



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

6 October 2016  
EMA/626261/2014, Rev. 1

## European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts

POLICY/0044

Status: Public

Effective date: 1 December 2016

Review date: No later than 1 December 2019

Replaces: Policy/0044, dated 24 April 2015 (EMA/626261/2014, Corr. 1)

### 1. Introduction and purpose

EU legislation<sup>1</sup> clearly states that the members<sup>2</sup> of the scientific committees and experts shall not have financial or other interests in the pharmaceutical industry that could affect their impartiality. They shall make an annual declaration of their financial interests. In addition, all indirect interests which could relate to the pharmaceutical industry shall be entered in a register held by the European Medicines Agency (referred to in this document as "Agency"), which is accessible to the public, on request, at the Agency's offices.

The Agency's Code of Conduct<sup>3</sup> provides general guidance on several aspects related to declarations of interests. Information is made available about what should be declared by whom and at what moment in time. In addition, clarification about some operational aspects is given by stating the tasks of the Agency's secretariat, the obligations of the individuals concerned and the meeting proceedings.

Experience with the handling of declarations of interests for the scientific committees' members and experts has been gained since the establishment of the Agency in 1995. With a view to continuously improving the processes in the context of its integrated quality management system, the Agency decided to review at regular intervals the procedures and arrangements in place and to strengthen its handling of declarations of interests taking into account the outcome of these reviews.

---

<sup>1</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

<sup>2</sup> The reference to members also applies to alternates.

<sup>3</sup> The EMA Code of Conduct (EMA/385894/2012).



A policy on the handling of conflicts of interests for the scientific committee members and experts was established in March 2004 and subsequently reviewed and updated in December 2005 in the light of experience gained over the first year of use.

Since 2006 further experience has been obtained, resulting in revisions, implemented on 29 September 2011, 3 April 2012 and 30 January 2015 respectively. The January 2015 revision took into account experience obtained since the implementation of the revision in April 2012 – including the outcome of *ex ante* and *ex post* controls – as well as the outcome of the 6 September 2013 EMA public workshop “Best expertise vs. conflicts of interests: Striking the best balance”.

The current revision addresses the outcome of the 2015 Agency’s annual review of its independence policies and their state of implementation, hereby demonstrating the Agency’s commitment to continue to develop a policy that effectively addresses the Agency’s specific needs.

The policy shall be reviewed within 3 years or at an earlier stage if considered necessary.

## 2. Scope

The scope of the policy relates to the handling of competing interests of scientific committees’ (i.e. the CHMP, CVMP, COMP, HMPC, PDCO, CAT and PRAC) members (including, where relevant, alternates) and experts involved in activities at the level of the Agency. Involvement in the Agency’s activities means all activities carried out at the Agency in the context of the authorisation, supervision and maintenance of medicinal products for human and veterinary use. This includes meeting attendance, involvement in the scientific assessment and guidance development, as well as participation in inspections.

The scope of this policy does not relate to staff and experts at the level of the NCAs participating in the (evaluation) work (with respect to the authorisation, supervision and maintenance of medicinal products) at national level for services provided to the Agency. This is in line with the MoU<sup>4</sup> concluded between the NCAs and the Agency.

## 3. Definitions

### 3.1. Abbreviations

- CAT: Committee for Advanced Therapies
- CHMP: Committee for Medicinal Products for Human Use
- CME: Continuing Medical Education
- COMP: Committee for Orphan Medicinal Products
- CPD: Continuing Professional Development
- CRO: Clinical Research Organisation
- CV: Curriculum Vitae
- CVMP: Committee for Medicinal Products for Veterinary Use

---

<sup>4</sup> Memorandum of Understanding between the European Medicines Agency and the National Competent Authorities of the Member States on the monitoring of the scientific level and independence of the evaluation carried out by the National Competent Authorities for services to be provided to the Agency (EMA/150487/2010).

- DoI: Declaration of Interests
- EMA: European Medicines Agency
- EU: European Union
- HMPC: Committee for Herbal Medicinal Products
- MAH: Marketing Authorisation Holder
- MoU: Memorandum of Understanding
- NCA: National Competent Authority
- PDCO: Paediatric Committee
- PRAC: Pharmacovigilance Risk Assessment Committee
- SAG: Scientific Advisory Group

## **3.2. Definitions**

### **3.2.1. Direct versus indirect interests**

Taking into account the aforementioned EU legislation applicable to the Agency in the field of declarations of interests, two categories of interests are possible, i.e. direct and indirect interests.

- 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

Each of these interests is further defined below. However, it should be emphasised that some of the definitions cannot address all the various scenarios which may exist. Additional guidance is included in the document “Procedural guidance on inclusion of declared interests in the European Medicines Agency’s electronic declaration of interests form (for scientific committees’ members and experts)” (EMA/627294/2014, Rev. 1).

#### **3.2.1.1. Direct interests**

- **Employment with a pharmaceutical company** shall mean: any form of occupation, part-time or full-time, paid or unpaid, in a pharmaceutical company.
- **Consultancy to a pharmaceutical company** shall mean: 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.

It should be noted that scientific advice provided by the NCA of a Member State is not considered a consultancy activity.

- **Strategic advisory role for a pharmaceutical company** shall mean: 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.

It should be noted that:

- Data monitoring committees (composed of independent external experts reviewing unblinded clinical trial data independently of the sponsor/pharmaceutical company) fall outside the scope of this definition. Experts participating in these fora are considered in the same way as principal investigators (for definition of principal investigator see below).
- Involvement of an expert in research work for a pharmaceutical company is considered an indirect interest.
- **Financial interests** shall mean any economic stake in a pharmaceutical company including:
  - Holding of stocks and shares, stock options, equities, bonds and or partnership interest in the capital of such pharmaceutical company. The holding of financial interests through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements would not need to be declared provided that they are diversified (i.e. not exclusively based on the pharmaceutical sector) and they are independently managed (i.e. the individual has no influence on their financial management).
  - Compensation, fees, honoraria, salaries, grant or other funding (including rents, sponsorships and fellowships) paid by a pharmaceutical company to the expert in a personal capacity, other than payment for or reimbursement of expenses incurred with the research work or reimbursement of reasonable expenses directly related to a conference/seminar attendance (i.e. accommodation and travel costs).
  - Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal product owned by the individual or of which the individual is directly a beneficiary.

### 3.2.1.2. *Indirect interests*

- **Principal investigator** shall mean: an investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre pharmaceutical industry instigated/sponsored trial or the leading investigator of a monocentre pharmaceutical industry instigated/sponsored trial, or the coordinating (principal) investigator signing the clinical study report<sup>5</sup>.
- **Investigator** shall mean: an investigator involved in a clinical pharmaceutical industry instigated/sponsored trial at a specific trial site which can be the responsible lead investigator of the trial at that specific site or a member of the clinical trial team who performs critical trial related procedures and makes important trial related decisions.

---

<sup>5</sup> This definition does not include a national coordinating investigator in a multinational trial.

- **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.

### 3.2.2. Other definitions

There are a number of other definitions, relevant to the Agency's policy:

- **Rival product** shall mean: a medicinal product that targets a similar patient population with the same clinical objective (i.e. to treat, prevent or diagnose a particular condition), and constituting a potential commercial competition.
- **Expert witness** shall mean: an expert whose role is limited to testify and give specialist advice on a specific issue by providing information and replying to any questions only. Such expert witness can be invited to participate at scientific committee, working party, SAG or *ad hoc* expert group meetings.
- **Close family members** shall mean: first-line members of the family of the expert (i.e. a spouse or a partner, children and parents).
- **Pharmaceutical company** shall mean: any legal or natural person whose focus is to research, develop, manufacture, market and/or distribute medicinal products. For the purpose of this policy, the definition includes companies to which activities relating to the research, development, manufacturing, marketing and maintenance of medicinal products (which might also be carried out in house) are outsourced on a contract basis.

In this regard CROs or consultancy companies providing advice or services relating to the above activities, fall under the definition of a pharmaceutical company.

Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control of a pharmaceutical company, shall be considered as pharmaceutical companies for the purposes of this policy.

Independent researchers and research organisations including universities and learned societies are excluded from the scope of the present definition.

## 4. Policy statement

The following aspects are addressed in this policy:

- Objectives of the policy
- Principles of the policy
- Preparatory steps for the operation of the policy
- Practical operation of the policy

## **4.1. Objectives of the policy**

The main objective of the policy is to ensure that the scientific committees' members and the experts participating in the Agency's activities have no interests in the pharmaceutical industry which could affect their impartiality, as per the requirements of EU legislation. This has to be balanced with the need to secure the best (specialist) scientific expertise for the evaluation and surveillance of medicinal products for human and veterinary use. It is, therefore, of utmost importance to strive for the optimal balance between the cooling-off period for the declared interests versus maintaining the experts' knowledge.

In order to achieve this objective and to strike the aforementioned balance the focus will first be on the nature of the declared interest before determining the length of time any restrictions will apply.

## **4.2. Principles of the policy**

The policy focuses on 3 pillars, i.e.:

- robustness,
- efficiency, and
- transparency of the process for the handling of competing interests of scientific committees' members and experts.

### **4.2.1. Achieving a robust process**

The following principles apply:

#### **4.2.1.1. Declared interests**

##### **Direct interests versus indirect interests versus no interests declared**

In terms of declarations of interests 3 interest levels can be identified:

- "direct interests declared" (i.e. interest level 3);
- "indirect interests declared" (i.e. interest level 2);
- "no interests declared" (i.e. interest level 1).

The primary focus is on direct interests in pharmaceutical industry leading to the most pronounced restrictions in involvement in the Agency's activities.

Indirect interests in pharmaceutical industry will be addressed through mitigating actions to reach the best possible balance between limiting the involvement in the Agency's activities and the need for the availability of the best (specialist) scientific expertise.

Looking at the nature of the declared interest, three categories have been identified:

- Category 1: leading role during previous employment with a pharmaceutical company which results in non-involvement during the term of the mandate, on two possible levels:
  - Either executive role<sup>6</sup> within a pharmaceutical company, resulting in non-involvement during the term of the mandate for any medicinal product for which that pharmaceutical company is the MAH, irrespective if such involvement relates to a decision-making or an advisory body.
  - Or lead role<sup>6</sup> in the development of a medicinal product, resulting in non-involvement during the term of the mandate for that medicinal product, irrespective if such involvement relates to a decision-making or advisory body.
- Category 2: for certain declared interests, as specified below, it is assumed that the declared interest is considered over when such interest is no longer present, resulting in full involvement in the Agency's activities:
  - Financial interests<sup>7</sup>.
  - Grant or other funding to an organisation/institution<sup>7</sup>.
  - Interests related to close family members<sup>7</sup>.
- Category 3: for the remaining declared interests, not listed in categories 1 and 2, it is assumed that the declared interest is considered over following a 3 year cooling-off period. Mitigating measures will vary depending on whether the involvement of the expert relates to a decision-making or an advisory body, and will depend as well on the role of the expert (chairperson, rapporteur or equivalent leading/co-ordinating role, formally appointed peer reviewer).

#### **Other declarable interests**

- Involvement in academic trials and in publicly funded research/development initiatives, as well as membership of an ethics committee should be declared. This will not result in the Agency restricting involvement in its activities, unless a specific interest is identified.
- Attendance at courses and conferences funded by the pharmaceutical industry (including attendance at accredited courses or conferences with respect to continuing development of experts CPD/CME acquisition) do not need to be declared. However, in case the expert receives payment by pharmaceutical industry going beyond reimbursement of reasonable expenses (i.e. accommodation and travel costs) directly related to a conference/seminar attendance, this needs to be declared and this will be incompatible with involvement in the Agency's activities.

#### **4.2.1.2. Restricting involvement in the Agency's activities**

##### **Levels of restriction and timeframes**

- Involvement of the individual in the Agency's activities is restricted taking into account 3 factors: the nature of the declared interest, the timeframe during which such interest occurred, as well as the type of activity. The following methodology applies: first the nature of the declared interest within the frame of the specific Agency activity will be looked at, before determining the length of time any restrictions will apply.

---

<sup>6</sup> Further information is provided in the aforementioned "Procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form (for scientific committees' members and experts)" (EMA/627294/2014, Rev. 1).

<sup>7</sup> For the definitions, see sections 3.2.1. and 3.2.2.

- As a general rule, current<sup>8</sup> employment with a pharmaceutical company or current financial interests in pharmaceutical industry are incompatible with involvement in the Agency's activities. One exception to this general rule relates to the concept of expert witness. Current financial interests are compatible with this concept.
- The requirements for membership of decision-making bodies (i.e. scientific committees) are stricter than for advisory bodies (i.e. SAGs and *ad hoc* expert groups).
- The requirements are also stricter for chairpersons/vice-chairpersons of the scientific committees compared to the chairpersons/vice-chairpersons of other fora and compared to the members of the scientific committees and the other fora. Likewise the requirements are stricter for rapporteurs (or equivalent leading/co-ordinating role) and formally appointed peer reviewers compared to the other members of the scientific fora.
- The timeframe to be considered depending on the declared direct or indirect interest is either current, or within the past 3 years, or in certain cases, as stated before, for a longer period (see section 4.2.1.1. for further details). As already mentioned before, the nature of the declared interest will be considered first before deciding on the duration of any restrictions. However, individuals can always declare any interests beyond those periods limited in time (i.e. current, or within the past 3 years). They can always also restrict on their own initiative their involvement in the Agency's activities as a result of such declaration.
- Furthermore, if a scientific committee/working party/SAG/*ad hoc* expert group member intends to be engaged (either solicited or not) in occupational activities with a pharmaceutical company (such as employment) during the term of the mandate (irrespective if an employment contract with a company has been signed or not), the member shall immediately inform the Agency. The Agency will fully restrict the member from further involvement in the Agency's activities from the date of notification. The Nominating Authority will be informed by the Agency that the member can no longer be involved in the Agency's activities<sup>9</sup>.

### Specific case of rival products

For the specific case of rival products (formerly referred to as competitor products) a two tier approach is applied:

- The concept of rival products relates to those situations where there are only a very small number (1 to 2) of rival products. The same would apply for the brand leader when a generic product is under consideration.
- For broad indications, since many products are authorised for the same indication, the existing volume of competition dilutes adequately potential interests.

In situations characterised by only a very small number of rival products as specified above, consequences will relate to the (vice)-chairpersons of the scientific committees and the working parties, as well as the rapporteurs or other members in a leading/ co-ordinating role, or formally appointed peer reviewers.

---

<sup>8</sup> **Current** shall mean: at any time point during the term of the mandate of a member or at the time of involvement of an individual in a specific Agency activity.

<sup>9</sup> Further information is provided in the document "Guidance on the handling of declarations of interests in case of a scientific committee/other (scientific) forum member's intention to become an employee in a pharmaceutical company" (EMA/267183/2015).



#### 4.2.2. Achieving an efficient process

The following should enable the establishment of an efficient process:

- As regards the handling of competing interests a 2 step procedure applies: following receipt of the DoI an interest level is automatically assigned according to the aforementioned interest levels. Subsequently the level of participation in the Agency's activities is determined by the Agency's secretariat taking into account the assigned interest level and the restrictions which apply to participation in the various activities of the Agency.
- For scientific committees' members a proactive approach is applied as regards the possible identification of the need for restrictions in involvement in the Agency's activities through mandatory pre-screening by the Agency of the declared interests prior to any formal nomination by the Nominating Authority<sup>10</sup>. The Agency will provide feedback to the Nominating Authority on the outcome of the pre-screening for subsequent consideration by the Nominating Authority when launching the formal nomination process. Likewise, the possibility of pre-screening of any expert prior to involvement in the Agency's activities is offered to the Nominating Authority.
- A proactive approach is also applied with respect to the search for alternative experts in the field, making the best use of the established relationships with academia and learned societies. In addition, for the establishment of a new SAG or the renewal of the mandate of an existing SAG a public call for expression of interests is launched by the Agency.

#### 4.2.3. Achieving a transparent process

Transparency is achieved through:

- Publication on the Agency's website of the minutes of the scientific committees' meetings, including – where relevant – restricted involvement of the chairs, members and experts.
- Publication of the DoIs and CVs on the Agency's website of all experts, whilst ensuring that personal data legislation is adhered to, as well as publication on the Agency's website of the assigned interest levels.

The Agency processes personal data in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Further information is provided on the Agency's website under "Privacy statement".

### 4.3. Preparatory steps for the operation of the policy

Before any work can be undertaken by the Agency on the checking of declarations of interests, scientific committees' members and experts first need to be nominated as a European expert after which they need to be included in the Agency's experts database. The roles and the responsibilities of both the Nominating Authority and the Agency are summarised in the aforementioned MoU.

---

<sup>10</sup> Nominating Authority refers to both the Member States and the European Commission.

### **4.3.1. Nomination process**

#### **4.3.1.1. Nomination process for scientific committees' members**

Scientific committees' members<sup>11, 12</sup> (and, where relevant, alternates) are nominated by Member States for a term of three years, which may be renewed<sup>13</sup>. The Management Board is consulted on nominations prior to the appointment of CHMP and CVMP members. Scientific committees' members shall be chosen by reason of their role and experience in the evaluation of medicinal products for human and veterinary use, as appropriate, and shall represent their Competent Authorities.

#### **4.3.1.2. Nomination process for experts**

Member States shall transmit to the Agency a list of experts with proven experience in the evaluation of medicinal products in order to serve on working parties or SAGs, or to act as additional experts to scientific committees, working parties or SAGs. Nominations should be accompanied by a description of the experts' qualifications and their specific areas of expertise.

In addition, situations can arise where the need for additional expertise, not covered by nominations made by the Member States, is identified at the level of the scientific committees. In such circumstances, the nomination of the identified expertise is undertaken by the Agency.

### **4.3.2. Inclusion in the Agency's experts database**

All scientific committees' members and experts must be included in the Agency's experts database prior to the first appointment resulting in involvement in activities at the level of the Agency (meeting attendance, scientific evaluation, inspections, guidance development, etc.). Such inclusion is only possible once the following documents have been submitted to the Agency:

- Nomination form,
- Public declaration of interests and confidentiality undertaking form, and
- CV.

The Nominating Authority has to ensure, in close collaboration with the nominated member/expert, that all relevant material necessary for the Agency's review has been made available prior to the member's/expert's involvement in any activity of the Agency.

The list of experts is published on the Agency's website<sup>14</sup>. In addition, it should be noted that the declarations of interests submitted by members and experts are publicly available. Whereas the declarations of interests of experts can be consulted, upon request and in person, at the Agency's offices in London, the Agency has decided, in order to further increase its transparency, to make the declarations of interests and CVs of the chairpersons, members and alternates (where such alternates are nominated) of the scientific committees, as well as all experts available on the Agency's website.

---

<sup>11</sup> It should be noted that some scientific committees' members are nominated by the European Commission.

<sup>12</sup> It should be noted that at the level of some scientific committees the committee may decide to appoint co-opted members.

<sup>13</sup> In case of the PRAC, the mandate may be prolonged once and thereafter renewed.

<sup>14</sup> [http://www.ema.europa.eu/ema/index.jsp?curl=pages/about\\_us/landing/experts.jsp&mid=WCOb01ac058043244a](http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/experts.jsp&mid=WCOb01ac058043244a)

#### **4.4. Practical operation of the policy**

The consequences of the application of the principles laid down in this policy in terms of the allowable interests are summarised in annex 1 "Scientific committees' members and experts allowed involvement in medicinal product related matters".

In order to check the correctness of the information contained in the DoIs the Agency has introduced a quality assurance system, hereby applying *ex ante* and *ex post* control checks. In addition, a Breach of Trust Procedure is available in case of observed failure by a scientific committee member or expert to fill in the DoI in a complete and/or correct manner.

### **5. Related documents**

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
- EMA Code of Conduct (EMA/385894/2012 Rev.1).

### **6. Changes since last revision**

Changes introduced result from the outcome of the 2015 Agency's annual review of its independence policies and their state of implementation.

London, 6 October 2016

[Signature on file]

Guido Rasi  
Executive Director

## Scientific committees' members and experts allowed involvement in medicinal product related matters

Declared interest	Time since declared interest ended (in years)	Scientific committee (Vice)-Chair	Working party <sup>1</sup> (Vice)-Chair	Scientific committee / Working party <sup>1</sup> member	Scientific committee / Working party <sup>1</sup> expert	SAG/ad-hoc expert group (Vice)-Chair	SAG/ad-hoc expert group member/expert	Inspection	Expert Witness
Employee (executive role)	Current interest	X	X	X	X	X	X	X	X
	0 to 3	X	RC	XC-XRpC	XC	RC	DC	XI	Q
	> 3	RC	RC	XC-XRpC	XC	RC	DC	XI	Q
Employee (lead role in development of medicinal product)	Current interest	X	X	X	X	X	X	X	X
	0 to 3	X	RR	XP-XRpR	XP	RP	DP	XI	Q
	> 3	RP	RP	XP-XRpP	XP	RP	DP	XI	Q
Employee (cross company role other than executive role)	Current interest	X	X	X	X	X	X	X	X
	0 to 3	X	RC	XC-XRpC	XC	RC	DC	XI	Q
Employee (medicinal product involvement other than lead role in development of medicinal product)	Current interest	X	X	X	X	X	X	X	X
	0 to 3	X	RR	XP-XRpR	XP	RP	DP	XI	Q
Consultancy to company (cross medicinal products/general)	Current interest	X	X	X	X	X	X	X	Q
	0 to 3	X	RC	XC-XRpC	XC	RC	DC	XI	Q
Consultancy to company (individual medicinal product)	Current interest	X	X	X	X	RP	XP	X	Q
	0 to 3	X	RR	XP-XRpR	XP	RP	DP	XI	Q
Strategic advisory role for company (cross medicinal products/general)	Current interest	X	X	X	X	X	X	X	Q
	0 to 3	X	RC	XC-XRpC	XC	RC	DC	XI	Q
Strategic advisory role for company (individual medicinal product)	Current interest	X	X	X	X	RP	XP	X	Q
	0 to 3	X	RR	XP-XRpR	XP	RP	DP	XI	Q
Financial interests	Current interest	X	X	X	X	X	X	X	Q
	0 to 3	F	F	F	F	F	F	F	Q
Principal Investigator	Current interest	X	RR	XP-XRpR	XP	RP	DP	XI	Q
	0 to 3	X	RR	XP-XRpR	XP	F	F	XI	Q
Investigator	Current interest	X	RR	DP-XRpR	DP	F	F	XI	Q
	0 to 3	X	RR	DP-XRpR	DP	F	F	XI	Q
Grant/other funding to organisation/institution	Current interest	RC	RC	XRpC	F	F	F	F	Q
	0 to 3	F	F	F	F	F	F	F	Q
Close family member	Current interest	RC	RC	DC-XRpC	F	F	F	F	Q
	0 to 3	F	F	F	F	F	F	F	Q

<sup>1</sup> Medicinal product related working parties only, such as the BWP, the SAWP, or medicinal product related discussions at other working parties.

## Outcome of evaluation

Please select the outcome restriction level(s) in the dropdown list below.

Outcome restriction level	Impact of the outcome
X	No involvement in activity allowed.
Q	Involvement limited to testify and give specialist advice on a specific issue by providing information and replying to any questions only.
RC	To be replaced for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the relevant company.
RR	To be replaced for the discussions, final deliberations and voting as appropriate in relation to the relevant medicinal product or a rival product.
RP	To be replaced for the discussions, final deliberations and voting as appropriate in relation to the relevant medicinal product.
XC-XRpC	<ul style="list-style-type: none"> <li>No involvement with respect to medicinal products from the relevant company, i.e. no part in discussions, final deliberations and voting as appropriate as regards medicinal products from the relevant company (XC).</li> <li>Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer for medicinal products from the relevant company (XRpC).</li> </ul>
XC	No involvement with respect to medicinal products from the relevant company, i.e. no part in discussions, final deliberations and voting as appropriate as regards medicinal products from the relevant company.
DC-XRpC	<ul style="list-style-type: none"> <li>Involvement only in discussions with respect to medicinal products from the relevant company, i.e. no part in final deliberations and voting as appropriate as regards medicinal products from the relevant company (DC).</li> <li>Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer in relation to any medicinal product from the relevant company (XRpC).</li> </ul>
DC	Involvement only in discussions with respect to medicinal products from the relevant company, i.e. no part in final deliberations and voting as appropriate as regards medicinal products from the relevant company.
XRpC	Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer in relation to any medicinal product from the relevant company.
XP-XRpR	<ul style="list-style-type: none"> <li>No involvement with respect to procedures involving the relevant medicinal product, i.e. no part in discussions, final deliberations and voting as appropriate as regards the medicinal product (XP).</li> <li>Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer for the relevant medicinal product or a rival product (XRpR).</li> </ul>
DP-XRpR	<ul style="list-style-type: none"> <li>Involvement only in discussions with respect to procedures involving the relevant medicinal product, i.e. no part in final deliberations and voting as appropriate as regards the medicinal product (DP).</li> <li>Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer for the relevant medicinal product or a rival product (XRpR).</li> </ul>
XP-XRpP	<ul style="list-style-type: none"> <li>No involvement with respect to procedures involving the relevant medicinal product, i.e. no part in discussions, final deliberations and voting as appropriate as regards the medicinal product (XP).</li> <li>Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer for the relevant medicinal product (XRpP).</li> </ul>
XP	No involvement with respect to procedures involving the relevant medicinal product, i.e. no part in discussions, final deliberations and voting as appropriate as regards the medicinal product.
DP	Involvement only in discussions with respect to procedures involving the relevant medicinal product, i.e. no part in final deliberations and voting as appropriate as regards the medicinal product.
XI	Cannot participate in inspections relating to the relevant company (all medicinal products).
F	Full involvement in activity allowed.