How to develop/revise an Excipient Ph Eur monograph : an industry experience

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Pharmacopoeia Review & Harmonisation Committee
Chair

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Monograph elaboration: Ph Eur versus USP flow chart

Ph Eur COMMISSION
decides to elaborate or revise a monograph

GROUP of EXPERTS prepares a draft

Public Inquiry in PHARMEUROPA

GROUP of EXPERTS examines the comments and modifies the draft monograph accordinlgly

The draft monograph is proposed for adoption to the Ph Eur COMMISSION

Adopted | Not adopted

1

2

3

4

Development or revision of a monographs by EXPERT COMMITTEE

Public inquiry in PHARMACOPEIAL FORUM

EXPERT COMMITTEE evaluates the proposal

Defer | **Forward** | Cancel

The EXPERTS COMMITTEE ballots on the proposal

Approved | Not approved

How to interact/participate in Ph Eur work ?

Non Ph Eur members states

Via National Health Authority

Monograph proposal

Via Helpdesk Tool:
+ form :
"REQUEST FOR REVISION OF A MONOGRAPH OR GENERAL CHAPTER "

- 4 issues/year (JAN/APR/JULY/OCT)
- 90 days period
- Free access: *http://pharmeuropa.edqm.eu*

Comments

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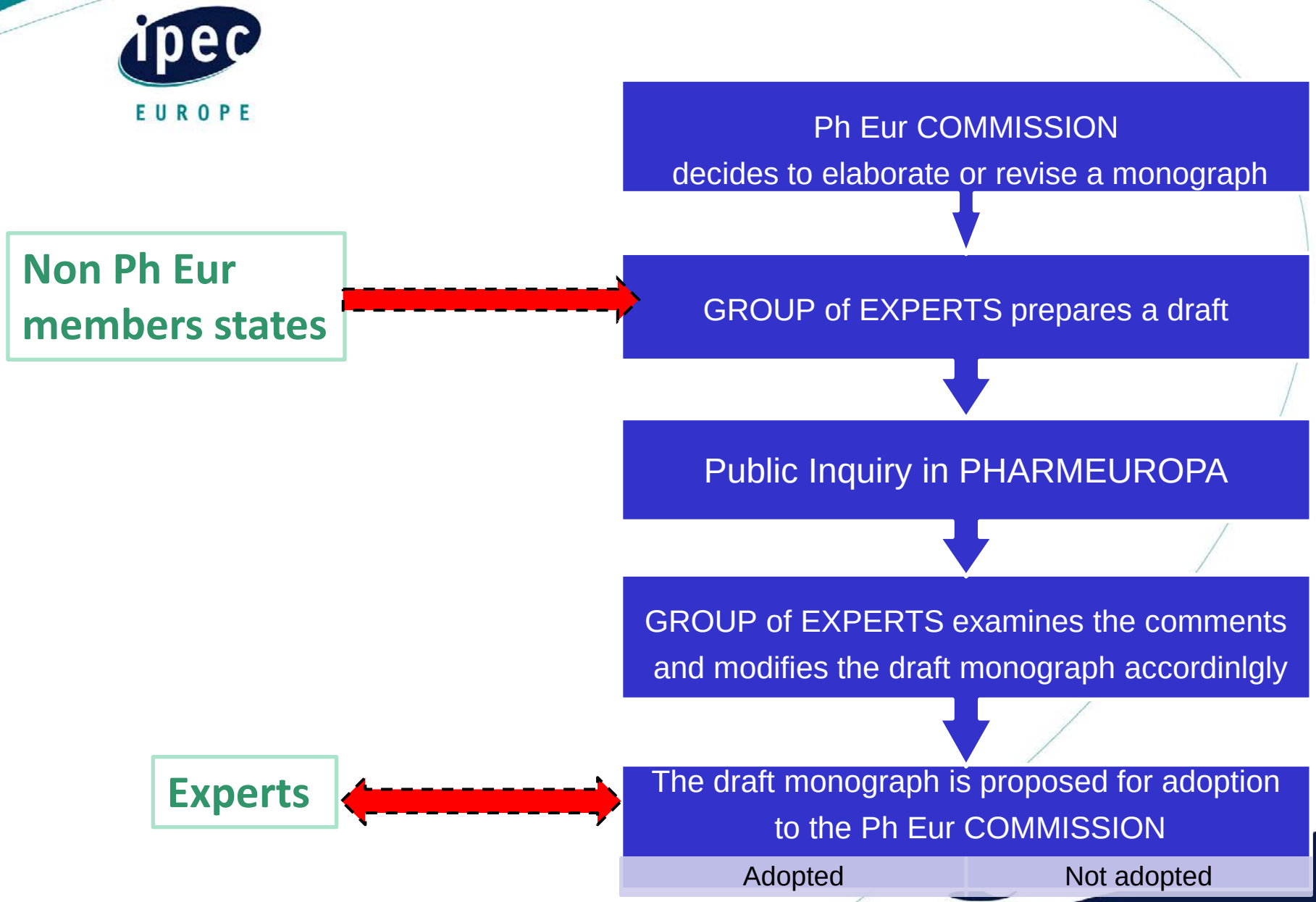
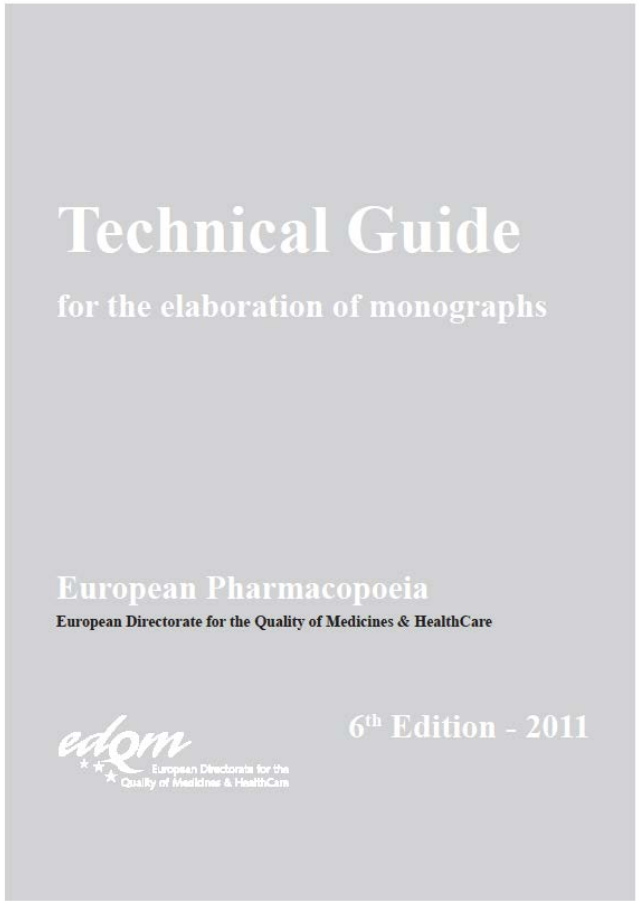
How to interact/participate in Ph Eur work ?



Some tools : TECHNICAL GUIDES

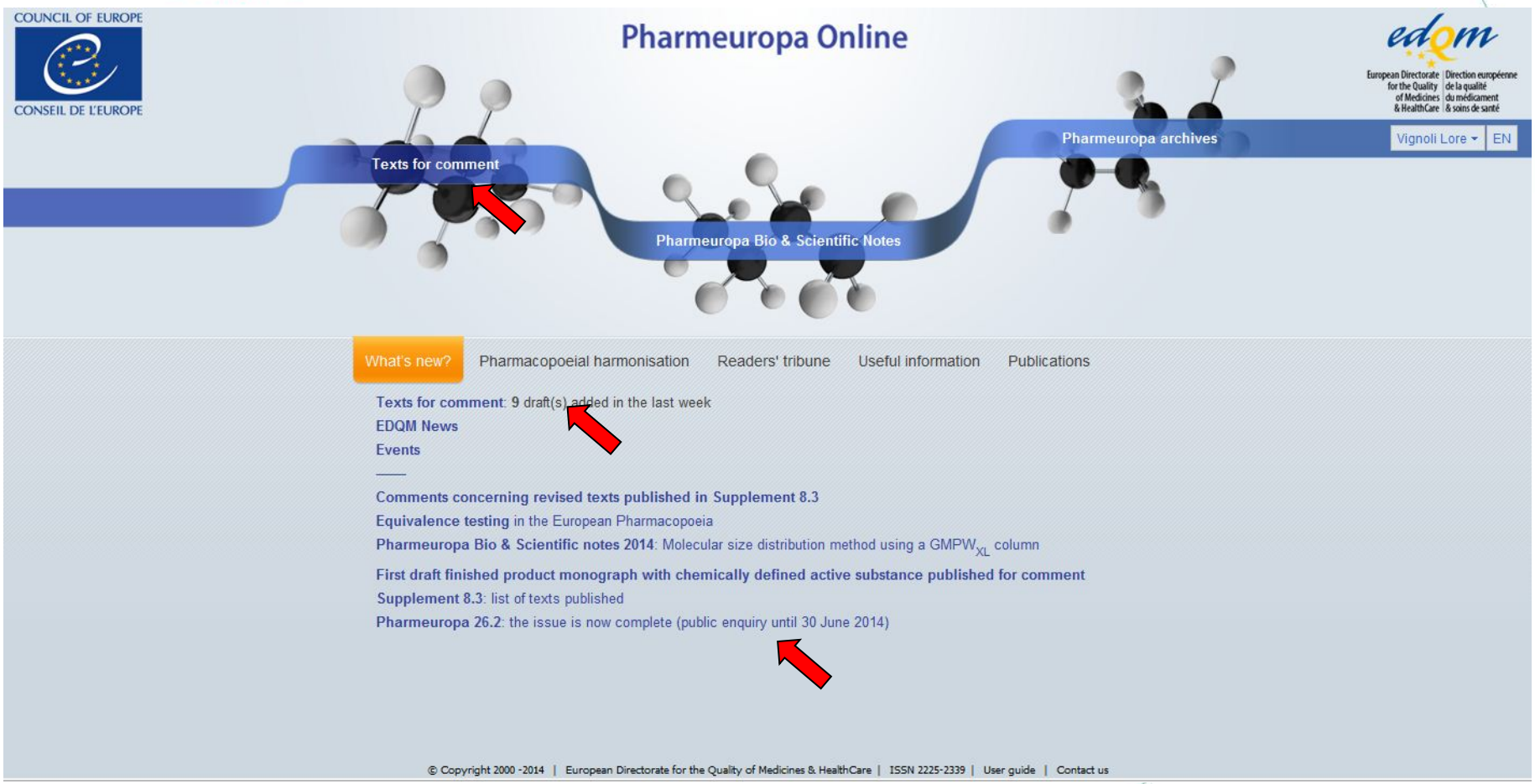
Download: http://www.edqm.eu/en/technical-guides-589.html

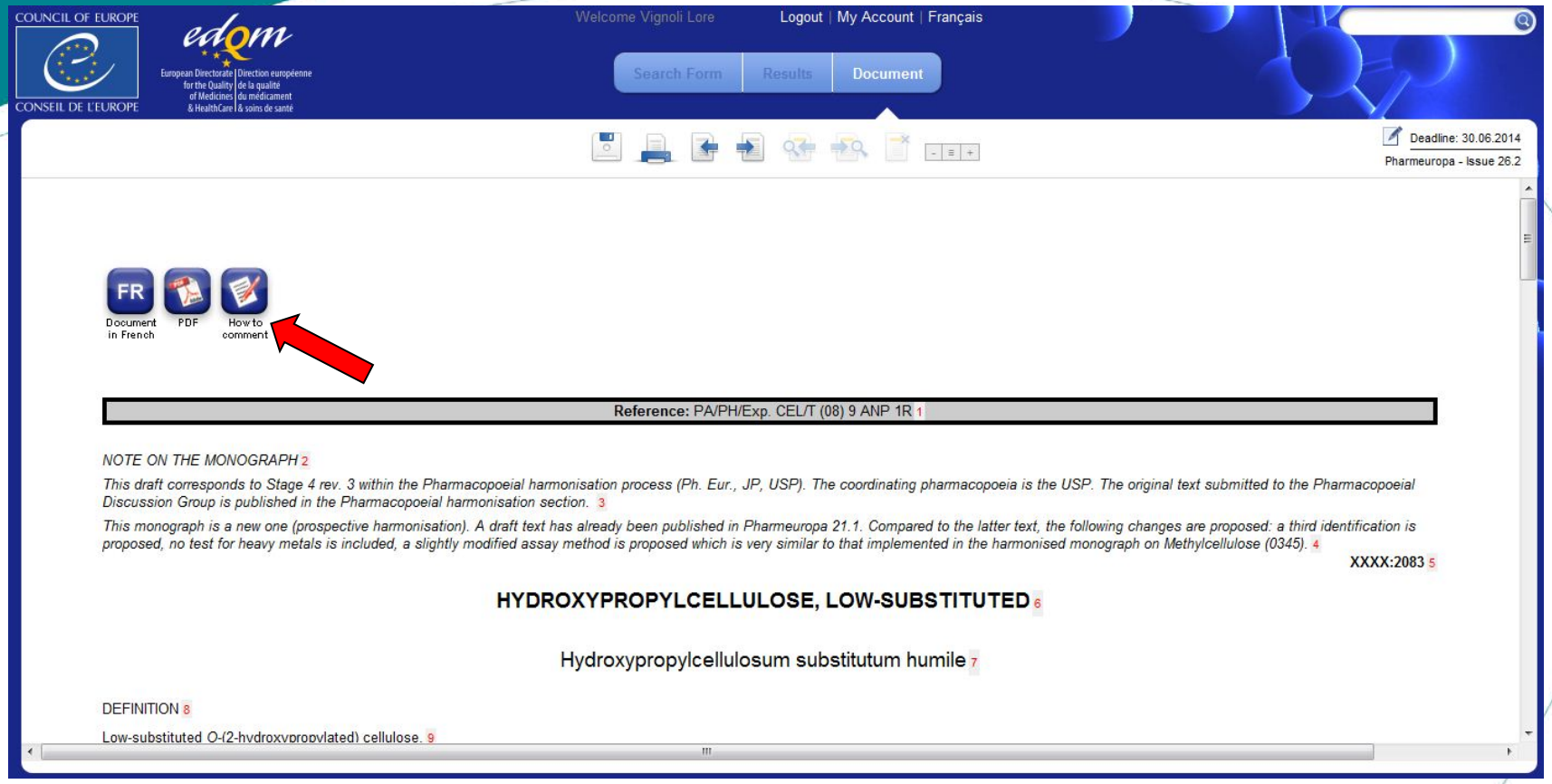


This document is a guidance for the authors of monographs and also a means of communicating to the users of the European Pharmacopoeia, especially industry, licensing authorities and official medicines control laboratories, the principles for the elaboration of monographs.
Since the principles applied and guidance given for the elaboration of monographs should be the same as those applied by licensing authorities, the Technical Guide may also serve as a guideline in the elaboration of specifications intended for inclusion in licensing applications.

Some tools: PHARMEUROPA

http://pharmeuropa.edqm.eu/home/





- for manufacturers and other interested parties from n**on-member states of the Ph. Eur. Convention**, and **for multinational** interested parties:

—preferably via the national pharmacopoeia authority of the member state where the product is authorised;

— in cases where comments are submitted to the EDQM Helpdesk, please indicate the member state(s) where the product is authorised

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Commission Sessions		8th Edition Supplements	Publication Schedule	Implementation Date
Session N°	Date			
–	–	**8th Edition**	**15 July 2013**	**1 Jan. 2014**
145	Mar. 2013	8.1	1 Oct. 2013	1 Apr. 2014
146	June 2013	8.2	1 Jan. 2014	1 July 2014
147	Nov. 2013	8.3	1 July 2014	1 Jan. 2015
148	Mar. 2014	8.4	1 Oct. 2014	1 Apr. 2015
149	June 2014	8.5	1 Jan. 2015	1 July 2015
150	Nov. 2014	8.6	1 July 2015	1 Jan. 2016
151	Mar. 2015	8.7	1 Oct. 2015	1 Apr. 2016
152	June 2015	8.8	1 Jan. 2016	1 July 2016
153	**Nov. 2015**	**9th Edition**	**15 July 2016**	**1 Jan. 2017**