Welcome

Empowering a healthy tomorrow

Global Health Standards Program

United States Pharmacopeia—Global Public Health

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Outline

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

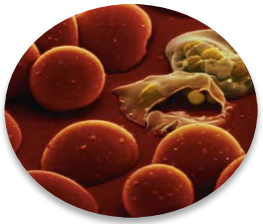
532 Products

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

REGULATORS

PHARMACEUTICAL INDUSTRY

MANUFACTURERS

GLOBAL HEALTH DONORS

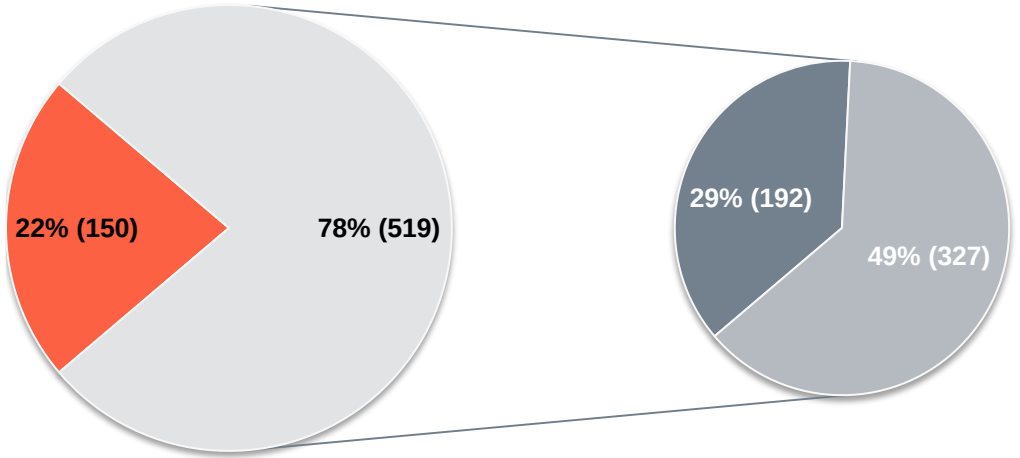
LEGAL AND TRADE SECURITY GROUPS

The global health significance of monographs

- 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

Percentage of available monographs for EML medicines across four major pharmacopeias

Currently 22% of Essential Medicines Do Not have Monographs

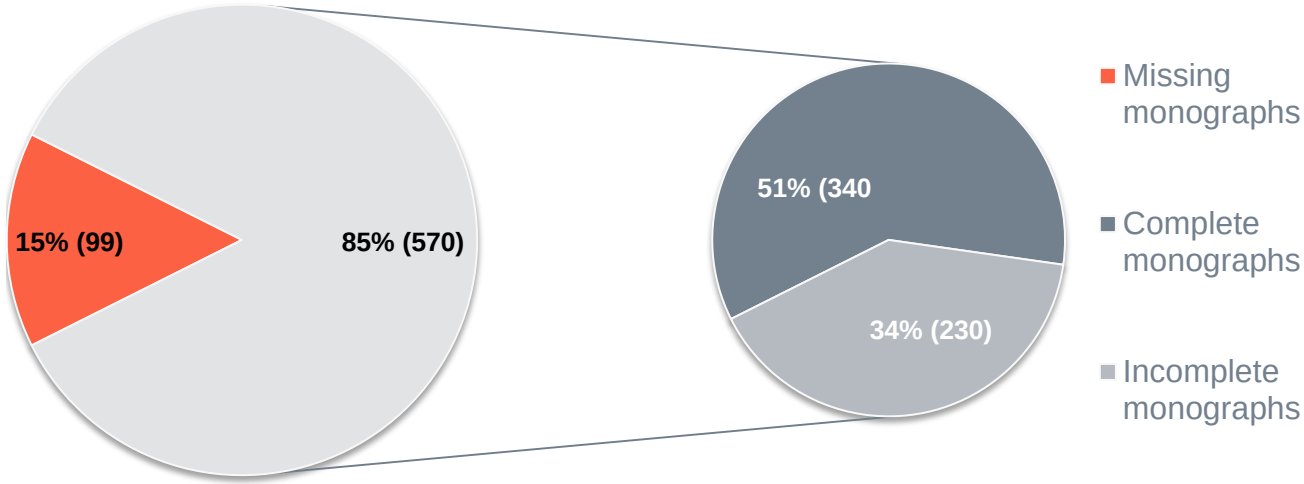


Essential medicines
"satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford"

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

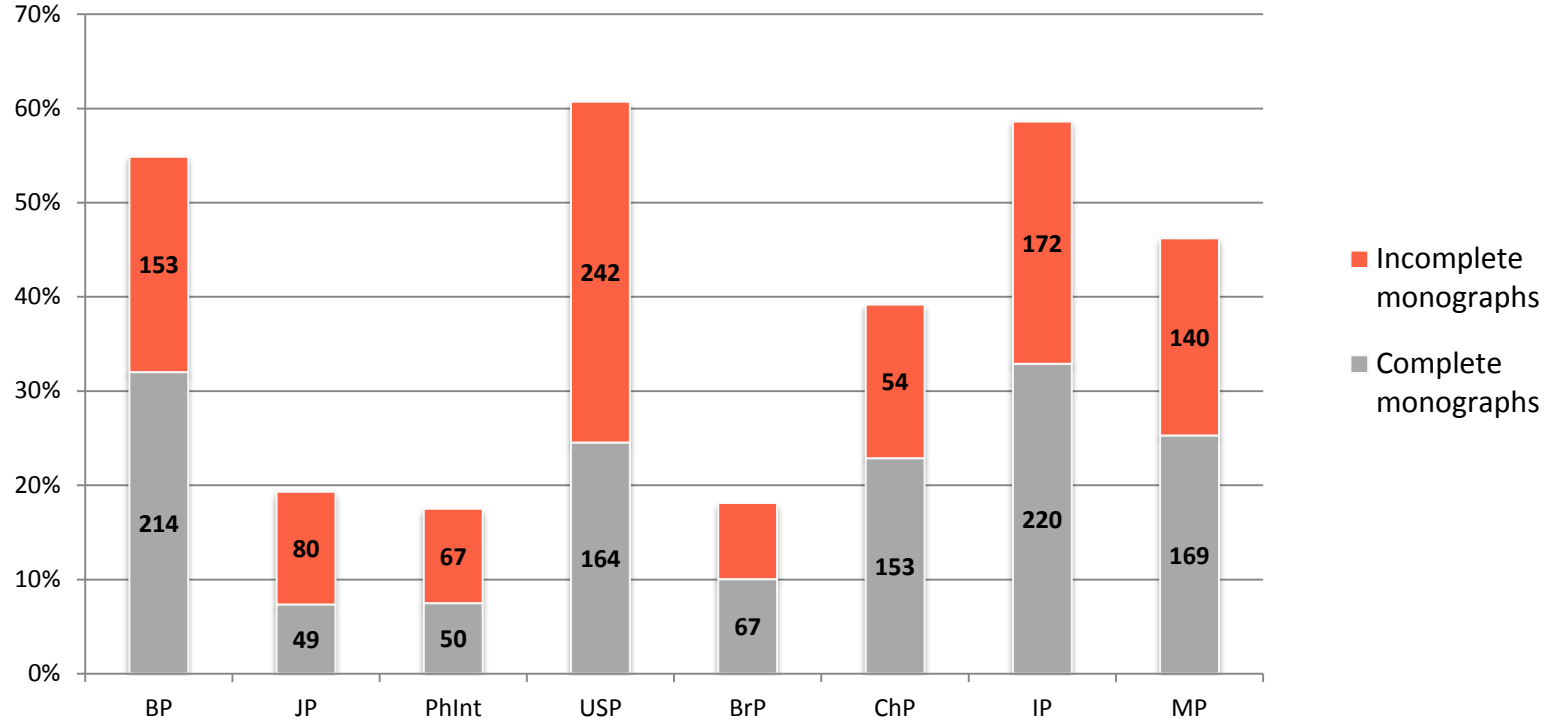
15% of Essential Medicines Do Not have Monographs



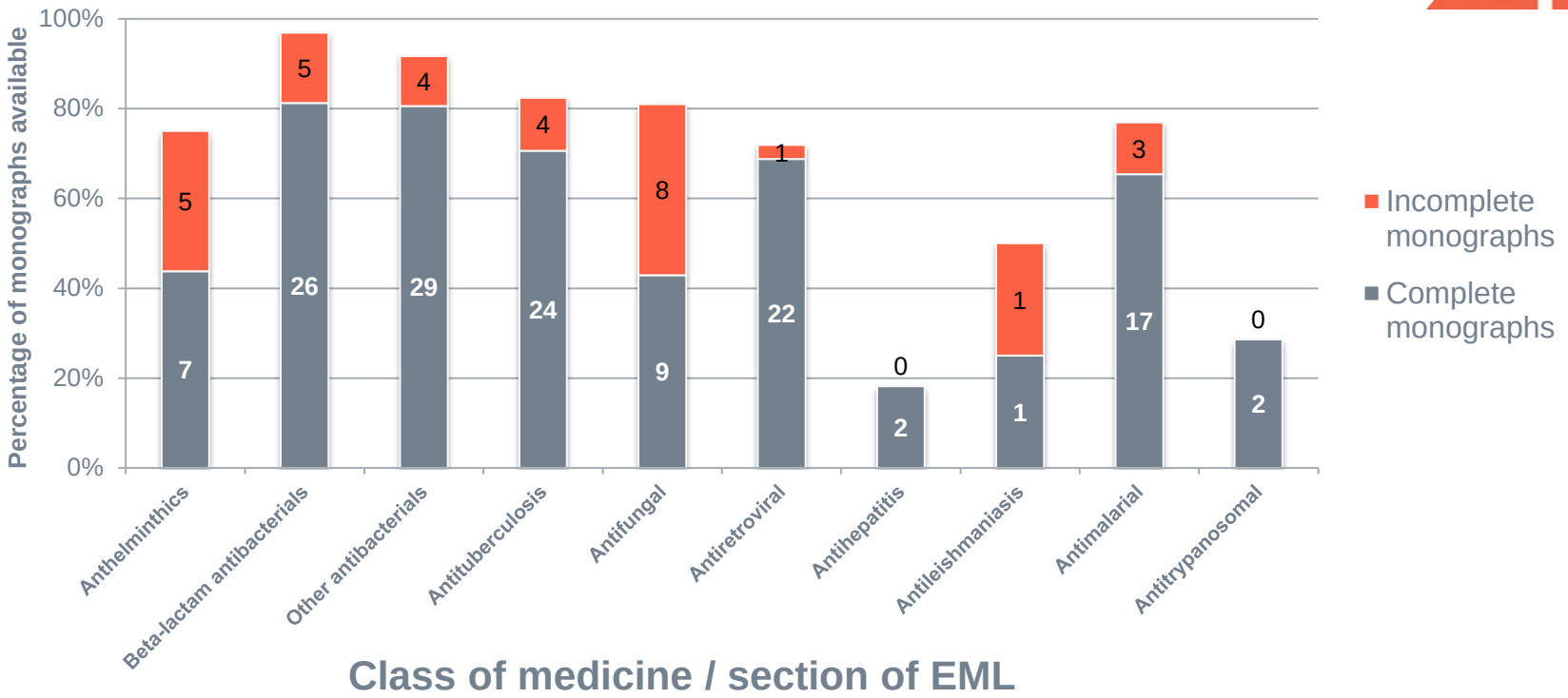
Of the 99 medicines currently without a monograph, 50 are anti-infective medicines

BP, JP, Ph. Int., USP, Brazilian P, Chinese P, Indian P, Mexican P.

Number and percentage of available monographs across eight pharmacopeias



Percentage of monographs available for major classes of anti-infective medicines



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

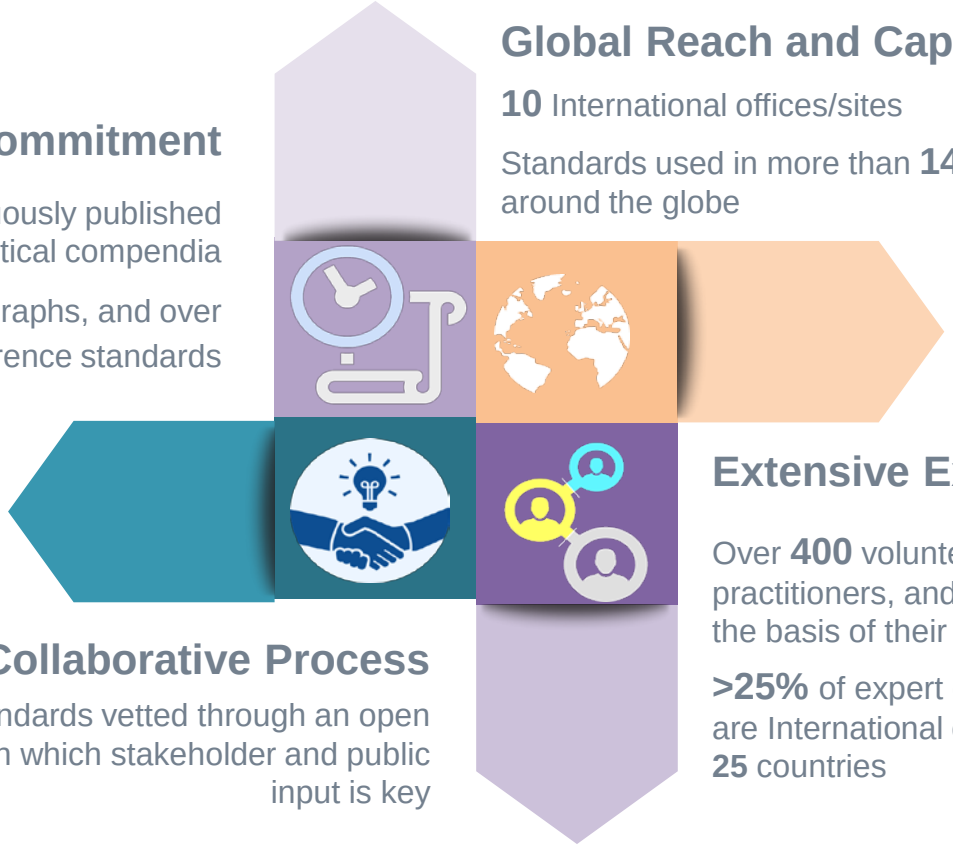
The oldest continuously published pharmaceutical compendia

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



Transparent/Collaborative Process

USP standards vetted through an open comment process, in which stakeholder and public input is key

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

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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.

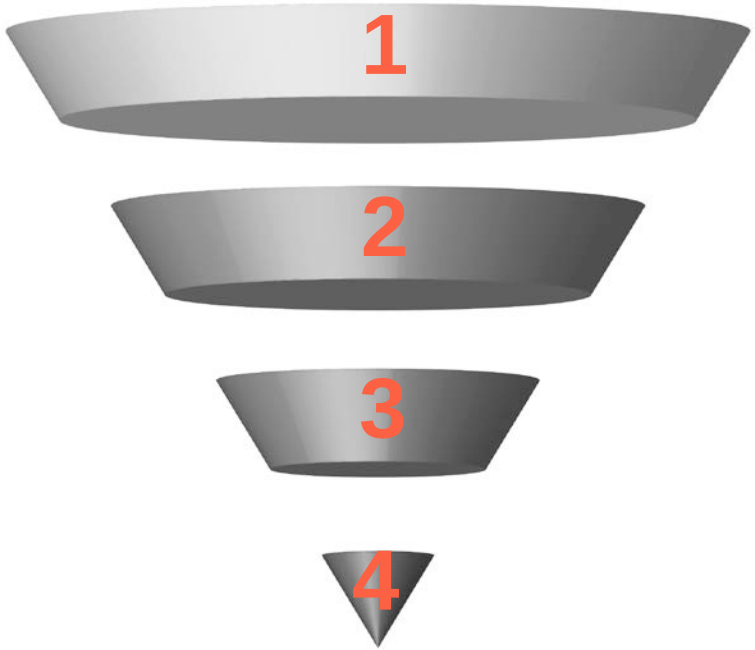
USP Vision: USP envisions a world in which *all* have access to high quality, safe, and beneficial medicines and foods.

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



GHS Universe including articles Legally marketed outside the US

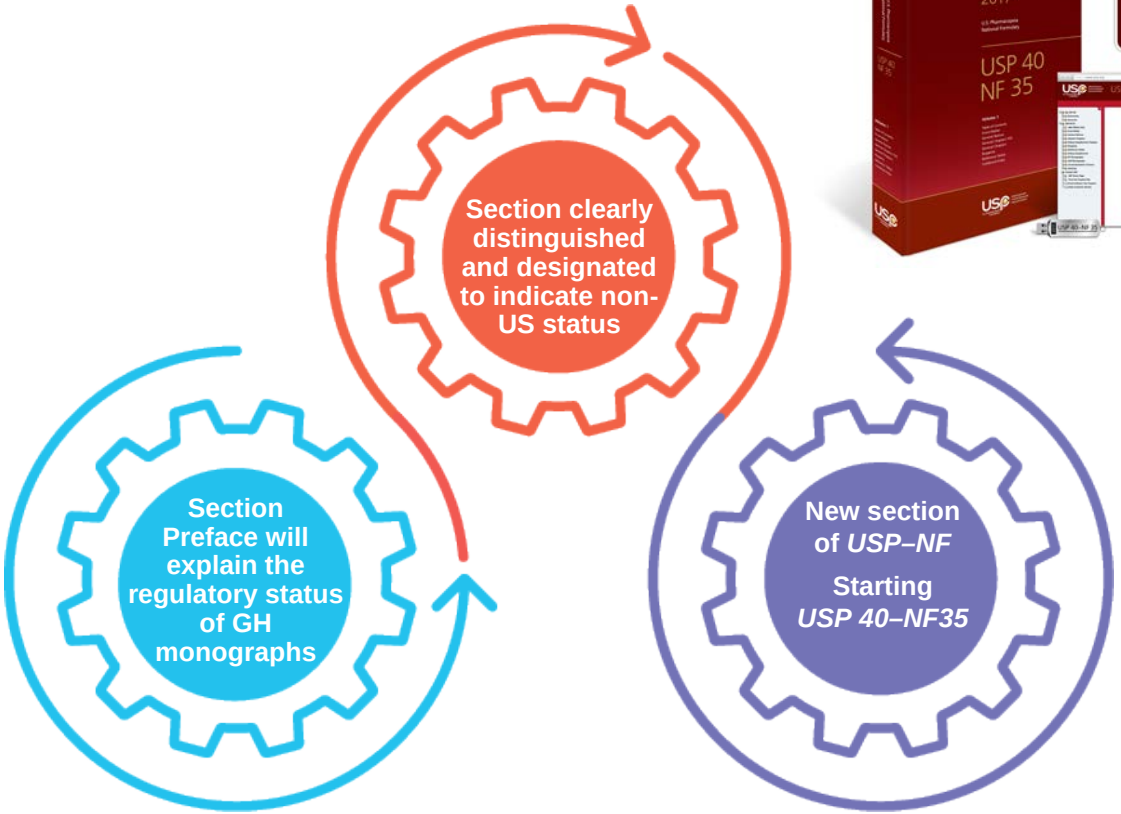
Authorized for use by SRA

Products lacking an up-to-date modern standard

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

Thank You

Empowering a healthy tomorrow