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European Medicines Agency

Procedural guidance to scientific committees' members and experts on completing the European Medicines Agency's declaration of interests in the Experts Management Tool

1. Aim

The purpose of this guidance is to help experts to complete the European Medicines Agency's (EMA) **declaration of interests** (DoI) in the **Experts Management Tool** (EMT) in accordance with the 'European Medicines Agency policy on the handling of declarations of competing interests of scientific committees' members and experts' (Policy 0044), as well as for EMA staff to guide experts in completing the DoI correctly. It highlights key aspects of declaring interests and clarifies what information should be mentioned in which section of the DoI. The guidance has been revised to reflect additional clarifications stemming from experience with handling declarations of interests (see section 5. Changes since last revision).

2. Who needs to complete a DoI?

Members, alternates and experts[1] involved in the activities of the Agency's scientific committees[2] (i.e. the CHMP, CVMP, COMP, HMPC, PDCO, CAT and PRAC), working parties and other groups (e.g. scientific advisory groups (SAG), ad hoc expert group (AHEG)) and other bodies, i.e. Emergency Task Force (ETF), Medicines Shortages Steering Group (MSSG), Medical Devices Shortages Steering Group (MDSSG), should complete a DoI.

Involvement in the Agency's activities covers all activities carried out in the context of:

- the development, evaluation, supervision and maintenance of medicinal products for human and veterinary use;
- preparing for, preventing, coordinating and managing the impact of public health emergencies and major events on medicinal products;

[1] Experts include staff members of National Competent Authorities or of academic institutions, healthcare professionals and patients – see European experts | European Medicines Agency (EMA).

[2] See Committees, working parties and other groups | European Medicines Agency (EMA).

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- preparing for, preventing, coordinating and managing the impact of public health emergencies on medical devices;
- monitoring, preventing, and reporting on shortages of medicinal products and medical devices.

These activities include meeting attendance, involvement in scientific assessments and guidance development, as well as participation in inspections, as applicable.

Please find below a table with examples of involvement in the Agency's activities falling and not falling within the scope of Policy 0044:

Examples of involvement in the Agency's activities falling under the scope of Policy 0044, thus requiring registration as medicine expert in EMT	**Examples of involvement in the Agency's activities NOT falling under the scope of Policy 0044, thus NOT requiring registration as medicine expert in EMT**
Attendance/participation in meetings (in-person or remotely) of EMA committees and of other groups referred to in Policy 0044.	Participation in meetings on **templates** (CxMP AR templates, SmPC template, etc.).
Attendance/participation in EMA meetings (in-person or remotely), including for involvement in scientific assessments of **medical devices**[3].	Participation in **workshops or trainings**, with or without industry representatives, organised by EMA.
Involvement in the development and update of **scientific guidelines**, including the provision of comments.	Participation in EudraVigilance Expert Working Group (EV-EWG) on Important Medical Terms (IME) list.
Written consultation by patient experts on medicinal products' applications (Scientific advice/Protocol Assistance procedure, Marketing Authorisation application, etc.).	
Participation in **inspections requested by EMA**.	

NB: The following participants in meetings falling under Policy 0044 do not require registration in EMT: European Commission representative in EMA's scientific committees, observer from non-EU/EEA regulators, invited speakers.

3. General considerations

3.1. Completing the DoI

The DoI should be completed in the EMT upon receipt of instructions on EMA account creation and EMT access. Please refer to the technical guidance available under 'Useful information' on the EMT landing page. At the time of registration in the EMT, ensure that you complete all registration steps from beginning to end, i.e. contact details, areas of expertise, DoI, CV, nominating authority and request submission. Also ensure to complete each step in one session, in particular the DoI and CV, for data to be saved (if you stop before the end of the step, the data already entered will be lost).

[3] This does not correspond to EXPAMED activities and registration in EMT as EXPAMED expert but to MDSSG activities and to EMA's regulatory responsibilities for different categories of medical device, including *in vitro* diagnostics.

You will not be able to save and submit your DoI in the EMT unless all sections have been filled.

The DoI also contains a confidentiality undertaking whereby you acknowledge your obligation of professional secrecy and commit (a) to treat all Confidential Information and Confidential Documents under conditions of strict confidentiality, (b) not to disclose, or authorise any other person to disclose, in any way to any third party any Confidential Information or Confidential Document and (c) not to use, or authorise any other person to use, any Confidential Information or Confidential Document other than for the purposes of your work in connection with EMA activities.

Prior to completing the DoI, please read carefully the policy. In particular, attention should be paid to the definitions (which are also included under the different sections and in Annex of this guidance), the explanatory notes included under each section of the DoI in the EMT and the additional guidance provided in this document.

You will need to declare all your interests in the pharmaceutical industry, the medical device industry as well as in research organisations. If you are a CAT member or alternate, you will also need to declare interests in the biotechnology sector.

Depending on the nature of the interest, you should declare:

- either *only current* interests (this is the case e.g. for 'financial interests', 'grant/funding to the expert's organisation/institution' and 'close family member interest');
- or *both current* and *past* interests.

Current interests are interests which are existing at the time of completion of the DoI, during the member's mandate or at the time of involvement of an individual in a specific activity. An engagement/contract with a company of a recurring nature is considered as a current interest.

Past interests are those that were held or ended anytime in the 3 years prior to submission of a DoI. It is therefore important to state clearly the start date and end date of the interest.

EMA applies restrictions in relation to companies as they are declared in DoIs, thus you should always state the name of the company to which the interest relates. You are not expected to refer **to any subsidiary or parent company(ies)** of the company to which your interest relates or to include the **city** and/or **country** where the company is based.

Upon submission of your DoI, an interest level will be assigned either as no interest declared, indirect or direct interest declared. Your DoI, assigned interest level and curriculum vitae will be **published on the European experts page of the EMA website**.

EMA processes personal data in accordance with the applicable legislation. For more information, you can refer to the 'Data Protection Notice regarding the Experts Management Tool and the handling of competing interests'.

This procedural guidance provides examples of activities that are expected to be declared (or not) for the various categories of interests, to help experts completing the DOI form. The list of examples is not meant to be exhaustive.

It is the responsibility of experts to fill in the declaration of interests in a complete and accurate manner.

3.2. Evaluation of the DoI

On the basis of the submitted DoI, and prior to your involvement in an EMA activity, the Agency evaluates the declared interests according to the tables provided in Annexes 1, 2 and 3 of Policy 0044. If any clarification is required during the evaluation of the DoI, EMA will contact you. EMA may request you to provide more information/details and/or to submit an updated DoI, as appropriate, to correctly reflect the declared interest(s).

The DoI evaluation determines your level of participation in the EMA activity concerned. Certain interests are incompatible with your participation in any of the Agency's activities, whereas for others, your involvement is possible but subject to certain restrictions.

The evaluation of your DoI **takes into account 3 factors**: the nature of the declared interest, the timeframe during which such interest occurred, as well as the type of involvement in the EMA activities (i.e. which group and your role in the group). The restrictions and associated codes can be found in the tables annexed to Policy 0044.

In the exceptional cases where you are prevented from declaring fully all your current and/or past interests **due to contractual arrangements** (e.g. a non-disclosure agreement with a former employer), you should inform EMA and this may affect your participation in the Agency's activities. **You have the obligation**, when attending EMA meetings (in person or remotely), to declare competing interests in relation to agenda items at the start of the meeting (at the latest when the agenda item comes up).

In case the Agency becomes aware/is informed of any interests that have not been included in your DoI, the Agency will contact you to request a clarification and, if required, request you to submit an updated DoI. Failure to fill in the DoI in a complete and/or correct manner may be considered as a breach of trust towards EMA. Appropriate actions may be taken in accordance with the procedure described in the 'European Medicines Agency breach of trust procedure for competing interests of and disclosure of confidential information by scientific committees' members and experts'.

3.3. Change to your interests or circumstances

Should you acquire any additional interests or should your interests have changed since your last DoI, you must submit an **updated DoI without delay** within the EMT. You also need to update your DoI on an annual basis, as required by legislation. An automated reminder will be sent to you to do so, via the EMT.

If you are a scientific committee/working party/SAG/ETF/MSSG/MDSSG member and intend to engage (irrespective if a contract has been signed or not) in paid or unpaid occupational activities (such as employment) with a pharmaceutical or medical device company or in activities in research organisations that are incompatible with participation in any activities at EMA, please inform the Agency immediately, refrain from involvement in any EMA activities and comply with any additional conditions which EMA may consider appropriate to impose. Please refer to the published 'Guidance on handling Management Board, scientific committee or other group member's intention to engage into occupational activities'.

4. Different types of interests

Before completing the DoI, it is essential to read and understand the **definitions** of the terms used in Policy 0044. These definitions are reproduced in this document in boxes, under the relevant interest category and in the Annex.

For some interests (e.g. employment, consultancy/strategic advisory role), you will need to specify whether:

- the activities undertaken pertain to 'general matters' (i.e. non-product/device specific). 'General matters' is understood as undertaking activities at the company that are non-product/device specific or holding a transversal role;
- or they are 'product/device-related' (i.e. related to one or more medicinal products/medical devices).

For 'product/device-related' interests, you will need to provide in the relevant DoI section:

- the name* of the medicinal product/medical device;
- the condition or the therapeutic indication of each medicinal product; for medical devices: the intended purpose;
- the name of the pharmaceutical company/medical device company.

* When declaring an interest related to medicinal product(s), please provide the name of the active substance i.e. preferably the **International Non-proprietary Name (INN)** or the product's code if an INN has not yet been assigned. You can search for INNs in the List of substances in the Substance Management Service (SMS) and EU Telematics Controlled Terms databases of EMA.

Your interests are to be declared irrespective of whether they relate to human or veterinary medicines.

A foundation or similar organisation bearing the name of a pharmaceutical or medical device company and/or funded by a single pharmaceutical or medical device company is considered equivalent to a pharmaceutical or medical device company.

It is your **responsibility** to ascertain whether any current or past activity corresponds to an interest to be declared under Policy 0044. It is especially advised that this is done prior to engaging with **any consortium, partnership, alliance or collaboration involving a private (industry) entity**.

4.1. Employment in a company

When completing the DoI, you should declare:

- any **past** employment in a pharmaceutical company (DoI section 2.1.1);
- any **past** employment in a medical device company (DoI section 2.2.1);
- *for CAT members & alternates only*: any **past** employment in a company in the biotechnology sector (DoI section 2.1.7.1).

Past employments to be declared are those **in the last 3 years**.

Employment with a company: any form of occupation, part-time or full-time, paid or unpaid.

Current employment in a pharmaceutical company or in a medical device company is incompatible with involvement in any of the Agency's activities. *For CAT only*: current employment in a company in the biotechnology sector is incompatible with participation as a member, alternate or chair of the CAT. If it is the case, the EMT will not allow you to submit the DoI form and thus to register as an expert.

If you were employed in a CRO or company providing consultancy services or if you were self-employed and had pharmaceutical and/or medical device companies amongst your clients, please:

(a) declare the name of the CRO, consultancy company or your business company under 'Employment' and
(b) declare under 'Consultancy or strategic advisory role' the names of the companies to which CRO or consultancy services were provided and, where relevant, the names of the medicinal product(s)/medical device(s) with the respective condition/therapeutic indication/intended purpose and the time period. See the comment above about the name of medicinal products.

If you were **employed in a notified body:**

(a) declare the name of the notified body under 'Employment' and

(b) declare under 'Consultancy or strategic advisory role' all medical devices which you have been involved with whilst employed at the notified body, indicating for each medical device: the name of the medical device company, the medical device's name and intended purpose and the time period.

If you were **employed by a recruitment agency** and you were **assigned to** work full-time or part-time at **one or more pharmaceutical or medical device companies**, declare the names of these companies under 'Employment' and, where relevant, the names of the medicinal product(s)/medical device(s) with the respective condition/therapeutic indication/intended purpose and the time period.

See the comment above about the name of medicinal products.

Where you carried out **both 'general matters' activities and 'product/device-specific' activities** during the same period of employment, please enter this information separately per activity. Click on 'Add' to create a new entry for the other activity and provide the sought information while mentioning the same company name and the same period.

In the event that your **activity within a company changed** during the period of employment, please enter this information separately per period. Click on 'Add' to create a new entry for the next activity and provide the sought information while mentioning the same company name and the relevant time period.

Expected to be declared in category 'Employment in a company'	Examples of what is NOT expected to be declared
Employment in companies manufacturing **active pharmaceutical ingredients**.	Employment in companies manufacturing only **non-active pharmaceutical ingredients/excipients**.
Employment in a **pharmaceutical or medical device company**.	Employment in an **intellectual property firm**, which provides legal advice and services to pharmaceutical and/or medical device companies (among others) relating only to their intellectual property interests (patents, supplementary

Expected to be declared in category 'Employment in a company'	Examples of what is NOT expected to be declared
	protection certificates, trademarks, designs, other intellectual property matters).
Employment in a **CRO or company providing consultancy services** (e.g. regulatory affairs, public affairs and advocacy, marketing and advertisement) to pharmaceutical and/or medical device companies.	Employment in a **retail pharmacy** (group) provided that it does not fall under any of the definitions in the Annex of this guidance.
Self-employment, with pharmaceutical and/or medical device **companies amongst your clients**.	Employment in companies developing IT applications/software for pharmaceutical and medical device companies, e.g. for managing products' stocks.
Employment in a **notified body** with a consultancy or strategic advisory role to medical device companies.	
If you were **employed by a recruitment agency** and you were assigned to work full-time or part-time at one or more pharmaceutical or medical device companies.	
Employment **activities pertaining to 'general matters'** in roles such as statistician, medical manager, global medical advisor, Qualified Person (QP), Qualified Person for Pharmacovigilance (QPPV) in a pharmaceutical or medical device company.	
Employment in a national or European **organisation or association representing an industry**. For example, a past employment in an industry trade association representing pharmaceutical companies should be declared as a past employment in a pharmaceutical company.	
Employment in a company developing **products at the borderline between medicinal products and medical devices** (e.g. implantable hydrogels) is to be declared as employment in a pharmaceutical company, even if the company is still investigating the applicable regulatory framework.	

4.2. Consultancy/strategic advisory role

When completing the DoI, you should declare:

- any **current** or **past** consultancy/strategic advisory role to a pharmaceutical company (DoI section 2.1.2);
- any **current** or **past** consultancy/strategic advisory role to a medical device company (DoI section 2.2.2);
- *for CAT members & alternates*: any **current** or **past** consultancy/strategic advisory role to a company in the biotechnology sector (DoI section 2.1.7.2).

Past consultancy/strategic advisory roles to be declared are those held **in the last 3 years**.

Consultancy or strategic advisory role to a company: any activity where the individual concerned provides advice to a company regardless of contractual arrangements or any form of remuneration. This includes lectures, presentations or training organised by individual companies, participation (with a right to vote/influence the outputs) in a(n) (scientific) advisory board, steering committee or executive committee with the role of providing advice/expressing opinions on the (future) strategy, direction and development activities of the company concerned.

If you provided services to companies, whilst employed in a CRO or company providing consultancy services or if you were self-employed and had pharmaceutical and/or medical device companies amongst your clients, please:

(a) declare the name of the CRO, consultancy company or your business company under 'Employment' and
(b) declare under 'Consultancy or strategic advisory role' the names of the companies to which CRO or consultancy services were provided and, where relevant, the names of the medicinal product(s)/medical device(s) with the respective condition/therapeutic indication/intended purpose and the time period.

See the comment above about the name of medicinal products.

Expected to be declared in category 'Consultancy/strategic advisory role'	Examples of what is NOT expected to be declared
Involvement in **lectures, presentations or training organised by individual companies**, given **to participants invited by the companies** (company staff or not) **and not open to the public** (at the company premises or not).	Participation in European societies/treatment groups/focus groups providing **general advice** (e.g. on development programmes, design of clinical studies & treatment strategy in a specific therapeutic area) **to several companies** (not one single company).
Consultancy/strategic advisory activities pertaining to **'general matters'** such as antimicrobial resistance, development of outcome measures, optimisation of treatment outcomes, disease treatment/management, disease landscape in EU.	Consultancy on other **general health related matters** e.g. human nutrition, animal feed, not connected to human or veterinary medicinal products.
Participation of patient organisations' representatives in a **non-public meeting** on the	Participation as speaker, panellist or in a similar role **in an industry symposium that is**

Expected to be declared in category 'Consultancy/strategic advisory role'	Examples of what is NOT expected to be declared
initiative of a company to discuss **patients' views** on diseases, conditions, treatments or on medicinal product's/medical device's development.	**satellite or parallel to a conference/congress/seminar** and **sponsored by more than one company**, as long as the symposium is open to all participants in the conference/congress/seminar and no speaker fee is received.
Interactions with pharmaceutical or medical device companies through involvement in **Community Advisory Boards**.	Involvement in a grant review panel from the European Institutions.
Involvement in a **Patient Advisory Committee** for a pharmaceutical company, even if participation is governed by an agreement with an advocacy network or foundation.	Provision of **advice to academia**.
Provision of training courses to **companies** or to **CROs** (whether on their direct request or via a for-profit entity).	Participation as **speaker, panellist or in a similar role at conferences[4], congresses and seminars sponsored by (or with the involvement of) more than one company** and **open to the public** (i.e. participants can decide individually to participate in the event, whether it is a fee or non-fee paying event) **with only reimbursement of reasonable expenses** incurred in relation to attendance (i.e. accommodation, meals and travel costs).
Provision of advice to a company as part of the activities undertaken under a private-public partnership/consortium/alliance.	**Advice provided by a competent authority**, e.g. scientific advice procedure, notified body consultation procedure, HTA consultation procedure.
Membership of the board of a **journal fully sponsored and/or published by a company**.	Review of manuscripts, including those submitted by a company, as **peer reviewer for a scientific journal**.
Involvement in the **board of a registry sponsored by a company**, i.e. patient, product or disease registry.	**Writing and/or editing activities on health-related topics** (diseases, medicines, health in general, etc.) provided that such work is not performed at the request of or sponsored by a company.
Involvement in a **committee/board/panel set up by a company**, e.g. an ethics committee, a board to distribute scholarships funded by the company to academic researchers, a panel to	

[4] Please refer to EMA Policy 0029 on participation to external events and membership in professional bodies.

Expected to be declared in category 'Consultancy/strategic advisory role'	Examples of what is NOT expected to be declared
assess the cost-effectiveness of a (combination) product.	
Participation in a **podcast** organised/sponsored by one company and where the podcast is available only on the website of the company.	

4.3. Financial interests

When completing the DoI, you should declare:

- any **current** financial interest in a pharmaceutical company (DoI section 2.1.3);
- any **current** financial interest in a medical device company (DoI section 2.2.3);
- *for CAT members & alternates*: any **current** financial interest in a company in the biotechnology sector (DoI section 2.1.7.3).

Past financial interests do not need to be declared.

Financial interests in a company

- Holding of stocks and shares, stock options, stock warrants, restricted stock units, equities, bonds, ownership or partnership interest in the capital of such company. *The holding of financial interests through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements do not need to be declared provided that they are diversified (i.e. not exclusively based on the sector concerned) and they are independently managed (i.e. the individual has no influence on their financial management).*

- Compensation, fees, honoraria, grant or other funding (including rents, sponsorships and fellowships) paid by a company to the individual in a personal capacity.

- Intellectual property rights including patents, trademarks, know-how and/or copyrights for a medicinal product, a medical device or relating to the biotechnology sector owned by the individual or for which the individual is a direct beneficiary.

In case you have declared current financial interests and prior to your involvement, EMA will contact you to inform you that such interests are **incompatible with involvement in the Agency's activities** and will ask you whether you intend to take any action in respect to the declared interests and if so, to submit an updated DoI.

Financial interests in any pharmaceutical company in the **human and/or veterinary domain** or in any medical device company from any class of medical device should be declared in the DoI, irrespective of the nature of the EMA activity in which you are involved. For example, even if you are involved only in medicinal products for veterinary use, it is still required that you declare financial interests, e.g. shares, in a pharmaceutical company with only medicinal products for human use.

Policy 0044 does not establish any threshold value for financial interests (above-mentioned stocks and shares, stock options, etc.), thus they have to be declared irrespective of the amount.

Please note the following:

- Salaries, compensation, fees or honoraria received in the context of employment should not be declared in this interest category: this is covered by the interest to be declared under section 2.1.1 or 2.2.1 'Employment'.
- Salaries, compensation, fees or honoraria received in the context of consultancy/strategic advisory role should not be declared in this interest category: this is covered by the interest to be declared under section 2.1.2 or 2.2.2 'Consultancy/strategic advisory role'.

Expected to be declared in category 'Financial interests'	Examples of what is NOT expected to be declared
Holding of **stocks** and **shares**, **stock options**, **stock warrants**, **restricted stock units**, **equities**, **bonds**, **ownership or partnership interest in the capital** of a pharmaceutical company or a medical device company, including companies manufacturing active pharmaceutical ingredients.	Shares and other financial interests in a **company other than** a pharmaceutical company and a medical device company (e.g. suppliers of non-active pharmaceutical ingredients/excipients).
Compensation, fees, honoraria, grant or other funding (including rents, sponsorships and fellowships) **paid by a company** to the individual in a personal capacity.	Investment in a **fund**, pension fund and/or interests in non-nominal unit trusts or similar arrangements that are **diversified** (i.e. not exclusively based on the sector concerned) **and independently managed** (i.e. the individual has no influence on their financial management).
Intellectual property rights including patents, trademarks, know-how and/or copyrights for a medicinal product, a medical device or relating to the biotechnology sector owned by the individual or for which the individual is a direct beneficiary.	**Participation in a pension fund** related to a past employment in a company, where the fund is organised for the employees and where the individual only receives the pension at the age of retirement and does not have any control on the composition of the fund or on the payment date of the pension.
Being the **owner of a patent** for a medicinal product or a medical device, **with or without financial compensation**.	**Inventorship of a patent** for a medicinal product or a medical device i.e. when you are **an inventor named on a patent without ownership or any form of financial compensation**.
Receipt of **financial compensation** from being the **direct beneficiary of a patent** for a medicinal product or a medical device.	**Pending patent** for a medicinal product or a medical device.
Receipt of **a fee/honorarium from a company for writing a scientific publication**.	Receipt of payment for or reimbursement of **reasonable expenses** (i.e. accommodation, meals and travel costs) **directly related to attendance at conferences/seminars/ courses** (including those accredited for **continuing development**) funded by the

Expected to be declared in category 'Financial interests'	Examples of what is NOT expected to be declared
	pharmaceutical industry or the medical device industry.
Receipt of a **speaker fee or lecturer's honorarium**, from a company for **delivering a presentation or training** on a disease/medical condition, treatments or results of research work on a disease/medical condition during a conference **open to the public**.	
Receipt of **a monetary prize as part of an award** sponsored by a **company**.	

4.4. (Principal) investigator

When completing the DoI, you should declare:

- any **current** or **past** investigator role or principal investigator role in a clinical study or clinical trial instigated/sponsored by a pharmaceutical company (DoI section 2.1.4);
- any **current** or **past** investigator role or principal investigator role in a clinical investigation or performance study instigated/sponsored by a medical device company (DoI section 2.2.4).

Past investigator and principal investigator interests to be declared are those held **in the last 3 years**.

Investigator: an individual responsible for the conduct of a clinical study, clinical investigation or performance study instigated/sponsored by a company, at a specific site. If a clinical study is conducted by a team of individuals at a clinical study site, the investigator who is the responsible leader for the team is the **principal investigator**. Participation in data monitoring committees (composed of independent external experts reviewing unblinded clinical study or clinical investigation data independently of the sponsor/company) falls within this definition.

The involvement of an individual as a (principal) investigator in a clinical study, clinical investigation or performance study instigated/sponsored by a company is considered ended/past after the last patient/last visit or when the study/investigation is terminated on other grounds.

Expected to be declared in category '(Principal) investigator'	Examples of what is NOT expected to be declared
(Principal) investigator in a clinical trial or clinical study for a medicinal product **sponsored by a pharmaceutical company**.	(Principal) investigator in **academic or investigator-initiated studies**/investigations.
(Principal) investigator in a clinical investigation or performance study **sponsored by a medical device company**.	**Other member** of a clinical trial/study/investigation or performance study team e.g. subinvestigator.
(Principal) investigator in a clinical trial or clinical study for a medicinal product **sponsored by a**	Role as a **clinical study coordinator** or in similar role in a hospital that implies, for example,

Expected to be declared in category '(Principal) investigator'	Examples of what is NOT expected to be declared
research organisation subject to an agreement with a company.	coordinating the study participants' appointments or sending out samples.
Member in an (**Independent**) **Data Monitoring Committee** (I)(DMC) for company-instigated studies/investigations.	Involvement, as a **blinded pathologist** employed in a hospital, in pathology assessments performed during studies/investigations.
Member in a **Data and Safety Monitoring Board** (DSMB) or a **Safety Review Committee** for company-instigated studies/investigations.	Membership or chairing of an **ethics committee** of a hospital or university.
Member in a **Clinical Ascertainment Board** for company-instigated studies/investigations.	
Role in an **adjudication committee** established in company-instigated studies/investigations.	

4.5. Grant/funding to the expert's organisation/institution

When completing the DoI, you should declare:

- any **current** grant/funding paid by a pharmaceutical company to the organisation/institution to which you belong and when you benefit directly from the grant/funding (DoI section 2.1.5);
- any **current** grant/funding paid by a medical device company to the organisation/institution to which you belong and when you benefit directly from the grant/funding (DoI section 2.2.5).

Past grant/funding to the organisation/institution to which you belong do not need to be declared.

Grant or other funding to the expert's organisation/institution: any funding from a company received by the organisation/institution to which the individual belongs, or for which he/she performs any kind of activity, and which is used specifically to support any activity of the individual.

Please note the following:

- Funding received in the context of a company instigated/sponsored clinical study, clinical investigation or performance study for which you are the (principal) investigator should not be declared in this interest category: this is covered by the (principal) investigator interest to be declared under section 2.1.4 or 2.2.4 '(Principal) Investigator'.
- Funding received in the context of an agreement with a company in the conduct of research and development activities relating to a medicinal product or a medical device in which you are involved should not be declared in this interest category: it should be declared in section 2.3.4 'Involvement in the conduct of research and development subject to an agreement with a company'.

Expected to be declared in category 'Grant/funding' IF current	Examples of what is NOT expected to be declared
Grant/funding received by your organisation/institution **from a pharmaceutical company or a medical device company** and with **direct benefits** to you, for example: - it contributes towards your salary - you can use it to purchase (laboratory) equipment or appliances - it supports and/or covers expenses for your activities, e.g. research projects, at the organisation/institution - it allows you to engage one or more staff member(s), PhD student(s), etc.	Grant/funding allocated to you by your organisation/institution where you are **not able to identify the source** of the grant/funding received by your organisation/institution.
	Honorarium received from a publisher for moderating a session in relation to a scientific publication/book chapter (honorarium paid from **a grant obtained by the publisher** as an independent medical education grant from a pharmaceutical company that has no role in selection of topics, scientists and presenters).

4.6. Close family members interests

When completing the DoI, you should declare:

- any **current** direct interests held, by a first-line member of your family, in a pharmaceutical company (DoI section 2.1.6);
- any **current** direct interests held, by a first-line member of your family, in a medical device company (DoI section 2.2.6).

Past close family member interests do not need to be declared.

Close family members interests: direct interests in a company held by first-line members of the individual's family (i.e. a spouse or a partner, children and parents). **Partner** is a natural person with whom the individual is registered as having a stable non-marital partnership legally recognised as such by a Member State or any competent authority of a Member State, acknowledging their status as non-marital partners.

First-line members are **a spouse or partner**, **children and parents**, irrespective if they are living at the same address as you or not. The exact relationship with the family member (e.g. 'spouse', 'husband', 'wife') should not be mentioned.

Please state the type of direct interest held by the family member and the name of the pharmaceutical or medical device company. In case of several interests of your family member, an entry per company should be included in the DoI.

If you become aware that the pharmaceutical or medical device company where your first-line family member is employed has **merged with another company**, please update your DoI to reflect the name of the current employer.

Expected to be declared in category 'Close family member interests'	Examples of what is NOT expected to be declared
Current employment of your first-line family members **in a pharmaceutical or medical device company** (as well as employment in a national or European organisation or association representing the pharmaceutical or medical device industry).	**Any past interests** of your first-line family members.
Current consultancy/strategic advisory role by your first-line family members **to a pharmaceutical or medical device company**.	Interests of **other family members** (e.g. sibling, brother-in-law, parent-in-law, cousin).
Current financial interests of your first-line family members **in a pharmaceutical or medical device company**.	
Current employment of your first-line family members in a **CRO or consultancy company**. If known, state in separate entry(ies) the name of the pharmaceutical or medical device company(ies) to which CRO or consultancy services are provided by your first-line family member.	

4.7. Affiliation to a research organisation

When completing the DoI, you should declare:

- any **current** affiliation to a research organisation (DoI section 2.3.1).

Affiliation to a research organisation: being employed by, associated with or otherwise belonging to a research organisation, part-time or full-time, paid or unpaid.

If you are **affiliated to more than one research organisation**, please declare each affiliation separately.

When affiliated to a university, please ensure that the name provided allows identification of the university concerned (include the name and the city, without its full address).

Please also complete the other parts of DoI section 2.3 if you are currently affiliated to a research organisation or were affiliated in the last 3 years as relevant.

Expected to be declared in category 'Affiliation to a research organisation'	Examples of what is NOT expected to be declared
Employment at a research organisation.	Affiliation to a hospital or organisation that does not pursue scientific research.

Expected to be declared in category 'Affiliation to a research organisation'	Examples of what is NOT expected to be declared
Lecturer, guest professor (or similar role) teaching and/or doing scientific research at a university.	Affiliation to an organisation allocating funding towards educational expenses, scientific research projects/initiatives, etc.
Guest researcher in a hospital.	Membership in **learned societies such as medical associations and scientific professional bodies** whose primary goal is not to pursue scientific research but to create a forum for the exchange of new research results, to offer continuing development courses and events, etc.
Membership in a university's committee for the evaluation of teaching and courses offered by the university's faculties.	Affiliation to or collaboration with European Reference Networks (ERN) for rare diseases.
Current enrolment into a research programme at university (e.g. PhD, post-doctorate).	

4.8. Involvement in a unit within a research organisation that manufactures medicinal products or medical devices

When completing the DoI, you should declare:

- any **current** or **past** involvement in a unit that manufactures medicinal products (DoI section 2.3.2);
- any **current** or **past** involvement in a unit that manufactures medical devices (DoI section 2.3.2).

Past involvements to be declared are those **in the last 3 years**.

Involvement in a unit that manufactures medicinal products or medical devices: any involvement (through employment or collaboration) in a research organisation's unit that manufactures medicinal products (including ATMPs under the hospital exemption) or medical devices. The term "**unit**" may also refer to a 'section', 'department' or 'entity', according to the term used within the research organisation.

Expected to be declared in category 'Involvement in a unit within a research organisation that manufactures medicinal products or medical devices'	Examples of what is NOT expected to be declared
Employment in **a research organisation's unit that manufactures medicinal products** (including ATMPs under the hospital exemption) or **medical devices**.	Involvement in a **hospital pharmacy** that manufactures magistral preparations, official (pharmacopeia) formula, medicinal products intended for clinical trials, radionuclides in the form of sealed sources, or medical devices **used only within the hospital concerned**.
Collaboration with **a research organisation's unit that manufactures medicinal products**	Involvement in a **hospital pharmacy** that prepares or reconstitutes medicinal products

Expected to be declared in category 'Involvement in a unit within a research organisation that manufactures medicinal products or medical devices'	Examples of what is NOT expected to be declared
(including ATMPs under the hospital exemption) or **medical devices**.	including radiopharmaceuticals **used only within the hospital concerned**.
Position within the research organisation **with oversight responsibilities for the activities conducted in the unit** that manufactures medicinal products or medical devices, for example the head of the research organisation.	
Employment in **not-for-profit blood donor services** that also manufacture medicinal products.	

4.9. Involvement in a unit within a research organisation that acts as a marketing authorisation applicant or holder for a medicinal product

When completing the DoI, you should declare:

- any **past** involvement in a unit that acts as a marketing authorisation applicant or holder for a medicinal product (DoI section 2.3.3).

Past involvements to be declared are those **in the last 3 years**.

Involvement in a unit that acts as a marketing authorisation applicant or holder for a medicinal product: any involvement (through employment or collaboration) in a research organisation's unit that acts as a marketing authorisation applicant or holder for a medicinal product. The term "**unit**" may also refer to a 'section', 'department' or 'entity', according to the term used within the research organisation.

Current involvement in a unit within a research organisation that acts as a marketing authorisation applicant or holder for a medicinal product is incompatible with involvement in any of the Agency's activities. If it is the case, the EMT will not allow you to submit the DoI form and thus to register as an expert.

Expected to be declared in category 'Involvement in a unit within a RO that acts as MA applicant/holder'	Examples of what is not expected to be declared
Employment at a research organisation that is the marketing authorisation applicant or holder of a medicinal product **and working in or collaborating with the unit** that is responsible for the submission and/or maintenance of the marketing authorisation and for the interaction with EMA.	
Collaboration with a research organisation's unit responsible for the submission and/or	

Expected to be declared in category 'Involvement in a unit within a RO that acts as MA applicant/holder'	Examples of what is not expected to be declared
maintenance of the marketing authorisation of a medicinal product and for the interaction with EMA.	
Position within the research organisation **with oversight responsibilities for the activities conducted in the unit** that acts as a marketing authorisation applicant or holder for a medicinal product, for example the head of the research organisation.	

4.10. Involvement in the conduct of research and development activities for a medicinal product or medical device subject to an agreement with a company

When completing the DoI, you should declare:

- any **current** or **past** involvement in the conduct of research and development activities for a medicinal product or a medical device subject to an agreement with a pharmaceutical or medical device company (DoI section 2.3.4).

Past involvements to be declared are those **in the last 3 years**.

Involvement in the conduct of research and development activities subject to an agreement with a company: any involvement in the conduct of research and development activities at a research organisation for a medicinal product or a medical device subject to an agreement with a company.

Please note the following:

- Involvement as a (principal) investigator in a clinical trial or clinical study for a medicinal product sponsored by a research organisation subject to an agreement with a pharmaceutical company should not be declared in this interest category: this should be declared in the DoI section 2.1.4 (Principal) investigator.
- Involvement as a (principal) investigator in a clinical investigation or performance study for a medical device sponsored by a research organisation subject to an agreement with a medical device company should not be declared in this interest category: this should be declared in the DoI section 2.2.4 (Principal) investigator.

Expected to be declared in category 'Involvement in the conduct of R&D activities subject to an agreement with a company'	Examples of what is NOT expected to be declared
Involvement in the conduct of research or (clinical) development of a medicinal product or a medical device through sponsorship or any form of commercial arrangement (e.g. specific	Agreement with a company for the sole purpose of enrolment of patients in a **compassionate use/expanded access programme**.

Expected to be declared in category 'Involvement in the conduct of R&D activities subject to an agreement with a company'	Examples of what is NOT expected to be declared
funding, licensing agreement, strategic alliance) with a company.	
Position with oversight responsibilities in a research organisation (including a public-private partnership or a consortium) that conducts R&D activities relating to a medicinal product or a medical device subject to an agreement with a company.	Agreement with a company related to the **provision of a medicinal product or medical device** for investigator-initiated trials.
Project manager, statistician or researcher of a non-profit organisation leading and coordinating the conduct of an independent trial but sponsored by a pharmaceutical company.	Involvement in the conduct of research and/or testing (e.g. microbiological purity test, cytotoxicity test) for companies other than pharmaceutical and medical device companies.

4.11. Regulatory engagement on academic research

When completing the DoI, you should declare:

- any **current** and **past** regulatory engagement on academic research (DoI section 2.3.5).

Past involvements to be declared are those **in the last 3 years**.

Regulatory engagement on academic research: any involvement in academic research (including those conducted as part of public-private partnerships) on a medicinal product or medical device subject to regulatory interactions with the Agency. This includes for example academic research subject to a request for scientific advice or qualification of novel methodologies, submission of paediatric investigation plan, submission of orphan designation request, request for support and advice on the repurposing of a medicinal product or early interaction tools offered by the Agency (e.g. Innovation task force, PRIME designation).

Regulatory interactions with the Agency such as scientific advice and all other interactions listed in the definition above and in the table below should be declared **only when you are, or were, involved in the interaction and**:

- when you or your research team is **currently preparing for** a regulatory interaction with the Agency, or
- when the regulatory interaction with the Agency **is ongoing**, or
- when the regulatory interaction with the Agency **took place within the past 3 years**.

Expected to be declared in category 'Regulatory engagement on academic research'	Examples of what is NOT expected to be declared
Involvement in academic research (including those conducted as part of public-private	Submission of clinical trial applications to national competent authorities.

Expected to be declared in category 'Regulatory engagement on academic research'	Examples of what is NOT expected to be declared
partnerships) on a medicinal product **subject to a request for scientific advice** at EMA.	
Involvement in academic research (including those conducted as part of public-private partnerships) on a **novel methodology subject to qualification procedure** at EMA.	Support received by EMA CTIS User Support Services during the submission of a clinical trial application.
Involvement in academic research (including those conducted as part of public-private partnerships) on a medicinal product **subject to submission of paediatric investigation plan** at EMA.	Involvement as data partner (data analyst, data programmer) in DARWIN EU studies.
Involvement in academic research (including those conducted as part of public-private partnerships) on a medicinal product **subject to submission of orphan designation request** at EMA.	Involvement in academic research (including those conducted as part of public-private partnerships) on the repurposing of a medicinal product subject to regulatory interactions **at national level**.
Involvement in academic research (including those conducted as part of public-private partnerships) on a medicinal product **subject to request for support and advice on the repurposing of a medicinal product** at EMA.	
Involvement in academic research (including those conducted as part of public-private partnerships) on a medicinal product or medical device **subject to early interaction tools** offered by the Agency (e.g. **Innovation Task Force**, **PRIME designation**).	
Involvement as investigator in **research commissioned by one of the Agency's scientific committees** (e.g. through DARWIN EU).	

4.12. Any other information

Please use section 2.4 of the DoI for additional information that you would like to declare, e.g. if you were asked for an expert opinion in the context of judicial proceedings relating to a medicinal product or medical device, as long as the participation is not subject to confidentiality of the proceedings, or in case you decide, at your own initiative, not to participate in a specific activity (voluntary restricted involvement).

5. Changes since last revision

Date	Revision	Scope of revision - sections revised (new or extended examples)
May 2025	Rev. 2	Adaptation to revised Policy 0044 entering into force on 1 May 2025
July 2025	Rev. 3	Sections 4.1, 4.2, 4.6, 4.7, 4.10, 4.11
March 2026	Rev. 4	Sections 4.1, 4.2, 4.3, 4.4, 4.10, 4.11, 4.12

Annex

Definitions

- **Affiliation to a research organisation**: being employed by, associated with or otherwise belonging to a research organisation, part-time or full-time, paid or unpaid.
- **Company in the biotechnology sector**: any legal or natural person involved in the biotechnology sector whose research, development, manufacturing, maintaining, marketing and/or distribution activities are closely linked to ATMPs, i.e.: blood, cells and tissues establishments and manufacturers of critical starting materials for ATMPs, e.g. viral vector manufacturers. The definition also includes natural and legal persons to which activities relating to the research, development, manufacturing, maintaining, marketing and/or distribution closely linked with ATMPs (which might also be carried out in house) are outsourced on a contractual basis.
  Consultancy companies providing advice or services relating to the above activities fall under the definition of companies in the biotechnology sector.
  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 company in the biotechnology sector), (ii) are controlled by or (iii) are under common control of the company in the biotechnology sector, shall be considered as a company in the biotechnology sector for the purposes of Policy 0044.
- **Medical device company**: any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medical devices or in vitro diagnostic medical devices. The definition also includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices or in vitro diagnostic medical devices (which might also be carried out in house) are outsourced on a contractual basis.
  Notified bodies, Contract Research Organisations (CROs) and consultancy companies providing advice or services relating to the above activities, or to activities linked with certification or other regulatory procedures, fall under the definition of a medical device 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 medical device company), (ii) are controlled by or (iii) are under common control of the medical device company, shall be considered as medical device companies for the purposes of Policy 0044.
- **Pharmaceutical company**: any legal or natural person whose focus is to research, develop, manufacture, market and/or distribute medicinal products. The definition also 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.
  Contract Research Organisations (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 Policy 0044.

- **Research organisation:** any entity, including but not limited to public or private non-profit organisations, universities, hospitals or learned societies, whose primary goal is to pursue scientific research or to do so alongside the provision of educational and/or healthcare services. However, and by way of an exception, any unit within a research organisation that develops or manufactures medicinal products (including ATMPs under the hospital exemption) or medical devices or acts as a marketing authorisation applicant or holder for a medicinal product may be considered in the same way as a pharmaceutical company or a medical device company. Other parts of the organisation to which the unit belongs are not considered as a pharmaceutical or medical device company.
  The term "**universities**" covers public or private higher education establishments awarding academic degrees. The term "**hospital**" includes (also) university hospitals. The term "**learned societies**" covers non-profit organisations that exist to promote an academic discipline or profession, or a group of related disciplines or professions.
- **Repurposing of a medicinal product** means the process of identifying a new therapeutic use for an existing medicinal product for which data exclusivity, market protection periods and basic patent/supplementary protection certificate (SPC) protection have lapsed.