Foundation for the Code for Pharmaceutical Advertising

Code of Conduct for Pharmaceutical Advertising

Code of Conduct per 1 July 2024

CHAPTER	**I**	**SCOPE**
Advertising in the widest sense of the word	1.1	The present Code of Conduct concerns advertising of, and information on, medicinal products in the widest sense of the words, viz. not only orally, in writing, disseminated with the aid of audio-visual methods, via exhibitions, conferences and symposiums, but also in any other way.
Responsible interactions of authorisation holders	1.2	The present Code of Conduct lays down standards for activities to ensure responsible interactions between authorisation holders and healthcare professionals, professional carers, patient organisations and other interested parties who directly or indirectly may influence the prescription, supply and/or use of medicinal products. This could include providing general information on medicinal products, offering hospitality at meetings or manifestations, granting or requesting bonuses or pecuniary advantages or benefits in kind, providing samples of medicinal products and market research regarding authorised medicinal products.

CHAPTER II SUPERVISION

Inspection Board, Code Commission, Commission for Appeal

2.1 The Inspection Board and the Code Commission and the Commission for Appeal set up by the *Stichting Code Geneesmiddelenreclame* (the Dutch Foundation for the Code for Pharmaceutical Advertising, hereinafter CGR*)*, are charged with supervising the compliance with the present Code of Conduct in conformity with the terms and conditions laid down therefor.

Obligation to cooperate

2.2 Authorisation holders and healthcare professionals are obliged to provide the cooperation which the supervisory bodies referred to in 2.1 above could reasonably require to perform their tasks.

CHAPTER III DEFINITIONS

3.1 In the purpose of this Code of Conduct, the following terms shall bear the following meaning:

Medicinal products

a. medicinal products: medicinal products covered by the Dutch Medicines Act (*Geneesmiddelenwet*), as well as blood products covered by the Dutch Blood Supply Act (*Wet inzake bloedvoorziening*).

Advertising to the general public

b. advertising to the general public: the advertising for a medicinal product which, in view of its content and the manner in which it is presented, is evidently also intended for persons other than healthcare professionals.

Act

c. the Act: the Dutch Medicines Act and/or the Dutch Blood Supply Act.

Healthcare professional

d. healthcare professionals: persons qualified to prescribe or supply prescription-only medicinal products.

Authorisation holder

e. authorisation holders: holders of a marketing authorisation or an authorisation as described in section 18 of the Dutch Medicines Act as well as holders of an authorisation as described in section 15 of the Dutch Blood Supply Act.

Medical sales representative

f. medical sales representatives: any persons whose principal task it is to provide medical-pharmaceutical information to and to consult with healthcare professionals on the application of medicinal products for diagnosing and/or treating patients, and who do so at the instruction of an authorisation holder and in personal contact with healthcare professionals.

Representative

g. representatives: persons who visit healthcare professionals, largely for purposes other than to provide medical-pharmaceutical information, and who do so at the instruction of an authorisation holder.

Advertising

h. advertising: any form of public and/or systematic, direct or indirect commendation of medicinal products and any services or images connected therewith, including offering or solicitation of goods or services in the interactions between authorisation holders and healthcare professionals.

Financial relation

i. financial relation: promising, offering or granting cash or services with a pecuniary value.

Inducements

j. inducements: financial relation with the apparent object of promoting the prescription, supply or use of a medicinal product.

k.

SPC

l. the abbreviation SPC stands for the summary of product characteristics, as approved by the Dutch Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen*) or the European Medicines Agency.

CHAPTER IV GENERAL RULES OF CONDUCT FOR AUTHORISATION HOLDERS AND HEALTHCARE PROFESSIONALS

Responsible conduct in the contacts between authorisation holders and healthcare professionals

4.1 Without prejudice to the relevant statutory provisions or the provisions elsewhere in this Code of Conduct, authorisation holders and healthcare professionals shall ensure that their contacts are conducted responsibly. This responsibility applies specifically to ensuring that their conduct is in accordance with the interests of end-users and of public health in general, including the fact that a significant proportion of the costs of medicinal products are covered out of funds raised for public services from the common purse. Authorisation holders and healthcare professionals shall be transparent on their relations and shall be accountable therefor.

Avoiding conflict with professional oath and inappropriate obligations

4.2 Authorisation holders and healthcare professionals shall ensure that their contacts do not conflict in any way with their professional oath or with any other obligations pursuant to professional practice or that they could feel inappropriately obliged vis-à-vis each other.

Internal checks on proper compliance

4.3 Authorisation holders and healthcare professionals shall organise their activities in connection with medicinal products in such a way as to safeguard the proper compliance with the present Code of Conduct and satisfactory checks on that compliance, and shall refrain from any act or omission which is not explicitly provided for in the present Code of Conduct, but which breaches the tenor or spirit thereof.

CHAPTER V ADVERTISING AND INFORMATION

§ 5.1 General

Conformity with statutory provisions and the Code of Conduct

5.1.1 Without prejudice to the provisions on this subject in or pursuant to the Act or to other statutory provisions which are also applicable, advertising of medicinal products in the Netherlands shall be in conformity with the present Code of Conduct.

Outside the scope of the Code of Conduct

5.1.2 The following are not covered by the Code of Conduct:

a. the labelling and the accompanying package leaflets for medicinal products;
b. the correspondence, i.e. written exchanges by post mail or email, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
c. factual informative announcements and reference material relating, for example. to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims; and
d. information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.

Distinction between information and advertising

5.1.3 Advertising is characterised by the promotional nature of a communication. The question whether a communication concerns information or advertising must be determined on a case-by-case basis, in which connection the following factors are (or could be) taken into account:

a. the addressee;
b. the content, presentation and design of the communication;
c. the context of the communication.

Frequently-asked questions (FAQs) on a medicinal product and the answers to such questions shall be deemed to be information, provided that these questions and answers:

a. concern the correct, safe and responsible use of medicinal products; and
b. cannot be deemed to be advertising in view of their content, presentation and design.

§ 5.2 Requirements for advertising

5.2.1 Advertising of medicinal products, whether oral, in writing, via audio, visual or audio-visual methods or in any other way, shall comply with the following:

Advertising for unauthorised medicinal products prohibited and exception

5.2.1.1

a. Advertising for a medicinal product for which no marketing authorisation has been granted is prohibited.
b. Notwithstanding the prohibition described in the preceding section, advertising for a medicinal product for which no marketing authorisation has been granted is permitted within an international scientific context, provided that it complies with the following conditions:

- the advertising is published in a scientific journal of an undeniably international nature or within the framework of a meeting which has a truly international nature in terms of organisation and where a significant proportion of the speakers and participants are from countries outside the Netherlands, and
- the advertising is undeniably not targeting the Netherlands, in terms of wording and content, and
- the medicinal product to which the advertising refers is registered in at least one major industrialised country.

Conformity with the SPC

5.2.1.2 The advertising may not be inconsistent with the government-approved SPC of the medicinal product, as prescribed by or pursuant to the Act.

Misleading advertising prohibited

5.2.1.3 The advertising of the medicinal product shall be in such a way that it encourages the rational use of that product in a pharmacotherapeutic sense and that the persons to whom the advertising is directed, are not misled in any way.

Design

5.2.1.4 The advertising shall be designed in such a way that the persons to whom the advertising is directed, can recognize its promotional nature.

Decency and good taste

5.2.1.5 Advertising shall otherwise also be in accordance with the Act and, in terms of text and presentation, shall comply with the relevant standards of decency and good taste to be observed, not only vis-à-vis the party targeted by the advertising, but also vis-à-vis the other parties within the industry.

5.2.2 When deciding whether advertising is in accordance with the rules of conduct defined above, it is necessary to establish whether the following criteria have been observed:

Dignity and due care

5.2.2.1 does the advertising observe the standards of dignity and due care in keeping with the nature of the product?

Avoiding vague terms and superlatives

5.2.2.2 in promoting the rational use of the medicinal product, has the advertising avoided using vague terms or superlatives and otherwise refrained from exaggerating the properties of the relevant medicinal product?

Accurate, correct and verifiable

5.2.2.3 if seen within the totality of the advertising, is the claim for the relevant medicinal product accurate, up-to-date and truthful and is it correct and verifiable in its detail?

Efficacy of the medicinal product; indications, clinical efficacy

5.2.2.4 does the totality of the advertising to healthcare professionals give an impression of the efficacy of the medicinal product which is as comprehensive and accurate as possible? This shall at any rate take account of the indications and the clinical efficacy according to the authorisation information, the adverse reactions and the contra-indications (see in this connection also sub-section 5.4.1).

Damage to reputation

5.2.2.5 does the advertising damage the reputation of the pharmaceutical industry, its products or the reputation of healthcare professionals?

The use of unpublished research

5.2.2.6 without prejudice to the provisions of the Dutch Code for Advertising Medicinal Products to the General Public (*Code Publieksreclame voor Geneesmiddelen)*, has the responsible investigator given his prior permission for the use of unpublished studies?

Quoting publications

5.2.2.7 are all the passages quoted from publications accurate and do they provide source references? Has care been taken to ensure that the use of such quotes does not detract from the tenor of the publication? Do the quoted publications reflect the latest state of scientific knowledge and technology?

Comparative advertising

5.2.2.8 if the advertising makes a comparison with another substance or another medicinal product and if it names a competitor or a medicinal product marketed by a competitor, explicitly or implicitly, has care been taken, without prejudice to the provisions of the Dutch Code for Advertising Medicinal Products to the General Public:

a. that the comparison is not misleading: that the medicinal products being compared provide for the same need or are intended for the same purpose, and that the comparison objectively compares one or more of the medicinal product's fundamental, relevant, verifiable and typical properties, for example their (clinical) efficacy?
b. that the comparison does not unnecessarily prejudice the value of those other substances or medicinal products?
c. that the comparison does not discredit the authorisation holder of those other substances or preparations, its trade name and/or the brand name of those other substances or medicinal products?
d. that the comparison does not cause any confusion between the substances or medicinal products being compared and their brand names and/or between the relevant authorisation holders and/or their trade names?
e. that the comparison does not present medicinal products as an imitation or copy of medicinal products with a protected trade mark or a protected trade name?
f. that the advertising does not constitute an unfair advantage as a result of the reputation of a competitor's brand name or trade name or as a result of other distinctive characteristics of a competitor?
g. that the comparison is scientifically verifiable as accurate and in conformity with the latest state of the art?
h. that the comparison is comprehensive in terms of the effect, adverse reactions, indications, contra-indications and the other relevant data of the substances or medicinal products being compared, and, in general, has otherwise attempted to observe due care not only vis-à-vis the other parties in the industry, but also vis-à-vis the party targeted by the advertising.

Assessing the substantiation for comparative claims

5.2.2.9 The condition referred to in sub-section 5.2.2.8 (g) shall be substantiated by one or more scientific studies.

A study can be used to substantiate a comparative claim if it has been published in a peer-reviewed journal, has sufficient quality and is sufficiently convincing.

When assessing the scientific quality of the study or studies, the following non-limitative factors can be taken into account:

a. unambiguous research question, formulated in advance:
b. a design and methodology appropriate for that research question;
c. a well-defined patient population;
d. the inclusion of a sufficient number of patients to adequately answer the research question;
e. a sound methodological basis.

When assessing the study's or studies' power to convince, the following non-limitative factors can be taken into account:

a. the size of the study or studies, in terms of the indication and the incidence/patient population;
b. the subject of the study or studies in terms of the objective quantification of the conclusions;
c. the research question (endpoint) of the study or studies. In the case of secondary endpoints, it shall be apparent that the study design was suitable for this;
d. the inclusion of the results of the study or studies in one or more official publication(s) issued by the government or other independent bodies within the framework of the assessment of medicinal products;
e. the importance which the relevant group of medical professionals demonstrably attaches to the study or studies, as evidenced e.g. by treatment guidelines, protocols and standards;
f. independent support for the results of the study or studies in other publication(s) and/or another study or studies;
g. the absence of relevant criticism on the results of the study or studies;
h. the international acceptance of the substantiation of the same claim by the same study or studies;
i. the results of the study or studies may not be contradicted to a relevant extent by the results of other studies.

5.2.3 Authorisation holders shall ensure proper compliance with the present Code of Conduct in their advertising and satisfactory possibilities for monitoring this. For that purpose:

Administration of advertising by authorisation holder

5.2.3.1 authorisation holders shall keep a detailed administration of all their advertising, including at least one sample of each advertising, indicating at least the persons to whom it was addressed, the method of distribution and first date of dissemination. The administration shall remain available for the party or parties charged with supervising the advertising of medicinal products for at least five (5) years;

Information to supervisory authorities or bodies

5.2.3.2 authorisation holders shall provide the authorities or bodies charged with supervising the advertising of medicinal products with the information and assistance necessary to undertake that supervision, and

5.2.3.3 authorisation holders shall ensure that any decisions made by such supervisory authorities or bodies are complied with immediately and in full.

5.3 Specific provisions for oral advertising

Education of medical sales representatives	5.3.1	Medical sales representatives shall have a suitable education and sufficient scientific knowledge to provide complete and precise information on the medicinal products they promote.
Satisfactory communications	5.3.2	Medical sales representatives shall be on such a footing with healthcare professionals that they can facilitate satisfactory communications with the authorisation holder they represent.
	5.3.3	The advertising undertaken by medical sales representatives shall comply with the rules of conduct set forth in chapter 5.
Making the SPC available	5.3.4	During each visit to a healthcare professional, medical sales representatives shall have available the SPC of each medicinal product they advertise. This means that medical sales representatives shall always have the relevant, most recent SPC available for examination, if so requested. Medical sales representatives may also refer to the Dutch Medicines Data Bank (*Geneesmiddelen Informatiebank voor Mensen*) kept for this purpose by the Dutch Medicines Evaluation Board. The relevant SPC shall always be made available when promoting new medicinal products.
Making an appointment	5.3.5	Medical sales representatives must not promise any benefits or use any false pretext to obtain an appointment with a healthcare professional.
Rules, frequency and scheduling visits	5.3.6	Medical sales representatives shall respect the wishes of healthcare professionals or the hospital rules and shall ensure that the frequency, scheduling and duration of the visits to healthcare professionals or hospitals as well as the manner in which such visits occur do not cause any inconvenience.
Precautions against loss and theft	5.3.7	Medical sales representatives shall take the necessary precautions to ensure the safety of the medicinal products in their possession, such as measures against theft and loss and for proper storage to safeguard their quality.
Advertising by phone	5.3.8	Oral advertising by telephone is not permitted, except by prior appointment with the relevant healthcare professional.
Reporting visits and administration	5.3.9	Medical sales representatives shall report every visit to a healthcare professional to the authorisation holder they represent, setting out the medicinal product or products they promoted, the date of the visit and the written information provided during that visit. Authorisation holders shall keep these reports for examination by the authorities and bodies charged with supervising the advertising of medicinal products for five (5) years as part of the administration referred to in sub-section 5.2.3.1 above. The authorisation holders shall furthermore ensure that this administration is organised in conformity with the Dutch Data Protection Act (*Wet Bescherming Persoonsgegevens*) and that the relevant reports are made available to the relevant healthcare professional in conformity with the provisions of that Act.

Information on medicinal products provided by healthcare professionals

5.3.10 If a healthcare professional provides a medical sales representative with information concerning the use, efficacy and, especially, any adverse reactions to the medicinal products promoted by him, the medical sales representative shall immediately pass this information on to the scientific service referred to in sub-section 5.9.1 of the authorisation holder represented by him.

Warranties by authorisation holder

5.3.11 Authorisation holders are responsible for ensuring that the medical sales representatives who represent them act in conformity with the present rules of conduct. Authorisation holders shall take the necessary steps to ensure that the medical sales representatives who represent them comply with the conditions laid down in the present Code of Conduct in terms of education, knowledge and skills.

5.3.12 The provisions of sub-sections 5.3.5, 5.3.6 and 5.3.7 are applicable *mutatis mutandis* to representatives.

§ 5.4 Specific conditions for written advertising to healthcare professionals

Conditions for written advertising

5.4.1 All written advertising to healthcare professionals shall comply with the requirements laid down in the present Code of Conduct and shall at any rate include the following information in conformity with the SPC:

a. the name of the medicinal product;
b. the name and address of the party responsible for marketing the products;
c. the qualitative and quantitative composition of the active ingredients;
d. the pharmaco-therapeutic group, to the extent relevant;
e. the pharmaceutical form;
f. the principal therapeutic indications;
g. the principal adverse reactions (according to frequency and severity);
h. the principal warnings (precautions connected with prescription and use);
i. the contra-indications; and
j. the classification of the medicinal product (prescription-only or not) for the purposes of supply;

in a position and in a font justified by the importance of that information. If, in the case of written advertising, the information referred to above is of such a size that the text cannot reasonably be included in a customary format, reference may be made in that medium to where that information can be found.

Reminder advertising

5.4.2 The criteria referred to in sub-section 5.4.1 are not applicable to any written advertising to healthcare professionals which have the sole purpose of:

a. reminding the reader of the name of the medicinal product and otherwise including no information other than:
   - the composition of the medicinal product;
   - a reference to the pharmaco-therapeutic group;
   - the name and address of the party responsible for the marketing of the product, or
b. practical information for identifying the medicinal product without making any pharmaco-therapeutic claim;

in that case, if the medicinal product has an international non-proprietary name, this shall be stated in addition to the name of the medicinal product.

Prior review by scientific service

5.4.3 Before any written advertising is disseminated, the scientific service referred to in sub-section 5.9.1 shall review it for compliance with the present Code of Conduct.

§ 5.5 Specific conditions for advertising at exhibitions and via audio, visual, audio-visual and/or other methods

Exhibitions and social media

5.5.1 Advertising at exhibitions and trade fairs or via audio, visual, audio-visual and/or other methods (such as social media) shall be conducted in conformity with and in the spirit of the above rules of conduct for oral and written advertising, taking account of the specific nature of these methods.

§ 5.6 Specific conditions for advertising to the general public

The Dutch Code for Advertising Medicinal Products to the General Public

5.6.1 Without prejudice to the provisions of the present rules of conduct in general and the provisions of sub-section 5.4.3 in particular, the Dutch Code for Advertising Medicinal Products to the General Public shall be observed when advertising to the general public. That Code is an integral part of the present Code of Conduct and is also referred to in Dutch as the CPG.

Advertising to the general public and sponsorship

5.6.2 Authorisation holders shall refrain from sponsoring the activities of third parties, if that third party's obligation, in return for that sponsoring, consists in whole or in part of advertising of medicinal products to the general public, if such products may be supplied on prescription only according to or pursuant to the Act.

§ 5.7 Requirements for information

5.7.1 Information on medicinal products:

a. may not be inconsistent with the information in the SPC or the package leaflet for that medicinal product. Information on off-label use is permitted, provided that this is based on the latest state of scientific knowledge and practice and within the bounds laid down in the Act;
b. shall be balanced and fair;
c. may not be misleading.

Name of party responsible and most recent update

5.7.2 Any communication including information on a certain medicinal product shall at any rate include the following:

a. the name and address of the party responsible for the information;
b. the date on which the information was most recently updated.

§ 5.8 Specific conditions for information to the general public on prescription-only medicinal products

5.8.1 In the following section, the term “information” shall be understood to mean information which refers, directly or indirectly, to a prescription-only medicinal product.

Not cause anxiety

5.8.2 Information may not cause anxiety, give rise to or reinforce superstition and shall be presented realistically.

The information may not include any improper, unnecessarily alarming or misleading pictorial representations of changes in the human body caused by disease or injury. Neither may such images be used for demonstrating the action of a method for treating the human body.

The information may not contain material which refers in improper, alarming or misleading terms, to claims of recovery.

Understandable language

5.8.3 Information shall be formulated in language which is understandable for an average consumer. Medical and scientific terminology shall be avoided to the extent possible to avoid confusion or ambiguity.

Avoid irrational use

5.8.4 Information may not:

a. encourage the irrational use of prescription-only medicinal products or a search for any unnecessary treatment for diseases;
b. lead (in)directly to one choice of various relevant treatments;
c. be designed to prevent the general public from seeking, or unnecessarily encourage them to seek, medical treatment, treatment advice or further medical examinations or have this as its consequence;
d. contain the suggestion that normal good health shall be improved, shall deteriorate or shall be affected by (not) taking a prescription-only medicinal product;
e. contain information which could lead to an erroneous self-diagnosis, for example by giving a description or a detailed presentation of a case history;
f. state or suggest that the effects of a treatment with a prescription-only medicinal product are guaranteed;
g. state or suggest that a treatment with a prescription-only medicinal product is safe.

The use of tests

5.8.5 The use of one or more different tests, including questionnaires for the self-diagnosis of disease, is permitted only if these have been scientifically validated and are verifiable.

Information to children

5.8.6 Information exclusively or principally targeting children shall be presented with care and in such a way that it does not encourage children, their parents or carers to use that treatment method.

No comparisons

5.8.7 No comparisons may be made with other relevant treatments and medicinal products which suggest that the effect of a treatment or prescription-only medicinal product is better than or equivalent to the effects of another relevant treatment or another relevant medicinal product.

Testimonials

5.8.8 Testimonials shall be a sincere reflection of the opinion or experience of the user (not being a healthcare professional or other person known to the general public) and may make no comparisons between the situation before and after treatment with a medicinal product.

Balanced and complete

5.8.9 Information shall be presented in a balanced manner and as complete as possible. The following criteria must be used for a balanced and as complete as possible enumeration of the relevant treatments, including enumerations of prescription-only medicinal products:

a. technical information for the users of medicinal products, such as dosage, contra-indications, adverse reactions etc., shall be provided comprehensively either for all products or for not one single product; if the brand names or the reimbursement status of prescription-only medicinal products are for example named, this shall be done in the same way for all prescription-only medicinal products. If applicable, the name of the substance shall always be mentioned in addition to the brand name;
b. no single treatment option may be highlighted, for example by the use of certain words, colours or images, the use of different fonts, markings or other means or instruments;
c. the positive and negative properties of no single treatment may be highlighted in such a way as to emphasize the advantages or disadvantages of a certain treatment;
d. treatments shall be categorised on the basis of generally-accepted classifications. Treatments or prescription-only medicinal products may for example be listed according to alphabet, therapeutic classification or category or treatment guidelines, but may not be listed according to "most recently introduced", giving rise to the impression or suggestion that “new is better”, or according to "most commonly-used".

If only one single medicinal product or treatment option is available for a disease, the information shall be presented with exceptional care and in such a way that it cannot be seen as prohibited advertising for that product.

If information is provided via various media, or if the material consists of various communications, which are too small in themselves to include all the necessary information, that necessary information may also be made available via another widely-accessible source, provided that there is a clear reference to that source.

Information to a patient, carer or professional carer

5.8.10 Information to a patient who has been prescribed a prescription-only medicinal product and any carers of the patient or professional carers involved in administering the prescription-only medicinal product, is subject to an exception to sub-sections 5.8.4 (b) and 5.8.9: when providing information on the disorder and the relevant prescription-only medicinal product, it is only necessary to include the factors which are relevant for an optimal treatment with that specific prescription-only medicinal product. This information shall be provided in such a way that it is not accessible to the general public.

Scientific studies

5.8.11 Information may include references to scientific studies and results, provided that these originate from published articles which are widely-

accepted in scientific circles. The source shall then always be quoted. The studies and results must largely originate from sources other than the authorisation holder and must be verifiable. Selective references are not permitted.

Internet

5.8.12 The name of the authorisation holder, an indication and/or a brand name of a prescription-only medicinal product may be used in an internet address. The brand name of a prescription-only medicinal product may also be named on corporate websites.

Websites with the brand name in the internet address and so-called corporate sites (websites on the authorisation holder in general) may only include technical information for users, such as the SPC of the medicinal product or the package leaflet. Such websites may only give a brief summary of the clinical picture; this shall be secondary in nature and shall contribute to a good understanding of the disorder for which the manufacturer markets a prescription-only medicinal product.

If the website provides information on specific prescription-only medicinal products, it shall include the full, unedited version of the summarised package leaflet text or a direct link to that information which encourages the reader to examine that information.

A hyperlink, banner or redirect on an internet site designed to link the general public on to another internet address or website is permitted, provided that such redirects lead to the homepage/landing page and provided that that site complies with the specific conditions for information included in the present Code of Conduct. If visitors are redirected to a third party's website, it shall be clear that the visitor is leaving the original website and is being redirected to a website not subject to the responsibility of the party whose website the visitor is leaving.

A website may include an email address where consumers can obtain further information, if they so wish.

§ 5.9 Scientific service

Scientific service

5.9.1 Authorisation holders shall ensure the availability of a scientific service charged with providing information on the medicinal products marketed by the holder and with conducting internal reviews of the content of the advertising of those products in the light of the provisions of the present Code of Conduct.

Qualified persons

5.9.2 The tasks of that scientific service shall be performed by persons qualified for that purpose and operating within their own professional responsibility. Those tasks shall be performed at the instruction of the relevant authorisation holder, via an employment contract or otherwise.

CHAPTER VI INDUCEMENTS AND OTHER FINANCIAL RELATIONS

§ 6.1 General

Inducements prohibited

6.1.1 Inducements are prohibited, unless they comply with the rules of conduct recorded in this Chapter.

Distinction between inducement and other financial relations

6.1.2 Inducement is a financial relation characterised by the evident object of promoting the prescription, supply or use of a medicinal product. The question whether this is the case shall be examined on a case-by-case basis, in which connection the following factors (can) play a part:

a. the involvement in or amount of influence of the beneficiary on the prescription, supply or use of a certain medicinal product;
b. the object of the financial relation in relation to the prescription, supply or use of a medicinal product;
c. the size of the compensation to the beneficiary in proportion to the objective of the financial relation.

Relations with non-healthcare professionals

6.1.3 The healthcare professional or other beneficiary is expected to check whether he complies with this Code of Conduct when entering into a financial relations. Offering inducements or accepting inducements after such offer are regarded as inducements, as prohibited under Article 6.1.1.

§ 6.2 Bonuses, gifts and other advantages

Gifts

6.2.1 Authorisation holders shall refrain from acting as follows vis-à-vis healthcare professionals:

a. offering or promising gifts in any shape or form;
b. offering or promising a discharge for the payment of invoices otherwise than for payment in full, without prejudice to section 6:127 of the Dutch Civil Code (concerning the settlement of reciprocal debts and claims);
c. making the price of medicinal products dependent on orders for other medicinal products or other products;
d. offering or promising other pecuniary advantages or benefits in kind;
e. any other act or omission as a result of which suppliers and prescribers could feel inappropriately obliged vis-à-vis the authorisation holders.

Inexpensive gifts

6.2.2 Gifts, pecuniary advantages or benefits in kind that are inexpensive and relevant to the practice of the healthcare professional are excluded from the provisions of sub-section 6.2.1. The word "inexpensive" refers to something which is modest in scope. That value shall also be seen in relation to frequency: inexpensive gifts should not be provided so often or in such a volume that the value thereof, in totality, becomes substantial.

It shall be assumed that a gift is inexpensive if the value does not exceed €50 per occasion, with a maximum of €150 per year. These sums are applicable per healthcare professional and per authorisation holder. The value of a gift is determined on the basis of the retail value including VAT.

Discounts

6.2.3 When supplying medicinal products, authorisation holders shall refrain from offering or granting discounts to healthcare professionals in the form of gifts (including bonus supplies of other medicinal products or of non-industry products). This clause does not apply to discounts granted for the supply of medicinal products, if, in the case of discounts in kind, such discounts are awarded in the form of bonus supplies of the same medicinal product, or, in the case of cash discounts, if these discounts are recorded explicitly and in writing (and specifically on the invoice or credit note).

Providing samples

6.2.4 Authorisation holders shall keep a satisfactory administration of the free samples of medicinal products provided by them and the name of the prescribing healthcare professionals to whom they provided these samples, recording the date on which and the quantity in which these were provided, without prejudice to the provisions on this subject in or pursuant to the Act, and with the additional condition that no new samples of the same medicinal product are provided for two (2) years after a prescribing healthcare professional has requested a sample. This administration shall be kept for five (5) years.

§ 6.3 Specific conditions for services and research with authorised medicinal products

Services

6.3.1 Services provided by a healthcare professional on behalf of an authorisation holder must be of importance for the practice of medicine, pharmacy, dentistry, nursing or obstetrics. Authorisation holders shall ensure that the payments to healthcare professionals for the services rendered by them – irrespective of whether this is done in cash or kind – are in a reasonable proportion to the performance provided by those healthcare professionals and that the services provided do not give rise to any tie between authorisation holders and healthcare professionals other than a direct connection with the service rendered.

Written agreement

6.3.2 The services (including the services to be rendered and the payment therefor) shall be recorded in one written agreement clearly defining the object (description of the content), execution (where and when) and payment (hours and fee) of the services to be provided, prior to the services.

This requirement is not applicable to agreements intended only for the once-only completion of simple questionnaires or surveys.

Reasonable payment

6.3.3 The payment shall be in a reasonable proportion to the services to be provided.

a. The actual expenses incurred qualify for payment.
b. In addition, payment is appropriate for the time spent by the healthcare professional. This payment shall be fixed on the basis of a reasonable estimate of the time necessary for the relevant work and a reasonable hourly rate.

Suitable venue

6.3.4 Events organised in connection with a service agreement shall comply with the principle of a suitable venue as described in sub-section 6.4.1.

Research involving medicinal products

6.3.5 This Code also apply to research involving medicinal products, unless it concerns scientific research that falls within the scope of the Dutch Medical Research Involving Human Subjects Act (WMO) or the Assessment medical research not subject to the WMO (*Toetsingskader niet-WMO-plichtig onderzoek*), applicable to the Dutch situation. The WMO and the Assessment medical research not subject to the WMO (*Toetsingskader niet-WMO-plichtig onderzoek*) include aspects on the scientific validity of the research, a positive assessment of a recognized medical ethics committee, rules on the protection of the person concerned (consent, privacy) and reasonableness of fees paid.

§ 6.4 Specific conditions on meetings and manifestations

Hospitality at meetings and manifestations

6.4.1 Authorisation holders shall ensure that, when providing hospitality to healthcare professionals as part of meetings and manifestations, this hospitality:

a. must be limited to what is strictly necessary for participation in the meeting or manifestation, and
b. is, in essence, fully restricted to the object intended by the meeting or manifestation. This is largely determined by the proportion between the time devoted to the scientific programme and the time devoted to the other parts of the programme; and
c. does not extend to parties other than the healthcare professionals.
d. The meeting/manifestation shall furthermore be held at a suitable venue.

Nurses

6.4.2 When providing hospitality as part of meetings, the term “healthcare professional” shall also be deemed to include a nurse administering or supplying medicinal products to patients in the course of his or her occupation and on the instructions of a physician, dentist or obstetrician.

Providing hospitality

6.4.3 Providing hospitality is defined as the compensation of or paying for the travel expenses, accommodation costs or participation costs of a meeting/manifestation. Such hospitality may not include relaxation (sport, recreation and so on).

Sponsoring a meeting/manifestation

6.4.4 The requirements for offering hospitality set by sub-section 6.4.1. are not only applicable to meetings or manifestations which are organised directly or indirectly by the authorisation holder, but also to meetings or manifestations which are sponsored directly or indirectly by the authorisation holder, for which the following requirements apply:

a. the sponsorship shall be recorded in a written agreement before the sponsorship commences. That agreement shall at any rate include a precise description of the meeting/manifestation which is being sponsored (including financial details) and the rights and obligations of all the parties involved;
b. the sponsorship may not include costs other than general organisational costs and hospitality with due observance of sub-sections 6.4.1 through 6.4.3.

Meetings

6.4.5 There is deemed to be question of a meeting in the following cases:

1. The content of the meeting has been qualified as scientific by a scientific association or a body which is independent of the

pharmaceutical industry and which is recognised by the relevant professional group. Not the organiser, but the content will after all determine the scientific nature of a meeting.

2. The organisation is in the hands of a grouping of healthcare professionals, scientific organisations or other groups or bodies independent of the pharmaceutical industry, in which connection the following is applicable:
   a. the organiser shall be able to decide, completely independently of the relevant authorisation holder, on the following:
      i. the content of the programme;
      The choice of subjects shall be decided on the basis of the independent needs of the healthcare professionals (and not on the basis of an arbitrary offer by the authorisation holder).
      ii. the choice of speakers during the meeting;
      iii. the choice of venue;
      iv. the duration of the meeting, and
      v. the target group for whom the meeting is intended.
   b. If a speaker has ties with the authorisation holder or a third party, the objectivity of the presentation shall be examined by the relevant (scientific) association of healthcare professionals.
3. The organisation is in the hands of or takes place at the instruction of an authorisation holder and the meeting has first been reviewed by the CGR in the light of sub-section 6.4.1 and its content, in which connection the following is applicable:
   a. the objectivity of the presentations must be sufficiently safeguarded, and
   b. the programme provides for an independent need for information amongst healthcare professionals.

Hospitality at meetings within reasonable bounds

6.4.6 In addition to sub-section 6.4.1. under a, it applies to meetings that:

1. the costs of that hospitality for account of the authorisation holder per healthcare professional do not exceed the sums which are strictly necessary and at any rate do not exceed €500 per occasion and €1,500 per year; or
2. the healthcare professional himself/herself bears at least 50% of all the costs (travel and accommodation and the costs of participation); and
3. the arrangements for the hospitality provided are recorded in a written agreement in which the execution should be clearly defined. This requirement does not apply if the hospitality covers only participation (including meals and drinks within reasonable bounds) in a meeting organised by the authorisation holder, without compensation of cost for travel and / or hotel accommodation.

Manifestations

6.4.7 Events with a programme which provides for the information needs of healthcare professionals, but which are not meetings in the sense of sub-section 6.4.5, are manifestations.

Hospitality at manifestations within reasonable bounds

6.4.8 In addition to sub-section 6.4.1. under a, it applies to hospitality at manifestations that:

1. the costs of that hospitality for account of the authorisation holder, per healthcare professional, do not exceed the sums which are strictly

necessary and at any rate do not exceed €75 per occasion and €375 per year; and
2. the arrangements for the hospitality provided are recorded in a written agreement in which the execution should be clearly defined. This requirement does not apply if the hospitality covers only participation (including meals and drinks within reasonable bounds) in a manifestation organised by the authorisation holder, without compensation of cost for travel and / or hotel accommodation.

Events outside the Netherlands

6.4.9 If the hospitality is being provided for a meeting/manifestation which is held outside the Netherlands, the details of this meeting/manifestation shall preliminarily be submitted to the Code Commission for approval.

Meetings of a truly international nature, in terms of organisation, and of which an important proportion of the speakers and participants originate from countries outside the Netherlands, are exempt from this obligation, provided that:

a. they are organised by a grouping of healthcare professionals, by a scientific organisation or other groups or bodies independent of the pharmaceutical industry; or
b. its content has been qualified as scientific by a scientific association or a body independent of the pharmaceutical industry and is recognised by that professional group.

§ 6.5 Specific conditions regarding certain other financial relations than inducements

Financial relations other than inducements

6.5.1 In any event, the following financial relations of an authorisation holder fall outside the concept of inducement under sub-section 3.1 under j:

a. Relations with parties other than healthcare professionals as defined in sub-section 6.5.2;
b. Sponsorship of projects as defined in sub-section 6.5.3;
c. (Partly) making scientific awards possible as defined in sub-section 6.5.4.

Relations with non-healthcare professionals

6.5.2 In case each of the following criteria are met, it is presumed that a financial relation between an authorisation holder and someone other than a healthcare professional falls under sub-section 6.5.1 under a:

a. The relation serves a healthcare interest or is considered to be normal in legal transactions;
b. The relations does not lead to the beneficiary being directly or indirectly influenced to promote the prescription, supply or (prior, current or potential future) use of medicinal products of the authorisation holder;
c. The nature and content of the relation do not extent beyond what is necessary to achieve its goal as intended in sub a;
d. The relation takes place in an honest and transparent manner, whereby the nature (or the execution), the purpose and the scope of the financial relation are laid down in writing in an agreement;
e. The relation does not affect the independence, reliability and credibility of the beneficiary, nor of other parties involved and of the sector; and
f. The amount of the reimbursement (with a pecuniary value) of the relation is limited to what is strictly necessary and does not go beyond

what applies to comparable financial relations with healthcare professionals under sections 6.2, 6.3 and 6.4.

Sponsorship

6.5.3 In case each of the following conditions are met, it is presumed that sponsorship of a project by an authorisation holder falls under sub-section 6.5.1 under b:

a. the sponsorship relates to innovative and/or quality-improving activities;
b. the sponsorship has as a goal the direct or indirect improvement of patient care or the advancement of medical science;
c. sponsorship is in principle provided to legal entities that may involve healthcare professionals as well as others;
d. the sponsorship does not oblige in any way the prescription, supply or (prior, current or potential future) use of medicinal products of the authorisation holder;
e. the nature and content of the relation do not go beyond what is necessary to achieve the intended goal under b. and the relation does not finance any costs that can or will be reimbursed to the beneficiary in another regular manner;
f. the sponsorship takes place in an honest and transparent manner, whereby the nature, object and scope are laid down beforehand in writing in an agreement;
g. the sponsoring may not demand any performance obligation on the part of the beneficiary, with the exception of mentioning the name of the authorisation holder;
h. the sponsorship may not lead to a deterioration of the independence, reliability and credibility of the beneficiary or any other involved parties and the sector.

This Code of Conduct does not apply to sponsorship that falls within the scope of the Medical Research (Human Subjects) Act (Wet medisch-wetenschappelijk onderzoek met mensen, “WMO”) or the Framework for non-WMO-related research (Normenkader niet-WMO-plichtig onderzoek), as is applicable to the Dutch situation. The WMO and the Framework for non-WMO-related research relate among other things to the scientific validity of the research, a positive opinion of a recognised medical ethics committee, rules concerning the protection of the person concerned (permission, privacy) and the reasonableness of the fees paid.

Sponsorship of a meeting or manifestation falls under the scope of sub-section 6.4.4.

Scientific awards

6.5.4 A scientific award is understood to mean the allocation of money or goods with a pecuniary value or services for a care-improving and/or medical-scientific performance with which the beneficiary has distinguished himself from other candidates. In case each of the following conditions are met, it is presumed that the contribution to a scientific award falls under sub-section 6.5.1 under c:

a. the care-improving and/or medical-scientific performance is assessed by an independent expert jury;
b. independence of the scientific award in relation to the authorisation holder who (partly) makes the scientific award possible is guaranteed;

c. the contribution of the authorisation holder proceeds in an honest and transparent manner, and is recorded in writing beforehand;
d. the contribution of the authorisation holder does not affect the reliability and credibility of the involved parties and the sector;
e. the contribution of the authorisation holder does not lead to any influence on the prescription, supply or use of medicinal products, and does not lead to any unsuited feeling of obligation towards one another;
f. the amount of money or the value of the goods or services with a pecuniary value is in reasonable proportion to the goal of the scientific award.

§ 6.6 Specific conditions for supporting patient organisations

Definition of patient organisation

6.6.1 A patient organisation is defined as a not-for-profit organisation (including the umbrella organisation to which it belongs) which is largely composed of patients and/or patient carers or other carers.

Support is permitted

6.6.2 An authorisation holder may support an activity undertaken by a patient organisation in the form of grants or sponsorship, in kind or otherwise, to the extent that the conditions laid down in sub-section 6.5.3. are complied with and the following is taken into account:
a. direct or indirect advertising for one or more specific prescription-only medicinal products is prohibited;
b. the information on prescription-only medicinal products shall comply with the requirements for information of sections 5.7 and 5.8;

Written agreement

6.6.3 Any support which an authorisation holder provides for a patient organisation's activity shall be recorded in a written agreement. That agreement shall at any rate include the following:
a. a description of the object of the support;
b. a detailed description of the rights and obligations of the patient organisation and the holder;
c. the scope of the support (in cash or kind), expressed in euros;
d. the patient organisation's obligation to communicate that the relevant activity has been sponsored in whole or in part by the authorisation holder.

Services

6.6.4 If the patient organisation agrees to a services contract with the authorisation holder, this is subject to the conditions set out by sub-section 6.5.2.

Hospitality

6.6.5 At an event within the framework of the support where the authorisation holder provides hospitality to (representatives of) the patient organisation, this hospitality shall:
a. must be limited to what is strictly necessary for participation in the meeting;
b. be secondary to the principal object of the event;
c. extend only to the participants in the main proceedings of the event;

d. not have the evident object of promoting the use of a certain medicinal product;
e. be provided at a suitable venue in conformity with sub-section 6.4.1.

Carers

6.6.6 By way of exception to sub-section 6.6.5 under c, an authorisation holder may provide hospitality to a carer of a patient who is a member of a patient organisation, provided that the health of this patient requires the accompaniment of this carer.

CHAPTER VII TRANSPARENCY

§ 7.1 General

Transparency

7.1.1 Authorisation holders as well as healthcare professionals, groupings of healthcare professionals, healthcare organisations in which healthcare professionals participate or work and patient organisations in the sense of article 6.3.3 shall be transparent about their relations under the rules of conduct laid down for this purpose if these could lead to a conflict of interests.

The Code of Conduct distinguishes three forms of transparency:

a. Recognisability of relations and positions
This form of transparency aims to ensure that:
- It is known that certain activities have been brought about with financial support by authorisation holders (article 7.1.2); and
- Healthcare professionals disclose their relations with authorities holders during presentations (article 7.1.3); and
- Representatives of authorisation holders are recognisable as such when acting in that capacity (article 7.1.4)

b. Internal notification or prior approval from the Board of Directors of a healthcare organisation. This form of transparency aims to ensure that Boards of Directors of healthcare organisation are informed about or authorise certain financial relations that (groupings of) healthcare professionals, who work at or are related to the healthcare organisation, have with authorisation holders (article 7.1.5).

c. Disclosure in Healthcare Transparency Register.
This form of transparency aims to, through a publicly available register, give an insight into the nature and size of certain financial relations between authorisation holders and (groupings of) healthcare professionals, healthcare organisations and patient organisations (paragraph 7.2).

Disclosure by organiser of an event

7.1.2 1. The organiser of an event that is brought about with financial support of one or more authorisation holders, should make the existence of financial support clearly known beforehand as well during the event. If an organiser offers the opportunity to an authorisation holder to organise their own part during or parallel to the main program, the organiser should also make this known. This obligation should be set out in the contract between the organiser of the event and the authorisation holder that offers financial support.

2. Patient organisations that organise an activity that is (partly) sponsored by one or more authorisation holders, are required to clearly communicate that the activity is (partly) enabled by the sponsor(s) in question.

Disclosure of relations

7.1.3 Relations between healthcare professionals that operate as service provider for authorisation holders or third parties that can potentially lead

to a conflict of interest, need to be disclosed by the healthcare professional during physical or written presentations.

Recognisability of authorisation holder representatives

7.1.4 Representatives of authorisation holders that operate in that capacity need to be recognisable as such, for example by carrying a badge during events and/or manifestations.

Internal transparency

7.1.5 1. The healthcare professional is required to disclose agreements on hospitality in the sense of articles 6.4.4. sub a, 6.4.6 under 3 and 6.4.8 under 2 to the Board of Directors in the healthcare organisation where the healthcare professional (predominantly) works, or in other words, where they perform their main activity.

Healthcare organisations ensure that procedures are in place for notifying payments or reimbursement of costs for hospitality to the Board of Directors of the healthcare organisation

2. The healthcare professional that want to provide remunerated services for and enter into a service agreement with authorisation holders in the sense of article 6.3.2, need to receive prior approval to enter into the agreement by the authorised board of the relevant organisation for which that agreement is relevant. The authorisation holder needs to verify that approval was granted before executing the service agreement.

3. The healthcare professional who is (also) responsible for entering into a sponsoring agreement in the sense of article 6.5.3 under f, between a grouping of healthcare professionals or organisation in which the healthcare professional works or participates on the one hand and an authorisation holder on the other hand, needs to ensure that the authorised board of the relevant organisation for which the agreement is relevant has provided prior authorisation. The authorisation holder needs to verify that authorisation was granted before executing the service agreement.

4. The approval as meant in the second and third clause of this article, will be apparent from the countersignature of the agreement by or on behalf of the authorised board of the relevant organisation.

5. If applicable, the healthcare professional will also notify the agreement to the other organisation(s) for which he or she works.

6. Healthcare organisations will internally take care of:
- a (central) set of procedures regarding granting approvals of sponsor- and service agreements, including potentially delegated competences for this purpose;
- (central) agreements with regard to administration and financial execution of authorised sponsor- and service agreements and being accountable for them.

§ 7.2 Disclosure of financial relations

Disclosure in Healthcare Transparency Register

7.2.1 1. In the Transparency Register for Healthcare, the following categories of financial relations as referred to in Article 3.1, subparagraph i, must be disclosed publicly:

a. Service agreements as referred to in Articles 6.3.2 and 6.6.4, distinguishing between the reimbursement of fees and expenses;
b. Agreements regarding the contribution to hospitality costs as referred to in Articles 6.4.6 under 3 and 6.4.8 under 2;
c. Sponsorship agreements for gatherings as referred to in Article 6.4.4 under a;
d. Sponsorship agreements in support of a project (Article 6.5.3 under f), a scientific prize (Article 6.5.4 under c), or a patient organization (Article 6.6.3);

to the extent that they have been established between, on the one hand:

- Healthcare professionals as referred to in Article 3.1, subparagraph d;
- Groupings of healthcare professionals and organisations in which healthcare professionals participate or work; or
- Patient organizations as referred to in Article 6.6.1;

hereinafter referred to as recipients,

and, on the other hand:

- Authorisation holders as referred to in Article 3.1, subparagraph e.

2. The obligation to disclose applies only insofar as the recipient is established and/or treats patients, prescribes medicinal products, and/or dispenses medicinal products in the Netherlands.

3. The obligation to disclose applies only if the total amount pursuant to (one or more) agreements between a specific authorisation holder and a specific recipient exceeds €500 per calendar year.

4. Excluded from the obligation to disclose as described in this article is the remuneration for services and sponsorship of research subject to the Medical Research Involving Human Subjects Act (*Wet medisch-wetenschappelijk onderzoek met mensen*) or the Non-WMO Research Standards (*Normenkader niet-WMO-plichtig onderzoek*).

5. The categories of financial relations mentioned in paragraphs 1a to 1d include agreements that are not entered into in the name of the recipient or the authorisation holder but are entered into by a third party on behalf of a recipient or an authorisation holder, and the rules in this section are applied as if these agreements were entered into in the name of the recipient or the authorisation holder.

6. Excluded from the agreements referred to in paragraph 5 are:
a. Market research conducted on behalf of an authorisation holder by an independent market research agency, involving healthcare professionals under the condition of mutual anonymity;
b. Agreements with an independent third party where payments to the recipient cannot be attributed to a specific authorisation holder.

Data to be disclosed

7.2.2 1. To give effect to Article 7.2.1, the following information must be publicly disclosed for each agreement in the Healthcare Transparency Register:

a. The nature of the financial relation based on one of the following categories:
   i. Services expenses
   ii. Services fee
   iii. Sponsorship meeting
   iv. Sponsorship project
   v. Hospitality reimbursement
b. The calendar year in which the agreement was executed.
c. The name of the authorisation holder.
d. The name of the recipient or executor of the agreement, as well as the recipient or executor's assigned BIG or Chamber of Commerce (KvK) number.
e. The amount paid.

2. In the event that the execution of (part of) the agreement can be attributed to a healthcare professional, while the agreement is in the name of and/or the financial compensation is actually paid to a grouping of healthcare professionals or healthcare organisation in which healthcare professionals participate or work, the relevant part of the financial relation is disclosed in the name (and BIG number) of the involved healthcare professional, deviating from section 1, part d.

3. The disclosure of the amount paid under section 1, part e, is:
a. Excluding VAT, insofar as it concerns a financial relationship with reciprocation for which VAT has been charged.
b. Including VAT, insofar as it concerns a financial relationship without reciprocation or concerns reimbursement of expenses.

4. The Healthcare Transparency Register may publicly release general overviews of authorisation holders who have reported financial relations, as well as BIG and Chamber of Commerce numbers and trade names of (legal) entities included in the Healthcare Transparency Register, provided with characteristics relevant to the purpose of the Healthcare Transparency Register, all within the conditions of the General Data Protection Regulation.

Data submission

7.2.3

1. The data that must be disclosed in accordance with articles 7.2.1 and 7.2.2 shall be submitted annually by the authorisation holder to the Healthcare Transparency Register no later than within a period determined by the Healthcare Transparency Register, in accordance with a format established for this purpose by the Healthcare Transparency Register.

2. Recipients or executors of the relevant agreements are given the opportunity, prior to the actual disclosure by the Healthcare Transparency Register, during a specified period, to verify the information reported about them and to (have) correct(ed) any factual inaccuracies.

3. In the absence of a written documentation as referred to in article 7.2.5 or if expressly agreed upon between the parties, an exception to the provision in paragraph 1 applies. Recipients or executors entering into financial relations that are disclosed based on articles 7.2.1 and 7.2.2, with either:
a. Authorisation holders located outside the Netherlands, or

b. Authorisation holders who are not members of any of the sector organizations affiliated with the Foundation for Pharmaceutical Advertising (CGR),
shall themselves ensure the submission of the data referred to in article 7.2.2, in accordance with the provisions of paragraph 1.

4. The authorisation holder shall have an internal procedure based on which compliance with the obligations in this section is ensured.

Duration of public disclosure

7.2.4 The disclosure based on this article applies for a period of 3 years. After 3 years, the data will be removed by the Healthcare Transparency Register.

Written agreement

7.2.5 In the agreements referred to in Article 7.2.1, paragraph 1, provisions must be included outlining the obligations for disclosure in the Healthcare Transparency Register based on this Code of Conduct.

Request for documentation

7.2.6 To facilitate the analysis of the annual financial relationships reported to the Healthcare Transparency Register under Article 7.2.2, the CGR foundation may request the documentation underlying these reports from the authorisation holder who made the report. Authorisation holders are required to cooperate with such a request. The request for documentation and any potential use thereof for general communication is carried out with the utmost care at all times, taking into account the interests of all parties involved.

CHAPTER VIII TRANSITIONAL LAW

Effective date of Code of Conduct

8.1 The present Code of Conduct shall become effective as of 16 May 2014, upon the simultaneous repeal of:

- the previous Code of Conduct for Pharmaceutical Advertising;
- the Elaboration of the Standards for Inducements of articles 12 and 13 and 16 to 22 inclusive of the Code of Conduct for Pharmaceutical Advertising (*Uitwerking Normen Gunstbetoon artikel 12 en 13, 16 tot en met 22 Gedragscode Geneesmiddelenreclame*);
- the Further Elaboration of Article 16 and the Guidelines for the Internal Procedure for Research not Subject to the WMO (*Nadere Uitwerking van artikel 16 en richtsnoeren interne procedure inzake niet-WMO-plichtig Onderzoek*);
- the Elaboration of the Distinction between Advertising for and Information on Medicinal Products (*Nadere invulling van het onderscheid tussen reclame en informatie voor geneesmiddelen*);
- the Guidelines for Information on Prescription-Only Medicines (*Leidraad Informatie UR-geneesmiddelen*);
- the Rules of Conduct for Sponsorship (*Gedragsregels in Sponsoring*);
- the Guidelines for Substantiating Comparative Claims (*Richtlijnen onderbouwen vergelijkende claims*);
- the Rules of Conduct for Sponsoring Patient Organisations (*Gedragsregels inzake sponsoring van patiëntenorganisaties*), and
- the Rules of Conduct for the Disclosure of Financial Relations (*Gedragsregels openbaarmaking financiële relaties*)

drawn up by the CGR. The Code of Conduct which was applicable on the date on which a request for an opinion or a complaint was submitted shall be applicable to the handling of requests for an opinion and to complaints in first and second instance.

The validity of previous decisions

8.2 Any decisions or opinions rendered by the Code Commission and the Commission for Appeal pre-dating 15 May 2014 shall remain applicable within the scope of the present Code of Conduct.