Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Transparency and Disclosure

Procedures Guide for Financial Support Provided by Medical and Food Companies

Vision and Mission of the Saudi Food and Drug Authority

Our vision...

Is based on scientific principles to enhance and protect, aiming to become a globally leading authority in public health.

Our mission...

Is to protect the community through effective legislation and regulatory systems to ensure the safety of food, drugs, medical devices, cosmetics, pesticides, and feed.

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Introduction

The relationship between medical companies supplying drugs and medical devices or food companies on one hand, and healthcare practitioners and providers on the other hand, is of paramount importance and clear impact on providing suitable medical and nutritional products for patients and beneficiaries. This relationship also benefits in the exchange of medical, nutritional, and technical information related to the quality and safety of medical and nutritional products, as well as their safe use. These relationships can benefit patients and beneficiaries by providing financial support for research related to the development of pharmaceuticals, herbal products, infant formula, and children's foods, as well as nutritional and medical food products. They also contribute to the therapeutic clinical research and technical research to evaluate the efficiency and safety of medical devices. Additionally, they contribute to the safety of practices to achieve the best therapeutic practices and the exchange of important information related to how drugs, pharmaceuticals, herbal products, infant formula, children's foods, and nutritional and medical food products can improve the health conditions of patients.

Legislative Basis for the Guide:

The Executive Regulations of the Authority's System issued by the Board of Directors Decision No. (M/6) dated 25/1/1428 AH, Article Two: "The basic purpose of the Authority is to regulate and monitor food, drugs, devices, and related medical products and to develop the necessary regulations for them.

Objectives of the Guide:

The guide aims to achieve the following:

1. Regulate and clarify financial relationships between medical or food companies and healthcare providers and institutions, and reduce the possibility of illegal or unethical financial relationships.

2. Enhance transparency in research funding (enhance transparency in all procedures related to the healthcare field).

3. Protect the rights of patients and beneficiaries by ensuring the integrity of medical decisions based on scientific and professional principles.

4. Reduce the possibility of conflicts of interest in regulatory decision-making.

5. Document direct and indirect financial support provided by medical and food companies.

6. Ensure compliance with the system for trading breast milk substitutes and its executive regulations issued by Royal Decree No. (M/49) dated 21/9/1425 AH, as well as relevant regulations and decisions.

Definitions:

Medical Companies:

Include commercial entities owning one or more companies operating in the manufacture, marketing, or distribution of pharmaceuticals, herbal products, medical devices, or similar items, such as pharmaceutical companies, herbal product companies, and medical device companies, holding licenses valid in the Kingdom of Saudi Arabia.

Food Companies:

Include manufacturers and companies engaged in the production, import, distribution, or marketing of food products with nutritional and medical uses, such as:

- Infant formula.
- Follow-on formula (6 - 36 months).
- Formula designated for special medical uses (0 - 12 months).
- Products used for special medical purposes containing all nutritional elements (complete nutritional formula).
- Products used for special medical purposes not containing all nutritional elements (incomplete nutritional formula).
- Products for metabolic diseases.

Healthcare Practitioner:

Any individual licensed to practice a healthcare profession in the Kingdom of Saudi Arabia.

Healthcare Institutions:

Public or private institutions licensed to provide healthcare services, including hospitals, primary healthcare centers, public medical complexes, specialized medical complexes, clinics, radiology centers, medical laboratories, day surgery centers, healthcare support services centers, and ambulance transport service centers.

Conflict of Interest:

Exists when there is a conflict between professional duty and personal interest, i.e., conflict between the healthcare practitioner's needs and responsibilities towards the patient.

Transparency Report:

A report submitted to the authority by healthcare practitioners and medical or food companies, disclosing financial or material transactions.

Third Party:

Any natural or legal person or entity other than the pharmaceutical, herbal, medical device, or food company (the first party) or the healthcare practitioner (the second party), involved in the financial relationship.

Pharmaceutical Product (Drug):

Any product manufactured pharmaceutically containing one or more substances used externally or internally in the diagnosis, treatment, or prevention of diseases.

Herbal Product:

Any plant or herb with medicinal claims prepared in pharmaceutical form.

Scope of the Guide (Field):

This guide applies to healthcare institutions, healthcare practitioners, and food companies, encompassing pharmaceuticals, herbal products, medical devices, as well as products such as infant formula, children's foods, and nutritional and medical food products.

The required data from healthcare practitioners and healthcare institutions, and the data required from companies when disclosing support provided to healthcare practitioners and institutions, are as follows:

For Healthcare Practitioners:

- Title (Eng, PhD, Dr, Mr, Miss).
- First name of the practitioner.
- Last name of the practitioner.
- Specialization.
- Classification and professional registration number from the Saudi Commission for Health Specialties.
- National ID / residency number for non-Saudis.
- Email address.
- Mobile number.
- Nature of financial support, whether transfer or cash.
- Amount paid.
- Purpose of the support.
- Date of support.

For Healthcare Institutions:

- Institution code.
- Institution location.
- City.
- Benefiting department/section.
- Nature of financial support, whether transfer or cash.
- Amount paid.
- Purpose of the support.
- Date of support.

Annual disclosure mechanism

1. Disclosure is made once a year according to the following table

The stage	Start date	End date	Duration
Sending the data	February 1	March 1	1 month
Data review (by the healthcare practitioner with the companies)	April 1	April 30	1 month
Data review and editing (by the company)	April 1	May 15	A month and a half
Disclosure approval	By June 30	-	-

Sending the data: February 1 - March 1

During this stage, data related to the previous year is sent via the transparency and disclosure portal.

Data review (by the healthcare practitioner with the companies): April 1 - April 30

During this stage, data is reviewed and verified for accuracy by the healthcare practitioner via the transparency and disclosure portal.

Data review and editing (by the company): April 1 - May 15

During this stage, the company reviews and edits as necessary.

Disclosure approval: By June 30

During this stage, the disclosure is reviewed and approved by the Saudi Food and Drug Authority.

2. Receiving disclosure data for the year 2020 will be limited to the following table:

The stage	Start date	End date	Duration
Sending the data	July 1	September 1	1 month
Data review (by the healthcare practitioner with the companies)	October 1	November 15	A month and a half
Data review and editing (by the company)	October 1	November 30	2 months
Disclosure approval	By December15	-	-

Sending the data: July 1 - September 1

During this stage, data related to the year 2020 is sent via the transparency and disclosure portal.

Data review (by the healthcare practitioner with the companies): October 1 - November 15

During this stage, data is reviewed and verified for accuracy by the healthcare practitioner via the transparency and disclosure portal.

Data review and editing (by the company): October 1 - November 30

During this stage, the company reviews and edits as necessary.

Disclosure approval: By December 15

During this stage, the disclosure is reviewed and approved by the Saudi Food and Drug Authority.

Nature of financial transactions

The concerned parties must inform the Saudi Food and Drug Authority .of all details of financial support provided if it exceeds 50 riyals or a total of 500 riyals in one year, including but not limited to:

1. Consultation fees.
2. Lecture fees.
3. Training course fees.
4. Providing care for healthcare practitioners to attend educational events.
5. Grants for research and educational grants (restricted and unrestricted).
6. Sponsorship of seminars and conferences.
7. Hospitality expenses.
8. Provision of scientific materials (such as books or tools).

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