Code of Conduct for Medical Devices 2024

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 2024

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.

PARAGRAPH 1 - 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.

i. *Healthcare Transparency Register (Transparantieregister Zorg or 'TRZ')*
Central, public register for the registration of financial relationships between, on the one hand, suppliers and, on the other hand, healthcare professionals (or collaborations between healthcare

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

professionals), institutions and patient organisations, 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**
Interactions between suppliers and healthcare professionals may not include any elements or incentives 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 (or collaborations between healthcare professionals), institutions and patient organisations must be transparent.

PARAGRAPH 2 – 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.

PARAGRAPH 3 – 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. demonstration models;
    c. 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. It is not permitted to pay for expenses related to participation in meetings other than those mentioned in this code of conduct.

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.

4. Arrangements concerning a financial contribution to the *organiser* of a meeting must be recorded in a written agreement. The payment must be made directly to the organiser of 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 amount of the costs that may be paid by the supplier is determined by Article 12.

6. Meetings to which this article applies are subject to paragraph 5 on transparency.

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/catering;
      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.

4. Meetings to which this article applies are subject to paragraph 5 on transparency.

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/catering;
      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.

4. Meetings to which this article applies are subject to paragraph 5 on transparency.

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/catering;
      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.

3. Meetings to which this article applies are subject to paragraph 5 (Article 23) on transparency.

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 a royalty in connection with intellectual property rights are made in the context of the service, this royalty must be reasonable and in line with the market. The amount and terms of the royalty may not be linked to future purchase, use, prescription of or advice on medical devices to which the intellectual property rights relate. The arrangements must be recorded in a written agreement.

7. Remuneration for services is subject to paragraph 5 on transparency.

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 manner in which the parties shall comply with any transparency requirements arising under Articles 23, 25 and 27-33.

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. the proposal for the project or study that is to be sponsored and a budget estimate have been made available to the sponsor prior to the decision to provide sponsorship;

   d. arrangements concerning sponsorship are recorded in writing in advance, in an agreement signed by all involved parties, which includes the objective of the sponsorship, the total sponsorship contribution amount (including any contribution in kind), an exact description of entitlements and obligations of both the sponsored party and the sponsor, including the sponsored party's obligation to account, and the manner in which the transparency requirements under Articles 22 et seq. are satisfied; and

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

3. Sponsorship may not lead to any adverse effect on the independence, reliability and credibility of either the sponsor and the sponsored party or of other involved parties and/or the sector, or otherwise lead to decisions regarding medical devices being made on grounds that are not healthcare related, rational and/or honest. Sponsorship may not be dependent on any quid pro quo agreement other than the quid pro quo agreements associated with acknowledgement.

4. An exception to the stipulations in Article 15.2(b) is that suppliers may sponsor a dissertation by an individual healthcare professional to a maximum of € 250. An exception to Article 15.2(d) is that this type of sponsorship does not need to be set down in a written agreement.

5. Sponsorship is subject to paragraph 5 on transparency.

Article 16. Specific forms of sponsorship; study grants

1. Sponsorship of study grants by suppliers is permitted, provided that the requirements in Article 15 are satisfied and 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, provided that the requirements in Article 15 are satisfied and 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.

    c. The written agreement contains, in addition to the requirements in Article 15.2(d), in any event the purpose of the research and arrangements concerning the use of any medical devices made available in the context of the research.

    Notwithstanding Article 15.2(e), 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.

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 '.

PARAGRAPH 4 - OTHER PROVISIONS

Article 19. Sponsorship of patient organisations

1. 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'.

2. It is permissible to pay patients and patient organisations (or representatives of patient organisations) for their services and to offer them hospitality. When establishing the amount of remuneration that is in line with the market and the reasonableness of the hospitality, parties should adhere as closely as possible to the principles and amounts applicable for healthcare professionals and to what is regarded in society as usual and reasonable for patients and patient organisations (or representatives of patient organisations).

3. Sponsorship of patient organisations is subject to paragraph 5 on transparency.

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.

PARAGRAPH 5 – TRANSPARENCY

Article 22. General

1. Interactions between suppliers on the one hand and healthcare professionals (or collaborations between healthcare professionals), institutions and patient organisations must be transparent.

2. This Code of Conduct distinguishes three forms of transparency:

   a. Disclosure/identifiability of positions and relationships

      The purpose of this form of transparency is to ensure that:

      - it is disclosed that certain activities have come about with financial support from suppliers, and

      - in the case of meetings for healthcare professionals; ties between speakers and suppliers and the presence of representatives are disclosed.

      The requirements for this form of transparency are set out in further detail in Article 23.

   b. Internal declaration to and prior approval by the board of an institution

      The purpose of this form of transparency is to ensure that institutions' boards are aware of and have granted permission for certain financial transactions that healthcare professionals working within the institution have entered into with suppliers. The same applies to collaborations between healthcare professionals who are associated with an institution.

      The requirements for this form of transparency are set out in further detail in Articles 24 to 26.

   c. Publication in Healthcare Transparency Register (*Transparantieregister Zorg* or 'TRZ')

      The purpose of this form of transparency is to use a register accessible to the general public to provide information on the nature and scope of certain financial relationships between suppliers and certain groups of healthcare professionals (or collaborations between these healthcare professionals), institutions and patient organisations.

      The requirements for this form of transparency are set out in further detail in Articles 27 to 33.

3. If interactions are entered into by a third party on the instructions of a supplier or healthcare professional (or collaboration between healthcare professionals), institution or patient organisation, the rules in this paragraph will be applied as though the interactions had been entered into in the name of the party giving the instructions.

Article 23. Disclosure/identifiability of positions and relationships

1. Representatives of suppliers attending a meeting in which healthcare professionals are taking part must at all times be identifiable as such, for example by wearing a badge.

2. The organiser of a meeting that takes place with financial support from one or more suppliers must disclose this clearly in advance and during the meeting. If an organiser offers a supplier the opportunity

to organise their own part of the programme during or in parallel with the main programme, the organiser should also disclose this clearly in advance and during the meeting. This obligation should be recorded in the agreement between the supplier providing financial support and the organiser of the meeting.

3. Speakers at meetings shall be transparent about their (financial and other) links with suppliers. They should declare their links with suppliers or other parties relevant in this context before commencing the substantive part of their presentation.

4. Healthcare professionals who conduct research that is funded (or partly funded) by one or more suppliers should declare this in all oral and written presentations and publications concerning this research.

5. Patient organisations that organise an activity that is funded (or partly funded) by one or more suppliers should communicate clearly that the activity has been made possible (or partly made possible) by the relevant sponsor(s).

INTERNAL DECLARATION TO AND APPROVAL BY THE BOARD

Article 24. Declaring hospitality

1. A healthcare professional who enters into an agreement with a supplier concerning the reimbursement or payment of costs involved in meetings to which Articles 9-11 apply should declare this to the board of the institution. This does not apply to meetings covered by Article 12.

2. If a healthcare professional works for more than one institution, the declaration should be made to the institution at which they carry out the majority of their work.

Article 25. Permission (and if appropriate declaration) concerning services and sponsorship

1. A healthcare professional (or collaboration between healthcare professionals) should obtain the board's permission before entering into the following agreements with a supplier:

    - a service agreement within the meaning of Article 13, and

    - a sponsorship agreement within the meaning of Articles 15 to 17.

2. The permission described in the clause above must be shown by countersigning of the agreement by or on behalf of the institution's board.

3. If a healthcare professional works for more than one institution, permission should be granted by the board of the institution that is relevant to the agreement concerned. The healthcare professional should also declare the agreement to the other institution(s) where they work.

Article 26. Institutions' obligations with respect to declaration/permission

1. Institutions shall make internal provision to ensure:

    - the establishment of a process (centralised or otherwise) with respect to the grant of approval for sponsorship and service agreements, including any delegated authorities applicable in this context;

- arrangements (centralised or otherwise) with respect to the administrative and financial implementation of the approved sponsorship and service agreements and accountability for the same;

- the establishment of records (centralised or otherwise) of the approved and declared sponsorship and service agreements.

2. Institutions shall ensure that procedure is in place for declaring to the board of the institution any payments or reimbursement of costs for meetings, including any delegated authorities applicable in this context.

PUBLICATION IN HEALTHCARE TRANSPARENCY REGISTER (TRZ)

Article 27. Publication in TRZ - general

1. The rules about publication in the TRZ apply to agreements between suppliers and

   a. healthcare professionals listed in the BIG register in the following categories:
      - doctor;
      - nurse;
      - nursing specialist;
      - physician assistant;
   b. collaborations involving the healthcare professionals referred to in subparagraph (a);
   c. institutions at which these healthcare professionals work,

   in each case as set out in more detail in this paragraph and further agreed between the parties in the relevant agreements.

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/collaboration or institution exceeds €500 per calendar year.

3. Publication in the TRZ shall take place in accordance with the requirements, deadlines and template of the TRZ applicable at that time.

4. Publication in the TRZ shall in principle by carried out by the supplier. If the supplier is established outside the Netherlands or is not affiliated (via one of the trade associations or otherwise) to the Foundation for the Code of Conduct for Medical Devices, publication shall be carried out by the healthcare professional, collaboration or institution, unless the parties to the interaction make different arrangements concerning this.

5. For the purposes of further interpretation of the annual publication of financial relationships by the TRZ, the Foundation for the Code of Conduct for Medical Devices may request the suppliers who reported the interactions to provide the documentation on which the report is based. Suppliers are obliged to cooperate with any such request. With respect to requests for documentation and any use of that documentation for the purposes of general communication, the greatest care shall be exercised and the interests of all parties concerned shall be taken into consideration.

Article 28. Publication in TRZ – services

1. The following information must be published in the TRZ each calendar year, for each service agreement:

a. If the service agreement is entered into under the name of a doctor, nurse, nursing specialist or physician assistant:

    a. the name and BIG registration number of the healthcare professional;
    b. the total amount of fees (excluding VAT) invoiced in that calendar year;
    c. the total amount of expenses (including VAT) invoiced in that calendar year;
    d. the name of the supplier.

b. If the service agreement is entered into under the name of a legal entity in which the doctor, nurse, nursing specialist or physician assistant is a director/majority shareholder:

    a. the name and BIG registration number of the healthcare professional;
    b. the total amount of fees (excluding VAT) invoiced in that calendar year;
    c. the total amount of expenses (including VAT) invoiced in that calendar year;
    d. the name of the supplier.

c. If the service agreement is entered into under the name of a collaboration involving the healthcare professional or an institution where the healthcare professional works:

    a. the name and Chamber of Commerce registration number of the collaboration/institution that is party to the contract;
    b. the name and BIG registration number of the doctor, nurse, nursing specialist or physician assistant who actually carried out the services (regardless of whether this healthcare professional is also the recipient of the amounts paid);
    c. the name of the supplier;
    d. the total amount invoice in that calendar year, which will be reported as follows:
        - under the name of the healthcare professional: the fee (excluding VAT) that can be attributed to them as the person actually performing the services, and
        - under the name of the institution: the remaining amount, comprising overheads/reimbursement of expenses (including VAT).

2. Service agreements relating to research to which the Medical Research Involving Human Subjects Act (*Wet medisch-wetenschappelijk onderzoek met mensen* or 'WMO') applies do not have to be reported in the TRZ.

Article 29. Publication in TRZ – sponsorship of projects/activities/research

1. The following information must be published in the TRZ each calendar year, for each sponsorship agreement covered by Articles 15-17:

    a. the name and Chamber of Commerce registration number of the collaboration/institution;
    b. the name of the supplier;
    c. the amount invoiced in that calendar year (excluding any VAT charged).

2. Sponsorship agreements relating to research to which the Medical Research Involving Human Subjects Act (*Wet medisch-wetenschappelijk onderzoek met mensen* or 'WMO') applies do not have to be reported in the TRZ.

Article 30. Publication in TRZ – sponsorship of meetings

The following information must be published in the TRZ each calendar year, for each sponsored meeting covered by Article 9:

a. the name and Chamber of Commerce registration number of the meeting organiser;
b. the name of the supplier;
c. the amount invoiced in that calendar year (excluding any VAT charged).

Article 31. Publication in TRZ – hospitality at meetings organised by third parties

The following information must be published in the TRZ each calendar year with respect to the reimbursement or payment of costs during a meeting covered by Article 9 for an individual doctor, nurse, nursing specialist or physician assistant, for each meeting:

a. the name and BIG registration number of the healthcare professional;
b. the name of the supplier;
c. the amount of the costs reimbursed/paid for registration, meals, overnight stays and travel relating to the meeting.

Article 32. Publication in TRZ – hospitality at meetings organised by supplier(s)

The following information must be published in the TRZ each calendar year with respect to the payment of costs in the context of a meeting covered by Articles 10 and 11 for an individual doctor, nurse, nursing specialist or physician assistant:

a. the name and BIG registration number of the healthcare professional;
b. the name of the supplier;
c. the amount of the costs for meals, overnight stays and travel paid by the supplier in the context of the meeting in connection with the healthcare professional's participation in the meeting.

Article 33. Publication in TRZ – sponsorship of patient organisations

The following information must be published in the TRZ each calendar year, for each sponsorship agreement with a patient organisation:

a. the name and Chamber of Commerce registration number of the patient organisation;
b. the name of the supplier;
c. the amount invoiced in that calendar year (excluding any VAT charged).

Explanatory Notes
on the Code of Conduct for Medical Devices 2024

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.

On 1 January 2018 legislation was also introduced relating to inducement in the medical devices sector. Article 6 of the Medical Devices Act (*Wet medische hulpmiddelen* or 'Wmh') 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. 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').

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 relating to the Medical Devices Act, 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 (*Wet kwaliteit, klachten en geschillen zorg* or 'Wkkgz'). This means that institutions includes all institutions that offer care as described by or under the Healthcare Insurance Act (*Zorgverzekeringswet* or 'Zvw') and

the Long-Term Care Act (*Wet langdurige zorg* or 'Wlz') and that offer support where actions are undertaken, within the meaning of Article 36 of the Individual Healthcare Professions Act (*Wet op de beroepen in de individuele gezondheidszorg* or 'WET BIG'), that are not related to care as described by or under the Healthcare Insurance Act or 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 24 to 26 for more specific provisions. With respect to internal transparency, the provisions in these articles include declaring certain interactions to the institution and/or obtaining prior written approval from the board of the institution with respect to entry into service agreements covered by Articles 13 and 14 and sponsorship agreements covered by Articles 15 to 17. Article 26 requires institutions to establish procedure for the relevant approvals, declarations and administration.

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. The definition of interaction only mentions the possibility of a supplier and a healthcare professional being parties to an interaction. However, where an interaction is entered into between a supplier and a collaboration between healthcare professionals or an institution, this also qualifies as an interaction.

To clarify, the term 'interaction' is not used in Article 6 of the Medical Devices Act or in the Policy Rules on Inducement relating to the Medical Devices Act. 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, on the one hand, a healthcare professional, collaboration or institution and, on the other hand, 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.

The TRZ is administered by the Foundation for the Healthcare Transparency Register (the 'TRZ Foundation'). The Code Foundation works closely with this foundation. The financial relationships that have to be registered with the TRZ are not limited to financial relationships between suppliers and healthcare professionals; they also include financial relationships between suppliers on the one hand and collaborations between healthcare professionals, institutions and patient organisations on the other hand.

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 a number of points in the Code of Conduct and in particular in the separate paragraph on transparency (Articles 22 to 33).

In the first place, for a large number of interactions an obligation to record the interaction in writing applies. In several situations, a written agreement is even required. In addition to this, Article 23 contains requirements concerning the disclosure of certain relationships, for example when speaking at or taking part in a meeting.

The Code of Conduct also contains 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 Article 24 on declaring the reimbursement or payment of costs involved in 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 25 on the requirement to obtain the board's permission before entering service agreements and sponsorship agreements). 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 Article 25.

The Code of Conduct also contains provisions on *external* transparency (Articles 27 to 33). 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 TRZ enables patients and other interested parties to verify, within certain parameters, whether a financial relationship exists between a healthcare professional (or collaboration between healthcare professionals), institution or patient organisation on the one hand and a supplier of medical devices on the other hand 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 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.

Attention should be paid to discounts where the amount is dependent on a minimum purchase of the same supplier's other products within a given time period. The 'sanction' for failing to reach the minimum purchase could form an undesirable incentive capable of compromising the healthcare professional's ability to make rational choices. See A23.03.

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 relating to the Medical Devices Act.

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 three exceptions to the scope of practice in this article. Product testers are generally not perceived as gifts and are therefore permitted (clause 5(a)). The same applies to demonstration models, although their value and appearance are also taken into consideration. For both these exceptions, see A14.01.

The exception under (c) 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 on Inducement relating to the Medical Devices Act 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(d) 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, organisation costs should be specified in a budget estimate and after the meeting an account of how the sponsorship monies (including any contribution in kind) 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. For example, in advice note A21.02, the Code Commission held that a zoo is not an appropriate location due to its association with recreation. 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. Under clause 2(c) only costs named and specified in Articles 9-12 may be paid.
Clause 3 contains the ban on covering costs, whether direct or indirect, for anyone other than healthcare professionals, such as partners or children.

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 in advance 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 accounted for after the event to show that the money 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, A20.05 and A22.01.
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 and A22.01). This obligation should be recorded in the agreement.

The final paragraph of 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, A20.05 and A22.01).

Clauses 3 and 4 contain requirements with regard to documentation. Arrangements must be recorded in writing and where sponsorship relates to the organisation of a meeting there is even a requirement to enter into a written agreement.

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 5 a few requirements are set for the programme and content, as well as for recording arrangements. With respect to the maximum costs that the supplier is permitted to cover, please refer to Article 12.

Please also refer to the paragraph in this Code of Conduct concerning transparency. This contains several provisions that may apply to meetings covered by Article 9. For example:

- the obligation for a healthcare professional to declare to the board that they have made written arrangements with a supplier concerning the reimbursement or payment of costs (Article 24);
- the obligation for the organiser of a meeting that takes place with financial support from suppliers to disclose this clearly in advance and during the meeting (Article 23(2));
- the obligation for the organiser of a meeting who offers suppliers the opportunity to organise their own part of the programme to disclose this clearly in advance and during the meeting (Article 23(2)).

With respect to the obligations for publication in the TRZ, see Articles 27, 30 and 31.

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 with respect to recording arrangements concerning participation in a product related meeting in writing.

Please also refer to the paragraph in this Code of Conduct concerning transparency. This contains several provisions that may apply to meetings covered by Article 10. For example, the obligation for a healthcare professional to declare to the board that they have made written arrangements with a supplier concerning the reimbursement or payment of costs (Article 24). With respect to the obligations for publication in the TRZ, see Articles 27 and 32.

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 requirement to record arrangements in writing also applies to these meetings.

Please also refer to the paragraph in this Code of Conduct concerning transparency. This contains several provisions that may apply to meetings covered by Article 10. For example, the obligation for a healthcare professional to declare to the board that they have made written arrangements with a supplier concerning the reimbursement or payment of costs (Article 24). With respect to the obligations for publication in the TRZ, see Articles 27 and 32.

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 have a certain substantive justification. This may also be of a commercial nature. 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 declared to the board. Nor is publication in the TRZ required.

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 must be in reasonable proportion to the services provided. Expenses may be reimbursed in full provided that they are reasonable. Working together with the Foundation for the Code for Pharmaceutical Advertising (self-regulation of medicinal products) and in consultation with the Dutch Ministry of Health and the IGJ, maximum hourly rates that can be regarded as 'in line with the market' have been established. It is emphasised that these are maximum rates. This means that, taking into consideration the experience and expertise required of the service provider, the parties may also agree an hourly rate lower than the maximum rate because this is reasonable in that specific case. The number of hours that are remunerated must also be reasonable, in which context factors such as the nature of the activities and the service provider's qualifications and expertise may play a role.

With effect from 1 January 2024, the following maximum hourly rates apply for the various categories of healthcare professionals, classified according to their level of education (including postgraduate training):

Category	Maximum hourly rate
Professor	€284
University degree + postgraduate medical training > 3 years	€199
University degree + postgraduate medical training ≤ 3 years	€142
University/Master's degree without postgraduate medical training	€121
Higher professional education (HBO)/Bachelor's degree	€107
Other	€92

These maximum amounts are subject to annual indexation, based on the indexation figures for staffing costs established by the government (known as the '*Overheidsbijdrage in de Arbeidsontwikkeling*' or OVA).

By way of explanation of the classification into categories:

- The maximum hourly rate for the category *professor* also applies to an emeritus professor. An *associate professor* is not covered by this category.
- There are two categories for *university degree and completed postgraduate medical training*: a category for postgraduate training lasting 3 years or less and a category for postgraduate training longer than 3 years. The website of the Code Foundation provides a list of the various postgraduate medical training programmes and their duration.
- The category *university/Master's degree without postgraduate medical training* applies to healthcare professionals who have obtained a Master's degree without any further postgraduate specialisation. This includes pharmacists (other than those listed in the BIG Register with the specialisation "public pharmacist"), dentists, doctors with general medical training (including assistant doctors not in specialist training (ANIOS) and assistant doctors in specialist training (AIOS)), the five categories of nursing specialists, physician assistants, clinical technologists, medical physicists, medical biologists, medical immunologists, medical technologists, virologists etc.
- The category *higher professional education (HBO)/Bachelor's degree* includes dietitians, physiotherapists, midwives, occupational therapists and optometrists educated at HBO level.
- The category *other* includes pharmacy assistants (educated at senior secondary vocational education (MBO) level), nurses who have completed an MBO or in-service training programme, opticians, hearing care professionals, qualified drugstore operators, patient representatives (patient advocates) etc.

To assist in determining the correct category, this link provides an overview of professions and postgraduate medical training programmes.

The parties to a service agreement must always be able to justify their decision to classify the healthcare professional into a particular category, including to the IGJ, which may in the context of monitoring compliance with the Policy Rules on Inducement relating to the Medical Devices Act assess whether remuneration can be classed as reasonable in accordance with the system in the Code of Conduct. In the case of a profession with a protected title or professions or specialisations registered in the BIG Register or other official registers, registration in the relevant register shall constitute sufficient evidence. In other situations, the burden of proving that the rate is reasonable lies with the parties to the service agreement. The parties are advised to give proper consideration to this, so that they are able to provide evidence showing that the healthcare professional concerned has been correctly classified in the relevant category.

The maximum hourly rates apply regardless of whether the service agreement is entered into with the relevant professional directly or via another contracting party who employs the professional. In the case of a combined service agreement, involving several professionals (and/or non-professionals), the cost outline will need to show the hourly rate charged for each person.

Advice note A21.01 shows that the applicable maximum hourly rates may not be exceeded, even if the healthcare professional providing the services has a specific additional qualification, for example relating to

specific expertise, reputation or popularity. 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).

The maximum rates also apply in the event that the nature of the service requires the work to be carried out in a foreign country.

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 to make an exception for business class. The mere fact that a flight is longer than 5 hours does not justify making an exception to this basic rule. See A12.04, confirmed in A22.03 and A22.04.

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 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.

Clause 6 relates to the payment of royalties and forms an exception to clause 3. Royalties are generally agreed as a percentage of the gross or net income obtained from the use of an invention or other intellectual achievement. This form of reward for intellectual efforts is usual and accepted, also where a healthcare professional is involved. Naturally a royalty is only justified if a healthcare professional must actually be regarded as the proprietor of the intellectual property right, or if the royalty required under any law or regulation. Under clause 6, royalties must comply with three requirements: the royalty must be reasonable and in line with the market and may not be linked to future use, purchase etc. of the medical devices to which the intellectual property rights relate. This second requirement is linked to the desired independence and the avoidance of undesirable incentives. In that context, it is conceivable that when calculating the royalties one might for example exclude the income generated by the healthcare institution to which the relevant healthcare professional is affiliated. See A23.02. In this context, the Code Foundation endorses Chapter 7 of the current MedTech Europe Code of Ethical Business Practice.
The third requirement relates to the recording of arrangements in a written agreement.

Please also refer to paragraph 5 concerning transparency. This contains several provisions that may apply to services. For example:

- the requirement to obtain permission from the board before entering into a service agreement, which must be evidenced by countersignature by or on behalf of the board (Article 25);
- if the service involves speaking at a meeting, the disclosure of this financial relationship prior to the presentation (Article 23(2));
- if the service involves research, the obligation to disclose the supplier's involvement in any presentations and publications (Article 23(4)).

With respect to the obligations for publication in the TRZ, see Articles 27 and 28. Royalties do not have to be disclosed in the TRZ.

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 TRZ 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. The board responsible for the relevant healthcare professional must also countersign. In this context, see Article 25(2): the fact that the board has given permission to enter into the service agreement must be evidenced by countersignature by or on behalf of the board.

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 Medical Research Involving Human Subjects Act (*Wet medisch-wetenschappelijk onderzoek met mensen* or 'WMO') 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, the sponsor applicant will need to provide information in advance, including information on the objective and design of the project or activity, as well as a budget estimate in support of the sponsorship application. This is described in and required under clause 2(c).

There are several matters that need to be recorded in the sponsorship agreement. They are summarised in Article 15(2)(d). It is important that the total amount of the sponsorship contribution is recorded. Any contribution in kind must also be indicated. For example, making products available at no charge. This is linked to the publication obligation under Articles 27-29. The sponsorship agreement must also include an obligation for the party receiving the sponsorship to provide a subsequent financial account of all expenditure, so that the sponsor is able to verify whether the sponsorship contribution (including any sponsorship in kind) has been spent in accordance with the arrangements in the agreement (and the Code of Conduct). Clear arrangements must also be recorded concerning the repayment or expenditure of any surplus, including appropriate accounting in the latter case. See A22.01.

It is crucial that sponsorship may not lead to undesirable influence, as a result of being linked, directly or indirectly, to the purchase or use (now or in future) of the sponsor's products (clause 2(e)). In this context, clause 3 must be applied. The sponsorship must not result in any obligations on the sponsored party (or on healthcare professionals affiliated to the sponsored party) other than the obligations, which are legitimate

and required under the Code of Conduct, relating to acknowledgement, transparency within the meaning of Article 22 et seq. and accountability within the meaning of Article 15(2)(d). An exception to this provision is contained in the last paragraph of Article 17, which provides that in the context of sponsorship of research it is permitted to make medical devices available at no charge to the extent that this is reasonably necessary in the context of the research.

Sponsoring of individual healthcare professionals is not permitted; the sponsored party must be an organised partnership, institution or faculty. Clause 4 contains an exception for theses: this is permitted up to a maximum amount of €250 and arrangements about this do not have to be recorded in a written agreement. However, even these interactions must be confirmed in writing.

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 contribution.

See also advice note A12.01.

Please also refer to the paragraph in this Code of Conduct concerning transparency. This contains several provisions that may apply to projects or activities. For example:

- the requirement to obtain permission from the board before entering into a service agreement, which must be evidenced by countersignature by or on behalf of the board (Article 25);
- if the sponsorship relates to research, healthcare professionals who conduct research that is financed (or partly financed) by suppliers must disclose this in all written and oral presentations concerning that research (Article 23(5)).

With respect to the obligations for publication in the TRZ, see Articles 27 and 29.

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 that is initiated by a collaboration between healthcare professionals or an institution, then this article applies. In situations where a healthcare professional, collaboration or institution works on research initiated by a supplier, this constitutes the provision of services and Articles 13 and 14 apply.

For the applicability of this Article 17, it is irrelevant whether the research 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 must comply with the requirements in Article 15. To supplement these general requirements for sponsorship, additional requirements are set out in Article 17. 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.

Sub-clause c provides that the written agreement (which pursuant to Article 15(2)(d) must be entered into in the event of sponsorship) shall in any event include the purpose of the research and arrangements concerning the use of any medical devices made available in the context of the research.

In all cases, the costs must be reasonable. If the sponsorship contribution is also used to pay for activities by healthcare professionals, then of course the hourly rates applied 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.

Supplementing the requirement for a written record in Article 15(2)(d), it is provided that the objective, design of the research and arrangements concerning the use of any medical devices made available in the context of the research and subsequent accounting must also be recorded in writing.
In this context, see also A22.02.

Article 15(3) sets out the important principle that undesirable influence must be prevented. In the case of sponsorship of research, 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.

For an explanation of the transparency obligations, see the explanatory note on the last paragraph of Article 15.

In addition to this, in the interests of transparency, the fact that the research was carried out with sponsorship from the supplier must always be reported, for example in a publication or presentation on the research. See Article 23(4).

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 Federation of Medical Specialists (formerly 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.

The second paragraph sets out the rules that apply if patients and patient organisations (or representatives of patient organisations) provide services for suppliers for payment. In this situation as well, the requirements in Articles 13 and 14 must be satisfied. For example, the hourly rates agreed must be in line with the maximum hourly rates as set out in the explanatory note on Article 13.

With effect from 2024, sponsorship agreements between suppliers and patient organisations must also be published in the TRZ. See Article 33.

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.

TRANSPARENCY

GENERAL

Article 22. General

The fundamental principle for self-regulation is that interactions are only permitted if they satisfy the substantive requirements as set out in Articles 5 to 28. Transparency is also an important principle: the fact that there are interactions between suppliers on the one hand and healthcare professionals (or collaborations between healthcare professionals), institutions and patient organisations on the other hand should be disclosed in certain situations. Even if all the substantive requirements are satisfied, it is important that others are also aware (or able to be aware) of the financial links between suppliers and these parties.

All the requirements concerning transparency are gathered together in this paragraph, with a distinction being made between three forms of transparency:

- disclosure of financial links and identifiability of positions and relationships (set out in further detail in Article 23);
- compulsory internal declaration to and prior approval by the board of an institution (set out in further detail in Articles 24 to 26);
- compulsory publication in the TRZ (set out in further detail in Articles 27 to 33).

The requirements for these three forms of transparency do not apply to all interactions. The obligation for publication in the TRZ does not apply to all healthcare professionals, but only to healthcare professionals who are listed in the BIG register in the categories ‘doctor’, ‘nurse’, ‘nursing specialist’ or ‘physician assistant’. So when applying the rules on transparency it is always very important to establish what type of interaction applies and which parties are involved. In the relevant provisions in this paragraph this is described as clearly as possible (and in some cases repeated to ensure clarity).

It is possible that agreements recording interactions may not be entered into in the name of a supplier or of a healthcare professional (or collaboration between healthcare professionals), institution or patient organisation, but instead in the name of a third party that is engaged to do so by one of these parties. For example a professional organisation agency that is engaged by a scientific society to organise a conference and in doing so enters into the agreements with sponsors, or that is engaged by a supplier to organise a meeting and in doing so enters into agreements with a healthcare professional who will give a speech. Transparency is about revealing the financial relationships between suppliers on the one hand and the parties involved in the decision-making process relating to medical devices and the organisations representing patients who use these devices on the other hand. So for the application of the transparency rules, the issue is the parties that are involved in this, not the third party who is engaged to carry out the agreement (or part of the agreement).

Consequently, the rules in this paragraph should be applied as though the interactions were entered into by the supplier and the healthcare professional (or collaboration between healthcare professionals), institution or patient organisation, regardless of the involvement of the third party. In the examples described, the interactions are regarded as being entered into between the scientific society and the suppliers/sponsors and between the supplier and the healthcare professional/speaker, respectively. The third party that is, as it were, “in between” is disregarded. The same principle also applies in the situation where a healthcare professional does not enter into a service agreement in their own name but in the

name of the legal entity of which they are the director/majority shareholder. On this subject, see Article 28 and the explanatory note on that article.

Article 23. Disclosure/identifiability of positions and relationships

In the context of transparency it is important that when attending meetings healthcare professionals know who they are dealing with and what interests play a role. This is why Clause 1 provides that representatives of suppliers attending a meeting must be identifiable as such, for example by wearing a badge.

Healthcare professionals also need to be able to find out prior to a meeting that it is taking place with (full or partial) financial support from one or more suppliers (Clause 2). This information could be relevant when deciding whether or not to participate in the meeting. During the meeting itself, the organiser must also disclose that the meeting is sponsored and which suppliers have provided sponsorship. If the organiser offers suppliers the opportunity to organise their own part of the programme during or in parallel with the main programme, this must also be clear to the healthcare professionals taking part. They need to be able to get clear information about who has organised which part of the programme both before and during the meeting. In this context, see also Article 9(5) on satellite symposia.

In this context, Clause 3 provides that before commencing the substantive part of their presentation speakers should declare their (financial and other) links with suppliers or other relevant third parties. For this purpose, 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 with the template used by the Foundation for the Code for Pharmaceutical Advertising (self-regulation of medicinal products).

Clause 4 contains the obligation for healthcare professionals who conduct research to provide transparency about any funding of that research by one or more suppliers. They should declare this in all oral and written presentations and publications concerning this research. Incidentally, this is common practice and frequently also a requirement in many academic journals.

Clause 5 contains the requirement that patient organisations that organise an activity that is funded (or partly funded) by one or more suppliers must clearly state who the relevant sponsors are. This is consistent with the provisions of Clause 2.

INTERNAL DECLARATION TO AND APPROVAL BY THE BOARD

Many healthcare professionals work for an institution and consequently form part of a larger organisational structure. In addition to the responsibilities of individual healthcare professionals to provide good care, within the larger organisational structure care should also be taken to ensure systematic monitoring, control and improvement of the quality of the healthcare. Ultimate responsibility for this lies with the board of the organisational structure. These board members should be aware of certain financial relationships that the healthcare professionals working in the institutions enter into with suppliers and in certain cases even need to give permission for this.

Anyone who bears ultimate responsibility but has a different title is treated as equivalent to the board. For healthcare professionals working completely independently, they themselves must be fully aware of and bear responsibility for their own actions. For this reason, the rules in Articles 24 to 26 do not apply to them.

The interactions that need to be declared to the board are hospitality, services and sponsorship. In the case of hospitality, there is an obligation to declare this. The conditions for this are set out in detail in Article 24.

For entry into service agreements and sponsorship agreements, prior permission from the board is required. The conditions for this are set out in detail in Article 25.

Article 24. Declaring hospitality

If a healthcare professional enters into an agreement with a supplier concerning the reimbursement or payment of costs for taking part in a meeting to which Article 9, 10 or 11 applies, this must be declared to the board (Clause 1). This also applies in the event that the supplier does not reimburse the costs to the healthcare professional but pays them directly (with the result that these costs are not charged to the healthcare professional). In all cases, the arrangements must be recorded in writing (see Articles 9(3), 10(3) and 11(3)).

The obligation to declare does not apply to participation by an individual healthcare professional in a meeting that is organised by a third party and sponsored by one or more suppliers (see Article 9(4)). Nor does the obligation to declare apply to reimbursement of costs involved in meetings covered by Article 12 or satellite meetings as described in Article 9(5).

Some healthcare professionals work for more than one institution. In that case, the hospitality should be declared to the institution at which they carry out the majority of their work.

Article 25. Permission (and if appropriate declaration) concerning services and sponsorship

If a healthcare professional or collaboration between healthcare professionals enters into a service agreement within the meaning of Article 13 or a sponsorship agreement within the meaning of Articles 15 to 17 with a supplier, a more onerous regime applies. A declaration alone is not sufficient in that situation. In that case, it must be shown that permission was obtained from the board before entry to the relevant agreement (Clause 1). This obligation to obtain approval applies not only to healthcare professionals who work as 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 on this subject). The approval obligation also applies to collaborations that are related to the institution, such as a specialism group, division, Medical Specialist Company or research foundation.

As Article 15(2)(b) prevents sponsorship relationships between a supplier and an individual healthcare professional, the contracting party for sponsorship will always be a collaboration between healthcare professionals or an institution. If the contracting party is the institution itself and the board signs the agreement on behalf of the institution, this confirms that permission has been given. In all other situations, the board must approve the agreement.

This approval must be evidenced by countersignature of the agreement by or on behalf of the board (Clause 2). This signature shows that the board consents to the entry into the relevant service or sponsorship agreement as such. Countersignature need not necessarily mean that the board is therefore a full contracting party to the agreement in the sense that it is also liable for full performance of the agreement.

If boards wish to delegate the grant of permission internally, they are at liberty to do so as they think best. It will need to be clear to suppliers to whom this authority has been delegated (and if appropriate on what conditions). They will need to be able to establish without too much effort whether the requirement for prior permission to be given by or on behalf of the board has been satisfied.

In practice, a healthcare professional may be associated with more than one institution. In that case, the obligation to obtain prior permission from several boards could create a significant administrative burden. For this reason, in this situation it is sufficient to obtain the approval of one board, namely the board of the institution for which the agreement concerned is most relevant. The agreement must also be declared to the board of the other institution where the health professional also carries out part of their work (Clause 3).
It will be necessary to assess on a case-by-case basis which institution is most relevant and therefore needs to give approval and which institution only needs to have the interaction declared to it.
For example: in the case of research that is carried out on the instructions of a supplier by a healthcare professional who works for two institutions, the approval of the board of the hospital where that research is carried out must be obtained. The healthcare professional should declare the services to the board of the other hospital. Another example is the situation where a group of medical specialists within a particular specialism enters into a sponsorship agreement with a supplier, for example to provide funding for a training place. The institution where the majority of the training takes place is then the most "relevant" and consequently it is there that the approval of the board needs to be obtained. If a specialist involved in that specialism group also works at a different institution, then this sponsorship should be declared in that hospital.

Article 26. Institutions' obligations

Institutions have an independent obligation to comply with the requirements in the Code of Conduct relating to declaring internally and prior permission, respectively. Under Clause 1, they must provide for:

- the establishment of a process (centralised or otherwise) with respect to the grant of approval for sponsorship and service agreements, including any delegated authorities applicable in this context;
- arrangements (centralised or otherwise) with respect to the administrative and financial implementation of the approved sponsorship and service agreements and accountability for the same;
- the establishment of records (centralised or otherwise) of the approved and declared sponsorship and service agreements.

Under Clause 2, they must ensure that procedure is in place for declaring to the board of the institution any payments or reimbursement of costs for meetings, including any delegated authorities applicable in this context. It is self-evident that this includes ensuring that clear information is provided to healthcare professionals about this process and that attention is paid to its workability. For example, having a clear template for the information to be provided and timelines.

The Code of Conduct does not impose any further requirements on the way in which institutions implement the provisions of Clauses 1 and 2. By way of illustration, reference is made to the Guidelines on Governance of financial relationships between healthcare professionals and industry. These Guidelines were drafted in 2023. Version 2.0 has now been endorsed by the Dutch Hospital Association (NVZ), the Dutch Federation of University Medical Centres (NFU) and the Federation of Medical Specialists (FMS).

General reference is also made to the importance of ensuring that privacy legislation is complied with in the context of the procedures for declaration and obtaining permission. It is recommended that this should be taken into account when entering into the agreements, for example by providing that both parties give one another permission to process the personal data included in the agreement to the extent that this is necessary for the implementation and processing of the agreement.

Due to the time required to complete the procedures for declaration and obtaining permission, it is important for all parties concerned to be aware that information (the written arrangements or agreements) needs to be available in good time.

PUBLICATION IN TRZ

Article 27. General

The purpose of external transparency is to give third parties, including the patient, the opportunity to check whether certain interactions exist between a healthcare professional and suppliers of medical devices. The requirement to include certain interactions in the publicly-accessible TRZ makes it possible for patients and other interested parties to see, within certain parameters, whether financial relationships exist between a healthcare professional and/or institution and suppliers and, if so, the nature of these relationships.

The requirement for publication in the TRZ applies to certain interactions between suppliers and healthcare professionals who are listed in the BIG register in the categories of doctor, nurse, nursing specialist or physician assistant and the collaborations and institutions within which these healthcare professionals work. Healthcare professionals listed in the BIG register in the category of doctor include consultants and general practitioners, together with all other medical specialists, doctors practising a discipline protected as a trademark and basic medical practitioners. Dentists are not included.

So any financial relationships that suppliers enter into with healthcare professionals not belonging to the four categories mentioned do not have to be disclosed in the TRZ (Clause 1).

The interactions that have to be disclosed in the TRZ are:
- remuneration for services (see Article 28);
- sponsorship of projects, activities and research (see Article 29);
- sponsorship of and provision of hospitality at meetings (see Articles 30-32).

Sponsorship of patient organisations by suppliers must also be disclosed in the TRZ (Article 33).

The publication requirement only applies if a threshold amount is exceeded. The total amount due to (one or more) interactions between a specified supplier and a specified healthcare professional or institution as referred to in paragraph 1 of this Article must be higher than €500 per calendar year (Clause 2). If this threshold is exceeded in any calendar year, all interactions invoiced in that year must be disclosed, including the amounts for interactions with a value lower than €500.

The financial relationships that are required under this Code of Conduct to be published, must be provided to the TRZ Foundation. This foundation is responsible for the administration and annual publication of the data. Instructions on the manner in which and period within which data must be provided to the TRZ can be found on the website of the TRZ Foundation [https://www.transparantieregister.nl/]. The TRZ is responsible for the procedures to verify the data and the removal of the data within the period agreed between the Code Foundation and the TRZ Foundation (3 years).

The basic rule is that the supplier shall be responsible for making the reports to the TRZ (Clause 4). 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 affiliated to the Code Foundation.

In these cases, the healthcare professional or the collaboration/institution must take responsibility for making a report to the TRZ, unless the parties have explicitly agreed otherwise. There are two routes by which suppliers may be affiliated to the Code Foundation: through membership of one of the sector organisations for suppliers that are affiliated to the Code Foundation or through a direct registration with

the Code Foundation's Compliance Register. This distinction is not relevant in practice. All suppliers who are affiliated to the Code Foundation are listed on the Code Foundation website. See this link.

The TRZ has a template available for making a report. As well as the data for publication in the TRZ, this template also requires the provision of some additional data that are required for the report to be processed correctly (such as the supplier's Chamber of Commerce registration number, email addresses for further correspondence etc.). Incidentally, it is not the case that all data that are required to be published in the TRZ must be reported in the template. For example, the TRZ system generates an automatic link between the healthcare professional's BIG registration number and their name. For more information, see the TRZ website.

Each year, at the time of publication by the TRZ, the Code Foundation publishes an analysis of a number of interactions that have been reported to the TRZ by the medical devices sector. The aim of this analysis is to give greater insight into a number of existing types of cooperation within the sector in relation to the legislation and self-regulation and to provide further interpretation of these. This interpretation also forms the basis for identifying issues that require attention and trends.

For the purposes of this annual further interpretation, the Code Foundation may request suppliers who have made a report in the TRZ to provide documentation relating to this report (Clause 5). For example, the agreements on which sponsorship or service provision is based. Suppliers who receive such a request from the Code Foundation are obliged to provide the documentation requested within the period appointed by the Code Foundation.

With respect to requests for documentation and any communication (including external communication) relating to this, the Code Foundation will exercise the greatest possible care. This means, among other things, that, if and to the extent that the Code Foundation uses the information supplied in external communication, this shall take place in such a way that:

- the identity of the parties involved in the financial relationship remains anonymous and cannot otherwise be deduced from the communication;
- no information whatsoever is included that can be traced back to natural persons;
- the confidentiality of any commercially sensitive information remains guaranteed.

The individuals at the Code Foundation who are involved in requesting the documents and analysing them shall deal with these documents in confidence and shall use the information solely in the context of the analysis.

Any text relating to a specific financial relationship shall always be provided in advance for review by the party who made the report.

The board of the Code Foundation reserves the right, where in relation to agreements requested in the context of this clause a material breach of the Code of Conduct is suspected, to refer the matter to the Code Commission in the form of a request for advice.

In general, when establishing the amount that must be reported for a specified calendar year, the invoice date is decisive. Consequently, the year in which a payment is made, the written arrangements are made, the conference or activity takes place or the service is performed is not decisive.

Article 28. TRZ – Services

Article 28 relates to the remuneration of services within the meaning of Articles 13 and 14. Under which name (which data) the report is required depends on the service agreement and the actual situation.

If the service agreement is entered into under the name of the healthcare professional themselves then – in addition to the name of the supplier – the name and BIG registration number of the doctor, nurse, nursing specialist or physician assistant concerned must be published. The total amount of fees and the total amount of expenses, in each case as invoiced in the relevant calendar year by the healthcare professional concerned in the context of the agreement, must be disclosed as two separate amounts.

If the service agreement is not entered into under the name of a healthcare professional, two situations may apply.

In the first situation, the service agreement is entered into under the name of a legal entity in which the doctor, nurse, nursing specialist or physician assistant is a director/majority shareholder (for example, a hospital consultant's limited company for consultancy activities). This legal entity is not relevant for the TRZ as such; it is the name of the healthcare professional that must be published. In this context, please refer to the explanatory note on Article 22.

In the second situation, the service agreement is entered into under the name of a collaboration involving the healthcare professional or an institution where the healthcare professional works. In that case, the following information must be published:

- the name and Chamber of Commerce registration number of the collaboration/institution that is party to the contract;
- the name and BIG registration number of the doctor, nurse, nursing specialist or physician assistant who actually carried out the services (regardless of whether this healthcare professional is also the recipient of the amounts paid);
- the name of the supplier.

With respect to disclosure of the amounts the following applies. The information to be disclosed under the name of the healthcare professional is the fee (excluding VAT) that can be attributed to them as the person actually performing the services and the information to be disclosed under the name of the institution is the remaining amount, comprising overheads/reimbursement of expenses (including VAT). With respect to expenses, see the explanatory note on Clause 13(4). The total amount disclosed must correspond to the total amount invoiced in the relevant calendar year. In this context, it is not relevant whose account the supplier paid the amounts to and whether the healthcare professional was the actual beneficiary and received the amounts disclosed themselves.

The remuneration of services in the context of research to which the Medical Research Involving Human Subjects Act (*Wet medisch-wetenschappelijk onderzoek met mensen* or 'WMO') applies is exempted from the publication requirement (Clause 2).

If it is agreed in one service agreement that several services will be provided in the course of several years, it is recommended that the service relationships invoiced in any specific year should be published separately in the TRZ in the year in which they are invoiced.

Article 29. TRZ – Sponsorship of projects/activities/research

Article 29 relates to the sponsorship of projects or activities as described in Article 15, study grants (as described in Article 16) and research (as described in Article 17). These sponsorship agreements may only be entered into between suppliers on the one hand and collaborations or institutions on the other hand (see Article 15(2)(b). This means that publication in the TRZ always takes place under the name of the collaboration or institution concerned. For sponsorship agreements relating to meetings organised by third parties as described in Article 9, see Article 30.

A sponsorship contribution will always fund (or partially fund) a particular project or activity. In the context of that project or activity it is conceivable that those sponsorship monies may be used to pay for the participation of healthcare professionals in a conference or training course or for the remuneration of services by healthcare professionals. If and to the extent that amounts can be attributed under the sponsorship agreement to a specific healthcare professional (for hospitality or services) and these amounts are required under Articles 26 and 28 to be published under the name of that healthcare professional, then these amounts may be deducted from the total amount of the relevant sponsorship agreement that is published under the name of the collaboration or institution. In other words: the amount that can be attributed to the healthcare professional is disclosed under their name and the rest is disclosed under the name of the collaboration or institution. This approach ensures that optimum transparency is achieved and also prevents double disclosure.

The sponsorship of research to which the Medical Research Involving Human Subjects Act (*Wet medisch-wetenschappelijk onderzoek met mensen* or 'WMO') applies is exempted from the publication requirement (Clause 2).

The total amount of the sponsorship contribution must be published and for this reason any contributions in kind must also be disclosed in the agreement. For example, the value of medical devices that are made available at no charge by the supplier and used in research to which the Medical Research Involving Human Subjects Act does not apply.

Article 30. TRZ – Sponsorship of meetings

Article 30 relates to the situation where a supplier sponsors a meeting organised by an independent third party as described in Article 9. This means that a financial contribution (sponsorship) is provided by the supplier to the organiser of the meeting.

If that organiser is a collaboration between healthcare professionals or an institution, then this must be published under the name of the collaboration or institution that received the financial contribution. The amount that must be published is the total sponsorship amount. In this situation, there is no obligation to publish under the name of the healthcare professionals attending; after all, with this type of (often large-scale) meetings it is not possible to establish this precisely. Sponsorship of organisers will generally involve costs such as venue hire, speakers, necessary documentation materials, communication and catering. Although these general costs that are directly associated with the organisation of the meeting are excluded from the calculation of hospitality costs (Article 10(2)(c), final paragraph, and Article 11(2)(c), final paragraph), the total sponsorship amount that is invoiced (per supplier) in any calendar year must be published.

If a third party, such as a conference agency, is engaged to organise the meeting, this third party is regarded as an adjunct to the party they are engaged by. Consequently, in such a situation, publication still takes place under the name of the collaboration or institution that engaged the conference agency. See also the explanatory note on Article 22.

Article 31. TRZ – Hospitality at meetings organised by third parties

Article 31 relates to the situation where a supplier pays or reimburses the costs for hospitality for a particular healthcare professional who takes part in a meeting organised by a third party (Article 9). In this case, publication is made under the name of the relevant healthcare professional who received the hospitality (or costs for hospitality). As well as the name and BIG registration number of the healthcare professional, the total amount of the hospitality costs reimbursed or paid for by the supplier must be published. In this situation, this involves the costs for registration, meals/catering, overnight stays and travel. Registration fees are not included.

Incidentally, the situation referred to in this article will not often arise, as businesses that are affiliated to Diagned, FMed and Nefemed and/or MedTech Europe are bound by the prohibition in the MedTech Europe Code of Ethical Business Practice on providing hospitality to individual healthcare professionals during meetings covered by Article 9.

Article 32. TRZ – Hospitality at meetings organised by supplier(s)

Article 32 relates to the situation where a supplier organises a meeting covered by Article 10 or 11. The name and BIG registration number of the healthcare professional and the name of the supplier must be published. And also the total hospitality costs paid for by the supplier, comprising the costs for meals, catering, overnight stays and any travel. Costs relating to organisation (such as venue hire or speakers) do not need to be included. In the context of these meetings organised by the supplier, it is conceivable that no costs are invoiced by the healthcare professional because the supplier has taken care of all relevant costs. In that situation, publication must occur in the calendar year in which the meeting took place.

Article 33. TRZ – Sponsorship of patient organisations

Sponsorship of patient organisations is permitted provided that the requirements in Article 19 are satisfied. Article 33 sets out the information that must be published in that situation. This comprises the name and Chamber of Commerce registration number of the patient organisation, the name of the supplier and the amount invoiced by the patient organisation in the relevant calendar year.

DISCLAIMER

These explanatory notes were most recently amended on 1 January 2024. Relevant passages from newsletters issued by the Code Foundation in previous years (up to and including October 2023) are included in the explanatory notes. References to advice notes issued by the Code Commission in the period 2012-October 2023 are 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 advice notes are not formally binding and must always be interpreted in the context of the facts of the relevant case and the questions raised.