BIOPHARMACEUTICAL SPOTLIGHT
The Biopharmaceutical Industry in the United States

OVERVIEW

The United States is the largest market for biopharmaceuticals, accounting for around a third of the global market, and is the world leader in biopharmaceutical R&D. According to the Pharmaceutical Research and Manufacturers Association (PhRMA), U.S. firms conduct over half the world's R&D in pharmaceuticals ($75 billion) and hold the intellectual property rights on most new medicines. The overall economic impact of the biopharmaceutical industry on the U.S. economy is substantial. The industry accounted for more than $1.3 trillion in economic output, representing 4 percent of total U.S. output in 2015. This total economic impact includes $558 billion in revenue from biopharmaceutical businesses and $659 billion from suppliers and worker spending.

More than 800,000 people work in the biopharmaceutical industry in the United States across a broad range of occupations, including scientific research, technical support, and manufacturing. Directly and indirectly, the industry supports more than 4.7 million jobs across the United States. The industry requires a highly-skilled and educated workforce from the administrative level up to and including Ph.D. scientists. A third of the jobs in the sector are in key STEM occupations.

The United States has one of the world's most supportive domestic environments for the development and commercialization of pharmaceuticals with minimal market barriers. Its strengths include an intellectual property system that rewards innovation through patent and data protection, a science-based regulatory system that is considered the most rigorous in the world, the largest scientific research base fostered by academic institutions and decades of government research funding, and robust capital markets. The United States attracts the majority of global venture capital investments in start-up biopharmaceutical enterprises.

INDUSTRY SUBSECTORS

Innovative (originator) chemically-derived drugs are developed from extensive R&D and clinical trials in both human beings and animals. The innovator relies on patents, regulatory data protection and other forms of intellectual property rights (IPR) to justify the investment required to bring a product to market. The U.S. patent term is 20 years, and drugs are eligible for at least five years of market exclusivity depending on the time between patent validity and U.S. Food and Drug Administration (FDA) approval.

Generic drugs are copies of innovative pharmaceuticals that contain the same active ingredient and are identical in strength, dosage form, and route of administration. In the United States, upon patent expiration or a successful challenge of relevant patents, a manufacturer can produce and sell a generic

drug as long as it meets FDA approval and bioequivalence standards. Generic companies typically focus on high volumes to earn profits, requiring efficient production methods and distribution chains. U.S. generic drug sales reached an estimated $72 billion in 2016, representing a quarter of the global market, due to many drugs going off-patent and healthcare reforms favoring generics.

Biologics (biotech drugs) include a wide range of products such as vaccines, therapeutic proteins, blood and blood components, tissues, etc. In contrast to chemically synthesized drugs, which have a well-defined structure and can be thoroughly verified, biologics are derived from living material (human, animal, microorganism or plant) and are vastly larger and more complex in structure. Biologic medicines are revolutionizing the treatment of cancer and autoimmune disorders and are critical to the future of the industry. Biologics now account for over a third of all new drugs in clinical trials or awaiting FDA approval.

Biosimilars (follow-on biologics) are versions of biologic products that reference the originator product in applications submitted for marketing approval to a regulatory body. Gaining regulatory approval in developed markets is far more complex for biosimilars than for chemical generics and may involve costly clinical trials. Those that succeed will also have to compete with the originator companies who are unlikely to exit the market. Biosimilars are usually priced 20 percent to 30 percent lower than the biologic reference product.

Over-the-counter (OTC) drugs are distinguished from innovative and generic drugs in that consumers do not need prescriptions to purchase them. OTC drugs are considered by regulators to be safe for self-diagnosis and self-medication. In the United States, there are an estimated 100,000 OTC drug products marketed and sold in a variety of outlets, such as pharmacies and convenience stores. The OTC market in the United States is expected to continue growing due to an aging population, consumer trends towards self-medication, and the conversion of drugs from prescription to OTC status.

Emerging sectors include precision medicine and regenerative medicine. In 2016, the U.S. Food and Drug Administration (FDA) approved 27 new medicines, including 22 new medicines approved by the FDA Center for Drug Evaluation (CDER). Among CDER's approvals, 36 percent were first in class medicines, representing entirely new ways of treating disease. Precision medicine includes treatment approaches that take into account individual variability in genes, environment, and lifestyle. More than 25 percent of the medicines approved by the FDA in 2016 and over 40 percent of new medicines in the current R&D pipeline have the potential to be precision medicines. Regenerative medicine includes rapidly evolving technologies such as cell and gene therapies and tissue-engineered biomaterials that repair or replace cells, tissues or organs. These technologies, which can cure diseases rather than simply slow its progression or manage symptoms, represent the next major innovation in healthcare. FDA has more than 500 active investigational new drug applications involving gene therapy products, and FDA has received more than one hundred such applications last year alone. This shows the intensity of scientific work going on in the regenerative medicine field.