Working Group of Quality Managers
Guide to Managing Declarations of Interests

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1. Introduction

1.1 Legal basis


“1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry which could affect their impartiality. These persons shall make an annual declaration of their financial interests.

2. In addition, the Member States shall ensure that the competent authority makes publicly accessible its rules of procedure and those of its committees, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes, including minority opinions.”

1.2 Regulatory independence

A conflict of interest may arise where persons involved in the opinion / decision making have competing professional or personal obligations or personal or financial interests which could make it difficult for them to fulfil their duties fairly and impartially, or where a person is in a position to influence the contracting authority’s opinion-/ decision-making process in order to further his own interests. It is important that the processes are seen to be impartial and in the best interests of public health. All medicines regulatory authorities can be exposed to the risk of conflict of interest and therefore it is important that such risks are managed effectively. If they are not handled correctly they can negatively affect the processes, give rise to scandals and cause reputational damage. There are a number of definitions of conflict of interest. For the purpose of this guideline, the definition by the Organisation for Economic Cooperation and Development (OECD) Guidelines ‘Managing Conflict of Interest in the Public Services’ which is referred to by the European Court of Auditors in their “Special Report Number 15 - Managing of Conflict of Interest in selected EU agencies” is “a conflict between the public duty and private interests of public officials, in which public officials have private-capacity interests which could improperly influence the performance of their official duties and responsibilities”.

The OECD reports that conflicts of interest in both the public and private sectors have become a major matter of public concern worldwide. Medicines regulatory authorities are no exception especially since they are involved in opinion- / decision- making, especially on applications for authorisation and surveillance of medicinal products.

Finding the right balance between ensuring managerial and resource effective processes to ensuring the impartiality of individuals (and minimizing CoIs as much as possible) and the need to ensure the best possible scientific expertise is a big
challenge to National Competent Authorities (NCAs). The ever increasing demands from the general public, politicians, etc. could result in a policy that members of committees and experts should have no/as little as possible involvement with pharmaceutical industry. The main concerns, primarily from academia/learned societies/patient organisations are that if the policy is too strict, it would discourage members / experts coming from academia / learned societies / patient organisations to be involved in the NCA’s work, which would have a negative impact on their work.

In view of the above, effective management of declarations of interest is essential to meet high standards for those working in medicines regulatory authorities.

1.3 Responsibilities

Article 126(b) of Directive 2001/83/EC is applicable to “members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products”.

It should be ensured that all members of the staff and experts of the NCA that are directly involved in the authorisation or surveillance processes (scientific, regulatory as well as administrative personnel) should be covered by the system to ensure impartiality.

Article 126(b) of Directive 2001/83/EC refers to “financial or other interests in the pharmaceutical industry which could affect impartiality”.

Each individual is responsible for the declaration of his interests. It follows from Article 126(b) of Directive 2001/83/EC that the holding of financial or other interests in the pharmaceutical industry is in principle incompatible with being a member of the management board, scientific committees or staff of an NCA. However, it does not prohibit the holding of financial or other interests and these are subject to public declaration. Financial and other interests which could affect impartiality should be scrutinised so that precautions can be taken in order to ensure impartiality of opinion / decision making. Appropriate actions could include precluding the individual from certain functions or tasks (e.g. rapporteur, expert, project manager) or requiring abstention from part of the relevant proceedings or voting in the meetings of the scientific committees and/or working parties or seeking a waiver in particular situations. In order to remain in office, the individual concerned would have to take appropriate action to suppress the conflict unless a waiver is granted.

2. Objective

These guidelines, issued by the Working Group for Quality Managers, outline the code of conduct and conflict of interest obligations that should apply to the handling of declarations of interests by NCAs.

The guidance is aimed at assisting NCAs in setting up internal policies and procedures to ensure the transparency and the impartiality of the opinion / decision making process, especially on applications for authorisation and surveillance of medicinal
products in order to promote public confidence in the integrity, legitimacy, impartiality and fairness of NCA’s scientific committees’ opinion / decision making processes.

The guidance provided in this document is not a substitute for legal advice or a set of legal requirements that may be in place in the individual Member States, which should continue to be respected. There is no obligation on NCAs to adopt this Guidance document and it is within the remit of the individual NCA to determine as to how the requirements of Directive 2011/83/EC are met.

NCAs should note that as a minimum the definitions given below should apply; NCAs can decide to apply stricter rules if required by national legislation or standards.

3. Definitions

3.1 Interests

These relate to direct or indirect interests depending on their likely or potential impact on the individual's behaviour at a given point in time and therefore have to be declared. (The European Medicines Agency Code of Conduct, 2013.)

3.1.1 Direct interests

Direct interests in the pharmaceutical industry – These refer to interests of personal benefit to the individual at any point in time, likely to influence or give the appearance of influencing his behaviour, e.g.
- Consultancy for a pharmaceutical company
- Employment with a pharmaceutical company
- Financial interests
- Strategic advisory role for a company

(EMA Policy 0044 Handling of declarations of interests of scientific committees’ members and experts.)

For the purpose of this guideline, the definitions of the EMA Policy 0044 Handling of declarations of interests of scientific committees’ members and experts should apply.

3.1.2 Indirect interests

Indirect interests in pharmaceutical industry – These are other interests that may have some influence over the individual’s behaviour and relate to:
- Grant or other funding
- Investigator
- Principal investigator

(EMA Policy 0044 Handling of declarations of interests of scientific committees’ members and experts.)

For the purpose of this guideline, the definitions of the EMA Policy 0044 ‘Handling of declarations of interests of scientific committees’ members and experts’ apply.
3.2 Other definitions

Close family member - A close family member is a first-line member of the family of the person concerned (i.e. a spouse or a partner, children or parent). (EMA Policy 0044 Handling of declarations of interests of scientific committees’ members and experts.) However, the definition of a close family member could vary between NCAs depending on the national legislation or policies.

4. Principles and Standards

Medicines regulatory authorities must provide a public service while behaving in an ethical way according to a particular set of values. Regulators should be dedicated to serving the public interest, and acting with honesty, integrity, confidentiality, impartiality and independence.

As a medicines regulatory authority, each NCA within EU Member States is required to maintain a high standard of professionalism and ethical conduct in its operations. It is essential that public confidence is maintained in the business of the NCA, and in particular in the integrity of the process for granting authorisations and surveillance of medicinal products. The opinion / decision making processes for authorisation and for surveillance of medicinal products must be, and must be seen to be, operating impartially. Consequently, all people performing functions including, but not limited to, rapporteurs, members of scientific decision-making committees, the staff and experts must:
- observe the Values and Code of Conduct for the NCA;
- act with integrity, objectivity, openness and honesty;
- be accountable for their opinions, decisions and actions;
- be subject to an appropriate level of scrutiny;
- provide assurances to the NCA that they will abide by the NCA confidentiality requirements;
- disclose to it any interests related to their official duties.

5. Best Practice

These guidelines aim to have a ‘best practice’ approach to handling declarations of interest which extends beyond strict legal compliance. A best practice is defined as simply a process or a methodology that represents the most effective way of achieving a specific objective. Best Practice is defined by the Oxford Dictionary as “Commercial or professional procedures that are accepted or prescribed as being correct or most effective”.

5.1 Code of Conduct

Each NCA should have in place a Code of Conduct. Members of the NCA Management Board, committees, staff and experts are expected to observe the code of conduct set out by the NCA in practice, and are obliged to ensure that they are familiar with the NCA’s Values and Codes of Conduct.
5.2 Policy for handling declarations of interest

Each NCA should have a policy for handling declarations of interests which should reflect the following framework:

**5.2.1 Scope of Policy**
Relates to Management Board members, members of scientific committees, staff (including those engaged on contract) and experts of the NCA involved in operational activities (authorisation and surveillance of medicines including meeting attendance, involvement in scientific assessment and guidance development, participation in inspections).

Where the medicines regulatory authority utilises the services of a third party for the authorisation and surveillance of medicinal products (for example the State or another Member State or the European Commission or a national institution or international government agency), the agreement or contract between the medicines regulatory authority and the third party should place clear obligations on the third party with regards to handling of declarations of interest that ensure that the requirements of this guideline are met (e.g. by requesting the individual staff of the third party involved in the outsourced process to declare their interests to the medicines authority).

**5.2.2 Objective**
To ensure that individuals listed in 5.2.1 above declare any direct / indirect interests in the pharmaceutical industry which could affect their impartiality, which has to be balanced with the need to secure the best (specialist) scientific expertise.

**5.2.3 Handling of declared interests**
The Policy applicable to all individuals listed in 5.2.1 above to cover:
- managing declaration of interest (DoI)
- acceptance of gifts and hospitality from pharmaceutical companies
- direct interests in pharmaceutical companies, such as financial interest (including patents) or consultancy work
- indirect interests in pharmaceutical companies, such as research (not resulting in personal financial benefits; these are direct interests) or authority/control over subsidies
- close family members related to individuals listed in 5.2.1 above with direct interest in pharmaceutical companies
- allowable and non-allowable interests and restrictions as applicable

**5.2.4 Allowable interests for NCA activities**
Direct / Indirect interests allowed and not allowed should be considered on an individual basis for each category of individuals listed in 5.2.1, for current and past engagements with the pharmaceutical industry in relation to each of the following:
- Employment
- Consultancy
- Strategic advisory role
- Financial interests
- Principal investigator
- Investigator
Also, engagements with the pharmaceutical industry in relation to the following indirect interests:
- Current grant or other funding to institution
- Current direct interests of close family members

The previous engagement in terms of previous number of years and specific restrictions where indicated should be defined in line with national regulations or internal policy of the NCA.

5.3 Managing Declarations of interest

Conflicts of interest are inevitable. Managing declarations of interest follows three stages:
Stage 1 – Recognising interests
Stage 2 – Disclosing interests
Stage 3 – Responding to disclosures

5.3.1 Stage 1 - Recognising interests
These guidelines are designed to ensure that all direct or indirect interests are identified and addressed in a rigorous and transparent way. Individuals should consider the need to declare interests in all possible situations including:
- professional positions;
- membership of scientific committees of other organisations;
- consultancies to the medicines regulatory authority;
- consultancies by members of staff to pharmaceutical industry;
- boards of directors;
- advisory groups;
- advisory to the medicines regulatory authority;
- member of review board to the medicines regulatory authority;
- close family members and personal relationships; or
- financial interests, including receiving recompense in the form of cash, services or equipment from outside bodies.

Primarily an individual should recognise the interest at hand, taking into consideration actual, apparent or potential conflict of interest, both direct and indirect. Individuals should regularly review their interests and update the declaration of interests form accordingly and ensure that the information provided is current. It is the individual’s duty to ensure that the information is kept current and that potential conflicts that are not covered by the annual DoI, but arise from routine work are immediately notified to the supervisor.

The practice of identifying interests is ongoing and can evolve through changes to the situation e.g. when taking up new roles or when a new interest arises, or when considering agenda of meetings.

5.3.2 Stage 2 – Disclosing interests
It is the obligation of every individual to declare all direct / indirect interests (as defined in Section 3). Individuals should submit a Declaration of Interest (DoI) form to the medicines regulatory authority prior to accepting an appointment with the medicines
regulatory authority. Individuals should provide a Declaration of Interest (DoI) to the medicines regulatory authority at least annually and to update that information as soon as possible if there is any significant change to their or their close family member’s personal interests as they become aware of those changes. Approval should be sought prior to engagement in additional employment outside the medicines regulatory authority while retaining their official position.

The Declaration of Interest (DoI) form should include sufficient detail to allow the medicines regulatory authority to take an informed decision about identification of any conflict of interest by understanding what the individual’s interest is, and why and how it might impact on his/her role within the medicines regulatory authority. The information should include:

- the position of the individual – role, functions and duties
- in the case of a financial interest, the potential value, if this can be measured
- historical and contextual information related to the interest

For direct or indirect interests, the individual should state, in particular, the type and nature of interests, specifying whether they are general or relate to a specific product or other (tender, recruitment etc). If the declaration is product-related, prior involvement of rapporteurs and experts should be stated in relation to rival products as well as past and current links with companies (The EMA Code of Conduct, 2013).

An employee should not hold or seek to acquire non-allowed direct interests specified in these guidelines during his employment with the NCA. Consequently such non-allowed direct interests should be disposed of prior to the start of employment with the NCA. An employee who passively acquires non-allowed direct interests during the course of his employment with the NCA, for example by way of an inheritance, should complete a declaration of interests and immediately inform the NCA. The employee should dispose of the non-allowed direct interests within a stipulated time frame from acquisition of title to such interests (for example for EMA this is by not later than six months). (EMA Decision on rules relating to Articles 11a and 13 of the Staff Regulations concerning the handling of declared interests of employees of the European Medicines Agency EMA/MB/500408/2011)

Each NCA should consider having the following in place:
- Procedure for the submission of electronic/paper Declaration of Interest form prior to being recruited / engaged by the NCA and subsequently on an annual basis or as soon as possible if any significant change to the interest.
- Procedure for inclusion of declared interests in the NCA’s electronic / paper form
- Guidance for submission of Declaration of Interest form
- Contact person/s for administering interest matters:
  - Be a contact point for disclosure outside meetings
  - Maintain a register recording the nature of members’ interests and restrictions if any
  - Be able to provide input into the development of agendas
  - Receive copies of appointment disclosure statements
  - Assistance for the Management Board in establishing and reviewing policies and procedures on DoI
- Procedures for handling of DoIs at Board/Scientific Committee meetings where DoIs will be recorded in a register and/or minutes of meetings or that are made available through the IT system where they will be available for the information of staff in preparation for scientific committee meetings, and may be displayed during scientific committee meetings for the information of members.
- A system in place that ensures that direct supervisors of staff are aware of restrictions where applicable.
- DoIs register (electronic or hard copy) which should be kept up to date and accurate and should include:
  - Initial DoIs on recruitment or appointment
  - Updated DoI following change in interests
  - Annual DoIs
- Procedure to ensure that NCA management has appropriate access to the DoI register in relation to matters where a potential conflict may occur.
- Arrangements for handling DoI at meetings
  - Disclosure of interest at any point in time between meetings
  - Pre meeting – disclosure after the agenda has been set but prior to the meeting
  - At meeting – meeting agendas should include standing items to accommodate disclosure and updating of interests and restrictions.
  - Minutes / Table of decisions / Conclusions should include:
    - Statement that information on the restricted involvement of participants has been provided / read out by the meeting secretariat at the start of the meeting, including clarifications or additional information as required.
    - Statement that the meeting participants were invited to declare any changes to their current DoI in relation to the items on the agenda.
    - Statement that discussions, deliberations and voting have taken place in full respect of the restricted involvement of participants as announced by the meeting secretariat at the start of meeting.
    - Outcome of the evaluation of declarations of interests and any changes to restrictions in involvement in the meeting for participants who declared changes to their current DoI in respect of on items on the meeting agenda at the start or during the meeting.
    - Information on replacement of a member by the alternate for voting in case restrictions for voting on a topic applied to the member, where applicable.

**5.3.3 Stage 3 – Responding to disclosures**

**Evaluation Procedure**

a) Procedures on inclusion and updating of individuals’ details in the NCA’s database or register.

b) Procedure for the evaluation of declarations of interest which should meet the obligations of NCA relating to their processing of personal data:
   - At recruitment or appointment stage
   - At least annually
   - When new interests arise

**Step 1 – Administrative Validation step**

a) DoI form submitted and signed successfully – proceed to Step 2
b) DoI form not updated or not signed – obtain the required update / endorsement

**Step 2 Levels of involvement**

The NCA should consider the restriction in a systematic way taking into account 3 factors, namely, the nature of the declared interest, the timeframe during which such interest occurred as well as the type of activity. The following three levels of involvement in assignment of tasks in relation to role are provided for consideration by NCAs:

**No involvement:**

**Current direct** interests in the pharmaceutical industry:
- Current employment with a pharmaceutical company
- Current consultancy to a pharmaceutical company
- Current strategic advisory role for a company
- Current financial interests (including intellectual property rights such as patents)

**Restrictions applicable in assignment of work depending on the role within the NCA:**
- Past employment with, consultancy to or strategic advisory role for a pharmaceutical company. Consideration to be given to applying restrictions for a defined period (cooling off period) or an indefinite period of time depending on the role of the individual within the company (e.g. for EMA experts, a three-year cooling off period is required for past employment, consultancy and strategic advisory role and a lifetime non-involvement for leading roles during previous employment)
- Current or past principal investigator / investigator within the cooling-off period as decided by NCA
- Current grant or other funding to an organisation / institution
- Current declared direct interests of close family members

**Full involvement**
- No declared direct or indirect interests in the pharmaceutical industry
- Past employment with, consultancy to or strategic advisory role for a pharmaceutical company beyond the cooling off period as decided by the NCA
- Past financial interests (including intellectual property rights such as patents)
- Past principal investigator/investigator beyond the cooling off period as decided by the NCA
- Past grant or other funding to an organisation / institution
- Past declared direct interests of close family members

**Step 3 – Assessment of DoI in relation to role**

**Staff / external experts**
The NCA should have procedures in place for assignment of work to staff / external experts that takes into account assignment restrictions due to previous or current interests.
In the case of staff or external experts performing administrative, scientific or technical duties, where the declared interests, if any, of the employee/expert present a potential conflict of interest with respect to the specific procedure or duty, the NCA shall consider assigning other employees/experts with a lower or no risk or with no conflicts of interest. The authority may consider granting a waiver in certain limited circumstances, provided that statutory criteria are met, for example:
- The need for the individual's services outweighs the potential for a conflict of interest created by the interest involved.
- The individual’s service is necessary to afford the NCA essential expertise.

In cases where staff/experts with an identified conflict of interest have to be involved in assessment or surveillance activities due to lack of alternative resources, appropriate quality assurance steps have to be introduced e.g., additional peer review. However, it may be necessary that in order to remain in office, the individual concerned would have to take appropriate action to suppress the conflict.

Evaluation of Declaration of Interests against activity should be performed on an ongoing basis:
- initial evaluation at recruitment for acceptability and identification of any restrictions
- assignment of work to staff or external experts.

The DoIs register (electronic or hard copy) should be updated to include outcomes of the assessment of the declaration in respect of role.

**Scientific committees**
The NCA is required to screen members on scientific decision-making committees, all potential participants or staff members, prior to each meeting, to determine whether the potential of a conflict of interest exists. Scientific Committee members are prohibited from participating in a meeting or parts of a meeting if they have a disqualifying interest, unless a waiver is granted or the interest is covered by a regulatory exemption.

For staff/experts participating at a meeting, where the declared interests, if any, of the individual present a potential conflict of interest with respect to the specific medicinal product, the NCA should primarily consider assigning other employees with a lower or no risk or with no conflicts of interest. The authority may consider granting a waiver for staff/experts to which normally restrictions would apply allowing participation in specific meetings, provided that statutory criteria are met, for example:
- The financial or other interest is not so substantial as to be deemed likely to affect the integrity of the services provided by that individual.
- The need for the individual's services outweighs the potential for a conflict of interest created by the interest involved.
- The individual’s service is necessary to afford the scientific committee essential expertise.

Restrictions should be clearly specified e.g. voting, participating in scientific discussions or final deliberations, acting as rapporteur or chair/vice chair of scientific committee/working party.
Evaluation of Declaration of Interests of members of scientific committees should be performed on an ongoing basis
- initial evaluation for membership for acceptability and identification of any restrictions
- subsequent review of monthly meeting agendas for applicability of such restrictions

5.4 Enforcement of DoI policy

Non-compliance with the NCA’s DoI policy should be regarded as a ‘breach of trust’ which concerns any incomplete and/or incorrect DoI. Failure to fill in the DoI in a complete and/or correct manner may be considered as a *prima facie* breach of trust towards the NCA. Because of that failure, appropriate disciplinary or other actions may be taken. NCAs should consider having a breach of trust procedure in place.

5.5 Monitoring mechanisms

NCAs should have internal control mechanisms in place through internal auditing and compliance procedures and also complaints procedure to deal with allegations of non-compliance.

5.6 Record keeping

NCAs should have procedures for keeping declarations of interest in a secure register or database within the NCA and for performing DoI checks prior to assignment of work. Records, including those relating to the evaluation process and outcomes of evaluation, should be kept in line with the set procedures. This information will be reviewed on a regular basis by designated staff to ensure the information is accurate and to determine its relevance to current operations.

5.7 NCA obligations related to the MoU with EMA

NCAs’ obligations related to the MoU between EMA and NCAs on the monitoring of the scientific level and independence of evaluation carried out by the NCAs for services to be provided to the Agency.

5.7.1 Nomination of experts

- Oversee that the designated national contact point has uploaded the nomination form to the EMA’s Experts’ database and for submission of all documentation to the EMA.
- Review list of experts on an annual basis
- Submit an updated Declaration of Interest and Confidentiality Undertaking form to the EMA through the national contact point
- Promptly inform the EMA of any expert under judiciary investigation and removing such an expert from the EMA’s Experts’ database without delay

5.7.2 Monitoring of experts

- Put in place and maintain a documented system to ensure that NCAs’ staff / external experts participating in the (evaluation) work (with respect to the authorisation and surveillance of medicinal products) at national level for services
provided to the Agency, including experts appointed to the (co-)rapporteurs’ teams, have no financial or other interests in the pharmaceutical industry which could affect their impartiality
- Ensure that any request by the European Court of Auditors and / or European Anti Fraud Office to access, inspect and / or audit the records on the handling of declarations of interests can be accommodated within a reasonable timeframe

5.8 Staff leaving the NCA

Staff who take up an offer of future employment should be aware that it may give rise to a conflict of interest with their role within the NCA. NCAs should have procedures in place for staff to notify the agency if they believe such a conflict exists as soon as possible in order to allow for a review of their current activities in the light of their future employment.

Procedures should also be in place to remind staff who are leaving that they are prohibited from using any confidential information gained during employment in the NCA in their new employment or for personal gain.

5.9 Transparency

In order to meet the requirements of Article 126(b) of Directive 2001/83/EC, NCAs shall have a system in place to provide public access to its rules of procedure and those of its scientific committees, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes, including minority opinions.

The DoI of individuals should be made available under freedom of information requests to the public. It is recommended that DoIs are published on the website of the NCA.

5.10 Annual reports on management of CoIs (NCAs)

The European Parliament adopted a resolution on 17 April 2013, whereby the European Medicines Agency was called “to introduce a special section describing the actions taken to prevent and manage conflict of interest in each of its future annual activity reports, which should include, inter alia:

- the number of alleged conflict of interest cases verified,
- the number of revolving door cases,
- the measures taken in each category of cases,
- the number of breach of trust procedures launched and their outcomes,
- the sanctions applied”
(European Parliament resolution of 17 April 2013 with observations forming an integral part of its Decision on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2011 (C7-0252/2012 – 2012/2190(DEC)).

In the light of the above, NCAs are encouraged to take this resolution on board.