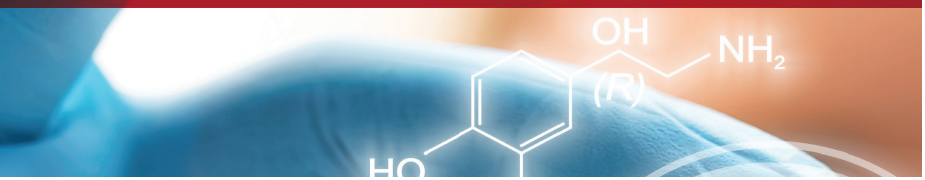
Baker McKenzie.

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



SWEDEN

Sweden

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The Regulatory Framework

Regulatory Rules

In Sweden, there are two separate sets of legislations governing the marketing of medical products. The Medical Products Act (1992:859) (*Läkemedelslagen*) contains specific provisions on the marketing of medical products, while the Marketing Practices Act (2008:486) (*Marknadsföringslagen*) relates to marketing more generally. The Marketing Practices Act also governs the marketing of medical devices as such term is defined by the Medical Devices Act (1993:584) (*Lag om medicintekniska produkter*).

The Medical Products Act was revised in May 2006 in order to implement Directive 2001/83/EC on the Community code relating to medical products for human use (the "Directive"). The implementation introduced several provisions relating to the marketing of pharmaceutical products to healthcare professionals as well as provisions regarding the marketing of such products to the general public. Clarifications of the Directive and the Medical Products Act are set out in the Medical Products Agency's Regulation (*Läkemedelsverkets föreskrifter* or LVFS 2009:6) regarding the marketing of medical products. The 1992 Medical Products Act will be repealed and replaced by a new Medical Products Act (2015:315) from 1 January 2016. The new Medical Products Act contains certain editorial changes but the provisions regarding the marketing of medical products will, in essence, remain the same.

The Medical Products Act does not include any definition of what constitutes advertising or marketing of medical products. However, according to LVFS 2009:6, the term "marketing of medical products" includes any form of door-to-door provision of information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medical products. In

addition, LVFS 2009:6 lists several measures that specifically should be included in the definition of "marketing of medical products," such as: (i) advertising to the public; (ii) advertising of medical products to persons qualified to prescribe or supply medical products; (iii) visits by medical sales representatives to persons qualified to prescribe medical products; and (iv) the supply of samples. LVFS 2009:6 also lists several measures that are not to be deemed as marketing of medical products, for example: package labelling and accompanying leaflets; communications considered necessary to answer a specific question about a particular medical product; and factual, informative announcements and reference material relating, inter alia, to packaging changes and adverse-reaction *warnings* as part of general drug precautions.

The Marketing Practices Act applies when marketing any kind of product. Under the Marketing Practices Act, the term "advertising" is seen as part of the broader concept of "marketing", which is primarily defined as "publicity and other measures in business activity, which aim to promote the sale and supply of products". Consequently, the sale itself, even though entirely passive, is considered to be a marketing measure. In addition, measures that aim to promote the supply of products are included in the definition. Thus, supplying scientific information to, for example, healthcare professionals could be considered as constituting marketing under the Marketing Practices Act.

Apart from the Medical Devices Act, there are no specific laws governing the marketing of medical devices. In this regard, the Medical Devices Act implements all of the main European directives relating to medical devices. Further particulars of the provisions are found in the Medical Devices Regulation (1993:876) (*Förordning om medicintekniska produkter*) and in four complementary authority regulations. In addition, the Act on the import and trade of syringes and injection needles (2012:595) (*Lag om införsel av och handel med sprutor och kanyler*) provides further provisions relating specifically to such devices.

Medical devices are defined in the Medical Devices Act as products that according to the manufacturer shall be used, separately or together with something else, to or on humans solely or essentially with the objective to:

- prove, prevent, monitor, treat or reduce illness;
- prove, prevent, monitor, treat, reduce or compensate an injury or a functional disorder;
- examine, change or replace the anatomy or a physiological process; or
- control fertilization.

Devices that achieve their primary intended effect through the use of pharmacologic, immunologic or metabolic substances are not considered medical devices within the meaning of the Medical Devices Act.

Self-Regulatory Rules

The trade association for the research-based pharmaceutical industry in Sweden (*Läkemedelsindustriföreningen* or LIF) has established so-called ethical rules governing inter alia information regarding medical products (the "LIF Rules"). The LIF Rules aim to lay down more precisely the responsibility of the pharmaceutical industry for supplying information on medical products and provide the basis for interaction between the pharmaceutical industry and healthcare professionals. In addition, in January 2014, the association for medical technology, Swedish Medtech, and the association for laboratory technology, Swedish Labtech, signed a cooperation agreement with the Swedish Association of Local Authorities and Regions (*Sveriges Kommuner och Landsting* or SKL) and LIF to implement parts of the LIF Rules in the Swedish medtech and labtech sectors.

The LIF Rules are based partly on codified laws, pharmaceutical legislation and other enactments and regulations issued by government

agencies and partly on non-statutory provisions, such as the International Code of Advertising Practice drawn up by the International Chamber of Commerce and the Code of Practice on the Promotion of Medicines adopted by EFTA's Pharmaceutical Industries Association (the "EFPIA Code"). The LIF Rules shall be regarded as a complement to current legislation, regulations and codes of statutes issued by governmental bodies, including, for example, the Marketing Practices Act, the Medical Products Act and the Medical Devices Act, existing anti-bribery legislation, the Code on Gifts, Rewards and other Benefits issued by the Swedish Anti-Corruption Institute, and rules on public procurement.

The LIF Rules are divided into five Chapters relating to different aspects of the appropriate ethical practice of pharmaceutical companies. Chapter I contains the ethical rules relating to information on medical products supplied to healthcare professionals and to the general public; Chapter II contains the ethical rules for cooperation between pharmaceutical companies and healthcare professionals; Chapter III contains the ethical rules for cooperation between pharmaceutical companies and organizations and politicians; Chapter IV contains the ethical rules for non-intervention studies; and Chapter V contains the ethical rules relating to (anti) bribery.

The LIF Rules also set out the duties of the Information Examiner (the "IGM") and the Information Practices Committee (the "NBL"). The IGM and the NBL have a duty to ensure LIF members' compliance with the LIF Rules. The NBL may also issue statements of guidance concerning an information or marketing-related matter of major importance. This is possible in connection with the consideration of a particular case; and a statement of guidance can also be issued at the request of LIF, the IGM, Swedish pharmacies, pharmaceutical companies that are members of LIF, associations of persons active in the medical field, or by a court or other public authority.

In addition, the European codes of practice (the EFPIA Code of 1 January 2006 as amended following Statutory General Assembly approval of 14 June 2011; and the International Federation of

Pharmaceutical Manufacturers Association's Code of Practice (the "IFPMA Code")), which are in principle implemented through the LIF Rules, must also be taken into account when marketing pharmaceutical/medical products in Sweden. For example, the EFPIA Code provides guidelines for Internet websites available to healthcare professionals, patients and the general public, a topic that is not addressed in the LIF Rules.

Permitted and Prohibited Practices

The Medical Products Act

The Medical Products Act lays down the general requirements with which marketing activities relating to medical products must comply. The Act also contains provisions that relate to certain marketing activities.

It follows from the general provision of the Medical Products that the marketing of medical products shall be objective, up-to-date and balanced, and that it shall encourage safe and appropriate use of the product. Such marketing shall moreover not be misleading and shall always be consistent with relevant "generally accepted practices."

Compliance with so-called generally accepted practices in the marketing of medical products means that pharmaceutical companies must act in accordance with established standards such as the LIF Rules, the EFPIA Code, the IFPMA Code and the International Chamber of Commerce's International Code of Advertising Practice.

In addition, marketing shall provide such information that is of particular importance to the general public or to the persons qualified to prescribe or supply medical products.

The Pharmaceuticals Act also contains an explicit ban on the marketing of pharmaceutical products that have not been granted market authorization in Sweden, as well as special rules regarding marketing to the general public. In short, the marketing of medical products may not be directed towards children and it is prohibited to

market prescription pharmaceuticals (RX) to the general public, with the exception of promoting vaccination campaigns to combat infectious diseases. The holder of a market authorization must have sufficient scientific competence and an appropriate role within the company to enable him or her to supervise all information regarding the pharmaceutical product subject to authorization.

The Marketing Practices Act

The Marketing Practices Act's material rules consist of one general rule and a number of specific rules for certain practices. The general rule states that: "Marketing practices shall be consistent with generally accepted marketing practice." This provision expresses the basic idea of fair marketing practices.

The specific rules provide concrete form to a number of marketing practices and indicate in which circumstances they are permitted and in which circumstances they are not. These specific rules contain provisions regarding, for instance, identification in advertisements, misleading advertising, misleading packaging dimensions, clearance sales, discount sales, unsolicited products and special offers.

The general rule covers all marketing practices, including situations covered by the more specific rules. However, if a certain practice is covered by any of the specific rules, then its breach gives rise to additional sanctions than would be the case if it had been covered solely by the general rule.

The Medical Devices Act

As stated, the Medical Devices Act does not contain any specific rules on the marketing of medical devices. Therefore, the question regarding what product information a company is obliged to provide must be decided on a case-by-case basis. That being said, please note that depending on the type of medical device, market authorization may be required in order to place a medical device on the market. Such authorization is granted by the Medical Products Agency. In addition, the cooperation agreement between the Swedish Association

of Local Authorities and Regions, LIF and Swedish Labtech implements ethical rules covering medical devices and contains special provisions regarding product information and interaction with the healthcare sector, in line with the LIF Rules.

LIF Rules

As mentioned, the LIF Rules are divided into five chapters. For the purpose of this handbook, only Section I (rules governing information on medical products) of Chapter I, will be discussed.

Chapter I is divided into two sections. Section I contains the ethical rules relating to information that, in connection with marketing medical products, is targeted at physicians, dentists, veterinary surgeons, pharmacists or other personnel operating within the Swedish healthcare profession or associated with the distribution of medical products. The rules outlined in Section II apply to information provided by the pharmaceutical industry that, in connection with the marketing of the medical products, is targeted at the general public and are applicable to any media used by the pharmaceutical industry in such marketing. Both sections contain specific provisions and guidelines regarding the content and form of the information, including that such information must: (i) be truthfully presented; (ii) be clearly identifiable (i.e., that medical product information must be easy to recognize); (iii) be reflective of current knowledge (i.e., that medical product information must be up-to-date); (iv) cite relevant documentation and contain clear references; (v) contain comparisons between effects, active ingredients, costs of treatment, etc.; and (vi) contain particulars of any discreditation.

In addition, both sections provide specific rules regarding disseminating information, the form the information must take, product samples and responsibility for the information provided (including specific rules on the bearer of responsibility and burden of proof).

According to the statutes for the IGM and the NBL, the IGM is responsible for monitoring the market. In order for the IGM to be able

to carry out this task, pharmaceutical companies must send new, up-to-date medical product information to the IGM, such as publications, advertisements, invitations, mailings, commercial films and information included on websites. On request, the IGM may provide general advice on measures that have not yet been implemented. Such advice is non-binding upon IGM.

Gifts, Seminars, Hospitality and Entertainment

Gifts

The provision of gifts to healthcare personnel is addressed in the Directive but the Swedish legislator has not implemented any such rules in the Swedish legislation. Instead, the subject is regulated by self-regulatory rules, such as those included in the LIF Rules, the EFPIA Code and the IFPMA Code.

The LIF Rules correspond to the EFPIA Code and the IFPMA Code and provide that gifts may not be supplied, offered or promised to a healthcare company or its employees, with the exception of the following:

- Information and educational material may be provided under the condition that the material is (i) of low value; (ii) directly relevant to the practice of the recipient; and (iii) directly beneficial to the care of patients.
- Items of medical utility may be provided for the purposes of educating employees and for the care of patients under the condition that the item is (i) of low value; and (ii) not already routinely used in the recipient's business.

The definition of "low value" refers to an amount that is no higher than that which is determined by LIF's board, currently set at SEK450. However, information and educational material and items of medical utility may never be supplied, offered or promised to healthcare personnel as an incentive to recommend, prescribe, purchase, supply, sell or administer medical products.

Please note that according to the IFPMA Code, it is permissible, if allowed under local law, to provide healthcare professionals with an inexpensive gift not related to the practice of medicine on an infrequent basis in acknowledgement of significant national, cultural or religious holidays. The provision of such gifts, however, is not permitted in Sweden.

With regard to medical devices, according to the cooperation agreement entered into with, *inter alia*, LIF, it is not permitted for medical device companies to offer benefits, gifts or other forms of compensation to healthcare professionals. Gifts offered to medical institutions that could be considered as indirect gifts to the healthcare professionals working within the institution are, accordingly, also prohibited.

Seminars

The LIF Rules regulate, among other activities, healthcare professionals' participation in medical conferences and similar events arranged by pharmaceutical companies. According to the LIF Rules, conferences shall normally be carried out at the participants' place of work, in that same geographic area or as near to that area as possible. Conferences may be held in other locations only where special reasons so dictate. Conferences outside Sweden are only permitted in direct connection with international training and scientific conferences if the majority of the participating professionals are not from Sweden and equivalent sessions cannot be held within Sweden.

Invitations and offers from pharmaceutical companies regarding national and international scientific conferences or congresses shall be made to a healthcare professional's employer. A copy of the invitation may be sent directly to the relevant healthcare professionals. The time and location, and any additional activities associated with the conference, shall be clearly set out in the invitation. The duration and content of the agenda shall also be apparent. The employer shall be informed of which, if any, healthcare professionals have received

copies of the invitation. Each healthcare professional is responsible for ensuring that the employer has approved his or her attendance.

The LIF Rules contain extensive regulations regarding to what extent pharmaceutical companies may sponsor conferences and what can be provided to healthcare professionals during and in connection with conferences and congresses. For instance, pharmaceutical companies may never compensate individual participants for costs of travel and accommodation. Neither may pharmaceutical companies finance social events in connection with the event.

The pharmaceutical companies may, however, pay for the conference venue, speakers and study materials, as well as similar items that are necessary to carry out the conference or congress.

The choice of venues for seminars, congresses, conferences and similar events is regulated in the EFPIA Code. LIF states in its interpretation of the EFPIA Code that pharmaceutical companies should avoid using venues that are known for leisure activities, or which are in other ways viewed as having an exclusive purpose (e.g., winter sports resorts or golf clubs). The same applies to cities hosting, or used in connection with, major international events.

Also with regard to medical devices, the ability to provide for hospitality is limited. According to the cooperation agreements, it is prohibited for a medical device company to pay for meetings in connection with the preparation or execution of public procurements concerning products being supplied by the company. Regarding other meetings, the same rules as for pharmaceutical companies apply in principle, meaning that medical device companies may not sponsor participants' travel, food, and accommodation costs or conference fees.

All meals provided at conferences must be very modest. Alcoholic drinks may only be offered in limited quantities and only alongside food, and spirits may not be offered at all. Separate social or

recreational activities may likewise not be provided, even if it is in conjunction with conferences or other interactions.

Promotional Activities

Samples

In this area, the LIF Rules refer to the regulations issued by the government agency, the Medical Products Agency.

According to LVFS 2009:6, issued by the Medical Products Agency, free samples of medical products can be provided to any of the following: (i) persons qualified to prescribe the product; (ii) heads of pharmacies; (iii) retailers that have the right to supply pharmaceutical products; and (iv) pharmacists appointed by the nursing ward of a hospital pharmacy. The sample may only be supplied in response to a written request, which has been signed and dated by the requester. The request must be kept and filed by the pharmaceutical company and the pharmaceutical company must also check that the person sending the request is authorized to prescribe or dispense medical products. The sample must also be marked with "Medical sample, not for sale" or other wording with similar content, as well as the expiry date, and must be accompanied by a written summary of the medical product's characteristics.

Samples shall be distributed only with great restraint. Only one package of the smallest size can be supplied in a calendar year to the same recipient. Samples may only be distributed for new products. The term "new product" means a product that has not been available on the public market for more than two years.

Pharmaceuticals that are classified as narcotics according to the Medical Products Agency's regulations are not allowed to be supplied as samples.

Additionally, medical samples may not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a medical product.

The distribution of medical device samples is not explicitly regulated by Swedish law. Hence, the LIF Rules referred to above will govern such a situation.

Consequences of Breach

The Pharmaceuticals Act

The Swedish Medical Products Agency is the authority that supervises compliance with the Pharmaceuticals Act. The Medical Products Agency can demand information and issue orders and prohibitions necessary to ensure compliance with the Pharmaceuticals Act and the regulations issued based on the act in question. Such demands, orders and prohibitions can be backed by fines.

The Marketing Practices Act

Sanctions under the Marketing Practices Act can be divided into three main types:

- Prohibitions backed by fines and orders backed by fines
- Fines for disruptive marketing practices
- Damages

A prohibition backed by a fine is the main sanction under the Marketing Practices Act. Such a prohibition implies that an entity is prohibited from continuing with an activity that has been found contrary to the Marketing Practices Act. An order could mean that an entity is ordered to provide information in a certain way.

If a claimant can demonstrate probable cause for his or her claim, the court may make a provisional prohibition or order; these injunctions and orders may be backed by fines. Where there are breaches of specific rules, the court may impose a fine for disruptive marketing practices. The fine shall be a minimum of SEK5,000 and a maximum of SEK5 million. However, the fine may never exceed 10 percent of the undertaking's yearly turnover for the previous financial year.

Damages can be imposed for breaches of specific rules or for breaches of previous prohibitions under the Marketing Practices Act. The breach must have been caused intentionally or negligently. Damages under the Marketing Practices Act cover purely financial loss (e.g., loss of goodwill), although it is possible that the court may take into consideration circumstances that are not of an economic nature.

Where there is a breach of specific rules or where there is breach of a prohibition backed by a fine, the court may order the removal of representations that are misleading.

The Medical Devices Act

The Swedish Medical Products Agency is the authority that supervises compliance with the Medical Devices Act. The Medical Products Agency can demand information and issue orders and prohibitions necessary to ensure compliance with the Medical Devices Act. Such demands, orders and prohibitions can be subject to fines.

Under the Medical Devices Act, any person who intentionally or negligently places a medical device on the market without the product meeting the demands and conditions set forth by the Medical Devices Act, and the regulations issued based on the act in question, shall be fined or sentenced to imprisonment for a period of up to one year.

A manufacturer that omits hiring a notified body (when this is necessary) to participate in the evaluation of a medical device can be fined or sentenced to imprisonment for a period of up to one year.

LIF Rules

The IGM and the NBL are engaged in LIF's self-regulation. The Statutes of the Pharmaceutical Industry's Information Examiner and the Information Practices Committee contain the principal provisions set out below.

The task of the IGM and the NBL is to ensure that, regarding their products and company information and other aspects of their

marketing activities and conduct, pharmaceutical companies observe the LIF Rules and all relevant legal statutory provisions, as well as general non-statutory criteria for good business practice in the industry, and that they otherwise comply with good industrial practice.

The IGM's and the NBL's overall activities consist primarily of monitoring the market and assessing cases which consist of potential regulatory breaches. In addition, the NBL may issue statements of guidance explaining what is or ought to be considered good industrial practice in any particular case.

The IGM's task is to consider informational measures concerning medical products for human use and other marketing activities concerning medical products intended for human use, which the IGM finds cause to question in the course of monitoring the market, or which is questioned in a report to the IGM.

The NBL considers appeals against decisions taken by the IGM and cases reported by a public authority, where these are considered by the NBL at first instance. The NBL also considers cases concerning information-related measures regarding matters other than medical products for human use, which, in a report to the NBL, have been challenged by a party that is entitled to litigate.

Right To Litigate

Private persons, companies, associations and, under some circumstances, LIF's Compliance Officer have the right to complain to the IGM about an informational measure that a pharmaceutical company has itself adopted or which another party has adopted on its behalf. The right to complain to the NBL is granted to the IGM, private persons, companies, associations and public authorities.

IGM and NBL Charges

If, in making a decision, the IGM finds that a pharmaceutical company has adopted an informational measure, marketing measure

or general activity that is incompatible with good industrial practice, the company shall normally be ordered to pay an IGM charge.

If, in making its decision in a reported case, the IGM finds that criticism may not be levelled at the informational measure about which a complaint has been received, and if the complainant is – or represents – a rival pharmaceutical company, then this company shall normally pay an IGM charge.

If the NBL, following a complaint over the IGM's decision, changes such decision to impose a pharmaceutical company with an IGM charge, the obligation to pay the charge is set aside. In such cases, generally, the complainant (if this is a pharmaceutical company) shall pay an NBL charge. If the NBL upholds the IGM's decision, the infringing company shall in general pay an NBL charge.

Both the IGM's and the NBL's charges are set at a maximum of SEK500,000.

Professional Codes of Conduct

Given the fact that the LIF Rules and the LIF agreements are based on codified laws and certain self-regulatory codes on good trade practice, the LIF Rules, including any cooperation agreement referring to the LIF Rules, can be said to represent a compilation of the most important codes of conduct in this area.

Liability Under Criminal and Civil Law

The Swedish legislation concerning bribery and corruption in the penal code has undergone several changes. New offences have been introduced, such as bribery and acceptance of bribery, trading in influence and negligent financing of bribery. Furthermore, the legislation addresses more persons as the rules of prosecution have changed.

To receive, accept a promise of or request an improper benefit for the carrying out of an employment service or assignment may constitute

acceptance of a bribe, which is criminalized. This also applies in situations where a person receives, accepts a promise of or requests a benefit for someone other than himself or herself. In addition, the person who provides, promises or offers an improper benefit to an employee or contractor may be sentenced for bribery.

In assessing the severity of a crime, special consideration is given to whether the act constituted an abuse or assault on a position of particular responsibility, concerned a benefit of considerable value, or was a part of systematic or large-scale criminal activity, or otherwise was of an especially dangerous nature.

A person may be found liable for trading in influence, in cases other than those referred to above, if that person (i) receives, accepts a promise of or requests an improper benefit in order to influence a person who exercises public authority or has responsibility for the issuance of public procurements; or (ii) provides, promises or offers an improper benefit in order for the recipient to influence the decision-maker when exercising public authority or deciding on the issuance of a public procurement. In addition, so-called gross financing of bribery, whereby someone provides money or other assets to someone who represents them in order to promote bribery, gross bribery or trading in influence, is criminalized in Sweden.

According to the preparatory works of the statute, the assessment of what shall be considered as improper is to be made on case-by-case basis and based on the circumstances of each specific situation. If it can be established that there is an intention to induce the receiver of the benefit to do something that he or she would not otherwise have done, and which would be to the advantage of the party providing the benefit, the benefit is seen as improper.

The value of a gift is of importance but there is no defined limit on when a gift is considered a bribery. Consideration must also be given to, for example, whether the gift is received in violation of the rules of the principal and in what activity the official is engaged. The requirement for precaution is particularly called for in activities of

official authorities and with regard to public procurement matters. It seems clear that to provide gifts or similar awards to a healthcare professional with the intention of promoting prescriptions of a pharmaceutical product, thereby seeking to induce the healthcare professional to select that product before other competing products, would constitute a bribe.

Marketing practices that resemble bribery but do not necessarily constitute a crime under the Penal Code could be a violation of the general rule in section 4 of the Marketing Practices Act (see section on Permitted and Prohibited Practices).

Contracts with Healthcare Professionals and Medical Institutions

Apart from the LIF Agreements mentioned above, there are a few other agreements entered into by LIF in this area.

LIF and the Swedish Association of Local Authorities and Regions have entered into an agreement concerning clinical trials. The purpose of this agreement is to state the preconditions for cooperation between the parties in clinical trials initiated by entities within the pharmaceutical industry, and to provide a starting point for establishing an agreement between the pharmaceutical company and the health principal concerned. Subject to the Medical Products Agency's approval of the trial, the agreement covers the approved conduct of clinical trials that are financed, either partly or completely, by pharmaceutical companies.

Furthermore, the agreement contains provisions on preconditions for clinical trials, the start of clinical trials, the conduct of clinical trials and the formation of an advisory body.

LIF has also adopted ethical rules as to cooperation between LIF member companies and user organizations/interest groups. Organizations and interest groups mean disability organizations, patient associations and relatives' associations and other interest

organizations that influence opinion within the health service, such as pensioners' organizations, the Swedish Cancer Society, the Swedish Red Cross and the Swedish Heart-Lung Foundation. The purpose of the ethical rules is to ensure that cooperation between organizations and LIF member companies takes place in a responsible and meaningful manner, and that their cooperation, and information and training provided are also conducted in such a manner that the parties' independence from one another is not jeopardized or questioned from either a legal or ethical standpoint. The ethical rules are supplemented by an agreement template that can be used when pharmaceutical companies enter into an agreement with an organization or interest group.

Recommendations

Because of the complexity of the regulatory framework, medical product companies should carefully consider their advertising and other marketing measures.

This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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