

## Format of disclosure slide for speakers at refresher training meetings

Disclosure of speaker's interests	
No (potential) conflict of interests	
Relations that could be relevant for the meeting <sup>1</sup>	Company names
<ul style="list-style-type: none"><li>• Sponsorship or research funds<sup>2</sup></li><li>• Payment or other (financial) remuneration<sup>3</sup></li><li>• Shareholder<sup>4</sup></li><li>• Other relation, viz. ...<sup>5</sup></li></ul>	<ul style="list-style-type: none"><li>•</li><li>•</li><li>•</li><li>•</li></ul>

### Explanatory notes

Under the rules on pharmaceutical advertising (the Dutch Medicines Act (Policy Rules on Inducements) and the Code of Conduct of the CGR) every speaker during a refresher training meeting should be transparent with regard to his/her relations with the industry. The Dutch Healthcare Inspectorate (the "IGZ") has found during an investigation into the level of compliance with the advertising rules during refresher training for medical specialists (November 2012) that speakers are insufficiently complying with their obligation to disclose their ties with the industry prior to their presentation. The IGZ has announced that it will actively monitor the disclosure of ties between speakers and pharmaceutical companies.

In order to help speakers comply with their obligation to be transparent with regard to their ties during refresher training, the KNMG and the CGR have developed this format for a disclosure sheet after consultations with the IGZ. The format links up with existing obligations to disclose (financial) ties with the industry, such as the Dutch Code to Prevent Inappropriate Influence due to Conflicting Interests prepared by the KNAW/KNMG (to be further referred to as: the KNAW Code), the rules on transparency in the Code of Conduct of the CGR (Chapter 7) and the publication of clinical trials in the Dutch Trial Register. The format developed by the European Union of Medical Specialists (UEMS) has also been looked at.

Speakers are expected to show a disclosure sheet in accordance with this format (if necessary, in their own layout) before they start their actual presentation. The audience should be able to familiarise themselves with the content of the disclosure sheet. The disclosure sheet must also be part of the handouts of the presentation and will also be used when reviewing the refresher training for accreditation purposes.

The various fields of the disclosure sheet will be explained in more detail below.

#### 1. Relations that may be relevant for the meeting

Here, the speaker must disclose relations with companies in the pharmaceutical industry, the biotechnological industry, the medical device industry and the medical food industry. These are the relations that are also considered relevant for registration in the Dutch Trial Register. Contributions from governments and not-for-profit organisations (funds) do not come under this.

## **2. Sponsorship or research funds**

The KNAW Code provides the following: “Externally funded research may lead to a conflict of interests. In many fields no public sources, or hardly any public sources, are available (such as funding by universities or the NWO, *Nederlandse Organisatie voor Wetenschappelijk Onderzoek*, the Dutch Organisation for Scientific Research) and research is only possible through contract research, where the research is funded by the government or industry and the research question is usually very accurately defined. The initiative for contract research can be taken by either a university or a financier, but the universities guarantee an independent implementation (including the researchers' freedom to publish and full accountability for the funding sources). Universities have developed standard contracts for this type of research and the KNAW has drafted a Code of Conduct (recorded in its opinion "Science to Order" from 2005). Even so, such a relation can still make a scientist more susceptible to the interests of the party funding the research. For this reason the risk that this form of dependence may make a scientist vulnerable to a conflict of interests must always be borne in mind.”

If the speaker has been (or is still) involved in research or in a project (co-)financed by one or more companies (see above under point 1), he/she is expected to report this in the disclosure sheet. All sums received in excess of € 500 (per company, cumulatively per year) in the past 4 years must be disclosed. Usually it will concern data which will be disclosed via the Dutch Trial Register or the Dutch Healthcare Transparency Register.

## **3. Payment or other (financial) remuneration**

The KNAW Code provides the following: “Personal financial interests are the most obvious reason why conflicts of interests arise. A good example is a member of an advisory committee who is employed by a company that operates in a field targeted by the advice [...]. It is also imaginable that an expert has personal financial interests in a particular opinion in view of his or her advisory role for a company or for an interest group.”

If the speaker provides (or has provided) services for one or more companies (on the basis of, for instance, a contract for services or a contract of employment) (see at point 1 above), he/she should disclose this if the payment represents a value in excess of €500 (per company, cumulatively per year) and the services have been provided within a period of 4 years prior to the date of the presentation. Consultancy services may for instance have been provided (e.g. on a company's advisory committee), an article may have been written at the instruction of a third party or a presentation may have been held. The fact that the speaker him-/herself is the recipient of the fee is not decisive. The relation should also be mentioned if payment has not been made to the speaker directly, but has been granted to another legal person (e.g. the work practice of the speaker, a (research) foundation, a healthcare institution/hospital or an organisational or speakers' agency). The relevant data will generally be included in the Healthcare Transparency Register.

## **4. Shareholder**

Holdings of shares or options in a company may also point to a personal financial interest, which may give rise to a conflict of interests and must be disclosed, but only if a "substantial" interest is held in a company. A substantial interest exists if the speaker holds 5% or more of the shares in the company (including the shares held by his/her partner) and also if the speaker has such an interest via another legal entity. The definition used in the tax law has been linked up with here.

## **5. Other relations, viz. ...**

There may also be other relations which could give rise to some form of conflicting interests, such as personal relations with people from a speaker's immediate vicinity (for instance a partner and/or children) who work for a company which stands to gain from a certain representation of matters by the speaker. The speaker is considered to report this in the disclosure sheet.