



Foundation for the Code for Pharmaceutical Advertising

Code of Conduct for Pharmaceutical Advertising

Code of Conduct per 1 January 2017

| CHAPTER | I | SCOPE |
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| 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 between authorisation holders and the industry | 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. This could include providing general information on medicinal products, offering hospitality, granting or requesting bonuses or pecuniary advantages or benefits in kind, providing samples of medicinal products and research with authorized 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:

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| Medicinal products | a. medicinal products: medicinal products covered by the Dutch Medicines Act (<i>Geneesmiddelenwet</i>), as well as blood products covered by the Dutch Blood Supply Act (<i>Wet inzake bloedvoorziening</i>). |
| 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 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. |
| Inducements | i. inducements: promising, offering or granting cash or services with a pecuniary value with the apparent object of promoting the prescription, supply or use of a medicinal product. |
| Therapeutic classification | j. a therapeutic classification is defined as an ATC main group, being the first level of the 'Anatomical Therapeutical Chemical' classification system adhered to by the WHO. |
| SPC | k. the abbreviation SPC stands for the summary of product characteristics, as approved by the Dutch Medicines Evaluation Board (<i>College ter Beoordeling van Geneesmiddelen</i>) or the European Medicines Agency. |



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

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| 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 | <p>The following are not covered by the Code of Conduct:</p> <ol style="list-style-type: none"> 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 | <p>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:</p> <ol style="list-style-type: none"> a. the addressee; b. the content, presentation and design of the communication; c. the context of the communication. <p>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:</p> <ol style="list-style-type: none"> 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 | <ol style="list-style-type: none"> 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.

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| 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? |



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| 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 (<i>Code Publieksreclame voor Geneesmiddelen</i>), 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 | <p>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:</p> <ol style="list-style-type: none">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 | <p>The condition referred to in sub-section 5.2.2.8 (g) shall be substantiated by one or more scientific studies.</p> <p>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.</p> <p>When assessing the scientific quality of the study or studies, the following non-limitative factors can be taken into account:</p> |



- 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**



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| 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 | <p>During each visit to a healthcare professional, medical sales representatives shall have available the SPC of each medicinal product they advertise.</p> <p>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 (<i>Geneesmiddelen Informatiebank voor Mensen</i>) kept for this purpose by the Dutch Medicines Evaluation Board. The relevant SPC shall always be made available when promoting new medicinal products.</p> |
| 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 (<i>Wet Bescherming Persoonsgegevens</i>) and that the relevant reports are made available to the relevant healthcare professional in conformity with the provisions of that Act. |



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| 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 <i>mutatis mutandis</i> 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.

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| 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 |



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| | 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 | <p>Information may not cause anxiety, give rise to or reinforce superstition and shall be presented realistically.</p> <p>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.</p> <p>The information may not contain material which refers in improper, alarming or misleading terms, to claims of recovery.</p> |
| 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 | <p>Information may not:</p> <ol style="list-style-type: none">encourage the irrational use of prescription-only medicinal products or a search for any unnecessary treatment for diseases;lead (in)directly to one choice of various relevant treatments;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;contain the suggestion that normal good health shall be improved, shall deteriorate or shall be affected by (not) taking a prescription-only medicinal product;contain information which could lead to an erroneous self-diagnosis, for example by giving a description or a detailed presentation of a case history;state or suggest that the effects of a treatment with a prescription-only medicinal product are guaranteed;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. |



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| 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 | <p>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:</p> <ol style="list-style-type: none">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;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;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;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". <p>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.</p> <p>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.</p> |
| 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.

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| 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. |
| Financial relations other than inducements | 6.1.2 | <p>Financial relations which do not have the evident object of promoting the prescription, supply or use of a medicinal product are not deemed to be inducements. 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:</p> <ol style="list-style-type: none">whether the beneficiary is involved with or can influence the prescription, supply or use of a certain medicinal product or is involved in the authorisation of medicinal products;whether the object of the financial relations is the direct or indirect enhancement of patient care or the advancement of medical science;whether the compensation to the beneficiary is in a reasonable proportion to the objective of the financial relation. |
| Relations with non-healthcare professionals | 6.1.3 | Financial relations with parties other than healthcare professionals are permitted only if the requirements of sub-section 6.1.2 are complied with, in which connection the tenor of the other provisions of this Chapter concerning relations with healthcare professionals shall also be observed. |
| | § 6.2 | Bonuses, gifts and other advantages |
| Gifts | 6.2.1 | <p>Authorisation holders shall refrain from acting as follows vis-à-vis healthcare professionals:</p> <ol style="list-style-type: none">offering or promising gifts in any shape or form;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);making the price of medicinal products dependent on orders for other medicinal products or other products;offering or promising other pecuniary advantages or benefits in kind;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 | <p>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.</p> <p>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, per authorisation holder and per therapeutic classification. The value of a gift is determined on the basis of the retail value including VAT.</p> |



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| Soliciting or accepting advantages etc. by healthcare professionals | 6.2.3 | Without prejudice to the provisions of sub-section 6.2.2, healthcare professionals shall refrain from soliciting or accepting pecuniary advantages or benefits in kind, as described in sub-section 6.2.1. |
| Discounts | 6.2.4 | 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 | 6.2.5 | 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 | 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 | <p>The services (including the services to be rendered and the payment therefor) shall be recorded in one written agreement clearly defining the object and execution of the services to be provided.</p> <p>This requirement is not applicable to agreements intended only for the once-only completion of simple questionnaires or surveys.</p> |
| Reasonable payment | 6.3.3 | <p>The payment shall be in a reasonable proportion to the services to be provided.</p> <p>a. The actual expenses incurred qualify for payment.</p> <p>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.</p> |
| 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. |



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| 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 (<i>Toetsingskader niet-WMO-plichtig onderzoek</i>), applicable to the Dutch situation. The WMO and the Assessment medical research not subject to the WMO (<i>Toetsingskader niet-WMO-plichtig onderzoek</i>) 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. |
| Review of research not subject to the WMO | 6.3.6 | This article is expired on 01-07-2015. See subsection 8.4. |
| | § 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. does not exceed reasonable bounds, 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 participants in the main proceedings of the meeting/manifestation. 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 registration fees 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 hospitality 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 Hospitality at meetings is deemed to remain within reasonable bounds if:
1. the costs of that hospitality for account of the authorisation holder, per healthcare professional and per therapeutic classification, do not exceed the sums which are strictly necessary and at any rate do not exceed €500 per occasion and €1,500 per year, in which connection the maximum of €1,500 per year also includes the sums already received for other meetings organised by third parties for the same therapeutic classification; 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 Hospitality at manifestations can be deemed to be within reasonable bounds if
1. the costs of that hospitality for account of the authorisation holder, per healthcare professional and per therapeutic classification, do not exceed the sums which are strictly necessary and at any rate do not exceed €75 per occasion and €225 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 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 for sponsoring projects

Definition of sponsorship

- 6.5.1 Sponsorship is defined as support of a financial nature or other compensation provided by an authorisation holder, with or without anything having to be done in return for it, to healthcare professionals, grouping of healthcare professionals and/or an institute in which healthcare professionals participate or by which they are employed and/or another third party, for the purpose of activities in which healthcare professionals are involved.

Sponsoring events

- 6.5.2 The sponsorship of hospitality for events shall be assessed according to sub-section 6.4.4.

Sponsoring individual healthcare professionals

- 6.5.3 Support of a financial nature or other support with a pecuniary value to individual healthcare professionals is not permitted. The following are exempt from this rule:
- a. providing financial support for dissertations and theses;
 - b. a gift in conformity with sub-section 6.2.2;
 - c. services in conformity with section 6.3;
 - d. providing hospitality in conformity with section 6.4.

Integrity

- 6.5.4 The parties involved in the sponsorship shall treat and address each other with mutual respect. The sponsorship:
- a. shall never breach current rules, regulations and legislation, including the relevant self-regulatory rules;
 - b. shall take place with integrity and in a fair and transparent manner;



- c. shall not prejudice the independence, reliability or credibility of the sponsor or sponsored party or any of the other parties or of the industry;
- d. shall not entail that the parties feel obliged vis-à-vis each other in an inappropriate manner.

Objects

- 6.5.5 Sponsorship is permitted if there is evidence of the following:
- a. the support is for innovative and/or quality-enhancing activities, and
 - b. the support is intended to achieve a direct or indirect improvement of patient care or to advance medical science, and
 - c. that activity is not funded or not funded fully via normal channels.

Support within the framework of sponsorship may not be requested for the personal gain of the sponsored party, the sponsor's support may not have a directly commercial object.

Written agreement

- 6.5.6 Sponsorship agreements shall be recorded in writing before the sponsorship commences.

The agreement shall at any rate include an exact description of the project or activity to be sponsored (including the financial basis) and of the rights and obligations of all the parties involved.

No exclusivity

- 6.5.7 It is not permitted to negotiate exclusive sponsorship, unless this is for a specific project.

Goods or services in return

- 6.5.8 Goods or services in return for sponsorship, if any, may not lead to any undesirable influence on the sponsored party's prescription, purchase or supply patterns.

Sponsorship may not be meant to obtain, whether directly or indirectly, any undesired influence on the sponsored party's policy or activities by the sponsor.

§ 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, sponsorship or payment for services, in kind or otherwise, to the extent that the following conditions are complied with:
- 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;
 - c. the independence of the patient organisation is safeguarded;
 - d. no exclusivity may be negotiated, unless this is for a specific project.



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| Written agreement | <p>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:</p> <ul style="list-style-type: none">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. |
| Goods or services in return | <p>6.6.4 If the patient organisation is required to do something in return for the authorisation holder's support, this:</p> <ul style="list-style-type: none">a. shall be intended to improve, whether directly or indirectly, patient care or to advance medical science;b. may create no tie between the authorisation holder and (representatives of) the patient organisation other than one that is directly connected with the goods or services in return;c. shall provide for a justified need on the part of the authorisation holder and may not be more extensive than is reasonably necessary to achieve the object described under a. above;d. be in a reasonable proportion to the work to be undertaken in conformity with sub-section 6.3.3. |
| Hospitality | <p>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:</p> <ul style="list-style-type: none">a. remain within reasonable bounds;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 | <p>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.</p> |

CHAPTER VII TRANSPARENCY

§ 7.1 General

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| Transparency | 7.1.1 | Authorisation holders and healthcare professionals shall be transparent about their relations under the rules of conduct laid down therefor if these could lead to a conflict of interests. |
| Disclosure by speakers | 7.1.2 | Ties between speakers and authorisation holders or third parties shall be disclosed before the speaker's presentation. |
| Recognisability of authorisation holder's representatives | 7.1.3 | Medical sales representatives and other representatives of an authorisation holder may only attend events in that capacity if they are recognisable as such, for example by wearing badges (transparency). |

§ 7.2 Disclosure of financial relations

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| Financial relations | 7.2.1 | In this paragraph, the term "financial relation" is defined as a direct or indirect financial compensation in cash or in kind or otherwise provided by an authorisation holder to a healthcare professional practicing in the Netherlands or to a patient organisation based in the Netherlands. |
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The present rules of conduct are applicable to financial relations arising from the following agreements categories:

- a. Service agreements in conformity with sub-section 6.3.2;
- b. Agreements regarding hospitality in conformity with sub-section 6.4.6 under 3 and 6.4.8 under 2;
- c. Sponsorship agreements in conformity with sub-section 6.4.4 and sub-section 6.5.6;
- d. Agreements for the support of patient organisations in conformity with sub-section 6.6.3.

In this section, the agreements referred to under a to d shall be deemed identical to agreements which are not directly concluded between an authorisation holder and a healthcare professional or patient organisation, but with a grouping of healthcare professionals, an institution in which healthcare professionals participate or by which they are employed or another third party (hereafter: "grouping and/or institute"). In case the other third party has acted on behalf of an authorisation holder respectively a healthcare professional, a grouping or an institute or a patient organisation, the rules of this section shall be applied as if these agreements had been directly concluded between the authorisation holder and the healthcare professional, grouping or institute respectively the patient organisation.

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| Disclosure | 7.2.2 | If the total sum payable pursuant to one or more financial relations between an authorisation holder and a healthcare professional, a grouping and/or institute and/or other third party respectively a patient organisation, exceeds € 500 per calendar year, the parties shall disclose the following on the relevant financial relation(s) once a year and within 3 months of the end of the calendar year in which the parties have executed the relation(s): |
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- a. the nature of the agreement on the basis of the selection table fixed by the CGR and the calendar year in which the agreement was performed, and
- b. the authorisation holder's name, registered address and/or Chamber of Commerce number, and
- c. as far as the service agreement as described in sub-section 7.2.1 under a can be attributed to a healthcare professional:
the personal particulars (name, specialisation and place of residence) of the healthcare professional who provided the actual services (irrespective of whether this professional is also the final beneficiary of the sums paid) and per service agreement the fee attributed to this healthcare professional, and, where applicable, as a separate financial relationship, the total reimbursed expenses attributed to the healthcare professional; and
- d. as far as the service agreement as referred to in sub-section 7.2.1 under a is closed with a grouping or institute or other third party and the services cannot be attributed to (a) specific healthcare professional(s):
the particulars (name, registered address and/or Chamber of Commerce number) of the grouping and/or institute and/or other third party and the total sum of the fee paid thereto, provided that such fees have not already been reported on the basis of part c of this sub-section, and, where applicable, as a separate financial relationship, the total expenses paid; and
- e. for the category agreements as referred to in sub-section 7.2.1 under b:
the personal particulars (name, specialisation and place of residence) of the healthcare professional and per event the total sum of hospitality costs, compensated by the authorisation holder; and
- f. as far as the sponsorship agreement as referred to in sub-section 7.2.1 under c is closed with a healthcare professional, sponsoring the expenses of a thesis:
the personal particulars (name, specialisation and place of residence) of the healthcare professional with whom the financial relations exists, as well as per sponsorship agreement the sums paid to it; and
- g. as far as the sponsorship agreement as referred to in sub-section 7.2.1 under c is closed with a grouping or institute or other third party:
the particulars (name, registered address and/or Chamber of Commerce number) of the grouping, institute or other third party with which the financial relations exists, as well as per sponsorship agreement the sums paid to it, whereby the fees for the sponsorship agreement attributed to a healthcare professional on the basis of sub-sections c and e of this sub-section are disclosed according to these sub-sections on the name of the healthcare professional and are deducted from the total amount of the respective sponsorship agreement that is disclosed on the name of the grouping, institution or other third party; and
- h. as regards the category agreements described in sub-section 7.2.1 under d:
the particulars (name, registered address and/or Chamber of Commerce number) of the patient organisation being supported as well as per agreement the sums paid to it (in cash or in kind) in the relevant calendar year.



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| Written record | 7.2.3 | The financial relations to be disclosed shall be recorded in a written agreement which shall at any rate record the following: a. the data to be disclosed, as described in sub-section 7.2.2; b. the way in which and by whom the data described in sub-section 7.2.2 are to be disclosed. |
| Means of disclosure | 7.2.4 | Disclosure in conformity with sub-section 7.2.2 shall be effected by the party required to do so on the basis of the agreement described in sub-section 7.2.3 in the Dutch central register set up for the purpose of registering financial relation. |
| Internal procedure | 7.2.5 | The authorisation holder shall set up a satisfactory internal procedure as part of which the disclosure of its financial relations is reviewed according to the provisions of this section. |
| Annual overview | 7.2.6 | The authorisation holder will ensure that to every healthcare professional, grouping and/or institute and/or other third party, as well as every patient organisation with whom or with which a financial relation has been agreed, an annual overview of the data to be disclosed or disclosed will be made available in conformity with sub-section 7.2.2 and shall do so within three months of the end of the calendar year. |
| Duration of the public disclosure | 7.2.7 | The public disclosure in conformity with sub-section 7.2.2 and sub-section 7.2.4 shall be maintained for three years. That data will be removed from the central register by its manager after three years. |

CHAPTER VIII TRANSITIONAL LAW

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| Effective date of Code of Conduct | 8.1 | <p>The present Code of Conduct shall become effective as of 16 May 2014, upon the simultaneous repeal of:</p> <ul style="list-style-type: none">• 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 (<i>Uitwerking Normen Gunstbetoon artikel 12 en 13, 16 tot en met 22 Gedragscode Geneesmiddelenreclame</i>);• the Further Elaboration of Article 16 and the Guidelines for the Internal Procedure for Research not Subject to the WMO (<i>Nadere Uitwerking van artikel 16 en richtsnoeren interne procedure inzake niet-WMO-plichtig Onderzoek</i>);• the Elaboration of the Distinction between Advertising for and Information on Medicinal Products (<i>Nadere invulling van het onderscheid tussen reclame en informatie voor geneesmiddelen</i>);• the Guidelines for Information on Prescription-Only Medicines (<i>Leidraad Informatie UR-geneesmiddelen</i>);• the Rules of Conduct for Sponsorship (<i>Gedragsregels in Sponsoring</i>);• the Guidelines for Substantiating Comparative Claims (<i>Richtlijnen onderbouwen vergelijkende claims</i>);• the Rules of Conduct for Sponsoring Patient Organisations (<i>Gedragsregels inzake sponsoring van patiëntenorganisaties</i>), and• the Rules of Conduct for the Disclosure of Financial Relations (<i>Gedragsregels openbaarmaking financiële relaties</i>) <p>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.</p> |
| The validity of previous decisions | 8.2 | <p>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.</p> |