



# news release

## Scientific and regulatory experts meet in Lima for regional conference to explore harmonized approaches for biotherapeutic and biosimilar medicines

- Region-wide conference focuses on biotherapeutic medicines and on harmonizing regulatory standards
- Meeting brings together scientific experts and representatives of international, regional and national health regulatory authorities

**Lima and Geneva, 19 November 2013** – Beginning today an international scientific and regulatory conference is taking place in Lima to enhance regulation of biotherapeutic medicines. The conference, Biotherapeutic medicines: sharing experiences and best practices, involves the participation of leading scientific, regulatory and academic experts from Argentina, Brazil, Chile, Ecuador, Mexico, and Peru. Other speakers include representatives of the World Health Organization, Health Canada, and industry. Experts will discuss the current challenges in regulating biotherapeutic and biosimilar medicines and exchange national and regional best practices.

The conference is organized by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) in cooperation with its Latin American national and regional member associations: ALAFARPE (Peru), AFIDRO (Colombia), AMIIF (Mexico), CAEMe (Argentina), cif (Chile), Fedefarma (Central America), FIFARMA (South America Region), IFI (Ecuador), and Interfarma (Brazil).

Ahead of the conference, IFPMA Biotherapeutics Group Chair Fermin Ruiz de Erenchun (Roche) said, "Due to the complex nature of biotherapeutic medicines, harmonized regulatory standards are needed to best serve the interests of patients and healthcare systems throughout the region. We hope this conference will offer a constructive platform for dialogue in which national and regional health authorities and international experts will share and discuss current norms and best practices."

Biotherapeutic medicines are larger and more complex than many chemically-synthesized small molecule medicines. Derived from living organisms, their characteristics and properties are highly dependent on the manufacturing process and conditions. These medicines have benefitted more than 350 million patients worldwide in treating both common as well as rare diseases. Because these medicines' complexity poses important new challenges for regulators, the conference focuses on technical challenges in manufacturing biotherapeutics, evaluation and registration of biotherapeutic and biosimilar products, immunogenicity and safety monitoring, interchangeability, and pharmacovigilance.

IFPMA Director General Eduardo Pisani said, "Biotherapeutic medicines open new treatment possibilities for patients and offer cures for some diseases that were previously considered untreatable. With more than 200 biotherapeutic medicines now registered and many others in the pipeline, science-based, harmonized regulatory approaches are

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needed to make them readily available for patients. This conference is an important platform for sharing regulatory best practices among leading experts."

**About IFPMA:**

IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 1.3 million employees research, develop and provide medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

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