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Short Communication

A Short Note on Biopharmaceuticals

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A biopharmaceutical, also known as a biological medical product, or biologic, is any pharmaceutical drug product manufactured in, extracted from, or semi synthesized from biological sources. Different from totally synthesized pharmaceuticals, they include vaccines, whole blood, blood components, allergenics, somatic cells, gene therapies, tissues, recombinant therapeutic protein, and living medicines used in cell therapy.

Biologics can be composed of sugars, proteins, nucleic acids, or complex combinations of these substances, or may be living cells or tissues. They (or their precursors or components) are isolated from living sources-human, animal, plant, fungal, or microbial. They can be used in both human and animal medicine [1].

Terminology surrounding biopharmaceuticals varies between groups and entities, with different terms referring to different subsets of therapeutics within the general biopharmaceutical category. Some regulatory agencies use the terms biological medicinal products or therapeutic biological product to refer specifically to engineered macromolecular products like protein-and nucleic acid-based drugs, distinguishing them from products like blood, blood components, or vaccines, which are usually extracted directly from a biological source. Specialty drugs, a recent classification of pharmaceuticals, are high-cost drugs that are often biologics. The European Medicines Agency uses the term advanced therapy medicinal products (ATMPs) for medicines for human use that are often biologics. The european medicines agency uses the term advanced therapy medicinal products (ATMPs) for medicines for human use that are "based on genes, cells, or tissue engineering", including gene therapy medicines, somatic-cell therapy medicines, tissue-engineered medicines. They are proteins (including antibodies), nucleic acids.

It is used for therapeutic or in vivo diagnostic purposes, and produced by means other than direct extraction from a native (non-engineered) biological source. The first such substance approved for therapeutic use was recombinant human insulin. The large majority of biopharmaceutical products are pharmaceuticals that are derived from life forms [2]. A potentially controversial method of producing biopharmaceuticals involves transgenic organisms, particularly plants and animals that have been genetically modified to produce drugs. When a new biopharmaceutical is developed, the company will typically apply for a patent, which is a grant for exclusive manufacturing rights. This is the primary means by which the developer of the drug can recover the investment cost for development of the biopharmaceutical.

The patent laws in the United States and Europe differ somewhat on the requirements for a patent, with the European requirements perceived as more difficult to satisfy. The total number of patents granted for biopharmaceuticals has risen significantly since the 1970's. In 1978 the total patents granted was 30. This had climbed to 15,600 in 1995, and by 2001 there were 34,527 patent applications. In 2012 the US had the highest IP (Intellectual Property) generation within the biopharmaceutical industry, generating 37

percent of the total number of granted patents worldwide; however, there is still a large margin for growth and innovation within the industry. A revision to the current IP system to ensure greater reliability for R&D (Research and Development) investments is a prominent topic of debate in the US as well. Blood products and other human-derived biologics such as breast milk have highly regulated or very hard-to-access markets; therefore, customers generally face a supply shortage for these products. Institutions housing these biologics, designated as 'banks', often cannot distribute their product to customers effectively.

Conversely for reproductive cells are much more enhance Fertility treatment. Bio pharmaceutics examines the interrelationship of the physical/chemical properties of the drug, the dosage form (drug product) in which the drug is given, and the route of administration on the rate and extent of systemic drug absorption [3].

The importance of the drug substance and the drug formulation on absorption, and in vivo distribution of the drug to the site of action, is described as a sequence of events that precede elicitation of a drug's therapeutic effect. First, the drug in its dosage form is taken by the patient either by an oral, intravenous, subcutaneous, transdermal, etc, route of administration. Next, the drug is released from the dosage form in a predictable and characterizable manner. Then, some fraction of the drug is absorbed from the site of administration.

REFERENCES

1. Gleason PP, Alexander GC, Starner CI, et al. Health plan utilization and costs of specialty drugs within 4 chronic conditions. J Manag Care Spec Pharm 2013; 19(7): 542-8.
2. Rader RA. Redefining biopharmaceutical. Nat Biotechnol 2008; 26(7): 743-51.
3. Walsh G. Biopharmaceutical benchmarks 2018. Nat Biotechnol 2018; 36(12):1136-45.