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Some Considerations about Biosimlar Safety

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Abstract

Biosimilar safety is important step to be approval. Biosimilar safety related with the adverse drug reactions as a result of their pharmacological actions and immuno-genicities. The purpose of this study is to describing of some consideration about biosimilar safety such as Naming ,Immunogenicity,Manufacturing,Pharmaco-vigilance, Interchangeability, Labeling, Preclinical studies, Clinical studies, and Post-Approval Studies. Naming of biosimilar is important step for safety, Immunogenicity study is important for safety assessment, Biosimilars, to be approved interchangeable, it must meet a higher standard ,Preclinical studies, Clinical studies, Post- Approval Studies , must be achieved. Recommendations: Reaching to Unified name, Standard definition for biosimilar and close guideline, and demonstrate other aspects about biosmilar safety.

Background

Biosimilar is a biological product which have highly similar to the reference product not withstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the biological product and the innovator product in terms of the safety, purity, and potency. Biosimlar safety indicate to adverse drug reactions to biopharmaceuticals are only the result of their pharmacological actions and immunogenicities. It is therefore essential to have a deep understanding of the intended mechanism of action of the product in order to guide pharmacovigilance activities.

Methods

Naming :

Naming of biosimilar is important to differentiate biosimilar from the reference product as a part of safety. The ability to track and identify the specific biologic product received by a patient is critical in the event of an adverse event.

Immunogenicity :

Biosimlars are proteins and having capacity for inducing of immune response that may be humoral or cellular, which become apparent in a many methods such as anaphylaxis, hypersensitivity and infusion reactions, cross-reactivity to endogenous proteins, altered pharmacokinetics of the molecule, or loss or lack of clinical efficacy**.**

Manufacturing:

Small alterations in the source materials or production process of any biologic product may lead to changes in molecular structure, and potentially its biologic effects, manufacturing processes are carefully controlled at each step

Pharmacovigilance:

pharmacovigilance planning include efforts beyond post marketing spontaneous reporting and designed for enhancing and expedite the biosimilar manufacturer's acquisition of safety information. It includes all activities relating to the detection, assessment, and understanding of adverse events, including pharmacoepidemiologic studies, postmarketing surveillance, case reports and events associated with other products in the same pharmacologic or biologic class.

Interchangeability:

Biosimilars, to be approved interchangeable, it must meet a higher standard. This higher standard requires that the biosimilar "can be expected to produce the same clinical result as the reference product in any given patient.

Labeling :

Labeling is critical to the safe and effective use of a medicinal product. When an adverse reaction to the drug is encountered, information in the label is used to decide whether a specific adverse event/safety issue is already identified as a risk or could be a new, potential safety issue.

Preclinical studies:

Preclinical studies help resolve uncertainties regarding biosimilarity that remain following extensive structural and functional investigations. These studies used animal models to preliminarily assess toxicity, including immunogenicity.

Clinical studies :

These studies including an assessment of immunogenicity and PK or pharmacodynamics (PD).it must be sufficient to demonstrate similar safety in one or more appropriate conditions for which the reference product is licensed and intended to be used, and for which licensure of the biosimilar is sought.

Post-Approval Studies:

The need for post-approval studies to establishing efficacy in indications not studied during the approval process and long-term safety studies to establish immunogenic potential and other safety issues which may be different from the reference product.

Conclusions

1- Naming of biosimilar is important step for safety.
2- Immunogenicity study is important for safety assessment.
3- Biosimilars, to be approved interchangeable, it must meet a higher standard
4- Preclinical studies, Clinical studies, Post-Approval Studies , must be achieved.

Recommendations:

Reaching to Unified name, Standard definition for biosimilar and close guideline, and demonstrate other aspects about biosimilar safety .

References

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