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.

In Panama, the main regulatory framework for pharmaceuticals and medical devices is set forth in the Panamanian Health Code (Código Sanitario), approved by Law 66 of 10 November 1947.

On the other hand, Law 90 of 26 December 2017, establishes the regulatory framework applicable to medical devices and related products ('Law 90'). As set forth in Article 1 of said law, it

> '[r]egulates the manufacturing, conditioning, import, export, re-export, information, advertising, labeling, distribution, marketing, storage, and final disposal of medical devices and related products that exist or may exist in the national territory, including fiscal or special customs territories, such as free zones, processing zones, or equivalents, as well as everything related to the Operating License, Certificate of Free Sale, Certificate of Good Manufacturing Practices, Certificate of Good Storage Practices, Certificate of Good Distribution Practices, and other similar certifications of the establishment that markets medical devices, the Sanitary Registration of Medical Devices, and the surveillance of such products, by the health authority. It will also regulate matters related to the Technical Verification Certificate of Medical Devices acquired in public institutions in the country. Medicines, active ingredients, excipients, raw materials for medicines, radiopharmaceuticals, and contrast media regulated by other legislation are exempt from this Law.' (unofficial translation)

In addition, Executive Decree No 83 of 26 April 2019 ('Executive Decree 83') further regulates Law 90 to include provisions regarding the issuance, renewal, correction, update, suspension and cancellation of Health Permits ('Registro Sanitario'), the Certificate of Free Sale, the Technical Verification Certificate of Medical Devices and related products, and the Operating License for economic agents engaged in the commercialisation of medical devices and related products.

Moreover, Law 419 of 1 February 2024 ('Law 419') regulates pharmaceuticals and other products for human health, as well as the public acquisition of pharmaceuticals, other products for human health supplies, medical devices and equipment. This law will come into effect 90 days after its promulgation, but as of the day hereof, is still pending the development of its regulation.

Regarding its scope, Article 1 of Law 419 states the following:

> 'This law regulates the overall management of the manufacturing, quality control, health registration, import, marketing, distribution, acquisition, and information and advertising of products for human health, such as finished medicines, pharmaceutical specialties, psychotropic and narcotic substances, biological products, medicaments developed through genetic engineering, therapeutic dietary supplements, homeopathic products, phytopharmaceuticals, radiopharmaceuticals, medicinal gases, chemical precursors for medicinal use, cosmetics, domestic and public health pesticides, antiseptics, hospital disinfectants, hygienic products, personal hygiene products, and any other product related to human health, whether existing or potential, except for veterinary products'.

The Ministry of Health, through the National Directorate of Pharmacy and Drugs, is authorised to verify compliance with the health provisions established in this law in companies located in fiscal or special customs territories, such as free zones and processing zones, dedicated to the import, conditioning, manufacturing or other activities related to medicines or products for human health destined for abroad, with the exception of the health registration process.

Likewise, it establishes the mandatory rules and procedures that will govern the processes of bidder selection and the acquisition of medicines, medical devices and medical supplies by the health entities of the Ministry of Health, the Social Security Fund, health boards and public institutions, as well as those carried out with public funds or national assets (unofficial translation).

Finally, the General Directorate of Public Health of the Ministry of Health enacted Resolution No 523 of 21

February 2019 ('Resolution 523'), which regulates and establishes the procedures to request the approval of any advertising and/or propaganda material for any product, equipment or service related to hygiene, medicine, cosmetics, food and, in general, anything that is related or may affect the physical and/or mental health of the population in the Panamanian territory.

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

The law does not define 'advertising' nor distinguishes between the promotion and advertising of pharmaceuticals or medical devices. However, Law 90 defines 'commercialisation' as 'making available, with the intent to distribute and/or use in the market, a new medical device or related product not intended for clinical investigations'.

Nonetheless, Resolution 523 clearly establishes the provisions applicable to the approval of any advertising and/or promotional material of the aforementioned products. In addition, all promotions, offers and advertising must comply with applicable legislation on consumer protection and antitrust.

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 Ministry of Health is the regulatory and supervisory authority that regulates and enforces the promotion and advertisement of pharmaceuticals and medical devices.

The National College of Pharmacists of Panama, established by Law 24 of 29 January 1963, is a non-profit professional organisation, where membership is not mandatory. Its purpose is to safeguard the honour and dignity of those practising the profession of pharmacy in Panama. Additionally, it is responsible for ensuring compliance with and application of the regulations and authorities outlined in the by-laws, Law 419 and other laws of the Republic of Panama.

Nonetheless, pursuant to Panamanian law, there are no self-regulatory processes applicable to medical devices. Given that this is a highly regulated sector, the only supreme regulatory authority is the Ministry of Health, through its different directorates.

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?

Yes, other products such as biological products, medicaments developed through genetic engineering, therapeutic dietary supplements, homeopathic products, phytopharmaceuticals, radiopharmaceuticals, medicinal gases, chemical precursors for medicinal use, cosmetics, domestic and public health pesticides, antiseptics, hospital disinfectants, hygienic products, personal hygiene products and any other product related to human health, whether existing or potential, except for veterinary products, fall under the purview of Law 419.

There are no special considerations for the promotion of the aforementioned product types.

Nonetheless, to the extent that such other products fall under the category of 'food products' or 'supplements', in addition to compliance with the provisions established by the Ministry of Health regarding Sanitary Permits and others, the Panamanian Authority of Food Security (Autoridad Panameña de Seguridad de Alimentos or APA) imposes other requirements applicable to import and distribution.

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?

It is possible to direct such promotion to the public, as long as the pharmaceuticals and medical devices have the corresponding permits and licences issued by the Ministry of Health, and that proper authorisation for the promotion and advertisement by the General Directorate of Public Health has been granted.

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?

No, the promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media is not specifically regulated in Panama. Nonetheless, such promotion (and advertising) should comply with Resolution 523, regardless of the means used for advertising.

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)?

Yes, all promotions and/or advertisement of pharmaceuticals and medical devices must receive prior approval from the General Directorate of Public Health of the Ministry of Health.

To request approval for advertising and propaganda, the interested party must submit to the General Directorate of Public Health the material for approval, accompanied by the following requirements, documents, and/or elements for the approval of advertising and propaganda:

1. An application letter for the approval of advertising material, addressed to the General Directorate of Public Health. This request may group various materials or advertising elements that make up the same advertising campaign, provided that they are duly numbered and identified, allowing the Advertisement and Propaganda Commission (the 'Commission') to refer to each one separately. The formal written request must include the following: name of the advertiser and/or economic agent, product name, media in which it will be scheduled, version of the material and duration of the commercial.
2. In the event that the approval request for advertising material is submitted through a lawyer or special representative, a power of attorney is necessary.
3. A simple copy of the commercial licence and/or document accrediting the responsible economic agent in the Republic of Panama.
4. A simple copy of the registration issued by the Panamanian Food Safety Authority (AUPSA) for the product to be advertised (when applicable).
5. A simple copy of the Sanitary Registration issued by the National Directorate of Pharmacy and Drugs (when applicable).
6. A simple copy of the Sanitary Registration of the Food Protection Department of the product to be advertised (when applicable).
7. A simple copy of the Sanitary Registration of the Department of Regulation and Surveillance of Medical Technologies (when applicable).
8. A simple copy of the Sanitary Registration of the Central Reference Laboratory in Public Health (when applicable).
9. A simple copy of product labels duly approved by the National Directorate of Pharmacy and Drugs or AUPSA, as the case may be.
10. A simple copy of product labels duly approved by the Food Protection Department (when applicable).
11. In the case of printed advertising and/or propaganda, the printed material must be presented in colour and in the size in which it will be published, except for billboards and street marketing advertisement media (commonly referred to as '*mupis*'), which will be presented in size 8 1/2 x 14.
12. In the case of television and/or radio advertising and propaganda, the audio-visual material must be presented on CD, DVD or USB, in good quality, MP4 format, or another easily reproducible standard.
13. In the case of audio-visual material in a language other than Spanish, a written translation into Spanish by an authorised public translator must be provided.
14. In the case of dubbed audio-visual material, a simple copy of the resolution granting the licence to the local announcer by the National Public Services Authority must be presented.
15. To the extent any of the promotions or advertisements involve a raffle that needs to be approved by the Game Control Board (agency of the Ministry of Commerce), a copy of the petition filed before such an agency must be provided.
16. When the advertising and propaganda make reference to qualities, characteristics, recommendations or benefits, or attribute preventive and/or curative properties in health matters, different from those approved in the sanitary registration (Departamento de Protección de Alimentos or DEPA and Pharmacy and Drugs) or product registration (AUPSA), scientific studies supporting them will be required. Scientific studies from abroad must be submitted in physical form, duly legalised or apostilled, as applicable, and if not in Spanish, they must be translated by an authorised public translator.
17. If advertising and propaganda include testimonials, the identification, address and general

information of the person must be additionally provided.

18. In the case in which recommendations or testimonials from health professionals are submitted, a simple copy of the health professional's registration issued by the Technical Health Council of Panama must also be provided.

In the case of television or radio advertising and propaganda, the interested party may submit, for approval prior to the presentation of the audio-visual material, a graphic script (storyboard or storyline). In this case, the Commission will give approval for the recording of the commercial. Once the advertising recording is completed, it must be submitted to the Commission for comparison with the originally presented material, and the Commission will recommend its approval or rejection.

The General Directorate of Public Health, on its own initiative and on the recommendation of the Commission, may request any other document, additional information or clarification it deems necessary before approving or rejecting an advertising and propaganda request.

The General Directorate of Public Health will forward the request, documentation and attached material to the president of the Commission of Advertisement and Propaganda, who will schedule it in the order of registration to be discussed in a Commission meeting.

At such a meeting, the Commission will make the recommendation to approve, object, not consider or reject the request.

The General Directorate of Public Health will issue their final decision regarding the request by means of a resolution, which shall be notified to the attorney in fact.

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

No, information on unauthorised pharmaceuticals and/or off-label information may not be promoted or advertised.

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?

Law 45 of 31 October 2007, as amended as of today, as implemented by, Executive Decree 46 of 23 June 2009, are the regulations applicable to consumer protection and antitrust in Panama ('Consumer Protection and Antitrust Regulatory Framework'), which in turn sets forth the regulatory framework applicable to advertising. It states that any advertisement or notice related to the transactions covered by the law must adhere to the truth, and the advertiser must ensure that facts are not distorted, and the advertisement or publication does not mislead or confuse.

Pursuant to the Consumer Protection and Antitrust Regulatory Framework, deceptive advertising refers to messages that provide inaccurate, limited, false, exaggerated, partial, artificial or tendentious characteristics or information related to any goods, products or services, leading to error or confusion.

In a broad concept, deceptive advertising includes the omission of information, exaggerated or false attributions about the product or service, advantages, benefits and features that it lacks, and even presenting prices as more attractive than they really are.

In retrospect, comparative advertisement is not permitted because it could mislead or confuse the customer. Additionally, the use of another company's information, such as brand name, logos and any other intellectual property of such company, might be deemed to infringe intellectual property rights and laws.

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?

In Panama, a healthcare professional is defined as the person who obtains a bachelor's degree or its equivalent in the health field, with a minimum of four years of credit hours fulfilled in a national or

international university duly recognised by the University of Panama.

There are no specific regulations that restrict promotional (advertisement) communications directed to healthcare professionals.

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?

There are no specific rules governing promotional (and advertising) activity conducted virtually. Nonetheless, all promotional and advertising activities must follow the requirements and standards set forth in the Consumer Protection and Antitrust Regulatory Framework, as well as those imposed by the Ministry of Health.

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?

In Panama, there are no specific restrictions outlined for including endorsements by healthcare professionals in promotional materials. However, it's crucial to note that all promotional content, including endorsements, must undergo approval by the General Directorate of Public Health in consultation with the Advertisement and Propaganda Commission. This process ensures that the endorsements meet ethical and legal standards.

It's essential to highlight that any promotional material deemed misleading, exploitative or harmful to the public will not be approved by the General Directorate, and the endorser may be subject to fines if such approval is not granted. Therefore, endorsements must adhere to strict guidelines to ensure they are not misleading or detrimental to public health to obtain approval.

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.

Yes, it is possible to provide healthcare professionals with samples of medicinal products and medical devices in Panama. However, strict regulations and ethical guidelines govern these practices. According to the Code of Ethics of the Panama Medical College, medical professionals must prioritise patient wellbeing and refrain from engaging in any contractual relationships that compromise medical ethics. Similarly, the Code of Good Conduct of the Ministry of Health prohibits the exploitation of positions within the Ministry for personal gain or benefit, including benefits for third parties.

Regarding the provision of gifts or donations of money to healthcare professionals, this is strictly prohibited under Panamanian regulations. Any such actions would violate ethical guidelines and may result in penalties or sanctions. Therefore, there are no monetary limits specified because giving gifts or donations of money to healthcare professionals is not permitted.

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

The rules governing the offering of hospitality to healthcare professionals primarily revolve around ethical conduct, patient care standards and oversight by the Ministry of Health. These regulations are outlined in the Panamanian Health Code, which also prohibits certain promotional activities related to healthcare services and products. Additionally, laws and regulations, such as Law 69 of 2013 and its modifications under Law 89 of 2013, address the hiring of foreign healthcare professionals and emphasise the state's responsibility for public health, as stated in Article 109 of the Constitution of the Republic of Panama. It is also important to underscore that healthcare professionals must also adhere to the Ministry of Health's Code of Conduct, and they shall in no way accept and/or receive unauthorised compensation from a third party.

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?

Only donations intended for public healthcare institutions are regulated in Panama through Executive Decree No 48 of 12 April 2022 (Executive Decree 48). Executive Decree 48 specifically addresses the donation of medicines, medical devices, biomedical equipment and other products for human health, and establishes that the receiving entity can be the Ministry of Health, its dependencies or organisations affiliated with the health sector. While this decree outlines the parameters and requirements for donations, it does not explicitly classify them as promotional tools. However, it emphasises the need for prior

approval from the Ministry of Health before donations can be made.

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?

There are no specific provisions regarding whether pharmaceutical laboratories or manufacturers of medical devices can support scientific or educational meetings. Nonetheless, all activities of these companies must adhere to the principles and ethical guidelines outlined in the aforementioned law. While Law 419 distinguishes between medical devices and equipment, and medicines and cosmetics, both sectors are subject to the same standards and obligations regarding the promotion of their products.

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

In Panama, patient organisations may operate within the legal framework established for non-profit organisations. These organisations play a crucial role in advocating for patient rights, providing support and information to individuals with specific health conditions, and promoting public health initiatives. While there is no specific legislation dedicated solely to patient organisations, they must adhere to the broader legal requirements governing non-profit entities.

Under Panamanian law, a non-profit must register with the Ministry of Government to obtain legal standing. This registration process entails submitting the organisation's by-laws, objectives and other relevant documentation for approval. Once registered, non-governmental organisations (NGOs) are subject to certain obligations, such as maintaining transparent financial records and reporting activities to regulatory authorities.

In terms of funding, patient organisations may rely on various sources of support, including membership fees; donations from individuals and businesses; grants from government agencies or international organisations; and fundraising events. However, they must ensure that their financial practices comply with legal and ethical standards, including transparency in fundraising activities and proper utilisation of funds for the organisation's stated purposes.

While there are no specific regulations governing the relationships between patient organisations and industry stakeholders, such as pharmaceutical companies or healthcare providers, these interactions must adhere to general principles of transparency and independence. Patient organisations should avoid conflicts of interest and maintain autonomy in their decision-making processes to uphold their credibility and serve the best interests of their members and the broader community.

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?

Yes, it is possible to delegate promotional activities to a third party through a service agreement in Panama. However, there are specific conditions and regulations that must be followed. For instance, advertising related to health services and products is governed by the Panamanian Health Code, established by Law 66 of 10 November 1947.

Furthermore, Article 171 of the Health Code, as amended by Article 31 of Law 13 of 24 January 2008, prohibits the publication or promotion of hygiene, medicinal, pharmaceutical or cosmetic products that have not been previously approved by the Ministry of Health. Additionally, relevant laws include the Consumer Protection and Antitrust Regulatory Framework, addressing consumer protection, and Article 37 of Executive Decree 230 of 6 May 2008, which establishes the Advertising and Propaganda Commission.

The Advertising and Propaganda Commission sets procedural requirements for advertising materials, including submission to the General Directorate of Public Health, review by the Commission, and a decision by the General Directorate. If the General Directorate issues a negative response, there is an appeal process.

Compliance with these steps and obtaining a positive response from the General Directorate ensures that the advertising material complies with legal requirements. While there are no specific rules for delegating promotional activities, any promotional material must be approved through the aforementioned process. Third-party involvement in advertising must also undergo the approval process to ensure compliance. The Ministry of Health has the authority to prohibit advertising of any drug if it poses a threat to public health or is shown to be harmful.

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

In Panama, reporting transfers of value made by permit or authorisation holders to healthcare professionals is not mandatory. However, this is because both public and private healthcare professionals are prohibited from receiving anything of value, remuneration, gifts or payments.

The Code of Good Conduct of the Ministry of Health mandates employees to adhere to moral and legal norms to prevent improper conduct (which is only applicable to professionals working for state-owned health institutions). Furthermore, Article 14 specifically prohibits using one's position within the Ministry for personal gain or benefit, extending this prohibition to third parties, including entities and political parties related to public officers. While the code does not require reporting transfers of value, it strictly prohibits the acceptance of any object or gift by public officials and related third parties.

Similarly, the Code of Ethics of the Panama Medical College regulates the conduct of private healthcare professionals. Article 58 prohibits paid physicians from receiving additional fees or compensation for services provided during working hours, whereas Article 59 prohibits physicians working in public agencies from using their position to promote their private practice.

Overall, while reporting transfers of value is not mandatory in Panama, strict regulations prohibit healthcare professionals and ministry employees from accepting any form of payment or benefit.

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?

Sanctions and penalties associated with violations related to product promotion are outlined in the Health Code, statutes of the General Directorate of Public Health, and the Commission of Advertising and Propaganda. The Ministry of Health and these entities are authorised to impose sanctions, which include written warnings, fines ranging from US$10 to US$100,000 and temporary suspension of activities.

The General Directorate of Public Health can impose fines ranging from US$5,001 to US$100,000 and may close businesses temporarily or permanently, depending on the severity of the infraction. The gravity of the sanction considers factors, such as risk to public health, economic capacity of the offender, social repercussions, benefits gained from the offence, impact on minors and number of infractions.

Entities involved in publishing or advertising unauthorised material may also face sanctions. Any breach of statutory requirements outlined by the Commission's internal regulations will be subject to sanctions as well. Supervisory authorities actively impose penalties and sanctions, and these actions are publicly announced.

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 enforcement of promotion and advertising rules in Panama falls under the responsibility of the Ministry of Health. Predominantly, Article 171 of the Health Code (Codigo Sanitario) mandates the Ministry of Health, through its advisory organs, to approve all advertising materials or propaganda before they are disseminated to the public. The code also requires the Ministry of Health to object to any misleading or exploitative materials. Furthermore, Panamanian law prohibits misleading or exploitative advertising materials that are scientifically proven to be damaging to public health.

In the case of a promotion and advertising infringement, competitors in Panama can take direct action through the circuit courts. However, the extent to which competitors can do so may depend on various factors, including the specific circumstances of the case and the evidence presented.

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?

As discussed above, Law 419 was approved in February 2024, replacing the existing law governing these matters. We expect that the regulations that further develop and implement this new legislation should be

drafted and approved within the next calendar year.