


Pricing of Biosimilars

With the market introduction of generics after patent expiry of originator products, price reductions for equivalent products can help to sustain high-quality healthcare for patients. Biological products have contributed to improve the life of patients with serious and often life-threatening diseases since their first introduction in the early 1980's. Analogous to generics of small chemical compounds, biosimilar products come to market after patent expiry of the originator product. Some payers and healthcare insurances have expressed their expectation, that biosimilars should have a similar range of price reduction as generics of small chemical compounds. Europe's regulatory biosimilar pathway ensures that biosimilars have comparable clinical profiles than their reference product. While the amount of pre-clinical and clinical data needed for a biosimilar approval is reduced as compared to the development of a new biological product, it extends by far the requirements for the approval of small chemical generics. Submitted data are based on extensive, comparative pre-clinical and clinical studies on top of a comprehensive and comparative quality dossier. Therefore, the development of biosimilars is longer and more costly as compared to generics of small chemical compounds.

Novartis perspective

Novartis believes that biosimilars can contribute significantly to sustainable patient access to high-quality healthcare. A biosimilar offers an alternative treatment option that matches the quality, safety and efficacy of its reference product at a lower price. Innovative biopharmaceuticals will increasingly play an important role in the treatment of so-far insufficiently treatable diseases.

Novartis supports the robust protection of intellectual property rights that are needed to incentivize innovation and investment into the development of new medicines. At the same time, Novartis supports the fair competition of medicinal products in the market place, including post-patent competition between biopharmaceutical reference products and biosimilars.



Due to the complexity of biological products, biosimilars are not treated like generics of small chemical compounds during their regulatory approval procedure. This implies the need for careful evaluation whether concepts used with generic drugs can be transferred to biosimilars without adaptation.

Novartis believes that a biosimilar should be priced competitively vs. the originator product and that the price should be set based on a competitive and sustainable market environment and not be linked in a static manner to the originator product.