Update on Implementation of Recommendations:

12th International Conference of Regulatory Authorities

PAHO/WHO Region of the Americas
AMRO/PAHO and Mechanisms of Integration in the Americas
1. Safety & Pharmacovigilance

• Situational analysis of pharmacovigilance in the Americas;
• Countries actively moving to strengthen pharmacovigilance systems
• Document on Good Practices on pharmacovigilance for centers;

2. Bioequivalence

• PANDHR document adopting WHO Guidelines, specifically Annex 7 and 8, Expert Committee Report No. 40 (Nov. 08)
• Implementation strategy with a sanitary risk approach
• Country capacity building on application of WHO Guidelines, including biowaivers
3. Pharmacoeconomics

- Proliferation of new and high cost technologies
- Renewed interest in the region, with meetings of 7 NRAs (in MEX, BRA) on processes to incorporate health technologies in health systems
- Important regional meetings being organized (Cuba Oct 08, Brazil, 09)
- Discussion on role of the NRA in HTA and regulation of medicines pricing

4. Advertising & Promotion

- Renewed focus in the region recognizing the impact on the rational use of medicines, and medicines cost.
- Comparative study on legislation for specific products
5. Counterfeiting

- Promoting standards in commercialization of products
- Medicines traceability
- Coordination with IMPACT (pre-PANDHR meeting, Argentina)
- Regional meeting, Panama August 2008

6. Vaccines and Biologicals

- Countries examining licensing requirements for vaccines
- Harmonized Guidelines (LA / Canada) developed for registration of vaccines
- Assessment of biosimilar regulations completed in 17 countries following regional meeting, June 2008, Dominican Republic
- SANEVA Group and active notification of post marketing surveillance for rotavirus vaccine
7. Blood and Blood Products

- All countries in Latin America now have Blood Programs compared with one in the Caribbean
- External performance evaluations in 17 countries in Latin America, and in 18 countries in the Caribbean (centers)
- Data from diagnostic testing and marker presence indicate increased risks in blood transfusion since 2003
- Regional meetings on production of blood products and sera in 2007 (PANAFTOSA and HEMOBREAS) to discuss production, transfer technology and regulation
- Regional mechanism for the evaluation of blood products
8. Harmonization

- PANDHR Conference, November 2008, Buenos Aires
- Presentation of revised statutes focus on prioritization and decision making process
- Articulation with ICH / GCG, dissemination of norms, proposals for training in specialized areas
- AMRO/PAHO support in capacity building to MERCOSUR in GMP and Risk Analysis, February 2008

9. Strengthening Core Functions of NRAs

- 6 meetings of NRAs in 2007 and 2008 to strengthen regulatory capacity in Latin America
- Adoption of WHO Guidelines for assessment and recognition of NRAs with participation of NRAs in LA
- Revision of PQ procedures for the Strategic Fund with increased participation of NRAs
THANK YOU