

Transparency and Payments Disclosure Guidance for Medical Companies

Version 2.2

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Version 2.1

Please visit SFDA's website at for the latest update

Comments to Drug Sector Drug.Comments@sfda.gov.sa

Comments to Medical Device
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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

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I. Introduction

The relationship between medical companies supplying medicines and medical devices on the one hand, and health care professionals (HCPs) and health care institutions (HCIs) on the other hand is important and has a clear impact on the availability of medical products proper to the needs of patients and beneficiaries. This relationship is also useful in the exchange of medical and technical information regarding the quality, safety medical products and their safety using. These relationships can benefit patients by providing researchers with funds for drug development and clinical research or scientific research and evaluating the efficacy or safety of medical devices, sharing ideas for best clinical practices, and exchanging information on how new drugs can improve patients' conditions.

Generally, medical companies like a pharmaceutical companies and medical devices companies provide financial support related to HCPs and HCIs. These financial relationships include payments for consulting, sponsorships for conferences or speaking engagements, pay for travel, donations for research, and others either direct or indirect. Consumer advocates, therefore, have long been concerned about the conflicts of interest and demanded transparency in these relationships.

Because of the interest in making such relationships transparent, a number of countries have begun initiatives to this end. To ensure continued public trust, many countries have developed specific laws to bring transparency to the financial relationships among pharmaceutical companies, HCPs, and HCIs to ensure that the trust of society maintained.

II. Glossary and Abbreviations

- Medical companies: includes Commercial Institutions that owner of one or more of the company engaged in the manufacture, marketing, or distribution of pharmaceutical products or medical devices or the like, such as pharmaceutical companies and medical devices companies and have licensed to operate according to existing regulations in the Kingdom of Saudi Arabia.
- Health care professional (HCP): is any person licensed to practice a health care profession in the Kingdom of Saudi Arabia.
- Health care institution (HCI): is a public or private health care facility that provides health care services, including hospitals, primary health care centers, general medical complexes, specialized medical complexes, clinics, radiology centers, medical laboratories, one-day surgery centers, health care service support centers, and ambulance transport service centers.
- Conflict of interest: is a contradiction between the professional or personal interests and needs of an HCP and his or her professional responsibilities toward a patient.
- Transparency report: The report submitted by medical companies discloses the names of HCPs and HCIs that have received payments or other transfers of value.
- Beneficiary Third party is a person or organization other than the pharmaceutical company and medical devices (first party) or HCP (second party) involved in the financial relationship.

III. Objectives of the Disclosure project:

The main objective of this project is to improve transparency of financial relationships among medical companies, HCPs, and HCIs. Such transparency will help achieve the following:

1. Organizing and clarifying financial relationships between medical companies, HCPs and HCIs, and limiting any potential of illegal or unethical relationships.
2. Improving transparency of research funding (Increase transparency in all health-related procedures)
3. Protect the patient rights and beneficiaries by ensuring the integrity of medical decisions based on scientific and professional basis.
4. Minimizing potential conflicts of interest for regulatory related decisions
5. Documentation of direct and indirect financial support data provided by medical companies.

IV. Nature of Payments

Medical companies must report to Saudi Food and Drug Authority (SFDA) all financial supports provided if the amount exceeds 50 SR or 500 SR per year, including but not limited to, the following activities:

1. Consulting fees
2. Speaking fees
3. Training fees
4. Sponsorship of HCPs to attend an educational event
5. Research or educational grants (restricted or unrestricted)
6. Symposium or conference sponsorships
7. Hospitality
8. Supplying scientific materials (e.g., books or instruments).