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European Medicines Agency policy on the handling of competing interests of Management Board members

POLICY/0058
Effective date: 1 December 2016
Review date: no later than 1 December 2019
Replaces: Policy 0058 dated 17 December 2015 (EMA/MB/715362/2015)

1. Introduction and purpose

In accordance with Article 63(2) of Regulation (EC) No 726/2004[1], members[2] of the Management Board (MB) shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. In addition, all indirect interests which could relate to pharmaceutical industry shall be entered in a register held by the European Medicines Agency (referred in this document as "Agency") which is accessible to the public, on request, at the Agency's offices.

The Agency's Code of Conduct[3] provides general guidance on several aspects related to declarations 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.

The MB adopted its policy on the handling of conflicts of interests of MB members in 2006. Taking into account experience accumulated and the revised policy for the handling of conflicts of interests of scientific committees' members and experts (policy 0044) adopted in 2010, the MB adopted a revised policy in March 2012. Such revision recognised that the role and responsibilities of the MB differ from those of the Agency's scientific committees as the MB takes strategic decisions and oversees corporate activities of the Agency as opposed to scientific or medicinal product specific matters. It should also be recognised that MB members represent Member State or institutional interests. A further revised policy

[1] 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.
[2] The reference to members also applies to alternates.
[3] The EMA Code of Conduct (EMA/385894/2012).

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to take into account experience obtained since March 2012 and to ensure alignment, where relevant, with the revised policy 0044, became effective 1 May 2016.

The current revision of the MB policy addresses the outcome of the 2015 Agency's annual review of its independence policies and their state of implementation.

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 competing interests of MB members, alternates and observers[4] involved in MB activities. This policy also applies to members of the MB sub-committees.

3. Definitions

3.1. Direct versus indirect interests

Taking into account the aforementioned EU legislation applicable to the Agency in the field of declarations of interests, two categories of interests are possible, i.e. direct and indirect interests.

The definitions which are set out in the policy on the handling of declarations of interests of scientific committees' members and experts also apply to this policy, and are included below:

- Direct interests in pharmaceutical industry are:
  - Employment with a company
  - Consultancy to a company
  - Strategic advisory role for a company
  - Financial interests
- Indirect interests in pharmaceutical industry are:
  - Principal investigator
  - Investigator
  - Grant or other funding to an organisation/institution

Each of these interests is further defined below.

3.1.1. Direct interests

- **Employment with a pharmaceutical company** shall mean: any form of occupation, part-time or full-time, paid or unpaid, in a pharmaceutical company.
- **Consultancy to a pharmaceutical company** shall mean: any activity where the concerned MB member provides advice (including training on a one-to-one basis) to a pharmaceutical company regardless of contractual arrangements or any form of remuneration.

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

[4] Observers are representatives from Iceland, Liechtenstein and Norway.

- **Strategic advisory role for a pharmaceutical company** shall mean: any activity where the MB member is participating (with a right to vote/influence the outputs) in a(n) (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. MB members participating in these fora are considered in the same way as principal investigators (for definition of principal investigator see below).

  – Involvement of a MB member in research work for a pharmaceutical company is considered an indirect interest.

- **Financial interests** shall mean any economic stake in a pharmaceutical company including:

  – Holding of stocks and shares, stock options, equities, bonds and or partnership interest in the capital of such pharmaceutical company. The holding of financial interests through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements would not need to be declared provided that they are diversified (i.e. not exclusively based on the pharmaceutical sector) and they are independently managed (i.e. the individual has no influence on their financial management).

  – Compensation, fees, honoraria, salaries, grant or other funding (including rents, sponsorships and fellowships) paid by a pharmaceutical company to the MB member in a personal capacity, other than payment for or reimbursement of expenses incurred with the research work or reimbursement of reasonable expenses directly related to a conference/seminar attendance (i.e. accommodation and travel costs).

  – Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal product owned by the individual or of which the individual is directly a beneficiary.

3.1.2. Indirect interests

- **Principal investigator** shall mean: an investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre pharmaceutical industry instigated/sponsored trial or the leading investigator of a monocentre pharmaceutical industry instigated/sponsored trial, or the coordinating (principal) investigator signing the clinical study report[5].

- **Investigator** shall mean: an investigator involved in a clinical pharmaceutical industry instigated/sponsored 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 to an organisation/institution** shall mean: any funding received from a pharmaceutical company by an organisation/institution to which the MB member belongs, or for

[5] This definition does not include a national coordinating investigator in a multinational trial.

which he/she performs any kind of activity, and which is used to support any activity of the MB member whether or not it is related to research work.

3.2. Other definitions

There are a number of other definitions, relevant to the Agency's policy:

- **Close family members** shall mean: first-line members of the family of the MB member (i.e. a spouse or a partner, children and parents).
- **Pharmaceutical company** shall mean: any legal or natural person whose focus is to research, develop, manufacture, market and/or distribute medicinal products. For the purpose of this policy, the definition includes companies to which activities relating to the research, development, manufacturing, marketing and maintenance of medicinal products (which might also be carried out in house) are outsourced on a contract basis.

  In this regard Clinical Research Organisations (CROs) or consultancy companies providing advice or services relating to the above activities, fall under the definition of a pharmaceutical company.

  Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control of a pharmaceutical company, shall be considered as pharmaceutical companies for the purposes of this policy.

  Independent researchers and research organisations including universities and learned societies are excluded from the scope of the present definition.

4. Policy statement

The following aspects are addressed:

- Objectives of the policy
- Principles of the policy
- Implementing the principles
- Specific arrangements in case of exceptional MB discussions on scientific/medicinal product related matters
- Operational arrangements

4.1. Objectives of the policy

The main objective of the policy is to ensure, as per the requirements laid down in EU legislation, that the MB members participating in MB activities have no interests in the pharmaceutical industry which could affect their impartiality. In order to achieve this, the best possible balance has to be found between managing competing interests of MB members versus the specific role and responsibilities of the MB. This will be undertaken by applying the methodology described in section 4.2.1.3 "Determining involvement in MB activities".

In addition, the policy also aims to increase transparency in relation to competing interests with industries other than the pharmaceutical industry. Although there is no specific legal requirement for MB members to declare interests with non-pharmaceutical industry, the MB already in its 2012 policy

recognised the need to declare such interests, taking into account the MB's specific role and responsibilities. Therefore, personal interests, other than interests in pharmaceutical industry should be declared in view of further increasing transparency in this field.

4.2. Principles of the policy

The policy focuses on three principles, i.e.:

- robustness,
- efficiency, and
- transparency of the process for the handling of competing interests of MB members.

4.2.1. Achieving a robust process

The following principles apply:

4.2.1.1. Declared interests – Interests in pharmaceutical industry

Direct versus indirect interests

Reference is made to section 3 "Definitions" where clarification is provided on what constitutes a direct or an indirect interest in pharmaceutical industry.

The primary focus is on direct interests in pharmaceutical industry leading to the most pronounced restrictions in involvement in MB activities. Indirect interests in pharmaceutical industry will be addressed through mitigating actions.

Looking at the nature of the declared interests, three categories have been identified. For each category, where applicable, a cooling-off period has been set.

- Category 1: Direct interests in a pharmaceutical company (i.e. employment, consultancy, strategic advisory role). It is assumed that the declared interest is considered over following a three year cooling-off period. Involvement during such cooling-off period is restricted.
- Category 2: Consists of either direct (i.e. financial) or indirect (i.e. grant/other funding to an organisation/institution, close family members) interests whereby it is assumed that the declared interest is considered over when such interest is no longer present, resulting in full involvement in MB activities.
- Category 3: Consists of indirect interests (i.e. (principal) investigator), whereby taking into account the specific role and responsibilities of the MB, such indirect interests should only be declared to ensure transparency, without any restrictions in terms of involvement in MB activities.

Other declarable interests

- Involvement in academic trials and in publicly funded research/development initiatives, as well as membership of an ethics committee should be declared. This will not result in the Agency restricting involvement in MB activities, unless a specific interest is identified.
- Attendance at courses and conferences funded by pharmaceutical industry (including attendance at accredited courses or conferences with respect to CPD (Continuing Professional Development)/CME (Continuing Medical Education) acquisition) do not need to be declared. However, in case the MB member receives payment by pharmaceutical industry going beyond reimbursement of reasonable

expenses (i.e. accommodation and travel costs) directly related to a conference/seminar attendance, this needs to be declared and this will be incompatible with involvement in MB activities.

4.2.1.2. Declared interests – Personal interests, other than interests in a pharmaceutical company

As stated in section 4.1. "Objectives of the policy", the main objective of declaring such personal interests is to increase transparency, and any mitigating measures to be introduced should, therefore, be proportionate.

MB members should declare the following personal interests:

- Interests in other entities possibly providing services to the Agency (i.e. in the areas of IT, infrastructure, catering[6]), as well as interests in other areas such as medical devices/diagnostics/reagents not linked with medicinal products[6] which may be discussed at the MB. Such interests should not result in mitigating measures unless they are relevant to the issues being discussed by the MB. In addition, the mitigating measures should be proportionate to the nature of the interest declared.
- Positions (either a managerial role or other influential roles) in a governing body (irrespective if such position is paid or not) of a professional organisation[7] with an interest in the field of pharmaceuticals other than a pharmaceutical company. Such interests should not in principle result in mitigating measures but should always be declared for transparency reasons. However, in exceptional cases such interests may result in restrictions, to be decided on a case-by-case basis.

4.2.1.3. Determining involvement in MB activities

In order to determine involvement in the MB activities on the basis of the declared interests, a risk-based approach will be applied, as follows:

General principles:

- Involvement in the MB activities/topics is determined taking into account 4 factors:
  - the nature of the declared interest,
  - the timeframe during which such interest occurred,
  - the type of MB activity/topic, and the likelihood of the impact of the MB decision on pharmaceutical industry, or other industry in relation to the specific MB topic (as regards the latter in case of declared personal interests other than interests in pharmaceutical industry),
  - the action requested from the MB (has a decision (i.e. adoption or endorsement) to be taken by the MB or not).
- In order to achieve the best possible balance between managing competing interests of MB members versus the specific role and responsibilities of the MB the following methodology is applied:
  - First the nature of the declared interest will be looked at, before determining the length of time any restrictions will apply.

[6] It should be noted that this is a non-exhaustive list.
[7] It should be emphasised that organisations such as patients', consumers' or healthcare professionals' organisations are covered under section 3.1.2 "Indirect interests", in particular the sub section "Grant or other funding to an organisation/institution".

- Secondly, the type of MB activity/MB topic and the likelihood of the impact of the outcome of the MB discussion on (pharmaceutical) industry will be evaluated, but always in the context of the action required from the MB (i.e. has a decision to be taken by the MB or not).

- The restrictions in case of membership of MB subcommittees are the same compared to those for the MB itself.
- The timeframe to be considered depending on the declared direct or indirect interest is either current, or within the past 3 years.

Implementing the general principles:

As stated above, in order to determine the level of participation in MB activities/topics, the following is considered:

- Current[8] direct interests in pharmaceutical industry (i.e. current employment with a pharmaceutical company, current financial interests in pharmaceutical industry, current consultancy to a pharmaceutical company, current strategic advisory role for a pharmaceutical company) are incompatible with MB membership.
- Once the nature of the declared interest has been identified, the duration of any restrictions will be set, i.e. as long as the interest exists or for 3 years after the cessation of the interest. However, individuals can always declare on their own initiative any interests beyond these periods limited in time (i.e. current, or within the past 3 years). They can always also restrict on their own initiative their involvement in the MB activities as a result of such declaration.
- The likelihood of the impact of the MB decision on pharmaceutical industry for each MB activity/topic is evaluated. It should be noted that the likelihood of an impact on pharmaceutical industry is assessed without any further qualification or quantification of such possible impact. Only those MB activities/topics for which an impact on pharmaceutical industry is identified are subject to possible restrictions in participation at the MB in case of a declared interest.
- The action required from the MB members. In case the MB topic is for decision (i.e. adoption or endorsement) restrictions in participation at the MB meeting (or via written procedure) will apply to MB members. In case the MB topic is for information/discussion at the MB meeting (irrespective if a decision has to be taken at a subsequent MB meeting) MB members are allowed to participate in the discussion. Allowing MB members with declared interests to contribute to the MB discussion, whilst excluding them from deciding on matters and whilst maintaining a high level of transparency to allow for public scrutiny (see section 4.2.3 “Achieving a transparent process” for further information), is considered important to achieve robust decision-making.
- For those MB activities/topics for which an impact on pharmaceutical industry has been identified, and for which the MB is invited to take a decision (i.e. adoption or endorsement) allowed involvement is summarised in Annex 1. For those MB activities/topics for which no impact on pharmaceutical industry has been identified, full involvement is allowed. Likewise, Annex 1 elaborates on the allowed involvement in case of declared personal interests, other than interests in a pharmaceutical company.

Other principles:

Furthermore, if a MB member or alternate intends to be engaged (either solicited or not) in occupational activities with a pharmaceutical company (such as employment) during the term of the mandate (irrespective if an employment contract with a company has been signed or not), the member

[8] Current shall mean: at the moment of nomination and at any time point during the term of the mandate of a MB member.

or alternate shall immediately inform the Agency. The Agency will fully restrict the MB member or alternate from further involvement in the activities of the MB from the date of notification. The Nominating Authority will be informed by the Agency that the member or alternate can no longer be involved in MB activities.

4.2.2. Achieving an efficient process

The following should enable the establishment of an efficient process:

- A proactive approach is applied as regards the possible identification of the need for restrictions in involvement in the MB activities by offering the possibility of a pre-screening by the Agency of the declared interests of proposed MB members prior to any formal nomination by the Nominating Authority[9]. In such situation, 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.
- In order to facilitate the evaluation of declared interests and to optimise the handling of competing interests, MB activities/topics will be screened by the Agency to assess the likelihood of the impact of the MB decision on pharmaceutical industry. In determining the restrictions to be applied, the Agency will take better into account the specific role and responsibilities of the MB which are distinct from the role and responsibilities of the Agency's scientific committees.

4.2.3. Achieving a transparent process

Transparency is achieved through:

- Publication on the Agency's website of the minutes of the MB meetings, including – where relevant – restricted involvement of the MB Chair/MB Vice-Chair and MB members.
- Publication of the Declarations of Interests (DoIs) and CVs of MB members on the Agency's website, whilst ensuring that personal data legislation is adhered to.

The Agency processes personal data in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Further information is provided on the Agency's website under "Privacy statement".

4.3. Specific arrangements in case of exceptional MB discussions on scientific/medicinal product related matters

In case of exceptional discussions at the MB on scientific/medicinal product related matters similar rules compared to those applicable to the handling of DoIs of the Agency's scientific committees are put in place. However, taking into account the specific role and responsibilities of the MB which is distinct from the role of the Agency's scientific committees, the arrangements put in place should be proportionate to the nature of the MB's role. Therefore, MB members will not have to declare upfront specific medicinal product information in their DoIs. Instead, the protocol outlined below is followed in those exceptional cases where scientific/medicinal product related discussions at the MB take place.

[9] Nominating Authority refers to the Member States, the European Commission, or the European Parliament.

Proceedings for declaring interests:

- Prior to the discussion, the MB Chair/Vice-Chair and the MB members will be invited first to declare if there are any updates to the already declared interests (as per the latest publically available DoI).
- Subsequently, the MB Chair/Vice-Chair and the MB members will be invited to declare any current or past (within the past three years) direct or indirect interests in relation to the medicinal product(s) which is/are subject to discussion at the MB.

The resulting mitigating measures will be as described below:

- In case of declared interests, as outlined above, the MB Chair cannot act as Chair and will be replaced by the MB Vice-Chair, whilst the MB members with declared interests will be allowed to participate in the discussion only. The applicable restrictions will be minuted. Such minutes including the restrictions are made public.

4.4. Operational arrangements

MB members should update their DoI annually or as soon as their interests change, informing the MB Chair and the Executive Director of any changes to their declared interest without undue delay. In case where, following the expiry of a DoI, a MB member is late to provide an updated declaration, meeting documents and correspondence will not be sent to the member or his/her support staff until the updated DoI is received.

The MB Chair (in case of absence/unavailability the MB Vice-Chair) will be informed prior to the MB meeting on the outcome of the assessment on the declared interests performed by the Agency as regards the allowed involvement of MB members in the MB meeting.

The MB will be informed at the start of each meeting of the competing interests declared by MB members and the resulting restrictions. This information will be recorded in the MB meeting minutes. At the start of each meeting the MB Chair will also ask MB members to declare any additional competing interests not yet declared in the DoI in relation to the items on the agenda. Such additional competing interests will be minuted and the MB member will be asked to submit an updated DoI without delay for subsequent publication on the Agency's website. In addition, MB members will be asked by the MB Chair to declare interests which can be considered prejudicial to their independence with respect to the items on the agenda at the beginning of each MB meeting and any declared interests will be recorded in the MB meeting minutes.

In order to check the correctness of the information contained in the DoIs of MB members the Agency has introduced a quality assurance system, hereby applying *ex ante* and *ex post* control checks. In addition, in case of incomplete and/or incorrect DoIs a breach of trust procedure may be initiated by the Agency.[10]

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.
- EMA Code of Conduct (EMA/385894/2012 Rev.1).

[10] European Medicines Agency breach of trust procedure on declarations of interests for Management Board members (EMA/MB/309079/2012, Rev. 1).

- European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts – Policy 0044 (EMA/626261/2014, Rev. 1).

6. Changes since last revision

Changes introduced result from the outcome of the 2015 Agency's annual review of its independence policies and their state of implementation.

London, 6 October 2016

[Signature on file]

Christa Wirthumer-Hoche
Chair of the Management Board

Annex 1

Management Board members allowed involvement in Management Board activities

Declared interests in pharmaceutical industry

Declared interest	Time since declared interest ended (in years)	MB Chair/Vice-Chair	MB member	MB topic coordinator
Employment / Consultancy / Strategic advisory role	Current interest	X	X	X
	0 to 3	XC	XD	XTC
Financial interest	Current interest	X	X	X
	0 to 3	F	F	F
Grant or other funding	Current interest	XC	F	XTC
	0 to 3	F	F	F
Close family member	Current interest	XC	XD	XTC
	0 to 3	F	F	F
(Principal) investigator	Current interest	F	F	F
	0 to 3	F	F	F

Declared personal interests, other than interests in a pharmaceutical company

Declared interest	Time since declared interest ended (in years)	MB Chair/Vice-Chair	MB member	MB topic coordinator
Interests in other entities possibly providing services to the EMA (i.e. IT, infrastructure, catering), as well as interests in other areas such as medical devices/diagnostics/re-agents not linked with medicinal products	Current interest	RC	XD	XTC
	0 to 3	F	F	F
Position in a governing body of a professional organisation	Current interest	F	F	F
	0 to 3	F	F	F

Outcome restriction level	Impact of the outcome
X	No involvement in MB allowed.
XC	Cannot act as MB Chair/Vice-Chair.
RC	To be replaced for the decision and discussion in relation to the specific MB topic.
XD	Cannot take part in the MB decision for the specific MB topic.
XTC	Cannot act as topic coordinator for the specific MB topic.
F	Full involvement in MB allowed.