
Training session for patients and consumers involved in EMA activities – 25 November 2014

Presented by Luc Van Santvliet
Scientific Committee Support Department
What the legislation says

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

Members of [...] 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 ...

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EMA policy on handling of conflicts of interests of scientific committees’ members and experts

Applies to:

- Scientific committee members and alternates
- Experts involved in Agency 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

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Requirements for involvement in EMA activities: Experts database

Experts must be included in Experts database prior to first appointment

- Signed **nomination form**
  - Signed by Head of NCA (MS experts) or Head of Division (EMA experts)
- Up-to-date **e-DoI** signed/validated by the expert
- Up-to-date **e-CV** (required to validate/sign e-DoI)
- Request for creation of new expert in Experts database
  - from NCA (MS experts) or Experts database coordinator (EMA experts)
Completion of e-DoI

Direct interests – °current, *within past 5 years

- Employment with a company°*
- Consultancy for a company°*
- Strategic advisory role for a company°*
- Financial interests°
- Ownership of a patent for a medicinal product°

Definitions and explanatory notes in e-DoI form
Completion of e-DoI

Indirect interests – °current, *within past 5 years

- Principal investigator°*
- Investigator°*
- Grant or other funding to institution/organisation°

- Direct interests of household members° (resulting as indirect interest of the individual)

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Completion of e-CV

- Work experience
- Education/training
- Expertise, Publications, Projects, Memberships, Other

- Tick box for ‘Patient representative’ – if ticked, further completion of e-CV is not mandatory, but recommended for committee member

*Online editor or download from Europass in EMA Meetings Portal*
e-DoI validity

- Valid for 1 year
  Experts database sends automated e-mail to expert, approx 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 (e.g. organisation gets additional grants/funding from pharma industry), expert must update and resubmit e-DoI
How to submit e-DoI and e-CV

- Complete blank nomination form
- Return to NCA or EMA by e-mail
- Complete e-DoI (blank form or current e-DoI)
- Click on ‘Submit by email’ and click ‘OK’
- Select method of sending and click ‘Continue’
- Send the automatically generated e-mail (Outlook) or create and send e-mail with xml file attached (webmail)
- When receiving a confirmation e-mail, click on the link in the e-mail
- Log in with single-sign-on credentials (same as for MMD, Eudralink, MMS – provided by the Agency)
How to submit e-DoI and e-CV

• In MMSe, go to the Curriculum Vitae tab
• Tick the box ‘I am a patient representative’
• Update e-CV as appropriate or upload a new version of CV from the Europass website
• Tick the box ‘I confirm my CV is up-to-date’ (bottom of page)
• Click on ‘Submit CV’
• In MMSe, go to the Declaration of interests tab
• Tick ‘I confirm the information declared on this form is accurate to the best of my knowledge and I acknowledge that …’
• Click on ‘Validate selected submission’
Nomination Form for European Experts

This form requires Adobe Acrobat Reader version 7.0

Please fill in all sections of the Nomination Form as required:
- Mandatory fields for Experts are indicated with 🟠
- After completion click Submit by Email, type in the To: field the e-mail address of your Contact Point
- Click Print Form to keep a record of this form

**Title:**

1. **Last Name:**

2. **Gender:**
   - Male
   - Female

3. **First Name:**

4. **National of:**

5. **Business Tel:**

6. **Business Fax:**

7. **Business E-mail:**

8. **Qualifications - Degrees, Diplomas and Professional Affiliations [i]:**

9. **Present position and time in current assignment [ii]:**

10. **General Category of Activities**

<table>
<thead>
<tr>
<th>Medicines Evaluation</th>
<th>Biologics/Biotechnology products</th>
<th>Chemicals</th>
<th>Herbal/Traditional Products</th>
<th>Inspections</th>
<th>Pharmacovigilance</th>
</tr>
</thead>
<tbody>
<tr>
<td>H [iii] [iv]</td>
<td>V</td>
<td>[ii]</td>
<td>[v]</td>
<td>[vi]</td>
<td>[vii] [viii]</td>
</tr>
</tbody>
</table>

11. **Specific Functional Expertise [vi]**

   - Quality
     - Biotechnology products
     - Immunologicals/Biologicals
     - Vaccines
     - Blood products

12. **Availability**

   - Dossier Evaluation
   - Scientific Advice
   - Guidelines
   - Other Specify:

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15. Detailed Areas of Expertise
(Please select main areas only)

15.a Quality
- 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 gases
  - Structural similarity

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

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15.g Patient / Consumer Representation

- Patients *
- Consumers
- Policy issues
- Communication
- Advocacy
- Medicines' Safety
- Social Sciences

* If you have patients experience in a specific therapeutic area, please indicate in section 15.c Clinical
Public Declaration of Interests and Confidentiality Undertaking

INSTRUCTIONS

This document consists of three parts, your Personal Details, the 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.

SECTION 1: PERSONAL DETAILS

First name: ____________________________

Last name: ____________________________

Organisation / company: ____________________________

Country: ____________________________

E-mail address: ____________________________

Type of activity: EMA Expert (nominated for involvement in EMA activities)

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

NOTE: Please write your full first and last name as mentioned on your identity card/passport.

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 past 3 years should be declared. In the case of 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 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 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.

I do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests in the pharmaceutical industry I have currently (at the time of completion of the form) or have had (in the last 3 years and in case of previous employment in an executive role or lead role in the development of a medicinal product at any stage of my career) are those listed below:

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Yes

No

2.3 Strategic Advisory Role

No

Yes

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2.1 Employment

Training session for patients and consumers involved in EMA activities (including supply or service companies which contribute to the research, development, production and marketing of a medicinal product)

2.2 Consultancy

Yes

No

Section 3: Confidentiality Undertaking

In view of the following definitions:

- EMA (European Medicines Agency) is the agency responsible for the assessment and approval of medicinal products in the European Union.
- Confidential Information includes all information, facts, data, and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my participation in 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, during the course 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 protect all Confidential Information and Confidential Documents under conditions of strict confidentiality;
- to not disclose (or authorize any other person to disclose) in any way to any third party any Confidential Information or Confidential Document;
- to use the Confidential Information only 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: ____________________________

Should there be any change to the above due to the fact that I European Medicines Agency and complete a new Declaration and not discharge me from my obligation to disclose any potential conflicts I participate.

Submit by E-mail

“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 party 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: John Papadopoulos

1. Third party does not include employees, members of my immediate family or other persons who are encompassed by confidentiality obligations or are directly involved in the work which is the subject of this undertaking.

2. You are about to submit your e-DOI form. A confirmation email will be sent to you shortly with instructions on how to sign and validate the e-DOI. Using your sign-on credentials. Signing and validating your e-DOI is mandatory to finalize the submission process.

SUBMISSION AND VALIDATION PROCEDURE

After completion of this form, you will be sent an email to the address specified in the To field. If your submission is successful, you will be notified by email. Any errors that may have occurred during validation (sign-off 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.


Submit by Email
Outlook

1. 
2. 
3. 

The attached file contains data that was entered into a form. It is not the form itself.

The recipient of this data file should save it locally with a unique name. Adobe Acrobat Professional 7 or later can process this data by importing it back into the blank form or creating a spreadsheet from several data files. See Help in Adobe Acrobat Professional 7 or later for more details.
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1. Thank you for submitting your electronic Declaration of Interests form and confidentiality undertaking to the European Medicines Agency (EMA).

The next important step in this submission process is the validation of the declaration of interests form, which links your submitted declaration of interest to a unique set of credentials (user name and password available only to yourself). This allows the system to verify that the declaration of interest 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 declaration of interests can be validated only by the person who is the subject of this form. Submitted Declaration of Interests will be valid for 1 year from the date of the validation. You will be requested to update your Declaration of Interests on an annual basis.

If you are a new expert, who has not previously been involved in EMA activities, you will also be requested to provide an electronic CV. You can either complete this directly, following the instructions in the link below, or, if you already have a CV in a Europass format, you can upload this format. Existing experts, who have already submitted an e-CV, are requested to confirm that their CV is up to date at the time of annual update of their DoI.

Those steps must be carried out before you can be involved in EMA activities.

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

If you have not yet been provided with a user name and password (which is also used for access to other EMA systems - BudrLink, EMA travel portal, wifi, etc), or 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 the password.

Once you have these details, please click the following link and follow the instructions provided: https://mmse.ema.europa.eu/mmse/edo/id=1.1468029098403

Please DO NOT reply; this is an automatically generated email.

2. ORACLE Identity Management

Sign In

Sign In

Enter your Single Sign-On user name and password to sign in.

User Name: papadopoulos
Password: **********
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1. ...

2. ...

or ...

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e-DoI and e-CV submission guidance

• Guidance document on e-DoI submission:

• Guidance document on e-CV submission:
Transparency

- Publication of e-DoI and e-CV in pdf format as well as risk level of all active experts on EMA website in European experts list

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/experts.jsp&mid=WC0b01ac058043244a
Revision of EMA policy on handling of declarations of interests

• Implementation date: 30 January 2015

• e-DoI form – version 2: required for involvement in activities after 30 January 2015, can be submitted by experts in advance of that date

• Publication of completed e-DoI – version 2 on website on 30 January 2015

• Some of the changes:
  - Change in section 2.1 Employment – expert to tick function of employment
  - Family members interests
  - Calculation of interest level (3 years)
  - Revision of restrictions applicable to experts with declared interests
Questions