An Analysis on leveraging the patent cliff with drug sales worth USD 251 billion going off-patent and analysis of different drug pricing methodologies for Indian Generic Pharmaceutical companies.

Study conducted by Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India
AUGUST, 2023

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1. INTRODUCTION

1.1. Background

Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers is nodal agency for the scheme “Strengthening of Pharmaceutical Industry (SPI)", with a total financial outlay of Rs.500 Cr for the period from FY 21-22 to FY 25-26. The scheme aims to address the rising demand in terms of support required to existing Pharma clusters and MSMEs across the country to improve their productivity, quality and sustainability.

The objectives of the Scheme “Strengthening of Pharmaceutical Industry (SPI)” are to strengthen the existing infrastructure facilities in order to make India a global leader in the Pharmaceutical Sector. Under the Scheme, there is a provision for the financial assistance to pharma clusters for creation of Common Facilities.

Further, in order to upgrade the production facilities of SMEs and MSMEs so as to meet the national and international regulatory standards (WHO-GMP or Schedule-M), the incentives like interest subvention or capital subsidy on their capital loans is being provided to facilitate the growth in volumes as well as in quality of drugs in India.

The SPI Scheme of Department of Pharmaceutical has broadly 3 components / sub-schemes:

Assistance to Pharmaceutical Industry for Common Facilities (APICF): To strengthen the existing pharmaceutical clusters’ capacity for their sustained growth by creating common facilities. Under the API-CF sub-scheme, support for clusters for creation of common facilities with the focus on R&D Labs, Testing Laboratories, Effluent Treatment Plants, Logistic Centres and Training Centres in this order of priority with an outlay of 178 Cr for the scheme period of five years is proposed.

Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS): To facilitate Micro, Small and Medium Pharma Enterprises (MSMEs) of proven track record to meet national and international regulatory standards. Under the PTUAS sub-scheme, support for about SME Industries is proposed, either through up to maximum of 5% per annum (6% in case of units owned and managed by SC/STs) of interest subvention or through Credit linked Capital subsidy of 10%. In both the cases, the loan supported under this is to a limit of 10 Crores and the eligible components of the loan has been listed out in the scheme guidelines. An outlay of 300 Cr has been earmarked for sub scheme for the scheme period of five years.

Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS): To facilitate growth and development of Pharmaceutical and Medical Devices Sectors through study/survey reports, awareness programs, creation of database, and promotion of industry. Under the PMPDS sub-scheme, knowledge and awareness about the Pharmaceutical and MedTech Industry will be promoted. This will be done by undertaking studies, building databases and bringing industry leaders, academia and policy makers together to share their knowledge and experience for overall development of the Pharma and Medical Devices sector. An outlay of 21.5 Cr has been earmarked for the sub scheme for the scheme period of five years. It is expected that the units supported under this scheme will act as Demonstration Firms

for the pharma clusters and MSE Pharma Industries, to develop on quality and technology upgradation fronts.

In the years between 2022-30, the pharmaceutical sector in India will undergo landmark changes as a number of drugs are expected to go off-patent and provide an opportunity for the entry of generic products. Expiry of patents is very promising for the Indian generic drug market as it is expected to expand and grow further with inclusion of these new drugs. With ongoing developments, India has started focusing on self-reliance at a large scale. Hence, it is imperative to identify these drugs beforehand, draft and implement strategies which help in their timely entry into the market by promoting generic drug manufacturing. Under the same PMPDS Scheme, the department took an initiative to conduct an independent study on analysis on leveraging the impending patent cliff, with drug sales worth USD 251 billion going off-patent and to analyse the different drug pricing methodologies particularly w.r.t to these patented drugs going off-patent.

1.2. Study Assumptions and Study Definition

Study Assumptions:

- The study assumed that the information available on various secondary sources of data regarding the drugs going off-patent and their sales worth USD 251 billion is accurate and reliable.
- It also assumed that the patent expiration dates, historical pricing data and associated sales data that were publicly available were reliable to be accessed for analysis.

- The study assumed that the drug pricing methodologies under analysis were representative of the broader pharmaceutical industry and did not represent any specific company's pricing policies.

Study Definition: The assessment study, "**An Analysis on Leveraging the Patent Cliff with Drug Sales Worth USD 251 Billion Going Off-Patent and to Analyse Different Drug Pricing Methodologies,**" aimed to investigate the implications of the patent cliff on the Indian pharmaceutical industry and analyse various drug pricing methodologies which should be opted by Indian generic pharmaceutical companies to capture the maximum market share created as a result of this patent Cliff.

The study encompassed the following key components:

- **Identification and Analysis of Drugs Going Off-Patent**: The study was commissioned to identify a comprehensive list of drugs of 20 plus drugs with sales worth USD 251 billion that were approaching or have recently reached their patent expiration dates. The analysis considered the major US patents for the uniformity of analysis and the potential impact of their patent expiry on the pharmaceutical market, including changes in market dynamics, competition, and pricing due to the entry of Indian Generic Pharmaceutical Players.
- **Assessment of the Patent Cliff:** The study examined the patent cliff phenomenon, which refers to a period when a significant number of drugs lose their patent protection, leading to increased competition from generic alternatives. The assessment also explored the magnitude of the patent cliff and its implications for pharmaceutical companies, healthcare providers, and consumers.
- **Evaluation of Drug Pricing Methodologies**: The study analysed the different drug pricing methodologies employed by pharmaceutical companies. This analysis also encompassed a range of factors, such as cost-based pricing, value-based pricing, market-based pricing, and other relevant strategies.
- **Recommendations and Implications**: Based on the findings of the study, the assessment agency has provided recommendations for Indian Generic pharmaceutical companies, policymakers, and other stakeholders regarding leveraging the patent cliff and selecting appropriate drug. The implications of the study's findings for the industry, healthcare systems, and consumers will also be discussed.

1.3. Base Estimates and Working

Base Estimate:

- **Duration:** The study was estimated to be conducted over a period of 6 months.
- **Resources:** The study required a team of researchers, analysts, and subject matter experts with expertise in the pharmaceutical industry, drug pricing, patent expiration, and market analysis. The team allocated by BHPL included experienced

individuals in the above-mentioned areas along with skills in data analysis, research methodology, and report writing in Pharmaceutical Sector.

- **Data Sources**: The study primarily relied on publicly available data sources such as patent databases, industry reports, regulatory filings, and scholarly articles. Additionally, interviews with industry experts and key stakeholders were conducted to gather insights and opinions.

Working Approach:

The study employed a combination of quantitative and qualitative research methods, including data analysis, literature review, industry perspective and expert opinions. The aim is to provide a comprehensive assessment of the patent cliff's impact and different drug pricing methodologies to support informed decision-making in the pharmaceutical industry.

2. RESEARCH FRAMEWORK

2.1. Primary Research

The study primarily included secondary research. However, some discussions were conducted with the experts from the pharmaceutical industry, patents, and drug pricing to gather diverse perspectives.

2.2. Secondary Research

Reputable and reliable sources of information relevant to the research objectives were identified and utilized in secondary data collection. A Systematic literature review was conducted to gather relevant academic articles, research studies, case studies related to the patent cliff and drug pricing methodologies and scholarly publications. These sources included, but were not limited to:

- **Academic databases:** Databases like PubMed, Scopus, or Google Scholar to access scholarly articles and research studies related to the patent cliff, drug pricing methodologies, and pharmaceutical industry dynamics.
- **Industry reports:** Reports published by market research firms, industry associations, or consulting agencies that provide insights on the pharmaceutical industry, latest market trends, and drug pricing strategies.
- **Regulatory databases:** Access regulatory databases such as the U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) databases to gather information on drug approvals, patent expirations, and regulatory policies.
- **Government Patents databases**: Patent databases like the United States Patent and Trademark Office (USPTO) or the World Intellectual Property Organization (WIPO) database to identify relevant patents, expiration dates, and associated drug sales.
- **Subscription based patent Database**: Drug Patent watch

- **Government publications:** Reports and publications from governmental bodies such as health departments or regulatory agencies that may provide insights into drug pricing policies and their implications.

2.3. Data Triangulation

The data was validated by cross-referencing the information obtained from different sources. The quantitative and qualitative data gathered from various sources, including primary and secondary sources was combined to enhance the robustness of the analysis. a result of this holistic understanding of the data in the key insights were derived from the triangulation process.

2.4. Insight Generation

The key findings were interpreted within the broader context of the pharmaceutical industry, market dynamics, patent regime, regulatory environment, and relevant economic factors to synthesize insights. Different drug pricing methodologies were analysed in the study to identify the strengths, weaknesses, advantages, and disadvantages of each methodology. Further, different strategies were assessed for their suitability for leveraging the patent cliff effectively and their potential impact on market dynamics and profitability for the generic pharmaceutical companies in India. The generated insights were validated by checking their alignment with the data, analysis, and research objectives. It was ensured that the generated insights were logical, supported by evidence, and consistent across different sources and methods used in the study.

EXECUTIVE SUMMARY

3. EXECUTIVE SUMMARY

3.1 Definition and Explanation

The approval process for new innovative drugs and for follow-on drugs or generics is very different. There are three basic mechanisms for small-molecule drugs. New small-molecule drugs are approved by submitting a New Drug Application (NDA) to the FDA. Generic drugs are approved through an Abbreviated New Drug Application (ANDA) process, and there is a hybrid process named by its regulatory section, 505(b)(2), which applies to modifications of new drugs which are neither novel, nor generics. For biologics, new drugs and followers are approved by Biologics License Applications (BLAs). New biologic drugs are approved through section 351(a), and follower biosimilars are approved through section 351(k) of the US Public Health Act.

Generic product development cost specially for small molecule drugs is substantially lower than the costs of initial research and development. So, once a drug is known to be safe and effective, it can generally be reverse-engineered without much difficulty. Without market protections for innovators, the generic manufacturers would be able to produce copies of innovative drugs and sell them at a fraction of the cost of innovators, reflecting their greatly-reduced research and development costs. For this reason, patent protection and regulatory exclusivity are a kind of reward for innovators for engaging in research areas with a high risk of failure. In the absence of protections companies, their employees, and their investors would lack the motivations to spend years and hundreds of millions of dollars researching and developing innovative new drugs.

Patents across various industries, including drugs, arise from the intellectual property spurred from the innovation to raise the rewards for discovery, which also grants a monopoly in discovery. Patents foster innovation as they provide the manufacturer with the opportunity for a temporary monopoly for a period of market exclusivity. The term of drug patents varies. The basic term for a patent is 20 years from the date of patent filing, which generally occurs several years before a drug is approved. This means that drugs may have 6-12 years of patent-protected sales after launch. There are conditions under which drug patents can be extended, for example to compensate for time spent waiting for Food and Drug Agency (FDA) review, or for responding to an FDA request for paediatric testing.

Consequently, the expiry of patents decreases the overall market returns of individual pharmaceuticals due to post-expiration reduction in marketing share. The term "patent cliff" refers to a significant event in the pharmaceutical industry when a large number of patents for branded or innovator drugs are set to expire within a relatively short period, typically within a few years. This expiration of patents creates an opportunity for generic drug manufacturers to enter the market and produce lower-cost versions of the previously patented drugs. When a drug is initially developed and approved, the pharmaceutical company typically obtains a patent that grants them exclusive rights to manufacture and sell the drug for a specified period, usually around 20 years. During this time, the company can charge higher prices to recoup the costs of research, development, and marketing. This exclusivity allows the company to enjoy a monopoly on the drug, without facing competition from generic alternatives.

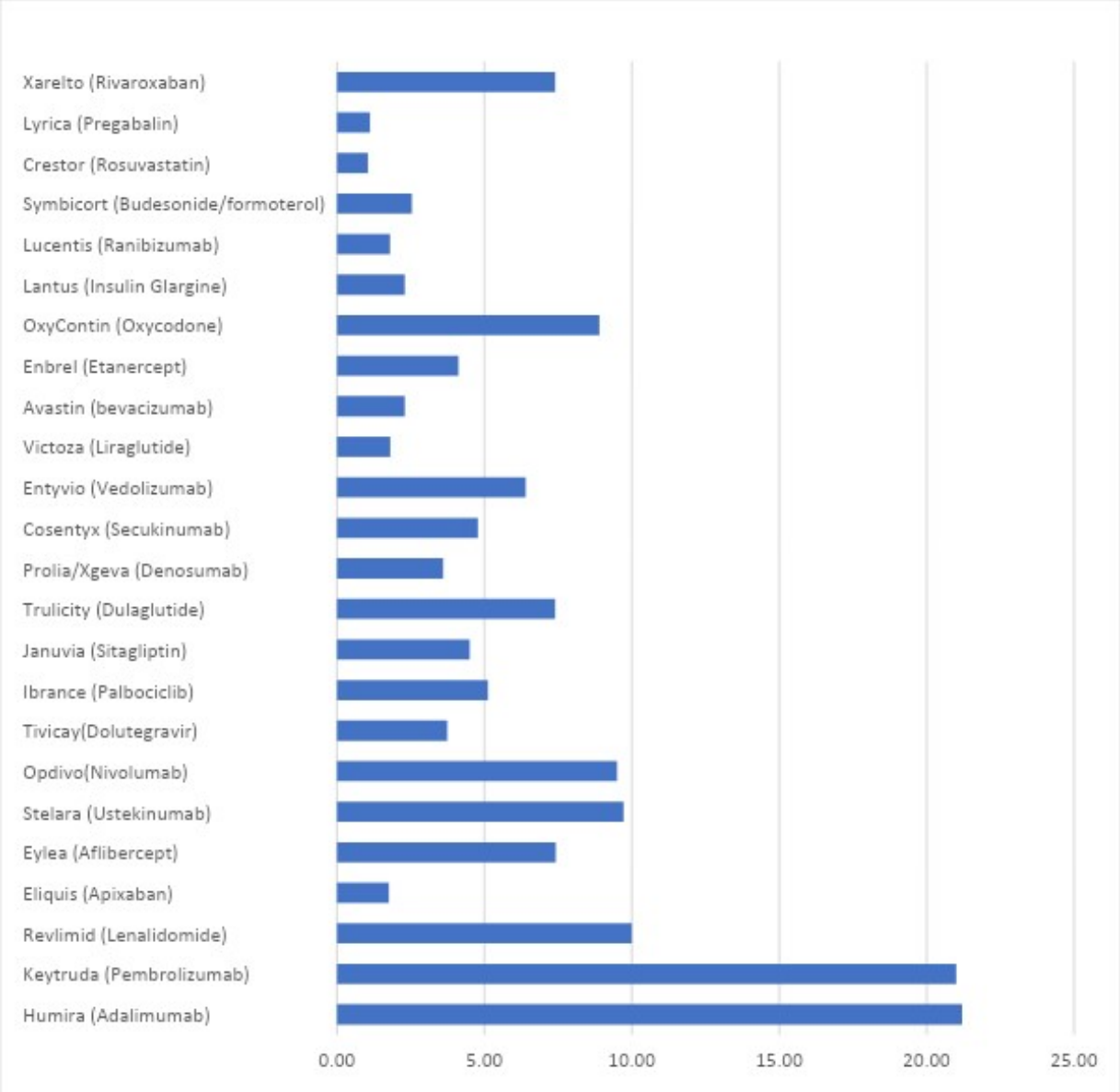
However, once the patent nears expiration, other pharmaceutical companies can apply for approval to produce and sell generic versions of the drug. These generic drugs contain the same active pharmaceutical ingredients as the innovator drugs and are typically sold at lower prices. As a result, when the patent expires and the market becomes open to generic competition, sales of the branded drugs often experience a significant decline.

The term "patent cliff" is used to describe this period of patent expirations and the subsequent revenue loss experienced by pharmaceutical companies as their drugs face generic competition. It is called a "cliff" because the revenue drop-off can be steep and sudden, as multiple drugs lose their patent protection simultaneously. The patent cliff brings both challenges and opportunities for the pharmaceutical industry. While it can lead to a decline in sales and profitability for innovator companies with drugs going off-patent, it also creates opportunities for generic manufacturers to enter the market, increase competition, and provide more affordable options to healthcare providers and patients. It also incentivizes the innovation as pharmaceutical companies strive to develop new drugs and maintain their competitive advantage in the market by bringing new drugs to market.

The period from 2023 to 2030 is projected to witness a significant patent cliff in the pharmaceutical industry, with numerous high-revenue drugs facing patent expirations (Exhibit 1). This timeframe marks a critical phase for pharmaceutical companies as they navigate the challenges and opportunities associated with the expiration of these patents. The specific drugs and their corresponding patent expiration dates may vary, but it is expected that

several blockbuster drugs will be affected during this period. The patent cliff from 2023 to 2030 will likely result in increased competition from generic drug manufacturers entering the market.

Exhibit 1: Annual Sales figures of Top Blockbuster drugs in USD Billion in year 2022



Source: Product Sales data and CAGR as per Global data/ Statista/Company's Annual reports

Pharmaceutical companies impacted by the patent cliff try to adapt their strategies to mitigate the expected revenue losses by launching new drugs to replace the lost sales, seek partnerships or acquisitions, invest in research and development, or explore other revenue streams such as biologics, biosimilars and specialty drugs.

For healthcare systems and patients, the patent cliff can be beneficial as it expands access to more affordable medications. The availability of generic versions of previously expensive drugs can help reduce healthcare costs and improve affordability for patients.

3.2 Distinction between Patent Protection and Regulatory Exclusivity

Drug patents are typically sought for the compound itself if the product is a new chemical entity that is not already approved and patented in the United States. However, patents can also be granted for the process (methodology, equipment) used to manufacture that compound, the formulation (dosage form) of the compound, or the method of use of the compound. In addition to protections derived from patents, the USFDA and some other regulators may grant market exclusivity to drugs meeting specific conditions.

The motivation to grant exclusivity is to foster innovation and to promote the development of drugs for applications that might otherwise offer insufficient motivation. Patents and regulatory exclusivity work in a similar fashion but are distinct from one another and governed by different statutes. Patents are a property right granted by the U.S. Patent and Trademark Office (USPTO). They may be enforced at any time and can encompass a wide range of claims.

Regulatory exclusivity on the other hand is granted by the U.S. Food and Drug Administration and similar regulatory bodies in other countries, which prevents the regulatory approval of competitor drugs. While some regulatory exclusivities such as paediatric clinical trial exclusivity are attached to the end of patents, in most cases patents and regulatory exclusivity are independent. For example, patents can be asserted against drugs which are in development, against the drugs for which approval is sought, or after a drug launches. By contrast, regulatory exclusivity tends to affect only drug approvals.

In US, the market exclusivity and patent terms for drugs are governed by The Drug Price Competition and Patent Term Restoration Act of 1984, or more commonly known at the Hatch-Waxman Act. This act is held as a federal law aligned with the United States Food and Drug Administration (FDA) drug approval processes. The act aims to strike a balance between protecting innovation while increasing competition, by using exclusivities and patent extensions to protect innovation and creating the modern abbreviated new drug application (ANDA) approval pathway to facilitate market entry of lower-cost generics. Following the formation of this amendment, the pharmaceutical industry and generic entrants battleground plays out uniquely for each drug in the marketplace. Consequently, having an information advantage can benefit all the involved players. It creates provisions for patent term extensions with exclusivity, expedited FDA approvals for generic drugs, and a simplified patent litigation process tied to generic drug submissions to FDA. Exclusivity can be granted in addition to USPTO patent terms following the approval of a drug if the product has orphan drug designation, classification as a new chemical entity, done additional clinical studies, or studies in paediatric populations.

3.3 Global Impact and Implications of Impending Patent Cliff

Pharmaceutical companies with products going off patent closely monitor their patent portfolios and release information about impending patent expirations as part of their financial disclosures. Overall, the patent cliff from 2023 to 2030 is expected to be of tectonic magnitude and represents a critical period in the pharmaceutical industry, where companies will face challenges and opportunities as they navigate the expiration of patents for high-revenue drugs and the ensuing competition from generic alternatives. The global impact of the patent cliff from 2022 to 2030 is expected to be significant and will depend on various factors, including the specific drugs facing patent expiration, regional market dynamics, healthcare policies, and the ability of pharmaceutical companies to adapt to the changing landscape. The innovator companies will be monitoring market trends and regulatory changes and will employ various strategies to navigate the implications of the patent cliff during this period. However, some of the potential implications of impending Patent cliff 2022-2030 are mentioned below:

- **Steep Revenue Loss for Pharmaceutical Companies with small molecules**: Innovator Pharmaceutical companies that hold patents on drugs facing expiration will experience a decline in sales as generic competition enters the market. This revenue loss can have a considerable impact on these companies' financial performance, potentially leading to decreased profits, restructuring, and strategic adjustments. For example, during the last patent cliff, for the biggest selling statin Lipitor, the annual sales fell from nearly $11 billion in 2010, the year before it faced generics in the U.S., to $4 billion in 2012. Pfizer's overall revenue fell from $68 billion to $59 billion over the same period. The impending cliff will affect most big biopharma companies, but some will feel more pressure than others. Pfizer Inc., Novartis AG, Merck, Eli Lilly and Bristol Myers Squibb are poised to face steep patent cliffs.

- **Gradual Revenue Loss for Pharmaceutical Companies with Large molecules**: The companies with large molecules like Biosimilars and Mono Clonal Antibodies (MABs) also going to face price erosion resulting in loss of revenues however this will be gradual. This is because large molecules are more expensive to develop and manufacture and their manufacturers won't be able to afford cutting prices by nearly as much as by manufacturers of generic small molecules. For example; The pattern of sales decline for drugs like AbbVie's blockbuster biosimilar Humira is expected to be different as such drugs won't be interchangeable, or directly substitutable, by pharmacists. Physicians also may be reluctant to switch stable patients on the branded drug to biosimilars. Therefore, it is expected that newly diagnosed patients are most likely to receive biosimilars in the beginning after launch of biosimilars. With the introduction of generic alternatives, patient and healthcare provider education becomes crucial. Clear communication and education initiatives can help dispel concerns about the efficacy and safety of generic medications. It is important to ensure that patients and healthcare providers are informed about the availability of generic options, their cost-saving potential, and the importance of therapeutic equivalence.

- **Savings for the Patients and Healthcare Systems:**
  The expiration of patents during this 2023-30 will pave the way for multiple generic drug manufacturers to enter the market and produce lower-cost alternatives to brand-name drugs. This increased availability of affordable medications can improve access to essential treatments for patients worldwide, particularly in regions with limited healthcare budgets. Generic medications are typically priced up to 90% lower than their brand-name counterparts, allowing healthcare providers and insurers to achieve substantial cost savings. This will reduce financial burdens on payers in the healthcare systems and potentially lead to expanded coverage and access to more comprehensive healthcare.

- **Market Competition and Innovation:**
  The patent cliff fosters increased market competition, as generic manufacturers compete with brand-name companies. This competition can drive innovation and encourage the development of new drugs, as companies strive to differentiate themselves in the market. Pharmaceutical companies may focus on research and development efforts to introduce novel therapies, potentially leading to advancements in treatment options for various diseases and conditions.

- **Market Share Shifts:**
  The Patent cliff and resulting loss of exclusivity can reshape the competitive landscape and influence market dynamics within the pharmaceutical industry. As per historical data, the sales of a small molecule that goes generic, 50- 80% of the market can be lost in 30 to 90 days and the price can go down by 90%. The expiration of patents can result in major shifts in market shares between innovator and generic drug manufacturers. Generic manufacturers may gain market share as they offer lower-priced alternatives, while innovator companies may experience a decline in their market position unless they come up adequate strategies.

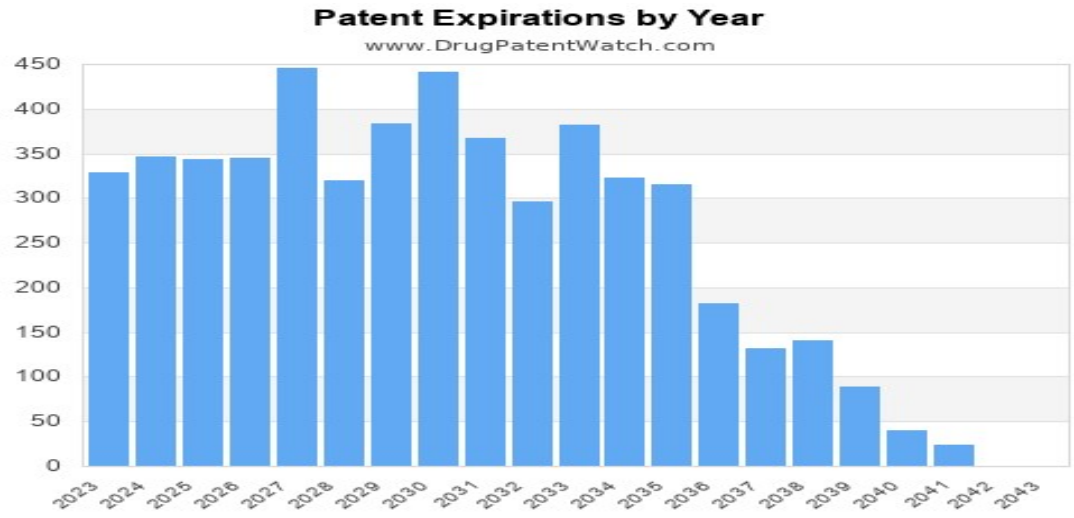
- **Regional and Global Market Variations:**
  It's important to note that the specific drugs and their patent expiration dates during the 2022-2030 period will vary. Further, the impact of the patent cliff will also vary across different regions and countries due to variations in healthcare systems, political, economic, social, legal and regulatory frameworks. Some regions may experience a more pronounced impact, depending on factors such as the prevalence of brand-name drugs facing patent expirations and the availability of generic manufacturers in the market.

3.4 Patent Expirations by numbers (Patent cliff 2020-2030)

As per the report by drug patent watch during the patent cliff period of 2022-2032 there will more than 300 drug patents (Exhibit 2) in different categories and different geographies expiring every year. A list of 300 plus US patents expiring between 2020-2030

is attached as Annexure A at the end of the report. This trend is going to continue till the year 2036. However, the most important and high value patents for the blockbuster (Annual sales more than USD 1 Bn) drugs are going to expire between the years 2022-2030.

Exhibit 2 : Patent Expirations by Year



Source: Drug Patentwatch.com

3.5 Major Blockbuster drug Patent Expirations during the Patent cliff 2020-2030

As per our analysis, 24 major blockbuster drug patents are going to expire during the period of 2022-2030. This will include the loss of exclusivity for the mega-seller like Humira (adalimumab) in the US beginning in 2023. Biosimilars to Humira were already launched in Europe in 2019, which has already frayed at the brand's sales, though Europe already was a substantially smaller market for Humira revenues compared to the US. In India, multiple companies have been permitted by the Indian government to manufacture Adalimumab under the provisions of compulsory licensing since 2018. Biocon has become the first company from India to launch its Biosimilar Hulio in US in July,2023. Johnson & Johnson will have to navigate a challenging period around the same time, with the company's top-selling drug Stelara (Ustekinumab) expected to lose patent protection in the US in 2023, followed by Simponi (golimumab) in 2024.

Similarly, Pfizer is headed over the cliff with the potential US loss of the rheumatoid arthritis drug Xeljanz (tofacitinib) in 2025, the blood thinner Eliquis (Apixaban) in 2026, and the cancer drugs Ibrance (Palbociclib) and Xtandi (enzalutamide) in 2027. BMS which markets Eliquis with Pfizer but will experience other losses as well. This year, it is already under pressure, facing the loss of Revlimid (lenalidomide) in Europe and Japan and on a volume-limited basis in the US.

Opdivo (Nivolumab) is going to be off-patent in 2028. At Merck, meanwhile, the entire plotline is pivoting on its checkpoint inhibitor Keytruda (Pembrolizumab) and how the company will reduce its dependence on the big anchor brand before it faces loss of exclusivity in 2028.

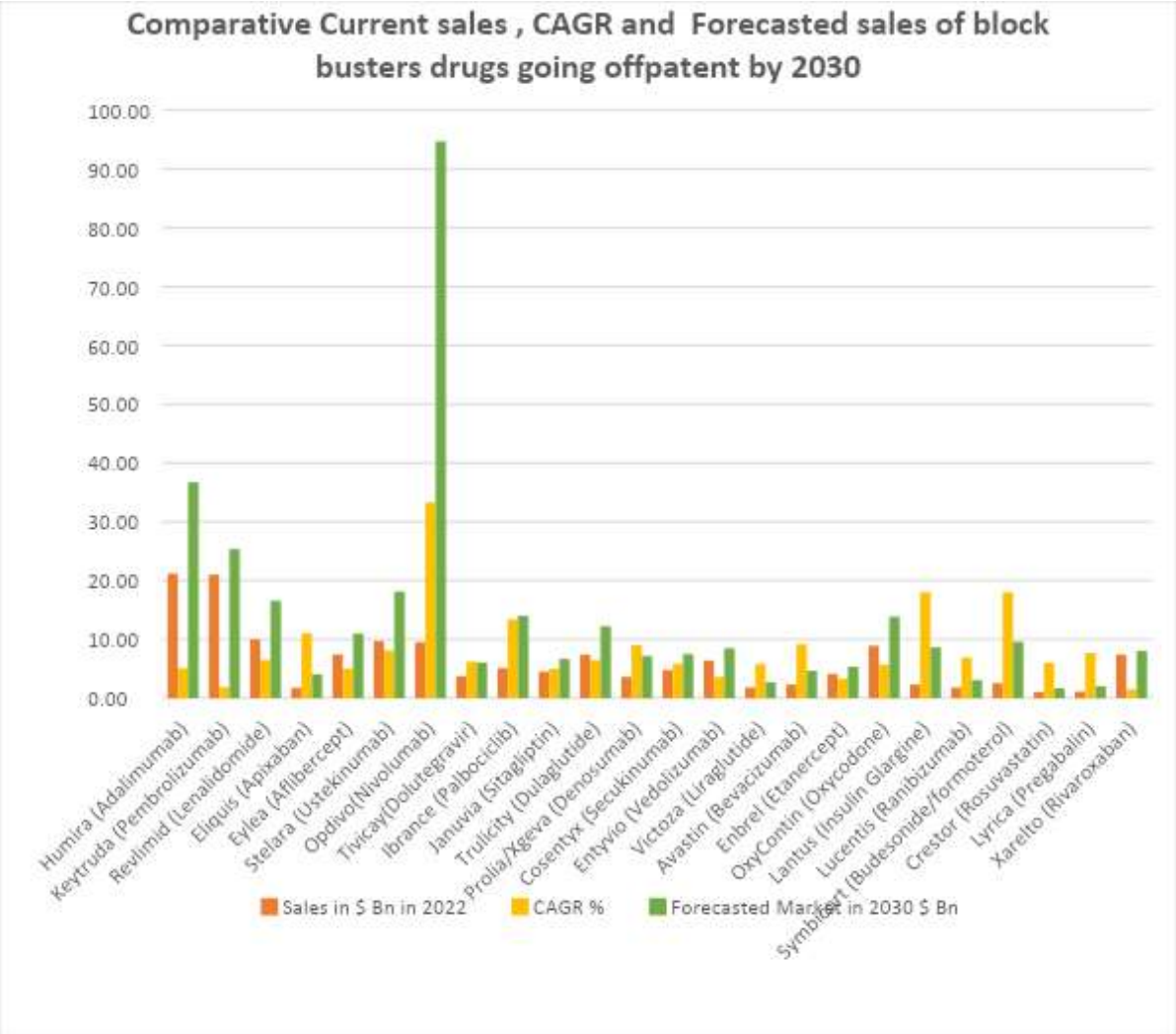
Exhibit 3 and Exhibit 4 below mentions the top 24 blockbuster drugs going off-patent during the patent cliff, their respective sales in year 2022, their annual CAGR and forecasted sales for year 2026, 2028 and 2030.

Exhibit 3: Top 24 blockbuster drugs going off-patent during the patent cliff 2022-2030

S. No	Name of the Drug/ Active Ingredient	Type pf molecule	Sales in $ Bn in 2022	CAGR %	Forecasted Market in 2026 $ Bn	Forecasted Market in 2028 $ Bn	Forecasted Market in 2030 $ Bn
1	Humira (Adalimumab)	Large	21.20	5.11	25.87	28.58	36.72
2	Keytruda (Pembrolizumab)	Large	21.00	1.87	22.62	23.47	25.36
3	Revlimid (Lenalidomide)	Small	10	6.5	12.86	14.59	16.55
4	Eliquis (Apixaban)	Small	1.76	11	2.67	3.29	4.05
5	Eylea (Aflibercept)	Large	7.42	5	9.01	9.94	10.96
6	Stelara (Ustekinumab)	Large	9.72	8.1	13.27	15.51	18.12
7	Opdivo (Nivolumab)	Large	9.50	33.3	29.99	53.29	94.7
8	Tivicay (Dolutegravir)	Small	3.74	6.2	4.75	5.39	6.05
9	Ibrance (Palbociclib)	Small	5.12	13.4	8.46	10.88	14
10	Januvia (Sitagliptin)	Small	4.50	5.02	5.47	6.09	6.66
11	Trulicity (Dulaglutide)	Large	7.40	6.48	9.51	10.78	12.23
12	Prolia/Xgeva (Denosumab)	Large	3.60	9	5.08	6.03	7.17
13	Cosentyx (Secukinumab)	Large	4.78	5.8	5.98	6.7	7.5
14	Entyvio (Vedolizumab)	Large	6.40	3.6	7.37	7.91	8.49
15	Victoza (Liraglutide)	Large	1.81	5.8	2.26	2.53	2.69
16	Avastin (Bevacizumab)	Large	2.30	9.2	3.27	3.9	4.65
17	Enbrel (Etanercept)	Large	4.12	3.3	4.69	5	5.34
18	OxyContin (Oxycodone)	Small	8.90	5.7	11.1	12.41	13.86
19	Lantus (Insulin Glargine)	Large	2.30	18	4.46	6.2	8.64
20	Lucentis (Ranibizumab)	Large	1.80	6.9	2.35	2.6	3.07
21	Symbicort (Budesonide)	Small	2.54	18.01	4.92	6.86	9.55
22	Crestor (Rosuvastatin)	Small	1.05	6	1.42	1.48	1.67
23	Lyrica (Pregabalin)	Small	1.12	7.67	1.51	1.74	2.02
24	Xarelto (Rivaroxaban)	Small	7.40	1.5	7.85	8.09	8.04

Source: Product Sales data and CAGR as per Global data/ Statista/Company's Annual report

Exhibit 4:



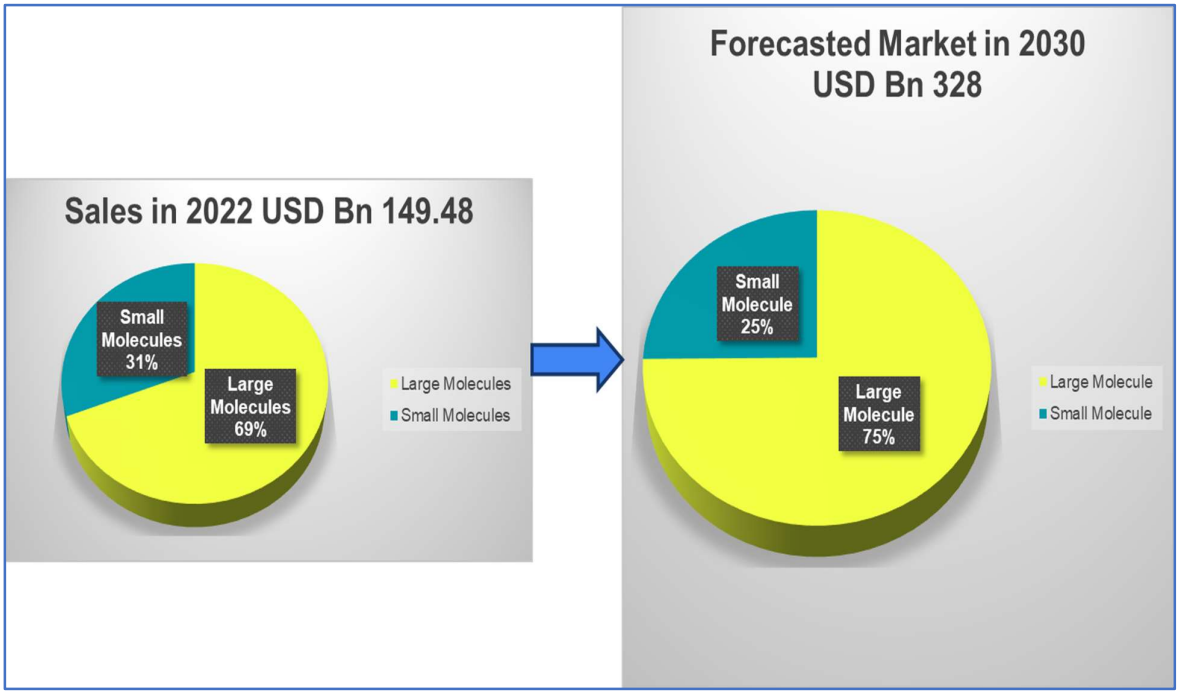
Source: Product Sales data and CAGR as per Global data/ Statista/Company's Annual reports

3.6 Cost Savings from generic drug prescription: The estimated annual cost savings from the prescription of generic drugs can vary significantly depending on the specific country, healthcare system, and the volume of generic drug use. However, generic drugs are generally known to be much more cost-effective than their brand-name counterparts, leading to substantial savings for individuals, healthcare systems, and governments. According to various studies and reports, the cost savings achieved by using generic drugs can range from 20% to 90% compared to the price of brand-name medications. As per our analysis, on average, generic chemical drugs after launch tend to cost around 51 % less than brand-name drugs for a few years. In case of biosimilars, the cost can be around 60% less than innovator products for a few years, It is to be noted that with passage of time and entry of new players, the prices of both chemical generics and biosimilars reduce

substantially. The lower R&D and manufacturing costs, relatively easier and quick regulatory approvals bring cost efficiencies, thereby promoting inter-generic competition and offers the price benefits to patients and insurance providers especially for chronic conditions or high-prevalence diseases.

3.7 Shift from Chemical generics to Biosimilars by 2030: As per the data analysis conducted for the sales of 24 blockbuster drugs, biologics like biosimilars, immunomodulators and monoclonal antibodies are going to further dominate the pharmaceutical industry between 2022-2030. The biosimilar revenues which comprised 69 % of overall revenues of these 24 blockbuster drugs in 2022 is going to increase to 75% by 2030 (Exhibit:5) New pharmaceutical technological advancements like high-throughput screening, molecular profiling, next-generation sequencing, bioinformatics analysis, proteomics, and other molecular profiling techniques have paved the way for personalized medicine approaches in drug development which has led to more biologics reaching the market.

Exhibit 5



Source: Market Forecast /Intelligence (BHPL)/ DrugPatentwatch.com

3.8 Classification of Blockbuster Drugs going off-patent between 2022-2030 (On the basis of Type of molecule, Disease/ Indication, Pharmacological classification and Dosage form)

Drugs can be roughly split into two categories based on their technical characteristics, and into two other categories based on their regulatory characteristics. The two technical categories are pharmaceutical drugs, commonly referred to as small-molecule drugs, and biotech drugs, commonly referred to as biologic drugs. The most popular, and oldest, technical category of drugs is small-molecule drugs. These drugs, also commonly called pharmaceutical drugs, tend to be orally administered as tablets, capsules, or liquids. Most small-molecule drugs are able to cross the stomach lining into the bloodstream where they travel throughout the body until they arrive at their therapeutic target. The

therapeutical target of the drug describes its pharmacological classification. Some of the analysed blockbuster drugs have application in multiple therapeutic areas and disease indications providing a much bigger market opportunity for such drugs. Exhibit 6 Table below for the classification of the blockbuster drugs going off patent between 2022-2023 on the above-mentioned parameters.

Exhibit: 6 Classification of Blockbuster Drugs going off-patent between 2022-2030 (On the basis of Type of molecule, Disease/ Indication, Pharmacological classification and Dosage form)

Drug/Active Ingredient	Parent Company	Disease Indication/s	Type of Molecule	Dosage Form	Pharmacological Classification
Humira (Adalimumab)	AbbVie	Arthritis, plaque Psoriasis, Hidradenitis Suppurativa, Crohn's Disease, Ankylosing Spondylitis, Ulcerative Colitis, Non-Infectious Uveitis	Large	Injection	Tumor necrosis factor (TNF) Blockers
Keytruda (Pembrolizumab)	Merck & Co	Melanoma, lung cancer, head and neck cancer, Hodgkin lymphoma, stomach cancer, cervical cancer, breast cancer	Large	Injection	Monoclonal Antibody
Revlimid (Lenalidomide)	Celgene Corporation, a Bristol-Myers Squibb Company	Myeloma, smoldering myeloma, and myelodysplastic syndromes	Small	Capsules	Immunomodulatory Drugs (ImiDs)
Eliquis (Apixaban)	Bristol-Myers Squibb Company	Treats and prevents blood clots and to prevent stroke	Small	Tablet	Factor Xa inhibitors
Eylea (Aflibercept)	Regeneron and Bayer	Wet macular degeneration and metastatic colorectal cancer	Large	Injection	Vascular endothelial growth factor A (VEGF-A) antagonists

Stelara (Ustekinumab)	Jansssen Biotech	Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis	Large	Injection	Human IgG1 Monoclonal Antibody
Opdivo (Nivolumab)	Bristol Myers Squibb	Cancer	Large	Injection	Human Monoclonal Antibody
Tivicay (Dolutegravir)	ViiV Healthcare	HIV/AIDS	Small	Tablet	HIV integrase inhibitors
Ibrance (Palbociclib)	Pfizer Oncology	Breast Cancer	Small	Capsule	CDK 4/6 inhibitors
Januvia (Sitagliptin)	Merch & Co.	Type 2 Diabetes	Small	Tablet	Dipeptidyl peptidase-4 (DPP-4) inhibitor
Trulicity (Dulaglutide)	Eli-Lilly	Type 2 diabetes to prevent cardiovascular diseases	Large	Injection	Glucagon-like peptide-1 (GLP-1) agonists
Prolia/Xgeva (Denosumab)	Amgen	Osteoporosis, treatment-induced bone loss, metastases to bone, and giant cell tumor of bone	Large	Injection	Monoclonal Antibodies
Cosentyx (Secukinumab)	Novartis	Psoriasis, Ankylosing spondylitis, Psoriatic arthritis	Large	Injection	Monoclonal Antibodies
Entyvio (Vedolizumab)	Millenium Pharmaceuticals	Ulcerative colitis and Crohn's disease	Large	Injection	integrin receptor antagonists

Victoza (Liraglutide)	Novo Nordisk	Type 2 diabetes, obesity, and chronic weight management	Large	Injection	GLP-1 Analog
Avastin (Bevacizumab)	Genentech	First-line treatment of unresectable, locally advanced, recurrent or metastatic non–squamous non–small cell lung cancer in combination with carboplatin and paclitaxel	Large	injection	Monoclonal Antibody and anti-angiogenesis drug
Enbrel (Etanercept)	Immunex Corporation	Active ankylosing spondylitis (AS), plaque psoriasis	Large	Injection	anti-TNFs or TNF blockers
OxyContin (Oxycodone)	Purdue Pharma LLP	Moderate to severe pain	Small	Tablet	opiate (narcotic) analgesics.
Lantus (Insulin Glargine)	Sanofi	Pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia	Large	Injection	long-acting insulin
Lucentis (Ranibizumab)	Genentech	macular edema following retinal vein occlusion (RVO)	Large	Injection	vascular endothelial growth factor A (VEGF-A) antagonists

Symbicort (Budesonide/formoterol)	Astrazeneca	Asthma in patients 12 years of age and older and COPD	Small	Respules	Long-acting beta agonists
Crestor (Rosuvastatin)	AstraZeneca	Homozygous familial hypercholesterolemia, Hyperlipidemia, Mixed dyslipidemia, primary dysbetalipoproteinemia, hypertriglyceridemia, and prevention of cardiovascular disease	Small	Tablet	HMG-CoA reductase inhibitors (statins)
Lyrica (Pregabalin)	Pfizer	Fibromyalgia, diabetic nerve pain, spinal cord injury nerve pain, and pain after shingles in adult patients. LYRICA is also indicated to treat partial-onset seizures	Small	Tablet/ Syrup	Alpha-2 delta ligand.
Xarelto (Rivaroxaban)	Janssen Pharmaceuticals/Bayer	To reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation (AF).	Small	Tablets	Factor Xa inhibitors

Source: Company's Websites/ Annual Reports/ CTRI/ Product Brochures/Leaflets

3.9 US Patent Number and Patent Expiry Date of Blockbuster Drugs going off-patent between 2022-30

Exhibit 7 below details the US Patent Number/s and Patent Expiry Date of Blockbuster Drugs going off-patent between 2022-30

Exhibit 7

Drug/Active Ingredient	Parent Company	US Patent Number/s	Year of Patent Expiry
Humira (Adalimumab)	AbbVie	US6090382A US9187559B2 US8969024B2 US9315574B2 US9273132B2 US9085618B2 US9284371B2 US8663945B2	December 31, 2016 April 11, 2025 May 10, 2032 November 12, 2033 April 04, 2027 March 14, 2033 September 13, 2027
Keytruda (Pembrolizumab)	Merck & Co	US94458307P US8551967B2	June 13, 2028 September 5, 2031
Revlimid (Lenalidomide)	Celgene Corporation, a Bristol-Myers Squibb Company	US7855217 US7465800	November 24, 2024 April 27, 2027
Eliquis (Apixaban)	Bristol-Myers Squibb Company	US6967208	November 21, 2026
Eylea (Aflibercept)	Regeneron and Bayer	US7070959B2	November 11, 2024

Stelara (Ustekinumab)	Jansssen Biotech	US7279157B2 US9409984B2 US7166285B2 US8080247B2 US6902734B2	January 13, 2022 February 27, 2022 May 3, 2022 August 2, 2022 September 25, 2023
Opdivo (Nivolumab)	Bristol Myers Squibb	US9393301B2 US8168179B2 US9067999B1 US9073994B2 US9439962B2 US9402899B2 U57595048B2 US8728474B2	July 2, 2023 July 2, 2023 July 2, 2023 July 2, 2023 July 2, 2023 February 5, 2024 August 8, 2024 August 8, 2024
Tivicay (Dolutegravir)	ViiV Healthcare	US8129385 US9242986 US10426780	October 5, 2027 December 8, 2029 January 24, 2031
Ibrance (Palbociclib)	Pfizer Oncology	US6936612 US7208489 USRE47739 US10723730	January 16, 2023 January 16, 2023 March 5, 2027 February 8, 2034
Januvia (Sitagliptin)	Merch & Co.	US7326708	May 24, 2027
Trulicity (Dulaglutide)	Eli-Lilly	US10369003132 US10376376B2 US10610371B2 US11083591B2 US905601892 US986771292 US10695187B2 US8273854B2 US10130493B2 US8535379B2 US11135072B2	October 15, 2024 October 15, 2024 October 15, 2024 October 15, 2024 October 15, 2024 October 15, 2024 June 28, 2025 May 15, 2026 July 17, 2026 December 13, 2026 April 11, 2027
Prolia/Xgeva (Denosumab)	Amgen	US8409578B2 US8058418B2 US7364736B2	June 25, 2022 November 30, 2023 February 19, 2025
Cosentyx (Secukinumab)	Novartis	US7807155	Feb 09. 2030

Entyvio (Vedolizumab)	Millenium Pharmaceuticals	WO2016086147A1	June 2023
Victoza (Liraglutide)	Novo Nordisk	US6268343 US8114833	February 22, 2023 February 13, 2026
Avastin (Bevacizumab)	Genentech	US20150147317A1	January 2022
Enbrel (Etanercept)	Immunex Corporation	US8163522B1 US8063182B1 NL300129I2	April 24, 2029 November 22, 2028 July 02, 2023
OxyContin (Oxycodone)	Purdue Pharma LLP	US10696684 US10407434 US9522919 US9073933	March 30, 2025 March 30, 2025 March 30, 2025 March 30, 2025
Lantus (Insulin Glargine)	Sanofi	US8048854B2 EP2575865B1	July 05, 2027 May 27, 2031
Lucentis (Ranibizumab)	Genentech	DE202012011260U1	November 24, 2022
Symbicort (Budesonide/formoterol)	AstraZeneca	US20210069215A1	January 29, 2023
Crestor (Rosuvastatin)	AstraZeneca	US6316460B1 US6858618	August 04, 2020 June 17, 2022
Lyrica (Pregabalin)	Pfizer	US8044227B2	October 10, 2028
Xarelto (Rivaroxaban)	Janssen Pharmaceuticals/Bayer	US7157456	August 28, 2024

Source: Drugpatentwatch.com

3.10 Ease of Technology Transfer & Potential Indian Generic companies that can benefit from the Patent Cliff:

Biologic drugs are much larger than small-molecule drugs and are generally injectables. Unlike small-molecule drugs, which are often synthetic chemicals which never occur naturally, many biologic drugs are synthetic versions of naturally-occurring proteins, such as growth factors, monoclonal antibodies, hormones, and immune-system signalling molecules. These differences also have product development technology transfer, legal and regulatory consequences. Indian generic companies have wide experience of reverse engineering the chemical drugs to develop generic versions and transfer the technology for the mass production. However, for the Biosimilar, the development and technology transfer are challenges. Further, the types of patents used for small-molecule and biologic drugs, and the strategies for using (or attacking) these patents are also very different from Biosimilars. Likewise, the regulatory and commercial consideration in gaining approval for new or follower small-molecule and biologic drugs are very different making the Biosimilars a riskier and complex proposition for Indian generic companies. However, a few Indian companies have explored this foray and developed the initial capabilities. The table mentioned below (Exhibit 8) captures the potential Indian generic companies which have a opportunity to grab the market share which is going to be created in between 2022-2030.

Exhibit 8

Drug/Active Ingredient	Parent Company	Ease of Technology Transfer	Generic companies with capability to tap the Opportunity
Humira (Adalimumab)	AbbVie	Low	Biocon, Hetero Healthcare, Zydus, Cipla, Reliance Life sciences, Cadila, RGP life sciences, Glenmark, Alkem, IPCA, Torrent
Keytruda (Pembrolizumab)	Merck & Co	Low	Zuvius Lifesciences, Beta drugs Ltd., Taj Oncology, Getwell oncology
Revlimid (Lenalidomide)	Celgene Corporation, a Bristol-Myers Squibb Company	Moderate	Intas, Fierrece, Natco, Dr Reddy's, Hetero, Cipla, Zydus
Eliquis (Apixaban)	Bristol-Myers Squibb Company	Moderate	Gland, Shinepro, MITS, Bharat Serums & Vaccines Ltd,

Eylea (Aflibercept)	Regeneron and Bayer	Low	Hetero Healthcare, Macleods, Aculife, Natco, Biocon
Stelara (Ustekinumab)	Jansssen Biotech	Low	Orion, Biocon, Hetero Healthcare, Zydus, Cipla, Reliance Life sciences, Cadila, RGP life sciences, Glenmark, Alkem, IPCA, Torrent
Opdivo (Nivolumab)	Bristol Myers Squibb	Low	Alembic Pharma, Dr. Reddy, SG BioPharma, Intas, Emcure
Tivicay (Dolutegravir)	ViiV Healthcare	Moderate	Cipla, Natco, Mylan, Hetero, Emcure, Aurobindo, Laurus, Adcock, SUN Pharma
Ibrance (Palbociclib)	Pfizer Oncology	Moderate	Alembic Pharma, Dr. Reddy, SG BioPharma, Biozenta, Healthkind, Intas, Emcure
Januvia (Sitagliptin)	Merch & Co.	Moderate	Menarni, Dr Reddy's, Actis generics, Akum's Lifesciences, Teva pharmaceuticals
Trulicity (Dulaglutide)	Eli-Lilly	Low	Lupin
Prolia/Xgeva (Denosumab)	Amgen	Low	Cadila, Intas, Dr Reddy’s, Zydus, Alkem

Cosentyx (Secukinumab)	Novartis	Low	Hetero Healthcare, Zydus, Cipla, Reliance Life sciences, Cadila, RGP life sciences, Glenmark, Alkem, IPCA, Torrent
Entyvio (Vedolizumab)	Millenium Pharmaceuticals	Low	Biocon, Hetero Healthcare, Zydus, Cipla, Reliance Life sciences, Cadila, RGP life sciences, Glenmark, Alkem, IPCA, Torrent
Victoza (Liraglutide)	Novo Nordisk	Low	Cipla, Lifesciences, Glenmark, Zydus
Avastin (Bevacizumab)	Genentech	Low	Reliance Life sciences, Hetero, Intas, Dr Reddys, Zydus, Lupin
Enbrel (Etanercept)	Immunex Corporation	Low	Cipla, Intas
OxyContin (Oxycodone)	Purdue Pharma LLP	Moderate	Lupin, Sun Pharmaceuticals,
Lantus (Insulin Glargine)	Sanofi	Low	Biocon Biologics
Lucentis (Ranibizumab)	Genentech	Low	Intas

Symbicort (Budesonide/formoterol)	AstraZeneca	Moderate	Glenmark, Intra Labs, Lupin, Macleods, Dr Reddy's, Cipla, Intas.
Crestor (Rosuvastatin)	AstraZeneca	Moderate	Sun Pharma, Aurobindo Pharma and Glenmark Pharma, Biocon, MSN Laboratories, Lupin, Glenmark, Unichem, Torrent,
Lyrica (Pregabalin)	Pfizer	Moderate	Intas, Glenmark, Aristo, Abbott, Sun pharma, , Cipla, Zydus Cadila, Unichem, Torrent, Lupin
Xarelto (Rivaroxaban)	Janssen Pharmaceuticals/Bayer	Moderate	Dr Reddy's, Taj Generics, Natco,

Source: Company's Websites/ Annual Reports/ CTRI/ Product Brochures/Leaflets

4. ASSESSMENT OF BLOCKBUSTER DRUGS GOING OFF-PATENT BETWEEN 2022-2030

Humira

Innovator Company: Abbvie Inc.

API/Salt/Composition: Adalimumab

Pharmacological Classification:

Tumor Necrosis Factor (TNF) Blockers

Dosage Form: Subcutaneous Injection

Dosage Strength:

- **Single-dose prefilled pen** (HUMIRA Pen): 80 mg/0.8 mL, 40 mg/0.8 mL, and 40 mg/0.4 mL
- **Single-dose prefilled glass syringe**: 80 mg/0.8 mL, 40 mg/0.8 mL, 40 mg/0.4 mL, 20 mg/0.4 mL, 20 mg/0.2 mL, 10 mg/0.2 mL, 10 mg/0.1 mL

Patent Number and Expiration Date:

- US6090382A December 31, 2016 (Expired)
- US9187559B2 April 11, 2025
- US8969024B2 May 10, 2032
- US9315574B2 November 12, 2033
- US9273132B2 April 04, 2027
- US9085618B2 March 14, 2033
- US9284371B2/ US8663945B2, September 13, 2027

The company owns **257 Humira-related** patents including ancillary Uses, such as manufacturing methods and administering Humira.

Indications: Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis, Hidradenitis Suppurativa and Uveitis

Global Market:

The revenue of the pharmaceutical product Humira has increased from 2011 to 2022, generating 7.9 billion U.S. dollars in 2011 and a record high of 21.2 billion U.S. dollars in 2022. Humira is expected to continue its success soon. The global market is expected to grow at a CAGR of 5.11% between 2023 to 2028. As a result, the market size is anticipated to grow by USD 11.6 billion in 2028. [1,2]

Potential Generic Manufacturers in INDIA:

The Indian market for Adalimumab was estimated to be USD 16.16 Million in the year 2014. It has been steadily growing @annual CAGR of around 5% since then. Many companies in India have announced the biosimilar launch of Adalimumab. Biocon Biologics, a subsidiary of Biocon launched a biosimilar version of Humira in the US market under brand name HULIO in July,2023. Hetero Drugs had launched its biosimilar Mabura in 2018 in Indian market, while Glenmark Pharmaceuticals Ltd signed a licencing agreement with Zydus Cadila to create another adalimumab brand, Adaly. Cadila had already launched their generic version Cadalimab in 2020 in Indian market.

1.https://www.statista.com/statistics/318206/revenue-of-humira

2. https://marketdataforecast.com/market-reports/global-humira-market

Keytruda

Innovator Company:

Merck & Co.

API/Salt/Composition:

Pembrolizumab

Pharmacological Classification:

Monoclonal Antibody

Dosage Form:

Intravenous Injection

Dosage Strength:

- **For injection:** 50 mg lyophilized powder in a single-use vial for reconstitution
- **Injection:** 100 mg/4 mL (25 mg/mL) solution in a single-use vial

Patent Number and Expiration Date:

- US94458307P June 13, 2028
- US8551967B2 September 5, 2031

Merck has filled 129 patents linked to Keytruda which could extend its exclusivity to 2036. 74% cover different indications and formulations of the drug, not the key antibody

Indications:

Melanoma, Non-small Cell Lung Cancer, Head and Neck Cancer

Global Market:

Keytruda is one of the best-selling drugs worldwide, generating nearly 21 billion U.S. dollars in revenue during 2022 & forecast to bring annual revenue of 22.2 billion U.S. dollars by 2025. [1,2]

Potential Generic Manufacturers in INDIA:

NeuClone and Serum Institute of India has agreed to co-develop biosimilar monoclonal antibodies and has reached the Preclinical Phase.

1. https://www.statista.com/statistics/1269401/revenues-of-keytruda/
2. https://www.pharmaceutical-technology.com/comment/keytruda-projections/

Revlimid

Innovator Company:

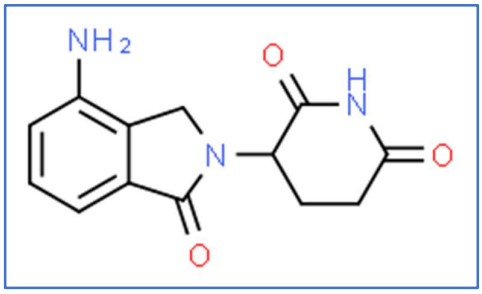
Celgene (Bristol Myers Squibb)

API/Salt/Composition: Lenalidomide

Pharmacological Classification:

Immunomodulatory Drugs (ImiDs)

Dosage Form: Capsules



Dosage Strength:

- 2.5mg, 5mg, 10mg, 15mg, 20mg, 25mg

Patent Number and Expiration Date:

- US7855217 November 24, 2024
- US7465800 April 27, 2027

As per FDA's orange book, Celgene has 27 patents for Revlimid listed. Four are listed as patents for active ingredient & five are "drug product" patents.

Indications:

Multiple Myeloma, maintenance therapy following autologous hematopoietic stem cell transplantation, Transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS), Mantle cell lymphoma (MCL), follicular lymphoma, Marginal zone lymphoma (MZL)

Global Market:

Top product Revlimid between 2008 to 2022 became the leading cancer drug, generating 10 billion US dollars. The Global Lenalidomide market is growing at a CAGR of 6.5% in the forecast period (2023-2030).[1,2]

Potential Generic Manufacturers in INDIA:

The Indian market for Revlimid was estimated to be around USD 2.3 Billion in the year 2021. Many generic lenalidomide variants are present in the Indian market. Natco Pharma Ltd, Dr Reddy's Laboratories Ltd, Sun Pharmaceuticals Ltd, Cipla Ltd, Panacea Biotec Ltd, United Biotech Pvt Ltd, Intas Pharmaceuticals Ltd, SR Pharmaceuticals, Zydus Cadila are the companies that have launched their generics in the Indian market.

1. https://www.statista.com/statistics/1269411/revenues-of-revlimid/

2. https://dataintelo.com/report/lenalidomide-drug-market

Eliquis

Innovator Company:

Bristol Myers Squibb / Pfizer

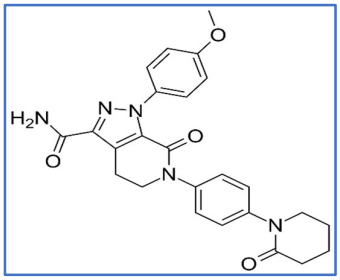
API/Salt/Composition: Apixaban

Pharmacological Classification: Factor Xa Inhibitors

Dosage Form: Tablets

Dosage Strength:

- 2.5mg, 5mg



Patent Number and Expiration Date:

- US6967208 November 21, 2026

There are 169 international patents filed for Apixaban by Bristol Myers Squibb.

Indications:

- Stroke risk reduction in nonvalvular AF
- DVT/PE treatment & reduction in risk of recurrence following initial therapy
- Prophylaxis of DVT after hip or knee replacement surgery

Global Market:

Eliquis has added over $1 billion in sales each year since 2014. While the strong growth could continue for Eliquis in the coming years. It is estimated that the drug's revenues could grow at a CAGR of 11%. In 2022, the market was valued at USD 1.76 billion and would grow to USD 2.90 Billion by 2030.[1,2]

Potential Generic Manufacturers in INDIA:

Cipla planned to launch the generic version of Apixaban under the probable brand name Apigy. Emcure, Natco, Pulse, Intas, La Renon Healthcare, Cadila, Torrent, Sun, and Micro Labs had already launched their apixaban generics in India.

1. https://www.forbes.com/sites/greatspeculations/2019/08/23/can-eliquis-continue-to-add-1-billion-in-annual-sales-for-bristol-myers-squibb/?sh=2ee2b3712267

2. https://www.databridgemarketresearch.com/reports/global-apixaban-market#:~:text=The%20market%20was%20valued%20at,USD%202%2C908.17%20million%20by%202030.

Eylea

Innovator Company:

Regeneron and Bayer

API/Salt/Composition:

Aflibercept

Pharmacological Classification:

Vascular Endothelial Growth Factor A (VEGF-A) antagonists

Dosage Form: Intravitreal Injection

Dosage Strength:

- 2 mg/0.05 mL

Patent Number and Expiration Date:

- US7070959B2 November 11, 2024

Regeneron listed **29 patents** in connection with EYLEA, four of which do not expire until 18 August 2040

Indications:

- Neovascular (Wet) Age-Related Macular Degeneration (AMD)

Global Market:

Eylea's Market size was valued at USD 7.2 Billion in 2021, USD 7.42 billion in 2022 to USD 7.79 billion in 2023 with a compound annual growth rate (CAGR) of 5.0% and is projected to reach USD 10 Billion by 2030, growing at a CAGR of 3.72% from 2023 to 2030.[1,2]

Potential Generic Manufacturers in India:

Joint venture Bayer Zydus Pharma of Bayer Healthcare and Zydus Cadila has been operating in the Indian Market, focusing on women's healthcare, metabolic disorders, diagnostic imaging, cardiovascular diseases, anti-diabetic treatments and oncology. This joint venture has launched Eylea in the Indian Market.

1. https://www.verifiedmarketresearch.com/product/eylea-market/

2. https://www.researchandmarkets.com/report/eylea

Stelara

Innovator Company:

Janssen Biotech

API/Salt/Composition:

Ustekinumab

Pharmacological Classification:

Human IgG1 Monoclonal Antibody

Dosage Form:

Subcutaneous Injection, IV Infusion

Dosage Strength:

- 130 mg/26 mL

Patent Number and Expiration Date:

- US7279157B2 January 13, 2022
- US9409984B2 February 27, 2022
- US7166285B2 May 3, 2022
- US8080247B2 August 2, 2022
- US6902734B2 September 25, 2023

Still, there are **23 Patents protecting** Stelera.

Indications:

- Moderate to Severe Active Crohn's Disease
- Moderate to Severe Active Ulcerative Colitis

Global Market: Stelara was introduced in 2009 and has been J&J's top-selling drug since 2019, with sales reaching USD 9.7 billion in 2022. Currently, it is expected J&J to bring in USD 54.5 billion in 2025. According to Market Statsville Group, the global ustekinumab market size is expected to grow at a CAGR of 8.1% from 2023 to 2033. [1,2,3]

Potential Generic Manufacturers in INDIA: Indian drugmaker Intas Pharmaceuticals received a grant for rights to commercialise DMB-3115, a proposed biosimilar to Janssen's Stelara (ustekinumab), in all global markets excluding Japan, South Korea and other Asian countries.

1. https://www.globaldata.com/data-insights/healthcare/the-global-drug-sales-of-stelara-1127413/

2. https://www.reuters.com/business/healthcare-pharmaceuticals/stelara-patent-deal-puts-jj-back-path-57-bln-2025-revenue-forecast-2023-06-05/

3. https://www.linkedin.com/pulse/ustekinumab-market-size-expected-grow-cagr-81-2033-manjeet-ahirwar/

Opdivo

Innovator Company: Bristol Myers Squibb

API/Salt/Composition: Nivolumab

Pharmacological Classification:

Vascular Endothelial Growth Factor A (VEGF-A) antagonists

Dosage Form: Intravitreal Injection

Dosage Strength:

- 2 mg/0.05 mL

Patent Number and Expiration Date:

- US9393301B2 July 2, 2023
- US8168179B2 July 2, 2023
- US9067999B1 July 2, 2023
- US9073994B2 July 2, 2023
- US9439962B2 July 2, 2023
- US9402899B2 February 5, 2024
- U57595048B2 August 8, 2024
- US8728474B2 August 8, 2024

There are still One hundred and **92 patents active** for Opdivo.

Indications:

Non-Small Cell Lung Cancer (NSCLC), Melanoma, Advanced Kidney Cancer, Bladder or Urinary Tract Cancer (Urothelial), Colorectal Cancer (MSI-H/dMMR), Classical Hodgkin Lymphoma, Gastric or Gastroesophageal Junction or Esophageal Cancers, Malignant Pleural Mesothelioma

Global Market:

The Global Drug size of Opdivo was USD 1.78 billion in 2020 and sales stood at **USD 9.5 Billion in 2022** and are expected to reach USD 25.68 billion by 2028, at a CAGR of 33.3% during the forecast period.[1,2]

Potential Generic Manufacturers in INDIA:

There is no generic/biosimilar for Nivolumab in India to date. But many potential Anticancerous drug manufacturers that can launch their biosimilars are Sun Pharma, Cadila, Dr Reddy's, Natco, Hetero, Glenmark etc.

1. https://www.globaldata.com/data-insights/healthcare/the-global-drug-sales-of-opdivo-1127420/

2. https://dataintelo.com/report/global-nivolumab-drugs-sales-market/

Tivicay

Innovator Company:

Viiv Healthcare

API/Salt/Composition:

Dolutegravir

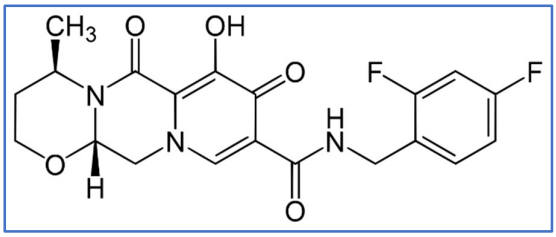
Pharmacological Classification:

HIV integrase Inhibitors

Dosage Form:

Intravitreal Injection

Dosage Strength:



- **Tablets:** 10mg, 25mg, 50mg
- **Paediatric Oral Suspension:** 5mg

Patent Number and Expiration Date:

- US8129385 October 5, 2027
- US9242986 December 8, 2029
- US10426780 January 24, 2031

This drug has patent family members in 33 countries,

Indications:

- HIV/AIDS

Global Market:

Dolutegravir and Its Combination Drug market are expected to grow **annually by 6.2**% (CAGR 2023 - 2030), and the global revenue of Tivicay was USD 3.74 Billion in 2022(£ 285 million). [1,2]

Potential Generic Manufacturers in INDIA:

Aurobindo Pharma, Cipla and Emcure Pharmaceuticals have launched their generic Dolutegravir for HIV treatment in India.

1.https://www.marketwatch.com/press-release/dolutegravir-and-its-combination-drug-market-size-global-revenue-volume-market-share-production-cost-and-forecast-at-a-forecasted-62-cagr-forecasted-from-2023-to-2030-2023-05-04

2.https://www.gsk.com/media/9847/fy-2022-results-announcement.pdf

Ibrance

Innovator Company: Pfizer

API/Salt/Composition: Palbociclib

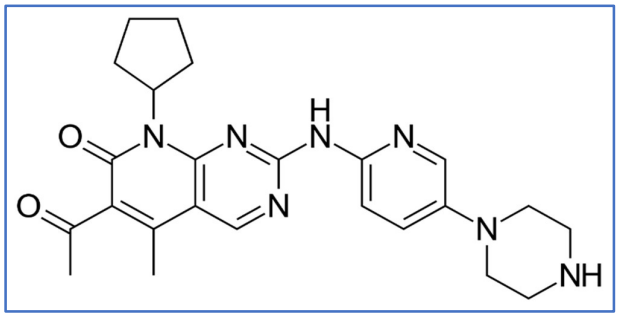
Pharmacological Classification:

CDK 4/6 inhibitors

Dosage Form: Capsules, Tablets

Dosage Strength:

- **Capsule/Tablet:** 125mg



Patent Number and Expiration Date:

- US6936612 January 16, 2023
- US7208489 January 16, 2023
- USRE47739 March 5, 2027
- US10723730 February 8, 2034

There are 6 patents protecting Ibrance and two Paragraph IV challenges.

Indications:

Hormone Receptor-Positive (HR+), Human Epidermal Growth Factor Receptor 2-Negative (HER2-) Breast Cancer

Global Market:

Palbociclib (Ibrance) is expected to generate the largest revenue of USD 37.6 Billion by the end of 2030, up from a revenue of USD 5.3 Billion in 2020 & USD 5.12 Billion in 2022 at the expected highest CAGR of 13.4% during the forecast period. The market is segmented into pre-menopausal, post-menopausal, and others. Out of these, the post-menopausal segment is expected to generate the largest revenue of USD 35.7 Billion in 2030. [1,2]

Potential Generic Manufacturers in INDIA:

BDR Pharmaceuticals recently launched a new generic drug Palbociclib with the brand name Bdpalbo for the advanced treatment of metastatic breast cancer in India. Other than this Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy's, Natco and Wembrace Biopharma has their biosimilar in the Indian Market.

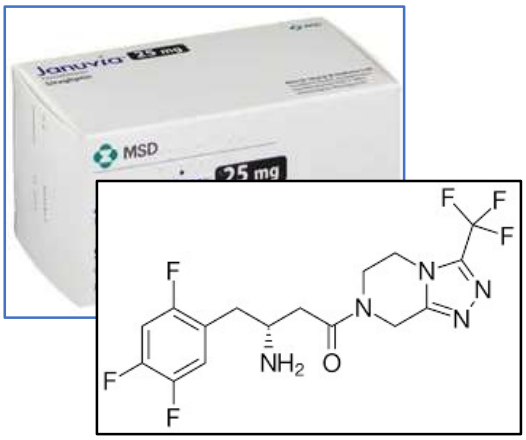
1. https://www.researchnester.com/reports/cdk-46-inhibitor-drugs-market/2533

2. https://www.globaldata.com/data-insights/healthcare/the-global-drug-sales-of-ibrance-1127394/

Januvia

Innovator Company: Merck & Co.

API/Salt/Composition: Sitagliptin



Pharmacological Classification:

Dipeptidyl Peptidase-4 (DDP-4) inhibitor

Dosage Form: Tablet

Dosage Strength:

- **Tablet:** 25mg, 50mg, 100mg

Patent Number and Expiration Date:

- US7326708 May 24, 2027

This drug has one hundred and twenty-seven patent family members in forty-six countries. There has been litigation on patents covering JANUVIA.

Indications:

- Type-2 Diabetes

Global Market:

Januvia comprises the molecule Sitagliptin and Janumet contains Sitagliptin with metformin. Both drugs treat type-2 diabetes and have a market size of USD 5.2 Billion & USD 4.5 Billion for the full year globally in 2021 & 2022 respectively. The global diabetes treatment market is forecasted to grow at a CAGR of **5.02% from 2023 to 2028** and will be worth USD 118.77 billion by 2028 from USD 92.97 Billion.[1,2,3]

Potential Generic Manufacturers in INDIA:

Indian market for Sitagliptin was estimated to be around INR 3600 Crores in year 2022. Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma have launched their Generics of Sitagliptin in the Indian Market.

1.https://www.merck.com/news/merck-announces-fourth-quarter-and-full-year-2022-financial-results/

2. https://www.marketdataforecast.com/market-reports/global-diabetes-treatment-market

3. https://www.drugdiscoverytrends.com/50-of-2022s-best-selling-pharmaceuticals/

Trulicity

Innovator Company: Eli Lilly

API/Salt/Composition: Dulaglutide

Pharmacological Classification: Glucagon-like peptide-4 (DPP-4) Inhibitor

Dosage Form: Injection

Dosage Strength: Injection: 0.75mg, 1.5mg, 3.0mg, 4.5mg (0.5ml)

Patent Number and Expiration Date:

- US10369003132 October 15, 2024
- US10376376B2 October 15, 2024
- US10610371B2 October 15, 2024
- US11083591B2 October 15, 2024
- US905601892 October 15, 2024
- US986771292 October 15, 2024
- US10695187B2 June 28, 2025
- US8273854B2 May 15, 2026
- US10130493B2 July 17, 2026
- US8535379B2 December 13, 2026
- US11135072B2 April 11, 2027

Trulicity is covered with 31 low-certainty patents filed by Eli Lily with an estimated patent expiry year up to 2040.

Indications: Type-2 Diabetes and Cardiovascular Diseases,

Global Market:

In 2022, Trulicity was Eli Lilly's biggest revenue generator with about 7.4 billion U.S. dollars. The global glucagon-like peptide 1 (GLP-1) market was valued at **USD 16.53 billion** in 2021 and is probable to reach USD 24.10 billion by 2027. [1,2]

Potential Generic Manufacturers in INDIA:

There are currently no biosimilar alternatives to Trulicity only Lupin has launched its biosimilar as Aplevant in the Indian Market.

1. https://www.statista.com/statistics/278214/eli-lilly-and-companys-top-products-based-on-revenue

2. https://www.prnewswire.com/news-releases/global-glucagon-like-peptide-1-glp-1-market-report-2023-a-24-1-billion-market-by-2027-from-16-53-billion-in-2021-w

Prolia/Xgeva

Innovator Company: Amgen

API/Salt/Composition: Denosumab

Pharmacological Classification:

Monoclonal Antibodies

Dosage Form: Injection

Dosage Strength:

- **Prolia** 60 mg/1 mL single-use prefilled syringe: 1 syringe every 6 months
- **Xgeva** 120 mg/1.7 mL single-use vial

Patent Number and Expiration Date:

- US8409578B2 June 25, 2022
- US8058418B2 November 30, 2023
- US7364736B2 February 19, 2025

Amgen seeks a declaratory judgement of infringement of 21 patents that cover denosumab (the active ingredient in Prolia and XGEVA)

Indications:

Giant Cell Tumor of Bone, Hyperglycaemia of Malignancy, Bone Metastases from solid tumour and Multiple Myeloma

Global Market:

Prolia/Xgeva had combined worldwide net sales of USD 3.6 billion in 2022 and sales of Prolia and Xgeva has been growing @approximate CAGR 9% per year.[1,2,3,4]

Potential Generic Manufacturers in INDIA:

Dr Reddy's, Intas, Cipla, Alkem, Zydus, Bioelite Lifesciences, RPG Lifesciences, and Biorange Biologicals have launched their Biosimilars in the Indian Market of Prolia/Xgeva.

1. https://www.gabionline.net/biosimilars/general/Biosimilars-of-denosumab

2.https://www.amgen.com/newsroom/press-releases/2023/01/amgen-reports-fourth-quarter-and-full-year-2022-financial-results

3. https://www.amgen.com/newsroom/press-releases/2022/02/amgen-reports-fourth-quarter-and-full-year-2021-financial-results

4. https://www.drugdiscoverytrends.com/50-of-2022s-best-selling-pharmaceuticals/

Entyvio

Innovator Company:

Millennium Pharmaceuticals

API/Salt/Composition: Vedolizumab

Pharmacological Classification:

Integrin Receptor Antagonist

Dosage Form: Injection

Dosage Strength:

- **Injection**: 300mg in a single dose

Patent Number and Expiration Date:

- WO2016086147A1 June 2023

Entyvio is covered with 23 Low Certainty patents.

Indications:

- Moderately to severely active Ulcerative Colitis
- Moderately to severely active Crohn's Disease

Global Market:

According to Global Data, the Entyvio global market size was USD 6.4 Billion in 2022, it is estimated that the market growth for ulcerative colitis and Inflammatory Bowel disease is expected to grow at a compound annual growth rate (CAGR) of 3.6% and 5.7% from 2023 to 2030 respectively.[1,2,3]

Potential Generic Manufacturers in INDIA:

There are no other Biosimilar of Vedolizumab in the market only Baxter India Pvt Ltd and Takeda have launched it as Kynteles in Indian market.

1. https://www.globaldata.com/data-insights/healthcare/the-global-drug-sales-of-entivio-1127430/

2. https://www.researchandmarkets.com/reports/5457623/inflammatory-bowel-disease-treatment-market

3. https://www.alliedmarketresearch.com/ulcerative-colitis-market

Victoza

Innovator Company: Novo Nordisk

API/Salt/Composition: Liraglutide

Pharmacological Classification: GLP-1 Analog

Dosage Form: Injection

Dosage Strength: 1.2mg/1.8mg

Patent Number and Expiration Date:

- US6268343 February 22, 2023
- US8114833 February 13, 2026

This drug has one hundred and 97 patent family members in 32 countries. There has been litigation on patents covering VICTOZA.

Indications:

- Along with diet and exercise to lower blood sugar (glucose) in adults and children 10 years of age and older with type 2 diabetes mellitus.
- To reduce the risk of major cardiovascular events such as heart attack, stroke, or death in adults with type 2 diabetes mellitus with known heart disease.

Global Market:

According to the Novo Nordisk annual report, the global sale of Victoza was recorded at USD 1.80 Billion in 2022. It is estimated that the market size for liraglutide drugs is expected to grow at a CAGR of 5.8% from 2021 to 2028.[1,2]

Potential Generic Manufacturers in INDIA:

The Indian market for Liraglutide is estimated to be INR 27 Crores in the year 2023.There are no current biosimilars of Liraglutide available in the market. But many market players are good in this therapeutic area, including Biocon.

1. https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2023/novo-nordisk-annual-report-2022.pdf

2. https://dataintelo.com/report/global-liraglutide-drugs-market/

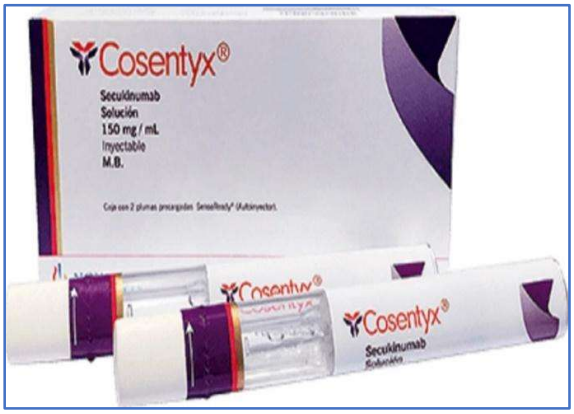
Cosentyx

Innovator Company: Novartis

API/Salt/Composition: Secukinumab

Pharmacological Classification:

Monoclonal Antibodies



Dosage Form:

Subcutaneous Injection

Dosage Strength:

- **Injection**: 150 mg/mL solution in a single-use Sensoready® pen
- **Injection**: 150 mg/mL solution in a single-use prefilled syringe
- **For Injection:** 150 mg, lyophilized powder in a single-use vial for reconstitution for healthcare professional use only

Patent Number and Expiration Date:

- US7807155 Feb 09, 2030

There are **47 patents** protecting this drug of Novartis.

Indications:

- Moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.
- Adults with active psoriatic arthritis (PsA).
- Adults with active ankylosing spondylitis (AS).

Global Market: The Global Drug sales of Cosentyx stood at USD 4.78 Billion in 2022. And is expected to grow at a CAGR growth rate of 5.80% by 2029.[1,2]

Potential Generic Manufacturers in INDIA: There are no currently other biosimilars in the market for Secukinumab. Glenmark, Dr Reddy's, and Sun Pharma are among the top companies in India that manufacture medicines in plaque psoriasis and ankylosing spondylitis.

1. https://www.globaldata.com/data-insights/healthcare/the-global-drug-sales-of-cosentyx-1127410/

2. https://www.databridgemarketresearch.com/reports/global-secukinumab-market

Avastin

Innovator Company:

Genentech

API/Salt/Composition:

Bevacizumab

Pharmacological Classification:

Monoclonal Antibody and Anti-Angiogenesis Drug

Dosage Form: Intravenous injection

Dosage Strength:

- 100mg/4 mL

Patent Number and Expiration Date:

- US20150147317A1 2022

There are 24 High confidence patents covering Genentech's Avastin.

Indications:

Metastatic Colorectal Cancer, Non-small Cell Lung Cancer (NSCLC), Glioblastoma (GBM), Metastatic Kidney Cancer (mRCC), Advanced Cervical Cancer (CC), Ovarian Cancer (OC), Hepatocellular Carcinoma (HCC)

Global Market:

The Global Drug Sale of Avastin is USD 2.32 Billion in 2022. As the patent is expiring the market of Bevacizumab is estimated to reach USD 12.96 Billion in 2030 and is expected to CAGR of 9.2%.[1,2]

Potential Generic Manufacturers in INDIA:

Indian market for Bevacizumab was estimated to be INR 223 Cr in the year 2018. Mumbai-based Reliance Life Sciences has launched a biosimilar and is the first company that brings the first biosimilar of Bevacizumab to India.

1. https://www.globaldata.com/data-insights/healthcare/the-global-drug-sales-of-avastin-1127427/

2. https://www.databridgemarketresearch.com/reports/global-bevacizumab-market

Enbrel

Innovator Company: Amgen

API/Salt/Composition: Etanercept

Pharmacological Classification:

Anti-TNFs or TNF blockers

Dosage Form:

Subcutaneous Injection

Dosage Strength:

- 2 mg/0.05 mL

Patent Number and Expiration Date:

- US8163522B1 April 24, 2029
- US8063182B1 November 22, 2028
- NL300129I2 July 02, 2023

Amgen holds **19 active patent applications** and many approved patents

Indications:

- Moderate to severe Rheumatoid Arthritis
- Psoriatic Arthritis
- Moderate to severe Plaque Psoriasis
- Ankylosing Spondylitis
- Moderate to severe polyarticular Juvenile Idiopathic Arthritis

Global Market:

The global market size of Enbrel was USD 4.12 Billion in 2022 and is expected to grow up to 20.8 billion USD at a CAGR growth rate of 3.3%. [1,2]

Potential Generic Manufacturers in INDIA:

Indian Companies Like Intas, Cipla, Taj Pharma, Reliance Life Sciences, and Lupin have Launched their biosimilar as Intacept, Etaacept, Enbrol, Etanerrel, and Rymti respectively for Pfizer's Etanercept.

1. https://www.statista.com/statistics/312378/enbrel-global-revenues-by-region-amgen/

2. https://www.globenewswire.com/en/news-release/2022/05/10/2440034/0/en/At-CAGR-of-3-3-Global-Etanercept-Market-Size-Share-2022-2028-Projected-to-Hit-at-USD-20-8-Billion-Etanercept-Industry-Trends-Value-Analysis-Forecast-Report-by-Facts-Factors.html

OxyContin

Innovator Company: Purdue Pharma LLP

API/Salt/Composition: Oxycodone

Pharmacological Classification:

Opiate (narcotic) analgesics

Dosage Form: Tablets

Dosage Strength:

- **Tablets:** 10mg, 20mg, 40mg, 80mg, 160mg

Patent Number and Expiration Date:

- US10696684 March 30, 2025
- US10407434 March 30, 2025
- US9522919 March 30, 2025
- US9073933 March 30, 2025

Oxycodone hydrochloride has **602 patent family members** in forty-nine countries. There are twelve drug master file entries for oxycodone

Indications:

- Moderate to Severe Pain

Global Market:

The Oxycodone Market Size is projected to exceed value to USD 8.9 Billion by 2022 this marks a significant increase from its current value of USD 5.11 Billion in 2023 and is expected to grow at a CAGR of 5.7% between 2023 to 2033.[1,2]

Potential Generic Manufacturers in INDIA:

Taj Pharma is the only Oxycodone generic manufacturer in India at present.

1. https://finance.yahoo.com/news/oxycodone-market-estimated-cross-worth-163000919.html

2. https://www.futuremarketinsights.com/reports/oxycodone-market

Lantus

Innovator Company:

Sanofi

API/Salt/Composition:

Insulin Glargine

Pharmacological Classification:

Long-acting insulin

Dosage Form: Subcutaneous Injection

Dosage Strength:

- 100Units/ml

Patent Number and Expiration Date:

- US8048854B2 July 05, 2027
- EP2575865B1 May 27, 2031

Sanofi has filed **74 patent applications in 2018,** on Lantus in the U.S. with the aim of preventing competition for a total of 37 years.

Indications:

Paediatric patients with Type 1 diabetes mellitus and adults with Type 2 diabetes mellitus

Global Market:

Lantus was Sanofi's second best-selling pharmaceutical product in 2022 according to the company's latest annual financial report and generated USD 2.3 Billion, is expected to reach USD 6.2 Billion by 2028, growing at a CAGR of 18 % during the forecast period (2022-2028).[1,2]

Potential Generic Manufacturers in INDIA:

Indian market for Insulin Glargine was estimated to be USD 376 Million in the year 2020.Biocon has launched its biosimilar of Insulin Glargine with the name BASALOG in India and some other countries like Malaysia, Algeria, Morocco, Tanzania, Colombia, and Kazakhstan.

1. https://www.statista.com/statistics/266506/sanofi-top-pharmaceutical-products/
2. https://www.coherentmarketinsights.com/market-insight/insulin-glargine-market-5231

Lucentis

Innovator Company: Genentech (Roche)

API/Salt/Composition: Ranibizumab

Pharmacological Classification:

Vascular Endothelial Growth Factor A (VEGF-A) Antagonists

Dosage Form: Intravitreal Injection

Dosage Strength:

- **Single-use prefilled syringe 0.05 mL for intravitreal injections: -**
  10 mg/mL solution (LUCENTIS 0.5 mg)
  6 mg/mL solution (LUCENTIS 0.3 mg)
- **Single-use glass vial 0.05 mL for intravitreal injections: -**
  10 mg/mL solution (LUCENTIS 0.5 mg)
  6 mg/mL solution (LUCENTIS 0.3 mg)

Patent Number and Expiration Date:

- DE202012011260U1 November 24, 2022

Lucentis is covered with 36 US Patents and 9 High Confidence Patents.

Indications:

Wet age-related macular degeneration (Wet AMD), Diabetic retinopathy and diabetic macular oedema (DR and DME), Myopic choroidal neovascularisation (mCNV), Macular oedema following retinal vein occlusion (RVO)

Global Market:

Lucentis' global sales of USD 1.8 billion in 2022. The age-related macular degeneration market size was valued at USD 9.84 billion in 2021 and is expected to expand at a compound annual growth rate (CAGR) of 6.9% from 2022 to 2030.[1,2]

Potential Generic Manufacturers in INDIA:

Sun Pharmaceuticals and Intas Pharmaceuticals received the grant to manufacture Ranibizumab and launched biosimilars such as Oceva and Razumab.

1. https://www.novartis.com/investors/financial-data/product-sales

2. https://www.grandviewresearch.com/industry-analysis/age-related-macular-degeneration-market-report

Symbicort

Innovator Company: AstraZeneca

API/Salt/Composition:

Budesonide/Formoterol

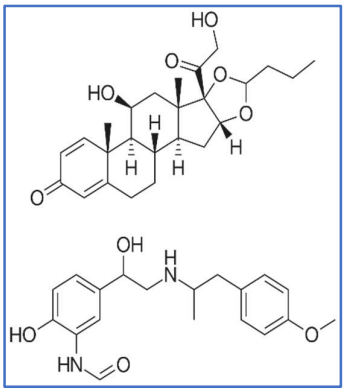
Pharmacological Classification:

Long-acting beta-agonists

Dosage Form: Inhalation Aerosol

Dosage Strength:

- Budesonide (80 or 160 mcg) + Formoterol (4.5mcg)



Patent Number and Expiration Date:

- US20210069215A1 January 29, 2023

There are 11 patents protecting this drug and one Paragraph IV challenge. This drug has 258 patent family members in 43 countries.

Indications:

- Asthma
- Chronic Obstructive Pulmonary Disease (COPD)

Global Market:

The global revenue of Symbicort was USD 2.54 Billion in 2022, global smart inhaler market size is estimated to be **valued at USD 4.86 Billion by 2028**, growing at a promising CAGR of 18.01% from 2023 to 2028. [1,2,3]

Potential Generic Manufacturers in INDIA:

Indian market for Budesonide/Formoterol was estimated to be USD 226.4 Million in the year 2021. Cipla, Lupin, Zydus Cadila, Macleods Pharma, Glenmark, Mankind, Intas, and Sun Pharmaceuticals are the companies that have launched their generics in the Indian Market.

1. https://www.fiercepharma.com/special-reports/top-10-drugs-losing-us-exclusivity-2023

2. https://www.marketdataforecast.com/market-reports/smart-inhaler-market

3. https://www.astrazeneca.com/content/dam/az/PDF/2022/fy/Full-year-and-Q4-2022-results-announcement.pdf

Crestor

Innovator Company: AstraZeneca

API/Salt/Composition: Rosuvastatin

Pharmacological Classification:

HMG-CoA Reductase Inhibitors (Statins)

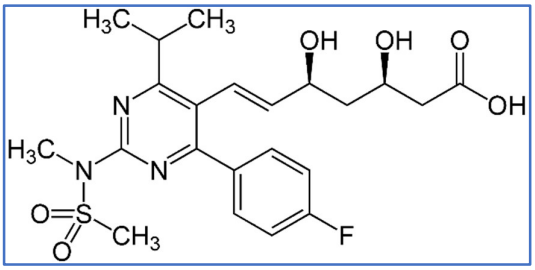
Dosage Form: Tablet

Dosage Strength:

- **Tablets**: 5 mg, 10 mg, 20 mg, and 40 mg

Patent Number and Expiration Date:

- US6316460B1 August 04, 2020
- US6858618 June 17, 2022



This drug has 43 patent family members in thirty-four countries. There are 42 drug master file entries for the compound.

Indications:

- Risk of Stroke, Myocardial Infarction and arterial revascularisation
- As an adjunct to diet to LDL-C
- As an adjunct to diet for the treatment of adults with:
    - Primary Dysbetalipoproteinemia.
    - Hypertriglyceridemia

Global Market:

Crestor, Rosuvastatin had already become the number one lipid-lowering drug in the world with a sales value of over USD 6 billion in 2012. In 2022, the revenue amounted to 1.05 billion U.S. dollars and is expected to grow at a CAGR of 6% from 2022 to 2030. [1,2,3]

Potential Generic Manufacturers in INDIA:

Like many other drugs rosuvastatin also have its generics in the Indian Market from Sun Pharma, USV Ltd, Torrent, Lupin, Dr Reddy's, Cipla, Eris Lifesciences and Intas.

1. https://www.reportsanddata.com/report-detail/rosuvastatin-market

2. https://dataintelo.com/report/global-rosuvastatin-market/

3. https://www.astrazeneca.com/content/dam/az/PDF/2022/fy/Full-year-and-Q4-2022-results-announcement.pdf

Lyrica

Innovator Company: Pfizer

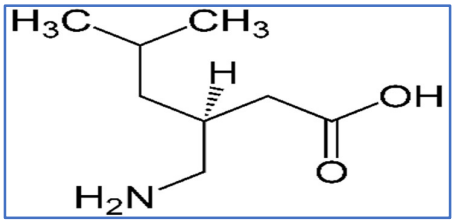
API/Salt/Composition:

Pregabalin

Pharmacological Classification: Alpha-2 Delta Ligand

Dosage Form:

Capsule/Oral Solution



Dosage Strength:

- **Capsules**: 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg
- **Oral Solution:** 20mg per ml

Patent Number and Expiration Date:

- US8044227B2 October 10, 2028

There are three patents protecting this drug and two Paragraph IV challenges. There are forty-one drug master file entries for the compound.

Indications:

- Fibromyalgia
- Diabetic Nerve Pain
- Spinal Cord Injury Nerve Pain
- Pain After Shingles
- Partial Onset Seizure

Global Market:

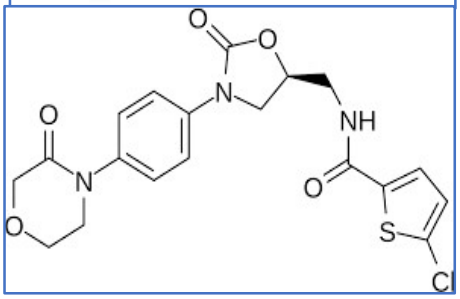
Worldwide total Lyrica revenue in 2018 was USD 1.13 Billion, with an expected projected value of USD 1.12 Billion in 2023, and is expected to grow at a CAGR of 7.67%, to reach a staggering USD 1.89 Billion by 2030. [1]

Potential Generic Manufacturers in INDIA:

Indian market for Pregabalin was estimated to be USD 244 Million 2022. Dr Reddy's Laboratories is one of the leading manufacturers and suppliers globally for Pregabalin API. Sun Pharmaceuticals, Torrent, Intas, Unichem, La Renon, Icon and IPCA have Pregabalin generics in India.

1. https://www.researchandmarkets.com/report/pregabalin

Xarelto



Innovator Company: Janssen Pharmaceuticals/Bayer

API/Salt/Composition: Rivaroxaban

Pharmacological Classification:

Factor Xa Inhibitors

Dosage Form: Tablets/Oral Suspension

Dosage Strength:

- **Tablets:** 2.5mg, 10mg, 15mg, 20mg
- **Oral Suspension:** 1mg/ml

Patent Number and Expiration Date:

- US7157456 August 28, 2024

This drug has 156 patent family members in 47 countries. There has been multiple litigation on patents covering XARELTO.

Indications:

- Risk of Stroke and Systemic Embolism, Deep Vein Thrombosis (DVT) & Pulmonary Embolism (PE), Prophylaxis of DVT which may lead to PE, Venous Thromboembolism (VTE) and recurrent VTE, Prophylaxis of Venous Thromboembolism (VTE)
- Thromboprophylaxis in pediatric patients aged 2 years and older with congenital heart disease

Global Market:

Xarelto is approved in over 130 countries by respective regulatory bodies. The U.S. global rivaroxaban market size was valued at USD 5.6 Billion in 2017, 7.4Billion in 2022 and is expected to witness a CAGR of 1.5% over the forecast period (2018 – 2026) on account of patent expiry during the forecast period.[1,2]

Potential Generic Manufacturers in INDIA:

Like Pregabalin, For Rosuvastatin is also Dr Reddy's one of the leading manufacturers and suppliers globally for Rivaroxaban API. Zydus Cadila, Cheminnova Lifesciences, Alniche Life Sciences, Cadila, Macleods, Tas Med, Conatus, and HAB Pharma are some companies that have their generics in India.

1. https://www.drugdiscoverytrends.com/50-of-2022s-best-selling-pharmaceuticals/

2. https://www.coherentmarketinsights.com/market-insight/rivaroxaban-market-1962

5. GENERIC PHARMACEUTICAL INDUSTRY

5.1 Overview and Market Size of Global Generic Pharmaceutical Industry

The global generic pharmaceutical market is a significant segment of the overall pharmaceutical industry. Generic drugs are copies of brand-name drugs that have lost their patent protection. These drugs are bioequivalent to the original brand-name drugs and offer the same therapeutic effects but at lower costs. The global generic pharmaceutical market has been experiencing steady growth over the years. Factors such as the expiry of patents on branded drugs, increasing healthcare costs, the need for affordable medications, and growing demand for generic drugs in emerging economies have been driving this growth. According to a report by Grand View Research, the global generic drugs market was valued at approximately $228 billion in 2020 and is expected to reach a value of $380 billion by 2030, growing at a compound annual growth rate (CAGR) of around 6.2% during the forecast period.

The global generic pharmaceutical market is highly competitive, and several major players operate on a global scale. These companies have established themselves as leaders in the generic drug industry, supplying a wide range of affordable medications worldwide. Below are some of the major global generic pharmaceutical players:

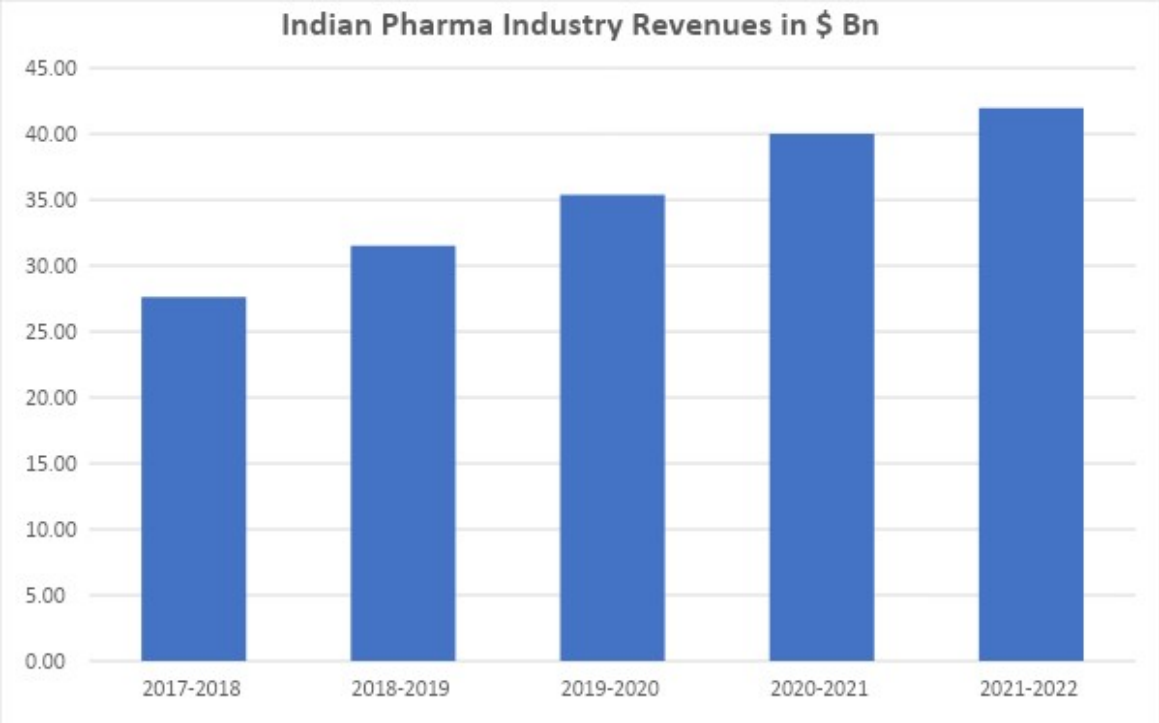
1. **Teva Pharmaceutical Industries Ltd. (Israel)**
2. **Mylan N.V. (United States)**
3. **Sandoz International GmbH (Switzerland)**
4. **Sun Pharmaceutical Industries Ltd. (India)**
5. **Dr Reddy's Laboratories Ltd. (India)**
6. **Lupin Limited (India)**
7. **Cipla Limited (India)**
8. **Aurobindo Pharma Limited (India)**
9. **Zydus Cadila (India)**
10. **Torrent Pharmaceuticals Ltd. (India)**
11. **Hikma Pharmaceuticals PLC (Jordan)**
12. **Endo International PLC (Ireland)**
13. **Fresenius Kabi AG (Germany)**
14. **Apotex Inc. (Canada)**
15. **STADA Arzneimittel AG (Germany)**

These companies have a global presence, extensive product portfolios, and established distribution networks. They supply generic drugs to various markets, including the United States, Europe, Asia, Africa, and Latin America. Additionally, some of these companies also engage in research and development (R&D) activities to develop new generic formulations and enhance existing products.

5.2 Indian Generic Pharmaceutical Industry

The Indian generic pharmaceutical industry is one of the largest and fastest-growing sectors in the country. It has gained significant prominence both domestically and globally due to its cost-effective production capabilities and high-quality generic drugs. The Indian generic pharmaceutical market has witnessed remarkable growth over the years. As per the Department of Pharmaceutical's Annual report 2022-23, the total annual turnover of Pharmaceuticals in the fiscal year 2021-22 in India was approximately USD 42.34 Bn (Exhibit:9) and the pharmaceutical sector contributed around 1.32% of the Gross Value Added (at 2011-12 constant prices) of the Indian Economy in 2020-21

Exhibit 9: Indian Pharma Industry Revenues growth over the last years



Source: Department of Pharmaceutical Annual report 2022-23

India plays a significant role in the global generic pharmaceutical market. Indian pharmaceutical industry also plays significant role globally. India has the highest number of United States Food and Drug Administration (USFDA) compliant Pharma plants outside of USA. As per the Fiscal year 2022 report on State of Pharmaceutical Quality published by USFDA, India boasts of more than 600 USFDA registered manufacturing sites, constituting nearly 12.5% of all registered manufacturing sites operating outside US. There are 500 API manufacturers contributing about

8% in the global API Industry. India is the largest supplier of generic medicines with 20% share in the global supply by manufacturing 60000 different generic brands across 60 therapeutic categories. Access to affordable HIV treatment from India is one of the greatest success stories in medicine. India is one of the biggest suppliers of low-cost vaccines in the world. The country is recognized as the "pharmacy of the world" due to its substantial production and export of generic drugs. Here are some key aspects of India's contribution:

Cost-Effective Production: India has a competitive advantage in terms of cost-effective production capabilities. The country has a vast network of pharmaceutical manufacturers that can produce high-quality generic drugs at lower costs compared to many other countries.

Large Export Market: India is one of the largest exporters of generic drugs worldwide. Indian pharmaceutical companies export generic drugs to various countries, including the United States, Europe, Africa, and other emerging markets. Indian generics are known for their affordability and accessibility. With Indian pharmaceutical exports reaching $25.4 billion in FY23, the future looks promising for the Indian pharmaceutical industry as it continues to contribute significantly to global healthcare. Interestingly, India exports approximately 30% of its total pharmaceutical exports to the US.

Strong Domestic Market: India also has a robust domestic market for generic pharmaceuticals. The country has a large population and a growing middle class, resulting in increased demand for affordable medications. This domestic market contributes significantly to the overall sales and growth of the Indian pharmaceutical industry.

1. **Regulatory Compliance:** Indian generic pharmaceutical companies adhere to international quality standards and regulatory requirements. They follow the guidelines set by regulatory bodies such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and World Health Organization (WHO).
2. **Research and Development (R&D):** Indian pharmaceutical companies invest in R&D activities to develop new generic drugs and improve existing formulations. This focus on innovation enables them to bring cost-effective alternatives to the market, expanding the range of available generic medications.

Competitive Landscape: The industry exhibits intense competition among both domestic and multinational companies. The major players compete based on factors such as product quality, pricing, research and development capabilities, manufacturing capacities, distribution networks, and regulatory compliance. This competition drives innovation and cost efficiency in the industry.

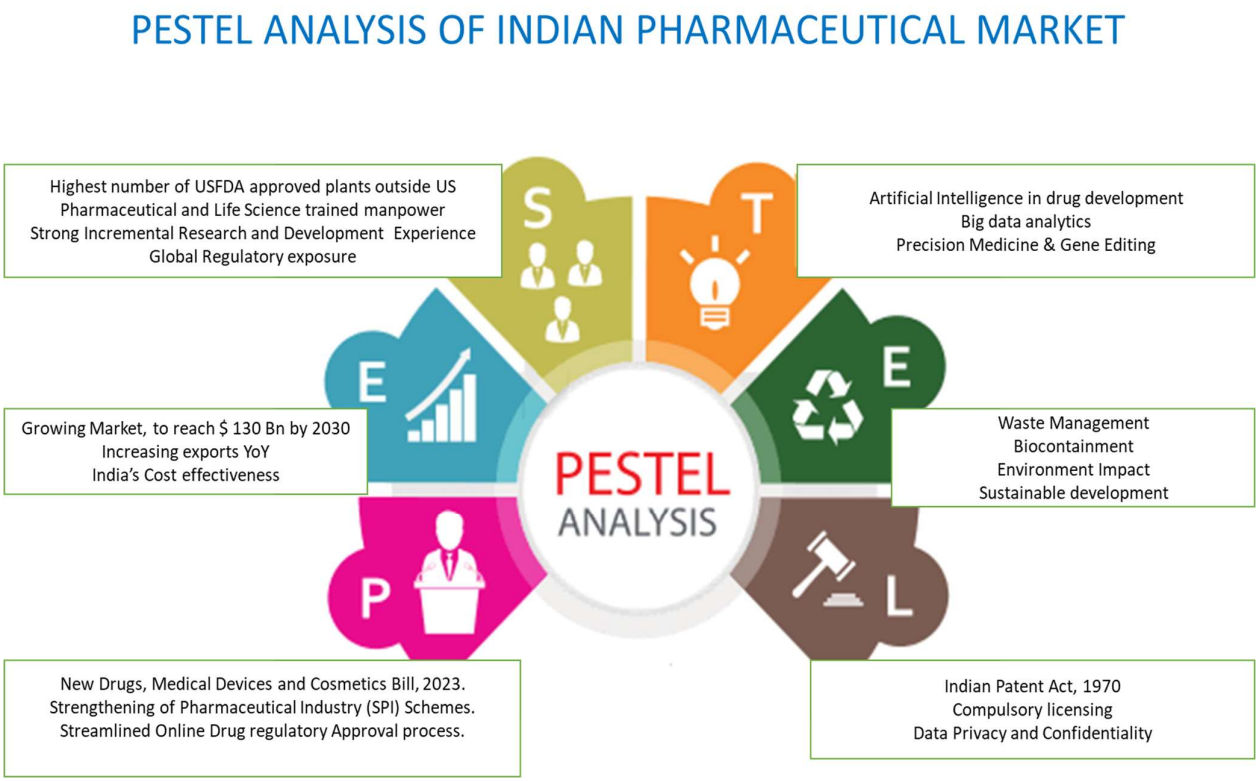
Regulatory Environment: The Indian pharmaceutical industry operates under the regulation of several authorities, including the Central Drugs Standard Control Organization (CDSCO) and the Drug Controller General of India (DCGI).

5.3. PESTEL Analysis of Indian Pharmaceutical Industry

Understanding the political, economic, sociocultural, technological, environmental, and legal factors is vital for assessing the opportunities and challenges in the pharmaceutical market in India. The industry must adapt to changes in these external factors, navigate regulatory requirements, leverage technology advancements, and align their strategies with the evolving needs of the pharmaceutical industry to succeed in the global market.

Exhibit 10 Below Table summarizes the PESTEL Analysis for the Indian Pharmaceutical Industry:

Exhibit 10 : PESTEL Analysis of India CRO Market



5.3.1. Political

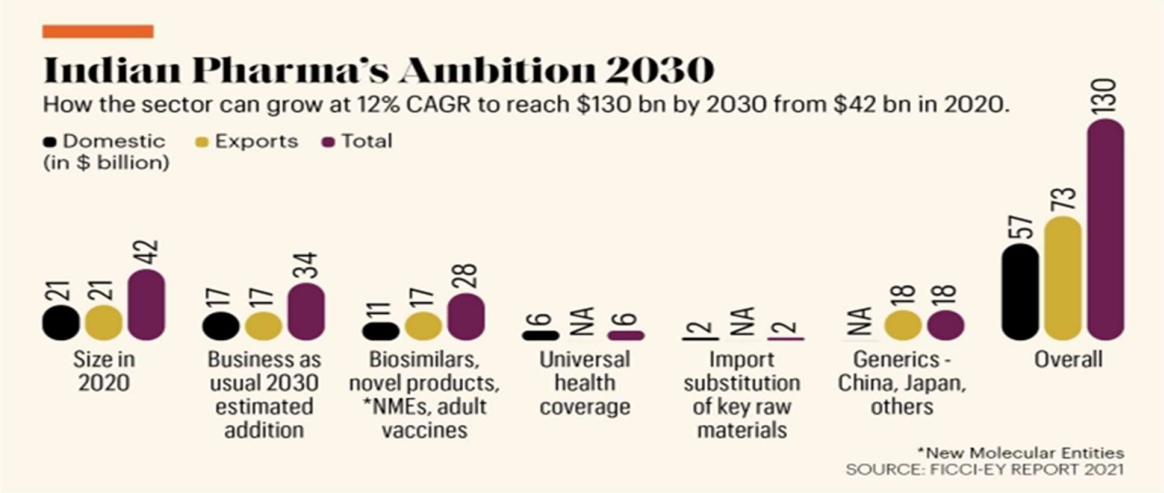
The political landscape in is quite stable with a government which believes in promoting the Indian Pharmaceutical industry at a global level. The government has consistently raised the budget spending on healthcare which has gone up by 13 per cent to Rs 89,155 crore in FY24. Of this, Rs 2,980 crore has been earmarked for healthcare research. Department of Pharmaceuticals under the aegis of Ministry of Chemicals and Fertilizers, Government of India has been running various schemes under the initiative "Strengthening of Pharmaceutical Industry (SPI)", with a total financial outlay of Rs.500 Cr (USD 60.9 million) for the period from FY 21-22 to FY 25-26. The key regulatory bodies overseeing the industry are the Department of Pharmaceuticals (Ministry of Chemicals and Fertilizers), Central Drugs Standard Control Organization (CDSCO) and the Ministry of Health and Family Welfare. The regulatory scenario in India, including drug approval processes, clinical trial regulations, and intellectual property protection has significantly improved significantly post 2014. Further progressive and industry friendly changes in government policies, regulations, and the enforcement of ethical guidelines are going to positively influence the operational and legal frameworks within which pharmaceutical industry operate. The

government is planning to table New Drugs, Medical Devices and Cosmetics Bill, 2023, in the Indian Parliament in the upcoming session which seeks to regulate "the import, manufacture, distribution and sale of drugs, medical devices and cosmetics; and ensure their quality, safety, efficacy, performance and clinical trial of new drugs and clinical investigation of investigational medical devices and clinical performance evaluation of new in vitro diagnostic medical device including AYUSH drugs, medical devices and cosmetics with the objective of highest possible regulatory standards and a transparent regulatory regime and to repeal the Drugs and Cosmetics Act, 1940.

5.3.2. Economical

India's economic growth and overall investment in healthcare and pharmaceutical sectors play a significant role in the growth of the CRO market. The Indian economy is expected to grow at an average rate of 6.7 percent till 2026 fiscal. Per capita income of India is steadily increasing implying more spending on healthcare specifically by middle class and rich Indians. This also means that pharmaceutical companies will have to invest more in R&D to understand the health profile of their consumer segment. As per a latest report by FICCI (refer Exhibit 11) the total Market size of Indian Pharmaceutical industry is expected to reach US$130 bn by 2030.In addition, India's comparatively lower labour costs and operational expenses contributes to the growth of the Indian Pharmaceutical market. The Government has allowed up to 100 percent FDI through automatic route to Greenfield pharmaceutical projects. For Brownfield projects also Indian government has permitted the FDI allowed is up to 74% through automatic route and beyond that through government approval.

Exhibit 11: Indian Pharma's ambition 2030 (Source FICCI report 2021)



Source: FICCI-EY Report 2021

5.3.3. Social

India has a huge population of 1.4 billion with one of highest disease burden. There is an urgent need for new drugs, therapies medical devices and healthcare facilities to cater to increasing healthcare need of this populations. The prevailing lifestyle of Indians specially in urban areas has resulted in life long chronic lifestyle disease. There is also a big chunk of old and elderly people above 60 years of age (numbering about 138 million) in this population who require specialized healthcare services. The availability and quality of healthcare infrastructure in India impact the capabilities and attractiveness of the pharmaceutical market. State of Art manufacturing plant and research and development centre

approved by international regulatory agencies, adequate healthcare facilities, medical and para medical resources, well qualified pharmacy and life sciences educated workforce etc. contribute to create a conducive environment for the growth of Indian Pharmaceutical industry.

5.3.4. Technological

Indian Pharma industry has been gradually acknowledging the rapid advancements in technology and are adopting technologies such as Artificial intelligence, Machine learning, High throughput drug screening, electronic data capture, cloud computing and big data analytics. Many companies have started focussing on high end Precision medicine and Gene Editing based products which are crucial to pharmaceutical development. In future, these technologies could become the turning point in the quest to discover new drugs. Indian pharma industry needs to stay updated with emerging technologies to enhance their capabilities, improve efficiency, and offer innovative solutions to pharmaceutical clients.

5.3.5. Environmental

Increasing environmental awareness and regulations regarding waste management, biocontainment, local municipality rules and environmental impact influence the pharmaceutical industry. The pharmaceutical companies need to ensure compliance with applicable environmental regulations and adopt sustainable practices.

5.3.6. Legal

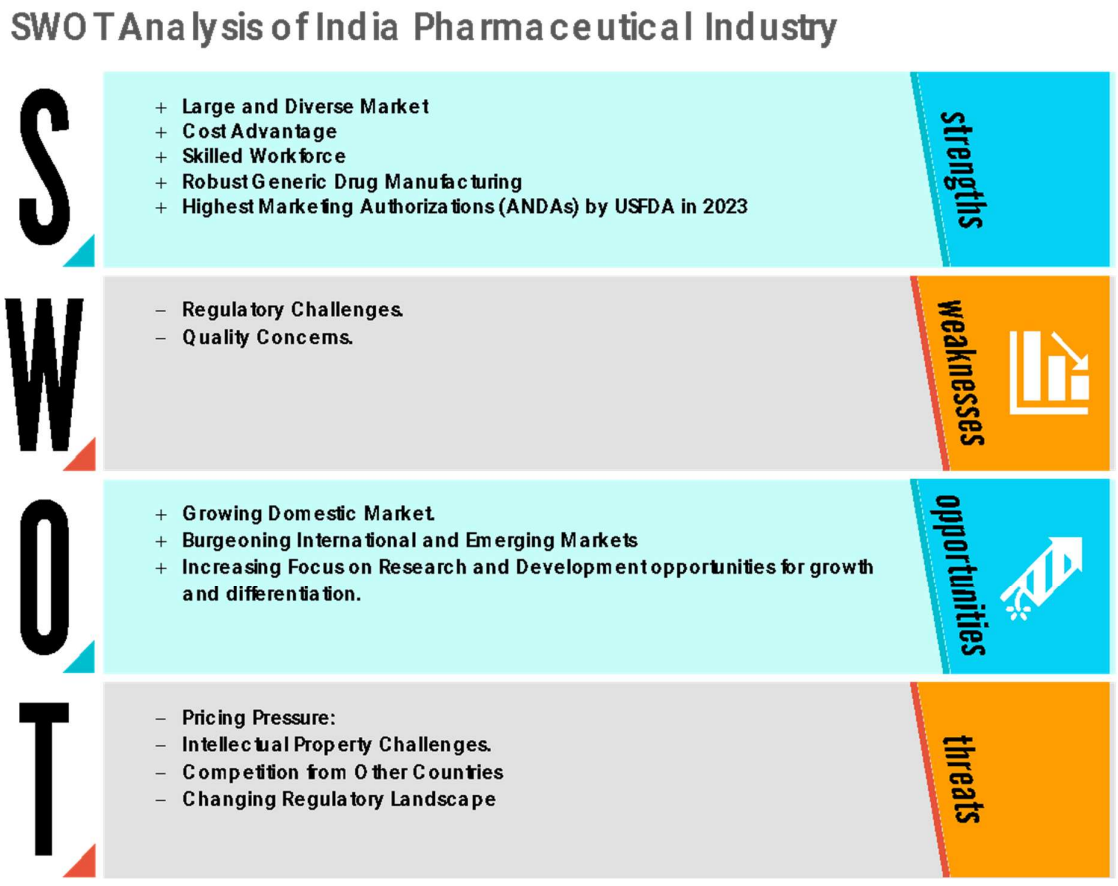
The Indian Patents Act, 1970, governs the granting and protection of patents. The Patents Act governs the grant, administration, and revocation of patents in India. It allows for the grant of product patents for inventions that are novel, non-obvious, and have industrial applicability. However, there are specific provisions within the Act to prevent the grant of patents for certain categories of inventions, including those related to traditional knowledge and pharmaceutical substances. India has IPR laws in place to protect pharmaceutical innovations and ensure a balance between promoting innovation and providing affordable access to medicines. The Patents Act, 1970 (Act) is an example of a well-balanced legislation, which balances the interests of the pharmaceutical industry as well as the public. The Act encourages the pharmaceutical industry to come up with 'actual inventions' by excluding incremental inventions from the purview of patentability, thereby safeguarding public health. Such provision ensures that essential medicines remain accessible to the public at affordable price. The United Nations Secretary General's High-Level Panel on Access to Medicines Report, 2016 stated as follows in respect of India's Patent Laws: 'India is the most often cited example of how a government used their freedom to adapt domestic intellectual property laws to meet national objectives". The legal framework and regulations also included The Acts like Drugs and Cosmetics Act 1940 and Rules 1945, schedule Y for clinical research by Central Drugs Standard Control Organisation or CDSCO and the ICMR and GCP guidelines covers a set of regulations to assure safety, protection and welfare of subjects in conducting clinical trials in India. In addition, Clinical Trial Rules, 2019 issued by Government of India has comprehensive set of rules which regulates the process for approval of medicines in India. These rules cover new drugs, investigational new drugs for human use, clinical trials, bio equivalence studies, bio availability studies and provide for the constitution, registration and role of the ethics committees in a clinical trial. India pharmaceutical industry is also governed by The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 which prohibits the pharmaceutical companies from

advertising and promotion of drugs by making false or misleading claims about their efficacy or safety. On the price front, the National Pharmaceutical Pricing Authority (NPPA) under the aegis of Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers regulates the prices of essential medicines through the Drug Price Control Order (DPCO)] to ensure their availability and affordability.

5.4. SWOT Analysis of Indian Pharmaceutical Industry:

As per the Annual report of Department of Pharmaceuticals for the year 2022-2023, the pharmaceutical industry contributes around 1.32% to the gross domestic product (GDP) of the India. The Indian pharmaceutical industry is currently the world's third-largest in volume and tenth-largest in size. A SWOT Analysis of this industry in Exhibit 12 can help policy makers in making informed decisions on the interventions for future.

Exhibit 12 : SWOT Analysis of Indian Pharmaceutical Industry



5.4.1. Strengths of Indian Pharmaceutical Sector:

- **Large and Diverse Market:** The Indian pharmaceutical industry benefits from a large and diverse domestic market, providing opportunities for a wide range of products and therapeutic areas. The overall scale of the industry (including medications and medical

devices) is about US$43 billion and is currently seeing a growth pace of 7–8% in the drug market. Net exports (medicines and medical equipment) amount to about US$20 billion, of which about 90% are medicines (DoP, 2022). Branded generic products lead the Indian pharmaceutical industry, contributing 70% of the market share in revenues. The generic drug market contributes 21%, while over-the-counter contributes 9% of the Indian pharmaceutical market of overall US$ 20 billion revenue.

- **Cost Advantage:** India has a competitive advantage in terms of cost of production, including lower labour costs and affordable manufacturing infrastructure. This allows Indian pharmaceutical companies to offer products at competitive prices globally.

- **Skilled Workforce:** India has a strong pool of scientific and technical talent, including skilled researchers, scientists, and professionals in the pharmaceutical field. This talent pool contributes to the industry's research and development capabilities.

- **Generic Drug Manufacturing Hub:** India is one of the leading global manufacturers of generic drugs, supplying a significant portion of the world's generic medications. Indian generic medications account for 20% of global exports, making the country the world's top provider of generic pharmaceuticals in volume. Indian products are shipped to over 200 countries around the globe, with Japan, Australia, West Europe and the US as the main destinations.

- **Regulatory Exposure** : As of April 2023, Indian pharmaceutical companies have secured 6316 market authorizations granted by the US Food and Drug Administration (USFDA)(Source:www.thehindubusinessline.com). In addition to a large number of WHO approved manufacturing Plants, there has been a consistent increase in the registration of manufacturing sites in India approved by the US and European regulators as well.

5.4.2. Weaknesses of Indian Pharmaceutical Sector

- **Regulatory Complexity & Challenges:** Regulatory frameworks and policies can change, both domestically and internationally, impacting market access, pricing, and compliance requirements. Adapting to evolving regulations and meeting global quality standards can be a challenge for the industry. Companies need to navigate through various regulatory processes, including drug approvals, pricing controls, and intellectual property rights.

- **Quality Concerns:** Maintaining consistent quality and compliance with Good Manufacturing Practices (GMP) is crucial for the reputation and success of pharmaceutical companies. Instances of non-compliance or quality issues can lead to regulatory actions, import bans, and damage to the industry's image. While India has many reputable pharmaceutical manufacturers, the industry has also faced concerns

regarding the quality and compliance of some products. The Indian pharmaceutical market has faced challenges with counterfeit and substandard drugs. These products not only pose risks to patient safety but also harm the reputation of the industry. Strengthening regulatory oversight and implementing robust supply chain controls are necessary to address this issue. Recent instances of non-compliance with quality and regulatory standards have brought India into media's scrutiny from regulatory authorities.

5.4.3. Opportunities for Indian Pharmaceutical Sector:

- **Growing Domestic Market:** The Indian pharmaceutical market continues to grow due to factors such as increasing healthcare awareness, rising disposable income, and expanding healthcare infrastructure. This presents opportunities for both domestic and international pharmaceutical companies to cater to the growing demand.

- **Increasing Focus on Research and Development:** The Indian pharmaceutical industry is gradually shifting its focus towards research and development activities. Investments in R&D can lead to the development of innovative drugs and novel therapies, providing opportunities for growth and differentiation.

- **Expansion into Emerging Markets:** In the years between 2022-30, the pharmaceutical sector in India will undergo landmark changes as a number of drugs are expected to go off-patent and provide an opportunity for the entry of generic products. Expiry of patents is very promising for the Indian generic drug market as it is expected to expand and grow further with inclusion of these new drugs. Indian pharmaceutical companies can explore opportunities in these markets, where there is a growing demand for affordable healthcare and generic medications. Expansion into these markets can contribute to revenue growth and market diversification.

5.4.4 Threats for Indian Pharmaceutical Sector

- **Pricing Pressure:** Price controls and regulations in India, both for domestic and export markets, can put pressure on the profitability of Indian pharmaceutical companies. The global pharmaceutical industry, including India, faces pricing pressure due to factors such as healthcare cost containment measures, competitive markets, and the rise in price of APIs and excipients. Price erosion can impact profitability and sustainability of Indian Pharmaceutical companies.

- **Intellectual Property Challenges:** Intellectual property rights and patent protection continue to be a challenge for the Indian pharmaceutical industry. Patent litigation and potential restrictions on the production and export of generic drugs can impact the industry's competitiveness. Striking a balance between promoting generic drug

manufacturing and protecting intellectual property rights remains an addressable subject.

- **Research and Development (R&D) Investment**: Indian generic business investors have limited risk appetite. Limited R&D spending, compared to global counterparts, hampers the development of new drugs and therapies in India. Therefore; while the Indian pharmaceutical industry has made immense progress in generic pharmaceutical industry, there is still a need for increased investment in innovative research.

- **Global Competition:** Indian pharmaceutical companies face competition from both domestic and international players. Global competition, particularly from countries like China, can impact market share and pricing dynamics. Indian companies need to stay competitive by investing in technology, innovation, and expanding their global presence India faces competition from other countries, particularly in the generic drug manufacturing sector. Countries like China and emerging Southeast Asian economies also have competitive advantages in terms of cost and manufacturing capabilities.

5.5. Major Pharmaceutical Players in the Indian Market

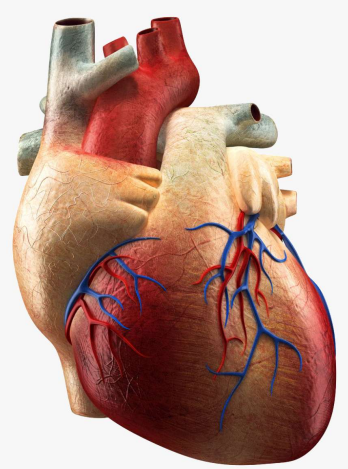
The Indian generic pharmaceutical industry consists of numerous players, ranging from large multinational companies to small and medium-sized enterprises. Some of the major players in the industry include:

1. **Sun Pharmaceutical Industries Ltd.**
2. **Cipla Limited**
3. **Dr Reddy's Laboratories Ltd.**
4. **Lupin Limited**
5. **Aurobindo Pharma Limited**
6. **Cadila Healthcare Limited**
7. **Torrent Pharmaceuticals Ltd.**
8. **Glenmark Pharmaceuticals Ltd.**
9. **Alkem Laboratories Ltd.**
10. **Biocon Limited**

5.6. Major Therapeutic Areas Opportunities for Indian Generic Companies

The patent cliff will provide an opportunity to Indian generic companies to enter the US and other regulated markets and produce more affordable versions of those medications. It's important to note that while the patent cliff presents opportunities for Indian companies, there are many challenges for Indian companies have to face in developing new generic drugs. Indian companies seeking to manufacture or distribute generic drugs require up-to-date information on any existing ANDAs and the exclusivity patents recognized by the FDA. Gathering and organizing the FDA guidance along with drug technical data can be challenging and must be kept current. These company need to comply with the appropriate approval processes and demonstrate bioequivalence and therapeutic efficacy to ensure the safety and effectiveness of their generic products before launch in global markets. This presents several opportunities for Indian generic companies in various therapeutic areas.

5.6.1. Cardiovascular diseases:



Global Market Size in 2020: USD 82 Billion

Expected Global Market Size in 2026: USD 110 Billion

Expected CAGR: 5%

Types of Conditions that come under the therapeutic area:

- Hypertension
- Dyslipidaemia Heart failure
- Ischemic heart disease

Key Drivers of the Global Cardiovascular Market:

Several factors contribute to the growth of the cardiovascular therapeutic area. These include the rising prevalence of cardiovascular diseases globally

- An ageing population,
- unhealthy lifestyles,
- increasing awareness about early diagnosis and treatment.

Additionally, advancements in drug therapies and innovations in medical devices for cardiovascular interventions drive market growth.

Key Drug Classes in Cardiovascular Area: The global cardiovascular therapeutic area encompasses various drug classes. Some of the key drug classes include:

- Antihypertensive agents (such as ACE inhibitors, beta-blockers, and calcium channel blockers),
- Lipid-lowering agents (such as statins and PCSK9 inhibitors),
- Antiplatelet agents, anticoagulants, and heart failure medications (such as beta-blockers and angiotensin receptor blockers)

Prominent Markets for Cardiovascular Drugs:

The global cardiovascular market is geographically diverse. North America, including the United States, holds a significant market share, driven by a high prevalence of cardiovascular diseases and robust healthcare infrastructure. Europe also accounts for a considerable portion of the market, primarily due to the ageing population. The Asia-Pacific region, particularly countries like China and India, is expected to witness substantial growth due to increasing awareness, rising healthcare spending, and a growing patient population.

Competitive Landscape: The global cardiovascular market is highly competitive, with both multinational pharmaceutical companies and generic drug manufacturers competing in this space. Major pharmaceutical companies such as Pfizer, Novartis, AstraZeneca, Merck & Co., and Bristol Myers Squibb have a strong presence in the cardiovascular therapeutic area. However, generic manufacturers, including Indian companies like Sun Pharma, Dr Reddy's, and Lupin, also play a significant role in providing affordable cardiovascular medications.

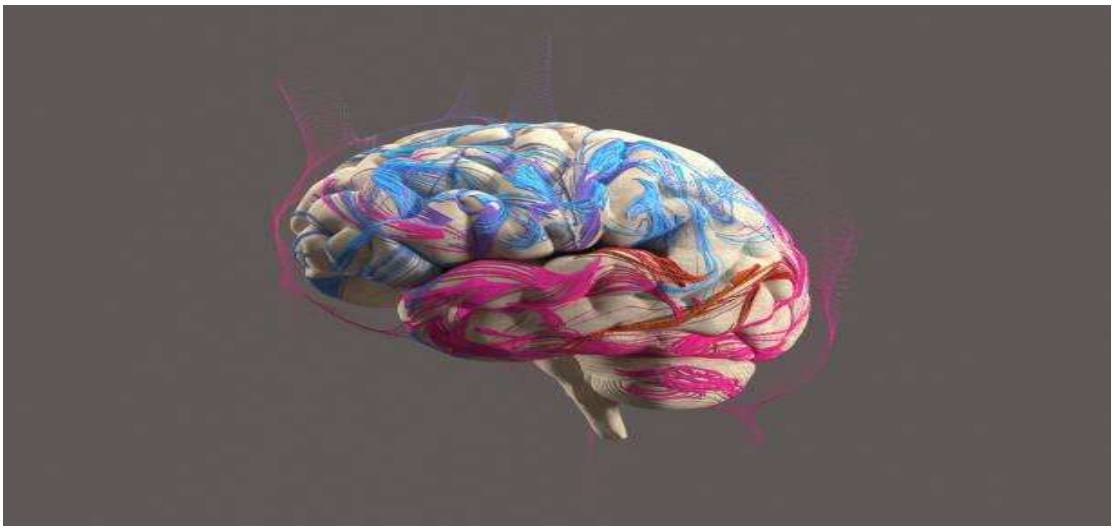
Emerging Therapies in Cardiovascular Area: The cardiovascular therapeutic area is witnessing advancements in treatment approaches. There is an increasing focus on precision medicine, targeted therapies, and innovative drug delivery systems. Additionally, research and development efforts are underway to explore new therapeutic modalities like gene therapies and regenerative medicine for cardiovascular conditions.

Challenges in the Cardiovascular Area: The cardiovascular therapeutic area faces challenges such as stringent regulatory requirements, pricing pressures, and the need for rigorous clinical trials to demonstrate efficacy and safety. Additionally, access to healthcare in developing regions and compliance issues related to medication adherence remain areas of concern. Overall, the global cardiovascular therapeutic area presents significant opportunities for pharmaceutical companies, including generic manufacturers, as the demand for effective and affordable cardiovascular treatments continues to rise. The market growth is driven by the increasing prevalence of cardiovascular diseases and the need for improved management and preventive strategies. Many patents for widely used cardiovascular drugs have expired or are set to expire soon. This includes medications for high blood pressure, cholesterol management, and antiplatelet agents. Indian generic companies can capitalize on these opportunities by manufacturing and distributing generic versions of these drugs, providing affordable options to patients. Several Indian generic companies have been actively working on Abbreviated New Drug Application (ANDA) submissions in the cardiovascular therapeutic areas.

Below are some of reputed Indian generic companies that have been successfully involved in developing generic versions of cardiovascular drugs and pursuing ANDA submissions:

1. **Sun Pharmaceutical Industries Ltd**
2. **Dr. Reddy's Laboratories Ltd**
3. **Lupin Ltd.**
4. **Torrent Pharmaceuticals Ltd**.
5. **Zydus Cadila**

5.6.2 Central Nervous System Disorders:



Global Market Size in 2020: USD 83 Billion (Source: Statista)

Expected Global Market Size in 2026: USD 105 Billion. Expected CAGR: 4%

Types of Conditions that come under the therapeutic area:

- Alzheimer's disease
- Parkinson's disease
- Epilepsy
- Depression
- Anxiety disorder
- Schizophrenia, and
- Multiple sclerosis

Key Drivers of Global CNS Market: Overall, the global CNS therapeutic area presents significant opportunities for pharmaceutical companies, including generic manufacturers. The market growth is driven by the increasing prevalence of CNS disorders, advances in neuroscience research, and the need for improved treatments.

Key Drug Classes in CNS area:

- Antidepressants
- Antipsychotics
- Anxiolytics
- Mood stabilizers
- Antiepileptic drugs
- Cognitive enhancers
- Neurodegenerative diseases

Competitive Landscape: The CNS therapeutic area is highly competitive, with both multinational pharmaceutical companies and generic manufacturers competing in this space. Major pharmaceutical companies such as Johnson & Johnson, Pfizer, Novartis, Eli Lilly, and AstraZeneca have a strong presence in the CNS market. Additionally, there are several specialized biopharmaceutical companies and generic manufacturers that focus on CNS disorders.

Challenges in CNS areas: The CNS therapeutic area faces challenges such as complex disease mechanisms, the blood-brain barrier limiting drug delivery, high failure rates in clinical trials, and the need for long-term safety and efficacy assessments. Additionally, the stigma associated with mental health disorders and the high cost of treatment pose challenges for patients' access to care.

Below are some of reputed Indian generic companies that have been successfully involved in developing generic versions of nervous system disorder drugs and pursuing ANDA submissions:

1. **Sun Pharmaceutical Industries Ltd**
2. **Dr. Reddy's Laboratories Ltd**
3. **Lupin Ltd.**
4. **Torrent Pharmaceuticals Ltd**.
5. **Zydus Cadila**
6. **Intas Pharmaceuticals**
7. **Aurobindo Pharmaceuticals**

5.6.3. Oncology

Global Market Size in 2020: USD 150 Billion (Source: Statista)

Expected Global Market Size in 2026: USD 250 Billion

Expected CAGR: 8%

Types of Conditions that come under the therapeutic area:

The oncology therapeutic area encompasses various cancer types, including

- Breast cancer
- Lung cancer
- Colorectal cancer
- Prostate cancer
- Leukaemia
- Lymphoma
- Melanoma

Each cancer type requires different treatment approaches and has specific market dynamics.

Key Drivers of the Oncology Market: Several factors contribute to the growth of the oncology therapeutic area. These include the increasing prevalence of cancer worldwide, advancements in cancer research and treatment, a growing ageing population, and the introduction of innovative therapies such as targeted therapies, immunotherapies, and precision medicine approaches. Additionally, rising awareness, early detection, and improving access to healthcare services drive market growth.

Major Treatment Therapies:

- Chemotherapy
- Radiation therapy
- Surgery
- Targeted therapies
- Immunotherapies
- Hormonal therapies

Competitive Landscape: The global oncology market is highly competitive, with major pharmaceutical companies actively involved in the development and commercialization of oncology drugs. Key players in the industry include Roche, Novartis, Pfizer, Merck & Co., Bristol Myers Squibb, AstraZeneca, and Johnson & Johnson, among others. Additionally, smaller biopharmaceutical companies and generic manufacturers play a role in providing cost-effective oncology therapies.

In terms of Emerging Therapies, the oncology therapeutic area is witnessing rapid advancements, particularly in the field of targeted therapies and immunotherapies. Precision medicine approaches, such as genomic profiling and liquid biopsies, are gaining prominence, allowing for personalized treatment decisions.

Additionally, cell-based therapies like CAR-T cell therapy and gene therapies are emerging as potential game-changers in certain cancer types.

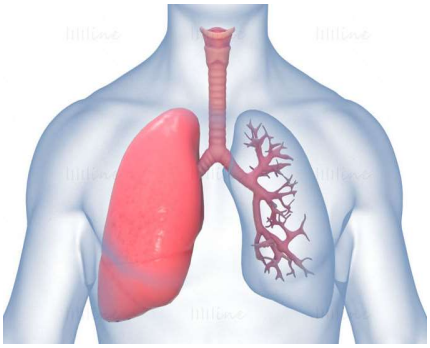
Challenges: The oncology therapeutic area faces challenges such as high development costs, complex regulatory pathways, increasing pricing pressures, and the need for extensive clinical trials to demonstrate safety and efficacy. Additionally, access to innovative therapies and the affordability of cancer treatments pose challenges in some regions.

The global oncology therapeutic area presents significant opportunities for pharmaceutical companies, with strong market growth driven by the increasing incidence of cancer and advancements in treatment options. The industry's focus is shifting towards precision medicine and targeted therapies, providing personalized and effective cancer treatments. Below Indian generic companies that have been involved in developing generic versions of oncology drugs and have made multiple ANDA submissions:

1. **Natco Pharma Limited**
2. **Cipla Limited**
3. **Glenmark Pharmaceuticals Limited**

4. **Aurobindo Pharma Limited**
5. **Intas Pharmaceuticals Ltd**

5.6.4. Respiratory Disorders:



Global Market Size in 2020: USD 40 Billion (Source: Statista)

Expected Global Market Size in 2026: USD 55 Billion

Expected CAGR: 5%

Types of Conditions that come under the therapeutic area:

The respiratory therapeutic area covers various respiratory conditions. Asthma and COPD are the most prevalent respiratory diseases, affecting a large population globally. Other respiratory conditions include

- Respiratory tract infections,
- Pulmonary arterial hypertension,
- Idiopathic pulmonary fibrosis, and
- Sleep apnea

Major Treatment Modalities in Respiratory Area:

- Corticosteroids
- Bronchodilators
- Combination therapies
- Immunomodulators
- Antibiotics
- Mucolytics
- Inhalers and Nebulizers

Prominent Markets for Respiratory Drugs: North America, particularly the United States, accounts for a significant share of the global respiratory market due to a high prevalence of respiratory conditions and a well-established healthcare system. Europe also holds a considerable market share, driven by an aging population and environmental factors.

The Asia-Pacific region, including countries like China and India, is witnessing significant growth due to improving healthcare infrastructure, rising pollution levels, and increasing awareness of respiratory diseases.

Competitive Landscape: The global respiratory market is competitive, with both multinational pharmaceutical companies and generic manufacturers operating in this space. Key players in the market include GlaxoSmithKline, AstraZeneca, Boehringer Ingelheim, Novartis, and Teva

Pharmaceuticals. Generic manufacturers also play a role in providing affordable respiratory medications.

Emerging Therapies in Respiratory Area: The respiratory therapeutic area is witnessing advancements in treatment approaches. There is ongoing research and development to explore innovative therapies, including biologics, gene therapies, and targeted therapies, for respiratory conditions like severe asthma and cystic fibrosis.

The COVID-19 pandemic has significantly impacted the respiratory therapeutic area. The demand for respiratory medications and devices surged due to the respiratory complications associated with COVID-19. The development of vaccines and antiviral therapies targeting respiratory infections has also gained prominence.

Additionally, digital health solutions, such as telemedicine and remote patient monitoring, are being integrated into respiratory care.

Challenges: The respiratory therapeutic area faces challenges such as increasing healthcare costs, regulatory complexities, and adherence to treatment regimens. Furthermore, environmental factors such as air pollution and tobacco smoking contribute to the rising burden of respiratory diseases.

Overall, the global respiratory therapeutic area presents significant opportunities for pharmaceutical companies and generic manufacturers. The market growth is driven by the increasing prevalence of respiratory conditions, environmental factors, and advancements in treatment options. However, challenges related to pricing pressures, regulatory requirements, and the impact of external factors like pollution remain important considerations in the respiratory market

Below are a few examples of Indian generic companies that have been involved in developing generic versions of respiratory drugs and pursuing ANDA submissions:

1. **Cipla Limited**
2. **Sun Pharmaceutical Industries Ltd**
3. **Lupin Limited**
4. **Glenmark Pharmaceuticals Limited**
5. **Zydus Cadila**

5.6.5 Diabetes:

Global Market Size in 2020: USD 26.5 Billion (Source: Statista)

Expected Global Market Size in 2026: USD 42.4 Billion

Expected CAGR: 8.1%

Types of Conditions that come under the therapeutic area:

The diabetes therapeutic area covers conditions like Type-1 Diabetes and Type-2 Diabetes.

With the expiration of patents for various antidiabetic drugs, Indian generic companies can play a significant role in providing affordable options for patients with diabetes. This includes generic versions of oral antidiabetic agents, insulin, and other related medications. Indian generic companies have been actively working on ANDA submissions in the diabetes therapeutic areas as well. Here are a few examples of Indian generic companies that have been involved in developing generic versions of diabetes drugs and pursuing ANDA submissions:

1. **Biocon Ltd**
2. **Sun Pharmaceutical Industries Ltd**
3. **Dr Reddy's Laboratories Ltd**
4. **Lupin Limited**
5. **Torrent Pharmaceuticals Ltd**
6. **Zydus Cadila**

5.6.6 Autoimmune Disorders:

Global Market Size in 2020: USD 62 Billion

Expected Global Market Size in 2026: USD 100 Billion

Expected CAGR: 8%

Types of Conditions that come under the therapeutic area:

The autoimmune diseases therapeutic area encompasses a wide range of disorders, including

- Rheumatoid arthritis,
- Psoriasis,
- Systemic lupus erythematosus (SLE),
- Multiple sclerosis (MS),
- Inflammatory bowel disease (IBD),
- Type 1 diabetes, and others.

Treatment Modalities in Autoimmune Therapeutic Area: Various treatment modalities are used in the autoimmune diseases therapeutic area. These include immunosuppressants, disease-modifying anti-rheumatic drugs (DMARDs), biological therapies, corticosteroids, nonsteroidal anti-inflammatory drugs (NSAIDs), and targeted therapies. The use of biologics and targeted therapies has been transformative in managing certain autoimmune disorders.

Prominent Markets of Autoimmune Therapeutic Area: North America, particularly the United States, holds a significant share of the global autoimmune diseases market due to a high prevalence of autoimmune disorders, advanced healthcare infrastructure, and favourable reimbursement policies. Europe is also a prominent market, driven by increasing disease prevalence and investments in research and development. The Asia-Pacific region, including countries like China and India, is witnessing significant growth due to improving healthcare infrastructure, increasing awareness, and rising disease burden.

Competitive Landscape: The global autoimmune diseases market is highly competitive, with major pharmaceutical companies actively involved in the development and commercialization of therapies. Key players include AbbVie, Johnson & Johnson, Pfizer, Novartis, Bristol Myers Squibb, and Roche. Additionally, specialized biopharmaceutical companies and generic manufacturers also play a role in providing affordable therapies for autoimmune diseases.

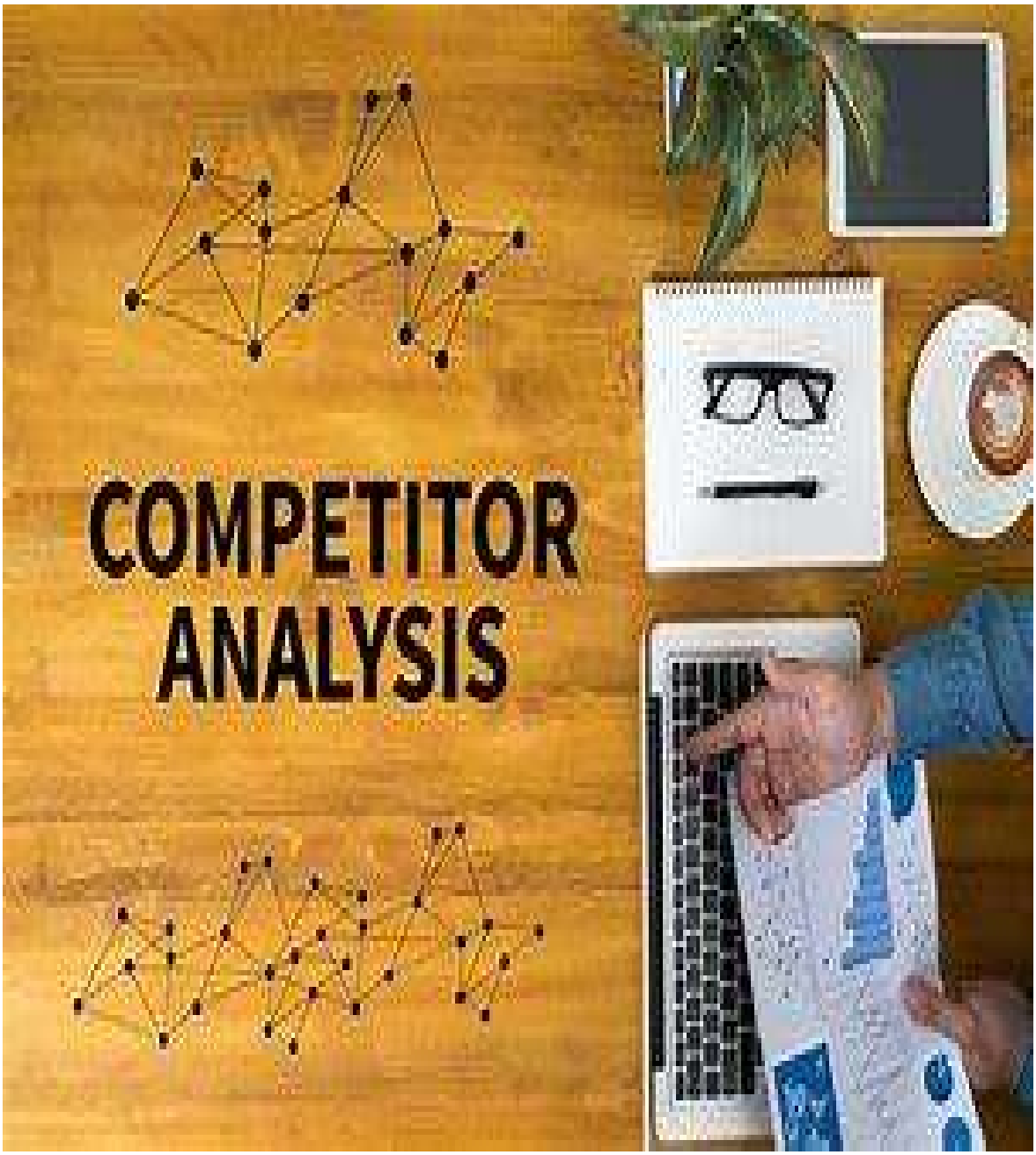
Emerging Therapies in Autoimmune Disorders Area: The autoimmune diseases therapeutic area is witnessing advancements in treatment options. There is ongoing research and development to explore novel drug targets, develop more specific and effective therapies, and harness immunomodulatory approaches. Additionally, personalized medicine and precision therapies are gaining attention in certain autoimmune disorders. The COVID-19 pandemic has had an impact on the autoimmune diseases therapeutic area. Concerns about immunosuppressive therapies and their effects on COVID-19 susceptibility and severity have emerged. Additionally, disruptions in healthcare services and delays in clinical trials have affected the development and access to new therapies

Challenges in the Development of Drugs in the area of Autoimmune Disorder: The autoimmune diseases therapeutic area faces challenges such as complex disease mechanisms, high development costs, regulatory requirements, and the need for long-term safety assessments. Additionally, autoimmune disorders often require a multidisciplinary approach, and managing comorbidities and treatment adherence can be challenging.

Below are of few of Indian generic companies that have been involved in developing generic versions of autoimmune drugs and pursuing ANDA submissions:

1. **Sun Pharmaceutical Industries Ltd**
2. **Lupin Limited**
3. **Dr. Reddy's Laboratories Ltd**
4. **Zydus Cadila**
5. **Torrent Pharmaceuticals Ltd**

5.7. Competitive Landscape for Indian Generic Companies



The industry exhibits intense competition among both domestic and multinational companies. The major players compete based on factors such as product quality, pricing, research and development capabilities, manufacturing capacities, distribution networks, and regulatory compliance. This competition drives innovation and cost efficiency in the industry. In addition to the innovator companies, the Indian generic companies face competition from other global generic companies as well. The profiles of some of such global generic companies are mentioned ahead in the report.

Teva

Headquarters: Petah Tikva, Israel

2021 generic drug sales: $8.99 billion

2020 generic drug sales: $9.31 billion

Change: -3%

About Company and their Mission:

Teva's mission is to be a global leader in generics and biopharmaceuticals, improving the lives of patients across the world. In a complex world, their mission is simple: to improve the lives of patients across the globe. They believe that everyone should have access to quality medicines whether it be for managing disease, fighting infections, or simply improving overall health. Teva played a key role in developing the industry over the last 40 years. Teva sells more than 550 generic products and has more than 1,100 generics in its pipeline. Teva have strong operational base, global infrastructure with 53 production sites globally.

Management Team:

Richard Francis	President and Chief Executive Officer, Member of the Board of Directors
Richard Daniell	Executive Vice President, European Commercial
Dr. Sven Dethlefs	Executive Vice President, North America Commercial
Eric Drape	Executive Vice President, Global Commercial
Dr Eric A. Hughes	Executive Vice President, Global R&D and Chief Medical Officer

Focus Therapeutic Area:

Teva is focused on developing innovative medicines in core therapeutic areas in movement disorders and neurodegeneration, Migraine, Neuropsychiatry and Respiratory.

Key Developments:

- Alvotech and Teva Secures U.S. License for Stelara® Proposed Biosimilar AVT04 on June 12,2023
- Teva and Natco Launched additional strengths for Generic Version of Revlimid® (lenalidomide) Capsules, in U.S. on March 09, 2023
- Teva collaborated with Rimidi & Healthsnap to expand its Respiratory Digital Health Platform on November 14, 2022.
- Teva launched First Market Generic Version of Narcan® (Naloxone Hydrochloride Nasal Spray), in the U.S on December 22, 2021
- Teva launched generic of Epiduo® Forte Gel (adapalene and benzoyl peroxide) on December 01, 2021

https://www.fiercepharma.com/pharma/top-10-generic-drugmakers-2021-revenue

www.tevapharm.com

https://www.tevapharm.com/news-and-media/latest-news/

Novartis' Sandoz

Headquarters: Basel, Switzerland

2021 generic drug sales: $7.5 billion

2020 generic drug sales: $7.7 billion

Change: -2.6%

About Company and their Mission:

Sandoz is a global leader in generic pharmaceuticals and biosimilars and a division of the Novartis Group. Sandoz contributes to society's ability to support growing healthcare needs by pioneering novel approaches to help people around the world access high-quality medicine. Their global portfolio comprises approximately 1 000 molecules, covering a wide range of therapeutic areas, which accounted for 2022 sales of USD 9.2 billion.

Management Team:

Richard Saynor	Chief Executive Officer
Francisco Ballester	President International
Martin Bischof	Head of Ethics, Risk and Compliance

Focus Therapeutic Area:

Sandoz holds strong global positions in areas ranging from generic cardiovascular, central nervous system (CNS), pain and ophthalmology to oncology and respiratory. Their broad portfolio is backed by a range of state-of-the-art technologies, formulations and devices, including prolonged-release and multiple-unit tablets, creams and gels, orodispersible films, transdermal patches, lyophilized products, implants and inhalers.

Key Development:

- Sandoz received positive CHMP opinion for multiple sclerosis biosimilar natalizumab on July 24, 2023
- Sandoz made an announcement about the plan to build a biosimilar Technical Development Centre in Slovenia to support future growth of biosimilar pipeline on July 20, 2023.
- Sandoz has launched Hyrimoz (adalimumab-adaz) high concentration formulation, in US on July 01, 2023.
- Sandoz's application for marketing authorization for biosimilar denosumab accepted by EMA on May 25, 2023.

https://www.fiercepharma.com/pharma/top-10-generic-drugmakers-2021-revenue

https://www.sandoz.com

https://www.sandoz.com/news/news-archive

Viatris

Headquarters: Pittsburgh, Pennsylvania

2021 generic drug sales:

$5.63 billion (excluding complex generics)

2020 generic drug sales:

$5.29 billion (excluding complex generics)

Change: +6%

About Company and their Mission:

Viatris are uniquely positioned to deliver their mission of empowering people worldwide to live healthier at every stage of life. As a global healthcare company, improving access and sustainably delivering high-quality medicine is our relentless pursuit. Viatris has more than 40 manufacturing facilities.

Management Team:

Robert J. Coury	Executive Chairman
Scott A Smith	Chief Executive Officer
Rajiv Malik	President
Sanjeev Narula	Chief Financial Officer

Focus Therapeutic Area:

Viatris offers quality treatment options across more than 10 major therapeutic areas covering a wide variety of noncommunicable and communicable diseases like Cardiovascular, CNS and Anesthesia, Dermatology, Diabetes and Metabolism, Eye Care, Gastroenterology, Immunology, Infectious diseases, Oncology, Respiratory and Allergic and Women Healthcare.

Key Developments:

- Viatris seeked approval for a generic Tyrvaya on June 13, 2023
- Viatris and Mapi Pharma highlighted achieved results of Multiple Sclerosis Research at American Academy of Neurology 75th Annual Meeting on April 24, 2023.
- Viatris got Approval for Emissions Reduction Targets by the Science Based Target initiative (SBTi) on December 14, 2022
- Viatris completed their transaction of Biosimilars with Biocon Biologics on November 29, 2022.

https://www.fiercepharma.com/pharma/top-10-generic-drugmakers-2021-revenue

https://www.viatris.com/en

https://newsroom.viatris.com/press-releases

Fresenius Kabi

Headquarters: Bad Homburg, Germany

2021 generic drug sales: $3.72 billion (estimate)

2020 generic drug sales: $3.58 billion (estimate)

Change: +4%

About Company and their Mission:

Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. Fresenius Kabi's products and services are used for the therapy and care of critically and chronically ill patients.

Management Team:

Sanjay Gupta	Managing Director - South Asia
Kaushal Gupta	Chief Financial Officer - South Asia

Focus Therapeutic Area:

Fresenius Kabi offers quality treatment options across various therapeutic areas like Anaesthesia, Blood volume substitution, critical Illness, Diabetes Fluid management, Internal and External Administration, Liver Insufficiency, Maldigestion/Malabsorption, Nutritional Support, Oncology, Paediatrics, Renal Insufficiency, Transfusion medicine and cell therapies and Biosimilars.

Key Developments:

- Fresenius Kabi's tocilizumab biosimilar candidate MSB11456 received positive CHMP opinion on July 21, 2023.
- Fresenius Kabi has launched citrate free Idacio (adalimumab-aacf) biosimilar in the US on July 03, 2023.
- On July 12, 2023: Fresenius Kabi's denosumab biosimilar FKS518 has showed positive clinical trials results.
- Fresenius Kabi was awarded breakthrough technology agreement with premier Inc. for the Ivenix Infusion System on May 23, 2023.
- Fresenius Kabi has launched its biosimilar Stimufend® (pegfilgrastim-fpgk) in the U.S. on February 16, 2023.

https://www.fiercepharma.com/pharma/top-10-generic-drugmakers-2021-revenue

https://www.fresenius-kabi.com/

https://www.fresenius-kabi.com/news

Aspen Pharmacare

Headquarters: Durban, South Africa

2021 generic drug sales: $2.2 billion

2020 generic drug sales: $1.96 billion

Change: +12%

About Company and their Mission:

With a 170-year heritage, Aspen is a global specialty and branded multinational pharmaceutical company with a presence in both emerging and developed markets. Aspen focuses on marketing and manufacturing a broad range of post-patent, branded medicines and domestic brands covering both hospital and consumer markets through their key business segments. The key business segments are Manufacturing and Commercial Pharmaceuticals comprising Regional Brands and Sterile Focus Brands. The manufacturing capabilities cover a wide variety of product types including steriles, oral solid dose, liquids, semi-solids, biologicals and active pharmaceutical ingredients.

Management Team:

Stephan Saad	Group Chief Executive
Sean Capazorio	Chief Financial Officer
Gus Attridge	Group Chief Advisor
Richelle Crots	Regional Chief Executive Officer, SA Commercial

Focus Therapeutic Area:

Aspen provides high quality, affordable medicines and products, focusing on niche therapeutic areas like Anaesthetics, Thrombosis, High Potency & Cytotoxics, Nutraceuticals and some regional brands for sleeping aid, respiratory analgesic, ARV and Uric Acid production inhibitor.

Key Developments:

- Aspen, Saudi Chemical Company holding and its subsidiary AJA Pharma enter into a memorandum of understanding on March 07, 2023.
- Aspen, CEPI and the Bill & Melinda Gates Foundation has expanded their commitments of improving access to vaccines in Africa on December 12, 2023.

https://www.fiercepharma.com/pharma/top-10-generic-drugmakers-2021-revenue

https://www.aspenpharma.com/
https://www.aspenpharma.com/media/press-releases

Hikma

Headquarters: London

2021 generic drug sales: $1.88 billion

2020 generic drug sales: $1.73 billion

Change: 9%

About Company and their Mission:

Hikma creates high-quality medicines and making them accessible to the people who need them, Hikma are helping to shape a healthier world that enriches all our communities. They are a trusted, reliable partner and dependable source of over 760+ high-quality generic, specialty and branded pharmaceutical products that hospitals, physicians and pharmacists need to treat their patients across North America, MENA and Europe. Hikma has 32 manufacturing plants and 8 R&D centres.

Management Team:

Said Darwazah Executive Chairman and Chief Executive Officer

Mazen Darwazh Executive Vice Chairman, President of MENA

Focus Therapeutic Area:

Hikma brings patients across North America, MENA and Europe a broad range of generic, specialty and branded Injectables and Ophthalmic pharmaceutical products

Key Developments:

- Hikma launched Neostigmine Methylsulfate Injection prefilled syringe on June 15, 2023.
- Hikma launched Midazolam in 0.9% Sodium Chloride Injection in the US market on june 30, 2023.
- Hikma launched Dobutamine injection exceeding 150 injectable medicines in US market on June 14, 2023.
- Hikma and Celltrion Healthcare has signed exclusive licensing agreement for ustekinumab & YuflymaTM for the Middle East and North Africa region on January 03, 2023 & July 18, 2022 respectively.
- Hikma Ventures has lead Series A extension in NuvoAir to support its platform for patient-centric care and clinical trials on January 19, 2022.

https://www.fiercepharma.com/pharma/top-10-generic-drugmakers-2021-revenue

https://www.hikma.com/

https://www.hikma.com/newsroom/

6. CHALLENGES FOR INDIAN GENERIC COMPANIES - PATENT CLIFF 2022-30

6.1 Overview: Indian companies involved in developing generic versions of drugs going off-patent face several challenges and risks. Despite these challenges and risks, Indian companies have been successful in the generic drug industry by leveraging their manufacturing capabilities, cost advantages, and regulatory expertise. It is important for Indian companies to proactively address these challenges and perform risk assessment and build strong capabilities to navigate the evolving landscape of generic drug development and manufacturing. Developing and filing a 505(b)(2) ANDAs for the drugs nearing patent expiry can present opportunities for Indian generic manufacturers to enter the much more bigger and lucrative markets. By carefully assessing and managing the risks, Indian generic companies can navigate the regulatory landscape and seize market opportunities out of the impending patent cliffs.

Some of the key challenges and risks include:

6.1.1 Complex Intellectual Property Landscape: Developing generic drugs involves navigating complex intellectual property landscapes. Indian generic companies face legal challenges from patent holders who may try to extend their exclusivity rights or sue the Indian companies for patent infringement. Most of the originator companies choose to initiate patent litigation against the Indian generic manufacturer. Resolving these disputes can be time-consuming and costly. This results in delays in the approval and launch of the generic version, as well as additional substantial legal costs for the Indian generic companies. Further, the patent landscape is dynamic, and new patents or changes to existing patents can impact the development of generic drugs. Indian companies need to closely monitor patent expiration dates, patent challenges, and legal developments to identify opportunities for generic drug development. The innovator companies also try evergreening the patents by extending the exclusivity period of the drugs by obtaining additional patents or regulatory exclusivities. This can delay the entry of Indian generic competitors into the market.

6.1.2 Lack of R&D and Innovation: Developing generic drugs requires reverse engineering of the drugs many time the incremental innovation in the pharmaceutical products. Indian generics have the technical know-how for these processes however it requires significant investment in research and development (R&D) and ensure bioequivalence with the original branded drug. Indian companies face the challenge of balancing R&D investments with the cost pressures of generic manufacturing.

6.1.3 Regulatory Compliance: Indian companies need to adhere to stringent regulations and guidelines set by regulatory bodies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Further, regulatory policies and requirements can change over time, potentially affecting the drug approval processes. Changes in regulations, guidelines, or interpretation of regulatory standards can create uncertainties and impact timelines for approval for Indian companies. Filing a 505(b)(2) ANDA requires demonstrating that the proposed generic drug has the same active ingredient as the reference listed drug (RLD) and relies, in part, on data from studies

conducted by others. There are challenges in obtaining the necessary data, navigating the regulatory requirements, and addressing any deficiencies or inquiries from the regulatory authorities. Non-compliance leads to delays in approvals or even rejection of the generic versions.

6.1.4 Manufacturing and Quality Issues: Like any industry, the pharmaceutical sector is subject to regulatory oversight and quality control measures to ensure the safety and efficacy of drugs. Regulatory authorities such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and India's Central Drugs Standard Control Organization (CDSCO) have systems in place to monitor and regulate pharmaceutical manufacturing practices. Ensuring compliance with Good Manufacturing Practices (GMP) and maintaining consistent quality during manufacturing is crucial. Any deviations or issues in the manufacturing process can result in delays in approval or even rejection of the ANDA. Failure to meet the prescribed GMP standards can result in recalls, regulatory penalties, and damage to the company's reputation Maintaining high-quality standards is crucial for generic drug manufacturers. Occasional instances of quality and safety concerns have recently arisen due to factors such as manufacturing issues, inadequate quality control, human errors, or non-compliance with regulatory standards through-out the world and India is no exception to it. While the majority of Indian pharmaceutical companies maintain high standards of quality and safety, there have been some instances where quality and safety compromises have been reported in Indian generic companies resulting in the import ban on the products manufactured by such Indian companies. However, it is important to note that such instances are generally exceptions rather than the norm, and the vast majority of Indian generic pharmaceutical companies strive to maintain high-quality standards and comply with safety, efficacy and regulatory requirements. When quality or safety issues arise, regulatory authorities typically investigate the matter, take appropriate actions, monitor the companies and may impose penalties or restrictions to ensure compliance and protect public health. Additionally, many Indian pharmaceutical companies have taken steps to address these issues, improve their quality control systems, and strengthen their manufacturing practices Indian companies need to move up the ladder and comply with Good Manufacturing Practices (GMP) as per the standards of USFDA and EU rather than mere WHO standards. This will help their products reach the more lucrative and profitable pharmaceutical markets rather than supplying to third world countries of world. The increasing number of recognized manufacturing sites by USFDA can reinforce India’s credibility as a reliable and quality-focused pharmaceutical manufacturer.

6.1.5 Competition and Market Dynamics: The patent cliff is going to expand the market size for global generic drugs as the expiration of patents allows multiple companies to enter and compete. The $251 billion USD patent cliff presents a substantial opportunity for generic companies to capture the market, share and generate revenue. However, navigating the competitive landscape requires strategic planning, international

expansion, Life cycle management, efficient operations, regulatory compliance, and a focus on differentiation to succeed in the impending evolving and dynamic market. Market Barriers can pose as hurdles in accessing international markets as the Indian companies have to navigate complex regulatory processes and obtain marketing approvals from multiple authorities in different countries. Market-specific regional factors such as local pricing policies, reimbursement systems, and market acceptance of generics also pose challenges The acceptance of a generic drug by physicians, patients, and healthcare providers can vary. The Indian companies sometimes face hurdles in establishing relationships with distributors, pharmacy benefit managers (PBMs), or negotiating favourable reimbursement agreements with payers. Further, the pricing of generic drugs is subject to intense competition. When multiple generic versions of a drug enter the market after patent expiry, it can lead to intense competition and price erosion over the period. The pricing of the generic drug can be significantly lower compared to the originator's product, impacting the profitability of the generic manufacturer. Indian companies face challenges in maintaining profitability due to price erosion caused by increased competition from other generic manufacturers. Additionally, fluctuations in raw material costs and currency exchange rates can affect the profitability of generic drug manufacturing.

7 WAY FORWARD FOR INDIAN GENERIC COMPANIES TO MITIGATE BUSINESS RISKS

1. **Investment in Incremental Innovation:** Indian generic companies have a limited risk appetite for the new drug development. However, the Indian companies are not hesitant to invest in research and development (R&D) of generic incrementally innovative pharmaceuticals formulations. This includes the development of novel drug delivery systems, improved dosage forms, and enhanced therapeutic efficacy. Innovation helps generic companies differentiate themselves from competitors and gain a competitive edge in the market. In addition, R&D investment is necessary to comply with stringent regulatory requirements. Generic pharmaceutical companies must demonstrate bioequivalence to the reference product or the innovator drug through comprehensive studies and clinical trials. Investing in R&D enables companies to generate the necessary clinical data and evidence required for regulatory submissions and approvals. By investing in R&D, generic companies can develop patents, trademarks, and proprietary technologies. This helps in building a strong IP portfolio, protecting their innovations, and ensuring market exclusivity for a certain period, thus providing a competitive advantage. R&D investment allows generic companies to expand their product portfolio by developing and launching a wider range of generic drugs. This diversification enables them to target different therapeutic areas, address unmet medical needs, and cater to a larger customer base. generic companies in managing the lifecycle of their products effectively. By investing in R&D, they can extend product life cycles through various strategies such as line extensions, reformulations, and developing combination therapies. This allows them to maximize product value and market presence even after the expiry of the reference product's patent. A well-diversified portfolio enhances revenue opportunities and reduces dependency on a few products.

2. **Market Differentiation:** R&D investment enables generic companies to develop niche or specialty products that may have limited competition. These products may target rare diseases, orphan indications, or specific patient populations. By focusing on specialized therapeutic areas, generic companies can differentiate themselves, command higher pricing, and establish a unique market position. Unique product portfolio opens doors for Indian generic companies to collaborations and partnerships with other global pharmaceutical companies, research institutions, and academic organizations. Such partnerships can leverage shared expertise, resources, and infrastructure to accelerate the development of new generic products, access external knowledge, and gain a competitive advantage.

3. **Cost Reduction and Efficiency:** Indian companies need to invest into their process improvements to ensure operational efficiencies and cost optimization. By investing in research, generic companies can discover more efficient manufacturing techniques, improve quality control processes, and reduce production costs. This can result in competitive pricing, higher profit margins, and improved operational efficiency.

4. **Product Diversification:** Product diversification is crucial for Indian generic companies to reduce risk, enhance competitiveness, and achieve sustainable growth in the ever-changing pharmaceutical industry. By expanding their product offerings and targeting diverse markets, generic companies can build resilience, adapt to market dynamics, and capture a larger share of the global healthcare market Product diversification is the need of hour for Indian generic companies for several reasons. The pharmaceutical industry is highly competitive, and generic companies face numerous risks such as long and costly patent litigations, regulatory hurdles, and intense competition. Diversification helps mitigate these risks by spreading them across multiple products and therapeutic areas. If one product faces challenge or fails to perform as expected, other products can compensate for the loss, reducing the overall impact on the company's financial health. By diversifying their product portfolio, Indian generic companies can target a broader range of therapeutic areas, which allows them to access larger markets and reach a wider customer base. This helps reduce reliance on a single product or therapeutic category, making the company less vulnerable to fluctuations in demand or changes in market dynamics. A well-diversified product portfolio provides more stable revenue streams. Different products may have varying lifecycles, market dynamics, and competitive landscapes. By having a mix of products at different stages of their lifecycle, Indian generic companies can balance revenue fluctuations and maintain a consistent revenue stream over time. Diversification enables generic companies to differentiate themselves from competitors. By offering a wide range of products, they can cater to diverse customer needs and preferences. This can create a competitive advantage by attracting a larger customer base, better distributorship network, building brand recognition, and establishing strong relationships with healthcare providers.

5. **Partnerships and Collaborations:** Indian Generic companies need to always look for Partnerships and collaborations to take advantage of the potential opportunities created due the patent expiration. In case of inadequate inhouse research and development capabilities or limited products in R&D kitty, partnering with research institutions, academic organizations, or other pharmaceutical companies provides generic companies with access to additional R&D capabilities and expertise. This enables them to accelerate the development of generic versions of drugs whose patents are expiring. Collaborations can help expedite the research process, reduce development costs, and enhance the likelihood of timely market entry.

6. **Knowledge and Technology Transfer:** Collaborating with partners who have expertise in specific therapeutic areas or technologies allows generic companies to gain valuable insights and knowledge. This knowledge transfer can aid in understanding the intricacies of the branded drugs and their formulations, facilitating the development of effective generic alternatives. Access to partner technologies can also improve manufacturing processes and enhance the quality of generic products. Establishing local manufacturing capabilities or entering into technology transfer agreements can enhance market

presence of Indian generic companies and overcome the country specific trade barriers. Local production can lead to cost savings, improved supply chain efficiency, and regulatory advantages, while technology transfer facilitates knowledge sharing and capacity building, supporting local economic growth and market expansion. Regulatory requirements for generic drug approvals vary across different regions, and partnering with companies or organizations experienced in navigating regulatory landscapes can help expedite the approval process. Collaborators can assist in compiling the necessary documentation, conducting bioequivalence studies, and addressing regulatory queries, ensuring a smoother path to market entry.

7. **Market Access and Distribution:** Partnering with established pharmaceutical companies or distributors can help Indian generic companies gain access to established distribution networks and market channels across the globe. Collaborations can provide opportunities to leverage existing sales and marketing capabilities, enabling generic products to reach a wider customer base more efficiently. Partnerships can also help navigate complex market dynamics, negotiate pricing and reimbursement agreements, and create market entry strategies. By joining forces with complementary partners, generic companies can offer value-added services, differentiated product formulations, or unique therapeutic combinations. Such collaborations enhance the competitive advantage and increase the attractiveness of generic alternatives in the market.

8. **Risk Sharing and Cost Optimization:** Collaborations allow for risk sharing and cost optimization. Developing generic alternatives to branded drugs requires significant investments in R&D, clinical trials, and regulatory compliance. By partnering with other companies or organizations, the financial burden and risks associated with these activities can be shared. Collaboration can help reduce costs, increase efficiency, and improve resource allocation, thereby maximizing the potential return on investment.

9. **Business Development and Licensing Opportunities:** Collaborations can provide Indian generic companies with access to potential licensing and business development opportunities. Partnering with innovative pharmaceutical and biopharmaceutical companies or research institutions may open avenues for in-licensing or acquiring new drug candidates or technologies. This enables generic companies to expand their pipeline, explore new revenue streams, and drive future growth. Partnering with other pharmaceutical companies can facilitate portfolio expansion and diversification. By combining resources and capabilities, generic companies can expand their product offerings and target a broader range of therapeutic areas. This enables them to capture a larger market share, mitigate risks associated with a single product, reduce dependence on a limited portfolio and establish a stronger presence in the market

10. **Market Research:** Conducting thorough market research is essential for Indian generic companies to understand the demand, competition, pricing dynamics, and regulatory

landscape in different geographies. By identifying market opportunities, unmet needs, and emerging trends, Indian generic companies can develop targeted strategies for market entry and expansion. Customizing product offerings based on regional market needs can enhance acceptance and adoption of Indian generic companies and their products. Gradual expansion into new geographical regions is a common approach whereby Indian companies can start by targeting regions with favourable regulatory environments, growing healthcare infrastructure, and high demand and acceptance of generic drugs. Once a strong foothold is established, further expansion into neighbouring countries or other strategic markets can be pursued by such companies. Investing in regulatory expertise and building a strong regulatory affairs team can further facilitate market access and expansion of Indian generic companies. Indian Generic pharmaceutical companies can collaborate with international pharmaceutical companies for licensing, distribution, or manufacturing agreements to access new markets. Developing an efficient and reliable supply chain is crucial for global expansion. Once the Indian company develops any international collaboration, ensuring uninterrupted supply of raw materials (API and excipients) & finished products, reducing lead times, and managing logistics effectively are essential to meet customer demand in different regions. Collaborating with reliable suppliers, optimizing inventory management, and implementing robust distribution strategies are key elements of a successful global supply chain. Partnering with established local companies in foreign countries that have a strong presence and distribution networks in specific regions can help Indian generic companies navigate regulatory complexities and cultural nuances, enabling market entry and expansion. Acquiring or merging with local companies or competitors in target markets can expedite market entry and expansion for Indian companies. This strategy provides access to established infrastructure, distribution networks, customer relationships, and regulatory knowledge.

11. **Authorized Generics Model:** In some cases, Indian generic companies may enter into agreements with the original brand manufacturer to produce and market an "authorized generic" version of the drug. These authorized generics are essentially identical to the branded drug and are often priced competitively (substantially less than the innovator but relatively higher than the generic products) to capture a significant market share. This strategy leverages the brand recognition of the original drug while offering a more affordable alternative. Pharma major Dr Reddy's Laboratories Ltd has expanded its collaboration with Amgen in India to market and distribute three of the latter's medicines in the domestic market. As part of the collaboration, Hyderabad-based Dr Reddy's commercialized Amgen's XGEVA (denosumab), Vectibix (panitumumab) and Prolia (denosumab) in the therapeutic areas of oncology and osteoporosis.

8. WAY FORWARD FOR INDIAN GENERIC COMPANIES TO MITIGATE QUALITY RISKS

Quality assurance and safety are paramount during the development of generic versions of patented drugs. When evaluating the quality and safety of pharmaceutical products, it is essential for Indian generic companies to consider the overall regulatory framework, compliance track record, and reputation of the specific company. Regulatory authorities, such as the FDA, EMA, and CDSCO, play a critical role in ensuring adherence to standards and addressing any reported issues. By adhering to stringent quality assurance measures, conducting thorough testing and evaluations, and complying with regulatory requirements, generic drug manufacturers can mitigate safety concerns and ensure that their products are safe, effective, and of high quality for patients. Generic pharmaceutical companies exploring the markets of off-patent drugs need to implement robust quality assurance and compliance measures to ensure the safety, efficacy, and quality of their products. By implementing the quality assurance and compliance measures, generic pharmaceutical companies can ensure the consistent quality of their products, meet regulatory requirements, and build trust among healthcare professionals and patients. A strong focus on quality, compliance, and patient safety is paramount to the success and reputation of Indian generic companies in the global marketplace. Below are some key measures that should be taken by Indian Generic companies:

1. **Establish a Quality Management System (QMS):** Establishing a comprehensive QMS is vital for Indian generic companies with global aspirations. A well-designed QMS encompasses procedures, policies, and processes that ensure consistent quality throughout the entire product lifecycle, from product development to manufacturing, distribution, and post-marketing surveillance. This includes documentation control, change management, internal audits, and continuous improvement initiatives. Implementing a culture of continuous improvement is crucial for generic companies to stay competitive and maintain high-quality standards. This involves monitoring key performance indicators, conducting regular quality reviews, and implementing corrective and preventive actions to address any deviations or non-conformities. The Indian generic companies with global aspirations should establish robust testing protocols and employ analytical techniques, such as chromatography, spectroscopy, and dissolution testing, to assess the product's compliance with established specifications. Learning from quality incidents, customer feedback, and emerging industry trends helps drive continuous improvement initiatives.

2. **Active Pharmaceutical Ingredient (API) and Key Starting Material (KSM) Sourcing:** Generic manufacturers need to ensure the quality and safety of the API and KSM used in their products. Most of this raw material is imported by Indian companies from countries like China. Indian Generic companies should have a robust supplier qualification process in place to ensure the quality and reliability of raw materials, APIs, and other components sourced from external suppliers. Conducting regular audits of suppliers, assessing their quality systems, and verifying compliance with quality standards are important steps to mitigate supply chain risks. The Indian companies need

to perform proper due diligence before the selection of API suppliers and should not be dependent only on the documents like Certificate of Analysis (CoA) issued by the suppliers of raw materials. The Indian generic companies should have systems in place for the testing of incoming raw materials ensuring compliance with regulatory requirements for purity, stability, and impurity levels. If the companies, do not have the such inhouse testing capabilities for checking the quality of incoming APIs and KSMs, they can outsource the testing activities to NABL accredited laboratories after proper due diligence of such labs. Ensuring the quality of imported APIs and KSMs is the most important step Indian companies need to take with the immediate effect.

3. **Manufacturing Standards**: Generic drug manufacturers need to adhere to Good Manufacturing Practices (GMP) to maintain quality standards throughout the manufacturing process. GMP regulations cover various aspects, including facility design, equipment qualification, raw material sourcing, process controls, packaging, labelling, and quality control testing. However, surprisingly the GMP standards have a unsaid grading system whereby GMP standards of USFDA & European countries are rated above the WHO GMP and the GMP requirements of semi-regulated markets. Indian generic companies should keep a long-term perspective and invest in facilities, equipment, and systems as per the requirements of regulators like USFDA and EMEA. Compliance with GMP as per US & EU standards ensures consistent quality and safety of the generic drugs. Rigorous quality control testing should be conducted throughout the manufacturing process to ensure that the generic drug meets the required specifications for identity, strength, purity, and quality. These tests include assays, dissolution testing, impurity analysis, stability testing, and other quality parameters to confirm product quality and safety. In addition, the generic companies should establish comprehensive batch release procedures to ensure that each batch of the product meets the required specifications before being released for distribution. Batch release includes a thorough review of manufacturing records, quality control test results, and compliance with applicable regulatory requirements. The documentation associated with batch release should be maintained as part of the company's quality records.

4. **Conducting Bioequivalence Studies of Generic Drugs in reputed CROs**: For the generic pharmaceutical products, the pharmaceutical companies do not need to go through entire clinical development cycle of Phase I to Phase IV. It is because the innovator drugs are in the market for a long period and have been already been proven to be safe and efficacious in a particular disease indication. In such case, generic versions of drugs must demonstrate bioequivalence to the Reference Listed Drug (RLD) in terms of pharmaceutical equivalence and bioavailability. Indian generic companies need to conduct Robust comparative studies, including pharmacokinetic and pharmacodynamic assessments, to establish the similarity of the generic drug to the RLD. Ensuring bioequivalence is crucial for the safety and efficacy of the generic version and also a part of the regulatory dossiers submitted to various regulatory agencies to obtain marketing authorisation in respective countries. Most of the pharmaceutical companies outsource the Bioequivalence studies to the specialized BA/BE CROs in India. There have been

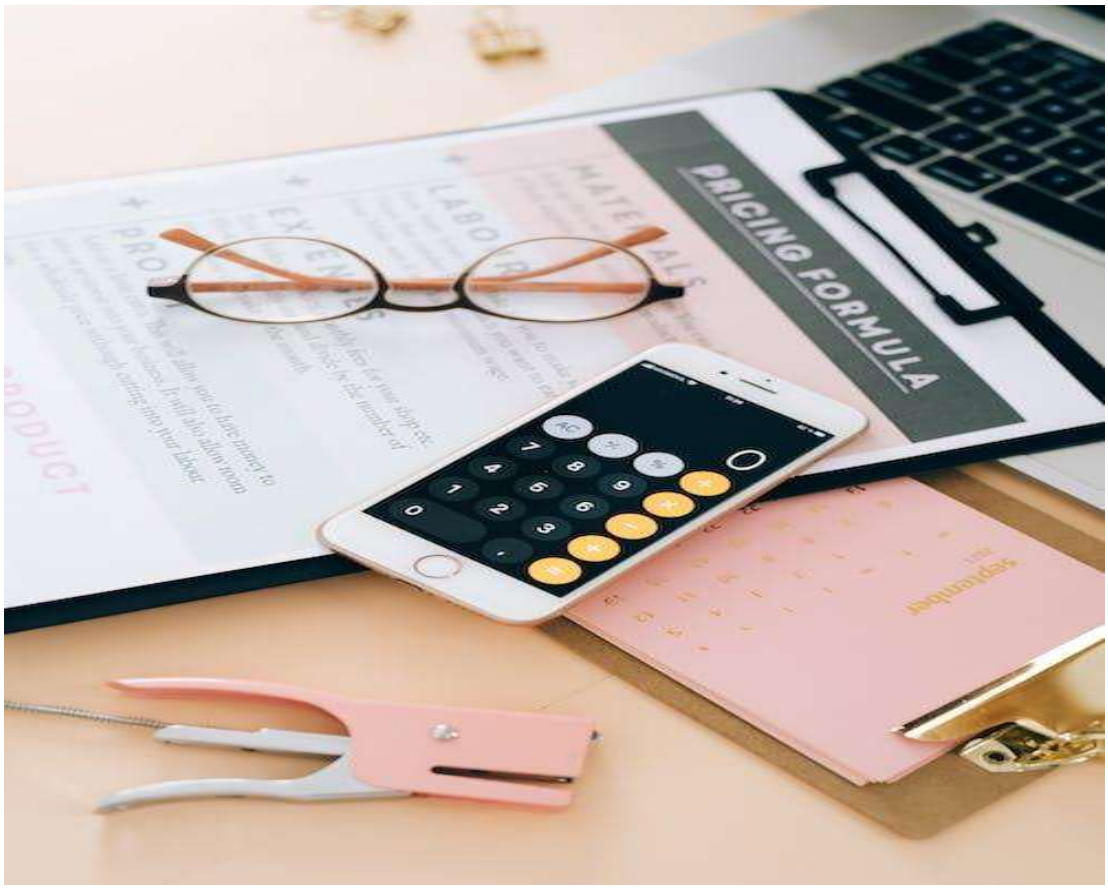
some instances related to misconduct and data integrity violations by their hired CROs particularly working in the domain clinical bioequivalence and bioavailability studies. The Indian generic companies need to be very careful and conduct proper due diligence while selecting the CROs for conducting the bioequivalence studies because the data integrity issues can lead to jeopardizing the entire ANDA submission of the generic pharmaceutical companies.

5. **Stability Testing:** Pharmaceutical companies need to conduct stability testing as per the different zone requirements to assess the shelf life and storage conditions of the generic drugs. Conducting product stability studies is crucial to determine the shelf life and storage conditions of off-patent drugs. These studies assess the chemical, physical, and microbiological stability of the product over time and under different environmental conditions. It helps to determine the expiration date and provide for the shipping and storage recommendations to ensure that the drug maintains its quality, safety, and efficacy during the transient and throughout its intended shelf life.

6. **Pharmacovigilance and Adverse Event Reporting:** Continuous monitoring of the generic drug's safety and effectiveness after it enters the market is essential. Post-marketing surveillance programs help detect and assess any potential safety issues that may not have been apparent during clinical trials. Timely reporting and response to safety concerns are crucial to ensure patient well-being. Implementing a robust pharmacovigilance system is crucial for monitoring and reporting adverse events associated with off-patent drugs. Indian Generic companies with global aspirations should establish processes to capture, evaluate, and report any safety concerns promptly. Compliance with pharmacovigilance regulations ensures the ongoing

7. **Labelling and Patient Information**: Generic companies need to ensure compliance with applicable regulatory requirements of labelling in each market they operate in. This includes obtaining necessary regulatory approvals, adhering to labelling and packaging regulations, and complying with pharmacopeial standards. Keeping abreast of regulatory updates and changes is essential to maintain compliance and meet evolving regulatory expectations. Accurate and comprehensive labelling and patient information are essential for ensuring the safe use of generic drugs. Clear instructions, warnings, and precautions must be provided to healthcare professionals and patients to minimize any potential risks and promote safe and effective use of the medication.

9. PRICING STRATEGIES FOR INDIAN GENERIC COMPANIES



Patent expiration a natural milestone in a product's lifecycle and could mean the end of a product's value however the innovator companies similar to market launch strategically plan it to ensure optimum returns. Prior to executing a successful generic product launch strategy, it is critical to understand existing product dynamics across stakeholders, namely physician, pharmacy and patient. Indian Generic pharmaceutical companies have several pricing strategies that they can consider after the patent of a drug expires. Implementing competitive pricing strategies, especially in price-sensitive markets, can facilitate market penetration and expansion. There is no standard pricing model which can be opted by all Indian companies for all types of drugs. Indian generic pharmaceutical companies can explore differential pricing models based on regional economic factors and healthcare systems to ensure affordability and improve accessibility.

The Indian companies need to monitor the market dynamics, generic competitor's pricing strategy, innovator's pricing actions and customer feedback to assess the effectiveness of their pricing strategies and make the necessary adjustments as needed. In addition, the factors such as production costs, competition, market demand, regulatory requirements, and reimbursement scenario need to be factored in while determining the pricing strategies. Given the high variation in affordability and lower prices of branded generics, patent cliff is going to

create economic incentives for physicians and patients (and payors in limited cases) to shift volume from innovator brands to generics. The resulting rapid decline in a brand's volume and market share becomes the primary concern of brands facing loss of exclusivity (LoEs). While some degree of branded volume erosion due to generics seems inevitable, the extent of a brand's decline can be mitigated even by the innovator companies through strategic initiatives. Key factors which influence the prices of generic/biosimilar drugs are tabled below:

Key factors influencing the prices of biosimilars/ Generics

S. No.	Factor(s)	Impact on price
1.	Market share	The price varies as per the market share of generic medicines. Competition from generic medicines leads to price reductions. Generic market share is directly proportional to a decrease in prices.
2.	Market competition and demand	The chances of generic suppliers responding to factors influencing demand size and market competition are high. Originators set prices strategically to reduce compulsory licensing and generic competition threats.
3.	Entry of new biosimilar/Generics	The introduction of the new biosimilar/generic drug generally result in substantial cost savings for healthcare.
4.	Efficacy and safety	A biosimilar/generic's price is only one aspect of its full value. In addition to taking into account development and manufacturing expenses, the outcomes of efficacy and safety in comparison to the reference biologic/innovator's medicine are also taken into account.
5.	Per capita income	Per capita GDP is important factor while pricing the drugs. For example, the price of insulin drugs originating from OECD countries is higher than that imported from developing countries.
6.	List prices, net prices, discounts	The price drop is observed for originators after the entry of biosimilars/generics or other substitutes in the market. The entry of biosimilars/generics stops the increase in list prices but net prices commence to decrease due to discounts offered by companies.

7.	Trust and confidence of the physician	To increase the market acceptance of biosimilars/generics, clinicians' and users' trust and confidence are essential. This may increase the demand and impact the price.
8.	Originator vs generics	Switching originator drugs to generics can result in savings of upto 65% for patients.
9.	Selection strategy	The price of the originator varies with the selection strategy between branded and generic drugs in out-of-hospital pharmacies, but not in in-house pharmacies of medical facilities.
10.	Differential pricing policies	Differential pricing policies are feasible mostly for 'global' diseases, where drugs through worldwide sales recoup their R&D costs. The differential prices vary with the pharmaceutical industry and do not encourage sustainability or autonomy in developing countries.
11.	Pricing policies	Despite many efforts toward the implementation of policies like internal reference, tendering and generic substitution to increase biosimilar/generics adoption, a large difference remains in the price and uptake of medicines between countries.
12.	Price cap Regulations	A continuous decline in the ceiling prices is associated with a high incidence of exit of innovator firms from markets.

The ultimate objective of any generic company is to offer affordable alternatives to the branded drugs while quickly maximizing market share and profitability. Engaging in discussions with governments, payers, and healthcare providers to promote the benefits of generic medicines and advocate for favourable reimbursement policies can also support market access. Below are some of the pricing strategies that can be opted by Indian Generic companies:

1. **Competitive Pricing Strategy:** Generic companies often adopt a competitive pricing strategy to gain a significant market share. They typically set their prices lower than the branded drug but higher than other generic competitors. This strategy aims to attract customers who prioritize cost savings while still maintaining a reasonable profit margin. For example, the price of the generic version of Lipitor, a cholesterol-lowering drug, is 70% to 90% lower than the branded version's price. Generic Pharmaceutical companies use reference pricing to compete with other generic drug manufacturers in the market.

2. **Cost-Plus Pricing Strategy:** Cost-plus pricing involves determining the manufacturing and distribution costs associated with the generic drug and adding a predetermined

profit margin to arrive at the selling price. This strategy ensures that the price reflects the actual costs incurred by the generic company while allowing them to generate a reasonable profit. The development of a new drug can cost between $2.6 billion to $3 billion for innovator companies. Innovator Pharmaceutical companies add a markup to the production cost, which can range from 50% to 500%, to set the drug's price. Generic companies do not have to spend on the fundamental research and development of these drugs and therefore once they have the marketing approval for their generic version, they can play on the markup depending on the region, patient base and the reimbursement policies.

3. **Market Penetration Pricing Strategy**: Market penetration pricing involves setting the initial price of the generic drug lower than the competing branded drug or other generic alternatives. This strategy aims to quickly capture a significant market share by enticing customers with a lower-priced option. Once the market share is established, the company may consider adjusting the price upwards to align with competitors

4. **Price Skimming Strategy:** After the loss of exclusivity, the Indian generic Companies specially the ones which are able to get exclusivity for 3 months can set the initial price of the generic drug relatively high to capitalize on customers who are willing to pay a premium for early access to the generic version. They can set the price slightly lower than the innovator company so as to provide a small cost benefit to the customers who are early adopters. This strategy is often employed when there is limited initial competition in the market. Over time, as more competitors enter the market, the price is gradually reduced to attract price-sensitive customers. In Indian scenario, this has been a quite prevalent trend followed by the generic companies.

5. **Value-Based Pricing Strategy:** Value-based pricing focuses on pricing the generic drug based on the perceived value it provides to patients, healthcare providers, or payers. The price is determined by considering factors such as therapeutic benefits, cost-effectiveness, convenience, and patient outcomes compared to the branded drug. This strategy requires a deep understanding of the market and the ability to demonstrate the value proposition of the generic product. For example, a drug that can cure a life-threatening disease has a higher perceived value than a drug that treats a common ailment. Pharmaceutical companies use value-based pricing to set the price of high-value drugs, such as cancer medications.

6. **Differential Pricing Strategy:** Differential pricing strategy, also interchangeably known as ‘tiered pricing’ or ‘equity pricing’, refer to the adjustment of drugs' costs according to the consumer's ability to purchase the goods. This strategy could take an important part in improving access to essential medicines by regulating prices so that the medicines are more affordable for the people in developing countries. Once the Indian generic companies get the Marketing authorisation in regulated markets like US and

Europe, the companies can go ahead with setting different prices for different market segments or geographic regions based on factors such as purchasing power, market demand, and competitive dynamics. Because larger doses are sold in developing countries, differential pricing may be beneficial for all stakeholders. Differential pricing can also be feasible as there are substantial fixed costs, and variable or marginal costs (the costs of production and distribution) are relatively low as the pharmaceutical industry may have invested heavily on this in the high-income economies. Hence, differential pricing allows low-income markets to pay only for marginal costs and high-income countries to pay more than marginal costs to cover the costs of research and development. Differential pricing can be in the interests of all parties as far as the markets could be effectively segregated. The segmentation would prevent diversion of low-priced products into high-income markets and a readiness on the part of consumers in high-income economies to accept the higher prices. Indian Generic companies may offer lower prices in less affluent regions or negotiate discounted prices with bulk purchasers, such as government healthcare programs or hospital chains, while maintaining relatively higher prices in more affluent markets.

However sometimes, the highly skewed income distributions within lower-middle and middle-income countries seriously hinder the ability of the generic companies to do differential pricing. Inter-country differential pricing cannot guarantee affordable prices to the poorest population segments in lower-middle and middle-income countries, as that would imply pharmaceutical companies forego the profits from the higher income segments in these countries. At the same time, the poorest segments and their advocacy groups feel —entitled to the prices provided to low income and least developed countries. Differential pricing is however not based on differences in the prices offered on contract but on a complex system of rebates and discounts. The price of drugs paid by the consumer is determined by a system of negotiated volume-rate contracts between manufacturers, pharmacy benefit managers (PBMs), wholesale distributors, pharmacies, and health insurance companies. The price charged by each entity in the chain is largely driven by the ability of contracting entities to sell specific volumes of certain drugs or achieve a certain share of a specified market. It is also affected partially by the value each entity brings to the subsequent actors in the supply chain.

Differential pricing solutions are generally unworkable unless the different categories of buyers can be prevented from trading with one another. Covid Vaccines present good examples of intra-country differential pricing. For example, the Covid -19 vaccine was offered Serum Institute at two different price points within India. It was sold to the private sector market around INR 700, and to the government and NGOs around INR 200/dose. Other examples of differential pricing that has been successfully implemented in pharmaceutical industry include oral contraceptives; and medicines for human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), tuberculosis (TB) and malaria. With differential pricing, some of these drugs, namely

vaccines and oral contraceptives, cost as much as 200 times less for low-income markets. As a result, millions of people obtained access to these pharmaceutical products. However, some of the limitations of differential prices include the availability at minimum cost on a long-term basis, transparency in prices and setting minimum conditions to verify the eligibility of developing countries.

10. REFERENCES

Below mentioned product specific literature has been referred to

https://www.rxabbvie.com/pdf/humira.pdf

https://www.keytruda.com/

https://www.drugs.com/keytruda.html

https://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf

https://www.revlimid.com/

https://medlineplus.gov/druginfo/meds/a608001.html

https://www.eliquis.bmscustomerconnect.com/

https://en.wikipedia.org/wiki/Apixaban

https://www.medicalnewstoday.com/articles/eylea

https://eylea.us/s

https://www.stelarainfo.com/

https://www.drugs.com/stelara.html

https://www.rxlist.com/opdivo-drug.htm

https://www.opdivo.com/

https://us.tivicay.com/

https://www.webmd.com/drugs/2/drug-164908/tivicay-oral/details

https://www.ibrance.com/about-ibrance

https://www.januvia.com/

https://www.trulicity.com/

https://www.xgeva.com/

https://www.prolia.com/

https://www.novartis.com/us-en/sites/novartis_us/files/cosentyx.pdf

https://content.takeda.com/?contenttype=PI&product=ENTY&language=ENG&country=USA&documentnumber=1

https://www.novo-pi.com/victoza.pdf

https://www.gene.com/download/pdf/avastin_prescribing.pdf

https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Enbrel/enbrel_pi_CURNT.pdf

https://app.purduepharma.com/xmlpublishing/pi.aspx?id=o

https://products.sanofi.us/Lantus/Lantus.pdf

https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125156s105lbl.pdf

https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021929s021lbl.pdf

https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021366s016lbl.pdf

https://www.lyrica.com/en

https://www.rxlist.com/lyrica-drug.htm

https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/XARELTO-pi.pdf

India's Cadila launches first cheaper copy of world's top-selling drug | Reuters

Natco Pharma announces launch of first generic of top selling cancer drug Revlimid - The Economic Times (indiatimes.com)
Top diabetic drug goes off patent, prices to fall by 3rd - Times of India (indiatimes.com)
Dr Reddy's laboratories: Dr Reddy's launches Roche's Avastin biosimilar in India - The Economic Times (indiatimes.com)
India: insulin and biosimilars market value 2020 | Statista
https://www.indianpharmapost.com/drug-approval/alembic__pharmaceuticals-receives-pas-approval-from-usfda-for-pregabalin-capsules-13493
https://www.statista.com/statistics/1202009/india-market-value-of-leading-molecules-in-cardiac-segment/#:~:text=Rosuvastatin%20was%20the%20leading%20molecule,top%20ten%20molecules%20that%20year
https://twitter.com/CapitalMarket17/status/1730132935817175060

ANNEXURE - A

S.No	Drug	Salt	Indication	Molecular Size	Patent Number	Year of Patent Expiry	Parent Company	Potential Indian Generic Manufacturers	Dosage Form	Pharmacological Classification
1	Tafinlar	Dabrafenib Mesylate	Braf (V600)-Mutated Metastatic Melanoma	Small	US7994185 US8415345 US8703781	January 20, 2030 January 20, 2030 October 15, 2030	Novartis Pharmaceuticals Corp	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Reversible ATP-Competitive Kinase Inhibitor
2	Cosentyx	Secukinumab	Moderate To Severe Plaque Psoriasis In Adult Patients Who Are Candidates For Systemic Therapy Or Phototherapy. Adults With Active Psoriatic Arthritis (Psa). Adults With Active Ankylosing Spondylitis (AS)	Large	US7807155	February 09, 2030	Novartis Pharmaceuticals Corp	Intas, Cipla, Reliance , Lupin	Subcutaneous Injection	Monoclonal Antibodies
3	Copiktra	Duvelisib	Chronic Lymphocytic Leukemia, Small Lymphocytic Lymphoma, And Follicular Lymphoma	Small	US8193182 USRE46621	February 13, 2030 May 17, 2032	Secura Bio Inc	Natco, Dr Reddy's, sun pharma, Cipla, Panacea Biotec, United Bioted, Intas Pharma, SR pharma, Zydus Cadila	Oral	Kinase Inhibitor
4	Seglentis	Celecoxib/Tramadol Hydrochloride	Management And Treatment Of Pain	Small	US10238668 US9012440 US8598152 US10245276	April 19, 2030 April 19, 2030 April 19, 2030 April 19, 2030	Kowa Pharmaceutical America Inc	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Oral	Opioid Analgesics
5	Veltassa	Patiromer	High Blood Potassium	Small	US8337824	May 29, 2030	Vifor Pharma Inc	Lupin, Cipla, Unimark	Oral	Potassium Removing Agent
6	Olumiant	Baricitinib	Rheumatoid Arthritis And Covid-19	Small	US8158616	June 8, 2030	Eli Lily and Co	Intas, Cipla, Reliance, Lupin	Oral	Janus Kinase (Jak) Inhibitor
7	Voxzogo	Vosoritide	Achondroplasia	Large	US8198242	June 11, 2030	Biomarin Pharmaceutical Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Subcutaneous	C Type Natriuretic Peptide (CNP) Analog
8	Apadaz	Acetaminophen/Benzhydrocodone Hydrochloride	Moderate To Severe Pain	Small	US9132125 US9549923 US8748413 US8461137	July 1, 2030 July 1, 2030 July 10, 2030 February 22, 2031	Kvk Tech Inc	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Subcutaneous	Analgesics (Pain Relievers) And Antipyretics (Fever Reducers)/Narcotic Analgesics
9	Segluromet	Ertugliflozin-Metformin Hydrochloride	Type 2 Diabetes	Small	US8080580	July 13, 2030	Merch Sharp and Dohme Corp	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Subcutaneous	Sodium-Dependent Glucose Cotransporters Inhibitor/Biguanides
10	Qinlock	Ripretinib	Advanced Gastrointestinal Stromal Tumor	Small	US8188113 US8461179	July 27, 2030 June 7, 2032	Deciphera Pharmaceutical Llc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors
11	Parsabiv	Etelcalcetide	Secondary Hyperparathyroidism	Small	US9701712 US9278995 US8377880 US8999932	July 29, 2030 July 29, 2030 July 29, 2030 February 7, 2031	kai pharmaceutical Inc	Abbott, Macleods, Intas, Lupin	Intravenous	An Oligopeptide
12	Alunbrig	Brigatinib	Non Small Cell Lung Cancer	Small	US9012462 US10385078	July 31, 2030 November 10, 2035	Takeda Pharmaceutical USA Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Tyrosine Kinase Inhibitor
13	Brexafemme	Ibrexafungerp Citrate	Vulvovaginal Candidiasis	Small	US8188085 US10174074 US10927142	August 28, 2030 January 19, 2035 January 19, 2035	Scynexis Inc	Abbott, Cadila	Oral	Triterpenoid Antifungal Agent
14	Nubeqa	Darolutamide	Non-Metastatic Castration-Resistant Prostate Cancer	Small	US8975254 US9657003 US11046713 US10711013 US10383853 US10010530 US11168058	October 27, 2030 October 27, 2030 October 27, 2030 October 27, 2030 January 28, 2036 January 28, 2036 February 27, 2038	Bayer Healthcare Pharmaceuticals Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Androgen Receptor Inhibitors
15	Harvoni/Hepcinat-LP	Ledipasvir/Sofosbuvir	Hepatitis C	Small	US8822430 US8088368 US10039779	November 12, 2030 November 12, 2030 July 30, 2034	Gilead Sciences Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Direct-Acting Antiviral Agents
16	Rinvoq	Upadacitinib	Rheumatoid Arthritis And Psoriatic Arthritis	Small	USRE47221 US8962629 US10981923 US9951080 US11186584	December 1, 2030 January 15, 2031 October 17, 2036 October 17, 2036 October 17, 2036	Abbvie Inc	Intas, Cipla, Reliance , Lupin	Oral	Janus Kinases Inhibitor
17	Nerlynx	Neratinib	Breast Cancer	Small	US7399865	December 29, 2030	Puma Biotechnology	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors
18	Lamictal Odt	Lamotrigine	Epilepsy	Small	US7919115	January 4, 2029	GlaxoSmithKline	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Triazine
19	Wakix	Pitolisant Hydrochloride	Excessive Daytime Sleepiness	Small	US8207197	February 25, 2029	Harmony Biosciences Llc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	H3 Autoreceptors Blocker
20	Caplyta	Lumateperone Tosylate	Schizophrenia And Bipolar Disorder	Small	US9586960 USRE48825 US8648077	March 12, 2029 March 12, 2029 December 1, 2029	Intra-cellular Therapies Inc	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Oral	Atypical Antipsychotics
21	Desyrel	Trazodone Hydrochloride	Major Depressive Disorder, Anxiety Disorders, And Difficulties With Sleep	Small	US8133893	March 13, 2029	Pragma Pharmaceutical	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Oral	Serotonin-Antagonist-And-Reuptake-Inhibitor

22	Neuraceq	Florbetaben F-18	Alzheimer's Disease	Small	US7807135	March 18, 2029	Life Molecular Imaging Ltd	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Stilbenoids
23	Monoferric	Ferric Derisomaltose	Iron Deficiency Anemia	Small	US10414831 US8815301	March 25, 2029 August 14, 2029	Pharmacosmos As	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Iron Carbohydrate Oligosaccharide
24	Gemtesa	Vibegron	Overactive Bladder	Small	US8653260 US8247415	April 2, 2029 December 1, 2030	Urovant Sciences Gmbh	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Beta-3 Adrenergic Agonists
25	Kerendia	Finerenone	Kidney Function	Small	US8436180	April 12, 2029	Bayer Healthcare Pharmaceuticals Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Mineralocorticoid Receptor (MR) Antagonists
26	Triferic	Ferric Pyrophosphate Citrate	Iron Deficiency Anemia	Large	US7816404	April 17, 2029	Rockwell Medical Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Phosphate Binders And Iron Replacement Products
27	Cipro	Ciprofloxacine	Bacterial Infection	Small	US9603796	April 21, 2029	Alk-Abello Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral, Intravenous, Topical	Fluoroquinolones
28	Veklury	Remdesivir	Antiviral	Small	USRE46762 US8318682 US8008264 US10065958 US9724360 US9949994	April 22, 2029 April 22, 2029 September 6, 2029 September 16, 2031 October 29, 2035 October 29, 2035	Gilead Sciences Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Nucleoside Analog
29	Zejula	Niraparib Tosylate	Anti-Cancer	Small	US8436185 US8071623	April 24, 2029 March 27, 2031	GlaxoSmithKline	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Active Poly (ADP-Ribose) Polymerase (PARP) Inhibitor
30	Zeposia	Ozanimod Hydrochloride	Multiple Sclerosis And Ulcerative Colitis	Small	US8481573 US8796318	May 14, 2029 May 14, 2029	Celgene International Li Sarl	Sun Pharma, Alkem, Micro Labs, Abbott, Intas, Lupin, Torrent, IPCA	Oral	Sphingosine L-Phosphate Receptor Modulators
31	Tauvid	Flortaucipir (18F)	Radioactive Diagnostic Agent	Small	US8932557	May 19, 2029	Avid Radiopharmaceuticals Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Small Lipophilic Tracer
32	Opana Er	Oxymorphone Hydrochloride	Severe Pain	Small	US7851482 US8871779	July 10, 2029 November 22, 2029	Endo Pharmaceuticals Inc	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Oral	Opioid Agonist
33	Braftovi	Encorafenib	Melanoma	Small	US8946250 US8541575 US9593099 US8501758	July 23, 2029 February 26, 2030 August 27, 2030 March 4, 2031	Array Biopharma Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Kinase Inhibitors.
34	Odomzo	Sonidegib Phosphate	Cancer	Small	US8178563 US8063043	July 24, 2029 September 15, 2029	Sun Pharmaceutical Industries Ltd	BDR pharmaceuticals, Alkem, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	A Hedgehog Signaling Pathway Inhibitor
35	Zepatier	Elbasvir/Grazoprevir	Hepatitis C	Small	US7973040 US8871759	July 24, 2029 May 4, 2031	Merch Sharp and Dohme Corp	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	HCV NS5A Inhibitors/Protease Inhibitors
36	Talzenna	Talazoparib Tosylate	Breast Cancer	Small	US8420650 US8012976 US10189837 US8735392	July 27, 2029 October 19, 2029 October 20, 2031 October 20, 2031	Pfizer	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Poly (ADP-Ribose) Polymerase (PARP) Inhibitors
37	Evotaz	Atazanavir Sulfate/Cobicistat	HIV/AIDS	Small	US8148374	September 3, 2029	Bristol-Myers Squibb Co	Cipla, Emcure Pharma, Sun Pharma	Oral	Protease Inhibitor / Pharmacokinetic Boosters
38	Piqray	Alpelisib	Breast Cancer	Small	US8476268 US8227462	September 10, 2029 September 28, 2030	Novartis Pharmaceuticals Corp	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors
39	Tykerb	Lapatinib Ditosylate	Breast Cancer	Small	US8821927	September 18, 2029	Novartis Pharmaceuticals Corp	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors
40	Treanda	Bendamustine Hydrochloride	Chronic Lymphocytic Leukemia, Multiple Myeloma, And Non-Hodgkin's Lymphoma	Small	US8445524	September 26, 2029	Cephalon Inc	Natco, Dr Reddy, Sun Pharma, Cipla, Panacea Biotec, United Biotech, Intas Pharma, SR Pharma, Zydus Cadila	Intravenous	Alkylating Agents
41	Ingrezza	Valbenazine	Tardive Dyskinesia	Small	US8039627 US10065952 US10844058 US10851103 US10851104 US10906902 US10919892 US10906903	October 6, 2029 October 28, 2036 October 28, 2036 October 28, 2036 October 28, 2036 December 22, 2036 December 22, 2036 December 22, 2036	Neurocrine Bioscience Inc	Dr Reddy's, Sun Pharma, Intas Pharma, Reliance Formulation	Intravenous	Vesicular Monoamine Transporter 2 Inhibitors
42	Vitrakvi	Larotrectinib Sulfate	Cancer	Small	US9127013 US8513263 US10172861 US10799505	October 21, 2029 December 23, 2029 November 16, 2035 August 15, 2036	Bayer Healthcare Pharmaceuticals Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors
43	Rezurock	Belumosudil Mesylate	Chronic Graft Versus Host Disease	Small	US8357693	October 30, 2029	Kadmon Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Serine/Threonine Kinase Inhibitors
44	Cotellic	Cobimetinib Fumarate	Cancer	Small	US7803839 US10478400 US10590102	November 10, 2029 June 29, 2036 June 30, 2036	Genentech Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors

45	Recarbrio	Imipenem/Cilastatin Sodium/Relebactam	Urinary Tract And Complicated Intra-Abdominal Infections	Small	US8487093	November 19, 2029	Merch Sharp and Dohme Corp	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Carbapenem Antibiotics/ Dehydropeptidase Inhibitors/ Beta Lactamase Inhibitor
46	Belsomra	Suvorexant	Insomnia	Small	US7951797	November 20, 2029	Merch Sharp and Dohme Corp	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Orexin Receptor Antagonists
47	Verzenio	Abemaciclib	Breast Cancer	Small	US7855211	December 15, 2029	Eli Lily and Co	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors
48	Tavneos	Avacopan	Anti-Neutrophil Cytoplasmic Auto Antibody-Associated Vasculitis	Small	US8906938 US8445515	December 21, 2029 February 3, 2031	Chemocentryx Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Complement Inhibitors
49	Ibsrela	Tenapanor Hydrochloride	Irritable Bowel Syndrome	Small	US8541448 US8969377	December 30, 2029 December 30, 2029	Aedelyx Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Sodium/Hydrogen Exchanger Isoform 3 Transporter Inhibitor
50	Eucrisa	Crisaborole	Atopic Dermatitis	Small	US8039451	December 29, 2029	Anacor Pharmaceuticals Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Topical	Phosphodiesterase Inhibitors
51	Mutamycin	Mitomycin	Upper Gastro-Intestinal Cancers, Anal Cancers, And Breast Cancers	Small	US9539241	January 2, 2028	Biochem Pharmaceutical Industries	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Intravenous Powder For Injection	Antineoplastic Antibiotic
52	Farydak	Panobinostat Lactate	Various Cancer	Small	US7989494	January 17, 2028	Secura Bio Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Latency-Reversing Agents
53	Sivextro	Tedizolid Phosphate	Complicated Skin And Skin-Structure Infections (CSSSIS)	Small	US8420676 US7816379 US9624250 US9624250 US8426389	February 23, 2028 June 20, 2028 February 3, 2030 February 3, 2030 December 31, 2030	Cubist Pharmaceuticals	Cipla, Mylan, Zydus Cadila, Alkem, United Biotech	Oral, Intravenous	Oxazolidinone-Class Antibiotic
54	Xenleta	Lefamulin	Pneumonia	Small	US8153689 US8071643 US9120727	March 19, 2028 January 16, 2029 May 23, 2031	Nabriva Therpeutics	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral, Intravenous	Pleuromutilin Antibiotics
55	Vosevi	Sofosbuvir/Velpatasvir/ Voxilaprevir	Hepatitis C	Small	US7129232 US8685957 US8476425 US8906898	May 15, 2028 September 27, 2032 September 27, 2032 May 28, 2034	Gilead Sciences Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Nucleotide Polymerase Inhibitors/ HCV NS5A Replication Complex Inhibitors / HCV NS3/4A Protease Inhibitor, And P-Glycoprotein Inhibitor, And Breast Cancer Resistance Protein Inhibitor, And Organic Anion Transporting Polypeptide 1b1 Inhibitor And Organic Anion Transporting Polypeptide 1b3 Inhibitor
56	Zerbaxa	Ceftolozane/Tazobactam	Urinary Tract Infection	Small	US8242294	May 16, 2028	Merck & Co	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Cephalosporin Antibiotic / Beta-Lactamase Inhibitor
57	Tepmetko	Tepotinib	Non-Small Cell Lung Cancer	Small	US8921357 US8329692 US8580781	May 30, 2028 October 30, 2029 March 19, 2030	EMD Serono Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors
58	Kisqali	Ribociclib	Breast Cancer	Small	US8324225 US8415355 US8685980 US9193732	June 17, 2028 August 21, 2029 May 25, 2030 November 9, 2031	Novartis Pharmaceuticals Corp	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors
59	Osmoprep	Sodium Phosphate Monobasic Monohydrate / Sodium Phosphate Dibasic Anhydrous	Constipation	Small	US7687075	June 22, 2028	Salix Pharmaceuticals Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Saline Laxatives
60	Rozlytrek	Entrectinib	Non-Small Cell Lung Cancer	Small	US9029356 US8299057 US9085565 US10738037	July 8, 2028 March 1, 2029 May 22, 2033 May 18, 2037	Genentech Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors
61	Minivelle	Estradiol	Menopause	Small	US9724310 US8231906	July 10, 2028 July 4, 2030	Noven Pharmaceuticals	Bayer Zydus, Abbott, Bharat Serum & Vaccine, Emcure, Mylan, Serum Institute of India, Intas	Transdermal	Estrogenic Steroid
62	Truseltiq	Infigratinib	Cholangiocarcinoma	Small	US9067896 US8552002	August 6, 2028 August 25, 2029	Helsinn Healthcare Sa	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Kinase Inhibitors
63	Syndros	Dronabinol	Nausea And Vomiting Caused By Chemotherapy	Small	US9345771 US8222292 US10265293 US11253472	August 6, 2028 August 6, 2028 August 6, 2028 August 6, 2028	Benuvia Therapeutics Inc	Dr Reddy's, Glenmark, Torrent, Alkem	Oral	Cannabinoids
64	Vizimpro	Dacomitinib	Non-Small Cell Lung Cancer	Small	US7772243	August 26, 2028	Pfizer	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors
65	Viekira Pak	Ombitasvir/Paritaprevir/ Ritonavir	Hepatitis C	Small	US8501238 US8188104 US8642538 US8420596 US8691938	September 17, 2028 May 17, 2029 September 10, 2029 April 10, 2031 April 13, 2032	Abbvie Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Hepatitis C Virus (HCV) NS5A Inhibitor / Acylsulfonamide Inhibitor / Protease Inhibitors

66	Epclusa	Sofosbuvir/Velpatasvir	Hepatitis C	Small	US8580765 US8334270 US9085573 US7964580 US8633309 US9284342 US8618076 US8575135 US8921341 US8940718	September 21, 2028 September 21, 2028 September 21, 2028 September 26, 2029 September 26, 2029 March 13, 2031 June 11, 2031 May 16, 2033 May 16, 2033 May 16, 2033	Gilead Sciences Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Nucleotide Polymerase Inhibitor / HCV NS5A Replication Complex Inhibitors
67	Lyrica	Pregabalin	Fibromyalgia, Diabetic Nerve Pain, Spinal Cord Injury Nerve Pain, Pain After Shingles, Partial Onset Seizure	Small	US8044227B2	October 10, 2028	pfizer	Dr Reddy's, Sun, Torrent, Intas, Unichem, La Renon, Icon, IPCA	Capsule/Oral Solution	Alpha-2 Delta Ligand
68	Inqovi	Decitabine/Cedazuridine	Myelodysplastic Syndromes (MDS) And Chronic Myelomonocytic Leukemia (CMML)	Small	US9567363 US8268800	October 16, 2028 August 22, 2030	Otsuka Phamaceuticals Co Ltd	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Hypomethylation Agents / Cytidine Deaminase Inhibitors
69	Erivedge	Vismodegib	Basal-Cell Carcinoma	Small	US7888364	November 11, 2028	Genentech Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Hedgehog Pathway Inhibitors
70	Zemdri	Plazomicin	Urinary Tract Infection	Small	US9688711 US8383596	November 21, 2028 June 2, 2031	Cipla USA inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Aminoglycoside Antibiotic
71	Remodulin	Treprostinil	Pulmonary Arterial Hypertension	Small	US9604901 US9593066	December 15, 2028 December 15, 2028	Biochem Pharmaceutical Industries	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous, Subcutaneous	Prostacyclin Vasodilator
72	Vraylar	Cariprazine	Schizophrenia, Bipolar Mania, And Bipolar Depression	Small	US7943621 US7737142	December 16, 2028 September 17, 2029	Allergan	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Oral	Atypical Antipsychotics
73	Procysbi	Cysteamine Bitartrate	Cystinosis	Small	US9925158 US9925157 US9925156	January 26, 2027 January 26, 2027 January 26, 2027	Horizon Therapeutics	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral, Eye Drops	Mercaptoethylamine Compound
74	Ongentys	Opicapone	Parkinson's Disease	Small	US8907099 US8168793 US9630955	May 12, 2027 April 2, 2029 December 12, 2032	Neurocrine Biosciences, Inc	Dr Reddy's, Sun Pharma, Intas Pharma, Reliance Formulation	Oral	Peripheral, Selective, And Reversible Catechol-O-Methyltransferase (Comt) Inhibitor
75	Iclusig	Ponatinib Hydrochloride	Chronic Myeloid Leukemia (CML) And Philadelphia Chromosome-Positive (Ph+), Acute Lymphoblastic Leukemia (ALL).	Small	US8114874 US9493470 US11192897	January 24, 2027 December 12, 2033 December 12, 2033	Takeda Pharmaceutical	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Kinase Inhibitors
76	Ovide	Malathion	Pediculosis	Small	US7560445	February 1, 2027	Taro Pharmaceutical	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Topical	Organophosphate Agent
77	Altabax	Retapamulin	Impetigo	Small	US7875630	February 14, 2027	GlaxoSmithKline	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Topical	Pleuromutilin Antibacterial
78	Stribild	Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil	HIV/AIDS	Small	US7176220 US7635704 US8981103	February 27, 2027 April 26, 2027 April 26, 2027	Gilead Sciences Inc	Cipla, Emcure Pharma, Sun Pharma	Oral	Antivirals
79	Duavee	Conjugated Estrogens/Bazedoxifene	Hot Flashes, Osteoporosis	Small	US7683051	March 10, 2027	Wyeth Pharmaceuticals Llc	Alkem, Bayer Zydus, Abbott, Bharat Serum & Vaccine, Emcure, Mylan, Serum Institute of India, Intas	Oral	Hormones / Selective Estrogen Receptor Modulators (Serms)
80	Zolinza	Vorinostat	Cutaneous T Cell Lymphoma	Small	US7456219	March 11, 2027	Merck & Co	Natco, Dr Reddy's, sun pharma, Cipla, Panacea Biotec, United Bioted, Intas Pharma, SR pharma, Zydus Cadila	Oral	Histone Deacetylase Inhibitors
81	Erleada	Apalutamide	Prostate Cancer	Small	US9388159 US8445507 US9481663	March 27, 2027 September 15, 2030 June 4, 2033	Janssen-Cilag International NV	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Androgen Receptor Inhibitors
82	Varubi	Rolapitant Hydrochloride	Nausea And Vomiting Caused By Chemotherapy	Small	US8178550 US7049320	April 4, 2027 August 19, 2028	Tesaro	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Antiemetics
83	Symdeko	Tezacaftor-Ivacaftor	Cystic Fibrosis	Small	US10239867 US8623905 US7645789 US7776905	April 9, 2027 May 1, 2027 May 1, 2027 June 3, 2027	Vertex Pharmaceutical	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Cystic Fibrosis Transmembrane Conductance Regulator Correctors / Cystic Fibrosis Transmembrane Conductance Regulator Potentiators
84	Synjardy	Empagliflozin/Metformin	Type 2 Diabetes	Small	US7713938 US7579449	April 15, 2027 August 1, 2028	Boehringer Ingelheim/Eli Lilly And Company	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Oral	Enzyme Inhibitor/Biguanide Class
85	Savaysa	Edoxaban Tosylate	Venous Thromboembolism	Small	US7365205	April 18, 2027	DaiiChi Sankyo	Sun Pharma, IPCA, Macleods, Torrents, MSN Laboratories, Intas, Zydus Cadila, Alkem	Oral	Factor Xa Inhibitor
86	Amyvid	Florbetapir (18f)	Alzheimer's Disease	Small	US8506929 US7687052	April 30, 2027 April 30, 2027	Avid Radiopharmaceuticals Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Radiopharmaceutical compound
87	Mekinist	Trametinib Dimethyl Sulfoxide	Melanoma	Small	US7378423	May 29, 2027	Novartis	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Kinase Inhibitor
88	Altavera/Alysena/Amethyst	Ethinylestradiol/Levonorgestrel	Contraception	Small	US7838042	June 1, 2027	Bayer Healthcare Pharmaceuticals Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Oral Contraceptives / Progestins

89	Antizol	Fomepizole	Ethylene Glycol And Methanol Poisoning	Small	US7553863	June 30, 2027	Paladin Labs	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Competitive Inhibitor Of Alcohol Dehydrogenase
90	Vokanamet	Canagliflozin/Metformin Hydrochloride	Type 2 Diabetes	Small	US7943788 US8513202 US7943582	July 14, 2027 December 3, 2027 February 26, 2029	Janssen-Cilag International NV	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Intravenous	Sodium-Glucose Co-Transporter 2 Inhibitors / Biguanide Class
91	Asacol/Lialda/Pentasa	Mesalazine	Ulcerative Colitis And Crohn's Disease	Small	US7645801	July 24, 2027	Tillotts Pharma Ag.	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Oral, Rectal	Aminosalicylates
92	Daklinza	Daclatasvir Hydrochloride	Hepatitis C	Small	US9421192 US8642025 US8329159 US8629171	August 8, 2027 August 11, 2027 July 24, 2029 June 13, 2031	Bristol-Myers Squibb Co	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Direct-Acting Antiviral Agent Against Hepatitis C Virus (HCV)
93	Xtandi	Enzalutamide	Prostate Cancer	Small	US7709517	August 13, 2027	Astellas Pharma Inc.	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Androgen Receptor Inhibitors
94	Azilect	Rasagiline Mesylate	Parkinson's Disease	Small	US7815942	August 27, 2027	Teva Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Monoamine Oxidase Type B Inhibitors
95	Tivicay	Dolutegravir Sodium	HIV/AIDS	Small	US8129385 US9242986 US10426780	October 5, 2027 December 8, 2029 January 24, 2031	Viiv Healthcare	Cipla, Emcure Pharma, Sun Pharma	Oral	HIV Integrase Inhibitors
96	Imcivree	Setmelanotide	Genetic Obesity	Small	US9458195 US8039435	October 13, 2027 October 13, 2027	Rhythm Pharmaceutical	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Subcutaneous	Melanocortin 4 Receptor Agonists
97	Xcopri	Cenobamate	Partial Epilepsies	Small	US7598279	October 30, 2027	SK Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Subcutaneous	Anticonvulsants
98	Pylarify	Piflufolastat F-18	Prostate Cancer Metastasis	Small	US8487129 US9861713 US8778305 US10947197	November 7, 2027 July 31, 2029 September 21, 2030 June 9, 2037	Progenics Pharmaceuticals	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Intravenous	Radioactive Diagnostic Agent
99	Korsuva	Difelikefalin	Itching	Small	US10793596 US10017536 US8536131 US7727963 US7713937 US7402564	November 12, 2027 November 12, 2027 November 12, 2027 November 12, 2027 November 12, 2027 November 12, 2027	Cara Therapeutics	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Kappa Opioid Receptor Agonists
100	Empaveli	Pegcetacoplan	Paroxysmal Nocturnal Hemoglobinuria	Small	US9169307 US7989589 US7888323 US10125171 US10875893 US10035822	November 18, 2027 December 4, 2027 December 4, 2027 August 2, 2033 November 15, 2033 November 15, 2033	Apellis Pharmaceuticals/ Swedish Orphan Biovitrum	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Subcutaneous	Pegylated C3 Inhibitor
101	Tabrecta	Capmatinib Hydrochloride	Non-Small Cell Lung Cancer	Small	US8461330 US7767675 US8420645 US10596178	November 19, 2027 November 19, 2027 June 5, 2031 July 22, 2035	Novartis Pharmaceuticals Corp	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Subcutaneous	Kinase Inhibitors
102	Turalio	Pexidartinib Hydrochloride	Tenosynovial Giant Cell Tumor	Small	US9169250 US8404700 US8722702 US7893075 US10730876 US9802932	November 21, 2027 November 21, 2027 November 21, 2027 October 13, 2028 May 5, 2036 May 5, 2036	DaiiChi Sankyo Company	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Subcutaneous	Kinase Inhibitors
103	Toradol/Biorolac	Ketorolac Tromethamine	Pain	Small	US8008338 US7842714	November 24, 2027 August 15, 2029	Cadila Healthcare Limited	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Oral, Intramuscular, Intravenous, Eye Drops, Nasal Spray	Nonsteroidal Anti-Inflammatory Drug Class
104	Entresto	Sacubitril/Valsartan	Heart Failure	Small	US8877938	November 24, 2027 August 15, 2029	Novartis Pharmaceuticals Corp	Dr Reddy's, Leeford, Glenmark, Intas, Natco, Macleods	Oral	Neprilysin Inhibitors / Angiotensin II Receptor Blocker
105	Xermelo	Telotristat Ethyl	Carcinoid Syndrome Diarrhea	Small	US7709493 US7553840 US8193204	December 11, 2027 December 11, 2027 February 27, 2031	Lexicon Pharmaceuticals	Sun Pharma, Lupin, Mankind, Dr Reddy's, Torrent, Alembic, Cipla, Alkem, Zydus Cadila	Oral	Tryptophan Hydroxylase Inhibitor
106	Jakafi	Ruxolitinib Phosphate	Myelofibrosis	Small	US8415362 US7598257 US8722693	December 24, 2027 December 24, 2027 June 12, 2028	Incyte Corp/Novartis	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral, Topical	Janus Kinase Inhibitor
107	Nexavar	Sorafenib Tosylate	Renal Cell Carcinoma	Small	US8877933	December 24, 2027	Bayer/Onyx Pharmaceuticals	Natco, Bayer Zydus, Cipla, Arechar, Intas, Hetero	Oral, Topical	Kinase Inhibitors
108	Avycaz	Ceftazidime / Avibactam Sodium	Intra-Abdominal Infections, Urinary Tract Infections, And Pneumonia	Small	US7112592 US8471025 US9284314 US9695122 US8969566	January 7, 2026 August 12, 2031 June 15, 2032 June 15, 2032 June 15, 2032	Allergan	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous Infusion	Cephalosporin / Beta-Lactamase Inhibitors

109	Tavalisse	Fostamatinib Sodium	Chronic Immune Thrombocytopenia	Small	US8211889 US7538108 US7989448 US8163902 US7449458	January 19, 2026 March 28, 2026 June 12, 2026 June 17, 2026 September 4, 2026	Rigel Pharmaceuticals	Sun Pharma, IPCA, Macleods, Torrents, MSN Laboratories, Intas, Zydus Cadila, Alkem	Oral	Kinase Inhibitors
110	Bridion	Sugammadex Sodium	Reversal Of Neuromuscular Blockade Induced By Rocuronium	Small	USRE44733	January 27, 2026	Merck & Co	Dr Reddy's, Sun Pharma, Intas Pharma, Reliance Formulation	Intraveous	Selective Relaxant Binding Agent
111	Briviact	Brivaracetam	Partial-Onset Seizures In People 1 Month Of Age And Older	Small	US6911461	February 21, 2026	UCB Group	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral, Intravenous	Anticonvulsant
112	Procoralan	Ivabradine	Symptomatic Management Of Stable Heart-Related Chest Pain And Heart Failure	Small	US7361650 US7361649 US7879842 US7867996	February 22, 2026 February 22, 2026 February 22, 2026 December 12, 2026	Servier	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Oral	Hyperpolarization-Activated Cyclic Nucleotide-Gated (HCN) Channel Blocker
113	Pradaxa	Dabigatran	Blood Clots, Stroke	Small	US7932273	March 7, 2026	Boehringer Ingelheim	Cipla, Emcure, Natco, Intas, La Renon, Cadila, Torrent, Sun pharma	Oral	Direct Thrombin Inhibitors
114	Ozempic	Semaglutide	Type 2 Diabetes	Small	US8536122 US8129343	March 20, 2026 December 5, 2031	Nov Nordisk	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Oral, Subcutaneous	Glucagon-Like Peptide-1 Receptor Agonist
115	Byetta/Bydureon	Exenatide Synthetic	Type 2 Diabetes	Small	US6515117	April 4, 2026	Astrazeneca	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Subcutaneous	Glucagon-Like Peptide-1 Receptor Agonist
116	Rexulti	Brexpiprazole	Schizophrenia, Major Depressive Disorder	Small	US7888362 USRE48059	April 12, 2026 December 23, 2028	Otsuka America Phamaceuticals Co Ltd	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Oral	Atypical Antipsychotics
117	Aveed / Jatenzo	Nebido (Testosterone Undecanoate)	Low Testosterone Levels In Men	Small	US11179402 US10617696	April 14, 2026 April 12, 2030	Endo Pharmaceuticals Inc	Zydus Cadila, Abbott, Sun Pharma, Cipla, Leeford, Intas	Oral, Intramuscular Injection	Androgens, 3-Oxoandrosten (4) Derivative
118	Aptiom	Eslicarbazepine Acetate	Partial-Onset Seizures Epilepsy	Small	US9206135	April 21, 2026	Sumitomo Pharma Co	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Aromatic Anticonvulsant
119	Vocabria	Cabotegravir	HIV/AIDS	Small	US8410103 US10927129	April 28, 2026 April 28, 2026	Viiv Healthcare	Cipla, Emcure Pharma, Sun Pharma	Oral, Intramascular Injection	HIV Integrase Inhibitors
120	Jevtana	Cabazitaxel	Metastatic Castration-Resistant Prostate Cancer	Small	US7241907	June 10, 2026	Sanofi-Aventis	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Intravenous	Taxane And Antineoplastic Agent
121	Voltaren	Diclofenac	Inflammatory Disease Such As Gout	Small	US8097651 US7759394	June 16, 2026 June 16, 2026	GSK	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral, Rectal, Intramuscuar, Intravenous, Topical	Non-Steroidal Anti-Inflammatory Drug
122	Trintellix	Vortioxetine Hydrobromide	Major Depressive Disorder	Small	US7144884 US8722684	June 17, 2026 June 30, 2031	Takeda Pharmcaceuticals	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Oral	Serotonin Modulator
123	Zelboraf	Vemurafenib	Late Stage Melanoma	Small	US8143271 US7504509 US7863288 US8741920	June 21, 2026 October 22, 2026 June 20, 2029 July 27, 2030	Genentech Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Kinase Inhibitor
124	Rhopressa	Netarsudil Mesylate	Glaucoma	Small	US8450344 US9096569 US10174017 US10654844 US8394826 US9931336 US10588901 US9415043	July 11, 2026 July 11, 2026 January 27, 2030 January 27, 2030 November 10, 2030 March 14, 2034 March 14, 2034 March 14, 2034	Aerie Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Eye Drops, Topical	Kinase Inhibitor
125	Gilotrif	Afatinib Dimaleate	Non-Small Cell Lung Cancer	Small	USRE43431 US8426586	July 13, 2026 April 10, 2030	Boehringer Ingelheim	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Tyrosine Kinase Inhibitor
126	Beleodaq	Belinostat	Hematological Malignancies And Solid Tumor	Small	US6888027	August 10, 2026	Acrotech Biopharma	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Intravenous	Histone Deacetylase Inhibitors
127	Cometriq	Cabozantinib S-Malate	Medullary Thyroid Cancer, Renal Cell Carcinoma, And Hepatocellular Carcinoma	Small	US7579473 US11091439 US8877776	August 14, 2026 January 15, 2030 October 8, 2030	Exelixis	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Tyrosine Kinase Inhibitor
128	Isturisa	Osilodrostat Phosphate	Cushing's Disease	Small	US8835646 US8314097 US9434754	August 23, 2026 March 27, 2029 January 13, 2031	Recordati Rare Diseases Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	11beta-Hydroxylase (Cyp11b1) Inhibitor
129	Samsca	Tolvaptan	Hyponatremia	Small	US8501730	September 1, 2026	Otsuka America Phamaceuticals Co Ltd	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Vasopressin V2 Receptor Antagonist
130	Sprycel	Dasatinib	Chronic Myelogenous Leukemia (CML) And Acute Lymphoblastic Leukemia	Small	US7491725	September 28, 2026	Bristol-Myers Squibb Co	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Kinase Inhibitor
131	Aklief	Trifarotene	Acne Vulgaris	Small	US7807708	October 1, 2026	Galderma Laboratories	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Topical	Retinoic Acid Receptor Agonist
132	Symproic	Naldemedine Tosylate	Opioid-Induced Constipation	Small	USRE46375 USRE46365 US9108975 US10952968	October 5, 2026 January 11, 2028 November 11, 2031 May 13, 2033	Shionogi & Co	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Peripherally Acting Mu-Opioid Receptor Antagonist

133	Saphris	Asenapine	Schizophrenia	Small	USRE46375 USRE46365 US9108975 US10952968	October 5, 2026 January 11, 2028 November 11, 2031 May 13, 2033	Merck sharp & Dohme	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Sublingual	Atypical Antipsychotic
134	Uptravi	Selexipag	Pulmonary Arterial Hypertension	Small	US7205302 US8791122	October 31, 2026 August 1, 2030	Actelion Pharmaceuticals	Emcure, Intas, Lupin, Torrent, Mankind, Glenmark, Alembic	Oral, Intravenous	Selective Nonprostanoid IP Prostacyclin Receptor Agonists
135	Bevyxxa	Betrixaban	Venous Thrombosis	Small	US7598276	November 8, 2026	Portola Pharmaceuticals	Sun Pharma, IPCA, Macleods, Torrents, MSN Laboratories, Intas, Zydus Cadila, Alkem	Oral	Direct Factor Xa Inhibitor Anticoagulant
136	Orkambi	Lumacaftor / Ivacaftor	Cystic Fibrosis	Small	US9216969 US10597384 US8507534	November 8, 2026 December 4, 2028 September 20, 2030	Vertex Pharmaceutical	Lupin, Glenmark,	Oral	Cystic Fibrosis Transmembrane Conductance Regulator Corrector / Cystic Fibrosis Transmembrane Conductance Regulator Potentiators
137	Eliquis	Apixaban	Blood Clots	Small	US6967208	November 21, 2026	Bristol-Myers Squibb Co	Cipla, Emcure, Natco, Intas, La Renon, Cadila, Torrent, Sun Pharma, Micro Labs	Oral	Factor Xa Inhibitors
138	Calquence	Acalabrutinib	Non-Hodgkin Lymphoma, Mantle Cell Lymphoma	Small	US7459554 US9290504 US9796721	November 24, 2026 July 11, 2032 July 1, 2036	Astrazeneca	Natco, Dr Reddy's, sun pharma, Cipla, Panacea Biotec, United Bioted, Intas Pharma, SR pharma, Zydus Cadila	Oral	Kinase Inhibitors
139	Sirturo	Bedaquiline	Multi-Drug-Resistant Tuberculosis	Small	US7498343 US8546428	December 1, 2026 March 19, 2029	Janssen Therapeutics	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Anti-Mycobacterials
140	Adempas	Riociguat	Pulmonary Hypertension	Small	US7173037 US10662188 US11203593	December 4, 2026 February 18, 2034 February 18, 2034	Bayer	Emcure, Intas, Lupin, Torrent, Mankind, Glenmark, Alembic	Oral	SGC Stimulators
141	Moxatag	Amoxicillin	Bacterial Infection	Small	US8778924	December 8, 2026	Pragma Pharmaceutical	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral, Intravenous	Penicillin-Like Antibiotics
142	Inrebic	Fedratinib	Myeloproliferative	Small	US7528143 US7825246	December 16, 2026 December 16, 2026	Impact Biomedicines	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Tyrosine Kinase Inhibitor
143	Imbruvica	Ibrutinib	Chronic Lymphocytic Leukemia	Small	US8697711 US9181257 US8957079 US8735403 US7514444 US8008309 US10125140 US9725455 US10106548 US9296753	December 28, 2026 December 28, 2026 December 28, 2026 December 28, 2026 December 28, 2026 November 13, 2027 June 3, 2033 June 3, 2033 June 3, 2033 October 30, 2033	Janssen Biotech	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Kinase Inhibitor
144	Kalydeco	Ivacaftor	Cystic Fibrosis	Small	US8754224 US7495103	December 28, 2026 May 20, 2027	Vertex Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Cystic Fibrosis Transmembrane Conductance Regulator Potentiator
145	Xalkori	Crizotinib	Non-Small Cell Lung Cancer	Small	US8785632 US7230098 US7858643 US8217057	March 01, 2025 August 26, 2025 October 8, 2029 November 6, 2029	Pfizer	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitor
146	Omegaven	Fish Oil Triglycerides	Parenteral Nutrition-Associated Cholestasis	Small	US9566260 US9629821 US10350186	July 11, 2025 July 11, 2025 November 05, 2024	Fresenius Kabi USA LLC	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous; Emusion	Antilipemic Agent
147	Yupelri	Revefenacin	Chronic Obstructive Pulmonary Disease	Small	US7491736 US7521041 US7550595 US7585879 US7910608 US7288657 US10550081 US9765028 US8541451	March 10, 2025 March 10, 2025 March 10, 2025 March 10, 2025 March 10, 2025 December 23, 2025 July 14, 2030 July 14, 2030 August 25, 2031	Mylan Ireland Ltd	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Solution; Inhalation	Anticholinergics
148	Sprycel	Dasatinib	Chronic Myeloid Leukemia (CML), Acute Lymphoblastic Leukemia (ALL)	Small	US8680103	February 04, 2025	Bristol-Myers Squibb Co	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Kinase Inhibitor
149	Bosulif	Bosutinib Monohydrate	Chronic Phase Philadelphia Chromosome-Positive Chronic Myelogenous Leukemia	Small	US7417148 US7767678 US7919625	December 11, 2025 November 23, 2026 December 11, 2025	PF Prism CV	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Tyrosine Kinase Inhibitor
150	Cresemba	Isavuconazonium Sulfate	Invasive Aspergillosis And Mucormycosis	Small	US6812238	October 31, 2025	Astellas Pharma US Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Azole Antifungal
151	Antara	Fenofibrate	High Cholesterol And Triglycerides (Fatty Acids) In Blood	Small	US8026281	April 22, 2025	Lupin Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Antilipemic Agent

152	Lysteda	Tranexamic Acid	Cyclic Heavy Menstrual Bleeding	Small	US7947739 US8022106 US8273795 US8487005 US8791160 US8809394 US8957113 US9060939	March 04, 2025 March 04, 2025 March 04, 2025 March 04, 2025 March 04, 2025 March 04, 2025 March 04, 2025 March 04, 2025	Amring Pharmaceuticals Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Antifibrinolytic
153	Bepreve	Bepotastine Besilate	Itching Of The Eyes Due To Allergies	Small	US8784789 US8877168	January 13, 2025 July 30, 2023	Bausch And Lomb Inc	Sun Pharma, Cipla, Lupin, Intas	Eye Drops	Histamine 1 (H1) Receptor Agonist
154	Sancuso	Granisetron	Nausea And Vomiting Caused By Chemotherapy	Small	US7608282	January 22, 2025	Kyowa Kirin Inc	Dr Reddy's, Glenmark, Torrent, Alkem	Transdermal	5-HT3 Receptor Antagonist
155	Nucynta	Tapentadol Hydrochloride	Moderate To Severe Pain	Small	US7994364	June 27, 2025	Collegium Pharmaceuticals	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Oral	Opiate (Narcotic) Analgesic
156	Nexlizet	Bempedoic Acid, Ezetimibe	Reduce The Amount Of Cholesterol And Other Fatty Substances In Blood	Small	US7335799	December 03, 2025	Esperion Therapeutics Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Adenosine Triphosphate-Citrate Lyase Inhibitor / Selective Cholesterol-Absorption Inhibitor
157	Vyzulta	Latanoprostene Bunod	Intraocular Pressure In Patients With Open-Angle Glaucoma Or Ocular Hypertension	Small	US8058467 US7910767 US7273946	January 5, 2025 January 5, 2025 October 3, 2025	Bausch And Lomb Inc	Emcure, Intas, Lupin, Torrent, Mankind, Glenmark, Alembic	Eye Drops	Prostaglandin Analog
158	Trilipix	Fenofibrate	Abnormal Blood Lipid Levels	Small	US7259186	January 7, 2025	Abbvie Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Antilipemic Agent
159	Duaklir	Aclidinium Bromide/Formoterol	Chronic Obstructive Pulmonary Disease	Small	USRE46417	February 10, 2025	Almirall, SA	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Inhalation	Bronchodilators / Long-Acting Beta Agonist
160	Arcapta	Indacaterol	Chronic Obstructive Pulmonary Disease	Small	US6878721	February 25, 2025	Novartis Pharmaceuticals Corp	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Inhalation	Long-Acting Beta Agonists
161	Rukobia	Fostemsavir	HIV/AIDS	Small	US8461333 US7745625	February 25, 2025 November 19, 2027	Viiv Healthcare	Cipla, Emcure Pharma, Sun Pharma	Oral	HIV Attachment Inhibitor
162	Incivek	Telaprevir	Hepatitis C	Small	US7820671	February 25, 2025	Johnson & Johnson	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Direct-Acting Antiviral
163	Viberzi	Eluxadoline	Diarrhea And Abnormal Pain	Small	US10213415 US8609709 US7786158 US9115091 US8691860 US7741356	March 14, 2025 March 14, 2025 March 14, 2025 July 7, 2028 July 7, 2028 May 27, 2029	Allergan	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Oral	Mu-Opioid Receptor Agonist
164	Glucophage	Metformin	Type 2 Diabetes	Small	US7780987	March 23, 2025	Merck & Co	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Oral	Biguanide
165	Roxicodone	Oxycodone	Moderate To Severe Pain	Small	US10696684 US10407434 US9522919 US9073933	March 30, 2025 March 30, 2025 March 30, 2025 March 30, 2025	Xanodyne Pharmaceuticals	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Oral, Sublingual, Intramuscular, Intravenous, Intranasal, Subcutaneous, Transdermal, Rectal, Epidural	Opiate (Narcotic) Analgesic
166	Tegsedi	Inotersen	Nerve Damage In Adults With Hereditary Transthyretin-Mediated Amyloidosis	Small	US8101743 US9061044	April 1, 2025 April 29, 2031	Akcea Therapeutics, Inc.	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Subcutaneous	Transthyretin-Directed Antisense Oligonucleotide
167	Reyvow	Lasmiditan	Migraine With Or Without Aura	Small	US7423050 US11053214	April 6, 2025 December 5, 2037	Eli Lily and Co	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral, Intravenous	Selective Serotonin Receptor Agonist
168	Humira	Adalimumab	Arthritis, Plaque Psoriasis, Hidradenitis Suppurativa, Crohn's Disease, Ankylosing Spondylitis, Ulcerative Colitis, Non-Infectious Uveitis	Large	US6090382A US9187559B2 US8969024B2 US9315574B2 US9273132B2 US9085618B2 US9284371B2/ US8663945B2	December 31, 2016 April 11, 2025 May 10, 2032 November 12, 2033 April 04, 2027 March 14, 2033 September 13, 2027	AbbVie	Intas, Cipla, Reliance , Lupin	Injection	Tumor Necrosis Factor Blockers
169	Kyprolis	Carfilzomib	Relapsed Or Refractory Multiple Myeloma	Small	US8207125 US7232818 US8207297 US7417042	April 14, 2025 April 14, 2025 April 14, 2025 July 20, 2026	Amgen	Natco, Dr Reddy, Sun Pharma, Cipla, Panacea Biotec, United Biotech, Intas Pharma, SR Pharma, Zydus Cadila	Intravenous	Proteasome Inhibitor
170	Biktarvy	Bictegravir/Emtricitabine/ Tenofovir Alafenamide	HIV/AIDS	Small	US7390791 US9296769 US8754065 US9216996 US9732092 US9708342	April 17, 2025 August 15, 2032 August 15, 2032 December 19, 2033 December 19, 2033 June 19, 2035	Gilead Sciences Inc	Cipla, Emcure Pharma, Sun Pharma	Oral	Nucleoside Reverse Transcriptase Inhibitors
171	Stendra	Avanafil	Erectile Dysfunction	Small	US6656935	April 27, 2025	Vivus Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Phosphodiesterase Inhibitor

172	Inlyta	Axitinib	Renal Cell Carcinoma	Small	US6534524 US8791140	April 29, 2025 December 14, 2030	Pfizer	Natco, Bayer Zydus, Cipla, Arechar, Intas, Hetero	Oral	Kinase Inhibitor
173	Camptosar	Irinotecan	Colon Cancer And Small Cell Lung Cancer	Small	US9782349 US9724303 US8992970 US10722508 US8329213 US8147867	May 2, 2025 May 2, 2025 May 2, 2025 May 2, 2025 January 6, 2027 August 29, 2028	Pfizer	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Intravenous	DNA Topoisomerase I Inhibitor
174	Jentadueto	Linagliptin/Metformin Hydrochloride	High Blood Sugar Levels Caused By Type 2 Diabetes	Small	US7407955	May 2, 2025	Boehringer Ingelheim	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Oral	Dipeptidyl Peptidase-4 Inhibitor / Biguanides
175	Pexeva	Paroxetine Mesylate	Symptoms Of Menopause	Small	US7598271 US8946251 US8658663	May 4, 2025 August 4, 2026 April 6, 2029	Sabela Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Selective Serotonin Reuptake Inhibitor
176	Doptelet	Avatrombopag	Thrombocytopenia Associated With Chronic Liver Disease	Small	US7638536	May 5, 2025	AkaRx Inc	Sun Pharma, IPCA, Macleods, Torrents, MSN Laboratories, Intas, Zydus Cadila, Alkem	Oral	Thrombopoietin Receptor Agonist
177	Lymphoseek	Technetium Tc 99m Tilmanocept	Identify Sentinel Lymph Nodes	Small	US6409990 US9439985	May 12, 2025 September 27, 2033	Navidea Biopharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Subcutaneous	Radiologic Conjugating Agent
178	Olysio	Simeprevir	Hepatitis C	Small	US7671032 US8349869 US8754106 US8741926 US9040562 US9856265 US8148399	May 19, 2025 July 28, 2026 July 28, 2026 July 28, 2026 July 28, 2026 July 28, 2026 September 5, 2029	Johnson & Johnson	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Serine Protease Inhibitor
179	Edarbi	Azilsartan	Hypertension	Small	US7157584	May 22, 2025	Takeda Pharmaceutical	Emcure, Intas, Lupin, Torrent, Mankind, Glenmark, Alembic	Oral	Angiotensin-Receptor Blocking
180	Onpattro	Patisiran	Polyneuropathy In People With Hereditary Transthyretin-Mediated Amyloidosis	Small	US8334373 US8168775 US10240152 US11079379	May 27, 2025 October 20, 2029 October 20, 2029 August 27, 2035	Alnylam Pharmaceutical	Dr Reddy's, Sun Pharma, Intas Pharma, Reliance Formulation	Intravenous	RNA Interference Therapeutic Class
181	Diprivan	Propofol	Used To Help Patients Relax Before And During General Anesthesia For Surgery	Small	US8476010	June 1, 2025	Fresenius Kabi USA LLC	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Non-Barbiturate Sedative
182	Kazano	Alogliptin/Metformin	Blood Sugar Control In Adults With Type 2 Diabetes	Small	US8288539 US7807689	June 24, 2025 June 27, 2028	Takeda Pharmaceutical	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Oral	Selective Dpp-4 Inhibitor / Biguanide
183	Amondys 45	Casimersen	Duchenne Muscular Dystrophy (DMD)	Small	US9447415 US8524880 US10287586 US9228187	June 28, 2025 April 2, 2026 November 12, 2030 November 12, 2030	Sarepta Therapeutics.	Macleods, Zuventus,, Mankind, Alkem, Aristo, Lupin, IPCA	Intravenous	Antisense Oligonucleotide Of The Phosphorodiamidate Morpholino Oligomer Subclass
184	Exondys 51	Eteplirsen	Duchenne Muscular Dystrophy (DMD)	Small	US10781451 US9018368 US9243245	June 28, 2025 June 28, 2025 October 27, 2028	Sarepta Therapeutics.	Macleods, Zuventus,, Mankind, Alkem, Aristo, Lupin, IPCA	Intravenous	Synthetic Antisense Oligonucleotide And A Phosphorodiamidate Morpholino Oligomer
185	Vyondys 53	Golodirsen	Duchenne Muscular Dystrophy (DMD)	Small	US10227590 US9994851 US9024007 US10968450 US10421966	June 28, 2025 June 28, 2025 June 28, 2025 June 28, 2025 June 28, 2025	Sarepta Therapeutics.	Macleods, Zuventus,, Mankind, Alkem, Aristo, Lupin, IPCA	Intravenous	Synthetic Rna Antisense Oligonucleotide
186	Vyleesi	Bremelanotide	Low Sexual Desire In Women	Small	US6794489	June 28, 2025	Palatin Technologies	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Subcutaneous	Melanocortin Receptor Agonists
187	Zydelig	Idelalisib	Blood Cancer	Small	USRE44638 US8865730 US10730879 US9469643	August 5, 2025 March 5, 2033 March 5, 2033 September 2, 2033	Gilead Sciences Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Phosphoinositide 3-Kinase Inhibitor
188	Duzallo	Lesinurad/Allopurinol	Gout	Small	US8003681 US8546436	August 25, 2025 February 29, 2032	Astrazeneca	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Triazoles / Xanthine Oxidase Inhibitor
189	Prolensa	Bromfenac	Ocular Inflammation And Pain After Cataract Surgery	Small	US8129431	September 11, 2025	Bausch And Lomb Inc	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Eyedrops	Nonsteroidal Anti-Inflammatory Drugs
190	Nuplazid	Pimavanserin	Parkinson's Disease Psycosis	Small	US7923564 US7732615 US7601740	September 26, 2025 June 3, 2028 April 29, 2030	Acadia Pharmaceuticals	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Oral	Atypical Antipsychotic
191	Baxdela	Delafloxacin	Acute Bacterial Skin And Skin Structure Infections	Small	US9539250 US8273892 US7728143 US8871938 USRE46617	October 7, 2025 August 6, 2026 November 20, 2027 September 23, 2029 December 28, 2029	Melinta Therapeutics	Cipla, Mylan, Zydus Cadila, Alkem, United Biotech	Oral, Intravenous	Fourth Generation Fluoroquinolone

192	Lenvima	Lenvatinib	Thyroid Cancer	Small	US7253286 US7612208 US11186547 US10407393 US10259791	October 24, 2025 September 19, 2026 August 26, 2035 August 26, 2035 August 26, 2035	Eisai Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitor
193	Cresemba	Isavuconazole	Aspergillosis And Mucormycosis	Small	US6812238	October 31, 2025	Astellas Pharma	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral, Intravenous	Triazole
194	Lybalvi	Olanzapine/Samidorphan	Schizophrenia And Bipolar Disorder	Small	US7262298 US9119848	November 23, 2025 August 30, 2031	Alkermes, Inc	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Oral	Second-Generation (Atypical) Antipsychotic / Opioid Antagonist
195	Opsumit	Macitentan	Pulmonary Arterial Hypertension	Small	US7094781	December 5, 2025	Actelion Pharmaceuticals	Emcure, Intas, Lupin, Torrent, Mankind, Glenmark, Alembic	Oral	Endothelin Receptor Antagonist
196	Latuda	Lurasidone	Schizophrenia And Bipolar Disorder	Small	USRE45573	December 23, 2025	Sunovion Pharmaceuticals	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Oral	Atypical Antipsychotic
197	Klisyri	Tirbanibulin	Actinic Keratosis	Small	US8980890 US8236799 US7300931 US7851470 US10669236	December 28, 2025 December 28, 2025 February 6, 2026 February 2, 2029 September 7, 2038	Almirall, SA	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Topical	Microtubule Inhibitor
198	Signifor	Pasireotide	Cushing’s Disease	Small	US8299209 US7473761	December 27, 2025 December 14, 2026	Recordati Rare Diseases Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Subcutaneous Injection, Intramuscular Injection	Somatostatin Agonist
199	Mulpleta	Lusutrombopag	Thrombocytopenia	Small	US7601746 US8889722 US8530668	September 05, 2024 July 29, 2028 January 21, 2030	Shionogi & Co	Sun Pharma, IPCA, Macleods, Torrents, MSN Laboratories, Intas, Zydus Cadila, Alkem	Oral	Thrombopoietin Receptor Agonist
200	Invokamet XR	Canagliflozin; Metformin Hydrochloride	Type 2 Diabetes	Small	US8785403 US8222219	July 30, 2024 March 11, 2025	Janssen Pharmaceuticals	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy’s, Medipol, Zydus, Aristo and Quest Pharma	Tablet, Extended Release; Oral	Sodium-Glucose Co-Transporter 2 Inhibitor / Biguanide Class
201	Revlimid	Lenalidomide	Multiple Myeloma And Myelodysplastic Syndromes	Small	US7855217 US7465800	November 24, 2024 April 27, 2027	Celgene Corp	Natco, Dr Reddy, Sun Pharma, Cipla, Panacea Biotec, United Biotech, Intas Pharma, SR Pharma, Zydus Cadila	Oral	Immunomodulatory Drugs
202	Rydapt	Midostaurin	Acute Myeloid Leukemia	Small	US7973031 US8222244	October 17, 2024 October 29, 2022	Novartis Pharmaceuticals Corp	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral; Capsule	Kinase Inhibitor
203	Prevymis	Letermovir	Cytomegalovirus (CMV) Infection	Small	US7196086 US8513255	May 22, 2024 May 22, 2024	Merck sharp & Dohme	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Solution; Intravenous	Antivirals
204	Vyndaqel	Tafamidis Meglumine	Transthyretin Amyloid Polyneuropathy	Small	US7214695 US7214696 US8168663 US8653119	April 27, 2024 December 19, 2023 December 19, 2023 January 28, 2024	Foldrx Pharmaceuticals Inc Sub Pfizer Inc	Dr Reddy's, Sun Pharma, Intas Pharma, Reliance Formulation	Capsule; Oral	Transthyretin Stabilizer
205	Lynparza	Olaparib	Advanced Ovarian Cancer, Fallopian Tube Cancer	Small	US7151102 US7449464 US7981889 US8912187	April 29, 2022 October 11, 2024 October 11, 2024 March 12, 2024	Astrazeneca	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Capsule; Oral	Polyadenosine 5'-Diphosphoribose Polymerase (PARP) Enzyme Inhibitor
206	Tasigna	Nilotinib	Chronic Myelogenous Leukemia (CML) And Acute Lymphoblastic Leukemia	Small	US7169791 US8415363 US8163904 US9061029	January 04, 2024 January 18, 2027 February 23, 2029 October 7, 2032	Novartis Pharmaceuticals Corp	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Capsule; Oral	Kinase Inhibitor
207	Xopenex HFA	Levalbuterol Tartrate	Chronic Obstructive Pulmonary Disease And Asthma	Small	US7256310	October 08, 2024	Sunovion Pharmaceuticals	IPCA, Sun Pharma, Intas, Taj Pharma	Aerosol, Metered; Inhalation	Beta Agonist
208	Vandazole	Metronidazole	Bacterial Vaginosis	Small	US7456207	September 22, 2024	Teva Pharmaceuticals	Abbott, Cadila	Gel; Vaginal	Nitroimidazole Antimicrobial
209	Prialt	Ziconotide Acetate	Pain Reliever	Small	US8653033 US8765680 US9707270	October 10, 2024 October 10, 2024 October 10, 2024	TerSera Therapeutics	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Injectable; Intrathecal	Selective N-Type Voltage-Gated Calcium Channel Blocker
210	Aloxi	Palonosetron Hydrochloride	Acute Nausea And Vomiting	Small	US7947724 US7947725 US7960424 US8518981 US8598218 US9173942 US9439854 US9457020	January 30, 2024 January 30, 2024 January 30, 2024 January 30, 2024 January 30, 2024 January 30, 2024 January 30, 2024 January 30, 2024	Helsinn Healthcare Sa	Dr Reddy's, Glenmark, Torrent, Alkem	Intravenous	5-Ht3 Receptor Antagonist
211	Dificid	Fidaxomicin	Clostridioides Difficile-Associated Diarrhea (CDAD)	Small	US8586551 US7378508 US7863249	January 23, 2024 January 31, 2028 January 31, 2028	Merck sharp & Dohme	Sun Pharma, Lupin, Mankind, Dr Reddy's, Torrent, Alembic, Cipla, Alkem, Zydus Cadila	Oral	Macrolide Antibiotics

212	Linzess	Linaclotide	Irritable Bowel Syndrome	Small	US7371727 US7745409 US8080526 US7704947 US7304036	January 28, 2024 January 28, 2024 January 28, 2024 January 28, 2024 August 30, 2026	Allergan	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Guanylate Cyclase-C Receptor Agonist
213	Myfembree	Relugolix/Estradiol/Norethisterone Acetate	Heavy Mentrual Bleeding	Small	US7300935 US8058280	January 28, 2024 January 28, 2024	Myovant Sciences	Bayer Zydus, Abbott, Bharat Serum & Vaccine, Emcure, Mylan, Serum Institute of India, Intas	Oral	Gonadotropin-Releasing Hormone Receptor Antagonist / Estrogenic Steroid / Second-Generation Progestin
214	Auryxia	Ferric Citrate	Hyperphosphataemia And Iron Deficiency Anaemia	Small	US9328133 US9757416 US8338642 US7767851	February 18, 2024 February 18, 2024 February 18, 2024 February 18, 2024	Akebia Therapeutics	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Phosphate Binder
215	Isentress	Raltegravir	HIV/AIDS	Small	US7119093 US6762180	February 21, 2024 October 1, 2025	Merck sharp & Dohme	Cipla, Emcure Pharma, Sun Pharma	Oral	HIV Integrase Inhibitor
216	Zontivity	Vorapaxar	Peripheral Arterial Disease	Small	US7304078 US7713999	April 6, 2024 May 30, 2024	Merck sharp & Dohme	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Protease-Activated Receptor-1 Antagonist
217	Bosulif	Bosutinib	Chronic Myelogenous Leukemia	Small	USRE42376 US7767678	April 13, 2024 November 23, 2026	Pfizer	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Kinase Inhibitor
218	Omontys	Peginesatide	Anemia	Small	US7084245 US7414105 US7919118 US7528104	May 12, 2024 May 12, 2024 May 12, 2024 May 12, 2024	Affymax Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Subcutaneous, Intravenous	Erythropoietin
219	Aliqopa	Copanlisib	Relapsed Follicular Lymphoma	Small	US7511041 USRE46856 US10383876	May 13, 2024 October 22, 2029 March 29, 2032	Bayer	Natco, Dr Reddy's, sun pharma, Cipla, Panacea Biotec, United Bioted, Intas Pharma, SR pharma, Zydus Cadila	Intravenous	Kinase Inhibitor
220	Mayzent	Siponimod	Multiple Sclerosis	Small	US7939519	May 19, 2024	Novartis Pharmaceuticals Corp	Sun Pharma, Alkem, Micro Labs, Abbott, Intas, Lupin, Torrent, IPCA	Oral	Sphingosine L-Phosphate Receptor Modulator
221	Prevymis	Letermovir	Cytomegalovirus (CMV) Infection	Small	US8513255 USRE46791	May 22, 2024 May 22, 2024	Merck & Co	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral, Intravenous	Antivirals
222	Xifaxan	Rifaximin	Traveler's Diarrhea, Irritable Bowel Syndrome, Hepatic Encephalopathy	Small	US7612199 US8835452 US8158781 US7045620 US7902206 US7906542 US8741904 US8193196	June 19, 2024 June 19, 2024 June 19, 2024 June 19, 2024 June 19, 2024 June 1, 2025 February 27, 2026 September 2, 2027	Salix Pharmaceuticals Inc	Sun Pharma, Lupin, Mankind, Dr Reddy's, Torrent, Alembic, Cipla, Alkem, Zydus Cadila	Oral	Antibiotics
223	Remodulin/Orenitram/Tyvaso	Treprostinil	Pulmonary Arterial Hypertension	Small	US9050311 US7417070 US8497393	May 24, 2024 July 30, 2026 December 15, 2028	United Therapeutics	Emcure, Intas, Lupin, Torrent, Mankind, Glenmark, Alembic	Subcutaneous, Intravenous, Inhalation, Oral	Vasodilators And Platelet-Aggregation Inhibitor
224	Tpoxx	Tecovirimat	Orthopoxviruses (Smallpox And Monkeypox)	Small	US8124643 US9339466	June 18, 2024 March 23, 2031	SIGA technologies	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Orthopoxvirus Vp37 Envelope Wrapping Protein Inhibitor
225	Nuvigil	Armodafinil	Excessive Daytime Sleepiness	Small	US7132570	June 18, 2024	Teva Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Wakefulness-Promoting Agent
226	Oriahnn	Elagolix/Estradiol/Norethindrone Acetate	Heavy Mentrual Bleeding	Small	US7419983 US7056927	July 6, 2024 September 10, 2024	Abbvie Inc	Bayer Zydus, Abbott, Bharat Serum & Vaccine, Emcure, Mylan, Serum Institute of India, Intas	Oral	Gonadotropin-Releasing Hormone Receptor Antagonist / Estrogenic Steroid / Second-Generation Progestin
227	Xeglyze	Abametapir	Head Lice Infestation	Small	US9839631	July 16, 2024	Dr Reddy's Laboratories	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Topical	Novel Pediculicidal Metalloproteinase Inhibitor
228	Ninlaro	Ixazomib	Multiple Myeloma	Small	US8546608 US8003819 US8530694 US7687662 US8859504 US7442830	August 12, 2024 August 6, 2027 August 6, 2027 August 6, 2027 June 16, 2029 November 20, 2029	Takeda	Natco, Dr Reddy, Sun Pharma, Cipla, Panacea Biotec, United Biotech, Intas Pharma, SR Pharma, Zydus Cadila	Oral	Proteasome Inhibitor
229	Prezista	Darunavir	HIV/AIDS	Small	US8518987 US7700645	August 16, 2024 June 26, 2027	Janssen Therapeutics	Cipla, Emcure Pharma, Sun Pharma	Oral	Proteasome Inhibitor
230	Xarelto	Rivaroxaban	Blood Clots	Small	US7157456	August 28, 2024	Janssen Therapeutics	Dr Reddy's , Zydus Cadila, Cheminnova Lifesciences, Alniche Life Sciences, Cadila, Macleods	Oral	Factor Xa Inhibitors
231	MoviPrep	POLYETHYLENE GLYCOL 3350	Use For Colonoscopy Bowel Preparation	Small	US7169381 US7658914	September 1, 2024 September 1, 2024	Velinor AG	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Osmotic Laxative
232	Aldara	Imiquimod	Genital Warts, Superficial Basal Cell Carcinoma, And Actinic Keratosis	Small	US7696159	October 1, 2024	3M Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Topical	Immune Response Modifier
233	Brilinta	Ticagrelor	Stroke, Heart Attack	Small	USRE46276	October 30, 2024	Astrazeneca	Cipla, Emcure, Natco, Intas, La Renon, Cadila, Torrent, Sun pharma	Oral	Platelet Activation And Aggregation Inhibitor

234	Xiidra	Lifitegrast	Signs And Symptoms Of Dry Eyes	Small	US7745460 US7928122 US7314938 US8084047 US9890141	November 5, 2024 November 5, 2024 March 10, 2025 May 17, 2026 October 21, 2030	Novartis Pharmaceuticals Corp	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Eye Drops	Lymphocyte Function-Associated Antigen-1 Antagonist
235	Nourianz	Istradefylline	Levodopa/Carbidopa In Adults With Parkinson's Disease	Small	US7541363	November 13, 2024	Kyowa Kirin Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Adenosine Receptor Antagonist
236	Ponvory	Ponesimod	Multiple Sclerosis	Small	USRE43728 US9062014	November 16, 2024 May 6, 2032	Janssen Pharmaceuticals	Sun Pharma, Alkem, Micro Labs, Abbott, Intas, Lupin, Torrent, IPCA	Oral	Sphingosine L-Phosphate Receptor Modulator
237	Tukysa	Tucatinib	HER2-Positive Breast Cancer	Small	US7452895 US8648087	November 16, 2024 April 12, 2031	Seagen Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitor
238	Asclera/Aethoxysklerol/Varithena	Polidocanol	Itching Caused By Eczema And Dry Skin	Small	US7731986	November 17, 2024	Methapharm Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Topical, Subcutaneous Injection	Sclerosing Agent
239	Zepzelca	Lurbinectedin	Metastatic Small Cell Lung Cancer	Small	US7763615	December 13, 2024	PharmaMar, S.A.	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Intravenous Injection	Alkylating Agent
240	Victrelis	Boceprevir	Hepatitis C -Genotype 1	Small	USRE43298	December 22, 2024	Merck & Co	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Protease Inhibitor
241	Entresto	Sacubitril; Valsartan	Chronic Heart Failure	Small	US8404744 US8796331 US7468390 US8101659	July 14, 2023 July 14, 2023 November 27, 2023 January 15, 2025	Novartis Pharmaceuticals Corp	Dr Reddy's, Leeford, Alkem, Glenmark, Intas, Natco, Macleods	Oral	Neprilysin Inhibitor / Angiotensin II Receptor Blocker
242	Spinraza	Nusinersen Sodiumz	Spinal Muscular Atrophy	Small	US7101993 US8110560 US7838657 US8361977	September 05, 2023 December 05, 2025 July 11, 2027 May 27, 2030	Biogen Idec Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intrathecal	Antisense Oligonucleotide Inhibitor
243	Tegsedi	Inotersen Sodium	Polyneuropathy	Small	US7015315 US7101993	March 21, 2023 September 05, 2023	Akcea Therapeutics, Inc.	Dr Reddy's, Sun Pharma, Intas Pharma, Reliance Formulation	Subcutaneous	Ransthyretin-Directed Antisense Oligonucleotide
244	Dalvance	Dalbavancin Hydrochloride	To Treat Severe Skin Infection	Small	US6900175 US7115564 US7119061 US8143212	December 25, 2023 November 14, 2023 November 14, 2023 November 14, 2023	Allergan Sales LLC	Cipla, Mylan, Zydus Cadila, Alkem, United Biotech	Intravenous; Powder	Lipoglycopeptide Antibiotic
245	Zykadia	Ceritinib	Lung Cancer	Small	US9416112 US8188276 US9018204 US8835430 US7893074 US9018204 US7964592 US8039479 US9309229	January 31, 2023 January 31, 2023 January 31, 2023 January 31, 2023 April 25, 2026 November 20, 2027 April 29, 2028 June 29, 2030 January 18, 2032	Novartis Pharmaceuticals Corp	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors
246	Promacta	Eltrombopag Olamine	Thrombocytopenia	Small	US7160870 US7547719	May 20, 2023 January 13, 2026	Novartis Pharmaceuticals Corp	Sun Pharma, IPCA, Macleods, Torrents, MSN Laboratories, Intas, Zydus Cadila, Alkem	Oral	Thrombopoietin Receptor Agonist
247	Rubraca	Rucaparib Camsylate	BRAC-Mutated Ovarian Cancer	Small	US6495541 US9045487 US8754072	November 22, 2023 February 10, 2031 February 10, 2031	Clovis Oncology Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Anticancer Drug And Poly (ADP-Ribose) Polymerase (PARP) Inhibitor
248	Mektovi	Binimetinib	Unresectable Or Metastatic Melanoma With A BRAF V600 Mutation	Small	US7777050 US8178693 US8193229 US8513293 US9562016	March 13, 2023 March 13, 2023 March 13, 2023 March 13, 2023 October 18, 2033	Array Biopharma	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Kinase Inhibitors
249	Zosyn	Piperacillin Sodium, Tazobactam Sodium	Bacterial Infection	Small	US6900184 US7915229 US8133883	April 14, 2023 April 14, 2023 April 14, 2023	Wyeth Pharmaceuticals LLC	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Injection	Penicillins And Beta-Lactamase Inhibitor
250	Boniva	Ibandronate Sodium	Osteoporosis	Small	US7192938 US7410957 US7718634	May 06, 2023 May 06, 2023 May 06, 2023	Hoffmann La Roche Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Injection	Bisphosphonates
251	Votrient	Pazopanib Hydrochloride	Soft Tissue Sarcomas And Advanced Renal Cell Carcinoma	Small	US7105530	October 19, 2023	Novartis Pharmaceuticals Corp	Natco, Bayer Zydus, Cipla, Arechar, Intas, Hetero	Oral	Kinase Inhibitors
252	Tyzeka	Telbivudine	Chronic Hepatitis B	Small	US7858594 US7589079	September 11, 2023 September 11, 2023	Novartis Pharmaceuticals Corp	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral; Solution	Nucleoside Analogue
253	Exforge	Amlodipine Besylate; Hydrochlorothiazide; Valsartan	Hypertension	Small	US8101599 US8475839	May 16, 2023 May 16, 2023	Novartis Pharmaceuticals Corp	Emcure, Intas, Lupin, Torrent, Mankind, Glenmark, Alembic	Oral	Calcium Channel Blocker / Hiazide Diuretic /Angiotensin II Receptor Blocker

254	Ozurdex	Dexamethasone	Macular Edema Following Branch Retinal Vein Occlusion (BRVO) Or Central Retinal Vein Occlusion (CRVO)	Small	US8034366 US8034370 US9192511 US10076526 US6899717 US8506987 US10702539	January 09, 2023 January 09, 2023 January 09, 2023 January 09, 2023 November 01, 2023 January 09, 2023 January 09, 2023	Allergan	Sun Pharmaceuticals, Intas Pharmaceuticals, Zydus Cadila	Implant; Intravitreal	Corticosteroid
255	Feraheme	Ferumoxytol	Iron Deficiency Anemia	Small	US6599498	June 30, 2023	Amag Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Iron Replacement Product
256	Patanase	Olopatadine Hydrochloride	Congestion, Sneezing, And Runny Nose Caused By Seasonal Allergies	Small	US7977376 US8399508	February 02, 2023 September 17, 2022	Novartis Pharmaceuticals Corp	Sun Pharma, Cipla, Lupin, Intas	Spray, Metered; Nasal	Mast Cell Stabilizer
257	Mozobil	Plerixafor	Non-Hodgkin's Lymphoma Or Multiple Myeloma	Small	US6987102 US7897590	July 22, 2023 July 22, 2023	Genzyme Corp	Natco, Dr Reddy, Sun Pharma, Cipla, Panacea Biotec, United Biotech, Intas Pharma, SR Pharma, Zydus Cadila	Subcutanous Injection	Hematopoeitic Stem Cell Mobilizer
258	Oraverse	Phentolamine Mesylate	Used For Reversal Of The Soft-Tissue Anesthesia	Small	US7229630 US7569230	June 20, 2023 October 17, 2023	Septodont Holding SAS	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Injection	Nonselective Alpha-Adrenergic Antagonist
259	Ryzolt	Tramadol Hydrochloride	Severe Pain	Small	US7988998	October 27, 2023	Purdue Pharma Products LP	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Tablet, Extended Release; Oral	Opiate (Narcotic) Analgesic
260	Toviaz	Fesoterodine	Overactive Bladder Syndrome	Small	US6858650	January 3, 2023	Pfizer	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Antimuscarinics
261	Ibrance	Palbociclib	HR-Positive And HER2-Negative Breast Cancer	Small	US6936612 US7208489 USRE47739 US10723730	January 16, 2023 January 16, 2023 March 5, 2027 February 8, 2034	pfizer	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	CDK 4/6 Inhibitors
262	Vizamyl	Flutemetamol	Used As A Diagnostic Tool For Alzheimer's Disease	Small	US7351401 US8236282 US7270800	January 24, 2023 May 21, 2024 September 3, 2025	GE Healthcare	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Radioactive Diagnostic Agent
263	Janumet	Sitagliptin/Metformin	Type 2 Diabetes	Small	US6699871 US7326708	January 26, 2023 May 24, 2027	Merck & Co	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Oral	Dipeptidyl Peptidase-4 (Dpp-4) Inhibitor / Biguanide
264	Lexapro	Escitalopram	Major Depressive Disorder Or Generalized Anxiety Disorder	Small	US6916941	February 12, 2023	Lundbeck	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Oral	Selective Serotonin Reuptake Inhibitors
265	Victoza	Liraglutide	Type 2 Diabetes, Obesity, And Chronic Weight Management	Large	US6268343 US8114833	February 22, 2023 February 13, 2026	Novo Nordisk	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Subcutaneous	Incretin Mimetics
266	Fosamax	Alendronic Acid	Osteoporosis And Paget's Disease Of Bone	Small	US7964212 US7488496	March 6, 2023 August 11, 2023	Merck & Co	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Bisphosphonates
267	Koselugo	Selumetinib	Neurofibromatosis Type I (NF-1)	Small	US8178693 US7425637 US9562017 US9156795	March 13, 2023 April 11, 2024 December 12, 2026 December 12, 2026	Astrazeneca	Dr Reddy's, Sun Pharma, Intas Pharma, Reliance Formulation	Oral	Kinase Inhibitors
268	Akynzeo	Netupitant / Palonosetron	Acute And Delayed Chemotherapy-Induced Nausea And Vomiting	Small	US6297375 US10233154 US9951016 US10961195 US10676440	March 17, 2023 September 25, 2035 September 25, 2035 September 25, 2035 September 25, 2035	Helsinn Therapeutics	Dr Reddy's, Glenmark, Torrent, Alkem	Oral, Intravenous	Neurokinin (NK1) Antagonists / 5-HT3 Receptor Antagonists
269	Kynamro	Mipomersen	Homozygous Familial Hypercholesterolemia	Large	US7015315 US7511131	March 21, 2023 January 29, 2027	Genzyme Corp	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Subcutaneous Injection	Oligonucleotide
270	Incruse Ellipta	Umeclidinium Bromide	Chronic Obstructive Pulmonary Disease	Small	USRE44874 US7498440 US7439393 US7488827	March 23, 2023 April 27, 2025 May 21, 2025 December 18, 2027	GlaxoSmithKline	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Inhalation	Anticholinergics
271	Xeljanz	Tofacitinib	Rheumatoid Arthritis, Psoriatic Arthritis, And Ulcerative Colitis	Small	US6965027 USRE41783	March 25, 2023 December 8, 2025	pfizer	Intas, Cipla, Reliance , Lupin	Oral	Janus Kinase (Jak) Inhibitor
272	Vocabria	Cabotegravir	HIV/AIDS	Small	US8080551 US7125879	April 11, 2023 April 21, 2025	Viiv Healthcare	Cipla, Emcure Pharma, Sun Pharma	Oral, Intramuscular	HIV Integrase Inhibitor
273	Dutrebis	Lamivudine/Raltegravir	HIV/AIDS	Small	US7820660	April 25, 2023	Merck sharp & Dohme	Cipla, Emcure Pharma, Sun Pharma	Oral	Reverse-Transcriptase Inhibitor / Integrase Inhibitor
274	Fotivda	Tivozanib	Relapsed Or Refractory Advanced Renal Cell Carcinoma (RCC)	Small	US6821987 US7166722	April 26, 2023 November 16, 2023	AVEO Pharmaceuticals	Natco, Bayer Zydus, Cipla, Arechar, Intas, Hetero	Oral	Kinase Inhibitor
275	Banzel	Rufinamide	Seizures Associated With Lennox-Gastaut Syndrome	Small	US6740669	May 14, 2023	Eisai Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Anticonvulsants
276	Nuzyra	Maralixibat Chloride	Community-Acquired Bacterial Pneumonia And Acute Skin And Skin Structure Infections	Small	US7553828 US7326696 US8383610	June 2, 2023 September 24, 2023 September 23, 2030	Paratek Pharmaceuticals	Cipla, Mylan, Zydus Cadila, Alkem, United Biotech	Oral, Intravenous	Ileal Bile Acid Transporter Inhibitor
277	Halaven	Eribulin	Breast Cancer And Liposarcoma	Small	US6214865	July 20, 2023	Eisai Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Intravenous	Microtubule Dynamics Inhibitor

278	Dexilant	Dexlansoprazole	Gastroesophageal Reflux Disease	Small	US6664276	July 30, 2023	Takeda	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Proton Pump Inhibitor
279	Onglyza	Saxagliptin	Type 2 Diabetes	Small	USRE44186	July 31, 2023	Astrazeneca	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Oral	Dipeptidyl Peptidase-4 Inhibitor
280	Vyvanse	Lisdexamfetamine	Attention Deficit Hyperactivity Disorder	Small	US7659253 US7655630 US7662787	August 24, 2023 August 24, 2023 August 24, 2023	Shire (Takeda)	IPCA, Sun Pharma, Intas, Taj Pharma	Oral	Central Nervous System Stimulant
281	Lumigan	Bimatoprost	High Pressure Inside The Eye Including Glaucoma	Small	US8038988 US7851504 US8629185	August 25, 2023 June 13, 2027 July 15, 2031	Allergan	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Eye Drops	Prostaglandin Analog
282	Vibativ	Telavancin	MRSA Or Other Gram-Positive Infections	Large	US6635618 US7531623	September 11, 2023 January 1, 2027	Theravance Biopharma	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Bactericidal Lipoglycopeptide
283	Lupron	Leuprorelin	Prostate Cancer, Breast Cancer, Endometriosis, Uterine Fibroids	Large	US8470359	October 15, 2023	Abbvie Inc	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Subcutaneous, Intramuscular	Gonadotropin-Releasing Hormone Agonist
284	Feraheme	Ferric Carboxymaltose	Iron-Deficiency Anemia	Large	US11123321 US9376505 US7612109	October 20, 2023 October 20, 2023 February 5, 2024	AMAG Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Iron Replacement Product
285	Ozanex	Ozenoxacin	Impetigo	Small	US6335447	November 9, 2023	Cipher Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Topical	Quinolone Antibiotic Drug
286	Stiolto® Respimat	Tiotropium/Olodaterol	Asthma	Small	US7491719 US7056916 US7220742 US7727984	November 10, 2023 December 7, 2023 May 12, 2025 January 19, 2027	Boehringer Ingelheim	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Inhalation	Anticholinergics / Long-Acting Inhaled Beta-Agonists
287	Otezla	Apremilast	Psoriasis And Psoriatic Arthritis	Small	US7893101 US7427638	December 9, 2023 February 16, 2028	Amgen	Intas, Cipla, Reliance , Lupin	Oral	Phosphodiesterase Inhibitor
288	Rapivab	Peramivir	Influenza	Small	US6562861	December 16, 2023	BioCryst Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Guanidines
289	VYNDAQEL	Tafamidis/Meglumine	Transthyretin Amyloidosis	Small	US8168663 US7214695 US9770441	December 19, 2023 April 27, 2024 August 31, 2035	Pfizer	Abbott, Macleods, Intas, Lupin	Oral	Oral Transthyretin Stabilizer
290	Coreg	Carvedilol	High Blood Pressure, Congestive Heart Failure (CHF), And Left Ventricular Dysfunction	Small	US7268156	December 27, 2023	GlaxoSmithKline	Dr Reddy's, Leeford, Glenmark, Intas, Natco, Macleods	Oral	Beta-Blocker
291	Hetlioz	Tasimelteon	Non-24-Hour Sleep-Wake Disorder	Small	US5856529 US10829465 US10071977	December 9, 2022 February 12, 2035 February 12, 2035	Vanda Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Melatonin Receptor Agonist
292	Taflotan	Tafluprost	Open-Angle Glaucoma	Small	US5886035	December 18, 2022	Santen Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Eye Drops	Prostaglandin Analog
293	Viibryd	Vilazodone	Major Depressive Disorder	Small	US7834020 US8673921	December 5, 2022 December 5, 2022	Allergan	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Oral	Serotonin Modulator
294	Norvasc	Amlodipine	High Blood Pressure And Coronary Artery Disease	Small	US6828339 US6696481 US7846961	November 20, 2022 April 15, 2023 October 5, 2029	Viatris	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Calcium Channel Blocker
295	Ocaliva	Obeticholic Acid	Primary Biliary Cholangitis	Small	US7138390 USRE48286 US10174073	November 16, 2022 February 21, 2027 June 17, 2033	Intercept Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Farnesoid X Receptor Agonist
296	Chantix	Varenicline	Smoking Cessation	Small	US6890927 US7265119	November 6, 2022 February 3, 2023	Pfizer	Dr Reddy's, Sun Pharma, Intas Pharma, Reliance Formulation	Nasal Spray	Alpha-4 Beta-2 Neuronal Nicotinic Acetylcholine Receptor Partial Agonist
297	Neurontin	Gabapentin	Partial Seizures And Neuropathic Pain	Small	US8048917 US6818787 US8026279	November 6, 2022 April 6, 2025 November 10, 2026	Pfizer	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Oral	Anticonvulsant
298	Movantik	Naloxegol	Smoking Cessation	Small	US6890927 US7265119	November 6, 2022 February 3, 2023	Pfizer	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Nasal Spray	Peripherally Acting Mu-Opioid Receptor Antagonist
299	Lupkynis	Voclosporin	Attack Of Lupus Nephritis	Large	US7332472	October 17, 2022	Aurinia Pharmaceutical	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Cyclosporin A Analog
300	Myrbetriq	Mirabegron	Overactive Bladder	Small	US6346532 US7342117	September 27, 2022 May 4, 2024	Astellas Pharma	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Beta-3 Adrenergic Agonist
301	Abilify	Aripiprazole	Schizophrenia And Bipolar Disorder	Small	US8993761 US9359302 US8642760 US8580796 US8399469 US10112903 US8431576	September 5, 2022 September 25, 2022 March 25, 2023 March 25, 2023 June 29, 2025 June 24, 2030 October 26, 2030	Otsuka America Phamaceuticals Co Ltd	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Oral	Atypical Antipsychotic
302	Bylvay	Odevixibat	Progressive Familial Intrahepatic Cholestasis	Small	US7132416 US10975046	September 5, 2022 June 20, 2039	Albireo pharma	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Ileal Bile Acid Transporter Inhibitor

303	Nucynta	Tapentadol Hydrochloride	Schizophrenia And Bipolar Disorder	Small	US8993761 US9359302 US8642760 US8580796 US8399469 US10112903 US8431576	September 5, 2022 September 25, 2022 March 25, 2023 March 25, 2023 June 29, 2025 June 24, 2030 October 26, 2030	Otsuka America Phamaceuticals Co Ltd	Sun Pharma, IPCA, Macleods, Torrents, MSN Laboratories	Oral	Norepinephrine Reuptake Inhibitor
304	Addyi	Flibanserin	Pre-Menopausal Women With Hypoactive Sexual Desire Disorder	Small	US7420057	August 1, 2022	Sprout Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Serotonin Receptor 1A Agonist/Serotonin Receptor 2A Antagonist
305	Macrilen	Macimorelin	Growth Hormone Deficiency	Small	US6861409	August 1, 2022	Æterna Zentaris	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Peptidomimetic Growth Hormone Secretagogue
306	Slynd	Drospirenone	Birth Control Pills To Prevent Pregnancy	Small	US6441168	July 30, 2022	Exeltis USA, Inc	Leeford, Organon (India), Serum Institute of India. Torrent, Mylan	Oral	Progestin And Antiandrogen
307	Velcade	Bortezomib	Multiple Myeloma And Mantle Cell Lymphoma	Small	US6958319 US6713446	July 25, 2022 July 25, 2022	Takeda	Natco, Dr Reddy, Sun Pharma, Cipla, Panacea Biotec, United Biotech, Intas Pharma, SR Pharma, Zydus Cadila	Intravenous	Proteasome Inhibitor
308	Folotyn	Pralatrexate	Relapsed Or Refractory Peripheral T-Cell Lymphoma	Small	US6028071	July 16, 2022	Acrotech Biopharma	Natco, Dr Reddy's, sun pharma, Cipla, Panacea Biotec, United Bioted, Intas Pharma, SR pharma, Zydus Cadila	Intravenous	Folate Analogue Metabolic Inhibitor
309	Lusedra	Fospropofol	Used In Diagnostic Or Therapeutic Procedures Such As Endoscopy	Small	US6204257	July 1, 2022	Eisai Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous	Sedative-Hypnotic Agent
310	Stivarga	Regorafenib	Metastatic Colorectal Cancer	Small	US7351834 US8637553 US9957232	June 28, 2022 February 16, 2031 July 9, 2032	Bayer	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors
311	Caprelsa	Vandetanib	Medullary Thyroid Cancer	Small	USRE42353	June 27, 2022	Genzyme Corp	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Kinase Inhibitors
312	Pepaxto	Melphalan Flufenamide	Multiple Myeloma	Small	US6992207	June 25, 2022	Oncopeptides	Natco, Dr Reddy, Sun Pharma, Cipla, Panacea Biotec, United Biotech, Intas Pharma, SR Pharma, Zydus Cadila	Intravenous	Alkylating Agent
313	Trulance	Plecanatide	Chronic Idiopathic Constipation And Irritable Bowel Syndrome	Large	US7799897 US7041786 US10011637	June 9, 2022 January 30, 2028 June 5, 2034	Salix Pharmaceuticals Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Guanylate Cyclase-C Agonist
314	Fycompa	Perampanel	Partial Seizures And Generalized Tonic-Clonic Seizures	Small	US6949571 US8772497	June 8, 2022 July 1, 2026	Eisai Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Anticonvulsants
315	Epidiolex	Cannabidiol	Seizures Associated With Lennox-Gastaut Syndrome, Dravet Syndrome, Or Tuberous Sclerosis	Small	US10195159 US11096905 US11207292	May 7, 2022 October 14, 2035 April 26, 2039	Greenwich Biosciences	Sun Pharma, Alkem, Micro Labs, Abbott, Intas, Lupin, Torrent, IPCA	Oral, Inhalation	Cannabinoid
316	Lynparza	Olaparib	BRCA-Mutated Advanced Ovarian Cancer	Small	US7151102 US7449464 US7981889 US8247416	April 29, 2022 October 11, 2024 October 11, 2024 September 24, 2028	Astrazeneca	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Oral	Polyadenosine 5'-Diphosphoribose Polymerase (PARP) Enzyme Inhibitor
317	Cerdelga	Eliglustat	Gaucher's Disease	Small	US6916802 US7196205	April 29, 2022 June 26, 2026	Genzyme Corp	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Glucosylceramide Synthase Inhibitor
318	Combigan	Brimonidine / Timolol	Glaucoma	Small	US7642258	April 19, 2022	Allergan	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Eye Drops	Alpha Agonist / Beta Blocker
319	Teflaro	Ceftaroline Fosamil	Methicillin-Resistant Staphylococcus Aureus (MRSA)	Small	US6417175	April 11, 2022	Allergan	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous Injection	Antibacterial Agent
320	Lexiscan	Regadenoson	Myocardial Perfusion Imaging	Small	US6403567 US8106183	April 10, 2022 February 2, 2027	Astellas Pharma	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Intravenous Injection	A2a Receptor Agonist
321	Leqvio	Inclisiran	Atherosclerotic Cardiovascular Disease And Heterozygous Familial Hypercholesterolemia	Large	US9074213 US8232383 US11078485 US10669544 US8809292 US9370582 US10806791 US10125369	March 9, 2022 February 20, 2023 November 4, 2023 March 8, 2024 May 10, 2027 December 4, 2028 December 4, 2028 August 18, 2034	Novartis Pharmaceuticals Corp	Dr Reddy's, Leeford, Glenmark, Intas, Natco, Macleods, Lupin	Subcutaneous Injection	Small Interfering Rna (Sirna) Molecule
322	Fusilev	Levoleucovorin	Toxicity Associated With Overdosage Of Folic Acid Antagonists Or Impaired Methotrexate Elimination	Small	US6500829	March 7, 2022	Spectrum Pharma	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Subcutaneous Injection	Folate Analog

323	Givlaari	Givosiran	Acute Hepatic Porphyria	Large	US8546143 US9708610 US10273477 US9708615 US9150605 US10131907 US8828956 US8106022 US10125364 US9133461 US10119143 US11028392	January 9, 2022 January 1, 2024 March 8, 2024 March 8, 2024 August 28, 2025 August 24, 2028 December 4, 2028 December 12, 2029 March 15, 2033 May 14, 2033 October 3, 2034 October 3, 2034	Alnylam Pharmaceuticals	Sun Pharma, IPCA, Macleods, Torrents, MSN Laboratories	Subcutaneous Injection	Sirna Drug
324	Vimpat	Lacosamide	Epilepsy And Partial-Onset Seizures	Small	USRE38551	March 17, 2022	UCB Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Oral	Anticonvulsant
325	Pristiq	Desvenlafaxine	Major Depressive Disorder	Small	US6673838 US8269040	March 01, 2022 July 5, 2027	Pfizer	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Oral	Selective Serotonin And Norepinephrine Reuptake Inhibitor
326	Vimovo	Esomeprazole/Naproxen	Osteoarthritis, Rheumatoid Arthritis And Ankylosing Spondylitis	Small	US8557285 US8852636 US8858996 US9161920 US9198888 US9345695 US9707181	May 31, 2022 May 31, 2022 May 31, 2022 May 31, 2022 May 31, 2022 May 31, 2022 May 31, 2022	Horizon Medicines Llc	Intas, Cipla, Reliance , Lupin	Oral	Proton Pump Inhibitor / Nonsteroidal Anti-Inflammatory Drug
327	Januvia	Sitagliptin	Type 2 Diabetes	Small	US6699871 US7125873	July 26, 2022 July 26, 2022	Merck sharp & Dohme	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Oral	Dipeptidyl Peptidase-4 Inhibitor
328	Avastin	Bevacizumab	Metastatic Colorectal Cancer, Non-Small Cell Lung Cancer (NSCLC), Glioblastoma (GBM), Metastatic Kidney Cancer (Mrcc), Advanced Cervical Cancer (CC), Ovarian Cancer(OC), Hepatocellular Carcinoma (HCC)	Large	US20150147317A1	January 2022	Genentech	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Intravenous Injection	Antiangiogenic Agent
329	Crestor	Rosuvastatin	Risk Of Stroke, Myocardial Infarction And Arterial Revascularization As An Adjunct To Diet To LDL-C As An Adjunct To Diet For The Treatment Of Adults With: Primary Dysbetalipoproteinemia. Hypertriglyceridemia	Small	US6316460B1	August 04, 2020	Astrazeneca	Cipla, Emcure, Natco, Intas, La Renon, Cadila, Torrent, Sun pharma	Tablet	HMG-CoA Reductase Inhibitors (Statins)
330	Enbrel	Etanercept	Moderate To Severe Rheumatoid Arthritis Psoriatic Arthritis Moderate To Severe Plaque Psoriasis Ankylosing Spondylitis Moderate To Severe Polyarticular Juvenile Idiopathic Arthritis	Large	US8163522B1 US8063182B1 NL300129I2	April 24, 2029 November 22, 2028 July 02, 2023	Amgen	Intas, Cipla, Reliance, Lupin	Subcutaneous Injection	Anti-TNFs Or TNF Blockers
331	Entyvio	Vedolizumab	Moderately To Severely Active Ulcerative Colitis, Crohn's Disease	Large	WO2016086147A1	June 2023	Millenium Pharmaceuticals	Sun Pharmaceuticals, Intas Pharmaceuticals, Zydus Cadila	Injection	Integrin Receptor Antagonists
332	Eylea	Aflibercept	Neovascular (Wet) Age-Related Macular Degeneration (AMD)	Large	US7070959B2	November 11, 2024	Regeneron and Bayer	Zydus Cadila	Intravitreal Injection	Vascular Endothelial Growth Factor A (VEGF-A) Antagonists
333	Lantus	Insulin Glargine	Paediatric Patients With Type 1 Diabetes Mellitus And Adults With Type 2 Diabetes Mellitus	Large	US8048854B2 EP2575865B1	July 05, 2027 May 27, 2031	Sanofi	Biocon	Subcutaneous Injection	Long-Acting Insulin
334	Lucentis	Ranibizumab	Wet Age-Related Macular Degeneration (Wet AMD), Diabetic Retinopathy And Diabetic Macular Oedema (DR And DME), Myopic Choroidal Neovascularisation (Mcnv), Macular Oedema Following Retinal Vein Occlusion (RVO)	Large	DE202012011260U1	November 24, 2022	Genentech (Roche)	Sun Pharmaceuticals, Intas Pharmaceuticals, Zydus Cadila	Intravitreal Injection	Vascular Endothelial Growth Factor A (Vegf-A) Antagonists
335	Opdivo	Nivolumab	Non-Small Cell Lung Cancer (NSCLC), Melanoma, Advanced Kidney Cancer, Bladder Or Urinary Tract Cancer (Urothelial), Colorectal Cancer (MSI-H/Dmmr), Classical Hodgkin Lymphoma, Gastric Or Gastroesophageal Junction Or Esophageal Cancers, Malignant Pleural Mesothelioma	Large	US9393301B2 US8168179B2 US9067999B1 US9073994B2 US9439962B2 US9402899B2 US7595048B2 US8728474B2	July 2, 2023 July 2, 2023 July 2, 2023 July 2, 2023 July 2, 2023 February 5, 2024 August 8, 2024 August 8, 2024	Bristol-Myers Squibb Co	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Intravitreal Injection	Human Monoclonal Antibody
336	OxyContin	Oxycodone	Moderate To Severe Pain	Small	US10696684 US10407434 US9522919 US9073933	March 30, 2025 March 30, 2025 March 30, 2025 March 30, 2025	Purdue Pharma Products LLP	Taj Pharma	Tablets	Opiate (Narcotic) Analgesic

337	Prolia/ Xgeva	Denosumab	Giant Cell Tumor Of Bone, Hyperglycemia Of Malignancy, Bone Metastases From Solid Tumour And Multiple Myeloma	Large	US8409578B2 US8058418B2 US7364736B2	June 25, 2022 November 30, 2023 February 19, 2025	Amgen	Dr Reddy's, Intas, Cipla, Alkem, Zydus, Bioelite Lifesciences, RPG Lifesciences, and Biorange Biologicals	Injection	Monoclonal Antibodies
338	Stelara	Ustekinumab	Moderate To Severe Active Crohn's Disease, Ulcerative Colitis	Large	US7279157B2 US9409984B2 US7166285B2 US8080247B2 US6902734B2	January 13, 2022 February 27, 2022 May 3, 2022 August 2, 2022 September 25, 2023	Janssen Biotech	Intas Pharmaceuticals	Subcutaneous Injection, Iv Infusion	Human Igg1 Monoclonal Antibody
339	Symbicort/ Breztri Aerosphere	Budesonide/Formoterol	Asthma, Chronic Obstructive Pulmonary Disease (COPD)	Small	US20210069215A1	January 29, 2023	Astrazeneca	Cipla, Lupin, Zydus Cadila, Macleods Pharma, Glenmark, Mankind, Intas, and Sun Pharma	Inhalation Aerosol	Long-Acting Beta Agonists
340	Trulicity	Dulaglutide	Type-2 Diabetes And Cardiovascular Diseases	Large	US10369003132 US10376376B2 US10610371B2 US11083591B2 US905601892 US986771292 US10695187B2 US8273854B2 US10130493B2 US8535379B2 US11135072B2	October 15, 2024 October 15, 2024 October 15, 2024 October 15, 2024 October 15, 2024 October 15, 2024 June 28, 2025 May 15, 2026 July 17, 2026 December 13, 2026 April 11, 2027	Eli Lily and Co	Lupin	Injection	Glucagon-Like Peptide-1 Agonists
341	Vistogard/ Xuriden	Uridine Triacetate	Hereditary Orotic Aciduria (Xuriden), Or For The Emergency Treatment Of Fluorouracil Or Capecitabine Overdose Or Toxicity (Vistogard)	Small	US6258795	July 10, 2023	Wellstat Therapeutics	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Granules	Pyrimidine Analog
342	Utibron	Glycopyrrolate/ Indacaterol Maleate	Long-Term Maintenance Treatment Of Air Flow Blockage In Patients With Chronic Obstructive Pulmonary Disease, Including Chronic Bronchitis And Emphysema. COPD Is A Long-Term Lung Disease That Causes Bronchospasm	Small	US8479730	October 11, 2028	Novartis Pharmaceuticals Corp	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Inhalation Powder	Adrenergics With Anticholinergics
343	Qvar Redihaler/Qnasl	Beclomethasone Dipropionate	Seasonal Or Perennial Allergic And Nonallergic (Vasomotor) Rhinitis And Prevent The Recurrence Of Nasal Polyps Following Surgical Removal	Small	US8132712	September 07, 2028	Norton Waterford	Sun Pharma, Cipla, Lupin, Intas	Inhalation Aerosol	Corticosteroids
344	Locametz	Gallium Ga-68 Gozetotide	Positron Emission Tomography (PET) Of Prostate- Specific Membrane Antigen (PSMA) Positive Lesions In Men With Prostate Cancer	Large	US11369590	August 15, 2028	Aaa USA Novartis	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Injection	Radiopharmaceutical Agent
345	Epsolay	Benzoyl Peroxide	Inflammatory Lesions Of Rosacea	Small	US9868103	August 08, 2028	Galderm Labs	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Cream	Topical Antibiotic
346	Intrarosa	Prasterone	Vulvar And Vaginal Atrophy In Postmenopausal Women Having Moderate To Severe Symptoms	Small	US8629129	August 07, 2028	Millicent	Abbott, Cadila	Vaginal Inserts	Steroids
347	Flonase Sensimist Allergy Relief/ Arnuity Ellipta	Fluticasone Furoate	Maintenance Treatment Of Asthma In Adult And Pediatric Patients Aged 5 Years And Older.	Small	US8347879	July 15, 2028	GlaxoSmithKline	Sun Pharma, Cipla, Lupin, Intas	Capsules	Corticosteroid
348	Tekturna HCT	Aliskiren Hemifumarate, Hydrochloroazide	Hypertension In Adults, To Lower Blood Pressure	Small	US8618172	July 13, 2028	Noden Pharma	Emcure, Intas, Lupin, Torrent, Mankind, Glenmark, Alembic	Tablets	Direct Renin Inhibitor /Diuretics
349	Osphena	Ospemifene	Moderate To Severe Dyspareunia And Vgainal Dryness, A Symptom Of Vulvar And Vaginal Atrophy, Due To Menopause	Small	US8642079	July 09, 2028	Duchesnay	Abbott, Cadila, Bayer Zydus, Bharat Serum & Vaccine, Emcure, Mylan, Serum Institute of India, Intas	Tablets	Selective Estrogen Receptor Modulator
350	Keytruda	Pembrolizumab	Melanoma, Lung Cancer, Head And Neck Cancer, Hodgkin Lymphoma, Stomach Cancer, Cervical Cancer, Breast Cancer	Large	US94458307P US8551967B2	June 13, 2028 September 5, 2031	Merck & Co	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Injection	Monoclonal Antibody
351	Doral	Quazepam	Insomnia Characterized By Difficulty In Falling Asleep, Frequent Nocturnal Awakenings, And/Or Early Morning Awakenings	Small	US7608616	June 03, 2028	Galt Pharms	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Tablets	Benzodiazepine Derivative
352	Zuragard	Isopropyl Alcohol	Antiseptic	Small	US8703828	May 23, 2028	Zurex Pharma	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Solution	Alcohol
353	Zetonna/Omnaris/ Alvesco	Ciclesonide	Nasal Symptoms Associated With Seasonal And Perennial Allergic Rhinitis	Small	US8371292	February 01, 2028	Covis	Sun Pharma, Cipla, Lupin, Intas	Nasal Spray	Corticosteroids
354	Implanon	Etonogestrel	Prevention Of Pregnancy	Small	US8722037	September 28, 2027	Organon	Leeford, Organon (India), Serum Institute of India. Torrent, Mylan	Contraceptive Implant	Long-Acting Synthetic Derived Progestin Contraceptive
355	Triferic	Ferric Pyrophosphate Citrate	Prevent Anemia In Patients With Chronic Kidney Disease Who Are On Dialysis	Large	US7857977	September 08, 2027	Rockwell Medical	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Injection	Hematinic
356	Lampit	Nifurtimox	Chagas Disease (American Trypanosomiasis) Caused By Trypanosoma Cruzi	Small	US8193196	September 02, 2027	Salix Pharmaceuticals Inc	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Tablets	Antiprotozoals
357	Byfavo	Remimazolam Besylate	Procedural Sedation	Small	US10961250	July 10, 2027	Acacia	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Injection	Ultra-Short-Acting Benzodiazepine

358	Embeda	Morphine Sulfate, Naltrexone Hydrocloride	Moderate To Severe Pain When Around-The-Clock Pain Relief Is Needed For A Long Time Period	Small	US8877247	June 19, 2027	Alpharma Pharms	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic, Intas, Sun Pharma	Capsule	Opiate (Narcotic) Analgesics/ Opiate Antagonists
359	Vitekta	Elvitegravir	HIV-1 Infection In Antiretroviral Treatment-Experienced Adults	Small	US7635704	April 26, 2027	Gilead Sciences	Cipla, Emcure Pharma, Sun Pharma	Tablets	Integrase Inhibitor
360	Lastacaft	Alcaftadine	Prevention Of Itching Associated With Allergic Conjunctivitis	Small	US10617695	March 19, 2027	Allergan	Sun Pharma, Cipla, Lupin, Intas	Ophthalamic Solution	Antihistamines
361	Tuzistra XR	Chlorpheniramine Polistirex, Codeine Polistirex	Cough And Symptoms Associated With Upper Respiratory Allergies Or A Common Cold	Small	US8790700	March 15, 2027	Tris Pharma	Sun Pharma, Cipla, Lupin, Intas	Oral Suspension	Antihistamines / Opioid
362	Dyanavel XR	Amphetamine	Attention Deficit Hyperactivity Disorder (ADHD)	Small	US10086087 US8337890	March 15, 2027 March 15, 2027	Tris Pharma	IPCA, Sun Pharma, Intas, Taj Pharma	Oral Suspension	Central Nervous System Stimulants
363	Advil Allergy Sinus	Chlorpheniramine Maleate, Ibuprofen, Pseudoephedrine Hydrochloride	Runny Nose. Itchy, Watery Eyes.	Small	US7863287	February 28, 2027	GlaxoSmithKline	Sun Pharma, Cipla, Lupin, Intas	Tablets	Antihistamine / Nonsteroidal Anti-Inflammatory Drug / Decongestant
364	Striverdi Respimat	Olodaterol Hydrochloride	Chronic Obstructive Pulmonary Disease (COPD), Including Chronic Bronchitis And/Or Emphysema	Small	US7727984	January 19, 2027	Boehringer Ingelheim	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Inhalation Solution	Long-Acting Beta-Agonist
365	Camcevi Kit	Leuprolide Mesylate	Hormone Dependent Advanced Prostate Cancer And For The Treatment Of High-Risk Localised And Locally Advanced Hormone Dependent Prostate Cancer	Small	US10646572	January 16, 2027	Accord	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Injection	GNRH And IS A GNRH Agonist
366	Epanova	Omega 3 Carboxylic Acids	To Reduce Triglyceride (TG) Levels In Adult Patients With Severe (≥500 Mg/Dl) Hypertriglyceridemia	Large	US7960370	December 20, 2026	Astrazeneca	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Capsules	Antilipemic
367	Axumin	Fluciclovine F-18	Positron Emission Tomography (PET) In Men With Suspected Prostate Cancer Recurrence Based On Elevated Blood Prostate Specific Antigen (PSA) Levels	Small	US10010632	November 28, 2026	Blue Earth	BDR pharmaceuticals, Alkem, Sun Pharma, Hetero, Zydus, Glenmark, MSN, Dr Reddy, Natco	Injection	Cyclobutanes
368	Synribo	Omacetaxine Mepesuccinate	Chronic Or Accelerated Phase Chronic Myeloid Leukemia (CML) With Resistance And/Or Intolerance To Two Or More Tyrosine Kinase Inhibitors (TKI)	Small	US6987103	October 26, 2026	Teva Pharmaceuticals	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Injection	Protein Synthesis Inhibitor
369	Juvisync	Simvastatin, Sitagliptin Phosphate	Type 2 Diabetes Mellitus	Small	US7326708	October 11, 2026	Merck sharp & Dohme	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Tablets	Hmg-Coa Reductase Inhibitor/ Dipeptidyl Peptidase-4 Inhibitor
370	Veregen	Sinecatechins	External Genital And Perianal Warts (Condylomata Acuminata) In Immunocompetent Patients 18 Years And Older	Small	US5795911	October 02, 2026	Ani Pharms	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Ointment	Keratolytic Agents
371	VALTURNA	Aliskiren Hemifumarate, Valsartan	Hypertension	Small	US8168616	July 03, 2026	Novartis	Emcure, Intas, Lupin, Torrent, Mankind, Glenmark, Alembic	Tablets	Renin Inhibitor / AT-1 Receptor Antagonist
372	Aplenzin	Bupropion Hydrobromide	Prevention Of Seasonal Major Depressive Episodes In Patients With A Diagnosis Of Seasonal Affective Disorder (SAD)	Small	US7241805	June 27, 2026	Bausch	Dr Reddy's, Sun Pharma, Intas Pharma, Lundbeck India, Reliance Formulation	Tablets	Atypical Antidepressant
373	Supprelin LA	Histrelin Acetate	Central Precocious Puberty	Small	US8062652	June 16, 2026	Endo Pharma	Bharat Serums & Vaccines, Sun Pharma, Intas, Emcure, Lupin	Subcutaneous Implants	Gonadotropin-Releasing Hormone Agonist
374	Natazia	Dienogest, Estradiol Valerate	Pregnancy Prevention	Small	US8071577	May 13, 2026	Bayer Healthcare	Leeford, Organon (India), Serum Institute of India. Torrent, Mylan	Tablets	Progestogen / Steroid Ester
375	Bridion	Sugammadex Sodium	Reversal Of Neuromuscular Blockade Induced By Rocuronium Bromide And Vecuronium Bromide	Large	USRE44733	January 27, 2026	Organon Sub Merck	Dr Reddy's, Sun Pharma, Intas Pharma, Reliance Formulation	Injection	Selective Relaxant Binding Agent
376	Otrexup	Methotrexate	Symptomatic Control Of Severe, Recalcitrant, Disabling Psoriasis	Small	US9629959	January 24, 2026	Otter Pharma	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Injection	Antimetabolites
377	Recorlev	Levoketoconazole	Endogenous Hypercortisolemia In Adult Patients With Cushing's Syndrome	Small	US11478471	January 10, 2026	Strongbridge	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Tablets	Cortisol Synthesis Inhibitor
378	Nevanac	Nepafenac	To Prevent And Treat The Pain And Inflammation That Can Occur After An Operation To Remove A Cataract From The Eye	Small	US8324281	December 02, 2025	Novartis	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Ophtalmic Solution	Nonsteroidal Anti-Inflammatory Drugs
379	Kombiglyze XR	Metformin Hydrochloride, Saxagliptin Hydrochloride	Type 2 Diabetes Mellitus	Small	US9339472	July 13, 2025	Astrazeneca	Sun Pharma, Torrent, Lupin, Glenmark, Dr Reddy's, Medipol, Zydus, Aristo and Quest Pharma	Tablets	Biguanide / Dipeptidyl Peptidase-4 Inhibitor
380	Troxyca ER	Naltrexone Hydrochloride, Oxycodone Hydrochloride	Management Of Pain That Is Severe Enough	Small	US8685443	July 03, 2025	Pfizer	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic, Intas, Sun Pharma	Capsules	Opiate (Narcotic) Analgesics/ Opiate (Narcotic) Analgesic
381	Edurant	Rilpivirine Hydrochloride	Short-Term Treatment Of HIV-1 Infection	Small	US7125879	April 21, 2025	Janssen	Cipla, Emcure Pharma, Sun Pharma	Tablets	Non-Nucleoside Reverse Transcriptase Inhibitor
382	Forteo	Teriparatide	Postmenopausal Women Who Have Osteoporosis	Large	US7517334	March 25, 2025	Eli Lilly	Abbott, Macleods, Intas, Lupin	Injection	Recombinant Parathyroid Hormone

383	Juxtapid	Lomitapide Mesylate	An Adjunct To A Low-Fat Diet And Other Lipid-Lowering Treatments, Including LDL Apheresis Where Available, To Reduce Low-Density Lipoprotein Cholesterol (LDL- C), Total Cholesterol (TC), Apolipoprotein B (Apo B), And Non-High-Density Lipoprotein Cholesterol (Non-HDL-C)	Large	US8618135	March 07, 2025	Amryt	Zydus Cadila, Abbott, Sun Pharma, Zuventus, Macleods, Mankind, Cipla, Torrent	Capsules	Microsomal Triglyceride Transfer Protein Inhibitor
384	Orilissa	Elagolix Sodium	Moderate To Severe Pain Caused By Endometriosis	Small	US7056927	September 10, 2024	Abbvie Inc	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic	Tablets	Gonadotropin-Releasing Hormone Receptor Antagonist
385	Contrave	Bupropion Hydrochloride, Naltrexone Hydrochloride	Chronic Weight Management	Small	US11278544	April 11, 2024	Nalpropion	Zydus Cadila, IPCA, Cipla, Dr Reddy's, Torrent, Alembic, Intas, Sun Pharma	Tablets	Norepinephrine/Dopamine-Reuptake Inhibitor , Opiate Antagonists
386	Thalomid	Thalidomide	Acute Treatment Of The Cutaneous Manifestations Of Moderate To Severe Erythema Nodosum Leprosum	Small	US7230012	December 09, 2023	Celgene	Cadila, Hetero, Intas, Alkem, United Biotech, Dr Reddy's, Sun Pharma, Getwell	Capsules	Interleukin (Il)-6 Production Inhibitor