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Biological/Biosimilar Drugs: A New Hope for Better and Low Cost Treatment

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Editorial

Biological and biosimilar drugs

Medicines that are derived from living cells/organisms are known as biological medicines. They consist of of highly complex molecular entities difficult to characterize. Certain degree of variations might found among biological medicines due to variation of the biological system and manufacturing process. A medicine that is very similar and clinically equivalent to a biological medicine is known as biosimilar medicine. Reference or originator medicine is an already approved biological medicine from which a biosimilar active medicine is derived. The biological product is highly similar to the reference product not withstanding minor differences in clinically inactive components; and there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. Biosimilar medicines are not the same as generic medicines, which contain simpler chemical structures and are identical, in terms of molecular structure, to their reference drugs [1].

Biological products are generally produced using a living system or organism. They may be manufactured through biotechnology, derived from natural sources, or produced synthetically. In the Public Health Service Act (PHS Act) now protein included as biological product. Some proteins have been approved as drugs under section 505 of the Federal Food Drug and Cosmetic Act (FFDCA) and other proteins have been licensed as biologics under section 351 of the PHS Act. Under the BPCI Act, a protein, except any chemically synthesized polypeptide, will be regulated as a biological product. Analytical, animal and clinical studies are used to demonstrate the biological product similarity to the reference product. These studies reveal minor differences in clinically inactive components, toxicity, immunogenicity and pharmacokinetics/pharmacodynamics assessment [2].

Cost saving potential of biosimilar drugs

Biologics are complex, protein-based drugs including insulin, monoclonal antibodies to block inflammation. They have capability to treat rheumatoid arthritis, cancer, multiple sclerosis, and other serious diseases. While biologics have revolutionized treatment for many conditions, they are often expensive in terms of cost per dose. The FDA (U.S. Food and Drug Administration) trying to release regulations for approval of low cost biosimilar drugs. It has been expected that the introduction of biosimilars might reduce prices, albeit to a lesser degree than small-molecule generics [3]. This is not hypothetical; in fact the perspective combines recent data and prior research which estimated the cost savings in the U.S. market. In a research sponsored by Sandoz, a Novartis Company, and conducted within RAND Health, a division of the RAND Corporation predicted that biosimilars will lead to a $44.2 billion reduction in direct spending on biologic drugs from 2014 to 2024, or about 4 percent of total biologic spending over the same period, with a range of $13 billion to $66 billion [3].

Biological and biosimilar medicine access to patients

It has been observed that in low-income countries, doctors are happy with biosimilars, but the people in charge of the budget are not interested to continue using these medicines as they are too expensive [4]. Sometimes the list of approved medicines is devoid of biosimilars leading to its difficult access. So even getting right diagnosis the patient won't able to get the medicine. Some barriers have been addressed to access these medicines that meet standards of EMA, WHO and FDA include [4]. They might include: medicine high price, governments poor knowledge and understanding about these medicines, lack of knowledge in clinicians and patients about these medicines, poor/lack of regulation regarding these medicines, low/lack political will, administration complexity, poor diagnosis, screening and testing [4]. It is good to see that the regulation of these medicines has improved globally in a satisfactory level. Many countries have developed or are in the process of developing laws and guidelines [4]. Different countries may develop their own guidelines regarding approval of these medicines but should be in accordance with the international quality. For example Brazil has used the WHO guidelines as a basis for their own regulatory guidelines, but with some differences [4].

Conclusion

The article gives an idea about biosimilar and biological medicine. Article gives an overview of what biological and biosimilar medicines, how they are helpful for patients and what are the barriers in their usage. The organizations and other stakeholders should concern about safety of biological medicines, their regulation and observation, prescription, as information and support available to patients. Treatment of many diseases has been revolutionized with the use of biological medicines and millions of people get benefitted worldwide. It have been expected that greater number of biosimilar medicines will be available worldwide in coming decades. That will produce an alternate medicinal platform for patients at lower cost. This will also increase better options for medicos, patients and healthcare systems in general.

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