Call for experts WEBINAR

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CoE/ EDQM

The Ph. Eur. - one decision body …

The Ph. Eur. Commission:
• 3 sessions per year
• 38 delegations (37 member states + EU) of up to three representatives
• All technical decisions by consensus
• Observers to the Ph. Eur. Commission are welcomed
Members and Observers

... covering a large portfolio ...

- In green: Ph. Eur. member states
- In yellow: Observers to the convention on the elaboration of a Ph. Eur.
- In pink: PDG members (Ph. Eur., USP and JP)
... and going in one direction: The Ph. Eur. ➔ A success story!

• A unique example of an efficient collaborative process between member states:
  37 member states contributing resources to this collaborative process rather than developing national standards (2 member states interested in one topic ➔ added on the Ph. Eur. work programme)

• Opportunities:
  • saving of resources
  • no subsequent need to harmonise national positions

• Concrete outcomes ➔ More than 2300 monographs and 360 general chapters adopted

The Ph. Eur. texts are ...

• Elaborated or revised by:
  • 20 Groups of experts: permanent groups
  • 38 working parties: appointed for a specific task / specific domains

• Adopted by the Ph. Eur. Commission for publication

• Legally binding in all 37 Ph. Eur. member states and used in over 100 countries worldwide
The Ph. Eur. network: an asset!

- More than 700 members in Ph. Eur. Groups
- Appointed by the Ph. Eur. Commission
- With a well balanced expertise:
  - Approx. 1/3 from Health Authorities
  - Approx. 1/3 from Industry
  - Approx. 1/3 from University, Hospital

- and the support of nearly 60 observers (from e.g. Algeria, Armenia, Australia, Belarus, Canada, Israel, Malaysia, Russian Federation, TFDA, USA)

- Until 2016 => Proposed by national secretariats from member states as of 2016: opened up to experts from all around the world!

For all candidates:

Useful information can be found on the EDQM website
If you are from one of the 37 Ph. Eur. member states

- Contact the National Pharmacopeia Authority of your Country

If you are not from one of the 37 Ph. Eur. member states (1/2)

1. Go on our website and consult the mandate and profile for experts of the Groups [Here]

Candidates from non-Ph. Eur. member states:

The Ph. Eur. welcomes input from experts from all around the world. Whether you are employed by a national authority, industry or academia, your contribution to preparing and maintaining Ph. Eur. texts is highly valued.

The terms of reference of the Ph. Eur. Groups of Experts are published on the website of the Council of Europe. Candidates from non-Ph. Eur. member states may apply in accordance with the terms of reference and profile for members of groups of experts and working formats available.

2. Check that your profile fulfills the criteria laid down under “Profile for experts” for the relevant group
Example

Groups of Experts No. 10A/B/C/D (Organic chemistry – synthetic and semi-synthetic products)

Terms of reference

• Drafting and revision of monographs allocated to the group by the Commission in the field of synthetic and semi-synthetic organic active substances and excipients
• Drafting and revision of finished product monographs with chemically defined active substance if / when allocated to the group by the Commission

Profile for experts

• Current expertise in pharmaceutical analytical methods, related to quality control of active substances, excipients and finished products with chemically defined active substance and in development of control methods
• Access to laboratory facilities for verification of methods proposed for inclusion in monographs, Essential: Active involvement in drafting of texts and laboratory verification of test methods
• Several years of experience in one or more of the following fields:
  • Quality control in a pharmaceutical manufacturing setting
  • Quality control of synthetic and semi-synthetic organic products in a bulk manufacturing setting
  • Market surveillance of quality in a regulatory authority
  • Pharmaceutical quality control of active substances, excipients and /or finished products with chemically defined active substances in an independent testing laboratory
  • Development of methods for control of active substances, excipients and /or finished products with chemically defined active substances in a research and development environment
  • Group 10D: development of control methods for amino-acids
  • Method development and verification in a regulatory authority

You are not from one of the 37 Ph. Eur. member states (2/2)

3. Complete the Nomination form and the Declaration of Interests (DoI) form

4. Update your Curriculum vitae

5. Send all documents (Nomination form, DoI form, CV) to the EDQM via the Helpdesk.
In all cases:

Please check that:

- Your profile fulfils the criteria laid down under “Profile for experts” for the relevant group;
- You have access to a lab if required in the profile; if not, and if required, please explain in the nomination form why the Ph. Eur. Commission should consider your candidature;
- Your experience in the field relevant for the Group is evident when reading the CV.

Groups of experts

Group of Experts No. 1 (Microbiology)
Group of Experts No. 6 (Biological and Biotechnological products)
Group of Experts No. 6B (Human Plasma and Plasma Products)
Group of Experts No. 7 (Antibiotics)
Group of Experts No. 9 (Inorganic Chemistry)
Group of Experts No. 9G (Medicinal Gases)
Group of Experts No. 10A/B/C/D (Organic chemistry – synthetic and semi-synthetic products)
Group of Experts No. 11 (Organic chemistry – natural, semi-synthetic and synthetic products)
Group of Experts No. 12 (Dosage forms and dosage form methods)
Group of Experts No. 13A/B (Herbal Drugs and Herbal Drug Products)
Group of Experts No. 13H (Fatty oils and derivatives, polymers)
Group of Experts No. 14 (Radiopharmaceutical Preparations)
Group of Experts No. 15 (Human Vaccines and Sera)
Group of Experts No. 15V (Veterinary Vaccines and Sera)
Group of Experts No. 16 (Plastic materials, plastic containers and closures)
Group of Experts P4
Working Parties

ALO Working Party (Allergens)
BET Working Party (Bacterial Endotoxin Test)
CE Working Party (Capillary Electrophoresis)
CEL Working Party (Cellulose)
CND Working Party (Conductivity)
COL Working Party (Colour determination)
CRB Working Party (Carbohydrates)
CST Working Party (Chromatographic separation techniques)
CTP Working Party (Cell Therapy Products)
DAG Working party (Dialysis)
EXP Working Party (Exipient performance)
EXT Working Party (Extracts)
GEL Working Party (Gelatin)
GIS Working Party (Glass Containers)
HMM Working Party (Heavy metals)
HOM Working Party (Homeopathic Manufacturing Methods)
ICP Working Party (Inductively-Coupled Plasma)

INH Working Party (Inhibitors)
LBFP Working Party (Live Biopharmaceutical Products)
LEC Working Party (Leucocytes)
MAA Working Party (Monoclonal Antibodies)
MS Working Party (General methods)
NRC Working Party (Non-Biological Compounds)
PBBO Working Party (Plasma Basic Bioassay)
PCC Working Party (Pesticide Residues)
PAT Working Party (Process Analytical Technology)
POW Working Party (Powders)
PRP Working Party (Preparation for Radiopharmaceutical Preparations)
PSF Working Party (Pesticide Residues)
ROP Working Party (Rules of Procedure)
ST Working Party (Standard Terminology)
SUT Working Party (Sutures)
TCM Working Party (Traditional Chinese Medicines)
VIT Working Party (Vitamins)
VSMADM Working party (Vibrational Spectroscopy and Analytical Data Modelling)
WAT Working Party (Water)

What is expected from experts?

(1/2)

- Fair contribution of work on a voluntary basis, including the provision of results of experimental work, where required, and respect the time limits set for assignments (Guide for work, § 2.3.4 & § 2.3.8)
- Maintain confidentiality concerning the work of the group. (Guide for work, § 2.3.9)
What is expected from experts? (2/2)

• Maintain proper communication with the Secretariat, for example by making regular reports on the progress of work (Guide for work, § 2.3.10)

• Attend all meetings of the Group (physically or via webex for ex.)

• Inform the Secretariat in good time if unable to attend a meeting. (Guide for work, § 2.3.11)

  - If an expert fails to attend three consecutive meetings, the Chair of the Group of Experts or Working Party and the Secretariat may decide to stop sending documents and other written communications to this expert. (Guide for work, § 2.3.12)

• When an expert attends and plays an active role in conferences organised by third parties on subjects relevant for the activities of the Ph. Eur. Commission, he shall keep informed the Chair of the Commission and the Secretariat prior to the conference. (Guide for work, § 2.3.14)

What information do experts receive?

• Experts receive all documents and other written communications intended to be studied by the Group (Guide for work, §2.3.9)

• List of basic documents provided to experts:
  • Rules of procedure of the European Pharmacopoeia Commission
  • Guide for the work of the European Pharmacopoeia
  • Code of Practice for the work of the European Pharmacopoeia

The Style Guide is made available on request.
Can anyone else participate?

- Only experts appointed by the Ph. Eur. Commission can participate in the Groups.
- Experts may involve other persons in their work for the Pharmacopoeia (Guide for work, § 2.3.13)
  - where this is useful for the advancement of the work
    In this case the expert is responsible for ensuring:
    - that these persons are aware of the confidential nature of information and data provided and
    - that the results of the work shall only be used by the Ph. Eur.
- Substitutes for experts from non Ph. Eur. member states are not allowed unless decided so by the Commission or, in urgent cases, by its Chair. (Guide for work, §2.5.2)

Please fill in one nomination form for each of the groups you are interested in.

Specify the Group of experts or working party in which you wish to become an expert.

For example: Dr, Prof., Mr or Ms

Please highlight any specific area of expertise you might have.

Please see the terms of reference and profile for experts of the concerned Group in which you wish to become experts.

Critical to fill in if you wish the Ph. Eur. Commission to consider your candidature and if you answered “No” above.
**Why become a Ph. Eur. expert?**

- Help shape Ph. Eur. texts at an early stage.
- Be part of a network that brings together experts from a wide variety of professional backgrounds including experts from national authorities (e.g. national pharmacopoeia authority, official medicines control laboratory, licensing authority, inspectorate), from the private sector (pharmaceutical or chemical industry), from academia or from a research organisation. This will give you a unique opportunity to share information and experience, to better understand difficulties linked to the elaboration and revision of pharmacopoeial texts, and to find a common way forward based on a mutual understanding.
- Network and exchange experiences in a European and international environment.
- Make your CV stand out from the crowd! Becoming an expert will give you a great opportunity to expand your knowledge of the Ph. Eur. and the European regulatory system.
- Get free access to the Ph. Eur. (for example)
Next steps

- All nominations received by EDQM by 24 October 2016 latest will be reviewed by the Ph. Eur. Commission at its 156th session (22 – 23 November 2016)
  - Decision communicated by EDQM to experts from non Ph. Eur. Member States as of December
  - Decision communicated by NPAs to experts from Ph. Eur. Member States
Declaration of Interests 
DOI

Dr Pierre LEVEAU
Head of the Quality, Safety & Environment Division
CoE/ EDQM

Why declaring interests?

Public Health considerations as well as integrity and objectivity as stated in the EDQM Core Values statement have a primary importance in all works undertaken under the aegis of the European Directorate for the Quality of Medicines & HealthCare (EDQM).
Why declaring interests?

Measures need to be taken to ensure that the best decision and assessment of scientific evidence are achieved in an independent atmosphere free of either direct or indirect pressures.

Impartiality is mainly related to individual responsibility. Nevertheless, actions can be put in place to give the highest level of confidence to EDQM interested parties and public.

Why declaring interests?

Decisions must be taken by informed, skilled, experienced professionals. Many experts have, or have had, connections with commercial entities (e.g. the pharmaceutical industry), and this may have an impact on their impartiality.

To reassure stakeholders that the decisions are impartial and for transparency reasons, a robust policy governing the declaration and management of interests has been put in place.
Declaration of Interests

Prior to their appointment, individuals taking part in the work of the EDQM will provide a written declaration of interests and confidentiality undertaking.

This is done through FORM/226 available on the EDQM website.

Definitions of terms used in FORM/226:

Close family members: mean first-line members of the family (i.e. spouse or partner, children and parents).

The expression “Concerned commercial entity” includes any commercial business, industry association, research institution or other enterprise whose funding is significantly derived from commercial sources with an interest related of the meeting or work.

Note: independent researchers and research organisations including universities and learned societies are excluded from the scope of the above definition.
Declaration of Interests

FORM/226 must be updated by the expert to reflect any significant changes in the individual’s interests arising during his/her period of tenure. Such information shall be provided in writing, prior to attendance at the next meeting or session and a regular update of the DoI will be requested by the EDQM.

FORMs are kept by the EDQM.

Declaration of Interests

Access to information:
All completed declarations of interests may be consulted at the EDQM.
Such requests must be made via the EDQM Helpdesk system.
No declaration is published on the EDQM website.
How to fill in FORM/226?

You are requested to declare any interests in a concerned commercial entity that you currently have or have had within the past 3 years.

You may also provide information on interests over 3 years ago. This information could be useful in the context of increased transparency regarding previous interests. If this should be the case, please declare under §2.6.

“Current” is interpreted as at the time of completion of the form.

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How to fill in FORM/226?

Part 1: Personal details.

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<thead>
<tr>
<th>Personal Details</th>
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<tbody>
<tr>
<td>First name:</td>
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<tr>
<td>Institution / Company:</td>
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<td>Contact e-mail address:</td>
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</tbody>
</table>

I hereby declare on my honor that, to the best of my knowledge, the only direct or indirect interests I have in concerned commercial entity are those listed below:

Please specify the interests that you currently have (at the time of completion of the form) or have had within the past 3 years.
How to fill in FORM/226?

Part 2: Declaration of interests.

2.1. Employment in a concerned commercial entity

- No
- Yes

2.2. Consultancy

- No
- Yes

2.3. Financial Interests

- No
- Yes

Financial Interests, including holding of shares in a concerned commercial entity and receipt of any other fees/honoraria

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<thead>
<tr>
<th>Name of concerned commercial entity</th>
<th>Financial Interest</th>
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Only the nature of the interest has to be mentioned, not the amount.

2.4. Grant / Funding to Institution/Organisation

- No
- Yes

2.5. Close Family Member Interests

- No
- Yes

Interest of Close Family Member

<table>
<thead>
<tr>
<th>Name of concerned commercial entity</th>
<th>Type of Interest Declared</th>
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Please indicate known interests currently held by first-line members of your family (i.e. spouse or partner, children and parents).

Neither the relationship nor the name need be declared.

Interests to be declared include all current Direct Interests (i.e. Employment, Consultancy, Current Financial interests or current Patent Ownership).
How to fill in FORM/226?

Part 2: Declaration of interests.

2.6. Any other matters that might be of interest for transparency purposes  
☐ No  ☐ Yes

Work for or provide expert advice to non-European pharmacopoeias:  
☐ No  ☐ Yes

Any other information you want to provide for transparency purpose can be added in the box.

How to fill in FORM/226?

Part 3: Confidentiality undertaking.

Read carefully the confidentiality undertaking agreement.

Signing this Declaration of Interests and confidentiality undertaking implies that you adhere to the information declared in this part.