Collaboration, Innovation and Scientific Excellence: the European Pharmacopoeia 11th Edition

Opening Plenary Session

Moderator: Petra Doerr, Director,
EDQM, Council of Europe

The impact of the COVID pandemic: a global perspective
Mariângela Batista Galvão Simão, Assistant Director General, World Health Organization (WHO)

The Pharmaceutical Strategy for Europe: shaping the EU medicines and policy and legislation

EDQM - European Pharmacopoeia 11th Edition

19/09/2022

Sylvain Giraud, Head of Unit Medical Products

DG SANTE , European Commission

"I want you to look at ways to help ensure Europe has the supply of affordable medicines to meet its needs. In doing so, you should support the European pharmaceutical industry to ensure that it remains an innovator and world leader."

President von der Leyen's mission letter to Stella Kyriakides

Pharmaceutical Strategy for Europe

- Adopted in November 2020
- Ambitious long-term agenda in the field of pharmaceutical policy
- Objective: creating a future proof regulatory framework and developing cooperation

European Commission

The Pharmaceutical Strategy for Europe

The strategy covers the full lifecycle of a medicine

Research and innovation

Authorisation, Health Technology Assessment and placing on the market

Securing supplies of medicines

Delivery to patients

European Commission

Revision of the general pharmaceutical legislation

Well functioning - recognised for safety/efficacy of medicines

Pharmaceutical legislation since 1965
2004 substantially amended
Authorisation of medicines
Quality, safety and efficacy of authorised medicines
Regulatory incentives

Medicines for rare diseases (orphans) since 2000
Incentives to support development of orphan medicines

Medicines for paediatric use since 2007
Obligations and rewards to study all medicines for children use

ESTIMATION
- **Directive 2001/83**: 13/14 titles revised – about 60-70% of 191 articles concerned.
- **Regulation 726/2004**: 4 titles revised – about 70% of the more than 65 articles concerned.

European Commission

Main items covered by the legislative review

- Revise the system of incentives and obligations in legislation to support innovation, address unmet medical needs, improve access to medicines across the EU
- Address in legislation the market effects impacting affordability
- Adapt legislation to cutting-edge products, scientific developments and transformations
- Revise the legislation to enhance security of supply and address shortages
- Revise manufacturing and supply provisions in the legislation to improve quality and develop preparedness
- Revise the legislation to strengthen environmental risk assessment requirements and improve environmental sustainability

European Commission

Revision of the EU pharmaceutical legislation

European Commission

Cooperation between the EU regulatory framework and EDQM

- Cooperation and financial support in the implementation the EU pharmaceutical and SoHO legislation.
  - The European Pharmacopoeia, a legally binding instrument referred to in the EU legislation
  - More than 35 ad-hoc technical cooperation projects
  - Mutual representation to align the regulatory work
  - Expertise to several EMA committees and working parties
  - Substances of Human origin : new and extended grant agreement

European Commission

Thank you

European Commission

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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European Pharmacopoeia 11th Edition at a glance

Cathie VIELLE
Head of the European Pharmacopoeia Department
EDQM, Council of Europe

11th Edition of the Ph. Eur.

+**1 Member state**: Albania
+**1 Observer state**: Mexico
+**81 new texts**
+**673 revised texts**

	NEW						REVISION	Total
	Monographs				Chapters	Total	Total	
Edition/Supp.:	P4 API	P4 FP	P1	Total				
10	3		9	12	4	16	128	144
10.1			9	9		9	43	52
10.2	1			1	1	2	51	53
10.3	4		5	9	4	13	143	156
10.4	3	4	3	10	1	11	80	91
10.5	1	1	8	10	1	11	64	75
10.6			9	9	4	13	101	114
10.7		2	6	8	1	9	59	68
10.8			3	3		3	66	69
11			7	7	3	10	66	76
Total 10.1 => 11	9	7	50	66	15	81	673	754

… on our way to the 12th Edition …

Chairs and experts

- (re)appointed at the next session of the Ph. Eur. Commission → *still time to contact NPAs or EDQM (more information here)*
- Join one of the 60 groups of experts or working parties covering many fields! → *for sure, one of interest to you*

  Including 3 new working parties on:
  - Analytical Quality by Design (AQbD)
  - Excipient Strategy (EXS)
  - mRNA Vaccines for human use (mRNAVAC)

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AQbD - Terms of reference

- Assess the feasibility and impact of incorporating analytical procedures developed using the concepts of analytical quality by design (aQbD) in Ph. Eur. monographs.
- Advise the Commission and expert groups on appropriate elaboration/revision strategies for incorporating such analytical procedures in monographs.
- Identify verification and revision approaches for analytical procedures developed using aQbD.
- Co-operation and consultation with other groups of experts and working parties in charge of the elaboration and revision of monographs, where relevant.

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  fields! → *for sure, one of interest t*

  Including 3 new working parties c
  - Analytical Quality by Design (AQbD
  - Excipient Strategy (EXS)
  - mRNA Vaccines for human use (mR

EXS - Terms of reference

- *Identify and discuss best possible approach(es) to address the quality and the standard setting process of excipients for pharmaceutical use in the Ph. Eur. in view of making concrete recommendations to the Ph. Eur. Commission.*

  This would include, but is not limited to:
  - *the typical structure and content of an individual monograph on such an excipient*
  - *the evaluation of the need for optional test(s) depending on the possible uses of the excipients (e.g. FRC section)*
  - *the evaluation of the need for (a) specific technical guide(s)*
  - *the review of terms of reference of groups of experts and working parties dealing with such excipients (including repartition of tasks between groups and ways of working between groups),*
  - *The review of existing general monographs (such as Substances for pharmaceutical use (2034)) to appropriately cover such excipients*
- *Considering the recent example of nitrites in excipients, the specific challenges related to setting specifications for excipients in the Ph. Eur., the discussion around impurities (to cite some examples), propose appropriate control strategies for excipients and consequently, approaches for elaboration and revision of Ph. Eur. Monographs (general or individual ones) and/or general chapters for excipients for pharmaceutical use*

… on our way to the 12th Edition …

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Including 3 new working parties on:

- Analytical Quality by Design (AQbD)
- Excipient Strategy (EXS)
- mRNA Vaccines for human use (mRNAVA

mRNAVAC - Terms of reference

- *Drafting and revision of texts in the field of mRNA vaccines for human use*

… on our way to the 12th Edition …

Chairs and experts:

- (re)appointed at the next session of the Ph. Eur. Commission → *still time to contact NPAs or EDQM*
- Join one of the 60 groups of experts or working parties covering many fields! → *for sure, one of interest to you*
- The conclusions and recommendations made at this conference will also enable the Commission to fine-tune its priorities for the next 3 years and feed its work programme…

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From an idea to the work programme …

1 Identification

Item proposed for addition to the work programme

Anyone can propose an item, e.g. Regulators, Industry, any other Interested Parties or Stakeholders …

2 Evaluation

Survey sent to NPAs (*in favor/ opposed/ not interested*)

This step is skipped in case of request for revision

3 Decision

/ Commission to decide

4 Allocation

If approved, item referred to a Group (or new Group created) 0

… Drafting by Group of Experts or Working Party…

Monographs are based on **approved specifications**

Call for interest

Commenting is a must

0 Assignment to a Group/ Procedure → 1 Assignment to a rapporteur + co-rapporteur Drafting of the text, lab verification → 2 Pharmeuropa (5 months) → 3 Adaptation if needed

Prerequisite

From Group

- **Data package** (current specifications, analytical procedures; validation data; batch and stability data)
- **Material** for testing
- *Candidate material for RS establishment*

- **Review** of data package
- **Laboratory study/ collaborative testing**
- **Draft** new or revised monograph

- **Draft published for comments** (eg testing of draft monograph) – 3 months commenting period for Public (+2months for NPAs)

Evaluation of stakeholder feedback (technical comments, data):

- Ph. Eur. member state → NPAs → *if supported, sent to EDQM*
- Others → *EDQM*

… From a draft to a legally binding standard!

Too late to provide comments…

Approx 6 months Approx 6 months

Text finalised => approval by the group => Submission to Commission for adoption → 3 Adoption by **Consensus** → 4 Publication → Implementation

- **Final review by NPAs** (+/- National groups of experts)
- Only open for comments to NPAs, for consideration by Ph. Eur. Commission
- No major comments at this stage (expected)

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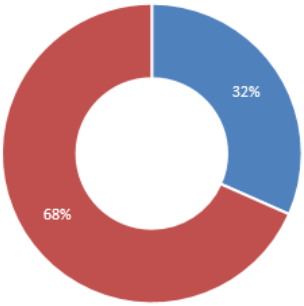
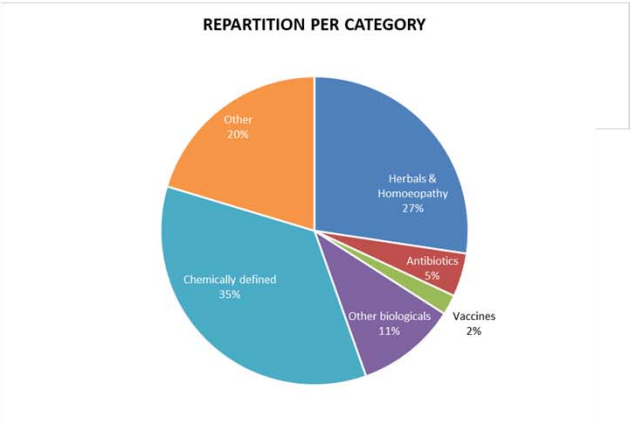
Work programme: 897* items in the pipeline

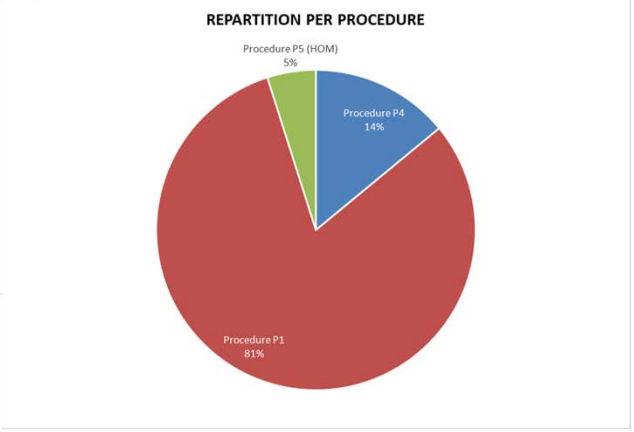


Elaboration of new texts (285* items)
"Technical" revisions (612* items)** → *publication in Pharmeuropa*

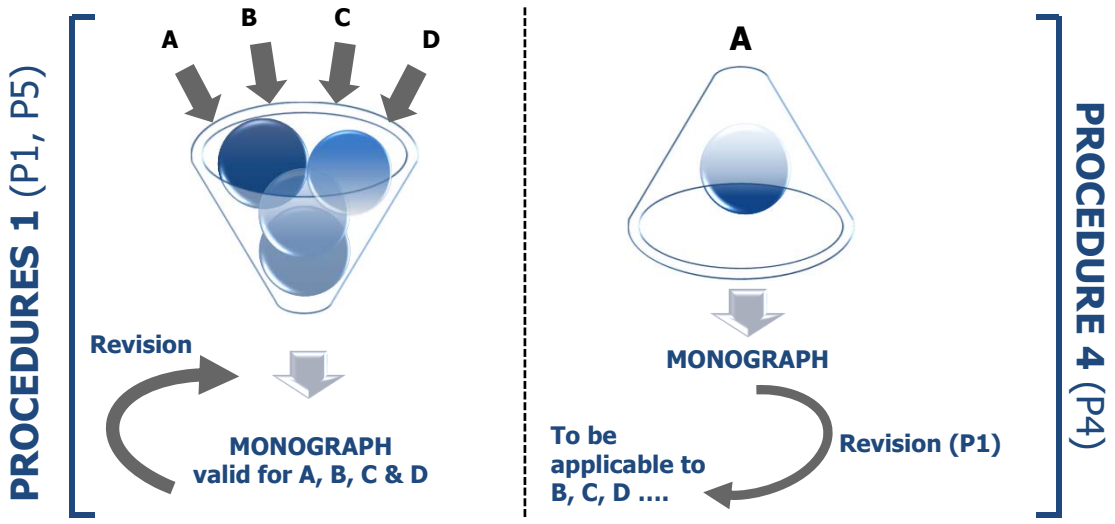
* June 2022; *** These numbers do not include "minor" revisions*

285 new texts to be elaborated by 39 groups





How are texts elaborated? Two main procedures



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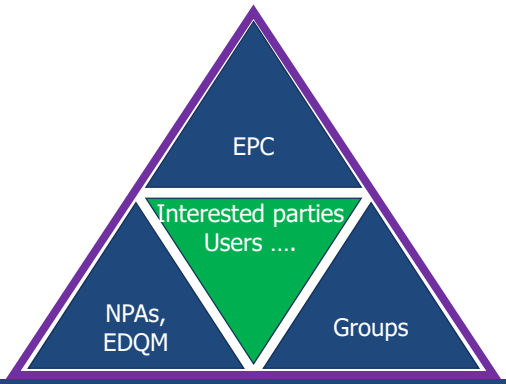


3 Ph. Eur. Community

The Ph. Eur. Community: … one decision body - the EPC

National Pharmacopoeia Authorities (NPAs):
Nominate experts; advise delegates to the EPC; analyse and forward comments to draft published; etc… → **Essential role!**

Presidium composed of:
Chair and two vice-chairs with Secretary to the EPC
Role: to support the EPC and prepare its sessions & decision-making

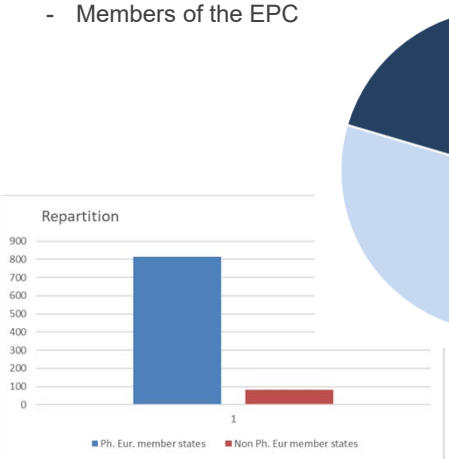
European Pharmacopoeia Commission (EPC):
THE decision body
One delegation per Member State; three sessions a year; texts adopted by consensus; observers welcome!

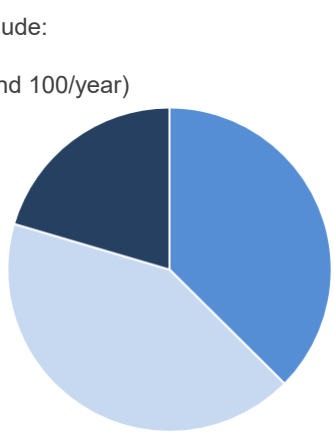
Groups of experts and Working parties => Nearly 900 experts mainly nominated by NPAs (*since 2016 also from non-members/non-observers*) and **all** appointed by EPC

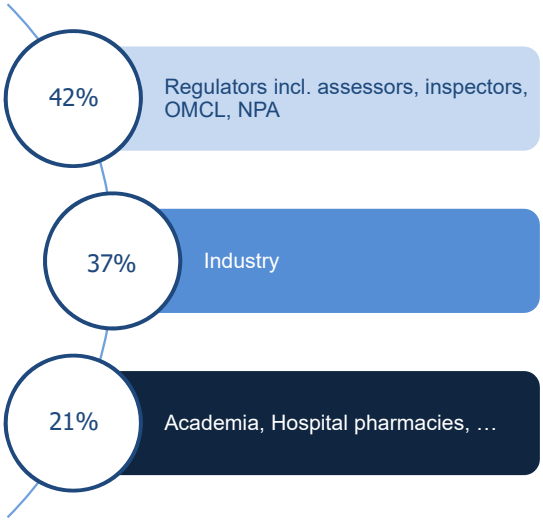
« **Secretariat** »: technical & admin. staff members of the EDQM/ Ph. Eur. Department supporting the Commission and all its Groups

… relying on nearly 900 experts[1] working together …

[1] This number does not include:
- Chairs of Groups
- ad hoc specialists (around 100/year)
- Members of the EPC







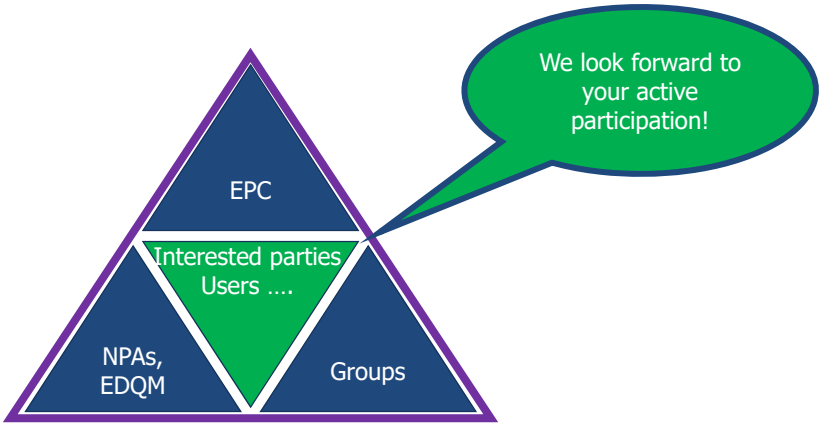
… in 60 groups covering many fields!

This includes groups of experts and working parties for:

- Microbiology & BET
- Dosage forms
- Standard Terms
- Radiopharma-ceuticals
- SoHo
- Methods (analytical procedures)
- Bio products
- Vaccines
- Chemically defined substances and products
- Antibiotics
- Homoeopathy
- Herbals, TCM
- Non-biological complexes
- Strategy & Procedure
- Gases
- Containers
- Formularies (PaedF)
- Others

Don’t miss the opportunity to join the Ph. Eur. Community!

Your opinion and input count!



The floor will be yours => don't miss this opportunity!

Thank you for your attention

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Facebook: **@EDQMCouncilofEurope**

swissmedic

Collaboration matters – the work of a National Pharmacopoeia Authority

EDQM Conference “Collaboration, Innovation and Scientific Excellence: the European Pharmacopoeia 11th Edition” | Strasbourg, 19-21 September 2022

Dr Tobias Gosdschan | Head of Division Pharmacopoeia

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Hallerstrasse 7, 3012 Bern
www.swissmedic.ch

This conference is about presenting the 11th ed. of the Ph. Eur.

Picture: EDQM

… and as you can imagine, there are many contributions necessary until such a comprehensive work can be presented !

The key roles in ensuring the elabortation of the Ph. Eur. are played by ...

... more than 800 experts

Picture: Pixabay

... the EDQM

Picture / logo: EDQM

... the signatory parties to the Ph. Eur. Convention

Flags: COE and EU Website

Within the signatory parties, a central role is played by the

Flags: COE and EU Website

National Pharmacopoeia Authorities (NPAs)

What is the role of the NPAs?

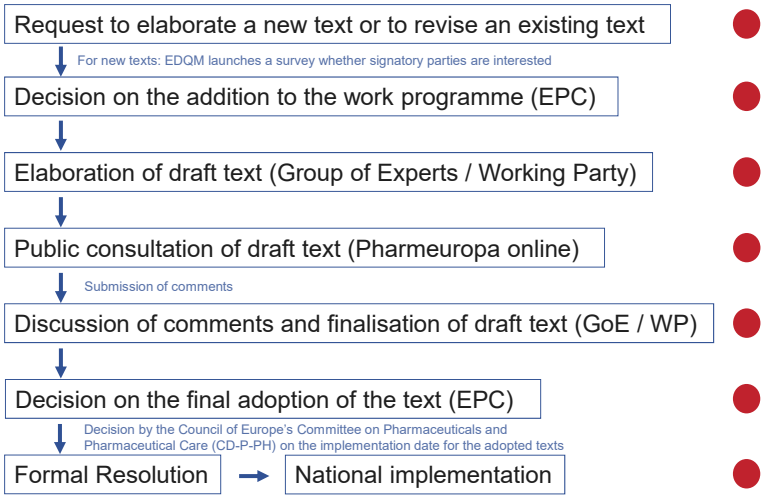
- Basis for the elaboration of the Ph. Eur. is the European Pharmacopoeia Convention
  - Partial agreement amongst members of the Council of Europe (intergovernmental treaty)
  - Established in 1964 (8 founding members: BE, CH, DE, FR, IT, LUX, NL, UK)
  - Today: 40 signatory parties (39 countries + EU)
  - Represented by the delegations in the European Pharmacopoeia Commission (EPC)
- By signing the Convention, the signatory parties commit themselves:
  - To participate in the elaboration of the Ph. Eur.
  - To ensure that the Ph. Eur. becomes an official, legally binding standard
- An important duty of the signatory parties is to appoint a National Pharmacopoeia Authority (NPA) with the role to ensure the fulfillment of the commitment given with the signature to the Convention
- NPAs represent an important link between the signatory parties and the EDQM, because
  - NPAs provide input from the signatory party to the EDQM
  - NPAs serve as official national contact point for the EDQM

What does this mean in practical terms?

Examples of concrete activities by NPAs

- Provisions of answers to surveys
- Nomination of experts / provision of own expertise
- Submission of national comments on draft texts
- Support of EPC delegation / participation in EPC sessions
- Initiation of national implementation

Process for elaborating Ph. Eur. texts



⇨ **NPAs are involved throughout the whole elaboration process**

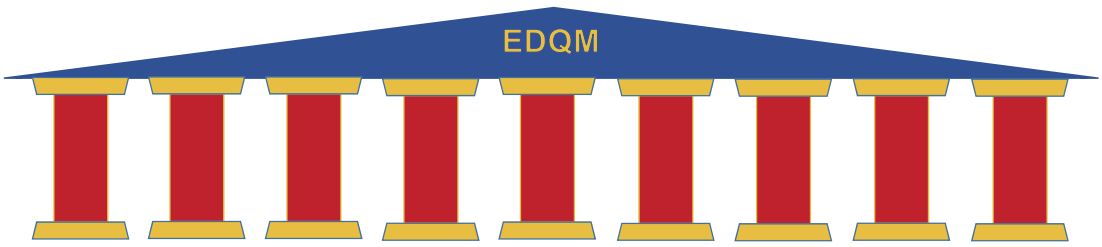
Further duties

- To provide information on the pharmacopoeia to local users
  (in addition to the user support provided by the EDQM HelpDesk)
- To attend to annual meetings and monthly videoconferences between the EDQM and NPAs, which is a great opportunity to exchange information, experiences and ideas
- If a national pharmacopoeia exists: to notify the EPC on the elaboration of national texts
  (so that the delegations can consider the elaboration of a European text)

You can see: NPAs have quite a pile of duties…

Picture: Pixabay

When trying to summarise the situation in one sentence, one could say that ...



… NPAs are the pillars under the roof of the EDQM

Let's now have a closer look on one of these pillars in order to illustrate what you have heard in the first part

The Pharmacopoeia Division at Swissmedic

Example: Swiss NPA

The Pharmacopoeia Division at Swissmedic

- Acts as Swiss NPA
  - Ensures the fulfillment of all the duties arising from the Swiss signature under the Ph. Eur. Convention (as explained before)
- In addition, the Pharmacopoeia Division is responsible for the Swiss Pharmacopoeia (Pharmacopoea Helvetica, Ph. Helv.)
  - Elaborates the texts of the Ph. Helv. – supported by experts in 5 national expert committees
  - Runs the Swiss expert committees
  - This includes the provision of the scientific secretariat of the national committees (i.e. organises and prepares meetings, takes minutes, coordinates the resulting work)
- Important: The Swiss expert committees also support the work of the Ph. Eur.
  - They support the review of Ph. Eur. draft texts and the discussion of received comments
    ⇨ Thanks to this, the submitted Swiss comments can be put on a broader basis and are not only based on a single opinion

Interim remark

Just a few words on the Swiss Pharmacopoeia (Ph. Helv.)

Picture: Swissmedic

- Represents a **national supplement** to the Ph. Eur. (no redundancy)
  - In the first instance, the aim is to develop a European text
  - Only if there is given reason, a Ph. Helv. text is considered (e.g. no interest on a European level or out of scope of the Ph. Eur.)
- From this you can see:

It is <u>not</u> the idea to create any rivalry


Picture: EDQM Picture: Pixabay Picture: Swissmedic

The idea is to close regulatory gaps

Back to the activities of the Swiss NPA

The most important prerequisite for fulfilling the mentioned tasks

Picture: Pixabay

Example: Swiss NPA

The key prerequisite for a successful collaboration

The Pharmacopoeia network in Switzerland

Delegation represents CH as member state

Participation in assessment and inspection activities (not part of NPA)

Political advice, if necessary

Appointment of CH-Delegation

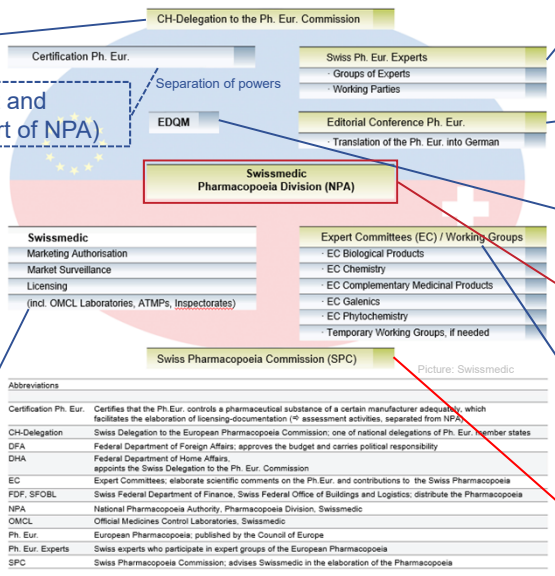
Distributor of the Ph. Eur. in CH

and of the Ph. Helv.

Support the NPA with expertise

Blue frames:
Activities for Ph. Eur.

Red frames:
Activities for Ph. Helv.



Abbreviations	
Certification Ph. Eur.	Certifies that the Ph.Eur. controls a pharmaceutical substance of a certain manufacturer adequately, which facilitates the elaboration of licensing-documentation (→ assessment activities, separated from NPA)
CH-Delegation	Swiss Delegation to the European Pharmacopoeia Commission; one of national delegations of Ph. Eur. member states
DFA	Federal Department of Foreign Affairs; approves the budget and carries political responsibility
DHA	Federal Department of Home Affairs, appoints the Swiss Delegation to the Ph. Eur. Commission
EC	Expert Committees; elaborate scientific comments on the Ph.Eur. and contributions to the Swiss Pharmacopoeia
FDF, SFOBL	Swiss Federal Department of Finance, Swiss Federal Office of Buildings and Logistics; distribute the Pharmacopoeia
NPA	National Pharmacopoeia Authority, Pharmacopoeia Division, Swissmedic
OMCL	Official Medicines Control Laboratories, Swissmedic
Ph. Eur.	European Pharmacopoeia; published by the Council of Europe
Ph. Eur. Experts	Swiss experts who participate in expert groups of the European Pharmacopoeia
SPC	Swiss Pharmacopoeia Commission; advises Swissmedic in the elaboration of the Pharmacopoeia

Provision of expertise for the Ph. Eur.

Translation of Ph. Eur. (collaboration DE/AT/CH)

Our European partner organisation

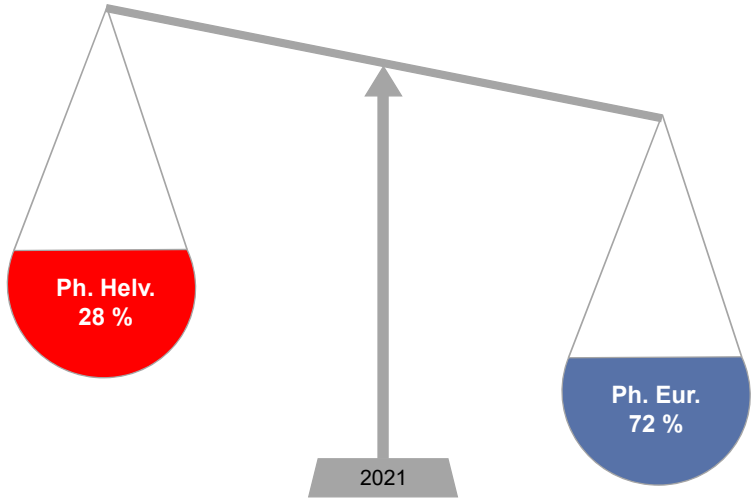
The Swiss NPA

Reviews Ph. Eur. drafts and elaborates Ph. Helv. texts

Advisory board to Swissmedic in terms of the Ph. Helv.

Labour shares

Work performed by the Swiss Pharmacopoeia network



To conclude my presentation, I would like to share:

Some personal experiences from the work in the Swiss NPA

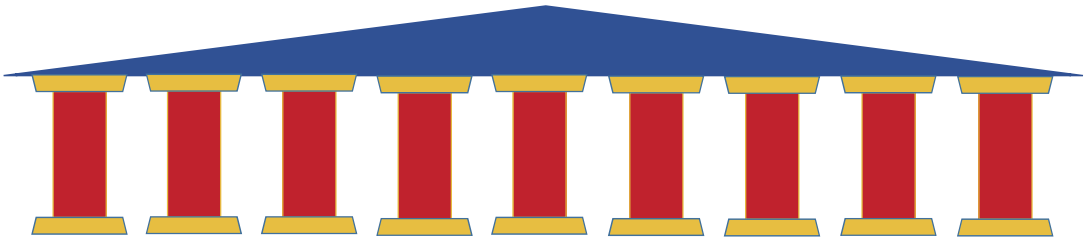
- The exchange with experts, the EDQM and other NPAs is immensely **enriching**
- The participation in the work within the «Ph. Eur. familiy» is highly **beneficial** - for all partners!
  - Ph. Eur. profits
    - from a rich fund of pooled expertise (39 member states, 28 observers, EDQM), ensuring that the elaborated standard is practice oriented and state of the art
  - Experts as well as participating countries and organisations benefit
    - from sharing the workload
    - from exchanging with colleagues that work in the same field
    - from the good feeling to jointly elaborate a standard that is beneficial for the health of patients
    - from the various services provided by the EDQM, which make many things become possible that could otherwise not be realised

      ⇨ A big thanks to all EDQM staff members at this occasion!

Conclusion

From what I have just outlined, you can not only see that I really enjoy the work for the Pharmacopoeia, but also that

Collaboration matters!



Thank you very much for your attention!

Flags: COE and EU Website / EDQM logo: EDQM Website

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

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Collaboration, Innovation & Scientific Excellence:
the European Pharmacopoeia 11th Edition
September 2022

EDQM pan-European networks: success built on trust, complementarity and mutual benefits

Petra DOERR | **EDQM Director**

Overview

- Why networks?
  - Trust, mutual benefits and complementarity
- The networks of the EDQM
  - European Pharmacopoeia Community
  - General Official Medicines Control Laboratory Network
  - Experts supporting the Certification Procedure
  - Intergovernmental Committees
  - Official Cosmetics Control Laboratory Network
- EDQM involvement in other networks
- Where do go from here?

Why networks?

- Trust
  - Basis for any collaboration and network – needs a long time to establish
    → confidence-building is key.
- Mutual benefits
  - Working together in a network has mutliple benefits
    - Sharing information and expertise
    - Building capacity
    - Work-sharing
    - Mutual recognition and reliance
- Complementarity
  - Avoiding overlaps with other networks and initiatives

Why networks?

Networks are a WIN-WIN for participating organisations and individuals!!

- Your network is you net worth… (Porter Gale)
- Pulling a good network together takes effort, sincerity and time… (Alan Collins)

Why networks?

Without networks, composed of experts from Europe and beyond with a wide variety of backgrounds and areas of expertise, …

… the EDQM would not be able to perform its mandate!

EDQM networks: an overview

1964
Ph. Eur. Convention/ Commission

1994
General European Official Medicines Control Laboratories Network (GEON)

1994
Certification of Suitability

2006-2009
Intergovern-mental committees

2010
Official Cosmetics Control Laboratories Network

The Ph. Eur. Community

The European Pharmacopoeia

- Single reference work for the quality control of medicines in the signatory states of the Convention on its elaboration.
- Official standards provide legal and scientific basis for quality control during the development, production and marketing processes.
- One main edition every 3 years, 8 supplements in the interim.

The General Official Medicines Control Laboratories Network

EU Commission and Council of Europe co-created network; established at EDQM.

- Aim: collaboration in the area of quality control of marketed medicinal products for human and veterinary use.
- **71 medicines control laboratories in 41 countries**
- Independent quality control programmes, covering licensed medicines and the detection/identification of falsified/adulterated products.

The Official Control Authority Batch Release Process

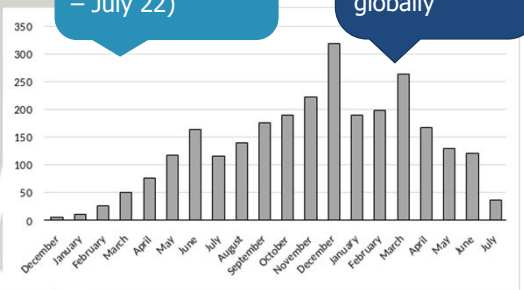
Based on EU legislation requiring (independent) testing of each batch of an immunological medicinal product or a medicinal product derived from human blood or plasma before it is placed on the market.

- EU/EEA countries and Switzerland (MRA) and Israel (ACAA) based on formal agreements.
- Mutual recognition among participating countries.
- Forum for confidential exchange of quality and technical information on human biological medicinal products and related methods.

COVID-19 vaccines release: A success story…

2750 batches released (Dec 20 – July 22)

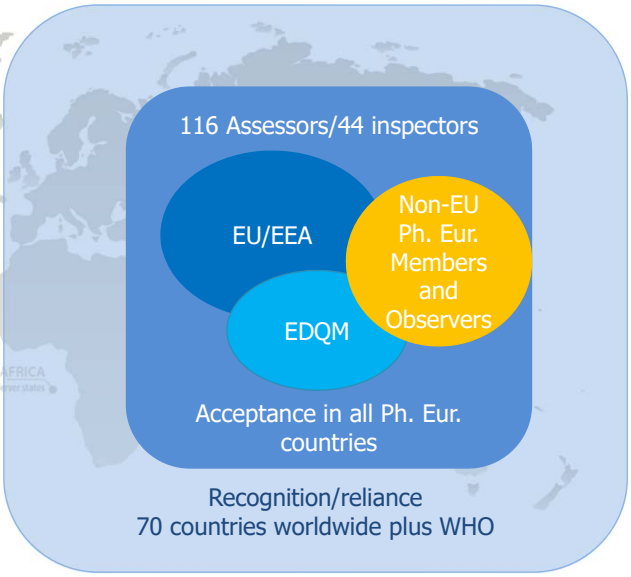
Corresponding to billions of vaccine doses for Europe and globally



Certification of Suitability

Based on CoE Resolution and embedded in EU legislation.

- Aim: Verifying compliance of pharmaceutical substances with Ph. Eur. and inspecting these manufacturers
- 5900 valid Certificates of Suitability (CEPs) issued to 1200 manufacturers of active pharmaceutical ingredients, mostly located in China (28%) and India (27%)
- Recognised/relied upon in 70 countries worldwide.
- Modernisation: "CEP for the future"



Intergovernmental committees

The EDQM coordinates/provides the secretariat for five Intergovernmental Committees (IGCs) or Steering Committees in the areas of:

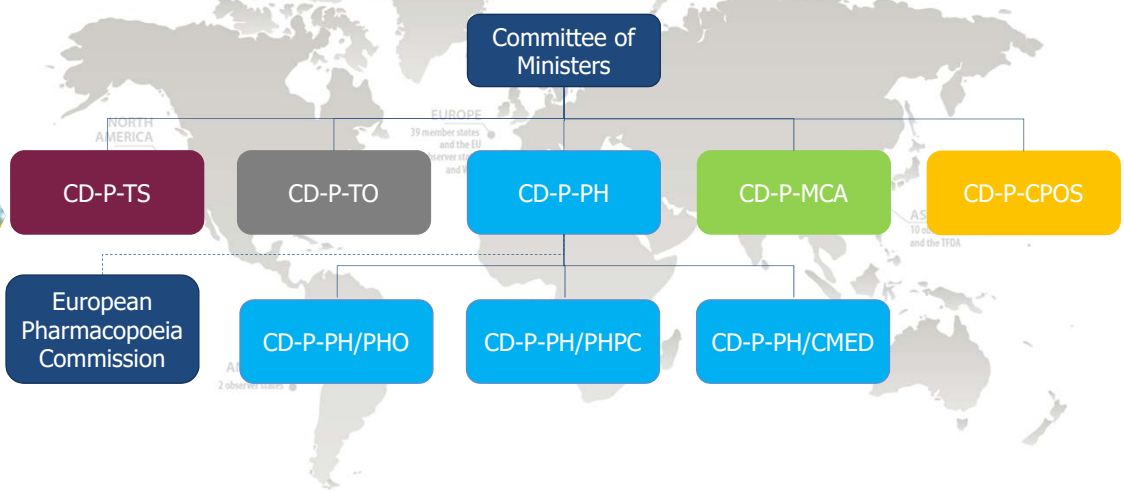
- Blood Transfusion (CD-P-TS)
- Organ Transplantation (CD-P-TO)
- Pharmaceuticals and Pharmaceutical Care (CD-P-PH)
- Food Contact Materials and Articles (CD-P-MCA)
- Cosmetics and Consumer Health (CD-P-COS)

Three subordinate bodies (expert committees) report into the European Committee on Pharmaceuticals and Pharmaceutical Care:

- Classification of Medicines as regards their supply (CD-P-PH-PHO)
- Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PHPC)
- Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED)

The committees mandate expert/working groups/parties to develop the work products.
The Ph. Eur. Commission reports into the CD-P-PH on non-technical matters.

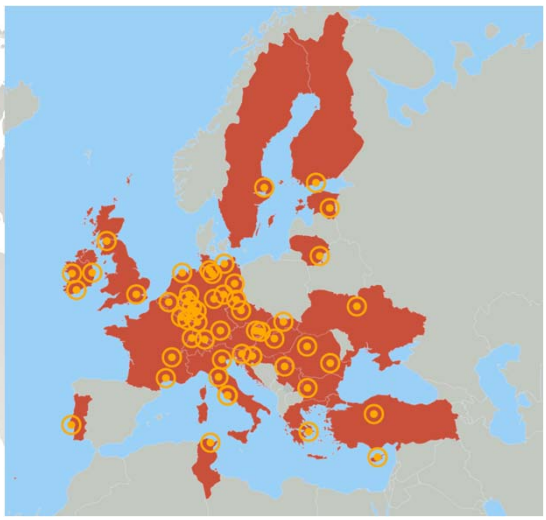
Intergovernmental committees



Official Cosmetics Control Laboratories

Network on a voluntary basis due to need identified for better collaboration.

- Aim: Foster cross-border collaboration, share technical expertise and enhance quality management in accordance with international standards.
- Open to all Ph. Eur. Countries; other may designate labs as associate members.
- **More than 50 OCCLs participate in the Network.**
- Market surveillance studies on quality control of cosmetics and sunscreens and Proficiency Testing Studies



Not on map: HSA (Singapore), TFDA (Taiwan)

EDQM involvement in other networks

- PDG: European Pharmacopoeia, Japanese Pharmacopoeia, US-Pharmacopoeia, Indian Pharmacopoeia Commission, WHO as observer
  - Harmonisation of pharmacopoeial texts
- EU regulatory network/framework; co-funded/collaborative projects
  - European Medicines Agency (EMA)
  - EU-Commission
  - Heads of Medicines Agencies (HMA)
- World-Health Organisation
  - International Meeting of World Pharmacopoeias
  - WHO Committees (ECSPP, ECBS)
  - Biologics NCL network
- ICH, IPRP, PIC/S
  - Harmonisation and convergence, promotion of reliance

Where do we go from here?

- Networks will continue to be of critical importance for the work of the EDQM in the future.
- EDQM is discussing stakeholder engagement as an expansion or evolution of the network concept
  - Increasing transparency, involvement, consultations with all relevant stakeholders
  - New platforms and tools…

...and finally...

THANK YOU for all your contributions over the years!!

PLEASE continue – or consider - to support our work to the benefit of the people in Europe and join the networks of the EDQM!!

Who better than the experts to talk about it?

Thank you for your attention

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