IFPMA *news release*

Scientific and regulatory experts meet in Moscow to explore harmonized approaches for biotherapeutic and biosimilar medicines

- First meeting of its kind in Russia brings together scientific experts and representatives of national health regulatory authorities from around the world
- Conference focuses on role and characteristics of biotherapeutic medicines, and on harmonizing regulatory standards

Moscow, 15 May 2013 – Beginning today an international scientific and regulatory conference takes place in Moscow to enhance regulation of biotherapeutic medicines. The conference, *Biotherapeutic medicines: regulatory challenges and current practices - approaches for harmonization* is the first international expert meeting of its kind to take place in Russia. Participating in the conference are leading experts from Russia, Belarus, Kazakhstan, Ukraine, the World Health Organization, Health Canada, several European national regulatory agencies, and industry. They will discuss current challenges in regulating biotherapeutic and biosimilar medicines and exchange best practices.

The conference is organized by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) in cooperation with the Association of International Pharmaceutical Manufacturers (AIPM). It is held with the support and participation of the Ministry of Health of the Russian Federation, the Russian Federal Service for Healthcare Supervision, the Eurasian Economic Commission, the State Duma Committee on Health Protection, and the Russian Academy of Medical Sciences.

Ahead of the conference, AIPM Executive Director Vladimir Shipkov 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 our region. I hope this conference will contribute to the establishment of a regulatory system for biotherapeutic and biosimilar medicines in Russia based on global best practices and established regulatory procedures."

Biotherapeutic medicines are larger and more complex than chemically-synthesized small molecule medicines. Derived from living organisms, their characteristics and properties are typically dependent on that organism and manufacturing processes and conditions. These medicines have benefitted more than 350 million patients worldwide in treating both widespread diseases as well as rare diseases. Because these medicines' complexity poses important new challenges for regulators, the conference focuses on 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 possibilities for medicines 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 needed. This conference is an important platform for sharing regulatory best practices among leading Russian and international experts."

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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.

About AIPM:
The Association of International Pharmaceutical Manufacturers (AIPM) comprises more than 50 international pharmaceutical companies operating in Russia that provide over 80% of the world's pharmaceutical products and over 60% of medicine imported to the Russian Federation.

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