



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Policy on Conflicts of Interests

What it means in practice for you





SCIENTIFIC COMMITTEE CHAIR / VICE-CHAIR

CANNOT:

- Be employed, consultant or have strategic advisory role within previous 5 years or during mandate.
- Have financial interests/own patent during mandate.
- Be (principal) investigator within previous 5 years, or during mandate.



SCIENTIFIC COMMITTEE CHAIR / VICE-CHAIR

CAN:

- Have financial interests/own patent within previous 5 years.
- Receive current grant/funding (to organisation), *with restrictions (chair to be replaced in discussions/conclusions/votes in relation to any medicinal product from company giving grant/funding)*.



SCIENTIFIC COMMITTEE OR WORKING PARTY MEMBER/EXPERT

CANNOT:

- Be employed, consultant or have strategic advisory role, during mandate/while participating (expert).
- Have financial interests/own patent, during mandate/while participating.



SCIENTIFIC COMMITTEE OR WORKING PARTY MEMBER/EXPERT

CAN:

- Be employed, consultant, have strategic advisory role or be principal investigator within previous 0-5 years, *with restrictions* :
 - 0-2 yrs: *no involvement in discussions/conclusions/votes of product (or competitor product).*
 - 2-5 yrs: *no involvement in conclusions /votes of product (or competitor product).*



SCIENTIFIC COMMITTEE OR WORKING PARTY MEMBER/EXPERT

CAN:

- Have financial interests/own patent within previous 5 years (no restrictions).
- Receive grant/funding (to organisation).
- Be investigator within previous 2-5 years.
- Be investigator within previous 0-2 years, *with restrictions (no involvement in conclusions / votes of product (or competitor product))*.



SAG / AD-HOC EXPERT GROUP CHAIR/VICE-CHAIR, MEMBER AND EXPERT

CANNOT:

- Be employed, during mandate/while participating.
- Have financial interests/own patent, during mandate/while participating.



SAG / AD-HOC EXPERT GROUP CHAIR/VICE-CHAIR, MEMBER AND EXPERT

CAN:

- Be consultant or have strategic advisory role, during mandate/while participating, *with restrictions (no involvement in discussions / conclusions / votes of product (or competitor product))*.
- Be employed, consultant or have strategic advisory role within previous 0-2 years, *with restrictions (no involvement in conclusions / votes of product (or competitor product))*.
- Be employed, consultant or have strategic advisory role within previous 2-5 years.



SAG / AD-HOC EXPERT GROUP CHAIR/VICE-CHAIR, MEMBER AND EXPERT

CAN:

- Have financial interests/own patent within previous 5 years.
- Be principal investigator, during mandate/while participating, *with restrictions (no involvement in conclusions / votes of product (or competitor product))*.
- Be principal investigator within previous 0-5 years.
- Be investigator, during mandate/while participating.
- Receive grant/funding (to organisation).



EXPERT WITNESS

CAN:

- Have any previous mentioned interests, apart from:

CANNOT:

- Current employment

The expert witness role is limited to providing advice on a specific issue and responding to defined questions.



PCWP MEMBERS

PCWP membership is governed by specific criteria which will be defined within the mandate and rules of procedure.

CAN:

- Have any previous mentioned interests, apart from:

CANNOT:

- Current employment



Q & A EXAMPLES / SCENARIOS..



Q: Would 'consultancy' be accepted if I am not paid for it?

A: NO, consultancy is defined as "any activity where the expert provides advice or services to a company, regardless of contractual arrangements or forms of remuneration."



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- Q:** What if I provide consultancy on a non-product related issue? For example I go to a company to give a presentation on the orphan drug regulation?
- A:** 'Consultancy' relates to any kind of advice/services provided to industry (product related or not).



Q: If a representative from my organisation acts as a consultant (paid or not), and gives advice to a company on its development plan or overall strategy:

a) Can I be a member of a scientific committee if I am not personally involved in this consultancy (even though my organisation employs me?)

A: YES (evaluation concerns the individual).

b) Can I be a member of a scientific committee if I am personally involved in this consultancy given by my organisation?

A: NO, not during the term of the mandate.



Q: I attended a conference held by pharma, would this incur a conflict for me at the Agency?

A: NO, as long as no compensation is paid.

Q: What if my travel and accommodation expenses to attend are covered by the company?

A: These kind of reimbursements are not considered as 'financial interests' (only other compensation, fees, honoraria, etc).

Note: financial interests = compensation, fees, honoraria, salaries paid directly to an individual ► direct interest, see above definitions.



Q: Two years ago I had some financial interests in a company which I no longer have, which activities can I partake in EMA?

A: All activities.



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- Q:** My organisation receives funding from several pharmaceutical companies, would this have implications when I am taking part in EMA activities on behalf of my organisation?
- A:** This is considered an indirect interest and so can partake in all EMA activities, although for Scientific Committee chair/Vice-chair there would be *restrictions (replaced for discussions/conclusions/votes concerning product from company giving grant/funding)*.