Meet the World Pharmacopoeias Symposium

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Outline

• Success Stories
• Why is harmonization/convergence a challenge?
• ‘Industry Expectations’
• Key messages
**Harmonization / Convergence Success Stories**

- Regional Pharmacopoeias, e.g. EU Pharmacopoeia
- Acceptance of standards from multiple pharmacopoeias
- ICH Q4B
- Pharmacopoeial Discussion Group
- WHO Good Pharmacopoeial Practices

Harmonization is not the only option, ‘alignment’ and ‘simplification’ are viable as well.

**WHO Good Pharmacopoeial Practices (GPhP)**

- “GPhP are designed to facilitate collaboration among pharmacopoeias, leading to possibilities for work-sharing, harmonization of standards and the recognition of published standards between NPAs and RPAs.”
- The establishment of GPhP may result in:
  - ‘improving cooperation’ between NPAs/RPAs and stakeholders (e.g. regulators, pharmaceutical industry) with a view to facilitating the harmonization of pharmacopoeial standards and reducing duplication of work’
  - ‘increasing access to and the availability of affordable, quality medicines’
- ‘Pharmacopoeias are encouraged to conform, where possible, to the work of harmonization initiatives’ (e.g. WHO, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the PDG)).’

Good pharmacopoeial practices; WHO TRS 996 Annex 1; 2016 – Emphasis added
Why is harmonization / convergence a challenge?

- **Legal Framework**
  - ‘Pharmacopoeias are embedded in national or regional regulatory systems with different public health priorities, business models and capacities.’
  - ‘Regulatory systems themselves need to converge to make pharmacopoeial harmonization possible.’

- **Prospective or Retrospective?**
  - ‘Retrospective harmonization of existing pharmacopoeial standards is difficult to achieve’
  - ‘Ongoing efforts therefore aim at prospective harmonization of new monographs’

- **Sustaining progress in a changing world**
  - ‘...developments in science and medical practice, globalization … require pharmacopoeias to evolve constantly.’
  - ‘...a coordinated maintenance process is required to preserve harmonization over time.’
  - ‘The process must also extend to related logistics, such as …reference standards’

‘Industry Expectations’

- **Principles described in GPhP are adopted:**
  - ‘Pharmacopoeias should harmonize standards wherever possible through monographs and general chapters.’
  - ‘Harmonization may occur through several processes including, but not limited to:’
    - adoption or adaptation of existing standards;
    - development of a new standard through coordinated consideration (prospective harmonization);
    - revision of a standard between two or more pharmacopoeias (bilateral or multilateral harmonization); and
    - creation or revision of standards through a harmonization initiative (e.g. PDG).’
**Potential next steps**

- Evaluate progress with implementation of GPhP by world pharmacopoeias
- Harmonization / convergence ‘proof of concept’ study
  - Move from ‘Theory’ to ‘Practice’ for some GPhP concepts
  - Opportunity for sustained industry engagement, e.g. a forum such as ‘Meet the World Pharmacopoeias Symposium’
  - Continuous dialogue with stakeholders on:
    - Lessons learned
    - Areas for further policy development

**What could a Harmonization/Convergence ‘proof of concept’ study evaluate?**

- Adoption of ‘Best practices’ by pharmacopoeias e.g.
  - Flexible, safety-based standards, e.g.
    - Reduced/simplified monographs or general chapters
    - Inclusion of alternative methodologies
    - Reference international guidelines (ICH Q3D etc.)
  - Stakeholder consultation on policy and standards development (including feedback to stakeholders), with appropriate timelines
- Expand adoption of PDG-harmonized chapters
- Development of collaborative process(es) for development and maintenance of new standards, e.g.
  - New Monograph development using General considerations and Technical guidance from GPhP
How can the R&D-based Industry help?

- Active engagement to support harmonization/convergence efforts by stakeholders
- Provision of information for any ‘proof of concept’ study, including
  - Single-source Drug Substance/Drug Product monograph development (excluding biotherapeutics)
  - Potential interest in multi-source monograph development also
  - Support for other content development
- Data collection
  - Information to support business case and decision-making by pharmacopoeias in harmonization/convergence initiatives

Key Messages

- Progress has been made with pharmacopoeial harmonisation/convergence
- GPhP provides a foundation to further collaboration between pharmacopoeias
- IFPMA would like to see further progress with the adoption and further development of GPhP
- IFPMA members willing to support further engagement and dialogue to advance harmonization/convergence
- IFPMA recommends creation of a ‘proof of concept’ study:
  - Practical implementation of GPhP principles
  - Involvement of stakeholders