Definitions

Abbreviated New Drug Applications (ANDAs): An application submitted to the U.S. Food & Drug Administration by a generic drug manufacturer challenging a patent held by an innovator company. Once approved, an applicant may manufacture and market the generic drug product of an existing formulation to the American public.

Active pharmaceutical ingredient (APIs): The primary, active ingredient(s) of a final pharmaceutical product, produced in the first stage of pharmaceutical production and usually in bulk quantities.

Biologicals: Medical preparation made from living organisms and their products, such as insulin, erythropoietin, and vaccines.

Blockbusters: industry term referring to drugs with very large sales, generally in excess of $1 billion.

Branded generics: Generic drugs for which a drug manufacturing company has attached its brand name and may have invested in its marketing to differentiate it from other generic brands.

Brand name drugs: innovator drugs patented by MNC pharmaceutical companies to prevent them from being copied or reverse engineered by other companies.

Bulk drugs: The active chemical substances in powder form, the main ingredient in pharmaceuticals – chemicals having therapeutic value, used for the production of pharmaceutical formulations. Major bulk drugs include antibiotics, sulpha drugs, vitamins, steroids, and analgesics.

Drugs: There are two types of drugs: bulk drugs (intermediates) and formulations.

Drug intermediates: These drugs are used as raw materials for the production of bulk drugs, which are either sold directly or retained by companies for the production of formulations.

Drug Master files (DMFs): Generic registration applications filed with the U.S. FDA in order to allow the active pharmaceutical ingredients (APIs) to appear in marketed drugs.

Essential drugs: Drugs classified as essential by the Indian government consist of antibiotics, antibacterials, anti-TB, penicillin and its salts, anti-parasitic, cardiovascular drugs, erythromycin and its preparations, vitamins and pro-vitamins, vaccines (polio, human and veterinary), preparations containing insulin, caustic and other hormones, and tetracycline and its preparations. Indian companies dominate this class of drugs with a domestic Indian market share of 71 percent. These drugs are subject to government price controls.

Formulations: Drugs ready for consumption by patients (generic drugs) sold as a brand or generic product as tablets, capsules, injectables, or syrups. Formulations can be subdivided into two categories: generic drugs and branded drugs.

Generic drugs: Copies of off-patent brand-name drugs that come in the same dosage, safety, strength, and quality and for the same intended use. These drugs are then sold under their chemical names as both over the counter and prescription forms. Also, referred to as unbranded formulations.

Innovator drugs: Are drugs with patents on their chemical formulation or on their production process. They have been tested and approved by the U.S. FDA after extensive clinical trials.

New Drug Applications (NDAs): the vehicle through which drug innovators formally propose that the U.S. FDA approve a new drug for sale and marketing in the United States.

Pharmaceuticals: Are used to prevent, diagnose, treat, or cure diseases in humans and animals.

Plain vanilla generics: commodity generics that are “off-patent” in the regulated markets. They offer little or no innovative value over the innovator’s product.

Prescription drugs: Medicines that encompass two classes, innovator drugs and generic drugs.

Proprietary drugs: Drugs that have a trade or brand name and are protected by a patent.
West/ Western: The United States, Canada, and Western Europe.