Welcome

Empowering a healthy tomorrow
Global Health Standards Program

United States Pharmacopeia—Global Public Health

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Presentation

- Global Snapshot of Poor Quality Medicines
- The Unmet Need of Public Pharmacopeias Standards (Monographs)
- USP’s Longstanding Commitment to Ensuring Medicines Quality Globally
- Global Health Standards Program
Poor quality medicines are a growing global health threat, disproportionately impacting LMICs

124 Countries
532 Products
7B People at risk

Many cases go unreported or undetected

Poor quality medicines endanger public health because they result in:

- Morbidity and Mortality
- Antimicrobial resistance
- Loss of Trust in the healthcare system
- Undermined efforts of regulators
- Jeopardized investments in global health
- Financial and brand value loss to industry
WHO Model List of Essential Medicines

- Minimum medicine needs for a basic health-care system
- Most efficacious, safe and cost–effective medicines for priority health care needs
- The EML guides:
  - the development of national and institutional EMLs
  - the procurement and supply of medicines in the public sector
  - schemes that reimburse medicine costs
  - medicine donations
  - local medicine production

Presence of an entry on the EML carries no assurance as to pharmaceutical quality

“It is the responsibility of the relevant national or regional drug RA to ensure that each product is of appropriate pharmaceutical quality (including stability)”
Monographs provide stakeholders with a standard to ensure the quality of medicines

- Monographs provide public standards used to determine a product’s quality
- Effectively ensure drug’s identity, potency, purity, consistency, and quality
- Useful as a tool to provide protection to patients throughout a product’s lifecycle
Currently 22% of Essential Medicines Do Not have Monographs

Essential medicines “satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford”

When looking only at the four major pharmacopeias – BP, JP, Ph. Int. and USP – 22% (150) of medicines have no monograph while a further 49% (327) do not have a complete monograph.
Percentage of available monographs for EML medicines across eight pharmacopeias

15% of Essential Medicines Do Not have Monographs

Of the 99 medicines currently without a monograph, 50 are anti-infective medicines.
### Number and percentage of available monographs across eight pharmacopeias

<table>
<thead>
<tr>
<th>Pharmacopeia</th>
<th>Incomplete Monographs</th>
<th>Complete Monographs</th>
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<tr>
<td>BP</td>
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<td>214</td>
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<td>140</td>
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<tr>
<td>MP</td>
<td>140</td>
<td>169</td>
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</tbody>
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- Incomplete monographs
- Complete monographs
97% of the beta-lactams have a monograph in at least one pharmacopeia, and 81% of all the beta-lactam monographs are complete. Contrastingly, 18%, 28% and 23% of antiTB, ARVs, and antimalarial medicines, respectively, do not have a monograph in any of the eight pharmacopeia.
United States Pharmacopeia has a longstanding commitment to global public health

Long-term commitment

The oldest continuously published pharmaceutical compendia
Includes over 4500 monographs, and over 3500 reference standards

Global Reach and Capacity

10 International offices/sites
Standards used in more than 140 countries around the globe

Extensive Expertise (Volunteer)

Over 400 volunteer scientists, academicians, practitioners, and other professionals elected on the basis of their knowledge and expertise
>25% of expert committees’ members standards are International experts from 25 countries

Transparent/Collaborative Process

USP standards vetted through an open comment process, in which stakeholder and public input is key
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USP’s standard setting activities for non-US medicines have rapidly evolved over the last decade

1985 Explore a Non-US standards Section
• USP Convention Resolution #6

2007 SALMOUS
• Legally marketed outside the US
• Renamed in 2009

2011 Medicines Compendium
• New approach to standard development
• Included US and Non-US Standards

2016 Global Health Standards Program
• New program launched in 2016
• Legally marketed only outside of the US, and do not have approval from the FDA
• Collaborative prioritization
The Global Health Standards program: Objectives

**USP Mission:** To improve global health through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods.

**USP Vision:** USP envisions a world in which *all* have access to high quality, safe, and beneficial medicines and foods.

**Global Health Standards Program Objectives**

The global health standards program’s objectives are to:

- Ensure **availability** of relevant, modern standards for the world’s most essential medicines;
- Enable **accessibility** of these standards in non-US settings; and
- Engage stakeholders for development, **adoption**, and implementation of these standards for improved public health outcomes
GHS program will focus on medicines of global health importance marketed outside the United States

1. GHS Universe including articles
   Legally marketed outside the US

2. Authorized for use by SRA

3. Products lacking an up-to-date modern standard

4. High priority for the global health community

GHS Program’s Monographs for Development
The Global Health Monographs have a new section in the USP–NF

Preface
“This section contains monographs for articles which are not currently legally marketed in the United States, but which have been approved by a stringent regulatory authority as defined by the World Health Organization and are used for essential purposes in other parts of the world. Selection and prioritization of new entries to this section will be accomplished in close collaboration with stakeholders throughout the global health community. These monographs are not applicable to articles marketed for use in the United States.”
GHS Program’s implementation strategy includes 4 key activities

**Collaborate & prioritize monographs for development**
- Collaborate with global stakeholders select new medicines for monograph development

**Develop monographs**
- Develop standards utilizing existing standards-setting capabilities, including USP Expert Committees

**Disseminate**
- Disseminate the standard to key quality assurance entities

**Enable Stakeholders**
- Enable partners to protect the quality of medicines