

Opportunities for expert involvement in our core assessment and related activities

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Options for core assessment & inspection work at NCA level

External experts engaged by NCAs

- Experts can be used for assessment and inspections
- Assessment includes scientific advice, marketing authorisation applications, clinical trial applications, etc.
- NCA selects, contracts & pays experts, manages conflicts of interest
- Remuneration commensurate with the amount of work required and negotiated upfront with NCA, subject to national rules
- Training will be provided by the contracting NCA
- Experts may be used by NCAs also for complimentary activities (e.g. training)

NCAs may also choose to employ experts as staff members

Opportunities for expert involvement



Involving experts in supportive activities via an EMA call

Process

- EMA may engage external experts following a call for expression of interest
- EMA selects, contracts & pays experts, and manages conflicts of interest
- Remuneration set in the call for expression of interest

Activities

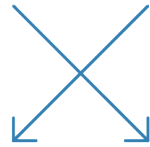
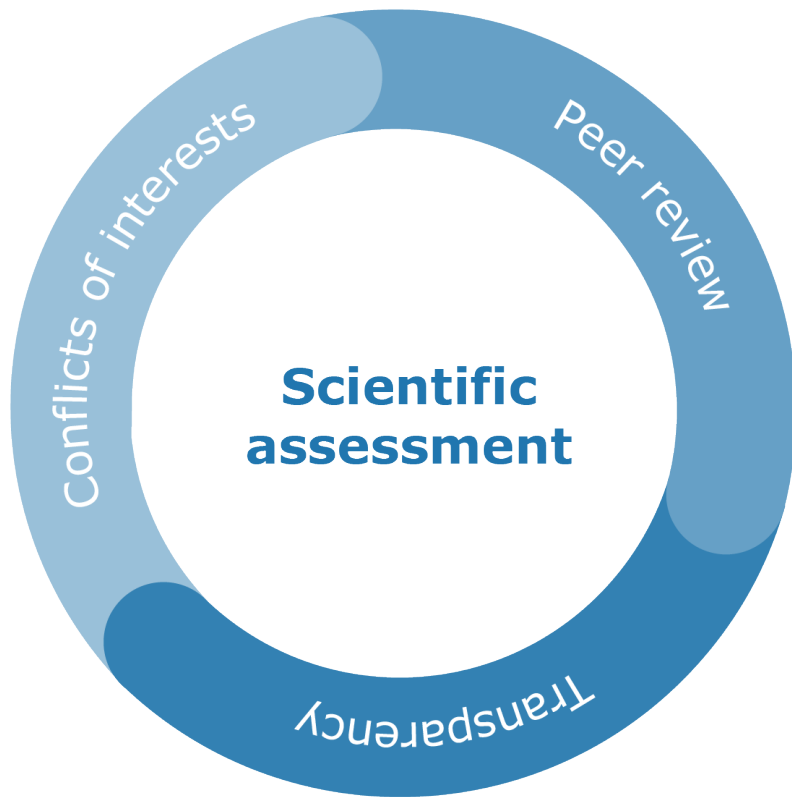
- Currently used for medical device experts, and for patient and healthcare professional representatives for specific tasks
- Additional activities may be considered (new call), e.g. for training
- Scope can not include core assessment and inspection work

Option for engagement of external experts for additional tasks to complement core assessment work at national level

Opportunities for expert involvement



Ensuring the independence of our work



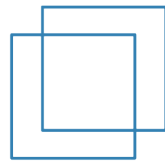
Managing conflicts of interests

EMA's scientific experts, staff and Management Board members must not have any financial or other interests that could affect their impartiality



Peer review

EMA's assessments are carried out by a rapporteur and a co-rapporteur, and are subject to committee discussions and peer review



Transparency

Assessment reports, agendas and minutes, allow public scrutiny of how EMA works and reaches its decisions

Opportunities for expert involvement

Conflicts of interest rules

- No involvement in assessment/inspection activities allowed in case of current employment, consultancy/strategic advisory role or financial interest in pharmaceutical or medical device companies, including consulting companies or CROs
- Restrictions apply on certain product-specific activities in case of such interests in the past 3 years, for current and past (principal) investigators and for current close family member interests
- Exclusions or restrictions apply for some activities in research organisations
- For further details, refer to EMA [Policy 44](#) on the handling of competing interests of scientific committees' members and experts and the [procedural guidance](#) on completing the EMA declaration of interest
- Competing interest policies at national level are similar to the EMA policy

In the event an expert is approached for a specific activity, a declaration of interest will be required

Building the pool of external experts



What?

- To build a pool of interested external experts
- Start with a post-webinar survey* where the interest can be confirmed and expertise areas indicated



Purpose

- Available for national competent authorities to contact/ engage as the need arises to support activities in a given area of expertise
- To reach out on new initiatives



Support for the pool

- Share updates on opportunities for engagement in EMRN activities
- Training may be offered for experts in the pool (e.g. on EU Regulatory aspects)

* - participation is voluntary, but necessary in order to be considered and to share updates

Opportunities for expert involvement



Thank you

