European Federation of Allergy and Airways Diseases Patients Associations

How to fill in the administrative forms at EMA

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EMA policy on conflict of interest of experts

All experts involved in EMA activities (meetings, review of documents) must be **included in EMA experts database**

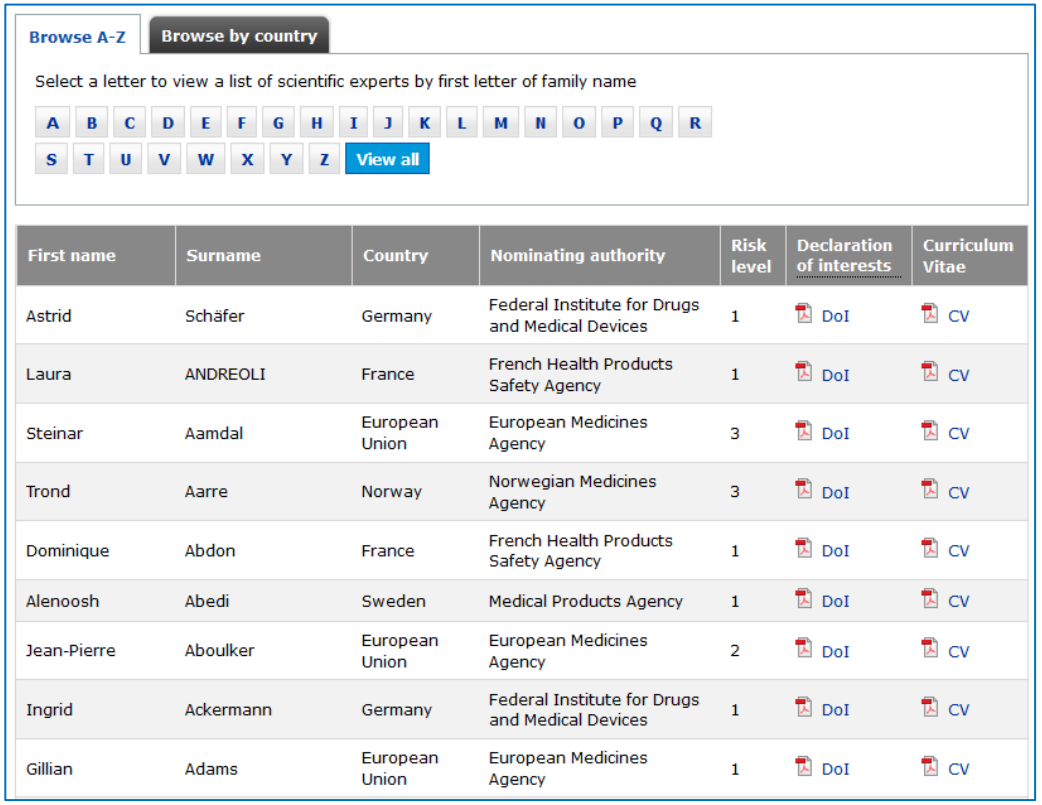
EMA should receive:

→**Nomination form**

→Public **declaration of interests** and **confidentiality undertaking** form

→**Curriculum vitae**

http://bit.ly/1g11mST



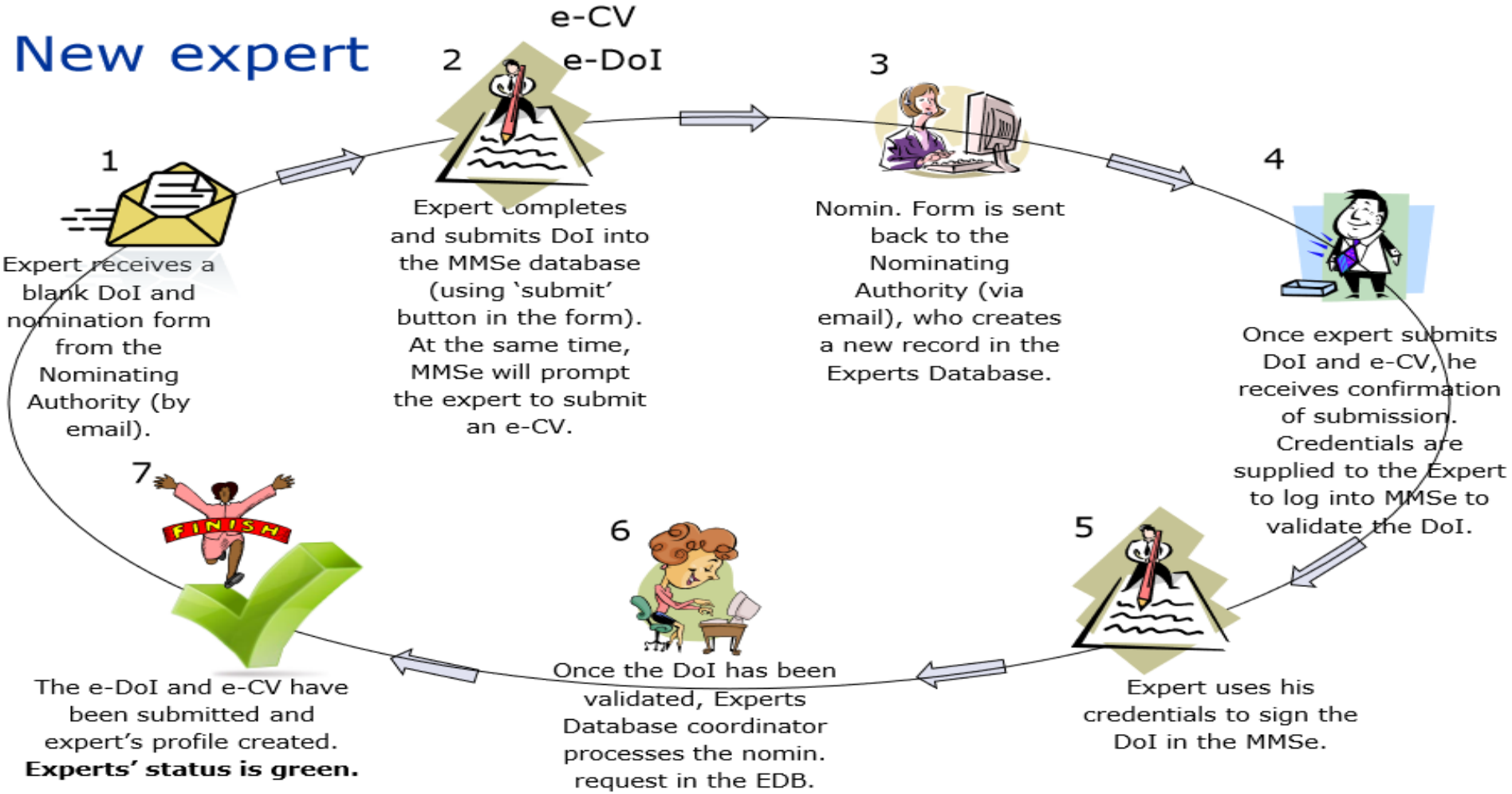
Browse A-Z | Browse by country

Select a letter to view a list of scientific experts by first letter of family name

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z View all

First name	Surname	Country	Nominating authority	Risk level	Declaration of interests	Curriculum Vitae
Astrid	Schäfer	Germany	Federal Institute for Drugs and Medical Devices	1	DoI	CV
Laura	ANDREOLI	France	French Health Products Safety Agency	1	DoI	CV
Steinar	Aamdal	European Union	European Medicines Agency	3	DoI	CV
Trond	Aarre	Norway	Norwegian Medicines Agency	3	DoI	CV
Dominique	Abdon	France	French Health Products Safety Agency	1	DoI	CV
Alenoosh	Abedi	Sweden	Medical Products Agency	1	DoI	CV
Jean-Pierre	Aboulker	European Union	European Medicines Agency	2	DoI	CV
Ingrid	Ackermann	Germany	Federal Institute for Drugs and Medical Devices	1	DoI	CV
Gillian	Adams	European Union	European Medicines Agency	1	DoI	CV

Nomination and annual review of experts



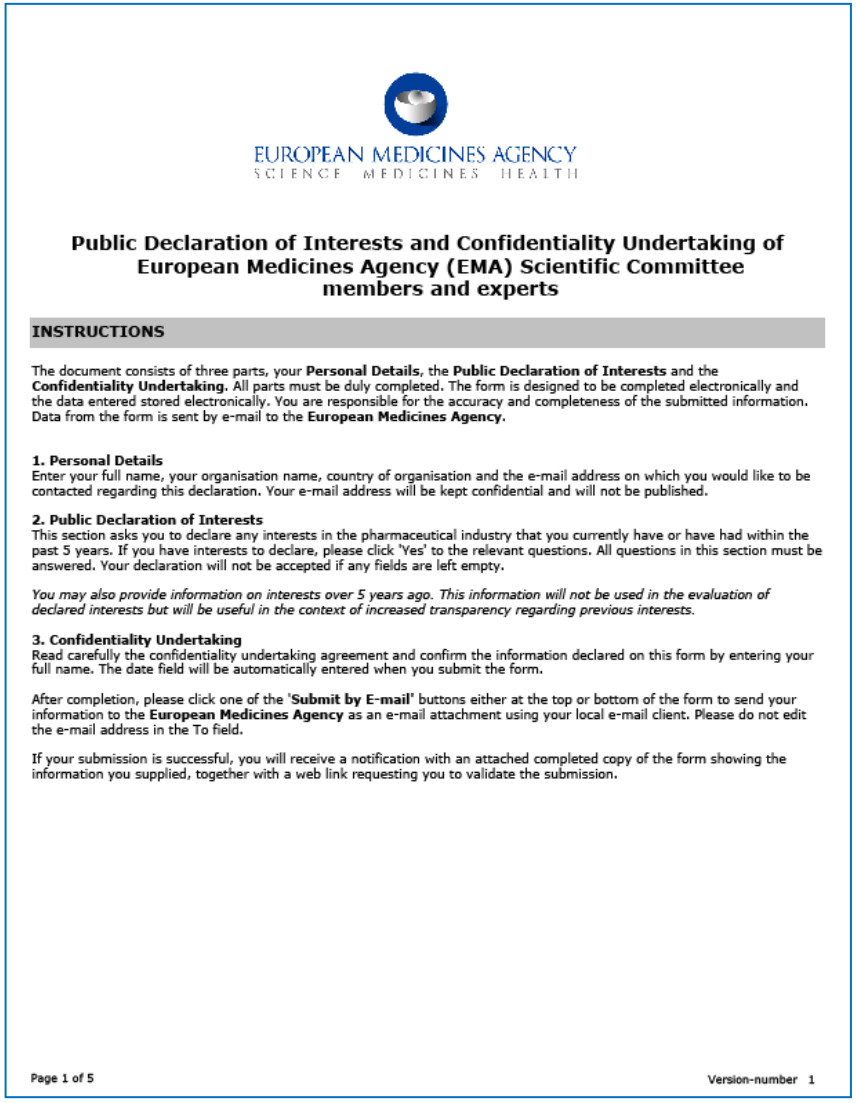
Before any involvement in EMA activities, a patient/consumer expert must be **formally nominated by the Agency**

Source: EMA

Electronic Declaration of Interest (e-DoI)

What to include?

- Any **current activities** as well as all **activities within the past 5 years** (current = the time of completion of the form)
- If unsure whether an **interest relates to a medicinal product or to a pharmaceutical company**, declare the information
- Should the expert acquire any additional interests or should interests change since last declaration of interest, an **updated e-DoI** must be re-submitted



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public Declaration of Interests and Confidentiality Undertaking of European Medicines Agency (EMA) Scientific Committee members and experts

INSTRUCTIONS

The document consists of three parts, your **Personal Details**, the **Public Declaration of Interests** and the **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. Data from the form is sent by e-mail to the **European Medicines Agency**.

1. Personal Details
Enter your full name, your organisation name, country of organisation and the e-mail address on which you would like to be contacted regarding this declaration. Your e-mail address will be kept confidential and will not be published.

2. Public Declaration of Interests
This section asks you to declare any interests in the pharmaceutical industry that you currently have or have had within the past 5 years. If you have interests to declare, please click 'Yes' to the relevant questions. All questions in this section must be answered. Your declaration will not be accepted if any fields are left empty.

You may also provide information on interests over 5 years ago. This information will not be used in the evaluation of declared interests but will be useful in the context of increased transparency regarding previous interests.

3. Confidentiality Undertaking
Read carefully the confidentiality undertaking agreement and confirm the information declared on this form by entering your full name. The date field will be automatically entered when you submit the form.

After completion, please click one of the '**Submit by E-mail**' buttons either at the top or bottom of the form to send your information to the **European Medicines Agency** as an e-mail attachment using your local e-mail client. Please do not edit the e-mail address in the To field.

If your submission is successful, you will receive a notification with an attached completed copy of the form showing the information you supplied, together with a web link requesting you to validate the submission.

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3 levels of conflict of interest

1. Level 1, lowest risk level: **no interests** declared in the pharmaceutical industry
2. Level 2, intermediate risk level: **indirect interests** in the pharmaceutical industry
3. Level 3, highest risk level: **direct interests** in the pharmaceutical industry

Direct interests:
employment, consultancy, strategic advisory role, financial interests, patent ownership

Indirect interests:
principal investigator, **organisation receiving grants or other funding**, household member linked with industry

Experts shall **not have financial or other interests in the pharmaceutical industry** that could **affect their impartiality**

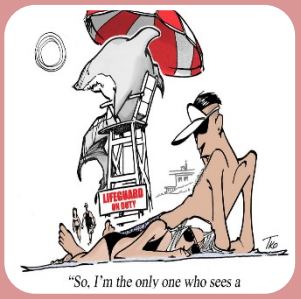
Allowed levels of involvement

No interests declared in the pharmaceutical industry

- Full, unrestricted involvement

Indirect interests in the pharmaceutical industry

- Involvement permitted, but with limitations and risk-mitigating actions



Direct interests in the pharmaceutical industry

- Severely restricted involvement

Employees of patient organisations ≠ volunteers representing patient organisations

Participation is less restricted for volunteers (YOU!)

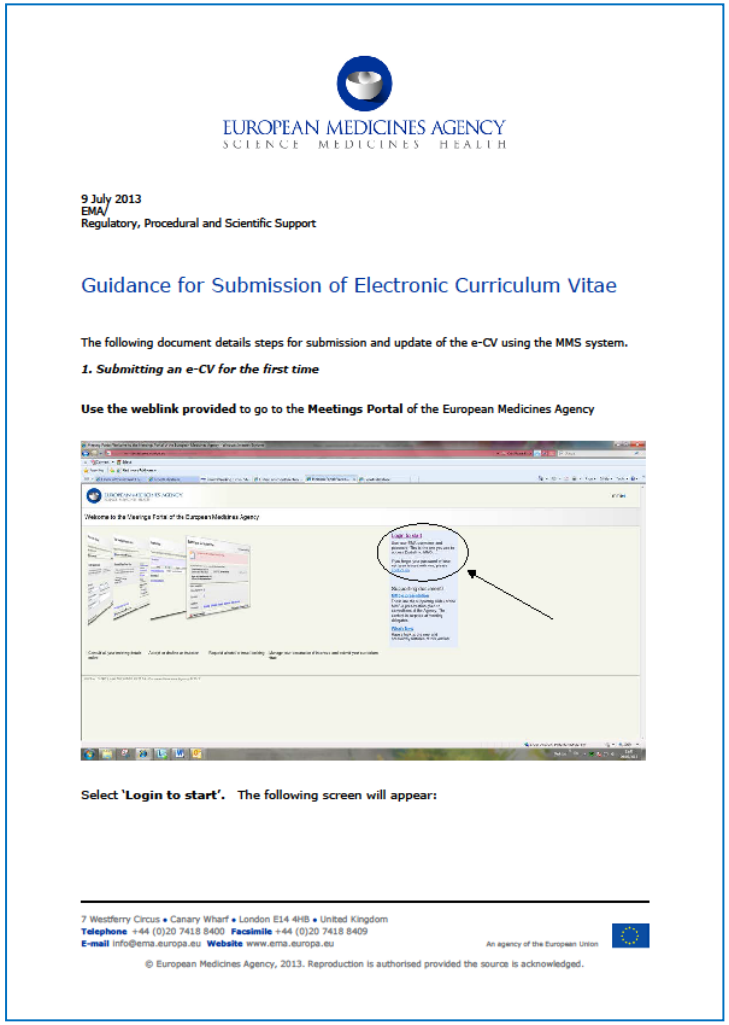
Electronic Curriculum Vitae (e-CV)

- e-CV (Europass format) published on EMA webpage (similarly to e-DoI)
- Mandatory to be completed: necessary to allow experts to participate in meetings/activities
- Required in order to validate the e-DoI: without the e-CV the system will not allow validation
- e-CV **to be updated on yearly basis** (at time of update of e-DoI)
- Information on qualifications and experience

BUT

- The e-CV template includes a tick box for "**Patient Representative**", completion of the other fields by patient representatives is not mandatory

Online safe system



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 July 2013
EMA/
Regulatory, Procedural and Scientific Support

Guidance for Submission of Electronic Curriculum Vitae

The following document details steps for submission and update of the e-CV using the MMS system.

1. Submitting an e-CV for the first time

Use the weblink provided to go to the **Meetings Portal** of the European Medicines Agency

Select **'Login to start'.** The following screen will appear:

7 Westferry Circus ▪ Canary Wharf ▪ London E14 4HB ▪ United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

European Federation of Allergy and Airways Diseases Patients Associations

Thank you for your attention!

European Federation of Allergy and Airways Diseases Patients' Associations (EFA)

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