Explanatory Notes
to the Dutch Code of Conduct for Pharmaceutical Advertising
Explanatory Notes per 1 October 2026

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Introduction
The Dutch Code of Conduct for Pharmaceutical Advertising (to be further referred to as: the Code of Conduct) was drafted in 1998 and has been amended and expanded on a regular basis since then. In 2014 the Executive Committee of the Foundation for the Code for Pharmaceutical Advertising ("the CGR") decided to include all the amendments and additions in one integral Code of Conduct.

The Code of Conduct lays down rules for pharmaceutical advertising which find their legal basis in the Dutch Medicines Act *(Geneesmiddelenwet)* and Directive 2001/83/EC on the Community code relating to medicinal products for human use. "Advertising" is defined here as any form of influencing with the aim of endorsing the prescription, supply or use of medicinal products. This not only covers promoting medicinal products, but also stimulating their prescription or supply by awarding, offering or promising benefits in cash or in kind (called "inducements" in the Dutch Medicines Act).

These Explanatory Notes to the Code of Conduct explain how the rules of conduct, as they have developed since 1998 as a result of amendments and additions (published in Newsletters) and decisions and advisory opinions of the Code Commission and Commission for Appeals of the CGR, must be applied and interpreted.

Chapter 1 – Scope
The Code of Conduct lays down the rules for the adverting of medicinal products as well as the rules for the financial relations between pharmaceutical companies (the authorisation holders) and healthcare professionals, other care professionals, patient organisations and other interested parties who directly or indirectly may influence the prescription, supply and/or usage of medicinal products. Activities aimed at people with no direct or indirect relation to the prescription, supply or use of medicinal products, do not fall within the scope of the Code of Conduct.

In the course of time the scope of the Code of Conduct has been expanded to include rules on information about medicinal products (sections 5.7 and 5.8) as well as on financial relations other than inducement, including relations with non-healthcare professionals (section 6.5) and patient organisations (section 6.6).

Chapter 2 – Supervision
The supervision of the Code of Conduct is performed by the Dutch Inspection Board for the Public Promotion of Medicinal Products ("*Keuringsraad";* to be further referred to as: the Inspection Board), the Code Commission and the Commission for Appeals of the CGR . The competences and procedures are laid down in the Rules of procedure on compliance to pharmaceutical advertising.

Chapter 3 – Definitions
A number of definitions will be explained in more detail below.

3.1.b Definition of "Advertising to the general public"
This definition has been aligned with the definition of advertising to the general public in the Dutch Code for Pharmaceutical Advertising to the General Public (*Code Publieksreclame voor Geneesmiddelen*, to be further referred to as: the "CPG"). In the advisory opinion A15.082 the question was raised to what extent advertising for prescription-only medicines in exhibition booths and congress materials at international scientific congresses for healthcare professionals, qualify as advertising

to the general public towards participants that are not healthcare professional. The Code Commission stated that under these circumstances the advertising may not be considered to be intended for persons other than healthcare professionals, meaning that passive cognizance of these persons with these advertising does not infringe the ban on advertising to the general public (see sub-section 5.6.1). See also the explanatory notes on sub-section 6.4.2.

3.1.d Definition of "healthcare professional"
The term "healthcare professional" is defined in section 82(1) (a) of the Dutch Medicines Act. As of 1 January 2012, five titles of nurse specialists (viz. preventive, acute, intensive, chronic and psychiatric) as well as the Physician Assistant were granted prescription authority. In addition, specialised nurses may acquire the authority to prescribe medicinal products and they, too, are healthcare professionals under section 82(1) of the Dutch Medicines Act for the purpose of the rules on advertising (viz. the nurse within the meaning of section 36(14) (d) of the Individual Healthcare Professions Act).

So healthcare professionals are physicians, pharmacists, dentists, obstetricians, physician assistants, pharmacist's assistants and nurses with the additional BIG registrations:

Specialised nurses (gespecialiseerd verpleegkundigen):
- Diabetes nurses
- Pulmonary care nurses
- Oncology nurses
  Specialised nurses may only be considered as healthcare professionals if their BIG registration states that they have prescription authority. For the transitional measures, see CGR Newsletters 2012/1, 2015/8 and 2016/3.

Nurse specialists (NS) (verpleegkundig specialisten):
- NS providing general healthcare
- NS providing mental healthcare

Physicians in training to become a specialist (*artsen in opleiding*) are also considered as healthcare professionals within the meaning of the Code of Conduct. Medical students are not considered healthcare professional (see Newsletter 2006/4).

Since the entry into force of section 36a of the Dutch Act on Individual Healthcare Professions (*Wet op de beroepen in de individuele gezondheidszorg)* (Govt. Gazette 2011, no. 568), certain categories of health professionals can be given a temporary authority to prescribe prescription-only medicinal products under an Implementing Order. When such authority is given, these health professionals will be considered as healthcare professional as defined in section 3.1.d.

As for offering hospitality to nurses without prescription authority, see sub-section 6.4.2.

3.1.h Definition of "advertising"
This definition has been expanded to express that advertising must be a form of public and/or systematic, direct or indirect, commendation, so that it corresponds with the definition of "advertising" in the Dutch Advertising Code (*Reclamecode*). The requirement of a systematic commendation is meant to distinguish one-to-one communications excluded from the scope of the Code of Conduct under sub-section

5.1.2 (b) from one-to-one communications with a standard content not just geared to the individual recipient, which can thus be considered as advertising.

The definition of advertising includes offering or solicitation of services. The Commission for Appeals has made it clear that any "service" solicited from a healthcare professional can only be considered as advertising if there is a connection between the “commendation of a medicinal product” and the “solicitation of service” (see case B09.006/09.03 dated 17 September 2009).

For the distinction between information and advertising, see section 5.1.3.

3.1.j Definition of “inducements”
This definition, which originates from the Dutch Medicines Act, has been added to the Code of Conduct in order to be able to link up with the system used in the Dutch Medicines Act (section 94 of the Dutch Medicines Act reads: inducements are prohibited, unless…, see sub-section 6.1.1 of the Code of Conduct).

Chapter 4 – General rules of conduct
Chapter 4 contains the general rules of conduct to be observed by authorisation holders and healthcare professionals, which have been further elaborated in the following chapters of the Code of Conduct. The rules of conduct are in line with the List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector drafted in 2012 by the Platform on Transparency and Ethics.[1] This Platform was comprised of representatives from the pharmaceutical industry, patient organisations, healthcare professionals, consumer organisations, NGO's and hospitals as well as European and national authorities.

Chapter 5 – Advertising and information

Sub-section 5.1.2 – Outside the scope of the Code of Conduct
Outside the scope of the Code of Conduct fall labelling and accompanying package leaflets for medicinal products. This clause is derived from section 86, second paragraph, first bullet point of Directive 2001/83/EC. This exemption only applies to the literal and complete reproduction of the labelling or package leaflet. When the information has been selected and rewritten which can be explained only by an advertising purpose, this information is considered advertising. See Court of Justice case C-316/09 MSD/Merckle, dated 5 May 2011.

Sub-section 5.1.3 – Distinction between information and advertising
It is not easy to draw the exact line between information (including education) and advertising. Neither the European legislator, nor the national legislator has made this distinction more concrete.

The question where the boundary between advertising and information lies was dealt with in a number of cases, before both the “regular” Dutch courts and the CGR. The CGR follows the balanced position taken by the Commission for Appeals, the Commission for the Advertising Code (*Reclame Code Commissie*) and the criminal court judgments of May 2002. The content of the message is the most important element. A judgment given by the Commission for Appeals (dated 15 November 2001) shows that the "connection" between the relevant communication and the rules on pharmaceutical advertising may be "too far removed". In this case the informative nature of the communication was decisive, with several factors playing a part in the

[1] http://www.eu-patient.eu/Documents/News/List-Guiding-Principles_Nov2012.pdf

judgment: the professional group targeted by the communication, the content of the brochure (in its entirety), the relevant passage in the communication objected to and the context in which it had been placed. This judgment has been partly taken over in sub-section 5.1.3.

According to the definitions in the Code of Conduct "advertising" (in so far as it is relevant here) is defined as “any commendation of medicinal products and any services or images connected therewith, including (…)”. Decisive for the distinction between advertising and information is the promotional nature of a communication. Sub-section 5.1.3 lists factors which may be used to judge whether any written communication is or is not promotional in nature. In this regard several factors will play a part. This means that the question whether any communication must be considered as information or advertising must be judged on a case-by-case basis. In addition, it is of course beyond discussion that the four cases mentioned in the Code of Conduct (sub-section 5.1.2) or the Medicines Act (and Directive 2001/83) respectively, to which the Code of Conduct or the Medicines Act (and the Directive) respectively do not apply, must at any rate be considered as information.

Every communication must be judged individually, allowing for, amongst other elements, the factors mentioned in sub-section 5.1.3. Press releases, press conferences and interviews can therefore not, by definition, be considered as advertising. In this connection reference is made to the advisory opinions given by the Code Commission on letters to physicians and pharmacists regarding a repayment scheme for medicinal products that would not be reimbursed, which was seen as being informative as long as the content of the letter did not stimulate physicians to prescribe the product (see the advisory opinions A10.011 dated 25 February 2010, A11.107 dated 7 November 2011 and A15.004/A15.029).

A difficult category is “positive information”: information which is demonstrably correct (e.g. “product X has no adverse reactions” or “product Y is currently the only medicinal product authorised for the treatment of disease A”) and which gives an - inevitably - positive picture of the medicinal product concerned. This does not mean that such positive information would, by definition, be promotional.

CGR has published a newsletter regarding the assessment of instructions for administration devices for medicinal products (Newsletter 2015/7). Such instruction how to use the device may become (in)direct advertising for the medicinal product. When an instruction has a compelling character and the device concerned forms an indivisible part of a medicinal product, such instruction will be considered advertising for the medicinal product. When the device concerned is intended solely for one or several medicinal products of the same (or cooperating) marketing authorisation holder(s), a compelling instruction may qualify as indirect advertising for the(se) medicinal product(s). When the device is intended for multiple medicinal products of several marketing authorisation holders, advertising for the device will less likely also qualify as advertising for a medicinal product. For further explanation see Newsletter 2015/7.

The second part of sub-section 5.1.3 makes it clear when a communication must be considered as information. The requirements for information on medicinal products can be found in sub-sections 5.7 and 5.8.

In practice certain questions appear to arise frequently, e.g. questions about adverse reactions, the effect of combinations with other medicinal products, the consequences of taking alcohol, the use of the product on holiday or the

consequences of missing a dose. The second part of sub-section 5.1.3 provides that the (standard) answers to frequently-asked questions are information. Of course such information may not be a disguised form of advertising. This is why the section also includes a number of restrictions relating to the content and the presentation of the answers and the questions.

The following must also be observed with regard to sub-section 5.1.3. It is possible that even though a communication is considered as information content-wise, its nature is actually promotional, giving the presentation, lay-out and/or context. This must always be decided on a case-by-case basis (see the first part of sub-section 5.1.3).

Sub-section 5.2.1.1 – Advertising for unauthorised medicinal products prohibited and exception

a. Advertising for unauthorised medicinal products is prohibited
In The Netherlands advertising for medicinal products that have not been authorised by the European Medicines Agency (EMA) or the Dutch Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen,* to be further referred to as: the CBG) is prohibited.

In this connection reference is made to a number of advisory opinions by the Code Commission regarding communications by pharmacists about products that had been prepared magisterially. Promoting unauthorised medicinal products that have been prepared magisterially is prohibited under sub-section 5.2.1.1a (advisory opinions A12.016 of 7 March 2012 and A12.084 of 20 September 2012), but information on these unauthorised products *is* permitted (advisory opinions A12.053 of 21 June 2012 and A12.108 of 30 October 2012) as well as advertising for the service of “magisterial preparation” (advisory opinion A12.127 of 10 January 2013).

b – Exception to the prohibition
In the Netherlands international scientific publications about medicinal products not yet authorised in, for instance, The Netherlands are distributed and read, whilst international scientific conferences are regularly held at which attention is also paid to such developments. This is done not only as part of the scientific part of the programme, but also in its margin, e.g. in advertising (in the case of foreign journals) and at booths (in the case of conferences). In such cases it is possible that medicinal products not yet authorised in the Netherlands are advertised. A strict application of the prohibition of sub-section 5.2.1.1a would strongly restrict the international exchange of information. It would also have strange - and, in the CGR's view, undesirable - consequences for foreign journals that are read here as well as making the Netherlands unattractive as a host country for international scientific conferences.

As an exception to prohibited advertising for unauthorised medical products, section 5.2.1.1b permits advertising for unauthorised medicinal products in a strictly international context. It must be advertising which is undeniably not targeting the Dutch market and which is placed within an international setting. Such advertising is permitted only if all the three conditions of sub-section 5.2.1.1b are met. As for the countries mentioned under c, other EU member states, the United States, Japan, Australia and Canada should be thought of. Based on Article 8 of the EFPIA Code of Practice, advertising should be accompanied by a written statement declaring that the medicinal product concerned is not registered in the Netherlands, while mentioning the countries in which it is registered.

Section 5.2.1.2 – Conformity with the SPC
In case K18.007, the Code Commission stated that when an advertisement relies on a claim used in the SPC text, it prefers in general to stay with the literal text thereof.

Section 5.2.1.4 – Design
This article demands that advertising is recognisable as promotion (see also Article 7 of the EFPIA Code of Practice). In case a marketing authorisation holder sponsors advertising, the sponsoring should be disclosed within the advertising.

Section 5.2.2 – criteria for promotion

The EFPIA Code of Practice sets out, amongst other things, the criteria for advertising (Articles 3 to 5). In addition to the requirements of completeness (Sections 5.2.2.3 and 5.2.2.4), the marketing authorisation holder is expected to answer any reasonable question a healthcare professional may have (Article 3.02 of the EFPIA Code of Practice). With regard to the use of publications (Sections 5.2.2.6 and 5.2.2.7), the EFPIA Code of Practice clarifies that potential images, graphs, and schematic displays need to be reproduced in a reliable manner: including source references and where necessary, explanations (see Article 3.06 in case local legislation gives rise to adjustments). When using terms and superlatives (Section 5.2.2.2), the EFPIA Code of Practice adds (in Articles 3.07 and 3.08) that words such as ‘safe’ and ‘new’ should not be used without clear qualification. Furthermore, claims that the use of a medicinal product does not lead to any side-effects, dangers of toxicity, or risks of addiction, should be omitted (Article 3.09 EFPIA Code of Practice).

Section 5.2.2.9 - Guidelines for the substantiation of comparative claims
Pharmaceutical advertising must meet high demands in order to prevent that a wrong and/or misleading picture is created and that the rational prescription behaviour is jeopardised. For that reason any claim must be in conformity with the approved Summary of the Product Characteristics (SPC). It must also be correct, accurate and verifiable and may not be misleading. Because a comparative claim involves comparing one medicinal product with another one, comparative claims must meet high standards. After all, the party making the claim is not only saying something about its own medicinal product, but also about one or more other medicinal products. In order to prevent an incorrect/misleading image from being created with regard to the medicinal products involved in the comparison, sub-section 5.2.2.8 requires that the comparison can be scientifically proven as accurate.

For the principle that there must be a scientific substantiation for a comparison, the quality and the authority of the studies are important, not their quantity. By judging every individual study on its merits as a starting-point, justice is done to the enormous variety in the types of studies and medicinal products existing in practice. One can think of, on the one hand, the very comprehensive international studies with tens of thousands of patients and, on the other, the limited research possibilities in the case of orphan drugs or orphan indications. This starting-point also does justice to the essence of the requirement that there is sufficient substantiation, which centres on whether the results of the study or studies can corroborate the correctness of the claim and whether not *more* is being claimed than is justifiable from a scientific point of view. The aim is to prevent that physicians and pharmacists are given the wrong picture of the medicinal products concerned.

The CGR believes that it is important to formulate factors which may serve as aids to answer the question whether a study has sufficient quality and authority to be able to substantiate a particular claim. Because every study is unique, the requirements have been explicitly formulated as factors that may be considered when deciding whether that study can serve to substantiate a claim. They serve as aids (only); the final judgment will depend on the circumstances of the individual case.

The quality and the authority of a study in particular will have to be determined on a case-by-case basis. The factors formulated within that framework are in fact arguments that may be raised in support of the quality or power to convince of a particular study. For this reason the factors mentioned are not limitative and may overlap each other. In some cases all the factors will play a part, whilst in other cases a limited number of factors can be decisive. The power to convince must appear from the overall picture that emerges from the arguments (the factors). The power to convince will of course in general be larger as there are more arguments in support of the quality and authority, which thus produce a positive picture of the study in support of the claim.

Sub-section 5.2.2.9 provides that a study may serve to substantiate a comparative claim if it meets a number of requirements in terms of the form of publication, its quality and its power to convince. The second paragraph explicitly provides that a study can only be used to substantiate a comparative claim if its results have been published in a peer-reviewed journal. The background of mandatory publication is that it allows physicians to easily check the correctness of the claim, without wasting time. The requirement of publication in a peer-reviewed journal offers a guarantee that the study has been judged by authoritative peers and has been found suitable for publication. Needless to say, the authority of the journal itself will also carry weight. The preference is for publication in a renowned journal. If a study has not been published in such a journal, this does not mean to say that this study can never serve to substantiate a claim. But in this case there must be good reasons for publication in a different medium as well as other guaranties for the quality of the study. See within this context Code Commission decision K14.011.

In order to be able to judge in the most objectified way whether a study has sufficient qualify in a scientific sense to substantiate a claim, a number of parameters have been formulated in the third paragraph of sub-section 5.2.2.9, which may serve as aids in its review. These parameters link up with the requirements for research not subject to the WMO (*Wet medisch-wetenschappelijk onderzoek*, the Medical Research Involving Human Subjects Act). These parameters are:

a. an 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.

The fourth paragraph of sub-section 5.2.2.9 mentions a number of factors which may play a part in determining a study's power to convince. Here, too, the factors are not limitative and partly overlap each other. Parts a up to and including i of the fourth paragraph of sub-section 5.2.2.9 will be explained in more detail below:

a. First of all, the size of the study, in terms of the indication area and the incidence/patient population, may be considered when assessing a study's power

to convince. The value of a study will partly depend on whether the results found are sufficiently representative and statistically relevant. For instance, the results of two comparative studies into the efficacy of two medicinal products for the treatment of high blood pressure including 100 patients will naturally say less than the outcome of just one comparative study into the efficacy of both medicinal products involving thousands of patients. What matters is the (degree of the) objective measurability of the conclusions which may be drawn on the basis of the studies.

b. To assess the outcome of the study (and the admissibility of the relevant claim), the exact subject of the research (and of the claim) may be considered. In studies relating to relative properties, such as efficacy and/or safety, the results will almost always have to be interpreted and be placed in a context. After all, in some cases certain results (e.g. percentages) can be telling, whilst in other cases less importance needs to be attached to those same percentages. Allowance must not only be made for a clear (statistic) substantiation, but also for the conclusions drawn from it as well as any reservations and comments included in the discussion by the authors themselves, for instance with regard to the need for follow-up research. On the other hand, research into parameters which can be measured or determined in a (reasonably) objective way, such as temperature, speed and size, can be judged differently, because no or hardly any scientific debate has arisen or can arise about such characteristics. Usually, there can be less discussion about the results of such studies.

c. For the review of the results of a study the question whether it concerns primary or secondary endpoints can also be important. If it concerns secondary endpoints, a critical eye must be cast at whether the design of the study (such as its set-up and conclusion) are actually suitable for that purpose. After all, the study may not have been organised for an end-point that was formulated at a later stage, so that its conclusions have less scientific relevance.

d. The power to convince may also be evidenced by the fact that the results of the study have been included in official texts of competent authorities within the scope of granting a marketing authorisation, for instance in the SPCs and assessment reports. The power to convince may also appear from the importance that is attached to the studies in authoritative opinions and reports playing a part within the scope of the decision on whether or not to reimburse and/or fund the costs of medicinal products. A good example are the decisions given by the National Healthcare Institute (*Zorginstituut Nederland*) about whether a product must be included in the Dutch Medicines Reimbursement System or the so-called Package Management for specialist medicines. The background of all this is that importance must be attached to the judgment of these bodies and professional groups who must be considered as experts. Of course one must also critically look at the context within which such bodies have assessed and judged the studies.

e. The importance attached to the study or studies by the relevant medical professional group may also be a relevant argument. This may be evidenced by e.g. treatment guidelines, protocols, etc. of the relevant acknowledged professional groups, but also by reports on conferences and other meetings, comments and other communications. It is important that the study is widely valued within the relevant professional group, which may e.g. appear from the size of the group voicing their opinion and from the authority and arguments with

which this is done.

f. Relevance may also be attached to the fact that the outcome of the study is endorsed in e.g. editorials or prefaces or in other publications with authority. The editorials or prefaces in journals often pay attention to the articles appearing in that issue by e.g. placing them in a certain context and making positive or critical comments. Studies (or the articles in which the results are published) can also be commented on in other journals. All these sources can be relevant for answering the question whether the study or studies quoted in support of the relevant claim are actually sufficiently convincing for that purpose.
The fact that there is other research that corroborates the results of a study is of course strong evidence that the study can be used to substantiate a claim. However, if there are no other studies, this does not automatically mean that this one study cannot be used to substantiate a comparative claim, as it is not the number of studies quoted that matters, but the convincingness of their results. One study which can be objectively measured may have greater authority and more impact than two other studies. If there are no further studies, the following points can also be taken into account, in addition to the earlier-mentioned points, for assessing the study:

   1. Possible objections to a second comparative study for practical reasons. There are indication areas where (comparative) research meets with implementation-technical objections, for instance research in the case of orphan products or orphan indications. A second comparative study will not be possible in such cases, simply because patient numbers are too small.
   2. Possible objections to a second comparative study for ethical reasons. Any comparative medical-scientific study must (almost) always be reviewed in advance by a METC (recognised ethics committee), which will consider the importance and necessity of the research, amongst other issues. Permission will be refused it the METC does not expect that the research will advance the state of the science. The more convincing the results of the prior research were, the less easily permission will be given.
   3. The need for a second comparative study from a methodological/ epidemiologic point of view. Frequently, a particular picture emerges from the results of a study, but further research is required or desirable in order to corroborate them from a methodological, statistical or epidemiologic point of view. The authors themselves will often indicate this in their conclusions. If this is the case, less value must be attached to the study concerned.

g. If critical comments have been voiced in e.g. editorials or other studies or publications on a particular study, this may cast doubt on the value and the authority of this study. However, not every comment will mean that the study concerned is "disqualified". What matters is whether the outcome/results and/or the conclusions have been contradicted *to a relevant degree* and *for good reasons*.

h. The international context can also play a part. Increasingly often, pharmaceutical advertising campaigns are international and the same claims with the same substantiation are used in different countries. The fact that the substantiation of the claim with the same study has been approved in another EU member state in which a code adapted to the EFPIA code is in force after having been reviewed or advised on by the government or self-regulatory bodies is a sign that this study can support the claim.

i. Under i., finally, it is made clear that the authority of a study may be undermined if its outcome is contradicted to a relevant degree by the results of other studies. Of course the quality and the authority of those other studies must also be considered here - in this connection also see under g. and the explanation to it.

Section 5.2.3.1 – Administration advertising by authorisation holders
As part of the duty to administer their accounts, authorisation holders are expected to keep any mailing lists up to date and to respect any wishes by a healthcare professional to be taken of the mailing list.

Section 5.4.1 – Conditions for written advertising to healthcare professionals
The European Union (EU) has introduced a new procedure for the product information for medicinal products, which is monitored extra carefully by the medicines agencies. The package leaflet of these products says that they are under 'additional monitoring', which is supported visually by a black triangle. The CGR believes that this information is important for the prescription of medicinal products and thus requires, as part of section 5.4.1 under g that – where applicable– the black triangle must be included in written advertising, accompanied by the following sentence:

▼ Dit geneesmiddel is onderworpen aan aanvullende monitoring.
(This medicinal product is subject to additional monitoring.)

Section 5.4.2 – Reminder advertising
Sections 86(2) and 91(5) of the Dutch Medicines Act offer possibilities for reminder advertising. Reminder advertising only mention the name of the medicinal product. The purpose of this is to remind the reader of the name or the trademark of the medicinal product. In accordance with Directive 2001/83/EC the reminder advertising must also include the international non-proprietary name, if there is one. For the remaining part reminder advertising does not affect the prohibition of public advertising for prescription-only products. The authorisation holder must take this into account when choosing a name for a new self-medication (over-the-counter) product.

Section 5.5.1 – Advertising at exhibitions and via social media

Advertising at exhibitions and trade fairs
It is not unusual for authorisation holders to present themselves during scientific conferences with their own booths and with advertising in conference materials. As long as the conference is visited by healthcare professionals only, there is no objection to this. In practice problems may arise if the conference is also open to non-healthcare professionals (other care providers, care professionals, policy makers, journalists, researchers, representatives of patient organisations). Advertising to non-healthcare professionals are covered by the prohibition of advertising for prescription-only medicinal products to the general public (under the CPG, the Dutch Code for Advertising Medicinal Products to the General Public) and must be avoided. The Code Commission has given directions in various advisory opinions as to which measures could be taken – such as a special conference booklet without advertising for non-healthcare professionals and separate areas for the booths of authorisation holders, which are accessible only to healthcare professionals – to prevent that the prohibition of advertising to the general public is violated (see advisory opinions A09.005 of 19 February 2009, A09.098 of 27 November 2009 and A10.014 of 23 March 2010).

Social media
The main rule is: all that applies “offline” also applies “online”. The reach of social media often does not stop at a country's borders. The Code of Conduct applies only to communications that are accessible in the Netherlands and which, in terms of their wording and content, are undeniably targeted at the Dutch audience. This can be established on the basis of:
a. the language of the communication;
b. the nationality of the provider;
c. the question whether and (if so) in what manner the social media are announced in the national media;
d. the presence of references to the use, availability or price of (certain) medicinal products in the Netherlands;
e. a typically Dutch setting and other associations with the Netherlands.

The mere fact that the medicinal product is also available in the Netherlands is not decisive.

General requirements that (also) apply to social media:
a. advertising must always be recognisable as such (sub-section 5.2.1.4);
b. the party that sends the message or who is (co-)responsible for its content must be recognisable (section 7.1.3);
c. it must be possible to determine who the addressees are (see below);
d. responsibility for the content of own websites and media to which visitors are referred/redirected (also see sub-section 5.8.12).

When using social media, care must be taken to observe the prohibition of advertising of prescription-only medicinal products to the general public and that the information to the public is in agreement with section 5.8. This means that it must be possible to properly identify and select the addressees. The goal is to only direct advertising towards those healthcare professionals that have an interest in obtaining the information (see Article 6.01 of the EFPIA Code of Practice). In this regard, it is important that those who will receive advertising have already approved of receiving advertising (Article 6.03 of the EFPIA Code of Practice). Social media have technical possibilities for this purpose by means of pre-registration and/or the use of user names and passwords. An example how LinkedIn may be used, can be found in advisory opinion A19.001.

It is also important that any information that the authorisation holder obtains via social media about the adverse effects of medicinal products in particular is followed up within the applicable pharmacovigilance rules (see sub-section 5.3.10). For further explanation, see CGR Newsletter 2012/4.

Section 5.6.1 – The CPG
The CPG (Dutch Code for Advertising Medicinal Products to the General Public) forms an integral part of this Code of Conduct. Of particular interest here is the prohibition of advertising medicinal products to the general public which:
a. are available on medical prescription only;
b. contain substances defined as psychotropic or narcotic (List I or II of the Dutch Opium Act (*Opiumwet)*.

See also the explanatory notes on sub-section 3.1 under b (definition of advertising to the general public).

Section 5.7.1 – Requirements for information
It is evident that information on medicinal products must meet high demands. The rules of section 5.7 apply to communications which refer directly or indirectly to prescription-only medicinal products. The Code of Conduct does not cover information on public health or human diseases, to the extent that it contains no reference, not even indirectly, to a medicinal product (see section 5.1.2 (d)).

The information may of course not be inconsistent with the government-approved texts (such as the package leaflet and the SPC). This means that there is room for information about new developments, but this room may not be used for advertising in disguise.

The information must also be balanced and fair. This criterion has been included under (b) and will have to elaborated out on a case-by-case basis, considering the context and e.g. the medium used. The background of this requirement is that the information may not result in the wrong use of medicinal products or to irrational prescription behaviour (for more details see sub-section 5.8.9).

Just like advertising, information may not be misleading. The information provided must be in conformity with the most recent state of scientific knowledge and current practice. The information may not contain factual errors or misleading elements.

Section 5.8.3 – Understandable language
Where scientific terminology is used, it must be explained as much as possible. The terminology must be geared to the target group/recipients and preferably correspond with the terms used in the package leaflet.

Section 5.8.4 – Avoid irrational use
Part b requires that the information may not result in one particular choice. The choice of a treatment that is best for the patient's specific situation must always be made on the basis of the relation between the patient and the care provider/prescriber (also see sub-section 5.8.10). If certain treatments are not mentioned, it must be possible to underpin this on the basis of, for instance, generally accepted treatment guidelines. For information provided to a patient or carer after the medicinal product was prescribed, reference is made to sub-section 5.8.10.
As for part c: information may contain references for requesting further information from e.g.: a physician, pharmacist, other healthcare professionals, nurses, patient organisations, etc. Information suggesting that a medical consultation or surgical operation is not necessary is not permitted.

Section 5.8.6 – Information to children
Information on diseases and treatment methods in the case of children shall mainly be targeted at their parents/carers. The age limit will vary with the nature of the information. In most cases one can speak of a child up to the age of 12 and thus this provision does not relate to teenagers and adolescents.

Section 5.8.8 – Testimonials
Describing and/of picturing people's health or the state of the disease both before and after the treatment with prescription-only medicinal products may create the suggestion that this effect will always take place in every patient and to that degree (also see sub-section 5.8.4 (e)). Because the general public may also be given the wrong expectation about the speed with which the effect may set in, so-called before-and-after testimonials are prohibited altogether. If the experience of a healthy user is described, the provisions of sub-section 5.8.4 (d) emphatically apply. Testimonials

may be performed by actors, provided the content of the testimonial complies with the requirements of this section.

Section 5.8.9 – Information must be balanced and complete

The information must reflect the current state of scientific knowledge in a balanced way and as complete as possible. When providing information, all relevant factors must be included. All the information must be stated and pictured in a balanced manner, in terms of both content and lay-out, with the same degree of detail. Information on different forms of therapies may be given, in which case all the relevant treatments must be mentioned, including any pharmacotherapy and other options, such as adjusting one's living habits, life style or diet. Relevant treatments are understood to mean the care that is customary within the professional group, as recorded in, for instance, treatment guidelines. The requirement that the information must be complete aims to prevent that information is deliberately withheld without good reason.
In the case of an enumeration of prescription-only products as part of the pharmaco-therapeutic treatment options, all the relevant prescription-only medicinal products for that treatment must be mentioned.

As for the last paragraph of sub-section 5.8.9, the following applies: if e.g. a TV commercial refers to an internet site, this site must comply with all the criteria of sub-section 5.8. This also applies to any other information referred to.

Ledenadministratie@pvda.nl

Section 5.8.10 – Information to a patient or caregiver

There is a special category for communications containing technical and specific user information on the relevant prescription-only product targeting patients who have already been prescribed a medicinal product. There is a requirement that this information may not be generally available. The point is that an additional effort (for instance a separate search action) is required from the person wishing to obtain the information, which is seen as an adequate threshold for not considering the information as being public. For the internet this means that this information must be placed behind a password (for instance the RVG number) and for written communications this means that they may not be made available in public areas such as waiting rooms, etc. This category of communications is governed by the provisions of sub-section 5.8.10 and is therefore an exception to the main rule that information must be complete and balanced (see sub-section 5.8.9). Sub-section 5.8.10 also applies to information for the care professionals (not being healthcare professionals) who are involved in the administration of the prescription-only medicinal product. In case a patient or consumer turns to the marketing authorisation holder for personal advice, it will advise to contact the treating healthcare professional.

Section 5.8.11 – Scientific studies

Information given with the results of the studies must be stated in an objective and neutral manner and may not contain information which directly results in a specific treatment. If reference is made to specific treatment guidelines, the source must be stated, together with the most recent version. Any references to scientific literature must have been published in the original issue of the journal concerned. This journal must have been peer-reviewed and/or be included in the top 5 scientific journals in that therapeutic area.

Section 5.8.12 - Internet
The provisions on information on the internet relate to Dutch websites. They also apply to foreign sites, if the information has been posted on the site by or at the instruction of an authorisation holder (including an affiliated company) who is responsible for the marketing of a prescription-only medicinal product in the Netherlands and if the information, in terms of its wording and content, specifically targets a Dutch audience.

Websites which are accessible to the general public having the brand name in their URL addresses, also called "product sites", are permitted only if general technical user information is provided there. The same applies to the corporate website of the manufacturer of the relevant prescription-only product. Further information about the general clinical picture on this type of publicly accessible websites is not permitted, because in that case a link would immediately be made to the relevant prescription-only medicinal product in breach of the requirements of sub-section 5.8.9.

When visitors are redirected to other websites, the requirement of completeness must be observed (sub-section 5.8.9) and care must be taken that any reference may not result in one particular choice (sub-section 5.8.4 under b).

Section 5.9.2 – Qualified individuals
Individuals who qualify for scientific service include at least physicians and pharmacists.

Chapter 6 – Inducements and other financial relations
Chapter 6 contains the rules on inducements and other financial relations. In practice, many and diverse relations exist between pharmaceutical companies on the one hand and healthcare professionals and other interested parties who directly or indirectly may influence the prescription, supply and/or use of medicinal products (non-healthcare professionals) on the other hand. However, this does not mean that these relations can, by definition, be considered as inducements. Inducement is one of the means of influencing the behaviour of persons or organisations with an apparent sales promotion object (see TK 29539 nr. 3, p. 30 and 31). Inducement must be distinguished from other forms of financial relations that serve a healthcare interest and/or are considered to be normal in legal transactions. These financial relations do not fall under the definition of inducement if there is no apparent object to promote the prescription, supply or use of a medicinal product. In order to be able to separate the “wheat from the chaff” here, the nature, purpose and content of the relevant relation must be known.

The starting-point of the Code of Conduct is that patients/consumers must be able to rely on objective information and education about, and a sound choice for, certain medicinal products. High-quality care and the patient's interest are of paramount importance. Generally speaking, the rules on inducements must ensure that the parties who prescribe and supply medicinal products display a rational prescription and supply behaviour and are not improperly influenced in their actions. Transparency and reasonableness are the key terms in this respect.

Inducements are prohibited by the Code of Conduct (sub-section 6.1.1.) and the Dutch Medicines Act (clause 94). Specific exemptions for relations with professionals are provided (sections 2 to 4 of Chapter 6 of the Code of Conduct and clause 94, paragraphs 1 through 4 of the Medicines Act). Certain financial relations (insofar as they fall within the scope of the Code of Conduct, see sub-section 1.2) that fall outside the definition of inducements, are further regulated in section 6.5.

For the application of the Code of Conduct, relations with individual healthcare professionals will be primarily assessed on the basis of the rules in sections 6.2 to 6.4, because it is certain that the rules regarding inducements are met without it being necessary to determine the apparent sales promotion object of the relation. Relations of authorisation holders in the framework of pharmaceutical care with parties other than healthcare professionals, including healthcare institutions, can only take place if they do not have the obvious goal of promoting the prescription, supply or use of a medicine. For some of these relations, section 6.5 provides the framework for assessment.

Sub-section 6.1.1 – Inducements are prohibited

This section provides that inducements are prohibited, unless the rules of conduct of chapter 6 are complied with. The definition of inducements can be found in section 3.1 under i and corresponds with the definition of this term in the Dutch Medicines Act.

Sub-section 6.1.2 – Financial relations other than inducements

Only financial relations whose evident object is the promotion of the prescription, supply or use of a medicinal product (to be further referred to as: “sales promotion object”) come under the definition of inducements. Pharmaceutical companies also form relations which are not covered by the term inducements, also with non-healthcare professionals. Sub-section 6.1.2 aims to give tools for determining when there is a sales promotion object. The factors enumerated here originate from the Policy Rules on Inducements (*Beleidsregels gunstbetoon*) and the Code Commission's advisory opinions (see for instance advisory opinion numbers A12.021 and A12.034), in which certain inducements were considered to be a special form of advertising. The elements status of beneficiary (addressee), object (content) and scope (context) of the benefit that are used to distinguish advertising from information (sub-section 5.1.3) must also be considered here. This will be explained in more detail below.

Status of beneficiary

Whether there is question of an apparent sales promotion object within the scope of a financial relation will largely depend on the beneficiary's status. If the beneficiary does not have an involvement in or influence on the prescription, supply or use of medicines, it can be assumed that the apparent sales promotion object is lacking and the financial relation is clearly outside the scope of the Code of Conduct (sub-section 1.2). If this person can exert influence in this way, care must be taken that the information exchanged about the medication therapy is balanced and as complete as possible. Restraint should be observed when entering into financial relations with people involved in the authorisation of medicinal products. See advisory opinion A14.039, where a training for nurses was considered to have a sales promotion object, resulting that providing of all kinds of valuable services (in the form of hospitality or the training itself) was qualified as inducements.

Object

Whether there is an apparent sales promotion object within a financial relation will mainly be determined by what the other party must do and what payment will be received in return for this. This can be compared with project sponsoring in accordance with section 6.5, which will generally not come under the definition of

inducements based on its object. A services contract relating to the exchange of knowledge between a pharmaceutical company and a care professional will, in principle, not have a sales promotion object, provided care is taken that the exchange of information about the medication therapy is balanced (in accordance with section 5.8, more specifically sub-section 5.8.10). Knowledge can also be exchanged with a non-healthcare professional in his role of consultant (individually, as member of an advisory committee or as a speaker) or as a participant in a scientific conference as mentioned in sub-section 6.4.5. If the care professional has the obligation to encourage the use of certain medicinal products, then the relation will have a sales promotion object and will be prohibited under the Code of Conduct and the Dutch Medicines Act.

Size

If the payment (with a pecuniary value) for services or expenses received by the other party exceeds the amount considered as being reasonable, a sales promotion object may be presumed. If something must be done in return for the payment, then a reasonable payment consisting of a fee in keeping with market rates and the customary payment of travelling and accommodation expenses will be permitted. Whether the fee reasonable can be determined on the basis of the customary rates charged by the care professional involved.

Sub-section 6.1.3 – Relations with non-healthcare professionals
The prohibition of inducements is reciprocal pursuant to Clause 1, paragraph 2 of the Medicines Act. This reciprocity also applies on the basis of the Code of Conduct; on the basis of Chapter IV of this Code of Conduct and more specifically for financial relations, pursuant to this sub-section.

Sub-section 6.2.1 – Gifts
For the application of sub-section 6.2.1 the gift must be for the benefit of a healthcare professional. If it is a product meant for patients that the healthcare professional must pass on, it will not be a gift for the benefit of a healthcare professional (see advisory opinion A10.090 of 13 September 2010).

Sub-section 6.2.2 – Inexpensive gifts
It must remain possible for authorisation holders to bring existing or new products to the attention of healthcare professionals who are involved in the prescription, supply or use of medicinal products using promotional material or gifts. On this point the pharmaceutical industry is no different than other sectors of industry. Authorisation holders, too, must be able to distinguish both their products and their companies from other products and companies by undertaking marketing activities, especially in the light of the aim for more market forces. The boundary lies where improper influence is exerted on the prescription and/or supply behaviour.

Sub-section 6.2.1 provides that no gifts may be given or received. Sub-section 6.2.2 is an exception to this: unless the gifts are inexpensive and may be relevant to the practice of the healthcare professional.

The term "inexpensive'" has been chosen to link up with the rules for accepting gifts by Dutch public servants. Reference is made to the circular letter from the Minister of Interior Affairs and Kingdom Matters dated l4 July 1999/no. AD 1999/U75958 (Government Gazette, 154, 13 August 1999). The Code of Conduct has set maximum amounts per healthcare professional. As for the value of a gift, the retail

value including VAT must be started out from.

There is also a requirement that the gifts must actually be of significance for the healthcare professional's practice. This means that the gifts may not be usable only in a "private sphere". The gift must therefore be relevant for the ordinary performance of the recipient's profession. It must fit in with the recipient's practice and be able to have a function in it. Following the EFPIA Code of Conduct it can be inferred from this that the following gifts with a minimal value are permitted:

a. informational or educational materials, provided they are directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients,
b. items of medical utility aimed directly aimed at the education of healthcare professionals and patient care, provided they do not offset routine business practices of the recipient.

Certain materials made available by authorisation holders do not come under the term 'gift', for instance pens, writing pads and conference bags made available during scientific meetings or refresher training organised by the authorisation holder for making notes on and storing instructional materials. The materials may not in such cases be used as promotion materials through the way in which they are made (more than a minimal value) or by mentioning product names; as soon as this is the case, the object of providing them is more than just offering course materials.

Superfluously, it is observed that the above is without prejudice to the rules applying to sponsoring (section 6.5) or services (section 6.3), which, after all, have nothing to do with the present rules for gifts.

In this connection attention must also be paid to the so-called indirect gifts, such as giving computer equipment on loan and then writing it off favourably (without any professional service being provided for this in return). The essential question to be answered here is whether there are goods or services in return. If this is the case, the amounts mentioned must be adhered to (see a.o. advisory opinion A15.016). What is an important question of course is whether the gifts are only beneficial for the recipient or also serve a wider interest. Support to a healthcare professional's practice, science in general or a specific therapy must also be judged in particular against the basic rule of encouraging a rational use of medicinal products.

Sub-section 6.2.3 – Discounts and bonuses

Section 94 under d of the Dutch Medicines Act provides that discounts and bonuses relating to the purchase of medicinal products are exempt from the prohibition of inducements. Sub-section 6.2.4 elaborates this rule by stating that discounts in kind (provided they are given in the form of bonus supplies of the same medicinal products) or discounts in cash are permitted, provided the discounts are granted in a transparent way. See in this connection advisory opinion A10-047 of 6 July 2010. A 100% discount on the supply of medicinal products is in principle in conformity with the Code of Conduct when this does not have a compelling character. See also the explanatory notes on sub-clause 5.1.3 regarding repayment schemes.

Section 6.2.4 – Providing samples

A limited number of free samples of medicinal products may be provided. Section 92 of the Dutch Medicines Act provides that a prescribing healthcare professional may not receive more than 2 samples of the same medicinal product per calendar year, without, however, giving any time-limit. In agreement with the EFPIA Code of Conduct section 6.2.5 provides that samples of the same medicinal product may be provided only within a period of two years after the healthcare professional's first

request for the sample. If further to a variation procedure regarding a medicinal product's strength and/or pharmaceutical form the product is also authorised for a new therapeutic indication, it will be considered as a new medicinal product for which samples may again be provided. If the strength and/or pharmaceutical form of a medicinal product are varied, but no new indication is awarded, this rule does not apply.

Sub-section 6.3.1 - Services

Healthcare professionals provide services to authorisation holders. There is, in principle, no objection to this and there is no reason whatsoever to prevent such services, provided they are relevant to the practice of medicine, pharmacy, dentistry, nursing or midwifery (see clause 94 under a of the Dutch Medicines Act). The nature of the services may differ. The healthcare professional can hold a lecture, give advice or co-operate in medicine trials. Services aimed at obtaining relevant marketing information and/or marketing data may also be considered as services (see the decision of the Commission for Appeals dated 20 September 2004, B03.025/04.01 Van der Linde – Bayer). It is important that the healthcare professional is asked to provide an actual service, e.g. when input is requested during an advisory session, this input should be distinctive from an event as referred to in paragraph 6.4, in which participants discuss a certain theme, presented by a lecturer (see as an illustration advisory opinion A18.055).

This section also applies to service agreements that are closed with a grouping of healthcare professionals and/or an institute in which healthcare professionals participate or by which they are employed, that provide for services, performed by (a) healthcare professional(s).

The parties involved in this service relation will only be confronted with the rules on inducements if there are improper motives for the services and/or doubts about the healthcare professional's independence given the relation between the service to be provided (the performance) and the payment to be received for this.

Sub-section 6.3.2 – Written agreement

The service agreement must be recorded in writing in advance. Transparency entails that the agreement must be recorded in one written document (also see the above-mentioned decision of the Commission for Appeals), in which the object of the service and the parties' mutual rights and obligations are clearly recorded.

The following elements must be included in the agreement:

a. a description of the services (content and nature) to be provided;
b. the result or goal intended to be achieved;
c. in what capacity does the healthcare professional provide the services ;
d. what the payment (of fees and expenses, as based on which (hourly) rates) will be;
e. how many hours will be spent on providing the service;
f. where the services will be provided;
g. when the services will be provided.

In this regard it is important that the marketing authorisation holder adheres to criteria on the basis of which the healthcare professionals (and the selected number of healthcare professionals) qualify and are selected for the execution of the service in question.

The use of framework agreements is allowed, provided the elements of “where”, “when” and “number of hours” are clearly recorded in the agreement or in an annex to it. For a further explanation, see Newsletter 2012/5.

The legal requirement that the services contract must be entered into in writing does not mean that the agreement cannot be concluded electronically (by e-mail) (see Clause 6: 227a Dutch Civil Code). However, it is required that the receiving party agrees to the agreement and confirms it (by e-mail).

Incidentally, the obligation of the written agreement does not only apply to the agreement between the authorisation holder and the healthcare professional. If a third party (such as a conference organiser or market research agency) purchases services from a healthcare professional who is (partly) financed by an authorisation holder, this service must be recorded in writing.

Sub-section 6.3.3 – Reasonable payment
If a physician (healthcare professional) receives no (direct or indirect) compensation whatsoever for his services (in any form whatsoever), the risk that his prescription behavior will be improperly influenced as a result of a financial relation is excluded. The provisions on inducements therefore do not apply to activities of a physician/healthcare professional for which no compensation is received.

The starting-point must be that the payment for the services provided by healthcare professionals must be in a reasonable proportion to what they must do in return for it. This also fits in with the statutory provisions on service provision (including sections 7:405 and 7:406 of the Dutch Civil Code). Healthcare professionals are entitled to a reasonable payment, also of their expenses.

Reasonable payment

What a reasonable payment is in concrete cases will depend on various factors, such as the scope and nature of the services, the time required to provide them and the discipline of the relevant healthcare professional. The judgment will basically be made on the basis of the time spent and an hourly or daily rate. As for the latter element, it will be possible for some professionals (and in particular if the services to be provided include the direct or indirect treatment of patients) to link up with the applicable standard (hourly) rates used for the relevant healthcare professionals. Because the payment is required to be reasonable, the CGR sees no reason to differentiate in excess of the reasonable standard rates based on the qualifications of the healthcare professionals involved. The standard rates are considered as being "maximally" reasonable, regardless of the qualification of the person involved (e.g. that he or she is a “key opinion leader” in a certain area).

The website contains the maximum hourly rates to the categories of healthcare professionals (categorised on the basis of prior education), see https://cgr.nl/themas/#thema-uurtarieven .

Clarification

- The hourly rates will be indexed annually as of 2022 in line with the annual indexation rates laid down by the Dutch government: the ‘Government contributions to development of employment’ (in Dutch: Overheidsbijdrage in de Arbeidsontwikkeling (OVA)).

- The hourly rates constitute maximum rates. This means that parties can set a rate that is conform market practices on the basis of the requested experience and expertise of the service provider whilst being lower than the maximum hourly rate set out above.
- The maximum hourly rates can be applied, regardless of whether the service agreement was made directly with the service provider or with the employer of the service provider as a contractual party. In case of a compounded service agreement, which concerns multiple healthcare professionals (and/or non-healthcare professionals), the budget will have to show which hourly rates were applied for which (non-)healthcare professional.
- The maximum hourly rates also apply in cases where the nature of the service demands services to be carried out abroad.
- The maximum hourly rate for the category *Professor* also applies to *Professor emeritus.*
- There are two categories of *university/master + healthcare-related education*. One category constitutes finalised healthcare-related education that requires more than 3 years, while the other requires less than 3 years.
- The category *university/master without additional healthcare-related education* includes healthcare professionals that have finished a master's degree without having a further specialisation through health-care related education. This includes, amongst others, pharmacists (which are not registered in the BIG-register as 'openbare apotheker'), dentist, doctors without specialisation (incl. doctors in training for a specialisation and doctors working without being in training for a specialisation), the five categories of nurse specialists, physician assistant, clinical technician, clinical physicist, medical biologist, medical immunologist, medical technician, virologist, etc.
- The category *HBO/bachelor* includes dietician, physiotherapist, obstetrician, ergo therapist, optometrist with HBO-education.
- The category *Other* includes, amongst others, pharmaceutical assistant (MBO education), nurse with MBO or in service education, optician, hearing care professional, chemist, patient advocate, etc.
- For further explanation of the different professions, we refer you to the Annex to article 6.3.3.

Parties to a service agreement need to be able to substantiate at all times their choice for assigning a healthcare professional to a certain category of the maximum hourly rates. It might be necessary to substantiate the choice to the Dutch Inspection Healthcare and Youth (in Dutch: Inspectie Gezondheidszorg en Jeugd (IGJ)) who inspects the compliance with the policy guidelines of the Medicines Act and who inspects whether payments are reasonable and in line with the rates set by the CGR. For professions with a protected title, or professions or specialisations that are registered in the BIG-register or other official registers, the registration in such registers will serve as sufficient evidence. If there is no such registration, the burden of proof to show that the payment is reasonable lies with the parties to the service agreement. Parties are advised to pay sufficient attention to this subject, so as to ensure that parties can substantiate that the healthcare professional as rightly been assigned to a certain category.

Reasonable compensation of expenses
In addition to the right to a reasonable hourly rate, a provider of services is also entitled to the payment of his/her reasonable expenses (section 7:406 Dutch Civil Code). As for the expenses in relation to the services provided, a distinction can be made between travelling expenses and accommodation expenses (dinner and

staying the night). In addition, there may be expenses (such as overhead or administrative costs, use of space, supporting service providers and equipment) incurred by the institution where the healthcare professional works. The starting-point is that the costs must be appropriate for the services to be provided and must stay within reasonable bounds. Costs for meals should be reasonable, with a maximum of € 108 (incl. drinks) for the Netherlands.

As for travelling expenses the expense allowances for Dutch civil servants can be linked up with:
- By car: € 0.37 per kilometre.
- By train: costs of first class travel (regardless of whether the person involved holds a season ticket).
- By taxi: in full, in addition to public transport.
- By plane: no first class travel. Business class is permitted for intercontinental flights.

A frequently-asked question is whether it is justifiable to pay an hourly rate for the time spent travelling. It may be reasonable to offer a financial compensation for the time spent travelling during normal working hours for the loss of income, but this does not apply outside working hours. In this regard allowance must be made for the possibility that a healthcare professional can prepare for the requested services during the journey; a "double" payment, viz. both for the time spent travelling and the time spent to prepare, is not allowed.
For the other expenses incurred by an institution, these must be able to be substantiated or otherwise made plausible (compare the guidance on reimbursements and time spent for the execution of non-WMO-related research with medicines initiated or sponsored by pharmaceutical companies, “Guidance voor vergoedingen en tijdsbesteding voor de uitvoering van niet-WMO-plichtig onderzoek met geneesmiddelen geïnitieerd of gesponsord door farmaceutische bedrijven”).

Annex to article 6.3.3 of the Code of Conduct CGR

Sub-section 6.3.4 – Suitable venue
In order to determine whether the accommodation costs stay remain within reasonable bounds, sub-section 6.3.4 provides that allowance must be made for the standards for the suitable venue (no gourmet restaurant or luxury resort). If the services are provided abroad, there must be an objective justification for this. For the term "suitable venue" see the explanatory note to sub-section 6.4.1.

Sub-section 6.3.5 - Research with medicinal products
In cases where a recognised independent body has reviewed research on the basis of the relevant provisions of the Dutch Medical Research Involving Human Subjects Act (to be further referred to as: the WMO) or the Assessment of research not subject to the WMO (to be further referred to as the Assessment, http://nwmostudies.nl), it would not be appropriate if the CGR reviewed the objects, soundness and design of this research again. The review on the basis of the WMO and Assessment provide for its own supervision and procedures. In case research is positively reviewed, it may be considered not to have a sales promotion object, provided that (in accordance with sub-sections 6.3.2 to 6.3.4) the remuneration to the researchers involved is reasonable in relation to the work performed. See Newsletter 2016/3. On the basis of section 6.5.2, this also applies to the situation that one or more authorisation holders act as sponsor of such a research. See Newsletter 2017/5.

For other studies that involve medicinal products that do not fall under the WMO or the Assessment, such as market research on the position and possibilities for use of a medicinal product, the provisions of the Code apply in full.

Sub-section 6.4 - Offering and enjoying hospitality as part of meetings and /manifestations

This section contains the framework for assessing the provision of hospitality during meetings and events within the standards of inducements. The framework is in line with the legal framework, more specifically clause 94 section b of the Medicines Act and the Policy Rules on Inducements 2018.

Offering and enjoying hospitality as part of events (conferences, symposia, training courses, etc.) is permitted to some extent. This applies to both events which are scientific in nature (meetings) and events in the nature of sales promotion (manifestations). These rules apply for physical as well as virtual (such as online trainings and e-learnings) meetings. Most importantly, not everything that is related to meetings/manifestations is, by definition, an 'inducement".

There will, for instance, be no question of an inducement if there is a reasonable proportionality between the other party's obligation and the financial contribution received from the company. Whether it concerns an inducement in such a contractual relation (e.g. on the basis of service provision) will depend on the relation between the mutual obligations (see under section 6.3).

Financial contributions in individual cases to individual healthcare professionals as part of meetings/manifestations without any performance required in return will, in principle, come under the scope of the advertising rules. *That* is defined as hospitality by both the Dutch Medicines Act and Directive 2001/83/EC and so is subject to the rules on hospitality in the Code of Conduct (section 6.4).

Sub-section 6.4.1 - Hospitality at meetings and manifestations

From the very beginning the main rule of this section has been that authorisation holders must ensure, when providing hospitality as part of conferences, symposia or other events, that the following conditions have been met: the hospitality

- must be limited to what is strictly necessary for participation in the meeting; and
- must be restricted to the main object of the event;
- may extend only to healthcare professionals;
- may extend only to the reasonable travel expenses, accommodation costs and registration fees. The hospitality offered or provided may not include relaxation (sport, recreation), see sub-section 6.4.3;
- must be provided at a suitable venue: if the event is held abroad, hospitality may be provided only if there is an objective justification for this location abroad (e.g. in the case of participants from several countries or the presence of the resource or expertise that is relevant for the subject of the meeting in another country).

Ad. a: Limited to what is strictly necessary

For the interpretation of the standard "limited to what is strictly necessary", it must be determined whether the costs of hospitality (provided or enjoyed) remain within reasonable limits. The costs for provided or enjoyed hospitality of a meeting must be congruous to the duration of the meeting. A deliberate decision was made to elaborate the term ‘within reasonable bounds’ in a fairly detailed and concrete way in order to offer more certainty to all those involved. For providing a meal, the limit for ‘within reasonable bounds’ is defined as not exceeding the amount of € 108. This is a threshold that applies to the Netherlands. In other countries, other limits for the

interpretation of the term "within reasonable bounds" for the provision of meals can apply and will be leading (see for example advisory opinion A16.036, in which higher dinner costs for Switzerland were deemed acceptable). Whether the hospitality provided is within reasonable bounds depends on the circumstances, that may differ per healthcare professional. Compensation of accommodation costs for healthcare professionals that live nearby the congress location may not be within reasonable bounds (see advisory opinion A16.016). Overall, maximum amounts apply for the total hospitality that may be offered at different types of meetings (see sub-sections 6.4.6 and 6.4.8).

Ad. b: Secondary to the main object
When judging the question whether the hospitality is secondary to the main objective of the meeting/manifestation, the mutual connection between all the facets of the meeting/manifestation and the hospitality to be provided as part of it must be considered. The starting-point is that the professionally relevant content of the meeting/manifestation must be the most important reason for participating, and not the hospitality (the manner in which and the environment in which the meeting/manifestation is presented or embedded). The ratio of time spent between the (scientific) program, the other components and the total duration of the program should be examined. If the balance of time spent between the (scientific) program and the other components is missing, the offered hospitality is not strictly limited to the main objective. An example is when a drink is offered at an evening meeting when the participants have already been offered a meal. Coffee and tea breaks, lunch, drinks and dinners must be logical interruptions of the program. Overnight stays must be justified.

Ad. c: For healthcare professionals only
The hospitality may not extend to persons other than healthcare professionals. Contribution of authorisation holders to partner programs is not allowed. For hospitality offered to others than healthcare professionals, see sub-section 6.5.2. of the Code of Conduct.

Ad. d: Suitable venue
As for the place where the meeting/manifestation is held sub-section 6.4.1, last paragraph, provides that it must be a suitable venue, which aims to ensure that hospitality is kept modest and excesses are prevented.. This can be both a physical location and a virtual one, such as in the case of an online training. The following criteria will be used to determine if a location is suitable:
a. is it secondary, in terms of its facilities and appearance, to the main objective of the meeting/manifestation? and
b. is there an objective justification for this geographical location?

A location will be secondary to the main objective of the meeting/manifestation in terms of its facilities and appearance if it is not so attractive that it is likely that the location itself is the main reason why healthcare professionals participate in the meeting/manifestation (e.g. a gourmet restaurant or luxury resort). A location with a (very) luxurious appearance (e.g. a castle or estate) and elaborate facilities will not easily be deemed fitting for a scientific meeting.

There may be an objective justification for a location abroad in, for instance, the following cases:
a. if the meeting/manifestation can be attended by healthcare professionals from several countries: when choosing the location, allowance has been made for its accessibility from all the various countries;

b. the location is a logical choice from a geographical point of view (a meeting/manifestation organised in Aachen for GPs or physicians from the South of Holland will be more logical than one organised on the island of Texel);
c. if there is a direct relation between the subject and/or the objective of the meeting/manifestation and the location;
d. if there is a relevant research institute, company, etcetera present at the location chosen.

N.B. this is a non-limitative enumeration.
As to part d, reference is made to advisory opinion A19.006, in which the Code Commission state that when a location abroad is justified by means of a visit to a production or research venue, it should be determined whether this visit is necessary for the (scientific) purpose of the event and subsequently, whether the duration and added value of this visit is proportionate to the total program of the event and the hospitality offered.

Sub-section 6.4.2 - Nurses
Since 1 January 2012 section 82(2) of the Dutch Medicines Act has provided that nurses who, in practice, supply or administer medicinal products to patients may attend meetings organised by scientific institutes or by authorisation holders, if the aim of such meetings is to enhance the scientific knowledge and skills of healthcare professionals, combined with a certain degree of hospitality. As a result, providing hospitality to nurses during scientific meetings within the meaning of sub-section 6.4.5, is possible. This group of nurses may, however, not receive any form of inducements other than hospitality. For the purposes of advertising of medicinal products, too, this group of nurses must be considered as being part of the general public, which means that no advertising for prescription-only medicinal products is allowed during meetings which in view of its content and the manner in which it is presented, is evidently also intended to this group of nurses. Normal participation in a meeting must, however, be possible. In order to prevent this group of nurses from being actively approached with advertising, they must be recognisable for the authorisation holder.

Sub-section 6.4.3 – Costs of hospitality
Providing hospitality is defined in sub-section 6.4.3 as the compensation of or paying for the travel expenses, accommodation costs or participation costs of a meeting/manifestation. Participation costs may include those costs incurred by an individual participant (such as registration fees for a meeting or online trainings, or study materials not handed out during a meeting). This also includes potential cancellation fees when the person concerned refrains from participation. Other costs may also be involved in a meeting/manifestation, which cannot be directly considered as travel expenses, accommodation costs or registration fees. If these are costs relating to relaxation, recreation, and so on they may not be paid for by authorisation holders.

There can, however, also be general organisational costs relating directly to the meeting/manifestation, such as fees for lecturers, the costs of hiring conference rooms, technical costs for making available an online trainings etc. The question has arisen if and to what extent such costs may be paid for by authorisation holders. If the hospitality at a meeting/manifestation complies with all the rules given by the Code of Conduct (on, for instance, their nature, location, connection with the programme and amount (percentage)), the general organisational costs of meetings/manifestations will, in general, no longer be a point of discussion. These

costs will therefore, in principle, not be considered as costs for hospitality.

The background of this approach is that it would be undesirable if such general costs, which are closely related to the content and quality of the meeting/manifestation, had to be considered as costs of hospitality. If, for instance, the organisers wish to invite a leading speaker and/or researcher from abroad, the costs will often be substantial. If such costs were seen as costs of hospitality, organisers will be less inclined to involve such leading speakers in meetings/manifestations. The rules on inducements must curb hospitality, but may not have a negative effect on the content and quality of the meeting/manifestation.

There are, incidentally, circumstances imaginable in which certain costs considered as "general organisational costs" by the organisation must indeed be considered as (disguised) costs of hospitality, e.g. excessive costs for hiring conference rooms, etc. When exactly this will be the case must be decided by the Code Commission on a case-by-case basis.

Sub-section 6.4.4 – Sponsoring events

In order to prevent things from happening which violate the letter and spirit of the Code of Conduct under the banner of "collective sponsoring", the requirements for hospitality have also been declared applicable if an authorisation holder makes a meeting/manifestation financially possible in any way, whether in full or in part. The sponsoring of meetings and/or manifestations by authorisation holders is deemed to be the same as providing hospitality to individual healthcare professionals as part of meetings and/or manifestations. Meetings and/or manifestations may only be organised or sponsored – in any manner whatsoever – if such meetings and/or manifestations comply with the requirements set out in section 6.4. From the point of view of transparency, the sponsorship agreements for meetings and/or manifestations must be recorded in writing and clearly set out the rights and obligations of the parties involved, such as making available space for booths or being allowed to place advertising.

In Newsletter 2016/2, further instructions are given how to comply with section 6.4 in case one or more authorisation holders sponsor a conference organizer. In the first place the budget of the conference should tell to what extent participants are sponsored in hospitality costs. When the budget contains costs relating to relaxation or recreation, own contributions of participants fees should compensate these. As determined in sub-section 6.4.3, hospitality provided by authorisation holders should no include relaxation or recreation. Secondly, the amount of hospitality costs in the budget should be determined. These include travel and accommodation expenses as well as registration costs of the conference. Registration costs should be distinguished from general organisational costs, that in principal may be fully compensated (see the explanatory notes on sub-section 6.4.3). Registration costs include those costs that may be attributed to participants, such as congress materials and bag. Contingencies and a credit balance are counted by means of precaution as hospitality costs, unless the conference organizer proves that the assignment of this credit balance is in accordance with the Code of Conduct. What costs belong to what category of expenses is further elaborated in the Instructions of self-evaluation to avoid inducements in education accreditation. When the amount of hospitality cots is determined, a calculation can be made to what extent these are sponsored by authorisation holders (to deduct own contributions of participants that are not attributed to relaxation and recreation costs). When the amount of sponsored hospitality costs is divided by the number of participants, the extent of provided

hospitality per participant can be determined. This should be in accordance with section 6.4.

In advisory opinion A16.005, the Code Commission stresses that healthcare professionals should be made aware of the extent of hospitality costs sponsored (on top of potential own contributions to the conference) when they join a sponsored conference. These costs are maximized to €2,160 per year according to the first part of sub-section 6.4.6. The CGR board considers it as an obligation to conference organizers to inform healthcare professionals. See newsletter 2016/2.

There are also other forms of sponsoring which are not directly related to meetings /manifestations and in which there is no direct relation between the authorisation holder and individual healthcare professionals. For these forms of sponsoring the principles and standards laid down in section 6.5 will apply, as long as the rational use of medicinal products is not affected.

Sub-section 6.4.5 - Meetings
A conscious distinction has been made between meetings and manifestations. The underlying provisions of Directive 2001/83 show that a certain amount of hospitality is permitted, not only at scientific events, but also at events designed to promote sales. The CGR believes that there should be more scope for hospitality at meetings with a scientific objective than at manifestations that cannot be described as such. This is also due to the fact that, in the course of time, authorisation holders are increasingly involved with organising and facilitating meetings.

When describing a certain ‘event’ as a meeting, the CGR is proceeding on the basis of the principle that it is the content that is relevant and not the organiser. The scientific objective of an event can be deduced from an accreditation by a recognised body, such as a scientific association. But even if it has not been accredited, an event can still qualify as a meeting in two cases. Firstly, if the organisation is independent, for which the conditions are set out in sub-section 6.4.5 (2). And secondly, an event organised by an authorisation holder could still qualify as scientific if the CGR has first reviewed and approved its content and the hospitality to be provided there (sub-section 6.4.5 (3)). When reviewing that content, the CGR will for example consider the speaker's relations with authorisation holders or third parties using the speaker’s disclosure slide (see the explanatory note to sub-section 7.1.2 below).

Sub-section 6.4.6 – Hospitality at meetings within reasonable bounds
If an event falls into any of the three categories referred to in sub-section 6.4.5, it is deemed to be a meeting. This means that there are two options for the permitted hospitality:

a. An authorisation holder can contribute to the costs, provided that these are strictly necessary in relation to the duration of the meeting, and provided that this does not exceed €720 per occasion, with a maximum of €2,1600 per year (see sub-section 6.4.6 (1)). In this regard, the reimbursement of the total amount of €720 will most likely only be the case for multi-day meetings. In case of sponsored meetings, see explanatory notes on sub-section 6.4.4.

b. The option of sub-section 6.4.6 (2) can also be chosen. In practice, an authorisation holder often arranges for the logistics of attending a meeting, such as the journey, the stay and the registration, and at a certain point, it will bill the healthcare professional for all or a part of these costs. Sub-section 6.4.6 (2) in

this case provides that an authorisation holder must at any rate charge a healthcare professional 50% of these costs. In that case, there is no inducement because of the reasonable proportionality of the healthcare professional's obligation (see explanatory notes on section 6.4). It goes without saying that this must be based on a transparent and valid settlement and that the costs must be realistic.

Every meeting must, furthermore, comply with the requirements formulated in sub-sections 7.1.2 and 7.1.3, and (naturally) with the general requirements arising from sub-section 6.4.1. Whether these requirements have been met will have to be decided on a case-by-case basis.

In the case of the meetings referred to in sub-section 6.4.5 (1) and (2), an authorisation holder will be unable to influence the relation between the hospitality offered by that meeting's organisers and the main objective of the meeting, in view of the fact that it cannot influence the organisation. In the case of the meetings referred to in sub-section 6.4.5 (3), the authorisation holder will naturally be responsible for ensuring that there is a reasonable proportionality between the hospitality offered at that meeting and the main objective of the meeting.

The agreement for providing hospitality directly to a healthcare professional should be recorded in a writing and clearly set out the arrangements. The agreement should indicate which event (place, date and duration) it concerns and what arrangements have been made relating to compensation (in cash or in kind, with or without a contribution of the healthcare professional) of the hospitality costs. The format of the agreement is not defined and can therefore occur in a confirmatory letter from the authorisation holder. The requirement that the agreement must have been entered into in writing does not mean that it cannot be concluded electronically (by e-mail) (see Section 6: 227a Dutch Civil Code). However, it is required that the receiving party agrees to the agreement and confirms it (by e-mail).

This requirement does not apply if the hospitality covers only participation (including meals and drinks within reasonable bounds and potential parking costs) in a meeting organised by or on behalf of an authorisation holder, without compensation of cost for travel and / or hotel accommodation. In that case it is sufficient when the authorisation holder informs the participants about the amount of hospitality costs provided (in extent of the own contribution to the meeting, when applicable). See explanatory notes on sub-section 6.4.4.

Sub-section 6.4.8 – Hospitality within reasonable bounds at manifestations
If a meeting does not fall into any of the three categories described in sub-section 6.4.5, it is deemed to be a manifestation, provided that there is a programme that provides for a need for information amongst healthcare professionals (see the advisory opinions 11.042, A13.063 and A13.068). After the amendment of the Inducements Medicines Act Policy Rules (*Beleidsregels gunstbetoon Geneesmiddelenwet)* as per 2018, the sums for hospitality at manifestations have been set to a maximum of €108 per occasion and € 540 per year.

Also the agreements for compensation of hospitality costs related to the participation in a manifestation, directly provided to a healthcare professional, should be recorded in a writing. This does not mean that the agreement cannot be concluded electronically (by e-mail) (see Clause 6: 227a Dutch Civil Code). However, it is required that the receiving party agrees to the agreement and confirms it (by e-mail). No written agreement needs to be concluded 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. In that case it is sufficient when the authorisation holder informs the participants about the amount of hospitality costs provided (in extent of the own contribution to the meeting, when applicable). See explanatory notes on sub-section 6.4.4. See further the explanatory notes of sub-section 6.4.6.

Sub-section 6.4.9 – The obligatory review of meetings outside the Netherlands
The following should be pointed out with regard to the question whether satellite symposiums (meetings linked to an event outside the Netherlands) must also be reviewed first:
Satellite symposiums organised by an authorisation holder do not need to be reviewed first if they are an integral part of a meeting outside the Netherlands which is exempt from the obligatory prior approval under the second paragraph of sub-section 6.4.9 (or if those symposiums themselves qualify for exemption according to that sub-section). Satellite symposiums will at any rate constitute an integral part of meetings outside the Netherlands if they:

a. are conducted with the approval of the organisers of the meeting outside the Netherlands; and
b. are conducted at the same venue and during the meeting outside the Netherlands; and
c. take up a restricted amount of the time of the meeting outside the Netherlands; and
d. are intended only for the participants of the meeting outside the Netherlands.

Sub-section 6.5.1 – Financial relations other than inducementsUnder the Medicines Act, only healthcare professionals may receive inducements within the framework of parts a through d of section 94 of the Medicines Act and the Policy Rules on Inducements 2018. This has been further elaborated in sections 6.1 to 6.4 of the Code of Conduct. Inducements to non-healthcare professionals are prohibited; there are no legal grounds for exemption for this group. Nevertheless, money or goods (with a pecuniary value) can be promised, offered or granted, insofar as this does not have an apparent purpose of promoting the prescription, supply or use of a medicine. When assessing if this 'apparent sales promotion object' is indeed absent, the extent to which the beneficiary has or can influence the prescription, the supply and use of medicinal products, and the purpose and scope of the financial relation (see sub-section 6.1.2 of the Code of Conduct) must be taken into account. Only if this assessment leads to the conclusion that there is no apparent sales promotion object, as described above, the financial relation is not subject to the prohibition on inducements and therefore permitted. There are also other financial relations involving healthcare professionals and non-healthcare professionals that are not covered by the legal exemption grounds regarding inducements. Special categories are sponsorship of healthcare activities and projects and contributions to scientific awards. These financial relations are also only permitted if it is determined that an apparent sales promotion object is lacking. In this section, a framework is given for these three categories of relations with cumulative conditions in which it is presumed that there is no evident sales promotion object. The Policy Rules on Inducements 2018 give these cumulative conditions for sponsoring, which have been adopted in sub-section 6.5.3 of the Code of Conduct. Sub-section 6.5.2 contains cumulative conditions for financial relations with non-healthcare professionals and sub-section 6.5.4 for contributions to scientific awards. Financial relations that authorisation holders enter into with third parties outside the healthcare sector where there is no direct or indirect involvement in or influence on the prescription, supply and/or use of

medicinal products (see the scope of the Code of Conduct, sub-section 1.2), fall completely outside the scope of the Code of Conduct.

Sub-section 6.5.2 –Relations with non-healthcare professionals

Sub-section 6.5.2. provides cumulative conditions under which an apparent sales promotion object is lacking in a financial relation between an authorisation holder and a non-healthcare professional. They are conditions that, depending on the potential influence that the non-healthcare professional has on the prescription, supply or use of medicinal products, have to be examined. First, it has to be established if the non-healthcare professional has influence on or may influence the prescription, supply or use of medicinal products. If that is not the case, the financial relation with the non-healthcare professional falls out of the scope of the Code of Conduct (see sub-section 1.2). If indeed there is a non-healthcare professional with a possible influence on the prescription, supply or use of medicinal products, it can be determined if an apparent sales promotion objective is lacking based on the conditions set out in sub-section 6.5.2.This group of non-professionals can be considered to include carers who are involved in the dispensing of medicines but cannot prescribe or supply medicines (such as general practice assistants, see for example advisory opinions A15.109 and A16.068), healthcare professionals who are involved in the diagnosis (such as clinical chemists, clinical geneticists, clinical molecular biologists, pathologists and microbiologists (see, for example, advisory opinions A15.039, A17.019 and A17.080)), researchers (see, for example advisory opinion A16.071), directors of healthcare institutions, care groups or health insurers and representatives of patient organisations. Relations with these non-healthcare professionals are, for example, services contracts that include a certain payment or (whether via a third party or not) hospitality offered during a training meeting. For hospitality offered at scientific meetings, nurses who administer or provide medicines in the exercise of their profession are regarded as healthcare professionals (see sub-section 6.4.2 of the Code of Conduct).
A further explanation of the conditions follows below.

Ad. a: The relation serves a healthcare interest

This condition targets the object of the financial relation (see sub-section 6.1.2 under b). It is of importance that the financial relation serves a healthcare interest or is considered to be normal in legal transactions. It is a condition that also applies to relations with healthcare professionals, such as:

- the condition for a services contract to serve an interest relevant to the practice of medicine, pharmacy, dentistry, nursing or obstetrics;
- the condition for meetings that the scientific program must be the main objective of the meeting.

Ad. b: The relation does not influence the beneficiary to promote the sale of medicines from the sponsor

This condition stipulates that the financial relation must not influence the beneficiary in any way, with the apparent goal of promoting the sale of a medicinal product. Of course, the financial relation can lead to a certain 'spin-off', such as greater brand awareness and/or a better image of the authorisation holder. Direct or indirect linking of money or services or goods with a pecuniary value to the buying or advising of certain medicinal products is not acceptable. Any (appearance of) influence with the apparent goal of promoting the turnover of a medicinal product, such as the involvement of marketing of authorisation holders, should be avoided. For the provision of a refresher course (including hospitality), it is important that the meeting does not involve direct or indirect advertising (see advisory opinions A14.039 and A17.056 and the prohibition on advertising of prescription-only medicinal products

under sub-section 5.6.1). Participation in a manifestation - in which an apparent sales promotion goal is assumed - is therefore not permitted.

Ad. c: The nature and content do not go beyond the intended goal
On the basis of this condition, the necessity and reasonableness of the financial relation must be tested (compare with condition e. of sub-section 6.5.3). If, for example, it is not certain that the presence of (certain) non-healthcare professionals at a meeting for healthcare practitioners is useful for the exchange of knowledge, there is no justification for offering hospitality to these non-professionals.

Ad. d: The relation takes place in an honest and transparent manner and is recorded in writing
This condition stipulates that the financial relation must first be laid down in a written agreement, with the associated requirements (in accordance with sub-section 6.3.2 for services contracts and sub-section 6.4.4 under a for sponsoring meetings respectively sub-section 6.4.6 paragraph 3 for the individual reimbursement of hospitality costs).

Ad. e: The relation does not affect the independence, reliability and credibility of the beneficiary and other stakeholders
This condition concerns the essence of preventing authorisation holders and non-healthcare professionals from feeling obligated towards each other. In the case of a direct reimbursement of, for example, travel and/or accommodation costs to a non-healthcare professional for participation in a meeting, the non-healthcare professional will feel more obliged to the authorisation holder than when the contribution for the participation takes place via the institution to which the non-healthcare professional is connected or when sponsoring from the business is via an independent conference organiser. If the compensation comes from several authorisation holders, this will benefit the independence of the financial relation. What matters further is that the integrity, independence and image of all parties involved are not compromised.

Ad f. The amount of the reimbursement is limited to what is strictly necessary and does not go beyond comparable relations with professionals
On the basis of this condition, financial relations with non-healthcare professionals with regard to reimbursement must not go beyond what is strictly necessary and in any case within the standards that apply to relations with professionals on the grounds of sections 6.2 to 6.4. This means, among other things, that the reimbursements must meet the basic principles that apply to healthcare professionals too. In the case of a services contract, the amount of the fee paid must fit within the system of maximum hourly rates for the different categories of healthcare professionals as laid down in article 6.3.3.. Offered hospitality should be limited to what is strictly necessary for participation in the meeting (see for example advisory opinions A16.068, A16.071 and A17.019). Provisions within sections 6.2 to 6.4 that specifically refer to healthcare professionals (such as sub-sections 6.2.3 and 6.2.4) and the more procedural obligations (such as sub-section 6.4.9) do not apply to relations with non-healthcare professionals.

Sub-section 6.5.3 – Sponsorship
For the purposes of this sub-section, the term “sponsorship” is understood to include all forms of support, with or without quid pro quo and irrespective of the qualification given by the parties. That means, for example, that support in the form of a certain amount of money for a project without quid pro quo (a ‘donation’ or ‘grant’), also qualifies as sponsorship in the context of sub-section 6.5.3.

In accordance with the Policy Rules on Inducements, sub-section 6.5.3. contains cumulative conditions with regard to sponsorship.

Ad. A: Innovative and/or quality-improving care
This condition expresses the fact that sponsorship is permitted if it focuses on “extra” matters: innovative and/or quality-improving activities that would not, or with great difficulty, get off the ground without sponsorship. Whether a (care)activity is suitable for sponsorship must be determined on the basis of the circumstances of the individual case. Time is an important, but constantly changing factor. Progressive insights and developments in the field of practice must be closely monitored. After all, a certain (care)activity may qualify for sponsorship at a certain moment X, but may be followed up so much that one can speak of a ‘best practice’. The activity will therefore then belong to regular healthcare. In that case, sponsorship will only be allowed if it can be made plausible that no regular funding is available for this regular healthcare (see ad c.).

Ad. b: Improving patient care or advancing medical science
Sub-section 6.5.3 under b stipulates that sponsorship must aim at direct or indirect improvement of patient care or the advancement of medical science. Only if it can be made plausible that ultimately the patient can benefit directly or indirectly from the sponsorship or if the sponsorship contribute to science, will the sponsorship be permissible. Moreover, this requirement will almost always be met if it concerns an innovative or quality-improving activity as referred to in sub-section 6.5.3 unedr a. To illustrate: sponsoring a laptop that allows patients in the Department of Paediatric Oncology to communicate remotely with their environment can indirectly improve care and sponsoring research on a rare genetic disorder can be seen as a contribution to the medical science that the patient (through improved patient care) may ultimately benefit from.

Ad. c: Sponsorship is in principle provided to legal entities
Sub-section 6.5.3 applies to sponsorship of projects of collaborations of healthcare professionals, such as partnerships or other legal entities in which healthcare professionals are active. This could include foundations set up by doctors to promote training activities, care groups or collaborating general practitioners with or without pharmacists. This may encompass projects of “informal” collaborations, provided that more than one doctor or pharmacist is responsible for the sponsorship on the side of the recipient. FT(T)O’s are explicitly excluded, because the Board of the CGR does not consider it desirable that FT(T)O’s are sponsored by authorisation holders. Even in the case where a project is sponsored at the request of an individual healthcare professional and the actual payment of the sponsor money occurs to the institution that is the employer of the healthcare professional, the sponsor rules of sub-section 6.5.3 apply. If the sponsorship benefits an individual professional, an apparent sales promotion objective is generally assumed, therefore subjecting the sponsorship to be assessed on the basis of sections 6.2 to 6.4 of the Code of Conduct (see, among other things, advisory opinion A16.037). An exception is the sponsorship of a medical PhD student that stays limited to the printing costs of a thesis; in that case it can be assumed that there is no apparent sales promotion objective with the undesired influence on a person’s prescription behaviour, but rather a form of support that is considered normal in legal transactions.

Ad. d: No obligation to prescribe, supply or (prior, current or potential future) use of medicinal products
The sponsorship falls outside the scope of the prohibition on inducements in so far as it does not have the apparent goal of promoting the sales of medicinal products. It is

therefore important that sponsorship does not oblige the prescription, supply or use of certain medicinal products.

Ad. e: The nature and content of the relation do not go beyond what is necessary to achieve the intended goal and the relation does not finance any costs that can be reimbursed to the beneficiary in a regular manner
Asking or giving support may not be motivated by personal gain or direct commercial purposes. This condition is closely related to the generally formulated integrity requirement of sub h. See the decision of the Committee of Appeal in cases B15.004/B15.03. The mere circumstance that sponsorship may at any moment lead to a personal or commercial gain, does not prevent its admissibility. What matters is that both the recipient and the donor of support have the primary aim to improve the care of patients or to advance medical science.
If regular funding exists for the activities for which sponsorship is asked (e.g. by the government, health insurer, institution and/or subsidy provider), sponsorship means additional financing, which leads to savings and thus a possible benefit for the beneficiary. In those cases, sponsorship is prohibited. See for example advisory opinion A10.076 of August 24th 2010 and the decision of the Code Committee in case K15.004. Sponsorship is permitted if there is no, or only partly, regular funding. The sponsored amount may only concern the costs not covered by regular funding. The authorisation holder must motivate why the project cannot be funded through regular funding and/or regular (reimbursed) care. Cases that belong to normal practice or business operations must of course be financed by the care provider or institution itself (for example the replacement of an outdated computer system or the layout of the practice area). Support for the purchase, maintenance etc. of such matters would directly lead to a saving and thus a benefit for the beneficiary. For example, the financing of regularly funded jobs should also be considered to fall under the scope of this sub-section. If funding is available, for example through a government budget, for practice support for general practitioners or if a performance assessment has been determined for the activity in question by the NZa, no sponsoring can be obtained from an authorisation holder.

Ad. f: The sponsorship takes place in an honest and transparent manner and is recorded in writing
Agreements regarding sponsorship must, prior to the sponsorship, be recorded in writing. The agreement must in any case contain a precise description of the activity to be sponsored (object and structure of the project, possible start and end criteria) and the rights and obligations of all parties involved, including a financial substantiation. Also in the case of a donation, it is important to record everything in writing, such as the purpose of the donation and the fact that it is without quid pro quo.
This means, among other things, that the selection of beneficiaries must take place on the basis of transparent, objectively-substantive criteria (see Committee of Appeal in case B15.004 of February 22nd 2016, paragraph 4.9.1).

Ad. g: The sponsorship may not demand a performance obligation on the part of the beneficiary, with the exception of mentioning the name of the authorisation holder
(Financial) support may possible lead to improper influence. In order to guarantee the independence of the execution, it must be prevented that the beneficiary is subject to a performance obligation. The exemption to this is the mentioning of the name of the authorisation holder. In this, sponsorship distinguishes itself from a rendered service (assignment). In the case of rendered services (or a services contract), there is a bilateral act (offer and acceptance, reciprocity) in which parties have a reciprocal

enforceable obligation to perform. Sponsorship is a unilateral act, in which there is no obligation on the part of the beneficiary to execute the sponsored project. This does not mean that the authorisation holder is not allowed to impose conditions (in the form of certain performances) on the sponsorship. Sponsorship will often focus on carrying out activities within a certain project, for which the beneficiary can be held accountable (in the form of a report, presentation or expert meeting). However, the execution of the sponsored project itself is not enforceable. If the sponsorship conditions are not met, the sponsorship amount can be set to a lower amount or even to nothing, and recovery could be made on the basis of undue payment.

Ad. 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 condition requires guarantees with regard to an independent execution of the sponsored project. Those who are involved in the execution of the project must be independent and may not be employed by the authorisation holder (see, among others, advisory opinions A14.110, A16.053). Those involved in the execution of the project may be paid by the authorisation holder, provided that the independence is contractually established and guaranteed. Any contact between the authorisation holder-sponsor and beneficiary should be limited to what is necessary and justified for the execution of the project, such as necessary trainings or the exchange of information on, for example, pharmacovigilance obligations (see, among others, advisory opinion A16.092). This also applies to (the recording of) the agreements on (interim) evaluation (when, how and to whom).

Support of the project by several sponsors will benefit its independence. A conscious limitation to one sponsor may endanger the independence of the beneficiary and is therefore not allowed. However, such exclusivity may be agreed upon in the context of a specific short-term project (e.g. support of a pilot project for a certain innovative form of care). Structural exclusivity must however be prevented.

Sub-section 6.5.4 – Scientific awards

The subject of the scientific award is of great importance to determine an apparent sales promotion object. For an award in the form of a competition, contest or quiz, an apparent sales promotion object can be assumed, even if the subject is scientific. If the award may lead to (in)direct advertisement for prescription drugs, the apparent sales promotion object can also be assumed. The Code of Conduct does not obstruct sponsoring an award from, for example, a scientific association that sees to actual (in)direct improvement of patient care or the advancement of medical science. However, the objectivity and independence of the award must be sufficiently guaranteed. The objectivity must firstly be assessed by looking at the content of the performance that the contestant must deliver. This should be care improving and/or medical-scientific and should be judged by an independent jury. The performance may, for example, consist of a scientific speech or a poster presentation. More may be expected, content wise, from healthcare professionals than from non-healthcare professionals that operate outside of care services. Moreover, no further performance may be required from the contestants, other than the performance for competing for the award.

Secondly, the independence of the award must be guaranteed by having the winner selected by a jury that is independent from the authorisation holder. Independence can be assumed if the award is granted by (and in the name of) a third party e.g. a scientific association), that selects the winner on the basis of a judging by an expert jury, independently of the authorisation holder. The independence may also be guaranteed by the lack of a link (indirect as well) between the award and the

company name of the authorisation holder, if at least three company names are linked to the award.
From the point of view of transparency, it is desirable that the company name of the authorisation holder is communicated at announcement and distribution of the award, unless it is undesirable for reasons of independence that the company name is (in)directly linked to the award.

The contribution may not lead to undesired influencing of the prescription, supply or use of a medicinal product. It is important whether the (intended) award winner is a collective of (non-)healthcare professionals or an individual. In case of an award granted to a collective, a direct influence on the turnover of a medicinal product will be less likely than when the award is granted to an individual who has an influence on the prescription, supply or use of medicinal products. This requires a precise guarantee of the independence of the award.
If the magnitude of the award (with a pecuniary value) is disproportionate to its object, an apparent sales promotion subject may – independent of the goal of the award – be assumed. The compensation should therefore be reasonable in relation to the subject. To determine the reasonableness, the standard rates for services of involved healthcare professionals can be taken into account.
The reasonableness of the compensation also depends on the assignment it has been given. For example, if the prize money concerns a contribution to a hospital for further research into a particular disease or condition, a relatively high amount may be considered reasonable. The rules regarding sponsoring (sub-section 6.5.3 of the Code of Conduct) are leading here. If the award is granted in the form of a gift, it must be prevented that this gift has a promotional character.
See, amongst others, Newsletter no. 10 of October 2014 and advisory opinions A14.103, A15.117 and A16.093.

Section 6.6
There have always been contacts between patient organisations and authorisation holders because, as users and developers/manufacturers of medicinal products, they are natural partners. Both parties benefit from the exchange of knowledge of medicinal products and of experiences, wishes and expectations for the future. In the light of this, patient organisations and authorisation holders therefore often work together in various fields. But there are two aspects of this collaboration which could result in inappropriate influence: communications and funding.

In communications specific medicinal products often (also) play a part. Authorisation holders may only advertise medicinal products within a very strict framework; advertising of prescription-only medicinal products to the general public is not permitted, but providing information naturally is. The rules laid down for this purpose, and especially the distinction between advertising and information, are of great importance to both authorisation holders and patient organisations.

Patient organisations are largely dependent on external sources for funding. Now that government funding is steadily shrinking, patient organisations are becoming more and more dependent on private organisations: authorisation holders, but also other parties. Authorisation holders are bound by the rules of sub-sections 6.5.2and 6.5.3, when it concerns relations with non-healthcare professionals and sponsoring. These sub-sections see to the guarantee that an apparent sales promotion goal is lacking, and to prevent undesirable influence. To also avoid any association with such influence in the relations with patient organisations, section 6.6 lays down additional pre-conditions for a responsible collaboration.

Although the rules of section 6.6 were largely designed for the relations between patient organisations and authorisation holders, the CGR believes that, on account of their universal nature, these are also applicable, by analogy, to any relations which patient organisations have with the members of the CGR (such as prescribers and suppliers).

Sub-section 6.6.2 – Support is permitted
Support is possible in various ways. A patient organisation can for example be supported with a certain sum, but support could also be given 'in kind', for example by making manpower or a venue available. Support can also be linked to a specific activity, such as an event, or goods or services in return, such as a certain item of expenditure or a campaign. The point of departure is that it must be clear to the outside world *that* support is being provided (see specifically sub-section 6.5.3 (f) and sub-section 7.2.1 (c)).

The condition under a). arises from the general prohibition of advertising for prescription-only medicinal products to the general public. Authorisation holders may therefore not advertise to patients, not even indirectly by making use of the patient organisations. This does not negate the right of the marketing authorisation holder to correct incorrect factual statements included in communication by patient organisations or to deliver careful and balanced scientific texts to patient organisations when they so request.

The independence of a patient organisation is of the utmost importance and any support provided may not undermine this independence in any way. Within this framework transparency is naturally very important (see above). It is also desirable in this connection that patient organisations also render (financial) account, for which purpose the Dutch Code of Conduct for Fund-Raising in the Healthcare Industry (*Gedragscode voor de Fondsenwerving in de Zorgsector*) also provides for such an obligation.

A conscious decision to accept the support of just one sponsor could threaten patient organisation's independence and is therefore undesirable, which is why it is not permitted to demand exclusivity (see sub-section 6.5.3 under h), except for a specific project (such as a specific item of expenditure or a specific meeting), provided it is a short-term project.

Sub-section 6.6.3 – Written agreement
Transparency is of paramount importance, which implies that any agreements must be recorded in writing and must be available for inspection. This sub-section elaborates the conditions in more detail (that are also applicable on the basis of sub-section 6.5.3 under f). Reference is also made to sub-section 7.2.1 (c), which requires the disclosure of financial relation in the Dutch Healthcare Transparency Register (*Transparantieregister Zorg*). Paragraph (b) provides that such an agreement must at any rate record all the parties' rights and obligations.
Paragraph (d) requires that the transparency must also be reflected in a statement that a certain activity has been made possible, in whole or in part, thanks to an authorisation holder's support. The patient organisation's obligation to do so must be recorded in the agreement.
The EFPIA has drafted a standard template for the written agreement (see Annex I to the EFPIA Code of Practice on Relations between the Pharmaceutical Industry and Patient Organisations).

Sub-section 6.6.4 – Services

The EFPIA Code of Practice on Relations between the Pharmaceutical Industry and Patient Organisations includes rules in the event that an authorisation holder requires a patient organisation to do something in return for its support. This could for example be participation in an advisory board, acting as a speaker or other forms of consultancy. Such service agreements are permitted, provided that they are agreed in writing (sub-section 6.5.2 sub d and sub-section 6.6.3) and provided that the services provide for a justified need on the part of the authorisation holder which is appropriate for the purpose of improving patient care or advancing medical science.

Netherlands Patient Federation (Patiëntenfederatie Nederland) has published a Guideline for interactions between patient organisations and pharmaceutical companies, which describes the different roles that patients can play:

- a patient organisation can cooperate with companies and make agreements regarding transparency and continuity;
- patient advocates can represent patient organisations;
- experience experts (people who suffer from the illness themselves) can explain what their needs are and what they find important for quality of healthcare and life, based on their own experiences.

The rules set out in article 6.6.4 see to patient organisations and their representatives with relevant experience and knowledge (for example, after participating in EUPATI and EURORDIS Summerschool). As a maximum hourly rate for patient advocates, parties can use the category *Other* as laid down under article 6.3.3. The tariff is explicitly a maximum hourly rate. Parties can come to a fair remuneration on the basis of the requested expertise and experience. For experience experts there is no hourly rate. However, experience experts can receive reimbursement for attending meetings. In the past, the Code Commission has ruled that a total reimbursement of € 75 in a specific context was fair (see advisory opinions A17.004 and A18.032).

Sub-section 6.6.5 - Hospitality

It is possible to envisage that an event is organised where representatives of a patient organisation are provided with hospitality as part of the support. This type of hospitality is, however, only permitted if there is no evident object to promote the use of a medicinal product (see sub-section 6.1.2). If that is the case, this hospitality comes under the definition of "inducements", which are prohibited pursuant to sub-section 6.1.1.

Chapter 7 – Transparency

Sub-section 7.1.1 Transparency

The starting point for self-regulation is that financial relations are only allowed if they meet the substantive conditions as set out in Chapter 6. In addition, transparency is an important principle: the fact that there are financial relations between authorisation holders on the one hand and (groupings of) healthcare professionals, healthcare organisations, and patient organisations on the other hand, should be known in certain cases. Even if all substantive conditions are met, it is important that others can also know about the financial relations between authorisation holders and the mentioned healthcare parties.

All requirements regarding transparency are consolidated in this paragraph, distinguishing between three forms of transparency:

- Recognizability of relations and positions (further set out in articles 7.1.2 to 7.1.4)

- Mandatory internal notification with or prior approval from the Board of Directors of an institution (further elaborated in Article 7.1.5).

- Mandatory disclosure in the Healthcare Transparency Register (further elaborated in paragraph 7.2).

The requirements for these three forms of transparency do not apply to all financial relations. When applying the transparency rules, it is crucial to always clearly establish the nature of the financial relations and which parties are involved. In the relevant provisions of this section, this is described as clearly as possible.

Sub-section 7.1.2 – Disclosure by organiser of an event
Healthcare professionals must also, prior to a meeting, be informed that it is (partly) brought about with financial support from one or more authorisation holders. This information may be relevant in assessing whether or not to participate in the meeting. Also during the meeting itself, the organiser must make it known that the meeting is sponsored and by which authorisation holders. If the organisation offers authorisation holders the opportunity to organise their own part of the program during or parallel to the main program (such as a satellite meeting), this should also be clear to the participating healthcare professionals. They should have a clear understanding in advance and during the meeting of which part of the program is organised by whom. Patient organisations also need to be transparent about the sponsorship received from authorisation holders (based on the Code of Conduct of the Patient Federation regarding fundraising and sponsorship).

Sub-section 7.1.3 – Disclosure of relations
Article 7.1.3 establishes the principle of transparency: for attendees of a meeting and readers of scientific articles, it must be clear in advance what affiliations the speakers or authors have with authorisation holders. This requires cooperation from the involved healthcare professionals. Organiser of events and publishers of articles will have to rely on the disclosure provided by the healthcare professional regarding their relations with the industry. In this context, it can be expected that the healthcare professional specifies for which authorisation holders they have performed activities as an advisor, researcher, or in other capacities in the preceding four years. This timeframe aligns with the disclosure of financial relationships in the Healthcare Transparency Register (retention period of 3 years preceding the current year).

In line with the Policy Rules on Inducements Medicines Act (*Beleidsregels gunstbetoon Geneesmiddelenwet)*, as of 23 January 2012 the Code of Conduct contains the obligation that healthcare professionals also disclose connections with parties other than authorisation holders. This is in line with the principle that inducement extends beyond just the relationships between healthcare professionals and authorisation holders. It also corresponds to the Code for the prevention of improper influence through conflicts of interest,[2] which also extends beyond interests with the pharmaceutical industry.

For the method of disclosing these relations, reference is made to the format of the disclosure slide for speakers at refresher training meetings (Appendix 1 of these Explanatory Notes).

[2] The Code was drawn up by: Koninklijke Nederlandse Akademie van Wetenschappen (KNAW), Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst (KNMG), Gezondheidsraad (GR), Centraal BegeleidingsOrgaan (CBO) and Nederlands Huisartsen Genootschap (NHG). The code can be downloaded through the websites of these organisations.

Sub-section 7.1.4 Recognisability of authorisation holder representatives
In light of the principle of transparency, it is important that healthcare professionals at meetings or on a social media platform know who they are dealing with and what interests are at play. Therefore, article 7.1.4 stipulates that present representatives of authorisation holders must be identifiable as such, for example, through a badge.

Sub-section 7.1.5 Internal transparency
Many healthcare professionals work in organisations, forming part of a larger organisational structure. In addition to the responsibilities that individual healthcare professionals bear for providing good care, it must also be ensured that systematic monitoring, control, and improvement of the quality of care is taken care of within the larger organisational structure. The ultimate responsibility for this lies with the board of the organisational entity. These board members must be aware of certain financial relationships that healthcare professionals working in the institutions may have with authorisation holders, and in certain cases, they may need to give their permission for such relations. The term "board of directors" is also considered to include those who, under another title, bear ultimate responsibility. For fully independent healthcare professionals working solo, these rules are not applicable, as they are fully aware of and responsible for their own actions.

The financial relations that the board of directors must be informed of include hospitality as defined in articles 6.4.4 under a, 6.4.6 under 3, and 6.4.8 under 2, services as defined in article 6.3.2, and sponsorship as defined in article 6.5.3. In the case of hospitality, there is an obligation to report. This applies both to individual agreements with healthcare professionals as well as for sponsored gatherings, such as medical department events or grouping of professionals, for which the involved healthcare professional is (partly) responsible. The conditions for this are detailed in clause 1.

For entering into service and sponsorship agreements, prior approval from the Board of Directors is required. The conditions for this are detailed in sections 2 and 3.

Reporting Hospitality
When a healthcare professional enters into an agreement with an authorisation holder regarding reimbursement of costs for participating in a meeting as per articles 6.4.6 under 3 and 6.4.8 under 2, this must be reported by the healthcare professional to the Board of Directors (clause 1). This also applies if the authorisation holder does not reimburse the costs to the healthcare professional but directly bears them (resulting in the healthcare professional not being billed for these costs). When an authorisation holder sponsors a gathering as defined in article 6.4.4, the healthcare professional (partly) responsible for the agreement must report this to the organisation for whom the gathering is relevant. In all cases, agreements must be documented in writing. The reporting obligation does not apply to the participation of an individual healthcare professional in an event organised by a third party and sponsored by one or more authorisation holders.

It is possible for a healthcare professional to be associated with multiple organisations. In such cases, hospitality must be reported to the institution where they are predominantly employed.

Permission (and possibly reporting) for services and sponsorship
If a healthcare professional or a grouping of healthcare professionals enters into a service agreement as defined in article 6.3.2 or a sponsorship agreement as defined in article 6.5.3 with an authorisation holder, a stricter regime applies. In these cases,

reporting alone is not sufficient. In such situations, there must be demonstrable prior approval for entering into the respective agreement from the Board of Directors. This approval requirement applies not only to employed healthcare professionals but also to healthcare professionals working on other bases, e.g., as self-employed medical specialists based on an admission agreement. The approval requirement also applies to groupings of healthcare professionals that are related to the organisation, such as a department, a division, the 'MSB' (*Medisch Specialistisch Bedrijf*), or a research foundation.
Since article 6.5.3 under c prevents a sponsorship relationship between an authorisation holder and an individual professional, the contracting party for sponsorship will always be a grouping of healthcare professionals or organisation. If the contracting party is the healthcare organisation itself, and the Board of Directors signs the agreement on behalf of the organisation, it is established that approval has been given. In all other cases, the Board of Directors must agree to the agreement.

Approval must be evidenced by the signature of or on behalf of the Board of Directors on the agreement. This signature indicates that the Board of Directors agrees with entering into the respective service or sponsorship agreement as such. The co-signature does not necessarily mean that the Board of Directors becomes a full-fledged contracting party to the agreement, in the sense that it is also liable for the complete execution of the agreement.
If and to the extent that Boards of Directors want to internally delegate the granting of approval, they are free to arrange this at their discretion. However, authorisation holders must be informed of to whom (and possibly under what conditions) this authority has been delegated. They should be able to easily determine whether the required prior approval by the Board of Directors has been obtained. In practice, a healthcare professional may be associated with more than one healthcare organisation. In such cases, obtaining approval from multiple Boards of Directors could lead to a significant administrative burden. Therefore, in such cases, the approval of one Board of Directors is sufficient, namely the Board of Directors of the organisation for which the respective agreement is most relevant. The Board of Directors of the other organisation where the healthcare professional also performs work part-time should be informed by the involved healthcare professional (under 5).

From case to case, it will have to be determined in which healthcare organisation – as most relevant – approval must be obtained, and in which organisation the interaction only needs to be reported. For example: if it concerns a project carried out by a healthcare professional on behalf of an authorisation holder who works in two organisations, approval is required from the Board of Directors of the hospital in which that project is being carried out. The healthcare professional must report the service to the Board of Directors of the other hospital. Another example is the situation in which a group of medical specialists enters into a sponsorship agreement with an authorisation holder for the financing of, for example, a training position. The organisation where the training mainly takes place is then the most "relevant," and approval from the Board of Directors must be obtained there. If a specialist involved in that group also works in another organisation, this sponsorship must be reported in that hospital.

For authorisation holders, it is important that the execution of a service or sponsorship agreement can only proceed if it is co-signed by or on behalf of the competent board of the hospital. Before executing the relevant agreement, the authorisation holder must verify that it has been co-signed by or on behalf of the competent board. Hospitals will have established procedures for this, as set out in section 6 of this article.

Obligations for organisations
Organisations have a separate obligation to comply with the provisions of the Code of Conduct regarding internal reporting and prior approval. According to section 6 of this article, there must be:

- a (central) process in place for approving sponsorship and service agreements, including any delegated authorities in this regard;
- (central) agreements regarding the administration and financial execution of approved sponsorship and service agreements, and how to hold accountability for them;
- the establishment of a (central) administration of approved and reported sponsorship and service agreements.

According to section 1, the second paragraph, there must be a process for reporting payments or reimbursements of costs for provided hospitality to the Board of Directors of the organisation, including any delegated authorities in this regard. It is evident that clear information on this process is provided to healthcare professionals, and attention is paid to its feasibility. This may include a clear format for the information that needs to be provided and under what timelines. The Code of Conduct does not impose specific requirements on how organisations should implement the provisions of section 1, the second paragraph, and section 6. For illustration, reference is made to the Governance Handbook for financial relations between healthcare professionals and industry. This Handbook was developed in 2023 and is endorsed by the NVZ, NFU, and FMS. In general, it is emphasised that privacy legislation should also be complied with in the context of reporting and approval procedures. It is recommended to take this into account when entering into agreements, for example, by specifying that both parties give mutual consent to process the personal data included in the agreement as necessary for the execution and settlement of the agreement. Due to the time required to complete the reporting and approval procedures, it is important that all parties involved are aware that information (written agreements or contracts) should be available in a timely manner.

Section 7.2 – Disclosure of financial relations
In 2012, the CGR adopted rules regarding the disclosure of financial relations. The purpose of these rules is to meet the societal need for insight into the financial relations between authorisation holders on the one hand and (groupings of) healthcare professionals, healthcare organisations, and patient organisations on the other hand. The underlying principle is that this insight supports citizens in assessing healthcare professionals, healthcare organisations, and patient organisations, as well as their services and/or advice. To achieve this, a central public register has been established in which the relevant financial relations are disclosed, known as the Healthcare Transparency Register.

The rules for disclosing financial information align with the general principle that authorisation holders, healthcare professionals, healthcare organisations, and patient organisations should be transparent about their relations that may lead to conflicts of interest (see Article 7.1.1 of the Code of Conduct). Thus, disclosure of the information is a necessary condition for the execution of the involved financial relations and must be documented in writing in the underlying agreement based on the Code of Conduct. This also forms the basis for the processing of personal data of the involved healthcare professionals, where they themselves are a party. The data

remains public for 3 years, after which it is removed from the Healthcare Transparency Register.

Sub-section 7.2.1 – Disclosure in Healthcare Transparency Register

This article determines which financial relations need to be disclosed publicly. This concerns financial relations that require a written agreement based on the Code of Conduct. These involve financial relations between an authorisation holder on the one hand and healthcare professionals and patient organizations on the other hand. In practice, financial relations are often established with legal entities associated with professionals, such as groupings of healthcare professionals (such as a scientific association of healthcare professionals, a foundation in which healthcare professionals collaborate, or a company of which one or more healthcare professionals are shareholders) and healthcare organisations (such as hospitals) where healthcare professionals work. The disclosure rules also encompass these financial relations.

The obligation to disclose applies only if the total amount concerned with (one or more) financial relations between a specific authorisation holder and a specific recipient exceeds €500 per calendar year. This threshold aligns with the proportionality principle, balancing on the one hand the protection of privacy of the involved healthcare professionals and the administrative burdens imposed by the disclosure rules, and on the other hand the importance of being transparent about financial relations. This threshold does not imply that disclosures cannot be made for financial relations of lesser value.

Exempt from the disclosure requirement are all forms of financial contributions to research subject to the Dutch Medical Research Involving Human Subjects Act (WMO) or the Non-WMO-regulated Research Framework. These forms of research, including their funding, are evaluated by a medical-ethical (or nWMO) review committee and disclosed through other means. This means that financial relations related to these types of research do not need to be reported in the Healthcare Transparency Register, regardless of whether these financial relations arise from service remuneration or sponsorship.

According to the EFPIA Code of Conduct, the exception for disclosure does not apply to financial relations related to retrospective non-intervention research (even though this research falls under the Non-WMO-regulated Research Framework). Additionally, the EFPIA Code stipulates that expenditures on research and development must be published annually as an aggregated amount per EU member state. The obligation of the EFPIA Code has been adopted as a binding decision by the Association of Innovative Medicines (VIG) and applies to companies affiliated with the VIG.

In the fifth section, it is clarified that the applicability of the disclosure rules does not depend on whether agreements are made directly between an authorisation holder and a healthcare professional (or grouping of healthcare professionals or healthcare organisation) or patient organization, or whether there is a third party in between. In certain occurrences, the agreement in which financial relations are laid down, are not concluded in name of an authorisation holder, a (grouping of) healthcare professional(s), healthcare organization or patient organization but is concluded in the name of a third party who has received a mandate from one of the aforementioned parties. For example, a professional congress bureau that organizes a congress on behalf of a scientific association for which the bureau concludes

contracts with sponsors, or a bureau that organizes an event on behalf of an authorisation holder and concludes contracts with a healthcare professional who will give a contribution as a speaker. Transparency focuses on the clarity of financial relations between authorisation holders on one hand and the parties involved in the decision-making process regarding medicinal products and patient organizations using these products on the other hand. Therefore, the transparency rules are concerned with these parties, not the third party enlisted to execute the agreement (partially). According to section 5, the transparency rules must be applied as if the financial relations were entered into by the authorisation holder and the (grouping of) healthcare professional(s), the healthcare organization or the patient organization, regardless of the intervention of that third party. In the aforementioned examples, the financial relations are deemed to have been entered into between the scientific association and the authorisation holders/sponsors, or between the authorisation holder and the healthcare professional/speaker. The third party that was "in between" essentially disappears. The same principle applies in case a healthcare professional does not enter into a service agreement in his own name but in the name of the legal entity of which he is a director (see Article 7.2.2 section 2).

This is different if, on behalf of an authorisation holder, a bureau conducts market research among healthcare professionals who are chosen and approached completely independently of the authorisation holder, and where the anonymity of the authorisation holder and healthcare professionals is guaranteed vice versa. In this case, no direct relationship is established between the authorisation holder and the healthcare professional, and it will usually involve very limited services and amounts. This also applies if an independent conference organizer is sponsored by multiple authorisation holders and independently contracts healthcare professionals for giving presentations, with the authorisation holder not knowing which healthcare professional will benefit from its contributions.

Not all financial relations disclosed in the Healthcare Transparency Register relate to Dutch healthcare. In the Netherlands, there are relatively many international associations for healthcare professionals that organize large international conferences sponsored by (the international headquarters of) authorisation holders. The financial relationship with these international associations will also need to be published in the Healthcare Transparency Register with the Dutch Chamber of Commerce number of the association, even though the often significant sponsorship amounts have an international context and do not pertain to Dutch healthcare.

Section 7.2.2 - Data to be disclosed

This article lays down which data needs to be disclosed. Regarding the name of the authorisation holder (section 1, part c), the corporate name is used, without distinguishing whether the payment was made from the Dutch or foreign branch of the corporation.

The personal data of healthcare professionals are disclosed through their BIG number. The legal basis for this is defined in Article 13c, section 1 of the Healthcare Professions Act (*Wet op de beroepen in de individuele gezondheidszorg*), in conjunction with Article 13a of the Decision Medicines Act (*Besluit Geneesmiddelenwet*).

There may be situations where the agreement is not concluded between the authorisation holder and the healthcare professional who will perform the services, but between the authorisation holder and a grouping of healthcare professionals or

healthcare organisation where the healthcare professional is employed (such as a hospital), or between the authorisation holder and a legal entity of which the healthcare professional is the director/shareholder (such as a consultancy company owned by a medical specialist). In such cases, the part of the total amount paid based on the agreement that can be attributed to the respective healthcare professional is reported in the name of that healthcare professional. It is not relevant to which bank account the authorisation holder deposited the amounts or whether the healthcare professional was the actual beneficiary and received the amounts. Any remaining amount (the total amount paid by the authorisation holder minus the amount attributable to the healthcare professional) must be reported in the name of the grouping, healthcare organisation, or legal entity. This can include certain overhead costs. This approach ensures optimal transparency and prevents double reporting.

Section 7.2.3 – Data submission

The main rule is that the authorisation holder is responsible for submitting notifications to the Healthcare Transparency Register.

An exception applies in the event that a healthcare professional or grouping/healthcare organisation interacts with an authorisation holder:

1. located outside the Netherlands, or
2. that is not a member of any of the sector organizations affiliated with the CGR.

Based on the EFPIA Code of Practice, authorisation holders must comply with the national transparency rules of European countries, even if they are not established in the respective country. Therefore, the agreement with recipients practicing and/or based in the Netherlands should specify that the relevant financial relationship will be directly submitted to the central register by the foreign authorisation holder or disclosed through the affiliated entity established in the Netherlands. For financial relations not submitted to the central register in this manner, the obligation of disclosure lies with the recipient, unless expressly agreed otherwise between the parties.

Whether an authorisation holder is affiliated with one of the sector organizations associated with the CGR can be verified at https://www.cgr.nl/nl-NL/Stichting-CGR/Deelnemers.

The procedure for data submission is determined by the TRZ foundation. More information can be found at https://www.transparantieregister.nl/home. If an agreement spans multiple years, it is recommended to report the fees invoiced in the specific year separately in the year of invoicing in the Healthcare Transparency Register.

In the fourth paragraph, the obligation for authorisation holders is established to implement within the company an adequate procedure to assess the disclosure of their financial relations in light of the provisions of these guidelines. This includes a description of the methodology, such as how multi-year agreements are disclosed, how VAT is handled, and how foreign currencies are taken into account. In this regard, refer to Article 4.3 of the Code of Conduct.

Sub-section 7.2.4 – Duration of public disclosure
Data regarding a financial relationship will be made public for a period of 3 years. After 3 years, it is assumed that information about the financial relationship is no longer sufficiently current and, therefore, not relevant, considering the privacy interests of the healthcare professional. The data will be removed from the central register by the Healthcare Transparency Register Foundation three years after the initial publication.

Sub-section 7.2.5 – Written agreement
Transparency is the objective of this chapter of the Code of Conduct. In order to achieve transparency, obligations between parties need to be documented in writing, and agreements should include specific provisions regarding transparency.

Section 7.2.6 – Request for documentation
The CGR annually publishes, at the time of the disclosures by the Healthcare Transparency Register, an analysis of a number of interactions reported by the pharmaceutical sector in the Healthcare Transparency Register. The purpose of this analysis is to provide a better understanding of various forms of collaboration in the sector in relation to legislation and self-regulation, and to further clarify these interactions. The clarification also serves as a basis for identifying points of concern and trends.

For this annual detailed analysis, the CGR may request, from authorisation holders who have disclosed contracts, documentation about these contracts. This may include agreements underlying activities such as sponsorship and services. Authorisation holders who receive such a request from the CGR are obligated, in accordance with Article 2.2, to provide the requested documentation within the timeframe specified by the CGR.

The CGR will exercise the utmost care with requesting documentation and with communicating externally about this information. This means that, insofar the CGR uses the provided information in external communication, it will be done in a manner that:
- Maintains the anonymity of the parties involved in the financial relationship and prevents their identification from the communication.
- Avoids including any data that can be traced back to natural persons.
- Ensures the confidentiality of commercially sensitive information.

Individuals at the CGR involved in requesting documents and analyzing them will treat these documents confidentially and will use the information solely for the purpose of this analysis. The texts drafted related to a specific financial relationship will always be submitted to the relevant authorisation holder for verification before publication.

Chapter 8 – Transitional law

Annex 1: Disclosure slide

Format of disclosure slide for speakers at refresher training meetings

Disclosure of speaker's interests	
No (potential) conflict of interests	
Relations that could be relevant for the meeting[1]	**Company names**
• Sponsorship or research funds[2] • Payment or other (financial) remuneration[3] • Shareholder[4] • Other relation, viz. …[5]	• • • •

Explanatory notes

Under the rules on pharmaceutical advertising (the Dutch Medicines Act (Policy Rules on Inducements) and the Code of Conduct of the CGR) every speaker during a refresher training meeting should be transparent with regard to his/her relations with the industry. The Health and Youth Care Inspectorate (the "IGJ") has found during an investigation into the level of compliance with the advertising rules during refresher training for medical specialists (November 2012) that speakers are insufficiently complying with their obligation to disclose their ties with the industry prior to their presentation. The IGJ has announced that it will actively monitor the disclosure of ties between speakers and pharmaceutical companies.

In order to help speakers comply with their obligation to be transparent with regard to their ties during refresher training, the KNMG and the CGR have developed this format for a disclosure sheet after consultations with the IGJ. The format links up with existing obligations to disclose (financial) ties with the industry, such as the Dutch Code to Prevent Inappropriate Influence due to Conflicting Interests prepared by the KNAW/KNMG (to be further referred to as: the KNAW Code), the rules on transparency in the Code of Conduct of the CGR (Chapter 7) and the publication of clinical trials in the Dutch Trial Register. The format developed by the European Union of Medical Specialists (UEMS) has also been looked at.

Speakers are expected to show a disclosure sheet in accordance with this format (if necessary, in their own layout) before they start their actual presentation. The audience should be able to familiarise themselves with the content of the disclosure sheet. The disclosure sheet must also be part of the hand-outs of the presentation and will also be used when reviewing the refresher training for accreditation purposes.

The various fields of the disclosure sheet will be explained in more detail below.

1. Relations that may be relevant for the meeting

Here, the speaker must disclose relations with companies in the pharmaceutical industry, the biotechnological industry, the medical device industry and the medical food industry. These are the relations that are also considered relevant for registration in the Dutch Trial Register. Contributions from governments and not-for-profit organisations (funds) do not come under this.

2. Sponsorship or research funds

The KNAW Code provides the following: “Externally funded research may lead to a conflict of interests. In many fields no public sources, or hardly any public sources, are available (such as funding by universities or the NWO, *Nederlandse Organisatie voor Wetenschappelijk Onderzoek,* the Dutch Organisation for Scientific Research) and research is only possible through contract research, where the research is funded by the government or industry and the research question is usually very accurately defined. The initiative for contract research can be taken by either a university or a financier, but the universities guarantee an independent implementation (including the researchers' freedom to publish and full accountability for the funding sources). Universities have developed standard contracts for this type of research and the KNAW has drafted a Code of Conduct (recorded in its opinion "Science to Order" from 2005). Even so, such a relation can still make a scientist more susceptible to the interests of the party funding the research. For this reason the risk that this form of dependence may make a scientist vulnerable to a conflict of interests must always be borne in mind.”

If the speaker has been (or is still) involved in research or in a project (co-)financed by one or more companies (see above under point 1), he/she is expected to report this in the disclosure sheet. All sums received in excess of € 500 (per company, cumulatively per year) in the past 4 years must be disclosed. Usually it will concern data which will be disclosed via the Dutch Trial Register or the Dutch Healthcare Transparency Register.

3. Payment or other (financial) remuneration

The KNAW Code provides the following: “Personal financial interests are the most obvious reason why conflicts of interests arise. A good example is a member of an advisory committee who is employed by a company that operates in a field targeted by the advice […]. It is also imaginable that an expert has personal financial interests in a particular opinion in view of his or her advisory role for a company or for an interest group.”

If the speaker provides (or has provided) services for one or more companies (on the basis of, for instance, a contract for services or a contract of employment) (see at point 1 above), he/she should disclose this if the payment represents a value in excess of €500 (per company, cumulatively per year) and the services have been provided within a period of 4 years prior to the date of the presentation. Consultancy services may for instance have been provided (e.g. on a company's advisory committee), an article may have been written at the instruction of a third party or a presentation may have been held. The fact that the speaker him-/herself is the recipient of the fee is not decisive. The relation should also be mentioned if payment has not been made to the speaker directly, but has been granted to another legal person (e.g. the work practice of the speaker, a (research) foundation, a healthcare institution/hospital or an organisational or speakers' agency). The relevant data will generally be included in the Healthcare Transparency Register.

4. Shareholder

Holdings of shares or options in a company may also point to a personal financial interest, which may give rise to a conflict of interests and must be disclosed, but only if a "substantial" interest is held in a company. A substantial interest exists if the speaker holds 5% or more of the shares in the company (including the shares held by his/her partner) and also if the speaker has such an interest via another legal entity. The definition used in the tax law has been linked up with here.

5. Other relations, viz. …

There may also be other relations which could give rise to some form of conflicting interests, such as personal relations with people from a speaker's immediate vicinity (for instance a partner and/or children) who work for a company which stands to gain from a certain representation of matters by the speaker. The speaker is considered to report this in the disclosure sheet.