EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Experience following implementation of revised Policy on Handling of Conflicts of Interest

Guidance on Completion of e-DoI

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Conflicts of Interest - a Regulator's Challenge

- Providing the best framework for the protection of public health
- Finding the right balance between minimising conflicts of interests and securing the best scientific expertise
- Otherwise the problem shifts towards an inferior scientific assessment

Background Information

- EMA Policy on CoIs for Scientific Committees' Members and Experts in place since March 2004
- Important revision of the Policy undertaken in 2010 and endorsed by the MB in October 2010
- Introduction of electronic DoI in July 2011
- Implementation of the revised Policy on 29 September 2011
- Publication of online list of Experts and their DoIs on 30 September 2011
- Publication of risk levels for Experts on 29 February 2012

Experience obtained with implementation of revised policy…..

- Implementation of the Policy has been continuously monitored and experience obtained has been analysed
- Limited impact in terms of need for discontinuation of membership due to current direct interests
- Greater impact in terms of restricted involvement of Committee members – with respect to involvement in discussions / voting on procedures involving products / companies in which previous interest was declared.
- Need for further strengthening of robustness of handling of conflicts of interest identified further to experience of implementation of revised policy, as well as comments and feedback received from third parties (incl. Court of Auditors).

…… lead to additional measures to further increase quality assurance

- Proposals for a further strengthening of the process were presented to the Management Board on 22 March 2012 – leading to endorsement by the Board of a **revision of the Policy** and a **Breach of Trust Procedure**
- Clarification on restrictions relating to **receipt of grants**
- Initiative to **check the correctness of information** provided in the DoIs by comparison of interests declared versus Curriculum vitae of expert – based on request of European Parliament for Agency to verify DoIs of scientific Committee members and experts in context of Discharge procedure
- Development and update of **guidance on submission of Electronic Declaration of Interest** and on **Guidance on inclusion of declared interest in e-DoI form**

March 2012 Revision of the CoI Policy: What's New? (1/5)

- Further strengthening: amendments to the CoI Policy:
  - Further **clarification** of certain elements in the Policy
  - Better **alignment of risk and related restrictions for the different roles in the scientific decision process**
  - Strengthening of the **rules in the case of grants** from pharmaceutical industry

March 2012 Revision of the CoI Policy: What's New? (2/5)

- Definitions:
  - Ownership of a patent: clarification that individual needs to be a beneficiary
  - (Principal) investigator: relates to participation in a pharmaceutical industry instigated/ sponsored trial
  - Grant or other funding to the department of an academic institution

- Principles:
  - Involvement in academic trials and in publicly funded research/development initiatives, as well as membership of an Ethics Committee need to be declared, with no restriction in involvement unless a specific CoI is identified

March 2012 Revision of the CoI Policy: What's New? (3/5)

- Principles (cont'd):
  - Declaration of interests in relation to the activities of the institution/organisation: restrictions will apply for **Scientific Committee (Vice)-Chair, Rapporteur** (or **equivalent leading/coordinating role**) or a **peer reviewer**
  - In these situations the individual either needs to be replaced (Scientific Committee chair/vice-chair) for the discussions, final deliberations and voting as appropriate, or can not act as rapporteur (or equivalent leading/coordinating role) or as a peer reviewer in relation to any medicinal product from the pharmaceutical company **giving a grant or other funding to the Institution/Organisation** * or for which current direct interests of (a) household member(s) have been declared.

* Such restrictions applicable to employees (and not to volunteers) of organisations

March 2012 Revision of the CoI Policy: What's New? (4/5)

- Principles (cont'd):
  - If a Member intends to be engaged (either solicited or not) in occupational activities with a pharmaceutical company (such as employment) during the term of the mandate
    - Member shall immediately inform the EMA
    - Member shall refrain from any activities which may have an impact on that company
    - Member shall comply with any additional conditions/limitations the EMA may impose

March 2012 Revision of the CoI Policy: What's New? (5/5)

- Practical operation of the Policy:
  - A system of ex-post control checks is applied by the EMA: cross checks to look into the declared CoIs at the EMA versus the CV of the Member/Expert
  - A Breach of Trust Procedure is available

Breach of Trust Policy

What does it involve?

Why

- To further strengthen the robustness of the Agency's handling of conflicts of interests.
- Linked to the EMA policy on the handling of conflicts of interests of Scientific Committee members and experts.

Scope

- Applies to Scientific Committees' members and experts.
- Concerns any incomplete and/or incorrect e-DoIs.

Breach of Trust Policy

Procedure (1/4)

1. Following knowledge of information not consistent with information included in e-DoI, where information should have been declared, expert is
   - informed in writing
   - asked to clarify situation / provide rationale for absence
   - requested to submit updated e-DoI

   cc. Nominating Authority.

2. EMA may suspend expert's involvement in EMA activities until reply is received and assessed.

Breach of Trust Policy

Procedure (2/4)

3. Start of internal procedure:
   - assessment of information received
   - establish if omission is breach of trust vis-à-vis Agency:
     . missing information is declarable interest
     . expert did not declare it intentionally
     or expert did not declare it through gross negligence
     or expert failed to meet obligations under policy.

4. In case of breach of trust, expert is
   - notified of opening of the procedure
   - invited for a hearing to express point of view.

Breach of Trust Policy

Procedure (3/4)

5. Executive Director takes decision.
6. Expert can appeal decision.
7. In case of breach of trust:
   - for Scientific Committee member: consultation of Management Board
   - for other experts: no consultation of MB
   - exclusion of expert from membership of Scientific Committee/scientific forum and/or any other EMA activity
   - inform expert and Nominating Authority.

Breach of Trust Policy

Procedure (4/4)

8. EMA reserves right to make information public.
9. In case of suspected fraud, OLAF is informed (OLAF = European Anti Fraud Office)

Breach of Trust Policy

Integrity of the Scientific Review

Irrespective of outcome of breach of trust procedure:

- Decision taken internally to check integrity.
- Internal checking of scientific outputs adopted by scientific forum to which expert provided input in order to ensure integrity of scientific review process.
- Upon finalisation of internal checking, decision if further remedial action is necessary (e.g. scientific re-evaluation).
- Management Board and Audit Advisory Committee are informed.

Completion of the e-DoI

Who needs to complete an e-DoI?

Experts falling within the scope of the 'European Medicines Agency (EMA) policy on the handling of conflicts of interests of Scientific Committee members and experts' and requiring evaluation of conflicts of interests:

- **Members, alternates and experts** attending a Scientific Committee, Working Party, Drafting Group, Working Group, Scientific Advisory Group or Ad Hoc Expert Group meeting at the Agency, i.e. face-to-face meeting, virtual meeting e.g. via Vitero or Adobe Connect, participation in the meeting via teleconference.
- **Inspectors** performing inspections requested by a scientific committee.
- **Management Board members**

Completion of the e-DoI

What to include

- Before any involvement in EMA activities, the expert must be formally nominated by a National Competent authority, the European Commission or the Agency.
- **Any current activities as well as all activities within the past 5 years** must be declared (current is interpreted as the time of completion of the form).
- If unsure whether an interest relates to a medicinal product or to a pharmaceutical company, declare the information under the relevant section of the form
- In completing the form, please take note of the definitions and explanatory notes included under each section of the form and the additional guidance in this document
- Should the expert acquire any additional interests or should interests change since last e-DoI, he / she must submit an **updated e-DoI**

Completion of the e-DoI

Employment

- Current employment with a pharmaceutical company is incompatible with involvement in EMA activities.

Consultancy

- Provision of advice or services to a pharmaceutical company regardless of contractual arrangements or remuneration. If the consultancy is current and subject to a fee, to be declared under *Current Financial Interests* instead.

- Includes consultancy activities related to lectures, presentations and training organised by individual pharmaceutical companies and given to participants invited by pharmaceutical companies and not open to public.

Completion of the e-DoI

Strategic Advisory Role

- Participation in (scientific) advisory boards/steering committees of pharmaceutical companies, with a right to vote / influence the outcome of that body.

Current Financial Interests

- Current financial interests are incompatible with involvement in EMA activities.
- Includes holding of shares in a pharmaceutical company, compensation, fees, honoraria and salaries paid directly by a pharmaceutical company.
- Participation as a speaker, panellist or in a similar role at conferences organised by or with the involvement of pharm. companies is allowed, but no fees / honoraria can be accepted for such participation.

Completion of the e-DoI

Current Financial Interests (continued)

- Does not include payments of expenses incurred with research work or in relation to conference / seminar attendance; fees received from organizations which are not pharmaceutical companies (e.g. not for profit organizations) and shares in a non-pharmaceutical company.

Ownership of a Patent

- All process and product patents relating to medicinal products and/or patents with a link to a particular medicinal product (e.g. diagnostic tests, medical devices), currently owned by either the expert or the institution, to the extent that the expert is aware, and for which he / she are a beneficiary.

- If the expert owns a patent but are not a beneficiary, this should be included under "In case of any other interests or facts, please specify" section for transparency.

Completion of the e-DoI

Principal Investigator / Investigator

- Participation in (clinical) trials involving pharmaceutical products instigated and/or sponsored by pharmaceutical companies.
- Academic trials, publicly funded research/development initiatives and membership in an Ethics Committee should falls under “any other interests or facts”.

Grant / Funding to Institution

- All grants and other funding from pharmaceutical companies, received by the institution, irrespective of whether the expert is employed or a volunteer, and receives no personal gain.

Completion of the e-DoI

Household Member Interests

- Current direct interests (employment, consultancy, strategic advisory role, financial interests or patent ownership) of the members of your household, to the best of your knowledge

Completion of the e-DoI

Evaluation of declared interests

- On the basis of the submitted e-DoI, **the Agency evaluates possible conflicts of interests according to the table of allowed interests** and determines if the member, alternate or expert can participate in the concerned EMA activity.

- If during the evaluation of the conflicts of interests clarification is required, **the Agency may contact the expert and request him / her to provide more information** and/or to submit an updated e-DoI as appropriate.

- If for any reason the expert is **not in a position to fully detail all activities relating to his / her involvement in medicinal products and/or pharmaceutical companies**, e.g. due to contractual arrangements, the Agency may decide not to allow that expert to participate in EMA activities.

Completion of the e-DoI

Evaluation of declared interests(continued)

- In case the Agency becomes aware / is informed of any interests which have not been included in the e-DoI, the Agency may contact the expert regarding these interests and, if required, request him / her to submit an updated e-DoI.

- Failure to fill in the eDoI in a complete and / or correct manner may be considered as a *prima facie* breach of trust towards the EMA. Because of that failure, appropriate actions, including the exclusion of the concerned person from the EMA activit(y)ies, may be taken by the Agency.

- The Agency may apply restrictions to such participation or even not allow an expert to participate.

- **Be aware that the Agency will publish e-DoIs on its website**.

Completion of the e-DoI

Once involved in EMA activities

- **During the membership and involvement** in EMA activities, members, alternates and experts should **not accept any personal payment** from pharmaceutical companies.

- Scientific Committee and Working Party members should **not engage in consultancies or provide strategic advice** (with or without any financial interest).

- If the expert intends to engage in occupational activities with a pharmaceutical company during his / her membership (such as taking up employment), please inform the Agency immediately, refrain from any activities which may have an impact on the pharmaceutical company concerned and comply with any additional conditions which the Agency may consider appropriate to impose.

Questions?