



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 October 2010  
EMA/513078/2010

## European Medicines Agency policy on the handling of conflicts of interests of Scientific Committee members and experts

POLICY/0044

Effective date: 2<sup>nd</sup> Quarter 2011 (exact date to be determined)

Review date:

Supersedes: Not applicable

### 1. Introduction and purpose

EU legislation<sup>1</sup> clearly states that the members<sup>2</sup> of the Scientific Committees and experts shall not have financial or other interests in the pharmaceutical industry that could affect their impartiality. They shall make an annual declaration of their financial interests. In addition, all indirect interests which could relate to the pharmaceutical industry shall be entered in a register held by the European Medicines Agency (referred to in this document as "Agency"), which is accessible to the public, on request, at the Agency's offices.

The Agency's Code of Conduct<sup>3</sup>, and in particular Annex 1, provides guidance on several aspects related to conflicts of interests. Information is made available about what should be declared by whom and at what moment in time. In addition, clarification about some operational aspects is given by stating the tasks of the Agency's Secretariat, the obligations of the individuals concerned and the meeting proceedings.

Experience with the handling of conflicts of interests for the Scientific Committee members and experts has been gained since the establishment of the Agency in 1995. With a view to continuously improving

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<sup>1</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

<sup>2</sup> The reference to members also applies to alternates.

<sup>3</sup> The EMEA Code of Conduct (Doc. Ref. EMEA/6470/03/2368).



the processes in the context of its Integrated Quality Management system, the Agency decided to review at regular intervals the procedures and arrangements in place and to strengthen the handling of conflicts of interests taking into account the outcome of these reviews.

A Policy on the handling of conflicts of interests for the Scientific Committee members and experts was established in March 2004 and subsequently reviewed and updated in December 2005 in the light of experience gained over the first year of use.

Since 2006 further experience has been obtained. The two main findings have been demands by the wider community for the Agency to strengthen its handling of conflicts of interests, as well as requests from stakeholders for the Agency to ensure that the best scientific expertise is involved in the assessment process.

This has resulted in an in-depth review of the current Policy, and a revised Policy was endorsed by the Management Board at its 7 October 2010 meeting.

The Policy shall be reviewed within 3 years or at an earlier stage if considered necessary.

## 2. Scope

The scope of the Policy relates to the handling of conflicts of interests of Scientific Committee (i.e. the CHMP, CVMP, COMP, HMPC, PDCO and CAT) members (including, where relevant, alternates) and experts involved in activities at the level of the Agency. Involvement in the Agency's activities means all activities carried out at the Agency in the context of the authorisation and surveillance of medicinal products for human and veterinary use. This includes meeting attendance, involvement in the scientific assessment and guidance development, as well as participation in inspections.

The scope of this Policy does not relate to staff and experts at the level of the NCAs participating in the (evaluation) work (with respect to the authorisation and surveillance of medicinal products) at national level for services provided to the Agency. This is in line with the MoU<sup>4</sup> concluded between the NCAs and the Agency.

The Policy currently does not yet include the handling of conflicts of interests of members of the Management Board for which the previous Policy is still applicable at this point of time.

## 3. Definitions

### **Abbreviations**

- CAT: Committee for Advanced Therapies
- CHMP: Committee for Medicinal Products for Human Use
- COMP: Committee for Orphan Medicinal Products
- CVMP: Committee for Medicinal Products for Veterinary Use
- DIAG: Declaration of Interests Assessment Group
- DoI: Declaration of Interests
- EU: European Union

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<sup>4</sup> Memorandum of Understanding between the European Medicines Agency and the National Competent Authorities of the Member States on the monitoring of the scientific level and independence of the evaluation carried out by the National Competent Authorities for services to be provided to the Agency (Doc. Ref.:EMA/150487/2010).

- EPAR: European Public Assessment Report
- HMPC: Committee for Herbal Medicinal Products
- MoU: Memorandum of Understanding
- NCA: National Competent Authority
- PDCO: Paediatric Committee
- SAG: Scientific Advisory Group

### **Definitions**

- Direct interests in pharmaceutical industry are:
  - Employment with a company
  - Consultancy for a company
  - Strategic advisory role for a company
  - Financial interests
  - Ownership of a patent
- Indirect interests in pharmaceutical industry are:
  - Principal investigator
  - Investigator
  - Individual's Institution receives a grant or other funding
- Consultancy for a company: is to be interpreted as an activity where the concerned expert provides advice or services to a pharmaceutical company regardless of contractual arrangements or any form of remuneration.

It should be noted that scientific advice provided by the NCA of a Member State is not considered a consultancy activity.

- Strategic advisory role for a company: is to be interpreted as meaning that the expert is participating (with a right to vote on/influence the outputs) in a (Scientific) Advisory Board/Steering Committee with the role of providing advice/expressing opinions on the (future) strategy, direction and development activities of a pharmaceutical company, either in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration.

It should be noted that:

- Data Monitoring Committees (composed of independent external experts reviewing unblinded clinical trial data independently of the sponsor/pharmaceutical company) fall outside the scope of this definition. Experts participating in these fora are considered in the same way as principal investigators (for definition of principal investigator see below).
- Involvement of an expert in research work for a pharmaceutical company is considered an indirect interest.

- Financial interests relate to:
  - Holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pension schemes that are not exclusively based on the pharmaceutical sector.
  - Compensation, fees, honoraria, salaries paid directly by a pharmaceutical company to the individual, other than payment for expenses incurred with research work or re-imburement of reasonable expenses incurred in relation to conference/seminar attendance (i.e. accommodation and travel costs).
- Ownership of a patent: relates to a patent for a medicinal product/competitor product owned by either the individual or the individual's Institution.
- Principal investigator: is the investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre trial or the leading investigator of a monocentre trial, or the coordinating (principal) investigator signing the clinical study report<sup>5</sup>.
- Investigator: is an investigator involved in a clinical trial at a specific trial site which can be the responsible lead investigator of the trial at that specific site or a member of the clinical trial team who performs critical trial related procedures and makes important trial related decisions.
- Grant or other funding: two situations need to be considered:
  - Individual's Institution (either a NCA or an academic Institution) receives a grant or other funding (e.g. sponsoring of a Chair at the University department) from a pharmaceutical company for research work and the individual receives no personal gain;
  - Organisation (e.g. Patient Organisation) receives a grant or other funding from a pharmaceutical company for non-research work and the individual (irrespective if the individual is employed by the Organisation or is a volunteer and acts as a representative) receives no personal gain.
- Expert Witness: is an expert whose role is limited to testify and give specialist advice on a specific issue by providing information and replying to any questions only. Such Expert Witness can be invited to participate at Scientific Committee, Working Party, SAG or Ad-Hoc Expert Group meetings.
- Pharmaceutical company: also includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product.
- Competitor product: is defined as a medicinal product that targets a similar patient population with the same clinical objective (i.e. to treat, prevent or diagnose a particular condition), hence constituting a potential commercial competition.

It should be emphasised that the aforementioned definitions can not address all the various scenarios which may exist. Therefore, in order to determine if a particular situation is covered by the definition the Agency's DIAG will evaluate on a case-by-case basis.

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<sup>5</sup> This definition does not include a national coordinating investigator in a multinational trial.

## 4. Policy statement

The following aspects are addressed in this Policy:

- Objectives of the Policy
- Principles of the Policy
- Preparatory steps for the operation of the Policy
- Practical operation of the Policy

### 4.1. Objectives of the Policy

The main objective of the Policy is to ensure that the Scientific Committee members and the experts participating in the Agency's activities have no interests in the pharmaceutical industry which could affect their impartiality, as per the requirements of EU legislation. This has to be balanced with the need to secure the best (specialist) scientific expertise for the evaluation and surveillance of medicinal products for human and veterinary use.

In order to achieve this objective and to strike the aforementioned balance the Policy focuses on 3 important pillars, i.e.:

- robustness,
- efficiency, and
- transparency of the process for the handling of conflicts of interests of Scientific Committee members and experts.

### 4.2. Principles of the Policy

As mentioned before a 3 pillar approach is envisaged: robustness, efficiency and transparency.

#### **Achieving a Robust Process**

The following principles apply:

##### Direct versus indirect interest

- The focus is on direct interests in pharmaceutical industry, leading to the highest risk level (level 3) with a more restricted involvement in the Agency's activities.
- Indirect interests in pharmaceutical industry lead to an intermediate risk level (level 2) with mitigating actions to reach the best possible balance between limiting the involvement in the Agency's activities and the need for the availability of the best (specialist) scientific expertise.
- The obligation for the individual to declare interests in relation to the activities of his/her Institution/Organisation is subject to the extent that the individual has knowledge of the Institution's/Organisation's activities.
- Individuals are requested to declare current direct interests of (a) household member(s) (i.e. spouse, partner or child living at the same address as the individual) but such interest will not be taken into account to determine the participation level in the Agency's activities.

### Restricting involvement in the Agency's activities

- Involvement of the individual in the Agency's activities is restricted taking into account the nature of the declared interest, the timeframe during which such interest occurred, as well as the type of activity.
- As a general rule, current employment with a pharmaceutical company or current financial interests in pharmaceutical industry are incompatible with involvement in the activities of the Agency. One exception to this general rule applies to the concept of Expert Witness. Current financial interests are compatible with such concept.
- The requirements for membership of decision-making bodies (i.e. Scientific Committees) are stricter than for advisory bodies (i.e. SAGs and Ad-Hoc Expert Groups).
- The requirements are also stricter for chairpersons / vice-chairpersons of the Scientific Committees compared to the chairpersons / vice-chairpersons of other fora and the members of the Scientific Committees and the other fora. Likewise the requirements are stricter for rapporteurs (or equivalent leading / co-ordinating role) compared to the other members of the scientific fora.
- The timeframe to be considered for the declared direct or indirect interest is either current (i.e. at any time point during the term of the mandate of a member or at the time of involvement of an individual in a specific Agency activity), or within the past 2 years, or within the past 2 to 5 years. Interests need to be declared up to 5 years after the interest ceases to exist. However, individuals can declare any interests beyond the 5 years timeframe. They can also restrict on their own initiative their involvement in the Agency's activities as a result of such declaration.

### ***Achieving an Efficient Process***

The following should enable the establishment of an efficient process:

- Conflicts of interests are classified into 3 categories, i.e. direct versus indirect versus no interests declared. Direct interests are assigned the highest risk level (level 3), indirect interests an intermediate risk level (level 2), and in case no interests are declared a risk level 1 is assigned.
- A 2 step procedure applies: following a review by the Agency's Secretariat of the DoI form a risk level is assigned according to the above classification. Subsequently the level of participation in the Agency's activities is determined taking into account the assigned risk level and the restrictions which apply to participation in the various activities of the Agency.
- A proactive approach is envisaged as regards the possible identification of conflicts of interests through an obligatory screening by the Agency of the declared conflicts of interests of Scientific Committee members prior to any formal nomination by the Competent Authority<sup>6</sup>. The Agency will provide feedback to the Nominating Authority on the outcome of the pre-screening for subsequent consideration by the Nominating Authority when launching the formal nomination process. Likewise, the possibility of pre-screening of any expert prior to involvement in the Agency's activities is offered to the Nominating Authority.
- A proactive approach is also applied with respect to the search for alternative experts in the field, making the best use of the established relationships with academia and learned societies. In addition, for the establishment of a new SAG or the renewal of the mandate of an existing SAG a public call for expression of interests is launched by the Agency.

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<sup>6</sup> Competent Authority refers to both the Member States and the European Commission.

## ***Achieving a Transparent Process***

Transparency is envisaged through the following initiatives:

- Introduction of transparency on declared conflicts of interests throughout the whole scientific review process, starting with the (Co)-Rapporteur assessment reports (or the assessment reports from equivalent leading / co-ordinating individuals) to the minutes of the various fora up to a specific section in EPARs (or equivalent public documents) on all conflicts of interests declared throughout the scientific review.
- A gradual extension of the publication of the DoIs on the Agency's website of all experts included in the Agency's experts database, whilst ensuring that personal data legislation is adhered to.

### ***4.3. Preparatory Steps for the Operation of the Policy***

Before any work can be undertaken by the Agency on the checking of conflicts of interests members of the Scientific Committee and experts first need to be nominated after which they need to be included in the Agency's expert database. The roles and the responsibilities of both the Nominating Authority and the Agency are summarised in the aforementioned MoU.

#### ***Nomination Process***

##### Nomination process for Scientific Committee members

Scientific Committee members<sup>7, 8</sup> (and, where relevant, alternates) are nominated by Member States for a term of three years, which may be renewed. The Management Board is consulted on nominations prior to the appointment of CHMP and CVMP members. Such members shall be chosen by reason of their role and experience in the evaluation of medicinal products for human and veterinary use, as appropriate, and shall represent their Competent Authorities.

##### Nomination process for experts

Member States shall transmit to the Agency a list of experts with proven experience in the evaluation of medicinal products in order to serve on Working Parties or SAGs, or to act as additional experts to Scientific Committees, Working Parties or SAGs. Nominations should be accompanied by a description of the experts' qualifications and their specific areas of expertise.

In addition, situations can arise where the need for additional expertise, not covered by nominations made by the Member States, is identified at the level of the Scientific Committees. In such circumstances, the nomination of the identified expertise is undertaken by the Agency.

#### ***Inclusion in the Agency's Expert Database***

All Scientific Committee members and experts must be included in the Agency's experts database prior to the first appointment resulting in involvement in activities at the level of the Agency (meeting attendance, scientific evaluation, inspections, guidance development, etc.). Such inclusion is only possible once the following documents have been submitted to the Agency:

- Nomination form,
- Public declaration of interests and confidentiality undertaking form, and
- Curriculum Vitae.

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<sup>7</sup> It should be noted that some Scientific Committee members are nominated by the European Commission.

<sup>8</sup> It should be noted that at the level of some Scientific Committees the Committee may decide to appoint co-opted members.

The Nominating Authority has to ensure, in close collaboration with the nominated member/expert, that all relevant material necessary for the Agency's review has been made available prior to the member's/expert's involvement in any activity of the Agency.

The list of experts is published on the Agency's website<sup>9</sup>. In addition, it should be noted that the declarations of interests submitted by members and experts are publicly available. Whereas the declarations of interests of experts can be consulted, upon request and in person, at the Agency's offices in London, the Agency has decided, in order to further increase its transparency, to make the declarations of interests of the chairpersons, members and alternates (where such alternates are nominated) of the Scientific Committees available on the Agency's website. As mentioned before, in a next phase the gradual extension of the publication of the DoIs of all experts is envisaged.

#### **4.4. Practical Operation of the Policy**

The consequences of the application of the principles laid down in this Policy in terms of the allowable conflicts of interests are summarised in the document "Overview of the Allowable Interests for the EMA Scientific Activities" (Doc. Ref.: EMA/358101/2010).

### **5. Related documents**

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
- EMEA Code of Conduct (Doc. Ref. EMEA/6470/03/2368).

### **6. Changes since last revision**

New Policy.

London, date

Signature on file

Thomas Lönngren

Executive Director

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<sup>9</sup> [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2009/10/WC500004666.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004666.pdf)