BIOTECHNOLOGICAL DRUGS IN 10 QUESTIONS

1 What is biotechnology?

What biotechnology is to find solutions to problems and produce beneficial products by using biological system and processes. In product and technological processes, using bio systems and organisms or their derivatives is the fundamental of biotechnology. Today, biotechnology has an ever-increasing significance in many industries from pharmaceutics to agriculture, stock breeding, textile and defense to energy.

BIOTECHNOLOGICAL DRUGS IN 10 QUESTIONS

2 What is biotechnological drug?

Biotechnological production in the pharmaceutical sector, which first began with the production of penicillin by Alexander Fleming in 1928, was first used in the early 1980s for the treatment of diabetes with human insulin produced by recombinant DNA technology. Hormones (erythropoietin, somatropin growth factors), insulin, immunomodulators, monoclonal antibodies (mAbs), blood coagulation factors and vaccinations can be counted as the drugs used in several treatment areas within the scope of biotechnological drugs. These products are classified into two groups as reference biotechnological drugs and biosimilars.

BIOTECHNOLOGICAL DRUGS IN 10 QUESTIONS

3 How are biotechnological drugs produced?

Conventional drugs are generally produced by a process called chemical synthesis the basis of biotechnological drug production is based on cell-basis production. The cells consist of master cell bank and working cell bank enable the production of a specific protein. Drug production includes processes such as seperation and purification for cell reproduction after fermentation.

BIOTECHNOLOGICAL DRUGS IN 10 QUESTIONS

4 In what ways are biotechnological drugs different from conventional drugs?

Biotechnological drugs have higher molecular weights and complex structures compared with conventional drugs since they are based on peptides and proteins. Conventional pharmaceuticals are chemical synthesis products while biotechnological pharmaceuticals are biological products obtained from live cells.

BIOTECHNOLOGICAL DRUGS IN 10 QUESTIONS

5 What is reference biotechnological drug?

It is the first product released by an innovator company.

6 What is biosimilar?

Since the two cell lines developed independently will not be the same, the expression of 'biosimilar' is used in biotechnological drugs instead of the expression of 'generic' which is used in conventional drugs. In comparison to reference biotechnological products, biotechnological drugs which are confirmed in terms of quality (production methods and inspections), effectiveness (desired affect) and reliabiity (risk/benefit assessment) but have their own development and production methods are referred as biosimilars.

Biosimilar and reference biotechnological drugs have the same biological substance as active pharmaceutical ingredient but they may show few differences due to their complex natures and production methods. During the approval process, it must be proven that these variance and other differences of biosimilar and reference biotechnological pharmaceuticals do not affect the efficiency and reliability of the product.

According to the Biosimilar Medicinal Products Guide, issued by the Turkish Medicines and Medical Devices Agency of The Turkish Ministry of Health (TMMDA), biosimilar drugs differ from reference biotechnological pharmaceuticals only in terms of their commercial name, appearance and packaging characteristics.

BIOTECHNOLOGICAL DRUGS IN 10 QUESTIONS

7 What is biobetter?

By the development of analytical benchmarking techniques and production technologies, innovation can be achieved with minor structural changes in the product's function, antigenic structure and pharmacokinetic and pharmacodynamic (PK/ PD) profiles that are developed and produced by following the reference biotechnological products. The products that gained more sufficient quality, efficiency and reliability characteristics with such changes compared with reference product are referred as 'biobetter' or 'biosuperior'.

BIOTECHNOLOGICAL DRUGS IN 10 QUESTIONS

8 Does the approval process of biosimilars differ from generics?

The legislation and legal process for the approval of biosimilars are different from generics. Especially Phase I and Phase III studies must be performed for the approval of the comparability and similarity requirements of biosimilar products. In our country, TMMDA implements this assessment. The drug development and inspection practices apply to reference biotechnological pharmaceuticals are applied in the same way to biosimilars.

BIOTECHNOLOGICAL DRUGS IN 10 QUESTIONS

9 Is there any difference between biosimilar and reference biotechnological product in terms of quality, efficiency and reliability?

No. A biosimilar is expected to have the same reliability and efficiency profile with a reference biotechnological product. Biosimilars are produced by following the standards followed by reference biotechnological pharmaceuticals. TMMDA assesses whether the new biosimilar drug has an effectiveness, quality and reliability profile comparable with reference drug through its scientific committee, before approving a biosimilar drug in Turkey.

Detailed information on all approved biosimilars in our country is available on the website of TMMDA.

www.titck.gov.tr

BIOTECHNOLOGICAL DRUGS IN 10 QUESTIONS

10 Are the side effects of biosimilars different from the side effects of reference biotechnological pharmaceuticals?

No. An approved biosimilar is expected to have the same reliability and efficiency profile of reference drug including the side effects.

Biotechnological pharmaceuticals have the potential of being detected as foreign proteins by the body and they may cause undesired immune responses. This is referred as immunogenicity. There is no evidence or scientific justification explaining that biosimilars cause more undesired immune response than reference drugs.