Code for the prevention of improper influence due to conflicts of interest

The code was drawn up by:

The Royal Netherlands Academy of Arts and Sciences (KNAW)
The Royal Dutch Medical Association (KNMG)
The Health Council of the Netherlands (GR)
The Dutch College of General Practitioners (NHG)
The Dutch Association of Medical Specialists (FMS; formerly the Order of Medical Specialists, OMS)

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The code is also endorsed by:

Association of the Dutch Generic Medicines Industry (BOGIN)
Central Committee on Research Involving Human Subjects (CCMO)
Medicines Evaluation Board (CBG)
National Health Care Institute (ZIN)
Dutch Federation of Biomedical Scientific Societies (FEDERA)
Huisarts en Wetenschap (H&W) (monthly periodical published by the Dutch College of General Practitioners)
Comprehensive Cancer Centre the Netherlands (IKNL)
Dutch National Knowledge Platform on Electromagnetic Fields and Health (EMF Platform)
Royal Dutch Society for Physical Therapy (KNGF)
Dutch Federation of Cancer Patient Organisations (NPK)
Dutch Federation of University Medical Centres (NFU)
Netherlands Youth Institute (NJI)
Dutch Dental Association (NMT)
Federation of Patients and Consumer Organisations in the Netherlands (NPCF)
Dutch Association of the Research-Oriented Pharmaceutical Industry (Nefarma)
Dutch Association of Dieticians (NVD)
Dutch Association of Pharmaceutical Medicine (NVFG)
Netherlands Society for Clinical Chemistry and Laboratory Medicine (NVKC)
Dutch Association for Speech Therapy and Phoniatrics (NVLF)
Netherlands Journal of Medicine (NTvG)
National Institute for Public Health and the Environment (RIVM)
Trimbos Institute
Dutch Association of Parent and Patient Organisations (VSOP)
V&VN Dutch Nurses' Association
Scientific Council for Government Policy (WRR)
Netherlands Organisation for Health Research and Development (ZonMw)
Netherlands Association of Health Care Insurers (ZN)
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Preamble

The organisations that have endorsed this code are responsible for preparing scientific advisory reports and health-care guidelines in the Netherlands.

Experts are asked to participate in committees,¹ in which they are expected to weigh scientific data and knowledge in an impartial manner. A balanced composition of these committees offers a good starting point for a balanced process of open deliberation, in which no angles are excluded and all relevant aspects can be discussed. This will ensure a balanced distribution across the relevant scientific disciplines and fields of interest. Distribution as described above makes it virtually impossible for one person to determine the outcome of an advisory procedure. In many cases, the advisory procedure will include an open consultation round or public meeting. A transparent process is an important prerequisite for the acceptance and effectiveness of the final decision. Society must be confident that this decision was reached without undue pressure or improper influence.

Scientists and the business community are increasingly working together. The Dutch government has a strong focus on promoting public-private partnerships, which undertake initiatives to commodify the acquired knowledge. The Dutch government also welcomes the patenting of new technologies and products by scientists. This will allow research results to be effectively transposed into social and practical applications, and may help to generate additional research funding. Scientists also occupy key positions within social organisations, such as professional organisations and patient groups. Effective cooperation between universities, businesses and civil society is beneficial to scientific progress. As a consequence, however, leading experts are becoming an increasingly integral part of relational networks. Therefore, the organisations must be fully informed about the relationships of prospective experts when composing the committees. This need for transparency also applies to relationships between the committee members themselves and communications with broader society. In order to continue to standardise transparency procedures, the organisations have prepared this common code. The code is a dynamic document and will be amended according to the needs of society and/or the participating organisations.

¹ The term ‘committee’ used further on in this text and declaration also refers to the advisory council, working group, project group or other term used to describe a group of experts.
Declaration of interests

All prospective parties involved in preparing scientific advisory reports and guidelines will be requested to fill in, sign and return the enclosed declaration of interests.

If an expert indicates that he or she has specific ties, this does not imply any moral judgement about these relationships. Nor does it imply that the expert is suspected of letting this relationship affect his or her advisory role. However, some relationships do pose an obstacle to participation in committees, or may only be allowed under certain conditions. Any semblance of a conflict of interest also plays a role in this context, as it may comprise the authority of the recommendation or tarnish the reputation of the expert concerned.

Transparency in relationships and interests

A clear understanding of the relationships and interests of prospective committee members enables organisations to make informed choices regarding the composition of committees. In order to ensure that organisations can effectively assess the value of these statements, prospective members must ensure that their statements are sufficiently detailed. To this end, the various relationships and interests mentioned below must be specified in the declaration.

1. **Principal and ancillary positions** clarify the affiliation of an expert. It is conceivable that an employer or another organisation to which an expert is attached has an interest in the recommendation formulated by the committee.

2. **Personal financial interests** are the most obvious cause of a potential conflict of interest. This could involve a member of an advisory committee who is employed by a company operating in the sector affected by the recommendation, or holds shares or stock options in such a company. In other cases, an expert might have personal financial interests in a specific recommendation in connection with consultancy services to a company or special interest group. In addition, ownership of a patent or product may give rise to financial gain for an expert.

3. **Personal relationships** can make an expert vulnerable to conflicts of interest if he or she is close to people who could benefit from a particular recommendation or the outcome thereof.

4. **Externally funded research** may give rise to conflicts of interest. In many areas, little or no public funding (such as funding from universities or the Netherlands Organisation for Scientific Research, NWO) is available, and studies can only be carried out on a contract research basis. In such cases where research is funded by government or industry, research questions tend to be well-defined. Although contract research can be initiated by both universities and financiers, the universities are responsible for ensuring that it is conducted independently (including the freedom of publication for the researchers and full accountability in terms of funding sources). Universities have standard contracts for this type of research and the KNAW has developed a Code of Conduct. Nonetheless, it is important to bear in mind the risk that financial dependence on another party can make a scientist vulnerable to conflicts of interest.

5. **Interests pertaining to intellectual property and reputation** may constitute a ground for conflicts of interest. A situation could, for instance, arise where the recommendation may lead to increased recognition for intellectual property. This could occur even without any personal financial gain but might be beneficial to an expert in that he or she will consequently acquire name recognition. Furthermore, an expert and/or his or her employer may have an interest in participating in a committee for the purpose of safeguarding their own reputation/position or gaining recognition. This could similarly apply if the expert is involved in an interest group, where he or she fulfils the role of figurehead for a patient organisation or professional association.
Policy on the prevention of improper influence

When developing policy on conflicts of interests, organisations should be guided by the following three basic principles: transparency, proportionality and responsibility.

- **Transparency** firstly implies the systematic registration of prospective committee members’ relationships and interests, and secondly clear-cut procedures regarding the handling of the registered data.

In order to provide optimal insight into the registered data, clear guidelines must be put in place regarding the information that each party is required to provide on their respective interests. To this end, a ‘Declaration of interests’ form accompanying this Code has been created. All prospective members must fill in this form before commencing activities.

The members’ statements will be discussed at the first committee meeting, so that the parties can read each other’s statements and ask any questions that may arise. This form of social control is an important means of preventing improper influence. The members must report both their existing interests prior to and any new interests arising during the advisory procedure. In some cases, members may be approached by parties that have an interest in the outcome of the report. This could give rise to conflicts of interest over the course of the process. All participants must proactively report any changes to their original statement to the chairman of the committee. These changes will then be discussed during the next meeting.

These procedures must be fully transparent not only for the parties concerned (such as prospective members) but also for society at large. To this end, the organisations endorsing the ‘Code for the prevention of improper influence due to conflicts of interest’ have published this Code on their website.

In order to ensure optimal transparency, the organisations must also publish the composition of the committee and the statements of the committee members. These statements will be actively disclosed at the start of the advisory procedure. The final report must obviously also be made public.

- **According to the concept of proportionality**, any measures taken to prevent improper influence must be proportionate to the gravity of the potential conflict of interest. Gravity is determined by two factors:

  1. the risk that an expert’s contributions will be influenced by his/her interests;
  2. the damage that this could do in terms of the recommendation’s contents and credibility.

Any decisions as to whether or not an expert will be allowed to participate, or the specific terms and conditions to which such participation is subject, will be based on the following principle:

If an expert can be expected to gain financially from a specific outcome of the advisory or guideline procedure, he or she will be fully excluded from participation in all cases.

In view of the fact that there is no way of developing clear-cut, general criteria, there will always be room for debate as to the balance between these two opposites (full participation and full exclusion). The greater and more relevant to the subject the interest is deemed to be, the more serious the reservations in terms of participation (principle of proportionality).

If exclusion could result in the loss of indispensable expertise, the expert in question may be allowed to participate in the committee under the precondition that he/she stops taking part in the discussions during the processing of and decision-making on a specific dossier. In some cases,
the expert will not be allowed to take part in the committee, but may be asked to provide expertise by means of a hearings procedure. In both cases, it must be unequivocally clear that the expert is not involved in the process on a structural basis.

- It should be clear which parties within the organisation are responsible for policy on improper influence. To this end, the organisation must clearly define which persons are responsible for taking action in the event of a potential conflict of interest. The declaration of interests should specify which person within the organisation was responsible for deciding whether or not a specific expert is allowed to take part (either unconditionally or subject to preconditions). This person will also be responsible for ensuring the independence of employees from the organisation providing the official committee secretary.
A focus on scientific and individual integrity

In all cases, the ultimate focus should be on the scientific and individual integrity of the committee experts. The above section outlines the procedures that organisations can apply to achieve this objective. However, this process cannot be fully enshrined in guidelines, as there is always a potential for exceptional situations. The management of the organisation concerned is responsible and accountable for the assessment of the prospective members. To assist with the implementation of the Code, a guide has been drawn up, which is available on the KNAW website: www.knaw.nl.
Sources

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