Distribution and Marketing of Drugs Global Guide 2015

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Distribution

Pre-conditions for distribution

1.

What are the legal pre-conditions for a drug to be distributed within the jurisdiction?

Authorisation

Before a drug can be introduced into the market it must be authorised (also referred to as having received a marketing authorisation) by the Medicines Evaluation Board (*College ter beoordeling van Geneesmiddelen*) (MEB). The MEB is part of the Ministry of Health, Welfare and Sport.

The MEB evaluates the drug based on criteria cited in the Medicines Act 2007 (*Geneesmiddelenwet*) and sets the conditions for authorising the product for marketing in The Netherlands. The responsibility for the evaluation, authorisation and pharmacovigilance of medicinal products for human use (including homeopathic and herbal medicines) rests with the MEB, which consists of doctors, pharmacists and scientists. The MEB has independent authority to take decisions on the availability of these medicinal products. The MEB is responsible for both the authorisation and monitoring of effective and safe medicinal products and is jointly responsible for the approval of the medicinal products throughout the EU.

Exceptions

There are several exceptions to the obligation to acquire a marketing authorisation. No marketing authorisation is required for:

- Any drug prepared in a pharmacy in accordance with a medical prescription for an individual patient.
- Any drug that is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question.
- Drugs intended for research and development trials.
- Whole blood, plasma or blood cells of human origin, except for plasma that is prepared by a method involving an industrial process.
- Intermediate products intended for further processing by an authorised manufacturer.

2.

Do any types of named patient and/or compassionate use programmes operate? If so, what are the requirements for pre-launch access?

Article 5(1) of Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive), as regards the prevention of the entry into the legal supply chain of falsified medicinal products has been transposed by the Netherland's legislator. At the national level, the legal conditions have been included in the Medicines Act 2007 (*Geneesmiddelenwet*). "Named patient" is an individual patient and falls under the jurisdiction of the Healthcare Inspectorate (*Inspectie voor de Gezondheidszorg*). The Medicines Evaluation Board (*College ter beoordeling van Geneesmiddelen*) (MEB) can approve compassionate use programmes.

Named patient

Permission to supply a pharmaceutical product without marketing authorisation must be obtained from the Healthcare Inspectorate (*Article 3:17, Medicines Act Regulation (Regeling Geneesmiddelenwet)*). Such permission can be sought by a manufacturer, distributor, established pharmacist or a general practitioner that administers his own pharmacy. A separate application form must be completed for each product. The application must state the condition that the product is intended to treat. The first application must be accompanied by a declaration signed by the doctor wishing to prescribe the product. The manufacturer remains liable for the safety of the product at all times.

Compassionate use programmes

Permission to supply a pharmaceutical product without a marketing authorisation must be obtained from the MEB (*Article 3:17, Medicines Act Regulation*).

A company must submit a request to the MEB for implementing a compassionate use programme. This request must indicate how the cohort of patients will be defined and which patients fall under this definition.

The application must include:

- A clear aspect of compassion in case there is no registered alternative medicine.
- Confirmation that the criteria under Article 83(2) of Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency are fulfilled and there is therefore a need to set up a compassionate use programme.
- An overview of the available (pre-) clinical data and, if necessary, quality data.
- An overview of any studies still running and how the company guarantees that the compassionate use programme will not interfere with this.
- Information about which phase the possible marketing authorisation process is in (there should be a successful registration in the near future).
- Whether a compassionate use programme has been started in other EU countries.
- Whether a marketing authorisation dossier has been submitted to the Committee for Medicinal Products for Human Use (CHMP) or whether the CHMP has given an opinion on a compassionate-use programme.

The MEB assesses the request (taking into account the CHMP recommendation where available). If the board decides to allow the request for a compassionate use programme, then the company is notified. The Healthcare Inspectorate is then informed that a compassionate use programme has been approved and the conditions under which this was done. If the board decides to reject the request then both the company and the Healthcare Inspectorate are informed of this decision.

Both positive and negative decisions of the board concerning the permission of a compassionate use programme are published on the MEB website. The Healthcare Inspectorate is responsible for supervising the implementation of the compassionate use programme.

Licensing

3.

What is the procedural structure regarding licensing a drug for distribution?

Structure

Applicants can request two forms of marketing authorisation for a drug:

- A national marketing authorisation.
- A European marketing authorisation.

There are four different procedures by which marketing authorisation can be obtained:

- The national procedure.
- Decentralised procedure (DCP).
- The centralised procedure (for a European marketing authorisation).
- The mutual recognition procedure (MRP).

Regulatory authority

The Medicines Evaluation Board (*College ter beoordeling van Geneesmiddelen*) (MEB) concentrates on the efficacy, safety and quality of the drug when performing its assessment. Homeopathic drugs on the other hand are assessed for safety and quality, but not for efficacy. Once the MEB has assessed and approved a medicinal product then it issues a marketing authorisation. The drug is then added to the Register of Medicinal Products. The "Summary of Product Characteristics" or product information is part of the marketing authorisation. This is the scientific text that contains all the key data about the product. Package leaflets are based on this text. Manufacturers submit a draft for these texts but the final version is drawn up by the MEB.

4.

Is there a simplified licence proceeding, or relaxed licensing conditions, for drugs which have already been licensed for distribution in another jurisdiction?

As an EU member state, in The Netherlands, the simplified licence procedures of the decentralised procedure (DCP) and mutual recognition procedure (MRP) are available. These procedures are based on the principle that member states recognise marketing authorisations issued in another EU member state. The assessment report of the country that granted the first marketing authorisation for the drug in question is made available to other member states.

There is also a simplified procedure for parallel imports. Parallel imports are defined in Article 48 of the Medicines Act 2007 (*Geneesmiddelenwet*). This provision sets out the conditions for the parallel importation of medicines for which a marketing authorisation has already been granted in The Netherlands. A person in The Netherlands who wants to introduce a pharmaceutical product that has been put on the market in another member state of the EU or European Economic Area (EEA) can, at his request, be registered by the Medicines Evaluation Board (*College ter beoordeling van Geneesmiddelen*) (MEB) as a parallel marketing authorisation holder.

During the processing of a request for a parallel marketing authorisation, it must be evaluated whether the product that is to be parallel imported differs from the Dutch reference product in relation to safety and efficacy. The parallel product must be interchangeable with the Dutch reference product.

5.

Is virtual drug distribution possible from your jurisdiction?

Virtual drug distribution is possible. For example, a distributor with a Dutch wholesale licence could use a logistic service provider based in another country, for example Germany. The distributor can distribute drugs from the warehouse in Germany towards another country, for example the UK. Physical products never enter The Netherlands but are distributed using the authorisation obtained in The Netherlands.

6.

What is the procedure to appeal (legal remedy) a licensing decision?

The refusal to grant a marketing authorisation is a decision open to appeal (*Article 1:3, General Administrative Law Act (Awb)*).

The notice of appeal must be submitted to the authority that took the decision within six weeks of the date that the decision was announced. A decision must be reached within six weeks of receipt of the notice of appeal (*Article 7:10, Awb*). The decision can be postponed for a maximum of four weeks.

The Medicines Evaluation Board (*College ter beoordeling van Geneesmiddelen*) (MEB) has delegated hearings in the context of the appeals procedure to an internal committee, which is the appeals committee.

The appeals committee does not make any decisions during the hearing, but reports to the MEB in the form of an opinion. The MEB then reaches a decision on the appeal.

The MEB has drafted a policy appeal document (*Bezwaarschriftenprocedure*) (latest update 5 November 2012) on the subject. The decision of the MEB is open to appeal too. The notice of appeal must be submitted to the administrative court. The appeal must be lodged no later than six weeks after being notified of the decision of the MEB.

7.

What are the costs of obtaining licensing?

The fee for a first national application of a new active substance is EUR43,900. The fee for an application via the mutual recognition procedure (MRP) with The Netherlands as the reference member state (RMS) is EUR19,570. The fee for an application via the decentralised procedure (DCP) with The Netherlands as the RMS is EUR63,470.

All fees can be found on the website of the Medicines Evaluation Board (*College ter beoordeling van Geneesmiddelen*) (MEB) (*http://english.cbg-meb.nl/human/for-marketing-authorisation-holders/contents/technical-requirements/product-types-and-fees*).

Distribution to consumers

8.

What are the different categories of drugs for distribution?

The availability of drugs is divided into two main groups:

- Medicines available only on prescription from a doctor or specialist (PO).
- Medicines available without prescription (over-the-counter) (OTC).

The Medicines Evaluation Board (*College ter beoordeling van Geneesmiddelen*) (MEB) determines whether a drug requires a PO or not.

9.

Who is authorised to distribute prescription drugs and over-the-counter drugs to consumers?

Prescription drugs

Prescription drugs are only dispensed at pharmacies (*apotheken*).

Under certain conditions, a GP can distribute prescription drugs to patients, if they are a dispensing GP or for other GPs in case of emergency.

Over-the-counter drugs

Since the enactment of the Medicines Act 2007 (*Geneesmiddelenwet*), over-the-counter (OTC) medicines have been divided into three categories of legal status of supply. The aim of the legislator was to ensure a good balance between availability and risks. These categories are:

- Pharmacy only (PH): medicines with a relatively mild potential risk. These can only be obtained from a pharmacy.
- Pharmacy and drugstore (that does not require employment of a pharmacist) (PDO): medicines with a relatively low potential risk. These can only be obtained from a pharmacy or drugstore.
- Without restriction (GS): medicines with a very low potential risk. These drugs are available not only from pharmacists and chemists, but also from other sales channels such as supermarkets or service stations.

10.

What drugs can an attending physician distribute and under what circumstances?

Under certain conditions, a GP can distribute prescription drugs to consumers, such as a dispensing GP or in an emergency.

11.

Who is authorised to prescribe prescription drugs to consumers?

The provision of the authorisation to prescribe prescription drugs to consumers is regulated by the Individual Healthcare Professions Act (*Wet op de beroepen in de individuele gezondheidszorg*) (*Wet BIG*). According to the Wet BIG the following healthcare professionals can prescribe prescription drugs to consumers:

- Doctors, such as a GP or hospital doctor.
- Dentists.
- Obstetricians.
- Physician assistants.
- Nurse specialists for somatic disorders.
- Specialised diabetes nurse.
- Specialised long nurse.
- Specialised oncology nurse.

12.

Is direct mailing/distance selling of drugs permitted in your jurisdiction?

Conditions

Prescription drugs can only be prescribed by qualified physicians and can only be supplied to consumers by authorised pharmacists operating from qualified premises. Physicians can only prescribe prescription drugs online to patients if the physician and the patient have previously met in person and the medication history of the patient is available to the physician. If those requirements are met, drugs can, in principle, be ordered by a consumer using the internet, provided that the prescription is in writing, on paper and submitted to the pharmacist.

When offering drugs through the internet, Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Electronic Commerce Directive) and Directive 97/7/EC on the protection of consumers in respect of distance contracts (Distance Selling Directive) (both implemented in the Civil Code) provide that certain information must be provided, such as the contact details, price and main characteristics of the drugs.

Cross-border sales

In principle it is possible to sell drugs over The Netherlands' border, but it depends on the local legislation.

13.

What regulatory authority is responsible for supervising distribution activities?

The Healthcare Inspectorate can monitor compliance with the marketing authorisations and can exercise its powers if required. Under the Medicines Act 2007 (*Geneesmiddelenwet*), the Healthcare Inspectorate can impose an "administrative fine" for any breach.

The Healthcare Inspectorate can impose a fine if, for example:
- The guidelines for preparation of medicines are not followed.
- A product is offered for sale without the required marketing authorisation.
- Trials of a drug are conducted without the necessary licences and permits.

The amount of the fine depends on a number of factors, including the:
- Seriousness of the incident.
- Potential risk to public health.
- Size of the company in question.

Indicative tables of the fine amounts can be found in the Policy Guidelines on Administrative Fines (*Beleidsregels Bestuurlijke Boete*) (*www. overheid.wetten.nl*).

14.

What is the procedure to appeal (legal remedy) a distribution decision?

Any party whose interests are directly affected by a decision (that is an interested party) can submit a notice of appeal (*Article 7:1, General Administrative Law Act (Awb)*). The notice of appeal must be submitted to the Healthcare Inspectorate within six weeks of the date that the decision was announced. A decision must be reached within six weeks of receipt of the notice of appeal (*Article 7:10, Awb*). The decision can be postponed for a maximum of four weeks.

The decision of the Healthcare Inspectorate is open to appeal too. The notice of appeal must be submitted to the administrative court. The appeal must be lodged no later than six weeks after being notified of the decision of the Healthcare Inspectorate.

15.

What are the legal consequences of non-compliance with consumer distribution laws?

Marketing a drug without a marketing authorisation is a criminal offence, which can be punished with imprisonment of up to six months or a fine of up to EUR450,000 depending on whether, for example:
- The breach was committed intentionally.
- It concerned a legal entity.
- The breach was a repeat offence.

The Minister of Health can impose an administrative fine for breach of the marketing authorisation's terms. The maximum fine under the Minister's policy rules for a first offence is EUR4,500 for infringements, except those concerning advertising, where the standard fine for large companies (50 employees or more) is EUR150,000.

Indicative tables of the fine amounts can be found in the Policy Guidelines on Administrative Fines (*Beleidsregels Bestuurlijke Boete*) (*www. overheid.wetten.nl*).

Wholesale distribution

16.

What is the legal regime regarding wholesale distribution of drugs?

Distributors and importers of drugs intended for human use must hold a wholesale licence. A wholesale licence is required to be allowed to obtain, store or resell drugs within the European Economic Area (EEA) (that is, the EU countries plus Norway, Iceland and Liechtenstein) and the delivery of them. For the import of drugs from outside the EEA, a manufacturer permit is required. A wholesale dealer can provide drugs to any of the following parties:

- Pharmacists.
- GPs that administer his or her own pharmacy.
- Other holders of a wholesale license.

Farmatec, a unit of the Ministry of Health, deals with applications for manufacturing, import and wholesale authorisations, as well as the decision-making procedures relating to pricing and reimbursement. The Healthcare Inspectorate also advises the Minister of Health on issuing or revising manufacturing or wholesale licenses.

17.

What regulatory authority is responsible for supervising wholesale distribution activities?

Regulatory authority

The Healthcare Inspectorate enforces this legal obligation in The Netherlands.

Supervision

The inspections are primarily concerned with compliance of the Good Distribution Practice (GDP) guidelines. The Healthcare Inspectorate focuses on storage and other elements of the GDP guidelines during inspection for the wholesale licence.

Rights of appeal

The notice of appeal must be submitted to the Healthcare Inspectorate within six weeks of the date that the decision was announced. A decision must be reached within six weeks of receipt of the notice of appeal (*Article 7:1, General Administrative Law Act (Awb)*). The decision can be postponed for a maximum of four weeks.

The decision of the Healthcare Inspectorate is open to appeal too. The notice of appeal must be submitted to the administrative court. The appeal must be lodged no later than six weeks after being notified of the decision of the Healthcare Inspectorate.

18.

What are the legal consequences of non-compliance with wholesale distribution laws?

Under the Medicines Act 2007 (*Geneesmiddelenwet*), the Healthcare Inspectorate can impose an administrative fine for any non-compliance. Indicative tables of the fine amounts are to be found in the Policy Guidelines on Administrative Fines (*Beleidsregels Bestuurlijke Boete*) (*www.overheid.wetten.nl*). Breach of the terms of a wholesale licence could lead to an administrative fine of up to EUR450,000. It is also considered as a crime punishable by imprisonment.

Marketing

Promotion

19.

What is the general legal regime for the marketing of drugs?

Legal regime

The marketing requirements set out in Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) have been implemented in Articles 83–96 of the Medicines Act 2007 (*Geneesmiddelenwet*). The Healthcare Inspectorate has also issued policy rules that further explain the rules stipulated in the Medicines Act regarding two subjects:

- Provision of inducements.
- Administrative penalty.

Limits to marketing activities

The Medicines Act sets out the following general limits to marketing activities directed at the general public and at healthcare professionals:

- Marketing of drugs for which a marketing authorisation has not been granted is prohibited.
- Prescription drugs cannot be marketed to the general public in any media.
- Marketing of prescription drugs to healthcare professionals is permitted, but is also subject to strict conditions.
- Marketing of over-the-counter (OTC) medicines to the general public is permitted, but is subject to strict conditions.
- Providing objective information on drugs is allowed, but is also subject to strict conditions.

20.

Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organisations)?

The rules stipulated in the Medicines Act 2007 (*Geneesmiddelenwet*) have been included and refined in a voluntary Code of Conduct for Pharmaceutical Advertising (*Gedragscode Geneesmiddelenreclame*), a regulation of the self-governing Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame*) (CGR). The CGR has also issued explanatory notes regarding the way the Code is to be interpreted. The Code of Conduct on Marketing

Directed at the General Public (*Code voor de Publieksreclame van Geneesmiddelen*) (CPG) forms an integral part of the Code of Conduct for Pharmaceutical Advertising.

Marketing to consumers

21.

What is the legal regime for marketing to consumers?

Legal regime

The rules on marketing to consumers are set out in the Medicines Act 2007 (*Geneesmiddelenwet*) and the Code of Conduct on Marketing Directed at the General Public (*Code voor de Publieksreclame van Geneesmiddelen*) (CPG).

Products

The Medicines Act and CPG state that any marketing of drugs for which a marketing authorisation has not been granted is prohibited. An exception to this rule is for marketing in a strictly international context that is not at all directed at the Dutch market (for example, in scientific journals). Marketing of prescription drugs and over-the-counter (OTC) medicines that contain substances as referred to in list I and II of the Dutch Opium Act directed at consumers is prohibited under all circumstances. Marketing of homeopathic drugs without approved therapeutic indications is prohibited. Marketing of OTCs to consumers is permitted, but is subject to strict conditions.

22.

What kinds of marketing activities are permitted in relation to consumers and the products which may be advertised to them?

Marketing directed at consumers is only permitted for over-the-counter (OTC) medicines. Such marketing must:

- Make clear that it concerns an advertisement of a drug.
- Contain the name of the drug and a generic name of the active ingredient in the event the drug contains only one active ingredient.
- Contain information that is necessary for proper use of the drug, such as indications and contraindications.
- Contain an explicit request to read the instruction leaflet or the text on the outer package.

All marketing to consumers must be approved by the Inspection Board for the Advertising of Medicinal Products to the General Public (*Keuringsraad Openlijke Aanprijzing Geneesmiddelen*) (KOAG).

The Medicines Act 2007 (*Geneesmiddelenwet*) and Code of Conduct on Marketing Directed at the General Public (*Code voor de Publieksreclame van Geneesmiddelen*) (CPG) set out further rules on marketing to consumers. All the rules apply to marketing in writing. Some exceptions to the rules are made for marketing in radio broadcasts and for recollection advertisements. For example, the generic name of the active ingredient does not have to be mentioned in a radio broadcast advertisement. A recollection advertisement only needs to contain the name of the drug and, if applicable, the generic name of the active ingredient.

Pharmaceutical companies cannot sponsor activities of a third party (such as healthcare professionals, patient organisations and pharmaceutical service providers) that offers marketing of prescription drugs to consumers in return.

Testimonials are allowed as long as they represent an accurate overview of the user experience. Testimonials cannot contain any direct or indirect promotion by scientists, healthcare professionals or celebrities.

Pharmaceutical companies can provide "objective" information on prescription drugs. The CPG contains specific guidelines regarding provision of information to consumers on prescription drugs. These guidelines are applicable to the provision of objective information about a disease, its clinical features and treatment, whereby a prescription drug is mentioned directly or indirectly, as well as general and technical information about the use of a prescription drug without a specific request by a patient to provide such information. The second category of information cannot be generally available to the public. With the internet, such information must be protected by a password. All communication must mention the name and address of the person or entity responsible for the provision of this information and the date on which the information was updated for the last time.

23.

Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers (for example, "buy-one-get-one-free")?

The Code of Conduct on Marketing Directed at the General Public (*Code voor de Publieksreclame van Geneesmiddelen*) (CPG) stipulates that marketing that does not encourage the rational use of a medicine is prohibited. Therefore it is not permitted to:

- Give samples of medicines free of charge.
- Make direct or indirect price offers, provide coupons or organise "refund campaigns".
- Make the purchase of the medicine a condition for participation in competitions and games and to receive small gifts.

The distribution of small gifts is only permitted as long as there is no obligation to purchase and the words "no purchase obligation" are incorporated in a readable font in the corresponding advertisement.

Price offers such as "now for …", "buy three, get fourth free", "in our shop only for…" or those that suggest a price offer by mentioning the price of the drug in a large font or by introducing the word "only" preceding the price, are prohibited. General (price) offers for certain ranges of drugs, such as savings systems or a reduction on the total range are permitted.

24.

Are there particular rules of practice on the use of the internet/social media regarding drugs and their advertising?

The marketing of prescription drugs to consumers is prohibited under all circumstances. This rule applies to all marketing activities, including marketing via internet and social media.

The Code of Conduct on Marketing Directed at the General Public (*Code voor de Publieksreclame van Geneesmiddelen*) (CPG) contains specific rules regarding the provision of objective information on prescription drugs to consumers via the internet. For example, it can use the name of the pharmaceutical company, the indication or the trade mark of a prescription drug in the name of the website. This website can only contain a complete insert of the drug and clinical features that are concise and subordinate in nature. The website must also state the name and address of the person or entity responsible for the content of the website and the date on which the information was updated for the last time. The website can also contain an e-mail address that the consumers can use to request additional information. Hyperlinking is permitted so long as the website to which the link is provided complies with the rules of the CPG and it is obvious to the internet user that the original website is left on clicking on the hyperlink.

The Inspection Board for the Advertising of Medicinal Products to the General Public (*Keuringsraad Openlijke Aanprijzing Geneesmiddelen*) (KOAG) has issued specific guidelines on marketing prescription drugs to consumers via social media (*Handleiding KOAG/KAG inzake Digitale communicatie/Social Media*). The general rule of thumb is that the rules for offline advertising are also applicable to online communication. In practice this means that if a pharmaceutical company advertises via digital media (for example, via Facebook, LinkedIn or Twitter) then it has an obligation to pre-screen on a daily basis, and, if necessary, remove posts of the public that are in violation of the CPG. Any company or product related website, Facebook or LinkedIn page and any digital advertising has to be pre-approved by the KOAG.

For marketing over-the-counter (OTC) medicines to consumers via social media, the general rules set out by the Dutch Advertising Code Authority in the Advertising Code for Social Media (*Reclamecode Social Media*) apply. Generally, any advertising via social media must be clearly recognisable as such. Any relationship between the advertiser and the distributor of the post must be disclosed.

For further rules with regard to sale of drugs via the internet, see *Question 12*.

25.

What regulatory authority is responsible authority is responsible for supervising marketing activities to consumers?

Regulatory authority

The Healthcare Inspectorate is responsible for supervising marketing activities to consumers.

Supervision

In practice, the Healthcare Inspectorate leaves it to the Inspection Board for the Advertising of Medicinal Products to the General Public (*Keuringsraad Openlijke Aanprijzing Geneesmiddelen*) (KOAG), the Inspection Board for the Promotion of Health Products **(***Keuringsraad Aanprijzing Gezondheidsproducten***)** (KAG) as well as the Advertising Code Committee (*Reclame Code Commissie*) (RCC) (both self-regulatory bodies) to supervise marketing activities directed at consumers. The RCC has jurisdiction over complaints filed against an advertisement by consumers. The Code Committee (*Codecommissie*) of the KOAG and KAG has jurisdiction over complaints filed by others than consumers.

Rights of appeal

Appeals against the decisions of the RCC can be filed with the Board of Appeal of the RCC. Appeals against the decisions of the Code Committee of KOAG and KAG can be filed with the Committee of Appeal of the KOAG and KAG.

26.

What are the legal consequences of non-compliance with consumer marketing laws?

For violation of the Code of Conduct on Marketing Directed at the General Public (*Code voor de Publieksreclame van Geneesmiddelen*) (CPG), the Advertising Code Committee (*Reclame Code Commissie*) (RCC) will recommend that the advertiser discontinues the advertising. The compliance department monitors compliance with the RCC's decision. With non-compliance of the RCC decision, the RCC publishes its decision on its website under non-compliance, which will attract the attention of the authorities.

Where the Code Committee of the KOAG and the KAG decides on whether to allow the complaint it can impose disciplinary measures on the advertiser, ranging from a reprimand to an order to rectify the advertisement and a recall of all material containing the advertisement. The Code Committee of the KOAG and KAG cannot impose a fine. However, it can decide that the advertiser has to refund the court fee of the complainant (amounting to EUR500) and/or has to compensate the costs of the assessment of the complaint made by the Code Committee. These costs are set on a yearly basis.

Although the KOAG and KAG and the RCC are primarily responsible for supervising marketing activities directed towards consumers, the Minister of Health is authorised by the Medicines Act 2007 (*Geneesmiddelenwet*) to impose an administrative fine up to EUR450,000 for violation of the provisions of the Medicines Act regarding marketing to consumers. The maximum fine under the Minister's policy rules for a first offence is set at EUR150,000. Indicative tables of the standard fine amounts can be found in the Policy Guidelines on Administrative Fines (*Beleidsregels Bestuurlijke Boete*) at *www.overheid.wetten.nl*. Where the advertiser is fined twice for the same violation within a period of 24 months, this violation constitutes a criminal act and can be punished by six months imprisonment or a criminal fine amounting to EUR8,100.

Marketing to professionals

27.

What kinds of marketing activities are permitted in relation to professionals?

The following types of marketing activities with respect to professionals are permitted:

- Marketing of prescription drugs to healthcare professionals is permitted, but is subject to strict conditions.
- Marketing of non-interventional studies that are not subject to the Medical Scientific Research with Humans Act (*Wet Medisch Wetenschappelijk Onderzoek met Mensen*) (WMO) and therefore do not need to be approved in advance by an official Medical Ethic Testing Committee (*Medisch Ethische Toetsing Commissie*) (METC) is permitted, but is subject to strict conditions.

28.

Are there any restrictions on marketing to professionals?

Marketing activities

The following types of marketing activities to professionals are not permitted:

- Any marketing of drugs for which a marketing authorisation has not been granted is prohibited. The one exception to this rule is for marketing to professionals in a strictly international context, that is not in any way directed at the Dutch market (for example, in scientific journals).
- Sponsoring of individual healthcare professionals is prohibited (*see Question 31*).
- Provision of inducements, meaning holding out the prospect of, offering or granting money or valuable goods or services for the purpose of inducement of prescription, supply or use of specific drugs, is prohibited. The Netherlands Healthcare Inspectorate (*Inspectie voor de Gezondheidszorg*) (IGZ**)** has issued policy rules that relate to the provision of inducements. Exceptions are made for the provision of hospitality, gifts, discounts and bonuses and services (*see Question 31*).

Frequency

The Code of Conduct on Marketing Directed at the General Public (*Code voor de Publieksreclame van Geneesmiddelen*) (CPG) contains some general rules on promotional activities by sales representatives. Medical sales representatives must ensure that the frequency, scheduling and duration of the visits to healthcare professionals or hospitals, as well as the manner in which these visits occur, do not cause any inconvenience.

Oral advertising by telephone is not permitted, except by prior appointment with the relevant healthcare professional.

Provision of hospitality

The Medicines Act 2007 (*Geneesmiddelenwet*), the CPG and policy rules regarding provision of inducements, set out restrictions on meetings or manifestations with groups of professionals and the provision of hospitality.

Under the CPG a distinction is made between the provision of hospitality at meetings and at manifestations:

- A meeting is an event with a scientific objective that has been accredited by a recognised body, such as a scientific organisation. If the event has not been accredited, it can still qualify as a meeting if either:
    - the organisation is independent;
    - it is organised by a pharmaceutical company and the Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame*) (CGR) has first reviewed and approved its content and hospitality to be provided there.
- A manifestation is an event with a programme that provides for the information needs of healthcare professionals but does not qualify as a meeting.

The CPG provides that the place, duration and date of the meeting or manifestation cannot lead to confusion or doubt regarding its nature. Hospitality has to fulfil the following requirements:

- It must remain within reasonable limits.
- It must be subordinate to the main purpose of the meeting or manifestation.
- It cannot be provided to anyone other than participants of the scientific part of the meeting or manifestation.

Hospitality in meetings held in The Netherlands is deemed to remain within reasonable bounds if either:

- The costs do not exceed EUR500 per occasion and EUR1,500 per year per healthcare professional and per therapeutic class (the limit of EUR1,500 per year includes amounts received for a different meeting organised by a third party for the same therapeutic class).
- The healthcare professional bears at least 50% of all the costs (travel and accommodation and the costs of participation).

Hospitality at manifestations held in The Netherlands is within reasonable bounds when the costs for the account of the pharmaceutical company do not exceed EUR75 per healthcare professional per therapeutic classification per occasion and EUR225 per year.

For providing a meal in The Netherlands, the limit is set at EUR75.

These rules apply both to meetings and manifestations directly or indirectly organised by a pharmaceutical company and meetings or manifestations that are sponsored by a pharmaceutical company.

The provision of hospitality (unless travel and accommodation costs are not compensated), must be set out in writing in advance and must contain an exact description of the project or activity and the rights and obligations of the parties. The contract also must specify the location, date and length of the meeting or manifestation as well as which costs are compensated. Information about agreements exceeding a value of EUR500 a year must be made available to the Healthcare Transparency Register (*Transparantieregister Zorg*) within three months of the end of the calendar year and be disclosed on its website.

29.

What information is it legally required to include in advertising to professionals?

According to the Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame*) (CGR), all marketing material in written form must state:

- The name of the drug.
- The name and address of the entity responsible for putting the drug on the market.
- The qualitative and quantitative composition of the active ingredients.
- The pharmacotherapeutic group, where applicable.
- The pharmaceutical form and the main therapeutic indications.
- The most important side effects (based on frequency and gravity).
- The most important warnings (precautionary measures regarding use).
- All contra-indications.
- The supply qualification of the drug.
- Conditions for reimbursement by social security bodies.
- The date on which it was drawn up or last revised.

Some exceptions to the above-mentioned requirements are made for recollection advertisements.

All marketing materials in written form have to be approved by an internal scientific department of the pharmaceutical company.

30.

Are there rules on comparisons with other products that are particularly applicable to drugs?

The Code of Conduct on Marketing Directed at the General Public (*Code voor de Publieksreclame van Geneesmiddelen*) (CPG) contains specific rules on comparative advertising. Any comparative advertising that explicitly or by implication makes reference to a competitor or competing drugs or substances must comply with the following conditions. The comparison:

- Cannot be misleading.
- Cannot be detrimental to the value of the drugs in question.
- Cannot discredit or denigrate the competitor or its trademarks or trade names.
- Cannot create confusion between the drugs and their trade marks or between the pharmaceutical companies involved and their trade names.
- Cannot present the drugs in question as imitations or replicas of drugs that are protected by trade marks of trade names.
- Cannot take unfair advantage of the reputation of a trade mark, trade name or other distinguishing marks of a competitor.
- Must be demonstrably scientifically correct and in line with the most recent state of the science (this must be demonstrated by means of one or more scientific studies).
- Must be complete with regard to the effects, side-effects, indications and contra-indications and all other relevant information.

31.

Is it permitted to provide professionals with indirect incentives?

Discounts

Discounts in the form of gifts (such as bonus deliveries of other drugs or other products from a different industry) are prohibited. This rule does not apply to discounts made for the delivery of drugs by the pharmaceutical companies to healthcare professionals (such as pharmacists and general practitioners), provided that it concerns bonus deliveries of the same drug or a discount in cash, insofar as explicitly stated in writing (for example, in an invoice or a credit note).

Generally, pharmaceutical companies must refrain from:

- Offering or promising gifts.
- Waives of payment.
- Bonuses.
- Any other benefits in cash or in kind.

It is also not permissible to make the price of a certain drug dependent on the purchase of other drugs or products. This does not apply to gifts that are of minor value and are relevant to the practice of the healthcare professional. The Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame*) (CGR) has indicated that a gift is presumed to be minor in value if the value does not exceed EUR50 (based on shop value and including VAT) per time, with a maximum of EUR150 per year, per healthcare professional, per pharmaceutical company and per therapeutic class.

Free samples

Provision of free samples of drugs to healthcare professionals is prohibited, unless:

- A healthcare professional qualified to prescribe drugs has filed a request, personally signed and dated, to that extent with the pharmaceutical company.
- The sample is no larger than the smallest presentation of the drug available on the market.
- A healthcare professional cannot receive more than two samples of the same drug per calendar year.
- The sample itself is marked with the text that it is "free of charge" and "not for sale".
- A copy of the summary of product characteristics of the drug is provided with the sample.
- The entity or person providing the samples must keep records of the professionals that requested the samples, on which date and in which quantities for a period of five years.

Each healthcare professional can only receive free samples of a particular drug for two years after he first requested samples of that particular drug. It is also prohibited to provide free samples of drugs containing substances as referred to in lists I and II of the Dutch Opium Act to healthcare professionals.

Sponsorship of professionals

The Code of Conduct on Marketing Directed at the General Public (*Code voor de Publieksreclame van Geneesmiddelen*) (CPG) contains specific rules regarding

sponsorship. These rules apply to sponsorship by pharmaceutical companies of professionals and associations of professionals. The CPG stipulates that the provision of financial support or any other monetary support for individual professionals, with the exception of sponsorship of a doctoral thesis, is prohibited unless it meets strict conditions as set out below. Any type of support (for example, a donation) is qualified as sponsoring under these rules.

Sponsoring of healthcare professionals is allowed under the following strict conditions. Briefly, these conditions relate to sponsoring, transparency and integrity. The parties involved must be able to demonstrate that the purpose of sponsoring is:

- To support innovative and/or quality-improving activities.
- Directed at the direct or indirect improvement of the healthcare of patients or the promotion of medical science.
- Does not concern activities that can be funded in part or in whole in any other way (for example, by the government, healthcare insurers or subsidies).

Sponsoring cannot, under any circumstances, lead to personal gain of the healthcare professional or constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific drugs.

The sponsorship contract must be set out in writing before the sponsoring commences and must contain an exact description of the project or activity and the rights and obligations of the parties. Structural sponsorship exclusivity (a conscious decision to limit sponsoring to only one sponsor) is prohibited. The CPG also stipulates that certain information about sponsorship contracts exceeding a value of EUR500 per calendar year must be made available to the Healthcare Transparency Register within three months of the end of the calendar year and will be disclosed on its website.

Other indirect incentives

Pharmaceutical companies can use healthcare professionals as consultants and advisors. Compensation for such services must be reasonable and must reflect the fair market value of the services provided. A written contract must be agreed in advance of the commencement of the services and must specify the purpose and the nature of the services to be provided.

The CPG stipulates that if the value of the contract exceeds EUR500 per calendar year then information regarding the contract must be made available to the Healthcare Transparency Register within three months of the end of the calendar year and will be disclosed on its website.

32.

What regulatory authority is responsible for supervising marketing activities regarding professionals?

Regulatory authority

The Healthcare Inspectorate is responsible for supervising marketing activities to healthcare professionals.

Supervision

In practice, the Healthcare Inspectorate leaves it to the self-regulatory body that is the Code Committee of the Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame*) (CGR) to supervise marketing activities regarding professionals.

Rights of appeal

Appeals against the decisions of the Code Committee of CGR can be filed with the Committee of Appeal of CGR.

33.

What are the legal consequences in case of non-compliance with professional marketing laws?

Where the Code Committee of the Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame*) (CGR) decides to allow the complaint, it can impose disciplinary measures on the advertiser, ranging from a reprimand to an order to rectify the advertisement and a recall of all advertising material containing the advertisement. The Code Committee of CGR cannot impose a fine. However, it can decide that the advertiser has to compensate the costs of the assessment of the complaint made by the Code Committee of CGR and to refund the court fee of the complainant (ranging from nothing to EUR1,250 in the first instance, depending on the persona of the complainant). The costs of assessment of the case are set on a yearly basis.

Although the CGR is primarily responsible for supervising marketing activities directed towards professionals, the Minister of Health is authorised by the Medicines Act 2007 (*Geneesmiddelenwet*) to impose an administrative fine up to EUR450,000 for violation of the provisions of the Medicines Act regarding marketing to professionals. The maximum fine under the Minister's policy rules for a first offence is set at EUR150,000. Indicative tables of the standard fine amounts can be found in the Policy Guidelines on Administrative Fines (*Beleidsregels Bestuurlijke Boete*) (*www.overheid.wetten.nl*). If the advertiser is fined twice for the same violation within a period of 24 months, this violation constitutes a criminal act and can be punished by six months imprisonment or a criminal fine amounting to EUR8,100.

Engagement with patient organisations

34.

What kinds of activities are permitted in relation to engagement with patient organisations? What are the restrictions that are imposed on relationship with patient organisations?

Because members of the general public participate in patient organisations, the general rules on marketing to consumers are applicable. Therefore, only the following activities are permitted with respect to engagement with patient organisations:

- Marketing of over-the-counter (OTCs) is permitted under strict conditions.
- Provision of objective information on drugs is permitted under strict conditions.

- Financial support (for example, sponsoring, subsidising or support in kind) is permitted, but is subject to strict conditions. Generally, financial support cannot compromise the independence of the patient organisation, its policy or activities.

Prescription drugs cannot be marketed through patient organisations under any circumstances. Sponsorship exclusivity is not permitted, unless it concerns a specific, short term project, such as a publication or organising a meeting.

Reform

35.

Are there any plans to reform the law on the distribution and promotion of drugs in your jurisdiction?

The Code of Conduct on Marketing Directed at the General Public (*Code voor de Publieksreclame van Geneesmiddelen*) (CPG) is reviewed by the Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame*) (CGR) on a regular basis. The most recent changes were made in January 2015 as a result of the implementation of the Disclosure Code of the European Federation of Pharmaceutical Industries and Associations (EFPIA**)**. No specific reforms of the CPG are planned in the foreseeable future.

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