Code of Conduct for Medical Devices 2021

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 for Medical Devices 2021

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 healthcare professionals 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. The rules are reciprocal: 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 for Medical Devices.

Relationship to legislation
Since 2018 in addition to self-regulation there has also been legislation on inducements for medical devices. The Dutch Health and Youth Care Inspectorate monitors compliance with this legislation. The Foundation for the Code of Conduct for Medical Devices and the Health and Youth Care Inspectorate have Working Arrangements which cover, among other things, coordination of standards and demarcation of roles. These Working Arrangements are entered into for a specified period and reviewed when they are extended.

GENERAL PRINCIPLES

Article 1. Definitions

a. *Medical Device*
A medical device or medical device for *in vitro* diagnostics as defined in Article 1 of the Dutch Medical Devices Act[1].

b. *Healthcare Professional*
Any individual who, in the Netherlands, 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.[2]

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.

[1] Law of 24th October 2019, Official Gazette 2019, 400.
[2] Law of 7th October 2015, Official Gazette 2015, 407, as amended since then.

i. *Healthcare Transparency Register*
Central, public register for the registration of financial relationships between suppliers and healthcare professionals, which is administered by the Foundation for the Healthcare Transparency Register.

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 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. **Transparency**
Interactions between suppliers and healthcare professionals must be transparent, which entails, among other things, that certain interactions must be reported in advance to the healthcare institution or the employer. Prior approval must be given for service and sponsorship agreements within the meaning of Article 13 and Article 15, respectively. Institutions shall ensure that an administration of these agreements is maintained.
It may also be important for a patient to check whether certain interactions exist between a supplier and a healthcare professional. For this reason there are rules on compulsory reporting in the Healthcare Transparency Register.

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 fulfil 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 in a personal context, 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.

7. Speakers at meetings shall be transparent about their (financial and other) links with suppliers of medical devices. They should declare their links with suppliers or other parties relevant in this context

prior to their substantive presentation.

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. 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.

6. If, and to the extent that, Articles 22 et seq. apply, the information relating to hospitality referred to in those articles shall be published in the Healthcare Transparency Register. The written arrangements referred to in Articles 9.3, 9.4 and 9.5 shall record the manner in which the parties shall comply with these transparency requirements.

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.

General costs directly related to the organisation of the meeting (such as the costs of room hire, trainers, experts and essential printed materials and facilities) do not have to be included, provided that the other requirements of this article are met.

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 agreement either with the board of the institution or the employer.

4. If, and to the extent that, Articles 22 et seq. apply, the information relating to hospitality referred to in those articles shall be published in the Healthcare Transparency Register. The written arrangements referred to in Article 10.3 shall record the manner in which the parties shall comply with these transparency requirements.

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.

      General costs directly related to the organisation of the meeting (such as the costs of room hire, speakers and essential printed materials) do not have to be included, provided that the other requirements of this article are met.

      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.

4. If, and to the extent that, Articles 22 et seq. apply, the information relating to hospitality referred to in those articles shall be published in the Healthcare Transparency Register. The written arrangements

referred to in Article 11.3 shall record the manner in which the parties shall comply with these transparency requirements.

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 than €75 per meeting with a maximum of € 375 per healthcare professional per year in the above-mentioned costs.

      General costs directly related to the organisation of the meeting (such as the costs of room hire, speakers and essential printed materials) do not have to be included, provided that the other requirements of this article are met.

      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. Institutions shall maintain an administration of the agreements approved under this article.

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. The written agreement referred to in Article 13.2(c) shall record the manner in which the parties shall comply with these transparency requirements.

Article 14. Service 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);
    e. the manner in which the parties shall comply with the transparency requirements arising under Articles 22 et seq.

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, including an obligation on the sponsored party to account for the expenditure of the sponsorship contribution if requested; 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, except as provided in Article 17.1(d).

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. Institutions shall maintain an administration of the agreements approved under this article.

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 Register. The written agreement referred to in Article 15.2(c) shall record the manner in which the parties shall comply with these transparency requirements.

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, 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 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, institution or association.

Article 17. Specific forms of sponsorship; research

1. The sponsorship of research by suppliers in situations involving healthcare professionals is permitted, on the provision that all of the following conditions are met:

    a. The research involves clinical or nonclinical studies whose objective is legitimate and whose design and execution meet the relevant legal, scientific and ethical requirements;

    b. The sponsorship is limited to reasonable reimbursement for:
        a. activities by healthcare professionals, within the boundaries set out in Article 13;
        b. support activities by persons other than healthcare professionals;
        c. expenses, and/or
        d. the use of facilities, rooms and equipment.

    Notwithstanding Article 15.2(d), the supply at no charge of medical devices or other products needed in the context of the research is permitted to the extent that this is reasonably necessary in the context of the research.

    c. The study design and a budget estimate shall be recorded in writing prior to the decision to provide sponsorship;

    d. The arrangements concerning the sponsorship of the research shall be recorded in advance in a written agreement signed by all the parties concerned, which shall in any event describe the objective of the research and the precise details of the rights and obligations of all the parties, including an obligation to account, on request, for the expenditure of the financial contribution and the use of any medical devices supplied.

    e. Sponsorship may not have any detrimental effect on the independence, reliability and credibility of the parties concerned, or in any other way result in decisions relating to medical devices being taken otherwise than on substantive healthcare-related, rational and/or ethical grounds.

    f. 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.

    g. The healthcare professional shall mention the fact that the research was carried out with the sponsorship of the supplier in all oral 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 '.

Article 19. Sponsorship of patient organisations

Sponsorship of a patient organisation by suppliers is permitted, provided that all of the following conditions are met:

a. 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.

b. 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.

c. 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.

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

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

f. The supplier who sponsors a patient organisation, sets the condition that the patient organisation declares that it endorses and applies the Netherlands Patients' Federation's code of conduct for fundraising and sponsorship.

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 for Medical Devices:

    a. sponsorship and the provision of hospitality, within the meaning of Articles 9 to 11;

b. remuneration of services, within the meaning of Article 5.3(d) in conjunction with Articles 13 and 14,
c. 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'. 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:

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

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

3. for written agreements relating to **hospitality**, as described in Article 22.1(a):

a. in the case of sponsorship of hospitality for an individual healthcare professional as described in Article 9.3, for each meeting:
   i. the personal details (name, place of residence and BIG registration number) of the healthcare professional who received the hospitality (or reimbursement of costs for hospitality);
   ii. the total amount of hospitality costs reimbursed or paid by the supplier as described in Article 9.2(c);

b. in the case of sponsorship of hospitality for a collaboration or institution as described in Article 9.4, for each meeting:
   i. the details (name, registered address and/or Chamber of Commerce registration number) of the collaboration or institution;
   ii. the financial contributions paid to it under the agreement;

c. in the case of the provision of hospitality as described in Articles 10 and 11:
    i. the personal details (name, place of residence and BIG registration number) of the healthcare professional who received the hospitality (or reimbursement of costs for hospitality);
    ii. the total amount of hospitality costs reimbursed or paid by the supplier as described in Articles 10.2(c) and 11.2(c);

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

    a. where the service agreement is entered into **in the name of a healthcare professional**: the personal details (name, place of residence and BIG registration number) of the healthcare professional and the total amount of the fee (excluding any expenses reimbursements) paid in the relevant calendar year;

    b. where the service agreement is entered into **in the name of a collaboration/institution** in which the healthcare professional takes part or works or **in the name of a legal entity of which the healthcare professional is a director/majority shareholder**:

        I. the personal details (name, place of residence and BIG registration number) 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 and/or attributed to that person for actually carrying out the services in the relevant calendar year; and (if applicable);
        II. the details (name, registered address and/or Chamber of Commerce registration number) of the collaboration or institution or the legal entity and the total amount paid to the same in the relevant calendar year, less the amount described in I.

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

    a. the details (name, registered address 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 for 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. Written agreements regarding publication

It is not permitted to enter into agreements containing provisions that could obstruct existing or future requirements for publication in the Healthcare Transparency Register under this Code of Conduct.

Entered into force on 1 January 2012
Amended on 1 January 2014, on 1 January 2015, on 1 January 2017, on 1 January 2018 and most recently on 1 January 2021.

Explanatory Notes
on the Code of Conduct for Medical Devices

Since 2012 self-regulation has been in place concerning responsible dealings between suppliers of medical devices and healthcare professionals. The Code of Conduct for Medical Devices (the 'Code of Conduct') is binding on members of the umbrella organisations of suppliers, healthcare professionals and hospitals that are affiliated to the Code of Conduct. Individual suppliers can also become affiliated to the Code of Conduct by registration in the Register for Compliance with the Code of Conduct [link].

On 1 January 2018 legislation was also introduced relating to inducement in the medical devices sector. Article 6 of the Medical Devices Act (formerly Article 10h of the Medical Devices Act) [link] contains a general prohibition on inducement, which provides for a number of exceptions, to be interpreted restrictively. This provision is further expanded on in the Policy Rules on Inducement relating to the Medical Devices Act [link]. Responsibility for monitoring compliance with the legislation on inducement has been given to the Dutch Health and Youth Care Inspectorate (*Inspectie voor Gezondheidszorg en Jeugd* or 'IGJ') [link].

The intention behind the legislation on inducement was to align with the substantive requirements in the Code of Conduct, despite the fact that the system and terminology used are not entirely identical. On the introduction of the legislation and the Policy Rules on Inducement, the IGJ and the foundation responsible for the Code of Conduct (the 'Code Foundation') established that there are no substantive differences between the legislation and the Code of Conduct. In the context of the working arrangements between the IGJ and the Code Foundation, consultation takes place between the IGJ and the Code Foundation on a regular basis, including discussion of possible differences in interpretation. This does not alter the fact that the legislation always takes precedence over self-regulation and the fact that everyone must comply with the legislation.

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 Medical Devices Act. All medical devices covered by this act fall within 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 involving healthcare professionals working in the Netherlands (see also Note at Article 2). The setting in which the healthcare professional works is not relevant, whether they are employed by an institution, working in a partnership or similar collaboration format, or self-employed. The applicability of the code of conduct cannot be circumvented, for example by having certain arrangements relating to interactions take place through 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 actions of that third party will be attributed in full to the party who engaged them. 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. 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 Healthcare 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.

Institutions play a role in monitoring compliance. See, among other places, Articles 3 and 20 for general provisions and Articles 9.3, 10.3, 11.3, 13.7 and 15.5 for more specific provisions. The provisions in these articles include notifying and/or obtaining approval from the institution with respect to certain interactions. Records of such notifications/approvals should be maintained.

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 (A15.02).

This code of conduct discusses interaction. This term is broadly described to demonstrate that the code of conduct has a broad application. To clarify, the term 'interaction' is not used in Article 6 of the Medical Devices Act or in the Policy Rules. These documents use the term inducement.

Where discussed, reimbursement of expenses in this code of conduct means the payment or sponsorship of costs. After all, an interaction can be said to take place where a benefit with a monetary value is offered or promised in the relationship between a healthcare professional and a supplier; for classification as an interaction, the form this takes and the name or title that the parties themselves give to it are not relevant.

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 an interaction entered into by an affiliated company registered in another country (for example, another subsidiary of the same parent company) will depend on how the company based in the Netherlands is involved in this.

Article 3. General Principles

Article 3 contains the general principles that underlie the code of conduct: 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). This internal notification and approval requirement applies not just to healthcare professionals who are employees, but also to healthcare professionals working on another basis, for example as an independent medical specialist on the basis of an admission agreement. See A13.03.

The principles of good management, as set out in the Healthcare Governance Code, mean that in the relationship between the board and the medical staff and the Medical Specialist Company, respectively, arrangements are made concerning the consent requirement.

It follows from the principle of transparency that an administration of the service and sponsorship agreements (which are covered by the Code of Conduct) must be maintained within healthcare institutions. The boards of institutions therefore have an obligation to ensure that an administration is maintained of all service and sponsorship agreements that are approved and entered into in accordance with Articles 13 and 15, respectively.

The Code of Conduct also contains provisions on *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. 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.

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. Article 6.2(a) states that giving a discount in kind is only permitted if the discount is given in the form of sector-related products. This provision is interpreted restrictively: a discount in the form of, for example, providing a communication training session or developing a practice website, does not satisfy the requirements (see A14.03).

The requirements imposed in clauses 2(b) and 2(c) mean that the bonus or discount may only be settled with the party stated on the invoice.
Under clause 3 it is not permitted for the establishment of a business transaction to be made dependent on financial benefits in favour of third parties. 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.

From advice notes issued, the following conclusions may also be drawn.

There is a clear distinction between giving a discount on the one hand and payment for services on the other. If services have in fact been carried out then it is not permitted for this to be remunerated in the form of a discount (13.08).
The Code of Conduct does not impose any requirements or limits on the amount of any bonuses or discounts. Article 6 of the Code of Conduct does not therefore in principle prevent bonuses or discounts being given such that a device is supplied for less than the cost price or such that a 100% discount is given, with the result that the device is actually supplied at no charge (15.01, confirmed in 19.01).
From the advice notes it is apparent that the Code Commission applies Article 6 more generally, with respect to the specific features of trade practices in the medical devices sector. For example, in A15.01 attention is given to services related to medical devices, such as service and maintenance work, equipment installation and the adaptation of medical devices to the specific needs of users.
In 19.01, consideration is given to the different ways in which business transactions and the corresponding financial arrangements can be structured from a legal perspective. Besides a purchase agreement with transfer of ownership (immediate or otherwise) it is also possible to consider a loan, rental, lease or purchase in instalments. In the context of these other types of business transactions it is logical that different types of financial arrangements will be made. The Code of Conduct is not intended to make this impossible. The rationale for Article 6 of the Code of Conduct is to allow normal trading practices between suppliers of medical devices and the users of these products to continue and to further these practices. With this in mind, it is up to the parties themselves to determine how they structure a business transaction in legal terms and what financial arrangements apply to it. The Code of Conduct does not prevent this. However, some additional requirements are imposed in a general sense; see the advice note. This also applies to trial installations.

For the specific situation where institutions engage a third party as an intermediary for the purchase of medical devices, see A16.01 and A16.02.

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 Rules on Inducement.

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 fulfil 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. For example, in a specific case the Code Commission held that a conference bag and badge are not perceived as a gift, unless their value and appearance are such that they cannot be regarded solely as a practical item for use during the conference but also have value beyond that conference (A13.02). This was confirmed in another advice note (A18.01). This last advice note dealt with the 'gimmicks' offered on stands during conferences, such as pens and bottles of water. Only items of very low value, with a business appearance and practical use in the context of a conference, may be offered on stands. Offering visitors to a stand a reusable water bottle displaying the company logo is not permitted. Even if such a bottle has a low value, it does not benefit the healthcare professional's practice or patient care, nor does it fulfil a purely educational function (A20.02).

In that case, the conditions in Article 7 of the Code of Conduct must be satisfied and the value must in any event remain under €50 and the bag must be related to the doctor's practice. Whether this last requirement is satisfied will largely depend on whether it is a bag that will primarily be used in the recipient's private life. The chairman considers it unlikely that a badge will be perceived as a gift. See A13.02 and A18.01.

The amount 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 (clause 5(a)). See also A14.01.

The exception under b makes it possible to give, for example, a bouquet of flowers or a bottle of wine for a one-off special occasion in a personal context, such as promotion or a relevant anniversary, without contravening this Code of Conduct, provided that such gift is reasonable and appropriate. This exception must be applied restrictively; the exception does not apply to giving small gifts in the context of the (present or future) commercial relationship between the supplier and the healthcare professional in their role of (present or future) customer. For example, giving gifts in the context of recurring general celebrations (birthdays, Easter or Christmas) is not permitted. See A19.03.

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. For the record, it should be noted that different terms are used in the Medical Devices Act (Article 6 distinguishes between meetings and events). However, from the Policy Rules we see that the definition of 'meetings' in the legislation corresponds to the types of meetings described in Articles 8.1(a), 8.1(b) and 8.1(c). The meetings described in Article 8.1 are referred to in the legislation and the Policy Rules as an 'event'. Although the criteria for reimbursing expenses for meetings are formulated slightly differently in the Policy Rules, in essence they correspond with the requirements for the programme, location and expenses imposed in the Code of Conduct.

For online meetings, such as webinars, the same conditions apply as for meetings at which participants are physically present. However, providing a webinar at no charge can only be regarded as an interaction where it has an actual market value (A20.01). The requirements that apply to meetings and relate to programme and location will not generally create a problem. Expenses for hospitality will not apply, so the only costs that are paid with the financial sponsorship contribution must be regarded as organisation costs that do not count towards the maximum amounts (Article 9.3(c)). For a sponsorship application, these organisation costs should be specified in a budget estimate and after the meeting an account of how the sponsorship monies have been spent should be provided, with any surplus being paid back to the sponsors (A20.05).

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.
See in this connection, among others, A13.01 (Concert), A13.05 (Vlieland), A14.04 (Curacao) and A19.02 (Majorca).

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.

From advice notes, we see that, particularly for meetings abroad, the Code Commission critically examines whether there is a valid justification for the geographical location (A12.02 (Frankfurt), A12.03 (Dubai), A14.04 (Curacao), A15.03 (Vienna) and A19.02 (Majorca). For meetings in the Netherlands, the location also needs to be justified (A13.06 (Vlieland)). With regard to the interpretation of the nature and image of the location see, among others, A12.03 (Dubai), A15.03 (Vienna), A14.04 (Curacao) and A19.02 (Spain).

In terms of expenses, only certain costs may be paid for by the supplier and then only in so far as these are reasonable. In connection with the nature and context of the various categories of meetings, these amounts are detailed specifically for each category in the subsequent Articles 9 to 12.

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.

In the interests of transparency, it is important that healthcare professionals know who they are dealing with at meetings. For this reason, clause 6 provides that all suppliers' representatives attending should be recognisable as such, for example by wearing a badge.
Clause 7 provides for the same purpose that speakers must, before proceeding to the substance of their presentation, declare their connections (financial or otherwise) with suppliers or other relevant third parties.

To assist with this, the Code Foundation has developed a standard template for a disclosure slide [http://www.gmh.nu/index.php?option=com_content&view=article&id=206:disclosure-sheet&catid=39&Itemid=264], which corresponds to the template used by the Foundation for the Code for Pharmaceutical Advertising.

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). On this subject, also see the note for Article 8, including references to relevant advice notes.

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.

If a healthcare professional bears at least 50% of the costs themselves, in accordance with Article 9.2(c), subparagraph (b), then this amount shall not count towards the maximum of €1500 per year stated in Article 9.2(c), subparagraph (a).

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 A19.02 (Spain) this last point is explicitly confirmed: suppliers are not permitted to make a financial contribution to a meeting that does not comply with the requirements in terms of the programme and location, even if this contribution were only to be made to the costs of organisation. Due to the reciprocity of the rules, the above also means that healthcare professionals are not permitted to participate in this meeting.

The Code of Conduct imposes the condition that suppliers are only permitted to reimburse costs that are reasonable. To assess whether this is the case, information about the programme, location and expenses will always need to be available. When assessing reasonableness, these factors cannot be viewed in isolation. A detailed budget estimate will therefore always need to be available. More detailed information about the programme and the location of the meeting is also indispensable in this context.

If a sponsor contributes to the general organisation costs for a meeting, these expenses – including costs for speakers, room hire and printed materials – will need to be specified such that it is possible to establish that the amounts made available by the sponsor will only be spent on general costs directly related to the organisation of the meeting and that the money that will be made available will in fact only be used for that purpose. It is up to the organiser who is requesting sponsorship to supply the necessary information, enabling the supplier to assess whether sponsorship is permitted. See A13.07, A14.02 and A20.05.
The sponsor is always at liberty to request after the meeting an account of how the sponsorship monies have been spent, in order to verify whether the Code of Conduct has been complied with. The party receiving the sponsorship must cooperate with this in the interests of transparency (A20.05).

Article 9.2 explicitly prescribes that the sponsorship of general organisation costs for meetings must relate to costs directly related to the meeting for which the funding is granted. Any surplus (that was not budgeted for) shown in the final accounts after the meeting must in principle be repaid (A20.05). It might be possible to make a contractual agreement that any such surplus would be used to cover the general organisation costs of a future conference, naturally subject to the provisions in Articles 8 and 9 of the Code of Conduct. In the interests of transparency, in such a situation this will also need to be justified to the sponsors as such (see A13.07, A14.02 and A20.05).

In clauses 3 and 4 requirements are recorded with regard to internal transparency and documentation. Recording arrangements and informing anyone that is relevant and responsible within the institution are essential. On this subject, see also the note on Article 8.

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.

With effect from 2021, the provision of hospitality by suppliers at meetings organised by independent third parties must be reported in the Healthcare Transparency Register. The details required are further described in Article 22 et seq. Article 9.6 refers explicitly to these provisions, so that parties cannot fail to be aware of them. In the arrangements relating to the provision of hospitality that are required under clauses 3, 4 and 5 to be recorded in writing, the parties should also record how reporting to the Healthcare Transparency Register will be carried out, so that it is clear in advance which details must be reported and which party is responsible for reporting them.

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 the Policy Rules on Inducement relating to the Medical Devices Act. 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.

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.

The specific nature of product related meetings means that they may involve different types of general organisation costs from meetings as described in Articles 9, 11 and 12. Instruction and training in the application of medical devices require, in addition to supervision by trainers and experts, the necessary materials and facilities. After all, these are indispensable for the essential feature of a product related meeting: training with that product in a specific setting.
This is also the reason why the costs associated with the use of the devices and materials necessary for the product related meeting are regarded as general organisation costs. This also applies to the costs associated with the use of special facilities, to the extent that these are necessary in order to organise a product related meeting.
In all circumstances, the general organisation costs need to be reasonable and directly related to the product related meeting.

Some examples of costs directly related to product related meetings that have been provided (purely by way of illustration):

- In the case of bioskills lab sessions (human anatomic specimens workshops): the costs associated with the necessary 'human anatomic specimens' (bodies or cadavers) and/or parts (arms, legs etc.), including any costs for preparation, disposal and logistics, permits, the use of facilities, specific instruments, disposables.
- In the case of simulation sessions (for example with pacemakers and ICDs): the costs of simulators (patient) for the purposes of pacing/defibrillation, working pacemakers/ICDs necessary for simulation.

- In the case of virtual reality training sessions: virtual reality workstations; 'hands on' training using real-time cath lab simulations.
- In the case of laboratory equipment: the costs of making available (various) systems/modules, kits, reagents, disposables, preparation of training and test materials, any accompanying support from visual aids etc.

Article 10.3 contains requirements concerning written records and reporting to the board of the institution or the employer. See also Article 8.

With effect from 2021, the provision of hospitality by suppliers at product related meetings must be reported in the Healthcare Transparency Register. The details required are further described in Article 22 et seq. Article 10.4 refers explicitly to these provisions, so that parties cannot fail to be aware of them. In the arrangements relating to the provision of hospitality that are required under Article 10.3 to be recorded in writing, the parties should also record how reporting to the Healthcare Transparency Register will be carried out, so that it is clear in advance which details must be reported and which party is responsible for reporting them.

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. 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. On this subject, see also the general explanation in the note on Article 8.

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), provided that these are reasonable and appropriate.

The requirements concerning written records and reporting to the board of the institution or the employer also apply to these meetings. See also the note on Article 8.

With effect from 2021, the provision of hospitality by suppliers at organised and accredited meetings must also be reported in the Healthcare Transparency Register. The details required are further described in Article 22 et seq. Article 11.4 refers explicitly to these provisions, so that parties cannot fail to be aware of them. In the arrangements relating to the provision of hospitality that are required under clause 3 to be recorded in writing, the parties should also record how reporting to the Healthcare Transparency Register will be carried out, so that it is clear in advance which details must be reported and which party is responsible for reporting them.

Article 12. Other meetings organised by suppliers

Meetings in this 'remainder' category (referred to in the Policy Rules on Inducement relating to the Medical Devices Act as 'events') 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.

Hospitality at meetings falling within Article 12 does not have to be reported in the Healthcare Transparency Register.

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. The Code of Conduct has sought to be consistent with the rates applied in the self-regulation of medicinal products (the Code for Pharmaceutical Advertising). This was decided in consultation with the Dutch Ministry of Health and the IGJ. The following maximum hourly rates are regarded as 'in line with the market':

Professor	€	200
Medical specialist	€	140
General practitioner	€	100
Pharmacist	€	100
Dentist	€	85
Nursing specialist	€	75
Physician assistant	€	75
Specialised nurse	€	75
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 matters such as 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.

Where services are provided by a multidisciplinary team, made up of various healthcare professionals with different backgrounds and expertise, the different hourly rates applicable for those healthcare professionals must be taken into account. The hourly rate applied for the services of the team may never exceed the sum of the maximum hourly rates applicable for the various healthcare professionals. This must be stated in the service agreement (A20.03). Remuneration the services of a healthcare professional in the form of a percentage of the profit obtained from a specified activity is not permitted as this may result in a remuneration that exceeds the maximum amount permitted in the Code of Conduct (A20.05). In the case of services whose scope cannot be established in advance, it is the responsibility of the healthcare professionals providing the services to account for the time spent, in which context they should comply with the obligations already applicable to medical specialists in the context of providing specialist care to record all diagnosis and care activities carefully and correctly ('Code of Conduct for Correct Billing' prepared by the Dutch Federation of Medical Specialists) (A20.04).

As a standard for the reimbursement of travel expenses incurred in the context of providing services it has also been decided to be consistent with the rules applied in the Code for Pharmaceutical Advertising. The following reimbursement of travel expenses for providing services is 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	economy class only

Reimbursement of first class and business class travel is not considered reasonable. However, in very specific individual circumstances there may be a justifiable reason for an exception to this fundamental principle. The mere fact that a flight is longer than 5 hours does not justify making an exception to this basic rule. See A12.04.

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 agreements (and sponsorship agreements) 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, with co-signature being the preferred option. This requirement applies not just to healthcare professionals who are employees, but also to healthcare professionals working on another basis, for example as an independent medical specialist on the basis of an admission agreement. See A13.03.

It follows from the principle of transparency that information must be available within institutions concerning which service and sponsorship agreements have been approved. The boards of institutions therefore have an obligation to ensure that an administration is maintained of all service agreements that are approved and entered into in accordance with Article 13.

For the record: the requirements and maximum amounts referred to in this article do not apply to healthcare professionals working outside the Netherlands, as the Code of Conduct does not apply to them. See also the note on Article 1.

Remuneration for services should be reported in the Healthcare Transparency Register. The details required are further described in Article 22 et seq. Article 13.8 refers explicitly to these provisions, so that parties cannot fail to be aware of them. In the written services agreement required under clause 2(c), the parties should also record how reporting to the Healthcare Transparency Register will be carried out, so that it is clear in advance which details must be reported and which party is responsible for reporting them.

Article 14. Service Agreement

This article stipulates the matters that must be agreed, as a minimum, in the service agreement required under Article 13. Agreements should be entered into for a fixed period; tacit or automatic renewal is undesirable.

Arrangements concerning services must always be recorded in a written agreement. It is important that these matters are recorded carefully and in full. After all, it must be apparent from the agreement that the requirements are satisfied. The following information must always be contained in a service agreement:

1. A clear description of the service. This must be explicit and full in terms of what is expected of the service provider. This means that it must clearly describe what activities the health professional will carry out, with what purpose, where and when.

2. A clear description of the remuneration received by the healthcare professional. This must state the amount of time (and any preparation time) that will be remunerated and the rate applied. This must be specified in detail; merely including a lump sum is not sufficient. It must be possible to deduce from the contract how much time/hours are being remunerated and at what hourly rate. If arrangements are made concerning payment of travel time, travel expenses and any other expenses, then this must be specified separately.

3. Where publication in the Healthcare Transparency Register is mandatory, the agreement must contain a provision recording how this will take place and who will carry it out. This also establishes that the healthcare professional agrees to publication.

The agreement may, of course, also contain arrangements concerning duration, termination, transfer etc.

A service agreement must be signed by all the parties.

It is in principle permitted to use a framework agreement, in which general arrangements are recorded with respect to services during a specified period (e.g. a specified calendar year). Please note that for each specific assignment carried out under the auspices of this framework agreement it will be necessary to record additional specific arrangements, for example in an addendum. It will also need to be clear what is expected of the service provider in a specific situation: what services, with what purpose/result, where and when.

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 under the Code of Conduct, 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.

To be able to assess whether the requirements for sponsorship are met, information will need to be available, including information on the objective, setup and costs of the project or activity.

The sponsorship agreement must also include an obligation to account for expenditure if requested, so that the sponsor is able to verify whether the sponsorship contribution has been spent in accordance with the arrangements in the agreement (and the Code of Conduct). In connection with this it would seem obvious that a budget estimate should be supplied in support of the sponsorship application. The parties receiving the sponsorship may also be expected to cooperate with this in the interests of transparency.

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, see clause 4.

To ensure transparency and responsibility sponsorship agreements 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.

It follows from the principle of transparency that information must be available within institutions concerning which service and sponsorship agreements have been approved. The boards of institutions therefore have an obligation to ensure that an administration is maintained of all sponsorship agreements that are approved and entered into in accordance with Article 15.

The Code of Conduct does not contain any provisions relating to the sponsorship of charities by suppliers. This is outside the scope of the Code of Conduct.
A supplier may sponsor the participation of a healthcare professional in a sponsorship event for the benefit of a charity, provided that the following requirements are satisfied:

1. The supplier shall transfer their sponsorship contributions to the charity directly (no payments may take place between the supplier and the healthcare professional);
2. The supplier shall not contribute to the expenses incurred by the healthcare professional themselves for participation in the sponsorship event;
3. The healthcare professional shall have no involvement in how the charity will spend the sponsorship monies;

4. An exception to this provision is set out in Article 17.2, which provides that in the context of sponsorship of research medical devices may be made available at no charge to the extent that this is reasonably necessary in the context of the research.

See also advice note A12.01.

Sponsorship of projects or activities should be reported in the Healthcare Transparency Register. The details required are further described in Article 22 et seq. Article 15.6 refers explicitly to these provisions, so that parties cannot fail to be aware of them. In the sponsorship agreement required under clause 6, the parties should also record how reporting to the Healthcare Transparency Register will be carried out, so that it is clear in advance which details must be reported and which party is responsible for reporting them.

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

In practice, a great deal of research is carried out with medical devices. This may be research initiated by the supplier (for example in the context of requirements under the legislation for medical devices) or initiated by healthcare professionals/institutions. If and to the extent that in the context of research suppliers make a financial contribution to such research, then this article applies. For the applicability of this article, it is irrelevant which party initiated the research, whether it is clinical or non-clinical research and what name is given to the research (such as trial, registry, clinical performance study, post marketing surveillance (PMS) study, etc.).

Sponsorship of research by suppliers is permitted provided that the objective is legitimate and the design and execution satisfy the relevant legal, scientific and ethical requirements. Imposing these requirements prevents research from encouraging or resulting in undesirable influencing of decisions relating to medical devices.

Sub-clause b states the costs that may be paid using the supplier's financial contribution. These are the costs relating to:

a. activities by healthcare professionals;
b. support activities by persons other than healthcare professionals;
c. expenses; and/or
d. the use of facilities, rooms and equipment.

In all cases, the costs must be reasonable. For the remuneration of activities by healthcare professionals this means, among other things, that the hourly rates must not exceed the rates stated in the note on Article 13 on services. This also applies to the reimbursement of the relevant healthcare professional's expenses, such as travel expenses.

To ensure clarity, it is stated that making medical devices or other products necessary in the context of the research available at no charge is also permitted to the extent that this is reasonably necessary in the context of the research.

The requirement in sub-clause d for a written record corresponds with the similar requirements in Articles 14 and 15.2(c), provided that the objective and design of the research must also be recorded in writing in advance.

Sub-clause e ties in with the general principle in Article 3 and also with Article 15 concerning the prevention of undesirable influence and independence. In the case of a registry this requirement means, for example, that supporting arguments must be provided as to why the number of patients to be included is justifiable in the context of the objective of the research, in which context there may be cause to limit the maximum number of patients per healthcare professional (and consequently the total payment) in order to prevent undesirable influence.

Sub-clause 5 contains the requirement for written approval that can also be found in Articles 13 and 15.

In the interests of transparency, the healthcare professional must also report the fact that the research was carried out with sponsorship from the supplier, for example in a publication or presentation on the research.

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 endorses and applies the Netherlands Patients' Federation's code of conduct for fundraising and sponsorship.

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 2021, the following categories of interactions must be published in the Healthcare Transparency Register:

a. sponsorship and provision of hospitality, as referred to in Articles 9 to 11;
b. remuneration for services, as referred to in Article 5(3)(d) in conjunction with Articles 13 and 14, and
c. sponsorship of projects or activities other than meetings, as referred to in Article 5(3)(e) in conjunction with Articles 15 to 17.

where they take place between suppliers of medical devices and healthcare professionals listed in the BIG Register in the category 'doctor'.

Please note: with effect from 2021, the transparency rules apply to all doctors, so to medical specialists and general practitioners and all other specialists in medicine, and also to doctors with general medical training or expertise in a 'profile' area such as preventive or social medicine.

Hospitality should be reported where this is hospitality at meetings organised by independent third parties (Article 9), product related meetings organised by suppliers (Article 10) or accredited meetings organised by suppliers (Article 11). This covers both hospitality provided to individual healthcare professionals and hospitality in the form of a financial contribution (sponsorship) provided to the organiser of the meeting. Hospitality at other meetings organised by suppliers as described in Article 12 does not have to be reported in the Healthcare Transparency Register.

For services, the remuneration of services in the context of research to which the Dutch Medical Research involving Human Subjects Act applies is also excluded from the publication requirement.

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.

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

Article 23 sets out for each interaction the information that must be reported. In doing so, it distinguishes between various situations that may arise in practice, for example because the arrangements are made between a supplier and a collaboration or institution, but individual healthcare professionals are involved in them.

The basic principle is that the publication requirement applies to interactions that have to be recorded in writing and that the parties also make written arrangements about which details must be reported and which party is responsible for reporting them to the Healthcare Transparency Register.

The information described in sub-clauses 1 (nature of the financial relationship) and 2 (supplier) must be published for *all interactions*. The information concerning the beneficiary differs according to the type of interaction. This is further expanded on in sub-clauses 3 (hospitality), 4 (services) and 5 (sponsorship of projects). The basic principle underlying this is that no 'duplicate reports' should take place. The total amount of the interaction is reported either under the name of the healthcare professional or under the name of the collaboration, institution or legal entity with which the healthcare professional is involved.

In the case of hospitality at a meeting organised by a third party (Article 9) the situation may arise where a supplier pays the costs of hospitality for a healthcare professional or reimburses these to the healthcare professional after the event. In that case, the report is made under the name of the relevant healthcare professional who received the hospitality (or reimbursement of costs for hospitality). In addition to the healthcare professional's personal details (name, place of residence and BIG registration number), the total amount of the hospitality costs reimbursed or paid by the supplier must also be reported. The amount covers the costs of registration, meals, overnight stays and travel expenses.

In the case of sponsorship of a collaboration or institution at a meeting organised by a third party, the report must be made under the name of the collaboration or institution that received the financial contributions. The amount to be reported is the total amount of the sponsorship. In this situation there is no obligation to make a report under the name of the healthcare professionals present; after all, at meetings of this type this cannot be established accurately. The amount covers the costs of meals, overnight stays and travel expenses. The costs for organisation do not have to be included in this report. After all, general costs directly related to the organisation of the meeting (such as costs for room hire, trainers, experts and necessary printed materials and facilities) are excluded from the calculation of the costs for hospitality (Articles 10.2(c) and 11.2(c)).

Hospitality at other meetings organised by suppliers (Article 12) does not have to be reported to the Healthcare Transparency Register.

The reporting of services is subject to the following. If a supplier wishes to have certain services carried out by a healthcare professional, the contract does not always have to be in the name of this healthcare professional. However, in the interests of transparency it is important that, in any event, the fee received by or attributable to the healthcare professional is reported under the healthcare professional's name. This will be easiest when the contract is also entered into in the name of the individual healthcare professional. In that case, the healthcare professional's personal details (name, place of residence and BIG registration number) and the total amount of the fee (excluding any expenses reimbursements) paid in the relevant calendar year shall be reported in the Healthcare Transparency Register.

Situations may arise where the contract is not entered into between the supplier and the healthcare professional who will carry out the services but between the supplier and a collaboration or institution in which the healthcare professional works (a hospital) or between the supplier and a legal entity in which the healthcare professional is a director/shareholder (for example a medical specialist's consultancy company). In these situations, that part of the total amount that is paid under the agreement and can be attributed to the relevant healthcare professional shall be reported under the name of the healthcare professional. It is

not relevant in this case which account the supplier paid the amounts to or whether the healthcare professional was the ultimate beneficiary and received the amounts. Any remaining amount (the total amount paid by the supplier less the amount attributable to the healthcare professional) should be reported under the name of the collaboration, institution or legal entity. This may relate to overhead costs, for example. This way, optimum transparency is achieved and duplicate reporting is avoided.

Sponsorship agreements relating to projects or activities as described in Article 22.1(b) may only be entered into between suppliers and collaborations or institutions. This means that the report will always need to be made under the name of the relevant collaboration or institution. For sponsorship agreements that relate to meetings organised by third parties within the meaning of Article 9, see clause 3(b).
If and to the extent that there are amounts that can be attributed to a certain healthcare professional (for hospitality or services) on the basis of a sponsorship agreement and these amounts are required to be published under the name of the healthcare professional under clauses 3 and 4, then these amounts can be deducted from the total amount of the relevant sponsorship agreement that is published under the name of the collaboration or institution. This way, optimum transparency is achieved and duplicate reporting is avoided.

Article 24. Supply of information and publication method

The basic rule is that the supplier shall be responsible for making the reports to the Healthcare Transparency Register.

An exception to this rule applies where a healthcare professional or collaboration/institution enters into an interaction with a supplier:

1. who is established outside the Netherlands, or
2. who is not a member of one of the sector organisations that are affiliated to the Code Foundation.

In these cases, the healthcare professional or the collaboration/institution must take responsibility for making a report to the Healthcare Transparency Register, unless the parties have explicitly agreed otherwise.

Information on whether a supplier is a member of one of the sector organisations that are affiliated to the Code Foundation is available at
[http://www.gmh.nu/index.php?option=com_content&view=article&id=135&Itemid=86].

The procedure for reporting information is determined by the Foundation for the Healthcare Transparency Register. More information is available at [https://www.transparantieregister.nl/].

Article 25. Duration of publication

Three years after publication in the Healthcare Transparency Register, the information will be removed from the Healthcare Transparency Register.

Article 26. Written agreements regarding publication

Under Articles 9, 10, 11, 13 and 15, the parties must also indicate in the written agreements how they will comply with these transparency obligations. The requirement to publish information in the Healthcare Transparency Register cannot be impeded by agreements made between parties that would prevent publication. This means that it is no longer permitted to include confidentiality clauses in agreements such that the publication requirement under the Code of Conduct cannot be complied with.

DISCLAIMER

These explanatory notes were most recently amended on 1 January 2021. As part of this amendment relevant passages from Code of Conduct newsletters from previous years were included in the explanatory notes. References to advice notes issued by the Code Commission in the period 2012-2020 were also included by way of illustration and clarification. These references are not intended to provide a full overview of all advice notes. It is emphasised that the advice notes have no formally binding status and must always be interpreted in the context of the facts of the relevant case and the questions raised.