



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Declarations of Interests: a practical guide

An agency of the European Union 

In this video we will take you through a step by step process of how to complete and submit the forms required by all experts participating in EMA activities...



What the legislation says

Extract from Article 63(2) of Regulation (EC) No 726/2004

Members of [...] the committees, rapporteurs and experts **shall not have** financial or other **interests in the pharmaceutical industry which could affect their impartiality.**

They shall undertake to act in the public interest and in an independent manner, and shall make an **annual declaration of their financial interests.** All indirect interests which could relate to this industry shall be entered into a register held by the Agency which is accessible to the public, on request, at the Agency's offices ...



The EMA has a policy on the handling of declarations of interests, which is a requirement of the Regulation that is shown here.



EMA Policy on the handling of declarations of interests of committees' members and experts

Right balance between access to leading experts and guaranteeing experts have no ties to industry affecting their independence and impartiality

Applicable to

- Scientific committee and working party members and alternates
- Experts involved in EMA activities
 - In the context of authorisation and surveillance of medicinal products for human and veterinary use
 - Meeting attendance
 - Involvement in scientific assessment and guidance development
 - Participation in inspections

2 Handling declarations of interests



The spirit of the policy is to strike the right balance for involving experts in EMA activities.

All experts need to demonstrate their independence and impartiality.

This applies to members and alternates of scientific committees and working parties as well as other experts involved in any Agency activities.



Requirements for involvement in EMA activities

Experts must be included in the Experts database prior to first appointment in a committee or working party or first involvement in an EMA activity.

Experts must have completed the following documents:

1. Up-to-date **Declaration of Interests (DoI)/ Confidentiality undertaking form**
2. Up-to-date **curriculum vitae (CV)** (required to validate the DoI)
3. Up-to-date **Expert Nomination form**

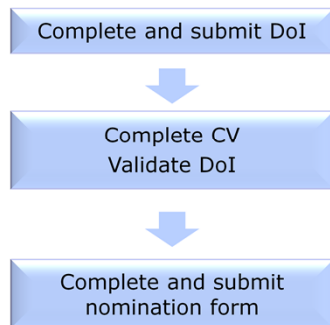
To participate in EMA activities, an expert must first be included in the Experts database.

They must complete

A Declaration of interests and confidentiality form,
a curriculum vitae
and an expert nomination form.

Process

Expert



In the next few minutes we will take you through the process of completing and submitting these 3 documents.



Declaration of Interests / Confidentiality undertaking form

SECTION 1: PERSONAL DETAILS

SECTION 2: PUBLIC DECLARATION OF INTERESTS

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

SECTION 3: CONFIDENTIALITY UNDERTAKING

Let's begin with the Declaration of Interests and Confidentiality form. This document consists of 3 sections:

Personal details,

Declaration of Interests

and the Confidentiality undertaking.

Section 1 – Personal details



Public Declaration of Interests and Confidentiality Undertaking

INSTRUCTIONS

This form consists of three parts: your Personal Details, Public Declaration of Interests and Confidentiality Undertaking. All parts must be duly completed. The form is designed to be completed electronically and the data entered stored electronically. You are responsible for the accuracy and completeness of the submitted information. Please be advised that once you have submitted and signed the form, the Agency will publish your declaration of interests on its website.

WARNING - If you are already registered in the EMA's Experts database you should not fill in this blank form but rather ask us for your previous declaration for update.

SECTION 1: PERSONAL DETAILS Please click on any of the footnotes for further information.

First name:	<input type="text"/>	<small>NOTE: Please write your full first and last name as mentioned on your identity card/passport.</small>
Last name:	<input type="text"/>	
Organisation / company ¹ :	<input type="text"/>	
Country ² :	<input type="text"/>	
E-mail address:	<input type="text"/>	
Type of activity ³ :	<input type="text" value="EMA Expert (nominated for involvement in EMA activities)"/>	

1. Patients not part of any organisation or company can leave this field blank.
2. Scroll down for a full list of countries.
3. Scroll down for a list of activity types.

SECTION 2: PUBLIC DECLARATION OF INTERESTS

If you have interests to declare, please click 'Yes' to the relevant questions and provide further information. All questions in this section must be answered. Your declaration will not be accepted if any fields are left empty.

All current and/or past interests from the last 3 years should be declared. In the case of previous employment in a pharmaceutical company in an executive role or lead role in the development of a medicinal product (see section 2.1), please declare all such past interests from your entire career.

For more information on which interests to declare, please see the European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts and the procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form.

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- Complete your personal details.
- Note that all experts need to select 'EMA expert' as Type of activity

In Section 1 of the DoI form, complete the details requested.

Please ensure that you use your first and last name as they appear on any official identification papers such as a passport or identity card.

Section 2 – Public declaration of interests Employment

2.1 Employment

No Yes

Employment with a pharmaceutical company means any form of occupation, part-time or full-time, paid or unpaid, in the company. A pharmaceutical company means any legal or natural person whose focus is to research, develop, manufacture, market and/or distribute medicinal products. This 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. CROs or consultancy companies providing advice or services relating to the above activities, also fall under the definition of a pharmaceutical company. Independent researchers and research organisations including universities and learned societies are excluded from the scope of the definition of a pharmaceutical company.

Employment in a pharmaceutical company in an **executive role** and/or a **lead role** in the development of a medicinal product **AT ANY STAGE OF YOUR CAREER** should be declared. **Cross product** responsibility other than an executive role and/or **individual product** responsibility other than lead role in the development of a medicinal product **IN THE LAST 3 YEARS** should be declared.

EMPLOYMENT Please click on any of the footnotes for further information.

Time period¹: Current Past

From month: From year: To month: To year:

Name of pharmaceutical company²:

Function³:

- Executive role (at any stage of your career)
- Lead role in the development of a medicinal product (at any stage of your career)
- Cross product responsibility other than executive role (in the last 3 years)
- Individual product responsibility other than lead role in the development of a medicinal product (in the last 3 years)

Executive role means responsibility for the strategic and operational direction of a pharmaceutical company, a key role in the decision-making at strategic and operational level. **Lead role** means direct responsibility for the development of a medicinal product, other than support provided which should be reported under individual product responsibility. **For both of these roles, restrictions apply as long as you are a European expert.**

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Describe current or past employment with a pharmaceutical company and provide details.

In section 2.1, you must provide information on any employment with a pharmaceutical company.

Employment in an executive role or lead role in the development of a medicine at any stage of your career should be declared.

All other employment should be declared if it is current or within the last 3 years.

This information should correspond with what you show in your CV.

You can add more information by clicking on 'add employment'.

Consultancy

2.2 Consultancy

No Yes

Consultancy means provision of advice (including training on a one to one basis) to a pharmaceutical company regardless of contractual arrangements or any form of remuneration. A pharmaceutical company means any legal or natural person whose focus is to research, develop, manufacture, market and/or distribute medicinal products. This 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.

Note i: Scientific advice provided by the NCA of a Member State is not considered a consultancy activity. Conference/Seminar attendance is not considered as consultancy but should be mentioned under section 2.4 Financial Interests if subject to a fee/honoraria and if current.

Note ii: If you are or have been an employee of a CRO or consultancy company (i.e. a professional business offering advice or services to pharmaceutical companies), please declare this under Section 2.1 Employment.

Consultancy Please click on any of the footnotes for further information.

Time period¹: Current Past

From month: From year: To month: To year:

Name of pharmaceutical company²:

Individual product related³ Cross product relates/ general (non product related)⁴

Product name:

Therapeutic indication:

Provision of advice (including training on a one to one basis) to a pharmaceutical company regardless of contractual arrangements or any form of remuneration and of the subject matter.

Note: Employment at a consultancy company or CRO, should be declared under section 2.1 Employment.

Describe current or past (within last 3 years) consultancy to a pharmaceutical company and provide details.

In section 2.2, you must describe any consultancy activities with a pharmaceutical company that are current or within the past 3 years.

Consultancy is considered any occasion that you engage with a pharmaceutical company regardless of the subject.

This does not include participation in public meetings such as conferences

Select whether your involvement was related to an individual medicinal product or if it was cross product or non-product related.

Additional activities can be added.

Strategic advisory role

2.3 Strategic advisory role

No Yes

Strategic advisory role means participation (with a right to vote or influence the outputs) in a(n) (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the (future) strategy, direction or 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. A pharmaceutical company means any legal or natural person whose focus is to research, develop, manufacture, market and/or distribute medicinal products. This 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.

Note: Involvement in Data Monitoring committees is not included in this category. Such involvement should be recorded under section 2.6 Principal Investigator. Involvement in clinical research should be listed under section 2.5 Principal investigator or 2.6 Investigator as appropriate.

Strategic advisory role Please click on any of the footnotes for further information.

Time period¹: Current Past

From month: From year:

Name of pharmaceutical company²:

Individual product related³ Cross product related/ general (non-product related)⁴

Product name:

Therapeutic indication:

Participation (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, in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration and of the subject matter.

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Describe current or past (within last 3 years) strategic advisory role for a pharmaceutical company and provide details.

Any strategic advisory role for a pharmaceutical company needs to be declared regardless of the topic or whether you were paid for this activity.

A strategic advisory role is where you have a voting right or can influence company decisions – please refer to the definition for full details

More than one activity can be added as required.

Financial interests

2.4 Financial interests

No Yes

Financial interests mean any economic stake in a pharmaceutical company including:

- **CURRENT** holding of stocks and shares, stock options, equities, bonds and or partnership interest in the capital of a pharmaceutical company with the exclusion of the holding of financial interests through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements 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).
 - **CURRENT** compensation, fees, honoraria, salaries, grant or other funding (including rents, sponsorships and fellowships) paid by a pharmaceutical company to you in a personal capacity, other than payment for or reimbursement of expenses incurred with research work or reimbursement of reasonable expenses directly related to conference/seminar attendance (i.e. accommodation and travel costs).
 - **CURRENT** intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal product owned by you or of which you are directly a beneficiary.
- (**CURRENT** is interpreted at time of completion of this form).

Current financial interests Please click on any of the footnotes for further information.

Name of pharmaceutical company ¹	Financial interest	Add
		X

- Holding of shares, bonds, investment funds, etc in pharmaceutical companies.
- Compensation, fees, honoraria, salaries paid by a pharmaceutical company to you in a personal capacity.
- Intellectual property rights including patents relating to medicinal products owned by you or of which you are directly a beneficiary.

Describe current financial interests in a pharmaceutical company and provide details.

Declare any current financial interests in a pharmaceutical company in section 2.4.

These includes

- shares in a pharmaceutical company,
- fees or honoraria paid by a company directly to you in a personal capacity
- patents relating to a medicine for which you are the patent owner or a direct beneficiary.

Fill in the name of the pharmaceutical company and the type of financial interest.

Use the add button to declare more interests.

Principal investigator – investigator

2.5 Principal investigator

No Yes

Principal investigator means 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. This definition does not include a national coordinating investigator in a multinational trial. Involvement in Data Monitoring Committees should be included in this section.

Note: Academic trials and publicly funded research/development initiatives involving pharmaceutical products should be included under section 2.9 Any other interests or facts.

Principal investigator Please click on any of the footnotes for further information.

Time period¹: Current Past

From month: From year: To month: To year:

Name of pharmaceutical company²:

Product name³:

Therapeutic indication:

Add principal inv.

2.6 Investigator

No Yes

Investigator means an investigator involved in a pharmaceutical industry instigated/sponsored trial at a specific trial site who 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.

Note: Academic trials and publicly funded research/development initiatives involving pharmaceutical products should be included under section 2.9 Any other interests or facts.

Involvement in a clinical trial instigated/sponsored by a pharmaceutical company as principle investigator (2.5) or investigator (2.6)

Describe current or past (within last 3 years) principal investigator and provide details.

In sections 2.5 and 2.6, you must declare if you have been a principle investigator or an investigator in a clinical trial sponsored by a pharmaceutical company.



Grant or funding to organisation/ institution

2.7 Grant / Funding to organisation/institution No Yes

Grant or other funding to an organisation/institution means any **CURRENT** funding (other than compensation for services provided, as requested by National Competent Authorities) received from a pharmaceutical company by an organisation/institution to which you belong, or for which you perform any kind of activity, and which is used to support any of your activities whether or not they are related to research work. Any other funding received from a pharmaceutical company by an organisation/institution to which you belong, or for which you perform any kind of activity do not need to be declared. If you want to declare such funding for transparency purposes, please report under 2.9 Any Other Interests or Facts.

(**CURRENT** is interpreted at time of completion of this form).

Current grant or other funding Please click on any of the footnotes for further information.

Name of pharmaceutical company¹:

Subject matter :

Describe current grants or funding from a pharmaceutical company and provide details.

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.

If the organisation or institution to which you belong, currently receives grants or funding from a pharmaceutical company and you and your activities at your organisation or institution benefit directly from these grants or funding, then this needs to be described under section 2.7.

Close family member interest

2.8 Close family member interest

No Yes

Close family member means first-line member of your family (i.e. a spouse or a partner, children and parents). Interests to be declared include **CURRENT** employment, consultancy, strategic advisory role and financial interests.

(CURRENT is interpreted at time of completion of this form).

Current interest of close family member *Please click on any of the footnotes for further information.*

Name of pharmaceutical company ¹	Type of interest declared	Add
		X

Describe current interests of close family members in a pharmaceutical company and provide details.

Current employment, consultancy, strategic advisory role, financial interests of spouse/partner, children or parents, to the best of your knowledge.

If your close family members, being your spouse or partner, children or parents, have current interests in a pharmaceutical company, you must declare it in section 2.8.

This includes employment, consultancy, strategic advisory role and financial interests.



Any other interests or facts

2.9 Any other interests or facts

For transparency purposes, please also provide information on the following activities in this section:

- Academic trials and publicly funded research/development initiatives involving pharmaceutical products.
- Membership of an Ethics Committee (you do not need to state a list of trials you were involved in)
- If you work in an organisation/institution where your colleagues provide consultancy advice to pharmaceutical companies, but you are not directly involved in the provision of such advice. Examples include employees of Official Medicines Control Laboratories, staff members of academic departments, etc.
- Participation in European societies/research foundations/strategy boards/treatment groups/focus groups, which may be funded in full or in part from unrestricted grants from pharmaceutical companies (not from one single company), with or without involvement of industry participants and which may provide general advice (on development programmes, clinical study design, strategy, etc.) to several pharmaceutical companies (not one particular company) in a specific therapeutic area.

Not to be declared: attendance at courses and conferences funded by a pharmaceutical company if limited to reimbursement of reasonable expenses for travel and accommodation.

Provide information on:

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

Other information for transparency purposes can be provided in section 2.9

These include

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

No restrictions in participation in EMA activities apply to this information .

Attendance at courses and conferences funded by a pharmaceutical company do not need to be declared if the funding is limited to reimbursement of reasonable expenses for travel and accommodation.

Any payment beyond these reasonable expenses, e.g. a speaker's fee, is considered a financial interest and should be declared in section 2.4.



Section 3 – Confidentiality Undertaking

SECTION 3: CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

"EMA Activities" encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the European Medicines Agency's Management Board, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on assessments; work as an expert on guidance development.

"Confidential Information" means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my EMA Activities.

"Confidential Documents" mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

I understand that I may be invited to participate either directly or indirectly in certain EMA activities and hereby undertake:

- to treat all *Confidential Information and Confidential Documents under conditions of strict confidentiality, not to disclose (or authorise any other person to disclose) in any way to any third party¹ any Confidential Information or Confidential Document.*
- not to use (or authorise any other person to use) any *Confidential Information or Confidential Document other than for the purposes of my work in connection with EMA activities.*
- to dispose of *Confidential Documents as confidential material as soon as I have no further use for them.*

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

I confirm the information declared on this form is accurate to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

FULL NAME:

Date:

¹ Third party does not include employees of the National Competent Authorities who either have employment contracts that provide confidentiality obligations or are encompassed by confidentiality obligations under national legislation on professional secrecy.

Read the text carefully before typing your name in full.

In this final section of the DoI form, it is important to carefully read the information regarding confidential information and documents.

By including your full name in the red box in this section, you confirm the interests declared and your undertaking regarding confidentiality.

The date will be filled in automatically once you submit the form.



Submitting your declaration of interests form

other than for the purposes of my work in connection with EMA activities.
to dispose of Confidential Documents as confidential material as soon as I have no further use for them.

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

I confirm the information declared on this form is accurate to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

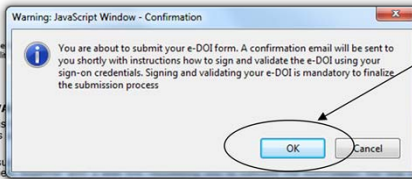
FULL NAME: Date:

¹ Third party does not include e-DOIs encompassed by confidentiality obligations or are

SUBMISSION AND VALIDATION
After completion of this form, you must use your single sign-on credentials (user name and password) as provided to you by the EMA. Once validated, your electronic declaration of interests form will be published automatically on the EMA website. A guidance document on how to submit and validate the electronic declaration of interests form is available on the EMA website link.

the European Medicines Agency as field. information you supply electronically), you must use your single sign-on credentials (user name and password) as provided to you by the EMA. Once validated, your electronic declaration of interests form will be published automatically on the EMA website. A guidance document on how to submit and validate the electronic declaration of interests form is available on the EMA website link.

http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2011/07/WC500109481.pdf



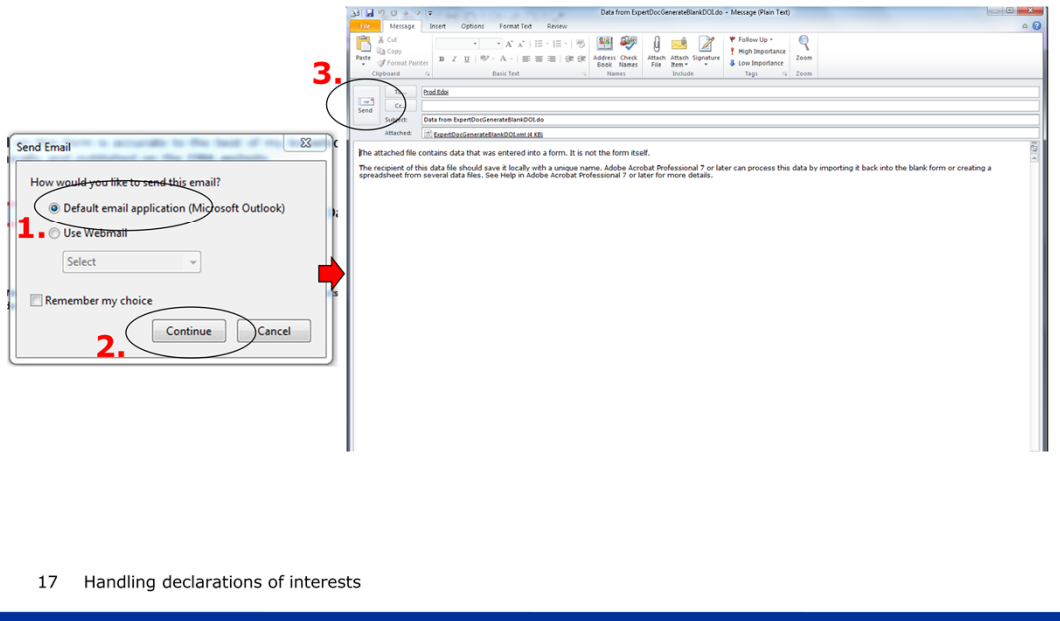
2.

1.



When the DoI form is completed and you are ready to submit it to EMA, click on the 'submit by email' button at the end of the form and click 'OK' on the window that will appear.

Submitting using Outlook



If you use Outlook for your emails, select this as your method for sending and then click 'Continue'.

An xml version of your DoI is automatically generated and added as an attachment to an email message addressed to the EMA.

Do not change anything in this email message. Simply click on the 'send' button.

Submitting using Webmail (e.g. gmail, hotmail)

1. Add Gmail...

2. E-mail Address: e.g. johnsmith@my-webmail.com

3. Continue

4. Save DoI in xml format

5. Send email to edoi@ema.europa.eu

6. Open

7. With eDoI in xml format attached

If you do not use outlook, you can select a web based mail such as gmail, hotmail etc.

Select the Use Webmail option and select an existing email address from the drop-down list or add a new address by typing your email address in the window that appears when you select add mail.

Click on 'continue'.

You will need to manually save your DoI which will have the extension .xml. You can save this file where you like on your computer.

You will then need to open your webmail account, go to your normal email box and 'compose' an email to the email address shown here edoi@ema.europa.eu

You will need to make sure you attach the xml file from wherever you saved it and click on send.

EUROPEAN MEDICINES AGENCY

EMA e-Dot submitted - ACTION REQUIRED - Message (HTML) (Read Only)

From: Experts@ema.europa.eu
To: 6.p@ema.europa.eu
Subject: EMA e-Dot submitted - ACTION REQUIRED
Date: 11/01/2016 09:23

EMA Declaration of Interests form ready for validation - ACTION required.

Thank you for submitting your electronic Declaration of Interests form and confidentiality undertaking (e-Dot) to the European Medicines Agency (EMA).

The most important step in this submission process is the provision or update of an electronic CV and the validation of the submitted declaration of interests form. An e-CV and a validated e-Dot are required before you can be involved in EMA activities.

Once you received your user name and password or if you already have them, please click on the following link and follow the instructions below:
<https://connect.ema.europa.eu/ema/submit/eDot/141031732685> **1.**

Log in with your username and password

- In the **My Profile** tab, go to the Curriculum Vitae tab
- Complete or update your e-CV (Work experience, Education, Expertise, Publications, Projects, Memberships, Others) or upload it from Europass
- Tick the box "I confirm my CV is up-to-date" (bottom of the webpage) - for e-CV updates only
- Click on "Submit CV" (bottom of the webpage)
- In the "Meeting Portal" application, go to the Declaration of interests tab
- Tick "I confirm the information declared on this form is accurate to the best of my knowledge..."
- Click on "validate selected submission"

For new experts, if you have not yet been provided with a user name and password (which is also used for access to other EMA systems - Eudralink, EMA travel portal, wifi, etc), or for existing experts if you have forgotten them, please contact the IT Service Desk (Experts@ema.europa.eu) to request them. Please retain this e-mail until you have received these details.

Validation of your submitted e-Dot links it to a unique set of credentials (user name and password available only to yourself). This allows the system to verify that the e-Dot has been submitted by the expert concerned rather than by any other party, and replaces the need for a signed paper copy.

Please note therefore that the e-Dot can be validated only by the person who is the subject of this form. Submitted e-Dots will be valid for 1 year from the date of submission. You will be requested to update your Declaration of Interests form on an annual basis.

Please note that your Declaration of Interests form and CV (PDF versions) will be published on the Agency's public website.

This is an automatically generated e-mail; please do not reply to this e-mail address. For queries, please e-mail the Experts database contact point in your National Competent Authority, the Experts database co-ordinators at the EMA (Experts@ema.europa.eu) or your contact person at the EMA.

Best regards,
 European Medicines Agency
 30 Church Place | Canary Wharf | London E14 5EU | United Kingdom
 Tel: +44 (0)20 2666 0000 | Fax: +44 (0)20 2666 5555
<http://ema.europa.eu>

This message and any attachments contain information which may be confidential or otherwise protected from disclosure. It is intended for the addressee(s) only and should not be relied upon as legal advice unless it is otherwise stated. If you are not the intended recipient(s) or authorized by an addressee who received this message, access to this e-mail, or any disclosure or copying of its contents, or any action taken in reliance on it is unauthorized and may be unlawful. If you have received this e-mail in error, please inform the sender immediately.

Please consider the environment before printing this e-mail

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ORACLE Access Manager

Welcome

Enter your Single Sign-On credentials below

2.

Username:

Password:

Login

After you have sent the email to EMA, you will receive a confirmation e-mail. If you do not receive this email immediately, contact the IT service desk or your EMA contact person.

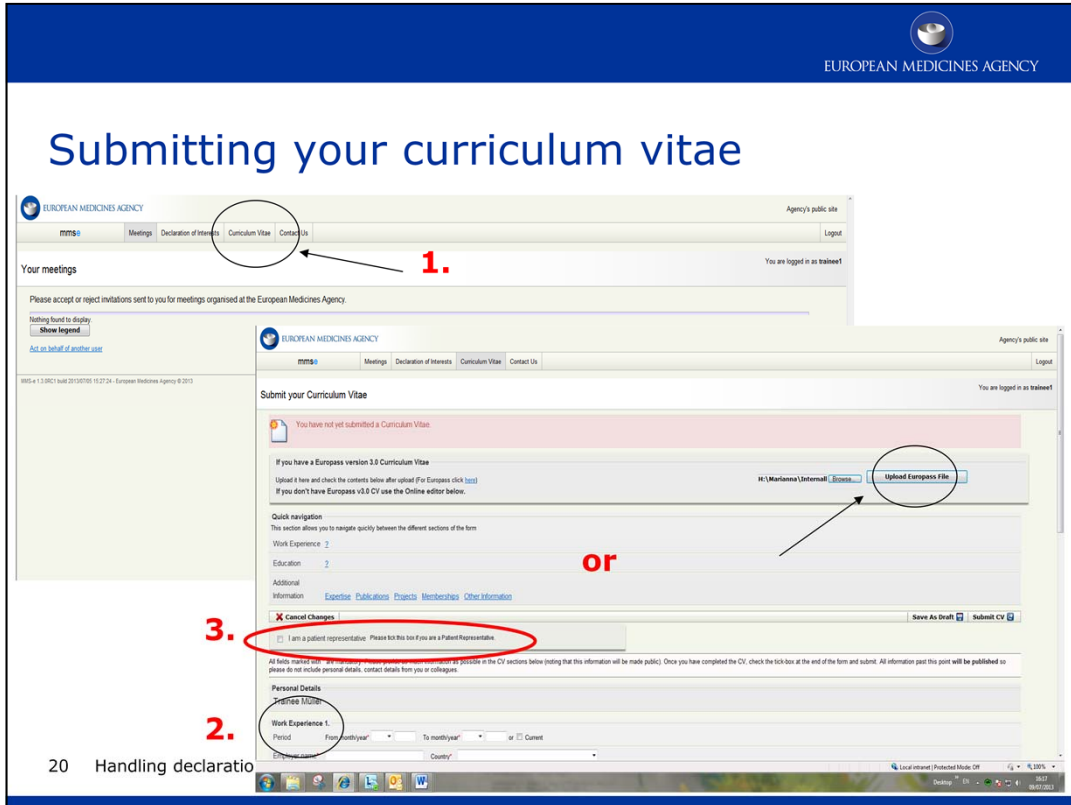
Do not delete this email, as you will need the link to access the EMA system for validation of your DoI.

You should receive a second email with single-sign-on credentials (a username and password)

If you already have your username and password from other EMA tools such as MMD or Eudralink, you can use them.

If you did not receive any credentials, please contact the IT Service Desk – the details are provided at the end of this video.

Click on the link in the email and login to the EMA system with your username and password.



In order to validate your DoI you will first need to submit a curriculum vitae.

To do this - Go to the Curriculum vitae tab.

There is the option of using the online editor in the system directly or uploading your own Europass CV as shown here.

If you are a patient, you can use the Tick box option for 'Patient representative' as shown here.

In this case, further completion of the CV is not mandatory, but still required if you have relevant experience.

In all cases, please make sure that your CV matches with your DoI.

Submitting your curriculum vitae

The screenshot displays the 'Additional Information' section of the EMA CV submission form. It includes tabs for 'Expertise', 'Publications', 'Projects', 'Memberships', and 'Other'. The 'Expertise' tab is active, showing a text area for 'Please enter your areas of Expertise' with the placeholder text '<p>Europeas Expertise</p>'. A red '1.' with an arrow points to a checkbox labeled 'I confirm my CV is up-to-date' at the bottom left. A red '2.' with an arrow points to the 'Submit CV' button at the bottom right. The 'Cancel changes' button is also visible at the bottom left.

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Further information on expertise, publications, projects and memberships can also be provided.

Confirm that your CV is up-to-date and ready for submission by ticking the box 'I confirm my CV is up-to-date' at the very bottom of the screen.

Then click on 'Submit CV'.

Scroll back up to the top of the page and go to the Declaration of interests tab.

EUROPEAN MEDICINES AGENCY

Agency's public site

mms^e Meetings Declaration of Interests Curriculum Vitae Contact Us Delegates Information Logout

Your Electronic Declaration of Interest submission You are logged in as papadopoulosj

You can validate your Declaration of interest submission only after submitting your CV. You have not submitted your CV or your CV is not up-to-date. Please **submit your CV** and then validate your Declaration of interest submission.

New declaration of interest submissions

Select Electronic Declaration of Interest submission*

09/09/2014 00:00:00 • Electronic Declaration of interest • Submission number 2

1. I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the EMA website. *

The accuracy of the e-signature will be verified by the EMA. If the form has been signed by anyone other than the concerned person, the submitted form will be invalidated and the expert requested to re-submit.

2. I am the owner of this declaration of interest. *

3.

Updating your declaration form

To submit a new declaration, please download a form with the button below. Fill it in and send by e-mail. Once the declaration is submitted, return to this page to validate it.

22

Select the submitted DoI that you want to validate.

Tick the box 'I confirm the information on this form is accurate to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website'.

You must also tick the 'I am the own of this declaration of interest box' .

Finally click on the 'Validate selected submission' button.

This concludes the submission and validation of your DoI and CV.

Nomination form



Nomination form for European experts

Please note that * indicates mandatory fields, to be completed by the expert

Title		5. * Business phone no. (incl. int. code)	*
1. * Family name		6. Business fax no. (incl. int. code)	*
2. * First name		7. Business e-mail address (block capitals)	
3. * Nationality		8. * Qualifications - degrees, diplomas and professional affiliations ¹	
4. * Organisation/ company name and professional address		9. * Present position and time spent in current assignment ²	

10. * General category of activities

Hⁱⁱⁱ V^{iv}

Medicines evaluation

Biological/biotechnological products	<input type="checkbox"/>	<input type="checkbox"/>
Chemicals	<input type="checkbox"/>	<input type="checkbox"/>
Herbal/traditional products	<input type="checkbox"/>	<input type="checkbox"/>
Inspections	<input type="checkbox"/>	<input type="checkbox"/>
Pharmacovigilance	<input type="checkbox"/>	<input type="checkbox"/>
Regulatory affairs	<input type="checkbox"/>	<input type="checkbox"/>

Yes No

* Are you a member of staff of the competent authority? Yes No

* Are you an external expert? (e.g. university, hospital, member of staff of another organisation or a pharmaceutical company, etc.)? Yes No

1.

* Are you a member of a Patient Organisation / Interest group / Charity? Yes No

11. * Specific functional expertise

Hⁱⁱⁱ V^{vii}

Quality

Biotechnology products	<input type="checkbox"/>	<input type="checkbox"/>
Immunologicals/biologicals	<input type="checkbox"/>	<input type="checkbox"/>
Vaccines	<input type="checkbox"/>	<input type="checkbox"/>
Blood products	<input type="checkbox"/>	<input type="checkbox"/>
Chemicals	<input type="checkbox"/>	<input type="checkbox"/>

Safety

Immunologicals/biologicals	<input type="checkbox"/>	<input type="checkbox"/>
Chemicals	<input type="checkbox"/>	<input type="checkbox"/>

Environmental risk assessment

Genetically modified organisms	<input type="checkbox"/>	<input type="checkbox"/>
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Clinical

Immunologicals/biologicals	<input type="checkbox"/>	<input type="checkbox"/>
Chemicals	<input type="checkbox"/>	<input type="checkbox"/>
Pharmacovigilance and risk management	<input type="checkbox"/>	<input type="checkbox"/>

Inspections

Laboratory procedures	<input type="checkbox"/>	<input type="checkbox"/>
GMP	<input type="checkbox"/>	<input type="checkbox"/>
GCP	<input type="checkbox"/>	<input type="checkbox"/>
GLP	<input type="checkbox"/>	<input type="checkbox"/>

The final document to complete is what is the nomination form for European experts. All experts need to complete this form to indicate one or more areas of expertise.

On the first page, please complete your details and indicate the general categories of activities and specific functional expertise applicable to you.

If you are a patient representative, you can select the 'I am a member of a patient organisation/interest group or charity' box.

There is no need to sign this form.



15. Detailed Areas of Expertise

(Please select main areas only)

Chemicals:

- Analytical chemistry
- Synthetic chemistry
- Development pharmaceuticals
- Stability
- Phytochemistry
- Radiopharmaceuticals
- Premixes for medicated feed production
- Drug/Device combinations
- Packaging
- Manufacture of medicines
- Peptide chemistry
- Medicinal gasses
- Structural similarity

15.a Quality

Biotechnology products:

- Development genetics
- Genetic engineering: expression factor
- Cell culture - Fermentation
- Protein purification
- Protein analysis - characterisation; purity testing; biological assay
- Virology: validation of inactivation/removal steps, cell bank qualification; choice of viruses
- Microbiological testing
- Monoclonal antibodies
- Blood products
- Allergens
- Vaccines
- Gene therapy
- Cell therapy
- Tissue engineering
- Plant biotechnology
- Nanobiotechnology

Risk Assessment of GMOs:

- Vaccines
- Gene therapy/ biotechnology
- Transgenic plant

Manufacturing Process, Development and Validations:

- Blood products
- Biological products
- Biotechnology products
- Vaccines
- Cell therapy

15.b Pre-Clinical

- Toxicology
- General toxicology:
 - Acute/chronic toxicity, etc
- Special toxicology:
 - In vitro toxicology
 - Immunotoxicity
 - Reproduction toxicity
 - Genetic toxicity
 - Carcinogenicity
 - Toxicokinetics
- Pharmacology in laboratory and target animals
- Pharmacodynamics
- Pharmacokinetics
- Pathology
- Environmental Risk Assessment
- Residue safety assessment
- Behavioural toxicology
- Occupational toxicology
- Microbiology:
 - Bacteriology
 - Parasitology
 - Mycology
 - Virology
- Safety Pharmacology

15.c Clinical

(Please select 2-3 areas only)

- AIDS
- Intensive care
- Ophthalmology
- Plastic Surgery
- Anaesthesiology
- Internal medicine
- Organ transplantation
- Pneumology / Respiratory

If you have any specific areas of expertise, please indicate them here. Otherwise please leave them blank

For patients and consumers

15.g Patient / Consumer Representation

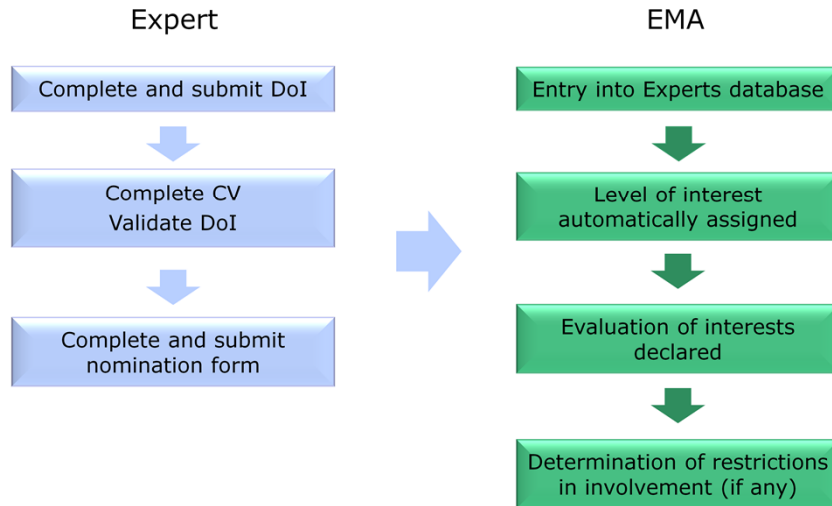
<input type="checkbox"/> Patients *
<input type="checkbox"/> Consumers
<input type="checkbox"/> Policy issues
<input type="checkbox"/> Communication
<input type="checkbox"/> Advocacy
<input type="checkbox"/> Medicines' Safety
<input type="checkbox"/> Social Sciences

Other (please specify):

* If you have patients experience in a specific therapeutic area, please indicate in section 15.c Clinical

For patient and consumer representatives, please select the appropriate boxes in section 15g

Process



If you are an expert nominated by the EMA, return the completed form to your contact person at EMA.

For experts nominated by an EU member state, you should return this form to your contact point in the national agency.

Once EMA has received the three documents, we will progress with your inclusion into the Experts database.

An interest level will be assigned based on your declared interests. Your interests are evaluated to determine if you can be involved in EMA activities and if any restrictions apply.

Interest level and restrictions

Interest declared	Interest level	Involvement in EMA activities
Direct interest (current or within last 3 years) Employment, Consultancy, Strategic advisory role, Financial interests	3	No involvement or Severely restricted involvement
Indirect interest (current or within last 3 years) Principle Investigator, Investigator, Grant or funding to institution/organisation, Close family member interests	2	Involvement permitted but restrictions apply
No interest or interests over 3 years (except executive role or lead role)	1	Full, unrestricted involvement

27 Handling declarations of interests

The type of interests declared determine the interest level.

Interest level 3 applies to direct interests in a pharmaceutical company such as employment,

Interest level 2 for indirect interests such as principal investigator and interest level 1 is where no interests are declared or if interests are older than 3 years, except for employment in an executive or lead role.

Interest level 1 experts have no restrictions in EMA activities.

For interest level 2 or 3 experts, restrictions on involvement apply depending on the interest declared and on the EMA activity.

Some interests such as current employment in a pharmaceutical company results in no involvement in any EMA activity.

For more details please go to the policy document.



Declaration of Interests

- Valid for 1 year
- Experts database sends automated e-mail to expert, 1 month before expiry, requesting to update e-DoI
- (up-to-date) e-CV required before validation of e-DoI
- Important: If anything changes in profile of interests (e.g. organisation gets additional grants/funding from pharma industry, new consultancy, clinical trial), expert must update and resubmit e-DoI

Finally,

Your DoI is valid for one year.

One month before it expires, you will receive an email requesting you to update it.

You can only validate your updated DoI if you update your CV or confirm that it is still up-to-date.

Please note that if your circumstances change during the year, it is important to inform the Agency by submitting an updated DoI.



Reference documents

[Declaration of Interest \(DoI\) policy](#)

[Procedural guidance on inclusion of interests in e-DoI](#)

[Guidance on submission and validation of e-DoI and e-CV](#)

[Guidance on handling DoIs in case of intention to become an employee in a company](#)

More information on declarations of interests can be found in the policy and its guidance documents.

Please click on the links available in the pdf version of this talk.

Contact



EMA [Handling conflicts of interests webpages](#)

EMA website: www.ema.europa.eu

Frequently Asked Questions: [FAQ](#)

**Contact IT service desk: tel. +44 (0)20 3660 8520 or
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For any technical issues, please contact the IT service desk at <https://servicedesk.ema.europa.eu>