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Potential value of biosimilars- will biosimilars be cost effective compared to the branded equivalents?

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The most important issues facing global drug regulators are the scientific and technical factors related to a determination of biosimilarity or interchangeability. Biosimilar drugs are demanding and expensive to get approved, complicated and challenging to manufacture, and have a short shelf life. The result is that the price difference between innovator biologic drugs and biosimilar drugs will be far narrower than the price between brand-name chemical drugs and their generic counterparts. The likely modest cost difference between an innovator biologic drug and its biosimilar clone will make it economically feasible for the innovator company to compete with its biosimilar competition. Hence, the cost savings to public programs from requiring patients to use biosimilar substitutes are likely to be much lesser than the policymakers' expectation. The European experience demonstrates that the market cost of a biosimilar drug is roughly 20% to 30% of the innovator price. In some cases, biosimilars have been developed for older biologicals, for which second-generation originator biologicals are marketed and have become the standard treatment, like the second-generation erythropoietins and G-CSFs. This implies that the cost-effectiveness of the first-generation biosimilar needs to be determined relative to the second-generation originator biological. As a biosimilar is likely to be less expensive than the reference biopharmaceutical, the assessment of the cost-effectiveness of a biosimilar depends on the relative effectiveness. If appropriately designed clinical studies demonstrate equivalent effectiveness between a biosimilar and the comparator, then a cost-minimisation analysis needs to be carried out and the least expensive medicine is chosen. The improved affordability of healthcare that could result from the use of biosimilar medicines is tangible. By 2020, the savings through biosimilars would be more than 8 billion EUR. Biosimilar medicines can be expected to be offered at a price lesser than that of the reference product, as a result of production process efficiencies, reduced costs of a streamlined development program and as a result of competition. This price differential should lead to a significant release of healthcare funds. Therefore, the national governments should develop measures to stimulate the uptake of biosimilars. Such policies will increase access to biosimilars and contribute to major cost savings for healthcare systems.

Biography

Shabana Khan, a medical professional by background and a Post graduate in clinical research and international regulatory affairs, is currently associated with Ecron Acunova. Her domain and expertise lies in analyzing the feasibility and pharmaceutical market research for the conduct of clinical trials in various therapeutic areas, globally, along with sound knowledge of project management activities. Her current interest is in exploring the guidelines framed by different regulatory agencies towards the biosimilars which possess the clear potential for payers in the emerging "pharmerging" markets, such as India, Brazil and China. In context, she had presented a speech titled, 'A Global Regulatory Perspective on the Evolving Biosimilars Landscape', recently in CPhI, Jakarta.

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