Understanding biological & biosimilar medicines

Frequently Asked Questions

Q. What is a biological medicine?

A. Biological medicines, including biosimilars, are derived or monufactured from a living biological system. They include hurmones (e.g. insulin), enzymes (to speed up obstical reactions), blood factors (to regulate clotting), antibodies (to support the immune system), voccines and advanced therapies (such as reff. gene and tissue therapy products).

Histogical medicines are among many of today's most important medicines. By acco. It is predicted that seven of the top ten medicines worldwide will be biologica."

Q. What is a biosimilar medicine?

A. A bioximiliar in a biological medicine that is developed to be similar to an approved biological medicine (the 'originator' biological medicine) and can only be marketed after the patent and data endiantery period has expired. As its name suggests, a bioximilar is not an exact suggest of its originator biological medicine due to its complex makerular structure and unique manufacturing process. Manufacturers of bioximilars are required to demonstrate that there are no-clinically meaningful differences between the bioximilar and originator biological medicine in terms of safety, quality and efficient, "

Q. What is a small molecule medicine?

A. Small molecule medicines are made by combining certain chemicals in a defined series of chemical reactions. Because these molecules are smaller and involve fewer process steps than biological medicines, they are easier to displicate. This kind of modicine is often taken scally, most often as a pill. Generic medicine: A medicine that contains an exact copy of the active pharmaceutical impredicat of the small molecule originator medicine.

Biological sordicioe: Biological medicines, including bioximitars, that bave been developed in living organisms.

Originator modicine: The original medicine on which a bioximilar or generic drug bases its application for marketing authorisation.

Q. How are biological medicines different?

A. There are several key differences between biological and small malerale medicines:

- Molecular structure biological medicines are much larger and more complex than small molecule medicines.
- Development and manufacture biological medicines have complex manufacturing processes that must be tightly controlled to provide a consistent product.
- Introducing due to their size and complexity, biological medicines have the potential to induce unwanted or unexpected immune reactions.
- Administration most biological medicines, including bioximilars, must be administered by injection or infection.
- Transport and storage biological medicines generally degrade quickly if subject to high temperatures.
 Therefore, biological medicines, including biosimulars, meanly need to be stored in a refrigerator.





Questions And Answers On Biosimilar Medicines Similar

L Cohen

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