

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



VIETNAM

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Vietnam

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Legislation on Advertising Pharmaceuticals

Regulatory Framework

The advertising of pharmaceutical products is governed primarily by the Law on Pharmacy¹, Circular No. 13², and the Advertisement Ordinance³ along with their implementing regulations.

Advertising of medicines means the activity of introducing medicines as directly performed by an entity conducting business in medicines or by another entity that a medicine company coordinates, sponsors, or authorizes in order to promote the prescription, supply, sale and/or appropriate, safe and effective use of medicines⁴.

Permitted and Prohibited Practices

Information about pharmaceutical products must be true, accurate, clear, objective, and substantiated by scientific evidence. Such information must be presented with a high ethical standard, in compliance with the latest product information approved by the Ministry of Health (“MOH”), and in such a way as not to be misleading or ambiguous.

Medicines on the over-the-counter (“OTC”) medicines list issued by the MOH with an effective registration number may be advertised in print, outdoor, and digital media. In order for an OTC medicine to be advertised on radio or television, however, the OTC medicine must contain active pharmaceutical ingredients permitted by the MOH.

¹ Pharmacy Law No. 34/2005/QH11 promulgated by the National Assembly of Vietnam on 14 June 2005 (“Pharmacy Law”).

² Circular No. 13/2009/TT-BYT of the Ministry of Health dated 1 September 2009 guiding information and advertising of drugs (“Circular No. 13”).

³ Advertisement Ordinance No. 39/2001/PL-UBTVQH10, dated 16 November 2001 (“Advertisement Ordinance”).

⁴ Article 2.3, Circular No. 13.

The law prohibits the advertising of prescription medicines, vaccines, or medical biological products used for disease prevention, as well as of OTC medicines that should be restricted or require doctor supervision⁵.

The following indications are not permitted to be included in medicine advertisements: indications for treatment of tuberculosis and leprosy; indications for treatment of sexually transmitted diseases; indications for treatment of chronic insomnia; indications as an aphrodisiac; indications for treatment of cancer and neoplastic diseases; and indications for treatment of diabetes or other similar metabolic diseases⁶.

Off-label uses of medicines are not allowed to be promoted in Vietnam.

The law also prohibits the following acts:

- Providing information on and advertising cosmetics, functional foods, and non-drug products with unclear contents that may lead to consumers' misunderstanding of those products as drugs
- Using material or financial benefits in any form to influence physicians and drug users in order to promote the prescription and use of drugs
- Making use of drug circulation registration numbers granted by the Drug Administration of Vietnam or the drug management agencies of other countries to advertise drugs
- Using the name, symbol, image, position, prestige, or letters of a medical or pharmaceutical organization to advertise or recommend drugs

⁵ Article 5.1, Circular No. 13.

⁶ Article 25, Circular No. 13.



- Using medical workers or thank-you letters from patients to advertise or recommend drugs
- Advertising drugs in the form of physicians' instructions on disease prevention or treatment, or in the form of drug use instructions in newspaper articles and radio or television broadcast programs
- Using clinical research results that lack scientific grounding and medical evidence for drug information provision and advertising
- Making use of test results and certifications issued by competent agencies or medals granted to products and/or units in exhibitions and fairs to advertise drugs
- Providing information on and advertising drugs with contents irrelevant to Vietnam's fine traditions and customs
- Making use of animal images or other irrelevant images to provide information on and advertise drugs, leading to users' confusion
- Making publically-available drug information documents intended solely for medical workers
- Using sentences, words, images, and sounds suggesting that a drug is optimal or best in its effects
- Making comparisons for the purpose of advertising that suggest one's drugs are better than those of other organizations and individuals
- Advertising and providing information on drugs without registration numbers or with expired registration numbers

- Providing information on and advertising drugs before submitting registration dossiers of drug information provision and advertisings to competent state management agencies
- Providing information on and advertising drugs at variance with registered contents
- Providing information on and advertising drugs whose dossiers are being considered and processed under regulations

Consequences of Breach

Depending on the specifics of a given violation, the monetary fine can range from VND5 million (approximately USD250⁷) to VND40 million (approximately USD2,000). Additional sanctions can also be imposed, such as revocation of the pharmaceutical practice certificate, the certificate of satisfaction of conditions for drug trading, or the license for foreign companies conducting operations in medicine in Vietnam⁸.

Other Promotional Activities

Samples

The provision of drug samples to healthcare professionals (“HCP”) is prohibited. However, this restriction does not apply to medical devices.

Gifts

Gifts are regulated under Vietnam’s anti-corruption laws. According to Decision No. 64⁹, gifts or gratuities include, but are not limited to, the following:

⁷ At the exchange rate of US\$1:VND20,000.

⁸ Decree No. 93/2011/ND-CP, on sanctioning of administrative violations related to medicines, cosmetics and medical devices, issued by the Government on 18 October 2011 (“Decree No. 93”).

⁹ Decision No. 64/2007/QĐ-TTg promulgating the regulation on giving, receipt and hand-over of gifts by State budget-funded agencies, organizations and units and



- Vietnamese currency, foreign currencies, saving certificates, stocks, bonds, checks and valuable papers
- Material items, goods and assets
- Entertainment including, without limitation, services of domestic or overseas sightseeing tours and travels
- Healthcare services, education/training, internship and refresher training, and other kinds of services
- Rights to buy assets, houses, land use rights and equipment use rights; non-State prescribed privileges; use of assets, houses, land and equipment of other persons, which are free of charge or undercharged¹⁰

State officials and public employees can receive gifts given by their relatives or family members, or by agencies, units or individuals have no relations with the State duties of such State officials and public employees¹¹.

Apart from the above-specified case, State officials/public employees can receive gifts of less than VND500,000 (approximately USD25) when they are ill or suffering from an accident, or for occasions of mourning, weddings, or traditional festivals such as the Lunar New Year, provided that the gift-giving is not related to prohibited acts and purposes — for instance, the giver having relations with State duties that the State official/public employee is handling, the gift-giving having no clear purpose, or having a corrupt intent¹².

cadres, public employees and servants, issued by the Prime Minister on 10 May 2007 (“Decision No. 64”).

¹⁰ Article 3, Decision No. 64.

¹¹ Article 11, Decision No. 64.

¹² Article 12.4, Decision No. 64.

Gimmicks

“Gimmicks” or “give-aways” are an industry term and are not regulated by Vietnamese law. There is no specific threshold regulated by law for the value of gimmicks or give-aways. However, please note that the value of gifts regulated by Decision No. 64 is less than VND500,000, therefore, using this value for gifts as a reference, give-away items should only be nominal as not to be considered an “influence” on HCPs.

Hospitality and Sponsorship

Sponsorships for HCPs to attend events are generally permitted if properly structured and subject to specific ethical control procedures with medical institutions.

Hospitality during events should be limited to refreshments and meals incidental to the main purpose of the event. The value should be moderate and reasonable as judged by local standards. Hospitality should not be extended to persons other than the HCP participating in the event.

Liability Under Criminal Law

In Vietnam, there are two different sets of law dealing with corruption-related issues.

The Law on Anti-Corruption¹³ is considered a “code of conduct” for State officials and public employees in the discharge of their official duties. The Law on Anti-Corruption covers prohibited acts of State officials and public employees with official positions or powers and forms the basis for the application of the Penal Code¹⁴ with respect to bribery offenses. It does not address the act of giving bribes or provide specific sanctions for noncompliance.

¹³ Law on Anti-Corruption, passed by the National Assembly on 29 November 2005, effective on 1 June 2006 as amended in 2007 (“Law on Anti-Corruption”).

¹⁴ Penal Code, passed by the National Assembly on 21 December 1999, effective on 1 July 2000 as amended in 2009 (“Penal Code”).



For noncompliance, the Law on Anti-Corruption refers to either the Penal Code or the Law on Cadres and State Officials¹⁵ and the Law on Public Employees¹⁶ on handling violations pertaining to the receipt of bribes, depending on the seriousness of such violations.

The Penal Code deals with both acts of giving and receiving bribes. It provides the following crimes: giving bribes; receiving bribes; and acting as intermediary for bribes by meeting elements constituting such crimes.

Violations of the Penal Code will trigger individual criminal liability. The Penal Code does not provide for corporate criminal liability.

Provisions on Bribery Under the Penal Code

Under Article 279 of the Penal Code, those who abuse their positions and/or power, have accepted or will accept, directly or through intermediaries, money, property, or other material interests in any form valued at VND2 million (approximately USD100) or above, or under VND2 million with an element of serious consequence, for performing or not performing certain jobs for the benefit or at the request of the bribe givers, shall be subject to criminal liability for the crime of receiving a bribe. Depending on the seriousness of the case, criminal liability for receiving a bribe can include the death sentence.

Under Article 289 of the Penal Code, those who give a bribe valued at VND2 million or more, or under VND2 million with an element of serious consequence, or those who have given bribes before, shall be subject to criminal liability for the crime of giving a bribe. Depending on the seriousness of the case, criminal liability for giving a bribe can include life sentence.

¹⁵ Law on Cadres and State Officials, passed by the National Assembly on 13 November 2008, effective on 1 January 2010 (“Law on Cadres and State Officials”).

¹⁶ Law on Public Employees, passed by the National Assembly on 15 November 2010, effective on 1 January 2012 (“Law on Public Employees”).

Contracts with HCP and Medical Institutions

If a member of the industry wants to sign a contract with an HCP in order to engage the HCP for services such as speaking at and chairing meetings, translating medical documents, writing a medical article, or giving medical training, the arrangements covering legitimate provisions of such services should meet the following conditions:

- Written pre-approval should be obtained from the medical institution's head, which proves that the HCP is permitted to engage in the service contract and that the execution and performance of the contracts does not violate internal regulations of the medical institution.
- There should be a written contract that specifies the nature of the services to be provided and the basis for payment of those services.
- Payment to HCP service providers should be based on market criteria and be proportionate to the time devoted, the work done and the responsibilities assumed, and must be adequately documented. Payments of service fees must not be made in advance. Cash payment is prohibited.
- There should be a legitimate need for the services of the HCP and the relevant person should be an appropriate candidate based on their qualifications and experience in the relevant subject matter or activity.
- The hiring of the HCP to provide the relevant services must not be an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicine (i.e., no *quid pro quo*).

However, please note that HCPs are not allowed to be consultants for companies, organizations, or individuals in affairs related to State



secrets, professional secrets, or for affairs the HCP has the power to resolve or for which they participate in the resolution process¹⁷.

¹⁷ Article 37.1c, Law on Anti-Corruption



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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