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.

For the advertising of medicines, medical devices and health products, in addition to the general rules on misleading and comparative advertising (Articles 6:194–6:196 of the Dutch Civil Code), specific advertising rules are important in the Netherlands.

Medicines

Medicines advertising regulations in the Netherlands are based on European regulations. In 1992, European Directive 92/28/EEG was adopted with rules for the advertising of medicines, which was implemented in 1994 by the Advertising of Medicines Decree. The European rules were subsequently adapted and incorporated into Directive 2001/83. The Dutch Medicines Act (Geneesmiddelenwet) was subsequently enacted in 2007. In 2018, the favouritism (*gunstbetoon*) rules were supplemented by the Medicines Act Favoritism Policy Rules 2018 (Beleidsregels Gunstbetoon Geneesmiddelenwet 2018).

The Code of Conduct on Pharmaceutical Advertising (Gedragscode Geneesmiddelenreclame) is additionally there as a form of self-regulation, and also the Code for the Public Advertising of Medicines (Code Publieksreclame voor Geneesmiddelen) of the Code Geneesmiddelenreclame (CGR).

Medical devices

European Medical Device Regulation ((EU) 2017/745 Medical Device Regulation or MDR) has been applicable since 26 May 2021. Since 26 May 2022, the European regulation for medical devices for in-vitro diagnostics ((EU) 2017/746, In-Vitro Diagnostics Regulation or IVDR) also applies. These European regulations apply directly in the Netherlands. Some issues, such as supervision and requirements for the language of the instructions for use, are additionally regulated in national legislation. In the Netherlands, this is laid down in the Medical Devices Act, the Medical Devices Decree, the Medical Devices Regulation and the Policy Rules on Favoritism Medical Devices Act (Beleidsregels gunstbetoon Wet medische hulpmiddelen).

For medical devices, there is the Medical Devices Code of Conduct (Gedragscode Medische Hulpmiddelen or GMH) as a form of self-regulation, and for the public advertising of medical devices, the Code for Public Advertising of Medical (Self-Care) Devices.

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

Medicines

The Dutch Medicines Act (Geneesmiddelenwet) defines 'advertising' as any form of influencing with the apparent aim of promoting the prescription, supply or use of a medicine, or giving the order to do so (Article 1.1.xx).

Medical devices

The Medical Devices Act, the Medical Devices Decree and the Medical Devices Regulation do not define advertising. It is also not defined in the European Medical Device Regulation 2017/745. The Medical Devices Code of Conduct only defines 'expressions', as any form of written, oral or electronic communication relating to a medical device, whether promotional in nature or not.

The difference between promotion and advertisement is not relevant in this jurisdiction.

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?

Monitoring compliance with the advertising rules for medicines and for medical devices lies primarily with the Healthcare and Youth Inspectorate (Inspectie Gezondheidszorg en Jeugd or IGJ). The Medicines Advertising Code Foundation (CGR) monitors compliance with the rules for advertising of pharmaceuticals aimed at professionals. This foundation sets up and implements self-regulation in the field of drug advertising. The foundation Keuringsraad Openlijke Aanprijzing Geneesmiddelen/Keuringsraad Aanprijzing Gezondheidsproducten (KOAG/KAG) is the self-regulatory body that supervises public advertising on behalf of the industry. Like the CGR, the KOAG/KAG has detailed rules: the Code for the Public Advertising of Medicines. For medical devices, the GMH and Keuringsraad oversee the Medical Devices Code of Conduct and Code for Public Advertising of Medical (Self-Care) Devices. The scope of work of the Health and Youth Inspectorate overlaps with the scope of self-regulation (CGR, KOAG/KAG and GMH). Therefore, working agreements have been made on the handling of reports.

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?**

Those product types fall under different regulations.

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?**

Medicines

The public advertising of prescription-only medicines, and of medicines that may be dispensed without a prescription but contain substances referred to on List I or II of the Opium Act, is prohibited in the Netherlands.[1] For other forms of pharmaceuticals, public advertising must meet certain requirements:[2]

- advertising is presented in such a way that the message comes across as advertising to the public and it is absolutely clear to the public that it concerns a medicinal product;
- the advertisement contains the name, as well as the common name if the medicinal product contains only one active ingredient;
- the advertisement contains information that is indispensable for the proper use of the medicine; and
- the advertisement contains an explicit request to read the package leaflet or the text on the outer packaging.

There are also restrictions:

- The advertising of a herbal medicine shall contain the indication that it is a traditional herbal medicine, for which indications it is used and that the indications are based exclusively on long-standing use.[3]
- Advertising to the general public is prohibited if it states or, by its wording or illustrations, creates the impression that:[4]
  - the use of the medicine makes a medical examination or a surgical operation unnecessary;
  - the medicine has no side effects, or the effect is better than or equal to that of another medicine or medical treatment;
  - the normal good health of a person can be improved by the use of the medicine;
  - a person's normal good health may be affected if the medicine is not used; and
  - the safety or efficacy of the medicine is due to it being a natural substance.
- Public advertising is further prohibited if:
  - it is aimed exclusively or primarily at children;
  - it contains a commendation or reference to a commendation by scientists, professionals or persons known to the public;
  - it equates the medicinal product with a foodstuff, cosmetic product or other goods; and
  - it may lead to misdiagnosis through its description or detailed portrayal of a pathological history;
  - it refers in a misleading manner to cures;

- it makes frightening or misleading use of depictions of changes to the human body resulting from disease or injury, or of the action of the medicine in the human body; and
- it states that entitlement to the medicinal product exists under the statutory social health insurance schemes.

Medical devices

For medical devices, it is possible to promote a medical self-care device under certain conditions.[5] This is a medical device in a pharmaceutical manifestation with a physical action, insofar as it is intended to be used by the public itself without the intervention of a healthcare professional. Some of the restrictions for this advertising are, for example:

- Advertising medical self-care devices that do not meet the legal requirements of the Medical Devices Act and the Medical Devices Decree is prohibited.
- Advertising is permitted only for self-care of indications that can be determined by the user him/herself without the intervention of a physician or once determined by a physician, or as additional self-care for indications determined by a physician and treated using other means.
- Advertising must not contradict the information on the package and in the enclosed instructions for use.
- Advertisements shall contain at least: the name of the medical self-care device; the statement 'medical device'; the main purposes of use and the situations in which use is discouraged; and an explicit request to read the instructions for use.
- Advertising for a medical self-care device should present an objective representation and should not mislead.
- Advertising shall not be directed exclusively or primarily at children.
- Advertising shall not appeal to feelings of fear.

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?

Not specifically for pharmaceuticals and medical devices.

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)?

No prior approvals.

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

No.

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?

In the Netherlands there are general rules on misleading and comparative advertising (Articles 6:194–6:196 of the Dutch Civil Code) that also apply to medicines and medical devices. Comparative advertising is permitted. Comparative advertising explicitly or implicitly mentions a competitor, or goods or services offered by a competitor. Comparative advertising is subject to rules, however, for example, misleading advertising is not permitted. The comparison must objectively compare one or more relevant, verifiable characteristics of the goods. The advertising must not damage the competitor's good name. If these rules are violated, the court may not only impose an injunction but also order a rectification and award damages. It would not be possible to refer to a competitor's product or indication that has not yet been authorised.

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 Dutch Medicines Act defines a healthcare professional as a natural person who is independently authorised to prescribe prescription-only drugs, a pharmacist, pharmacy assistant or natural person, or a

certain legal entity.[6] For medical devices, the Medical Devices Code of Conduct (GMH) defines a healthcare professional as follows: a natural person who, whether employed or not or in cooperation with others, uses medical devices in the context of care or support him/herself and/or decides on the purchase or use thereof and/or is involved in the process of prescribing, selecting, fitting and/or advising on the use of medical devices.

There are regulations that restrict promotional (advertisement) communications directed to healthcare professionals. For medical devices: the Medical Devices Act and the Policy Rules on Favoritism Medical Devices Act. For medicines, the Dutch Medicines Act and the Medicines Act Favoritism Policy Rules 2018.

Medicines

Advertising or showing favouritism with regard to medicine for which no marketing authorisation has been granted is prohibited.[7] Advertising aimed at professionals states:

- the composition, therapeutic indications, contraindications, action and adverse reactions of the medicinal product consistent with the summary of product characteristics; and
- the classification of the medicinal product with respect to its dispensing.

In addition to this, documented advertising handed over or sent to professionals shall also state:

- whether there is an entitlement to provision of the medicine under the statutory social health insurance schemes; and
- the date on which the documents were drawn up or last amended.

The data included in the documents as referred to is so exact, up-to-date, verifiable and complete that the practitioner can form an opinion on the therapeutic value of the medicine. Citations or tables or other illustrations taken from scientific publications or medical journals included in those documents shall be reproduced exactly with an accurate source indication. The aforementioned does not apply if the advertising has the sole purpose of reminding professionals of the name of the medicine.

Medical devices

For medical devices, favouritism toward professionals is prohibited unless certain conditions are met.[8] Rules on favouritism in relation to medical devices are also laid down in the Medical Devices Code of Conduct (GMH) and in the Policy Rules on Favoritism Medical Devices Act.

As appears from Article 6 paragraph 1 of the Wmh (Medical Devices Act), favouritism only exists if an 'apparent purpose to promote the sale of a medical device or an in vitro diagnostic medical device' is involved. In the case of sponsorship by suppliers, this apparent sales-promoting purpose need not always be considered present. 'Sponsorship' refers to an essentially large group of financial contributions made, directly or through intermediaries or legal entities, by suppliers of medical devices or in vitro diagnostic medical devices. These may include financial contributions for the purpose of scientific research or of chairs or scholarships. If each of the following conditions is met, there is a presumption that these forms of sponsorship have no apparent sales promotion purpose and therefore fall outside the scope of the legal prohibition on favouritism: sponsorship is provided solely for purposes that are in no way related to the purchase, use, application or recommendation of the sponsor's products or otherwise linked to previous, current or potential future use of the sponsor's products or services.

There are four exceptions to the prohibition of favouritism, which are contained in Article 6, paragraph 3, Wmh: successively, the reimbursement of participation fees; the reimbursement of services; the offering of gifts; and the offering of discounts and bonuses when purchasing medical devices or in vitro diagnostic medical devices.

Apart from favouritism, the following general principles apply to promotional communications directed to healthcare professionals (Medical Devices Code of Conduct):

- Prevention of undesired influence: interactions between suppliers and healthcare professionals may not contain elements or incentives that could lead to decisions regarding (use or purchase of) medical devices being taken on grounds other than care-related grounds, rationality and/or integrity. Decisions may not be influenced by, for example, excessive or inappropriate benefits, or by false or misleading advertising.
- Justified basis and reasonableness: interactions between providers and healthcare professionals should have a legitimate basis and payments, and any other monetisable benefits should be

reasonable and proportionate.
- Documentation: interactions between vendors and healthcare professionals should be demonstrable and understandable through written documentation.
- Transparency: interactions between suppliers and (alliances of) healthcare professionals, institutions and patient organisations must be transparent.

In addition, the following applies (Article 5 of the Code of Conduct):

1. Suppliers may offer or promise healthcare professionals monetisable benefits, provided they do so in the form and within the framework of interactions permitted under the Code of Conduct.
2. Healthcare professionals may request or accept cash benefits from suppliers, provided this is done in the form and within the framework of the interactions permitted by this Code of Conduct.
3. For the purposes of this Code of Conduct, the following categories of interactions are distinguished:
   (i) bonuses and discounts related to business transactions;
   (ii) gifts;
   (iii) financial contributions to the costs of (participation in) meetings for healthcare professionals;
   (iv) fees for services; and
   (v) sponsorship of projects or activities other than meetings.
4. The interactions referred to in number 3 under (ii) to (v) may never be linked to a decision regarding the purchase, use, prescription and/or recommendation of medical devices.
5. Suppliers and healthcare professionals further refrain from any other act or omission that could make them feel obligated to each other in an improper manner.

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?

Medical devices

For online meetings, such as webinars, the same conditions apply as for meetings where participants meet physically.[9]

Medicines

The same applies to medicines. The Code of Conduct on Pharmaceutical Advertising applies to advertising in the broadest sense of the word: to the advertising of and information about medicinal products, that is, whether orally, in writing, using audio-visual methods, through exhibitions, congresses and symposia or by other means. The main rule is: whatever applies to 'offline' also applies to 'online'. Previously, social media's reach did not stop at national borders. The Code of Conduct only applies to communications that are accessible in the Netherlands and are unmistakably aimed at the Dutch public in terms of words and content. The mere fact that the medicine is also available in the Netherlands is not decisive. There are some general requirements that (also) apply to social media, for example: recognisability of the person who sends the messenger or is (jointly) responsible for its content, and responsibility for the content of own websites and media is realised/linked. When using social media, it is important that public advertising for prescription medicines is prohibited. The basic principle is that advertising communications are only aimed at professionals who have an interest in the information. Furthermore, it is important that information obtained by the marketing authorisation holder via social media about named side effects of medicines is allowed within the prohibited rules of pharmacovigilance.

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?

The general rules apply.

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.

Medicines

It is also only permissible to give free samples of medicines to professionals under certain conditions:[10]
a dated and personally signed application by a professional authorised to prescribe unrated (UR) medicines has been submitted to the operator concerned; the sample is no larger than the smallest

package on the market; no more than two samples of the same medicine per calendar year are supplied to a professional; it is stated on the sample that it is free of charge and may not be sold; the sample is accompanied by a copy of the summary of product characteristics; and the person providing the free sample keeps records recording to whom it was provided, on what date and in what quantity. Supplying a professional with samples containing substances referred to on List I or II of the Opium Act is prohibited. Is it possible to give gifts or donations of money to healthcare professionals under restrictions, see the response to Question 10.

Medical devices

The same applies for medical devices. Giving gifts or donations of money to healthcare professionals is prohibited, unless (Article 6 of the Medical Device Act):

- it concerns reimbursement of or not charging for participation fees, provided it is limited to what is strictly necessary to participate in the meeting or event;
- it concerns a service, provided that it is reasonable in relation to the money provided or offered, or to the goods or services that can be valued in money; is set out in a written agreement; and is relevant to the supplier or to the professional practice of the natural person involved in the application of a medical device or of an in vitro diagnostic medical device;
- it relates to money or services, or goods that can be valued in money, against which there is no performance by the natural person involved in the application of a medical device or in vitro diagnostic medical device, provided that they are of low value and are relevant to the exercise of his profession; and
- it concerns discounts and bonuses relating to the purchase of medical devices or in vitro diagnostic medical devices.

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

Medicines

The provision and enjoyment of hospitality, as referred to in section 94(b) of the Medicines Act, is permitted in the context of a meeting or event. Hospitality must be limited to what is strictly necessary to attend the meeting or event. Hospitality means the reimbursement or not charging of travel, lodging and registration fees for a meeting or event. Reimbursement or not charging for other expenses is not permitted.[11]

Medical devices

Professionals may receive compensation in the form of a reimbursement (or non-charging) of participation costs, provided that this is limited to what is strictly necessary to participate in the meeting or event.[12]
When assessing whether charging or not charging is acceptable, there are three criteria that apply to both meetings and events:

1. participation costs must be strictly limited to the main purpose of the meeting or event;
2. the meeting or event must take place at a suitable location; and
3. the compensation must be limited to what is strictly necessary to participate in the meeting or event.

In addition, the criterion for meetings is that:

- there is transparency about the ties between speakers and suppliers or third parties.[13]

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?

Medical devices

In the case of sponsorship by suppliers, this apparent sales-promoting purpose need not always be considered present. 'Sponsorship' refers to an essentially large group of financial contributions provided, directly or through intermediaries or legal entities, by suppliers of medical devices or in vitro diagnostic medical devices. These may include financial contributions for the purpose of scientific research, chairs or scholarships. If certain conditions are met, there is a presumption that these forms of sponsorship have no apparent sales promotion purpose and therefore fall outside the scope of the legal prohibition on favouritism:

- sponsorship is provided solely for purposes that are in no way related to the purchase, use, application or recommendation of the sponsor's products, or otherwise linked to previous, current

or potential future use of the sponsor's products or services;
- sponsorship is useful and necessary to contribute to the intended health interest;
- the nature, purpose and extent of sponsorship must be set forth in writing in advance; approved in advance in writing by the board of the recipient's institution; and must also be otherwise transparent;
- sponsorship must not require any quid pro quo from the recipient, with the exception of name recognition;
- decisions on the use of the sponsored financial contribution must be made independently and without influence from the sponsor; and
- in the case of sponsorship for scientific research, the research must meet the standards of scientific quality, objectivity and integrity (Article 3 of the Policy Rules on Favouritism Medical Devices Act.

Medicines

A special category consists of sponsorship. 'Sponsorship' refers to financial contributions of various kinds for the benefit of healthcare activities or projects provided by entrepreneurs in principle to legal entities in which both professionals and non-professionals may be involved. These are innovative and/or quality-improving activities aimed at directly or indirectly improving patient care or promoting medical science. If each of the following conditions is met, there is a presumption that these forms of sponsorship do not have an apparent sales promotion purpose and therefore fall outside the scope of the legal ban on favouritism:
- sponsorship in no way obliges the recipient to prescribe, dispense or use the sponsor's medicines or previous, current or potential future use of the medicines;
- sponsorship is useful and necessary to contribute to the intended health interest;
- the nature, purpose and extent of sponsorship must be laid down in writing in advance;
- sponsorship must not require any performance obligation on the part of the recipient, with the exception of naming and shaming;
- sponsorship may not affect the independence, reliability and credibility of the sponsored party, other involved parties and the sector; and
- in the case of sponsorship for the purpose of scientific research, the research must meet the standards of scientific quality, objectivity and integrity (Article 3.1 of the Medicines Act Favoritism Policy Rules 2018).

Section 94(c) of the Medicines Act defines gifts as money or goods or services that can be valued in money. The giving and receiving of gifts is permitted in this article provided the gift is of small value and is relevant to the professional practice. The concept of low value was set in 2003 at €50 per occasion, with a maximum of €150 per year. For the interpretation of the concept of small value, a connection has been sought with the regulations regarding the acceptance of gifts by civil servants. These amounts apply per professional, per licensee and per therapeutic class. The value of the gift is determined by the retail value including VAT. A gift must be significant to the practitioner's practice and thus cannot be used only in private. In the case of indirect gifts, such as computer equipment on loan, the question is whether there are monetary benefits. If that is the case, the amounts mentioned should be adhered to (Article 2.1.C of the Medicines Act Favoritism Policy Rules 2018).

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?

They can under certain conditions; there is some difference between the two sectors from the perspective of rules on the promotion of products.

Medical devices

The involvement of suppliers in meetings for healthcare professionals is permitted, in the sense that that suppliers may organise or financially facilitate meetings, or make it possible for an individual healthcare professional to participate, and in that context cover costs, on the provision that the following conditions are met:
- the programme is balanced and reasonable in terms of programme structure, and does not include recreational and social activities unrelated to the meeting;
- the location is justified in terms of location and facilities; and
- the costs are reasonable.

It is not permitted for suppliers to cover the costs of people other than healthcare professionals, directly or indirectly (Medical Devices Code of Conduct 2024).

Medicines

The following requirements apply to the sponsorship of a meeting:

- sponsorship must be recorded in writing in an agreement prior to sponsorship; the agreement must, in any case, contain a precise description of the sponsored meeting/event (including financial substantiation) and of the rights and obligations of all parties involved;
- sponsorship may not extend to costs other than general organisational costs and hospitality costs; and
- 6.4.4 Code Of Conduct on pharmaceutical advertising.

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

This concerns the Rules of Conduct on Sponsorship of Patient Organizations. This includes requirements for sponsorship to patient organisations:

- The financial support of a patient organisation in the form of subsidy, sponsorship and so on is permitted. Support 'in kind' is also permitted. Support may be linked to a specific activity.
- For any form of support, care must be taken not to compromise the independence of the patient organisation, its policies and activities.
- Agreements regarding support are recorded in writing in an agreement prior to the support.
  - The agreement contains at least a precise description of the rights and obligations of both the patient organisation and the sponsor.
  - The agreement is retrievable by third parties. Moreover, once a year companies announce which patient organisations they sponsor.
  - If support relates to a specific activity, the agreement states that the patient organisation clearly communicates that that activity was (partly) made possible by the sponsor in question (eg, by placing a logo).
  - If support does not take place directly but through third parties, this will have to be clear from the agreement.
- In the relationship between sponsor and patient organisations, stipulating exclusivity is not permitted, unless it is for a specific project.
- The direct or indirect promotion of one or more specific prescription drugs is prohibited.

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?

This is not regulated, but a communications agency or the media, for example, must also follow the advertising rules.

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

It is not mandatory, but starting in 2013, financial ties between pharmaceutical companies, physicians and pharmacists have been made public. In the Healthcare Transparency Register, it is possible to see, for each healthcare provider, what cooperation in the exchange of knowledge and expertise there was with which companies in the past year and for what amount. These are all companies affiliated with umbrella organisations, which must adhere to the Rules of Conduct on Disclosure of Financial Relationships. These rules of conduct come from:

- Medicines Advertising Code (CGR)
- Code of Advertising of Veterinary Products (CAVP);
- Medical Devices Code of Conduct (GMH).

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?

Medical devices

When favouritism rules are violated, the inspectorate (IGJ) usually imposes an administrative fine (Article

14 of the Medical Device Act).

Medicines

Chapter 11 of the Medicines Act deals with enforcement. The Minister of Health, Welfare and Sport (Ministerie van Volksgezondheid, Welzijn en Sport or 'VWS') has established policy rules. These policy rules state the violations for which a fine can be imposed. They also state the amount of the fine. In addition, they specify whether the inspectorate first issues a warning or proceeds directly to a fine. The standard amount for a fine is €150,000 for large companies. The amount of the fine depends on the size of the company and the severity and seriousness of the violation. Citizens can also be fined when violating drug advertising rules.

Due to the amended Health Act/Youth Act, the inspectorate has been obliged to make certain information public since 1 February 2019, even without being requested. Since 1 February 2019, the inspectorate has actively published reports, notifications about enhanced supervision and information about enforcement measures as standard. In the event of enforcement measures, the inspectorate makes a summary (business representation) of the (administrative law) decision public. The Inspectorate does not publish inspection reports on administrative fines, investigations or criminal measures.[14]

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 Health and Youth Care Inspectorate (IGJ) is responsible for the enforcement of both medical devices and medicines. Competitors may also take direct action through the courts in relation to promotion (advertising) infringements, this is separate from enforcement by the IGJ (civil versus administrative law).

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?

No significant developments are expected this year/no trends.

Note

The answers are not exhaustive, but are a global representation.

Notes

[1] Art 85 Dutch Medicines Act.
[2] Art 86 Dutch Medicines Act.
[3] Art 87 Dutch Medicines Act.
[4] Art 88 Dutch Medicines Act
[5] Code for Public Advertising of Medical (self-care) Devices.
6 See Art 82 Dutch Medicines Act.
7 See Art 84 Dutch Medicines Act.
8 Art 6 Medical Devices Act.
[9] Code of Conduct for Medical Devices 2024.
[10] Art 92 Dutch Medicines Act.
[11] Art 2.1.B of the Medicines Act Favoritism Policy Rules 2018.
[12] Art 6 Medical Devices Act.
[13] Policy rules on favouritism Medical Devices Act.
[14] See www.igj.nl/onderwerpen/openbaarmaking accessed 3 June 2024.