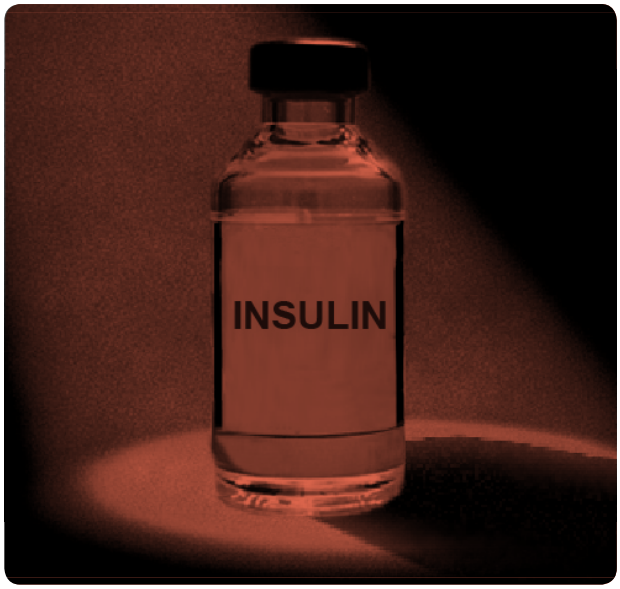
Biosimilar Insulin Regulatory Profile

The Biosimilar Insulin Regulatory Profile discusses the regulatory pathways and challenges faced by companies seeking marketing authorisation for insulin biosimilars, particularly in highly-regulated markets such as the European Union (EU) and the United States (US). It also includes a case study of two manufacturers who sought marketing authorisation from the European Medicines Agency (EMA) for insulin products. The profile, and related fact sheet, is one of several profiles published on the global insulin market by the Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) Study.



Biosimilar insulin

- Biosimilars are 'similar' versions of biological medicines, principally recombinant proteins such as insulin. In contrast, generics are considered identical versions of chemical medicines. Gaining marketing authorisation for biosimilars is important as it ultimately increases competition.
- Although the price reductions at market launch for biosimilars (between 20 – 30 percent) are modest compared to generics (up to 80 percent), the higher prices of biologicals, and the increasing contribution of biologicals to healthcare expenditure means that these savings can substantially impact treatment affordability and thus their accessibility.

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All profiles and fact sheets can be accessed on the ACCISS Study section of HAI's website: http://haiweb.org/what-we-do/acciss/

Please note, all references in this fact sheet come directly from the Biosimilar Insulin Regulatory Profile.

Barriers to Biosimilar Regulatory Approval

- To gain marketing authorisation, all medicines are evaluated for quality, safety and efficacy by national medicines regulatory authorities (or regional authorities such as the EMA). Not all countries have regulatory procedures for approving biosimilars. Of the countries that do, many have adopted the EMA's regulatory process.
- The authorisation requirements for biosimilars are more challenging than for generics. The main issue is satisfying the requirements of similarity to the reference insulin product, with respect to its chemical structure, post-translational modifications, presence of variants, impurity profile, physicochemical properties, stability, and other parameters.
- The stronger the evidence about structural, biological and formulation similarity between the biosimilar and the reference insulin product, the less non-clinical and clinical data will be needed for approval. This is discussed in detail in the profile, along with the comparative case study of Eli Lilly and Marvel Life Sciences' applications to the EMA.
- Substitutability and interchangeability are key issues for insulins. If biosimilar insulin is not legally defined as this, it will hinder use even if it has a lower price. The US Food & Drug Administration (FDA) do take a position on interchangeability, but it is left to individual states in the US to decide. The EMA leaves this to national authorities.
- As regulatory experience is still growing in many jurisdictions for biosimilar insulin applications, prior consultation with regulators is likely to aid the process. Following their advice, or providing robust explanations for any deviations or alternate strategies prior to making the change, will be important for success.

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