



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mad Medicine: Do Conflicts of Interest Drive You Crazy?

The European Medicines Agency Handling of Conflicts of Interests

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An agency of the European Union





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



What Has the EMA Done?

- Conflicts of Interests Policy for EMA Scientific Committee members and experts is in place since March 2004
- Implementation of the Policy has been continuously monitored and experience obtained has been analysed
- Lessons learnt have been taken into account when revising the Policy



Revised EMA Policy: Scope

- Relates to EMA Scientific Committee 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)
- Enters into force on 29 September 2011



Revised EMA Policy: Objectives

- Need to ensure that members and experts involved in EMA activities have no interests in the pharmaceutical industry which could affect their impartiality, which needs to be balanced with the need to secure the best (specialist) scientific expertise
- In order to achieve this the Policy focuses on
 - Robustness
 - Efficiency
 - Transparency



Revised Policy: Definitions (1/3)

- Direct versus indirect interests
 - Direct interests:
 - Employment with a company
 - Consultancy for a company
 - Strategic advisory role for a company (either in terms of general strategy or product related strategy, as opposed to involvement of the individual in the context of research work for a pharmaceutical company which is considered to be an indirect interest)



Revised Policy: Definitions (2/3)

- Direct versus indirect interests (cont'd)
 - Direct interests (cont'd):
 - Financial interests (relate to holding of shares of a pharmaceutical company (with the exclusion of investment funds/pension schemes), as well as compensation, fees, honoraria, salaries paid directly to the individual other than payment made for expenses incurred with research work)
 - Ownership of a patent by either the individual or the institution (to the extent that the individual has knowledge of the institution's activities)



Revised Policy: Definitions (3/3)

- Direct versus indirect interests (cont'd)
 - Indirect interests:
 - Principal investigator
 - Investigator
 - Individual's institution receives a grant or other funding (e.g. sponsoring of a Chair at the University department) from a pharmaceutical company (whereby the individual receives no personal gain) for research work (non-product related)



Revised Policy: 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)



Revised Policy: 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 $0 \geq 2$ years versus $>2 \leq 5$ years



Revised Policy: Principles: Efficiency

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



Revised Policy: Principles: Transparency

- Increased transparency throughout the whole scientific review process
- Extension of the publication of declarations of interests on the EMA website



			CXMP Chair	CXMP Member	Rapp	WP Chair	WP Member	SAG Chair/Member	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



Current Status and Next Steps

- All Scientific Committees members and experts have been asked to fill in a revised eDoI (electronic Declaration of Interests)
- eDoIs are in the process of being evaluated and involvement in EMA activities is being reviewed taking into account the revised criteria
- All eDoIs will be made publically available on the EMA website as of 30 September 2011
- A report on the implementation of the revised Policy will be provided at regular intervals to the Agency's Management Board



Conclusions

- EMA takes care to ensure that its Scientific Committee members and experts do not have any financial or other interests that could affect their impartiality
- Revised Policy aims to introduce a more robust, efficient and transparent process
- EMA will carefully monitor the implementation of the revised Policy and introduce any necessary changes