Baker McKenzie.

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

NETHERLANDS

The Netherlands

Michiel Bijloo, Derk Christiaans

Introduction

Medicinal product advertising in the Netherlands is regulated by two complementary systems. In addition to laws and regulations based on the Medicines Act, there is a system of self-regulation, based on codes of conduct drawn up by organizations within the pharmaceutical and healthcare industry. Medicinal products are advertised by means of public advertising and by inducement. In this chapter, we mainly focus on the latter form of advertising.

The Regulatory Framework

The Medicines Act

At the European level, requirements for medicinal product advertising are laid down in the Directive on the Community code relating to medicinal products for human use (Directive 2001/83/EC). The relevant title on advertising has been implemented in the Netherlands in the Medicines Act.

The Medicines Act provides general rules for the entire pharmaceutical sector. This framework act has been developed in more detail by, *inter alia*, the Medicines Act Decree, the Medicines Act Regulation, as well as policy rules. In this regard, the Ministry of Health, Welfare and Sports (VWS) has issued policy rules that contain a more elaborate description of the concept of inducement as laid down in the Medicines Act (the "Policy Rules Inducement Medicines Act").[1]

[1] Policy rules of the Minister of Health, Welfare and Sports of 27 March 2014, regarding inducement as laid down in Article 94 of the Medicines Act, Official Gazette 2014 no. 9496, 4 April 2014.

Self-Regulation

Supplementary to statutory advertising rules, a system of self-regulation further regulates the advertising of medicinal products in the Netherlands. In principle, the characteristics of the product determine which code applies, as for example, the Code for the Advertising of Medicinal Products to the General Public (*Code voor de Publieksreclame voor Geneesmiddelen*) applies to the (public) advertising of over-the-counter medicinal products, whereas the Code of Conduct for Pharmaceutical Advertising (*Gedragscode Geneesmiddelenreclame*, the "CGR Code") also applies to the advertising of prescription medicinal products and blood products.

An important section of the CGR Code is the chapter on Inducements and other Financial Relations, which applies to both pharmaceutical companies and practitioners authorized to prescribe or supply medicinal products. The Inspection Board, the Code Commission and the Commission for Appeal set up by the Dutch Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame*, jointly the CGR) are entrusted with supervising compliance with the CGR Code. In general, the Code Commission and Commission for Appeal will only assess a promotional activity after a party has filed a complaint with the CGR. Stakeholders are also able to request (non-binding) advice from the Code Committee regarding the compatibility of their own (envisaged) behavior with the CGR Code.

The Royal Dutch Medical Association (KNMG) has drawn up the Code of Conduct for Physicians, which also contains a provision on inducement. The Code of Conduct for Physicians stipulates in general terms that "doctors should have an open and honest relationship with the business community and should avoid a conflict of interests that may harm the patient." It further states that "accepting favors is allowable to a small extent, in accordance with the standards set out in the CGR Code." Physicians who are members of the KNMG are obliged to observe the provisions of this code. In addition, the KNMG and several other (medical) professional associations have endorsed a

(distinct) code regarding the prevention of conflict of interest (i.e., as a precaution against improper influence through conflict of interest). This code forms a tightening of the already existing policy regarding inducement and is applicable to all signatories of this code.

Medical Devices

The abovementioned Dutch regulatory framework relating to advertising and inducement does not apply to medical devices, for which a separate code exists. The Code of Conduct Medical Devices 2015 (*Gedragscode Medische hulpmiddelen* 2015) applies to medical devices in the broadest sense and provides (among others) standards for correct interactions between suppliers and healthcare professionals.

On the other hand, the Code for the Advertising of Medical Devices to the General Public (*Code voor de Publieksreclame Medische Hulpmiddelen*) is only applicable to the advertising of so-called over-the-counter medical devices, which are available without the intervention of a doctor. However, if medical devices are used as a vehicle for the (indirect) promotion of a related medicinal product, the rules regarding medicinal products may nonetheless apply.

Please note that the specific rules regarding medical devices are not discussed in further detail in this chapter.

Permitted and Prohibited Practices

Inducement

Definition of Inducement

The Medicines Act provides the following definition of inducement: "To hold out, the prospect of, to offer or to award money or services or goods measurable in money with the apparent objective to enhance the prescription, delivery or use of a medicinal product."

It further considers inducement equivalent to "making an offer in order to enhance the prescription, delivery or use of a medicine with

the apparent objective to receive money, or services or goods measurable in money in return, or to accept such money, services or goods following an offer to enhance the prescription, delivery or use of a medicine." The rules on inducement are reciprocal: If one party is not allowed to offer or give something, this shall not be requested or received by the other party.

The Policy Rules Inducement Medicines Act issued by the Ministry of VWS and the CGR Code contain similar definitions.

The following financial relations are, to a certain extent, allowed: (i) to give (and receive) gifts; (ii) to provide hospitality; (iii) sponsorship; (iv) payment for services; and (v) discounts and bonuses. Other financial relationships that have as their purpose to enhance the sale, prescription or use of medicinal products, are prohibited.

Please note that services-, hospitality- and sponsorship agreements within the scope of the CGR Code are subject to disclosure obligations if the practitioner, partnership or institution concerned receives more than EUR500 (in money or in kind) from a pharmaceutical company in any calendar year. The CGR Code provides for detailed rules applicable to these transparency obligations. In essence, disclosure takes place each year following the year-end by reporting to a central transparency register. In principle, the responsibility to report lies with the pharmaceutical company, except for situations in which a practitioner has entered into a financial relationship with a pharmaceutical company based abroad.

Gifts

Giving and receiving gifts (i.e., money or services/goods measurable in money) is allowed if the gifts are of minor value and are relevant for professional practice. The latter criterion implies that the gift should not be solely usable in the private sphere.

The Policy Rules Inducement Medicines Act and the CGR Code provide for maximum amounts that may be offered to – or received by – any practitioner. The value of gifts may amount to EUR50 per

occasion and EUR150 per year. This value is determined based on the retail value including VAT. As a result, each gift should be appraised to determine whether the maximum amount is exceeded. The maximum amounts apply per practitioner, per license holder and per therapeutic class. In the case of indirect gifts (e.g., giving computer equipment on loan), which qualify as an advantage measurable in money, these maximum value amounts also apply.

Hospitality

Providing hospitality may consist of reimbursing or not charging registration-, travel- and accommodation expenses of a meeting or manifestation. Reimbursing or not charging for other costs (e.g., sport and recreation) is not allowed.

Two forms of hospitality can be distinguished: (i) hospitality at scientific meetings ("meetings") and (ii) hospitality at non-scientific meetings ("manifestations").

The definition of "meeting" is given in the Medicines Act and has been further considered in the Policy Rules Inducement Medicines Act and the CGR Code, which set out specific requirements an event should meet in order to qualify as a meeting. As a rule of thumb, a meeting has the apparent exclusive purpose to enhance the scientific knowledge and expertise of practitioners. Any other event is considered to be a manifestation (i.e., an organized gathering of practitioners the purpose of which is to enhance the prescription or supply of medicinal products). In principle, providing or receiving hospitality for meetings and manifestations is allowed if the hospitality is limited to what is strictly necessary in order to be able to participate in the event and does not exceed reasonable bounds. In addition, three criteria apply to both meetings and manifestations to determine whether providing or enjoying hospitality is acceptable:

1. The hospitality must remain strictly limited to the main purpose of the meeting or manifestation. This is largely determined by the division of time spent on the (scientific) program compared to the other elements of the agenda.

2. The hospitality may only include those who qualify as practitioners/participants for the purpose of the meeting or manifestation.

3. The location must be suitable.

For meetings and manifestations within the scope of the CGR Code, the hospitality arrangements should be recorded in a written agreement in which the execution should be clearly stated. However, this requirement does not apply if the hospitality only covers participation in a meeting (including meals and drinks within reasonable bounds) without compensation for travel and/or hotel accommodation.

- Hospitality at meetings (scientific meetings)

Hospitality at meetings remains within reasonable bounds if the hospitality costs remain below the maximum amounts per practitioner per therapeutic class of EUR500 per occasion and EUR1,500 per year. Sums of money already received for other meetings organized by third parties for the same therapeutic class should also be included for the yearly maximum amount. As an alternative, a practitioner may also bear at least 50 percent of all the costs himself (the "50% option").

Relationships between speakers and companies or third parties (e.g., the pharmaceutical industry) should be made public in advance. Attending representatives of the industry should be recognizable as such, for instance by wearing a badge.

- Hospitality at manifestations (non-scientific meetings)

Hospitality at manifestations remains within reasonable bounds if the hospitality costs remain below the maximum amounts per practitioner per therapeutic class of EUR75 per occasion and EUR225 per year. The 50% option does not apply to manifestations.

- Meetings and manifestations abroad

The abovementioned criteria also apply to hospitality provided and/or enjoyed with regard to meetings and manifestations held outside the Netherlands. In light of the third criterion (a suitable location) attention should, inter alia, be paid to whether the meeting is organized by a foreign or international association or body, whether the meeting is open to practitioners from various countries, and whether there is a direct link between the subject or purpose of the meeting and the location.

With regard to events within the scope of the CGR Code, the details of the foreign meeting or manifestation should be submitted to the Code Commission for prior approval. Meetings of a truly international nature are exempt from this obligation if:

- a significant proportion of the speakers and participants originate from countries outside the Netherlands; and
- they are organized by a grouping of healthcare professionals, by a scientific organization or other groups or bodies independent of the pharmaceutical industry; or
- its content has been qualified as scientific by a scientific association or a body independent of the pharmaceutical industry and is recognized by that professional group.

The CGR has stated that it is possible for a Dutch subsidiary to be held liable for breach of the Dutch rules by a foreign parent company in certain cases.[2] The Code Commission believes that such far-reaching imputation is justifiable to ensure that the Dutch rules are not circumvented.

According to the CGR, the maximum amounts and the 50% option are not applicable to practitioners who do not live or work in the

[2] Code Committee of the CGR, 6 February 2003, JGR 2003/2, no 16.

Netherlands. These practitioners are subject to the laws and regulations of the country where they live or work.

Sponsoring

The CGR Code also regulates sponsorship (i.e., support of a financial nature or other compensation provided by a license holder with or without any consideration to (groupings of) practitioners and/or institutes in which they participate or by which they are employed). The main principle of regulation of sponsorship is to ensure that the integrity, independence and image of all the parties involved are not jeopardized. For the sake of transparency, sponsorship agreements must be recorded in writing before the sponsorship commences. Exclusive sponsorship is not permitted, unless for a specific project.

Support by means of sponsorship is permitted if it is for innovative and/or quality-enhancing activities and is aimed at achieving either a direct or indirect improvement of patient care or advancing medical science and that activity is not or not fully funded via normal channels.

Support to individual practitioners of a financial nature or measurable in money is only permitted if it concerns financial support for dissertations or theses or if the support is in line with the abovementioned categories of inducement.

With regard to the sponsoring of events, the requirements for hospitality at meetings and manifestations similarly apply. In addition, the sponsorship agreement must be recorded in writing before commencement of the sponsorship and should clearly set out the rights and obligations of the parties involved. The sponsorship may not include costs other than general organizational costs and hospitality.

Sponsoring of patient organizations is allowed under specific conditions, which are mainly comparable to those described above.

Payment for Services

Payment to practitioners for services provided, such as giving lectures, providing advice or performing medicinal product research is allowed if the payment is reasonably proportionate to the practitioner's performance and the performance is of importance for the exercise of medicine, pharmaceutics, dentistry or midwifery.

The practitioner has the right to a reasonable payment and reimbursement of expenses incurred. In essence, verification thereof occurs based on the time spent and an hourly or daily rate, taking, *inter alia*, the nature and scope of the services, the position and the qualifications of the practitioner concerned into account. The tariffs determined by means of the Healthcare (Market Regulation) Act may also serve as a useful reference point.

Each service (which includes services to be performed and the payment) has to be recorded in writing and must contain a clear description of the purpose of the service to be rendered and execution of the service to be provided.

The CGR Code also applies to research involving medicinal products, unless it concerns scientific research that falls within the scope of the Dutch Medical Research Involving Humans Subjects Act (*Wet medisch-wetenschappelijk onderzoek met mensen* or WMO) or the Assessment framework medical research not subject to the WMO (*Toetsingskader niet-WMO-plichtig onderzoek*). Both instruments provide for their own supervisory mechanism and possibilities of appeal and objection. Therefore, the CGR does not have to assess these research activities on purpose, soundness and design.

Discounts and Bonuses

Offering or granting discounts and/or bonuses is allowed if these relate to the purchase of prescription medicinal products by pharmacists, drugstores and general practitioners. According to the CGR Code, discounts may be cash discounts or discounts in kind (i.e., discounts awarded in the form of bonus supplies of the same

medicinal product), provided that they are recorded explicitly and in writing. Suppliers of medicinal products shall refrain, however, from offering or granting discounts to practitioners by means of gifts.

Please note that in certain circumstances, price differentiation may infringe rules of competition law – and may therefore be unlawful.

Samples

Free samples may only be provided if a dated and personally signed request was filed with the company by a practitioner authorized to prescribe prescription-only medicinal products for that purpose. However, not more than two samples of the same medicine may be provided to a practitioner per calendar year. In addition, the sample may not be bigger than the smallest packaging on the market and shall contain an indication that it is free of charge and may not be sold. Furthermore, a summary of the characteristics of the medicinal product should be attached to the sample. The party providing the sample must keep records registering to whom, when and in which amount samples were provided.

Consequences of Breaching Laws and Regulations

Monitoring and Enforcement

The Netherlands Healthcare Inspectorate (IGZ) is entrusted with the supervision of the Medicines Act. Although the Medicines Act provides for a statutory basis for the CGR Code, the CGR and IGZ have agreed upon the CGR being the primary authority for monitoring compliance with the CGR Code.

Civil Law Consequences

A company or practitioner who breaches one or more statutory provisions on medicinal product advertising may be held liable under civil law.

In addition, anyone may file a complaint with the CGR about infringements of the CGR Code by (representatives of)

pharmaceutical companies or practitioners within its scope. The Code Commission will investigate the complaint and may impose sanctions if infringement is proved. There is a possibility of appeal at the Commission of Appeal. The decisions of the Commission of Appeal are binding and can only be challenged by bringing the proceedings before a regular court.

Administrative Law Consequences

For infringement of the inducement provisions of the Medicines Act, the IGZ has the power to impose administrative fines of up to EUR450,000.

Criminal sanctions may be imposed, however, if an administrative fine was imposed twice for the same behavior within the preceding 24 months. In such case, the sanction can be up to six months' imprisonment or a fine of up to EUR8,100 for natural persons and EUR20,250 for legal persons.

Disciplinary and Other Consequences

Failure to comply with regulations relating to inducement by certain practitioners may be subject to (statutory) disciplinary law and may lead to a sanction for the practitioner.

According to the KNMG Code of Conduct for Physicians, internal disciplinary proceedings may apply to disputes concerning a rule of conduct between colleagues who are both members of the KNMG. As this code only has an internal effect, non-KNMG members are not bound to these rules. However, the internal rules may be used by a civil court when assessing a doctor's actions with respect to the disciplinary standards applicable in the Netherlands. This code of conduct is therefore also important for those not affiliated with the KNMG.

Liability Under Criminal Law

Under Dutch criminal law, bribery comprises providing or offering a gift, a promise or a service to a 'public official' or a 'private sector employee' with the intent to make the person concerned do or omit something. The bribe can be anything that represents a certain value to the recipient. Both active (giving) and passive (receiving) bribery to/by public officials and to/by private sector employees are considered criminal offences.

The definition of 'public official' is broad and includes anyone appointed by the Public Administration in a public appointment (*publieke aanstelling*) to carry out a government task. Whether the person is a public official under employment law is not decisive. If a person is employed by an organization that carries out government responsibilities under government control and oversight, this person is a public official. The definition of public official also includes a person to be appointed as well as a former public official.

Upon infringement of the bribery prohibitions, criminal sanctions of up to six or four years' imprisonment for bribing to/by public officials or private sector employees, respectively, and fines of up to EUR81,000 for natural persons and EUR810,000 or 10 percent of the respective worldwide turnover for legal persons per occasion may be imposed. In the case of bribing of a public official, additional penalties may be imposed, such as dismissal from employment or appointment of both the bribed and the bribing person.

Recommendations

- Be aware in interactions with healthcare practitioners. Depending on the kind of interaction, different rules may apply that could restrict or prohibit the interaction.
- Always keep in mind that the main principle in relation to promoting medicinal products is that the other party may not be unduly influenced in any way.

- Obtain legal advice in case of doubt. Noncompliance could not only have serious civil, administrative and criminal law consequences, but it may also have a negative impact on your company from a commercial perspective (e.g., tainted public reputation).

This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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