provides for as follows: “Scientific lectures directed to healthcare practitioners and campaigns of raising awareness about the diseases and health education shall be subject to the conditions and controls approved by the Saudi Food & Drug Authority (SFDA)”. In addition, Paragraph (5) of Article (31) of the said Implementing Regulations states that: “SFDA approval shall be obtained before holding scientific lectures directed to healthcare practitioners and publishing campaigns of raising awareness about the diseases and health education directed to the public”. Based on the tasks of SFDA associated with organizing the market of pharmaceutical and herbal products and scientific lectures held under the sponsored of pharmaceutical companies or their representatives and directed to the healthcare practitioners and for realizing the importance of continuous health education, this Manual is issued. This is to determine the controls and procedures of holding scientific lectures directed to the healthcare practitioners.

Definitions:

The following words and expressions shall have the meanings shown in front of each one of them:

- **KSA:** This shall mean the Kingdom of Saudi Arabia.
- **SFDA:** This shall mean the Saudi Food & Drug Authority.
- **Scientific Lecture:** This shall mean each gathering targeting the discussion of a health or scientific theme produced by a lecturer in the attendance of a number of healthcare practitioners under the full, partial or indirect sponsorship of pharmaceutical companies or their representatives.
- **Products:** This shall mean the pharmaceutical and herbal products.

Scientific Lectures:

(3-1) General Conditions of Scientific Lectures:

- 1- The Attorney or third party may apply for holding scientific lecture to the pharmaceutical companies or any other entity delegated by them.
- 2- The entity organizing the scientific lectures shall respond to the representative of SFDA and follow up all that submitted.
- 3- The scientific lectures include the attendance lectures and virtual lectures.
- 4- SFDA shall be obtained if the lecture is going to be held outside KSA remotely (virtual lectures) in case the number of healthcare practitioners attending and resident in KSA exceeds 45% of the attendees in the lecture itself.

(3-2) Controls of Holding the Scientific Lectures:

1- SFDA approval shall be obtained before holding any scientific lecture.

2- The financial consideration of (SAR 1,000) shall be paid regarding the application of approving the holding of one event associated with a scientific lecture directed to healthcare practitioners to the system of the issue of invoice for paying the financial consideration.

3- The organizer of the scientific lecture shall abide by the theme, place, date, time, lecturers and session manager as included in the application submitted by it.

4- If it is impossible to hold the scientific lecture or the Company desires to defer the same, then SFDA shall be notified of the same before the actual date of holding the scientific lecture via the following email: promo.drug@sfda.gov.sa.

5- In case of the desire to make a change regarding the scientific lecture agreed, the following shall be observed:

- SFDA shall be notified of such change via the following email: promo.drug@sfda.gov.sa before the actual date of holding the lecture. This is provided that the application shall include the details of the change required.
- The change application does not include the change of the city in which the lecture is held (except for the virtual lectures).
- In case of changing the lecturer or session manager, then the requirements of approving the same shall be attached.
- Copy of the lecture shall be attached to be approved in advance as accompanied by the request for the new change.

6- The approval shall be limited to the scientific lectures directed to health practitioners only, regardless of the number of health practitioners attending the lecture, whether it is just one health practitioner or more.

- 7- The applicant shall determine the class targeted of the scientific lectures.
- 8- The applicant shall fill all the paragraphs of the forms required and shall further complete the form of scientific curriculum vitae of all attendees and session managers. This is provided that names shall be added as certified in the official documents.
- 9- The session manager shall not be the same lecturer in the scientific lectures.
- 10- The applicant shall abide by the approval, rejection, amendment or addition regarding the scientific lecture as seemed appropriate to SFDA after presenting the application.
- 11- It is a condition that the application shall be submitted for holding one scientific lecture. There is no objection that the one application is for more than one city in KSA.
- 12- No propaganda or advertisement shall be made for the products in scientific lectures, whether the product is registered or unregistered.
- 13- No doubt shall be raised about the effectiveness or quality of other products registered in KSA.
- 14- The scientific lecture shall not include any statement causing Abuse to the products.
- 15- The scientific lecture shall not include any mistake information about the products.
- 16- It shall not be indicated that any product does not have any side effects or toxic risks at all.
- 17- No comparison shall be made between the active substances of other products without the existence of considered clinical studies.

- 18- It is prohibited to cause Abuse to any entity be explicit or indirect offense.
- 19- It is prohibited to submit cash payments or gifts to the attendees.
- 20- It is prohibited to distribute products free of charge among the attendees or to sell them to the attendees.
- 21- It is prohibited to offer luxurious programs (sporting or social programs).
- 22- Hospitality shall be limited to the persons invited and directly connected to the scientific lecture.
- 23- The content of the scientific lecture shall not contradict with the teachings of the Islamic Sharia or habits and traditions of the Saudi community.
- 24- The requirements of the Saudi Code of Ethics for Practicing the Marketing of Pharmaceutical Products in KSA and published on SFDA website shall be observed.
- 25- The financial consideration relating to the application for approval of holding the scientific lecture shall not be recovered, whether the approval is obtained or not.
- 26- In case a letter is issued by SFDA (for deferring the approval or determination of the application), the applicant shall answer the said letter within (5) business days from the issue of the letter.
- 27- SFDA shall be provided with the link of having access to the virtual scientific lecture before the date of holding the lecture. A copy of the approval for holding the lecture shall be attached via the following email:
promo.drug@sfda.gov.sa.
- 28- The scientific lecture held in attendance shall be held in a place proper for the scientific lectures.

(3-3) Requirement for the Approval of Holding the Scientific Lectures:

First: The application shall be prepared as including the following:

- 1- Official letter in Arabic language directed to the Section of Propaganda and Advertising License of SFDA as holding the logo and seal of the Company to ask for holding the scientific lecture (20) days as a minimum before holding the lecture.
- 2- The application form of holding the scientific lecture shall be completed. Such application shall include the following:
 - Form (1): Form of application for holding a scientific lecture.
 - Form (2): Form of abstract of the scientific lecture.
 - Form (3): Form of curriculum vitae of the lecturer/s.
 - Form (4): Form of curriculum vitae of the session manager/s.
- 3- A copy of (rating card and professional registration) or (professional registration card) of Saudi Commission for Health Specialties for the lecturer and session manager of its equivalent shall be attached if the lecturer works outside KSA.
- 4- The financial consideration shall be paid and copy of the invoice of the financial consideration shall be attached to the system of invoice issue.

Second: The application shall be submitted after being prepared by any of the following ways:

- 1- The application shall be submitted by being directed to the Propaganda and Advertising License of the Operation Sector. This is provided that all the requirements mentioned hereinabove shall be printed.
- 2- The application shall be sent via the following email Communications.Adm@sfd.gov.sa All attachments shall be included as one attach of PDF format. The official letter shall be in the first page of the file. The client shall be answered by the number of registering the application.

(3-4) Conditions of Lecturer in Scientific Lecture:

- 1- The lecturer shall be an employee by the Company or its attorney.
- 2- The lecturer shall be a holder of a university degree having relevant competency relevant to the lecture submitted.
- 3- The lecturer shall have considered scientific efficiency.
- 4- The lecturer shall submit the documents and certificates in case they are requested by SFDA.

(3-5) Conditions of Session Manager in Scientific Lecture:

- 1- The session manager shall be a physician or pharmacist.
- 2- The session manager shall be a Saudi national.

4- Forms:

You can obtain the forms from the website of SFDA (field – medicines – forms – form of applying for holding a scientific lecture)

Form No. (3)

Form of Applying for Holding a Scientific Lecture

Information about Applicant:

| | | | |
|--|--|-------------------------------------|--|
| Company name | | Date of submitting the application: | |
| Person delegated to submit Authorized applicant application: | | Position: | |
| Email address: | | Mobile number: | |

Main information about the scientific lecture:

| | | | |
|---|--|-------------------------------------|--|
| Lecture title/theme: | | Date of submitting the application: | |
| Targeted class: | | Number of attendees expected: | |
| Way of presenting the scientific lecture: <input type="checkbox"/> Attendance lecture <input type="checkbox"/> Virtual lecture <input type="checkbox"/> All of the foregoing | | | |

Information about Applicant:

| | | | | | |
|---|--|--|--|--|--|
| Holding frequency | | | | | |
| Day | | | | | |
| Date in H.A. | | | | | |
| Date in A.D. | | | | | |
| City | | | | | |
| Place of holding * Especially the lecturers held in attendance | | | | | |
| Contac number of place | | | | | |
| Time / period (am/pm) | | | | | |
| Lecturer's name | | | | | |
| Session manager's name | | | | | |

Declaration:

I,, declare that the information included in this Application are correct and actual. I undertake not to hold the scientific lectures unless the final approval of SFDA is obtained. I also undertake to be fully responsible in case of the violation of the controls and procedures of approval for holding the scientific lectures.

Signature: Date:

Form (3)

Form of Curriculum Vitae of the Lecturer/s

Main information:

Name:

Nationality:..... Date of birth:.....

Contact information (tel. / mobile):

Email address:.....

Employer:..... Position:.....

Employer's contact means:.....

State / City:.....

Number of licenses by the Saudi Commission for Health Specialties (or its equivalent inside KSA) accompanied by copy of the registration card:

Scientific details:

Major:..... Accurate major:.....

Last academic qualification:

1- 2- 3-

Scientific Related Scientific fields:

Scientific lectures / papered submitted in the same major:

1- 2- 3-

4-

Declaration:

I,, declare that the information included in this Form are correct and actual. I shall bear the full responsibility in case of violating the same.

Signature: Date:.....

Form (4)

Form of curriculum vitae of the session manager/s

Main information:

Name:

Status card No.:

Contact information (tel. / mobile): Email address:
.....

Employer: Position:

Employer's contact means: State / City:

Number of license by the Saudi Commission for Health Specialties (or its equivalent inside KSA) accompanied by copy of the registration card:

Scientific details:

Major: Accurate major:

Scientific details:

Major: Accurate major:

Declaration:

I,, declare that the information included in this Form are correct and actual. I shall bear the full responsibility in case of violating the same.

Signature: Date:

