

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 Institute for Healthcare Improvement (CBO)

The Dutch College of General Practitioners (NHG)

The Dutch Order of Medical Specialists (OMS)

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The Dutch and English version can also be found at

www.knmg.nl/belangenverstremgeling or www.knmg.nl/code-improper-influence.

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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)
Health Care Insurance Board (CVZ)
Dutch Federation of Biomedical Scientific Societies (FEDERA) - under reserve
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) - under reserve
Royal Dutch Society for Physical Therapy (KNGF)
Dutch Federation of Cancer Patient Organisations (NFK)
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 Phoniatics (NVLFF)
Netherlands Journal of Medicine (NTvG)
Council for Public Health and Health Care (RVZ)
Dutch Council for Quality of Healthcare
National Institute for Public Health and the Environment (RIVM)
Trimbos Institute
Dutch Association of Parent and Patient Organisations (VSOP)
Dutch Association of Nurses and Care Providers (V&VN)
Scientific Council for Government Policy (WRR) – (supports the code's underlying principles)
Netherlands Organisation for Health Research and Development (ZonMw)
Netherlands Association of Health Care Insurers (ZN)

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

Preamble

The organisations that have endorsed this code are responsible for the creation of scientific opinion reports and clinical treatment guidelines. Experts are asked to participate in committees¹ in which they are expected to weigh scientific data and knowledge objectively. 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 opinion. Society must be confident that the opinion was formulated without undue pressure or improper influence.

Scientists and the business community are increasingly working together. 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 the proposed 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 adjusted according to the needs of society and/or the participating organisations.

¹ The term 'committee' used later on in the text and declaration also refers to the advisory council, project group or other term used to describe a group of experts.

Declaration of interests

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

If an expert indicates that he/she has specific business relationships this does not imply any moral judgment about these relationships. Nor does it imply that the expert is suspected of letting this relationship affect his/her advisory role. However, some relationships do present an obstacle to participation in committees, or may only be allowed under certain conditions.

Transparency in relationships and interests

A clear understanding of the relationships and interests of proposed 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, proposed 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 *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.
- 2 *Personal relationships* can make an expert vulnerable to a conflict of interest if he or she is close to people who could benefit from a particular recommendation or the outcome thereof.
- 3 The term reputation management refers to cases where an expert and/or his/her employer may have an interest in participating in a committee for the purpose of safeguarding their own reputation/position or gaining recognition. The same may apply to other interest groups. For example, this could apply to an individual who heads a patient organisation or professional association.
- 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 extremely well-defined. Although contract research can be initiated by both universities and financiers, the universities are responsible for guaranteeing its independent implementation (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 (set out in the report 'Science made to order' from 2005). However, such a relationship may make the scientist more susceptible to the interests of the party funding the research. It is important to bear in mind that this form of dependency can make a scientist vulnerable to conflicts of interest.

- 5 *Knowledge valorisation* has the potential to cause conflicts of interest. The Dutch government has a strong focus on promoting public-private partnerships. In addition to empirical research and evaluation studies, this also involves 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. Although this development is actively promoted by the government, that same government (and the rest of society) still expects independent recommendations from the researchers involved in such forms of knowledge valorisation. This requires special precautions to ensure that the expertise of the researchers involved can still be used for consultancy purposes. After all, there is always a potential for conflicts between the need for independent scientific assessment and potential personal interests in commodification.

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 the proposed 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 each party is required to provide on their respective interests. To this end, a 'Declaration of interests' form has been created. All proposed members must fill in this form before commencing activities.

The members' statements will be discussed at the first committee meeting, so that all proposed members 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 their interests both prior to and 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 proposed 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 should 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, and
2. the damage this may cause 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 this 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 who is responsible within the organisation for setting policy on improper influence. To this end, the organisation must clearly define which persons will be responsible for taking action in the event of a potential conflict of interest. The conflict of interest statement should specify which person within the organisation was responsible for deciding whether or not a specific expert will be 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 personal integrity of the committee experts.

The above section outlines the procedures organisations can apply to achieve this objective. However, this process cannot be fully enshrined in guidelines since special situations may arise. The management of an organisation is responsible and accountable for assessing the proposed members.

Sources

Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports – The National Academies, 12 May 2003.

Wetenschap op bestelling; over de omgang tussen wetenschappelijk onderzoekers en hun opdrachtgevers – KNAW, September 2005

Code of Practice for Scientific Advisory Committees, Government Office for Science, UK, Department for Innovation, Universities & Skills, December 2007

Gedragscode belangenverstrengeling NWO, October 2010

KNAW gedragscode belangenverstrengeling fondsen, prijzen en subsidies, 20 October 2008

Conflict of Interest in Medical Research, Education, and Practice – Bernard Lo and Marilyn J. Field (editors), Institute of Medicine of the National Academies, 21 April 2009

Toelichting bij procedures onafhankelijkheidsborging Gezondheidsraad, May 2009

Omgaan met betrokkenheid, Evaluatie Code Belangenverstrengeling NWO, June 2010.

Appendix 1

Working group members

Prof. Dr J. van der Meer, chairman

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Prof. Dr L.J. Gunning-Schepers

Prof. Dr J.A. Swinkels

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Process support

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Declaration of interests

The Code for the prevention of improper influence due to conflicts of interest requires that all proposed stakeholders involved in preparing scientific advisory reports and medical guidelines fill in, sign and return the enclosed statement.

The form will be assessed and subsequently made public.

Applicant's personal details

Committee

Member's name

Primary position(s)

Please specify the scope of each position if you have more than one

Ancillary positions

Please briefly describe the activities involved in each position, and state whether they are remunerated or not

Description of relationships and interests

For a more detailed explanation, see the Code paragraph entitled ‘Transparency in relationships and interests’.

Personal financial interests

Examples:

An advisory committee member that acts on behalf of a company operating in the sector covered by the recommendation/guideline.

Direct financial interests in a company (shares or stock options).

Personal relationships

Example:

Individuals in the (proposed) member’s immediate environment (such as family members, partners, friends and immediate colleagues) that could benefit from the outcome of a specific recommendation.

Reputation management

Examples:

Participation in (unremunerated) committees for the purpose of safeguarding one’s own reputation/position, the position of the employer or other special interest groups, or gaining recognition.

Head of a patient organisation or professional association.

Externally funded research

Example:

Participation in research funded by semi-government/ governmental organisations, funds or industry, whereby the financier may have an interest in specific outcomes.

Knowledge valorisation

Examples:

Unique, specialist expertise on the areas and sub-areas covered by the recommendation/ guideline, offering the potential for commodification. This may concern a medical product, procedure or intervention, as well as a new theoretical concept or model or a new organisational or logistical approach.

Ownership of a product patent.

Other interests

Do you or those around you have any other interests that could be a source of potential embarrassment to you, your environment or the organisation if made public?

Signature

- I. Hereby confirms to have taken cognisance of the Code for the prevention of improper influence due to conflicts of interest;
- II. Hereby agrees to treat all internal discussions as confidential;
- III. Hereby confirms that he/she has listed all relevant relationships and interests in good faith;
- IV. Hereby confirms that he/she will duly report any new interests that should arise in the interim, the termination of any existing interests, changes to existing interests or interests that will become more relevant over the course of the process.

Print out the form, sign and return to the organisation.

Signature of proposed member:

Date:

Submission (to be filled in by the organisation)

Decision (to be filled in by the organisation)

Member's name:

Committee:

- There are no circumstances precluding participation in the committee.
- Participation in the committee will be allowed under the condition that the member discontinues his/her participation in committee meetings during the processing of and decision-making on dossier [dossier name].
- Participation in the committee cannot be permitted due to an excessive potential risk of improper influence.
- Although participation in the committee cannot be permitted, the expert may provide the committee with the required expertise by means of a hearing procedure conducted during processing of the dossier and formulation of the final opinion.

Name:

Position:

Date:

Signature:

Explanation (optional):

