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Process of Drug Discovery in Pharmaceutical Industry

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Opinion Article

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DESCRIPTION

The pharmaceutical industry intended to cure, immunize or treat patient's symptoms and also discovers, develops, manufactures and promotes medicines or pharmaceutical drugs for used as medications given to patients (or self-administered). Pharma companies may sell both brand-name and generic drugs as well as medical equipment. They must abide by a number of laws and rules that control the marketing, testing, safety, efficacy, and patenting of medicines. In 2020, the global pharmaceuticals market will have generated therapies worth $1,228.45 billion with a 1.8% CAGR.

Research and development

The process of identifying or creating potential medications is known as drug discovery. In the past, the majority of medications were either accidentally discovered or the active ingredient was isolated from conventional treatments. Understanding the metabolic pathways connected to a disease state or pathogen, and then modifying these pathways using molecular biology or biochemistry is a common focus of contemporary biotechnology. Universities and research organizations have always been heavily involved in early-stage drug discovery.

Drug development is the process of testing a compound's suitability as a treatment after it has been recognized as a possible drug. The goals of medication development are to establish safety while figuring out the best formulation and dosage.

In most countries, only a small portion of chemicals researched for use in humans are ultimately approved by government-appointed medical institutions or boards, which must approve new pharmaceuticals before they can be commercialized there. Drug discovery and development are very expensive processes. The FDA approved 18 NMEs (New Molecular Entities) and three biologics in 2010, for a total of 21, down from 26 in 2009 and 24 in 2008.

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However, in contrast to 2006, when there were 22 approvals overall, 2007 saw just 18 approvals. The Center for Drug Evaluation and Research has approved 22.9 drugs year on average since 2001.

Product approval

The Food and Drug Administration (FDA) in the United States must certify that new pharmaceutical goods are both effective and safe before they are allowed on the market. Typically, this procedure involves submitting an investigational new drug file with adequate pre-clinical evidence to support moving forward with human trials. Three phases of progressively larger human clinical trials may be done after IND approval. Typically, healthy volunteers are used in phase I toxicity research. Phase II can include patient dosage and pharmacokinetics, while Phase III is a sizable efficacy investigation in the target patient group. The FDA receives a New Drug Application once phase III testing has been completed successfully. When the product is deemed to have a favorable benefit-risk assessment, the FDA evaluates the data.

Global issues

Despite a slight slowdown in growth in Europe and North America, prescription medication spending worldwide surpassed $954 billion in 2011. With $340 billion in annual sales, the United States leads the world pharmaceutical business by more than a third, followed by the European Union and Japan. China, Russia, South Korea, Mexico, and other emerging markets outgrew that market, rising by a staggering 81%. Sales for the top ten pharmaceuticals in 2013 came to $75.6 billion, with the anti-inflammatory drug Humira topping the list with $10.7 billion in sales. Enbrel and Remicade respectively were the second- and third-best sellers.

Marketing

Advertising appears frequently in medical journals as well as in more traditional media. They are authorized to advertise directly to the general public in various nations, most notably the US. Pharmaceutical corporations typically employ salesmen (commonly referred to as "drug representatives" or, in an earlier idiom, "detail men") to personally and directly advertise to doctors and other healthcare professionals. Pharmaceutical firms also hire lobbyists in several nations, most notably the US, to sway legislators. The federal Prescription Drug Marketing Act of 1987 governs the marketing of prescription medications in the US. The pharmaceutical marketing strategy includes the budgets, strategies, and ideas that will move the drug association and its products and services forward in the market.

An organization may submit an application to receive and be granted a patent for a drug, which would give it licensing rights for generally 20 years. The government will only let the corporation to produce and sell the drug after extensive research and testing, which typically takes 10 to 15 years. High profit margins for the branded drug allow the patent holder to recover the expenditures of research and development thanks to patent protection. A generic version of the drug is typically created and marketed by a rival business after the patent protection for it expires. Generic drugs can be produced and approved with less value, which enables them to be sold with less profit.