Regional meeting on regulation of biotechnological products
I Meeting of the PANDRH Working Group of biological/biotechnological products

Punta Cana, Dominican Republic
June 15 – 17, 2010

DAY 1	
8:30 am	Opening *(PAHO Local Representation, María de los Angeles Cortés Medicines and Health Technologies Project)* Objectives and logistics *(PAHO: María L. Pombo)*
9:00 am	WHO Initiatives: ICDRA recommendations: Emerging regulatory issues concerning biosimilars and biologicals Guidelines on evaluation of similar biotherapeutic products (SBPs), adopted by the Expert Committee on Biological Standardization (ECBS) in 2009 *(WHO: Ivana Knezevic)*
10:00 – 10:30 am	***Coffee break***
10:30 am	Advances, objectives and challenges on the harmonization of biotechnological products regulation - Issues identifying and actions by MERCOSUR *(MERCOSUR Representative)*
11:30 am	Comparability evaluations for products quality of biologics *(FDA/CDER: Emily Shacter)*
12:30 – 1:30 pm	***Lunch***
1:30 pm	Similar biological medicinal products regulation – Quality aspects to be considered – EMEA perspective, and Spanish experience on product's substitution and its traceability *(Agencia Española de Medicamentos y Productos Sanitarios, AEMPS: María Sol Ruiz Antúnez)*
2:30 pm	Cuban regulation for biotechnological and biosimilar products. Post-marketing surveillance measures
3:30 – 4:00 pm	***Coffee break***
4:00 pm	Pan American network on drug regulatory harmonization (PANDRH): history, objectives, recent activities and groups conformation *(PAHO: José Peña Ruz)*

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DAY 2	
9:00 am	- What is happening where biosimilars are currently available? The case of Latin America *(RANDOM Foundation of Colombia, University of Washington: Rafael Alfonso)*
10:00 – 10:30 am	***Coffee break***
10:30 am	- General principle's guidance, and product-specific non-clinical and clinical guidance - EMEA Experiences for similar biological medicinal products
11:30 am	- Situation of other Regions regarding the regulation of similar biotherapeutic products *(WHO: Ivanna Knezevic)*
12:30 – 1:30 pm	***Lunch (Activities following the lunch break are exclusively for National Regulatory Authorities, NRA)***
1:30 pm	NRA invited *(Argentina, Brazil, Canada, Colombia, Chile, Cuba, Mexico, Venezuela)* will present in 30 minutes the local advances and challenges in the area of regulation of biotechnological products
3:00 – 3:30 pm	***Coffee break***
3:30 pm	*NRA's presentations cont …/…*

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DAY 3	
Closed session exclusively for Members of the Working Group of biotechnological products of the Pan American network on drug regulatory harmonization (PANDRH)	
9:00 am	Establishment of: - Country coordinator for the Working Group - Objectives - Responsibilities - Calendar of activities
10:00 – 10:30 am	***Coffee break***
10:30 am	Draft report to be presented to the Steering Committee of PANDRH, conclusions and closing.
12:30 – 1:30 pm	***Lunch***