International Federation
of Pharmaceutical
Manufacturers & Associations

IFPMA

Meet the World Pharmacopoeias Symposium

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Outline

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- 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'

WHO Drug Information Vol. 28, No. 2, 2014

'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?

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- 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[1])
  - 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

[1]Reflection Paper on Product-specific Monographs for Biotherapeutic Products in Pharmacopoeias

Key Messages

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- 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