



SCDM's CODE OF ETHICS FOR MARKETING

MEDICAL DEVICES

1. INTRODUCTION

It is necessary that the marketing of medical devices be governed by ethical standards that guarantee any purchasing decision, which shall always be based on fundamental attributes such as Quality, Safety and Effectiveness.

These principles shall ensure that patients are the most important factor in a decision to purchase any device, and any violation of these principles shall affect the credibility and trustworthiness of anyone displaying such conduct.

Ethical interactions between medical device marketing Companies and Healthcare Institutions are important for implementing new products and Technologies and promoting innovation, while basically providing for respect for patients.

Any ethical interaction between medical device marketing Companies and Healthcare Institutions shall be based on the following **five fundamental Principles**:

Integrity. This means honest, sincere and fair relationships with all of the parties.

Independence. This means that the interactions of Healthcare Professionals ("PS") with Companies should not bias a medical decision in the best interest of the patient.

Pertinence. This means that agreements are made in accordance with appropriate business standards, and they are exact as well as exempt from corrupt purposes.

Transparency. This means that companies and Healthcare Professionals are open in terms of significant financial relationships between the parties.

Furtherance. This means that relationships are aimed at making advances in medical technology, innovation and patient care.

Interactions between medical device marketing companies and Healthcare Institutions **must also abide by the following additional Principles:**

1. **Cooperative interactions between companies and healthcare professionals are to maintain independent decision-making on the part of healthcare professionals** and guarantee public trust in the integrity with which products are selected, treatment and the different types of care afforded to patients to the extent that:
 - The agreement is to meet a legitimate business need or be responsive to a legitimate interest of the Company, and payments under the agreement are not to be contingent upon any purchases or prescriptions of products, and they are to be consistent with the fair market value.
 - Whenever interactions are in connection with rendition of services, these should be rendered by such persons or entities which have training whose evidence may be provided, experience, know-how or the ability to render services.

2. **Consulting contracts between companies and healthcare professionals should fund research and development** for making advances in medical science, new technological development, current product and service optimization and better quality and efficiency in patient care. Consulting contracts are not to be used as a means for securing inappropriate incentives. "Inappropriate incentive" means any "remunerated arrangement" for the purpose of obtaining any inappropriate influence in the medical decision on selecting a product. Contracts are to include comprehensive compensation agreements with the healthcare professional or institution; that is to say, all payments by way of fees, royalties and benefits, including any product and advertising samples whenever these are required.

3. **Financial support of companies for educating healthcare professionals**, for instance, by way of support for third-level educational programs and educational grants, **are to protect independent medical education, and they should not be used as a means to gain inappropriate incentives.**
 - 1.- Such financial support:
 - May be allocated to specific educational activities and not to promotional purposes.
 - May not include any product use or act as hidden discounts

- Conference invitations made to healthcare professionals for professional or educational purposes in the medical field are not to be contingent upon any obligation to prescribe or purchase any products.

2.- Locations where conferences and symposia take place are to be adequate for and ancillary to the main purpose of the event.

3.- No financial support shall be provided to non-educational activities, such as sporting and artistic events.

4. **Companies may deliver training to healthcare professionals in a specific medical device and its use and application to facilitate the safe and effective use of medical technologies.** Training is understood as a demonstration targeting a healthcare professional on the safe and effective use of a medical device. These training sessions include training sessions in new products or a specific use or training for updating.
5. **Companies are not to provide any entertainment and recreation to healthcare professionals as inappropriate incentives.** Any attendance to entertainment events, consent or agreement to receive any gift, commission or gratuity is to be deemed inappropriate for fostering appropriate business relationships.
6. **Meals, Trips, Lodging.** These expenses incurred when attending conferences or symposia or due to expenses related to a service payment arrangement are to be at adequate rates; they are not to include any luxury hotels, resorts, high-priced meals, entertainment, recreation and any expenses incurred by healthcare professionals for companions or spouses.
7. **Company donations to charity or other philanthropic purposes** should fund well-known (bona fide) charity organizations and missions, and they should not be a means to benefit any healthcare professional in particular or used as a marketing tool in terms of specific transactions with customers; they are to be made in a consistent manner and documented adequately in accordance with the following provisions:
 - a) Donations shall be used by Organizations pursuant to current law.
 - b) No donation shall bind any Organization to purchase, use, recommend or arrange for the use of any product of the donor Company.
 - c) None of the parties is to make any payment or offer or transfer any valuable to any government official [or] employee, any political official or candidate to public office or any other third party related to a transaction in such a way as to deem that it is corrupt in accordance with the Law on Transparency of the State.

8. **Free products are not to be used as a means for inappropriate incentivisation.** Nevertheless, companies may provide healthcare professionals with reasonable amounts of products for purposes of evaluation and demonstration. Occasional presents may be given to healthcare professionals; these are to have a scientific educational value, and they should not have the motivation to exercise any inadequate influence or gain reciprocity; further, their cost should be reasonable, and they should be consistent with circumstances.
9. **Educational Grants** are to be given solely to obtain more information on the safety and performance of a medical device and not as a means to promote a product or influence the decision on purchasing or prescribing products; these are to be evaluated on the basis of objective criteria, and they shall always be intended for supporting independent research.
10. Management and financial specifics are to be determined by way of an agreement in writing, and any compensation is to be consistent with the fair market value assigned to these activities. These grants are not to be approved or managed by any business division of the Companies' marketing or sales divisions, and they shall be intended to add value to the scientific and clinical development of healthcare professionals in benefit of their patients.
11. **Companies are to support this code of ethics:**
 - a) By way of senior reliable executive who observes this code.
 - b) By drafting an educational guide for enabling compliance with this code of ethics.
 - c) By training the staff to have them duly comply with this code of ethics.
 - d) By drafting an Ethics Handbook for providing for due compliance.
 - e) By creating the appropriate communication channels to enable any employee to give his opinion on topics involving business ethics.
 - f) By making sure that anyone involved in the product distribution chain is able to give his opinion whenever there is any doubt.
 - g) By making sure that any third party on the distribution chain becomes part of this code of ethics.

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