# How to participate in the Elaboration and Revision of Monographs

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# Basis for monographs

- Monographs must take account of all currently approved products
- 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*

  just revised (7th Edition – 2015) (available on the EDQM website)

## The interactive drafting process ensures that high quality and relevant Ph. Eur. standards are developed

Chair of Ph. Eur. Commission
Member states' delegations
Experts groups
EDQM

**Request for Revision/ Creation**

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Approval by the **Ph. Eur. Commission**

- **Define Working Procedure**
- **Assign to Working Group**

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**Ph. Eur. Expert** group works

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**Pharmeuropa** public enquiry

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Adoption by the **Ph. Eur. Commission**

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**Publication** in the Ph. Eur.






## Stages in elaboration or revision (1)

- Addition to work programme by Commission:
  public announcement
- Interested parties can **(and should!)** express an interest
- Elaboration, experimental checking of draft
- Publication in Pharmeuropa (3-months comment period)

# Stages in elaboration or revision (2)

- Study of **comments** by group of experts/working party
- **Submission to Commission** for adoption
- **Publication** within 6 months
- **Implementation** 1 year after adoption
  (see publication schedule available on website)

Overall timescale:

minimum 2-3 years

| Commission Sessions | | Edition Supplement | Publication schedule | Implementation date |
|---|---|---|---|---|
| Session No. | Date | | | |
| 153 | November 2015 | 9th Edition | July 2016 | 1 January 2017 |
| 154 | March 2016 | 9.1 | October 2016 | 1 April 2017 |
| 155 | June 2016 | 9.2 | January 2017 | 1 July 2017 |
| 156 | November 2016 | 9.3 | July 2017 | 1 January 2018 |
| 157 | March 2017 | 9.4 | October 2017 | 1 April 2018 |
| 158 | June 2017 | 9.5 | January 2018 | 1 July 2018 |
| 159 | November 2017 | 9.6 | July 2018 | 1 January 2019 |
| 160 | March 2018 | 9.7 | October 2018 | 1 April 2019 |
| 161 | June 2018 | 9.8 | January 2019 | 1 July 2019 |
| 162 | November 2018 | 10th Edition | July 2019 | 1 January 2020 |





# Work programme (1)

Based on proposals from:

- National delegations
- Groups of experts
- EDQM

*Manufacturers can submit proposals via one of the above*

# Work programme (2)

- Additions announced on:
  - ✓ EDQM website (http://www.edqm.eu/en/european-pharmacopoeia-work-programme-607.html)
  - ✓ Pharmeuropa-on-line (http://pharmeuropa.edqm.eu/home/) under "*useful information*"
- Status (steps 1-5) displayed on the website




# Work status: see Knowledge database

Key to information on State of Work (SoW):

**0** = on the work programme, no first draft
**1** = first draft (new or revised monograph)
**2** = published (or in press) in Pharmeuropa
**3** = submitted to the Commission
**4** = adopted, ready for publication
**5** = published

## The different procedures for drafting/revising monographs consider particularities of the substances/products

**Procedure 1** (group of experts):

- Multi-source products and monograph revisions

On request, data are handled confidentially by EDQM

**Procedure 5** (only for the HOM WP):

- **Follows Procedure 1**, but considers the traditional differences in Europe: e.g. where several national monograph exists, they can be adapted to produce a European monograph with harmonised requirements.

**Procedure 4** (working party of regulators):

- Single-source products, direct co-operation with innovator

Data are handled confidentially by EDQM





## New monographs: active pharmaceutical ingredients

Addition to the work programme depends on:

- therapeutic importance
- extent of use
- number of countries in which product is approved

# Proposing a new monograph

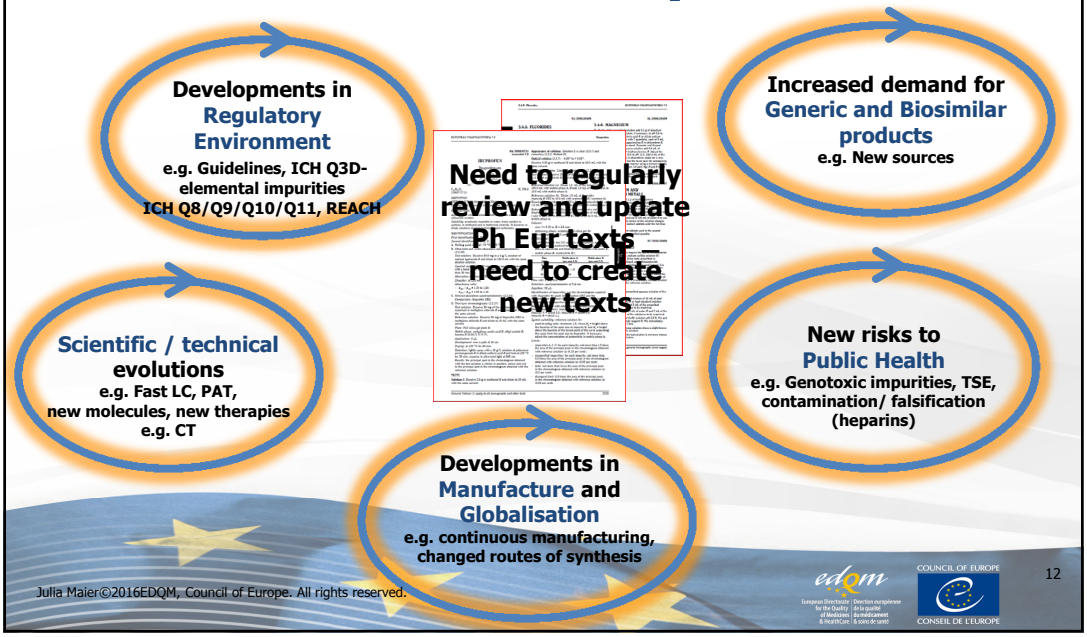
Contact your National Pharmacopoeia Authority (in Europe) or EDQM (from outside Europe)

- **Initial data**: countries where the product is approved
- **Data package**:
  - Current specifications
  - Validation reports
  - Batch and stability data
  - Samples of substances and impurities
  - Full description of data package is available





# Revision: why? (2)



# Revision: why? (2)

- New sources have new impurity profiles
- New quality issues arise
- Analytical methods change: more convenient methods, more powerful methods, more reliable methods become available
- International harmonisation (PDG, ICH, VICH)





# How can manufacturers request revision?

- Europe: via National Pharmacopoeia Authority
  (address list on EDQM website and in Pharmeuropa)
- Outside Europe: contact EDQM which will refer the matter to a group of experts or to the Commission
- Make clear what needs revising and if possible make a concrete proposal

# Data for revision

- Revision can only be undertaken if the request is backed up by sufficient data
- Give batch data, sample chromatograms, etc. to enable a decision on the need for revision
- Supply validated methods (if possible, cross-validated against official Ph.Eur method) and **samples** specially for all impurities controlled by the new method




# Revision programme

- Work programme is announced via EDQM website and to industry associations and pharmacopoeia liaison contacts
  (http://www.edqm.eu/en/european-pharmacopoeia-work-programme-607.html)
- Declare an interest for relevant items
- Make sure you see Pharmeuropa for revision proposals
- Provide samples, test draft proposal

## Reasons for revisions are explained with the Pharmeuropa enquiry and later on the Knowledge database

**FAQ**: "Why did you revise the monograph on…?"

You can find out via:

- Briefing notes in Pharmeuropa
- Collected briefing notes posted on the website for each new edition/supplement (http://pharmeuropa.edqm.eu/home/menupage/English/Useful%20Information/Supplementcomments82.pdf)
- Knowledge database (monograph history)

*No briefing notes for corrections*

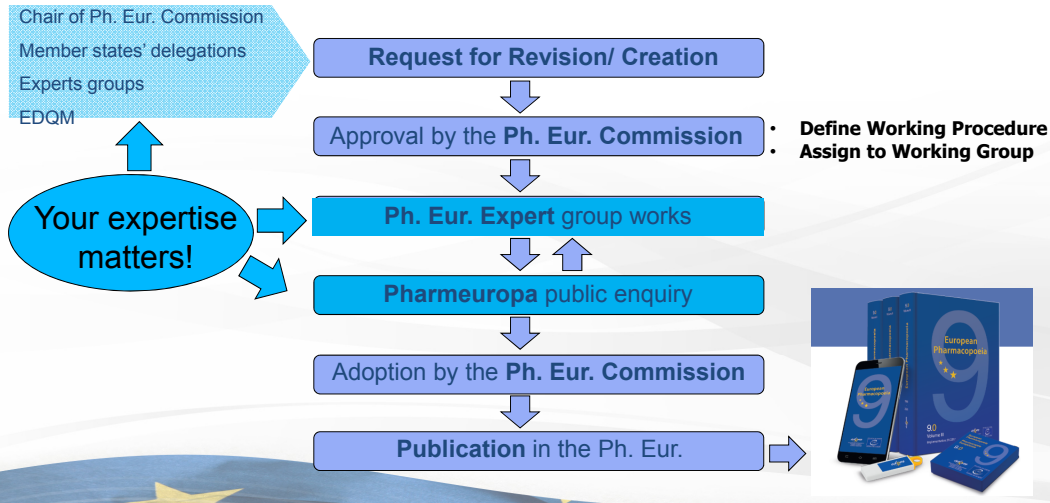




## Participation is possible for everyone with suitable expertise at several stages

- Participation depends on the procedure used
- For all procedures - provide samples for testing and participate as early as possible (*i.e.* before the text is published for comments in Pharmeuropa so at state of work 0 or 1)
- Only information on actives and excipients used in already approved products licensed in Europe is considered

# There are multiple possibilities to participate in the elaboration of the Ph.Eur.








# Become an expert - join the Ph.Eur. network

- **More than 700** experts mainly from the Ph Eur member and observer states and but also from "beyond"
  - Well balanced expertise approx. 1/3 from health authorities, 1/3 from industry, 1/3 from University/ Hospital
  - New: the Ph Eur Commission has opened up to the nomination of experts from non-European Pharmacopoeia member states and non-observers states
- Your profile should fulfil the criteria laid down under **"Profile for experts" for the relevant group**
- Nominations from Ph.Eur. member states are submitted by the national pharmacopeial authority; all others are submitted directly to EDQM
- **HMM** (Homoeopathic Manufacturing Methods) and **HOM** (Homoeopathic Raw Materials and Stocks): currently approximately 20 experts
- **more information available on the EDQM web site** : https://www.edqm.eu/en/join-network

# Thank you for your attention