PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

Pharmaceuticals

- Law on Advertising No 16/2012/QH13
- Law on Pharmacy No 105/2016/QH13
- Decree No 54/2017/ND-CP (as amended)
- Decree No 181/2013/ND-CP (as amended)

In addition, regulations on drug advertising are also mentioned in the two following professional pharmaceutical trade association guidelines: (1) Code of Ethical Practices issued by Pharma Group, European Chamber of Commerce in Vietnam (PG Code); and (2) Voluntary Codes on Business Ethics in Vietnam Pharmaceutical & Biopharmaceutical Sector issued by Vietnam Pharmaceutical Companies Association (VNPCA Code).

Medical devices

- Law on Advertising No 16/2012/QH13
- Decree No 98/2021/NĐ-CP (amended)
- Circular No 09/2015/TT-BYT

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

There is no specific definition of drug/medical device advertising under current regulations in Vietnam, only a general definition of advertising is provided. 'Advertising' is defined as the implementation of various means to present to the public products, goods, and services for profit; products and services not for profit; and organisations and individuals which are trading and providing the presented products, goods, and services, except for news, social policies, and personal information.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

Pharmaceutical advertisement/promotion:

Regulatory authorities

- Drug Administration of Vietnam (DAV) under the Ministry of Health (MoH)
- Provincial Service of Health (SoH) under the MoH

Supervisory authorities

- Inspectorate of the DAV
- Inspectorate of the SoH
- Inspectorate of the MoH
- Market Surveillance Officials

Medical devices

Regulatory authorities

- Infrastructure and Medical Device Administration (IMDA) under the MoH
- Provincial Service of Health (SoH) under the MoH

Supervisory authorities

- Inspectorate of the SoH
- Inspectorate of the Mo
- Market Surveillance officials

Self-regulatory processes operate independently of the competent authorities. In general, the entities would take responsibility for their own advertising activities. The authorities will inspect for advertising compliance and impose administrative penalties for any non-compliance.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

No. Food supplements and special nutritional products are required to follow other regulations on promotion (and advertisement).

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisements) in your country and, if so, which ones?

Pharmaceuticals
Under the regulations in Vietnam, a pharmaceutical can be advertised: (1) to the general public through medicine advertising activities; and (2) to healthcare professionals through medicine information activities. The requirements for the two activities above are as below.

Medicine advertisement
To advertise medicines to the general public, a certificate of medicine advertising content must be obtained from the DAV. Advertising prescription medicines to the general public in any form is strictly prohibited.

Medicine information
Medicine information for healthcare professionals may be provided through one of three forms: (1) via medical representatives; (2) medicine information documents: and (3) medicine instruction workshops. Before conducting the forms (2) and (3), a certificate of medicine information content must be obtained from the DAV, for form (2), or provincial heath authority, for form (3).

Medical devices
Medical device advertising content is not subject to prior regulatory approval. Before launching a medical device advertisement, the holder of the medical device registration number, in this context the Authorised Entity or the organisation authorised in writing by such holder, shall publicly post the expected content and form of advertising on the Medical Device Management Portal.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

Medicines

The following regulation is stipulated for the advertisement of medicines on websites.

Content of an advertisement with audio must be presented with the following information:
- medicine name;
- active ingredients or herbs;
- administration;
- contraindication, recommendations for special populations (pregnant, breastfeeding woman, etc.);
- name and address of manufacturer;
- The sentence 'Đọc kỹ hướng dẫn sử dụng trước khi dùng' (Read instructions carefully before use).

All the contents above, except for manufacturer's name and address, must be read aloud and clearly. If there are three active ingredients or more, each active ingredient or the generic name of vitamins, minerals and herbs must be read.

Advertisement content without sound must contain all information specified as below:
- medicine name;
- active ingredients or herbs;
- administration;
- dosage;

- contraindication, recommendations for special populations (pregnant, breastfeeding woman, etc.);
- cautions and warnings;
- undesirable effects;
- name and address of manufacturer;
- The sentence 'Đọc kỹ hướng dẫn sử dụng trước khi dùng' (Read instructions carefully before use);
- at the foot of the first page of medicine advertisement content, it must clearly state the MOH's Certification of medicine advertising contents serial number: .../ XNQC..., date... month... year...;
- for multiple-page advertising content, the pages must be numbered and the number of pages and the page that readers can obtain the details of the product must be stated on the first page;
- the content of medicine advertisement must include a note on supporting documents and specify the information cited in the documents – the citation must ensure accurate communication of information, and not inferior or truncated information in a way that causes misunderstanding about the safety and efficacy of the medicine.

If the advertising content is a sound recording or video recording with many pages or scenes, the pages or scenes of the advertisement must appear consecutively, stopping frequently enough for viewers to read all the information. Pages and scenes with product information must be stationary and not moving so that viewers can learn about the product information. The script must describe how content pages appear for multiple-page advertisements.

The advertisement of medicines in this form must be separate and must not overlap or alternately advertise many medicines at the same time to avoid misunderstanding.

Medical devices
There are no specific regulations on the matter.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

Pharmaceuticals

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8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

Medicines/medical devices that are advertised must have a valid MA or a valid import licence. Off-label information cannot be promoted.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

According to the Competition Law of Vietnam, directly comparative advertising is illegal and forbidden by law. Consequently, it is impossible to launch an advertisement in which one's own product or service is compared with a competing product or service.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

Healthcare professionals include civil servants, public employees, and persons in charge of professional operations in health facilities. Drug information provided to healthcare professionals must include the following: medicine name, composition, concentration, strength, dosage form, indication, contraindication, dosage and administration, use of medicine for special populations, information related to warnings and safety, and other necessary information.

Similar to drugs being advertised to the general public, the grounds to create drug information for provision to healthcare professionals include: (1) the Vietnamese National Drug Formulary; (2) the medicine package insert approved by the Ministry of Health (MOH); and (3) professional documents/instructions relating to the medicine issued or accepted by the MOH. Accordingly, in principle, information that is not included in the documents above may not be provided.

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

No, there are no specific rules governing virtual promotional (and advertising) activity.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how may such endorsements take place?

It is possible to use endorsements by healthcare professionals if they are true and not contrary to the law.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

Providing drug samples as a product promotion activity to healthcare professionals is prohibited in Vietnam.

The same ban is also regulated under the PG Code and VNPCA Code. However, these codes additionally provide three exemptions: (1) samples for tenders as requested by hospitals; (2) samples of vaccines and biological products for quality-testing purposes by a relevant authority before circulation in the market; and (3) samples requested by the health authorities.

These restrictions do not apply to medical devices.

According to Decree No 59/2019/ND-CP, office holding agencies, organisations, units, or individuals must not, in any form, receive gifts from the agencies, organisations, units, or individuals involved in their work or under their management.

PG Code

'Gifts (examples include but are not limited to sporting or entertainment tickets, sight-seeing trips including sight-seeing trips in conjunction with events, electronic items, social courtesy gifts, wreaths etc.) provided to healthcare professionals (HCPs) (either directly or indirectly) are prohibited. Providing or offering cash, cash equivalents, or personal services is also prohibited.

Items of medical utility:

- Items of medical utility may be offered or provided by PG member companies to HCPs if such items are of modest value (no independent value and not for personal benefit), do not offset routine business practices, are directly beneficial to enhancing the provision of medical services and patient care, and in line with Vietnamese laws.
- Items of medical utility should be given to HCPs on an occasional basis only, even if each individual item is appropriate.

- Items of medical utility can include the company name but must not be product branded, unless the product's name is essential for the correct use of the item by the patient, and in line with Vietnamese laws.

Educational items that enhance patient care:

- Informational and educational items that enhance patient care provided to HCPs for their education or for the education of patients on disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value.
- These informational and educational items can include the company name but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

The total value for items of medical utility or informational and educational items that enhance patient care given to HCPs must be less than VND2m per HCP per year (cumulative).

Items of medical utility or informational and educational items that enhance patient care must never be given to HCPs or medical institutions, organisations, or associations for the personal benefit of the HCP or to influence the recommendation, prescription, purchase, or usage of medicines and must never be formative of a quid pro quo arrangement.'

VNPCA Code

'Companies should not pay/give cash or gifts to healthcare professionals.

The company may offer gifts that are items that have educational, medical, or patient benefit (eg, medical books) to health workers. These gifts must conform to the specialised field of health workers.'

The VNPCA Code does not provide a specific threshold limit for such gifts.

14. What rules govern the offering of hospitality to healthcare professionals?

Vietnamese laws
Not specified

PG code
Hospitality provided to the HCPs must be limited to refreshments and/or meals incidental to the main purpose of the event and its value must be moderate and reasonable as judged by local standards. Alcoholic drinks are not allowed during an event lunch. Refreshments during dinner can include alcohol, with reasonable limits. Applicable laws must be respected.

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

Not specified under Vietnamese laws.

PG Code

- 'No financial benefit or benefit-in-kind (including grants, scholarships, subsidies, support, consulting contracts, or education or practice related items) may be provided or offered to an HCP that inappropriately influences prescribing, recommending, purchasing, supplying, or administering medicines or for a commitment to continue to do so (ie, no quid pro quo).
- Donations are prohibited from being given directly to individuals.
- Donations must be in a written agreement with examination and treatment establishments and public hospitals. It must be clearly stipulated that the donation recipients must (i) follow the procedures for the preparation, evaluation, and approval of the foreign non-governmental aid amount in compliance with applicable regulations; and (ii) manage and use the donation only for humanitarian objectives in accordance with its commitments in the agreement and not use the donation for any other purposes.'

VNPCA Code
'Funding, scholarships, subsidies, support, consulting contracts, education, etc. should not be provided to healthcare professionals to exchange, set the conditions of recommended use, drug prescription or unduly influence the ethics and independence of related healthcare professional. Companies should only

sponsor, grant scholarships, subsidise, etc. with the purpose of supporting legal education, scientific research, and/or medical research.'

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

Vietnamese laws
Not specified.

PG code
'Sponsorship to individual HCP to attend events

- PG members can organise or sponsor HCPs (either directly to HCPs or through their organisation) to attend in-country events or international events, provided that such international events derive participants from many countries. Any sponsorship for HCPs to attend such events must not be conditional upon an obligation to promote, recommend, prescribe or purchase, supply or administer any pharmaceutical product. Such sponsorship must:
  – Always be in line with the primary purpose of enhancement of scientific and medical knowledge, through obtaining information that is critical to the improvement of patient care and overall enhancement of healthcare delivery, and such sponsorship must be supported by written documentation;
  – Avoid any conflict of interest as stipulated in relevant Vietnamese laws and conform to the internal regulations of the HCP organisation; and
  – Comply with the PG Code and applicable laws.

- PG member sponsorship for HCPs to attend events must be subject to the following conditions:
  – The sponsorship must have legitimate scientific and medical knowledge enhancement purpose, and strictly follow applicable Vietnamese laws;
  – PG member must inform the HCP organisation and ensure full transparency about invitation or sponsorship for HCPs to attend events, including details of the sponsorship and the agenda of the event; and
  – The event programme must not include standalone entertainment, sight-seeing or side trips, or other inappropriate activities or located at an inappropriate venue.

- PG member sponsorship for HCPs to attend events must comply with the following requirements:
  – The selection of HCPs must be based on the expected added value of the event for their area of expertise, following a fair selection process and not give any potential appearance of inappropriateness or bias, and avoid any issue of conflict of interest. PG member must ensure that the HCPs have obtained the official permission from their organisation to attend the event.
  – Transport and accommodation should be provided as per reasonable standards considering the nature and venue of the event and the level of involvement of the HCPs. For example, business class tickets for local travel, luxurious or extravagant accommodation must not be provided. Sponsorship to stand-alone entertainment, sight-seeing or side trips or other leisure or social activities are not allowed. There must be a reasonable and justified timeframe for the departure and return of the HCPs to and from the event location.
  – Hospitality provided to the HCPs must be limited to refreshments and/or meals incidental to the main purpose of the event and its value must be moderate and reasonable as judged by local standards. Alcohol drinks are not allowed during the event lunch. Refreshments during dinner can have alcoholic drinks, with reasonable limit. Applicable laws must be respected.
  – Companies must not pay any costs associated with individuals accompanying the HCP, except in cases of medical necessity. HCPs can have accompanying individuals with them at their own expense, but PG members will not involve in logistic arrangement for accompanying people. Accompanying people (except in cases of medical necessity) should not be allowed to attend any event for HCPs.
  – All sponsorship arrangements must be appropriately documented before and after the event. Specifically, regarding sponsorship for HCPs to attend international events, there must be commitment from HCPs who attend the event to share the benefit of knowledge gained on their return to Vietnam, such as through presentation to other HCPs (no honorarium shall be provided) or a report to their organisation or other academic/medical institution.'

'Events organised in foreign countries
PG members must not organise or sponsor HCP to attend events that take place outside of their home country unless it is appropriate and justified to do so from a logistical or security point of view. PG

members can organise or sponsor HCP to attend international events, as these derive participants from many countries in this case the host country regulations and standards can be applied, unless otherwise provided by Vietnamese Laws.'

VNPCA Code
'Any financing of companies offering to individual healthcare professional are not tied to conditions and/or obligations and/or suggestions to prescribe, usage recommendation, or to promote any medicines.'

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

Under Vietnamese laws
It is prohibited for the medical representatives of drug trading companies to approach patients, collect information regarding the patients' medical records or drug prescriptions; or discuss or require information related to patients.

Under PG Code
'PG members must not answer requests from individual members of the public for advice on personal medical matters. Enquirers must be referred to their personal physicians. This includes toll-free information services. Medical representatives must never discuss medical matters with patients in any forum, including health fairs, pharmacies, hospitals, and physicians' waiting rooms, even if approached directly by a patient, nor may they instruct patients on how to use company products. Patients must be advised to seek advice directly from their physician, who, in turn, may contact PG members for further information. Disease awareness campaigns or patient education programmes can be supported by PG members by providing a grant to a competent medical association which is authorised to conduct such campaigns.

'PG members may support the work of independent patient associations but must ensure that their involvement has been declared and is transparent, that all of the arrangements comply with this Code and applicable Laws, and that a written agreement is in place. PG members must not influence the operation of the funded patient associations. The independence of this association must be fully kept.'

Under VNPCA Code
No specific provision is mentioned. In interactions with all relevant parties, a member company is committed to:

- Implement the highest ethical standards.
- Implement fully and responsibly all laws and regulations in force.
- Encourage medical professionals, government officials, and others working with the company always to respect and apply the appropriate ethical standards that conform to the VNPCA Code.
- The VNPCA Code is to ensure that the interaction of the company is done in a professional manner and aimed at bringing benefits to the patients.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

It is permitted to delegate advertising activities to an advertising service provider through advertising service contracts. An advertising service provider can be an organisation or individual that performs one, some, or all the phases of an advertising process depending on the advertising contract.

In cases of commercial advertising activities, the advertising service provider must be a trader. According to Vietnamese law, traders include lawfully established economic organisations and individuals that conduct commercial activities in an independent and regular manner and have business registrations.

In cases of advertising related to foreigners, foreign organisations and individuals not operating in Vietnam seeking to advertise their products or services in Vietnam must hire an advertising service provider in Vietnam. Moreover, the representative offices are only allowed to promote advertising, and cannot directly provide advertising services.

There are currently no specific provisions about co-promotion in Vietnam. However, to obtain an approval on drug advertising/promotion contents, a local pharma company or a representative office of an overseas pharma company must submit an application dossier. After getting the approval, a third party may conduct the advertising/promotion activities. There is no similar requirement for the advertising/promotion of medical devices.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

In light of the anti-corruption regulations, an HCP must refuse to receive a gift from permit/authorisation holders. In case the HCP cannot refuse, the HCP must report to the head of their agency, organisation, or unit or the head of the superior agency, organisation, or unit and return the gift for handling according to the provisions within the time limit of five working days from the date of receiving the gift.

The report must be presented in writing and include all the following contents: full name, position, agency, and address of the gift donor; type and value of the gift; time, place, and specific circumstances when receiving gifts; and relationship with the gift donor.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

Violations of regulations on pharmaceutical advertising can subject the violators to a fine of up to VND80m (approx. US$3,150). In addition, the right to use relevant licences such as a certificate of conformity to pharmaceutical business regulations, the acknowledgement of receipt of registration for product launch announcement, or the permit for healthcare service provision might be withheld for up to three months depending on the specific case. Further, in some cases the violator would be forced to correct information and to recall and remove infringing elements.

Violations of regulations on medical device advertising can subject the violators to a fine of up to VND40m (~ US$1,570). Further, in some cases the violator would be forced to correct information and to recall and remove infringing elements.

According to our observation, the supervisory authorities often impose the highest level of monetary penalties and other sanctions whenever they can be applied.

The decisions on handling violations related to pharmacy, including pharmaceutical advertising, can be uploaded on the official website of the DAV: https://dav.gov.vn/thong-tin-xu-ly-vi-pham-cn5.html.

However, there is no official platform for publicising violations related to medical devices.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

The authorities responsible for enforcement of advertising regulations are:

Pharmaceuticals
Supervisory authorities

- Inspectorate of the DAV
- Inspectorate of the SoH
- Inspectorate of the MoH
- Market Surveillance Officials

Medical devices
Supervisory authorities

- Inspectorate of the SoH
- Inspectorate of the MoH
- Market Surveillance Officials

The frequency of inspecting activities of the supervisory authorities may vary. However, once a violation is exposed, it is usually handled strictly as the supervisory authorities often impose the highest level of monetary penalty and other sanctions whenever they can be applied.

Competitors would rarely be able take any action through courts regarding promotion (advertising). According to Vietnam's Code of Civil Procedure, the competence of the court does not cover any petitions related to promotion (advertising) infringements, and only disputes between parties on compensation regarding promotion (advertising) infringements may be settled in court.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

The MOH of Vietnam has announced the Draft of Amended Law on Pharmacy, which is expected to be finalised at the end of 2024. The Draft contains amended provisions relating to pharmaceutical information and advertising as follows:

- The procedure for certifying pharmaceutical information and advertising prescribed in Article 78.3 and 79.3 of the Law on Pharmacy might be eliminated in accordance with the plan for simplification of administrative procedures prescribed in Articles 38, 39, 40, and 41 in Section I, Part II of Decision No 1661/QĐ-BYT approved by the Prime Minister.
- To amend, supplement, and eliminate provisions on responsibilities of pharmaceutical information providing, advertising establishment to align with the new management mechanism (post-inspection) in Article 6.10.
- To amend Article 76.3 of the Law on Pharmacy to assign the Government to detail the grounds for formulating drug information content for medical examination and treatment practitioners.

Over the last year, we have witnessed no significant changes in the enforcement practice in pharmacy and medical devices in Vietnam.