Understanding biological & biosimilar medicines

Frequently Asked Questions

Q. What is a biological medicine?

A. Biological modicines, including biosimilars, are directed or monufactured from a living biological system. They include burntones (e.g. inculin), enzymes (to speed up chemical tractions), blood factors (to regulate clotting), antibodies (to support the immune system), voccines and advanced therapies (each accell, 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 bioximillar in a biological medicine that in developed to be similar to an approved biological medicine (the 'originator' biological medicine) and can only be marketed after the patent and data endianterity period has expired. As its more suggests, a bioximilar is not an exact regy of its originator biological medicine due to its complex molecular 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 scena of safety, quality and efficient, "

Q. What is a small molecule medicine?

A. Small molecule medicines are made by combining certain obsessions in a defined series of chemical reactions. Because these molecules are smaller and involve fewer process steps thus biological medicines, they are easier to displacate. This kind of medicine is often taken smally, 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.
- Immunigation due to their size and complexity, biological medicines have the potential to induce surrounted 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 modicines, including biosimilars, meanly need to be stored in a refrigerator.





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Minjie Lin

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