The European Pharmacopoeia

Part 1
Ms Cathie Vielle

Agenda

• The European Pharmacopoeia or how to turn challenges into opportunities and successes
  • Nomination process
  • Ph Eur implementation strategy of the Q3D guideline
Ph. Eur. Commission: one decision body ...

- One delegation per member state or observer (always welcomed)
- 37 Member States plus a delegation from the EU (a representative from DG Health & Consumer and the EMA); 28 Observers including World Health Organization (WHO).
- Delegates come from health ministries, health authorities, pharmacopoeias, universities, or industry and are appointed by the national authorities on the basis of their expertise.
- Three sessions a year; draft texts are published for public consultation and adopted by unanimous vote.
- Currently 20 permanent Groups of Experts & more than 50 ad hoc Working Parties
- EDQM/EPD provides the secretariat

... and more than 70 groups ...

![Biologicals: 3,4%
Chemicals: 53,7%
Dosage forms: 3,0%
Fats: 5,1%
Herbals: 11,0%
Homoeopathy: 0,5%
Human vaccines: 4,7%
Radiopharm.: 0,8%
Blood deriv.: 1,2%
Antibiotics: 6,2%
Gases: 0,8%
Biologics: 3,4%
Vet. Vaccines: 4,7%](image)
… going into one direction: The Ph. Eur.  
\[\rightarrow\] A success story!

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

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

- Concrete outcomes \[\rightarrow\] More than 2200 monographs and 340 general chapters adopted

The Ph. Eur. needs to stay “State of the Art”— a constant challenge -

Developments in Regulatory Environment

Need to regularly review & update and create new Ph Eur texts

Increased demand for Generic and Biosimilar products

Scientific / technical evolutions

Developments in Manufacture and Globalisation

New risks to Public Health
The Ph. Eur. network: An asset!

- More than 700 members in Ph. Eur. Groups
- Nominated by the Ph. Eur. Commission
- With a well balanced expertise:
  - Approx. 1/3 from Health Authorities including observer from EMA => relationship with EU regulators is a strength!
  - 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)

Why still national Pharmacopoeias then?

- For texts of interest to one Member State only; for texts out of the scope of the Ph. Eur. (e.g. national formularies)
- Three main approaches (country specific):
  - Discontinuation of the national pharmacopoeia (e.g. Sweden, Finland, the Netherlands), Ph. Eur. as the only pharmacopoeia, potentially translated into national language
  - Maintenance of a national pharmacopoeia to complement the Ph. Eur.:
    - Inclusion of the Ph. Eur. in the national pharmacopoeia (e.g. BP, Royal Spanish Pharmacopoeia).
    - Publication of a National pharmacopoeia in addition to the Ph. Eur. (e.g. France, Germany, Switzerland, Austria)
The European Pharmacopoeia: a transparent process

• All revised and new texts published online in Pharmeuropa (the European pharmacopoeial forum, free access) for public enquiry
• Work programme available on EDQM website
• Style guide and technical guides freely available and downloadable on EDQM website
• Knowledge database (free access) useful information
• Organisation of hearings of interested parties

Basis for monographs

• Monographs must take account of all currently approved products on the European market
• Approved specification(s) are the main basis backed up by batch data
• Draft monographs are checked by regulatory authorities at Pharmeuropa stage
**Monographs: how?**

**Procedure 1**

- A
- B
- C
- D

**Revision**

**MONOGRAPH**

valid for A, B, C & D

Multi-source products and monograph revisions

On request, data are handled confidentially by EDQM

**Procedure 4**

- A
- B
- C
- D

**Revision**

**MONOGRAPH**

Applicable to

**Knowledge database**

History: contains information concerning certain technical modifications to some revised/corrected texts published since Ph.Eur. 5.0. This information complements the modifications indicated by lines in the margin in the supplements and is not necessarily exhaustive.

**Supplement 1.6**

The characterisation is based on the results of a series of tests conducted by the European Pharmacopoeia. A single test, a light microscope examination of the glass in the test tube, has been used to assess the presence of a single obstruction in the glass container. The results of the test are reported in the monograph under the heading "Light Microscopic Examination of Glass Containers" and are presented in the table below.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Light Microscopic Examination of Glass Containers</td>
<td>Single obstruction present in glass container</td>
</tr>
</tbody>
</table>

**Revision**

**MONOGRAPH**

valid for A, B, C & D

Single-source products, direct co-operation with innovator

Data are handled confidentially by EDQM

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The monograph has been authorised but work has not started yet.

1. Work has started (first draft).

2. The monograph has been submitted for adoption to the European Pharmacopoeia Commission.

3. The monograph has been adopted.

4. The monograph is about to be published or has been published (see the supplement number indicated and the calendar of the editions below).

The section reflects the status of the text with regard to the work of:
- the Pharmacopoeia Discussion Group (PDG), a joint collaboration between the United States Pharmacopeia, the Japanese Pharmacopoeia and the European Pharmacopoeia.
- the International Conference on Harmonisation (ICH) Quality Guideline on Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH (Q4B).

Further information can be found in chapter 5.8 (Pharmacopoeial Harmonisation) of the European Pharmacopoeia.

For guidance purposes: provides additional information to users e.g. column / trade names.

Of certificate(s) of suitability have been granted for the substance in question, their list is shown. This is an excerpt from the online List of CEP.

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2016: CALL FOR EXPERTS

• All groups to be re-appointed in November 2016
• **New**: nomination process opened up to experts from non Ph. Eur. member states and from non-Observers
• The **final decision** to nominate a member to a Group of experts or working party is taken by the Ph. Eur. Commission
How to become an expert?

- What is needed to apply?
  - A completed nomination form
  - A completed declaration of interest form
  - An up-to-date *Curriculum vitae* [highlighting the expertise in the technical field covered by the Group]

- What we will make available to support candidates:
  - The nomination form *to be completed*
  - The *declaration of interest form to be completed*
  - The terms of reference and profile for experts
  - Our time and support in case of questions ...

Why joining the Ph. Eur. network?

- To help shaping Ph. Eur. texts at an early stage
- To create and to participate in a network with assessors, OMCLs, academics and Industry representatives. This will provide you with unique opportunities:
  - To share experience and competencies
  - To better understand difficulties and opportunities,
  - To find a common way forward based on a mutual understanding,

  ➢ To network and exchange experiences in a European and International environment!
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Control of Elemental Impurities

**EU**

ICH Q3D for elemental impurities
Implementation schedule as decided by CHMP:
- For new products: June 2016
- For already existing products: December 2017

**Ph Eur**

Decision taken by the Ph. Eur. Commission to align revision of Ph Eur texts with latest implementation schedule of ICH Q3D in Europe i.e. Dec 2017:

- Individual monographs with cross-reference to Chapter 2.4.8 Heavy metals ➔ deletion of the cross-reference (Pharmeuropa 27.2) Implementation date: 01/01/17 (9th Edition)
- General monograph Pharmaceutical preparation (2619) ➔ will refer to Chapter 5.20 ➔ ICH Q3D will become legally binding in all Ph Eur signatory parties (Pharmeuropa 28.2)
- General monograph Substances for pharmaceutical use (2034) ➔ to clarify how to handle substances used in drug products outside of the scope of ICH Q3D guideline (Pharmeuropa 28.2)
- Chapter 5.20 ➔ revision to reproduce the principles of ICH Q3D instead of EMA GL
- Chapter 2.4.20 ➔ 1- revision to align with ICH wording ; 2- harmonisation with USP & JP
- Discussion ongoing: impact on monographs for substances of natural origin (e.g. mined excipients) where elemental impurities are potentially present and not intentionally added.

**EMA guideline on the specification limits for residues of metal catalysts or metal reagents**
- Date for coming into effect: 01/09/2008 (for new products)

**ICH Q3D for elemental impurities**
Implementation schedule as decided by CHMP:

EU, JP, US FDA, Health Canada, Swissmedic,]