

Prevention of Conflicts of Interest in NITAGs

March 2017

Principles and guidance to implement
Conflict of Interest management policy

March 2017

Agence de Médecine Préventive

21 Boulevard Pasteur | 75015 Paris | France

1. INTRODUCTION	2
2. FROM INTEREST TO CONFLICT OF INTEREST	3
3. TYPES OF INTEREST.....	4
3.1. WHERE CAN NITAG MEMBERS' INTERESTS EXIST?	4
3.2. WHAT ARE THE DIFFERENT CATEGORIES OF INTEREST?	4
3.2.1. PERSONAL VERSUS NON-PERSONAL INTERESTS.....	4
3.2.2. FINANCIAL VERSUS NON-FINANCIAL INTERESTS.....	5
3.2.3. SPECIFIC VERSUS NON-SPECIFIC INTERESTS	5
3.2.4. ADVANTAGE, NON-DISADVANTAGE, DISADVANTAGE	5
3.2.5. FORMER, CURRENT AND FUTURE INTERESTS.....	6
4. PREVENTION OF CONFLICTS OF INTEREST.....	6
4.1. WHAT IS THE PURPOSE OF A COI-MANAGEMENT POLICY?	6
4.2. WHOSE COI SHOULD BE PREVENTED?	7
4.3. HOW ARE INTERESTS DECLARED?	7
4.3.1. WHEN SHOULD INTERESTS BE DECLARED?	7
4.3.2. SHOULD DECLARATIONS BE PUBLICLY DISCLOSED?.....	8
4.4. HOW ARE DECLARED INTERESTS MANAGED?	8
4.4.1. ASSESSMENT OF INTERESTS.....	9
4.4.2. ASSESSMENT OF RISK OF COI AND PREVENTION OF COI	9
5. THE DEVELOPMENT OF A NITAG COI-MANAGEMENT POLICY	11
5.1. THE SCOPE OF COIS TO BE PREVENTED.....	12
5.2. PROCESS FOR COI PREVENTION	12
5.3. DEVELOPMENT OF TOOLS TO IMPLEMENT THE COI-PREVENTION POLICY.....	13
6. GENERIC COI-PREVENTION POLICY AND TOOLS FOR NITAGS.....	13
ANNEX: GENERIC CONFLICT OF INTEREST PREVENTION POLICY FOR NITAGS.....	14

1. Introduction

National Immunization Technical Advisory Groups (NITAGs) are responsible for advising the Minister/Ministry of Health (MoH) on immunization programmes and policies. The credibility of the NITAG depends on its independence, objectivity, and avoidance of pressure from interest groups of any kind.

Institutionally, the absence of direct or indirect supervisory relationships between the NITAG and the MoH, including the National Immunization Programme (NIP), defines its independence from government: none of the NITAG members report to the MoH, and the NITAG as a body is not under supervision of the MoH. Furthermore, individual core members are appointed on the basis of their specialized expertise: they participate in the NITAG in a personal capacity and not as representatives of an institution or interest group.

Beyond the institutional independence of the NITAG, individuals involved in NITAG activities (primarily the core members) have a duty of independence and integrity: they should not perform their mission within the NITAG while having interests of any kind that could interfere with, and possibly compromise, their impartiality when making recommendations. A Conflict of Interest (CoI) arises from a situation in which a person (or organization) has multiple interests, financial or other, any of which could possibly influence, or be perceived as influencing, the independence or motivation of the decision-making by that individual (or organization). Just the perception or suspicion of a possible CoI can be harmful to the NITAG and, in turn, to the NIP. This is such a critical issue that WHO considers the existence of a CoI-prevention policy to be one of the six basic process indicators for assessing the functionality of a NITAG.

The issue of CoI can be very sensitive, sometimes because it is misunderstood or misinterpreted. Confusion may also result from some differences between CoI policies and unclear definition of terms. Rules vary among settings and can vary in their stringency. These guidelines are intended to clarify the issues concerning CoI and help countries to develop and implement their own CoI-prevention policies.

The objectives of these guidelines are:

- ✦ To explain what CoI is and how it can arise at the NITAG level
- ✦ To explain the importance of preventing and managing CoIs at the NITAG level and how this can be achieved
- ✦ To provide guidance to NITAGs on the development and implementation of their own Conflict of Interest prevention policy, taking into account the country's specific circumstances
- ✦ To provide a generic and ready-to-use Conflict of Interest management policy for NITAGs (to be used as provided or after adjustment to better capture the country's specific situation).

2. From Interest to Conflict of Interest

INTERESTS ARE NOT CONFLICTS OF INTEREST

Individuals, as employees of an organization and as citizens, can have various interests in relation to various types of organization. Different types of interests are explained in section 3 and include, for example, receiving any form of payment from a vaccine manufacturer or a foundation in the field of immunization, or working in the NIP.

Such interests, within certain limits, do not necessarily prevent an individual from being a NITAG member, or from contributing to the work of the NITAG. However, it is crucial that these do not affect the member's capacity to perform their mission appropriately in accordance with an unbiased, public-oriented and science-based approach.

INTERESTS CAN LEAD TO CONFLICTS OF INTEREST IN CERTAIN SITUATIONS

In a broad definition (adapted from wikipedia), a **Conflict of Interest (Col)** arises from a situation in which a person (or organization) has multiple interests, financial or other, any of which could possibly influence, or be perceived as influencing, the independence or motivation of the decision-making by that individual (or organization). For NITAG members any interest that may affect, or may reasonably be perceived to affect, the expert's objectivity and independence can represent a potential Conflict of Interest (adapted from the declaration of interests for WHO experts).

An interest does not necessarily lead to a Col, but may lead to a Col in certain situations. A Col arises from a situation in which the expert's interest may, due to its strength (i.e. its degree and frequency) and nature, conflict with their independence, which is required to fulfill the mission within the NITAG.

In the context of serving on a NITAG, some interests of a member (or other individual involved in NITAG activities) can, in a given situation, potentially interfere with – and possibly diverge from – the member's mission and duties within the NITAG and thus undermine their credibility, impartiality and independence. In turn, **this could improperly impact the recommendations of the NITAG.**

Such influence can be exerted indirectly or unconsciously, even if the member intends to perform their duty without any consideration of their interest. So, in a given situation, because of divergent interests, the Col objectively exists even if the member would not actually be influenced by their interest nor use their membership to obtain a benefit. **The perception of a possible or potential interference can compromise the reputation and undermine trust** in both the member and the NITAG, and, by extension, the MoH and the NIP. The perception of a possible Col can be as harmful for the reputation and credibility as an influence actually exerted on recommendation-making.

Example of an interest leading (or not) to a Col

If a member works as a consultant on the rotavirus vaccine for vaccine manufacturer X, they may be influenced by the work performed or by the “marketing message” delivered by the manufacturer. They may also have personal interests related to the marketing of this vaccine (e.g. being offered a position or invitations to international conferences). Such a consultancy may alter their impartiality: they would be in a situation of Col if they had to discuss and vote about the introduction of a rotavirus vaccine in the NIP.

However, for another topic on the NITAG agenda which is not related to rotavirus vaccine or this manufacturer (i.e. a vaccine not developed or manufactured by manufacturer X), it is unlikely that this interest would influence the member during the discussion.

3. Types of interest

Interests can exist in relation to a wide range of organizations (section 3.1), and can be specified against a set of criteria (section 3.2). This identifies the nature of the interest.

3.1. Where can NITAG members’ interests exist?

Interests of members (and other individuals involved in NITAG activities) can exist in their relationship with:

- ✦ Private vaccine manufacturers (or companies involved in the sales or promotion of vaccines, or trade associations representing companies involved with vaccines)
- ✦ Public vaccine manufacturers
- ✦ Private donors, including private not-for-profit organizations
- ✦ Technical agencies and public health institutes
- ✦ Public donor agencies and international financial institutions (such as bilateral cooperation with a government, the European Commission, the World Bank, a regional development bank)
- ✦ Governments (including National Immunization Programmes and, more broadly, Ministries of Health)
- ✦ Academia and research institutes, especially for non-financial interests related to the career and reputation of the member (see 3.2.2)
- ✦ Professional associations.

3.2. What are the different categories of interest?

3.2.1. Personal versus Non-personal interests

A **personal interest** involves an advantage benefiting the member personally, directly or through one of their close family members:

- ✦ A **direct** personal interest benefits the member him/her self (typically a payment for a consultancy, an in-kind benefit, or a non-financial advantage to the member)
- ✦ An **indirect** personal interest involves a third party: the interest benefits a close family member (such as a spouse or domestic partner, siblings, parents).

A **non-personal interest** involves an advantage benefiting the department or organization in which the member works (but is not received by the member personally).

3.2.2. Financial versus Non-financial interests

- ✦ A **financial interest involves a material advantage** such as a financial benefit, with or without direct money transfer (but with a given value). Some are typically personal (that is applying to a person), for example:
 - Consultancy or fee-paid work (including participation on the board of an organization)
 - Employment (including part-time)
 - Financial support to attend a national or international conference / meeting
 - Gifts.
- ✦ Some financial interests may be non-personal (e.g. payment may go to the organization), for example:
 - Unrestricted grant or other financial support (e.g. donating equipment) contributing to the running cost of the department / organization in which the member works
 - Fellowship or other grant to sponsor a post or a member of staff in the department / organization of the member
 - Research grant or commissioning of work by the department / organization of the member.
- ✦ Some of the interests can be personal or non-personal (that is applying to a person or an organization), for example:
 - Shareholdings: holding of shares, bonds, share options or other types of asset holding in a private or public vaccine manufacturer
 - Intellectual property rights (patents, trademarks, etc.), including pending applications, that could be impacted by a NITAG decision.

A **non-financial interest** involves a non-material advantage. It can be related to:

- ✦ Personal beliefs (religious, political, etc) of the member
- ✦ An institutional relationship, i.e. affiliation with an organization that has an “official position” on topics under consideration by the NITAG (which may consciously or unconsciously exert pressure on the member to produce a recommendation in accordance with the institution’s stance)
- ✦ A member’s network, i.e. the personal or professional relationships that the expert may wish to protect (family members, friends and colleagues)
- ✦ Career advancement and honors which can enhance the member's professional or academic career in terms of promotion and exposure (typically in media or within a professional community).

3.2.3. Specific versus Non-specific interests

A **specific interest** is directly related to the vaccine / topic under discussion (typically, a consultancy for a company that markets, or plans to market, a vaccine targeting the disease under discussion).

A **non-specific interest** is not directly related (or only tangentially related) to the vaccine / topic under discussion.

3.2.4. Advantage, Non-disadvantage, Disadvantage

An interest can present in the form of:

- ✦ An advantage / benefit for the member (or a third party – an individual or an organization the member is linked to)
- ✦ A prevention of a disadvantage (for the member or a third party)
- ✦ A disadvantage for a third party, in a context of competition or enmity.

3.2.5. Former, current and future interests

Interests can be specified depending on their location in time:

- ✦ Former interests, which no longer exist
- ✦ Current (ongoing) interests
- ✦ Future (potential) interests that have already been identified as possibly arising in the near future (e.g. proposal for a grant that is being discussed). This may include changes to current interests (e.g. the extension of a consultancy agreement).

4. Prevention of Conflicts of Interest

There are several ways of ensuring the independence of individual members and preventing intellectual biases from influencing recommendations. One important measure is the use of a sound and systematic process for issuing evidence-based recommendations; this includes the development of a recommendation framework, the systematic search and appraisal of evidence, and the synthesis of the evidence. Transparency of the process, the analysis of the evidence, and finally what lies behind the recommendation, are also critical. The diversity of the group also limits the influence that one member could have because of their interest, as the recommendation is not made by a single individual but by a whole group. Disclosure of a short curriculum vitae and the affiliation of members can also give an indication of potential biases.

4.1. What is the purpose of a Col-management policy?

The objective of a Col-management policy is to prevent situations in which NITAG members (or any other individual involved in NITAG activities) would perform their work within the NITAG while having conflicting interests.

A Col-management policy specifically aims to collect the interests of members and limit or cancel the influence that such interests could have on the recommendation-making process. It sets out the process and measures taken to ensure that no Col occurs in the work of the NITAG. This is achieved by requiring members to declare their interests. Then, for each topic discussed within the NITAG, an assessment is made as to whether (and to what extent) the interests of the member involve a Col. Should the situation arise, their contribution to the specific topic may be cancelled or limited. Individuals should declare fully their relevant interests, without themselves predetermining whether or not they constitute a Col. Declaring interests is the responsibility of members; assessing whether they constitute a Col is the role of the Chair and the Secretariat (see 4.4).

Such a policy does not necessarily prevent NITAG members from having some interests, including (limited) professional relationships with the private sector. Its aim is to ensure transparency and that such relationships do not interfere with the members' impartiality within the NITAG.

Such a policy protects:

- ✦ **The NITAG member**, who could otherwise be suspected, rightly or wrongly, of having contributed to the topic under influence or of corruption.
- ✦ **The NITAG**, which can then appear as a truly legitimate, independent and science-based body, protected from the influence of the pharmaceutical industry or any other institutions.
- ✦ **The MoH**, which is in charge of appointing NITAG members and making immunization policy (decision-making level).
- ✦ **The NIP**, the credibility of which could otherwise be undermined. In the context of vaccine hesitancy, it is especially important that the immunization programme be above suspicion.

4.2. Whose Col should be prevented?

Cols can occur at any stage of the recommendation-making process: setting of the NITAG agenda, preparation of background documents, presentation and discussion during the NITAG plenary assembly, and voting (or consensus-reaching, if the NITAG does not reach decisions by voting). Cols should therefore be prevented at every stage of this process.

For this purpose, a Col management policy should not apply only to the NITAG Chair and core members but also to the Secretariat and any experts invited to contribute to the working groups.

4.3. How are interests declared?

4.3.1. When should interests be declared?

An efficient Col management policy should prevent any Col from influencing, seemingly or actually, a NITAG recommendation. To this end, declarations of interests should always be up to date with regard to the topics under consideration in the NITAG. A recommended process is to complete an initial declaration of interests and to regularly update it.

4.3.1.1. *Initial declaration of interests*

All NITAG members should submit a formal declaration of interests once they are appointed (or prior to being appointed, particularly if there is an application process favoring applicants with fewer and lesser interests). Considered interests should include current interests, and also former interests (for a certain time period, usually the previous 1 to 4 years) and possible future interests that have already been identified.

Other persons involved in a NITAG activity should declare their interests before the start of their involvement in the activity (typically a member of a working group should declare their interest before being enrolled in the group).

4.3.1.2. *Update of declaration of interests*

In order to ensure that any new interest which could influence recommendations is identified, declarations of interests should be regularly updated. This can be done:

- + Annually
- + And/or before each meeting, either for:
 - o Any new interest, or
 - o Only new interests relating to any of the topics to be discussed at the meeting
- + And/or proactively, as soon as there is a change in their situation involving new interest(s).

Updates can be done either by completing a new declaration of interests or by disclosing only new interests.

4.3.2. Should declarations be publicly disclosed?

RECORDING OF DECLARATIONS

Declared interests should be recorded and stored in a register that is kept up to date at the Secretariat.

DISCLOSURE OF DECLARATION OF INTERESTS

An important reason for completion of declarations of interests is to build trust within and beyond the committee, and thus declarations have to be disclosed. The extent to which the declarations of interests are made public can vary, and is correlated with the level of transparency the NITAG expects. The more transparent, the more the independence of the NITAG can be understood.

- + Declarations of interests must be made available upon request to any public institutions in charge of controlling the integrity of the independent bodies issuing recommendations for the government (e.g. parliament). This will typically occur in the case of an audit if a member's objectivity is disputed.
- + It is recommended that all NITAG members be aware of the interests declared by their peers and by other individuals involved in NITAG activities.
- + To increase transparency in relation to the general population, declarations of interests can also be publicly disclosed, either in full, or in a summarized version that keeps some information confidential (such as the exact amount of money received). Public disclosure is recommended (typically by making it available on the NITAG website).
- + Declared interests can also be publicly disclosed (e.g. on the MoH website) a few weeks prior to the meeting to allow comments from the general public.

Measures taken to prevent CoIs (see section 4.4.2) should similarly be disclosed.

4.4. How are declared interests managed?

Once interests have been declared, they are assessed by the NITAG Chair, possibly in collaboration with the Secretariat. Depending on the strength and the nature of the interest(s), they assess whether the interest(s) conflict with the expert's duties within the NITAG, and decisions are taken appropriately.

It is especially important for Chairs to be free of any relevant interests that could create a CoI, and they should proactively propose to abstain as necessary.

4.4.1. Assessment of interests

The strength of each interest can be assessed on the basis of:

- ✦ The amount of benefit considered
- ✦ The frequency of the relationship with this source of interest
- ✦ The age and duration of the interest (including how long the interest is expected to last in the future, if known).

Based on the nature, the strength and the extent to which they are related to the topic under discussion, interests can be classified into categories (usually into major or minor interests, but more categories can be defined). For example, a long-standing consultancy with a private vaccine manufacturer or a not-for-profit foundation, with high fees compared to the salary of the member, will necessarily be considered to be a major interest, whereas financial support for attending a regional conference four years previously can be considered as a minor or insignificant interest.

There are no standard rules for the assessment of interests for all NITAGS worldwide. The more stringent they are, the better they prevent the NITAG from being influenced by any kind of interest, and the more the NITAG can be seen as a truly independent body. It is however acknowledged that in some countries, the number of qualified individuals in certain areas of expertise is limited. Because of this scarcity, most of the experts are likely to be involved in many activities with a variety of stakeholders, and thus have several interests. Not using these experts may be counterproductive for the NITAG. The balance between expertise needed, availability of experts and the stringency of the Col-prevention rules is a difficult issue (see also 4.4.2).

Although **the assessment remains in part subjective and conducted on a case-by-case basis**, the Chair can, preferably, base the judgment on an analytical grid. The grid will provide guidance for categorizing the interest with pre-defined criteria, such as the frequency of the interest or the financial amounts involved. This can both facilitate the assessment and increase the transparency of the process.

4.4.2. Assessment of risk of Col and prevention of Col

The existence of an interest, even a major interest, does not necessarily mean that the individual will actually be influenced by the interest. But the possibility (or suspicion) of such an influence should be prevented.

Depending on the strength of the interest(s) and the nature of the interest(s), particularly its specificity in relation to a given topic, the Chair, possibly in collaboration with the Secretariat, should make a decision regarding the participation of the NITAG member (or other individual) in the discussion / vote or other NITAG activity. There are generally three potential outcomes for the NITAG member:

- ✦ Participation in the discussion and in the decision-making, (vote or consensus); this should take place only in situations where it is considered that there is no risk of Col.
- ✦ Participation in the discussion (possibly only answering questions from the Chair) but not in the vote
- ✦ Exclusion from both the discussion and the vote.

The Col policy should make clear the different situations that can be encountered and their subsequent outcomes.

SPECIAL SITUATION OF ALL QUALIFIED EXPERTS HAVING SOME INTERESTS

It may happen that all of the most qualified experts for a given topic have major interests related to this topic, and should therefore all be excluded from the NITAG discussions / activities on that topic. As a result, the NITAG can be deprived of qualified experts on the topic. A Col-prevention policy may consider this special situation in which the Chair should balance the experts' interests with the need for expertise. If so:

- ✦ Steps should be taken to limit the influence of these experts (e.g. exclusion from participation in the discussion and/or decision-making; not leading a working group).
- ✦ All members should be aware of the interests of the individuals participating in the activity / discussion.
- ✦ The situation should be documented, in order to remain transparent and to be able to explain why some individuals participated despite their interests, and that everyone in the NITAG was aware of their interests and considered this situation when deciding (by vote or consensus) on the recommendation.

SPECIAL CASE OF EXPERTS PAID BY THE GOVERNMENT

Receiving remuneration from the government can constitute a Col, especially for work in the National Immunization Programme. The NITAG should be independent from the NIP, the MoH and the government that it is intended to advise. If the MoH pays consultancy fees to individuals, such consultants may gradually become somewhat dependent on the MoH and less able to object to MoH views. This situation would undermine the independence of the NITAG with respect to the MoH.

A common rule is that staff within the NIP should not be core members of the NITAG but can contribute to the technical preparation of the work (if the NIP hosts the Secretariat) as this is limited to the collection, appraisal and synthesis of evidence following standard systematic processes (provided such processes are in place). Experts paid by the government whose position and work is not related to the NIP (e.g. university professors or clinicians in a public hospital) can stand as members, as there is limited risk that the government would exert any influence on their judgment on immunization programme-related topics.

SPECIAL CASE OF INDIVIDUALS PARTICIPATING IN NITAG BECAUSE OF THEIR INTERESTS

Some individuals may attend a NITAG meeting (or contribute to a NITAG activity) precisely because of the interests they have. For instance, a liaison member from an international agency or a professional association participates in the NITAG to represent this institution, which may have a particular position or interest towards the discussed topics. Some NITAGs also occasionally invite vaccine manufacturers to present data on their vaccines. These interests are not considered as Col to be prevented, as they are the reason for these individuals' presence.

5. The development of a NITAG Col-management policy

The key principles for the prevention of Cols at the NITAG level have been explained above.

In practice, **the policy of each NITAG should also consider the national setting**, and may therefore pay particular attention to certain types of interests which are highly critical in the country or include additional aspects which are specific to the setting. As explained in 4.4.1, the more stringent the rules are, the better the NITAG is protected from Cols and from the suspicion of biased recommendations and the better it can ensure its independence.

Parameters to be taken into account when designing a Col-management policy may include:

- ✦ The size of the country and the number of experts potentially available to the NITAG (as members or as other resources)
- ✦ The frequency and nature of professional relationships typically held between these experts and academia, technical agency partners, MoH, private sector, etc.
- ✦ The presence in the country of certain organizations (e.g. public vaccine manufacturer, influential international non-governmental organizations related to vaccines and immunization) and their potential relationships with NITAG resources
- ✦ The NITAG's Terms of Reference and / or legislative basis if it contains elements pertaining to the profile, activities or requirements of the members and individuals involved in NITAG activities
- ✦ The existing legislation regarding Col-management in the country to ensure compliance with it (more stringent rules can be developed for the NITAG, if appropriate); if there is a legal advisory structure in the government, it is appropriate to refer to it.
- ✦ Standards of practice in the country and cultural aspects regarding disclosure of interests.

It is recommended that the Col policy ensure high transparency with respect to the interests of the members and how they are managed.

Following the steps below can help to develop the Col-prevention policy and tools:

1. Clarification of the scope of Cols to be prevented
2. Definition of the Col-prevention process
3. Development of the tools to implement Col-prevention policy

It is recommended to communicate with the NITAG members during the preparation of the policy, typically by:

- ✦ Explaining the importance of such a policy
- ✦ Possibly involving some members in the design and development of the policy.

It should also be noted that, in addition to the Col-prevention policy, there are other means of avoiding the impact of undue influence and strengthening the independence of the NITAG and its recommendations, and these rest in **the robustness of the recommendation-making process**. They include the development of a recommendation framework, the systematic search for evidence, the review and appraisal of evidence, the

process for discussing and reaching a decision on the recommendation, and the transparency of these proceedings and the evidence reviewed.

5.1. The scope of ColS to be prevented

The first proposed step is to clarify **which ColS may occur and which should be prevented**. This involves mapping the interests to be taken into account, clarifying the conditions in which they may lead to a Col and deciding the measures to be taken in the event of a Col.

- ✦ Scope of considered interests
 - Whose interests should be declared and assessed in order to prevent a Col?
 - Where the interests to be considered / declared might stand? (see 3.1)
 - Which types of interests should be considered / declared?
 - For how long in the past should interests of members be considered / declared?
- ✦ Risks of ColS and rules to assess interests
 - Which rules to apply to assess whether declared interests lead to a Col?
 - What should be done when a member (or other resource for the NITAG) is in a situation of Col for a topic?

5.2. Process for Col prevention

The second proposed step is to **clarify the process to be applied to implement these rules**.

- ✦ Declaration and disclosure of interests
 - When should declarations of interests be completed and updated?
 - How should interests be declared at meetings (if applicable)? Orally and/or in writing? Should members declare interests or simply declare they have no ColS pertaining to the discussed topic(s)?
 - Who is in charge of recording the declarations?
 - Should declared interests (and prevention measures taken, should the case arise) be disclosed to the general population, for instance on the NITAG or MoH website? If not, to whom can they be disclosed and under what circumstances?
 - Should declared interests be posted on the website prior to the meeting to allow comments from the general public?
- ✦ Assessment of declared interests and measures to avoid ColS
 - Should interests be categorized (e.g. major, minor)? In how many categories? Based on what criteria?
 - Should a grid be used to categorize interests?
 - Who is responsible for assessing whether the interests can lead to a Col for a given topic?
 - Who is responsible for assessing the interests of the Chair?

5.3. Development of tools to implement the Col-prevention policy

The tools to support the implementation of this policy can then be developed. They may include:

- ✦ Templates for declaration of the interests (initial, annual, etc.)
- ✦ Grid tool to facilitate assessment of the strength of the interest (e.g. including thresholds below which the interest could be considered as minor) and guide the decision to be taken with respect to the member in the case of a Col for a given topic
- ✦ Charter or other document explaining the core principles of the Col-management policy for the NITAG (possibly signed by the Chair and/or high-level representatives of the MoH and/or deontological/ethical committee)
- ✦ Other documents to clarify other aspects of the Col-management policy (e.g. disclosure).

6. Generic Col-prevention policy and tools for NITAGs

The set of documents provided hereafter comprises a ready-to-use policy for Col management in NITAGs, with related tools. The documents can be used as presented below, or can be adjusted / completed to better reflect the country's specificities, as explained in section 0.

ANNEX: GENERIC CONFLICT OF INTEREST PREVENTION POLICY FOR NITAGs

(to be used as presented below or to be adjusted as necessary)

PREVENTION OF CONFLICTS OF INTEREST FOR THE NITAG OF XXX

INTRODUCTION

The NITAG's Conflict of Interest (Col) management policy aims to ensure its integrity and transparency.

A "yes" answer to one or more of the questions in the "declaration of interests form" does not necessarily indicate a Col, or imply that the member in question should be excluded from, or limited in, participating in NITAG meetings and other activities. However, members can have different kinds of interests and, in certain situations, one or more of these interests may be in conflict with the duty a member would carry out for the NITAG. A simple example is provision of paid consultancy services by a company whose a vaccine is being discussed at the NITAG. In such a situation, the interest(s) of the member may impair, consciously or unconsciously, the member's capacity to appropriately fulfill their mission with the required independent, public-oriented and science-based approach. Such interests may, at least potentially, improperly influence the recommendations issued by the NITAG.

The objective of this policy is to avoid situations in which members, or any other individuals involved in NITAG activities, would perform their work within the NITAG while having a Col. If the private-capacity interest(s) of the member related to a given topic appears to have the potential to influence the recommendation, the member will have to withdraw from the decision-making and possibly from the discussions for this specific topic. Thus, this policy protects the NITAG member, the NITAG, and, by extension, the Ministry of Health and the National Immunization Programme.

This policy is critical for the independence of the NITAG. Core members serve in their personal capacity and do not represent the interests of another organization, particular group or interested party. They should refrain from advocating for policies, opinions or any interests of the organization for which they work. Independence from government is defined by the absence of direct or indirect links of supervision with the immunization programme or more widely with the programme of the Ministry of Health. Members should feel free and encouraged to express their opinions even if they are in conflict with those of the immunization programme's officials or the policy of the Ministry of Health.

DECLARATION OF INTERESTS

The following persons should declare their interests:

- + NITAG core members
- + Other persons involved in NITAG technical activities, on a permanent or occasional basis. These include:
 - o Persons involved in the scientific Secretariat
 - o Persons contributing in a working group
 - o Other persons invited to a NITAG meeting or a working group meeting

For members (and other persons involved on a permanent basis), the process for declaring interests is the following:

- ✦ Once they are appointed, each member shall complete an "Initial Declaration of Interests" form.
- ✦ Before each meeting each member should declare any new interest they have, whether or not this interest relates to the topics on the agenda:
 - Should this situation occur, the member shall send a specific update to the Chair prior to the meeting.
 - In addition, the Chair shall check with all members at the opening of the meeting whether they have any new interest(s) that is(are) related to the topic(s) under discussion.
- ✦ At the beginning of each year, members shall complete an "Update of Declaration of Interests" form.

For persons involved on an ad hoc / occasional basis, a specific form is available.

Any person refusing to disclose interests will be excluded from involvement in NITAG activities. Members who refuse to disclose their interests will be excluded from the NITAG.

RECORD AND DISCLOSURE OF DECLARED INTERESTS AND MEASURES TAKEN

Record of declarations

All signed declarations of interests are scanned and recorded by the Secretariat. In addition to the electronic storage, original hard copies are retained.

Disclosure of declarations of interests

- ✦ Full declarations of interests are shared among NITAG members.
- ✦ Summaries of the members' interests are disclosed on the NITAG and MoH websites (amount of payment received, and other sensitive information are not publicly disclosed), and are updated as appropriate three weeks prior to each meeting. Members of the public are invited to make comments on the disclosed interests, and all comments received should be considered by the Chair when assessing the interests.
- ✦ Full declarations of interests will be made available upon request to any public institution responsible for overseeing the integrity of independent bodies issuing recommendations to the government (parliament, etc.). Typically, this might occur in the case of an audit if a member's objectivity is disputed.

Disclosure of measures taken

Measures taken (e.g. exclusion of a member from a discussion) are also recorded and disclosed.

Meeting report

All NITAG meeting reports shall include a paragraph about Col management, stating:

- ✦ That an assessment of the interests of the members and other persons participating in the NITAG was conducted by the Chair and the Secretariat.
- ✦ That, at the opening of the meeting, the Chair asked all members whether they had interests related to the topics under discussion. The report shall also include the answers to this question.
- ✦ What measures have been taken to prevent CoIs from influencing the discussion and the recommendation. If there were no conflicting interests, it shall be stated that after a careful assessment, it was considered that no members had conflicting interests. Should the case arise, it

should be recorded that some of the members (named) were excluded from discussion and/or vote because of divergent interests.

ASSESSMENTS OF INTERESTS AND RISKS OF COI FOR NITAG CORE MEMBERS

The declared interests are assessed by the Chair, in collaboration with the Secretariat. Considering the amount of the benefit, the frequency of the relationship and the duration of the interest, the Chair can classify some personal interests as minor. As a guide, minor interests are *a priori* the following:

- ✦ Paid work (by the member or a close relative) for a not-for-profit organization, an international technical agency, a public health institute, a public donor agency or an international financial institution, if the work ended more than 18 months previously and the total amount perceived for the work was less than US\$ 1,000
- ✦ Gift if the cumulated value over the previous two years is below US\$ 100 (gift from the industry excepted)
- ✦ Invitation to a conference / international meeting by a not-for-profit organization, an international technical agency, a public health institute, a public donor agency or an international financial institution, if this happened only once in the previous three years and not in the previous 18 months.

Classification of an interest as a minor interest is the responsibility of the Chair, and the assessment remains in fine subjective and conducted on a case-by-case basis. Decisions of the Chair shall be documented.

Depending on the category of interest (personal vs non-personal, specific vs non-specific), the following rules should apply:

	PERSONAL INTEREST	NON-PERSONAL INTEREST
SPECIFIC INTEREST	<ul style="list-style-type: none"> ✓ Member shall leave the room during the discussion and decision-making. ✓ If minor interest: member may participate in the discussion (unless the Chair exceptionally rules otherwise) but not in decision-making. 	<ul style="list-style-type: none"> ✓ Member may answer direct questions from the Chair (unless the Chair exceptionally rules otherwise) but not take part in decision-making.
NON-SPECIFIC INTEREST	<ul style="list-style-type: none"> ✓ Member may participate in the discussion (unless the Chair exceptionally rules otherwise) but not in decision-making. ✓ If minor interest: member may participate in the discussion and the decision-making. 	<ul style="list-style-type: none"> ✓ Member may participate in both the discussion and the decision-making (unless the Chair exceptionally rules otherwise).

ASSESSMENTS OF INTERESTS AND RISK OF COI FOR WORKING GROUP MEMBERS

Experts invited to contribute in a specific working group shall declare their interests. The general rule is that experts with a personal interest (specific or non-specific) or a non-personal specific interest cannot participate in working groups.

However, the Chair may exceptionally rule otherwise, in particular if it is considered that the expertise of the expert is essential for the working group, and that no other expert can bring this expertise. If so, this should

be documented in detail, and it should be communicated to all NITAG members that one expert who contributed to the working group had a conflict of interest. This should also be recorded in the meeting report.

SPECIAL CASES OF INDIVIDUALS PARTICIPATING IN NITAG ACTIVITIES BECAUSE OF THEIR INTERESTS

In some cases, individuals can be invited to a NITAG meeting precisely because of the interests they have (e.g. a representative of a vaccine manufacturer to present data on their vaccines or a liaison member from an international agency to represent this institution, which may have a particular position or interest regarding the discussed topics). These interests are not considered as CoI to be prevented, as they are the reason of the presence of the individuals concerned.

INITIAL DECLARATION OF INTERESTS FORM

INDEPENDENCE FROM GOVERNMENT

1. In the last 4 years, have you been an employee or served as a consultant for the National Immunization Programme, the Ministry of Health or another part of a governmental entity?

Yes / No

If Yes, please describe:

PERSONAL INTERESTS

2. In the last 4 years, have you received any kind of payment from the industry (public or private vaccine manufacturer, companies involved in the sales or promotion of vaccines, or trade associations representing companies involved with vaccines) for any kind of work (part-time or full-time employment, consultancy, participation on a board of directors, etc.)?

Yes / No

If Yes, please describe:

Industry	Period	Work	Amount received	Comment

3. Have you, in the last 4 years, received any kind of payment for any kind of work related to vaccines and immunization from any other organization, including private not-for-profit organizations, international technical agencies and public health institutes, public donor agencies and international financial institutions or other international organizations?

Yes / No

If Yes, please describe:

Organization	Period	Work	Amount received	Comment

4. In the last 4 years, have you received any kind of other support from any of the organizations listed in questions 1 & 2 (invitation to a conference, gifts, reimbursement of travel expenses, etc.)?

Yes / No

If Yes, please describe:

Organization	Period	Work	Support received	Comment

5. Do you have any assets related to vaccines that could be seen – rightly or wrongly – as possibly influencing your work at the NITAG (e.g. shareholdings in a vaccine manufacturer, intellectual property rights, etc.)?

Yes / No

If Yes, please describe:

Type of asset	Details	Comment

6. Do you have any other relationships, affiliation to groups, plans for your career or other interests that could influence your work at the NITAG, or could be seen – rightly or wrongly – as possibly influencing your work at the NITAG?

Yes / No

If Yes, please describe and comment as appropriate:

7. In the next 12 months and as far as you know today, do you have any other interests that may arise, or do you anticipate any expansion or changes to your current interests (e.g. renewal/change/revision of amount received for consultancies)?

Yes / No

If Yes, please describe and comment as appropriate:

8. Have any of your close relatives (spouse or domestic partner, siblings, parents, children or any other you can consider as a close relative), in the last 4 years, had (or are about to have) interests such as those described in questions 1 to 7 above?

Yes / No

If Yes, please describe:

Name	Relationship with you	Organization providing the interest (if any)	Details and comments about the interest

NON-PERSONAL INTERESTS

9. In the last 4 years, has the department / unit you work for received any kind of financial support from the industry?

- ✚ Unrestricted grant
- ✚ Fellowship or other grant to support a post (for scientific position: only if related to vaccines and immunization)
- ✚ Research grant or other support for research and activities related to vaccines and immunization
- ✚ Any other financial contribution (e.g., purchasing or donating equipment)

Yes / No

If Yes, please describe:

Industry	Period	Type of support and detail	Amount received	Comment

10. In the last 4 years, has the department / unit you work for received any kind of financial support (as described in question 8 above) from an organization as described in question 2 above for work related to vaccines and immunization?

Yes / No

If Yes, please describe:

Organization	Period	Type of support and detail	Amount received	Comment

11. As far as you know, does the organization you work for have any interests (e.g., shareholdings, intellectual property rights, any kind of financial or non-financial support, promotion of the activities of the organization, etc.) that could be impacted, in one way or other, by decisions taken by the Ministry of Health regarding vaccine and immunization programmes or policies?

Yes / No

If Yes, please describe and comment as appropriate:

12. In the next 12 months and as far as you know today, does the department / unit you work for anticipate any other interests (related to vaccines and immunization) to arise or anticipate changes to their current interests?

Yes / No

If Yes, please describe and comment as appropriate:

I declare on my word of honor that the information provided above is true and complete.

I am aware that I am required to immediately declare any significant changes, that I will be asked to provide annual updates of this declaration, and that I will be asked before each meeting (and before undertaking any activity within the NITAG) about any new interests that could be related to the topics discussed.

Name:

Location and date:

Signature:

ANNUAL UPDATE - DECLARATION OF INTERESTS

Update of interests (Year 20XX (past year))

Please declare only

- ✚ New interests (not declared before, or only as potential future interests)
- ✚ Update for some previously declared interests (renewal, change in amounts...)
- ✚ If some formerly declared interests have ended, please also provide the information

INDEPENDENCE FROM GOVERNMENT

1. Have you been an employee or served as a consultant for the National Immunization Programme, the Ministry of Health or another part of a governmental entity?

Yes / No

If Yes, please describe:

PERSONAL INTERESTS

2. Have you received any kind of payment from the industry (public or private vaccine manufacturer, companies involved in the sales or promotion of vaccines, or trade associations representing companies involved with vaccines) for any kind of work (part-time or full-time employment, consultancy, participation on a board of directors, etc.)?

Yes / No

If Yes, please describe:

Industry	Period	Work	Amount received	Comment

3. Have you received any kind of payment for any kind of work related to vaccines and immunization from any other organization, including private not-for-profit organizations, international technical agencies and public health institutes, public donor agencies and international financial institutions or other international organizations?

Yes / No

If Yes, please describe :

Organization	Period	Work	Amount received	Comment

4. Have you received any kind of other support from any of the organizations listed in questions 1 & 2 (invitation to a conference, gifts, reimbursement of travel expenses, etc.)?

Yes / No

If Yes, please describe :

Organization	Period	Work	Support received	Comment

5. Do you have any assets related to vaccines that could be seen – rightly or wrongly – as possibly influencing your work at the NITAG (e.g. shareholdings in a vaccine manufacturer, intellectual property rights, etc.)?

Yes / No

If Yes, please describe:

Type of belongings	Details	Comment

6. Do you have any other relationships, affiliation to groups, plans for your career or other interests that could influence your work at the NITAG, or could be seen – rightly or wrongly – as possibly influencing your work at the NITAG?

Yes / No

If Yes, please describe and comment as appropriate:

7. In the next 12 months and as far as you know today, do you have any other interests that may arise, or do you anticipate any expansion or changes to your current interests (e.g. renewal/change/revision of amount received for consultancies)?

Yes / No

If Yes, please describe and comment as appropriate:

8. Have any of your close relatives (spouse or domestic partner, siblings, parents, children or any other you can consider as a close relative) had (or are about to have) interests such as those described in questions 1 to 7 above?

Yes / No

If Yes, please describe:

Name	Relationship with you	Organization providing the interest (if any)	Details and comments about the interest

NON-PERSONAL INTERESTS

9. Has the department / unit you work for received any kind of financial support from the industry?

- ✚ Unrestricted grant
- ✚ Fellowship or other grant to support a post (for scientific position: only if related to vaccines and immunization)
- ✚ Research grant or other support for research and activities related to vaccines and immunization
- ✚ Any other financial contribution (e.g. purchasing or donating equipment)

Yes / No

If Yes, please describe :

Industry	Period	Type of support and detail	Amount received	Comment

10. Has the department / unit you work for received any kind of financial support (as described in question 8 above) from an organization as described in question 2 above for work related to vaccines and immunization?

Yes / No

If Yes, please describe:

Organization	Period	Type of support and	Amount	Comment

		detail	received	

11. As far as you know, does the organization you work for have any interests (e.g., shareholdings, intellectual property rights, any kind of financial or non-financial support, promotion of the activities of the organization, etc.) that could be impacted, in one way or other, by decisions taken by the Ministry of Health regarding vaccine and immunization programmes or policies?

Yes / No

If Yes, please describe and comment as appropriate:

12. In the next 12 months and as far as you know today, does the department / unit you work for anticipate any other interests (related to vaccines and immunization) to arise or anticipate changes to their current interests?

Yes / No

If Yes, please describe and comment as appropriate:

I declare on my word of honor that the information provided above is true and complete.

I am aware that I am required to immediately declare any significant changes, that I will be asked to provide annual updates of this declaration, and that I will be asked before each meeting (and before undertaking any activity within the NITAG) about any new interests that could be related to the topics discussed.

Name:

Location and date:

Signature:

INTERESTS TO DECLARE PRIOR TO A MEETING

Should you have any interest (not previously declared) that could lead to a conflict of interest (real or perceived) for one (or more) topics on the agenda of the forthcoming NITAG meeting, please describe it appropriately, and return this form to the Chair and the Secretariat at least one week prior to the meeting.

Date of the meeting:

Topic on the agenda:

Interest(s) to declare:

I declare on my word of honor that the information provided above is true and complete.

Name:

Location and date:

Signature:

DECLARATION OF INTERESTS FORM FOR ANY PERSON INVITED TO CONTRIBUTE ON AN AD HOC BASIS TO THE WORK OF THE NITAG

Purpose of the involvement in the NITAG activity: *To be completed by the Secretariat*

Expected date of work: *To be completed by the Secretariat*

INDEPENDENCE FROM GOVERNMENT

1. In the last 4 years, have you been an employee or served as a consultant for the National Immunization Programme, the Ministry of Health or another part of a governmental entity?

Yes / No

If Yes, please describe:

PERSONAL INTERESTS

2. In the last 4 years, have you received any kind of payment from the industry (public or private vaccine manufacturer, companies involved in the sales or promotion of vaccines, or trade associations representing companies involved with vaccines) for any kind of work (part-time or full-time employment, consultancy, participation on a board of directors, etc.)?

Yes / No

If Yes, please describe:

Industry	Period	Work	Amount received	Comment

3. Have you, in the last 4 years, received any kind of payment for any kind of work related to the purpose of your work with the NITAG from any other organization, including private not-for-profit organizations, international technical agencies and public health institutes, public donor agencies and international financial institutions or other international organizations?

Yes / No

If Yes, please describe:

Organization	Period	Work	Amount received	Comment

4. In the last 4 years, have you received any kind of other support from any of the organizations listed in questions 1 & 2 (invitation to a conference, gifts, reimbursement of travel expenses, etc.)?

Yes / No

If Yes, please describe:

Organization	Period	Work	Support received	Comment

5. Do you have any assets related to vaccines that could be seen – rightly or wrongly – as possibly influencing your work at the NITAG (e.g. shareholdings in a vaccine manufacturer, intellectual property rights, etc.)?

Yes / No

If Yes, please describe:

Type of belongings	Details	Comment

6. Do you have any other relationships, affiliation to groups, plans for your career or other interests that could influence your work with the NITAG, or could be seen – rightly or wrongly – as possibly influencing your work with the NITAG?

Yes / No

If Yes, please describe and comment as appropriate:

7. In the next 12 months and as far as you know today, do you have any other interests that may arise, or do you anticipate any expansion or changes to your current interests (e.g. renewal/change/revision of amount received for consultancies)?

Yes / No

If Yes, please describe and comment as appropriate:

8. Have any of your close relatives (spouse or domestic partner, siblings, parents, children or any other you can consider as a close relative), in the last 4 years, had (or are about to have) interests such as those described in questions 1 to 7 above?

Yes / No

If Yes, please describe:

Name	Relationship with you	Organization providing the interest (if any)	Details and comments about the interest

NON-PERSONAL INTERESTS

9. In the last 4 years, has the department / unit you work for received any kind of financial support from the industry?

- ✚ Unrestricted grant
- ✚ Fellowship or other grant to support a post (for scientific position: only if related to vaccines and immunization)
- ✚ Research grant or other support for research and activities related to vaccines and immunization
- ✚ Any other financial contribution (e.g. purchasing or donating equipment)

Yes / No

If Yes, please describe:

Industry	Period	Type of support and detail	Amount received	Comment

10. In the last 4 years, has the department / unit you work for received any kind of financial support (as described in question 8 above) from an organization as described in question 2 above, for work related to the purpose of your work with the NITAG ?

Yes / No

If Yes, please describe:

Organization	Period	Type of support and detail	Amount received	Comment

11. As far as you know, does the organization you work for have any interests (e.g., shareholdings, intellectual property rights, any kind of financial or non-financial support, promotion of the activities of the organization, etc.) that could be impacted, in one way or other, by decisions taken by the Ministry of Health related to the purpose of your work with the NITAG?

Yes / No

If Yes, please describe and comment as appropriate:

12. In the next 12 months and as far as you know today, does the department / unit you work for anticipate any other interests (related to the purpose of your work with the NITAG) to arise or anticipate changes to their current interests?

Yes / No

If Yes, please describe and comment as appropriate:

I declare on my word of honor that the information provided above is true and complete.

I am aware that I am required to immediately declare any significant changes, that I will be asked to provide annual updates of this declaration, and that I will be asked before each meeting (and before undertaking any activity within the NITAG) about any new interests that could be related to the topics discussed.

Name:

Location and date:

Signature: