



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Policy on the Handling of Conflicts of Interests of Scientific Committees' Members and Experts (endorsed by the MB on 22 March 2012)

Presentation to the EMA Scientific Committees and Other
(Scientific) Fora

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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 (1/2)

- EMA Policy on CoIs for Scientific Committees' Members and Experts in place since March 2004
- Implementation of the Policy has been continuously monitored and experience obtained has been analysed
- Important revision of the Policy undertaken in 2010 and endorsed by the MB in October 2010



Background Information (2/2)

- Scope of Policy: relates to Scientific Committees' Members and Experts involved in EMA activities (authorisation and surveillance of medicines including meeting attendance, involvement in scientific assessment and guidance development, participation in inspections)
- Objectives of Policy: need to ensure that Members and Experts have no 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
- Focus on: robustness, efficiency, transparency



Steps Taken

- 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
- 6 months' analysis of implementation of the revised Policy and proposals for a further strengthening of the process was presented to the MB on 22 March 2012
- At the same meeting a further revision of the Policy was presented and endorsed, and a Breach of Trust Procedure was also presented and endorsed



6 Months' Analysis (1/2)

- Impact on Committee membership of revised Policy implemented on 29 September 2011:
 - Discontinuation due to current direct interests rather low
 - More important impact in terms of restricted involvement (especially CAT and PDCO)



6 Months' Analysis (2/2)

- Proposals for a further strengthening: amendments to the CoI Policy:
 - Further clarification of some definitions
 - Introduction of more consistency and robustness
- Proposals for a further strengthening: increasing the QA:
 - Development of Breach of Trust Procedure
 - Checking of the correctness of information provided in the eDoI



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

- Definitions:
 - Consultancy: includes training on a one to one basis
 - Ownership of a patent: individual is a beneficiary
 - (Principal) investigator: participation in a pharmaceutical industry instigated/sponsored trial
 - Grant or other funding to the department of an academic institution



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

- Principles:
 - 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
 - Declaration of current direct interests of a household member: see above



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

- Principles (cont'd):
 - 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? (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 as well as the information on CoIs declared at national level (where available)
 - A Breach of Trust (BoT) Procedure is available



Breach of Trust Procedure (1/3)

- Scope concerns any incomplete and/or incorrect eDoIs
- Main procedural steps:
 - Following knowledge of information not consistent with the information included in the eDoI, Expert will be asked to clarify, cc. Nominating Authority
 - EMA may suspend Expert's involvement in EMA activities until reply is received
 - Start of an internal procedure (interaction with Expert during the process, including appeal possibility)



Breach of Trust Procedure (2/3)

- Main procedural steps (cont'd):
 - In case of breach of trust
 - EMA shall consult the MB for a Scientific Committee Member
 - For any other Expert no consultation with the MB
 - Exclusion of membership and any other EMA activity
 - EMA reserves the right to make the information public
 - In case of suspected fraud OLAF is informed



Breach of Trust Procedure (3/3)

- Integrity of the scientific review:
 - Decision taken internally irrespective of the outcome of the BoT procedure
 - Internal checking of the scientific outputs to ensure the integrity of the scientific review process (external expertise can be involved)
 - Upon finalisation of the internal checking a decision is made if further remedial action is necessary (e.g. scientific re-evaluation)
 - MB and AAC are informed



Implementation

- Implementation of the 22 March 2012 CoI Policy and BoT Procedure are with immediate effect
- Monitoring of implementation will take place and, where necessary, remedial action will be taken
- **Reminder: eDoIs have to be updated on an ongoing basis**