Biosimilar Factsheet

What is a biosimilar?

- Biosimilars are biological medicines, also known as biologics
- Biologics are large, complex molecules isolated from natural sources – human, animal or microorganism.[1] Because they are derived from living organisms, no two batches are identical.[2] Biologics are distinct from traditional pharmaceuticals, which are made from combining simple chemical ingredients to form small molecules[3]
- Biosimilars are so-called because they are developed to be highly similar to already marketed biologics, known as reference products.[3] They are typically made available at a lower cost than the reference product, after the patents and Supplementary Protection Certificates protecting that product have expired[4]
- Prior to approval by the European Medicines Agency, biosimilars undergo rigorous comparability testing for quality, safety and efficacy to ensure they are equivalent to the reference product[5]

Regulation

- A rigorous system has been developed to evaluate biosimilar medicines that follows strict criteria comparing the quality, safety and effectiveness of the biosimilar to the reference product
    - At the time of submission for approval, manufacturers of biosimilars are required to provide safety and efficacy data from non-clinical as well as clinical trials to ensure that they match in terms of quality, efficacy and safety, as well as post-approval monitoring and a risk management plan[5]
    - The submission of 'comparability data' is also essential to show that the biosimilar has no significant differences in comparison with the reference product[5]
- The active substance of a biosimilar and its reference product is the same, although there may be slight differences due to the complexities of the production process. As both the reference product and the biosimilar have a degree of natural variability, studies are undertaken to ensure that these differences do not affect the biosimilar's safety or effectiveness[6]
- In Europe, all biosimilars are assessed by the European Medicines Agency (EMA), which constitutes the scientific body of the European Commission responsible for the evaluation of medicines. They are approved by the European Commission based on a positive scientific opinion issued by the EMA and its main expert committee the CHMP (Committee on Human Medicinal Products)[7]

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- In 2006, the human growth hormone Omnitrope® (somatropin) became the first biosimilar to be approved by the EMA. There are now 20 biosimilars approved for use in Europe to treat conditions such as cancer, diabetes, inflammatory autoimmune diseases, heart attacks, stroke and multiple sclerosis[3,8]

- Both reference products and biosimilar medicines are made under carefully controlled conditions to ensure the products are consistent and of the required quality, which is known as Good Manufacturing Practice (GMP)[7]

- Where the reference product has multiple indications, the biosimilar is tested for safety and efficacy in the most sensitive patient population – i.e., the indication(s) in which any differences between the biosimilar and the reference product are most likely to manifest. These data may then be extrapolated to the other indications[9]

- Data extrapolation is an established scientific and regulatory tool that has been used for many years in the EU. For example, it has been accepted in cases where there have been changes in the manufacturing process of a reference biologic and in the introduction of a new subcutaneous formulation of an intravenous drug, where one clinical study is normally enough to grant all clinical indications approved for the intravenous drug product[10]

- Biosimilars can only be marketed once the period of data exclusivity on the reference product has expired; the reference product must have been authorised for at least 10 years before a biosimilar can be made available by another company[11]

Safety profile

- Biosimilars are expected to have the same safety profile as their reference products. A consensus information document published by the European Commission in 2013 states that there have been no specific safety concerns identified for approved and marketed biosimilar medicines at the time of publication[4]

- As with all medicines, pharmacovigilance systems are put in place to monitor the safety of biosimilars after authorisation[6]

- Under new EU pharmacovigilance legislation, biosimilars are some of the medicines that are identified by a black triangle. As they are not identical to the reference product, they are therefore subject to additional monitoring for safety and efficacy[12]

Cost-effectiveness

- Europe has an urgent need to control healthcare costs, particularly with an increasingly ageing population

    - The population of the EU is projected to reach 517 million in 2060, with nearly one third of the citizens aged 65 or over[13]

- This change is expected to have substantial consequences for public finances in the EU. Based on current policies, age-related public expenditures such as healthcare and long-term care are projected to increase by 4.1% to around 29% of GDP between 2010 and 2060[13]

- The use of biologics is growing at a much higher growth rate than that of the overall pharmaceutical market[7]

- Reports on global spending on medicines show that biologics are expected to represent between 19% and 20% of the total market value by 2017[14]

- Whilst biologics offer an effective treatment option for patients with chronic conditions, their price can prohibit widespread use[7]

- Biosimilars are often less expensive than the reference product [3], which means that they can offer healthcare systems cost effective solutions to patient needs[15]

- One of the most significant new developments is biosimilar monoclonal antibodies, which are forecast to cost 10%–30% less than their reference product. These have the potential to save EU healthcare systems between €1.8 billion and €20.4 billion between 2007 and 2020[15]

Biosimilars v generics

- Generics are small molecule medicines which are identical in dosage form, safety, strength, route of administration, quality and performance characteristics to their respective reference products[16]

- Unlike generics, biosimilars are not copies of the reference biologic. To receive approval, a comprehensive comparability exercise, including both pre-clinical and clinical evaluations, must be undertaken to demonstrate that a biosimilar is equivalent to the reference product in terms of quality, safety and efficacy[5]

- Generic medicines follow a less stringent process and clinical trials are not required to test safety and efficacy. A company applying to the EMA must provide information on the quality of the generic medicine and typically also needs to provide bioequivalence data which show that it produces the same levels of the active substance in the body as the reference product[17]

- The manufacturing process for biosimilars is far more sophisticated and resource-intensive than for generics, requiring devoted production lines and specialist training[4]

- Generics tend to be substantially lower in cost than their branded reference products due to their exceptionally low research and development costs.[18] The biosimilar discount compared with the reference product may be less with a generic, but the total cost savings are expected to be significant due to the high costs of the biologics[19]

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