

PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES
Authors: Att. Gwyneth Ong, Att. Jaime S. Fernandez and Att. Marie Claudine B. Bernas
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.
<p>The promotion and advertising of pharmaceuticals and medical devices is generally governed by the following:</p> <ul style="list-style-type: none">• Republic Act (RA) 7394 or the Consumer Act of the Philippines (Consumer Act);• RA 9711 or the Food and Drug Administration (FDA) Act and their respective Implementing Rules and Regulations (IRR);• RA 2382 or the Medical Act of 1959 and its IRR (Medical Act);• RA 6675, as amended or the Generics Act of 1988 and its IRR (Generics Act);• RA 5921, as amended or the Pharmacy Law and its IRR;• RA 11223, or the Universal Healthcare Act and its IRR (Universal Healthcare Act);• RA 8293 or the Intellectual Property Code of the Philippines and its IRR (Intellectual Property Code);• Department of Health (DOH) Administrative Order 65, series of 1989 or the Guidelines on Advertisement and Promotions of the Generics Act;• DOH Administrative Order No 55, series of 1988;• DOH Administrative Order No 53, series of 2015 or <i>the</i> Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices (PPPMD Guidelines);• DOH Administrative Order No 2021-0036;• Joint Department of Trade and Industry, DOH, and Department of Agriculture Administrative Order No 08-01, series of 2008 or <i>the</i> Rules and Regulations for Consumer Protection in a Transaction Covered by the Consumer Act of the Philippines (RA 7394) through Electronic Means under the E-Commerce Act (RA 8792);• FDA Advisory No 2022-0108, Reiteration of Warning Against the Promotion and Advertisement of Prescription Drug Products; and• FDA Circular No 2021-0021, the Guidelines on the Licensing of Retailers of Medical Devices in the Philippines <p>Codes of self-regulatory bodies</p> <ul style="list-style-type: none">• Philippine Medical Association (PMA) Code of Ethics;• Pharmaceutical & Healthcare Association of the Philippines Code of Practice (PHAP Code of Practice); and• Ad-Standards Council (ASC) for Responsible Advertising Guidebook.
2. How is ‘advertising’ defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?
<p>The Consumer Act defines ‘advertising’ as ‘the business of conceptualising, presenting or making available to the public, through any form of mass media, fact, data or information about the attributes, features, quality or availability of consumer products, services or credit’ and an ‘advertisement’ as ‘the prepared, and through any form of mass medium, subsequently applied, disseminated or circulated advertising matter’.</p> <p>It defines ‘sales promotion’ as a technique intended for broad consumer participation which contain promises of gain such as prizes, in cash or in kind, as reward for the purchase of a product, security, service or winning in contest, game, tournament and other similar competitions which involve determination of winner/s and which utilise mass media or other widespread media of information. It also means techniques purely intended to increase the sales, patronage and/or goodwill of a product.</p> <p>The PPPMD Guidelines define ‘promotions’ as ‘the practice of giving value to a brand, product, or service, to achieve specific marketing objectives. It includes the distribution of free/sample pharmaceutical products. It shall also refer to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.’</p>

The Consumer Act provides special advertising requirements for drugs and medical devices insofar as labelling, registration, and authenticity of claims, among others, are concerned.

The FDA IRR provides for the following general rules on advertisements, promotions, sponsorships and other marketing activities of pharmaceuticals and medical devices:

- a) No health product that has not been registered or authorised shall be advertised, promoted or subjected to any marketing activities;
- b) No claim in the advertisement, promotion and sponsorship, and other marketing activities shall be made other than those contained in the approved label or packaging of the health product, or as duly approved by the FDA;
- c) No claims, therapeutic or scientific otherwise, shall be made that has not been duly approved by the FDA; and that
- d) All health products that are permitted to be promoted must specifically state the authority or reference number that approved the same promotional, sponsorship, or marketing activities.

The Generics Act mandates that the generic name of drugs and medicines shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials. Exemptions from generic labelling requirements of various pharmaceutical products are provided in FDA Circular No 2013-012.

FDA Advisory No 2022-0108 specifically bans advertisement and promotion of prescription pharmaceuticals to the general public. Such prohibition does not apply to medical devices or prescription medical devices. However, the PPPMD Guidelines apply to and cover both pharmaceutical products and medical devices.

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?

The DOH and the FDA are the agencies primarily tasked with issuing the appropriate policies, standards, and guidelines to regulate the promotion and advertising of pharmaceuticals and medical devices.

While these primary agencies do not monitor self-regulatory processes required by the various self-regulating bodies such as the ASC, PHAP and PMA, they still necessarily regulate the conduct of the PPPMD companies insofar as they are licensed to engage in the business involving PPPMD.

With regard to the rules imposed by self-regulating bodies on its members, we note that the same remain tied to the regulatory framework of the supervisory and enforcement authorities insofar as these still require compliance with the fundamental regulatory framework governing PPPMD companies.

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?

The Consumer Act applies to all sorts of consumer goods and services including, but not limited to, food, cosmetics, and hazardous substances. However, depending on the product category, different product types may be subject to additional and/or different labelling and advertising restrictions imposed by the administrative agencies which have jurisdiction over the regulation of the marketing and/or use of such product.

For instance, FDA Memorandum Circular No 2015-003 and ASC Circular 2018-016 mandate all food/dietary supplement owners, manufacturers, distributors, importers, exporters, advertisers and/or their agents to strictly carry, in Filipino, the standard message or phrase: '*MAHALAGANG PAALALA: ANG (NAME OF PRODUCT) AY HINDI GAMOT AT HINDI DAPAT GAMITING PANGGAMOT SA ANUMANG URI ANG SAKIT*'. Loosely translated, this means '*Important Reminder: This (name of product) is not a medicine and should not be used for treating any type of illness*'. For audio advertisements or promotions, the same message or phrase shall be clearly and audibly voiced over, without being cut-off, in the last line of the advertisement or promotions regardless of its duration.

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?
<p>No, not all forms of pharmaceuticals and medical devices may be advertised or marketed. FDA Advisory No 2022-0108, provides that the promotion or advertisement of prescription drugs in the Philippines is prohibited and only FDA-registered non-prescription or over-the-counter drug products can be advertised or promoted to the general public.</p> <p>The same issuance provides that no pharmaceutical product categorised as a prescription or ethical drug shall be advertised or promoted in any form of mass media, except through medical journals, publications or literature exclusively meant for medical and associated professionals.</p>
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?
<p>Yes, Joint DTI-DOH-DA AO No. 08-01, series of 2008 provides for the adoption of fair marketing and advertising practices through electronic means, thereby explicitly applying the existing regulatory framework in the Consumer Act to e-Commerce transactions. To this effect, the specific issuance provides that retailers, sellers, distributors, suppliers or manufacturers engaged in electronic commerce with consumers are prohibited from engaging in any false, deceptive and misleading advertisement banned under the Consumer Act, and shall comply with the advertising and promotion requirements therein, and other advertising and promotion guidelines issued by the respective departments in compliance with other relevant laws.</p> <p>For transactions through the internet, the issuance also requires retailers, sellers, distributors, suppliers or manufacturers to disclose the following information: (1) their business registration, beneficial owner, principal address, website, email address, contact details, and Philippine representatives, if applicable; and (2) information about the product or service such as – (i) fair, accurate, clear and easily accessible information describing the products or services offered for sale such as the nature, quality and quantity thereof; (ii) fair, accurate, clear and easily accessible information sufficient to enable consumers to make an informed decision whether or not to enter into the transaction; and (iii) such information which allows consumers to maintain an adequate record of the information about the products and services offered for sale.</p> <p>Notably, under FDA Circular No. 2021-021, retailers are banned from the online selling of prescription medical devices. However, such retailers are still allowed to advertise prescription medical device online, provided that the advertisement does not contain a link for online purchase.</p>
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)?
<p>The promotion and/or advertisement itself does not need prior approval from regulators, but such product being promoted or advertised should be registered or authorised by the FDA.</p> <p>Regardless of the medium, advertisements for over-the-counter (OTC) drugs and home remedy (HR) products requires pre-screening and clearance from the ASC. Other pharmaceuticals and medical devices which do not fall within the classifications of OTC and HR products, however, are only subject to pre-screening and clearance, if the medium of the advertisement shall be through television and radio, cinema and out-of-home advertisements.</p> <p>While the same does not constitute prior approvals, the PPPMD Guidelines provide that the FDA may conduct post-audit of advertising, promotional or other marketing materials, whether written, audio or visual involving pharmaceuticals or medical devices.</p>
8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?
<p>The term 'off-label promotion' is not specifically defined in Philippine law or regulation. However, we understand 'off-label promotion' to mean the advertisement of the particular use of a medical or health product that is not in accordance with the prescribed or intended use approved by the FDA.</p>

Given the said definition, the practice of off-label promotion is not allowed under Philippine law since the act itself of advertising in a manner not in accordance with the approved label or packaging of the FDA is prohibited under the FDA Act. Also, if done for the purpose of inducing or is likely to induce, directly or indirectly, the purchase of a consumer product or service, could likewise be considered as a false, deceptive, or misleading advertisement that is unlawful under the Consumer Act.

However, under the 2.2 of the PHAP Code of Practice, insofar as PPPMD companies are concerned, the above-stated ban is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress.

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?

The ASC Guidebook provides for the general rules for comparative advertising across all product categories, including pharmaceuticals and medical devices. It defines a 'Comparative Claim' as one which claims advantage over another brand or service, previous formulation/properties, a set of products, or versus non-use of the product or service. This claim must always be properly qualified as to what it compares itself against. It may also be substantiated by an independent third-party data support. Notably, the same ASC Guidebook does not include pharmaceuticals and medical devices in the list of product categories which are allowed to be the subject of direct comparison advertising.

The PPPMD Guidelines provides the specific requirements for comparative claims for pharmaceuticals and medical devices:

- claims properly supported by scientific data and in accordance with local regulations may be allowed;
- the use of adverse drug reaction data to compare two drug products in promotional materials may be allowed to demonstrate a full, fair, and balanced comparison;
- superiority claims may be allowed if supported by competent (measuring up to all requirements) and well controlled clinical trials; and
- claims related to difference in efficacy between drugs may be allowed if it is clinically relevant and statistically significant.

The use of another company's information without that company's consent, as part of the comparison, may violate their intellectual property law and may expose the company using such advertising to liability.

Insofar as pharmaceuticals and medical devices are concerned, the same cannot be made reference to if it is not yet registered or authorised by the FDA.

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?

The PPPMD Guidelines define healthcare professionals (HCPs) as any member of the medical, dental, pharmacy or nursing profession or any other person who, in the course of their professional activities, may prescribe, recommend, purchase, supply, administer or dispense a health product accordingly.

The same issuance regulates the interactions between PPPMD companies and the HCPs. Particularly, promotions or advertisements by PPPMD companies to HCPs must comply with the following:

- information provided to HCPs shall be strictly evidence-based scientific data;
- promotional materials shall – (1) demonstrate the balance between risks and benefits; (2) comply with existing FDA and other pertinent regulations; (3) substantiate claims with up-to-date scientific evidence;
- informational/educational materials must show – (1) benefits and risks of the drug or device; (2) pharmacodynamics and pharmacokinetics of the drug; (3) indications and contraindications to use of the drug or device; (4) adverse effects and drug interactions;
- no employment or contracting of an HCP to promote, advertise, or endorse any pharmaceutical product or medical device in mass media, print, audio visual display or social media is permitted;

<p>The PPPMD Guidelines further prohibit the following claims or comments to HCPs:</p> <ul style="list-style-type: none"> ● one-sided information and any decisive statement based on inadequate or truncated evidence; ● superlatives, exaggerations and lines with hanging comparatives, without supporting data; ● unsupported comments about competitors and their products; ● unspecified, unreferenced claims about side effects, safety and efficacy; ● the use of the word ‘new’, unless the product or indication has been available and generally promoted for less than 12 months; ● ‘non-toxic’, and ‘no side effects’; and ● unspecified, unreferenced claims about safety and efficacy without proper qualification. <p>Moreover, the Code of Conduct of the Philippine Medical Association in relation to the Philippine Medical Act provides the following ethical guidelines with respect to the relationship between physicians and the health products industry:</p> <ul style="list-style-type: none"> ● Physicians shall not derive any form of material gain from product samples. ● Physicians may participate in post-marketing or similar activities where they are asked to try new products on patients provided that the patients are properly informed and have given their informed consent. Physicians are encouraged to report or share the result of such activities to the duly constituted authorities. ● Only gifts of reasonable value that primarily entail benefit to patient care or related to physicians’ work may be accepted by a physician from a health product company. ● Physicians may request donations for a charitable purpose for as long as it does not redound to his or her personal benefit. ● Research activities shall be ethically defensible, socially responsible, and scientifically valid. Any remuneration should be reasonable and should not constitute an enticement. ● Research trials conducted by physicians for an industry should be done in accordance with the national or institutional guidelines for the protection of human subjects.
<p>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?</p>
<p>Yes, the PHAP Code of Practice provides for the rules governing virtual engagements. Virtual engagements are defined under the PHAP Code of Practice as activities that use virtual or digital platforms in lieu of face-to-face interactions. These virtual platforms include but are not limited to emails, text messages, messenger applications, virtual meeting applications, social media and webinar facilities. Virtual engagements include both third party and company-sponsored events.</p>
<p>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?</p>
<p>Yes. The Code of Ethics of the Philippine Medical Association expressly prohibits a licensed physician from commercially endorsing any medical or health product. In the event an HCP violates the above-stated rule, they shall be subject to disciplinary action by the Professional Regulatory Board.</p> <p>Commercial endorsement includes the advertising or promotion of medical and health products, whether a physician is paid or not. It includes statements or declarations promoting or advertising medical or health products and the use of the names or the pictures of physicians in the advertisements or promotions. Favourable written or verbal reviews or statements of support for a medical or health product are included as commercial endorsements and are prohibited.</p>
<p>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.</p>
<p>Yes, the PPMD Guidelines allow the provision of samples to healthcare professionals, provided that the following conditions are met:</p> <ul style="list-style-type: none"> ● The samples are duly acknowledged by the HCP or Health Care Organisations (HCO). ● Manufacturers and distributors shall not give, directly or indirectly, samples of prescription pharmaceutical products or medical devices to the general public or gifts of any sort to any member of the HCP’s immediate family.

- Samples of prescription products should not be distributed to anyone other than licensed physicians and dentists.

On gifts and donations, the PPPMD Guidelines provide the following:

- Any item which does not have any direct patient benefit or is not related to the work of the HCP shall not be permitted.
- Gifts or personal services and benefits unrelated to the work of the HCP shall not be provided by any PPPMD company representative to HCPs or members of their families.
- PPPMD companies may provide promotional aids to HCPs, provided these (1) are of modest value; and (2) are relevant to the practice of the healthcare professions or education of the patients.
- PPPMD companies may occasionally provide items of medical utility, which should be of modest value, to HCO and HCPs such as textbooks, subscriptions to medical journals or anatomical models which benefit patients or serve a genuine educational function for the HCO or HCP.

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

The PPPMD Guidelines provide that PPPMD companies shall not provide any form of entertainment that would incur expenses for recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips (including any travel sponsorship, meals, or other expenses of accompanying guests of the HCP) to any HCP. Offering such form of entertainment is prohibited regardless of: (1) value; (2) whether the HCP is engaged by the PPPMD company as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.

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?

Yes, donations may be considered as promotions or advertising. The PPPMD Guidelines permit PPPMD companies to make donations to healthcare institutions or organisations, provided that the PPPMDs donated must be duly registered with the FDA. The use of the donated products is subject to monitoring by the FDA and shall not be sold at commercial outlets. The donee is required to execute an undertaking stating that the donated pharmaceuticals and medical devices will not be used for financial gain.

The PPPMD Guidelines further provide that any donations for charitable, humanitarian or health purposes and not for promotional reasons, are not restricted.

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?

Yes, the PPPMD Guidelines specifically allow PPPMD companies to support third-party seminars, scientific meetings, and third-party conferences, provided the following conditions are met:

- the meals provided are modest;
- no entertainment that would incur expenses is provided during the entire duration of the activity;
- conference organisers shall make a written request to the PPPMD company containing relevant information such as scientific content, attendees, duration and cost;
- the support provided is consistent with the PPPMD Guidelines;
- the venue is appropriate and conducive to the scientific/educational objectives of the event – no extravagant venues are allowed, unless there is no other suitable venue in the locality where the event is to be held;
- all forms of support and activities are well documented;
- attendees to such conference are legitimate or authorised; and
- speakers shall disclose any potential or actual conflict of interest prior to topic presentation during the event.

Third party conferences are defined as a conference sponsored or conducted by or on behalf of a professional associate that is independent, of an educational or scientific or policy making nature and for the purpose of promoting scientific knowledge, medical advancement or delivery of effective healthcare.

To allow the FDA to monitor compliance, PPPMD companies are required to notify and inform the FDA of any activities/events by it in conjunction with any medical society/association at least one month prior to holding of the said activity, if the said activity involves more than 100 HCP participants.

<p>The PPPMD Guidelines do not provide for any differences in treatment of Prescription Pharmaceutical Products Companies or Medical Devices Companies for purposes of supporting scientific or educational meetings.</p>
<p>17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.</p>
<p>The PPPMD Guidelines expressly allow PPPMD companies to provide support to patient organisations, provided that the autonomy of the said organisation is upheld and that the support is not intended to influence them to favour a particular product.</p> <p>Patient organisations are required to make a public disclosure of funding sources.</p>
<p>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?</p>
<p>Yes, promotions or advertising may be delegated to a third party. The PPPMD Guidelines covers 'all natural and juridical persons and entities engaged in the dissemination or publication of information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities of prescription pharmaceutical products and medical devices including their agents and/or their industry association.' Consequently, promotions or advertising for PPPMD conducted by a third party would fall within the coverage of the PPPMD Guidelines and would be subject to compliance under the same regulations. Notably, the Generics Act provides that the PPPMD company under whose name the drug product is registered will be held responsible for ensuring that its advertisement and promotions are compliant with the requirement that the generic name be prominently indicated. In the event that an advertisement or promotion is deemed violative of the Generics Act, it is the market authorisation holder who shall be held liable notwithstanding the advertisement or promotion being conducted by a third party.</p> <p>The term 'co-promotion' is not clearly defined in any regulatory issuance but the PHAP Code of Practice in defining 'Agents and Third Party Agents', refers to the term 'co-promotion agreements' as an example of an external sales force. Where 'co-promotion' takes the form of a licensing agreement, the provisions of the Intellectual Property Code will apply.</p>
<p>19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?</p>
<p>Yes, under Section 35(b) of the Universal Healthcare Act, all manufacturers of drugs, medical devices, biological and medical supplies registered by the FDA shall collect and track all financial relationships with HCPs and healthcare providers and report these to the DOH, which shall then make this list publicly available in accordance with existing laws.</p> <p>The IRR of the Universal Healthcare Act provides the definition of such 'financial relationships' as a form of emolument that may be contractual or non-contractual in nature, such as but not limited to cash, cash equivalent, in kind, stock, stock option or any ownership interest, dividend, profit or other return of investment, and transfers of value. Such transfer of value involves both direct and indirect transfer in any kind in connection with the development or sale of drugs, medical devices, and biological and medical supplies.</p> <p>These financial relationships shall be disclosed to the DOH pursuant to DOH Administrative Order No 2021-0036. Therefore, all persons covered under the disclosure requirements under the Universal Healthcare Act shall document, maintain records, submit to the DOH-FDA such Disclosure Reports and make publicly available all data and information on financial relationships directly or indirectly made with HCPs. These are to be submitted through the FDA Online Disclosure Report System (https://odrs.fda.gov.ph). Submissions of the Disclosure Reports shall be every six months.</p>
<p>ENFORCEMENT</p>
<p>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?</p>
<p>The PPPMD Guidelines in relation to the other applicable laws provide for the following sanctions for violations relating to the promotion or advertising of pharmaceuticals or medical devices. The FDA shall:</p> <ul style="list-style-type: none"> ● recommend the filing of appropriate charges with the government agency concerned or appropriate court;

- impose sanctions such as confiscation or seizure of the product, revocation or suspension of licence, and fines; and
- post/publish the imposition of sanctions on its website.

The posting/publication on the FDA website is a public announcement of such violations but there is lack of publicly available information on what type or frequency of sanctions are imposed in relation to investigations initiated *motu proprio* and/or as a result of complaints.

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 FDA is primarily responsible for administrative enforcement. The PPPMD Guidelines outline the procedure for filing complaints with the FDA. A private party or the FDA, *motu proprio*, may file a complaint or initiate an action. The FDA also has the power to recommend the filing of the appropriate charges with the government agencies concerned. It may also impose sanctions, such as fine and imprisonment, pursuant to RA 3720, RA 9502, and RA 7394.

Competitors may take direct action through Philippine Courts, depending on the cause of action, ie, claims for damages.

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?

Investigations in support of legislation are currently being conducted by Congress in relation to the practice of pharmaceuticals or pharmaceutical distributors' marketing of its products to HCPs. These may potentially result in legislation or the issuing of administrative rules.

Insofar as enforcement trends are concerned, the FDA has frequently published advisories and warnings on the consumption of various goods. The agency regularly receives complaints from the public and conducts online monitoring or post-marketing surveillance of the goods in the market in order to check for compliance with advertising regulations, among others.