Questions to panel members and for the general debate in the afternoon

Fernand Sauer,
Former executive director of the EMA

Main questions to the panel and for the afternoon session

1. How could the Agency make it more attractive for experts and widen the pool of available expertise?
2. Are the EMA safeguards adequate, not strong enough, or too restrictive?
3. What additional elements would be useful when revising the Agency's CoI policy and its practical operation?

NB: Could participants hand a short note to the chair, with name, question labelled number 1, 2 or 3, preferably before lunch break

Further suggestions to be e-mailed to Noel Wathion by 15 september

Incentives for best expertise

1. Better recognition in EU/international by peers, how?
2. Better recognition and career at home, how?
3. Welcome and support at EMA (satisfaction survey*?).
4. Should expert benefit from EMA payment to NCAs
5. Or should EMA compensate directly the experts?
6. Can we learn from Commission or EU other agencies?
7. Can we learn from best practices in NCAs, FDA, and scientific or professional associations?

**Future experts satisfaction surveys to include CoI questions?*

What level of restrictions?

1. Does everyone accept the approach of EMA safeguards?
2. Should specific EMA criteria such as 2 or 5 years, nature of activity, risk level assement be adjusted? How?
3. Personal involvement in research (public or private) to be distinguished from corporate interests of employer?
4. Allow more witness experts outside decision-making?
5. Patients: distinguish volunteers from staff and general consulting from product specific?
6. More fexibility for niches sectors (orphan, paed., vets)?

What else?
questions for the Panel

1. Importance of reputation, integrity, gratitude
2. What about the procedure of access to the expert list?
3. Can the dynamics of peer review and transparency neutralize residual conflicts of interest?
4. All CoIs are on the Web, where are the whistleblowers?
5. In case of breach of trust: should EMA name and shame
6. EFPIA sunshine proposals 2015/1016 for disclosure of payments to health care professionals and organizations.

What else?
Questions to the Commission

Commission assessment of EMA CoI policy, compared to other EU practises for CoI and expert fees

(DG SANCO, DG RTD, ECDC, EFSA)?

Commission position, as a nominating authority, on CoIs of patients experts ?

(volunteers v. staff _ general consulting v. product specific)

What else?
Questions to the NCAs

1. NCAs face similar CoI challenges in the decentralized system, how do they tackle the problem?
2. What CoI initiatives by Heads of Agencies?
3. EMA contracts expertise from NCAs at a cost of 77 mio €/year. Should there be a contractual « CoI garantee »?
4. In case of breach of trust, what about national sanctions?