

2016-03-11



Declaration of Interest – Information from the agencies

This document has been developed jointly by the Dental and Pharmaceutical Benefits Agency (TLV), the Health and Social Care Inspectorate (IVO), the Medical Products Agency (MPA), the National Board of Health and Welfare, the National Food Agency, the National Veterinary Institute (SVA), the Public Health Agency of Sweden, the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) and the Swedish eHealth Agency. It describes the various types of conflicts of interest and how the national agencies listed above view these issues. The primary purpose of this document is to inform external experts¹ who are, or could be, engaged by the agencies. A special *Declaration of Interest* form (Appendix 1) accompanies this document. An electronic version of the form is also available on the websites of the respective agencies. The information focuses primarily on conflicts of interest in relation to companies (business and industry). However, it is important to consider all types of potential conflicts of interest, including family and financial interests. The respective agencies may offer additional information about these matters via their websites or via other sources.

Roles and responsibilities of the agencies

The agencies have a fundamental responsibility to guarantee that the constitutional standards of objectivity, factuality, and impartiality are fulfilled in handling investigations and official matters. The provisions concerning conflict of interest in the Administrative Procedure Act do not formally cover external experts engaged by an agency. However, if an expert is assigned by an agency to participate in handling an agency matter, he or she must comply with the Administrative Procedure Act in the same manner as any other employee of the agency. Regardless of the affiliation between an expert and an agency, it is essential that nothing in the expert's background would hinder the agency from acting objectively and impartially on a matter in question, and which in turn could negatively affect the agency's credibility. It is an established fact that in this context it is easy to damage an agency's credibility, but extremely difficult and time-consuming to repair the damage. Hence, the impartiality of every external expert engaged by an agency must be assured beyond question. This is a prerequisite for an agency to be able to live up to the high standards expected of it.

Determining whether or not experts meet the standards placed on them is not easy and is becoming increasingly difficult. Experts today are expected to collaborate with others to a greater extent than in the past. For instance, the Higher Education Ordinance (1993:100) states that "the ability to cooperate with the surrounding community and inform others about

¹ In this context, the term "expert" includes those with special qualifications, eg, consultants, scientific advisors, and others who report on matters assigned by the agencies.

research and development activities” is desirable. This implies that the Government encourages collaboration with the business sector and private companies. Before an agency contacts an expert for an assignment, the agency looks into whether it has previous knowledge about the expert’s actual or potential conflicts of interest that could jeopardize confidence in impartiality and objectivity. If this is the case, normally the agency would not extend an invitation to that particular expert. An expert can never demand an assignment from the agency. A decision not to engage a particular expert for a given assignment is not an expression of questioning the expert’s qualifications or the quality of his or her research, but should be viewed as a necessary way to comply with the standards of objectivity and impartiality placed on the agencies by the Government. If an agency finds that giving an assignment to a particular expert is in compliance with the standards of objectivity and impartiality, but later the expert is criticized or comes into question based on information disclosed in the Conflict of Interest Declaration, it is the agency’s responsibility to defend its decision and also its expert. However, this does not have to be the case if the criticism or question concerns something not disclosed to the agency.

Conflicts of interest and other situations

The Administrative Procedure Act (1986:223) contains the fundamental provisions for handling matters at the administrative agencies. Sections 11 and 12 of the Act address the rules concerning conflicts of interest. Several situations are grounds for conflicts of interest. The most relevant in the present context are: *conflicts concerning personal involvement*, where the outcome of an assignment “can be expected to result in particular benefit or harm” to the expert, and more overarching *conflicts involving special circumstances that encompass* “any other special circumstance likely to undermine confidence” in the expert, and thereby in the agency. The specified grounds for conflicts of interest also apply to family members or other close relationships. Examples of *conflicts involving special circumstances* include the following situations:

- Holding shares in a private company combined with some other circumstance (holding a large amount of shares could be defined as a conflict concerning personal involvement)
- Friendship or hostility toward someone who is a participant in, has an interest in, or is a representative for anyone involved in the matter
- Markedly dependent relationship with the party or other interested party (this could also be defined as a conflict concerning personal involvement)
- Previous or ongoing position or engagement in the matter, to the extent that deficiencies in the conditions for impartiality can be suspected
- Previous or ongoing assignment involving a party or other interested party, eg. participation in another project at the party or the other interested party in question
- Close contact with the party or interest, but not regarding any specific past or present assignment, and without having similar contacts with other parties/interests in the same sector and
- Other circumstances that could raise suspicions of bias (loyalty or antipathy) towards the party or interest.

Area of uncertainty

According to the Administrative Procedure Act, a conflict of interest exists when rather clear and obvious circumstances indicate that a particular expert is inappropriate for a given assignment. In fact, the situations in which agencies are engaged are usually not so clear and obvious. Certain circumstances might not “feel right” and might therefore be called into question. In this sphere of different relationships, the nature of conflicts of interest between the considered or appointed expert and the assignment objective could be such that the agency’s credibility might be damaged even in the absence of an actual conflict of interest according to relevant provisions in the Administrative Procedure Act. Evaluations should also consider circumstances involving family members or other close relationships.

Fundamental perspectives

Transparency

Openness among all parties involved is essential to conduct thorough evaluations, maintain good relations between agencies and experts, and achieve strong public confidence. It should be noted that knowledge of all circumstances relevant to a particular expert cannot in itself “neutralize” a risk for negative influence on impartiality.

What should be evaluated?

Evaluating an expert’s possible appointment for a particular assignment must include the agency’s risk assessment regarding the relationship between the assignment and the expert’s background, and the effects these ties could have on the agency’s ability to act objectively and impartially.

Perceptions of other actors

How an expert’s relationship might be perceived by outsiders, eg. media, could be of importance, but not as an isolated argument for or against an expert’s assignment independent of the evaluation concerning the actual ties that exist.

Many concurrent assignments

If an expert is engaged in many smaller, concurrent assignments, eg. from several different companies, the scope of potential conflicts of interest could be difficult to overview and might require further evaluation.

Different “schools” of thought

Normally, experts should not be ruled out because they hold certain views, eg. concerning medical issues. To the extent that a profession encompasses different schools of thought, it is reasonable for these different views to be represented in the agency’s work on the matter in question.

Remuneration

Whether or not an expert is remunerated for an assignment is of some importance. As regards grants and funding, it is of importance whether the experts are directly remunerated or whether the money only covers other project costs, or is channelled, eg. via the higher education institution. The conditions placed on a grant are also of importance. If remuneration is granted, the amount is an important factor in the evaluation.

Previous assignments

It is difficult to specify the time required for “neutralization” of an expert’s past assignment, once regarded as an unacceptable conflict of interest, in order to allow a new assignment in a similar issue from an agency. Ideally, it would be possible to establish a fixed time limit, eg, 2 to 3 years. The length of such a period must however be dependent on the type and scope of the relationship, the nature of the assignment, and its economic significance.

Agencies can arrive at different conclusions

Because the agencies have different roles and missions, they might arrive at different conclusions regarding the participation of a given expert.

Nature of the assignment

The nature of the intended assignment is the point of departure for an agency’s evaluation. The “nature” of the assignment generally refers to the potential influence an expert has on the outcome for the assigning agency. For example, a factor of importance is whether the expert is assigned to work independently or in a group. Also, it is possible that an expert could be deemed inappropriate for a particular assignment in one agency, but appropriate for another. Other questions that must be evaluated involve the actual connection between the subject area concerned by the conflict of interest and the subject area that the expert represents. In addition to an evaluation of the nature of the assignment, general descriptions of different typical situations might be helpful in an agency’s risk assessment.

Typical situations

In addition to the more obvious and clear-cut cases that can be characterized as conflicts of interest in the context of the Administrative Procedure Act, the agencies have identified several typical situations. These situations are not listed with the intent to generally disqualify someone from an expert assignment, but because experience has shown that these situations deserve to be noticed and appraised. The situations can be categorized into three general groups. The risk of an unacceptable conflict of interest is generally higher in the situations that appear toward the top of the lists under the three category headings below. For instance, major economic involvement often suggests the possibility of a conflict of interest. But even if economic involvement is moderate or minor, the degree of personal involvement might indicate that a conflict of interest exists. Obviously, the typical situations mentioned below have many possible variations. The nature of the assignment is the point of departure. Again, it is important to note that *ultimately it is always the conditions of the individual case that are decisive in an evaluation.*

1. Established ties between an expert and a company/interested party

- a. Board assignment in a company
- b. Employment (fulltime or part time) in a company, eg, a pharmaceutical company
- c. Owner of a company with activities relating to the assignment
- d. Owner of patents related to the assignment.
- e. Consultant for a company
- f. Participation in professional or trade organizations assumed in part to represent interests within an area

- g. Participation in professional or trade organizations in which basically all interests in an area are represented
 - h. Participation of some type of innovative company (eg, biotech) that does not yet offer developed products
2. *The expert's assignment for a company/interested party*
- a. Participation in marketing or product development, "lending one's name"
 - b. Consultant/expert/scientific advisor for a company
 - c. Member of an advisory board, reference group, or similar body
 - d. Single member of a company's research council for assessing research applications
 - e. Remunerated by a company for lectures concerning the expert's research and expertise
 - f. Participation in a company's research council for assessing research applications, together with other experts
 - g. Expert adviser to company regarding grants for researchers/research
 - h. Participation on editorial board intended to scientifically appraise contributions to a company's magazine or similar publication.
3. *Jobs/positions/research grants/funding in which companies are involved*
- a. Personal professorship (or equivalent) funded by a company
 - b. Principal investigator (clinical)
 - c. Larger research grants to certain researchers for specially targeted research
 - d. Clinical trial position other than principal investigator
 - e. Smaller research grants/funding to certain researchers for basic research
 - f. Company financing of conference trips etc that conflict with the current agreement between LIF (the trade association for the research-based pharmaceutical industry in Sweden) and SKL (Swedish Association of Local Authorities and Regions) addressing forms of collaboration between the pharmaceutical industry and public health service employees
 - g. Professorships (or equivalent) appointed independently by a university or higher education institution with funds provided to a department (or equivalent) by a company
 - h. Research grants/funding from a company to a department (or equivalent)
 - i. Research grants/funding from a company to a county council
 - j. Own publications

Declaration of Interest form

It is essential that the experts engaged by an agency disclose their own actual or potential conflicts of interest. All experts must submit a completed "Declaration of Interest" form. If the status of any information on the form changes after it is submitted, the expert has the obligation to disclose the updated information. Although a duty to investigate eventual conflicts of interest lies upon the agency, the experts themselves carry the primary responsibility for disclosing any potential conflicts of interest so the agency can evaluate them. In addition, anyone with knowledge of a potential conflict of interest or similar circumstance shall, according to the Administrative Procedure Act, make this known.

Appendix 1

Declaration of Interest form