DIA 2nd Latin American Regulatory Conference
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Current Status of PANDRH Bioequivalence Working Group

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The views expressed in this presentation are those of the author and do not necessarily represent the views of the U.S. Food and Drug Administration

Pan American Network for Drug Regulatory Harmonization Buenos Aires, Argentina

17–19 November 2008

- **V Conference of the Pan American Network for Drug Regulatory Harmonization (PANDRH)**
- **Information and propositions of 9 working groups presented for consideration**

PANDRH V Conference
Working Group Reports

1. Bioequivalence and Bioavailability
2. Vaccines
3. Medicines Promotion
4. Pharmacovigilance
5. Drug Counterfeiting
6. Good Manufacturing Practices
7. Good Laboratory Practices
8. Good Clinical Practices
9. Registration Requirements

Bioequivalence and Bioavailability Working Group

Working Group

• Ricardo Bolanos	Argentina
• Silvia Giarcovich	ALIFAR
• Silvia Storpitis	Brazil
• Conrad Pereira	Health Canada
• Lizzie Sanchez	FDA - USA
• Justina Molzon	FDA – USA
• Roger Williams	USP – USA
• Regina Pezoa	Chile
• *Helgi Jung	Mexico
• Lidiette Fonseca Gonzalez	Costa Rica
• *Ana Lucia Valle	Guatemala
• Eugene Brown	Jamaica
• Rosario D'Alessio	PAHO
• Sabbine Kopp – Kubel	WHO
• Loreta Marquez	FIFARMA
• Irene Goncalves	Venezuela

PANDRH
Steering Committee Priorities

Urgent Issues:

- GMP (FDA)
- **BA/BE (FDA)**
- GCP (ANMAT)
- Counterfeit (ANVISA)

Proposals

- The Conference adopt the document: *Framework for Implementation of Equivalence Requirements for Pharmaceutical Products*
- The conference recommend training to promote implementation by the NDRA
  - On the document
  - On bioequivalence and statistics
- The Conference recommend the development of indicators to evaluate implementation of BE in the Americas

Topics Discussed

- Training required
- Need for case studies
- Need to establish BE centers
- Decision tree for prioritizing need to implement BE studdies
- Experience in implementing BE studies
- Need for DRA to link local innovator to product establishing safety and efficacy

Bioequivalence Centers

- Establish regional BE centers to perform studies for countries
  - Recognized, established, validated
- Established and supported by private sector

Decision Tree

- Questions on key decision points
- Decision tree modified to clarify concerns
- Satisfactory results=Meet f2 requirements
- If not met= case by case DRA decision

2006 WHO Guidelines Related to Bioequivalence Studies

- 40th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. Geneva, World Health Organization.
- WHO Technical Report Series, No. 937, 2006:
  - Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. Annex 7.
  - Proposal to waive in vivo bioequivalence requirements for the WHO Model List of Essential Medicines immediate release, solid oral dosage forms. Annex 8.
  - Additional guidance for organizations performing in vivo bioequivalence studies. Annex 9.

WHO Report 36 Annex 11

- Important to include reference to WHO Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generic) products. WHO Expert Committee on Specifications for Pharmaceutical Preparations, Annex 11, page161-180, WHO Technical Report Series 902,2002

WHO Guidelines Related to Bioequivalence Studies

- Update to Annex 11 anticipated
- Document should be linked to updated WHO guidelines on relevant topics
- Always use most current WHO guidelines generally linked to WHO Prequalification Program
- Include updates in text and decision trees

Training Suggested

- Document
  - DRA=Evaluation and inspection
  - Industry=Application and use
- Principles of BA/BE
  - FDA modules concepts
- BCS
- Statistics in BE study evaluation
- Case studies

Develop Case Studies

- To assist DRA and industry in implementation and application of the document
- Selection of reference product
  - Link generic to reference product demonstrating safety and efficacy
  - Promote discussion on implementation of requirement of linking local innovator with original product according to methodology of document

Education on Strategies and Technical Information

- To inform the public, industry and DRA about the need for and implication of BE studies and tests as registration requirements for some API and dosage forms
- Education programs focused on confidence building in generic drugs for the public and health care professionals

Capture Experience

- Annex 2 details experience in country
  - Chile, Costa Rica, Venezuela, Argentina
- Several countries asked to be included
  - Panama, Uraguay
- Important to capture and update Annex with implementation experience as countries implement BE studies
- Send information to Nelly Marin PAHO
  - marinnr@paho.org

Discussion

- During the implementation process PAHO should establish a mailbox for questions related to implementation of the Framework
- Questions answered by WG members and posted on PAHO web
- Will help monitor implementation process


V-Conf-PANDRH_Draft-Reportr[1].pdf - Adobe Acrobat Professional
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Create PDF Combine Files Export Start Meeting Secure Sign Forms Review & Comment
V PAN AMERICAN CONFERENCE ON DRUG REGULATORY HARMONIZATION
Buenos Aires, 17 - 19 November 2008
Preliminary Report, Conclusions and Recommendations
Internet


Gracias
Merci
Obrigado!
Thank You