



IPEC Federation - Stakeholder Expectations for Harmonization

Priscilla Zawislak

President, IPEC Federation

3 October 2019

PDG 30th Anniversary Symposium



- ⊗ Global organisation of regional associations promoting quality in pharmaceutical excipient
 - Established in January 2010 in Cannes, France
- ⊗ Recognises that the drug market is global, including excipient sourcing
- ⊗ Unique organisation structure: makers, distributors, and users of excipients; and
 - Share the same **'quality and safety'** vision; and
 - Represents **'one voice'** on common global excipient issues
- ⊗ Monitors regulatory developments from multiple perspectives and geographies



IPEC Federation Vision

Protecting patients through global partnerships in the innovation and safe supply of pharmaceutical excipients

Vision
Mission
& Values

**IPEC: International Pharmaceutical Excipients Council*

IPEC Federation Mission (abbreviated)

- 🌐 Develop and implement voluntary, harmonised guidelines to ensure excipients meet appropriate standards for quality, safety, and functionality;
- 🌐 Influence the adoption of scientific, risk-based global regulatory standards for excipients;
- 🌐 Educate and cooperate with other organisations to advance public health on matters relating to excipients;
- 🌐 Recognised as a professional, credible, and reliable source of information relating to excipients; and
- 🌐 Establish IPEC as the leading international organisation for excipient suppliers and users of excipients

Vision
Mission
& Values

IPEC Federation 2019 (High) Priorities & Deliverables

- 🌐 **Guides**
 - Create/revise/publish/promote IPEC Guides and Position Papers
- 🌐 **Compendial Compliance**
 - Direct harmonisation efforts to attain compliance across divergent compendia
 - ✓ Develop a multicompendial compliance strategy
- 🌐 **Innovation**
 - Re-engage science and innovation on the IPEC Federation agenda
- 🌐 **Stakeholder Collaboration**
 - Fulfill commitments with stakeholders to consolidate IPEC as a valued partner
 - ✓ Develop process for support and communication of ICH activities (Q3D, Q13 and future)
- 🌐 **IPEC Federation Profile**
 - Develop new communication tools
 - Direct support to regional IPEC events
 - ✓ Develop infographic
 - ✓ Issue IF bulletin (including ICH update) x2 yearly
 - ✓ Support external events in India, China and Japan

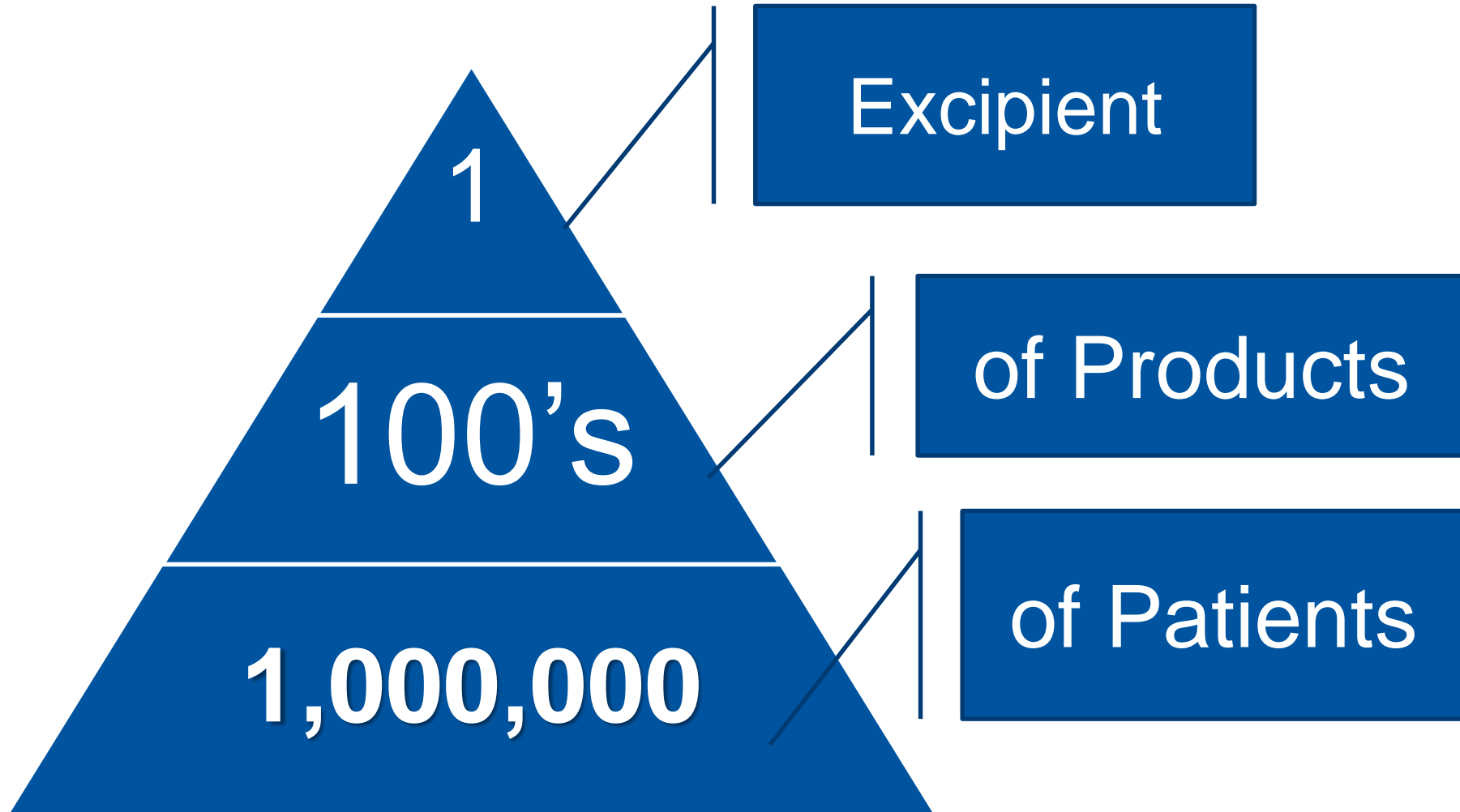
Over 1,200 excipients in use

Can represent up to 95% of the formulation

Patients consume more excipients than active ingredients

Serve important functions in formulations

Impact of Excipients



Where are we

Pharmacopoeial harmonization has been limited to PDG & original ICH countries

PDG has been limited to USP, EDQM and JP

Vision: Global Pharmacopoeia Excipient Recognition

IMPACT of LACK of BROADER HARMONISATION



Patients



Industry

NEED:

- Harmonisation is challenging
- Companies operate in a global environment
- Divergent excipient monographs can have a significant patient impact on the availability of necessary medicines in certain markets and/or regions

SCOPE:

- Monograph and/or general chapter modernization (e.g. state-of-the-art analytical methods)
- Retrospective recognition of existing excipient monographs
- Prospective harmonisation of new excipient monographs

Global Pharmacopoeia Excipient Recognition

FUTURE POSSIBILITIES:

Compendial Compliance - Develop communication plan to educate industry on the use and value of available tools to support harmonisation efforts.

Consortium Creation - Develop a broad international consortium to develop a process for collaborating on testing in order to minimize the impact of non-harmonised standards.

Mutual Recognition - build a rationale as to why mutual acceptance or recognition of pharmacopoeias should be considered

Collaboration – Collaborate with PDG and other pharmacopoeia to explore an effective means to increase engagement in the standards setting and revision process

Functional Equivalence – Mutual Recognition



What is it?

Performs the same function and provides the same utility



How is it used?

Allows recognition of standards where they are focused on public health, safety, quality



Opportunities

All compendia are focused on public health and safety

Stakeholder Thoughts

- ④ IPEC Federation welcomes any opportunities to collaborate with PDG on any of this
- ④ Consider expansion of PDG's scope to include more pharmacopoeias and collaboration with the WHO GPP
- ④ Could PDG take a leading role in driving harmonisation with the WHO forum?
- ④ Can PDG influence ICH to get excipients on the ICH agenda?

THANK YOU

The International Pharmaceutical Excipients Council – Federation (IPEC Federation)
Rue du Luxembourg 16B – B-1000 – Brussels – Brussels Capital Region
www.ipec.org – +32 2 210 74 40 – info@ipec-federation.org



The French-speaking Business Court of Brussels Capital Region is competent for dispute resolution and litigation.

The International Pharmaceutical Excipients Council - Federation

ipec.org |