VII Conference of the Pan American Network for Drug Regulatory Harmonization

AGENDA

Parallel session on biotherapeutic products

6 September 2013, Delta Ottawa City Centre, Ottawa, Canada

Objectives:

1. Raise awareness of the importance of well-defined national requirements for evaluation of BTP/SBP in line with internationally agreed principles such as those in WHO guidelines.
2. Facilitate implementation of the WHO principles into regulatory and manufacturers' practices (focus on clinical evaluation).
3. Define expectations from member states in the region for WHO role in improving convergence of regulatory requirements at the regional and global level.

6 September 2013 (Day 2)	
16:00 – 18:30 Ballroom A & B	
16:00	Introductory remarks [Speaker: M. Pombo] Implementation of WHO standards for regulatory evaluation of similar biotherapeutic products (SBPs) with a focus on clinical evaluation [Speaker: I. Knezevic]
16:30	Lessons learnt in reviewing clinical data of SBPs for the purpose of licensing [Speaker: A. Klein]
16:45	Establishing clinical similarity for similar biotherapeutic products – The concept of sensitive population [Speaker: T. Schreitmueller]
17:00 – 18:20 Panel discussion **What is the role of WHO in improving (or promoting) convergence of regulatory requirements for SBPs at regional and global level?**	
17:00	Brief overview of WHO survey with a focus on clinical aspects [Speaker: I. Knezevic]
17:10	Level of adoption and implementation of PANDRH Technical Document for the evaluation of SBPs [Speaker: P. Saidón]
17:20	ANVISA's experience with the review of clinical data of Omnitrope and clinical trials approval of products under development [Speaker: L. Castanheira]
17:30	Comments from other NRAs within the Americas Region
17:40	Diversity of national regulatory requirements for clinical evaluation of SBPs / some proposals [Speakers: ALIFAR and FIFARMA] General discussion
18:20 – 18:30 Wrap up	

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