DRUG FORMULATION AND CDMO MARKET

Marketysers Global Consulting

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The market research process for this study has been undertaken through secondary/desktop research and primary research, which involves discussing market status with leading participants and experts. The research methodology used is the Expert Opinion Method. Quantitative market information was sourced from interviews, primary research, and trusted portals. Therefore, the information is subject to fluctuations due to possible business and market climate changes.

Marketysers's estimates and assumptions are based on varying levels of quantitative and qualitative analyses, including industry journals, company reports, and information in the public domain. Forecasts, estimates, predictions, and other forward-looking statements contained in this report are inherently uncertain because of changes in factors underlying their assumptions, events, or combinations of circumstances that cannot be reasonably foreseen. Actual results and future events could differ materially from forecasts, estimates, predictions, or such statements. All financial and operational details of SAI Parenteral's Limited ("SPL") are for continuing operations and are provided by the company. Marketysers has prepared this study independently and objectively and has taken adequate care to ensure its accuracy and completeness. We believe that this study presents an accurate and fair view of the drug formulation and CDMO Market in selected geographies within the limitations of, among others, secondary statistics and primary research, varying scenarios created due to the COVID-19 pandemic, and it does not purport to be exhaustive. Our research has been conducted with an 'overall industry' perspective, and it may not necessarily reflect the performance of individual companies in the industry. Marketysers shall not be liable for any loss suffered because of reliance on the information contained in this study. This study should also not be considered a recommendation to buy or not to buy the shares of any company or companies as mentioned in it or otherwise.

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Global Economic Overview

Global growth faces uncertain prospects, with emerging economies leading the way by outpacing GDP growth in advanced economies.

The International Monetary Fund's (IMF) July 2025 update projects global real Gross Domestic Product (GDP) growth to moderate from 3.3% in 2024 to 3.0% in 2025 and bounce back to 3.1% in 2026. Major policy shifts are resetting the global trade system and giving rise to uncertainty that is once again testing the resilience of the global economy. The following underlying adjustments have taken place:

- **Advanced Economies:** Since February, the United States has announced multiple waves of tariffs against trading partners, some of which have invoked countermeasures. This has led to downward revisions in growth forecasts for Advanced Economies, particularly in Europe, which are more deeply integrated into the global trade system.
- **Emerging Markets:** Disruptions to commodity production and shipping—caused by conflicts, civil unrest, and extreme weather—have led to downgraded forecasts for the Middle East, Central Asia, and sub-Saharan Africa. Conversely, emerging Asia is set to benefit from rising demand for semiconductors and electronics, fuelled by AI investments, boosting its growth outlook. However, trade policy uncertainty is weighing on emerging market momentum, with the impact varying by country based on exposure to protectionism and geopolitical ties.

Inflation expectations now exceed central bank targets in most advanced economies as well as emerging market and developing economies, whereas their group averages between 2017 and 2021 were at or below target. Yields remain sensitive to inflation surprises and diminishing fiscal space. In economies already operating at or close to potential and facing potential inflationary pressures, including those from new trade policies and exchange rate movements, there is less leeway for central banks to 'look through' new negative supply shocks.

It is important to note that a new wave of credible trade agreements could usher in a broader reform momentum to lift medium-term growth. Progress on labour market policies for upskilling and a reduction of barriers to mobility, simplification of business regulations, and measures to enhance competition and innovation could become inevitable in a more challenging global economic environment.

TABLE 1. GLOBAL GDP TREND AND OUTLOOK (2023-2025, %)

		Projections	
	2024	2025 (P)	2026 (P)
World Output	3.3%	3.0%	3.1%
Advanced Economies	1.8%	1.5%	1.6%
United States	2.8%	1.9%	2.0%
Euro Area	0.9%	1.0%	1.2%
Japan	0.2%	0.7%	0.5%
United Kingdom	1.1%	1.2%	1.4%
Canada	1.6%	1.6%	1.9%
Other Advanced Economies	2.2%	1.6%	2.1%
Emerging Market and Developing Economies	4.3%	4.1%	4.0%
Emerging and Developing Asia	5.3%	5.1%	4.7%
China	5.0%	4.8%	4.2%
Emerging and Developing Europe	3.5%	1.8%	2.2%
Latin America and the Caribbean	2.4%	2.2%	2.4%
Middle East and Central Asia	2.4%	3.4%	3.5%

Source: IMF, April 2025 World Economic Outlook, Marketysers analysis

Indian Economic Overview

India remains the world's fastest-growing major economy, achieving a GDP growth of 6.5% in FY25.

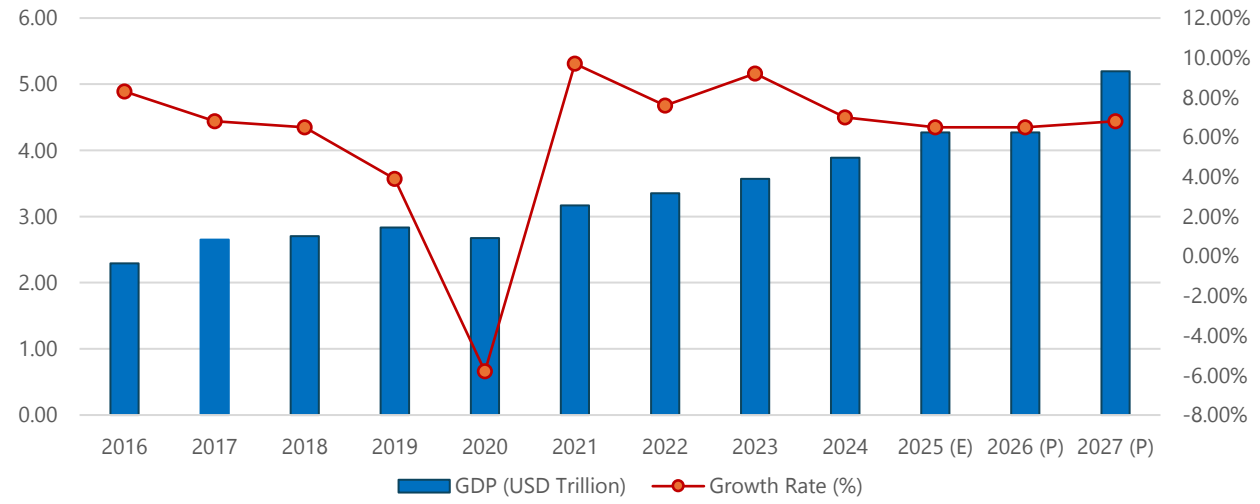
India's economic performance has been underpinned by strong domestic demand, a pickup in rural consumption, robust investment levels, and sustained momentum in manufacturing. In FY25, India's real GDP expanded by 6.5% YoY to reach $3.9 trillion. Growth in the first half of FY25 was supported by agriculture and services, with rural demand improving on the back of record Kharif production and favourable agricultural conditions. The manufacturing sector faced pressures due to weak global demand and domestic seasonal conditions. Private consumption remained stable, reflecting steady domestic demand.

In terms of sector-wise performance, construction has been a standout, gaining momentum since mid-FY21 and soaring approximately 15% above its pre-pandemic trend—an impressive feat driven by robust infrastructure development and housing demand. The utilities sector, including electricity, gas, water supply, and other services, reached its pre-pandemic trend by the end of FY23 and has consistently stayed above these levels. Manufacturing, while steadily recovering, remains slightly below its pre-pandemic trajectory. Within services, the recovery within the services sector has been uneven. Financial, real estate and professional services have taken the lead, surpassing pre-pandemic trend levels by the end of FY23. Public administration, defence, and other services followed suit, exceeding the trend for the first time in Q1 of FY25 since the onset of the pandemic.

The RBI adheres to a flexible inflation targeting framework, which aims to maintain inflation within a range of 2 to 6%. The RBI has taken a prudent approach, modifying the policy repo rate to manage inflation expectations while also fostering economic recovery. As of mid-2025, the repo rate is set at 5.5%, accompanied by a neutral liquidity stance, which indicates the central bank's aim to strike a balance between growth and price stability.

Looking ahead to FY26, the outlook remains balanced in a challenging global environment. India's real GDP is projected to grow by 6.5% and 6.8% in FY26 and FY27, respectively. Domestically, the translation of order books of the private capital goods sector into a sustained investment pick-up, improvements in consumer confidence, and corporate wage pick-up will be key to promoting growth. Rural demand backed by a rebound in agricultural production, an anticipated easing of food inflation and a stable macro-economic environment provides an upside to near-term growth. However, potential risks to this optimistic outlook include geopolitical tensions, volatility in trade policy and climate-related disruptions. Despite these challenges, India's resilient fundamentals position it as a global growth leader, reinforcing its status as the world's fastest-growing major economy.

FIGURE 1. INDIA GDP GROWTH TREND AND OUTLOOK AT CURRENT PRICES, FY16-FY27P, %



Source: World Bank Data, GST Council of India, World Bank Company Annual Report, Primary Interviews, Marketysers analysis

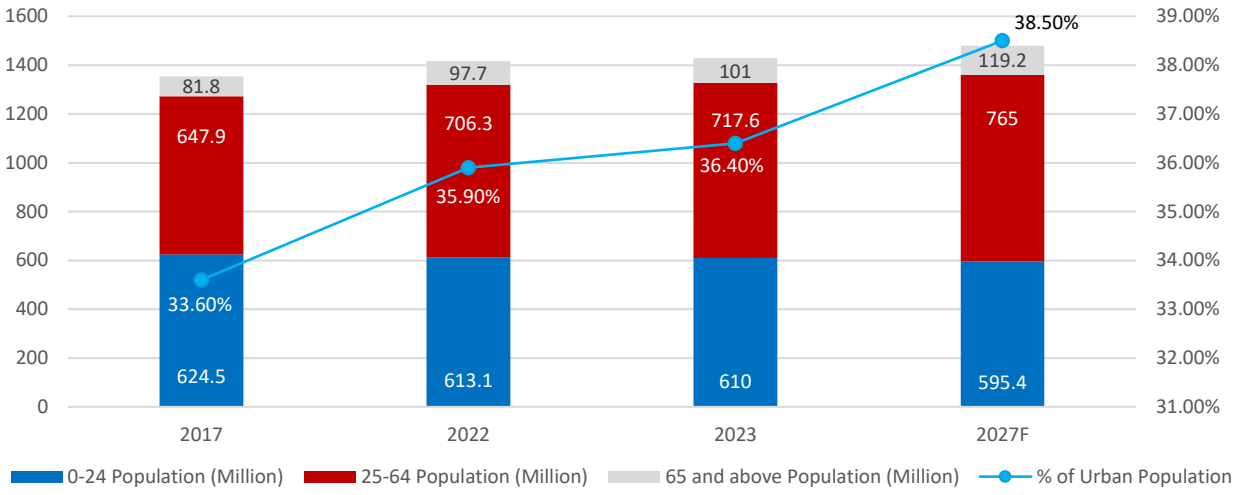
Note: The years refer to financial years

Growth Drivers of the Indian Economy

India's rapid economic development is underpinned by its young population, supportive government policies, and advancements in the digital and manufacturing sectors. Major growth drivers for the Indian economy are:

- **Strong domestic consumption:** At about 60% of total output, private consumption makes up the largest portion of India's GDP. Increased spending on consumer goods, housing, and services is a direct result of rising incomes, especially among India's expanding middle class. The per capita income in FY25 was around ₹205,000 (~USD 2,480), which led to a spike in demand for products like furniture, consumer electronics and cars. Furthermore, with more than 35% of the population currently residing in urban areas and that percentage expected to rise to 40% by 2030, urbanisation is changing consumption patterns. This change reinforces consumption-led growth by meeting the demand for contemporary housing, furnishings, food services, and entertainment.
- **Demographic dividend:** India’s young population, with a median age of 28.8, provides a dual advantage: a dynamic workforce and strong consumption demand. Additionally, the country’s large pool of English-proficient STEM graduates enhances its competitiveness, particularly in skill-intensive sectors like pharmaceutical R&D and manufacturing.

FIGURE 2. POPULATION DISTRIBUTION BY AGE GROUP, INDIA, 2017-2027P, MN



Source: Worldometers, United Nations ESCAP, World Bank, Marketysers analysis

- **Government policies for the manufacturing sector:** Manufacturing has historically contributed 16-17% of India's GDP pre-pandemic and is projected to be one of the fastest growing sectors. Policies like the Production-Linked Incentive (PLI) scheme, PM Gati Shakti-National Master Plan (NMP), and state-level industrial development initiatives aim to boost sectors such as automotive, engineering, chemicals, pharmaceuticals, and consumer durables. By 2030, India has the potential to become a global manufacturing hub, adding over $500 billion annually to the global economy. Skill development programs like Pradhan Mantri Kaushal Vikas Yojana are creating a trained workforce, further enhancing India's competitiveness in pharmaceutical R&D and manufacturing.
- **Government focus on infrastructure:** India's development aspirations require a substantial investment in infrastructure – physical, digital and social - over the next decade. Keeping this in view, the government has laid a special focus on infrastructure in the last five years. Reflecting this intent, the capital expenditure by the union government on major infrastructure sectors has increased at a trend rate of 38.8% from FY20 to FY24. The government has also instituted many complementary mechanisms to expedite planning, clearances and execution of projects. The National Infrastructure Pipeline (NIP) was launched with a forward-looking approach, targeting a projected infrastructure investment of around ₹111 lakh crore from FY20 to FY25. The NIP serves as a centralised platform for hosting projects of states, union territories and central ministries to facilitate their monitoring and review. As of July 2025, it encompasses over 2,927 projects and schemes across various sub-sectors.

Global and Indian Healthcare Expenditure

Healthcare spending is rising globally, driven by federal policies, healthcare reforms, lifestyle-related diseases, and increasing wellness awareness. Developed markets such as the US, UK, France, and Germany lead global spending as a share of GDP.

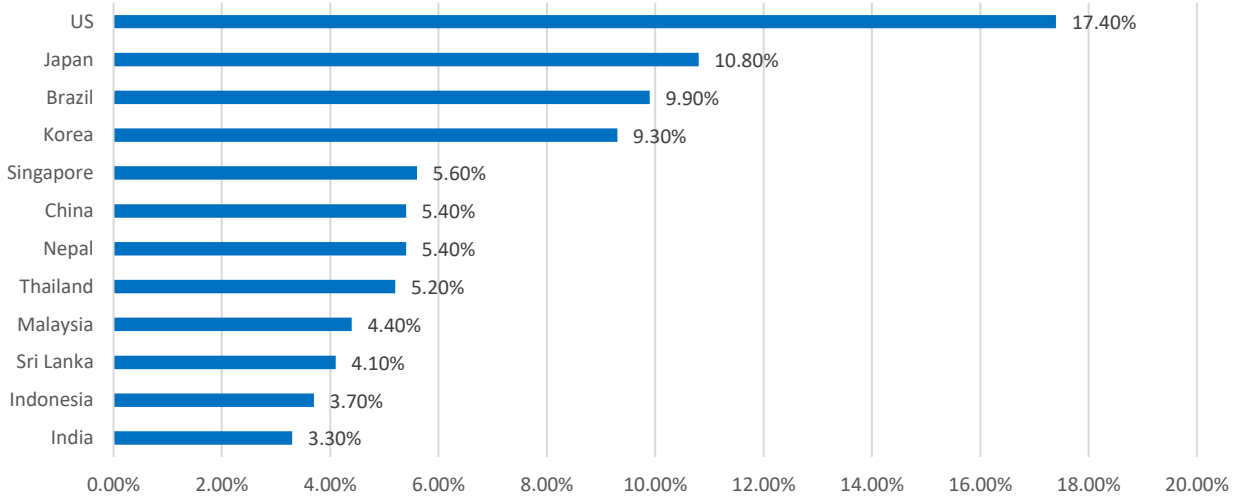
Global healthcare spending has grown alongside economic expansion, with rising public and private investment. The increasing prevalence of sedentary lifestyles and chronic diseases has further contributed to this trend, particularly in fast-growing economies. High-income economies remain the largest contributors to global healthcare spending, both in absolute and per capita terms. The US, UK, France, and Germany remain the top spenders on healthcare as a percentage of GDP.

Both voluntary and government expenditures have surged since the pandemic, leading to a significant increase in global healthcare spending, from 6.5% of global GDP in 2015 to 7.3% in 2021, representing a CAGR of 4.9% over the period. While global healthcare spending is on the rise, there are notable regional variations that underscore the diverse healthcare landscapes across different parts of the world, which are also influenced by a complex interplay of economic, demographic, and societal factors.

India's healthcare sector remains under-penetrated compared with global peers, but it is undergoing a rapid structural shift. India's public healthcare accounted for just 3.3% of GDP in 2021. This is well below not only developed nations like the US and UK but also developing countries such as Brazil, Nepal, Singapore, Sri Lanka, Malaysia, and Thailand. In 2022, India's Health Expenditure (CHE) per capita stood at just $74, underscoring the need for greater investment in healthcare infrastructure.

Despite low current spending, India's large population, rising disease burden, and favourable policy environment position it as one of the fastest-growing healthcare markets globally.

FIGURE 3. HEALTHCARE EXPENDITURE AS % OF GDP, 2021



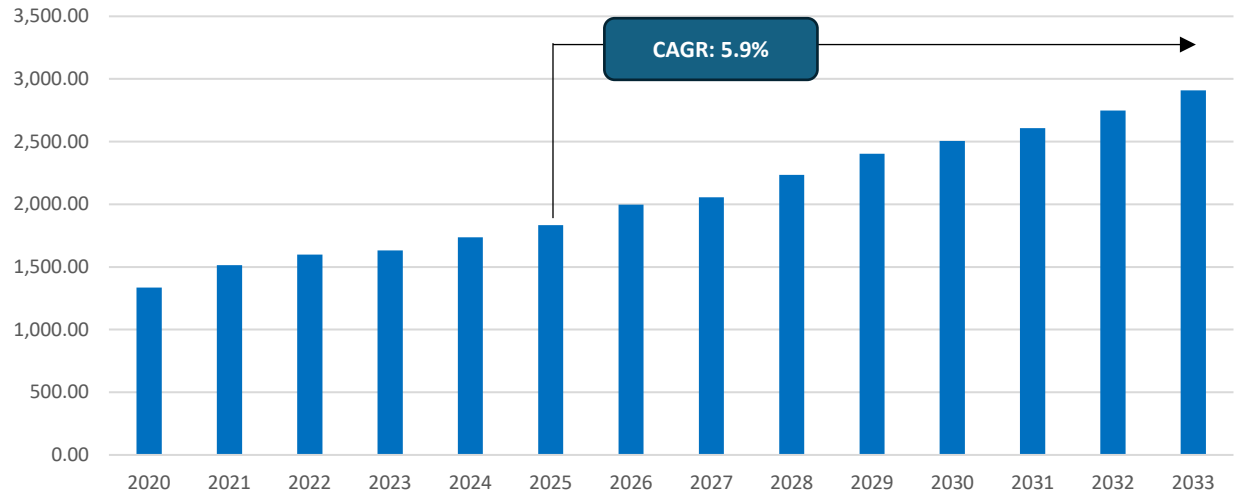
Source: Global Health Expenditure Database, Marketysers analysis

Note: CHE data is based on the same period during the year as a country's fiscal data. In the case of countries whose fiscal data are based on a fiscal calendar (e.g., July to June), this series would be the country's CHE over that same period.

Global Pharmaceutical Market Overview

Resilient and sustainable long-term growth has been evident in the global pharmaceutical market due to growing demand, advancing innovations and availability of affordable generics.

FIGURE 4. GLOBAL PHARMACEUTICAL MARKET SIZE, 2020-2033P, $ BN



Source: Marketysers analysis

The global pharmaceutical sector is undergoing a profound transformation across its entire value chain, driven by a strong emphasis on product innovation, healthcare equity (healthcare for all), operational efficiency and enhanced engagement with healthcare providers and patients. Despite facing inherent challenges within this transformative landscape, the pharmaceutical industry has demonstrated remarkable agility and delivered groundbreaking innovations, particularly highlighted during the COVID-19 pandemic, enjoying resilient growth.

The global pharmaceutical market is estimated at $1.8 trillion in 2025 and is projected to grow to $2.9 trillion by 2033, with a CAGR of 5.9% from 2025 to 2033. This growth is primarily attributable to factors like:

- **Aging Population and Disease Burden:** The global demographic shift towards an aging population is a significant driver of pharmaceutical market growth. With the percentage of the global population over 60 years old expected to nearly double from 12% to 22% and reach ~2.1 billion by 2050, an increase in the prevalence of chronic diseases and age-related conditions is expected to drive demand for drugs targeting conditions like hypertension, diabetes, osteoporosis, and neurodegenerative disease, to name a few.
- **Increasing incidence of chronic diseases:** While the aging population is susceptible to chronic diseases, there is a growing incidence among the younger population as well, largely due to lifestyle changes. For instance, in a study done in the US in 2019, approximately one-half of young adults reported at least one chronic condition, with the most common being obesity (25.5%), depression (21.3%), and high blood pressure (10.7%). Globally, approximately one in three adults suffers from multiple chronic conditions (MCCs). Since the management of chronic diseases requires life-long use of pharmaceutical drugs, it is further driving the market growth.
- **Increasing demand from developing nations:** Developing nations face a dual demand for pharmaceutical drugs, driven by both the rising incidence of chronic conditions and the persistent burden of infectious diseases. For instance, India has earned the moniker of "diabetes capital of the world" with its 77 million diabetic and 25 million

prediabetic population, reflecting a trend observed in many developing countries, mirroring developed markets' demand for similar drugs. Simultaneously, the continued epidemic of tropical and infectious diseases, such as malaria and dengue, maintains a high demand for drugs combating these conditions. To quantify, there were an estimated 249 million cases of malaria worldwide in 2022, with the majority occurring in Africa (94%). Similarly, Tuberculosis (TB) also imposes a substantial burden, with approximately 10.6 million new cases globally in 2022, with 46 % occurring in the Southeast Asia Region and 23% in the African Region.

- **Consumer awareness and trends in self-medication:** The COVID-19 pandemic has had an immense impact on heightened consumer awareness of health, wellness, and preventive care, leading to massive growth in the over-the-counter (OTC) pharmaceutical market segment.
- **Growing Investments in R&D:** R&D investments contribute to the discovery of breakthrough treatments for prevalent and emerging diseases, driving market growth by expanding the range of therapeutic options available to patients. The growth in R&D investments has resulted in the launch of several novel cell and gene therapies, monoclonal antibodies, and mRNA therapies, to name a few.

Emerging Trends in the Global Pharmaceutical Market

India's Emergence as a Global Outsourcing Powerhouse

India is central to WHO's pharmaceutical access narrative, delivering over 60% of global vaccine demand and supplying essential generics to more than 200 countries. Multinationals are outsourcing formulation, APIs and development activities to India to benefit from:

- Cost arbitrage
- Regulatory alignment (USFDA, WHO-GMP)
- Deep scientific talent

India's Contract Development and Manufacturing Organisations (CDMO) and Contract Research Organisations (CROs) sectors are fast becoming innovation partners, not just execution vendors, signalling a structural shift in outsourcing relationships. Several leading CDMO firms in India are making sizable investments to enhance their capabilities and expand their service offerings.

China Plus One

In response to geopolitical tensions and WHO's call for diversified, resilient pharmaceutical supply chains, companies are de-risking by adopting a China+1 model. The China+1 strategy, where global companies diversify supply chains beyond China, is boosting India's CDMO market. With the proposed US Biosecure Act aiming to reduce reliance on Chinese biotech firms, Indian CDMOs stand to gain as Western pharma companies seek alternative partners. India offers cost efficiency, skilled talent, and high-quality manufacturing capabilities, making it a preferred destination for drug development and production. Additionally, rising global biotech funding and India's strong generic drug expertise further strengthen its position. This shift enhances India's pharma exports, economic growth, and long-term investment opportunities in the sector.

Strategic Focus on Emerging & Semi-Regulated Markets

Global firms are intensifying their focus on non-traditional, high-growth markets across Africa, Southeast Asia, and Latin America. WHO's initiatives like the Medicines Transparency Alliance (MeTA) are improving regulatory visibility in these regions, making them more investible. These markets offer:

- Simplified registration timelines
- High unmet clinical need

Indian players are leveraging branded generics and therapeutic specialisation (e.g., anti-infectives, women's health) to capture early-mover advantage. Indian CDMOs are also investing in USFDA-approved plants, tapping into regulated markets and forming long-term partnerships with leading pharma companies in the US, Europe and Southeast Asia.

Monetising the Large Off-Patent Opportunity

A significant number of blockbuster drugs are approaching loss of exclusivity. WHO supports this lifecycle transition via its Essential Medicines List (EML) and Prequalification Programme, which accelerate generic penetration. Indian and global generic firms are capitalising on:

- Para IV filings in the US
- Complex generics and biosimilars
- Therapeutic substitution models in emerging markets

Patent holders can still make money off their inventions even after expiry by licensing vital information about them, such as proprietary processes and trade secrets. The licensing agreements offer the competitor technical expertise at a fee, creating a new revenue stream for the inventor. Previous patent owners may also partner with new players in the market to monetise from sharing their expertise. The upcoming patent cliff (expiry of patents for innovator drugs) represents a significant opportunity estimated at $130 billion+ over the next five years (in the developed market alone).

Also, according to the 10th edition of *The Impact of Biosimilar Competition* by IQVIA, biosimilars have gained significantly more traction than generics in the pharmaceutical market, as biologics still outpace small molecules by 3x. By 2030, 69 biologic medicines will lose exclusivity, creating a €28 billion market opportunity.

Shift to Monoclonal Antibodies

Monoclonal antibodies (mAbs) have emerged as a cornerstone in modern drug development, representing one of the fastest growing and most commercially successful segments of the pharmaceutical industry. Their precision in targeting specific antigens has transformed therapeutic approaches in oncology, immunology, and chronic diseases.

Over the past decade, the pharmaceutical landscape has seen a marked shift toward mAb-based therapies. Regulatory approvals have consistently risen, averaging between 3 and 5 new approvals annually. As of 2022, more than 160 monoclonal antibody therapies have received global market approval, with over 1,200 candidates advancing through clinical pipelines. This growth underscores not only strong clinical performance but also strategic prioritisation by drug developers.

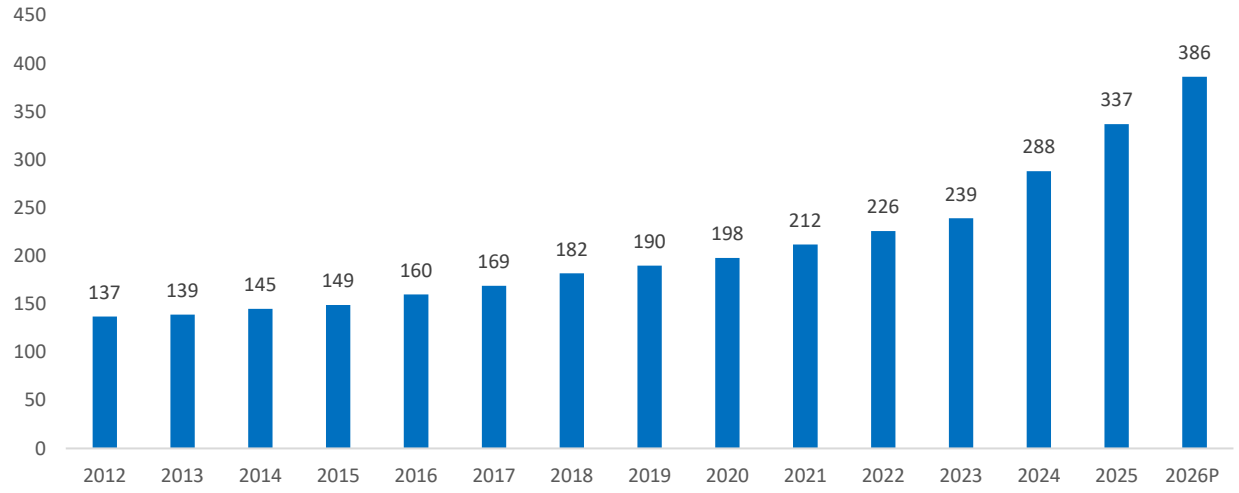
However, scaling up mAb manufacturing introduces significant challenges. Issues like cell line stability, upstream yield variability, and scaling downstream purification can delay timelines and impact product consistency. Modern

manufacturing now requires a shift toward platform-based approaches, automation, and single-use technologies to ensure flexibility and cost efficiency. On the clinical side, monoclonal antibodies have revolutionised cancer therapy and immunologic diseases by enabling checkpoint inhibition, receptor blockade and targeted delivery of cytotoxics. While highly effective, these therapies come with risks of immune-related adverse events and resistance over time—necessitating combination strategies and next-gen formats such as bispecifics and antibody-drug conjugates (ADCs).

Overview of R&D Investment in the Global Pharmaceutical Market

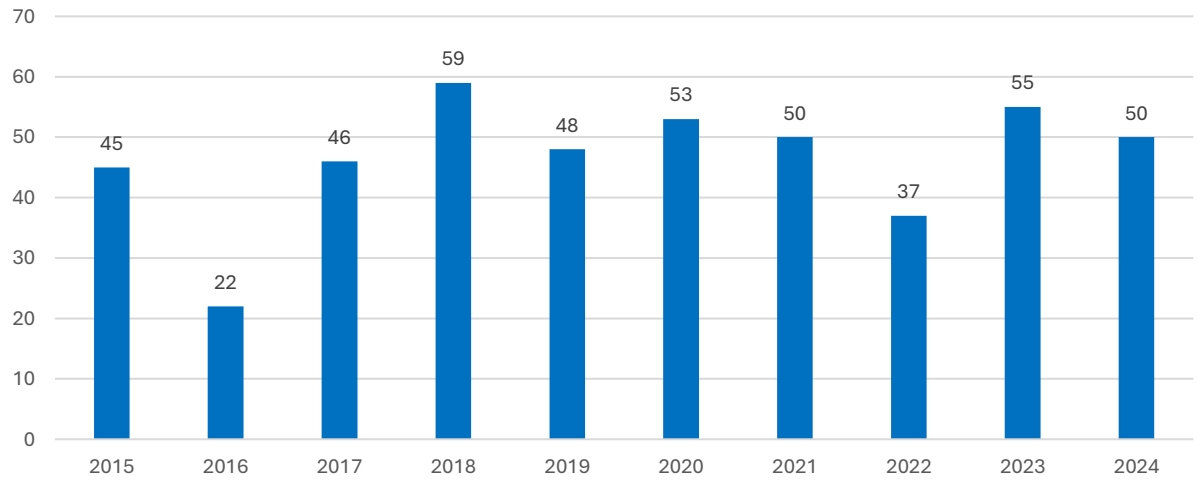
The pharmaceutical sector's increasing focus on R&D is driving greater drug complexity, particularly with the rise of biologics and personalised medicine. With tightening quality standards, companies offering end-to-end services—from formulation to commercial manufacturing—are well-positioned to meet rising demand. This trend is supported by the pharmaceutical industry's R&D investments, which grew to $288 billion in 2024.

FIGURE 5. PHARMACEUTICAL R&D SPENDING, 2012-2026P, $ BN



Source: IFPMA, Evaluate Pharma (2021) World Preview 2021, Outlook to 2026, Marketysers analysis

FIGURE 6. NUMBER OF NEW DRUG APPROVALS BY THE US FDA CDER, 2015 TO 2024



Source: USFDA, IFPMA, Evaluate Pharma (2021) World Preview 2021, Outlook to 2026, Marketysers analysis

In 2024, the global pharmaceutical industry witnessed the launch of 50 novel active substances (NAS), with a noteworthy share being first-in-class approvals. Within this, the U.S. FDA's Centre for Drug Evaluation and Research (CDER) approved 16 biologic therapies, accounting for 32% of all new drug approvals—almost identical to 2023, when 17 biologics represented 31% of approvals. Monoclonal antibodies (mAbs) dominated this cohort, with 13 approvals, the highest on record. mAbs now represent more than a quarter of all novel drug approvals, cementing their position as the most important therapeutic class, particularly across oncology, immunology, and rare disease indications.

On April 10, 2025, the FDA announced plans to phase out the long-standing requirement for animal testing in the development of monoclonal antibodies. The agency launched a pilot program enabling selected developers to use advanced New Approach Methodologies (NAMs), including AI-driven toxicity prediction models, human-cell-derived organoids, and organ-on-a-chip systems. These tools are designed to enhance translational relevance, cut preclinical timelines, and reduce reliance on traditional animal studies. Both FDA guidance and peer-reviewed analyses underscore that animal models often fail to predict human outcomes, particularly for biologics and complex immunotherapies. By endorsing these NAMs, the FDA is not only modernising regulatory frameworks but also accelerating the pathway for antibody-based drug development.

Practically, this shift is expected to streamline early-stage research, reduce failure rates, and lower costs for drug developers, thereby accelerating timelines for mAb approvals. Together with record-breaking approval volumes, the regulatory change signals the beginning of a new era where antibody-driven innovation is set to dominate the global market.

The role of emerging biopharmaceutical (EBP) companies in shaping this landscape is increasingly prominent. These firms have historically acted as innovation engines, licensing assets to larger pharma players for commercialisation. Over the past decade, however, their role has expanded materially. In 2024, EBPs originated 85% of the 48 novel active substances launched globally. Between 2020 and 2024, they accounted for 59% of NAS introductions, up from 53% during 2015–2019. The number of EBP-originated launches has steadily climbed, with 41 NAS entering the market in 2024, compared with 34 in 2019. Since 2016, more than half of all NAS launches have been attributed to EBPs, underscoring their central role in early-stage innovation and their growing influence on the global pharmaceutical ecosystem.

Global Drug Formulation Market Overview

The global drug formulation market represents a core segment of the pharmaceutical value chain, encompassing the development of dosage forms that ensure efficacy, stability, safety, and patient compliance.

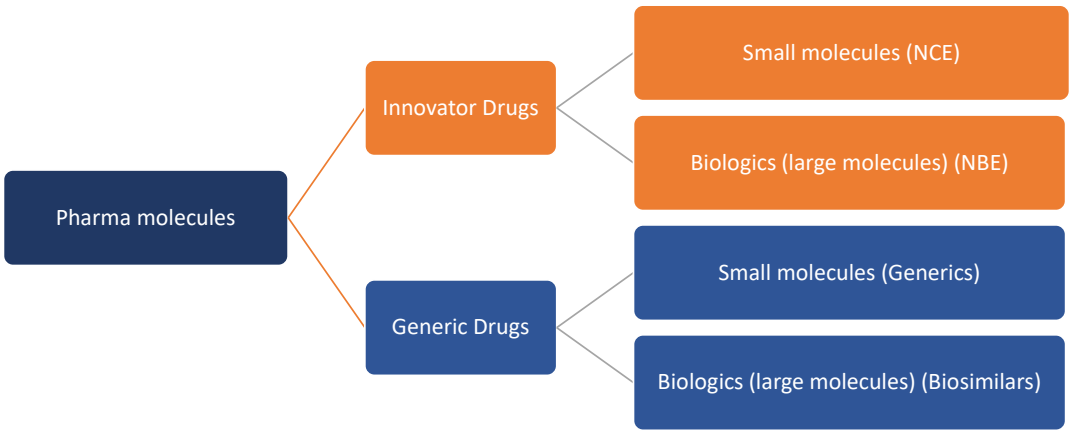
Supported by rising demand for innovative therapies, increasing generic penetration, and advancements in drug delivery technologies, the market has become a key driver of global healthcare access. The global drug formulation market is estimated at $1.5 trillion in 2025 and is projected to grow to $2.5 trillion by 2033, with a CAGR of ~5.9% from 2025 to 2033.

Global Drug Formulation Market by Innovation Type

Increasing push to switch to low-cost generics to control spiralling healthcare costs and make healthcare more equitable:

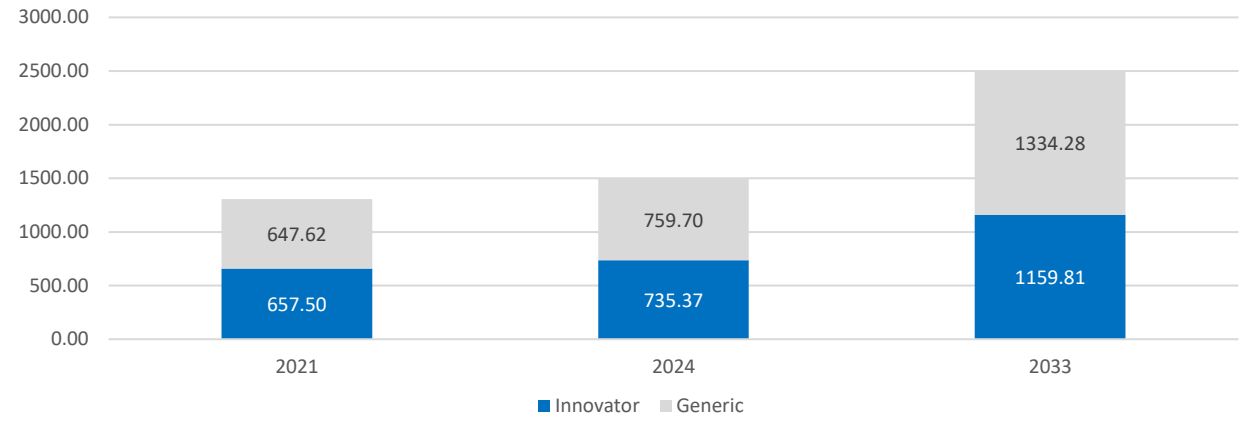
The pharmaceutical market can be divided into two types of drugs: innovators (comprising of new chemical entities (NCEs), and new biological entities (NBEs) and generics (including biosimilars).

FIGURE 7: GLOBAL DRUG FORMULATION MARKET BY TYPE OF MOLECULE



Source: Marketysers analysis

FIGURE 8: GLOBAL DRUG FORMULATION MARKET, BY INNOVATION TYPE, 2021-2033P, $ BN



Source: Marketysers analysis

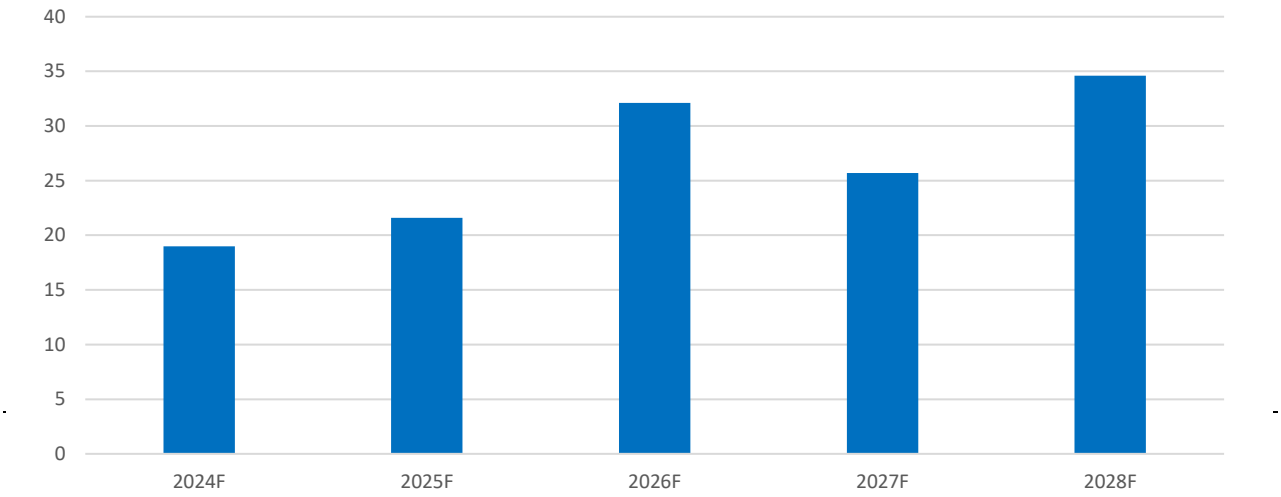
Innovator Drugs Market

Innovator drugs are the first version of NCE or NBE to be developed, approved, and marketed, which usually contain a new active ingredient and require extensive clinical development and a patent approval process for use. The innovator drug market, valued at $735 billion in 2024, is projected to reach $1,160 billion by 2033 at a CAGR of 5.2%, slower than the overall drug formulation market growth. This growth is driven by an increasing focus on R&D by pharmaceutical companies, leading to continued demand for novel, high-value curative therapies especially, those targeting complex and rare diseases.

Generic Drugs Market

Once the patent of an innovator drug expires, other companies can make and sell the same composition drugs, known as generic drugs. Generic drugs are equally safe and effective as innovator drugs and are usually cheaper. The generic drug segment accounts for 50.8% of the total pharmaceutical market by revenue in 2024 and is projected to grow at a CAGR of 6.5% between 2024 and 2033, reaching a value of $1,334 billion by 2033. The upcoming patent cliff (expiry of patents for innovator drugs) represents a significant opportunity estimated at $130 billion+ over the next five years (in the developed market alone). The introduction of cost-effective generics and biosimilars is expected to enhance accessibility and health equity by offering more affordable alternatives to high-cost originator drugs. Also, according to the 10th edition of *The Impact of Biosimilar Competition* by IQVIA, biosimilars have gained significantly more traction than generics in the pharmaceutical market, as biologics still outpace small molecules by 3x. By 2030, 69 biologic medicines will lose exclusivity, creating a €28 billion market opportunity.

FIGURE 9: OFF-PATENT OPPORTUNITIES FOR GENERIC SMALL MOLECULES, 2024F–2028F, $ BN



Source: Marketysers analysis

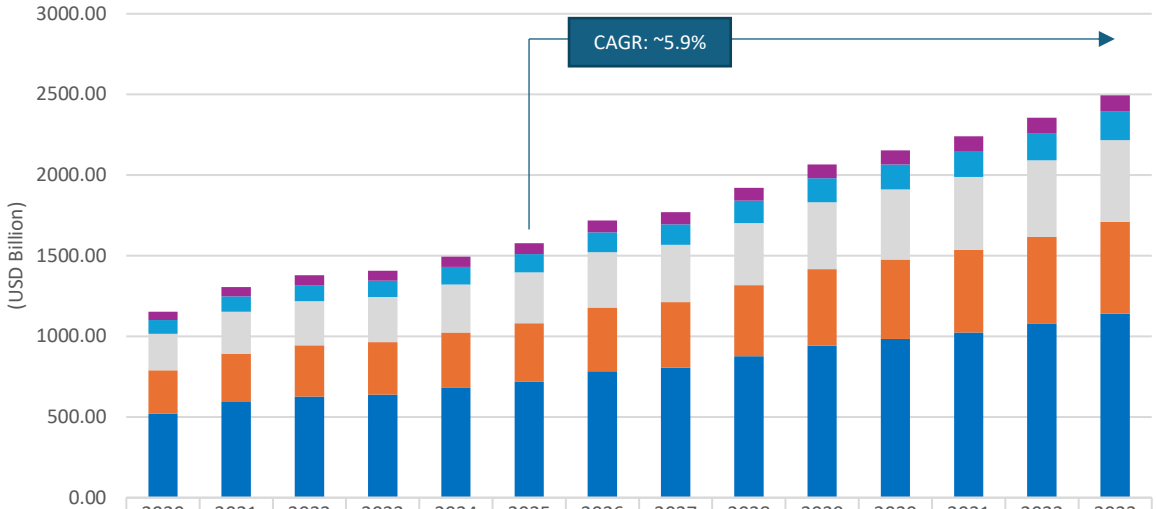
In addition to offering cost savings, generics pharma companies have transformed the pharma landscape by constantly innovating to improve drug efficiency, effectiveness, and ease of use and employing strategic operational tactics to drive continuous value addition.

Generic pharmaceutical firms have constantly strived to diversify their portfolios by introducing reformulated generics to include extended-release, inhalable, and implantable formulations, to name a few, to improve drug efficacy and, at the same time, patient convenience. Companies have also focused on increasing R&D to foray into complex and specialty generics. Additionally, companies diversify their sourcing and manufacturing networks to mitigate supply chain risks, while also embracing digital tools and technologies to enhance operational quality and productivity. Generic pharmaceutical companies are leveraging operational excellence, technology adoption, and streamlined supply chain management to achieve substantial cost savings while maintaining competitiveness and meeting regulatory requirements.

Global Drug Formulation Market by Region

Regulated markets, particularly the US, continue to exert dominance and influence over the global pharma market, driven by high demand, appetite for innovation and comparatively higher prices for comparable products.

FIGURE 10. GLOBAL DRUG FORMULATION INDUSTRY BY REGION, 2020-2033P, $ BN



	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Middle East & Africa	51.39	57.33	60.12	61.21	64.53	67.63	72.83	74.68	80.20	85.34	88.48	91.51	95.57	100.33
Latin America	84.47	95.27	100.42	102.45	108.63	114.46	124.30	127.83	138.43	148.41	154.56	160.53	168.60	178.10
Asia Pacific	227.70	258.86	273.80	279.73	297.79	314.87	343.82	354.26	385.68	415.42	433.82	451.75	476.01	504.72
Europe	266.42	301.21	317.81	324.37	344.37	363.22	395.09	406.55	440.96	473.41	493.42	512.89	539.19	570.22
North America	522.36	592.44	625.97	639.26	679.74	717.97	782.70	806.03	876.11	942.36	983.29	1023.1	1077.0	1140.7

Source: Marketysers analysis

Globally, Asia Pacific will outpace the growth among other regions with 6% CAGR. North America to be the second fastest growing market globally.

North America, led by the U.S., remains the largest market, contributing 45% of the global market size in 2024. This is mainly due to substantial healthcare spending in the U.S., even on high-cost therapies, and increased investments in R&D for new treatments. Similarly, Europe's leadership in R&D and innovative pharmaceutical introductions is reinforced by extensive reimbursement coverage and high treatment rates. Despite the historical precedence of these established markets, the burgeoning growth trajectory is distinctly observable in emerging markets across the Asia Pacific (APAC), Latin America, and the Rest of the World (ROW). These regions, characterised by dynamic economies such as the BRICS nations (Brazil, Russia, India, China, and South Africa) and the MIST countries (Mexico, Indonesia, South Korea, and Turkey), present new opportunities because of substantial population size, increasing affluence, and augmented financial capabilities of both governments (public health expenditure) and citizens (private health expenditure), enhanced life expectancy, improved access to pharmaceuticals, increasing coverage in medical insurance policies, better healthcare infrastructure along with awareness, changing disease patterns (from acute to chronic), and availability of low-cost generics. Additionally, price erosion and growing compliance costs in traditional high-growth markets like the U.S. are prompting companies to target under-tapped, semi-regulated markets through new customised products and local partnerships.

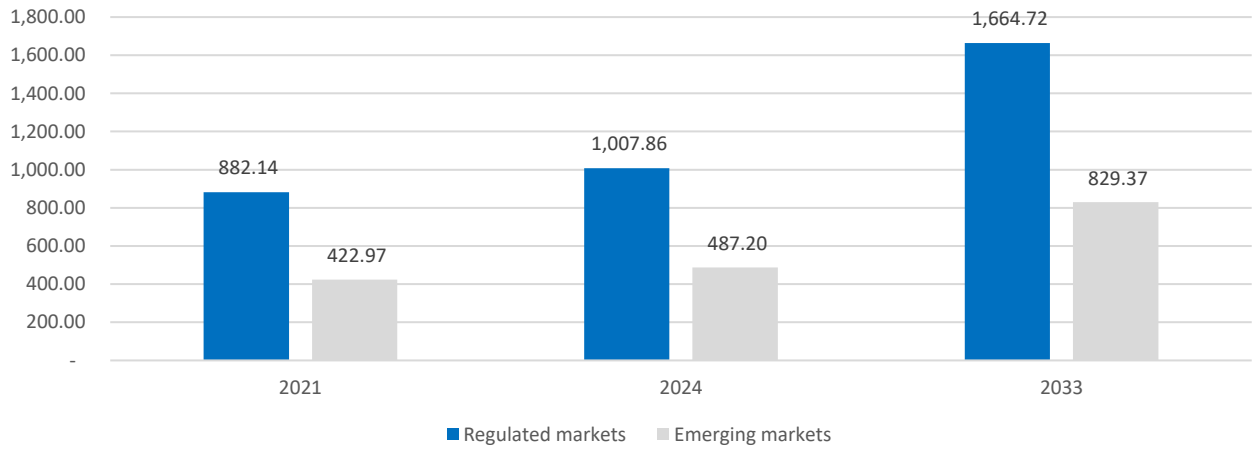
In the global drug formulation market, the classification of regulated and emerging markets is a critical consideration for market entry and growth strategies. These classifications are primarily based on the stringency of regulatory standards imposed on pharmaceutical manufacturing, quality control, and product approvals.

Regulated markets are characterised by stringent regulatory frameworks and oversight by authoritative bodies such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). These markets impose strict requirements for Good Manufacturing Practices (GMP), rigorous product testing, detailed documentation, and thorough inspection protocols. Emerging markets, typically in Asia, Africa, and Latin America, have more relaxed regulatory standards but still adhere to global quality norms. These markets are evolving towards stricter guidelines. Entry is less complex and costly compared to regulated markets. Accreditation in regulated markets, like GMP certifications from the FDA or EMA, acts as a key enabler for entering semi-regulated markets. These certifications enhance credibility, reduce regulatory barriers, and accelerate approvals, making it easier to expand globally.

Additionally, standards like PIC/S standards, which are internationally harmonised guidelines for Good Manufacturing Practice (GMP) developed by the Pharmaceutical Inspection Co-operation Scheme (PIC/S), promotes cooperation and harmonisation of inspection procedures, standards, and training among its 56 member authorities across Europe, Asia, Africa, and America. These standards are designed to improve quality and safety and enable easier entry into emerging markets for companies who adhere to this standard.

Overall, the regulatory drug formulations market accounted for a 67% share by value in 2024. The emerging drug formulation market, which includes high-growth regions of the Middle East and Africa, Latin America, and APAC countries like India, accounted for the remaining 33% in 2024 and is expected to outpace the growth of the global drug formulation market.

FIGURE 11: GLOBAL DRUG FORMULATION MARKET BY MARKET TYPE, 2021-2033P, $ BN



Source: Marketysers analysis

TABLE 2. SNAPSHOT OF KEY REGULATIONS IN SELECT COUNTRIES

REGULATION	DESCRIPTION
Regulated markets	
European Regulation (EC) No 536/2014	This is for clinical trials of medicinal products for human is part of a European regulatory framework in which the European Commission has wished to give a strong impetus to scientific research and industrial progress. It is a new regulation that fills a series of regulatory gaps in the Clinical Trials through the creation of a uniform framework for the authorisation of clinical trials by all interested Member States with a single assessment of the results.
The Therapeutic Goods Act 1989, Australia	The regulations and orders set out the requirements for inclusion of therapeutic goods in the Australian Register of Therapeutic Goods, including advertising, labelling, product appearance and appeal guidelines.
United States Federal Food, Drug, and Cosmetic Act (abbreviated as FFDCA, FDCA, or FD&C)	It is a set of laws passed by Congress in 1938 giving authority to the U.S. Food and Drug Administration (FDA) to oversee the safety of food, drugs, medical devices, and cosmetics.
European Regulation 726/2004 and Directive 2001/83/EC	The proposal adopted by the Commission revises and replaces the existing general pharmaceutical legislation. The revision aims to achieve the following main objectives: • Make sure all patients across the EU have timely and equitable access to safe, effective, and affordable medicines • Enhance the security of supply and ensure medicines are available to patients, regardless of where they live in the EU • Continue to offer an attractive and innovation-friendly environment for research, development, and production of medicines in Europe • Make medicines more environmentally sustainable • Address antimicrobial resistance (AMR) and the presence of pharmaceuticals in the environment through a One Health approach.
Regulation (EU) 2019/1381 of the European Parliament	Regulation (EC) No 178/2002 of the European Parliament and of the Council(4) lays down the general principles and requirements of food law, so as to form a common basis for measures governing food law at both Union and national level. It provides, inter alia, that food law is to be based on risk analysis, except where this is not appropriate to the circumstances or the nature of the measure.
Japan Pharmaceuticals and Medical Devices (PMD) Act	The Pharmaceuticals and Medical Devices (PMD) Act establishes the Regulatory framework for controlling pharmaceuticals, cosmetics, in-vitro diagnostic reagents, medical equipment, and regenerative and cellular therapy items on the Japanese market.
FDA Draft Guidance on AI Use in Regulatory Decision-Making	New guidance (Jan 2025) outlining risk-based credibility criteria for AI models used in drug/biologics decision-making. Emphasises data quality, transparency, continuous validation
Emerging markets	

Brazil Law no. 12,401/2011	Article 19-T of Law n. 8,080, already modified by Law n. 12,401/2011 2, which regulated the availability of medicines, national or imported, without market approval by Anvisa or for use other than the package leaflet indication
India Drugs Act and Cosmetics Act, 1940	• The Drugs and Cosmetics Act, 1940 is an act of the Parliament of India which regulates the import, manufacture and distribution of drugs in India.[1] The primary objective of the act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to state quality standards.[2] The related Drugs and Cosmetics Rules, 1945 contains provisions for classification of drugs under given schedules and there are guidelines for the storage, sale, display and prescription of each schedule. The Act oversees medication imports into India, ensuring that no substandard or counterfeit drugs enter the country. • The Act prohibits the production of inferior or counterfeit pharmaceuticals in the country. • The Act requires only qualified and competent personnel to sell and distribute medicines, as well as the manufacture, sale, and distribution of Ayurvedic, Siddha, Unani, and Homeopathic drugs. • The provisions of the Act control the import, manufacture, sale, and distribution of cosmetics. • To have drug inspectors visit licensed premises regularly. • Monitoring pharmaceutical and cosmetic standards by collecting samples and analysing them in accredited laboratories. • Creating distinctive regulations to control the manufacture, standardisation, and storage of biological and special products, as well as prescribing how different types of drugs and cosmetics should be labelled and packed.
ASEAN Common Technical Dossier (ACTD)	In the ASEAN regions, the applicant can suit the standard requirements set within the ASEAN Common Technical Dossier (ACTD) to urge approval within the member countries (Indonesia, Malaysia, Philippines, Singapore, Thailand, Brunei, Myanmar, Cambodia, Laos, and Vietnam). Almost identical documents are often used for national approval within the non-member countries of the Asia Pacific region with simple amendments.

Source: Marketysers analysis

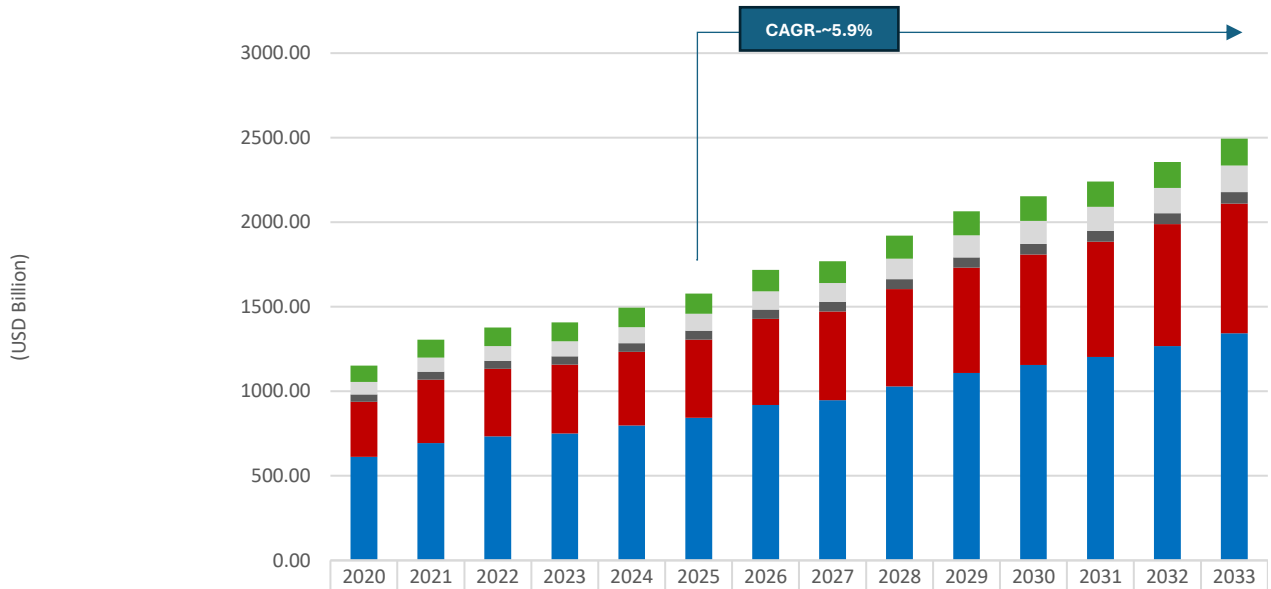
Global Drug Formulation Market by Dosage Form

Globally, the injectable segment is expected to witness the fastest growth at a CAGR of 6.5%, driven by improved bioavailability, faster therapeutic action, and dose customisation capabilities.

Traditionally, solid oral dosage forms—tablets and capsules—have maintained market dominance, owing to their mature manufacturing infrastructure and patient convenience. However, the landscape is evolving, with emerging formulation technologies such as orally disintegrating tablets, chewables, inlaid tablets, gummies, and multi-layered tablet-in-tablet systems gaining traction by addressing diverse patient needs and improving user experience.

Concurrently, the injectables segment is poised for accelerated growth, with a projected CAGR of approximately 6.5% over the next decade, underscoring a strategic shift in therapeutic delivery preferences. This momentum is underpinned by injectables' superior bioavailability, enhanced absorption profiles, and rapid onset of action facilitated through targeted delivery. Moreover, injectables offer a critical therapeutic advantage for patient populations with challenges in oral administration, such as paediatric, geriatric and critically ill patients, reinforcing their expanding role in personalised and acute care therapeutics.

FIGURE 12. GLOBAL DRUG FORMULATION INDUSTRY BY DOSAGE FORM, 2020-2033P, $ BN



	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Others	97.37	106.12	110.06	111.58	116.14	120.31	127.15	129.49	136.40	142.59	146.24	149.68	154.21	159.35
Topical	72.94	82.52	87.09	88.89	94.40	99.60	108.38	111.54	121.03	129.98	135.50	140.88	148.13	156.70
Other Parenteral Formulations	43.17	46.93	48.59	49.23	51.14	52.86	55.66	56.61	59.36	61.78	63.17	64.47	66.14	68.00
Injectable	326.73	374.81	398.08	407.34	435.63	462.50	508.23	524.84	574.89	622.57	652.22	681.21	720.56	767.29
Oral	612.12	694.74	734.29	749.97	797.75	842.88	919.32	946.88	1029.70	1108.03	1156.44	1203.59	1267.36	1342.75

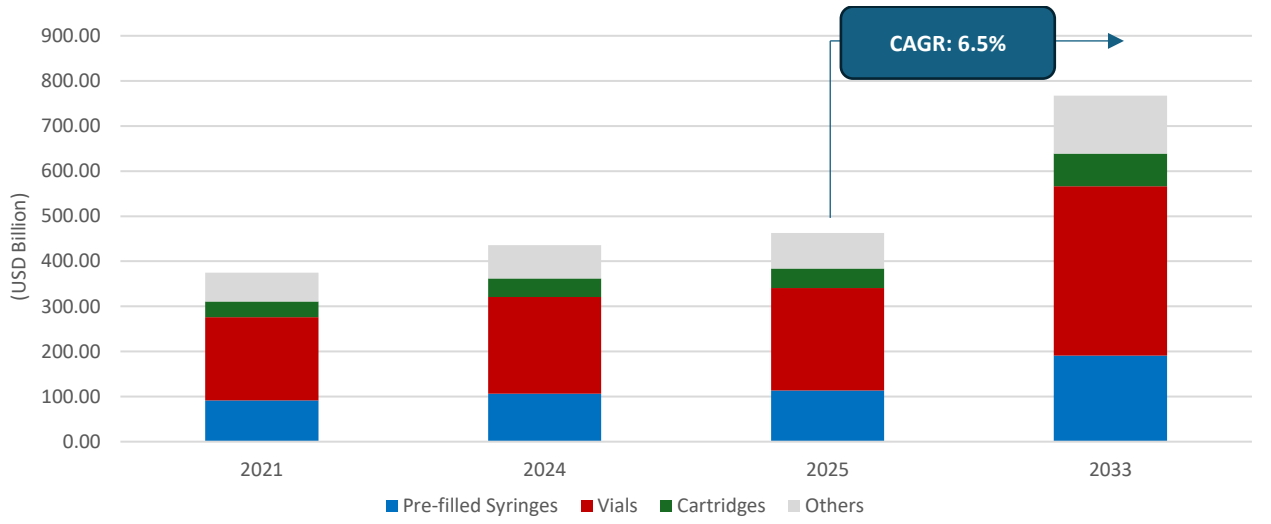
Source: Marketysers analysis

Overview of Global Injectable Market

Globally, injectables are the second largest form of drug delivery systems, accounting for ~29% of the global pharmaceutical market by value in 2024.

Injectables are delivered globally through multiple systems, including infusion systems, pre-filled syringes (PFS), vials, cartridges, ampoules, and other formats. Vials remain the most widely used format, accounting for nearly 49% of the global injectables market in 2024. Infusion therapy—an alternative to oral treatment where medication is administered intravenously—has traditionally been hospital-based but is now expanding into outpatient settings, specialised infusion centres, and even home care, supported by trained nurses. In parallel, patient-centric delivery devices such as auto-injectors and pen-injectors are gaining traction. Their convenience and suitability for at-home use are driving pharmaceutical companies to adopt these formats for chronic and age-related conditions such as diabetes and arthritis.

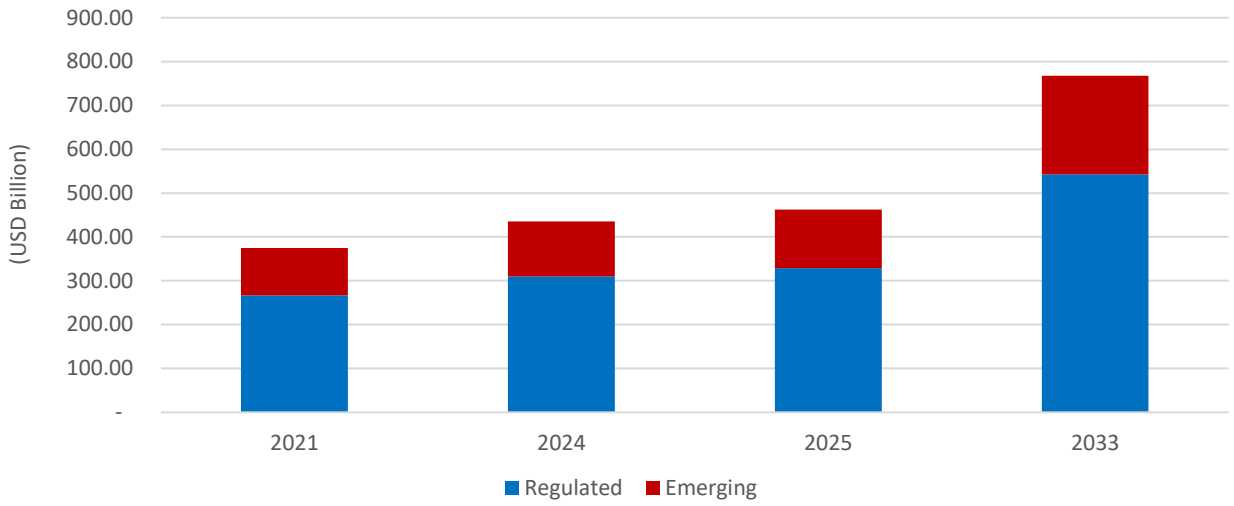
FIGURE 13. GLOBAL INJECTABLE MARKET: BY DELIVERY FORM, 2021-2033P, $ BN



Source: Marketysers analysis

Growth is expected across both regulated and emerging markets, with regulated markets continuing to account for a larger share driven by higher biologics penetration, stringent quality standards, and strong demand for chronic disease management. Emerging markets, however, are projected to grow at a faster pace, supported by expanding healthcare access, rising disposable incomes, and increasing adoption of advanced therapies. This dual-market momentum underscores the sustained and broad-based demand for injectable therapies over the next decade.

FIGURE 14: GLOBAL INJECTABLE MARKET: BY REGION, 2021-2033P, $ BN



Source: Marketysers analysis

Injectables have numerous advantages over other traditional dosage forms:

- Accelerated pharmacodynamic response: Injectable formulations bypass the gastrointestinal tract and first-pass metabolism, enabling almost immediate systemic availability, critical in acute therapeutic contexts. WHO reports that over 16 billion injections are administered annually, underscoring the scale of this route in urgent care settings. Boosted by its need in scenarios where oral intake is impossible, such as with unconscious patients, dysphagia, or severe vomiting—injectables ensure essential treatment continuity. Injectables enable targeted administration (intravenous, intramuscular, or subcutaneous), offering healthcare professionals the ability to calibrate dose intensity and localisation for optimal efficacy.
- Enabling self-administration via advanced devices: WHO strongly supports self-care protocols, notably endorsing self-administered subcutaneous injectable contraception (e.g., DMPA-SC), which evidence shows improves continuation rates by up to 27% versus provider-administered alternatives. Auto-injectors and prefilled pens significantly reduce barriers to home-based therapy, enhancing autonomy and adherence.
- Suitable for drugs with challenging physicochemical profiles: Many modern therapeutics exhibit poor oral bioavailability due to low solubility or permeability. Injectable administration remains the most viable method to deliver such compounds systemically.
- Safety-engineered devices to mitigate transmission risks: WHO mandates the exclusive use of safety-engineered syringes, including auto-disable and needlestick-protected designs—to lower the risk of bloodborne pathogen transmission and needle-stick injuries. These “smart syringes” are increasingly required globally.
- Rigorous procedural training to reduce administration errors: Injection delivery is a recognised high-risk intervention. WHO emphasises the pivotal role of structured training, compliance monitoring, and supportive safety tools to eliminate medication errors and adverse events

Growth Drivers

The growth of injectables is expected to be one of the fastest across all drug delivery formats, primarily due to the following factors:

Rising prevalence of chronic diseases

- There is a substantial increase in the prevalence of diabetes and other chronic diseases, for which treatment is primarily administered through injectables. According to International Diabetes Federation, Diabetes caused at least $1 trillion in health expenditure – a 338% increase over the last 17 years. 589 million adults (20-79 years) are living with diabetes and this figure is predicted to rise to 853 million by 2050. Consequently, there is an increase in the demand for injectables.
- Most chemotherapy drugs are delivered through injectables, which is one of the key growth drivers of injectables globally. According to the WHO – International Agency for Research on Cancer Fact Sheet, over 35 million new cancer cases are predicted in 2050, a 77% increase from the estimated 20 million cases in 2022.

Convenience and benefits of New Drug Delivery Systems ("NDDS")

- There is a rising demand for self-administered medications, which has now become a significant trend. The development of new injectable delivery devices such as auto injectors, pen injectors, pre-filled syringes ("PFS") and needle-free injectors has led to increased access to self-administered medications. These NDDS offer greater convenience and safety while self-administering, as well as allow patients to reduce the frequency of their hospital visits.

Rise of Lyophilised Injectables

- Lyophilised (freeze-dried) injectable formulations are gaining prominence due to enhanced stability, cold-chain independence, and logistical efficiency crucial for biologics, vaccines, and oncology drugs. FDA approvals for these freeze-dried drugs and biologics have surged by over 300% since the 2000s. Their extended shelf life makes them essential for stockpiling, evidenced by over 70% of antibiotics on the Essential Medicines List being supplied in this form. Lyophilisation also accelerates market access for innovative drugs, like the cancer immunotherapy Keytruda, which reached patients years sooner via lyophilisation while stable liquid formulations were developed. Despite manufacturing capacity challenges and their representation in drug shortages, demand continues to grow, prompting industry expansion and exploration of advanced technologies to meet future needs.

Barriers to entry

Injectables manufacturing is characterised by significant entry barriers, including high capital requirements, elevated operating costs, complex production processes, and stringent regulatory compliance owing to the sterile nature and rigorous quality standards of these products. As a result, competition in this segment remains more limited compared to other pharmaceutical categories. The specialised expertise required across development, formulation, and large-scale sterile manufacturing makes injectables a niche domain within the broader pharmaceutical industry, with only a select group of companies possessing the capability to operate effectively in this space. The high capital investment is ultimately necessary to ensure adherence to quality standards. However, relative to adding a new injectable facility, the addition of new injectable lines is much less capital-intensive.

High capital investments

- The capital investment for an injectables manufacturer is higher compared to that for oral solids. Injectable plants require 1.3-1.5 times more capital expenditure than oral solids plants. The high capital investment is necessary to ensure adherence to quality standards and minimise errors.

- **Machinery:** The cost of machinery, self-contained manufacturing lines, adherence to terminal sterilisation and/or aseptic manufacturing with sterile fill finish increases the capital expenditure for injectables plants. The cost associated with planning aseptic processes from drug components to packaging is high due to the use of aseptic processing isolators, which separate the materials inside them from the external cleanroom environment and minimise exposure to personnel.
- **Technology:** The capital expenditure for injectables manufacturing is high due to the type of automation systems that may be required for high-quality and sterility standards. Automation systems help reduce errors and ensure efficient processes. Sterile fill-finish equipment is designed to minimise the requirement for human intervention. Fillers in the machinery have automated vision systems to sort and process vials. Sterilise-In-Place technology allows for the sterilisation of equipment.
- **Lyophilisation:** Many parenteral drug products undergo sterile lyophilisation (i.e. freeze-drying) to generate a stable powder for storage and transport. Large-scale lyophilisers and the associated cleanroom facilities to accommodate sterile fill finish increase the capital expenditure cost.

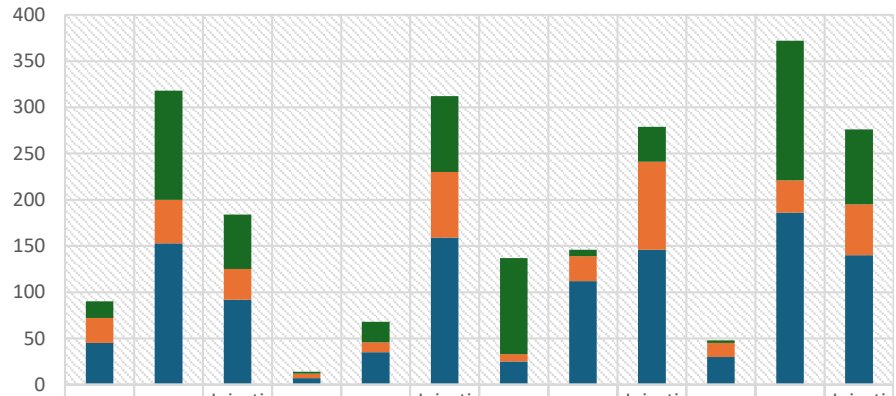
Manufacturing complexities to meet the stringent quality norms

- Injectables require strict manufacturing processes across development, packaging, storage and transport. The complexities involved in the manufacturing processes with stringent quality norms increase operational costs and make it a critical entry barrier for pharmaceutical companies.
- **Sterilisation:** Sterilisation is done through terminal sterilisation, aseptic manufacturing or sterile fill finish methods. With newer complex formulations, many products or containers cannot be terminally sterilised due to degradation of the drug product. Sterilisation is done across drug components to the packing material. Clean room facilities (highest level of air quality, class 100) are required for sterile fill-finish process. Cross-checking through contamination studies is essential for the final formulated product.
- **Packaging:** Products which are packaged in plastic undergo extractable and leachable testing to ensure that no additives in the plastic contaminate the drug product. In addition, compatibility studies must be conducted to ensure that there are no interactions between the drug product or solution and the glass, plastic container or rubber stoppers.
- **Stability:** The stability of injectables is assessed and maintained at every stage of development. Unlike most oral solids, injectables such as cold storage injectables are monitored after development and packaging for stability during transportation. Some formulations face stability issues in the liquid form and require lyophilisation to generate a stable powder form.
- **Key skills and knowledge:** Formulations that face stability issues in solution or ready-to-use form require sterile lyophilisation (freeze drying) to generate a stable powder form. Techniques used for lyophilisation require knowledge and skill specific to the process. Studies on crystal structure changes on freezing, heat transfer through a vial and temperature controls for a formulation are critical.
- **Personnel training:** Training activities for personnel involved in manufacturing sterile injectables are extensive and must be assessed regularly. Training and evaluation of personnel are critical to avoid contamination risks. Some processes are designed to limit human interventions, but processes followed by personnel in the cleanroom ensure sterility. An environmental monitoring team is also trained to detect any deviations and contaminations in aseptic monitoring. Costs associated with ongoing personnel training are high and increase operational costs in the facility.

Quality Requirements

- Quality standards for injectable manufacturers are more stringent due to the need for sterile products. Quality standards are evaluated and maintained across various stages of product development, formulation, packaging, storage and transportation. Multiple recent warning letters with USFDA cGMP norms have led to demands for good quality facilities.
- According to the latest data from the U.S. Food & Drug Administration (FDA) and the American Society of Health-System Pharmacists (ASHP), injectable medications account for approximately 6% of all active drug shortages of 271 in the United States as of 2024. A recent FDA study of number of new drug shortages per calendar year has declined from a high of 251 in 2011 to 55 in 2023. 40% of these shortages were attributed to quality issues (FDA, 2024; ASPE, 2024). The complexity of sterile manufacturing, limited supplier redundancy, and heightened quality compliance requirements continue to place injectable drugs at elevated risk of shortage. Despite federal efforts to enhance supply chain resilience, injectable products remain one of the most vulnerable categories in the U.S. pharmaceutical ecosystem.

FIGURE 15. DRUGS SHORTAGES BETWEEN 2020 AND 2023, BY YEAR, BRAND STATUS, AND DOSAGE FORM



	Topical	Oral	Injection	Topical	Oral	Injection	Topical	Oral	Injection	Topical	Oral	Injection
	2020			2021			2022			2023		
Number of Drug Shortages (9-digit NDCs), Dosage Form, Generics	18	118	59	2	22	82	104	7	38	3	151	81
Number of Drug Shortages (9-digit NDCs), Dosage Form, Brands	27	47	33	5	11	71	8	27	95	15	35	55
Number of Drug Shortages (9-digit NDCs), Dosage Form, All Drugs	45	153	92	7	35	159	25	112	146	30	186	140

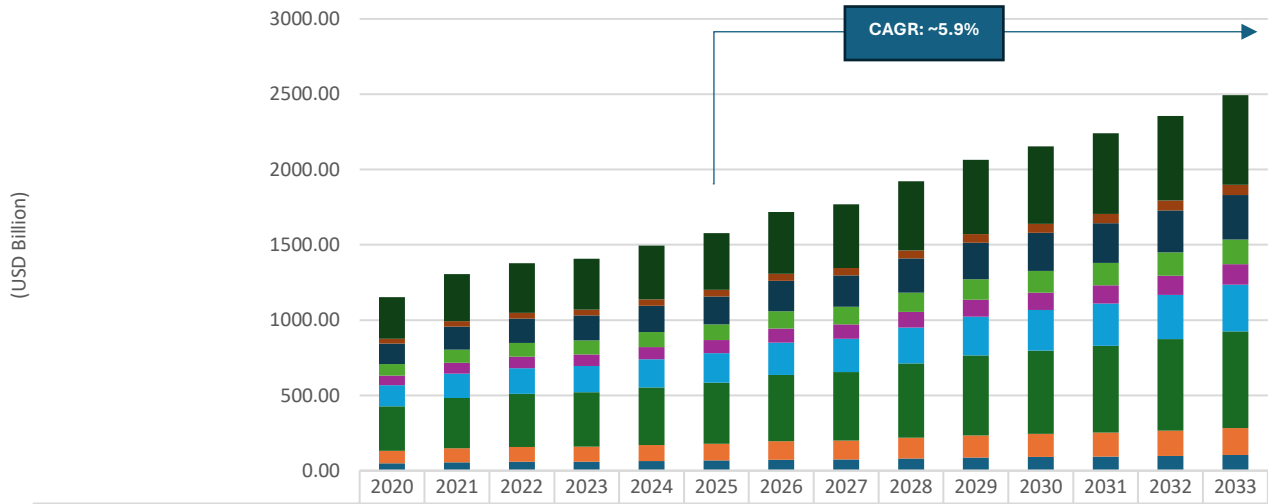
Source: FDA, U.S. Department of Health and Human Services (HHS), Marketysers analysis

Global Drug Formulation Market by Therapeutic Area

Chronic diseases like cancer, diabetes, Infectious diseases and Cardiovascular (CVS) dominate the global Drug formulation market with a combined market share of 49% in 2024. Cancer, Diabetes and autoimmune diseases are forecasted to be the fastest-growing therapeutic areas with a CAGR of ~6% between 2024 and 2033.

The global prevalence of chronic diseases has been on a steady rise in recent years, presenting a significant public health challenge. Factors such as unhealthy lifestyle choices and increasing urbanisation have contributed to this growth. Conditions like cardiovascular diseases, diabetes, and cancer are becoming increasingly common, creating a substantial demand for pharmaceutical drugs for nearly lifelong use. As a result, chronic diseases like cancer and diabetes are forecasted to grow the fastest between 2025 and 2033.

FIGURE 16. GLOBAL DRUG FORMULATION INDUSTRY BY THERAPEUTIC AREA (2020-2033P, $ BN)



	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Others	276.22	312.65	330.05	336.93	357.91	377.69	411.16	423.20	459.37	493.51	514.57	535.06	562.75	595.45
Dermatological Disorders	32.27	36.46	38.46	39.25	41.65	43.92	47.76	49.13	53.27	57.17	59.58	61.92	65.07	68.80
Autoimmune Diseases	134.82	152.91	161.57	165.00	175.45	185.31	202.02	208.04	226.13	243.23	253.79	264.08	277.99	294.43
Central Nervous System Disorders	76.75	86.82	91.63	93.53	99.32	104.79	114.03	117.35	127.34	136.76	142.57	148.22	155.86	164.87
Respiratory Diseases	63.61	71.79	75.68	77.22	81.91	86.33	93.79	96.47	104.51	112.08	116.75	121.28	127.40	134.63
Diabetes	142.08	161.26	170.44	174.08	185.17	195.65	213.39	219.79	239.01	257.19	268.43	279.37	294.17	311.67
Cancer	295.00	334.42	353.28	360.75	383.50	404.98	441.35	454.45	493.81	531.01	553.97	576.34	606.58	642.31
Cardivascular Diseases	82.05	92.95	98.15	100.22	106.50	112.43	122.47	126.08	136.94	147.19	153.52	159.68	168.01	177.84
Infectious Diseases	49.55	55.86	58.86	60.04	63.65	67.04	72.78	74.84	81.01	86.82	90.40	93.87	98.56	104.09

Source: Marketysers analysis

Risk and Challenges in Global Drug Formulation market

The following are risk and challenges in the global pharmaceutical industry:

- **Regulatory, Compliance and Quality:** Regulatory, compliance, and quality considerations collectively represent a critical and ongoing challenge for the global pharmaceutical industry. As companies pursue innovation through advanced therapies, digitalisation, and cutting-edge manufacturing technologies, they must also navigate increasingly complex regulatory frameworks that vary significantly across regions. These inconsistencies can hinder product approvals, delay market entry, and increase compliance burdens. Simultaneously, the integration of emerging technologies such as AI, machine learning, and advanced analytics introduces new regulatory ambiguities, particularly around data integrity, system validation, and oversight. Ensuring robust quality across the product lifecycle is further complicated by the need for greater transparency, proactive risk management, and adherence to evolving expectations around Quality Management Maturity (QMM).
- **Intellectual Property Protection:** Intellectual property (IP) protection serves as a crucial driver for private-sector investment in pharmaceutical innovation. However, this model becomes increasingly complex when addressing the needs of populations in markets with limited commercial potential. Low- and middle-income countries (LMICs), despite representing over 80% of the global population, account for a disproportionately small share, approximately 10%, of global pharmaceutical sales. This disparity stems from economic constraints that limit both purchasing power and access to essential medical products. In such environments, reduced effective demand often diminishes the commercial interest of profit-driven entities. Furthermore, global intellectual property frameworks provide certain flexibilities that, if effectively utilised, can support broader access to vital medicines.
- **Pricing Pressures:** Pharmaceutical pricing remains a contentious issue globally, with governments, insurers, and consumers exerting pressure to control healthcare costs. These cost escalations pose significant risks for manufacturers, especially in markets where price sensitivity and affordability are already pressing concerns. Generic drug producers, who typically operate on narrow profit margins are especially vulnerable. Increased active pharmaceutical ingredient (API) costs may compel some firms to scale back operations or withdraw from the market altogether, potentially reducing competition and contributing to price inflation. Branded pharmaceutical players, while more resilient due to higher margins, are not entirely insulated. Over time, increased operational and supply chain costs could cascade through the ecosystem, affecting insurers, healthcare providers, and ultimately, patients. Adding to these, Reimbursement challenges, pricing negotiations, and the rise of generic competition can further erode profit margins and impact the commercial viability of pharmaceutical products.
- **Market Access and Distribution:** Accessing diverse markets and establishing efficient distribution channels present formidable challenges for pharmaceutical companies, especially in emerging economies with fragmented healthcare systems. Regulatory hurdles, logistical complexities, and cultural considerations can impede market entry and distribution efforts.
- **Supply Chain Disruptions:** As evidenced during the pandemic, the global pharmaceutical supply chain is susceptible to disruptions stemming from various factors, including natural disasters, geopolitical tensions, and pandemics. Ensuring the resilience and continuity of the supply chain, including sourcing raw materials and managing manufacturing capacities, is critical to mitigate risks and maintain product availability.

Global CDMO Market

Today, Contract Development and Manufacturing Organisations (CDMOs) provide critical support across the value chain — from formulation development, analytical testing, and process optimisation to scale-up and commercial manufacturing.

The CDMO industry spans services in both drug development and commercial manufacturing. Traditionally, pharmaceutical companies focused on high-volume blockbuster drugs and engaged CDMOs primarily to expand production capacity. However, as the industry has shifted toward precision medicine, specialty indications, and complex therapies, CDMOs are increasingly viewed as strategic partners rather than just vendors.

TABLE 3. GLOBAL CDMO SERVICE SPECTRUM

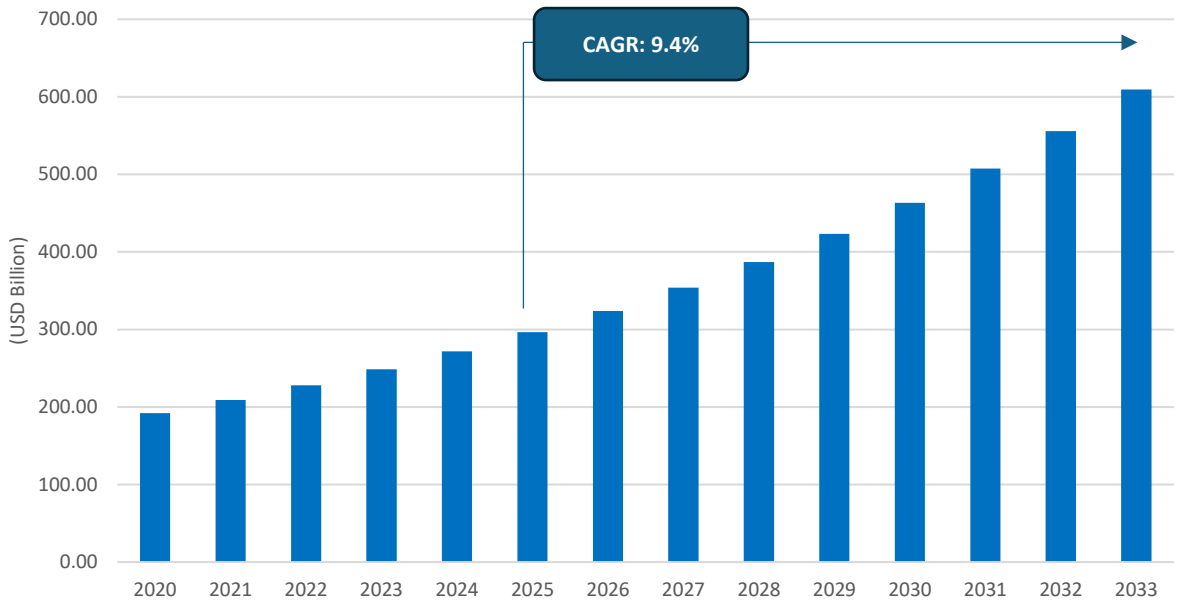
	CRO Services	Core CDMO Services			
	Drug Discovery	**Development**	**API Manufacturing**	**FDF**	**Packaging/Distribution**
Service Offering Focus	Target identification	Hit to lead	Extraction	Formulation and analytical development	Primary packaging (e.g., blister strip, bottle, prefilled syringe)
	Lead discovery	Sourcing	Synthesis	Oral Solids and Liquids	Secondary packaging (e.g., box, carton)
	Medical chemistry	Cell line development	Fermentation	Sterile and injectables	Tertiary packaging (e.g., barrel, container)
	Preclinical studies: In vitro	Scale up	HPAIs/Cytotoxic substances	Nutraceuticals and cosmetics	Specialty packaging
	Preclinical studies: In vivo	Technology transfer	Other Methods	NDDS and novel formulations	Direct to patient
		Process analytics development		Potent and niche products	Cold chain/Controlled temperature
Scale	**Pilot scale**	Small-scale production(preclinical to phase II)			
		Large-scale production (phase III, commercial)			

Source: *Marketysers analysis*

Pharma innovators now rely on CDMOs not only for cost efficiency but also for specialised expertise, advanced manufacturing technologies, and flexible capacity. The growing pipeline of complex drugs, coupled with rising demands for speed, quality, and regulatory compliance, has further accelerated outsourcing. Strong R&D and technical infrastructure, availability of skilled scientific talent, and a proven record of regulatory compliance remain key success factors for CDMOs.

The global CDMO market was valued at around $192 billion in 2020 and estimated to expand to $297 billion in 2025. It is forecast to reach over $609 billion by 2033, representing a CAGR of 9.4% over the period.

FIGURE 17: GLOBAL CDMO MARKET, 2020-2033P, $ BN



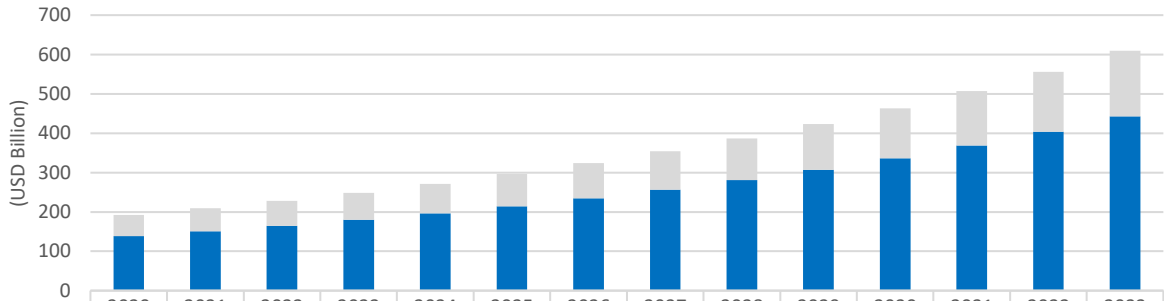
Source: Marketysers analysis

In the global CDMO market, small molecules continue to dominate, accounting for over 70% of the market, as they remain the backbone of pharmaceutical treatments across a wide range of diseases. While biologics and advanced therapies are expanding rapidly, small molecules continue to benefit from broad therapeutic applicability, increasing outsourcing penetration, and rising complexity in synthesis and formulation.

In 2025, the small molecule CDMO market is estimated at $215 billion, compared to $82 billion for biologics. Looking ahead, small molecules are projected to expand to $443 billion by 2033, reflecting a CAGR of ~9.5% between 2024 and 2033. Biologics CDMOs, while starting from a smaller base, are expected to grow at ~9.2% CAGR — from $82 billion in 2025 to $166 billion in 2033.

This trend highlights small molecules will continue to hold the dominant position in the global CDMO market through 2033.

FIGURE 18: MARKET SIZE OF CDMO MARKET, BY MODALITY, 2020-2033P, $ BN

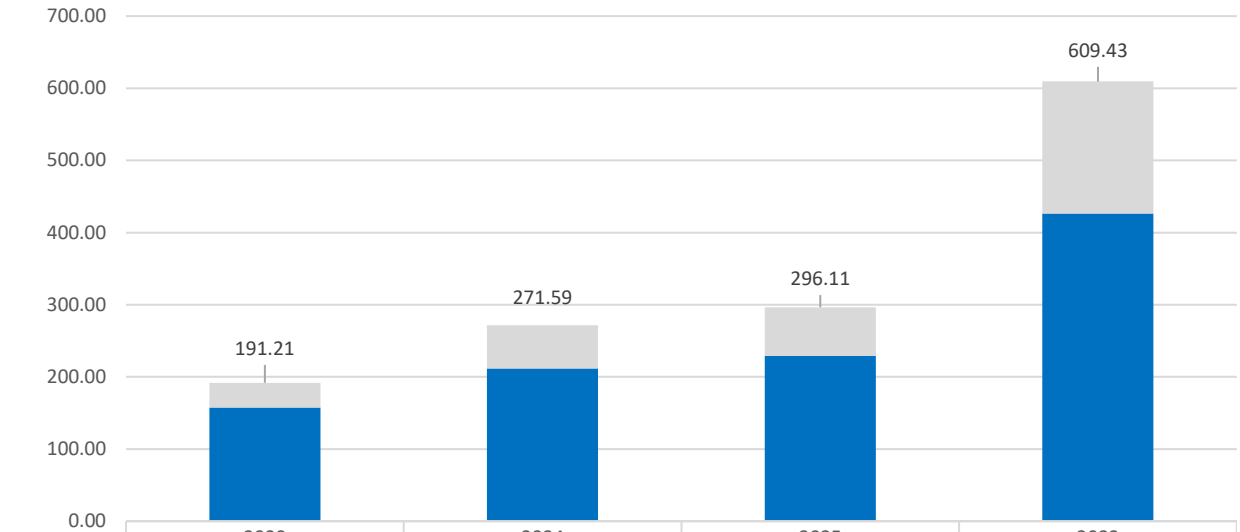


	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Biologics	53	58	63	69	75	82	89	98	106	116	127	139	152	166
Small Molecules	138	151	165	180	196	215	235	257	281	307	336	369	404	443

Source: Marketysers analysis

The CDMO market continues to be dominated by regulated markets, which is estimated to account for over 75% of global revenues in 2025 and are expected to maintain their leadership through 2033, driven by robust innovation pipelines and strict compliance requirements. However, the contribution of emerging markets is set to increase from around 23% in 2025 to 30% by 2033, supported by cost advantages, expanding technical capabilities and improving regulatory track records in countries such as India and China. By 2033, the overall market is projected to more than double in size, with regulated markets remaining the largest segment while emerging markets grow at a faster pace.

FIGURE 19: MARKET SIZE OF CDMO MARKET IN REGULATED AND EMERGING MARKETS, 2020-2033P, $ BN



	2020	2024	2025	2033
Emerging	34.38	59.75	67.54	182.83
Regulated	157.51	211.84	229.05	426.60

Source: Marketysers analysis

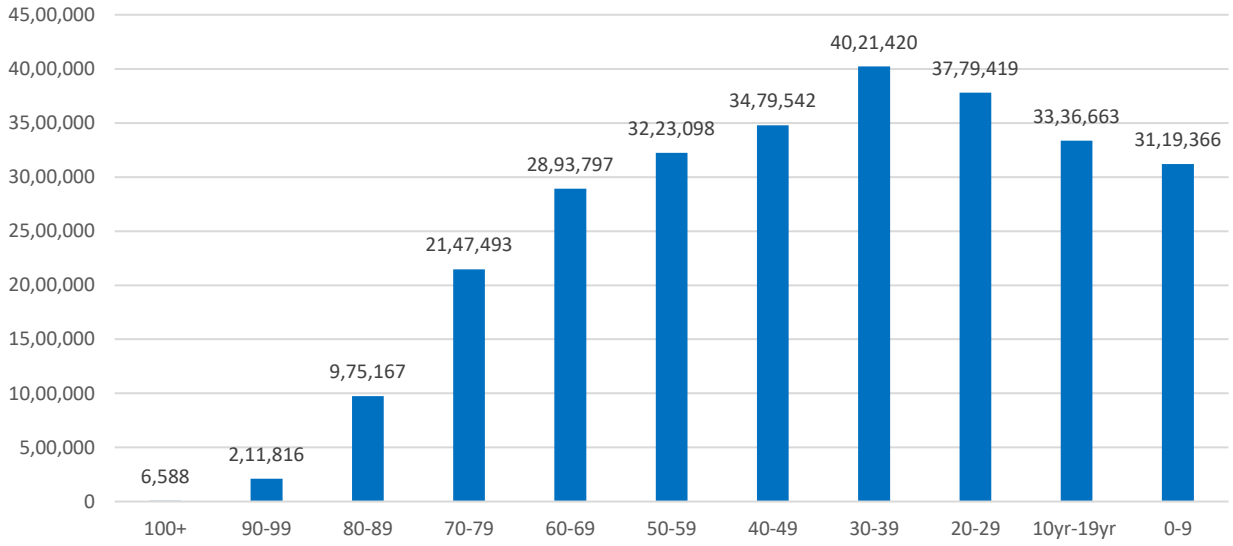
Australian and New Zealand Pharmaceutical market

The pharmaceutical industry across Australia and New Zealand is undergoing robust expansion, characterised by strong government support, increasing reliance on generics and an ageing population driving sustained demand for drug formulation.

The pharmaceutical markets in Australia and New Zealand are propelled by several interconnected factors:

- **Aging Population:** Both countries are experiencing a rapidly aging population, which significantly drives the demand for pharmaceutical products, particularly for chronic diseases and aged care. As the number of seniors increases, so does the need for prescription medications, OTC drugs, and health-related products, necessitating expanded pharmacy services and specialised care. Australia's population aged 85 and over is projected to grow by 180% from 2021 to 2041, directly increasing the demand for pharmaceuticals related to older people.

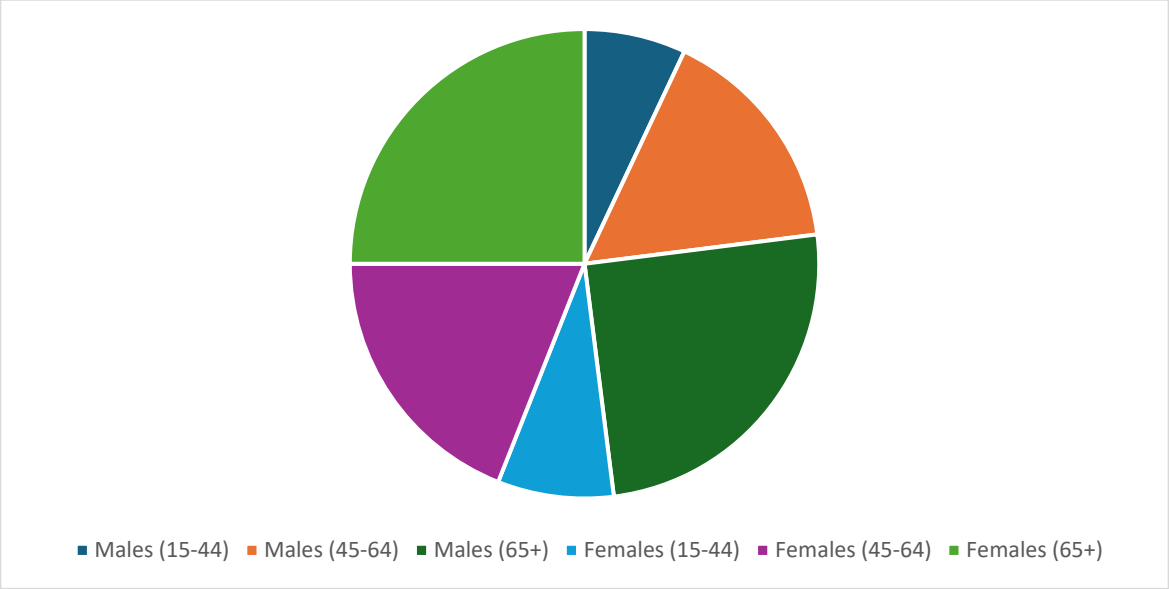
FUGURE 20. DEMOGRAPHIC SNAPSHOT, AT JUNE 2024 BY AGE



Source: aihw.gov, World Health Organisation (WHO), Centers for Disease Control and Prevention (CDC), Marketysers analysis

- **Rising Prevalence of Chronic Diseases:** The 2023 AIHW shows that chronic disease in Australia is increasing at an alarming rate. Almost half of adult Australian males have one or more of the 10 most common chronic conditions. About 1 in 3 males aged 15 and over have one chronic condition, 13% have two and 7% have three or more. The number living with chronic disease increases with age. 37% of males aged 15–44 have one or more chronic conditions, followed by 53% of males aged 45–64, and 75% of Aussie men aged 65 or older will experience at least one chronic condition.

FIGURE 21. CHRONIC DISEASE RATES BY AGE & GENDER (ESTIMATED PERCENTAGES)



Source: Marketysers analysis

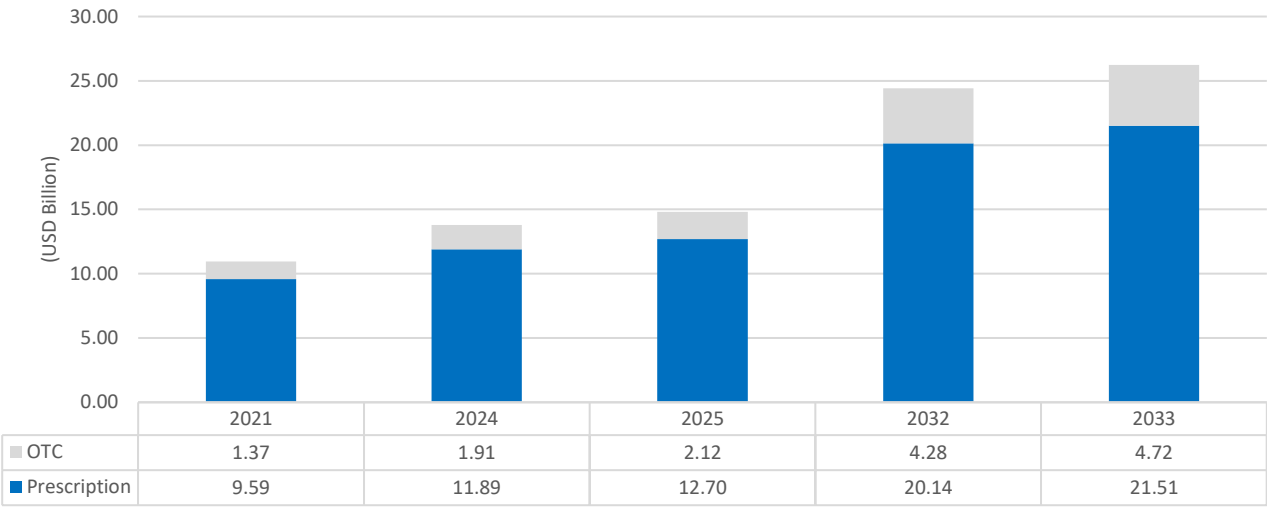
- **Government Support and Healthcare Funding:** Government initiatives play a crucial role in market growth. Australia's Pharmaceutical Benefits Scheme (PBS) ensures affordable access to essential medicines, subsidising prescription drugs and reducing out-of-pocket expenses for patients. In June 2024, the Australian government expanded the PBS to allow 60-day prescriptions, further reducing costs for patients with chronic conditions. Similarly, New Zealand's PHARMAC system, despite its unique funding model, ensures broad access to medicines. Significant investments in healthcare infrastructure and R&D tax incentives also foster market growth.

Australia Pharmaceutical Market Overview

Australia’s drug formulations market has become a resilient and essential pillar of the national healthcare system. Backed by a robust regulatory framework, significant public investment, and rising healthcare demand, the industry has steadily expanded over the past decade.

The market is broadly segmented into Prescription (Rx) and Over-the-Counter (OTC) medicines. Prescription drugs remain the dominant category, estimated at ~$13 billion in 2025 and forecasted to grow to ~$22 billion by 2033. The OTC segment, while smaller, is expanding at a faster pace, increasing from about $2 billion in 2025 to nearly $5 billion in 2033. Together, these segments form the foundation of Australia’s pharmaceutical market, with branded drugs capturing early share through innovation and exclusivity, while generics and private-label products drive long-term affordability and volume growth.

Figure 22. AUSTRALIAN PHARMA MARKET, BY OTC AND PRESCRIPTION, 2021-2033P, $ BN



	2021	2024	2025	2032	2033
OTC	1.37	1.91	2.12	4.28	4.72
Prescription	9.59	11.89	12.70	20.14	21.51

Source: Marketysers analysis

Market Segmentation

- **Prescription Medicines (Rx):** These products are dispensed only under the supervision of a healthcare professional and are typically prescribed for chronic or complex conditions. Rx drugs span diverse therapeutic categories—from oncology and immunology to cardiology and antivirals—and are subject to rigorous safety, efficacy, and approval protocols.
- **Over-the-Counter (OTC) Medicines:** Designed for the management of everyday health concerns, OTC medicines are readily accessible to consumers without a prescription. They are generally considered safe when used as directed and include common categories such as analgesics, cold and cough formulations, allergy relievers, and dermatological products.

TABLE 4. FINANCIAL PROFILE SNAPSHOT

Attribute	Branded Products	Private Label (Generic)
R&D spend	High	Minimal
Marketing costs	Intensive (physician and consumer-facing)	Low
Price realisation	Premium	Competitive/Volume-driven
Market share trends	Driven by innovation cycles	Driven by public health policies
Revenue lifecycle	Peaks during exclusivity period	Stable with long-tail opportunities

Source: Marketysers analysis

Emerging Trends in the Australian Pharmaceutical Market

While traditional oral solid dosage forms—such as tablets and capsules—remain dominant due to their convenience and ease of distribution, there's an increasing market shift toward more specialised formulations:

- **Injectables** – Critical for therapies requiring rapid bioavailability or targeted delivery, especially in hospital settings.
- **Topical Agents** – Including creams, gels, and sprays, see widespread use in skin conditions and localised pain.

- **Novel Dosage Forms** – Controlled-release tablets, nasal sprays, and dissolvable films are gaining ground for their enhanced compliance and user-friendly profiles.

These advancements reflect consumer expectations for personalised and effective treatment modalities across therapeutic areas.

Outlook by Therapeutic Area

The Australian pharmaceutical market is comprehensively segmented by Anatomical Therapeutic Chemical (ATC) classification or therapeutic class, covering a broad spectrum of disease areas. Key segments identified include Alimentary Tract and Metabolism; Blood and Blood Forming Organs; Cardiovascular System; Dermatological; Genito Urinary System and Sex Hormones; Systemic Hormonal Preparations; Anti-infectives and Immunomodulating Agents; Musculoskeletal System; Nervous System; and Respiratory System.

The Alimentary Tract and Metabolism segment has consistently held the largest market share, accounting for over 20% of the total market in both 2023 and 2024. This dominance is primarily attributed to the high prevalence of conditions such as diabetes, affecting approximately 4.3% of Australians with Type 1 and 2.9% with Type 2 diabetes in 2023, alongside various gastrointestinal disorders. The Cardiovascular System segment also commands a significant share, exceeding 15%, reflecting the ongoing and substantial demand for treatments addressing prevalent conditions like hypertension and heart disease.

TABLE 5: AUSTRALIA PHARMACEUTICAL MARKET SEGMENTATION BY THERAPEUTIC AREA (2024)

Therapeutic Area	Market Share (2024)	Key Conditions Driving Demand
Alimentary Tract & Metabolism	> 20 % (Largest share)	Diabetes (Type 1 & Type 2), Gastrointestinal Disorders
Cardiovascular System	> 15 % (Substantial share)	Hypertension, Ischemic Heart Disease, Stroke
Oncology (Cancer)	Significant contribution	Solid Tumors, Hematologic Malignancies, Emerging Targeted & Immuno-Oncology Agents
Infectious Diseases	Significant contribution	Bacterial & Viral Infections, Immunisations, Rising Antimicrobial Resistance
Respiratory System	Notable share	Asthma, Chronic Obstructive Pulmonary Disease (COPD), Allergic Rhinitis
Central Nervous System (CNS) Disorders	Moderate share	Epilepsy, Alzheimer's, Parkinson's, Depression
Autoimmune Diseases	Moderate share	Rheumatoid Arthritis, Lupus, Psoriasis, Multiple Sclerosis
Dermatological Disorders	Moderate share	Eczema, Psoriasis, Acne, Fungal Infections
Blood & Blood Forming Organs	Emerging share	Anemia, Hemophilia, Coagulation Disorders
Genito-Urinary & Sex Hormones	Emerging share	Hormone Replacement, Prostate Disorders, Contraception
Systemic Hormonal Preparations	Niche	Endocrine Disorders, Corticosteroid Therapies
Musculoskeletal System	Niche	Osteoporosis, Arthritis, Muscle Disorders
Others (incl. OTC & Minor Therapeutic Areas)	Aggregated minor share	Allergies, Cold & Cough, Pain Relief, GI Upset, Minor Skin Ailments, Rare/Orphan Conditions

Source: Marketysers analysis

As patients seek more accessible care options and quicker relief, OTC segments in these categories are expected to see sustained volume growth—while prescription options will continue to support chronic and complex case management.

TABLE 6. AUSTRALIA'S AGING POPULATION AND INCREASING CHRONIC DISEASE PREVALENCE ARE CATALYSING DEMAND ACROSS SEVERAL KEY THERAPEUTIC AREAS

Therapy Area	Growth Catalysts
Pain Management (Analgesics)	Aging demographics, arthritis, musculoskeletal disorders
Cold & Cough Remedies	Seasonal influenza patterns, allergy sensitivity, respiratory infections
Dermatological Treatments	High demand for antifungal, antibacterial, and acne-related solutions
Respiratory & Allergy Medications	Lifestyle-related respiratory issues, increased adoption of nasal and inhaler formats

Source: Marketysers analysis

The Australian Over-the-Counter (OTC) pharmaceuticals market is undergoing structural transformation, driven by heightened consumer self-medication trends, greater accessibility through pharmacy and retail channels, and increasing demand for symptom-targeted healthcare solutions. Among various therapeutic segments, Analgesics, Cold & Cough Remedies, Other OTC Pharmaceuticals, and Skin Treatment products are witnessing sustained momentum, underpinned by rising consumer awareness, convenience-driven usage, and broader acceptance of OTC medications for everyday ailments.

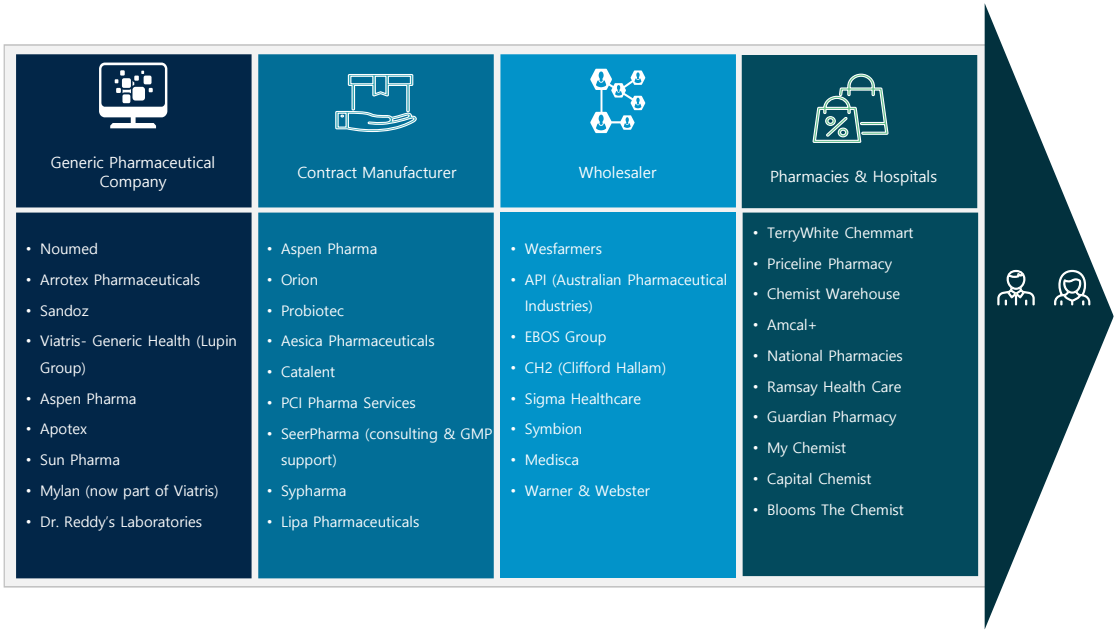
TABLE 7: AUSTRALIAN OTC PHARMACEUTICALS MARKET – SEGMENT DYNAMICS

Segment	Market Drivers & Trends	Outlook
Analgesics	• High demand for paracetamol/ibuprofen-based pain relief (musculoskeletal, menstrual, headaches) • Growth in dual-action and fast-acting variants • Rising preference for natural/low-risk alternatives	Sustained growth; strong pharmacy channel sales
Cold & Cough Remedies	• Seasonal resilience, stable long-term volumes • Demand for multi-symptom formulations • Niche paediatric category with sugar-free/non-drowsy options • Intensifying private label competition	Stable; innovation in multi-symptom products
Digestive & Other OTC	• Growth in digestive health (antacids, probiotics, laxatives) • Rising demand for sleep aids & stress-relief (herbal/non-habit forming) • Expanding nicotine replacement therapies (NRTs)	Moderate growth; fragmented but innovation-driven
Skin Treatments	• Core demand for corticosteroids, antifungals, acne solutions • Blurring lines between cosmeceuticals & OTC dermatology • Strong pharmacy-led recommendations	Growing; driven by therapeutic skincare demand

Source: Marketysers analysis

Competitive Landscape

FIGURE 23. SUPPLY CHAIN ANALYSIS



Source: Marketysers analysis

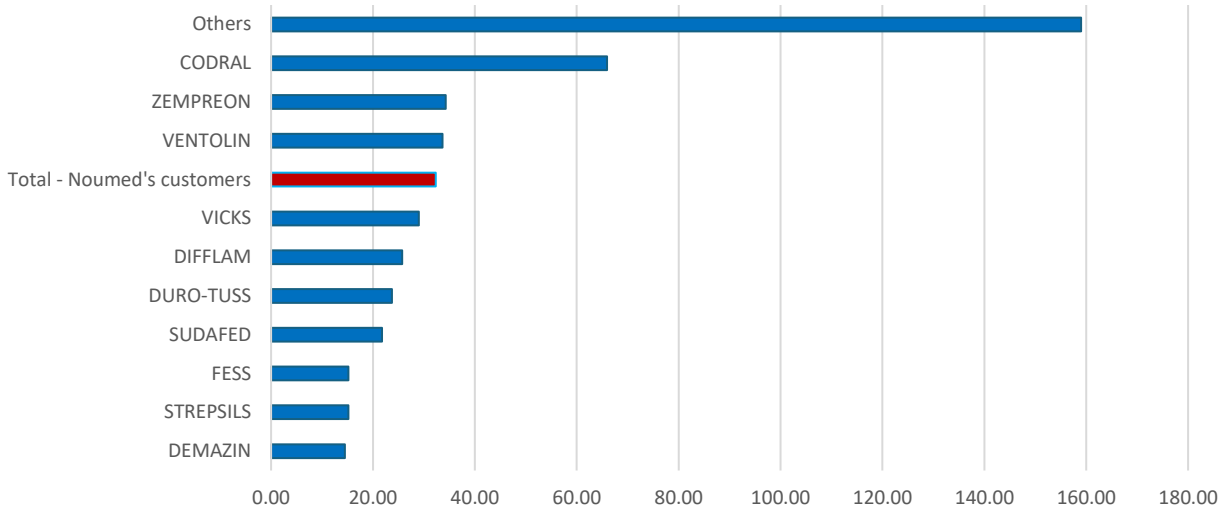
Australia's pharmaceutical market is competitive, characterised by the presence of large multinational generics companies, strong domestic players, and a growing cohort of specialty and OTC manufacturers. The industry is undergoing a clear shift toward affordability, resilience, and localised innovation, driven by regulatory reforms and government incentives to strengthen domestic manufacturing.

Within this context, Noumed Pharmaceuticals Pty Limited is positioning itself as a differentiated player by focusing on value-driven, high-volume therapeutic segments across both OTC and prescription categories. The company's strategy emphasises:

- 40-50%+ market share of private label OTC pharmaceutical products
- 451 dossiers
- Broad portfolio development across chronic and high-frequency conditions.
- Vertical integration of manufacturing and distribution, reducing reliance on third-party contract manufacturers.
- Establishment of an Adelaide manufacturing facility, providing supply chain control, cost efficiency, and alignment with the Australian government's Modern Manufacturing Initiative.

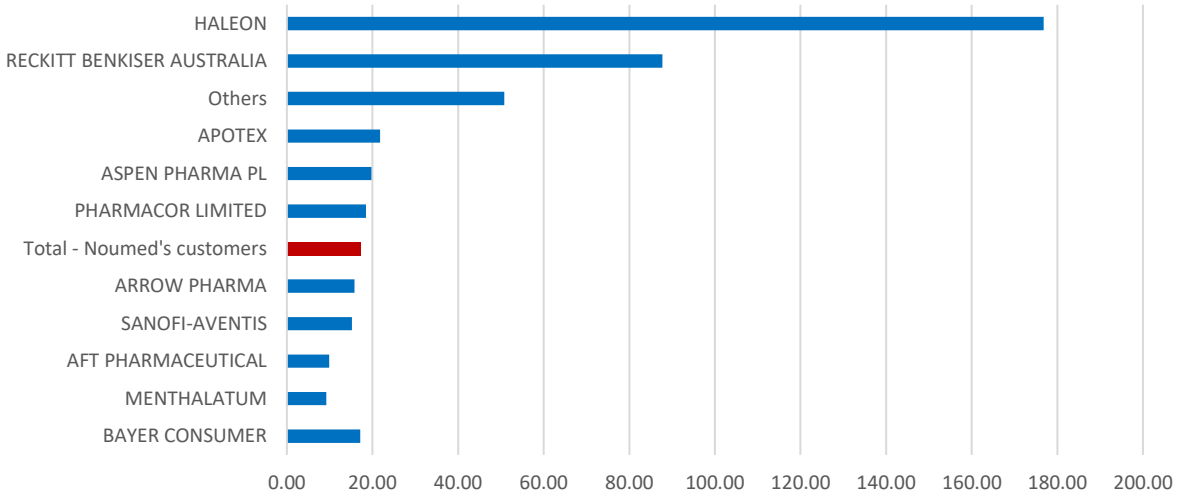
Noumed is expected to outpace the industry average, particularly in high-growth categories such as analgesics, dermatology, and cold & cough remedies, as healthcare systems continue to prioritise high-quality generics and cost-effective treatment solutions.

FIGURE 24. AUSTRALIAN COLD & FLU MARKET BY BRAND (AUD MN)



Source: Marketysers analysis

FIGURE 25. AUSTRALIAN PAIN RELIEF MARKET BY COMPANY (AUD MN)



Source: Marketysers analysis

Key Players

1. Generic Pharmaceutical & OTC Medicine Companies:

- Arrotex Pharmaceuticals – One of the largest generic medicine suppliers in Australia.
- Alphapharm (a subsidiary of Mylan, now part of Viatris) – A major player in generic pharmaceuticals.
- Apotex Australia – A leading generic drug manufacturer and distributor.
- Generic Health (now part of Arrotex) – Focuses on generic medicines.
- iNova Pharmaceuticals – Specialises in OTC and prescription medicines (e.g., Difflam, Demazin).
- PharmaCare (makers of brands like Nature's Way, Bioglan, and Sambucol) – Strong in OTC and wellness products.
- Blackmores – Known for vitamins and supplements but competes in the OTC healthcare space.
- Symbion (part of EBOS Group) – A major pharmaceutical wholesaler with some branded generic products.

2. Multinational Pharmaceutical Companies with Generic Divisions:

- Viatris (Mylan + Pfizer's Upjohn) – Operates in generics and branded generics.
- Sandoz (Novartis generics division) – A global generics leader with a presence in Australia.
- Teva Pharmaceuticals – Active in the Australian generics market.

3. Australian Pharmaceutical Distributors & Wholesalers:

- Sigma Healthcare – Distributes generic and branded pharmaceuticals.
- EBOS Group (including Symbion & TerryWhite Chemmart) – A major player in pharmaceutical distribution and retail pharmacy.

4. Niche & Specialty Pharma Competitors:

- Mayne Pharma – Focuses on specialty and generic pharmaceuticals.
- Aspen Pharmacare Australia – Known for branded generics and specialty medicines.
- Sanofi Consumer Healthcare (OTC products like Painaway, Betadine) – Competes in the OTC space.

As the sector evolves, the competitive dynamics are increasingly shaped by:

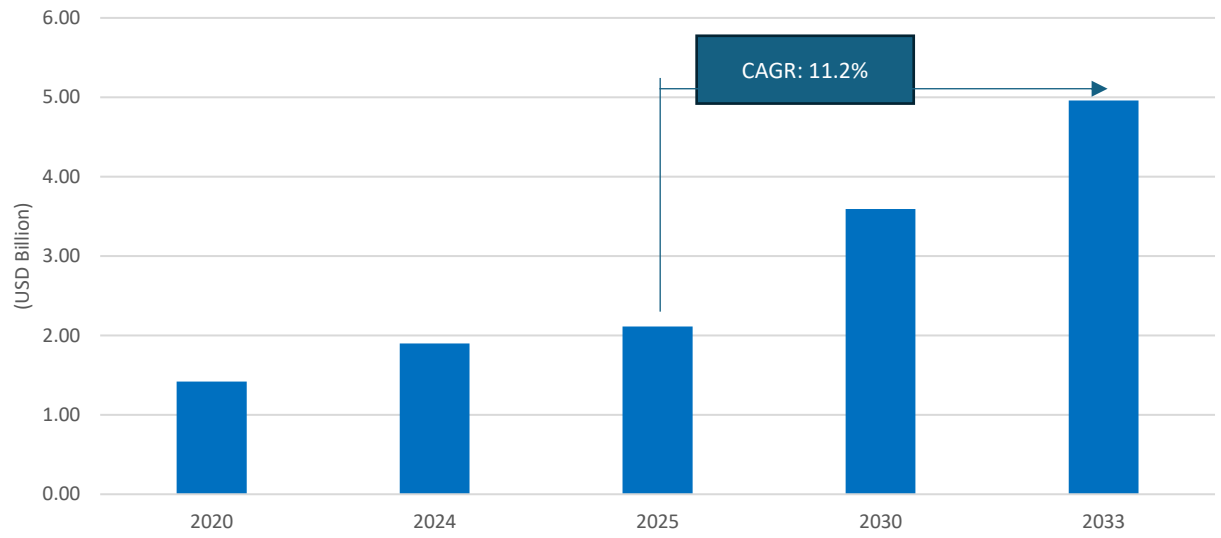
- PBS pricing reforms and regulatory harmonisation,
- Strategic alliances and licensing partnerships,
- Heightened focus on domestic manufacturing for critical medicines,
- Innovations in drug delivery systems and supply chain digitisation.

Australian CDMO Market

The Australia's CDMO market was estimated at ~$2 billion in 2024 and is expected to grow at a CAGR of 11.2% in terms of value in the forecast period 2025 to 2033.

The Contract Development and Manufacturing Organisation (CDMO) market in Australia is emerging as a strategic segment within the broader pharmaceutical and life sciences industry. As global pharma companies increasingly seek flexible, cost-effective, and compliant outsourcing solutions, Australia has positioned itself as a high-potential destination—particularly for small-to-mid scale production, early-stage development, and clinical supply manufacturing.

FIGURE 26: AUSTRALIAN CDMO MARKET, 2020-2033P, $ BN



Source: Marketysers analysis

Driven by a combination of government support, evolving regulatory standards, and a growing ecosystem of biotech and generics companies, the Australian CDMO landscape is steadily expanding. The demand for end-to-end services—from formulation development to finished dose manufacturing—has surged in recent years, spurred by the push for local sovereign manufacturing capability and the need to ensure supply chain resilience post-COVID.

Market Structure

The Australian CDMO market spans a wide range of services, typically categorised into:

- **Development Services**: Including pre-formulation studies, analytical development, scale-up, and clinical batch production. These capabilities are crucial for early-stage biotech firms and specialty pharma companies.
- **Manufacturing Services**: Covering commercial-scale production of oral solids, injectables, topicals, and sterile dosage forms. Both generics and specialty therapies are supported through this framework.
- **Packaging & Stability Services**: With growing importance for regulatory compliance, patient adherence, and temperature-sensitive products (e.g., biologics, ophthalmics).
- **Tech Transfer & Regulatory Support**: Including dossier preparation, TGA/EMA filing assistance, and lifecycle management to help international companies enter the ANZ region.

The majority of Australian CDMOs specialise in small-molecule development and manufacturing, though capabilities in biologics, sterile injectables, and high-potency APIs (HPAPIs) are gradually being built up. Several players are aligning their operations with international GMP standards to serve export markets, including Europe, Southeast Asia, and North America.

Growth drivers

Several key factors are propelling the growth of the CDMO sector in Australia:

- **Rising Biotech Activity**: Australia is home to a vibrant biotech sector, with over 400 clinical-stage companies that increasingly rely on outsourced R&D and GMP manufacturing partners to accelerate time-to-market.
- **Government Incentives and Sovereign Supply Push**: Policy frameworks such as the Modern Manufacturing Initiative (MMI) have provided direct funding support for pharmaceutical manufacturing infrastructure, enabling local CDMOs to scale operations and attract global clients.
- **Strong Clinical Trials Ecosystem**: With a globally recognised reputation for fast, high-quality clinical trials, CDMOs in Australia are often embedded early in drug development pipelines, providing clinical supply manufacturing services tied to local studies.
- **Stringent Regulatory Compliance**: The **Therapeutic Goods Administration (TGA)** enforces high-quality standards that align with EMA and PIC/S guidelines, enabling CDMOs to position themselves as globally compliant, export-ready manufacturing partners.
- **Shift Toward Virtual Pharma Models**: As lean biotech and generic companies move away from in-house manufacturing, demand for integrated CDMO support has grown significantly, especially in oral solid dose forms, injectables, and niche delivery platforms.

Outlook by Dosage Form

Over the next five years, the most robust growth is expected in the sterile injectables and high-value oral solid dosage segments, driven by expanding demand in oncology, CNS, and chronic care categories. Similarly, services supporting early-phase development, clinical packaging, and regulatory filings are projected to gain traction as smaller players continue to outsource non-core functions.

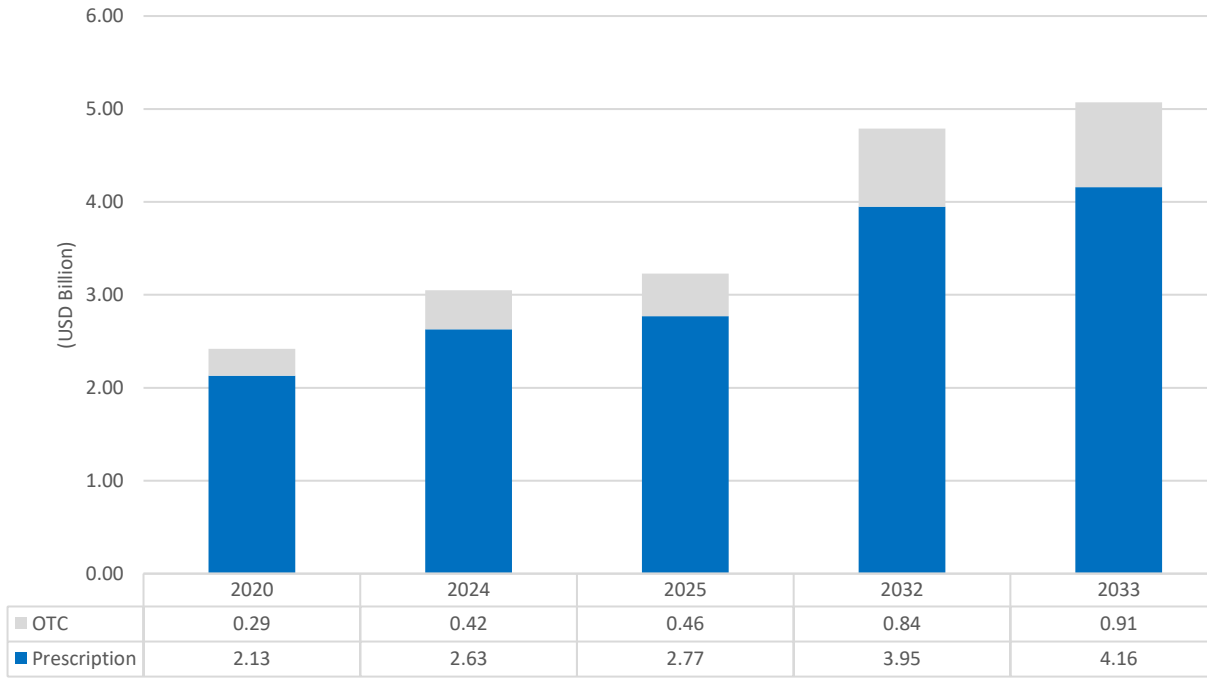
Additionally, controlled-release technologies, liquid-filled hard capsules, and modified-release tablets are anticipated to see demand increases, particularly in CNS and pain management therapies. The increasing incidence of chronic diseases, coupled with aging demographics and pressure on public health budgets, will further accelerate demand for high-quality, cost-efficient CDMO partnerships.

New Zealand Pharmaceutical Market Overview

New Zealand's pharmaceutical market is characterised by a distinct funding model and, historically, lower per capita pharmaceutical expenditure compared to many OECD countries, including Australia.

Despite the historical trends in per capita spending, specific segments within the New Zealand drug formulations market demonstrate robust growth. The Over-the-Counter (OTC)+Rx pharmaceuticals market is estimated to be valued at ~$3 billion in 2025 and is estimated to expand at a CAGR of 5.8% from 2025 to 2033, reaching $5 billion. This growth is driven by rising public awareness of general health issues and technological advancements in the pharmaceutical and healthcare sectors.

FIGURE 27: MARKET NEW ZEALAND PHARMA MARKET, BY OTC AND PRESCRIPTION MARKET, 2020-2033P, $ BN

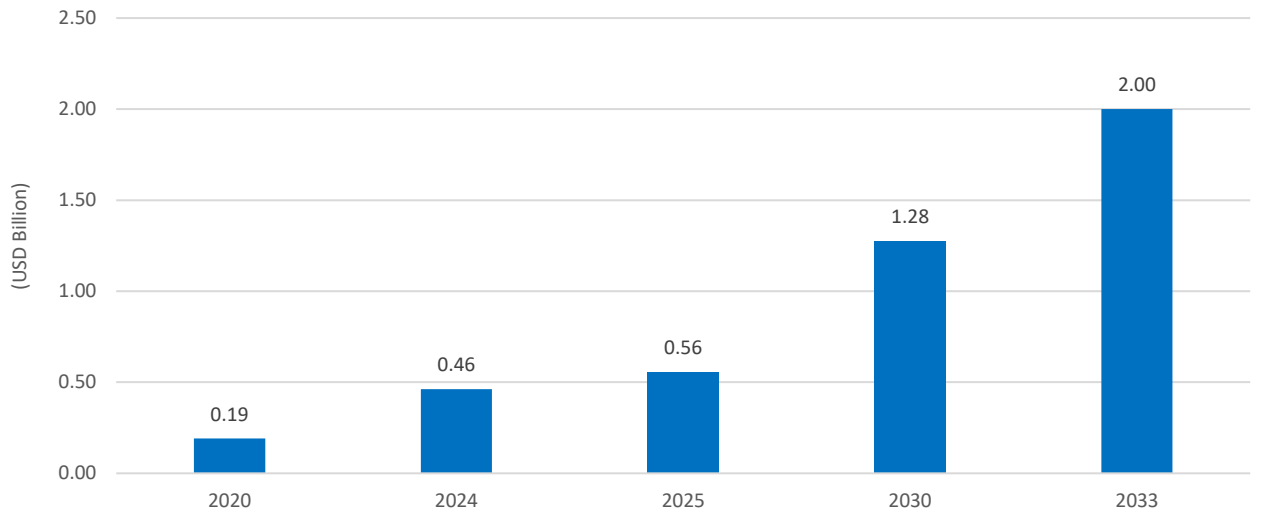


	2020	2024	2025	2032	2033
OTC	0.29	0.42	0.46	0.84	0.91
Prescription	2.13	2.63	2.77	3.95	4.16

Source: Marketysers analysis

Furthermore, the CDMO market in New Zealand is a significant and growing component, projected to rise from $0.56 billion in 2025 to $2.0 billion by 2033, representing a robust CAGR of ~17.3%. Contract manufacturing was the largest segment within this market, holding a revenue share of around 60% in 2023 and registering the fastest growth. This expansion is primarily attributed to the increasing prevalence of chronic and lifestyle diseases and the rising trend of outsourcing research and development processes.

FIGURE 28: NEW ZEALAND CDMO MARKET, 2020-2033P, $ BN



Source: Marketysers analysis

New Zealand's Unique Market Dynamics

New Zealand's pharmaceutical market operates under a unique funding model, primarily governed by PHARMAC, which negotiates drug prices and manages the Pharmaceutical Schedule. This centralised purchasing body aims for equitable access to cost-effective medicines, but has resulted in New Zealand spending significantly less per capita on pharmaceuticals compared to Australia and other OECD countries. While this model ensures affordability and broad coverage, it also means that the introduction of new, innovative medicines can be slower, with listings occurring, on average, 32.7 months after Australia.

Recent legislative changes, such as the Medicines Amendment Bill, aim to speed up access to safe, effective medicines already approved overseas. This bill introduces a "new verification pathway" or "Rule of Two," allowing fast-track approvals for medicines authorised by two recognised overseas regulators (e.g., EMA, TGA, Health Canada, US FDA) within 30 working days, a significant reduction from the previous 400 working days. This change is expected to reduce delays and increase the availability of medications in New Zealand. The government has also made a significant investment of $1.774 billion for the Combined Pharmaceutical Budget over the forecast period to address cost pressures and ensure ongoing access to medicines.

The country's pharmaceutical industry has a strong focus on research and development, with potential to add value through the discovery of innovative compounds, development of novel compounds, and provision of R&D services to the global drug development industry. This R&D focus, coupled with increasing government initiatives and improving healthcare infrastructure, contributes to market growth.

Outlook by Therapeutic Area

While detailed market share data for specific therapeutic areas within New Zealand's drug formulation market is less granular than for Australia, the overall pharmaceutical market addresses a range of health issues. The growing prevalence of chronic and lifestyle diseases is a major factor driving market growth. This aligns with global trends where therapeutic areas like oncology, infectious diseases, neurology, haematology, respiratory, cardiovascular, and dermatology are key segments in formulation development outsourcing.

Key Players and Competitive Landscape

The New Zealand pharmaceutical landscape is shaped by a mix of local manufacturers, international generics suppliers, and specialised distributors aligned with the government's centralised procurement system through PHARMAC. Among the most prominent local players is Douglas Pharmaceuticals, a vertically integrated company with strong manufacturing, R&D, and export capabilities. AFT Pharmaceuticals is another significant New Zealand-based entity, known for its branded generics and OTC products across Australasia and Southeast Asia.

In the generics and specialty medicines segment, companies such as Multichem NZ, Rex Medical, and Radiant Health play a critical role in sourcing and distributing affordable treatments to retail and hospital markets. Pharmaco (NZ) Ltd acts as a strategic commercial partner for various global manufacturers, offering regulatory, marketing, and distribution services across therapeutic areas. Link Healthcare, now part of Clinigen Group, supports the supply of niche and unregistered medicines, filling important therapeutic gaps.

Noumed Pharmaceuticals, while relatively new to the market, is actively building its presence by offering cost-effective, high-quality generics and prioritising consistent supply to meet PHARMAC's stringent reliability expectations. The competitive landscape is further influenced by small-scale compounding facilities and clinical trial support providers, reflecting New Zealand's growing role in early-phase pharmaceutical evaluation.

Regulatory Environment and Compliance

Australia: Therapeutic Goods Administration (TGA)

The Therapeutic Goods Administration (TGA) is Australia's national regulator, responsible for ensuring that all therapeutic goods meet strict safety, quality, and efficacy standards before they are supplied in the Australian market. The TGA operates under the Therapeutic Goods Act 1989, which outlines the products requiring approval, the standards they must meet, and how compliance is monitored and enforced. It is illegal to supply, advertise, or export regulated therapeutic goods in Australia without TGA approval or proper inclusion on the Australian Register of Therapeutic Goods (ARTG).

The TGA approval process involves several key steps: product classification, application submission with detailed technical and scientific evidence, TGA assessment, decision and inclusion on the ARTG, and ongoing compliance. The TGA typically takes 240 to 260 working days (around a full calendar year) from receiving a new medicine application to an approval decision. This timeframe is longer than that of the US Food and Drug Administration (FDA) (180 to 300 days). Delays can occur if the TGA requires additional safety or efficacy evidence not requested by other regions, or if new information about the drug emerges after overseas approval. To expedite the process, the TGA allows parallel applications for drug approval and Pharmaceutical Benefits Scheme (PBS) listing.

Risk and Challenges in the Australian and New Zealand Pharmaceutical Market

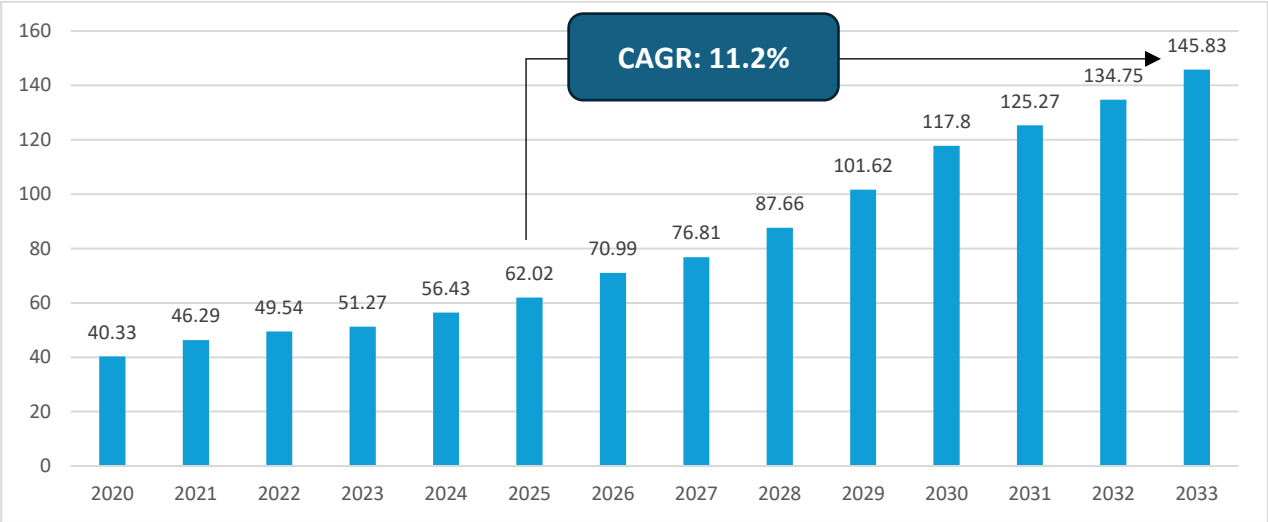
Despite the robust growth, the pharmaceutical markets in Australia and New Zealand face several challenges:

- **Supply Chain Disruptions:** Both nations heavily rely on global trade for pharmaceuticals and raw materials, making their supply chains vulnerable to disruptions. Australia imports 90% of its medications, including active pharmaceutical ingredients and excipients, leading to potential shortages if global supply is affected. Australia's relatively small market size compared to other OECD countries makes it less attractive to global suppliers during shortages, as they prioritise larger, more profitable markets.
- **Price Competition and Affordability:** While government schemes like PBS and PHARMAC ensure affordability, they can also make the market less attractive for pharmaceutical manufacturers due to underpinning pricing mechanisms. Traditional pharmacies face intensified price competition from discount retailers, necessitating a focus on quality, service, and strategic collaborations to maintain profitability.
- **Regulatory Timelines and Access to Medicines:** While Australia's TGA is a world-class regulatory agency, its approval process can be slower than some international counterparts, potentially delaying patient access to life-saving medicines. New Zealand has historically lagged in market access to modern medicines compared to other OECD countries due to its funding model and approval timelines. Although recent legislative changes aim to expedite approvals, the impact on overall market access remains to be fully realised.
- **Shortage of Skilled Professionals:** The pharmaceutical industry in Australia, like many other countries, experiences a scarcity of skilled professionals, including scientists, chemists, clinical researchers, and regulatory affairs associates. This makes it challenging for companies to attract and retain top talent amidst increasing competition.
- **Maintaining Profitability in a Competitive Market:** The competitive landscape, coupled with inflationary pressures and rising costs, necessitates strategic adjustments by pharmaceutical companies to maintain profitability.

Indian Pharmaceutical Market Overview

Changing disease patterns, increased affordability, access, awareness, and government and private insurance expansion are fostering increased demand and consumption of pharmaceutical drugs; however, high out of pocket expenditure keeps the demand in favour of affordable generics.

FIGURE 29. INDIAN PHARMACEUTICAL INDUSTRY SIZE, 2020-2033P, $ BN

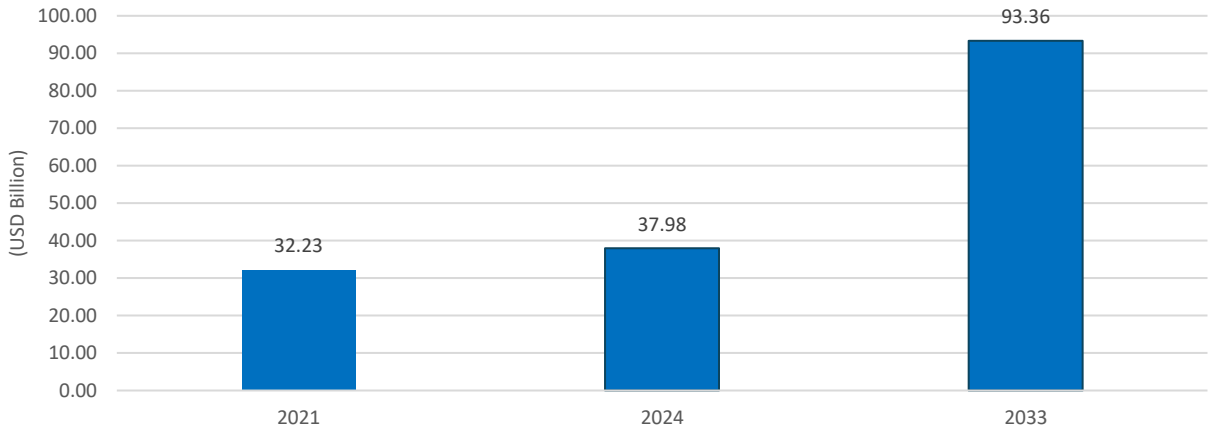


Source: Marketysers analysis

The Indian pharmaceutical industry is the world's third largest by volume and was estimated at $62 billion in 2025. It is expected to grow at a CAGR of 11.2% to reach $146 billion by 2033. The industry can be broadly classified into formulations and bulk drugs. Formulations can further be divided into domestic formulations and export formulations, both having almost an equal share in the market. At present, generic drugs constitute a large part of Indian exports.

The pharmaceutical market in India is dominated by generics, which account for ~90% of drug consumption in the country in terms of value.

FIGURE 30: INDIA GENERIC PHARMA MARKET, 2021–2033P, $ BN



Source: Marketysers analysis

Growth Drivers for the Indian Pharmaceutical Market

Increasing prevalence of chronic diseases:

India has a large and increasing patient pool with a high disease burden of communicable and non-communicable diseases, thereby providing a large market for the sale of drugs. For example, India contributes 15% of the global burden for highly prevalent diseases (respiratory infections, cardiovascular, diabetes, cervical cancer). The primary drivers of chronic diseases are social shifts, rapid urbanisation, detrimental physical environments, and unhealthy lifestyles. India is expected to undergo rapid urbanisation, with nearly an additional 50 million people expected in urban areas between 2023 and 2027. A sizable working-age group, coupled with this swift urbanisation process, contributes to a sedentary lifestyle, consequently elevating the risk of chronic diseases.

Growing product launches and investment by the pharmaceutical industry

Indian companies are strengthening product development and manufacturing capabilities to meet the growing demand for affordable, high-quality drugs in semi-regulated markets. The focus is increasingly shifting toward complex generics, biosimilars, and specialty formulations for both domestic and global markets.

Improved Drug access

In 2008, the Department of Pharmaceuticals launched Pradhan Mantri Bhartiya Janaushadi Pariyojana (PMBJP) to make generic medicines more affordable. Dedicated outlets known as Janaushadi Kendras, providing generic drugs at affordable prices, were opened under the scheme. With less than 100 Jan Aushadhi stores operational in 2014, the number has risen to 16,000+ as of June 2025, with a product basket of 2047 drugs and 300 surgical items. Besides affordability, the government is also focused on accessibility. For instance, as of June 2025, 1,77,617 Ayushman Arogya Mandir were functional in India.

Rise in insurance penetration

The increase in insurance penetration is allowing more and more of the Indian population to access healthcare across all cities and economic tiers. According to the IRDAI, the number of lives covered by insurance has increased from 482 million in FY18 to 678.93 million in FY23.

Rising government initiatives and support

The Indian pharmaceutical sector benefits from policies such as the Production-Linked Incentive (PLI) scheme, which has an outlay of ~₹2,300 crore in 2025-26 budget, aimed at enhancing the manufacturing ecosystem for essential drugs and boosting exports. In the budget 2025-26, the government allocated ~₹1,460 crore to develop bulk drug parks, intending to reduce dependency on imports for critical APIs and intermediates. Additionally, the notification of the Revised Schedule M Guidelines by the Government of India on December 28, 2023, is set to bring Indian pharmaceutical regulations at par with global standards.

Biologics and biosimilar development

Biologic drugs, providing targeted treatments for diseases like cancer and autoimmune disorders, are in high demand due to rising disease prevalence and an ageing population. The patent expirations of blockbuster biologics have fueled biosimilar development in India, with companies leveraging cost-effective production and regulatory support to capitalise on these opportunities.

Emerging Trends in the Indian Pharmaceutical market

Policy-Led Acceleration of Domestic Capabilities

Government initiatives are playing a pivotal role in recalibrating the industry's dependency on imports and enhancing global competitiveness. The PLI schemes, bulk drug parks, and the implementation of UCPMP (Uniform Code for Pharmaceutical Marketing Practices) are driving domestic API manufacturing, enforcing ethical marketing, and promoting vertical integration. Additionally, evolving trade agreements are creating new market access routes, particularly in semi-regulated and developed geographies.

Emergence of India as a Global CDMO/CRAMS Hub

India's positioning as a Contract Development and Manufacturing Organisation (CDMO) destination is solidifying. Global innovators are increasingly leveraging India's scientific expertise, cost advantages, and regulatory familiarity for early-phase research, formulation development, and scalable manufacturing. Indian players are upgrading infrastructure, adopting GMP-aligned digital frameworks, and offering integrated discovery-to-commercialisation services, establishing India as a strategic outsourcing partner across the pharma lifecycle.

Entry into Innovative Therapeutic Frontiers (e.g., GLP-1, Cell & Gene Therapy)

Indian pharmaceutical companies are rapidly diversifying into advanced therapeutic categories, including GLP-1 receptor agonists, cell therapies, and mRNA platforms. This marks a strategic departure from commodity-led portfolios, with companies focusing on patent cliff opportunities and long-term pipeline investments. The push into obesity care, rare disease treatment, and regenerative medicine is emblematic of the industry's aspiration to climb the value chain and engage in IP-led competition globally.

Rise of Biosimilars and Specialty Biologics

Indian pharma is transitioning from traditional generics to more complex and differentiated offerings such as biosimilars and specialty biologics. The growing demand for targeted therapies in oncology, autoimmune disorders, and metabolic conditions drives this shift. Indian firms are investing heavily in upstream R&D, regulatory capabilities, and advanced manufacturing to establish credibility in regulated markets. This trend reflects a broader strategic repositioning—from volume-led growth to value-driven innovation.

Digitalisation Across the Pharma Value Chain

AI, machine learning, and advanced analytics are being systematically integrated across discovery, clinical development, manufacturing, pharmacovigilance, and commercial operations. These technologies are driving predictive insights, reducing time-to-market, and enhancing regulatory compliance. Digital twin models, automated batch release systems, and smart clinical trial platforms are becoming mainstream, empowering Indian pharma to operate with global efficiency standards and data integrity.

Indian Drug Formulation Market Overview

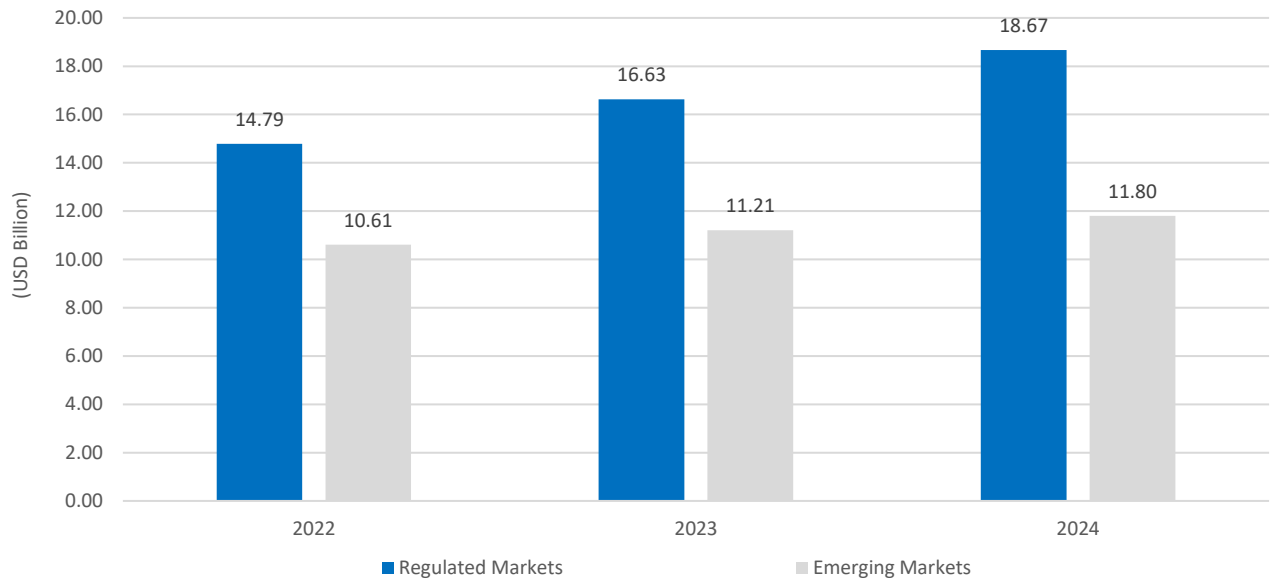
The Indian drug formulation market, estimated at ~$47 billion in 2025, is projected to reach $109 billion by 2033, reflecting a robust CAGR of 11.2% over the period.

India has emerged as a global hub for pharmaceutical manufacturing, housing the largest number of USFDA-approved plants outside the United States. Indian companies enjoy a strong presence in highly regulated markets, with a significant share in the US and EU prescription drug markets, while exporting to over 150 countries worldwide.

The industry benefits from an integrated ecosystem comprising state-of-the-art manufacturing infrastructure, highly skilled technical manpower, and leading pharmaceutical research and educational institutions. In addition, a well-developed base of allied industries—including contract research, clinical trials, and raw material supply—supports the sector's scale and competitiveness. This combination positions India not only as a low-cost manufacturing destination but also as a centre for innovation in complex generics, biosimilars, and specialty formulations.

India ranks third in the world in terms of volume and is the 11th largest in terms of value. Formulations and Biologics constituted the major portion of India's exports, followed by drug intermediates and bulk drugs. In FY24, the exports of formulation stood at $30 billion.

FIGURE 31: INDIA FORMULATION EXPORTS BY VALUE, 2022-2024E, $ BN



Source: Marketysers analysis

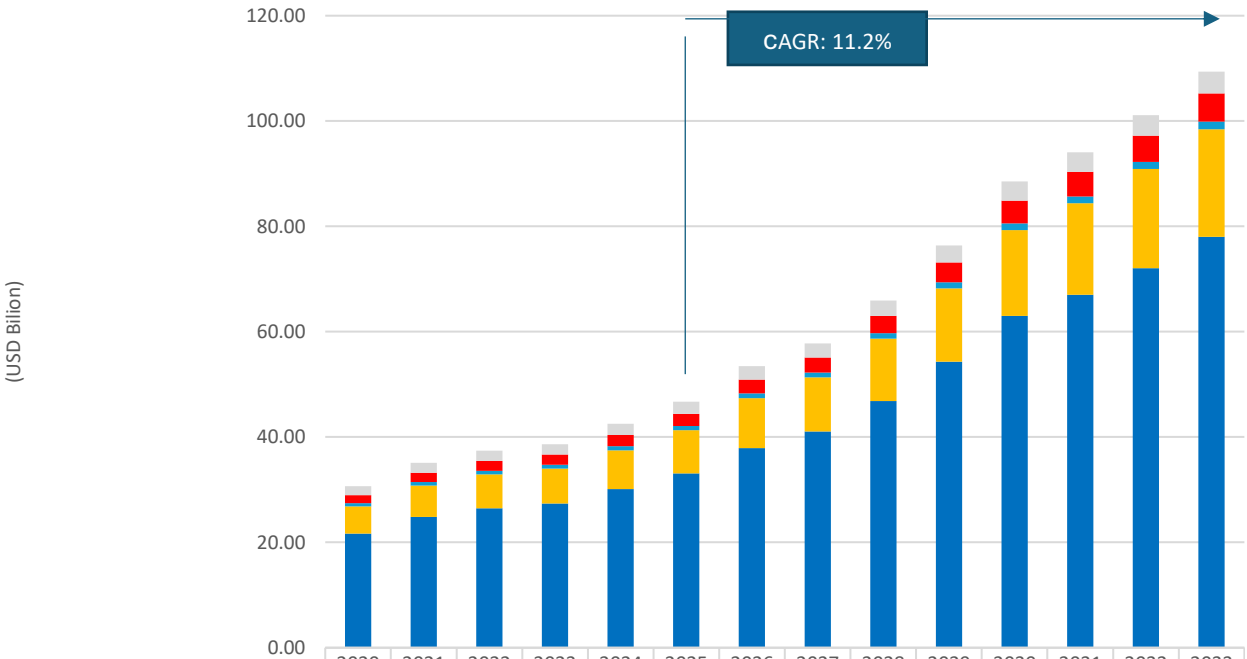
Outlook by Dosage Form

In contrast with global trends, 71% of the market is commanded by oral solids as opposed to the global average of 53%.

Oral solids have dominated the Indian pharma market, owing to ease of administration, patient comfort, flexibility in dosing, and ease of manufacturing- lower manufacturing costs translating to overall lower costs. Moreover, the market will continue to grow in the country, given the innovations in oral solid formulations ranging from modified release formats to orally disintegrating tablets, lipid-based formulations, coated particles, and multi-particulate systems, to name a few. Consequently, the oral solids segment is expected to grow at a CAGR of 11.3%, from $33 billion in 2025 to $78 billion by 2033.

At the same time, other formulations like injectables, inhalations, and liquids are also witnessing rapid growth. While injectables are preferred for fast-acting and precise dosing characteristics, topical formulations and inhalation products are preferred for their localised and disease-specific action. Injectable formulations are widely utilised across various therapeutic areas, including infectious diseases, oncology, diabetes, and cardiovascular disorders. One of the key drivers of the demand for injectable formulations in India is the country's significant burden of infectious diseases. Injectable antibiotics, antivirals, and vaccines play an important role in combating diseases such as tuberculosis, malaria, and pneumonia. Furthermore, injectable formulations are widely used in India for the treatment of chronic conditions such as diabetes and cardiovascular diseases. Oral liquids have also gained popularity in paediatric and geriatric formulations, while implants are also beginning to gain traction in the country.

FIGURE 32. INDIAN DRUG FORMULATION INDUSTRY BY DOSAGE FORM, 2020-2033P, $ BN



	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Others	1.66	1.84	1.93	1.98	2.13	2.28	2.52	2.66	2.93	3.25	3.59	3.74	3.92	4.13
Topical	1.54	1.76	1.87	1.94	2.13	2.33	2.66	2.87	3.27	3.78	4.36	4.63	4.97	5.37
Other Parenteral Formulations	0.60	0.66	0.69	0.71	0.76	0.82	0.90	0.95	1.04	1.15	1.26	1.31	1.37	1.43
Injectable	5.18	5.99	6.42	6.66	7.38	8.17	9.44	10.28	11.85	13.89	16.27	17.39	18.80	20.47
Oral	21.66	24.82	26.48	27.37	30.13	33.12	37.92	41.03	46.85	54.33	63.01	67.00	72.07	78.00

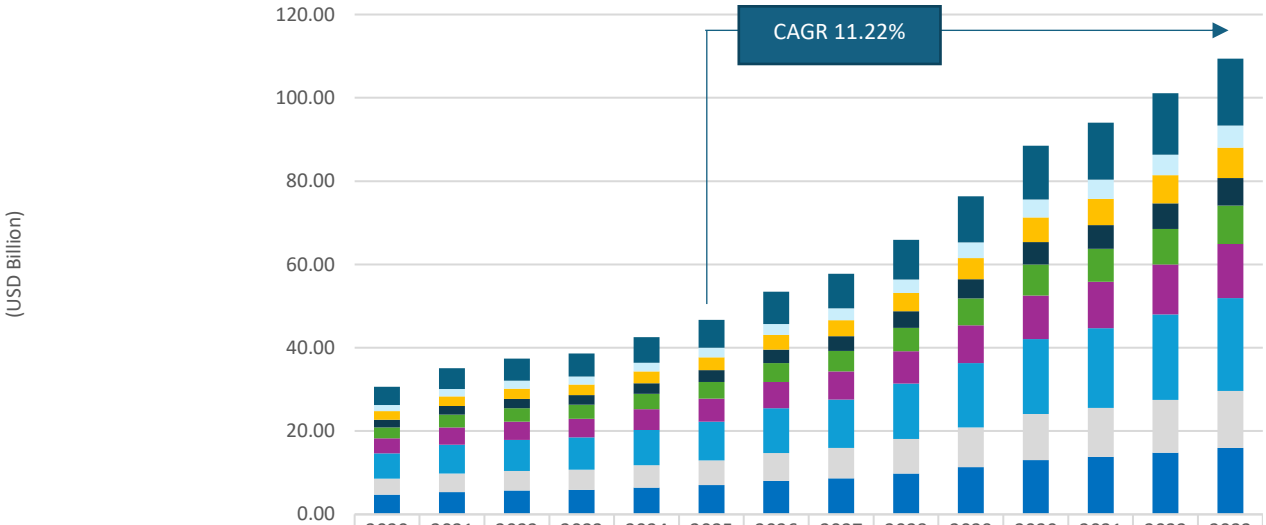
Source: Marketysers analysis

Outlook by Therapeutic Area

The top 3 therapeutic areas of cancer, infectious diseases, and Cardiovascular Diseases (CVS) are expected to contribute to 48% of the market in 2025.

Growth is broad-based across therapeutic areas, with oncology emerging as the largest and fastest-growing segment. Diabetes, cardiovascular diseases, and infectious diseases also represent major therapeutic areas, supported by India's rising disease burden and increasing access to advanced treatments. Autoimmune, dermatological, and central nervous system disorders are gaining traction, reflecting growing awareness, earlier diagnosis, and greater adoption of biologics and specialty drugs. This diversified therapeutic mix underscores India's position as one of the most dynamic formulation markets globally, driven by both domestic demand and export opportunities.

FIGURE 33. INDIAN DRUG FORMULATION INDUSTRY BY THERAPEUTIC AREA, 2020-2033P, $ BN



	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Others	4.36	5.01	5.35	5.53	6.10	6.72	7.71	8.35	9.56	11.11	12.92	13.75	14.81	16.05
Dermatological Disorders	1.53	1.74	1.86	1.92	2.10	2.31	2.63	2.84	3.24	3.74	4.32	4.59	4.92	5.32
Autoimmune Diseases	2.01	2.31	2.46	2.54	2.80	3.08	3.54	3.83	4.38	5.08	5.90	6.28	6.76	7.32
Central Nervous System Disorders	1.84	2.11	2.25	2.33	2.56	2.82	3.23	3.49	3.98	4.62	5.35	5.69	6.12	6.63
Respiratory Diseases	2.67	3.04	3.24	3.34	3.67	4.02	4.58	4.94	5.62	6.48	7.48	7.94	8.52	9.19
Diabetes	3.58	4.11	4.38	4.53	4.99	5.49	6.29	6.80	7.77	9.02	10.47	11.14	11.98	12.97
Cancer	6.08	6.98	7.45	7.70	8.49	9.35	10.72	11.61	13.28	15.44	17.94	19.09	20.56	22.28
Cardivascular Diseases	3.88	4.43	4.72	4.88	5.36	5.89	6.72	7.27	8.28	9.58	11.08	11.77	12.65	13.67
Infectious Diseases	4.70	5.35	5.69	5.87	6.44	7.05	8.02	8.65	9.82	11.31	13.03	13.82	14.82	15.98

Source: Marketysers analysis

Challenges and Risks in the Indian Pharmaceutical Market

High development costs: High development costs represent a significant barrier to entry and expansion in the Indian drug formulations market. The process of developing new drugs, from discovery to commercialisation, involves substantial investments in research, clinical trials, regulatory compliance, and manufacturing. Despite lower labor costs in India, R&D and compliance with international standards contribute to significant expenditure, especially for complex formulations and biologics. Smaller companies struggle to compete with larger players, and the high risk of failure in drug development compounds financial burdens.

Complex manufacturing processes: Complex manufacturing processes pose significant challenges to the sector's growth. Stringent quality control, regulatory compliance, and specialised equipment increase production costs and time-to-market. Regulatory bodies like the FDA and CDSCO impose strict guidelines, requiring significant investment in infrastructure and training, which adds strain on resources. Additionally, evolving drug formulations, such as personalised medicine, demand advanced technologies and expertise.

Drug delivery challenges: One of the primary challenges is ensuring efficient and targeted delivery of drugs to the intended site of action within the body. Many drugs face barriers such as poor solubility, rapid metabolism, and limited bioavailability, which can reduce their efficacy and therapeutic benefits. Overcoming these challenges requires innovative drug delivery technologies that can enhance drug stability, prolong circulation time, and improve tissue penetration, thereby maximising therapeutic outcomes. Moreover, the complexity of formulating drugs for various routes of administration adds another layer of challenge for pharmaceutical companies. Different routes, such as oral, parenteral, transdermal, and inhalation, require specific formulation approaches tailored to the physiological and anatomical characteristics of the target site. Achieving optimal drug formulations that balance factors such as drug release kinetics, tissue compatibility, and patient convenience demands extensive research and development efforts.

Dependence on China for APIs: India's pharmaceutical manufacturing ecosystem is heavily reliant on China for Active Pharmaceutical Ingredients (APIs). This dependency exposes the industry to significant vulnerabilities, especially during geopolitical tensions or disruptions in global logistics. The COVID-19 pandemic was a stark reminder of this fragility, as supply shortages from China impacted drug production timelines. Additionally, concerns around the consistency and quality of certain imported APIs pose reputational risks for Indian manufacturers, particularly in regulated markets. Although government-led incentives aim to boost domestic API manufacturing, progress remains gradual due to high setup costs, technical constraints, and scale inefficiencies.

Intellectual Property Rights (IPR) and Patent Issues: India's patent framework continues to be a contentious area, particularly with global innovators. While the country's IP regime supports the production of affordable generics by preventing patent evergreening and allowing compulsory licensing, it often results in legal friction with multinational pharma companies. The long-standing dispute involving Novartis' Glivec highlighted the divide between public health priorities and proprietary rights. Furthermore, India's obligations under the TRIPS agreement limit policy flexibility in accommodating public health needs. Striking the right balance between encouraging domestic innovation, ensuring access to affordable medicines, and upholding international IP norms remains an ongoing policy and operational challenge.

Overview of Key Government Schemes

- **Jan Aushadhi Pariyojana – Accessibility and Market Penetration:** The Jan Aushadhi Pariyojana is a government initiative launched to provide affordable, high-quality generic medicines to the public through dedicated retail outlets known as Pradhan Mantri Bhartiya Janaushadhi Kendras. This scheme aims to address the high costs associated with branded pharmaceuticals by promoting generic drug usage, making essential medications accessible to a larger demographic. The Jan Aushadhi Pariyojana not only aids low-income groups but also enables significant market penetration of generics, fostering competition and encouraging domestic pharmaceutical manufacturers. The scheme is also helping to shift consumer preferences toward generics, indirectly promoting local production and innovation within India's pharmaceutical industry.

  In 2008, the Department of Pharmaceuticals launched Pradhan Mantri Bhartiya Janaushadi Pariyojana (PMBJP) to make generic medicines more affordable. Dedicated outlets known as Janaushadi Kendras, providing generic drugs at affordable prices, were opened under the scheme. With less than 100 Jan Aushadhi stores operational in 2014, the number has risen to 16,000+ as of June 2025, with a product basket of 2047 drugs and 300 surgical items.

- **Ayushman Bharat:** The Ayushman Bharat program, one of the world's largest health insurance initiatives, targets vulnerable populations by providing coverage of up to INR 5 lakh per family per year for secondary and tertiary care. This scheme has had a transformative impact on domestic healthcare demand, increasing the need for affordable and accessible pharmaceuticals and expanding healthcare services across the country. As of June 2025, 1,77,617 Ayushman Arogya Mandir were functional in India. With enhanced funding and support from Ayushman Bharat, pharmaceutical companies benefit from a growing demand for drugs, treatments, and medical supplies to meet increased healthcare service utilszation. By creating a significant demand pull in the domestic market, Ayushman Bharat has strengthened the Indian pharmaceutical sector, prompting both established firms and smaller manufacturers to innovate and expand their portfolios to meet the needs of the healthcare infrastructure.

Together, *Jan Aushadhi Pariyojana* and *Ayushman Bharat* form an integral part of India's regulatory framework, driving affordability, accessibility, and growth in the domestic pharmaceutical sector while encouraging broader public health improvements.

Impact of Regulatory Changes on Indian Pharmaceutical Industry

- **UCPMP guidelines – compliance and ethical marketing practices:** The Uniform Code for Pharmaceuticals Marketing Practices (UCPMP) guidelines represent a significant step in fostering ethical marketing and compliance standards within the Indian pharmaceutical sector. These guidelines, though currently voluntary, aim to ensure that companies maintain ethical interactions with healthcare professionals, prohibit extravagant incentives, and promote transparency. In response to increasing scrutiny, many companies are investing in training programs and monitoring mechanisms to enhance adherence. There is, however, growing advocacy for making UCPMP mandatory, which would likely create a uniform compliance environment across the industry, promoting ethical practices and improving patient trust.
- **Evolving export regulations for injectables and formulation:** India's pharmaceutical exports, especially in injectables and formulations, are subject to evolving regulatory requirements aimed at maintaining global quality standards. Recently, stricter regulations on product quality, storage conditions, and certification processes have been implemented, particularly in response to quality concerns in key export markets like the United States and Europe. These new standards necessitate upgrades in production facilities, with a focus on enhanced quality control and compliance with Good Manufacturing Practices (GMP). As global regulatory frameworks become more stringent, India's formulation and injectable manufacturers must continually adapt to meet international quality benchmarks, thereby reinforcing the nation's position as a leader in affordable and high-quality pharmaceuticals.
- **Revised Schedule M Guidelines:** The notification of the Revised Schedule M Guidelines by the Government of India on December 28, 2023, aims to align Indian pharmaceutical regulations with global standards. The revised guidelines place significant emphasis on manufacturing premises, plant, and equipment, in addition to existing GMP requirements. The recent implementation of revised Schedule M under the Drugs and Cosmetics Act has created significant challenges for MSME pharmaceutical companies in India, particularly those with turnovers below ₹250 crore. The regulatory changes mandate stricter compliance with GMP standards, requiring substantial investments in facility upgrades, machinery, and technical improvements. Only around 2,000 units already meet WHO GMP certification as of early 2025, leaving about 6,500 MSME manufacturers still required to upgrade to meet the new norms, including infrastructure, equipment, and quality systems. While large firms faced a deadline of June 28, 2024, smaller manufacturers must comply by December 2025, sparking concerns of shutdowns due to financial and infrastructural constraints.

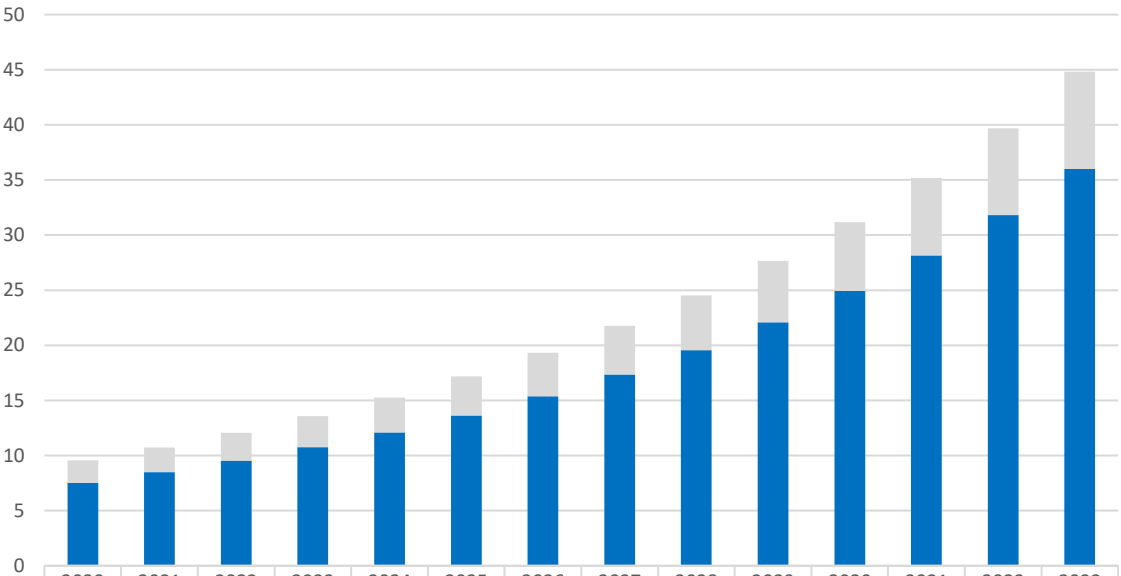
Indian CDMO Market

Indian CDMOs are increasingly participating in larger parts of the pharma value chain, from drug discovery to commercialisation across multiple geographies, in response to evolving trends in the global pharmaceutical industry.

Indian CDMO segment to sustain its strong growth trajectory over the next 10 years.

The market is estimated at $17 billion in 2025 and is projected to grow at a CAGR of 12.7% to reach $45 billion by 2033. Growth will be underpinned by increasing outsourcing of development and manufacturing activities by both Indian and multinational pharmaceutical companies, particularly for complex small molecules and biologics. Rising demand for cost-efficient, high-quality manufacturing, coupled with India's established talent base and regulatory compliance capabilities, is expected to further strengthen the country's position as a global CDMO hub.

FIGURE 34. INDIA CDMO MARKET SIZE, 2020-2033P, $ BN



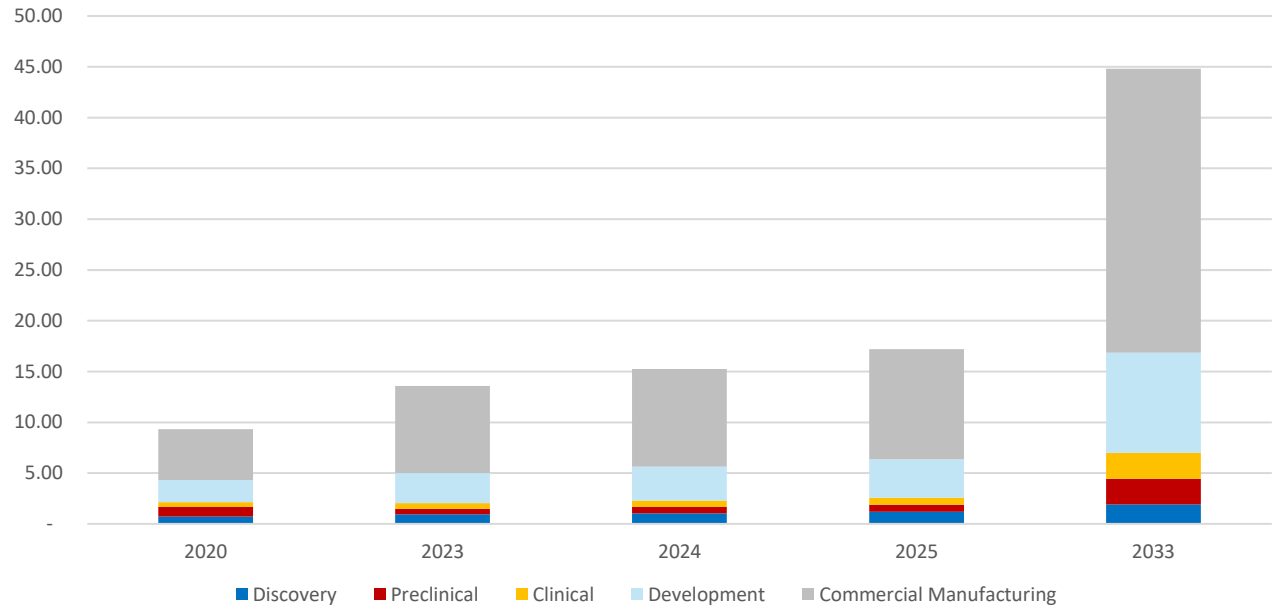
	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Biologics	2	2	3	3	3	4	4	4	5	6	6	7	8	9
Small Molecules	8	8	10	11	12	14	15	17	20	22	25	28	32	36

Source: Marketysers analysis

By product type, small molecules dominate the market, contributing the majority share, while biologics are steadily gaining traction with higher growth rates, supported by increasing biologics R&D and biosimilars demand. Small molecules are expected to expand from $14 billion in 2025 to $36 billion in 2033, while biologics will grow from $4 billion to $9 billion over the same period.

By value chain segment, commercial manufacturing accounts for the largest share of the market, reflecting India's role as a global hub for large-scale, cost-efficient production. At the same time, upstream activities—including discovery, preclinical, clinical, and development services—are witnessing rising outsourcing, particularly from multinational pharmaceutical companies seeking to leverage India's scientific expertise and cost advantages. Together, these trends underscore India's evolution from primarily a low-cost manufacturing base into a fully integrated CDMO hub spanning the entire pharmaceutical value chain, with opportunities across both small molecules and biologics.

FIGURE 35: INDIA CDMO, BY FUNCTION, 2020-2033P, $ BN



Source: Marketysers analysis

Key Growth Drivers for the Indian CDMO Market are:

Increasing pharmaceutical outsourcing to CDMOs for cost reduction: Outsourcing to CDMOs allows pharmaceutical firms to bypass significant capital investment in infrastructure and labour, thus reducing operational costs. CDMOs can leverage economies of scale, optimising production for multiple clients within a shared facility, which drives down per-unit costs and expedites time to market. By partnering with CDMOs, companies can better allocate resources to core competencies, such as drug discovery and development, while leaving manufacturing to specialists, enhancing overall efficiency.

Strong relationships with top pharmaceutical clients enhancing repeat business: CDMOs with established, strong relationships with major pharmaceutical clients benefit from high levels of repeat business. Trust and consistent delivery of high-quality products are essential for fostering these long-term partnerships, as clients prefer proven CDMOs with demonstrated expertise in regulatory compliance and large-scale manufacturing. Such relationships ensure a steady demand pipeline, providing CDMOs with recurring projects and enabling stable revenue streams.

Rapidly expanding biologics and complex drug molecule sectors: The growth of biologics and complex drug molecules has significantly boosted demand for specialised CDMO services, as these products require sophisticated manufacturing capabilities and stringent quality controls. Biologics, in particular, involve intricate production processes such as cell culture and recombinant DNA technologies that traditional pharmaceutical facilities may lack. With new biologics and complex drugs entering the pipeline, CDMOs have become critical partners, enabling faster production ramp-up and meeting the stringent requirements of these high-value products.

Growing need for scalable solutions in clinical to commercial-scale production: CDMOs provide flexible, scalable manufacturing capabilities that can support small batch sizes for early clinical trials and transition smoothly to large-scale production for market launch. This scalability is essential to accommodate varying production demands across different drug development stages. CDMOs with advanced, modular facilities can quickly adapt their capacity, allowing for rapid scale-up or scale-down as needed. By ensuring seamless scalability, CDMOs support faster time-to-market

and help pharmaceutical companies minimise the risks and costs associated with in-house capacity expansion, making them key strategic partners in drug development.

Rising Demand for Small-Molecule and Complex APIs in the CDMO Market: Small-molecule drugs, which remain central to pharmaceutical formulations, are becoming increasingly complex in structure, requiring specialised capabilities in synthesis, scaling, and quality control. As pharmaceutical companies face challenges in meeting production and regulatory standards, they are turning to CDMOs with advanced technological expertise in handling complex chemistries and regulatory requirements. The need for complex APIs, especially in oncology, cardiology, and central nervous system therapeutics, is expected to accelerate CDMO market growth. CDMOs with state-of-the-art infrastructure, specialised teams, and compliance with stringent regulatory standards can capitalise on this opportunity by supporting the production of intricate molecular structures that demand precision and high-level synthesis expertise.

Key Market trends in Indian CDMO market

Strong Momentum in Formulations and Research-Based Contract Services: India's CDMO sector is experiencing robust expansion, driven by increasing demand for outsourcing. This growth is primarily supported by a combination of patent expirations globally and the growing tendency of multinational pharmaceutical companies to externalise development and production functions.

Large-Scale Investments by Indian Players in High-Complexity Capabilities: Leading Indian pharmaceutical companies are undertaking substantial capital investments to expand their CDMO operations and meet rising global demand. Firms such as Aragen Life Sciences, Aurigene, Divi's Laboratories, Laurus Labs, and Jubilant Pharmova are enhancing infrastructure to support complex manufacturing, including biologics and sterile injectables. This includes new greenfield facilities, capacity expansions, and international acquisitions. These efforts reflect a deliberate move toward high-value offerings that require advanced technological platforms and stringent regulatory compliance, positioning Indian players as global-scale, innovation-capable CDMOs.

Growing Focus on Next-Generation Therapeutics and Specialised Services: The Indian CDMO industry is shifting toward complex and high-growth therapeutic categories beyond conventional small molecules. Companies are now building capabilities in biologics, cell and gene therapies, nucleic acid-based treatments, and antibody-drug conjugates (ADCs). This evolution is driven by the increasing demand from biotechnology and specialty pharma clients who are looking for integrated partners capable of managing early-stage development through to commercial manufacturing. Indian service providers are responding with specialised facilities, skilled scientific talent, and enhanced compliance protocols, enabling deeper engagement across the drug development lifecycle.

Strategic Policy Support and Global Supply Chain Realignment: Favourable government policies such as the Production Linked Incentive (PLI) scheme, combined with India's cost competitiveness and regulatory readiness, are significantly enhancing the country's attractiveness as a global CDMO destination. Many pharmaceutical clients are actively diversifying their supplier base due to geopolitical and supply chain risks, with India emerging as a preferred partner. The presence of a large number of US FDA and EU-approved manufacturing sites in the country further strengthens its position. With strong institutional support and growing infrastructure, India is well-placed to scale its CDMO offerings and cater to the global pharmaceutical ecosystem with reliability and agility.

TABLE 8. KEY SUCCESS FACTORS FOR GLOBAL VS. INDIA CDMOS (2025)

Key Factor	Global CDMOs	Indian CDMOs
Regulatory Excellence	Consistently operate under stringent USFDA, EMA, and PMDA frameworks	Improving alignment with global standards; increased audit readiness is a top priority
Scientific Capability	Strong expertise across complex biologics, advanced therapies, and drug delivery	Gaining ground in sterile injectables, HPAPIs, and biologics through targeted investments
Integrated Service Offering (End-to-End)	Offer end-to-end discovery-to-commercialisation platforms	Transitioning from standalone manufacturing to integrated CRDMO models
Cost-Quality Balance	Emphasise value-added innovation with premium pricing	Competitive cost advantage; focus on enhancing quality to match regulated market expectations
Digital Enablement	Adopt advanced technologies like AI, digital twins, and e-QMS	Gradual adoption; digitalisation seen as a differentiator for global client engagement
Client-Centric Delivery	Operate on long-term strategic partnerships with innovation-driven models	Flexible and scalable engagement models; relationship-building still maturing
Sustainability and ESG Focus	ESG metrics and compliance integral to partner selection	ESG practices evolving; alignment with green manufacturing and compliance norms gaining traction

Source: Marketysers analysis

Emergence of CRDMOs: Integrated Discovery, Development and Commercial Manufacturing Services Across the Pharma Value Chain

The pharmaceutical outsourcing model is undergoing a significant transformation with the ascent of Contract Research, Development, and Manufacturing Organisations (CRDMOs)—a consolidated model that merges the capabilities of CROs and CDMOs into a unified service platform. CRDMOs have become increasingly attractive to biotech startups and mid-sized pharma enterprises seeking agile, end-to-end partners capable of managing the entire drug lifecycle—from target identification through to commercial-scale production.

Traditionally, innovators engaged disparate service providers across different development stages, resulting in fragmented workflows, redundant validation protocols, and slower timelines. In contrast, CRDMOs consolidate discovery, preclinical development, clinical trial material manufacturing, and commercial production within a single organisational framework. This not only streamlines operations and reduces inter-organisational friction but also preserves institutional knowledge, enables faster decision-making, and ensures continuity in technical execution.

The CRDMO model is both capital-intensive and long-gestation. Building capacity ahead of demand—whether through talent acquisition, R&D infrastructure, or large-scale GMP manufacturing facilities—requires significant upfront capital deployment. Establishing credibility and securing a meaningful contract can take several years. Consequently, revenue inflow typically lags initial investments, and assets often remain underutilised in the early phase of operations.

As a result, early-stage CRDMO players frequently experience negative profit margins and suppressed ROICs until they reach a sustainable scale. This dynamic makes the sector highly selective and inherently suited for players with deep financial resilience, strong strategic vision, and a long-term commitment to innovation-led value creation.

Challenges and Risks in the Indian CDMO Market

- **Intellectual Property (IP) risks in outsourced development:** When companies outsource development processes to CDMOs, they often share sensitive, proprietary information such as patented formulations, specialised manufacturing techniques, and trade secrets. This knowledge transfer poses a risk of IP infringement, misappropriation, or unauthorised use, especially if the CDMO fails to uphold rigorous security protocols. Furthermore, cross-border collaborations exacerbate these risks, as different countries enforce varying IP laws and protection standards. For example, some regions may lack stringent regulatory frameworks, making it challenging to safeguard IP rights effectively. Companies may be hesitant to outsource due to these IP concerns, thereby restricting the overall growth of the CDMO market.

- **High cost of skilled workforce and technology:** CDMOs rely on specialised talent, including chemists, biotechnologists, and regulatory compliance experts, to deliver high-quality development and manufacturing services. However, the demand for such skilled professionals, coupled with industry competition, has driven up salaries and benefits. Additionally, cutting-edge equipment and technology—such as bioreactors, digital analytics platforms, and continuous manufacturing systems, are essential to meet industry standards and regulatory expectations. Smaller or mid-sized CDMOs may struggle to afford these resources, leading to limitations in scaling operations or enhancing service quality.

- **Maintaining quality:** As CDMOs expand globally, they must navigate a landscape where each country or region may have distinct regulatory frameworks, such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), or Japan's Pharmaceuticals and Medical Devices Agency (PMDA). For instance, a formulation or manufacturing process approved by one agency might necessitate additional tests, reformulations, or documentation to meet another's requirements, leading to increased time and resource investments. Another significant challenge is maintaining consistent quality across geographically dispersed facilities. Moreover, ensuring real-time quality monitoring and corrective actions across borders can be logistically difficult, especially in regions with limited digital infrastructure or regulatory oversight. These quality compliance challenges not only risk regulatory delays and product recalls but also threaten CDMO's reputation and client relationships.

- **Environmental compliance pressures and ESG mandates:** With increasing scrutiny from global clients and regulators, Indian CDMOs are now under heightened pressure to align with stringent Environmental, Social, and Governance (ESG) standards. The government has also tightened norms under the Central Pollution Control Board (CPCB) and state-level authorities, especially concerning waste disposal, effluent treatment, and carbon emissions. CDMOs operating in pharmaceutical clusters such as Hyderabad and Gujarat are facing rising compliance costs and operational disruptions due to mandatory upgrades in environmental infrastructure. Furthermore, global sponsors, particularly from Europe and North America, are demanding demonstrable sustainability metrics as part of vendor qualification processes. This rising emphasis on environmental compliance is placing a significant financial and operational burden on CDMOs, particularly those lacking capital flexibility or sustainability expertise, thereby constraining scalability and competitiveness.

Competitive Landscape

Competitive Landscape in Domestic Formulation Market

Attractive economics and relatively less strict regulatory framework have, however, led to more than 3,000 companies and almost 10,000 manufacturing units with significant variation in quality standards. Industry consolidation is expected to accelerate as players seek integrated capabilities and larger scale.

The Indian domestic formulation industry can be categorised into the chronic therapies segment and acute therapies segment. The chronic segment mainly comprises of anti-diabetic, cardiovascular, oncology etc. The acute segment mainly comprises of anti-infectives, gastro-intestinal, pain and analgesics etc.

Marketysers has evaluated some of the key players across the Indian formulation market which is given below. Marketysers has considered these peers based on their production capacity, capabilities and revenue profile vis-à-vis Sai Parenteral's Limited. Note that the list of competitors above is an indicative list and not an exhaustive list.

TABLE 10. FINANCIAL ANALYSIS OF SELECT INDIAN FORMULATION COMPANIES, FY25, INR MN

Parameter	Senores	Gland Pharma	Ajanta Pharma	Alembic	Caplin	SPL
	FY25	FY25	FY25	FY25	FY25	FY25
Revenue from Operations[1]	3,982.50	56,165.04	46,481.04	66,720.80	19,374.70	1,631.06
EBITDA[2]	1,089.60	14,825.32	13,539.84	10,507.84	7,433.60	400.22
EBITDA Margin (%)[3]	27.36%	26.40%	29.13%	15.75%	38.37%	25.00%
PAT[4]	583.40	6,985.26	9,203.82	5,820.08	5,410.90	144.54
PAT Margin (%)[5]	14.65%	12.44%	19.80%	8.72%	27.93%	8.90%
Total Borrowings[6]	3,047.68	2,692.14	25.90	11,955.74	5.50	939.54
Net worth[7]	8,122.40	91,507.41	37,902.90	51,895.20	28,863.90	957.79
Return on Net Worth (RONW) (%)[8]	7.18%	7.63%	24.28%	11.22%	18.75%	15.00%
Return on Capital Employed (ROCE) (%)[9]	9.34%	14.91%	30.11%	14.66%	23.34%	28.90%
Fixed Assets Turnover Ratio[10]	2.10	1.50	2.86	2.64	3.65	3.76

Source: Annual Reports, DRHP, MCA, Marketysers analysis

Note: Data for SAI Parenteral's Limited is as of FY25 provided by management

Notes:

1) Revenue from operations is calculated as revenue from operating activities; 2) EBITDA means Earnings before interest, taxes, depreciation and amortisation expense, which has been arrived at by obtaining the profit before tax/ (loss) for the year and adding back finance costs, depreciation and amortisation and impairment expense and reducing other income; 3) EBITDA Margin is calculated as EBITDA as a percentage of revenue from operations; 4) PAT represents net profit after tax for the year; 5) PAT Margin is calculated as PAT divided by revenue from operations; 6) Total Borrowings include current and non-current borrowings; 7) Net worth has been defined under Regulation 2(1)(hh) of the SEBI ICDR Regulations as the aggregate value of the paid -up share capital and all reserves created out of the profits and securities premium account and debit or credit balance of profit and loss account, after deducting the aggregate value of the accumulated losses, deferred expenditure and miscellaneous expenditure not written off, as per the audited balance sheet, but does not include reserves created out of revaluation of assets, write-back of depreciation and amalgamation; 8) Return on Net Worth is calculated as Net profit after tax divided by Net worth as at the end of the year; 9) Return on Capital Employed is calculated as EBIT divided by capital employed where (i) EBIT means EBITDA minus depreciation and amortisation expense and (ii) Capital employed means Net worth as defined in (8) above + total current & non-current borrowings– cash and cash equivalents and other bank balances; 10) Fixed Assets Turnover Ratio is calculated as revenue from operations divided by the sum of net block of property, plant and equipment as at the end of the year.

Competitive Landscape in the Indian CDMO Market

Indian CDMO is a fragmented and unorganised market characterised by several small-scale, privately owned businesses and only a handful of large-scale companies dominating the market.

Like the global CDMO market, the Indian CDMO market is highly fragmented and, similar to the global market, it is also consolidating. Trends of consolidation are evident in the global CDMO market with high-profile acquisitions such as Cambrex Corporation's acquisition of Snapdragon Chemistry, Inc. and Catalent, Inc.'s (Catalent) acquisition of Metric Contract Services, to name a few. M&A enables CDMOs to acquire new capabilities, enhance their services, and provide comprehensive solutions to customers.

While global companies are consolidating to offer end-to-end services, M&A in the Indian landscape is more geared toward capacity expansion to meet high-volume demands in the country. For instance, Akums acquired a facility from Ankur Drugs and Pharma Ltd. to increase the production of oral tablets and liquids. It also acquired Parabolic Drugs Ltd. to augment the production capacity for APIs. Likewise, Synokem Pharmaceuticals Ltd. (Synokem Pharma), backed by private equity firm TA Associates, has acquired a 74% stake in Nitin Lifesciences Limited to access injectable capabilities.

Marketysers has evaluated some of the key players across the Indian CDMO market which is given below. Marketysers has considered these peers based on their production capacity, capabilities and revenue profile vis-à-vis Sai Parenteral's Limited. Note that the list of competitors above is an indicative list and not an exhaustive list.

TABLE 13. FINANCIAL ANALYSIS OF SELECT INDIAN CDMOS, FY25, INR MN

Parameter	Senores	Sai life sciences	Innova Captab	Akums	Windlass	SPL
	FY25	FY25	FY25	FY25	FY25	FY25
Revenue from Operations[1]	3,982.50	16,945.70	12,436.76	41,181.58	7,598.78	1,631.06
EBITDA[2]	1,089.60	4,424.40	1,982.00	5,332.99	1,121.25	400.22
EBITDA Margin (%)[3]	27.36%	26.11%	15.94%	12.95%	14.76%	25.00%
PAT[4]	583.40	1,701.32	1,282.58	3,437.77	609.94	144.54
PAT Margin (%)[5]	14.65%	10.04%	10.31%	8.35%	8.03%	8.90%
Total Borrowings[6]	3,047.68	1,286.36	3,360.70	809.82	293.68	939.54
Net worth[7]	8,122.40	21,283.54	9,594.17	30,636.11	5,057.72	957.79
Return on Net Worth (RONW) (%)[8]	7.18%	7.99%	13.37%	11.22%	12.06%	15.00%
Return on Capital Employed (ROCE) (%)[9]	9.34%	12.52%	14.13%	11.80%	16.47%	28.90%
Fixed Assets Turnover Ratio[10]	2.10	1.43	1.62	3.35	3.89	3.76

Source: Annual Reports, DRHP, MCA, Marketysers analysis

Note: Data for SAI Parenteral's Limited are provisional financial statements as of FY25 provided by management

Notes:

1) Revenue from operations is calculated as revenue from operating activities; 2) EBITDA means Earnings before interest, taxes, depreciation and amortisation expense, which has been arrived at by obtaining the profit before tax/ (loss) for the year and adding back finance costs, depreciation and amortisation and impairment expense and reducing other income; 3) EBITDA Margin is calculated as EBITDA as a percentage of revenue from operations; 4) PAT represents net profit after tax for the year; 5) PAT Margin is calculated as PAT divided by revenue from operations; 6) Total Borrowings include current and non-current borrowings; 7) Net worth has been defined under Regulation 2(1)(hh) of the SEBI ICDR Regulations as the aggregate value of the paid -up share capital and all reserves created out of the profits and securities premium account and debit or credit balance of profit and loss account, after deducting the aggregate value of the accumulated losses, deferred expenditure and miscellaneous expenditure not written off, as per the audited balance sheet, but does not include reserves created out of revaluation of assets, write-back of depreciation and amalgamation; 8) Return on Net Worth is calculated as Net profit after tax divided by Net worth as at the end of the year; 9) Return on Capital Employed is calculated as EBIT divided by capital employed where (i) EBIT means EBITDA minus depreciation and amortisation expense and (ii) Capital employed means Net worth as defined in (8) above + total current & non-current borrowings– cash and cash equivalents and other bank balances; 10) Fixed Assets Turnover Ratio is calculated as revenue from operations divided by the sum of net block of property, plant and equipment as at the end of the year.