



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Declarations of Interest (DoI)

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Objectives of the policy

- Main objective of the policy is to ensure that the scientific committees' members and **experts** participating in the Agency's activities have no **interests** in the **pharmaceutical industry** *that could affect their impartiality*, as per the requirements of EU legislation (*Article 63(2) of Regulation (EC) No 726/2004*).
- This has to be balanced with the need to secure the best expertise.





Requirements for involvement in EMA activities

- Up-to-date **DoI** (including confidentiality statement) validated by the expert
- Up-to-date **e-CV** (tick box option for patients) required to validate eDOI
- Expert **Nomination** form (tick box option for patients)
 - Expert must be included in Experts database prior to first involvement
 - Applicable to experts participating in product related face-to-face meetings, teleconferences and written consultations



DoI and eCV

- Valid for 1 year
- If interests change, must submit updated e-DoI/eCV
- All declarations of conflict of interest (DoI) and eCVs are published on the EMA website in the [European experts list](#)



Elements of the DoI/Confidentiality form

SECTION 1: PERSONAL DETAILS

SECTION 2: PUBLIC DECLARATION OF INTERESTS

- *2.1 Employment*
- *2.2 Consultancy*
- *2.3 Strategic advisory role*
- *2.4 Financial interests*
- *2.5 Principal investigator*
- *2.6 Investigator*
- *2.7 Grant / Funding to organisation/institution*
- *2.8 Close family member interest*
- *2.9 Any other interests or facts*

SECTION 3: CONFIDENTIALITY UNDERTAKING



Two categories of interests are defined

Direct interests in pharmaceutical industry are:

- Employment with a company
- Consultancy to a company
- Strategic advisory role for a company
- Financial interests

Indirect interests in pharmaceutical industry are:

- Principal investigator
- Investigator
- Grant or other funding to an organisation/institution

Definitions cannot address all the scenarios which may exist; additional guidance included in "Procedural guidance on inclusion of declared interests in the EMA's electronic DOI form (EMA/627294/2014, Rev. 1).



Direct interests	Indirect interests
Employment at a company (currently or within the last 3 years)	Principal investigator (currently or within the last 3 years)
Consultancy for a company (currently or within the last 3 years)	Investigator (currently or within the last 3 years)
Strategic advisory role for a company (currently or within the last 3 years)	Institution/organisation currently receives grant/funding with direct benefit to the expert
Current financial interests (personal shares, fees, honoraria, patents, ... Not reasonable expenses for conference)	Close family member currently has interest in a company (employment, consultancy, strategic advisory role, financial)



Consultancy for a pharmaceutical company

Is defined as....

any activity where the concerned expert provides advice (including training on a one to one basis) to a pharmaceutical company

regardless of contractual arrangements or any form of remuneration.



Strategic advisory role for a pharmaceutical company

Defined as....

any activity where the expert is participating (with a right to vote/influence the outputs) in a(n) (scientific) advisory board/steering committee

with the role of providing advice/expressing opinions on the (future) strategy, direction and development activities of a pharmaceutical company, either in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration.



Grant or other funding to an organisation/institution

Shall mean: any funding received from

a pharmaceutical company by an organisation/institution to which the expert belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the expert whether or not it is related to research work.

Patients :

- Who are **volunteers** with their organisation do not have to include funding related to their organisation on their DOI (2.7), unless they are committee or working party members / alternates.
- who are **employees** of their organisation do have to include funding related to their organisation on their DOI under 2.7.



Other declarable interests

'Other Interests or Facts' to be declared (no restrictions apply)

- Involvement in academic trials
- Involvement in publicly funded research/development initiatives
- Membership of ethics committees

No need to declare

- Attendance at courses and conferences funded by companies

Unless: payment beyond reimbursement of reasonable expenses (i.e. accommodation and travel cost), this is considered as current financial interest



Status	Length of involvement (in years)	Committee / WP member	Committee / WP Expert	SAG member / Expert
Employee (depends on whether executive role, lead role or cross company role)	Current	No involvement	No involvement	No involvement
	0 to 3	Restrictions	Restrictions	Restrictions
	>3	Restrictions	Restrictions	Restrictions
Consultancy/ Strategic Advisory Role (depends whether cross product / general or individual)	Current	No involvement	No involvement	Restrictions
	0 to 3	Restrictions	Restrictions	Restrictions
Financial Interest	Current	No involvement	No involvement	No involvement
	0 to 3	Full involvement	Full involvement	Full involvement
Grant / funding to organisation / institution	Current	Restrictions	Full involvement	Full involvement
	0 to 3	Full involvement	Full involvement	Full involvement
Close family member	Current	Restrictions	Full involvement	Full involvement
	0 to 3	Full involvement	Full involvement	Full involvement



Questions





Contact



EMA [Handling conflicts of interests](#) pages

EMA website: www.ema.europa.eu

Frequently Asked Questions: [FAQ](#)

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