

Assessments of declarations of interest for the Strategic Advisory Group of Experts (SAGE) on Immunization

To be effective, the work of WHO and the contributions of its experts must be, and must be perceived to be, objective and independent. In this regard, to ensure the highest integrity and public confidence in its activities, WHO requires that experts serving in an advisory role disclose any circumstances that could give rise to a potential or reasonably perceived conflict of interest related to the subject of the activity in which they will be involved.

SAGE follows WHO's conflict of interest framework¹, which is designed to identify and avoid potentially compromising situations from arising, thereby protecting the credibility of WHO and its normative work. If not identified and appropriately managed such situations could undermine or discount the value of the work of SAGE. Robust management of conflicts of interest not only protects the integrity of SAGE but also protects the concerned SAGE member and the public interest in general.

The term "conflict of interest" means any interest declared by a SAGE member that may affect or reasonably be perceived to (1) affect the individual's objectivity and independence in providing advice to WHO, and/or (2) create an unfair competitive advantage for the individual or persons or institutions with whom the individual has financial or business interests (such as adult children or siblings, close professional colleagues, administrative or research unit).

A conflict of interest analysis is being performed before the nomination of a new SAGE member and after this, before each SAGE meeting. For this, the standard WHO declaration of interest (DOI)² form must be completed and submitted to the SAGE Secretariat.

All relevant interests will be individually discussed considering the nature and value of the interest i.e. intellectual property (e.g. patents), financial and/or investments. It noted whether the interest relates to the expert directly, an immediate family member, or the expert's research unit. The position and role of the SAGE member in their research unit, along with its relationship with WHO, is assessed. It is determined whether serving on SAGE enables the expert to obtain access to confidential information which could result in a relevant interest (e.g. advantage over competitors working on a similar issue). Further, the relevance and specificity of the declared interest in view of the subject matter of the SAGE meeting or work to be undertaken as well as the timeliness of the interest is evaluated. Conflict of interest applies to current interests that have arisen during a period of 4 years preceding the appointment for SAGE membership or the specific SAGE meeting.

Disclosure of the stated interests:

An interest is considered "personal" if it generates financial or non-financial gain to the expert, such as consulting income or a patent. Funding going to the expert's research unit needs to be declared (e.g. research grants), though it is stated as non-personal if this does not create direct financial gain to the expert. "Specificity" states whether the declared interest is a subject matter of the meeting or work to be undertaken. An interest has "financial significance" if the honoraria, consultancy fee or other received funding, including those received by expert's organization, from any single vaccine

¹ <http://www.who.int/about/declaration-of-interests/en/>, accessed July 2015

² <http://www.who.int/about/doi-form-blank-en.doc?ua=1>, accessed July 2015

manufacturer or other vaccine-related company exceeds 5,000 USD in a calendar year. Likewise, a shareholding in any one vaccine manufacturer or other vaccine-related company in excess of 1,000 USD would also constitute a “significant shareholding”.

There are three possible implications of a reported interest from a SAGE member as listed below:

1. SAGE member can take part in full in all of the discussions during the SAGE meeting when
 - the interest is non-personal and non-specific even if it has financial or non-financial significance.
2. Member will only be allowed to answer direct questions from the chair but not to take part in the discussion nor decision-making when
 - the interest is personal, has financial or non-financial significance but is non-specific.
 - the interest is specific, has financial or non-financial significance but is non-personal.
3. Member will be excluded from the discussion and decision-making, of that portion of the work where the conflict of interest has been identified, when
 - the interest is personal as well as specific and has also financial or non-financial significance.

A declared interest is insignificant or minimal if it is unlikely to affect or be reasonably perceived to affect, the (potential) SAGE member's judgment. Normally, insignificant or minimal interests are:

- unrelated or are only tangentially related to the subject of the activity or work and their outcome;
- nominal in amount or inconsequential in importance;
- expired and are unlikely to affect current behaviour.

A public disclosure of all reported interests of SAGE members will be posted on the WHO SAGE website at least two weeks prior to each SAGE meeting³.

The same procedure is in place for external experts serving on SAGE Working Groups. Potential conflicts of interests are assessed and made publically available on the SAGE working group website⁴.

³ <http://www.who.int/immunization/sage/previous/en/>, accessed July 2015

⁴ http://www.who.int/immunization/sage/working_mechanisms/en/, accessed July 2015