Pharmacopoeial Harmonisation and Convergence Collaboration with World Pharmacopoeias

Dr Susanne Keitel

Director, EDQM

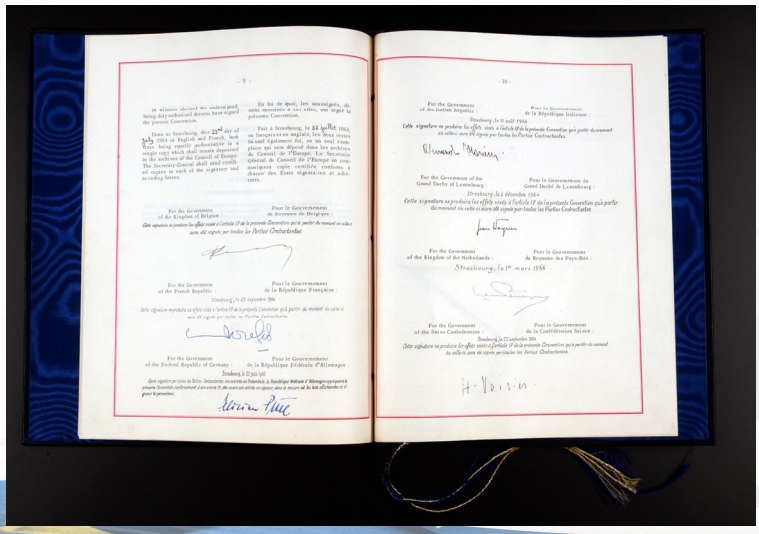
International Harmonisation Initiatives

- A bit of Background….
- Bilateral Harmonisation Initiatives
- International Meeting of World Pharmacopoeias
- Summary and Conclusion

The Need for Harmonisation

- Avoid redundant testing by suppliers and pharmaceutical industry to meet different standards
- Reduce the overall cost of pharmaceutical research by avoiding duplication of work (preparation of dossiers and studies)
- Reduce the time required for medicines to be made available to patients
- Facilitate free movement of goods
- .....

European Pharmacopoeia Convention



European Pharmacopoeia Convention

Objectives:

- To harmonise specifications for medicinal substances which, in their original state or in the form of pharmaceutical preparations, are of general interest and importance to the peoples of Europe
- To hasten the drawing up of specifications for the growing number of new medicinal substances appearing on the market

→ This aim can best be achieved by the progressive establishment of a common pharmacopoeia for the European countries concerned.

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?*

Other Harmonisation Activities

- Bilateral Memorandums of Understanding with regulatory bodies, e.g. ANVISA, Brazil, MHLW, Japan, or pharmacopoeia authorities, e.g. ChP, on collaboration and exchanges; involvement of observers in the elaboration of texts
- Informal bilateral harmonisation activities, e.g. EDQM/USP and individual manufacturers; ChPC/USP;
- Agreements for the use of Ph. Eur. texts/graphs by other pharmacopoeias, e.g. with WHO for Ph. Int., with USP, and *vice versa*;

International Meeting of World Pharmacopoeias

- New initiative for harmonisation at a global scale following a meeting of world pharmacopoeias in Geneva in March 2012.
- Additional 8 meetings of world pharmacopoeias:
  - New-Delhi, India, April 2013, co-organised by IP and WHO;
  - London, UK, April 2014, co-organised by MHRA and WHO;
  - Strasbourg, France, Oct. 2014, co-organised by EDQM and WHO;
  - Rockville, USA, April 2015, co-organised by USP and WHO
  - Suzhou City, China, Sept. 2015, co-organised by ChPh and WHO
  - Tokyo, Japan, September 2016, co-organised by JP and WHO
  - Brasilia, Brazil, July 2017, co-organised by ANVISA and WHO
  - Da Nang, Vietnam, April 2018, co-organised by the Vietnamese Pharmacopoeia and WHO

International Meeting of World Pharmacopoeias

- Primary goal: elaboration of "Good Pharmacopoeial Practices", a document describing policies and approaches to monograph development to facilitate prospective harmonisation and collaboration; drafted under auspices of WHO Expert Committee on Specifications for Pharmaceutical Products (ECSPP)
- Intended to serve as a basis for collaboration, work sharing and recognition between different pharmacopoeias.
- WHO as a "neutral platform"

International Meeting of World Pharmacopoeias

- Core "GPhP" document adopted by the WHO ECSPP in their Oct. 2015 meeting and published on the WHO website;
- Chapters on herbals, compounding and glossary finalised in 2017;
- However: survey conducted by IMWP in 2017 revealed that only few stakeholders are aware of GPhP; unclear how far participating pharmacopoeias really implement the principles described.

IMWP – the Future

- Drafting of GPhP identified substantial current differences between countries/regions => high-level, but important document
- Discussions on future work programme ongoing,
- BUT: IMWP has clear added value as forum for networking and (informal) exchanges, building trust and confidence between participating pharmacopoeias => excellent basis for future progress in pharmacopoeial harmonisation and collaboration

To Summarise

- ➔ Clear demand for pharmacopoeial harmonisation / convergence
- ➔ Ph. Eur. a successful model of work-sharing and harmonisation between currently 38 countries, but based on strong political will and legal commitment
- ➔ All current international initiatives have their short-comings, e.g. PDG and IMWP
- ➔ Essential to be clear on what we want to achieve together (clear definitions, shared expectations)
- ➔ Agreement on "smallest common denominator" or different initiatives at different speeds?

A Final Comment…

- Whatever model is selected,
- Whatever our differences are,
- We need to move ahead to fulfil our common mission: to protect Public Health

The EDQM/Ph. Eur. is committed to international harmonisation and is looking forward to continuing our collaboration with the ChPC and other partners!

Thank you for your attention!