THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)
EDQM’s Expectations on PDG

PDG 30th Anniversary Conference
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STRUCTURE

- Who we are
- International collaboration and harmonisation
- The Pharmacopoeial Discussion Group
The Council of 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
The Council of Europe

is not the European Union!

- **European Union (EU):** a unique economic and political partnership between currently 28 European countries
  
  \[\Rightarrow\] more than 500 million citizens

- **European Council:** the EU's main decision-making body. It defines the general political direction and priorities of the European Union
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
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
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 38 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; involvement of observers in the elaboration of texts.

• Global harmonisation (Good Pharmacopoeial Practices): EDQM together with PDG partners key player in IMWP (International Meeting of World Pharmacopoeias)
Interactions with National and European Authorities

- European Union: signatory party to the Convention on the elaboration of a European Pharmacopoeia
- EU decides on behalf of EU member states in all non-technical issues of the European Pharmacopoeia
- The European Medicines Agency (EMA) participates in the sessions of the Ph.Eur. Commission and working parties of interest
- EDQM participates in relevant committees and working parties at the level of the EMA
- NCAs (licensing authorities, inspectorates, OMCLs, national pharmacopoeia authorities) activitely participate in the Ph.Eur. Commission and its groups of experts and working parties, nominated by their government
Interactions with Stakeholders, including Regulators

Participation of all stakeholders is vital for the 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 Pharmpaeuropa 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....

• First of all ....

Now.... How would you describe PDG achievements?

A little bit of both
Some Challenges Faced by PDG

• 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

- Importance of relationship between individual Pharmacopoeias and Regulators
- Example of the EDQM / Ph. Eur.:
  - One 3rd of Ph. Eur. experts are from CAs
  - EDQM observer to QWP, BWP, etc... and vice versa

Industry (e.g. IPEC)  Pharmacopoeias  Regulators
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!

Industry (e.g. IPEC)  Regulators  Pharmacopoeias
PDG continues paving the way …

• To be recognised by external partners (such as regulators, Industry) as a key partner for international harmonisation

• To support international convergence of quality standards by liaising with other world pharmacopoeias (e.g. via IMWP) and by sharing knowledge
To conclude:

Yes, I did it!
I will do it
I can do it
I'll try to do it
How do I do it?
I want to do it
I can't do it
I won't do it

Which step have you reached today?
Thank you for your attention

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