
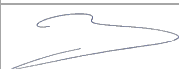





QUAMED's policy on conflict of interest and impartiality

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Introduction

QUAMED is aware of the importance of impartiality and of potential conflicts of interests in carrying out its assessments, audits, certifications and training and technical assistance activities.

QUAMED requires all its contracted staff and experts, as well as members of the Board of Directors and internal QUAMED committees to adhere to its conflict-of-interest policy and standard operating procedure as well to the QUAMED's code of conduct. This is the first step to ensure that the highest standards of integrity and impartiality are applied to all our activities wherever they are taking place.

Objective of this policy

This policy presents QUAMED's policy on "conflict of interest and impartiality" as it applies to:

- external evaluators (auditors, expert and others that are contracted by QUAMED to conduct and audit or a technical visit or any other service),
- members of internal or external advisory and review committees that are associated with QUAMED's services and operations and,

- QUAMED staff, board members and members of board committees.

These categories are referred to as “experts” for the purposes of this policy.

Definitions and principles

The common meaning of “conflict of interest” is a conflict between an individual’s private or personal interest and his or her duty. However, it may also refer to a situation where an individual has several duties which conflict without involvement of any private or personal interests.

A conflicting private or personal interest may be financial or non-financial as explained below. When a decision-maker or expert has a direct financial interest, however slight, in the matter to be decided, there is a conclusive presumption of bias, and the decision-maker or expert will thus be disqualified from acting.

Where a decision-maker or expert has a non-financial interest, which gives rise to a reasonable presumption of bias, the decision-maker or expert will be disqualified from acting. The test here is whether a reasonable observer would suspect that there is a possibility of bias, not whether that bias actually exists.

A relevant non-financial interest may arise, for example, out of personal or family involvement between a decision-maker or expert and a party whose interests are affected by the decision or recommendations. Such an interest may also arise where a decision-maker or expert is seen to have prejudged the issues, either through preconceived opinions or prior involvement with the facts of a case on which he or she is required to decide on recommendations.

Conflict of interest in relation to experts

There are a variety of situations in which experts may find themselves in a situation of conflict of interest between their professional activities (e.g., preparation of objective and independent evaluations or membership of independent committees) and personal and private interest (e.g., private consultancies, grants to cover travel and accommodation at company-sponsored conferences, shareholdings, research grants or honoraria). It is recognized that many of the experts that QUAMED employs, or contracts will have some potential conflict of interest because of present or past association with the pharmaceutical industry.

Some situations of conflict of interest are clear-cut and some are more difficult to determine. If an individual is an employee of, or a retained expert to, a pharmaceutical company, there is a clear possibility of conflict of interest. If an individual is an employee of a government organization, does no work on behalf of pharmaceutical companies, and is not in receipt of gratuities or funding, there is a minimal risk. Between these two situations is a spectrum of possibilities where the decision as to whether there is a conflict of interest may be less obvious.

Contracts are unlikely to be offered to experts in any one of categories 1 to 6 listed below.

1. The expert works in the pharmaceutical industry, either as an employee or as an owner or part owner (e.g. shareholder in the pharmaceutical company to be assessed).
2. The expert receives a retainer (fee) from one or more of the pharmaceutical companies whose products she or he must assess or which the new product is likely to replace.
3. The experts have a significant direct current relationship with one or more companies. This may take the form of (a) financial support for a current research project or projects; (b) sponsorship of graduate or postgraduate students; or (c) company employees who are under the direct responsibility of the expert.
4. He or she receives substantial financial assistance or expensive equipment to conduct research on behalf of the pharmaceutical company.
5. The expert acts or has acted as an expert for a pharmaceutical company that she or he has agreed to assess. Such a consultancy may include sponsorship as a speaker, or appointment as chairperson at professional meetings concerning the product, or attendance on behalf of the sponsoring company at national or international professional meetings concerning the company.
6. The expert has provided significant input to the planning or conduct of a clinical trial of products manufactured by the organisation to be assessed, for example as a principal investigator, signatory to the study report, or author of any published or unpublished paper or other report of the study. Participation limited to the inclusion of patients in a large-scale multicentre study is not considered a significant conflict of interest.

A conflict of interest is less likely to be seen in situations 7 to 10 (see below).

7. The expert has occasional contracts with one or more companies for projects, but does not have a significant relationship with any one company. She or he has not been directly involved with the product in question.
8. The expert owns or works for a consultancy, which does not provide advice to the pharmaceutical industry but may provide advice to other industries, such as the devices, food, or paint industries. However, it is unlikely that such experts will have the technical knowledge or experience to qualify as an expert in the pharmaceuticals field.
9. The expert occasionally provides advice to one or more companies on the design of clinical trials to be conducted prior to submission of an application for marketing authorization, but does not have a significant current relationship with any one company (e.g., points 1 to 6 above).

10. The expert has been invited to attend and contribute to national or international meetings organized by professional or academic associations.

The responsibility of experts

QUAMED cannot be aware of all the expert's involvements and their ramifications when a contract is offered. The onus is therefore on the expert to declare in writing any potential conflict or what may be seen as a potential conflict to the QUAMED staff member who negotiated the contract or committee membership. If there is any doubt, the potential conflict must be declared.

The expert may only proceed with the assessment, technical visit, evaluation of data or take up committee membership after any potential conflict has been discussed with QUAMED and found not to be significant. For this reason, each contract will contain a conflict-of-interest clause that the expert is required to sign. The clause states that the expert has no current conflict of interest and that, if the risk of such a conflict arises during the work for which she or he has been contracted, QUAMED will be notified immediately in writing.

The statement can be part of the contract that the evaluator signs or can be signed as a stand-alone document.

The evaluator is expected to cease the contracted activity immediately when she or he becomes aware of a conflict of interest and return the responsibility of the activity promptly to QUAMED. This applies to all type of activities.

We trust that this ensures that our activities are conducted in an independent and impartial manner.

Actions when potential conflict of interest are detected.

In this case, the standard operating procedure on Management of confidentiality, code of conduct and conflict of interest apply (SOP-G-001).












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