Explanatory Notes
to the Dutch Code of Conduct for Pharmaceutical Advertising
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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, additions and decisions 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.

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 with non-healthcare professionals (section 6.1) and patient organisations (section 6.6).

Chapter 2 – Supervision

The Code Commission and the Commission for Appeals of the CGR have been charged with supervising the Code of Conduct. Since 2012 the Dutch Inspection Board for the Public Promotion of Medicinal Products ("*Keuringsraad"*) (to be further referred to as: the Inspection Board) has fulfilled the front desk function of the CGR as well as performing a number of supervisory duties.

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").

3.1.d Definition of "healthcare professional"

The term "healthcare professional" is defined in section 82(1) (a) of the Dutch Medicines Act. 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. 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. The Dutch Minister of Public Health, Welfare and Sports has decided that these professional groups must also come under the term "healthcare professional" for the purpose of advertising of medicinal products. The newly chosen definition links up with the definition as used in the Inducements (Medicines Act) Policy Rules (*Beleidsregels gunstbetoon Geneesmiddelenwet)*. 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, pharmacist's assistants and nurses with the following BIG registrations:

Specialised nurses (gespecialiseerde verpleegkundigen):
- Diabetes nurses
- Pulmonary care nurses
- Oncology nurses
  Diabetes and pulmonary care nurses may only be considered as healthcare professionals as per 1 May 2014 if their BIG registration states that they have prescription authority.

Nurse specialists (NS) (verpleegkundig specialisten):
- NS providing acute care in the case of somatic diseases;
- NS providing chronic care in the case of somatic diseases;
- NS providing preventive care in the case of somatic diseases;
- NS providing intensive care in the case of somatic diseases;
- NS providing mental health care.

Physician Assistants (PA)
They are included in the Quality Register of the Netherlands Association of Physician Assistants (NAPA), see:
http://napa.artsennet.nl/Opleiding-Registratie-1/Register-inzien.htm

Physicians in training to become a specialist (*artsen in opleiding*) are also considered as healthcare professionals within the meaning of the Code of Conduct.

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).

3.1.i 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 is 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
Chapter 5 contains the provisions included in chapter 5 of the previous Code of Conduct, but has been expanded to include the rules of conduct on information previously occurring in the Elaboration of the Distinction between Advertising for and Information on Medicinal Products (*Nadere invulling van het onderscheid tussen reclame en informatie voor geneesmiddelen)* (section 5.1.3) and the Guidelines for Information on Prescription-Only Medicines (*Leidraad Informatie UR-geneesmiddelen)* (sections 5.7 and 5.8).

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 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.

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

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 decisions 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 decisions A10.011 dated 25 February 2010 and A11.107 dated 7 November 2011).

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.

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 decisions 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 (decisions A12.016 of 7 March 2012 and A12.084 of 20 September 2012), but information on these unauthorised products *is* permitted (decisions A12.053 of 21 June 2012 and A12.108 of 30 October 2012) as well as advertising for the service of “magisterial preparation” (decision 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.

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.

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. 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 5.4.1 – 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.)

This rule will take effect on 1 July 2014.

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 decisions 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 decisions 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. Social media have technical possibilities for this purpose by means of pre-registration and/or the use of user names and passwords.

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).

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)*).

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.

Section 5.8.10 – Information to a patient or carer
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 health care professionals) who are involved in the administration of the prescription-only medicinal product.

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).

Chapter 6 – Inducements and other financial relations
Chapter 6 contains the rules on inducements included in sections 12 up to and including 22 of the previous version of the Code of Conduct and in the Elaboration of the Standards for Inducements of the CGR (*Uitwerking Normen Gunstbetoon)*.

In practice many and divers relations exist between pharmaceutical companies on the one hand and healthcare professionals and non-healthcare professionals on the other. However, this does not mean that all these relations can, by definition, be considered as inducements. 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 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. These Explanatory Notes explain what 'improperly' means. Transparency and reasonableness are the key terms in this respect.

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 form many 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 Code Commission's decisions (see for instance decision numbers A12.021 and A12.034), in which certain inducements were considered to be a special form of advertising. The elements used to distinguish advertising from information (sub-section 5.1.3) must also be considered here. This will be explained in more detail below.

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. A pharmaceutical company's co-operation in the area of a medication therapy can go further with a care professional than with a patient (who is a 'hands-on' expert), without there being a sales promotion object. It is important to establish to what extent the person involved can exert influence on the prescription, supply or use of a medicinal product as a result of, for instance, his informing or educating role for patients or patient groups. 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.

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. Co-operation 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 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. 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.

If the payment (of 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 is in keeping with market rates can be determined on the basis of the customary rates charged by the care professional involved. In addition, the venue must be suitable. Payments to patients (who are 'hands-on' experts) must generally remain limited to a reasonable payment of expenses in cash or in the form of a gift with a minimal value that is related to the medical treatment or general health of the patient concerned. A payment for participation in scientific conferences will generally take place only via the conference organisation (so not to non-healthcare professionals directly) and will

thus accrue to all the participants in the conference. It is important that the payment does not exceed the direct costs of participating in the conference, inclusive of any coffee/tea and/or lunch breaks and exclusive of the individual travelling and/or accommodation expenses. The venue must also be suitable. Payment for participating in the non-necessary parts of the conference will generally have a sales promotion object.

Sub-section 6.1.3 – Relations with non-healthcare professionals
The exceptions to prohibited inducements relate only to relations with healthcare professionals. This means that financial relations with non-healthcare professionals can be formed only if there is no sales promotion object (see the explanation to sub-section 6.1.2 above).

Under sub-section 6.1.3 financial relations with non-healthcare professionals must comply with the tenor of the requirements for relations with healthcare professionals of sections 6.2 through 6.5. This, amongst other things, means that their co-operation must be recorded in a written agreement, with the accompanying requirements.

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 decision A10.090 of 13 September 2010).

Sub-section 6.2.2 – Permitted 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. Because an authorisation holder must be able to draw attention to several products, this maximum applies per therapeutic class and per authorisation holder. As for the value of a gift, the retail value including VAT must be started out from. The amounts will have to be reviewed on a regular basis in view of the inflation.

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. 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 6.2.4 – Discounts and bonuses

Section 94 under d of the Dutch Medicines Act provides that discounts and bonuses relating to the purchase of medicinal products by natural or legal persons within the meaning of section 62(1) (a), (b) and (d) of that Act 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 decision A10-047 of 6 July 2010.

Section 6.2.5 – 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. 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).

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.

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).

Sub-section 6.3.2 – Written agreement
The service agreement must be recorded in writing. 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 to be provided;
b. in what capacity the services will be provided;
c. what the payment (of fees and expenses) will be;
d. how many hours will be spent on providing the service;
e. where the services will be provided;
f. when the services will be provided.

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.

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 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.

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).

Having considered everything, the CGR has arrived at the following reasonable hourly rates for healthcare professionals in consultation with the IGZ (Dutch Healthcare Inspectorate) and the Dutch Ministry of Health, Welfare and Sports.[2] The CGR has not set standard rates for all the healthcare professionals (such as the various types of nurses) and other care providers and service providers with whom pharmaceutical companies co-operate. The proposed framework offers sufficient guidance to decide what a reasonable payment is for the other disciplines as well (such as a nursing specialist or a specialised nurse in relation to an obstetrician). The rates have applied since February 2014. Most of the rates link up with the hourly rates previously set by the IGZ in its Report “Advisory Boards for the Pharmaceutical Industry Tested Against the Rules on Advertising” (December 2012), which the CGR also followed in December 2012 (albeit with the exception of accommodation expenses). The new rates make it clear that there is no reason for any further differentiation based on special qualifications (the IGZ had used a margin of 25% for this purpose).

Medical specialist	€ 140
GP (huisarts)	€ 100
Pharmacist	€ 100
Hospital pharmacist	€ 140
Dentist	€ 85
Obstetrician	€ 75
Professor (hoogleraar)	€ 200

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). The starting-point is that the costs must be appropriate for the services to be provided and must stay within reasonable bounds.

[2] Based on a report prepared by KPMG for the Dutch Healthcare Authority (*Nederlandse Zorgautoriteit)* on methods for determining the labour costs in primary healthcare: http://www.nza.nl/104107/138040/NZa_Methodieken_ter_bepaling_van_de_'arbeidskosten'_eerstelijnszorg.pdf.

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.

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.

Section 6.3.5 - Research with medicinal products
Cooperating in research with medicinal products is a form of services. Sub-section 6.3.5 provides that the Code of Conduct applies to research with medicinal products, unless that research is subject to the Dutch Medical Research Involving Human Subjects Act (to be further referred to as: the WMO) and has been, is being or must be reviewed and approved by a recognised ethics committee METC or the CCMO (the Dutch Central Committee on Research involving Human Subjects) under section 3 WMO.

The question whether or not research is subject to the WMO must in the first place be determined by the METCs and/or the CCMO. The CGR is passive on this point. For a complete picture it is observed that the WMO applies to research meeting the following two criteria:
a. it concerns medical-scientific research, and
b. the subjects are subjected to acts and/or are required to behave in a certain way.

The law does not define the term ”medical-scientific research”. The CCMO, however, has drafted a separate guidance on this subject (November 2005). For the text of this guidance and other information on the scope of the WMO, reference is made to www.ccmo-online.nl.

In cases where a recognised independent body has reviewed research on the basis of the relevant provisions of the WMO (and possibly the GCP), it would not be appropriate if the CGR reviewed the objects, soundness and design of this research again. This means that an objection can always be made to research (or its performance) in every possible situation:

1. The research is subject to the WMO

    a. and has been approved by a METC under the WMO. In that case an appeal can be taken to the CCMO under section 23 WMO. The appeal must be taken within 6 weeks, but failure to take an appeal within that time-period may be excused, if the interested party only learnt of the approval some time after it was granted;
    b. and has been reviewed by a METC on the basis of the WMO, but has not been approved. The research may not be performed. If it is performed nevertheless, the IGZ can take enforcement action (see the penalty provisions in the WMO) and a complaint may be lodged with the Supervisory Commission of the GFB (the Foundation for the Code of Conduct for the Pharmaceutical Industry, Gedragscode Farmaceutische Bedrijfstak);
    c. and has been approved under the WMO. If facts/circumstances occur after approval has been obtained (during the performance of the research) entailing that the research cannot (or can no longer) be performed in accordance with the protocol, the researcher must notify the relevant METC of the relevant change in the protocol, which must reassess it (section 10(1) WMO, also see sub-sections 4.5.2, 3.3.7 and 3.1.2 of the GCP). If this is not done, the Dutch Health Inspectorate may step in (see the penalty provisions of the WMO) and a complaint may be lodged with the Supervisory Commission of the GFB.

2. If the research is not subject to the WMO, the research must comply with the rules of sub-section 6.3.5.

Complaints about communications which relate to the research, but which have not been, and did not have to be, considered in the assessment by the reviewing METC or the CCMO, can be submitted to the Code Commission of the CGR.

Research not subject to the WMO is mainly performed to gather information about physicians' experiences with a registered (new) medicinal product or with the use of a medicinal product for a newly registered indication. The findings obtained may form a valuable addition to the data already known (often obtained in clinical conditions only) with regard to the efficacy and safety of the medicinal product. It will mostly concern observational/non-interventional studies into e.g.:

a. the use of the product in practice in relation to:
    i. other, non-medicinal treatments;
    ii. living habits;
    iii. ease of use/ patient information;
b. compliance;
c. efficacy in daily practice;
d. development of measuring instruments or methods.

The relation between a physician and a pharmaceutical company may be considered as "services", with the co-operation in the research not subject to the WMO constituting the service, for which the physician receives payment.

The possible areas of tension can basically be subdivided into two main categories, viz.:

a. is the research not subject to the WMO objectively and in actual fact a form of "undesired influencing"?; and/or

b. is there a reasonable proportionality between the services provided by the healthcare professional (prescriber) and the payment received for it?

When approaching these aspects, allowance must in particular be made for the main objectives of the (legal) rules in this area, which provide that a rational prescription-behaviour must be encouraged as much as possible and that any undesired influence on the prescription behaviour must thus be prevented.

It is also important to realise that (here, too), black-and-white situations occur less frequently than shades of grey. For instance, a completely legitimate and scientifically sound and thorough study not subject to the WMO may have some promotional 'value'. The opposite is also possible, viz. that a purely promotional campaign also produces very useful scientific information about the medicinal product.

The review criteria under a up to and including i of sub-section 6.3.5 have been taken from Straus et al., Post-Marketing Surveillance: Scientific Research or Pharmaceutical Promotion? in "GP and Science" (*Huisarts en Wetenschap)* 1999; 42(11), pp. 505- 508). Also see the *Bekanntmachung über die Zulassung und Registrierung von Arzneimittels, Empfehlungen zur Planung und Durchführung von Anwendungsbeobachtungen*, 12 November 1998 (*Bundesinstitut für Arzneimittel und Medizinprodukte*). These review criteria serve as tools to determine in a more objectified way whether research not subject to the WMO is not a form of promotion in disguise. Although the intentions of the producer(s) and physician(s) involved play a part here, they are not, in themselves, decisive. The design and the methodology based on the research question must, for instance, be such that the research question can be answered by the research. So the review criteria only serve as aids and the final judgment will depend on all the circumstances of the case. For instance research not subject to the WMO encouraging a physician to start prescribing the medicinal product involved in order to receive payment for his participation in that research will be a 'counter-indication'.

Sub-section 6.3.6 – Review of research not subject to the WMO
Sub-section 6.3.6 imposes an obligation on authorisation holders to set up an adequate procedure within their companies, within the framework of which research not subject to the WMO is reviewed in the light of sub-section 6.3.5 in a standard way. In this regard reference is made to section 4.3, which provides that all authorisation holders must arrange for their promotional communications to be reviewed internally on their content by persons qualified to do so.

The internal procedure must at any rate contain the following elements:

1. Definition: What must be reviewed?
The internal review procedure must clearly indicate to what forms and types of research the procedure applies based on the following criteria:

a. The internal review procedure must apply to all (forms of) research with medicinal products, **unless** this research has been, is being or must be reviewed and approved by a recognised METC or the CCMO under the WMO.

b. The internal review procedure must set out which steps must be taken if there are doubts about the question whether certain research is or is not subject to the

WMO. The outcome of these steps must be that the decision as to whether or not the research is subject to the WMO is submitted to a recognised METC. If desired, a "fixed" METC can be designated for that purpose in advance.

c. The internal review procedure must apply to all (forms of) research with medicinal products to which the WMO does not apply, regardless of the name or designation under which this research is performed. Any activity aimed at gathering information about (the use of and experiences with) a medicinal product after its registration is covered by this requirement.

d. The internal review procedure must in any case apply to research activities:
   - in which healthcare professionals are involved,
   - who work in the Netherlands, and
   - who receive payment for their participation in the activity.

2. Procedure: Who is in charge of the review?

The internal review procedure must describe who is responsible for the internal review of research not subject to the WMO. In this respect the following requirements apply:

a. The following must be clearly described in the internal review procedure:
   - the name,
   - the function, and
   - the education/knowledge level

   of the person who is responsible for the internal review process. The expertise of this person must clearly appear from this description.

b. The internal review procedure must provide that the approval of a certain activity must be given by the responsible person in writing. Optionally, the procedure may provide that the approval must also be submitted to the medical director or general manager for agreement.

c. The internal review procedure must clearly provide that the research activities may start only after the required written approval has been obtained.

d. The internal review procedure must set out how long and by whom the information that is relevant for the review must be kept.

3. Criteria: against what criteria must the research be reviewed?

The review procedure must set out how the responsible person must review the research in the light of sub-sections 6.3.2, 6.3.3 and 6.3.5 of the Code of Conduct.

4. Other issues

The review procedure must set out in what way the procedure and any changes in it must be disclosed internally.

Sub-section 6.3.6 (c) ensures that authorisation holders are obliged to submit any research not subject to the WMO to the Code Commission for prior approval, if they do have not timely set up or do not possess an approved internal procedure as required under sub-section 6.3.6 (b).

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

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). 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 to healthcare professionals as part of conferences, symposia or other events, that the following conditions have been met: the hospitality

- must not exceed reasonable bounds; and
- must be restricted to the main object of the event;
- may extend only to healthcare professionals;
- may extend only to the travel expenses, accommodation costs and reasonable 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).

Within reasonable bounds

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 € 75. 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. 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).

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).

For healthcare professionals only
The hospitality may not extend to persons other than healthcare professionals. By way of illustration see the Code Commission's decision no. A07.017 dated 24 April 2007, in which an educational grant to nurses (who were not yet considered as healthcare professionals within the meaning of the Code of Conduct in 2007) was considered to be in violation of the Code of Conduct.

In practice, it regularly occurs that in addition to healthcare professionals within the meaning of the Code of Conduct, other persons involved (such as other care providers, care professionals, policy makers, journalists, researchers and representatives of patient organisations) are also invited to attend conferences and to enjoy (some) hospitality. The Code Commission has judged that this is permitted in specific circumstances, viz. when it concerns a meeting that is not concerned with the promotion of medicinal products and thus is not covered by the scope of the rules on pharmaceutical advertising. An important requirement in this regard is that the relevant non-healthcare professionals may not be involved in the prescription, supply or use of a certain medicinal product or in granting its market authorisation. The fact that the name of the authorisation holder may be advertised when offering hospitality does not change the conclusion that this in itself does not make this pharmaceutical advertising. See in this connection decisions A12.021 dated 5 April 2012 and A12.034 dated 23 May 2012.

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. 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, to the main objective of the meeting/manifestation? and
b. is there an objective justification for this location?

A location will be secondary to the main objective of the meeting/manifestation in terms of its facilities if it is not so attractive that it is likely that location itself is the main reason why healthcare professionals participate in the meeting/manifestation (e.g. a gourmet restaurant or luxury resort).

There may be an objective justification for a location 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.

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, scientific meetings within the meaning of sub-section 6.4.5 are possible for nurses and other relevant professional groups jointly. 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 targets 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 registration fees of a meeting/manifestation. 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, 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.

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, and provided that this does not exceed €500 per occasion, with a maximum of €1,500 per year (see sub-section 6.4.6 (1)). Because an authorisation holder must have the opportunity to contribute to increased knowledge on various therapeutic classifications or the products therein, this

maximum is applicable per therapeutic classification.

The last sentence of this option is designed to prevent healthcare professionals from taking unrestricted advantage of corporate hospitality. The maximum sums which a healthcare professional would be able to receive per therapeutic classification per year under sub-section 6.4.6 (1) is €1,500, and it is irrelevant whether this sum originates from one or more authorisation holders. If more than one authorisation holder is involved, it is the healthcare professional´s responsibility to observe the limits of the permitted hospitality.

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. It goes without saying that this must be based on a transparent and valid settlement and that the costs must be realistic.

The specific sums and percentages referred to in sub-section 6.4.6 are tailored to the Dutch situation, as the question whether the hospitality costs are within reasonable bounds is so closely linked to the local circumstances and the healthcare professional's background (and specifically the remuneration system and the tax aspects in the country where that health professional is based), that this aspect of the Code of Conduct cannot be applied to healthcare professionals residing or working outside the Netherlands.

Every meeting must, furthermore, comply with the requirements formulated in sub-sections 7.1.2 and 7.1.3, and (naturally) with the general requirement arising from sub-section 6.4.1 that the hospitality must be secondary to the main objective of the meeting and must be provided at a suitable venue. Whether these requirements have been met will have to be decided on a case-by-case basis, in which the relative length of the various parts of the programme will be an important factor.

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.

As of January 1, 2015 the agreement for providing hospitality directly to a healthcare professional, should be recorded in a writing and clearly set out the arrangements. The requirement of such a written agreement existed already in the occasion the authorisation holder sponsors the meeting itself (see sub-section 6.4.4 a). 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. This requirement does not apply if the hospitality covers only participation (including meals and drinks within reasonable bounds) in a

meeting organised by the authorisation holder, without compensation of cost for travel and / or hotel accommodation.

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 decisions 11.042, A13.063 and A13.068). After the amendment of the Inducements Medicines Act Policy Rules (*Beleidsregels gunstbetoon Geneesmiddelenwet)* as of 1 February 2012, the sums for hospitality at manifestations have been increased to a maximum of €75 per occasion and €225 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 requirement does not apply if the hospitality covers only participation (including meals and drinks within reasonable bounds) in a manifestation organised by the authorisation holder, without compensation of cost for travel and / or hotel accommodation (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 – Definition of sponsorship
For the purposes of section 6.5, the term “sponsorship” is used for any kind of support, irrespective of whether anything must be done in return for it and irrespective of how the parties themselves characterise their activities. This, for example, means that providing a certain sum for which nothing has to be done in return (a "donation") is also seen as sponsorship in the context of section 6.5. It is possible that (financial) support leads to inappropriate influence, and the question whether or not anything must be done in return for it is not relevant in this connection.

Section 6.5 is applicable to both the sponsorship of healthcare professionals and the sponsorship of groupings of such professionals, such as partnerships or other formal or informal forms of collaboration within which healthcare professionals operate. Examples are a foundation set up by physicians to promote continuing education, care groups or GPs working together, either alone or in conjunction with pharmacists.

These may be “informal” groupings, provided that the recipient of the sponsorship is more than one physician or pharmacist. The so-called Interdisciplinary Pharmaco-therapeutic Consultations (*farmacotherapeutisch transmuraal overleg* or FTTOs in Dutch) have been explicitly ruled out, because the Executive Committee of the CGR does not believe it is desirable for such groups to be sponsored. The sponsorship rules of section 6.5 are also applicable if the healthcare professionals being sponsored work on an employment contract and the sponsorship funds are in fact paid to the body operating as their employer.

Sub-section 6.5.2 –Sponsoring events
Section 6.5 is not applicable if an authorisation holder sponsors events for healthcare professionals (conferences, symposiums etc.). The rules for this type of sponsorship have been included in section 6.4 of the Code of Conduct.

Sub-section 6.5.3 – Sponsoring individual healthcare professionals
Sub-section 6.5.3 prohibits the sponsorship of individual healthcare professionals. Reference is made to the explanatory note to sub-section 6.5.1 above as to whether there is question of individual healthcare professionals or a grouping.

There are a number of exceptions to the prohibition, for example in the case of financial support for dissertations and theses. The payment in cash or in kind to an individual healthcare professional is, furthermore, permitted under the rules for gifts (section 6.2), services (section 6.3) and hospitality (section 6.4).

It is not always easy to distinguish clearly between payment for services and sponsorship. In general, it can be stated that in the case of services, one party acts as principal and the other works according to its instructions, the service /performance is key and the payment (fee) is a logical consequence. In the case of sponsorship, however, the (financial) support is key and could be out of all proportion to the goods or services given in return. For example, although sponsorship could involve goods or services in return in the form of cooperation or good publicity, the relation between that goods or services given in return and the financial support is not necessarily relevant. In the case of sponsorship, it is usually the sponsored party that takes the initiative: it requests (financial) support for a specific activity.

Sub-section 6.5.4 – Integrity
The principal objective of the Code of Conduct is to prevent the interaction between authorisation holders and healthcare professionals making them feel inappropriately obliged vis-à-vis each other, and the “ethical” principles set out in this sub-section must be read in this light. The principal objective of this section is ensuring that the integrity, the independence and the image of all the parties involved in the sponsorship are not jeopardised.

Sub-section 6.5.5 – Objectives
Sub-section 6.5.5 contains important, cumulative conditions for the objectives of the sponsorship. The parties to the sponsorship agreement must be able to provide evidence that:

a. the sponsorship supports innovative and/or quality-enhancing activities, and that
b. the sponsorship intends to enhance patient care or advance medical science, directly or indirectly; and that
c. the relevant activities are not already funded or not funded fully via any other normal channels.

For the sake of good order, it is pointed out that donations (sponsorship without any goods or services in return) are subject to the same rules. This means that a donation, e.g. a financial contribution to a clinic or other medical institution to promote research without anything having to be done in return, is permitted, provided that that object is in line with the provisions of this sub-section and provided that this is clearly recorded. Neither may the donation result in (personal) benefit or gain because sufficient finance was already available via another source. In this connection, reference is also made to the explanatory note to sub-section 6.5.6 requiring a written agreement.

As to a.: Innovative and/or quality-enhancing care
This condition reflects that sponsorship is permitted, if it is designed to provide "extras": innovative and/or quality-enhancing activities which would be difficult or impossible to achieve without sponsorship. Whether it concerns a "*sponsorfähige"* (care) activity will have to be decided on a case-by-case basis. The point in time is an important, but constantly changing factor in this regard: a close eye must be kept on changing ideas and developments in everyday practice, as a certain (care) activity could qualify for sponsorship at a certain point, but be taken up with such enthusiasm that it could subsequently become 'best practice'. That would mean that this activity evolves into standard care, and sponsorship will then only be permitted if it can be demonstrated that there is no finance, or no full finance, via normal channels for this standard care (see under 'as to c'. below).

As to b.: Enhancing patient care or advancing medical science
Sub-section 6.5.5 (b) stipulates that sponsorship must be designed to enhance patient care or advance medical science, directly or indirectly. A good example is the financial support for a certain scientific study in an institution (as already mentioned above). This will be permitted only if it can be demonstrated that in the end patient care can benefit from the sponsorship, directly or indirectly, or that the sponsorship will advance science. This requirement will, incidentally, be automatically be complied with in the case of an innovative or quality-enhancing activity within the meaning of sub-section 6.5.5.a.
By way of example: sponsoring a laptop with which sick children on an oncology ward can communicate with their family and friends at home could improve care indirectly, and sponsoring a study into a rare genetic disorder could be seen as making a contribution to medical science which could eventually benefit healthcare, and therefore patient care.

As to c.: the activity is not funded, or not funded fully, via normal channels
If the activity for which sponsorship is being requested is already being funded in full via the normal channels (e.g. the government, health insurers, institutions and/or subsidizers), sponsorship would mean additional finance, which would lead to a saving and which could therefor result in personal gain for the sponsored party. In cases such as these, sponsorship is not permitted. See by way of illustration decision A10.076 of 24 August 2010. Sponsorship is, however, permitted if an activity is not funded or not funded fully via normal channels, but it may then only be for the sum not already covered via those normal channels.

The costs which are a part of normal practice or business operations must of course be funded by healthcare providers or institutions themselves (for example replacing an out-dated computer system or furnishing their practice). If support was offered for

purchasing or maintaining such things, this would result in a direct saving and the sponsored party would thus benefit from it. Funding ordinary paid jobs are also covered by this sub-section. If a government agency, for example, provides budget for support staff in a GP's practice, it is not possible to obtain sponsorship for this from an authorisation holder.

The second paragraph of sub-section 6.5.5 makes it clear that requesting or providing support may not be motivated by the desire for personal gain or directly commercial objectives. This condition is closely connected with the integrity requirement formulated in general terms in sub-section 6.5.4. The mere fact that sponsorship could lead to a personal or commercial gain at a certain point does not impede the permissibility of sponsorship in itself, but the crux is that both the party requesting and the party providing the support must have the primary objective of enhancing patient care or advancing medical science.

Sub-section 6.5.6 – Written agreement
Transparency is essential, and that is why the Code of Conduct stipulates that all the agreements and all the data on which these are based must be recorded in writing and in advance. This prevents the sponsorship being provided in the absence of clear and specific agreements on the project or activity to be sponsored (including all the relevant financial details) or the rights and obligations of both parties. Even in the case of a donation, it is important to record everything in writing, for example the object of the donation and the fact that the other party is not required to do anything in return.

Sub-section 6.5.7 – No exclusivity
A conscious restriction to one sponsor could threaten the sponsored party's independence and is therefore not permitted, although it is possible to agree exclusivity for a specific short-term project (such as support for a pilot project for an innovative type of care). It is, however, important to avoid systematic exclusivity.

Sub-section 6.5.8 – Goods or services in return
Sponsorship may not give the sponsor an undesirable influence on the sponsored party's prescription, purchasing or supply behaviour. Sponsorship can naturally lead to a certain 'spin-off', such as a greater brand recognition and/or a better image for the authorisation holder. However, it is completely unacceptable to link sponsorship, directly or indirectly, to the purchase or prescription of certain medicinal products. A sponsor's influence on policies or activities is not by definition undesirable, but it is necessary to avoid (even a whiff of) undesirable influence.

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. When sponsoring healthcare professionals, authorisation holders are bound by the rules of sections 6.1 to 6.5, which are largely designed to prevent undesirable influence. To also avoid any association with such influence in the relations with patient organisations, section 6.6 lays down the 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 6.6.3 (d) 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.

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, 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 this implies that any agreements must be recorded in writing and must be available for inspection. This sub-section

elaborates the conditions in more detail. 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 Relationships between the Pharmaceutical Industry and Patient Organisations).

Sub-section 6.6.4 – Goods or services in return
The EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations was amended as of 2012 and now 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 6.6.3) 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.

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. 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 7.1.2 – Disclosure of relations by speakers
Sub-section 7.1.2 lays down the principle of transparency: it must be clear in advance to visitors to a meeting what relations the speakers have with authorisation holders. This requires the cooperation of the speakers. The organiser must be able to rely on the speaker's statement of his relations with the industry. Within that scope the speaker may be expected to disclose for which authorisation holders he has been working as a consultant researcher or otherwise during the last four years.

In conformity with the Dutch Inducements (Medicines Act) Policy Rules (*Beleidsregels gunstbetoon Geneesmiddelenwet)* this sub-section has been expanded as per 23 January 2012, requiring speakers to also disclose their relations with parties other than authorisation holders. This corresponds with the starting-point that inducements reach further than just the relations between healthcare professionals and authorisation holders. It is also in conformity with the Dutch Code of Conduct to Prevent Inappropriate Influence due to Conflicting Interests (*Code ter voorkoming van oneigenlijke beïnvloeding door belangenverstrengeling)*[3], which also

[3] This Code has been drafted by the Dutch organisations KNAW (*Koninklijke Nederlandse Akademie van Wetenschappen*, The Royal Netherlands Academy of Arts and Sciences), KNMG (*Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst*, The Royal Dutch Medical Association),

extends beyond the interests with the pharmaceutical industry.

As for the manner of disclosing relations, reference is made to the format of the disclosure slide for speakers at training meetings (Annex 1 to these Explanatory Notes).

Sub-section 7.2 – Disclosure of financial relations
Business relations between healthcare professionals and pharmaceutical companies (to be further referred to jointly as “parties”) have existed for a very long time. As the parties involved in prescribing and supplying medicines, they are "natural" partners. Pharmaco-therapeutic care stands to gain from the responsible cooperation between the parties. Cooperation is for instance called for within the scope of the development of new medicinal products and the development and exchange of knowledge about the application of medicinal products. In the light of this, the parties therefore often have financial relation in different areas.

In order to prevent inappropriate influence on the prescription or supply of medicinal products by healthcare professionals, the cooperation between healthcare professionals and pharmaceutical companies has been regulated. Payments to researchers and institutions with regard to medical-scientific research performed with medicinal products on humans (research subject to the WMO or not subject to the WMO) must first be reviewed by a medical-ethics committee. Other forms of cooperation either come under the standards set by the CGR, which has set maximum limits, or else the cooperation must be recorded in a written agreement in which the object and implementation are clearly described and there must be a reasonable proportionality between the work to be provided and the payment to be received for it.

Although transparency with regard to relations with pharmaceutical companies is part of the professional principles of a healthcare professional, there is a need within society to actively disclose the information on the financial relations between the parties. The then Minister of Public Health, Welfare and Sport, Ab Klink, urged the CGR on its tenth anniversary in May 2009 to draft standards for the Dutch equivalent of the Sunshine Act. The Sunshine Act requires the disclosure of payments made by the pharmaceutical industry to physicians and scientists in the United States.

Agreements with regard to transparency have already been made for various forms of cooperation. Research subject (or not) to the WMO is disclosed in public trial registries and on publication the names of the persons who carried out the research and of the parties who sponsored the research are stated. In addition to this, the present rules of conduct require pharmaceutical companies, healthcare professionals and organisations with which healthcare professionals are associated to disclose their financial relations under service and sponsorship agreements and reimbursed hospitality costs.

The rules of conduct of sub-section 7.2 are additional and without prejudice to the other initiatives promoting the transparency of the relations between the parties. For

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the Health Council of The Netherlands (*Gezondheidsraad*), CBO (*Centraal Begeleidings Orgaan*, Central Guidance Body) and NHG (*Nederlands Huisartsen Genootschap*, The Dutch College of General Practitioners) and can be downloaded via the websites of the organisations concerned.

instance, the Dutch organisations KNMG, KNAW, the Health Council of The Netherlands, CBO, NHG and the Dutch Association of Medical Specialists (*Orde van Medisch Specialisten)* have taken the initiative to draft a uniform Code on how to deal with possible inappropriate influence as a result of conflicting interests in the case of consultancy and the development of medical guidelines. The aim of this Code is to promote unambiguous decision-making procedures and transparency towards society. Within that context a uniform form (or statement of interests) has been developed which all the members of expert committees must complete in advance.

The rules of conduct of sub-section 7.2 and the central register within the meaning of sub-section 7.2.4 have been designed to provide for the need within society to gain insight into the financial relations resulting from the agreements mentioned in sub-section 7.2.1 and thus contribute to the principle that people should be able to make an informed choice for a specific medicinal product or healthcare professional based on objective information and/or advice.

The Code of Conduct imposes demands on financial relations between parties. "Financial relations" are defined as a direct or indirect compensation in cash or in kind or otherwise provided by an authorisation holder to healthcare professionals, groupings of healthcare professionals and/or institutes in which healthcare professionals participate or by which they are employed. Financial relations beyond the scope of the Code of Conduct, such as monitoring the research subject (or not) to the WMO, are also beyond the scope of sub-section 7.2.

Certain financial relations are excluded from the standards for inducements in the Code of Conduct. These are measures or trade practices in the area of prices, margins and discounts relating to trade relations as well as the provision of free samples. For financial relations for which nothing has to be done in return (such as gifts with a minimal value and hospitality provided as part of meetings), a specific standard has been introduced in order to prevent inappropriate influence on the prescription and/or supply behaviour of healthcare professionals. These types of financial relations have been sufficiently regulated within the present framework, and have thus been excluded from the financial relations of sub-section 7.2.1.

As for financial relations characterised by (specific) goods or services given in return (such as payment for services or sponsoring), the rule is that these must be recorded in a written agreement, which must clearly set out the object and the service to be provided; there must be a reasonable proportionality between the service and the compensation received for it (see sub-sections 6.3.2, 6.4.4 and 6.5.6). An example is the payment for services provided by healthcare professionals in the form of participation in a scientific advisory board, giving lectures or presentations or writing medical-scientific articles. A distinction is generally made in this respect between the payment of the costs actually incurred or payment to the institution with which the healthcare professional is associated and the actual fees or rates per unit of time received by the healthcare professional concerned. In general, sponsorship takes place in relation to institutions, for instance to enable a specific project from which healthcare will benefit. Sponsoring the printing costs of theses does not come under the financial relations of sub-section 7.2.1, since this is only a contribution towards the costs.

Furthermore, the Code of Conduct provides that authorisation holders and patient organisations must be transparent with regard to their financial relations. It has been

decided that these relations must also be disclosed in the Dutch Healthcare Transparency Register as from 1 January 2015.

Section 7.2 requires the parties to disclose their financial relations within the meaning of sub-section 7.2.1. The written agreement underlying the financial relation must provide by which party and in what manner the financial relation will be disclosed. As for authorisation holders and healthcare professionals, groupings of healthcare professionals and/or institutes in which healthcare professionals participate or by which they are employed which are based in the Netherlands, the rule is that the information must be disclosed within 3 months of the end of the calendar year. For this purpose, an independent central register will be set up.

A mandatory disclosure limit of €500,- will apply per year per healthcare professional, grouping of healthcare professionals and/or institutes in which healthcare professionals participate or by which they are employed. This limit links up with the opinion issued by the Dutch Council for Public Health and Healthcare (*Raad voor de Volksgezondheid en Zorg*) in 2008 in its report "Pharmaceutical Industry and the Use of Medicinal Products, the Balance between Public and Corporate Interests". In addition, this limit does justice to the principle of proportionality from the point of view of the protection of the privacy of the healthcare professionals concerned and between the administrative work caused by the rules of conduct on the one hand and the interest of the disclosure of financial relations on the other hand. This limit does not, however, mean that financial relations representing a lower value could not be disclosed. Healthcare professionals can also disclose their financial relations with suppliers of care products other than medicinal products, such as medical aids.

The following information must be disclosed:

a. The name of the recipient:
   For service agreements within the meaning of sub-section 7.2.1 (a): the personal data (the starting-point is the BIG number[4] on the basis of which the name, specialisation and place of residence are disclosed) of the healthcare professional who actually performed the services (irrespective of whether this healthcare professional is also the final beneficiary of the amounts paid).
   If the service agreement has been entered into by a grouping or institute, the data (starting-point is the Chamber of Commerce number, on the basis of which the name and registered office are disclosed) of the grouping/institute is disclosed, unless the services can be attributed to a healthcare professional who actually performed the services and the service in the name of this healthcare professional has been reported; and
   For agreements referred to in sub-section 7.2.1 (b): the personal data (starting point is the BIG-nummer[5], on the basis of which name, specialisation and place of residence are disclosed) of the healthcare professional that received the (cost for) hospitality.[6]
   For sponsorship agreements within the meaning of sub-section 7.2.1 (c): the data (the starting-point is the Chamber of Commerce number, on the basis of which the name and registered office are disclosed) of the grouping or institute with which the financial relation exists. If it concerns the sponsorship of the expenses

[4] Under section 8a of the BIG Registration Decision (Individual healthcare Professions Act) Decree (*Registratiebesluit BIG*).

[5] Under section 8a of the BIG Registration Decision (Individual healthcare Professions Act) Decree (*Registratiebesluit BIG*).

[6] This obligation applies as of January 1, 2015

of a thesis to a healthcare professional as referred to in article 6.5.3 (a): the personal data (starting point is the BIG-nummer[7], on the basis of which name, specialisation and place of residence be disclosed) of the healthcare professional.[8]
For sponsorship agreements within the meaning of sub-section 7.2.1 (d): the data (the starting-point is the Chamber of Commerce number, on the basis of which the name and registered office are disclosed) of the patient organisation with which the financial relation exists.

b. The name and registered office of the sponsoring party/authorisation holder.
c. The nature of the agreement. For the purpose of the standardised disclosure in the central register, the agreements have been classified according to their nature in the following selection table:

Service provision, consultancy	General individual consultancy work, also including writing articles/ scientific lectures commissioned by a third party
Service provision, advisory board	Participation in an advisory board, being a gathering of healthcare professionals at which they advise the company concerned
Service provision, speaker	Acting as speaker/giving a presentation
Service provision, other	Other forms of services not covered by one of the other categories
Service provision related expenses[6]	Expenses that, apart from the fee for the services, compensated by the authorisation holder (sub-section 6.3.3 under a)
Hospitality[7]	Compensation of travel, accommodation and registration costs of an event (sub-section 6.4.3)
Sponsoring an event	Sponsoring an event not organised by an authorisation holder (sponsoring within the meaning of sub-section 6.4.4)
Sponsoring, other	Sponsoring innovative and/or quality-enhancing activities aimed at directly or indirectly improving patient care or advancing medical science and which are not (or not fully) funded in any other regular manner and sponsoring of expenses of a thesis (sponsoring subject to sub-section 6.5 respectively 6.6)

d. The amount in whole euros.
For individual healthcare professionals this concerns the total amounts of their fee exclusive VAT (sub-section 6.3.3 under b) on the one hand and reimbursed expenses including VAT (pursuant to sub-section 6.3.3 under a or sub-section 6.4.3) on the other hand, to the extent that the total amounts per authorisation holder in the calendar year concerned exceeds €500,-.
For institutes, this concerns the total amounts for services (where possible broken down into fees and expenses) which cannot be assigned to a healthcare professional who actually performed the services or for sponsorship (including

[7] Under section 8a of the BIG Registration Decision (Individual healthcare Professions Act) Decree (*Registratiebesluit BIG*).
[8] This obligation applies as of January 1, 2015

VAT), to the extent that the total amounts per authorisation holder in the relevant calendar year exceeds € 500,-.
e. The calendar year to which the relevant agreement relates.

The disclosure must be made in retrospect (viz. at the beginning of the new calendar year in respect of the previous calendar year) and will be kept in the register for a period of three years. After three years the data will be removed.

Sub-section 7.2.1 – Financial relations
The rules of conduct relate to financial relations between authorisation holders and healthcare professionals (natural persons and legal entities), groupings of healthcare professionals and institutes in which healthcare professionals participate or by which they are employed based, practising in the Netherlands. This concerns (the involvement of) the healthcare professionals registered in the Dutch BIG Register. In addition, the rules of conduct will be extended as per 1 January 2015 to include relations with patient organisations.

A "financial" relation is defined as a direct or indirect financial compensation in cash or in kind or otherwise provided by a authorisation holder to healthcare professionals, groupings of healthcare professionals and/or institutes in which healthcare professionals participate or by which they are employed, based in and/or practicing in the Netherlands or to a patient organisation respectively. Thus it is the actual payment that is relevant, not the contractual relation as such. The term "indirect financial relation" refers to payments not made by (or in the name of) an authorisation holder directly, but made at an authorisation holder's instruction, for instance via another legal person who is not covered by the definition of "authorisation holder".

Disclosure is required of the following financial relations resulting from the following agreements:
a. service agreements between authorisation holders and (groupings of) healthcare professionals (in accordance with section 6.3);
b. agreements in which an authorisation holder shall compensate costs for hospitality to a healthcare professional (in accordance with sub-sections 6.4.6 under 3 and 6.4.8 under 2).[9]
c. sponsorship agreements between authorisation holders and healthcare professionals (limited to the expenses of a thesis) groupings of healthcare professionals and/or institutes in which healthcare professionals participate or by which they are employed (in accordance with sub-section 6.4.4 as well as section 6.5);
d. sponsorship agreements between authorisation holders and patient organisations (in accordance with section 6.6).[10]

Section 7.2.2 - Disclosure
This sub-section provides what data must be disclosed and by whom (to be referred to below as: the disclosing party). The relevant starting-points here, in addition to the evident importance of transparency, are proportionality and the need to prevent unnecessary administrative and organisational work. For the manner of disclosure of the data, reference is made to the general part of these explanatory notes.

[9] This obligation applies as of January 1, 2015
[10] This obligation applies as of January 1, 2015

Proportionality with a view to protecting the privacy of the healthcare professionals involved and the need to prevent excessive administrative work justify the setting of a lower limit of €500 for the total amount of one or more financial relations per healthcare professional, grouping of healthcare professionals and/or institute in which healthcare professionals participate or by which they are employed (or patient organisation respectively) per authorisation holder per year. If the total amount per financial relation or with a number of financial relations jointly is in excess of €500, the parties involved are obliged to disclose the financial relation.

Section 7.2.3 – Written record
Transparency is the objective of the present rules of conduct. In order to be able to realise transparency, the obligations between the parties must be recorded in writing and the agreements between them must include additional provisions on transparency. This sub-section provides further details. The agreement must, for instance, set out in which manner the financial relation will be disclosed and which party to the contract will undertake this responsibility. For this purpose the CGR has formulated a number of standard provisions, which the parties can use, if they so wish. The use of the standard provisions is therefore not obligatory.

In their agreements the parties must provide which party will take care of disclosing which data. Disclosure should, in principle, take place within 3 months from the calendar year in which the financial relation between the parties arose. Given the authorisation holder's obligation to make available an annual statement of the financial relations per healthcare professional, grouping of healthcare professionals and/or institute in which healthcare professionals participate or by which they are employed (or patient organisation respectively) (see sub-section 7.2.6), it has been decided that they must offer this data to the central register collectively and that this data will be the starting-point for disclosure. For financial relations not offered to the central register in this manner, for instance because the authorisation holder involved is based abroad, the obligation to disclose shall in any case lie with the healthcare professional, grouping of healthcare professionals and/or the institute in which healthcare professionals participate or by which they are employed.

Sub-section 7.2.4 – Manner of disclosure
Disclosure must be made in the central register of the Dutch Foundation for the Healthcare Transparency Register (*Stichting Transparantieregister Zorg)* (www.transparantieregister.nl).

Sub-section 7.2.5 – Internal procedure
Sub-section 7.2.5 requires authorisation holders to have an adequate procedure in place within their companies, within the framework of which the disclosure of their financial relations is reviewed against the provisions of these rules of conduct in a standard manner. In this connection reference is made to section 4.2 of the Code of Conduct.

Section 7.2.6 – Provision of annual overview by the authorisation holder
These rules of conduct do not lay down specific requirements for the organisation of the annual review, because that will be partly determined by the way in which the administrative organisation of each individual authorisation holder and the central register have been set up. The central Healthcare Transparency Register has been set up in such a way that the annual review is made available digitally to the

healthcare professionals, groupings of healthcare professionals and institutes in which healthcare professionals participate or by which they are employed or patient organisations respectively before the data is made available for public inspection.

Section 7.2.7 – Duration of the disclosure
The information on financial relations is maintained for a period of 3 years. The assumption is that after 3 years the information on financial relations will no longer be sufficiently up-to-date and therefore no longer relevant, taking into account the privacy interest of the healthcare professionals. After 3 years the data will be removed from the central register by the Dutch Foundation for the Healthcare Transparency Register.

Chapter 8 – Transitional law
Chapter 8 contains the transitional law with regard to the entry into effect of the Code of Conduct. The new rules of conduct will take effect with the observance of a certain transitional period.

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 Dutch Healthcare Inspectorate (the "IGZ") 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 IGZ 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 IGZ. 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.