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Regulatory updates on biosimilars: A review of the current global situation

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Biological products, as well as other medical supplies, are regulated in each country by the competent Health Authority (HA). According to the FDA, they are used to diagnose, prevent, treat and cure diseases and medical conditions. The difference with a more traditional drug is that the Active Pharmaceutical Ingredient (API), or APIs, is produced by processing chemical compounds, whereas in a biological drug, the active ingredient is known as Bulk Process Intermediate (BPI) and it is made by biotechnology in a living system, such as a microorganism, plant cell, or animal cell.

The first biopharmaceutical drug was approved in 1982 by FDA, recombinant human insulin. By 2022, FDA reports that there are over 621 FDA-licensed biologics products and the global biotechnology market size was estimated at USD 1, 023.92 billion in 2021, with an expected growth during the next years. With this in mind and considering that old patents are coming off, other companies can offer new biological products or biosimilar products. A biosimilar is defined by FDA as "A biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product" (a biological product previously approved).

Biosimilars can be seen as new therapeutic alternatives, as a way of reducing costs for the patients or the insurance and able to provide the patients with a faster product, as biosimilars typically have a timeline for approval of 8 years vs. <12 years of the reference or innovator drug, not to mention the reduce on the development budget of around 10-15%. Biosimilars look attractive for any of the involved parties, but they must be safe, of quality and effective. To make sure of this, HA had made different changes in their legislations. In this abstract, we will review recent changes and the current global situation of biosimilars with an emphasis on FDA & EMA.

Biography

Luis Gerardo Alcalá Carmona is a regulatory affairs expert based in Mexico City. During his career, he has shown a strong devotion to bringing into the market medical supplies of the best quality that are safe and effective for the patients. He has built differently proven regulatory strategies for national and international companies, having been able to collaborate with companies from around the World, such as the USA, Brazil, Argentina, Chile, Colombia, France, Germany, The UK, Italy, China, Japan, South Korea, among others. His expertise line includes medical devices, medical drugs and biotechnology drugs, which include generic and innovative drugs. He has worked with new registers, variations and renewals. Having been able to collaborate directly with Big Pharma Company, he also specializes in newly formed companies, always focusing on the best possible regulatory path and having in mind the safety of the patients, as he always says "We are all potential patients".

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