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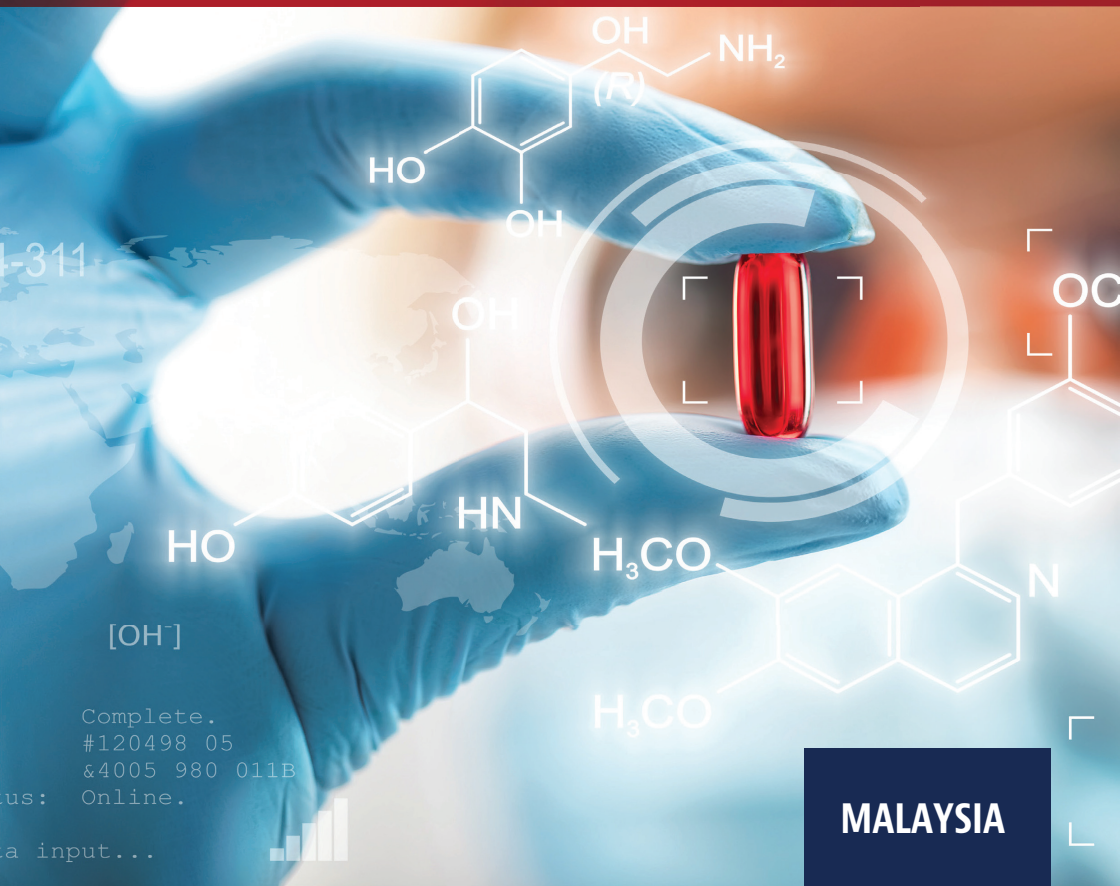
Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



MALAYSIA

Malaysia

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Introduction

In Malaysia, the advertising and promotion of medical products is generally regulated by legislation and industry codes.

The main legislation that governs the advertising and promotion of medical products are:

- Medicines (Advertisement and Sale) Act 1956
- Medical Device Act 2012

The industry codes that govern the advertising of medical products are:

- Codes of Conduct issued and administered by the Pharmaceutical Association of Malaysia ("**PhAMA**")
- Code of Conduct for Non Prescription (OTC) Products ("**OTC Code**") by PhAMA
- General advertising industry codes

Regulatory framework

The Medicines (Advertisement and Sale) Act 1956 ("**MASA 1956**") is the primary legislation governing the advertising of medical products in Malaysia. The Medical Devices Act 2012 ("**MDA 2012**") seeks to implement a regulatory framework for medical devices, which includes the introduction of the requirement to register medical devices as well as regulation of advertisements relating to medical devices.

Advertisements relating to medical products fall under the purview of the Medicine Advertisement Board (MAB), an agency of the

Pharmaceutical Services Division of the Ministry of Health. A Guideline on Medicines and Medicinal Products to the General Public ("**Guidelines**") issued by the MAB provides further guidance on the provisions of MASA 1956.

The term "advertisement" is broadly defined to include any notice, circular, report, commentary, pamphlet, label, wrapper or other document, and any announcement made orally or by any means of producing or transmitting light or sound.

Permitted and prohibited practices

MASA 1956 imposes the following restrictions on the advertising of medical products:

- Publication of any advertisement referring to a medical product or a medical device must be evaluated and approved by the MAB.
- Advertisements relating to medical products for a specified purpose, diagnosis, prevention or treatment of specified diseases or controlled medical products are strictly prohibited.

Both MASA 1956 and the Guidelines set out the types of diseases in which advertisements for medical products relating to such diseases will be prohibited.

Specified diseases

Section 3 of MASA 1956 generally prohibits advertisements for any article calculated to be used as a medicine for the treatment, prevention or diagnosis of the following diseases or conditions:

- Diseases or defects of the kidney
- Drug Addiction
- Diseases or defects of the heart

- Hernia or rupture
- Diabetes
- Diseases of the eye
- Epilepsy or fits
- Hypertension
- Paralysis
- Mental disorders
- Tuberculosis
- Infertility
- Asthma
- Frigidity
- Leprosy
- Impairment of the sexual function or impotency
- Cancer
- Venereal diseases
- Deafness
- Nervous debility, or other complaint or infirmity, arising from or relating to sexual intercourse

Specified purposes

Advertisements of certain pharmaceutical products are prohibited. This includes pharmaceutical products that are used to practice contraception among human beings; improve the condition or functioning of the human kidney or heart; improve the sexual function

or sexual performance of human beings; procure the miscarriage of women; and in relation to disease and conditions specified in the schedule to the Act. Advertisements relating to skill and service are also prohibited under the Act.

Controlled medicine or poison

The Guidelines, effective from 1 September 2015, prohibit the advertisement of controlled medicine, poison and products containing poison pursuant to Schedule 1 of the Malaysian Poison Act 1952, unless it is specifically exempted. Although the advertisement of a pharmaceutical product may include prescription drug terms, such advertisements will be prohibited if the substance of the prescription drug is classified as a "poison" under Schedule 1 of the Malaysian Poison Act 1952. Examples include Botox and Viagra.

Consequences of breach

For first conviction: a fine not exceeding MYR 3,000, imprisonment for any term not exceeding one year, or both.

For subsequent convictions: a fine not exceeding MYR 5,000, imprisonment for a term not exceeding two years, or both.

Defenses

MASA 1956 prescribes the following defenses that could be raised by a defendant in any proceedings for any breach of the abovementioned restrictions:

- The advertisement to which the proceedings relate was published in such circumstances that he/she did not know and had no reason to believe that he/she was taking part in the publication thereof.
- The said advertisement was published only in a publication of a technical character intended for circulation, mainly among persons of the following classes, or one or some of them, that

is to say: registered medical practitioners; registered dentists; registered nurses and midwives; registered pharmacists, chemists and wholesalers and retailers of poisons; or persons undergoing training with a view to becoming registered medical practitioners, registered dentists, registered nurses, or registered pharmacists or chemists.

Advertising guidelines

In the issuance of an approval for any advertisement relating to a medical product, the MAB requires an applicant to ensure that the advertisement that it seeks to publish to the public complies with the Guidelines.

The main objective of the Guidelines is to ensure responsible advertising in promoting the sale of medicines, appliances or remedies that may be purchased by the public without prescription and for which medical claims are made. In this regard, the Guidelines expressly state that advertisements to the general public ought to achieve the following objectives:

- Help people make rational decisions on the use of medicines, appliances and remedies determined to be legally available without a prescription
- Take into account people's legitimate desire for information regarding their health
- Not take undue advantage of people's concern for their health

General requirements

The general regulatory framework on the advertising and promotion of pharmaceutical products as stipulated by the Guidelines can be summarized as follows:

- Advertisements on medical products should contain information that is reliable, accurate, truthful, informative,

balanced, up-to-date, capable of substantiation and in good taste.

- Advertisements should not contain any misleading or unverifiable information or omissions that are likely to induce medically unjustifiable use or to give rise to undue risks.

- An advertisement should not contain any statement that either expressly or by implication disparages either the medical profession or the value of professional attention and treatment or another product, and not should not discredit or unfairly attack other products, advertisers or advertisements directly or by implication.

Notwithstanding the above, the Guidelines issued by the MAB also specifically prohibit the following types of advertisements:

- Relating to the prevention, diagnosis or treatment of the diseases and conditions of human beings as specified in the Schedule to The Medicines (Advertisement & Sales) Act 1956

- Relating to the practicing of contraception among human beings

- Relating to the improvement of the condition or functioning of the human kidney or heart, or improving the sexual function or sexual performance of human beings

- Relating to procuring the miscarriage of women

- Having any visual and/or audio presentation of doctors, dentists, pharmacists, scientists, nurses and other paramedics that give the impression of professional or scientific advice, recommendation or endorsement

- Containing statements or visual presentation that are contrary or offensive to the standard of morality or decency or in any way defamatory or humiliating to any segment of the public

- Those that are framed to abuse the trust of the customer, induce fear or play on superstition or exploit the superstitious
- Containing anything that support acts of violence or illegal activities
- Showing or referring to dangerous practices or manifest a disregard for safety
- Contain anything that might harm children or young people physically, mentally or morally, or which exploit their credulity, their lack of experience or their natural sense of loyalty

Professional codes of conduct

The codes of conduct regulating advertising and promotion of medical products include:

- Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products ("**PhAMA Code**") by PhAMA
- The OTC Code by PhAMA
- Code of Medical Ethics issued by the Malaysian Medical Association (MMA)
- Advertising Guidelines for Healthcare Facilities and Services (Private Hospitals, Clinics, Radiological Clinics and Medical Laboratories) by the MMA
- General advertising codes, which include the Code of Advertising Practice ("**Advertising Code**") and the Communications and Multimedia Content Code ("**Content Code**")

The PhAMA Code sets out the standards with which its members are required to comply to ensure ethical promotion of pharmaceutical products to healthcare professionals, and that member companies'

interactions with healthcare professionals are appropriate and perceived as such.

The OTC Code is separately administered by PhAMA to regulate over-the-counter products used in self-medication to treat ailments that do not require a doctor's prescription. The OTC Code is more focused on the interaction of pharmaceutical companies with consumers through advertisements.

The Malaysian Advertising Standards Authority and the Communications and Multimedia Content Forum have also issued general industry guidelines in the form of the Advertising Code and the Content Code, respectively. The Advertising Code governs print advertisements while the Content Code governs advertisements via electronic means.

Definition

Under the PhAMA Code, "pharmaceutical product" is defined as any pharmaceutical or biological product (irrespective of whether the product is patented and/or whether it is branded) that is intended to be used by prescription of, or under the supervision of, a healthcare professional, and which is intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.

"Healthcare professional" on the other hand, is defined as any member of the medical, dental, pharmacy or nursing professions, or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply or administer a pharmaceutical product.

Permitted and prohibited practices

The codes of conduct are issued by different regulatory bodies, although the specific guidelines provided therein are similar to one another and to those provided in the Guidelines. In essence, the

general principles governing advertising and promoting pharmaceutical products can be summarized as follows:

Content of the advertisements and promotional materials

- Promotional materials for pharmaceutical products should be accurate, fair and objective, and presented in such a way to conform not only to legal requirements but to high ethical standards and good taste.
- Information provided on the promotional materials or on the pharmaceutical products must be capable of being substantiated based on clinical and pharmacological evidence from properly conducted investigations and based on an up-to-date evaluation of the product.
- Information provided to medical professionals on the pharmaceutical products should be based on latest references (preferably less than five years).
- No advertisement shall contain exaggerated or all-embracing claims, direct or implied, and superlatives must not be used unless based on substantial scientific evidence and other responsible medical opinion.
- Advertisements for medical products should not refer to any skill or service relating to the treatment of any ailment, disease, injury or condition affecting the human body so as to induce any person to seek the advice of the advertiser.
- Advertisements should not contain any statement or illustration that is likely to induce fear on the part of reader, viewer or listener.
- Advertisement materials disseminated to the public must not include anything that offends good taste or decency, is offensive to public feeling, likely to encourage crime or lead to disorder, or is abusive or threatening in nature.

- Members of the medical, pharmaceutical, dental or related professions should not be depicted in any illustration of a product in such a way to suggest professional advice or recommendation.

- Claims in advertisements must not state categorically that a product has no side effects or toxic hazards, or does not pose risk of addiction.

Methods of promotion

- Promotion or marketing methods must not incite unfavorable comments or bring discredit upon, or reduce confidence in, the pharmaceutical industry.

Prizes, inducements and independence of healthcare professionals

- Interactions between pharmaceutical companies and healthcare professionals should be focused on information about products, providing scientific and educational information, and supporting medical research and education.

- Pharmaceutical companies are prohibited from organizing any prize competition that is likely to stimulate unnecessarily the use of OTC pharmaceutical products.

- The Code of Medical Ethics expressly states that any collusion between doctors and pharmaceutical chemists for financial gain is reprehensible. The code goes so far as to state that a doctor is prohibited from making arrangement with a chemist for the payment of commission, and from holding a financial interest in a chemist's shop in the area of his/her practice, and from giving professional cards to chemists for further distribution. It is deemed undesirable for messages for a doctor to be received and left at a chemist's shop.

- Similarly, with regard to prescribed medical products, any financial benefit or benefit-in-kind that may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products, or for a commitment to continue to do so, is strictly prohibited under the industry codes.

Gifts

- Payments in cash or cash equivalents, including gift certificates, gifts for personal benefit, such as tickets to sporting or entertainment events, and electronic items to healthcare professionals are prohibited, as are stand-alone entertainment or other leisure or social activities.
- Items of medical utility that are of modest value (not exceeding MYR 500 or approximately USD 128) and beneficial to the provision of medical services and for patient care are allowed.
- Educational medical material such as journals, textbooks and models not exceeding a limit of MYR 1,000 (approximately USD 255) are allowed. Although items of medical utility are appropriate, these items should not be offered on more than an occasional basis.
- Inexpensive gifts as a cultural courtesy with a monetary limit of MYR 100 (approximately USD 26) may be given on an infrequent basis to healthcare professionals in acknowledgement of significant national, cultural or religious occasions.
- Promotional aids (whether related to a particular product or of general utility) may be distributed, provided that it is of small value (not more than MYR 100) and relevant to the practice of medicine or pharmacy, or for the benefit of patient care. Promotional aids are items of insignificant and minimal value

related to the work of the recipient healthcare professional. Examples of such items are pens, notepads and surgical gloves. Promotional items intended for the personal benefit of the healthcare professional, such as music CDs, paintings or food baskets, would not be acceptable under the codes.

Sponsorships/donations

- Sponsorships for an association's or organization's social events (such as annual dinner or family day) are generally not allowed.
- Monetary donations to a hospital's social event are not allowed even if no promotional activities are carried out at the event.
- Inappropriate financial benefits to healthcare professionals to influence them to prescribe pharmaceutical products must not be offered.
- Support for charitable events organized by health societies or donations for charitable events where the proceeds benefit patients is allowed.
- Sponsorships for healthcare professionals to attend symposiums, congresses or other medical/healthcare or educational programs are permitted, provided that they are not conditional upon an obligation to prescribe and recommend any pharmaceutical product.
- Subject to limited sponsorships for travel, meals, registration fee, accommodation and entertainment, no payments should be made to compensate the healthcare professional for time spent in attending the sponsored event/program or to cover the cost of an accompanying guest or spouse.
- For overseas scientific meetings, sponsorship by pharmaceutical companies should be limited to basic economy

travel (if travel time is less than six hours), meals, lodging and registration fee.

"Kind discounts" to healthcare providers

- Kind discounts or gifts may include gift certificates, tickets to sporting events or concerts, travel vouchers or sponsorship for events (e.g., annual dinner).
- Kind discounts provided to healthcare providers who have achieved the sales target set by the pharmaceutical company are strictly prohibited.
- Kind discounts provided to healthcare providers who have agreed to purchase products from the pharmaceutical company are prohibited.

Consequences of breach

PhAMA Code and the OTC Code

A pharmaceutical company would be bound by the PhAMA Code and the OTC Code if it is a member of PhAMA.

A member's non-compliance with the PhAMA Code and the OTC Code may result in a penalty of up to MYR 100,000 (approximately USD 25,509). Breach of the PhAMA Code and the OTC Code would also likely result in adverse publicity as names of companies that are the subject of complaints will be published.

The Advertising Code

There are no legal sanctions for breach. The sanctions are principally the withholding of advertising space from advertisers and the withdrawal of trading privileges from advertisers/advertising agencies. Both sanctions are applied by the media.

There is the possibility of adverse publicity if there is a breach. The Advertising Standards Authority Malaysia may publish details of the outcome of any investigation it has undertaken.

The Content Code

The Malaysian Communications and Multimedia Commission (MCMC) has the power to direct any person to adhere to the Content Code.

Breach of the Content Code may result in various sanctions, including fines of up to MYR 50,000 (approximately USD 12,753) and other penalties (but not including imprisonment), which may be imposed by the Complaints Bureau.

Any person who fails to adhere to the direction issued by MCMC to comply with the Content Code is subject to a fine of up to MYR 200,000 (approximately USD 51,012).

Criminal and civil liability

Public procurement policies and fraud

The Malaysian government provides a procurement regime ("**Government Procurement Policies**"), which regulates the acquisition of government contracts in relation to works, supplies and services. As public hospitals in Malaysia are established by the federal government, any work, supply and services contract that is entered into by public hospitals is governed by the Government Procurement Policies.

Under the Government Procurement Policies, all individuals, companies or corporate bodies intending to participate in government procurement are required to undergo a registration process. However, if the procurement of supplies and services is of a value of up to MYR 50,000 (approximately USD 12,753) and is directly through an order issued by the government, the registration requirement is waived.

The Government Procurement Policies are essentially based on five main principles: public accountability; transparency; value for money; open and fair competition; and fair dealing.

Pharmaceutical companies dealing with public hospitals must adhere to the principles of the Government Procurement Policies. Any bribery or corruption by pharmaceutical companies would be in contravention of these principles.

Penalties

The government could also take disciplinary action and impose penalties on contractors who are in breach of the Government Procurement Polices. Penalties are imposed according to the seriousness of the deviations, ranging from warning, suspension of registration (if any) for a maximum period of five years, to blacklisting of the company from conducting further business with any government ministry, department or agency.

Malaysian Anti-Corruption Commission Act 2009

Malaysia anti-bribery law is provided under the Anti-Corruption Commission Act 2009 ("**MACC**").

The definition of gratification under the MACC has been defined widely to include the following:

- Money, donation, gift, loan, fee, reward, valuable security, property or interest in property being property of any description whether movable or immovable, or any other similar advantage
- Any office, dignity , employment, contract of employment or services, and any agreement to give employment or render services in any capacity
- Any payment, release, discharge or liquidation of any loan, obligation or other liability, whether in whole or in part

- Any valuable consideration of any kind, any discount, commission, rebate, bonus, deduction or percentage

Private hospitals

It is an offense to corruptly give, promise or offer to any person any gratification as an inducement to or a reward for doing or forbearing to do anything in respect of any matter or transaction, actual or proposed or likely to take place.

The offense of giving or accepting gratification under the MACC extends to acts conducted by an agent, which includes any person employed by or acting for another; an officer of a public body, or an officer serving in or under any public body; a trustee; an administrator or executor of the estate of a deceased person; a subcontractor; and any person employed by or acting for such trustee, administrator or executor, or subcontractor.

Public hospitals

It is an offense if any officer of a public body uses his/her position for any gratification as an inducement or a reward for the officer showing or forbearing to show any favor.

"Public body" under the act is defined to include, without limitation, government, local and statutory authorities, government departments, services or undertakings, and companies or a subsidiary over or in which any of the same has a controlling power of interest.

For public hospitals, "public body" will likely include employees of the hospitals that are able to have a functional influence on purchasing decisions, such as head physicians, nursing heads and pharmacists.

Consequences of breach

Under the MACC, any person who is found guilty of corruptly giving any gratification as an inducement will be subject to imprisonment and a fine. The offender may be imprisoned for a term of not less than 14 days and not more than 20 years. If the gratification is capable of

being valued or is of a pecuniary nature, the offender may be liable for a fine of not less than five times the sum or value of the gratification that is the subject matter of the offense, or MYR 10,000 (approximately USD 2,551), whichever is higher.

Contracts with healthcare professionals and medical institutions

Contracts entered into between healthcare professionals and medical institutions are governed by the PhAMA codes.

Research sponsorship and contract

- Clinical assessments, post-marketing surveillance, and experience programs and post-authorization studies should be conducted with transparency and must not be disguised as promotion.
- Such assessments, programs and studies must be conducted for scientific or educational purposes.
- Material sponsored by a company, relating to pharmaceutical products and their uses, irrespective of whether it is for the purpose of promotion or advertising, should clearly indicate the sponsor's name.
- The name and qualifications of healthcare professionals included in the publications should not be prominent.
- Remuneration paid to healthcare professionals for conducting such research should be reasonable.
- Pharmaceutical companies must ensure that healthcare professionals who have been engaged are suitably qualified so that the results of the research and studies are accurate, fair and objective.

Consulting contracts

- Reasonable remuneration should be given for services rendered by healthcare professionals. The basis of calculation for their fees should be stipulated in the contract.
- Healthcare professionals who are engaged to provide advice should have sufficient qualifications.

Speakers' contracts

- Sponsorship of healthcare professionals for such events should be limited to travel, meals, registration fee, accommodation, and also limited entertainment in relation to the event.
- Payment of honoraria to local speakers and presenters is not encouraged. If an honorarium is paid, a guidance amount of no more than MYR 1,500 (approximately USD 383) per engagement, with up to the maximum amount of MYR 3,000 (approximately USD 765) for multiple engagements per day.
- A detailed signed contract on the services is required for auditing purposes and to prove that such payment is not an inducement.
- The requirement of a signed contract similarly applies to the engagement of international speakers but pharmaceutical companies should check with the speaker's home country industry code, and apply the provisions accordingly.

Medical representatives' agreement

- Medical representatives that the company employs must be adequately trained and possess sufficient medical and technical knowledge to present information on the company's product in an accurate and responsible manner.

- Such requirements should not only apply to verbal presentations but also printed materials that are created by the healthcare professionals.
- The system of remuneration of representatives should not adversely influence the presentation of information on the products nor influence the proper prescription as well as usage of the products by patients/consumers.

Recommendations

The following are among the strategies that a medical product company could adopt to minimize the risk of contravening the restrictions that have been imposed on the promotion of medical products in Malaysia:

- Refrain from giving gifts, payments or donating to a healthcare professional for their personal use as a matter of good practice.
- If such gifts, payments or donations are to be given, the same should be given to the medical institution directly and must be in compliance with the industry code applied to the industry.
- Any gifts or benefits given to an individual healthcare professional or an institution should have the effect of benefiting patients.
- Establish board-level responsibility for any anti-corruption program.
- Ensure that a senior officer is directly accountable for overseeing the anti-corruption program.
- Design and implement a code of conduct that is in line with the anti-corruption program of the company.
- Implement a transparent gifts and entertainment policy.

- Conduct appropriate training for employees to develop awareness and ensure compliance with the anti-corruption policies of the company.
- Carry out appropriate due diligence on foreign partners, agents, consultants and entities.
- Establish financial controls to minimize risks.
- Implement an anonymous reporting mechanism to encourage reporting of any anti-corruption practices.
- Advertisements of any medical products should be reviewed and approved by the MAB under MASA 1956.
- Ensure that they register their medical devices.
- Avoid giving unilateral benefits that do not generally benefit the patients.

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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