



# statement

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Check against delivery*

*15.6 Regulatory system strengthening (resolution EB134.R19) Access to biotherapeutic products and ensuring quality, safety and efficacy*

Thank you for the opportunity to provide input to this important discussion. The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) represents the leading research-based pharmaceutical companies as well as national industry associations across the world.

Science-based regulatory standards for medicines are essential. Given the complex nature of biotherapeutic medicines and the resulting challenges in characterization, specialized testing is required to ensure their safety and efficacy. As a result, similar biotherapeutic products (or biosimilars) should be regulated via pathways that are distinct from those traditionally applied to generic medicines.

In 2009 WHO established *guidelines on evaluation of similar biotherapeutic products* followed in 2013 with *guidelines on the quality, safety, and efficacy of biotherapeutic protein products prepared by recombinant DNA technology*. Uniform regulatory requirements following World Health Organization (WHO) principles and guidance for all manufacturers should be developed to ensure that all biotherapeutic medicines are safe and efficacious.

Madam/Mr Chair, biotherapeutic medicines are an important and integral component of modern medicine that targets many chronic and acute disease areas with highly-specific treatments. These complex medicines allow both the individual patient, through improved quality of life, and ultimately, society to benefit from their use.

Thank you.