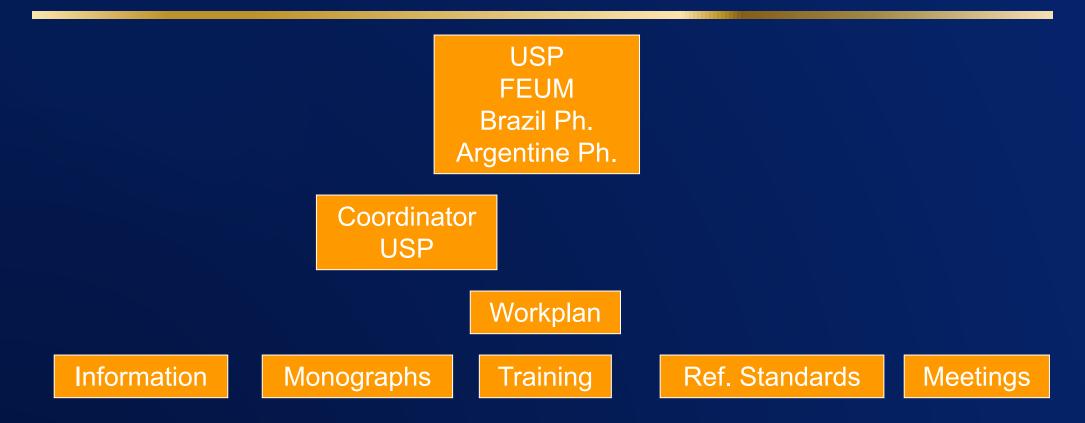


Pharmacopeias Working Group

Enrique Fefer, Ph. D. International Affairs, USP II Steering Committee Meeting March 23, 2001 Orlando, Florida



Pharmacopeias Working Group





What do Pharmacopeias do?

Pharmacopeias establish officially recognized standards of quality, strength, purity, packaging and labeling for medications and other health care products.



PHARMACOPEIAS ACTIVE IN THE AMERICAS

Title	ARGENTINA Farmacopea Nacional Argentina	BRAZIL Famacopea Brasileira		MEXICO Farmacopea de los Estados Unidos Mexicanos	USA The United States Pharmacopeia; The National Formulary
		3 rd Edition	4 th Edition		
# of Monographs	804	481	364	1210	3873
# of General Chapters	79	50	256	129	170
Mechanism for Public Comments	Internet	Diario Oficial	Internet	"Consult to the Industry", document for final users; forms and letters from other interested parties.	Pharmacopeial Forum
Reference Standards	43	0	0	134	1675



Why a PWG

Free Trade Area of the Americas
 reduced trade barriers
 regulatory harmonization
 Global harmonization
 Resource limitations



Pharmacopeial Harmonization

- A pharmacopeial general chapter or other pharmacopeial document is harmonized when a pharmaceutical substance or product tested by the procedure yields the same results, and the same accept/reject decision is reached
- Goal: Pharmacopeia of the Americas



Meetings

Washington, April 14, 2000
Sao Paolo, May 1, 2000
Porto Alegre, August 1, 2000
Orlando, March 26, 2001



PWG Workplan

Information sharing

- meetings
- publications
- other activities
- Training
- Monograph development
- Botanicals
- Reference standards



PWG Workplan

Industry/pharmacopeia meetings
 Expert committees

 exchange expertise

 PDG/ICH

 PWG participation



Bilateral Cooperation

"Adopt and adapt" agreements Argentina and Brazil India (pending)

Memorandum of Understanding Mexico



FEUM/USP Collaboration

Exchange of staff

- Exchange of monographs
- Workshop: Role of Pharmacopeias and Drug Quality
- Annual policy-level meeting



PAHO/USP Cooperation in Drug Quality

 Diagnostic Studies of Official Drug control Laboratories

- External Quality Control Program
- Dissolution Testing Courses
- Good Laboratory Practices Seminar
- Drug Procurement and Quality Workshop

USP Pharmacopeial Discussion Group

PDG

European Pharmacopoeia Japanese Pharmacopoeia United States Pharmacopeia



Thank you Muchas gracias Muito obrigado