



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA public workshop Best expertise versus conflicts of interests: Striking the right balance

Setting the scene

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An agency of the European Union





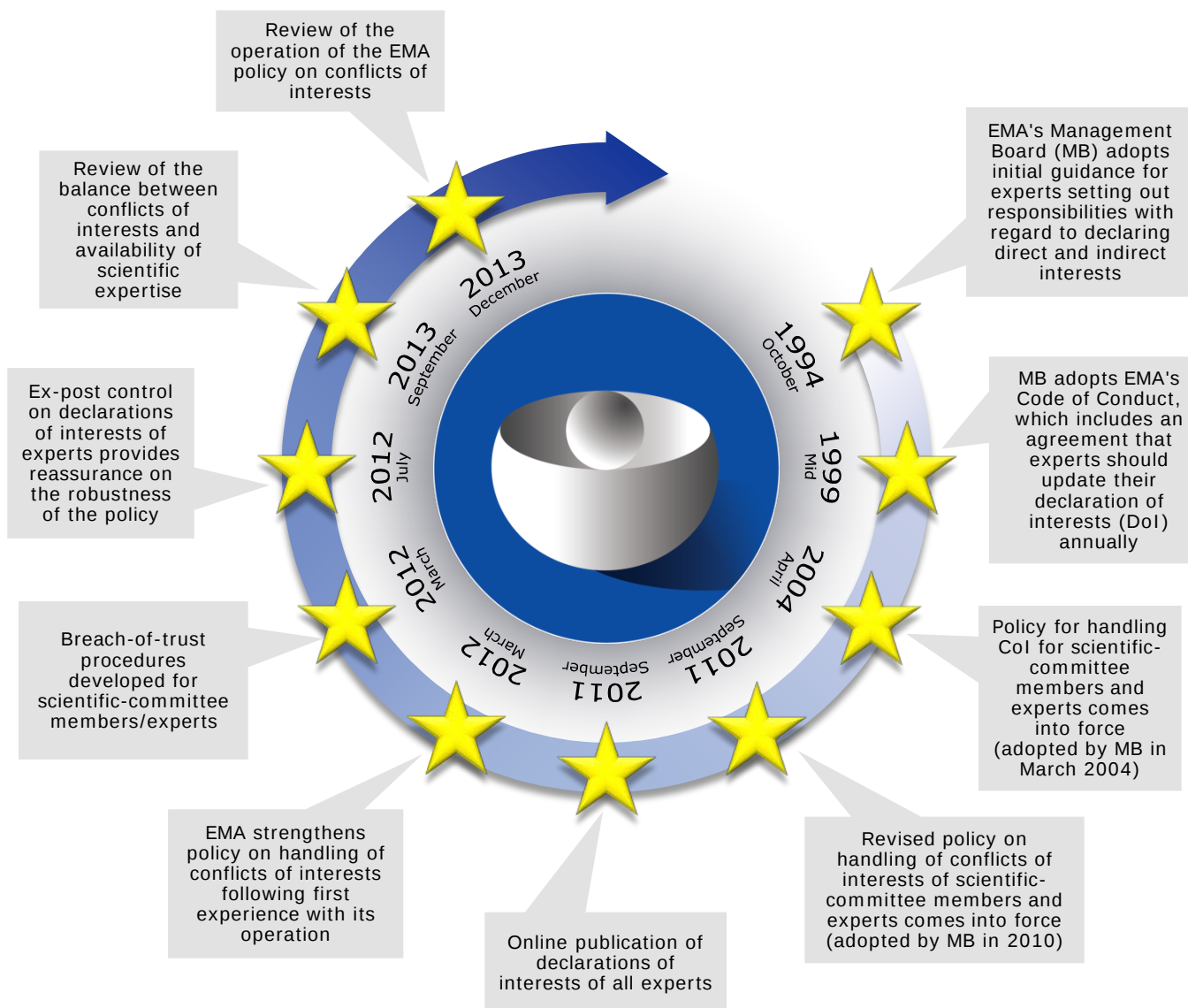
General considerations

- Conflicts of interests situations are a general phenomenon, not restricted to
 - Healthcare sector
 - Regulators
- Impact can be high
 - Raise doubts on the robustness of the decision-making
 - Loss of trust by society
 - Reputational damage
- Need for
 - Robust system to manage conflicts of interests
 - Utmost transparency to allow public scrutiny
 - Best expertise to deliver high-quality outputs



Conflicts of interests @ EMA

- EMA legislative framework aims to protect the scientific decision-making from undue financial or other interests
- Since 1995 EMA is committed to achieve this objective
 - Continuous monitoring of conflicts of interests
 - Several initiatives to enhance the robustness of its process and to increase transparency
 - Quality assurance is being built into the process





Where are we now?

- Robustness ✓
- Transparency ✓
- Quality assurance has started
- Right balance between conflicts of interests and best expertise?



Best expertise vs. conflicts of interests (1/3)

2012 restricted involvement of experts

Number of experts on EMA website (all risk levels)	Number of experts excluded from full involvement ¹
3,432	868 (these are experts with risk levels 2 and 3)

¹ Depends on the agenda topics; for “affected” agenda topics the level of restriction can vary



Best expertise vs. conflicts of interests (2/3)

2013 experience: example in the field of human medicines

Referral procedures (ad-hoc expert group meetings)	Experts contacted	Experts attending	Experts with restricted participation	Experts not invited due to conflicts of interests
8	172	71	9 ¹	19 ²

¹ Out of total attending (71)

² Out of total not attending (101)



Best expertise vs. conflicts of interests (3/3)

2013 experience: example in the field of veterinary medicines

Experts groups	Experts contacted	Experts attending	Experts with restricted participation	Experts not invited due to conflicts of interests
8	94	41	6 ¹	10 ²

¹ Out of total attending (41)

² Out of total not attending (53)



Right balance between conflicts of interests and best expertise?

- Experience shows room for improvement
- Other consideration: how to better identify the best expertise within the EU?
- Aim of today's workshop is to find solutions, hence contributing to
 - A more robust scientific review process
 - Increased trust of patients, healthcare professionals and the general public
- Therefore, what we don't want
 - Poor quality of expertise
 - Lower standards of conflicts of interests
 - Decline in trust