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

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

EDQM's Vision and Expectations for the IMWP

"Meet the World Pharmacopoeias"
Dr Susanne Keitel
EDQM Director

20 February 2020, Strasbourg, France

STRUCTURE

Who we are

The European Pharmacopoeia – the example of successful regional harmonisation

Challenges in pharmacopoeial harmonisation

IMWP achievements and future challenges

Priorities of the European Pharmacopoeia Commission

The Council of Europe

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

- Founded in 1949
- Headquarters in Strasbourg, France
- 47 MEMBER STATES
  ⇒ >820 millions citizens
- The oldest pan-European organisation dedicated to fostering co-operation in Europe
  - ➢ Promotes DEMOCRACY
  - ➢ Protects HUMAN RIGHTS
  - ➢ Protects THE RULE OF LAW

Member states

European Directorate for the Quality of Medicines & HealthCare

- A Council of Europe Directorate, based on the Convention on the Elaboration of a European Pharmacopoeia (PA, 1964)
- Mission: to contribute to a basic human right: access to GOOD QUALITY MEDICINES AND HEALTHCARE

Ph. Eur. Convention

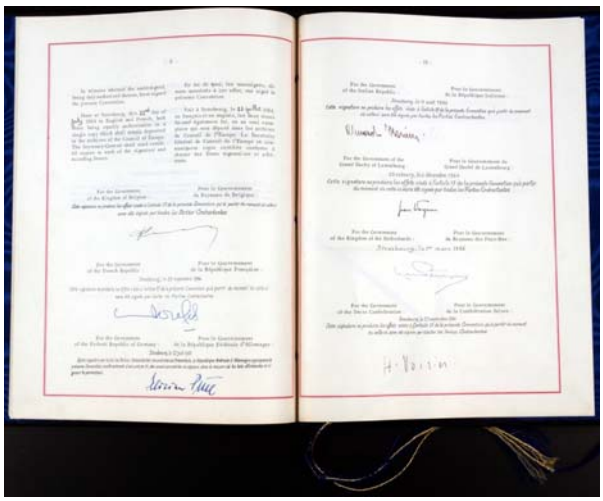
Article 1:

The Contracting Parties undertake:

a) progressively to ELABORATE a Pharmacopoeia which shall be common to the countries concerned and which shall be entitled "European Pharmacopoeia";

b) to take the necessary measures to ensure that the monographs which will be adopted… and which will constitute the European Pharmacopoeia shall become the OFFICIAL STANDARDS applicable within their respective countries.

Strasbourg, 22. July 1964



The global impact of the EDQM's activities in 2020

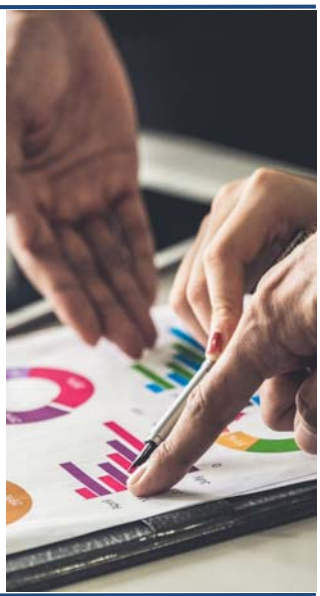
39 member states and the EU
29 observers (Uzbekistan in 2018)

Harmonisation – Why ?

- Global market: Pharmaceutical supply chain is GLOBALISED
- Harmonisation helps to increase AVAILABILITY of medicines, makes industry more efficient
  - Better able to serve multiple markets with the same processes and plants
  - Elimination of redundant testing
  - Minimises duplication of testing requirements
- Harmonisation helps to STRENGTHEN pharmacopoeias - strong, state-of-the-art standards reflecting the global reality
- Ultimately to the benefit of PATIENTS!

International Collaboration

- Ph.Eur.: successful model of work-sharing and harmonisation between currently 39 COUNTRIES, but based on strong political will and legal commitment
- EDQM, USP and the Japanese Pharmacopoeia, with WHO as an observer, are PDG PARTNERS
- Bilateral Agreements/MoUs with pharmacopoeia authorities on COLLABORATION and EXCHANGES (e.g. ANVISA, ChP, PMDA/MHLW, USP, WHO..) and confidentiality arrangements with authorities from around the world
- INVOLVEMENT of observers in the elaboration of texts
- GLOBAL HARMONISATION (Good Pharmacopoeial Practices): EDQM together with PDG partners key player in International Meeting of World Pharmacopoeias (IMWP)



Interactions with National and European Authorities

- European Union: SIGNATORY party to Convention on the elaboration of a European Pharmacopoeia
- EU DECIDES on behalf of EU member states in all non-technical issues of European Pharmacopoeia Commission
- European Medicines Agency (EMA) PARTICIPATES in sessions of Ph. Eur. COMMISSION and working parties of interest
- EDQM participates in relevant EMA COMMITTEES and working parties
- NCAs (licensing authorities, inspectorates, OMCLs, national pharmacopoeia authorities) actively participate in Ph.Eur. Commission and its groups of experts and working parties, NOMINATED by their government
- CONFIDENTIALITY arrangement with European Commission/EMA
- .....

Interaction with Stakeholders, including Regulators

Participation of **ALL** stakeholders vital for development of authoritative and relevant Ph.Eur. monographs:

- Publication of Ph.Eur. work programme and state of work of each Ph.Eur. text on internet
- Publication for consultation of new and revised texts in Pharmeuropa online
- Hearings/Workshops/Conferences with regulators and/or industry
- Annual bilateral meetings with trade associations
- Organisation of training sessions (at least 2 per year)
- EDQM Helpdesk (for submission of information, requests (e.g. revision proposals), questions)…

The European Pharmacopoeia

- An (if not *the*) example of a successful regional pharmacopoeial COOPERATION and HARMONISATION
- Technical decisions taken by consensus
- Some key success factors: strong political will, common legal basis, convergent/ harmonised regulatory environment

  → *Feasibility at an international level?*

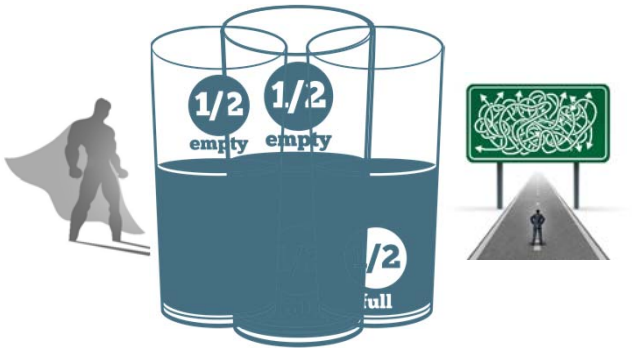
30 years of PDG in 2019….

First of all …. Congratulations !

30 YEARS ANNIVERSARY

30 years of PDG in 2019….

Now…. How would you describe PDG achievements?



A little bit of both

Challenges for Pharmacopoeial Harmonisation
- the PDG Example -

- Different, and even sometimes divergent REGULATORY environments and constraints
- Different HISTORY and working principles
- Different DECISION making processes
- Diverse SOURCE materials used in pharmaceutical manufacturing

→ make harmonisation difficult ...

Different, and even sometimes divergent regulatory environments and constraints, e.g.

- Heparin Case in 2008: PDG pharmacopoeias committed to come up with a harmonised approach,
  but: regulatory authorities in the three regions not fully aligned, but requesting pharmacopoeia to stay aligned with them
- Proposed policy change on Reporting Threshold in USP–NF Monographs following request by FDA: not aligned between regulators, will create havoc for pharmacopoeial harmonisation, including PDG signed-off texts
- …

Different, and even sometimes divergent regulatory environments and constraints

- Importance of relationship between individual PHARMACOPOEIAS and REGULATORS
- Importance of relationship and alignment between REGULATORS, e.g. via ICH, IPRP or bilateral agreements
- Example of the EDQM / Ph. Eur.:
  - One 3rd of Ph. Eur. EXPERTS are from CAs
  - EDQM OBSERVER to QWP, BWP, etc… and vice versa

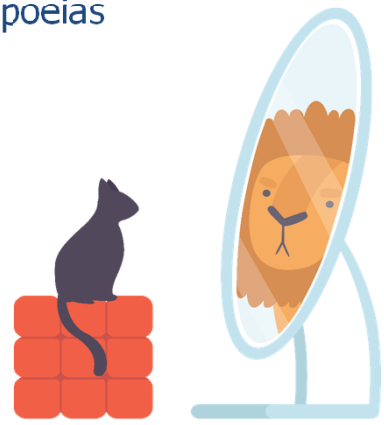
Different history and working principles

Not much we can do on our HISTORY, but for the rest….

Informal PDG process "woven" into the formal processes and committee structures of the three participating pharmacopoeias

PDG reforms APPROVED in 2017 :

- Restructuring meeting format to engage more at the technical level and introduce more direct exchange between the experts in the regions
- Streamlining of working procedure, reducing complexity => elimination of two stages to increase efficiency and improve focus.
- Strategic review of harmonization areas and individual work items currently in progress and for future consideration still ongoing.
- Cleaning of the work programme => identification of items to be considered outside of PDG (e.g. bilateral discussion)



Different decision making processes

☞ Transparency is key!

PDG to remain committed to be TRANSPARENT:

➢Towards other Pharmacopoeias:

- Discussion on how information on progress made by the PDG should be SHARED amongst the PDG member pharmacopoeias and other pharmacopoeias participating in the International Meeting of World Pharmacopoeias (IMWP)

➢Towards other harmonisation initiatives:

- New MAINTENANCE PROCEDURE on the ICH Q4B Annexes Adopted by the ICH Assembly

➢Towards users:

- PDG harmonisation policy under REVIEW to provide additional CLARITY to users.

Diverse source materials used in pharmaceutical manufacturing

PRIORITISATION scheme for excipient monographs and general chapter:

- Strategic review conducted of 10 excipient monographs and 5 general chapters
- Extension to remaining general chapters
- Discussion for excipient monographs continues!

And with a little help from our partners… set the RIGHT PRIORITIES!

So is there a future for the IMWP?

- An important platform to get to KNOW peers, build TRUST amongst pharmacopoeias, EXCHANGE knowledge and expertise, discuss modes of cooperation….
- Chose a "bottom up" APPROACH: agreed on principles first, e.g. monograph development, TRANSPARENCY, stakeholder CONSULTATION etc., enshrined in "Good Pharmacopoeial Practices"
- Already in place: ALERTING sister pharmacopoeias in case of incidents/crisis, e.g. nitrosamine contamination, to foster application of harmonised (re)action
- To be further formalised via Pharmacopoeial Alert System

So is there a future for the IMWP?

- Stay REALISTIC: challenges already faced by PDG have different dimension for IMWP as much larger/much more diverse membership, but take lessons LEARNT by PDG into account
- Pharmacopoeias to LIAISE with their regulatory counterparts to encourage regulatory ALIGNMENT
- PDG committed to support international convergence of quality standards by LIAISING with other world pharmacopoeias (e.g. via IMWP) and by SHARING KNOWLEDGE

The Ph. Eur.'s Position

- New chair and vice-chairs ELECTED in 2019 for 3 year mandate
- Presidium (chair, two vice chairs, EDQM director and secretary to the Ph. Eur. Commission) has finalised its PRIORITIES for the next 3 years, to be discussed/adopted by the Ph. Eur. Commission in March 2020
- Pharmacopoeial Harmonisation is HIGH on their agenda!

The Ph. Eur.'s Vision

"The Ph. Eur., via its Secretariat, is ACTIVELY engaged in a number of international harmonisation INITIATIVES such as:

- bilateral HARMONISATION efforts with other pharmacopoeias (especially prospective harmonisation of APIs and FPMs);
- Pharmacopoeial Discussion Group (PDG);
- the International Meeting of World Pharmacopoeias (IWMP), a WHO initiative, whose primary ACHIEVEMENT to date is the 'Good Pharmacopoeial Practices' guidelines (GPhP) that will serve as a basis for work-sharing and collaboration between the pharmacopoeias of the world.

In an increasingly globalised world, the need for global quality standards has become ever more pressing. Such NEEDS are regularly expressed by stakeholders, particularly industry, during conferences, for example. International COOPERATION and HARMONISATION will therefore remain a PRIORITY for the next 3 years."

Thank you for your attention

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