

# Transforming Alkermes into a Global Biopharmaceutical Company

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## Outline

- Overview
- Regulatory Entities
- Growth of the Pharmaceutical Industry
- Biggest Global Pharmaceutical Markets
- Top 10 Pharmaceutical Companies
- US Pharmaceutical Industry: Economic Impact
- Research and Development
- Domestic Market
- Trade: Import
- Trade: Export
- Challenges and Barriers

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## Overview

- The pharmaceutical industry discovers, develops, produces, and markets drugs or pharmaceutical drugs for use as medications.
- Pharmaceutical companies may deal in generic or brand medications and medical devices. They are subject to a variety of laws and regulations that govern the patenting, testing, safety, efficacy and marketing of drugs.

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## Overview

- Largest annual growth rates of all industries
- Strong global demographic and economic trends, accelerating pharmaceutical consumption
- Increasingly small populations
- Rise in chronic diseases
- Increased labor costs and higher disposable incomes
- Strong government expenditure on healthcare
- Growing demand for more effective treatments

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## Regulatory entities

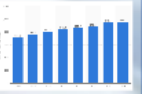
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Pharmaceuticals are subject to strict regulatory oversight. The regulatory process involves several steps, including pre-clinical testing, clinical trials, and approval by regulatory agencies. The regulatory process is designed to ensure the safety, efficacy, and quality of pharmaceuticals.

## Growth of the Pharmaceutical Industry

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## Biggest Global Pharmaceutical Markets

Rank	Country	Value of Pharmaceutical Market (in billions of \$)
1	USA	400,000
2	Japan	340,000
3	France	320,000
4	Germany	280,000
5	UK	270,000
6	Italy	260,000
7	Spain	250,000
8	China	240,000
9	India	230,000
10	South Korea	220,000

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## Top 10 Pharmaceutical Companies



## Research and development (R&D)

- The pharmaceutical sector has consistently been one of the most R&D intensive industries in the United States.
- R&D performed in the United States has become increasingly expensive relative to emerging economies in Asia.

## Domestic Market

- The United States is one of the world's most important domestic markets for the development and commercialization of pharmaceuticals with several market barriers.
- The United States is the world's largest drug-consuming market for pharmaceuticals.

- High incomes per capita
- Unmatched access to healthcare
- Large elderly population
- Culture of end-of-life prolongation
- High rates of chronic diseases and drug consumption

## US Pharmaceutical Industry Economic Impact

- The industry supports over 3.4 million jobs across the United States and added an estimated \$790 billion to the economy in 2016.
- Total pharmaceutical sales: \$390 billion (1.9% of GDP, 10.7% of total healthcare exp.)
- Per-capita pharmaceutical sales: \$1096

## US's top five sources of imports of pharmaceuticals



## Trade Import

- US imports were valued at over \$66 billion in 2019, making it the world's largest importer of pharmaceuticals.

## US's top five export destinations for pharmaceuticals



## Trade Export

- US exports in 2019 were valued at over \$66 billion, making it the world's largest exporter of pharmaceuticals.

## Challenges and Barriers

- Regulatory approval
- Pricing
- Tariffs
- Patentability
- Counterfeit

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U.S.'s top five sources of



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# Overview

- Expected annual growth rate of 4.9 percent.
- Several global demographic and economic trends are driving pharmaceutical consumption:
  - Rapidly aging world population
  - Rise in chronic diseases
  - Increased urbanization and higher disposable incomes
  - Greater government expenditure on healthcare
  - Growing demand for more effective treatments

# *Regulatory entities*

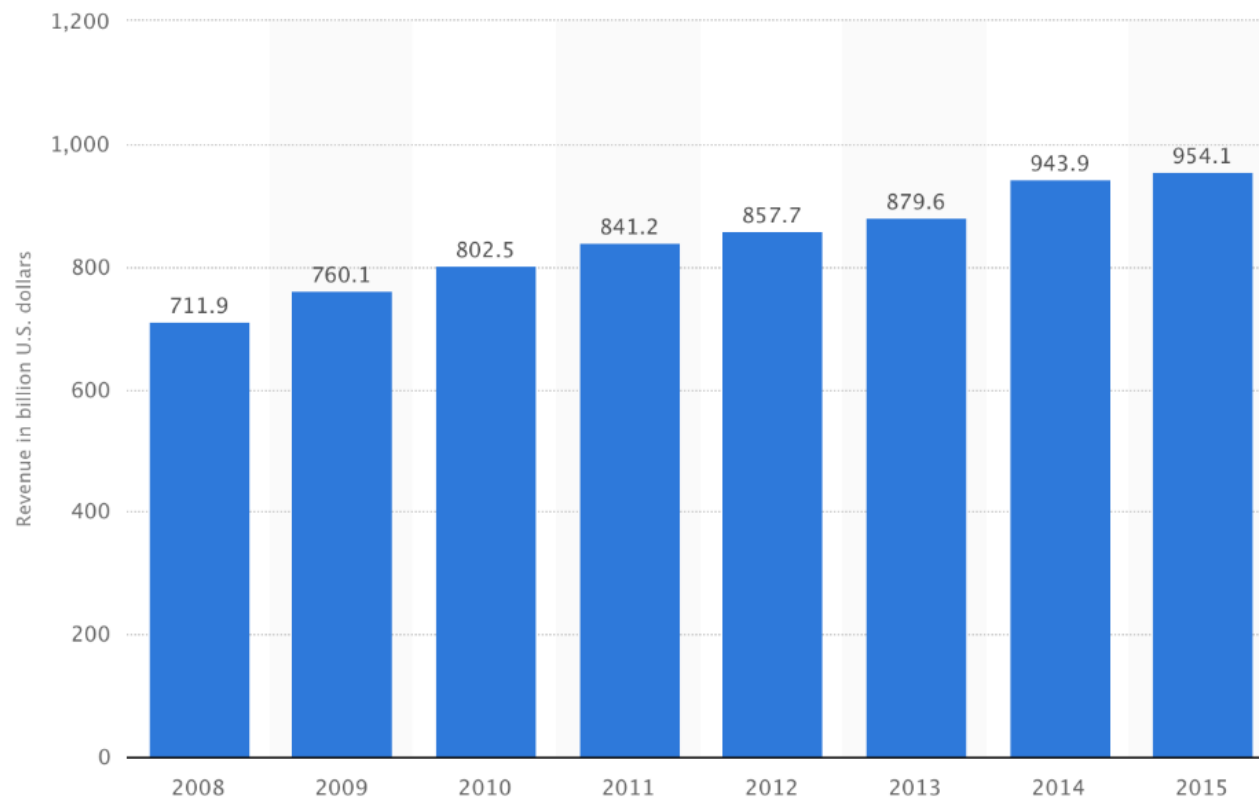
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WHO is charged with the tasks of developing and maintaining global norms, international standards and guidelines for the quality, safety and efficacy of drugs, and providing guidance in harmonization efforts.

# ***Growth of the Pharmaceutical industry***

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# ***Biggest Global Pharmaceutical Markets***

Rank	Country	Value of Pharmaceutical Market (in millions of \$)
1	USA	339,694
2	Japan	94,025
3	China	86,774
4	Germany	45,828
5	France	37,156
6	Brazil	30,670
7	Italy	27,930
8	UK	24,513
9	Canada	21,353
10	Spain	20,741