

# The European Pharmacopoeia

## Part 1

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## Agenda

- **The European Pharmacopoeia or how to turn challenges into opportunities and successes**
- Nomination process
- Ph Eur implementation strategy of the Q3D guideline

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## Ph. Eur. Commission: one decision body ...



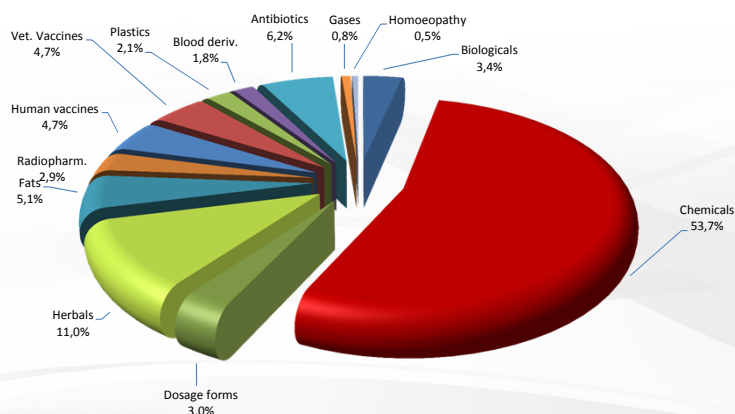
- One delegation per member state or observer (always welcomed)
- 37 Member States plus a delegation from the EU (a representative from DG Health & Consumer and the EMA); 28 Observers including World Health Organization (WHO).
- Delegates come from health ministries, health authorities, pharmacopoeias, 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

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## ... and more than 70 groups ...



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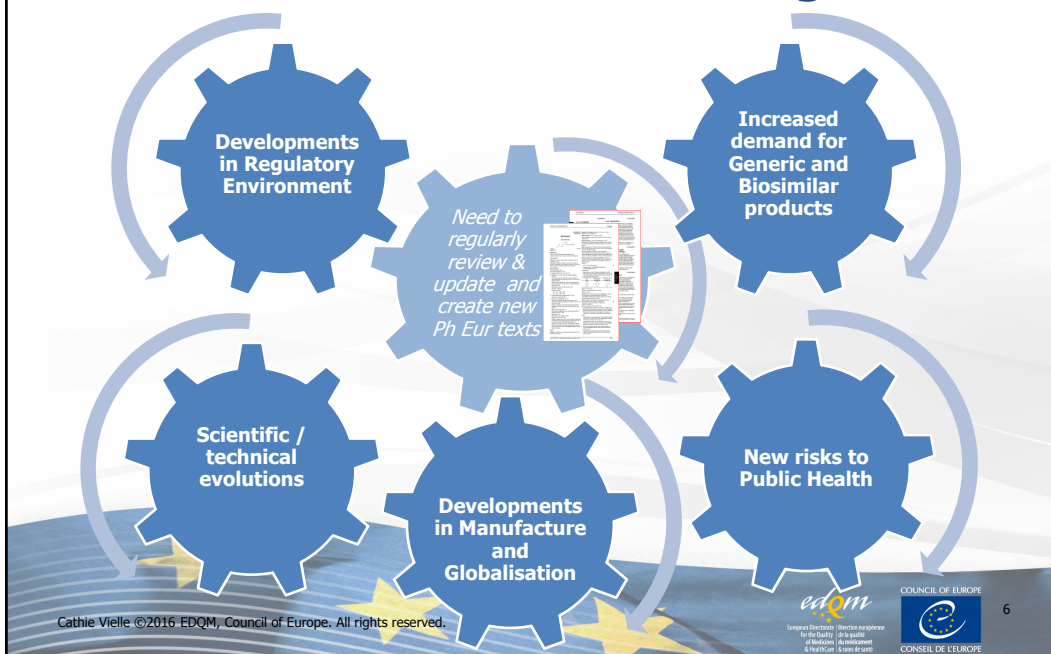


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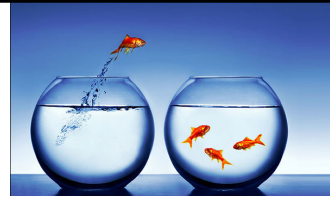
## ... going into one direction: The Ph. Eur. → A success story!

- 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 → added on the Ph. Eur. work programme)
- **Opportunities**:
  - saving of resources
  - no subsequent need to harmonise national positions
- **Concrete outcomes** → More than 2200 monographs and 340 general chapters adopted

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



## 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)

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## 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)

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## The European Pharmacopoeia: a transparent process

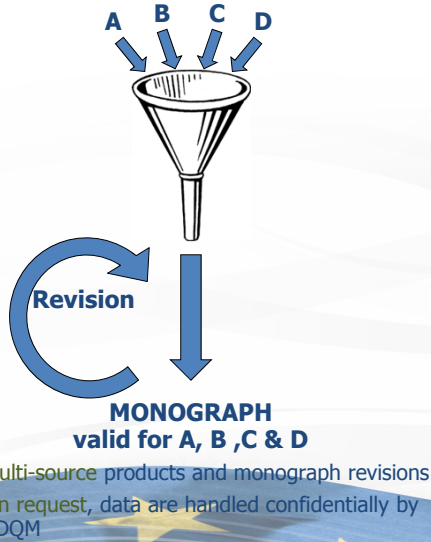
- All revised and new texts published online in **Pharmeuropa** (the European pharmacopoeial forum, free access) for public enquiry
- **Work programme** available on EDQM website
- **Style guide** and **technical guides** freely available and downloadable on EDQM website
- **Knowledge database** (free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

## Basis for monographs

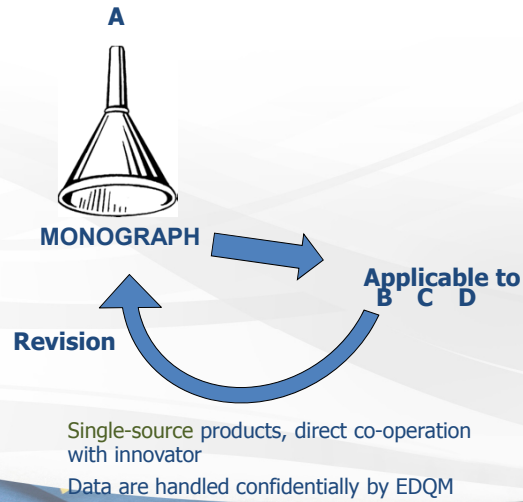
- Monographs must take account of all currently **approved products** on the European market
- **Approved specification(s)** are the main basis backed up by **batch data**
- Draft monographs are **checked by regulatory authorities** at Pharmeuropa stage
- Policy for monograph development is given in:  
*Technical Guide for the Elaboration of Monographs*  
**recently revised** (7<sup>th</sup> **Edition** – 2015) (available on the EDQM website)

# Monographs: how?

## Procedure 1



## Procedure 4



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# Knowledge database

Search Database online | 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.

Detailed view of .

Status	In use
Monograph Number	30201
English Name	Glass containers for pharmaceutical use (3.2.1.)
French Name	Réceptifs de verre pour usage pharmaceutique (3.2.1.)

### SUPPLEMENT 6.8

Test 6. Hydrolytic resistance of glass grains: the limits have been corrected to fit with the ISO 720 (1995) standard. The equivalence of alkali expressed as mass of Na<sub>2</sub>O per gram of glass has been deleted because this information is redundant.

**PUBLICATION 5.0:** for more than 50 years it has been known that alkaline or neutral preparations for parenteral use may affect the inner surface of glass containers. A small amount of alkali may be leached and can cause a change in the composition of the preparation. The intensity of the attack in comparable conditions depends on the nature of the product, and the composition of the glass type used for manufacturing the containers.

The last edition of the European Pharmacopoeia prescribed 2 tests for the classification of glass used in glass containers. The glass-grain test gives sufficient information on the glass as a material but inadequate information about what happens to the inner surface of the glass in contact with the solution. For this reason the hydrolytic surface test has been developed. The release of alkali from the glass surface is determined by titration as a mean value of a number of containers. This test can be done in laboratories with common equipment. The disadvantage is that there is no information about the standard deviation concerning the results of the single containers and no information about outliers.

In addition to the general chapter there are the following ISO standards:

ISO 720 - Glass-Hydrolytic resistance of glass grains at 121 °C.

ISO 4802 - Glassware-Hydrolytic resistance of the interior surfaces of glass containers:

Part 1: Determination by titration.

Part 2: Determination by flame spectrometry.

These standards are mainly based on the work of Technical Committee 2 of the International Commission on Glass (ICG). Recent studies and laboratory intercomparisons have shown that the results obtained using the titrimetric or the flame spectrometry method are not always comparable. Both methods cannot be considered equivalent nor interchangeable.

It has therefore been decided to keep the current titrimetric method as the official method but describe the flame spectrometry method in an annex to this chapter and restrict its use to specific cases.

In view of the fact that some reagents in the test for arsenic are rather toxic it was decided to replace the test by Atomic Absorption Spectrometry.

As the present method of measuring the light transmission is not very precise due to the scattering of the light on the glass surface it has been proposed to use a UV-VIS spectrophotometer equipped with a photodiode detector or equipped with a photomultiplier tube coupled with an integrating sphere.

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Chromatogram	Not available
Additional information	Not available
History	<a href="#">View history</a>
Interchangeable (ICH_Q4B)	NO
International Harmonisation chapter 5.8	NO
Reference standards	
To be used in test (s)	Brand Name
Trade Names	Test B. Hydrolytic resistance of glass grains. Steel mortar and pestle. Humboldt Manufacturing Co., 7300 West Agate, Norridge, Chicago, IL 60656, USA.

## Monograph under elaboration

- 0 The monograph has been authorised but work has not started yet  
 1 Work has started (first draft)  
 2 The monograph has been authorised for publication in Pharmedropa (see Pharmedropa number)  
 3 The monograph has been submitted for adoption to the European Pharmacopoeia Commission  
 4 The monograph has been adopted  
 5 The monograph is about to be published, or has been published (see the supplement number indicated and the calendar of the editions below)

Status	Elaboration
Monograph Number	02781
English Name	Tolterodine tartrate
French Name	Toltérodine (tartrate de)
Latin Name	Tolterodini tartras
Pinyin Name	
Chinese Name	
Pharmedropa	25.3
Published in English Supplement	
Published in French Supplement	
On-going	Elaboration
State of work	4 - DEF
Pharmedropa	25.3
Description	Elaboration
Chromatogram	Not available
Additional information	Not available
History	
Interchangeable (ICH_Q4B)	NO
International Harmonisation chapter 5.8	NO
Reference standards	
Trade Names	To be used in test(s) Brand Name Enantiomeric purity Column: Chiral AGP Related Substances Column: Hypersil BDS C18 Dwell volume: 1.3mL test
CEP	

The number of the last issue of Pharmedropa into which a draft of the monograph was published

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 Pharmacopoeia, 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.

## Monograph under revision

Two on-going revisions

Status	In use
Monograph Number	01210
English Name	Fentanyl
French Name	Fentanyl
Latin Name	Fentanylum
Pinyin Name	
Chinese Name	
Pharmedropa	
Published in English Supplement	7.6
Published in French Supplement	7.6
On-going	Deletion of impurity H as specified impurity
State of work	2 - Pharmedropa
Pharmedropa	
Description	reduce limit from 0.15 % as specified impurity to 0.10 % as unspecified impurity
On-going	Improvement of related substances test
State of work	0
Pharmedropa	
Description	
Chromatogram	Available
Additional information	Not available
History	<a href="#">View history</a>
Interchangeable (ICH_Q4B)	NO
International Harmonisation chapter 5.8	NO
Reference standards	Available since Cat. No. Name Batch No. Unit Quantity Price Fentanyl - reference spectrum E0054990 1 n/a 79 EUR 06/05/2014 Y0001509 Fentanyl for system suitability - * narc 2 15 mg 79 EUR
Trade Names	To be used in test(s) Brand Name Related substances Inertail ODS-3
Substance Number	Substance Holder Certificate Number Issue Date Status End date Type
L210	Fentanyl N.V. ORGANION NL 5349 AB Oss R1-CEP 2003-090-Rev 00 19/01/2009 VALID Chemistry
L210	Fentanyl Rusan Pharma Ltd. III 400 067 Mumbai R0-CEP 2003-164-Rev 00 06/10/2008 BY EDQM WITHDRAWN 13/11/12 Chemistry

- Aim of the revision  
 - State of work  
 - The number of the last issue of Pharmedropa into which a draft of the monograph was published

## Agenda

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- **Nomination process**
- Ph Eur implementation strategy of the Q3D guideline

## 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!**

# Agenda

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# Control of Elemental Impurities

