

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.
<p>General Health Law No 42-01 of 8 May 2001 ('Law No 42-01'), together with its rules for enforcement and ancillary regulations, make up the regulatory framework for sanitary regulations, including the promotion and advertising of pharmaceuticals and medical devices in the Dominican Republic.</p> <p>Therefore, in addition to the General Health Law as the main law, the promotion and advertising of pharmaceuticals and medical devices is also regulated by the followings rules: (2) Decree No 246-06 issued on 9 June 2006, that contains the Drug Regulation; and (2) Resolution No 000033 issued on 21 December 2015, which puts in force the Technical Regulation that regulates the advertising and promotion of medicines, cosmetics, health products, and personal and household hygiene products.</p> <p>Those regulations constitute the rules that prevail in all activities related to advertising and promotion of these regulated products and must be applied by all those who, in one way or another, are involved in these processes, strengthening the health system.</p> <p>In general, the Drug Regulation outlines the procedure necessary to apply for authorisation regarding the advertising of all types of medicines. In view of this, it systematically classifies advertising efforts according to the nature of the pharmaceutical and institutes strict prohibitions on such promotional activities.</p> <p>On the other hand, the Technical Regulation is aimed at regulating the sanitary surveillance related to the advertising and promotion of medicines, cosmetics, sanitary, and personal and household hygiene products. This regulatory framework refers specifically to products that, following the sanitary registration protocol, have been duly classified as suitable for advertising. This regulation applies to the advertising activities of over-the-counter (OTC) medications or without a prescription, promotion of prescription medications, cosmetics, personal hygiene products, household hygiene products, and health products, to be disseminated in the Dominican Republic, regardless of its origin and the media used for the promotion and advertise.</p> <p>It is noteworthy that Law No 42-01, together with its rules for enforcement and ancillary regulations, establish that it is the responsibility of the Ministry of Public Health and Social Assistance, in its role as governing body of the National Health System, to regulate all activities related to medicines, cosmetics, hygiene and medical devices, including the promotion and advertising of pharmaceuticals and medical devices.</p>
2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?
<p>Resolution No 000033 issued on 21 December 2015, which puts in force the Technical Regulation, defines 'advertising' as: any form or means of communication carried out directly or indirectly by a natural or legal person, public or private, in the exercise of commercial, industrial or professional activity, with the purpose of informing, motivating or inducing the acceptance and/or acquisition of the offer of goods and services.</p> <p>It is important to point out that the Technical Regulation subdivides the advertising of pharmaceutical products into: (1) advertising aimed to the general public; (2) advertising directed to professionals; (3) documentary advertising directed to professionals; and (4) word advertising.</p> <p>It is worth noting that the advertising of all pharmaceutical products and medical devices must be submitted for the approval of the Health Authority of the Dominican Republic, specifically before the General Directorate of Medicines, Food and Health Products (DIGEMAPS, per its Spanish acronym), before incorporating it into the market. This is in order to allow our Health Authority to know the type of audience to which the advertising will be directed, as well as the form or means of communication advertised.</p> <p>In addition, the health regulations establish a conceptual difference between 'promotion' and 'advertising' of pharmaceutical products or medical devices, as described below:</p> <ul style="list-style-type: none">• <i>Promotion</i>: it is any action carried out, organised, or sponsored by a pharmaceutical company aimed at health professionals to promote the prescription, recommendation, dispensing administration, or consumption of their pharmaceutical products through any means of communication.

<ul style="list-style-type: none"> • <i>Advertising</i>: any form or means of communication carried out directly or indirectly by a natural or legal person, public or private, in the exercise of commercial, industrial, or professional activity, with the purpose of informing, motivating or inducing the acceptance and/or acquisition of the offer of goods and services. <p>Despite the above, and as already mentioned, the difference between 'promotion' and 'advertising' of pharmaceutical products or medical devices is only conceptual, because in practice, for approval purposes and in light of health control regulations, promotion is included within advertising activities.</p> <p>However, the General Law for the Protection of Consumer or User Rights No 358-05, which contains the provisions relating to relationships between suppliers, consumers, and users of goods and services, defines 'sales promotion' as activities or actions, complementary to advertising, aimed at increasing sales, either at points of sale directly to the consumer, or to the intermediary and/or the wholesaler and that generally entail offers of some extra benefit or added value for the public sector to which they are directed.</p>
<p>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?</p>
<p>According to the regulatory framework of health control regulations, the Ministry of Public Health and Social Assistance, in its capacity as governing body of the National Health System, regulates and enforces all activities related to pharmaceutical products and medical devices in the Dominican Republic, including its promotion and advertisement, through the DIGEMAPS, the entity responsible for evaluating and approving any advertising application for this type of product.</p> <p>On the other hand, the National Institute for the Protection of Consumer Rights (PROCONSUMIDOR), the entity created after the promulgation of Law No 358-05, is the authority that establishes the regime of consumer and user rights to guarantee equity and legal security in the relationships between suppliers, consumers and users of goods and services. Likewise, it is the entity in charge of ensuring that advertising, whatever the means used, is compatible with the provisions that repress unfair competition and fraud, and establishes the minimum conditions for promotion and advertising activities.</p> <p>Thus, the Ministry of Public Health and Social Assistance is the authority in charge of approving all advertising related to pharmaceutical products and medical devices, and PROCONSUMIDOR supervises that consumers purchase such products in accordance with the conditions established by the market.</p> <p>Both authorities regulate promotion, advertising, and competition in the Dominican market, including the activities related to promotions and advertising of pharmaceutical products and medical devices.</p>
<p>4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, for example food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?</p>
<p>Decree No 246-06 issued on 9 June 2006, that contains the Drug Regulation, and Resolution No 000033 issued on 21 December 2015, which puts in force the Technical Regulation, apart from regulating the promotion and advertising of pharmaceutical products and medical devices, also regulates the advertising and promotion of cosmetics and personal and household hygiene products. Therefore, the promotion and advertising of cosmetics and personal and household hygiene products are governed by the same rules, and the entity responsible for the evaluation and approval of advertising applications for these products is the same, namely, through the DIGEMAPS of the Ministry of Public Health and Social Assistance.</p>
<p>CONSUMER MARKETING</p>
<p>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 (advertisement) in your country and if so, which ones?</p>
<p>Advertising of pharmaceutical products and medical devices is classified according to the public to which it is directed. This is determined whether it is an OTC or without a prescription or a prescription medication. Resolution No 000033, which puts in force the Technical Regulation, establishes that the forms of advertising include: (1) advertising of OTC medication intended for the general public, directly or indirectly, through different media; and (2) advertising and promotion of medication intended strictly for professionals or people authorised to prescribe them. Consequently, in the Dominican Republic it is prohibited to advertise</p>

or promote a prescription medication to the general public, since it is strictly intended for professionals or people authorised to prescribe them.

It is expressly excluded from advertising directed to the general public, pharmaceutical products that:

- do not appear in the current list of OTC drugs, issued by the Ministry of Public Health and Social Assistance; or
- products classified as controlled according to the Law on Drugs and Controlled Substances of the Dominican Republic No 50-88.

Medical devices will be promoted in accordance with the regulations established for their registration and control, according to their classification based on the level of risk.

In relation to the restrictions on public promotion, Article 6.4 of the Technical Regulation establishes the prohibition to all types of advertising and promotion of pharmaceutical products, as follows:

- Advertising and promotion that does not comply with the specifications and regulations included in the General Health Law No 42-01, the Drug Regulations, and the Technical Regulation governing the advertising and promotion of medicines, cosmetics, medical devices, and personal and household hygiene products.
- Advertising or promotion of raw materials, semi-finished products, magistral formulas, and officinal preparations.
- The advertising and promotion of a pharmaceutical product that has not obtained the corresponding health registration from DIGEMAPS. This prohibition includes drugs in the process of registration.
- The advertising of pharmaceutical products that, having been duly authorised for such purposes, introduces modifications, alterations or variations that differ substantially from the content of the originally approved advertising material.
- Advertising that incites or suggests not to resort to a physician, or that advises treatment by correspondence, via internet, or telephone.
- Advertising that uses misleading visual representations of the alterations of the human body produced by illnesses or injuries, or of the action of a medicine on the human body or parts thereof.
- Advertising that uses expressions that generate fear or distress to suggest that health may be affected if the pharmaceuticals products is not used; that uses messages, symbols or images that distort, mislead, or confuse regarding the benefits and indications approved by DIGEMAPS.
- Advertising that suggests that health may be affected in the case of non-use of the pharmaceutical products, except vaccines and immunogenic.
- Advertising that misleadingly suggests potency, and physical, sexual, intellectual, or emotional performance.
- Advertising that contains discriminatory elements to the condition of the human being for reasons of sex, age, race, social condition, sexual preference, health condition, among others.
- Advertising that directly or indirectly contains indications that could give rise to the interpretation that the Ministry of Public Health recommends its use.
- The delivery of pharmaceutical products samples under medical prescription in places such as: grocery stores, gas stations, motels, among others, as well as in public places, except in cases previously authorised by the Ministry of Public Health and Social Assistance.

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?

Dominican regulations regarding health control subdivides the advertising of pharmaceutical products and medical devices into those intended for the general public and those that are strictly intended for professionals or authorised persons to prescribe them, regardless of the form in which the promotion or advertising is carried out. However, with the understanding that advertising through the internet and social media will be carried out to the general public, the advertising of prescription medications is prohibited.

It is important to keep in mind that regardless of the way in which the advertising will be carried out, for example, through the internet and social media, it must be previously approved by the Ministry of Public Health and Social Assistance.

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)?

Any type of advertising of pharmaceutical products and medical devices must be submitted for prior approval before the DIGEMAPS of the Ministry of Public Health and Social Assistance of the Dominican Republic.

According to Article 250 of the Drug Regulation, the commercial advertising of medicines is subject to the following:

- The text must be written in Spanish, with faithful adherence to the norms of ethics, decorum, and veracity.
- Under no circumstances may the infallibility of a drug be admitted for the treatment of the disease or diseases for which it is intended, nor its application to symptoms for which it is not indicated in the registration documentation. The actions, degree of relief, and benefit of the medicine must also correspond to that authorised by the Ministry of Public Health and Social Assistance in the registration process.
- The advertisement shall not contain concepts that may mislead professionals or the public about the qualities of the drug, or attribute virtues to it that may lead to error or irrational use.
- Advertising should not be aimed at drawing the attention of children to the drug. Neither should images or any type of references that are inconsistent with the target public's situation or with internationally accepted public health recommendations appear in the advertisement.
- No indication may be introduced in the advertisement that, directly or indirectly, could lead to the interpretation that the Ministry of Public Health and Social Assistance recommends the use of the drug, nor the fact that the drug which has been approved by the health authorities be used as a claim, nor allude to studies or scientific works as proof of the differential benefit of the product, when the advertisement is directed to the public.
- Promotion or advertising should not suggest the delay or incitement of not seeking medical advice and/or diagnostic or rehabilitative procedures.

In addition to complying with the requirements established in the aforementioned Article 250, pharmaceutical advertising must:

- be presented with its International Nonproprietary Name (INN) and the name or brand, as applicable;
- promote the rational use of medications;
- ensure the information contained in advertising must be based on verifiable scientific evidence, be independent, exact, reliable, and true. The properties of the product should not be exaggerated beyond what is scientifically proven or that has not been approved by DIGEMAPS; and
- ensure that its content tends to be informative rather than persuasive.

Pharmaceutical establishments interested in obtaining the advertising authorisation must submit in writing an application before the DIGEMAPS of the Ministry of Public Health and Social Assistance, duly signed by the owner of the product, the legal representative or technical director of that establishment.

As established by Resolution No 000033 issued on 21 December 2015, which puts in force the Technical Regulation, all applications for obtaining prior approval of advertising authorisation shall contain the following:

- the name of the applicant establishment, which must be the titleholder of the health registration of the pharmaceutical product to be advertised, including the name of the legal representative or technical director of the requesting establishment;
- the name of the pharmaceutical product to be advertised, including the name or trademark, the International Nonproprietary Name (INN), concentration, and pharmaceutical form;
- the health registration number and indication of the marketing conditions established therein regarding its advertising; and
- documentation and annexed material, indicated in the application form, which will include, at least:
 - receipt of payment of fees;
 - printed and electronic format of the project or projects corresponding to all types of advertising material that will be used in the campaign, such as: texts, drawings, advertisements or press notices, flyers, posters, signs; and
 - if the advertisement were to be disseminated through media such as radio, television, cinema, or other visual media, they must also present reports containing the texts, the relationship of the sequences or scenes to be transmitted.

The advertising authorisation will be issued to the applicant through written certification from DIGEMAPS.

If the authorisation application does not comply with the requirements established in the current legal framework, DIGEMAPS will give reasons for its refusal and the interested party will be required to submit the required documents and/or information within a period of time.

Substantial content modifications to authorised advertising material will require a new authorisation request and compliance with the procedure established in the technical regulation.

All medication advertising must contain the legend: 'If symptoms persist, consult your doctor'.

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

Dominican health regulations, including the General Health Law No 42-01, together with its rules for enforcement and ancillary regulations, prohibit all types of public use for those regulated products, including pharmaceutical products and medical devices, that have not obtained the corresponding marketing health authorisation by the DIGEMAPS at the Ministry of Public Health and Social Assistance. This prohibition includes pharmaceutical products and medical devices that are in the process of registration before the DIGEMAPS and have not been declared as advertisable in the application.

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 General Health Law and the ancillary laws, as the Drug Regulation and the Technical Regulation that regulates the advertising and promotion of medicines, cosmetics, health products, and personal and household hygiene products, do not refer to comparative advertising. Information available on comparative advertising is contained mainly through resolutions of the PROCONSUMIDOR, which defines it as any advertising that explicitly or implicitly refers to a competitor or the goods and services that the competitor offers.

In general, comparative advertising of any type of product must be objective, thus it cannot: (1) be misleading; (2) compare goods or services that do not have the same purpose; (3) give rise to confusion in the market; and (4) denigrate or discredit brands or competitors. Therefore, offensive, or defamatory comparisons between products are prohibited and may be sanctioned.

It is important to point out that all advertising of pharmaceutical products and medical devices must be evaluated and authorised by the Ministry of Public Health and Social Assistance. Thus, in the case of comparative advertising with an unregistered product from a competitor, it would not be possible for the Health Authority to verify the technical information of the product to confirm whether the advertising is truthful, therefore, it would not be able to issue an approval.

Despite the above, there is no information available in this regard.

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 Technical Regulation governing the advertising and promotion of medicines, cosmetics, medical devices, and personal and household hygiene products does not define healthcare professionals. However, the regulation defines 'professionals authorised to dispense and prescribe medications' as the doctors and dentists with an authorisation (exequatur) to practice their profession in the Dominican Republic.

Without prejudice to the restrictions on promotional communications established in Article 6.4 (see Question 5 above), our Technical Regulation states the prohibitions related to advertising aimed at professionals, therefore, it is prohibited:

- granting, offering, or promising, within the framework of the promotion of medicines to prescribers, bonuses, pecuniary advantages, and advantages in kind. Likewise, it is forbidden for persons authorised to prescribe and dispense pharmaceutical products to request or accept incentives prohibited under the regulations. This prohibition extends to their family members and relatives up to the second degree; and
- the use of texts and illustrations in support material intended for physicians and health professionals, which are incompatible with the approved specialty pharmaceutical professional information sheet for the drug.

<p>This allows promotions to be targeted to clearly benefit the patient, so that they are not misinterpreted as a bribe to the healthcare professionals.</p>
<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>No, the rules governing promotional and advertising activities carried out virtually are the same as previously mentioned that apply to advertising directed at professionals or people authorised to prescribe medications that require a medical prescription.</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 such endorsements may take place?</p>
<p>According to the Technical Regulation governing the advertising and promotion of medicines, cosmetics, medical devices, personal hygiene, and household products, will not be permitted the advertising of pharmaceutical products that, having been duly authorised for such purposes, introduce modifications, alterations or variations that differ substantially from the content of the originally approved advertising material. Therefore, it is understood that it is prohibited the inclusion of endorsements by healthcare professionals in promotional or advertising materials.</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>According to the Technical Regulation governing the advertising and promotion of medicines, cosmetics, medical devices, personal hygiene, and household products, it is possible to provide samples of medicines to healthcare professionals under certain conditions and restrictions. Within these conditions, the regulations establish the following:</p> <ul style="list-style-type: none"> • the samples must be authorised by DIGEMAPS, implying that they must comply with certain quality and safety standards; • products may only be provided to individuals who are authorised to prescribe medications, such as physicians, dentists, and other health care professionals; • samples should be used exclusively for the purpose of promoting product awareness among healthcare professionals and distributed free of charge to patients who may benefit from their use; • they must meet certain specific criteria, such as containing novel active ingredients, offering therapeutic advantages compared to other products available on the market, and not containing psychotropic or narcotic substances; • it is important that samples are properly labelled with the words 'Free Sample. Not for sale' on the packaging to avoid any misunderstanding about their purpose and use; and • pharmaceutical laboratories supplying samples should maintain an adequate control system over the samples, which implies keeping a detailed record of the quantity and type of samples distributed, as well as being prepared to provide this information to the health authorities when required. <p>On the other hand, it is not possible to give gifts or donations of money to healthcare professionals in the context of drug promotion. It is strictly forbidden to offer bonuses, pecuniary or in-kind advantages to persons empowered to prescribe medicines, as established in the Technical Regulation. In addition, healthcare professionals may not request or accept incentives prohibited by these regulations. This prohibition extends even to their family members and relatives up to the second degree.</p>
<p>14. What rules govern the offering of hospitality to healthcare professionals?</p>
<p>There are no specific regulations.</p>
<p>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?</p>
<p>Donations, such as monetary, bonuses, benefits, made by the titleholders of marketing authorisation of pharmaceutical products and/or medical devices to healthcare professionals or institutions, are not considered promotion or advertising tools. On the contrary, such types of donations are prohibited by the</p>

<p>Ministry of Public Health and Social Assistance and are considered violations of the applicable laws and may be criminal and administrative sanctioned.</p> <p>Donations of pharmaceutical products and medical devices are regulated by Decree No 246-06, that contains the Drug Regulation, which establishes that all pharmaceutical products donations must be based on the needs officially expressed by the Health Authority. The pharmaceutical products to be donated will be those with active ingredients included in the Basic List of Essential Drugs, in the List of Pharmaceutical Provision of the Basic Plan of the Social Security, or those defined as priority at a given time by the Ministry of Public Health and Social Assistance of the Dominican Republic.</p>
<p>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?</p>
<p>There is no specific regulation regarding the possibility for pharmaceutical laboratories or medical device manufacturers, or their licensees to support scientific or educational meetings. However, the prohibition or possibility of supporting such activities will depend on the scope of the retribution to the laboratories or manufacturers.</p>
<p>17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.</p>
<p>No information is available through health regulations on this matter.</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>According to the Dominican regulations applicable to promotional and advertising activities of regulated products, it is possible to delegate such activities to third parties. Even though the application for authorisation to advertise pharmaceutical products and any other regulated product, must be requested only by the titleholder or the authorised representative, our regulations allow delegating the promotion or advertising to third parties duly appointed.</p> <p>However, third parties prior to initiating any promotion or advertising activity, are obliged to require a certified copy of the advertising authorisation issued by the Ministry of Public Health and Social Assistance.</p> <p>In relation to co-promotion, our regulations do not establish any prohibition, nor do they specifically refer to this. However, it applies in the same way as indicated above; in any scenario any third party must require a certified copy of the advertising authorisation prior to initiating any advertising of a pharmaceutical product or medical device.</p>
<p>19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?</p>
<p>There is no obligation in the Dominican Republic to this end.</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>Sanctions for violations of the provisions of the Technical Regulation established for the advertising of pharmaceutical products medical devices, cosmetics, and personal and household hygiene products, and the application procedure of the regulation will comply with the provisions of the General Health Law, without prejudice to the criminal or civil liability that corresponds to the offender.</p> <p>Therefore, the prohibitions on non-compliance of pharmaceutical products and medical devices advertising are contained in the General Health Law No 42-01, which establishes on Article 155 the following:</p> <p style="padding-left: 40px;">‘Constitute offenses under this Act, and shall be punishable by a penalty of three (3) months to two (2) years correctional imprisonment, or by fines ranging from fifteen to twenty-five times the national minimum wage, established by the legally competent authority or by law, or both penalties at the same time, the following offenses:</p> <p style="padding-left: 40px;">15. Manufacturing, handling, transporting, storing, importing, exporting, manufacture, transport, store, import, export, distribute, commercialize or supply, in any form, pharmaceuticals, food and</p>

beverages not medicines, food and beverages not suitable for consumption, because they do not meet the consumption, because they do not meet the requirements or conditions established in the regulations of the present law and norms in force on the matter. In addition, for its commercialization without complying with the requirements established by this law for the labeling of the mentioned products.'

Even though the text does not state per se a prohibition directly related to the advertising of pharmaceutical products or medical devices, as this is a procedure that requires prior approval from the Ministry of Public Health and Social Assistance, if it is not complied as stipulated, it would carry out as an infraction.

Supervisory authorities in the Dominican Republic actively enforce the provisions of the General Health Law No 42-01 related to the promotion and advertising of pharmaceutical products. When violations are identified, appropriate penalties and sanctions are imposed. These penalties may include fines, imprisonment, or both, depending on the severity of the offence.

The imposition of penalties and sanctions for violations related to the promotion or advertising of pharmaceutical products are typically announced publicly to raise awareness and deter future non-compliance. Public announcements serve as a means of transparency, ensuring that stakeholders, including pharmaceutical companies, advertising agencies, and the general public, are aware of the consequences of violating advertising regulations.

Overall, strict enforcement of advertising regulations, along with public announcements of penalties, aims to maintain compliance within the pharmaceutical industry and promotes consumer safety by ensuring that promotional activities adhere to established standards and guidelines.

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?

In the Dominican Republic, the Ministry of Public Health and Social Assistance holds primary responsibility for enforcing regulations related to pharmaceutical product promotion, including advertising. The Health Authority oversees compliance with the provisions set forth in the General Health Law No 42-01, which includes regulations governing pharmaceutical advertising.

Additionally, the PROCONSUMIDOR, plays a role in ensuring that pharmaceutical advertising does not mislead consumers. While the Ministry of Public Health and Social Assistance focuses on regulatory compliance within the pharmaceutical industry, PROCONSUMIDOR mandate includes protecting consumer rights and interests, which may involve monitoring advertising practices to prevent misleading or deceptive promotions.

The enforcement of rules related to pharmaceutical advertising varies in terms of stringency. Generally, regulatory authorities strive to enforce advertising regulations consistently and rigorously to uphold public health and safety standards. However, the extent to which rules are strictly enforced may be influenced by factors such as resource availability, capacity, and prioritisation of enforcement activities.

In the event of alleged infringements or violations of advertising regulations by competitors, direct legal action may be taken through the courts. Competitors have the right to challenge advertising practices that they believe contravene regulations or unfairly disadvantage them in the marketplace.

For example, competitors may file lawsuits alleging that advertising campaigns engage in false or misleading comparisons that harm their brands or misrepresent their products. These legal actions could be based on claims of trademark infringement, unfair competition, or violations of consumer protection laws.

However, it is important to note that while legal recourse is available, the initiation of legal proceedings against competitors for advertising infringements may not be common practice in the pharmaceutical industry in the Dominican Republic. This could be due to factors such as the presumption that advertising has been approved by regulatory authorities or the potential costs and complexities associated with litigation.

Overall, while competitors have the option to pursue legal action through the courts in response to advertising infringements, the frequency and effectiveness of such actions may vary depending on the specific circumstances and dynamics within the pharmaceutical industry.

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?

In the near future, no significant developments in the field of pharmaceutical or medical device promotion or advertising are expected in the Dominican Republic. The current regulatory framework, which was modified and issued in 2015, remains as the primary framework governing advertising and promotion practices in pharmaceutical products and medical devices, including new developments.

Over the past year or so, several practice and enforcement trends have become apparent in the Dominican Republic regarding promotion of pharmaceutical products and medical devices:

Increased Focus on Consumer Protection: Regulatory authorities have demonstrated a heightened focus on protecting consumer rights and interests in relation to pharmaceutical and medical device advertising. This includes efforts to prevent misleading or deceptive advertising practices that could potentially harm consumers.

Enhanced collaboration between regulatory agencies

The establishment of the alliance with the PROCONSUMIDOR, has facilitated better coordination and collaboration between regulatory agencies responsible for overseeing advertising practices. This collaborative approach aims to improve supervision and control of advertising and promotion to ensure compliance with regulatory standards.

Emphasis on accurate information for consumers

There is a growing recognition of the importance of providing consumers with accurate and reliable information when making decisions about pharmaceutical products. Regulatory efforts have focused on promoting transparency and ensuring that advertising materials convey truthful and scientifically accurate information about the benefits, risks, and proper use of pharmaceuticals and medical devices.

While these trends reflect ongoing efforts to strengthen advertising regulations and consumer protection measures, it is essential for industry stakeholders to remain proactive in complying with regulatory requirements and adapting to evolving enforcement practices and expectations.