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Editorial

EDITORIAL NOTE ON BIOPHARMACEUTICALS

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EDITORIAL

Drugs are substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Drugs are given in a variety of dosage forms or drug products such as solids (tablets, capsules), semisolids (ointments, creams), liquids, suspensions, emulsions, etc, for systemic or local therapeutic activity. Drug products can be considered to be drug delivery systems that release and deliver drug to the site of action such that they produce the desired therapeutic effect and are also designed specifically to meet the patient's needs including palatability, convenience, and safety. Drug product performance is defined as the release of the drug substance from the drug product either for local drug action or for drug absorption into the plasma for systemic therapeutic activity. Advances in pharmaceutical technology and manufacturing have focused on developing quality drug products that are safer, more effective, and more convenient for the patient biopharmaceutical, also known as a biologic(al) 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.

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 "based on genes, cells, or tissue engineering" including gene therapy medicines, somatic-cell therapy medicines, tissue-engineered medicines, and combinations Within EMA contexts, the term advanced therapies refers specifically to ATMPs, although that term is rather nonspecific outside those contexts. Gene-based and cellular biologics, for example, often are at the forefront of biomedicine and biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available. In some jurisdictions, biologics are regulated via different pathways from other small molecule drugs and medical devices. Biopharmaceutics is pharmaceutics that works with biopharmaceuticals. Bio pharmacology is the branch of pharmacology that studies biopharmaceuticals.

Biopharmaceutics 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. 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.

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