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Belgium
Pharmaceutical Advertising

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Belgium.

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Belgium: Pharmaceutical Advertising

1. What laws are used to regulate advertising on medicines in your jurisdiction?

In Belgium there are currently two Acts and three implementing royal decrees that mainly regulate advertising on medicines for human use:

a. the Act on Medicinal Products for Human Use of 25 March 1964 ("**AMP**") setting forth the general legal framework on advertising of medicines for humans;
b. the Royal Decree of 7 April 1995 ("**RDAMP**") regarding information and advertising of medicines;
c. the Royal Decree of 11 January 1993 establishing the conditions for the provision of medicinal products as samples;
d. the Act of 18 December 2016 on various provisions on health (the "**Sunshine Act")** containing a transparency obligation on pharmaceutical companies to document and disclose benefits granted to healthcare professionals and organisations and patient organisations;
e. the Royal Decree of 14 June 2017 executing the Sunshine Act.

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

There are four main self-regulatory deontological codes, which contain specific provisions on pharmaceutical advertising. They are identified on the basis of the issuing professional bodies:

i. **Pharma.be**, a professional association of innovative pharma/EFPIA companies based in Belgium
ii. **BACHI** (the Belgian Association for the Consumer Healthcare Industry), focusing on over-the-counter medicines and healthcare products sold in pharmacies
iii. **Mdeon**, a common platform between different professional associations and healthcare professionals/organisations
iv. **Medaxes**, a professional association of Belgium-based generic and biosimilar medicine companies

a. If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

The deontological codes are only binding on the members of the respective professional associations, provided, however, that the Mdeon Code of Ethics applies to all pharmaceutical companies interacting with healthcare professionals in Belgium (since Mdeon has been assigned specific tasks by the Belgian lawmakers).

b. What is the legal status of the self-regulatory codes?

It is a separate set of binding rules that can be enforced against the members by imposing various corrective, supervisory and financial sanctions in case of violation of the code.

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

Advertising for these purposes is "any form of door-to door information, canvassing activity or stimulation which is designed to promote the prescription, release, supply, sale or consumption of medicinal products" (article 9 AMP).

a. What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

The above definition is extended by naming specific examples, such as provisions of samples, visits to healthcare professionals, sponsorships of scientific conferences and incentives to deliver or prescribe medicines by providing financial or in-kind benefits (article 2 §2 RDAMP).

Excluded from the definition are patient information leaflets, product labels and general information regarding health and disease areas with no direct or indirect reference to a medicinal product, including disease-awareness campaigns.

Moreover, the definition does not cover medical information about a particular drug product given by a pharma company in reply to a patient's or healthcare professional's unsolicited request, as long as such information is strictly necessary to answer said request and does not contain unsolicited promotional content

b. Does the definition apply equally to all target audiences?

See above under question 3.a.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

In general, press releases regarding medicines for human use must comply with the general rules regarding advertisement of medicinal products. Pharmaceutical companies should at all times ensure that their press releases are factually correct, do not contain misleading information, and do not use sensational language or exaggerations. Note that specific guidance has been issued by the Belgian Financial Services and Markets Authority in its Opinion of 28 October 2020 for listed biotech companies, which are, in general, obliged to give updates on their pipeline and the progress and results of their clinical trials.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

Belgian law requires every pharmaceutical company to appoint and maintain a qualified person (responsible for the information) who will be accountable for the advertising and for providing scientific information on medicinal products for human use by said company (article 13 RDAMP). The qualified person should be a pharmacist or physician and registered with the Ministry of Health.

Medical information as well as advertisements to healthcare professionals and the general public should always be ratified in advance by that qualified person.

6. Do companies have to have material approved by regulatory bodies prior to release?

Yes, for advertisement to the general public through radio/television prior approval (visa) from the Ministry of Health is required. That approval is based on the advice from an independent Commission within the Federal Agency for Medicines and Health Products ("**FAMHP**"). This decision must be taken within 45 days as of the receipt of a valid request (article 16 §1 and article 17 §5 RDAMP).

All other forms of advertisement of medicinal products for human use to the general public (e.g. advertisements in a newspaper or on the internet), should be notified to the Ministry of Health 30 days prior to their publication (article 16 §2 RDAMP).

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

To the extent advertising of medicinal products for human use is allowed, the advertisement must additionally observe the rules set forth in general rules of legitimate comparative advertisement (article VI.17 Code of Economic Law). This means that comparative advertisements:

- must compare similar products;
- must compare one or more essential, relevant, verifiable and representative elements of the product (such as the price);
- must not be misleading;
- must not create confusion between the advertiser and the competitor or between their brands, trade names or other distinguishing marks;
- must not discredit or disparage the competitor and its products/activities; and
- must not represent products as being a counterfeit or imitation of products whose brand or trade name is protected.

In addition, the pharma.be Code of Deontology requires comparative advertisements to present the compared product in a way that is fair, complete, scientifically accurate and based on the most recently available data.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

All *advertising* of unauthorised medicines or unauthorised

indications is prohibited (article 9 AMP). However, providing scientific medical information on unauthorised medicines is allowed within the boundaries of the respective definition of information/advertisement (see above 3.a). This means, inter alia, that scientific information on unauthorised medicines:

i. can be published in independent scientific magazines, so long as these are not used as promotional material by a pharma company;
ii. can be presented to healthcare professionals during scientific meetings to the extent the presentation is strictly scientific;

The proactive communication of information of unauthorised medicines to healthcare professionals is in principle regarded as promotional. The reactive communication of information on unauthorized medicines to healthcare professionals following their spontaneous (i.e. unsolicited) request is in principle regarded as non-promotional (see above under question 3.a).

Note also, as set forth above, that for information to be regarded as scientific it must in all circumstances be factually correct, and it may not contain misleading information, promotional language or exaggerations.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, and include the information that must or must not be included.

Advertisement for prescription only medicines for human use to the general public is expressly prohibited under Belgian law. Advertisement for over the counter-medicines is authorised unless such advertisement: (i) gives the impression that a medical consultation or surgical operation is redundant; (ii) suggests that the effects of taking the medicinal product are guaranteed or that no side effects exist; (iii) suggests that the patient's health can be enhanced by taking the medicinal product or can be affected by not taking it; (iv) is directed exclusively or primarily at children; (v) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing, but who could encourage the medicinal products' consumption due to their status; (vi) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product; (vii) suggests that the efficacy or safety of the product stems from the fact that it is natural; (viii) could lead to an incorrect self-diagnosis; or (ix) uses improper, alarming or misleading terms or pictorial representations (see article 7 RDAMP).

Moreover, article 8 RDAMP requires that advertising of over the counter-medicines for human use should (i) be designed in such a way that it is clear that the message is an advertisement; and (ii) include the following minimum information:

- the name of the product (as well as the common name if the medicinal product contains only one active substance);
- the information required for correct use;
- the statement “this is a medicinal product, no long term use without medical advice";
- an explicit, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be. In case radio advertisements, such invitation must be explicit and clearly audible; and
- the (trade) name of the product's marketing authorisation holder.

Also bear in mind that all advertisements must present the characteristics of the medicinal product in such a manner that it (i) is compatible with the summary of the product characteristics (ii) that it ensures a rational use of the medicine (article 9 AMP).

The FAMHP has issued very specific guidance regarding the lay-out and readability requirements for advertising of pharmaceutical products for human use on written materials and on broadcasted mediums (Circular 407 and 441).

Lastly, certain means for any advertising of medicinal products for human use are prohibited like advertising by means of airplanes, billboards, telephone, text-messages, children's magazines, software programmes, etc. It is equally prohibited to promote medicinal products by promising, offering or granting any (in)direct compensation such the patient be unsatisfied with the product (article 5 RDAMP).

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

Belgian law does not contain provisions on relations with patient organisations. A patient organisation having a healthcare professional among its members should in any event be treated as a healthcare organisation to which article 10 AMP applies. Pharmaceutical companies

should make sure that their public interaction with patient organisations within a certain therapeutic area does not qualify as an advertisement to the general public regarding their related drug products.

Chapter 3 of pharma.be's Code of Deontology contains rules on relations with patient organisations. Pharmaceutical companies may (i) provide financial support to a patient organisation, (ii) call on patient organisations for the performance of certain services for the support of healthcare or research, or (iii) sponsor events organised by patient organisations if such support is covered by a written agreement.

These rules specify that in their interactions with patient organisations, pharma companies must assure the independence of patient organisations in terms of their political judgement, policies and activities, and all interactions between them must be based on mutual respect, with the views and decisions of each partner having equal value. Companies as well as patient organisations may not request to advertise a particular prescription drug. In addition, companies cannot require that they be the sole funder or sponsor, and must not influence the text of patient organisations' material they sponsor in a manner favourable to their own commercial interests

Moreover, patient organisations should not be involved in the promotion of a particular prescription-only medicine.

With respect to collaborations, their objectives and scope must be transparent, and financial and non-financial support must always be clearly acknowledged. For any (non-financial) support they must have in place a written agreement that includes as a minimum:

- the amount of the funding or, in case of indirect or non-financial support, a precise description of the support,
- the purpose of the funding, such as the allocation of an “unrestricted grant”, support for a particular meeting or publication, etc. and
- the code(s) of deontology applicable to the support

Finally, there are limits and restrictions on gifts, grants, hospitality and sponsoring that can be provided, and there are strict rules of engagement when calling upon patient organisations to provide scientific services.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example, can companies provide information about clinical trials, or reprints of scientific journal articles?

First, Belgian law provides that the presentation of a medicinal product in advertisements must (i) be accurate, up to date, objective, sufficiently complete, truthful, verifiable, and compatible with the most recent content of its marketing authorisation file, (ii) reflect the generally accepted scientific knowledge, and (iii) be backed by bibliographical data.

Specifically, advertisements for medicinal products for human use towards healthcare professionals must contain the following essential data, which must cover at least 50% of the total advertisement space (article 9 RDAMP):

i. the product's name, its qualitative and quantitative composition in terms of active substances and its pharmaceutical form;
ii. all information regarding indications, posology, contraindications and side-effects contained in the SmPC, or the package leaflet or the labelling in case of a homeopathic medicinal product; and
iii. the (trade) name of the marketing authorisation holder and the number of the marketing authorisation or product registration.

Advertisements towards healthcare professionals should also contain the applicable retail price per approved formulation/pack size and explicitly mention the date of the material's creation or the date of its last revision.

It is generally accepted that the inclusion in advertisements directed to healthcare professionals of information that is not part of the SmPC is allowed as long as such information confirms, clarifies or supplements (*i.e.*, does not directly or indirectly contradict) the specifications made in the SmPC, and is not misleading

The distribution by a pharmaceutical company to healthcare professionals of reprints that refer directly or indirectly to a drug product of said company will, in principle, be considered promotional and will be subject to advertising rules (including the prohibition of advertising of unauthorised products/off-label indications). Distribution by pharmaceutical companies will also be subject to the rules related to the provision of gifts to healthcare professionals.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any

monetary limits?

Under Belgian law, gifts to healthcare professionals are prohibited, with the exception of gifts with a limited value and being directly related to the medical profession (article 10 AMP). As a standard for limited value, it is generally accepted that gifts for a maximum total value of EUR 125 per healthcare professional per year would be acceptable, with each gift costing no more than EUR 50. Specific examples of appropriate and inappropriate gifts can be found in the MDeon Code of Ethics.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

The provision of free samples is allowed within certain limits as specified hereafter (article 12 AMP and the Royal Decree of 11 January 1993 determining the conditions subject to which the provision of samples of medicinal products for human consumption is permitted). Generally, samples may only be provided to a healthcare professional authorized to prescribe such product on his specific request, on the condition that a marketing authorization has been obtained in Belgium for such medicinal products. The provision of samples is limited to eight samples per product (in its smallest available pack size) per year per treating physician. Additionally, each healthcare professional may receive no more than 600 samples, in total, per year.

14. Are pharmaceutical companies permitted to sponsor scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Pharmaceutical companies are allowed the sponsoring of (i) the attendance of healthcare professionals to continuing medical education (including hospitality) and of (ii) the organization that organizes such continuing medical education. The hospitality offered to healthcare professionals within the framework of a scientific event must be limited to the organisation, payment or reimbursement of the healthcare professional's travel, meals, overnight stay and registration for the event. This is only allowed if (article 10 AMP):

i. the event is in nature exclusively scientific;
ii. the hospitality is strictly limited to the scientific objective of the event;
iii. the location, date, and duration of the event do not create confusion about the scientific nature of the event;
iv. the financial contribution to the participation (including the offered hospitality) is strictly limited to the official duration of the event; and
v. the coverage of the costs are strictly limited to the healthcare professionals concerned by the event.

For events with an overnight stay, a prior visa must be obtained from Mdeon. Mdeon has set out additional guidelines regarding the hospitality that can be offered to healthcare professionals in the framework of a scientific event. The requirements differ depending on whether the healthcare professional participates to the scientific event as attendee (i.e. to learn), or as consultant (i.e. performing scientific services on behalf of the event organiser or on behalf of a pharmaceutical company).

Meals may only be offered immediately before, during or immediately after a scientific activity (i.e., not along the way, at an airport or train station). There is a maximum of EUR 45 for a lunch (drinks included), EUR 90 for a dinner (drinks included) and EUR 23 for a coffee break. A maximum of EUR 135 euros per day with at least 6 hours of scientific program must be taken into account. If a day does not include 6 full hours of scientific program, a total maximum of EUR 23 € per full hour of scientific activities applies. Offering dinner on the eve of a scientific event may only be offered if there is a scientific program that eve. For consultanrs, meals that do not directly follow the scientific program (or meals offered on the eve) and/or that are more expensive may be offered provided they are justified and described (amount to be specified) in a contract. However, the price of the dinner offered must always be reasonable/legitimate and comply with the authorized amounts as described above, unless there is a reason justified by circumstances to offer a more expensive dinner (a justifiable reason is, for example, a dinner with foreign consultants to avoid that only the Belgian consultants have to get another (cheaper) meal or are completely excluded from a meal, thus not being able to eat together with their peers and therefore not being able to talk about science). This reason must be explained in the visa application.

The cost of an overnight stay is in any event limited to EUR 250. There is an exception for countries for which, according to the Ministerial Decree of January 10, 2023 the limit exceeds the maximum accommodation fee of EUR 250, under the following cumulative conditions: (i) at least 5 hotel offers are attached to the visa application showing that it is not possible to comply with the EUR 250 price, and the cheapest offer is chosen; (ii) the hotels must be located within a reasonable distance (max. 10 km) from the place of the scientific event; (iii) the chosen

hotel meets the reasonableness criteria as described in the Mdeon Code.

For travelling, additional limitations apply.

These rules are applicable to hospitality offered to Belgian healthcare professionals or healthcare professionals exercising their profession in Belgium, for scientific events in Belgium as well as abroad.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

As mentioned above, the hospitality offered to healthcare professionals within the framework of a scientific event must be limited to the organisation, payment or reimbursement of the healthcare professional's travel, meals, overnight stay and registration for the event. It may in no case contain the organisation or funding of any cultural, sports or other leisure activities or any other form of entertainment.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

Yes, on the condition that the services provided by healthcare professionals are of a scientific nature and have a legitimate character. Examples of such services are speaker engagements, participation in advisory boards, consultancy, clinical trial services, etc.

Specific Mdeon guidelines set forth that the healthcare professional's compensation should be (i) reasonable, (ii) proportionate, (iii) consistent, (iv) a reflection of the "fair market value" of the services, and (v) be in line with the scope and duration of the services (in function of the complexity, level of experience of the healthcare professional, degree of urgency, …). The prescription behavior of the healthcare professional ought not to be a factor for determining the applicable compensation. It is not allowed to use the provision of services by a healthcare professional as a loophole to provide (prohibited) advantages to healthcare professionals.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

Belgian law contains a broad prohibition to offer gifts to wholesalers, intermediaries, persons who are entitled to prescribe, dispense or administer medicinal products or to institutions where such prescriptions, dispersion or administration takes place (article 10 AMP). In principle, this means that donations to healthcare organisations fall within this prohibition.

In practice, however, the industry may donate (e.g. money to organise an activity, research equipment) to healthcare organisations for educational, humanitarian or philanthropic purposes. The pharma.be Code of Deontology further clarifies that such donations are only allowed if these are made available for the purpose of supporting healthcare or research and if these do not constitute an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products. Any donation or grant must be assessed on a case-by-case basis.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

The Sunshine Act makes it mandatory for pharmaceutical (and medical devices) companies, whether Belgian or foreign, to document and annually disclose on the platform betransparent.be (co-created by multi deontological organisations) the premiums and benefits that they grant (in)directly to healthcare professionals, healthcare organisations or patient associations (chapter 1 of title 3 of the Sunshine Act).

The transparency obligation covers (i) contributions to the costs of a scientific manifestation, (ii) fees for services and consultancy and (iii) donations or grants provided to – as applicable – (a) healthcare professionals having a practice in Belgium, (b) healthcare organisations established in Belgium or (c) patient organisations established in Belgium.

The provision of premiums and benefits must be made public on an individual basis (on behalf of the recipient who received them directly or indirectly). Each company

subject to the notification obligation must make public, for each individual beneficiary, the amounts of the premiums and benefits granted during a calendar year.

In general, companies are required to disclose, on a yearly basis (ultimately on 31 May of the year following the calendar year in which the transfer of value has been made), the relevant transfers of value as describe above. Bear in mind that when a premium or benefit was granted to a healthcare professional *indirectly,* e.g. through a healthcare organisation or corporation, the disclosure should still be made in the name of the healthcare professional.

The disclosure should provide the following details:

i. the name and company number of the company subject to notification;
ii. the name and company number/RIZIV-INAMI number of the beneficiary or any other number that allows the FAMHP to identify the beneficiary; and
iii. the total amount of the attributed premiums and benefits in respect of the relevant calendar year.

These transparency obligations are binding upon all companies within the pharmaceutical (and medical devices) sector, including pharmaceutical companies, importers, manufacturers and distributors, irrespective of whether they are based in Belgium or abroad.

According to article 3, section 1,3° of the RD Sunshine Act, companies subject to notification which are established outside the European Union must make the notification (a) by and in the name of an affiliated company established in the European Union or (b) by a legal representative established in the European Union.

The companies subject to the notification obligation are the holders of an authorisation for placing the medicinal products on the market, importers, manufacturers and distributors of medicinal products, persons engaged in the brokering of medicinal products, and distributors, retailers and manufacturers (article 41, section 1, 1° Sunshine Act). Companies that do not yet have a marketing authorisation are hence not subject to the notification obligation.

19. Are there any restrictions (whether by law or Codes of Practice) on advertising for medicines on social media directed to healthcare professionals or directed to the general public?

There are no specific rules for the advertising of medicinal products on social media in Belgium, hence the general rules on advertising apply. For the advertising of medicines on social media, question 20 below.

Advertising on social media will be regarded as advertising to the general public. The advertising of prescription medicines on social media therefore is forbidden.

20. Is advertising on the internet for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

The general rules for pharmaceutical advertising also apply to internet advertising. The FAMHP must be notified at least 30 days before the publication of advertising broadcast on media other than radio or television.

Book XII of the Code of Economic Law sets forth the rules on the digital economy and contains more specific rules on electronic advertising (on websites, by email or through other electronic means). Pharma.be has also issued guidelines on mandatory information to be included in internet advertising.

Any advertisement for medicines on the internet must comply with the following rules:

- it must contain a clearly visible, legible and unambiguous statement that it is an advertisement;
- the pharmaceutical company must be identifiable;
- the relevant general requirements for pharmaceutical advertisements must be complied with; and
- the advertisement must have been notified to the Ministry of Health in advance.

There are no specific rules regarding access security for advertisements directed at healthcare professionals. Nevertheless, a company should take all security measures necessary to prevent access by the general public to a website that contains information regarding prescription-only medicinal products. The same applies to websites that contain scientific information regarding non-authorised medicines.

It is a common practice for pharmaceutical companies to make certain parts of their website accessible to healthcare professionals only if they log in with their RIZIV/INAMI-number (RIZIV/INAMI is the Belgian National Institute for Health and Disability Insurance).

21. Are there any anti-bribery rules that apply to communications between pharmaceutical companies and healthcare professionals or healthcare organisations?

The Belgian Criminal Code provides for the anti-bribery rules concerning the bribery of private legal entities and private individuals (article 504bis and 504ter) and the bribery of public legal entities and individuals holding a public function (article 246 to 252). These apply also to advertising of pharmaceutical products.

22. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

It is prohibited to offer, supply or promise (in)direct benefits to healthcare professionals and healthcare organisations (For exceptions, see question 12).

23. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

The FAMHP, the public prosecutor and the criminal courts are primarily responsible for the enforcement of the pharmaceutical advertising rules (the AMP, RDAMP and the Belgian Criminal Code).

In addition, the pharmaceutical professional associations can also impose a separate set of penalties on their members following a breach of the applicable deontological code.

24. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

Under general rules governing fair market practices, competitors can act against pharmaceutical companies allegedly violating advertising rules. Under such rules, remedies include cease and desist procedures, injunctive relief and claims for damages.

25. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

Violating the rules governing advertisement of pharmaceutical products may give rise to sanctions, such as fines (from EUR 1 600 to EUR 120 000) and imprisonment (from 1 month to 1 year) for individuals and with fines ranging from EUR 4 000 to EUR 240 000 for legal entities.

26. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

The self-regulatory deontological codes are independent rules and means of enforcement. Nonetheless, the pharma.be Code of Deontology explicitly determines that no procedures can be started before the pharma.be deontological bodies if another procedure (on similar grounds) was already conducted in front of another competent authority. If a procedure is initiated before the deontological bodies of pharma.be and a separate procedure is initiated before another competent authority during such procedure, the decision by the pharma.be deontological body will be deferred until the other competent authority has taken a decision (Article 78 pharma.be Code).

It is also a possibility that a deontological organisation notifies a breach by one of its members to the regulatory authorities or the public prosecution (this is, for instance, explicitly provided for in the pharma.be Code of Deontology). Regulatory authorities, courts or the public prosecution will only be competent to decide on a breach of a deontological code if it also constitutes a breach of the applicable legal framework (notably the AMP and the RDAMP).

27. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

No specific enforcement trends are generally known.

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