

Biological and biosimilar medicinal products: safety and efficacy

Biological medicinal products are one of most innovative and promising methods of pharmacotherapy. During the last 20 years several original biological medicinal products have been registered and marketed. Their safety and efficacy have been investigated thoroughly at the level of pre-clinical and clinical studies. These are large, complex protein structures obtained through methods used in genetic engineering, or they are isolated from biological sources. Basically there are two types of biological products: 1) Those naturally present in the body like: Insulin, human growth factor, Factor VIII, erythropoietin; 2) Substances influencing certain mechanisms being the cause of the disease: anti-TNF; anti-IL 17; Anti-CD-20. These biological medicinal products can be divided into Blood and blood components, Vaccines, Allergen extracts, Proteins, Human tissues, Cell and gene therapy, Monoclonal antibodies. The size of biological products may vary between 4 500 D (enoxaparin) and 150 000 (monoclonal antibody) and more, while aspirin size is only 150 D. While biological products are attractive, most patients cannot afford their high cost (roughly estimated 550 US\$ a day). However, biosimilar products are much cheaper while offering a good therapeutical alternative with the same safety and efficacy features as the former. Currently, 200 companies worldwide have about 700 of biosimilars under the development. Consequently biosimilar products are having more success in the market and thus are more accessible to patients.

ABSTRACT

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The safety and efficacy of biological and biosimilar medicinal products will be discussed in the example of Monoclonal Antibodies being used for the treatment of psoriasis and rheumatoid arthritis.