Netherlands

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A. DISTRIBUTION

1. PRECONDITIONS FOR DISTRIBUTION

1.1 What are the legal preconditions for a drug to be distributed within the jurisdiction? Does the drug need to be licensed (authorised) for distribution? Are there exceptions or different categories such as compassionate use?

Before a drug may be brought onto the market in the Netherlands, 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.

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

- any drug prepared in a pharmacy in accordance with a medical prescription for an individual patient;
- any drug which 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 which is prepared by a method involving an industrial process; and
- intermediate products intended for further processing by an authorised manufacturer.

The MEB evaluates the drug based on criteria cited in the Dutch Medicines Act (*Geneesmiddelenwet*, Medicines Act) and sets the conditions for authorising the product for marketing in the Netherlands.

1.2 Are any kinds of named patient and/or compassionate use programs in place? If so, what are the requirements for pre-launch access? (for EU countries only: has Article 5 (1) of Directive 2001/83/EC been transposed by your national legislator?)

Article 5(1) of Directive 2001/83/EC has been transposed by the Netherland's legislator. At the national level, the legal conditions have been included in the Medicines Act. 'Named patient' is prescribed to an individual patient and falls under the jurisdiction of the Health Care Inspectorate (*Inspectie voor de Gezondheidszorg*, Inspectorate). The MEB has the authority to approve compassionate use programmes.

Named patient
Permission to supply a pharmaceutical product without marketing authorisation must be obtained from the Inspectorate, as stipulated under Article 3:17 of the Medicines Act Regulatory Instrument (*Regeling Geneesmiddelenwet*). Such permission can be sought by a manufacturer, distributor, established pharmacist or a general practitioner who administers his or her own pharmacy. A separate application form must be completed for each product. The application must state the condition which 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, as stipulated in Article 3:17 of the Medicines Act Regulatory Instrument.

A company should submit a request to the MEB for implementing a compassionate use program. 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;
- that the previously mentioned criteria are fulfilled and there is thus a need to set up a compassionate use program;
- 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 program 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 program has been started in other EU countries; and
- if there is an opinion formulated by the Committee for Medicinal Products for Human Use (CHMP).

The MEB assesses the request (taking into account the possible CHMP recommendation). If the board comes to a positive decision about the requested compassionate use program, then the company is notified. The Inspectorate is then informed that a compassionate use program has been approved and the conditions under which this was done. If the board decides negatively, then both the company and the Inspectorate will be informed of this.

From 1 January 2012 both positive and negative decisions of the board concerning the permission of a compassionate use program will be published on the MEB website.

The Inspectorate is responsible for supervising the implementation of the compassionate use program.

1.3 What is the structure of the procedure regarding licensing a drug for distribution? Which national body (agency) is responsible for licensing?

Applicants can request two forms of marketing authorisation for a drug: a national marketing authorisation or 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) and the mutual recognition procedure (MRP).

The 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 given a positive assessment of the drug, the manufacturer receives 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 which 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.

1.4 Is there a simplified license proceeding or are there relaxed licensing conditions for drugs which have already been licensed for distribution in another jurisdiction? What about parallel imports, is there a simplified procedure for these?

As a European Union member state, in the Netherlands, the simplified licence procedures; decentralised and mutual recognition are available. These procedures are based on the principle that member states recognise marketing authorisations issued in another European Union (EU) member state. The assessment report of the country which 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. This 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 EEA can, at his or her request, be registered by the 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 to be parallel imported does not differ from the Dutch reference product with respect to safety and efficacy; the parallel product should be interchangeable with the Dutch reference product.

1.5 Is it possible to distribute drugs 'virtually' from your jurisdiction (ie, the physical products never enter the country but are distributed using the authorisation obtained in your country).

Yes, this is possible. For example:

A distributor with a Dutch wholesale license could use a logistic service

provider based in another country, for example Germany. The distributor could distribute drugs from the warehouse in Germany towards another country, for example England. Physical products never enter the Netherlands but are distributed using the authorisation obtained in the Netherlands.

1.6 Is there a legal remedy (appeal) against licensing decisions?

According to Article 1:3 of the General Administrative Law Act (Awb) the refusal to grant a marketing authorisation is a decision open to appeal.

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

The MEB has delegated hearings in the context of the appeals procedure to an internal committee: 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* (MEB-09-4.0, latest update 28 January 2010), 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.

1.7 What are the costs of obtaining licensing?

The fee for a first national application of a new active substance is EUR 43,900. There is a surcharge of EUR 19,570 for an MRP with the Netherlands as the Reference Member State (RMS). The fee for an application via DCP with the Netherlands as the RMS is EUR 63,470.

All fees can be found on the website of the MEB.

2. DISTRIBUTION TO CONSUMERS

2.1 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) and medicines available without prescription (over-the-counter, OTC). The MEB determines whether a drug requires a PO or not.

2.2 Who is entitled to distribute prescription drugs to consumers? What authorisation do they require?

In the Netherlands, prescription drugs are dispensed only at pharmacies (*apotheken*).

Under certain conditions the General Practitioner (GP) is also allowed to distribute prescription drugs to patients, if they are a dispensing GP, and for other GPs in case of emergency.

2.3 Who is entitled to distribute over-the-counter drugs to consumers?

Since the enactment of the Medicines Act of 2007, 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:

- harmacy only (PH): Medicines with a relatively mild potential risk;
- Pharmacy and Drugstore (that does not require employment of a pharmacist) (PDO): Medicines with a relatively low potential risk;
- Without Restriction (GS): Medicines with a relatively very low potential risk.

Drugs in the PH category can only be obtained from a pharmacy, drugs in the PDO category can only be obtained from a pharmacy or drugstore, while drugs in the GS category can be obtained from other outlets as well. The last category means that these drugs are available not only from pharmacists and chemists, but also via sales channels such as supermarkets or service stations.

2.4 Which drugs may be distributed by the attending physician, and under what circumstances?

Under certain conditions the GP is allowed to distribute prescription drugs to consumers, such as a dispensing GP as well as in case of emergency.

2.5 Who may prescribe prescription drugs to consumers?

According to Article 14 of the Dutch Healthcare Professions Act:

- doctors, such as your GP or a hospital doctor;
- dentists;
- obstetricians;
- physician assistants;
- nurse specialists in case of somatic disorders;
- specialised oncology nurse;
- specialised diabetes nurse;
- specialised long nurse

2.6 Is direct mailing/distance selling of drugs permitted? Under what conditions, by whom, and to whom? Might sales be made beyond the borders of your country?

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.

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

When offering drugs through the internet, Directive 2000/31/EC on electronic

commerce and Directive 97/7/EC on distance selling (both implemented in the Dutch Civil Code), provide that certain information must be provided, such as the contact details, price and main characteristics of the drugs.

2.7 Which body (agency) is responsible for supervising distribution activities regarding consumers? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

The Inspectorate can monitor compliance with the marketing authorisations and can exercise its powers if required. Under the Medicines Act, the Inspectorate is entitled to impose an 'administrative fine' in respect of any breach. Indicative tables of the fine amounts can be found in the Policy Guidelines on Administrative Fines (*Beleidsregels Bestuurlijke Boete*) at *www.overheid.wetten.nl*.

Article 7:1 of the Awb states that any party whose interests are directly affected by a decision (ie, an interested party) may submit a notice of appeal. The notice of appeal must be submitted to the Inspectorate within six weeks of the date on which the decision was announced. Article 7:10 of the Awb states that a decision must be reached within six weeks of receipt of the notice of appeal. The decision can be postponed for a maximum of four weeks.

The decision of the 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 Inspectorate.

2.8 What are the legal consequences in case of non-compliance?

Marketing a drug without a marketing authorisation is a criminal offence, which can be punished with imprisonment for up to six months or a fine of up to a maximum of EUR 450,000 depending on, for example, whether the breach was committed intentionally and whether it concerned a legal entity. 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 EUR 4,500 for infringements, except those concerning advertising, where the standard fine for large companies (50 employees or more) is EUR 150,000.

3. WHOLESALE DISTRIBUTION

3.1 What is the legal regime regarding wholesale of drugs? Under what conditions, by whom, and to whom is wholesale of drugs permitted?

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

- pharmacists;
- general practitioners who administers his or her own pharmacy; and
- 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 Inspectorate also advises the Minister of Health on issuing or revising manufacturing or wholesale licenses.

3.2 Which body (agency) is responsible for supervising wholesale distribution activities? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

The Inspectorate enforces this legal obligation in the Netherlands.

The notice of appeal must be submitted to the Inspectorate within six weeks of the date on which the decision was announced. Article 7:10 of the Awb states that a decision must be reached within six weeks of receipt of the notice of appeal. The decision can be postponed for a maximum of four weeks.

The decision of the 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 Inspectorate.

3.3 What are the legal consequences in case of non-compliance?

Under the Medicines Act, the Inspectorate is entitled to impose an administrative fine in respect of any non-compliance. Indicative tables of the fine amounts are to be found in the Policy Guidelines on Administrative Fines (*Beleidsregels Bestuurlijke Boete) at www.overheid.wetten.nl*. Breach of the terms of a wholesale license could lead to an administrative fine of up to EUR 4,500. It is also considered as a crime punishable by imprisonment (*Beleidsregels Bestuurlijke Boete*) at *www.overheid.wetten.nl*.

B. MARKETING

4. PROMOTION (MARKETING)

4.1 What is the general legal regime regarding marketing of drugs (overview)? What are the general limits to marketing activities?

The marketing requirements set out in Directive 2001/83 have been implemented in Articles 83–96 of the Medicines Act of 2007 (*Geneesmiddelenwet*, the Act). In addition, the Inspectorate has issued policy rules that further explain the rules stipulated in the Act regarding two subjects: provision of inducements and administrative penalty.

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

- marketing of drugs in respect of 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 OTCs to the general public is permitted, but is subject to strict conditions; and

- objective information on drugs is allowed, but is also subject to strict conditions.

4.2 Besides the legal regime, are there other codes of conduct, eg, by professional or industry organisations? How are they implemented? What is the relationship between the industry code (if any) and the legal regime?

The rules stipulated in the Act have been included and refined in a voluntary Code of Conduct for Pharmaceutical Advertising (*Gedragscode Geneesmiddelenreclame*, the Code), a regulation of a self-governing foundation *Stichting Code Geneesmiddelenreclame* (CGR). CGR has in addition issued specific rules of conduct and guidelines regarding the way the Code is to be interpreted. An integral part of the Code is the Code of Conduct on Marketing Directed at the General Public (*Code voor de Publieksreclame van Geneesmiddelen*, CPG).

5. MARKETING TO CONSUMERS

5.1 What is the legal regime with respect to marketing to consumers (overview)? Which products might/might not be advertised to consumers?

The rules with respect to marketing to consumers are set out in the Act and CPG.

The Act and CPG state that any marketing of drugs in respect of which a marketing authorisation has not been granted is prohibited. The one exception to this rule is made for marketing in a strictly international context and, that is not in any way directed at the Dutch market (eg, in scientific journals). Furthermore, marketing of prescription drugs and OTCs 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.

5.2 What kinds of marketing activities are permitted with regard to consumers and the products which might be advertised to them?

Marketing directed at consumers is only permitted for OTCs and 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 which is necessary for proper use of the drug, such as indications and contraindications; and
- contain an explicit request to read the instruction leaflet or the text on the outer package.

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

The Act and CPG set out further rules with regard to marketing to consumers. All the rules apply to marketing in writing. Some exceptions to the above mentioned rules have been 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 are not allowed to 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.

Pharmaceutical companies are permitted to provide 'objective' information on prescription drugs. CGR has issued specific guidelines regarding provision of information to consumers with respect to prescription drugs (*Leidraad Informatie UR-geneesmiddelen*). These guidelines are applicable to provision of objective information about a disease, its clinical features and treatment thereof, 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 may not be generally available to the public. In case of internet, such information must be protected by a password. All communication must mention the name and address of the person/entity responsible for provision of this information and the date upon which the information was updated for the last time.

5.3 Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers eg, 'buy-one-get-one-free'?

The CPG stipulates that marketing that does not stimulate the rational use of a medicine is prohibited. Therefore it is not permitted to:

- hand out samples of medicines free of charge; or
- make direct or indirect price offers, hand-out coupons or organise 'refund campaigns'; or
- 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 3, get 4th free, 'in our shop only for ...' or those which 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.

5.4 Are there particular rules/codes of practice on the use of the Internet/Social Media in respect of drugs and their advertising?

Please note that 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 *Leidraad Informatie UR-geneesmiddelen* is applicable for the provision of objective information with respect to prescription drugs to consumers via the internet. Following this guideline, it is allowed to use the name of the pharmaceutical company, the indication and/or the trademark of a prescription drug in the name of the website. Such a website may only contain a complete insert of the drug and clinical features that are concise and subordinate in nature. Furthermore, the website must state the name and address of the person/entity responsible for the content of the website and the date upon which the information was updated for the last time. The website may also contain an email address that the consumers may use to request additional information. Hyperlinking is allowed, as long as the website to which the link is provided complies with the rules of this guideline and it is obvious to the internet user that the original website is left upon clicking on the hyperlink.

For further rules with regard to sale of drugs via the internet, please consult question 2.6.

5.5 Which body (agency) is responsible for supervising marketing activities to consumers? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

The Inspectorate leaves it to the Code Committee of KOAG/KAG and the Advertising Code Committee (*Reclame Code Commissie*, RCC) – 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 of KOAG/KAG has jurisdiction over complaints filed by people other than consumers.

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/KAG can be filed with the Committee of Appeal of the KOAG/KAG.

5.6 What are the legal consequences in case of non-compliance?

In the case of violation of the CPG, the RCC will recommend that the advertiser discontinue the advertising. The compliance department will monitor compliance. In case of non-compliance with the RCC decision, the RCC will publish its decision on its website under non-compliance, which will attract the attention of the authorities.

In the event the Code Committee of KOAG/KAG decides to allow the complaint, it can impose disciplinary measures upon 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 KOAG/KAG is not authorised to impose a fine. However, it can decide that the advertiser has to refund the court fee of the complainant (amounting to EUR 500) 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/KAG and the RCC are primarily responsible for supervising marketing activities directed towards consumers, the Inspectorate is authorised by the Act to impose an administrative fine up to EUR 450,000 for

violation of the provisions of the Act regarding marketing to consumers. In the event the advertiser is fined twice for the same violation within a period of 24 months, such violation constitutes a criminal act and can be punished by six months imprisonment or a criminal fine amounting to EUR 7,800.

6. MARKETING TO PROFESSIONALS

6.1 What kinds of marketing activities are permitted with regard to professionals?

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

- marketing of prescription drugs with regard 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) are permitted, but are subject to strict conditions. CGR has issued further guidelines regarding marketing of such studies (*Richtlijnen Niet-WMO-plichtig onderzoek*).

6.2 Are there particular types of marketing activities which are not permitted with respect to professionals (eg, provision of reprints, non-interventional studies, provision of and type of gifts/educational items)?

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

- any marketing of drugs in respect of which a marketing authorisation has not been granted is prohibited. The one exception to this rule is made for marketing to professionals in a strictly international context, that is not in any way directed at the Dutch market (eg, in scientific journals);
- sponsoring of individual healthcare professionals is prohibited (see question 6.9 below);
- 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. IGZ has issued policy rules that relate to provision of inducements. CGR has issued guidelines that further explain these rules (*Uitwerking Normen Gunstbetoon*). Exceptions are made for provision of hospitality (question 6.4), gifts, discounts and bonuses (question 6.7) and services (question 6.10).

6.3 Are there restrictions on how, when, where or how often professionals might be targeted by sales representatives?

Yes. Sales representatives that target healthcare professionals may not make appointments with healthcare professionals under false pretences and may not promise any benefits. Furthermore, sales representatives must respect the wishes of the healthcare professional or the rules of the hospital, and must

take care that the frequency, time and length of visits and the manner in which the visits take place are not a nuisance.

Marketing by telephone is prohibited, unless it follows a prior appointment with the individual healthcare professional.

6.4 What are the restrictions on meetings with groups of professionals and the provision of hospitality?

The Act, the Code and policy rules regarding provision of inducements, set restrictions on meetings with groups of professionals and the provision of hospitality. Briefly, the Code provides that the place, duration and date of the meeting may not lead to confusion or doubt regarding its nature. Hospitality should remain within reasonable limits, be subordinate to the main purpose of the meeting and may not be provided to anyone other than participants of the scientific part of the meeting. Hospitality is presumed to be within reasonable limits if:

- the healthcare professional contributes 50 per cent to the travel, hotel and registration costs of the meeting; or
- the costs that are covered by the pharmaceutical company do not exceed EUR 500 per time or EUR 1500 per year, per healthcare professional and per therapeutic class. The limit of EUR 1500 per year includes amounts received for a different meeting organised by a third party for the same therapeutic class.

These rules apply both to meetings directly or indirectly organised by a pharmaceutical company and meetings that are sponsored by a pharmaceutical company. CGR has issued special guidelines regarding provision of inducements (*Uitwerking Normen Gunstbetoon*) that further explain the rules set out in the above-mentioned legislation.

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

According to the Code, 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, in so far as 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; and
- 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.

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

The Code contains specific rules with regard to comparative advertising. The CGR has also issued guidelines regarding the way these rules have to be implemented (*Richtlijnen Onderbouwing Vergelijkende Claims*). Any comparative advertising which explicitly or by implication makes reference to a competitor or competing drugs or substances must comply with the following conditions. The comparison:

- may not be misleading;
- may not be detrimental to the value of the drugs in question;
- may not discredit or denigrate the competitor or its trademarks or trade names;
- may not create confusion between the drugs and their trademarks, and/or between the pharmaceutical companies involved and their trade names;
- may not present the drugs in question as imitations or replicas of drugs that are protected by trade marks of trade names;
- may not 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); and
- must be complete with regard to the effects, side-effects, indications and contra-indications and all other relevant information.

6.7 Are discounts permitted? If they are, under what conditions, by whom, and to whom?

The Code stipulates that discounts in the form of gifts (such as bonus deliveries of other drugs or other products from a different industry) are not permitted. This provision does not apply to discounts made in respect of 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, in so far as explicitly stated in writing (eg, in an invoice or a credit note).

Generally speaking, pharmaceutical companies should refrain from offering or promising gifts, waives of payment, bonuses, or any other benefits in cash or in kind. Nor should they 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. CGR has indicated in *Uitwerking Normen Gunstbetoon* that a gift is presumed to be minor in value if the value does not exceed EUR 50 (based on shop value and including VAT) per time, with a maximum of EUR 150 per year, per healthcare professional, per pharmaceutical company and per therapeutic class.

6.8 Is it permitted to provide professionals with free samples?

The Act prohibits provision of free samples of drugs to healthcare professionals, 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 may not 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; and
- 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.

The Code further stipulates that each health professional may only receive free samples of a particular drug for two years after he/she first requested samples of that particular drug.

It is prohibited to provide free samples of drugs containing substances as referred to in list I and II of the Dutch Opium Act to healthcare professionals.

6.9 Is sponsoring of professionals allowed? Under what conditions, by whom, and to whom and for what purpose(s)?

CGR has issued specific rules of conduct regarding sponsorship (*Gedragsregels sponsoring*). These rules apply to sponsorship by pharmaceutical companies of professionals and associations of professionals. The rules stipulate that the provision of financial support or any other support valuable in money for individual professionals, with the exception of sponsorship of a doctoral thesis, is prohibited unless it meets strict conditions as set out below. Please note that any type of support (eg, a donation) is qualified as sponsoring under these rules.

Sponsoring of healthcare professionals is allowed under the following strict conditions. Briefly, these conditions pertain to the purpose of sponsoring, transparency and integrity. The parties involved should be able to demonstrate that the purpose of sponsoring a) is to support innovative and/or quality-improving activities, b) is directed at direct or indirect improvement of healthcare of patients or promotion of medical science, and (c) does not concern activities that can be funded in part or in whole in any other way (eg, by the government, healthcare insurers and/or subsidies). Sponsoring may not, 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.

All sponsorship must be thoroughly documented in writing. Structural Sponsorship exclusivity (a conscious decision to limit sponsoring to only one sponsor) is prohibited. Furthermore, rules of conduct regarding publication of financial relations (*Gedragsregels openbaarmaking financiële relaties*) state that certain information about sponsorship contracts that exceed a value of EUR 500 per calendar year must be made public.

6.10 Are other indirect incentives allowed? Under what conditions, by whom, and to whom?

Pharmaceutical companies are allowed to use healthcare professionals as consultants and advisors. Compensation for such services must be reasonable and should 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.

Policy rules on provision of inducement and *Uitwerking Normen Gunstbetoon*, set out the rules that apply to such service contracts. Furthermore, *Gedragsregels openbaarmaking financiële relaties* stipulate that certain information about contracts that exceed a value of EUR 500 per calendar year must be made public.

6.11 Which body (agency) is responsible for supervising marketing activities regarding professionals? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

The Inspectorate leaves it to the Code Committee of CGR – a self-regulatory body – to supervise marketing activities regarding professionals. Appeals against the decisions of the Code Committee of CGR can be filed with the Committee of Appeal of CGR.

6.12 What are the legal consequences in case of non-compliance?

In the event the Code Committee of CGR decides to allow the complaint, it can impose disciplinary measures upon the advertiser, ranging from a reprimand to an order to rectify the advertisement and a re-call of all advertising material containing the advertisement. The Code Committee of CGR is not authorised to 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 and to refund the court fee of the complainant (ranging from nil to EUR 1,250, depending on the persona of the complainant). These 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 Inspectorate is authorised by the Act to impose an administrative fine up to EUR 450,000 for violation of the provisions of the Act regarding marketing to professionals. In the event the advertiser is fined twice for the same violation within a period of 24 months, such violation constitutes a criminal act and can be punished by 6 months imprisonment or a criminal fine amounting to EUR 7,800.

7. ENGAGEMENT WITH PATIENT ORGANISATIONS

7.1 What kinds of activities are permitted with respect to engagement with patient organisations?

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

- marketing of OTCs is permitted under strict conditions;

- provision of objective information on drugs is permitted under strict conditions;
- financial support (eg, sponsoring, subsidising or support in kind) is permitted, but is subject to strict conditions. As a general rule, financial support may not compromise the independence of the patient organisation, its policy or activities.

CGR has issued special rules of conduct regarding sponsoring of patient organisations (*Gedragsregels inzake sponsoring van patiëntenorganisaties*).

7.2 What are the restrictions that are imposed on relationships with patient organisations?

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