EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Policy on the Handling of Conflicts of Interests of Scientific Committee Members and Experts

Presentation to EMA Scientific Committees and Other (Scientific) Fora

Background Information (1/2)

- Key principles of a revised Policy and Impact Analysis were discussed at June 2010 Board meeting
- Agreement in principle by the Board with the possibility for Board Members to submit written comments within the next 2 weeks
- Comments received from Germany and Iceland
- Further discussions held at various fora including the CAT, COMP, the Patients' and Consumers' Organisations Working Party

Background Information (2/2)

- Management Board endorsed at its 7 October 2010 meeting the revised EMA Policy
- The Policy will be implemented 2ndQ 2011 once all practical arrangements have been put in place
- An interim report on experience obtained will be provided to the Board 6 months after the implementation date, and a full report within 18-24 months

Scope

- Relates to Scientific Committee members (alternates where relevant) and experts in the Agency's activities (authorisation and surveillance of human and veterinary medicines including meeting attendance, involvement in scientific assessment and guidance development, participation in inspections)
- Does not relate to NCAs' staff and experts covered by the MoU
- For Board members current Policy is still applicable at this point of time

Definitions (1/2)

- Direct versus indirect interests
  - Direct interests:
    - Employment with a company
    - Consultancy for a company
    - Strategic advisory role for a company
    - Financial interests
    - Ownership of a patent

Definitions (2/2)

- Direct versus indirect interests (cont'd)
  - Indirect interests:
    - Principal investigator
    - Investigator
    - Individual's institution receives a grant or other funding
- Each aspect is clearly defined in the Policy

Objectives

- Robustness
- Efficiency
- Transparency

Principles: Robustness (1/2)

- Focus on direct interests leading to the highest risk level
- Current direct interests of (a) household member(s) need to be declared
- Involvement in EMA activities is restricted taking into account the nature of the interest, the timeframe and the type of activity
- Current employment with a pharmaceutical company or current financial interests in pharmaceutical industry are incompatible with involvement in EMA activities (exception: Expert Witness for current financial interests)

Principles: Robustness (2/2)

- Membership of decision-making bodies: more restrictions compared to advisory bodies (likewise for (Vice)-Chairpersons of Scientific Committees compared to members of Scientific Committees and Chairpersons of other fora, and for Rapporteurs compared to other members)
- Timeframe: current versus 0 ≥ 2 years versus >2 ≤ 5 years

Principles: Efficiency

- 3 categories of risks
- 2 step procedure
- Proactive approach in identification of possible conflicts of interests and search for alternative expertise

Principles: Transparency

- Throughout the whole scientific review process
- Gradual extension of the publication of declarations of interests on the EMA website

Specific Concerns Raised by Patients' Organisations (1/3)

- Need to distinguish between
  - Participation of patients' organisations in the Agency's work
  - Involvement of individual patients' representatives in the Agency's activities, acting as members of Scientific Committees or experts in a particular field

Specific Concerns Raised by Patients' Organisations (2/3)

- Participation of patients' organisations in the Agency's work:
  - Is governed by specific eligibility criteria adopted by the Board
  - Is therefore not affected by the Policy on CoI as regards membership of the PCWP (the same applies to healthcare professionals in the HCP WG)

Specific Concerns Raised by Patients' Organisations (3/3)

- Individual patients' representatives participating in the Agency's activities:
  - Same criteria apply as for any other experts since it is not possible to have double standards
  - Consequences have been addressed in the Impact Analysis discussed at the June 2010 Board meeting and mainly relate to current employment / consultancy / strategic advisory role / financial interests / patent ownership at any time point during the term of the membership

			CHMP Chair	CHMP Member	Rapp	WP Chair	WP	SAG	EW
Direct	Employee	Current	N	N	N	N	N	N	N
		0 to 2	N	Y(exclude 6)	Y (exclude 8)	Y(exclude 9)	Y(exclude 6)	Y(disc. only 7)	Y
		>2 to 5	N	Y(disc. only 7)	Y (exclude 8)	Y(exclude 9)	Y(disc. only 7)	Y	Y
	Consultant	Current	N	N	N	N	N	Y(disc. only 7)	Y
		0 to 2	N	Y(exclude 6)	Y (exclude 8)	Y(exclude 9)	Y(exclude 6)	Y(disc. only 7)	Y
		>2 to 5	N	Y(disc. only 7)	Y (exclude 8)	Y(exclude 9)	Y(disc. only 7)	Y	Y
	Advisor	Current	N	N	N	N	N	Y(disc. only 7)	Y
		0 to 2	N	Y(exclude 6)	Y (exclude 8)	Y(exclude 9)	Y(exclude 6)	Y(disc. only 7)	Y
		>2 to 5	N	Y(disc. only 7)	Y (exclude 8)	Y(exclude 9)	Y(disc. only 7)	Y	Y
	Financial	Current	N	N	N	N	N	N	Y
		0 to 2	Y	Y	Y	Y	Y	Y	Y
		>2 to 5	Y	Y	Y	Y	Y	Y	Y
	Patent	Current	N	N	N	N	N	N	Y
		0 to 2	Y	Y	Y	Y	Y	Y	Y
		>2 to 5	Y	Y	Y	Y	Y	Y	Y
Indirect	PI	Current	N	Y(exclude 6)	Y (exclude 8)	Y(exclude 9)	Y(exclude 6)	Y(disc. only 7)	Y
		0 to 2	N	Y(exclude 6)	Y (exclude 8)	Y(exclude 9)	Y(exclude 6)	Y	Y
		>2 to 5	N	Y(disc. only 7)	Y (exclude 8)	Y(exclude 9)	Y(disc. only 7)	Y	Y
	I	Current	N	Y(disc. only 7)	Y (exclude 8)	Y(exclude 9)	Y(disc. only 7)	Y	Y
		0 to 2	N	Y(disc. only 7)	Y (exclude 8)	Y(exclude 9)	Y(disc. only 7)	Y	Y
		>2 to 5	N	Y	Y	Y	Y	Y	Y
	Grant	Current	Y (exclude 10)	Y	Y	Y	Y	Y	Y
		0 to 2	Y (exclude 10)	Y	Y	Y	Y	Y	Y
		>2 to 5	Y (exclude 10)	Y	Y	Y	Y	Y	Y

6 No involvement with respect to procedures involving the medicinal product or a competitor product, i.e. no part in discussions, final deliberations and voting as appropriate as regards these medicinal products.

7 Involvement in discussions only with respect to procedures involving the medicinal product or a competitor product, i.e. no part in final deliberations and voting as appropriate as regards these medicinal products.

8 Individual can not act as (Co)-Rapporteur in relation to the medicinal product or a competitor product.

9 Chair to be replaced for the discussions, final deliberations and voting as appropriate in relation to the medicinal product or a competitor product.

10 Chair to be replaced for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the pharmaceutical company giving a grant or other funding to the institution