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ASIA EDITION

India announces new biosimilar regulatory guidelines

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Boston: India has announced the much-awaited new and simple regulatory guidelines for similar biologics which have been approved and marketed in USA or Europe for more than four years.

The guidelines, released for the first time, at the ongoing BIO industry conference here on June 19 provided requirements for preclinical evaluation of those recombinant products that are claimed to be similar to the already approved biopharmaceutical products, referred as ' similar biologics'. Therefore the regulators will partly rely on the information from the already approved products for ensuring safety, purity, potency and effectiveness.

Releasing the guidelines, Dr Maharaj K Bhan, India's top biotech policy maker and secretary, department of biotechnology (DBT) said "this will be good news for governments and patients alike as it will lead to significant reductions in costs with the introduction of a similar biologic or biosimilar to the market."

DBT has been preparing the guidelines for the last two years with wide ranging consultation with the industry, regulatory agency the Central Drug Standard Control Organization (CDSCO) and other stakeholders. These guidelines prescribe the quality, preclinical studies and clinical trial requirements of similar biologics in India.

India has so far approved over 20 similar biologics that include recombinant therapeutics, monoclonal antibodies based on abridged regulatory requirements.

The new guidelines require demonstration of similarity between similar biologic and the reference innovator product, and consistency in production process. If differences are significant then more extensive evaluation will be required to prove similarity.

India's definition of similar biologic is: a biological product or drug produced by genetic engineering techniques and claimed to be "similar" in terms of quality, safety, efficacy to a reference innovator product, which has been granted a marketing authorization in India by a competent authority on the basis of a complete dossier, and with a history of safe use in India.