Code of Conduct Medical Devices

This translation is not legally binding. Where contradictions occur between the Dutch and English versions of the Code of Conduct, the Dutch version prevails.

Code of Conduct Medical Devices

Introduction and Setting

Medical devices and medical technology play an important role in the healthcare system. In countless situations in the care process medical devices and technology contribute to establishing the diagnosis and the prevention, monitoring, alleviation, cure or compensation for diseases, injuries and disabilities.

Various products, various parties

The world of medical devices is very diverse; from straightforward products used at home by the consumer, to technically very advanced products used in hospitals by professionals trained in their use, and from a simple sticking plaster to an advanced implant inserted into patients. Many different parties are involved in the decision to purchase or use, depending on the nature of the product, such as a physician (for a stent or artificial hip), a nurse (for a blood glucose meter), an audiologist (for a hearing aid) or at a higher level within the institution, the department of radiology or the laboratory and the hospital procurement department. As the party that reimburses a device, the health insurance company can also influence the final choice.

Contact Necessary

For years there has been intensive collaboration between companies that develop medical devices and place them on the market on one side and the (healthcare) professionals that use devices for the treatment and support of their patients/clients on the other. This collaboration is an important driving force for innovation, leading to new and improved products and technologies. Collaboration with physicians is necessary in the context of legally required clinical proof of medical devices by way of clinical trials. On the basis of good practice, close collaboration between those who bring the products on the market and those who use them is also necessary. Training, education and support for the benefit of safety and effective use are often necessary. Also, suppliers are dependent on contact with healthcare professionals. They have to be able to follow the efficacy and safety of the products in order to meet their legal obligations of vigilance and post-marketing surveillance. In many cases healthcare professionals are either the user of the product themselves or they are able to follow the patients' experiences with certain devices.

No undesired influence

The relationship between suppliers and healthcare professionals who use, apply, prescribe or (help) select is useful and necessary. In view of the commercial and public health interests that play a part, however, this relationship needs to be arranged in a responsible and careful manner. Advertising and promotion are permitted, but the basic principle applied is that the patient/client must be able to trust that decisions concerning a certain device or technology are made on honest grounds, related to patient care. This means on the basis of good, reliable information and without undesirable financial incentives.

Reciprocity

The regulations or behaviour recorded in this Code of Conduct are intended - in addition to the legislation in force - to give more substance to careful, transparent and responsible interaction between suppliers of medical devices and the parties involved in the decision-making process regarding their purchase and/or use, irrespective of the setting in which they are used. By signing the Code of Conduct parties undertake to comply with this Code. The aim is that as many of the parties in the field as possible endorse the Code of Conduct. In addition, express endeavours will be made to engage other involved parties in this Code of Conduct. After all, optimal interaction is founded on reciprocity; that which one party may not offer or give, the other party may not request or accept.

Monitoring

Compliance with the Code of Conduct will be monitored by an independent Code Commission and Appeals

Board. The manner in which monitoring is designed, is set down in the Statutes of the Code Commission and Appeals Board of the Foundation for the Code of Conduct Medical Devices.

GENERAL PRINCIPLES

Article 1. Definitions

a. *Medical Device*
The medical device designated on the grounds of the Medical Devices Act[1], Medical Devices Decree[2], Active Implants Decree[3] and the In vitro Diagnostics Decree[4].

b. *Healthcare Professional*
Any individual who, whether or not in the employment of or in collaboration with others, makes use of medical devices in the context of care or support and/or decides on their purchase or use and/or is involved in the process of prescribing, selecting, assessing and/or advising about the use of medical devices.

c. *Institution*
The organisation that provides care and/or support and is covered by the Dutch Healthcare Quality, Complaints and Disputes Act.[5]

d. *Supplier*
The (legal) entity that produces a medical device; brings it to the market; introduces, stocks, resells and/or delivers it; or delivers services related to a device.

e. *Consumer*
The individual who is dependent on personal use of a medical device.

f. *Interaction*
Any form of contact between a supplier and a healthcare professional in which a financial benefit is offered or promised to the healthcare professional.

g. *Statements*
Any form of written, spoken or electronic communication with regard to a medical device, regardless of whether this is promotional in nature.

h. *Patient Organisation*
The organisation of those who require and/or purchase healthcare services, including former patients, legal representatives, relations and surviving relatives.

Article 2. Scope of the Code of Conduct

This code of conduct concerns statements about medical devices in the broadest sense. Additionally, this code of conduct provides standards for responsible interaction between suppliers and healthcare

[1] Law of 15th January 1970, Official Gazette 1970, 53, as amended since then.
[2] Decree of 30th March 1995, Official Gazette, 243, as amended since then.
[3] Decree of 5th July 1993, Official Gazette 1993, 385, as amended since then.
[4] Decree of 22nd June 2001, Official Gazette 2001, 385, as amended since then.
[5] Law of 7th October 2015, Official Gazette 2015, 407, as amended since then.

professionals.

Article 3. General Principles

The following principles form the basis of this Code of Conduct:

a. **Prevention of Improper Practice**
Interaction between suppliers and healthcare professionals may include no elements of an incentive that could lead to decisions being made regarding (use or purchase of) medical devices on grounds that are not healthcare related, rational and/or honest. Decisions may not be influenced by, for example, extreme or inappropriate benefits or by erroneous or misleading advertising.

b. **Legitimate Foundations and Reasonableness**
Interactions between suppliers and healthcare professionals must have legitimate foundations. Remuneration, payments and any other financial benefits must be reasonable and proportional.

c. **Documentation**
Interactions between suppliers and healthcare professionals must be clearly and demonstrably recorded in writing.

d. **Accountability/Transparency**
Interactions between suppliers and healthcare professionals must be transparent, which entails, among other things, that the aim and the scope of the interaction must either be reported in advance to the board of the institution or the employer, or prior approval is received from either the board of the institution or the employer.

STATEMENTS

Article 4. Statements

1. Statements regarding medical devices:

   a. may in no way be misleading;
   b. must be accurate, up to date and truthful;
   c. must be correct and verifiable;
   d. may not harm the accepted norms of good taste and decency and the reputation of the industry, healthcare professionals and medical devices.

2. It must be possible to substantiate the accuracy of statements with appropriate evidence.

INTERACTIONS

Article 5. Interactions between suppliers and healthcare professionals

1. Suppliers may offer or promise healthcare professionals financial benefits, on the provision that it is done in the format and within the context of the interactions that are acceptable according to this Code of Conduct.

2. Healthcare professionals may request or accept financial or financial measurable benefits, on the provision that it is done in the format and within the context of the interactions that are acceptable according to this Code of Conduct.

3. Within the context of this Code of Conduct distinction is made between the following interaction categories:

    a. bonuses and discounts that are associated with business transactions, as detailed in Article 6;
    b. gifts, as detailed in Article 7;
    c. financial contributions to the cost of (participating in) meetings for healthcare professionals, as detailed in Articles 8-12;
    d. remuneration for services, as detailed in Articles 13 and 14;
    e. sponsorship of projects or activities other than meetings, as detailed in Articles 15-17.

4. The interactions referred to in clause 3 under b-e may never be linked to a decision related to the purchase, use, prescription and/or recommendation of medical devices.

5. Moreover suppliers and healthcare professionals refrain from any other business or forbearance that may create an improper sense of mutual obligation.

Article 6. Bonuses and discounts related to business transactions

1. Bonuses and discounts related to business transactions are defined as the measures or business practices concerning prices, margins and discounts related to a business transaction.

2. The giving and accepting of bonuses and discounts is permitted on the provision that:

    a. they are discounts in cash or in kind in so far as they concern industry related products;
    b. the bonuses and discounts in cash or in kind are expressly recorded in writing, and
    c. the bonuses and discounts are offset against the (legal) entities directly involved in the business transaction or directly involved in the distribution or delivery of the medical devices to which the business transaction is related.

3. It is not permitted to link the establishment of a business transaction to the offering or promise of an offering, respectively requesting or accepting financial benefits in favour of (legal) entities that are neither a direct party in the business transaction nor directly involved in the distribution or delivery of medical devices.

Article 7. Gifts

1. The occasional giving and receiving of gifts is permitted, on the provision that:

    a. the gift is of little value, and
    b. is related to the business of the healthcare professional, can be of benefit to patient care or can fulfill a purely educational function.

2. A gift is considered to be of little value if the retail value does not exceed more than € 50 (including VAT). Per healthcare professional there is a maximum of three gifts per year per supplier.

3. It is not permitted to bestow gifts in the form of cash or equivalents.

4. It is permitted to mention the brand or logo of a product or company on or with the gift.

5. The following are not considered gifts in the sense of this article:

a. product samples;
b. small gifts distributed in relation to a special one-off occasion provided this is reasonable and appropriate for the occasion.

Article 8. Financial contributions to the costs of (participating in) meetings for healthcare professionals; general principles

1. Within the context of this Code of Conduct distinction is made between the following categories of meetings for healthcare professionals:

    a. meetings organised by supplier-independent third parties (Article 9);
    b. a product related meeting organised by the supplier (Article 10);
    c. accredited meetings organised by the supplier (Article 11);
    d. other meetings organised by the supplier (Article 12).

2. The involvement of suppliers in meetings for healthcare professionals is permitted in the sense that suppliers may either organise meetings, financially facilitate, or facilitate the participation of individual healthcare professionals, and in this context may pay the costs, on the provision that the following conditions are met:

    a. the **programme** in terms of programme structure is balanced and reasonable and does not include any recreational and social activities that are not related to the meeting, and
    b. the **location** in terms of geographical position and facilities is legitimate, and
    c. the **costs** are reasonable,

    all these items are further detailed by category in Articles 9 -12.

3. It is not permitted for suppliers to pay expenses either directly or indirectly for persons other than healthcare professionals.

4. Should a meeting be realised with the financial support of one or more suppliers, the organiser must expressly state this in the invitation/programme.

5. It is not permitted to pay for expenses related to participation in meetings other than those mentioned in this code of conduct.

6. Where representatives of a supplier are present at a meeting in which healthcare professionals participate, they should be identifiable as such at all times, for example by wearing a badge.

Article 9. Meetings organised by independent third parties

1. Meetings organised by independent third parties are meetings that are (also) intended for healthcare professionals and are organised without any content-related involvement of suppliers. This means that the content of the programme, the invitation policy and the location of the meeting are established independently of suppliers.

2. Suppliers may pay expenses in the context of a meeting organised by an independent third party, provided the following conditions are met:

    a. *Programme*: the programme of the meeting is:

        1. aimed at improving the knowledge and/or skills related to (the improvement of) healthcare and/or medical progress, and

2. the content is of a sufficient standard, and
3. in terms of programme structure is balanced and reasonable.|

b. *Location*: the location where the meeting takes place, is legitimate, both in terms of facilities and geographical position.

c. *Costs*: the expenses reimbursed by the supplier are reasonable. This means that in cases concerned with the reimbursement of expenses to an *individual healthcare professional*, only the following expenses may be reimbursed:

1. registrations fees;
2. one or more reasonably priced meals;
3. necessary overnight stays, provided they are reasonably priced;
4. reasonable travel expenses.

Reimbursement of the afore-mentioned expenses is considered reasonable if:

a. the supplier does not contribute more than € 500 per meeting per healthcare professional to a maximum of € 1.500 per year for the above-mentioned costs, or
b. the healthcare professional pays at least 50% of the above-mentioned costs personally.

Amounts are inclusive of VAT.

If it concerns a financial contribution to a meeting *organiser* and this contribution is solely spent on general costs that are directly related to the organisation of this meeting, the aforementioned maximum amounts are not valid, on the provision that the other requirements of this article are met.

3. Arrangements concerning the reimbursement of expenses to *individual healthcare professionals* must be recorded in writing. One of these arrangements is that the healthcare professional involved registers these arrangements either with the board of the institution or with the employer.

4. A written agreement from the organiser (s) must underlie the payment of a financial contribution to the *organiser* of a meeting. The payment must be made directly to the organiser of the meeting. The financial support must be made known clearly before and during the meeting.

5. An exception to the stipulations in clause 2 applies where, in the context of the meetings referred to in this article, suppliers may purchase advertising space and hire a booth (stand) on the condition that:

a. the rate is in line with the market, and
b. any possible *surplus* does not benefit the participating healthcare professionals.

6. Suppliers may organise satellite symposia or parallel symposia that take place during, shortly before or shortly after the meetings referred to in this article or facilitate and organise presentations at these symposia on topics that fit within the programme of the meeting, on the condition that all presented information is honest, balanced and scientifically accurate. Suppliers may establish the content of these satellite symposia and who is invited to them. Arrangements between the organiser and suppliers concerning this must be recorded in writing. The organisation or facilitation must be mentioned in all materials related to the satellite symposium.

Article 10. Product related meetings organised by suppliers

1. Product related meetings organised by suppliers are meetings intended for healthcare professionals and that are necessary in the context of good use and maintenance of medical devices.

2. Suppliers may pay the costs of the product related meetings organised by them, on the provision that the following conditions are met:

   a. *Programme*: the meeting programme is:

      - suitable for demonstrations of the specific device and/or transfer of knowledge and/or skills regarding the use, application or maintenance of specific devices, and
      - in terms of schedule the planned time is balanced and reasonable and exclusively focused on the aim of the meeting.

   b. *Location*: the location where the meeting takes place is legitimate in light of the nature of the product related meeting, both in terms of facilities and geographic location. In terms of facilities this means that the meeting takes place in a clinical environment, laboratory, educational institution, or in another suitable environment, such as hired business meeting facilities or one's own (business) premises or offices. In terms of geographic location this means that the location has a logical association with the presence of the specific devices and/or the necessary training or educational facilities.

   c. *Costs*: in the context of the meeting referred to in this article the supplier may only pay for the following costs per individual healthcare professional:

      1. costs for the organization;
      2. one or more reasonably priced meals;
      3. necessary overnight stays, provided they are reasonably priced;
      4. reasonable travel expenses.

      Reimbursement of the afore-mentioned expenses is considered reasonable if:

      a. the supplier does not contribute more than € 500 per meeting per healthcare professional to a maximum of € 1.500 per year for the above-mentioned costs, or
      b. the healthcare professional pays at least 50% of the above-mentioned costs personally.

3. Arrangements concerning reimbursement of costs must be recorded in writing. One of these arrangements is that the healthcare professional involved register this agreement either with the board of the institution or the employer.

Article 11. Accredited meetings organised by suppliers

1. Accredited meetings organised by suppliers are all meetings organised by suppliers and which have been accredited by the professionally recognised faculty.

2. Suppliers may pay the cost of an accredited meeting organised by them on the provision that the following conditions are met:

   a. *Programme*: the programme is balanced and reasonable in structure.

   b. *Location*: the meeting location is legitimate, both in terms of facilities and geographic location.

c. *Costs*: the supplier may only pay the following costs per individual healthcare professional in the context of a meeting referred to in this article:

   1. organisational costs;
   2. one or more reasonably priced meals;
   3. necessary overnight stays, provided they are reasonably priced;
   4. reasonable travel expenses.

   Costs are considered reasonable if:

   a. the supplier does not contribute more than € 500 per meeting to a maximum of € 1,500 per healthcare professional per year, to the above-mentioned costs, or
   b. the healthcare professional pays at least 50% of the above-mentioned costs personally.

   The expenses associated with organisation (such as costs for speakers, room hire, printed documents) do not need to be included in the calculation.

   Amounts are inclusive of VAT.

3. Arrangements concerning reimbursement of costs must be recorded in writing. One of these arrangements is that the healthcare professional involved register this arrangement either with the board of the institution or the employer.

Article 12. Other meetings organised by suppliers

1. Other meetings organised by suppliers are all meetings organised by suppliers which do not fall under Article 10 or 11.

2. Suppliers may pay the cost of a meeting referred to in this article, provided the following conditions are met:

   a. *Programme*: the programme of the meeting is balanced and reasonable.

   b. *Location*: the meeting location is legitimate both in terms of facilities and geographical location. This means that the meeting takes place at or near the location where the healthcare professional is employed, unless it is necessary to hold the meeting elsewhere. In case of the latter the meeting must take place in a suitable environment that is conducive to the exchange of information.

   c. *Costs*: the costs paid for by the supplier must be reasonable. In the context of a meeting referred to in this article, the supplier may only pay for the following costs per individual healthcare professional:

      1. Organisational costs;
      2. one or more reasonably priced meals;
      3. necessary overnight stays, provided they are reasonably priced;
      4. reasonable travel expenses.

      Costs are considered reasonable if the supplier does not contribute more that €75 per meeting with a maximum of € 375 per healthcare professional per year in the above-mentioned costs.

      The costs associated with organisation (such as costs for speakers, room hire, printed material) do not need to be included in the calculation.

Amounts are inclusive of VAT.

Article 13. Remuneration for Services

1. Services in the context of this code of conduct are the delivery of certain services by a healthcare professional in return for remuneration, irrespective of the nature and indication of these services.

2. It is permitted to pay healthcare professionals for services, on the provision that the following conditions are met:

    a. the service has a legitimate objective that is of importance to the supplier;
    b. the choice of service provider is based on his qualifications and expertise in relation to the service requested;
    c. the service is recorded in writing in an agreement of a limited duration, and
    d. remuneration for the service meet the stipulations in clauses 3-6.

3. Remuneration for the service must be in line with the market. The term in line with the market is explained further in the explanatory note on this article. Remuneration for the service may in no way be linked to the volume or value of the medical devices the healthcare professional may have used in the past or may use in the future. All payments must meet the relevant fiscal and other statutory legal requirements.

4. Reasonable and actual expenses incurred by the healthcare professional during the delivery of the service may be reimbursed. The term reasonable expenses is explained further in the explanatory note on this article.

5. If a meeting takes place in the context of the service, the location must be suitable and the hospitality provided must be modest and in terms of duration and objective be subordinate to the primary (main) objective of the meeting.

6. If arrangements regarding intellectual property rights are made in the context of the service, remuneration for this must be reasonable and in line with the market. Remuneration may not be linked to future purchase, use, prescription of or advise on medical devices to which any new intellectual property rights may be related.

7. The healthcare professional ensures that he has received demonstrable prior approval for the delivery of the service from either the board of the institution or the employer.

8. If and to the extent that Article 22 and subsequent articles apply, the information in respect of the service referred to in such articles shall be published in the Dutch Healthcare Transparency Register.

Article 14. Service Delivery Agreement

1. In the written agreement referred to in Article 13 (2) (c) the following must always be recorded:

    a. the content, nature, duration and scope of the service;
    b. the results and/or objective to be achieved;
    c. the fees for the service and the reimbursement of possible expenses;
    d. the declaration from the involved healthcare professional that he has registered the objective and the scope of the agreement either with the board of the institution or the employer and has

gained the required approval as referred to in Article 13 (7).

2. If the service is related to research, the written agreement must refer to a research protocol or a scheme recorded in writing of the activities, and all relevant and/or required approval and consent for conducting this research must have been received.

Article 15. Sponsoring projects or activities other than meetings

1. Sponsorship in the context of this code of conduct is the bestowing of either financial support or support that can be valued in financial terms, irrespective of quid pro quo. The sponsor is the party who provides the support. The sponsored party is the party who receives the support. This article does not apply to the sponsorship of meetings and of patient organisations.

2. Sponsoring by suppliers is permitted on the provision that the following conditions are met:

   a. the objective of the sponsorship is:

      - the support of independent medical research and/or
      - the advancement of medical science and/or the improvement of patient care and/or
      - the stimulation and advancement of education, and/or
      - information provision.

   b. the sponsored party is an organised collaboration between healthcare professionals or an institution;

   c. arrangements concerning sponsorship are recorded in writing in advance, in an agreement signed by all involved parties, in which the objective of the sponsorship and an exact description of entitlements and obligations of both the sponsored party and the sponsor are defined; and

   d. the sponsorship is in no way related to the purchase, use or prescription of and/or advice on the sponsor's product or otherwise linked to previous, current or potential future use of the product or services of the sponsor.

3. Sponsorship may not lead to any adverse effect on the independence, reliability and credibility of either the sponsor and the sponsored party or of other involved parties and/or the sector.

4. An exception to the stipulations in Article 15 (2) is that suppliers may sponsor a dissertation by an individual healthcare professional to a maximum of € 250. An exception to Article 15 (2) (c) is that this type of sponsorship does not need to be set down in a written agreement.

5. The healthcare professional ensures that he has gained demonstrable prior approval for the sponsorship either from the board of the institution or the employer.

6. If and to the extent that Article 22 and subsequent articles apply, the information in respect of the sponsorship referred to in such articles shall be published in the Dutch Healthcare Transparency

Article 16. Specific forms of sponsorship; study grants

1. In addition to the stipulations in Article 15, sponsorship of study grants by suppliers is permitted, provided the following conditions are met:

a. the study grant is awarded by an educational institute, healthcare institution or professional association for the purpose of medical educational programmes and the grant selection process takes place independently of the sponsor; and

b. payment of the amounts is made to the educational institute, the healthcare institution or professional association and not to an individual person, unless supported by a specific request in writing by the board of the relevant institute.

Article 17. Specific forms of sponsorship; research

1. In addition to the stipulations in Article 15, the sponsorship of research by suppliers is permitted, on the provision that the following conditions are met:

   a. Sponsorship is related to clinical and nonclinical studies which meet the relevant legal, scientific and ethical requirements and which are initiated by healthcare professionals;

   b. Sponsorship concerns documented expenses, services in kind or free products that can be used for research activities;

   c. The request for sponsorship is made in writing, whereby the nature and objective of the research activity is stated;

   d. The arrangements are set down in a written agreement and signed by all involved parties. The signed agreement satisfies Article 15 (3) and always includes the stipulations on mandatory reporting of any unintended, relevant outcomes (adverse events); and

   e. The healthcare professional ensures he has received demonstrable, prior approval for sponsorship of the research either from the board of the institution or from the employer.

   f. The sponsored party mentions the sponsorship in all spoken and written presentations of the study results.

Article 18. Involvement in the formulation of advisory reports, guidelines

1. Healthcare professionals who participate in committees involved in drawing up (scientific) advisory reports or treatment guidelines, act in accordance with the 'Code for the prevention of improper influence due to conflicts of interest.' ('Code ter voorkoming van oneigenlijke beïnvloeding door belangenverstrengeling').

2. Suppliers endorse the 'Code for the prevention of improper influence due to conflicts of interest '.

OTHER PROVISIONS

Article 19. Sponsorship of patient organisations

Sponsorship of a patient organisation by suppliers is permitted, on the provision that the conditions stated in this article are met.

1. Sponsorship must be designed in such a way as to ensure that the independence of the patient organisation, its policy and activities are not put at risk.

2. Arrangements about sponsorship are recorded writing, prior to sponsorship, in an agreement signed by all involved parties. This agreement always contains a precise description of the rights and obligations of both the patient organisation and the sponsor. The agreement is available to third parties.

3. Where sponsorship is related to a specific activity, it is recorded in the agreement that the patient organisation clearly communicates that the activity is (partly) made possible by the sponsor involved.

4. If sponsorship does not take place directly, but via a third party, this must be made clear in the agreement.

5. In the relation between sponsor and patient organisations, the negotiation of exclusivity is not permitted, unless it concerns a specific project.

6. The supplier who sponsors a patient organisation, sets the condition that the patient organisation declares that it endorses and applies the Dutch Federation of Patients and Consumer Organisation's code of conduct for fundraising.

Article 20. Institutions

1. Institutions are obligated, where applicable, to comply with this code of conduct and to ensure that either their employees or the healthcare professionals who fall under their responsibility comply with this code of conduct.

2. Institutions ensure that either their employees or the healthcare professionals that fall under their responsibility can meet the regulations in the context of this code with reference to transparency.

Article 21. Health Insurance Companies, healthcare administrative offices, local councils

The regulations of this code of conduct apply equally to health insurance companies that offer or provide healthcare insurance, healthcare administrative offices and/or local councils that implement the Dutch Long-Term Care Act or the Dutch Social Support Act.

PUBLICATION IN HEALTHCARE TRANSPARENCY REGISTER

Article 22. Compulsory publication in Healthcare Transparency Register

1. The following categories of interactions must be published in the Dutch Healthcare Transparency Register or another public register appointed for the purpose by the management of the Foundation for the Code of Conduct Medical Devices:

    a. remuneration of services, within the meaning of Article 5.3(d) in conjunction with Articles 13 and 14, and
    b. sponsorship of projects or activities other than meetings, within the meaning of Article 5.3(e) in conjunction with Articles 15 to 17 inclusive,

in each case to the extent that these occur between:

i. healthcare professionals listed in the BIG Register in the category 'doctor' (other than doctors registered for the specialisms 'general practice medicine' and 'general practice medicine and pharmacy'). This includes any collaboration involving these healthcare professionals or, in the event that the interactions take place via the institutions at which these healthcare professionals are employed or participating, these institutions; and

ii. suppliers of medical devices.

2. The publication requirement only applies if the total amount due to (one or more) interactions between a specified supplier and a specified healthcare professional as referred to in paragraph 1 of this Article exceeds €500 per calendar year.

3. Remuneration of services for research to which the Dutch Medical Research involving Human Subjects Act applies is excluded from the publication requirement under this Article.

4. The categories of interaction described in paragraph 1(a) and (b) shall be deemed to include agreements that are entered into by a third party on the instructions of a supplier or healthcare professional, collaboration of healthcare professionals or institution rather than in its own name, with the rules in that paragraph being applied as though such agreements were made in the name of the supplier, healthcare professional, collaboration or institution.

Article 23. Information to be published

In the context of Article 22 the following information must be published in the Healthcare Transparency Register:

a. the nature of the interaction and the calendar year in which the interaction was carried out;

b. the supplier's name and branch address and/or Chamber of Commerce registration number;

c. for service agreements, as described in Article 22.1(a):

- the personal details (name, specialisation and work address) of the healthcare professional who actually carried out the services (regardless of whether this healthcare professional is also the recipient of the sums paid) and the total amount of the fee (excluding any expenses reimbursements) paid to the healthcare professional and/or attributed to that person for actually carrying out the services in the relevant calendar year, on the condition that the aforementioned total sum for the relevant calendar year exceeds €500; and

- (if applicable) the details (name, branch office and/or Chamber of Commerce registration number) of the collaboration of healthcare professionals and/or institution in which healthcare professionals are employed or participating and the total amount paid to the same in the relevant calendar year, where the contract for services is entered into with a collaboration or institution.

d. for sponsorship agreements as described in Article 22.1(b):

- the details (name, branch office and/or Chamber of Commerce registration number) of the collaboration or institution with which the agreement is entered into and for each sponsor agreement the amount paid under the agreement in the relevant calendar year.

Article 24. Supply of information and publication method

1. The information required to be made public under Articles 22 and 23 must be supplied to the Healthcare Transparency Register by the supplier annually within the period specified by the Healthcare Transparency Register, in accordance with a format prepared for the purpose by the Healthcare Transparency Register.

2. Prior to actual publication by the Healthcare Transparency Register, healthcare professionals and/or institutions will be given a specified period in which to check the information provided about them and correct factual inaccuracies (or arrange to have such inaccuracies corrected).

3. Contrary to the provisions of paragraph 1, healthcare professionals who enter into interactions required under this Code of Conduct to be made public with:

    a. suppliers established outside the Netherlands, or
    b. suppliers who are not members of one of the trade associations affiliated to the Foundation for the Code of Conduct Medical Devices,

    must take responsibility for supplying the information described in the previous paragraph, in each case in accordance with paragraph 1, unless explicitly agreed otherwise between the parties.

Article 25. Duration of publication

Publication under this paragraph applies for a period of 3 years. After 3 years the Healthcare Transparency Register will remove the information.

Article 26. Date of entry into force of publication requirement

1. The requirement for publication in the Healthcare Transparency Register under Article 22 is expanded with effect from 1 January 2017 and enters into force on that date. The requirement for publication that previously entered into force in 2015 as a pilot for certain suppliers of medical devices and certain healthcare professionals shall remain in force until the amended Article 22.1 takes effect.

2. All parties bound by the Code of Conduct Medical Devices are at liberty to publish interactions in the Healthcare Transparency Register on a voluntary basis ahead of and in addition to the requirements in the previous paragraph. In doing so parties shall act according to the procedure and instructions of the Healthcare Transparency Register.

Article 27. Written agreements regarding publication

All parties bound by the Code of Conduct Medical Devices shall ensure that with effect from 1 January 2015 they no longer enter into any agreements containing provisions that could obstruct a requirement for publication in the Healthcare Transparency Register under this Code of Conduct. This applies both with respect to the publication requirement that enters into force on 1 January 2015 and with respect to all other future publication requirements under this Code of Conduct.

Explanatory Notes
on the Code of Conduct Medical Devices

In drawing up the code of conduct every effort has been made to stay in line with the international codes of conducts from Eucomed, EDMA and COCIR, which are currently in force. The regulations currently in force in the Netherlands for showing favour in the context of advertising medical products have also been taken into consideration, as far as they are relevant and appropriate. In addition, the starting point was the practical applicability for the parties in the field that have to work with the code of conduct.

Article 1. Definitions

As far as possible the definitions are in line with the relevant legal definitions.

The definition of *medical devices* (Article 1 (a)) is in line with the Social Support Act and the executive acts based on it. Hereby, the complete supply of medical devices and medical technology fall under the scope of the code of conduct.

The definition of *healthcare professional* (Article 1 (b)) has been broadly formulated deliberately. A healthcare professional is any person who, in the context of the care and support he offers, is involved in the choice of use, purchase, selection and the like for medical devices. The involvement of a healthcare professional in this choice brings with it a responsibility to operate with care and integrity.

The code only applies to interactions in which healthcare professionals employed in the Netherlands are involved (see also Note at Article 2). However, the setting in which the healthcare professional is employed is not of relevance: whether employed at an institution or a company, as part of a partnership or similar collaboration format, or self-employed. The applicability of the code of conduct cannot be circumvented, for example through arrangements via a partnership, a legal entity or a healthcare institution. Neither can the code of conduct be circumvented by involving third parties or intermediaries. Also in such cases the code of conduct remains in full force and the transactions of the third party will be fully attributed to the third party it represents. Also see the Note at Article 2.

The definition of *institution* (Article 1 (c)) is in line with the Healthcare Quality, Complaints and Disputes Act, which replaced the Care Institutions Quality Act with effect from 2016. This means that institutions includes all institutions that offer care as described by or under the Healthcare Insurance Act and the Long-Term Care Act and that offer support where actions are undertaken, within the meaning of Article 36 of the Individual Healthcare Professions Act, that are not related to care as described by or under the Healthcare Insurance Act or the Long-Term Care Act.
This definition is broad; it concerns all forms of collaboration by or as a result of which care or support is provided. These will often be legal entities (hospitals, for example) but can also be partnerships, care groups or other forms of collaboration. In the Healthcare Quality, Complaints and Disputes Act a link is made to the Healthcare Insurance Act and the Long-Term Care Act. It is not relevant for the applicability of the code of conduct whether a specific device will or will not be reimbursed in a specific case. The setting in which the interaction takes place is key. If the situation does not involve healthcare as defined in the Heathcare Quality, Complaints and Disputes Act, the rules do not apply. In all other cases the rules do apply. See also the Note on Article 2.

It is also the intention to involve institutions in this code of conduct and to give them a role in monitoring compliance; not only Article 20 serves this purpose, but also the stipulations that demand that the healthcare professional concerned informs the board or manager within the institution where the

healthcare professional is employed, regarding certain interactions and in some cases also requests demonstrable approval.

The definition of *supplier* is also broadly formulated and intended (Article 1 (d)). Not only those who produce medical devices (manufacturers), but also those who sell, stock, deliver them or provide services in connection with medical devices (such as service and maintenance) fall under this definition and are bound by the code of conduct. The code is not only applicable to suppliers that are based in the Netherlands, but to every supplier that has interaction with healthcare professionals in the Netherlands. Also see the note at Article 2.
Attention must be given to the situation where a healthcare professional also acts as a supplier. Consider the pharmacist who has a role as healthcare provider, but who also sells medical devices, or the clinical chemist who develops and sells a certain test. The code of conduct is then fully applicable; which regulations apply depends on which role an individual plays in a specific case.

This code of conduct discusses interaction. This term is broadly described to demonstrate that the code of conduct has a broad application. The term “to show favour” has deliberately not been chosen, because this term has a specific meaning within the regulations for advertising medical products and is therefore less appropriate within the context of this code of conduct.

Where discussed, reimbursement of expenses in this code of conduct means the payment or sponsorship of costs.

Article 2. Scope of the Code of Conduct

The aim of the code of conduct is to realise that decisions related to, for example the use or purchase of a medical device by a healthcare professional, is not influenced in an undesirable manner. This influence can be undesirable, because of specific statements that are incorrect or misleading, or because there are incentives that can influence the choice. The code of conduct is therefore intended to keep the relationship between the supplier and the healthcare professional clear.

The code of conduct is applicable to all interactions between suppliers and healthcare professionals, regardless of the setting in which the healthcare professional is employed (also see the note at Article 1 for the definition of *healthcare professional*). The question as to whether the medical devices concerned are reimbursed by or under the Healthcare Insurance Act, the Long-Term Care Act or the Social Support Act (also see the note at Article 1 under *institution*) is not relevant. An exception to this is the situation in which devices are used outside the care setting as intended in the Healthcare Quality, Complaints and Disputes Act. For example, the medical devices included in a first aid box which sport clubs, emergency response team members or consumers purchase and pay for of their own initiative and for their own use.

The code of conduct is intended to be applicable to all interactions that could influence the decisions of healthcare professionals in the Netherlands. The scope of the code of conduct is therefore limited to interactions that are related to and statements that are intended for healthcare professionals employed in the Netherlands. In addition, the regulations apply to all suppliers, regardless of whether they are based abroad or in the Netherlands (as long as the supplier has signed the code of conduct). Whether a supplier based in the Netherlands can be held accountable for a transaction of a foreign affiliated company (for example a sister company) will depend on the involvement in the transaction of the company based in the Netherlands.

Article 3. General Principles

Article 3 contains the general principles that underlie the code of conduct. These principles are derived from diverse international codes, that are based on four principles: the principle of independence, proportionality, documentation and transparency. These general principles are specifically detailed for different types of interaction in the Articles 5 et seq of the code of conduct.

The principle that interactions must be transparent (Article 3(d)) can prevent undesirable interactions. This requirement finds further application at several points in the Code of Conduct.

In the first place, for a large number of interactions an obligation to record the interaction in writing applies. The Code of Conduct also contains at several points obligations with respect to *internal* transparency. Internal transparency is intended to create more awareness with respect to interactions within the organisations and/or collaborations in which healthcare professionals work. An *internal reporting requirement* therefore applies with respect to certain interactions. This means that the healthcare professional reports agreements about the interaction in question to his employer or to the board of the institution where he is employed (see Articles 9(3) and 9(4), Article 10(3) and Article 11(3) on meetings). For certain other interactions an *internal approval requirement* applies. In such cases the written agreements about the relevant interaction must be approved in advance by the employer or the board of the institution (see Article 13(7) on services and Article 15(5) on sponsorship).

With effect from 2015 the Code of Conduct contains a separate paragraph concerning *external* transparency. External transparency is intended to enable third parties, including the patient, to check whether certain interactions exist between a healthcare professional and suppliers of medical devices. This can have particular relevance in the case of patient-specific medical devices, which are generally selected by the healthcare professional. The requirement to record certain interactions in the publicly-accessible Healthcare Transparency Register enables patients and other interested parties to verify, within certain parameters, whether a financial relationship exists between a healthcare professional and the suppliers of certain medical devices and, if so, the nature of this relationship.

The requirement to publish interactions in the Healthcare Transparency Register applies in the first instance only to certain interactions between medical specialists listed in the BIG Register under the heading ‘cardiology’ or ‘orthopaedics’ and suppliers of the following implants: ICDs, pacemakers, stents and hip and knee prostheses. Depending on how this first phase is experienced, the publication requirement will be extended at a later stage to other groups of healthcare professionals and/or suppliers of medical devices.

Article 4. Statements

Requirements are imposed on advertising for medical devices to prevent the development of an incorrect and/or misleading image that may lead to decisions related to the purchase or use being made on incorrect grounds. Statements that mislead the receiver/reader must be prevented. Therefore a number of general requirements are set down in this article for statements concerning medical devices. A claim must be demonstrably correct, accurate and verifiable and not misleading. The principle is that any person who makes a claim, must be able to substantiate the correctness. This substantiation can be made, for example, with data from studies, referral to instructions for use and published articles. Because there are many different types of medical devices available on the market and claims can differ from one another widely in form, content and purpose, each case must be considered individually as to whether the claim is sufficiently substantiated. Acknowledgement of sources is important; these sources must also be made available.

From the broad definition of statement in Article 1 (g), it follows that Article 4 is applicable to every form of communication, regardless of the situation and context in which this takes place. It does not matter

whether the statement is promotional or not, and whether it is communicated in writing, verbally or electronically.

For the purpose of clarity it is pointed out that in the context of self-regulation for publicly advertising medicines, the Inspection Board for the Public Promotion of Medicines/the Inspection Board for the Promotion of Health Products (KOAG/KAG) has also set conditions for advertising specific medical devices. This explicitly concerns medical devices on a pharmaceutical basis with a physical application, intended to be used by the consumer without the official involvement of a healthcare professional. These requirements have been recorded in the Code Public Promotion Medical (self care) Devices (www.koagkag.nl). In so far as applicable these requirements apply in addition to what is specified in Article 4.

Article 5. Interactions between suppliers and healthcare professionals

The principle is that there is essentially nothing wrong with interactions between suppliers and care providers, but it is recognised that this can influence decisions concerning, for example, purchase or use. Therefore boundaries are set for the different forms of interaction. Interactions that do not remain within these boundaries, will be deemed to be able to have an undesirable influence. It is therefore not relevant whether a healthcare professional actually is or will be influenced. Where relevant and possible, in drawing up the boundaries, this document has stayed in line with what is deemed acceptable within healthcare concerning interactions related to medicines. Reciprocity has also been covered in this article: what may not be offered or given, may also not be requested or accepted.

Clauses 1 and 2 are complimentary and record the regulations for reciprocity. It has been decided to set down explicitly what one party may not offer or give and what the other party may not request or accept.

In clause 3 five types of interactions are distinguished. These are detailed in Articles 6-17. To establish which regulations apply, the qualification of the interaction is of great importance. The descriptions included in the respective articles serve this purpose. Other interactions or interactions that do not satisfy the conditions of the code of conduct are not permitted.

Clauses 4 and 5 provide more detail on the general principles expressed in Article 3. Clause 4 is a crucial stipulation: interactions may never be related to a decision concerning purchase, use, prescription and/or ordering medical devices, unless it concerns bonuses and discounts that satisfy Article 6. (Receiving) payment for the purchase or prescription of a certain medical device is therefore not permitted.

Article 6. Bonuses and discounts related to business transactions

Bonuses and discounts related to business transactions are permitted, on the provision that the listed cumulative requirements in this article are met. These are related to the type of discount and the desired transparency. It is explicitly prohibited to link the establishment of a business transaction to the offering or promising respectively, requesting or accepting of financial benefits in favour of third parties. Bonuses and discounts may benefit (legal) entities that are either directly involved in the business transaction or directly involved in the distribution or delivery of the medical devices that the business transaction is related to. It is not permitted, for example, to link a transaction to the payment of a person related to the healthcare professional or a research foundation.

Article 7. Gifts

It must be possible for a supplier of medical devices to develop marketing activities, just as is the case for other industries. Distributing promotional material or gifts can be an element of this. This is acknowledged

in Article 7, but in addition boundaries are set for the nature and value of the gifts, as well as for the frequency with which these may be given and received. The cumulative requirements and amounts named in Article 7 are in line with the regulation that applies to the acceptance of gifts for government officials and which also underlies the policy regulations on demonstration of favour which apply in the pharmaceutical sector.

In clause 1(b) the requirement is included that a gift must either be related to the practice of the healthcare professional, can benefit patient care or can fulfill a clear educational function. If it can be reasonably assumed that a gift will largely be used privately, it does not meet these requirements. Perception plays a role in this regard.
The amounts named in clause 2 is the retail value including VAT. It does not concern the purchase value for the company, but the market value. A relevant question is: What would the healthcare professional have to pay for this himself? There is a maximum amount per occasion, but also a maximum of three placed on the number of gifts that may be given or received, as the case may be, per year.

Clause 3 forbids bestowing gifts in the form of cash monies or, for example, book tokens. This ban also runs on from the requirement in clause 1.

Clause 5 contains two exceptions to the scope of practice in this article. Product testers are generally not perceived as gifts and are therefore permitted. The exception under b creates the possibility that it is not prohibited to, for example give a bouquet of flowers or a bottle of wine for a one-off, personal event such as promotion or a relevant anniversary on the basis of this code of conduct, on the provision that it is reasonable and appropriate. This exception must be applied sparingly; bestowing gifts in the context of recurring general celebrations (birthdays, Easter or Christmas) does not fall under this exception.

Article 8. Financial contributions to expenses (for participation in) meetings for healthcare professionals; general principles

Paying expenses related to a meeting can also be seen as interaction that can be influenced. Payment of expenses related to a meeting can also be seen as interaction that may possibly be of improper influence. In clause 2 the principle is recorded that suppliers may pay expenses related to meetings and may be otherwise involved in meetings for healthcare professionals, on the provision that the requirements of the code of conduct are met.

In Article 8 (1) four types of meetings are distinguished. These are detailed in Articles 9-12. The requirements are related to the programme, the location and the expenses. The specific interpretation of these requirements can differ for each type of meeting. This is due to the influence a supplier may or may not have on the programme or the location.

In general terms the *programme* of a meeting must be understandable and acceptable. For example tea and coffee breaks, lunches and dinners are logical intervals that must be part of the programme. Other programme elements that bear no relevance to the content, such as recreational and social activities (concerts and sports activities, etc.) are not logical. Naturally, some time may be allotted for relaxation, on the provision that it is reasonable and proportional in duration.

The *location* check contains two aspects: the geographic location and the facilities. Both must be legitimate and, if so this will differ per type of meeting. The facilities may not be attractive to such an extent that they are the reason that healthcare professionals want to participate in a meeting. The geographic location must be objectively legitimate. This may be the case if the location is a logical choice with respect to the origin of the speakers and invited participants or with respect to the accessibility. There may also be a direct relationship between the topic and/or objective of the meeting and the location, which makes it logical to

hold the meeting there. Examples of this are a visit to a relevant hospital, research institution, laboratory or company.

In terms of expenses, only certain costs may be paid for by the supplier and then only in so far as these are reasonable.

To determine which regulations apply, the qualification of the meeting is of great importance. For this purpose there are descriptions included in the respective articles.
Clause 3 contains the ban to cover costs, whether direct or indirect, for those other than healthcare professionals, such as partners or children and on the grounds of clause 5 only costs named and specified in Articles 9-12 may be paid.

Clause 4 is related to the desired transparency and is in line with Article 3 (d). In addition, in Articles 9-11 the mandatory recording of arrangements concerning the reimbursement of expenses to the board of the institution or the employer is laid down.

Article 9. Meetings organised by independent third parties

Article 9 is applicable to a meeting for healthcare professionals that is organised independently of the supplier. This is the case when the meeting is organised without the involvement of the supplier in the content of the programme, the invitation policy and the location of the meeting. The organiser determines and therefore supervises the content of the programme, the selection of speakers, presentations and materials. Companies may have no other influence on the programme than recommending speakers or giving feedback on the programme when requested.

As has already been mentioned in the note to Article 8, three requirements apply to all meetings related to the programme, location and expenses. When a supplier has absolutely no involvement with a meeting, the programme and the location will be determined independently of him. In spite of this, requirements are set, so that sponsoring or reimbursement of expenses in the context of a meeting organised by an independent third party is only permitted when the programme meets the requirements under sub-clause a and there is objective justification for the location, both in terms of facilities and geographic location (sub-clause b, also see the note for Article 8).

On the provision that the programme and location meet the requirements, a supplier may reimburse certain expenses. This only concerns registration fees, reasonable and necessary travel expenses and the costs of one or more reasonably priced meals and necessary overnight stays. Naturally, this only concerns the actual costs incurred.

Of course, by stating the maximum amount it is not implied that suppliers are always expected to reimburse expenses; what is meant is that in all cases no other expenses may be reimbursed than registered in Article 9. Moreover, there is a maximum to the costs a supplier may reimburse, both per meeting and per year.

Expenses can also be paid or reimbursed directly to the healthcare professional. The organiser can also be sponsored. Where a financial contribution is made to the organiser of a meeting and this contribution is *only used* for general costs that are directly related to the organisation of the meeting (such as costs for speakers, room hire, printed material) the maximum amounts do not apply. The condition does apply that all other requirements from this article are met, amongst other things in relation to the programme and location.

In clauses 3 and 4 requirements are recorded with regard to transparency and documentation. Recording arrangements and informing anyone that is relevant and responsible within the institution are essential.

In clause 5 an exception is made to the general regulations of Article 9 for the purchase of advertising space and stand hire by suppliers at meetings organised by third parties. In these cases it is not necessary to meet the requirements of clause 2 (programme, location and expenses) on the condition that the hire of a stand and the price for advertising space is in line with the market. In other words, it may not be disproportionately high. Costs other than the general organisation costs are not meant to be paid by high advertising income or hire income. This is in line with the requirement that any possible surplus may not benefit healthcare professionals. That the supplier may have absolutely no involvement in the organisation, stems directly from the first clause.

Suppliers may be involved with satellite meetings of parallel meetings that take place around the meetings referred to in this article, irrespective of whether the involvement is in the capacity of organiser, sponsor or any other. In clause 6 a few requirements are set for the programme and content, as well as for recording arrangements and other transparency aspects.

Article 9 A. Meetings organised by independent third parties; transitional ruling

(withdrawn). On the entry into force of the Code of Conduct in 2012 a transitional arrangement was provided for financial contributions to the costs (for the participation of healthcare professionals) of meetings organised by independent third parties as described in Article 9. This transitional arrangement applied to the years 2012 and 2013. As this transitional arrangement had no further relevance after this period and actually only raised questions, Article 9A was withdrawn in the amendment of the Code of Conduct with effect from 1 January 2015.

Article 10. Product related meetings organised by suppliers

Many medical devices can only be used, applied and maintained properly in a safe and responsible way after specific and regular product training. Usually it is necessary for such training to take place at locations that are specifically equipped for the training (for example training with implants in a clinical setting, skill labs). Financial contributions by suppliers to such so-called product related meetings have to meet the conditions of Article 10. These conditions regard the programme, the location and the expenses of product related meetings. For the sake of good order it is noted that the description of 'product related meeting' has been amended as from the 1st of January 2018 as a result of the entering into force of Inducements Medical Devices Act Policy Rules (Beleidsregels gunstbetoon medische hulpmiddelen). As a result of this amendment, product related meetings organised by suppliers intended for healthcare professionals that are necessary in the context of a possible decision for the purchase of medical devices no longer fall within the scope of Article 10.

The *programme* must not only be related to, but must also be suitable for the transfer of knowledge. This must be clear from the programme content and the qualifications and expertise of the trainers, support staff and speakers. In terms of programme design, coffee and tea breaks, lunches and dinners must be a logical pause in the programme. Overnight stays must be legitimate. Other programme elements that bear no relation to the content, such as recreational and social activities (concerts, sports activities, etc) are not permitted.

When assessing the legitimacy of the *location*, the nature of the specific medical device related to the meeting can play a role. Due to the size or complexity of the medical device it may be the most obvious and even necessary location for the training. In particular for these meetings the justification for the location and facilities are related to the aim of the meeting. For example, training will often take place in a clinical environment, on company premises or in a trial setup.
Any legitimate lunches and dinners must either take place at the location where the meeting takes place or at another suitable business environment.

As from 2018, a maximum applies to the *costs* a supplier may contribute to a product related meeting. The supplier may only cover costs that are directly related to the organisation, travel and overnight stays. The supplier does not contribute more than € 500 per meeting to a maximum of € 1,500 per year. Alternatively, the healthcare professional pays at least 50% of the above-mentioned costs personally.

Transparency is also regulated in this article, both in terms of written documentation and notification.

Article 11. Accredited meetings organised by suppliers

Suppliers of medical devices can organise meetings for healthcare professionals that are not related to a product in the sense of Article 10. These can, for example, be related to certain diseases, treatment methods or developments in care. Such meetings can deliver an important contribution to the knowledge of healthcare professional and thereby to good care. If the content of the programme has been assessed by an institution recognised by the professional group involved and subsequently accredited, the supplier may pay for the costs of such meetings, on the provision that the requirements set in this article are met. Indeed the accreditation records the quality and importance of the meeting.

The *programme* design must be balanced and reasonable; see the note to Article 8. The *location* must be legitimate, both in terms of facilities and geographic location. Concerning the latter, the accessibility of the location and the origin of the participants can play a role; facilities are legitimate when they have a professional image.

The *expenses* that the supplier may pay may only be related to the organisation, travel and overnight stay, on the provision that these expenses are reasonable and (for overnight stays) necessary and for travel and overnight stays do not go above the maximum amounts and frequency stated in this article. In addition, the supplier may cover all costs that bear a direct relationship to the organisation of the meeting (such as expenses for speakers, room hire and printed materials).

The requirement for transparency also applies for these meetings, both in terms of written documentation and in terms of notifying either the board of the institution or the employer.

Article 12. Other meetings organised by suppliers

Meetings in this 'remainder' category can be very diverse in nature but must be professional, for example product discussions, contract negotiations and so on. Meetings of a social and recreational character are not permitted.
It is possible to offer and accept hospitality at the meetings, but within the stricter boundaries of this article. Also see the note for Article 11 with reference to the costs.
The setting of this is that the meetings generally have a commercial component. When assessing the general requirements the specific character of these meetings must be taken into consideration. The requirements are therefore adjusted.

Article 13. Remuneration of Services

A healthcare professional can deliver various types of services to suppliers. For example, providing training and lectures, giving advice, participating in research or on an advisory board. Whether the service is provided either on an individual basis, by a number of healthcare professionals, whether or not in collaboration, is not of relevance.

There is no objection to the provision of these services and their remuneration, on the provision that the requirements of this article are met. These requirements are related to the content and legitimacy of the service, the remuneration for them, the manner of reporting and transparency. When a healthcare professional receives no remuneration, the article is not applicable.

The basic principle is that remuneration for the services is reasonable compared to the services provided. Expenses may be reimbursed in full provided that they are reasonable. When the Code of Conduct was established in 2012 it was decided in the first instance not to mention any standard amounts and merely to include a provision that the reimbursement should be 'in line with the market'. On the amendment of the Code of Conduct in 2015 the Code of Conduct Medical Devices decided, for the sake of uniformity and clarity, to follow the agreements made between the Foundation for the Code for Pharmaceutical Advertising and the Dutch Healthcare Inspectorate in 2014. With effect from 1 January 2015 the following maximum hourly rates may be regarded as 'in line with the market' in the context of the Code of Conduct Medical Devices:

Professor	€ 200
Medical specialist	€ 140
General practitioner	€ 100
Pharmacist	€ 100
Dentist	€ 85
Nurse	€ 70

These are maximum rates, which means that higher rates are not permitted, even if the relevant healthcare professional has special qualifications. Hourly rates for healthcare professionals not included in the above list may be inferred from the above list on the basis of relevant comparators such as training level. To make matters absolutely clear, it should be noted that the number of hours reimbursed must also be reasonable, with the nature of the activities and the qualifications and expertise of the individual providing his services playing a role in determining what is reasonable. The above rates also apply in the event that the nature of the services require that the activities must be carried out in another country.

As a standard for the reimbursement of travel expenses incurred in the context of providing services it has been decided – in line with the aforementioned agreements between the Code for Pharmaceutical Advertising and the Healthcare Inspectorate – to follow the expenses reimbursement arrangements for Dutch civil servants. Based on those arrangements, the following reimbursement of travel expenses for providing services are considered reasonable:

Car	€0.37 per km
Train	cost of first class travel (regardless of whether a subscription is held)
Taxi	full reimbursement, to supplement public transport

Aeroplane	first class not permitted, business class permitted for intercontinental flights

Depending on the circumstances it may be reasonable to provide financial compensation for travel time during normal working hours; outside working hours this is not permitted. In this context consideration should be given to the fact that it may be possible to prepare for the services requested while travelling; double remuneration for travel time and preparation time is not permitted.

If a healthcare professional participates in a meeting in the context of providing services, the location where the meeting is held should be appropriate and the hospitality should be modest and subordinate in duration and purpose to the primary (main) purpose of the meeting. The expenses paid in this context do not count towards the maximum amounts stated in Articles 9 to 12.

For the sake of transparency and accountability service provision contracts (and sponsorship contracts) must not only be reported to the board or the employer, but here also demonstrable approval must be given, for example by co-signing or explicit approval.

Article 14. Service Provision Agreement

In this article it is determined what minimal mandatory agreement for service provision must be laid down on the grounds of Article 13.
Please note clause 2, in which it is explicitly recorded that the agreement in the case of research must refer to a research protocol or a written plan of activities. In addition, all relevant and/or required approval and consent for conducting this research must be acquired. For example approval from a Medical Ethics Committee in the context of the Act on Medical Research with People and the local feasibility test.

Article 15. Sponsorship of projects or activities other than meetings

Sponsorship is a broad concept. In the context of this code of conduct all forms of financial or other forms of financial support of healthcare professionals and institutions as defined in Article 1 fall under this concept, regardless of whether there is a quid pro quo agreement (for example acknowledgement) and regardless of the name the parties give it (grant, donation, etc.). Sponsorship of meetings or patient organisations does not fall under this article; these forms are already dealt with elsewhere in the code of conduct (see Article 18).

The basic rule is that sponsorship by suppliers is permitted, on the provision that a number of requirements are met. Amongst other things, these concern the legitimacy of sponsorship. Sponsorship must finally benefit medical care or science.
Sponsoring of individual healthcare professionals is not permitted; an exception has been included for theses. The sponsored party must be an organised partnership, institution or faculty.
It is crucial that sponsorship may not lead to undesirable influence, because there is, for example a direct or indirect relationship to the purchase or use of the sponsor's products.

Arrangements concerning sponsorship must be recorded in a written agreement; an exception applies to the sponsorship of theses.

To ensure transparency and responsibility sponsorship contracts must not only be reported to the board or the employer, but demonstrable approval must also be given, for example by co-signing or explicit approval.

Article 16. Specific forms of sponsorship; study grants

The sponsorship of study grants must meet the requirements of Article 15 and in addition, a number of additional requirements, recorded in Article 16.

Article 17. Specific forms of sponsorship; research

Specific requirements also apply to the sponsorship of research, which are in addition to the requirements recorded in Article 15.

Article 18. Involvement in the formulation of advisory reports, guidelines

In 2012 the 'Code for the prevention of improper influence due to conflicts of interest' (in Dutch: 'Code ter voorkoming van oneigenlijke beïnvloeding door belangenverstrengeling', hereafter: 'Code conflicts of interest') came into force. This code has been drawn up by the Royal Dutch Academy of Sciences, Royal Dutch Society for the Promotion of Medicine, Health Council, Central Support Group, Dutch College of General Practitioners and the Order of Medical Specialists and is endorsed by a large number of other organisations.

This 'Code conflicts of interest' ensures that committee participants (as broadly defined in this Code), who contribute to advisory reports and guidelines, can provide their knowledge and insights without bias. Therefore, the starting point of the 'Code conflicts of interest' is that personal and business interests of healthcare professionals who participate in scientific advisory boards or other committees that draw up treatment guidelines or advisory reports, be made transparent. Explicitly referring to this 'Code conflicts of interest', in Article 18 of the 'Code for Medical Devices' not only ensures that healthcare professionals who are members of an umbrella organisation that has already endorsed this Code are once again reminded of this, but also encourages other healthcare professionals to conform to this Code. The same applies to suppliers; in the second paragraph of Article 18, they endorse the principles of the 'Code conflicts of interest'.

Article 19. Sponsorship of patient organisations

The basic principle recorded in this article is that the sponsorship of a patient organisation by suppliers is permitted, on the condition that the independence of the patient organisation is not damaged. The patient organisation must, in this context, declare that it subscribes to and applies The Federation of Patients and Consumer Organisations in the Netherlands (NPCF) Code of Conduct for fundraising.

Article 20. Institutions

Healthcare professionals are often employed in institutions (hospitals, independent treatment centres, healthcare groups). It is in the interest of all parties that institutions are also aware of the undesirability of improper influencing and in this context take a positive line. Therefore this article states the obligation of institutions to comply with this code of conduct and to ensure that those working under their responsibility comply with this code of conduct, and also facilitate compliance.

Article 21. Health Insurance Companies, healthcare administrative offices, local councils

Although health insurance companies, healthcare administrative offices and local councils are not healthcare professionals in the sense of this code of conduct, they have increasing influence on the decisions that are taken within healthcare, even when related to medical devices. For this reason it is

logical to declare the code of conduct equally applicable to the interactions between these organisations and suppliers, so that undesired influence is also avoided in these relationships.

Article 22. Compulsory publication in Healthcare Transparency Register

With effect from 2015 a separate paragraph has been added to the Code of Conduct relating to *external* transparency. External transparency is intended to enable third parties, including the patient, to check whether certain interactions exist between a healthcare professional and suppliers of medical devices. This can have particular relevance in the case of patient-specific medical devices, which are generally selected by the healthcare professional. The requirement to record certain interactions in the publicly-accessible Healthcare Transparency Register enables patients and other interested parties to verify, within certain parameters, whether a financial relationship exists between a healthcare professional and the suppliers of certain medical devices and, if so, the nature of this relationship.

The Healthcare Transparency Register was established in 2012 at the instigation of the Foundation for the Code for Pharmaceutical Advertising with the aim of providing insight into the financial relationships between healthcare providers and pharmaceutical companies and it is managed by the Healthcare Transparency Register Foundation. The management of the Foundation for the Code of Conduct Medical Devices has decided to use the Healthcare Transparency Register for the publication of interactions between medical device suppliers and healthcare professionals. This creates a single central public register that the general public can use to investigate what connections exist between healthcare professionals and the industry. More information on the Healthcare Transparency Register and the Healthcare Transparency Register Foundation is available at www.transparantieregister.nl.

The first phase of compulsory publication of interactions in the Healthcare Transparency Register came into force with effect from 1 January 2015. The first phase related to certain interactions between medical specialists listed in the BIG Register in the category ‘cardiology’ or ‘orthopaedics’ and suppliers of the following implants: ICDs, pacemakers, stents and hip and knee prostheses.

Following a thorough evaluation of this first phase, the management of the Foundation for the Code of Conduct Medical Devices decided in 2016 to expand the requirement to publish certain interactions in the Healthcare Transparency Register with effect from 1 January 2017. From that date under the amended Article 22 a publication requirement applies to the following categories of interactions:

- remuneration for services, as referred to in Article 5(3)(d) in conjunction with Articles 13 and 14, and
- sponsorship of projects or activities, as referred to in Article 5(3)(e) in conjunction with Articles 15 to 17.

between suppliers of medical devices and healthcare professionals listed in the BIG Register in the category ‘doctor’ (other than doctors registered for the specialisms ‘general practice medicine’ and ‘general practice medicine and pharmacy’). The publication requirement only applies if the total amount due to (one or more) interactions between a specified supplier and a specified healthcare professional as referred to in paragraph 1 of this Article exceeds €500 per calendar year.

Sponsorship of *meetings* is not required to be reported in the Healthcare Transparency Register.

Remuneration of services for research to which the Dutch Medical Research involving Human Subjects Act applies is also excluded from the publication requirement described.

The fourth paragraph makes it clear that it is irrelevant for the application of the rules on publication whether agreements are entered into directly between a supplier and a healthcare professional (or collaboration of healthcare professionals or institution) or via a third party. Examples would include a

conference agency that engages certain speakers on behalf of a supplier, acting as an agent for the supplier. The rules on publication then apply as though these agreements were entered into in the name of the supplier or the healthcare professional, collaboration or institution. The situation could be different if, for example, an agency carries out marketing research among healthcare professionals on the instructions of a supplier, but the healthcare professionals are selected and approached entirely independently of the supplier. In that case no direct relationship is created between the supplier and the healthcare professional and furthermore the services and amounts involved will generally be of very limited scope.

Article 23. Information to be published

p.m.

Article 24. Supply of information and publication method

p.m.

Article 25. Duration of publication

p.m.

Article 26. Date of entry into force of publication requirement

A pilot for the publication of certain interactions in the Healthcare Transparency Register was introduced with effect from 1 January 2015. This pilot related to certain interactions between doctors in the category ‘cardiology’ or ‘orthopaedics’ and suppliers of ICDs, pacemakers, stents and hip and knee prostheses. With effect from 1 January 2017 the requirement to publish certain interactions is expanded to apply to all suppliers of medical devices and all healthcare professionals listed in the BIG Register as doctors other than general practitioners. This means that the first time that this broad group will be required to supply data will be in 2018. That data will relate to the calendar year 2017. For the parties who were already covered by the pilot, the requirement that has applied to them since 2015 will remain in full force. This means that in accordance with the original requirement these parties will also have to report certain interactions to the Healthcare Transparency Register for the calendar years 2016 and 2017.

Article 27. Written agreements regarding publication

The requirement to publish information in the Healthcare Transparency Register cannot be impeded by agreements made between parties that would prevent publication. Pursuant to Article 26 it is no longer permitted, with effect from 1 January 2015, to include confidentiality clauses in agreements such that the publication requirement under the Code of Conduct cannot be complied with. This applies not only to the parties and interactions in respect of which the publication requirement enters into force in 2015. With a view to possible expansion of the requirements for external transparency in future it applies to all agreements recording interactions between healthcare professionals and suppliers of medical devices within the meaning of the Code of Conduct.

The management of the Foundation for the Code of Conduct Medical Devices has drafted standard clauses that may be included in agreements between suppliers and healthcare professionals and/or institutions for this purpose.

(original text of Article 22. Coming into Force and Transitional Provisions)

The original text of Article 22 was withdrawn with effect from 2015. The article concerned the date of entry into force of the Code of Conduct and also contained a transitional arrangement for obligations that already existed at that time. This transitional arrangement applied to the year 2012. As this transitional arrangement had no further relevance after this period and actually only raised questions, the original Article 22 was withdrawn in the amendment of the Code of Conduct with effect from 1 January 2015.