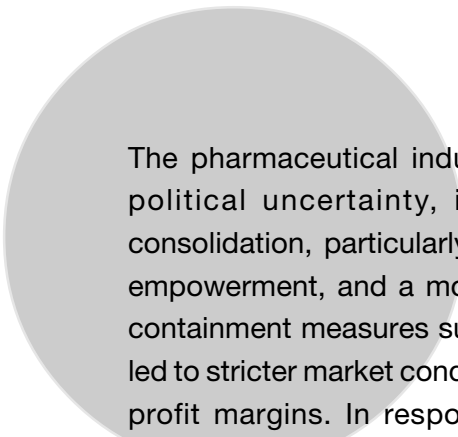


Global Pharmaceutical Industry: An Overview

It is easy to complain that pharmaceutical companies place profits over people and apparently care more about hair loss than TB. However, many in the pharmaceutical industry would be glad for the opportunity to reorient their research towards medicines that are truly needed, provided only that such research is financially sustainable.

— *Thomas Pogge, German Philosopher*



The pharmaceutical industry across the world continues to face political uncertainty, increased pricing pressures, channel consolidation, particularly in developed markets, increased patient empowerment, and a more stringent regulatory environment. Cost containment measures such as price and reimbursement cuts have led to stricter market conditions for drug manufacturers and shrinking profit margins. In response to these pressures, pharmaceutical companies are reassessing their strategies and marketing focus. The industry had to focus on structural changes to meet these challenges. Here are some of the significant ways the industry is dealing with:

- A. Increased focus on productivity using leaner and more integrated models
- B. Targeting new markets
- C. Inorganic capability building
- D. Higher adoption and leveraging of new technologies
- E. Increased emphasis on differentiation
- F. Focusing on unmet needs and
- G. Foraying into new and advanced fields of science

The Global Pharma Markets: The Next Five Years

The global pharmaceutical industry crossed the coveted USD one trillion-mark with annual sales of over \$1.2 trillion in 2018. It is likely to grow at a compound annual growth (CAGR) rate of 3 to 6 percent in the next five years to reach over the US \$1.5 trillion in the next five years, according to IQVIA's projections.

The IQVIA Institute of Human Data Science's report, *The Global Use of Medicine in 2019 and Outlook for 2023*, presents the growth projections for the global pharmaceutical industry by region and countries (Table 1.1).

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Table 1.1 Global Pharmaceutical Market 2019 to 2024
(Figures in US \$ Billion)

Region / Country	2019 (Actual)	2024 (Projections)	2020-24 CAGR (%)
Global	1250.4	1570 - 1600	3 - 6
Developed	821.5	985 - 1015	2 - 5
USA	510.3	605 - 635	3 - 6
Japan	87	88 - 98	0 - 3
EU 5 (Top 5 European Countries)	173.7		
1. Germany	52.1	65 - 69	3 - 6
2. France	34.9	37 - 41	(-1 to -2)
3. Italy	33.5	40 - 44	2 - 5
4. U K	28.7	33 - 37	1 - 4
5. Spain	24.5	27 - 31	1 - 4
Canada	22.5	89 - 93	(-3) - 0
South Korea	16	19 - 23	4 - 7
Australia	13	13 - 17	0 - 3
Pharmerging Markets			
China	141.6	165 - 195	5 - 8
Tier 2	71.2	90 - 120	7 - 10
Brazil	33.6	45 - 49	6 - 9
India	22	31 - 35	8 - 11
Russian Federation	15.6	23 - 27	8 - 11
Tier 3	145.1	195 - 225	5 - 8
Rest of World	71	85 - 95	2 - 5

(Source: Global Medicine Spending and Usage Trends Outlook to 2024, IQVIA Institute for Human Data Science)

Here are some major conclusions of global pharmaceutical markets in the next five years from a recent IQVIA Institute of Human Data Science report of January 2019:

- A. In the United States, while new products and brand pricing are likely to drive the market growth in the next five years,

patent expiries and generic launches will offset it to a certain extent. Additionally, there has been a spurt in cases where price increases by manufacturers on established products have come under greater scrutiny by the public and policymakers in recent times.

- B. Also, in the US, payors, insurers, and hospitals are no longer willing to pay simply for a product. They are looking for Value-Based Pricing (VBP), which depends on the success of the products. Although VBP comes with its share of risks and challenges, there is a vast potential to create a win-win situation for multiple healthcare stakeholders, if structured and implemented correctly.
- C. The top five markets in Europe (Germany, France, Italy, the United Kingdom, and Spain) will grow from the current (2019) size of \$173.7 billion to between \$211 and 237 billion in 2024. Government-led cost controls and decelerated growth on new products will reduce the pace from the earlier 4 to 7 percent to 1 to 4 percent during the 2019 - 2024 period.
- D. In Japan, the market will grow moderately from the current (2019) \$87 billion to \$88 to 98 billion by 2024. Increasing generic penetration is the primary reason for slow growth.
- E. The Pharmerging Markets (Pharma's Emerging Markets) include Brazil, China, India, the Russian Federation, and others in the Asia Pacific region, excluding Japan, South Korea, Australia, and New Zealand. These markets will grow at a faster pace of 5 to 8 percent from the current \$357.7 billion (2019) to between \$475 to \$505 billion by 2024.
- F. China is a vast market among emerging markets. It accounts for close to 40 percent of the total size of Pharmerging markets. The \$141.6 billion (2019) sizable Chinese pharmaceutical market will grow between 5 to 8 percent to \$165 to \$195 billion by 2024.
- G. Brazil, a prominent player in the Latin American region, will grow at a faster clip of 6 to 9 percent from the current \$33.6 billion to \$45 to \$49 billion by 2024.
- H. Although India is a significant player in the global pharmaceutical market and known as the pharmacy to the

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world, its domestic market is only a fraction of China's size. However, India shows a higher CAGR (Compound Average Growth Rate) of 8 to 11 percent in the next five years. Indian pharmaceutical market will expand from the current \$22 billion (2019) to anywhere between \$31 to \$35 billion by 2024.

1. The pharmaceutical market in The Russian Federation will expand at a CAGR of 8 to 11 percent during the next five-year period. It will grow from the current \$15.6 billion (2019) to between \$23 to \$27 billion by 2024.

Outlook for Top Drug Segments

The following table presents the growth trends for the top 15 therapeutic segments over the next five years.

Table 1.2 Top 15 Therapeutic Segments by 2024
(Figures in USD Billions)

Therapeutic Segment	2017 (Sales)	2024 (Projections)	CAGR (%)
1. Oncology	107	233	12.2
2. Anti-diabetics	46.1	59.5	3.3
3. Anti-rheumatics	55.7	56.7	0.2
4. Vaccines	27.7	44.6	7.1
5. Antivirals	42.4	39.9	(-) 0.9
6. Immunosuppressants	13.7	38.1	15.7
7. Bronchodilators	27.2	32.3	2.5
8. Dermatologicals	12.9	30.3	13
9. Sensory organs	21.6	26.9	3.2
10. Anti-hypertensives	23	24.4	0.8
11. Anti-coagulents	16.8	22.9	4.6
12. Multiple Sclerosis	22.7	21.5	(-) 0.8
13. Anti-fibrinolytics	12.7	20.4	7.1
14. Anti-hyperlipidaemics	11.3	16.4	5.5
15. Anti-anaemics	7.6	15.7	11
Total	448.4	682.6	

(Source: Visualizing the Future of Pharma Market by Jess Desjardins in visualcapitalist.com published on January 30, 2019)

Oncology, which was the most significant therapeutic segment by global sales of \$107 billion in 2017, will continue to be the leading therapy area with worldwide sales of \$233 billion by 2024.

While cancer-treating drugs will be the ones with the most sales, the fastest-growing therapy area is immunosuppressants—a segment of medicines that make a body less likely to reject a transplanted organ such as liver, heart or kidney. Immunosuppressants, growing at 15.7 percent over the next five years, will reach the sixth position among the top therapeutic segments by 2024.

While global pharmaceutical sales will be averaging 6.1 percent in annual growth, two of the top 15 segments that will see a negative yearly growth are antivirals (-0.9 percent) and multiple sclerosis therapies (-0.8 percent).

Growth Drivers

The factors that drive this growth are different for developed and pharmerging markets (Pharma's emerging markets). New product launches, especially specialty products, will be the growth catalysts in developed markets, whereas multiple factors drive growth in pharmerging markets. Consider these for example:

- A. improving percapita income
- B. increasing healthcare awareness
- C. aging population, and
- D. rising incidence of chronic ailments

There are five significant growth enablers of the overall global pharmaceutical market. These are:

- A. *Growing and Aging Population*: Global population is likely to exceed 9.3 billion by 2050, of which about 21 percent will be over 60 years and above.
- B. *Longer Life Expectancy*: As individuals become increasingly health-conscious and medical science continues to advance, life expectancy will increase. The life expectancy in countries

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like Japan, Singapore, Spain, and Switzerland will be 85 years by 2040. In about 59 countries, including China, life expectancy will be about 80 years during the same period.

- C. *Improving Purchasing Power*: Growing middle-class population and increasing per capita income will drive the demand for pharmaceutical products in Asia in general, and in China and India in particular.
- D. *Higher Prevalence of Chronic Diseases*: The growing population and increase in life expectancy accelerate the demand for healthcare products and services for treating chronic ailments. The higher prevalence of the need for chronic diseases will be more significant in developing nations.
- E. *Research Focus on Orphan Drugs*: The incentivization for orphan drug research has resulted in a growing focus on rare disease therapies leading to more orphan drugs. The United States Food and Drug Administration (US FDA), for example, has approved 80 orphan drugs in 2017-18.

The Next Ten Years: Nine Trends to Watch

Sarah Rickwood, a thought leader at IQVIA, presented a picture of how the pharmaceutical industry will look like in the future in her insightful article, *Nine Trends for the Next Ten Years*, published on January 4, 2020, in Pharmaphorum.

1. Longer drug development cycles shorten patent-protection years. Prescription drugs used to take about ten years from bench to bedside. It now takes about 13.8 years on average for new active substances launched in 2018.
2. Innovation in the pharmaceutical industry is becoming increasingly diverse. Until 2010, the industry-focused prescription drug research was almost entirely on small molecules or biologicals. The decade after that saw the emergence of newer and different pharmaco-therapies. In 2010, the US FDA approved Blue Star, the first prescription digital therapeutic for type II diabetes. In 2011, the industry moved to cell-based therapies with the approval of Provenge

(Dendreon Corporation) for treating prostate cancer. A gene-based treatment, Glybera (developed by UniQure and licensed to the South Korean biopharmaceutical firm, Chelsi), got approval for marketing in Europe. Although these early launches failed and Glybera withdrew from the market, the year 2019 proved to be the tipping point for non-conventional pharmaco-therapies. The US FDA approved four fundamental cell and gene therapies:

- A. Yescarta for treating non-Hodgkin Lymphoma by Kite, a Gilead Company
 - B. Kymriah for treating large B-cell Lymphoma by Novartis
 - C. Spinraza for treating SMA (Spinal Muscular Atrophy) by developed by Ionis Pharmaceuticals and marketed by Biogen
 - D. Zolgensma for treating SMA (Spinal Muscular Atrophy) in pediatric patients of less than two years of age, by AveXis, a Novartis company
3. The 2010s started with Biosimilars well established in Europe. In the US, however, biosimilars did not enter the market until 2015. The US FDA approved Sandoz's Zarxio (filgrastim) as the first biosimilar to Amgen Inc's Neupogen. In 2019, the US FDA approved Coherus BioSciences' Udenyca, a biosimilar to Amgen's Neulasta (Peg-filgrastim). Udenyca, launched in January 2019, has generated \$271 million in sales during the first nine months and is a commercial success. The growing product pipelines in the developed markets and pharmerging markets show that biosimilars will thrive in the 2020s.
4. China moved to the second position in the global pharmaceutical league table by value in 2019 after the United States. What is even more significant is China's progress on the pharmaceutical innovation front. The three factors indicating that 2019 might be a tipping point for drug research by Chinese firms are:
- China's drug regulatory authority approved Oligomannate by Shanghai-based Green Valley Pharmaceuticals. It is the first drug approval for Alzheimer's Disease anywhere in the past

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seventeen years. While there was skepticism surrounding the drug's data in the US, Alzheimer's patients welcome the drug.

- In November 2019, the US FDA approved Brukinsa (Zanubrutinib), a drug developed by BeiGene, a Chinese biopharmaceutical company for treating lymphoma.
 - Approvals are one thing; paying for the products is another. The primary reason to believe that China has reached an inflection point on innovation uptake is the updated drug reimbursement list, which included 218 new medicines in just four months, from August to November 2019.
5. Digital technologies will be the most transformative force for healthcare in the 2020s. Many leading healthcare systems have overt digital health strategies and policies and are creating technical infrastructure to deliver health services. What William Gibson, the famous writer and essayist said, *the future is already here—it is just not very evenly distributed* is undoubtedly true of digital health systems. The advanced healthcare systems of the US, Europe, and Japan vary significantly in their digital infrastructure progress. Further, the most significant health economies are not always the most advanced. Consider, for example, one very comprehensive analysis of digital health systems covering European countries and Canada places Estonia and Canada as the most and Germany and Poland as the least advanced on a survey of 34 criteria. Also, emerging economies may outpace developed ones by leapfrogging them because of the absence of legacy systems to impede digital infrastructure development.
 6. The 2020s will see more consistent maturity in the pharmaceutical industry in their digital engagement with their customers, especially healthcare professionals. Because in the 2020s, the first digital natives turn forty, making up the majority of the senior and experienced healthcare population. As a result, digital natives will inexorably grow their share of the most influential healthcare professional age groups during the 2020s, exiting the decade as the most dominant group. Digital engagement with customers is the way forward. Consider, for

example, from the fact that the most commercially successful launches are also the ones with the highest 'Year One' digital promotional activity.

7. Pharmaceutical companies will increasingly use Artificial Intelligence (AI) and Machine Learning (ML) in the 2020s to navigate the complex web of stakeholders relevant to today's highly specialist-oriented promotion and launches. AI and ML will also be extremely useful in recommending the best actions to the customer-facing teams engaging with healthcare professionals belonging to multiple specialties. Additionally, R&D-based biopharmaceutical companies will use AI and ML to optimize their use of best data available to generate insight on patients and their journey to effectively and rapidly identify the candidates for trial.
8. Patient insight data is crucial for understanding the genetic basis of diseases and the ability to treat genetically driven conditions with a range of gene-based therapies. Genomics will be one of the sources of increasingly sophisticated Real-World Evidence (RWE). RWE, which has been developing steadily since the 2010s, will see new relevance and power during the 2020s. The passage of legislation in 2016 by the US Congress requiring the Food and Drug Administration (FDA) to establish a program to evaluate the potential use of the Real World Evidence to support the new indications for approved drugs. The Real World Evidence Program by the FDA will determine the possible use of real-world evidence to recommend changes to the labeling of drug product effectiveness, adding or modifying an indication, change in dose, and administration route, among others. Perhaps the most promising future application of real-world data is integrating randomized clinical trials into conventional health systems to support their effectiveness-determination. Such integrated trials could collect data from Electronic Health Records (EHRs), laboratory or clinical data, or emerging technology (Actigraphy and Mobile Applications) to assess study outcomes, or streamline the trial's conduct by facilitating recruitment and enrollment.

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9. The biopharmaceutical company landscape is changing slowly, but surely. The global top-twenty pharma companies saw significant rearrangement in 2019, with three big acquisitions. If they all go through as planned, offer a new number one by pharma sales (AbbVie/Allergan); a much leaner Pfizer divested its mature Upjohn products, sold to Mylan, and a new giant in oncology (Bristol-Myers Squibb/Celgene). Furthermore, many small specialty biotech companies are developing and launching their assets since the 2010s triggering their move to next level. While the 2010s marked the rise of Specialty Pharma, the 2020s will be known for their diversity. Because the new product launches will increasingly be diverse—small molecule, biologic, cell-therapy, gene therapy, digital therapeutic, and firms from different geographical regions.

