Kingdom of the Netherlands

Pharmaceutical market in India: Critical generic drugs and potential suppliers for the Dutch market[1]

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Project Objective

- To strengthen the availability of medicines for Dutch patients by improving access to Indian APIs and generic drugs.
- While a lot of Indian companies supply to EU and Dutch market, they can still encounter difficulties due to the complex regulatory framework in Europe.
- This project aims to identify and facilitate inputs from high-potential Indian pharmaceutical companies to understand regulatory and logistical barriers faced by these companies in accessing the Dutch market and EU region, ensuring a reliable supply of critical generic medicines to the Netherlands.

Scope of Work

The scope of this research encompasses:

- Overview of the pharma value chain in India
- Longlisting Indian suppliers of critical generic drugs and APIs for the Dutch market and within the EU region
- Shortlisting Indian suppliers based on European quality standards and regulatory compliance.
- Qualitative assessment of shortlisted suppliers to understand key regulatory and logistical challenges faced by them in accessing EU and Dutch market.

[1] This report has been drafted under the responsibility of the Embassy of the Kingdom of the Netherlands in New Delhi, India, commissioned by the ministry of Health, Welfare and Sport of the Netherlands. We are thankful to KPMG in India for collaborating with us in preparing the report.

Executive Summary

1 Overview of Indian Domestic Pharma Market

- The Indian pharmaceutical industry has become a significant global contributor, driven by its manufacturing capabilities and strategic positioning during the COVID-19 pandemic.
- Key drivers include government policies like the Production Linked Incentive (PLI) schemes, rising foreign direct investments, demographic factors such as rising chronic disease rates, and cost efficiency with manufacturing costs 30-35% lower than in the US and Europe.
- Challenges like dependency on Chinese raw materials and regulatory compliance issues exist; however, the Indian government and industry stakeholders are addressing these challenges.
- Furthermore, increasing US tariffs are adding pressure on Indian exporters but also present opportunities, hence shifting focus towards the EU and emerging markets.

2 Assessment of API and Formulations Exports from India to EU and Dutch Markets

- India is a major player in the global pharmaceutical industry, supplying around 20% of the world's generics and 60% of vaccines.
- In 2024, India's exports of formulations and biologics reached ~€23B, growing at a 9% CAGR from 2019 to 2024.
- The US remains the largest importer of Indian pharmaceuticals, but the Netherlands has also seen significant growth, becoming the third-largest importer of APIs and the fifth-largest importer of formulations.
- This growth is partly due to the China Plus One strategy, which has boosted India's API exports by encouraging companies to diversify their supply chains beyond China.
- The Netherlands' pro-generic policies and increased demand for cost-effective medicines, especially during the COVID-19 pandemic, have further driven this trend.

3 Player Filtration and Scoring Methodology

- A weighted scoring methodology was developed, considering factors such as coverage of vital, essential, and necessary medicines, export value, supply capabilities, and coverage of shortage molecules.
- This section details the process of categorizing and assessing the critical medicines list, including the methodology for mapping medicines with the critical medicines list to identify Indian export capabilities in the Netherlands, Europe, and the US
- The section further describes the company filtration process, scoring parameters, and weighted scoring methodology employed to rank and shortlist potential suppliers.

4 Synthesis & Recommendations

- Aurobindo, Intas, Mylan, Zydus, and Dr. Reddy's emerged as leaders in supplying vital medicines, export value, supply capabilities, and coverage of shortage molecules; with the top 10 players capability to supply ~70% of the mapped medicines.
- For raw materials, MSN, Cipla, and Dr. Reddy's led in supplying vital APIs, export value, supply capabilities, and coverage of shortage molecules, with the top 10 players capable of supplying ~50% of the mapped medicines.
- Based on interactions with industry experts, they highlighted that Indian exporters face challenges such as multi-stage licensing approval processes which delays market entry and increase costs, while small-volume orders, patent extension mechanisms, and price-based tendering processes reduce profit margins and market penetration opportunities.
- Policymakers and industry stakeholders from both countries can address these challenges through joint GMP inspections, increased bilateral collaborations, negotiated trade agreements, expedited drug licensing pathways, and enhanced local regulatory support.

Section 1: Pharma Market Landscape

Overview of Indian Domestic Pharma Market

The Indian pharmaceutical industry has emerged as a significant contributor to the global pharmaceutical market, driven by its manufacturing capabilities and strategic positioning during the COVID-19 pandemic. The industry has evolved from being a relatively small player to emerging as one of the prominent 'drug producers' of the world. The industry not only exports affordable and high-quality generics, but also intermediates and active pharmaceutical ingredients (APIs), to both regulated and semi-regulated markets.

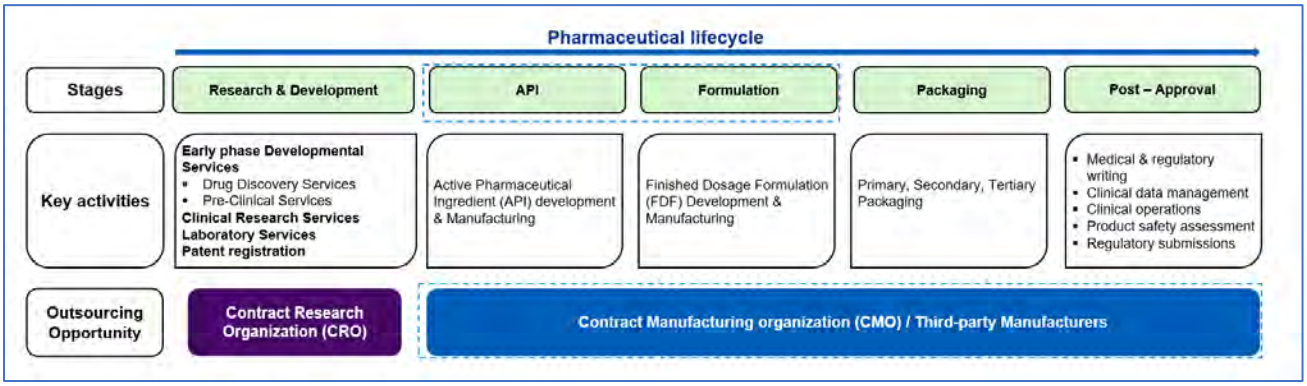
1	**Generic Medicine Dominance**	India commands a **~20%** market share in the global supply of generic medicines by volume, encompassing a diverse range of generic brands across multiple therapeutic categories.
2	**Global Reach**	India is the **3rd largest exporter (volume)** and **14th largest exporter (value)** of pharmaceutical finished dosage formulations (FDFs) globally. Indian pharmaceutical exports reach ~200 countries, supplying ~40% of the formulation demand in the US, ~20% in Europe, and ~1% in Netherlands.
3	**Robust Manufacturing Infrastructure**	The country has**~250-300 organized pharmaceutical companies**, **1400 WHO-GMP approved Pharma Plants, 253 European Directorate of Quality Medicines (EDQM)** approved manufacturing facilities, with the highest number of USFDA[(a)]-compliant plants outside the US. Local manufacturing meets about **75%** of India's medicine demand.
4	**Government Support and Strategic Initiatives**	The Government's **"Make in India"** initiative incentivizes domestic pharmaceutical manufacturing. Investments are rising and the sector is strengthening its manufacturing capacities, partly as a response to the global **"China plus one"** strategy to diversify supply chains away from China. The China Plus One strategy involves companies diversifying their supply chains beyond China to mitigate risks. Key actions include identifying alternative locations like India, establishing operations there, and navigating new regulations. For India, this presents an opportunity to attract global companies seeking supply chain diversification, leveraging its cost-effective manufacturing and improving regulatory environment. However, India needs to address infrastructure gaps, regulatory complexities, and ease of doing business challenges to fully capitalize on this opportunity.

Primary factors that make India a leading exporter include low capital requirements, economies of scale, operating facilities with minimal expenses along with well-established manufacturing processes and R&D infrastructure. Countries rely heavily on India to solve their rising healthcare expenses as India is a leading provider of affordable medicines.

Note(s): USFDA: US Food and Drug Administration
Source(s): PIB Government of India, Press Releases, Invest India Report, ASSOCHAM Report, Industry reports, External Agency Analysis

1.2 Overview of Pharma Value Chain

The Indian pharmaceutical Industry plays a pivotal role in the global pharmaceutical landscape, renowned for its strength across multiple segments of the pharmaceutical value chain.



Major components of the Indian pharmaceutical value chain

Key Segments:

1. **Active Pharmaceutical Ingredients (APIs) and Intermediates**
   - Active Pharmaceutical Ingredient (or API) is a crucial segment of the pharma industry, contributing to ~35% of the market.
   - India is the 3rd largest producer of API accounting for ~8% share of the global API industry (after China and the US).
   - 500+ different APIs are manufactured in India, and it contributes ~57% of APIs to prequalified list of the WHO.
   - The country excels in cost-effective manufacturing and advanced process capabilities.
2. **CRAMs: Contract Research and Manufacturing Services (CRAMS)**
   - End-to-end services from development to commercial manufacturing.
   - Cost efficiency due to skilled, low-cost manpower.
   - Patent cliff in regulated markets (many drugs' patent is expiring by 2026, leading to an opportunity for generics and biosimilars).
3. **Formulations**
   - India is a major provider of generic formulations, producing ~20% of generic drugs and ~60% of the world's vaccines.
   - Efficient bulk production of oral solid dosage, injectables and sterile formulations.
   - The large manufacturing base and economies of scale support this strength.

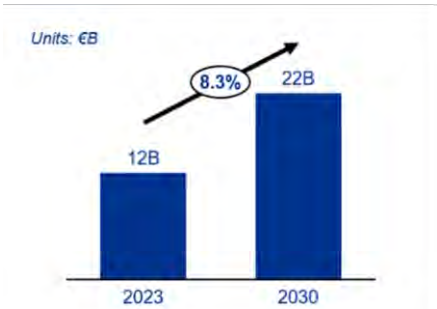
India's strong capabilities in cost-effective manufacturing, a broad API and generic formulations portfolio, and rigorous regulatory compliance establish it as a critical player in the global pharmaceutical value chain. However, to maintain and enhance this leadership, the industry needs to innovate in new chemical entities, reduce dependency on imports, and continuously adhere to stringent regulatory standards. Addressing these challenges will be key to sustaining growth and leveraging emerging global opportunities.

Source(s): Industry reports, Invest India Report, Secondary Research

1.3 Market Size, Key Trends, and Challenges

(A) Active Pharmaceutical Ingredients (APIs) and Intermediates Market

Indian API Market (2023-30F)[a]



Key API Players in the Indian Market

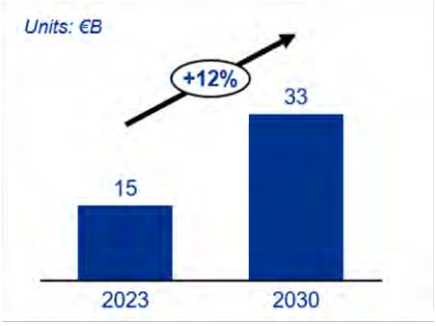
The Indian API market offers significant opportunities driven by government incentives, rising investments, and increased local production efforts by leading companies. The industry faces a few challenges such as dependency on Chinese raw materials and regulatory compliance issues exist; however, the Indian government and industry stakeholders are addressing these challenges through government policies. Additionally, the market has benefited from a rise in exports and the China Plus One strategy, which mitigates supply chain disruptions and dependency on imports.

- The Indian API industry is valued at ~€12B in 2023 and is expected to reach around €22B by 2030, growing at a CAGR of 8.3% driven by government incentives and rising investments, is anticipated to drive market growth.
- Leading Pharma companies are also increasingly focusing on local API production to reduce dependency on imports.
- There has been a significant increase in API exports from India since the COVID-19 pandemic, which has strengthened the adoption of the China Plus One strategy by several multinational companies (MNCs)
- Key Drivers and Inhibitors behind this shift include:
    - **Cost-effective Manufacturing:** India offers significantly lower manufacturing, operational, and labor costs compared to developed countries. Indian pharma companies often operate on a large scale, which allows them to achieve economies of scale.
    - **China Plus One Strategy:** Supply chain disruptions and increased costs in China have made India a preferred alternative, benefiting from its extensive EUGMP approved plants, USFDA-approved plants, and high ANDA[b] share. High ANDA share indicates that a large proportion of generic drugs in the US market are manufactured by Indian pharmaceutical companies.
    - **Rising Investments:** Indian government, global funds and major companies are investing in expanding API manufacturing capacity in India.
        - **Government Incentives:** Production Linked Incentive (PLI) Scheme: This scheme provides financial incentives to boost domestic manufacturing of critical Key Starting Materials (KSMs), drug intermediates, and APIs.
        - **Bulk Drug Parks:** These parks offer common infrastructure facilities to reduce manufacturing costs and enhance competitiveness. These initiatives aim to reduce dependency on imports and encourage self-reliance within the pharmaceutical sector.
        - **Private investment (PE):** Since the coronavirus outbreak, PE investors have already invested close to ~€1.3B in pharma companies for APIs. For example, Carlyle Group invested $210 million in Piramal Pharma Solutions, and Advent International acquired a significant stake in RA Chem Pharma.
- **Dependency Risks:** Despite the shift, a ~60% dependency on China still poses risks from supply chain disruptions and regulatory complexities. Efforts are ongoing to reduce this dependency and build a more resilient supply chain.

Note(s): (a) The market includes both Indian domestic and export market. (b) It is a submission to the FDA for the approval of generic drugs, demonstrating that the proposed drug is equivalent in safety, efficacy, and quality to a previously approved reference-listed drug (RLD)
Source(s): Industry reports, Invest India Report, Secondary Research

(B) CRAMS Industry Overview and Opportunities

Indian CRAMS Market (2023-30F)



Key API Players in the Indian Market

Sai, Divis, aragen, Akums, Syngene (Putting Science to Work), LAURUS Labs, Piramal

The Indian CRAMS market is set for significant growth due to cost advantages, regulatory support, and strategic initiatives by local companies and MNCs. Leading firms like Sai Life Sciences, Divi's Laboratories, Aragen Life Sciences, are driving this expansion through partnerships, R&D investments, and broadened service offerings. Key opportunities lie in low-cost outsourcing, MNCs' focus on core R&D, and supportive government incentives, though challenges such as rising labor costs, low utilization, regulatory issues, and capacity expansion need to be addressed.

- The Contract Research and Manufacturing Services (CRAMS) market in India involves outsourcing both research and manufacturing activities to reduce costs and improve efficiency.
- The CRAMs market is valued at ~€15B in 2023, the market is expected to grow at~12% by 2030 due to increasing global demand for cost-effective pharmaceutical solutions.
- Top CRAMS players are driving growth through strategic partnerships, increased R&D investments, and expanding their service offerings in drug development and manufacturing.
- **Drivers and Opportunities:**
  - **Outsourcing Trends:** Expiring patented products and demand for complex molecules make India an attractive outsourcing destination due to low-cost manufacturing and skilled labor.
  - **Shifting Focus of Multi-national companies (MNCs):** MNCs are outsourcing manufacturing to India to focus on core R&D amid rising competition and shrinking profit margins.
  - **Upstream Integration:** Indian contract manufacturers are moving up the value chain to offer value-added development services (e.g., Sai Life Sciences, Aragen).
  - **Government Incentives:** Supportive Foreign Direct Investment (FDI) policies, PLI, and Bulk Drug Park schemes boost local API and drug formulation manufacturing.

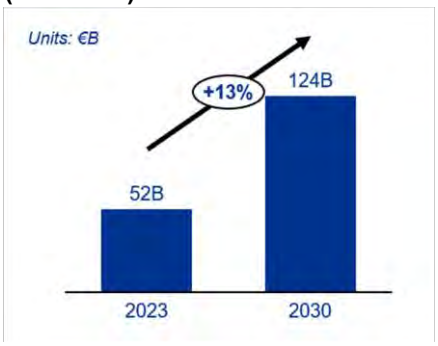
Challenges:

- **Rising Costs:** Increasing demand for skilled manpower is raising salary and compliance costs.
- **Low Utilization:** Many pharma units operate at only 30-40% capacity.
- **Regulatory Concerns:** US FDA non-compliance observations have impacted the goodwill of Indian pharma companies. Similarly, the European Medicines Agency (EMA) has also reported cases of non-compliance, particularly with Good Manufacturing Practices (GMP). In response to US FDA and EMA non-compliance observations, India's Central Drugs Standard Control Organization (CDSCO) is enhancing quality oversight through capacity-building projects and stricter regulatory measures.
- **High Potency APIs (HPAPIs)[(a)] and Biotechnology: Growth** in HPAPIs for oncology and biotech investments drive targeted investments.
- **Expanding Capacities and Partnerships:** CDMOs are expanding capacities to meet demand, while smaller players explore partnerships for global vaccine demand.

Note(s): High Potency Active Pharmaceutical Ingredients (HPAPIs) are special types of drug ingredients that are very effective even at low doses. They are used in medicines to treat serious diseases like cancer because they can target diseased cells very precisely
Source(s): Industry reports, Company Websites, Secondary Research

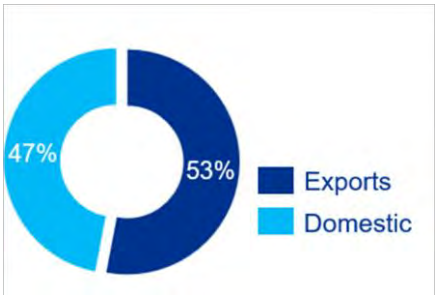
(C) Formulations Market in India

Indian Formulations Market (2023-30F)



Key Formulations Players in the Indian Market

Key Formulations Players in the Indian Market



- As of FY2023-24, the Indian pharma market is valued at ~€52B, expected to grow to ~€124B in 2030 at a CAGR of ~13%.
- Domestic market accounts for around €24B, primarily driven by a growing population, increasing healthcare awareness, and government initiatives.
- On the other hand, pharma exports account for about €28B, representing ~53% of the total market value.
    - Exports are expected to be a major driver for Indian pharma players due to their strong global presence and competitive advantages.
- Key Indian Players in the Pharma Market like Sun Pharmaceutical Industries, Cipla, Dr. Reddy's Laboratories, Lupin, etc. are renowned for their extensive portfolios in generic medicines, biosimilars, and active pharmaceutical ingredients (APIs), and their continual investment in research and development.

Drivers and Opportunities:

- **Generics and Patent Cliff*:** The upcoming patent cliff will release ~€240B worth of drugs by 2026, creating opportunities for Indian companies.
- **Biosimilars and Biologics:** The biosimilar market is growing at 25% YoY (year-on-year), reaching €34B by 2025. India's lower development costs and cheaper R&D talent make it a key player.
- **Peptide Manufacturing:** The global peptide synthesis market is valued at €490M, with ~60% outsourced. Indian companies have opportunities in manufacturing peptides for various therapeutic areas.
- **Government Incentives and Partnerships:** Initiatives like 'Make in India' and the PLI scheme boost domestic manufacturing, reduce import reduce dependency on imported APIs / bulk drugs by boosting local production, and attract MNC partnerships.

The Indian pharma market is estimated to be €52B as of 2023, with 53% driven by exports. The patent cliff and opportunities in biosimilars and peptides present key export opportunities for players. Government initiatives like 'Make in India' and the PLI scheme further boost domestic manufacturing and attract MNC partnerships.

Note(s): * A patent cliff refers to the expiration of patent protection for blockbuster drugs, allowing generic competition and a significant drop in sales for the branded drug manufacturers.
Source(s): Industry reports, Company Websites, Secondary Research

1.4 Regulatory Landscape

Overview of the regulatory framework governing pharma manufacturing and exports in India

India's pharmaceutical manufacturing and export sector is regulated by multiple government bodies, each responsible for different aspects of the industry. These regulatory bodies work to ensure compliance with international standards and promote the growth of the sector.

Key regulatory bodies and regulations

- Central Drugs Standard Control Organization (CDSCO)
- Drug Controller General of India (DCGI)
- State Drug Licensing Authorities
- Pharmaceutical Export Promotion Council of India (Pharmexcil)

a) Central Drugs Standard Control Organization CDSCO

The primary regulatory body Operates under the directorate General of Health Services, Ministry of Health & Family welfare. The CDSCO enforces the Drugs and Cosmetics Act. It also handles clinical studies and approves new drugs.

- Oversees New Drug Approvals, Standard of Drugs
- Amendments of act and rules
- Pharmacovigilance
- Regulates the market authorization of new drugs and clinical trial standards.

b) Drug Controller General of India (DCGI)

- Heads CDSCO and regulates pharmaceutical products and APIs.
- Oversees drug approval, clinical trials and pharmacovigilance.

The Indian drug manufacturers and exporters are expected to adhere to the standards implemented by the DCGI as well as those imposed by the drug regulators in the importing countries.

c) State Drug Licensing Authorities

(India has a decentralized drug regulation system, which grants significant authority to State Drug Regulatory Authorities)

- Monitors license for Manufacture, Sales and Distribution
- Monitors quality of drugs
- Investigations and prosecutions

d) Pharmaceutical Export Promotion Council of India (Pharmexcil)

- Pharmexcil is the authorized agency of the government of India for promotion of pharmaceutical exports from India.
- Facilitates exports of Pharmaceuticals and provides export-related advisory services to government.
- Organizes Trade delegations abroad.

Key Legislations

- Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945: This is the principal law regulating the import, manufacture, distribution, and sale of drugs and cosmetics in India. It lays down the standards for drug quality and provides for the establishment of laboratories to test the quality of drugs.

Source(s): DSIR, Industry reports, Secondary Research

- Pharmacy Act, 1948: This Act regulates the profession of pharmacy in India. It sets standards for the education and practices of pharmacists.
- Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954: This Act prohibits the advertisement of drugs and remedies that claim to have magical properties and outlines the conditions and restrictions for drug advertisements.
- Narcotic Drugs and Psychotropic Substances Act, 1985: This Act regulates the manufacture, possession, sale, and transportation of narcotic drugs and psychotropic substances, ensuring their use for medical and scientific purposes only.

Manufacturing Requirements

1. **Good Manufacturing Practices (GMP):**

    - India follows the WHO-GMP norms or could use the Schedule M guidelines specified under the Drugs and Cosmetics Act.
    - GMP requirements cover areas like hygiene in manufacturing, quality control, raw material handling, storage and distribution, and record maintenance.

2. **Site Inspections and Licensing:**

    - Manufacturing facilities must be inspected and licensed by the state drug control authorities. There are separate licenses for different categories of drugs.

3. **Compliance with Additional Guidelines:**

    - Depending on the type of drug (e.g., biologics, vaccines), additional guidelines may apply, which align with international standards to facilitate global trade.

Export Regulations

1. **Registration and Certification:**

    - The CDSCO oversees the registration of drugs for export. Manufacturers exporting pharmaceuticals must obtain a Certificate of Pharmaceutical Product (CPP) from CDSCO.
    - The CPP ensures that the product has been manufactured and is being marketed in India and thus complies with Indian standards.

2. **Export Inspection and Control:**
    - The Export Inspection Council (EIC) offers certification that products meet importing country specifications. This is crucial for countries that require evidence of compliance with their specific regulatory requirements.

3. **Compliance with International Standards:**

    - Manufacturers must ensure their products comply with the regulatory standards of the destination country, which often involves obtaining certifications from international bodies like the USFDA, EMA, etc.

1.5 Production Linked Incentive (PLI) Schemes

The Government of India, through the Department of Pharmaceuticals (DoP), is implementing the PLI scheme with INR 6,940 crore (~€745M) for PLI 1.0 and INR 15,000 crore (€1.7B) for PLI 2.0 to promote indigenous manufacturing of APIs and formulations. Additionally, three bulk drug parks are being developed with INR 1,000 crore (€107M) each to enhance local manufacturing, reduce import dependency, and strengthen the pharmaceutical supply chain in India.

Key Objective:

- Enhance Manufacturing Capabilities: Increase investment and production in the pharmaceutical sector.
- Product Diversification: Focus on high-value goods like biopharmaceuticals, complex generics, and patented drugs.
- Global Competitiveness: Create globally competitive companies from India using cutting-edge technology.

Categories:

- Category 1: Biopharmaceuticals, complex generics, patented drugs, etc.
- Category 2: Active Pharmaceutical Ingredients (APIs), Key Starting Materials (KSMs), Drug Intermediates (DIs).
- Category 3: Other drugs not covered in Categories 1 and 2, including repurposed drugs and in-vitro diagnostic devices.

Incentives

- Financial Incentives: Based on incremental sales over the base year, provided for a maximum of 6 years.
- Total Outlay: ~ INR ₹15,000 crore (~€1.7B) (PLI 2.0)

Target Groups	Quantum Of Incentive (Budget)
Group A: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods more than or equal to Rs 5,000 crore.	Rs 11,000 crore (€1.2B)
Group B: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods between Rs 500 (inclusive) crore and Rs 5,000 crore.	Rs 2,250 crore (€248M)
Group C: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods less than Rs 500 crore.	Rs 1,750 crore (€193M)

Recent Developments

- **Domestic manufacturing:** The scheme covers ~41 critical pharmaceutical ingredients, with a total allocation of Rs. 6,940 crores (€745M) until 2029-30
    - By September 2023, 48 projects had been approved, attracting an investment of Rs. 3,938.57 crore (€423M).
    - This scheme is expected to generate incremental sales of Rs. 2,94,000 crores (€31.5B) over six years, from 2022-23 to 2027-28.

- **New Plants**: >50 new greenfield manufacturing plants for pharmaceuticals and medical devices are expected to be completed by 2026.

- **Increased Exports**: The PLI scheme has catalyzed €9.5B in exports from India to countries with high regulatory standards.

- **Regulatory Reforms**: Upgrades in the regulatory framework to ensure quality and reliability, aiming to make India a reliable pharmacy of the world.

- **Top Beneficiaries:** Under India's Production Linked Incentive (PLI) scheme, key beneficiaries including Aurobindo Pharma, Cipla, Dr. Reddy's, Glenmark, and Sun Pharma have received incentive claims ranging from Rs 150 crore-330 crore (€16.5M-€36.3M).
    - The scheme, which submitted 278 applications in 2021 and selected 55 applicants, has driven the manufacturing of high-value drugs and APIs like biopharmaceuticals, complex generics, and specialized treatments.
    - In 2022, Aurobindo Pharma received PLI benefits for manufacturing Penicillin G under the Key Fermentation Based KSMs/Drug Intermediates category.
    - Similarly, MSN Labs and Hetero Labs were beneficiaries for producing Levofloxacin and Oxcarbazepine, respectively.
    - Other beneficiaries include companies such as Intas Pharma, Mylan Laboratories, Dr. Reddy's Laboratories, Lupin Limited, Cipla, Glenmark, and Sun Pharma for various pharmaceutical products.

Challenges in the PLI Scheme execution

- Under PLI 1.0, limited subsidy provided from the government resulted in several applicants withdrawing. Large number of caveats linked to the investment, pricing of the API or final product limited potential profitability for companies.
- There were 278 applications of which only 55 were selected and only 21% of the committed investment was deployed. Such challenges have pushed the government to re-invite applicants and extend timelines.
- Due to these roadblocks, the Government revisited its scheme and introduced PLI 2.0 (2021). This scheme has an extensive coverage of drug categories and more than doubled the expected incentives at INR 15,000 Cr (~€1.7B).
- The bulk drug park scheme outlaid INR 3000 Cr (~€330M) for 3 parks but is still in nascent stages with only "in-principle" approvals granted to 3 out of 14 states. In-principle approval means a provisional approval granted based on an initial assessment, indicating that the project or application meets the basic criteria but still requires further detailed evaluation and fulfillment of specific conditions before final approval is granted. Himachal Pradesh, Gujarat, and Andhra Pradesh received in-principle approvals in September 2022, submitted Detailed Project Reports in December 2022, and are awaiting final approvals, with various stages of progress and pending clearances, while no other states have received final approval or significant updates.

Source(s): Press Releases, Ministry of Chemicals and Fertilizers, DSIR, Industry reports, Secondary Research

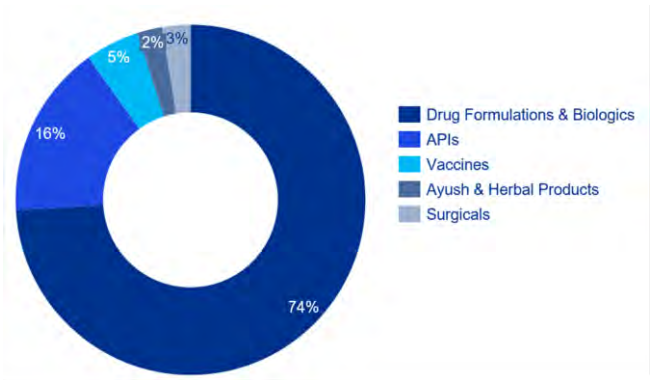
Section 2: Assessment of Formulations and API Exports from India to EU and Dutch Markets

2.1 Pharma Export Market Size from India

India is a leading global exporter of pharmaceuticals, known for cost-effective, high-quality products. It supplies ~20% of the world's generics and 60% of vaccines, ranking 3rd in volume and 14th in value. The country exports pharmaceutical products to >200 countries, contributing significantly to global healthcare.

Export Share by Category, 2023

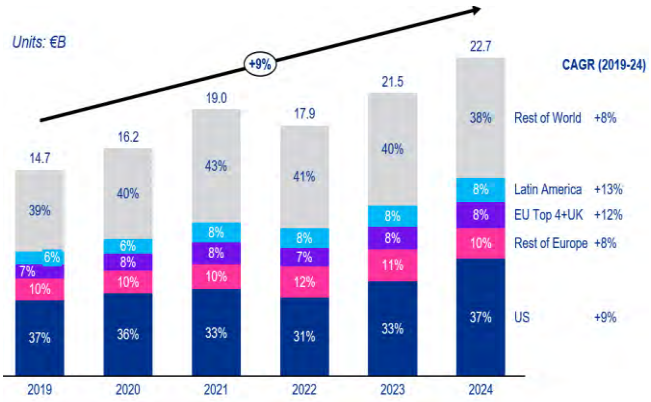
Export Value in 2023= ~€29B



- Formulations and Biologics dominate India's pharmaceutical exports at ~74%, due to their high value and global demand.
- API exports are growing as India aims to reduce dependency on China and meet rising demand for raw materials.
- As the country is the biggest vaccine exporter, about 65-70% of the World Health Organization (WHO) vaccine requirements are sourced from India.
- About 8 out of 20 global generic companies are from India and >50% of the exports from the country are to the highly regulated markets.

Formulations Exports

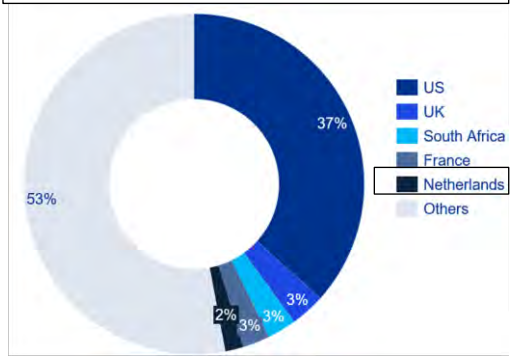
Total Global FDF Export by Region, 2019-24



Formulations Exports

Export Share by country, 2024

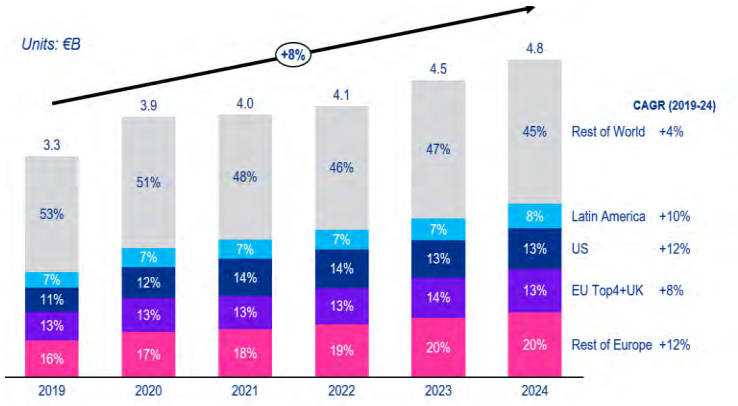
FDF Export Value in 2024 = ~€23B



- In FY24, India exported to >200 countries. FDF exports grew at a 9% CAGR over five years, reaching €22.7B in 2024.
- The US has been the largest importer due to strong trade ties and the reliability of Indian pharmaceuticals.
  - Indian pharmaceutical companies have received the highest number of market authorizations from the US Food and Drug Administration (USFDA) (outside US), with 6,316 approvals as of April 2023
- Exports to the EU top 4+UK grew by 12% from 2019 to 2024, driven by market penetration and acceptance.
- The Netherlands is the 5th largest importer of formulations (~€0.5B), hence making it a key partner in the Rest of Europe segment due to its strategic location, regulatory standards, and trade relationships.

API Exports

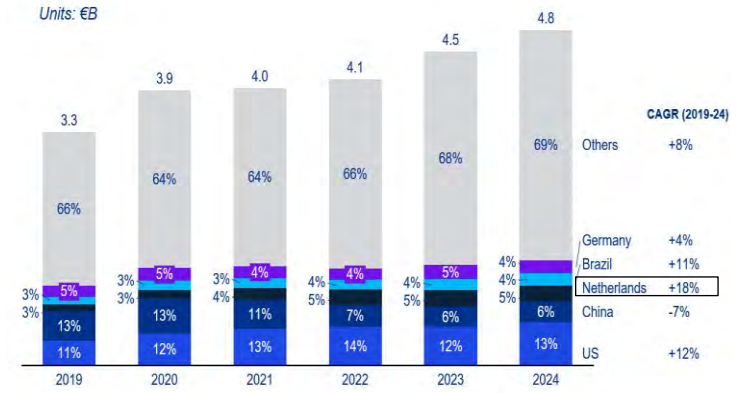
Total Global API Export by Region, 2019-24



- API Exports from India have grown at a CAGR of 8% in the last six years; In 2024, US and EU top 5 constituted ~26% of the total exports, driven by increased global demand and India's competitive pricing.
- Rest of Europe made up the largest portion at 20%. The Netherlands is the 3rd largest importer of APIs from India overall, with overall imports valued at $0.2B (~5% market share), while the other top countries in the Rest of Europe region are Switzerland, Ireland, Poland, Greece, and Slovenia contributing to ~6% market share.
- The China Plus One strategy has significantly boosted India's API exports by encouraging many global pharmaceutical companies to source APIs from India, further driving export growth.

API Exports

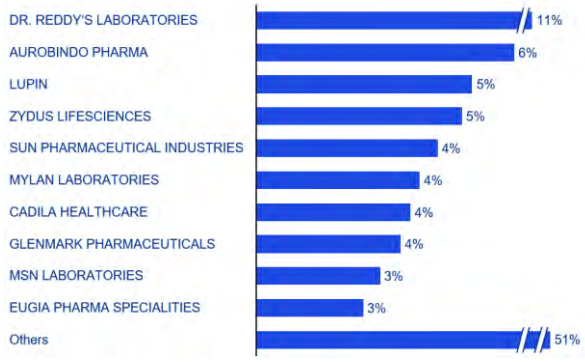
Total Global API Export by Country, 2019-24



- Netherlands is currently one of the top 5 countries importing APIs from India, witnessing fast paced growth at a CAGR of 18% from 2019-24, reinforcing their strong trade relationships with India.
- US and Brazil have witnessed a CAGR of 12% and 11% in last 5 years respectively; reflecting the increasing reliance on India as a supplier.
- Interestingly, API exports from India to China have declined by 7% owing to China's efforts to boost its own API production and reduce dependency on imports.

2.2 Key Indian Exporters Supplying to EU and the US

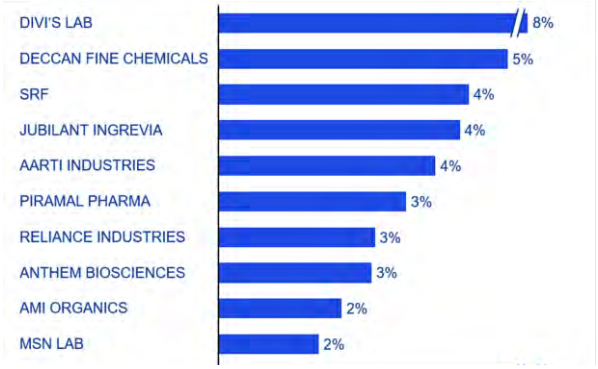
Top FDF Exporters from India to US and EU in 2024



- India's top formulation exporters, including Dr. Reddy's Laboratories, Aurobindo Pharma, Lupin, and Zydus Lifesciences have significantly contributed to the growth in exports to the EU4+UK, Rest of Europe, and the US, focusing on key therapy areas like oncology, cardiovascular, and diabetes.
- Their strengths in high-quality manufacturing, cost-effective production, and regulatory compliance have driven this success.

Source(s): APIFDF Data, IBEF, Industry Reports, Secondary Research

Top API Exporters from India to US and EU in 2024



- Indian firms like Divi's Laboratories, Neuland Laboratories, and Teva API India are leading exporters of high-quality APIs to the US, EU5, and the rest of Europe, bolstered by strong regulatory compliance and advanced manufacturing capabilities.
- These companies focus on various therapeutic areas, including oncology, cardiovascular, and respiratory, leveraging their significant R&D investments to meet strict international quality standards.

2.3 Key Products Supplied to EU and the US

Top FDF Products exported from India to EU Market in 2024

Top 10 Products exported from India	Share of products by value
LENALIDOMIDE	20%
MIRABEGRON	6%
ALBUTEROL	2%
PARACETAMOL (ACETAMINOPHEN)	2%
METFORMIN	3%
GABAPENTIN	2%
PANTOPRAZOLE	1%
ATORVASTATIN	1%
AMOXYCILLIN + CLAVULANIC ACID	1%
TIOTROPIUM	1%

Key formulation exports include high-value generics and specialty medications, such as oncology drugs like Lenalidomide, diabetes medication like Metformin, and common analgesics like Paracetamol, reflecting its capability to produce a diverse range of treatments at scale.

Top API Products exported from India to EU Market in 2024

Top 10 Products exported from India	Share of products by value
ACETIC ANHYDRIDE	3%
RIMEGEPANT SULFATE	3%
MONO METHYL ANILINE	3%
SACUBITRIL VALSARTAN SODIUM HYDRATE	2%
BENZENE	2%
2-ACRYLAMIDO-2-METHYLPROPANESULFONIC ACID	2%
CHALCONE	2%
BEDINVETMAB	1%
P-XYLENE	1%
SOYA LECITHIN	1%

India's high-demand API exports, including Acetic Anhydride, Rimegepant Sulfate, and Sacubitril Valsartan Sodium Hydrate, are driven by their applications; These APIs are essential for treating conditions like migraines and heart failure, with strong demand from the US and European markets due to India's cost-effective production and adherence to high-quality standards.

Source(s): APIFDF Data, IBEF, Industry Reports, Secondary Research

Section 3: Player Filtration and Scoring Methodology

3.1 Critical Medicines List for the Netherlands Market

The National Coordination Center for Medicines (LCG) publishes a list of critical medicines that are of great importance to the Dutch healthcare system. This list serves as a tool to help prioritize policies related to the availability of these medicines in the Netherlands, addressing the issue of regular shortages that affect patients, prescribers, and healthcare providers.

The critical medicines list categorizes drugs into three groups based on their importance: Noodzakelijk (Necessary) for basic healthcare needs, Essentieel (Essential) for treating serious conditions and ensuring continuity of care, and Vitaal (Vital) for life-saving treatments and critical interventions. To address the specific needs of different age groups, two separate lists were created, one for adults and one for children. These lists were presented to the Minister of VWS on November 6, 2024, and made publicly available on the LCG website.

Preliminary Assessment of the Critical Medicines List for Deep Dive Analysis

The assessment of the Dutch Critical Medicines List for deep dive analysis involved a detailed review process to ensure supplier identification process is accurate and comprehensive.

- **Step 1: Translation and Combination of Lists:** The initial step in the assessment process was to translate (to English) and combine the lists of critical medicines for both adults and children to conduct a deep dive analysis
- **Step 2: Removal of Duplicates:** Once the lists were combined, the next step involved removing duplicate entries (drugs that were repeated for multiple indications). Each medicine was carefully reviewed to ensure it was listed correctly based on its primary therapeutic use.
- **Step 3: Analysis of Combined List**: After combining the lists and removing duplicates, the medicines were grouped and analyzed under their respective therapeutic categories based on the ATC5[(a)] classification.
- **Step 4: Gathering of Other Important Datapoints for Analysis:** Additional data sources were gathered to enrich the analysis and provide a more comprehensive understanding of the critical medicines. These sources include:

    1. **Consumption Data (GIP):**
        - Data related to the consumption of medicines to understand usage patterns and demand.
    2. **Shortages Data (Farmanco):**
        - Information on medicine shortages to identify and prioritize critical medicines with supply issues.
    3. **Patented Molecules List:**
        - Data on patented molecules, including sources from the US and Europe, to distinguish between generic and patented medicines.
        - Sources include the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO).
    4. **Import-Export Data for APIs and FDFs:**
        - Data on the import and export of Active Pharmaceutical Ingredients (APIs) and Finished Dosage Forms (FDFs) with a focus on the Europe and the US.
        - This data is crucial for identifying the current Indian exporters to regulated markets and understanding their portfolio overlap with the critical medicines list.

Note(s): (a) ATC5 classification is Anatomical Therapeutic Chemical (ATC) Classification System, Level 5. This system classifies drugs based on the organ or system they act on and their therapeutic, pharmacological, and chemical properties. The fifth level (ATC5) specifically identifies the chemical substance of the drug.
Source(s): National Coordination Center for Medicines (Landelijk Coördinatiecentrum Geneesmiddelen), Industry Reports, Secondary Research, External Agency Analysis.

- **Step 5: Collation and Analysis for Supplier Identification:** The next step was to create a focused list for supplier identification by highlighting certain formulations and APIs that may not require mapping due to their:

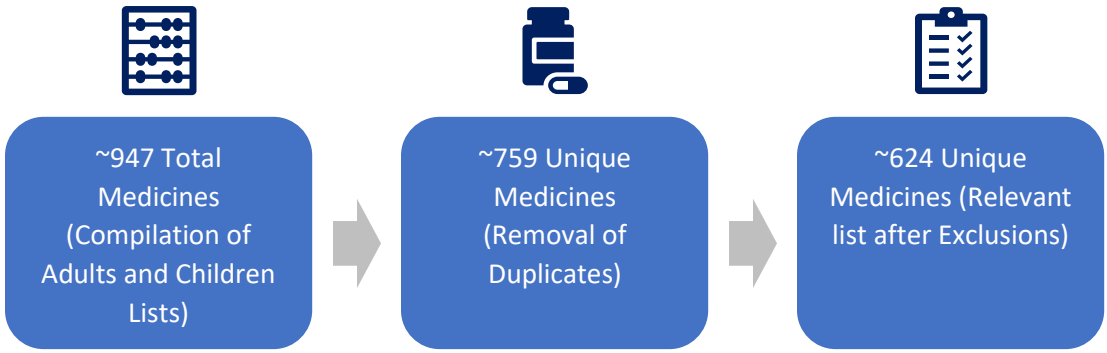
  a) **Patented Status:** Excluded patented medicines since the focus of the study was identification of generic suppliers, also low possibility of finding Indian exporters for patented medicines.

  b) **Lack of Commercial Viability for Export:** Excluded commonly used medicines such as electrolytes, water-for-injection, sugars, salts, etc.

  c) **Involvement of Complex Processes:** For APIs involving complex processes like vaccines, plasma-related substances, and recombinant factors, it was deemed unnecessary to identify API suppliers as these are produced using living organisms and involve complex processes, unlike conventional small molecule drugs.

  d) **Current Export Capabilities to Rest of World Market:** Excluded medicines with no evidence of export capabilities to regulated markets but which may have export capabilities to the rest of the world market.

  e) **Currently Not Manufactured in India:** Excluded medicines that are currently not manufactured in India.

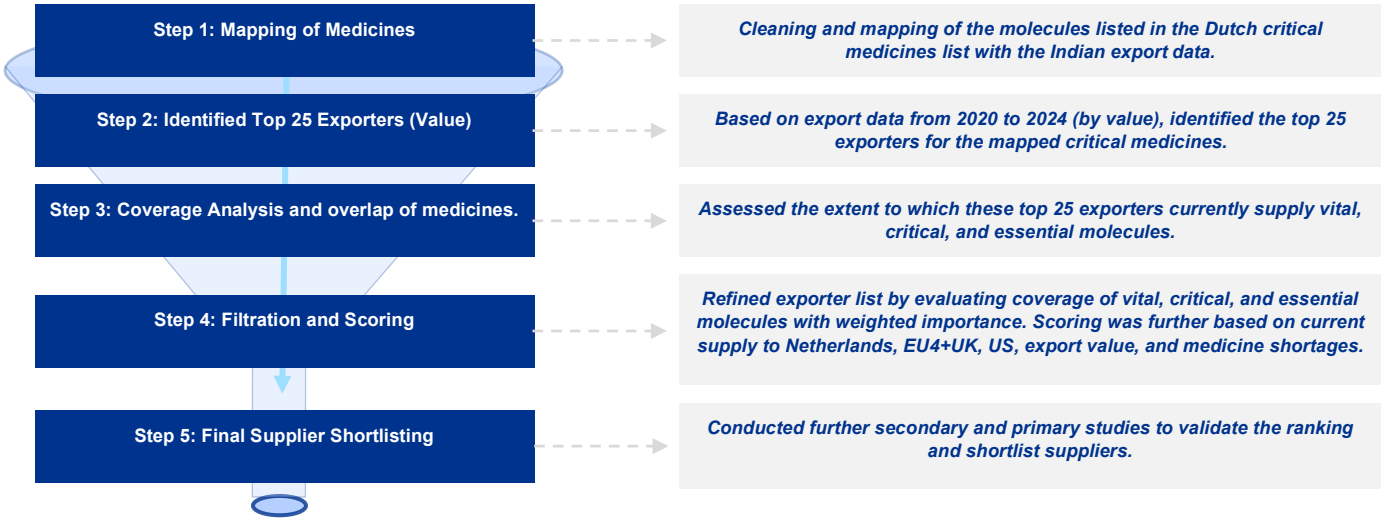


Categories	Total	Vital	Essential	Necessary
Total Medicines in Critical List (After Compilation)	947	209	465	273
Duplicates	188	31	105	52
Total Unique Medicines in Critical List (After Removal of Duplicates)	759	178	360	221
Excluded Medicines (Based on Step 5)	135	31	58	46
Total Unique Molecules in Critical List After Exclusions	624	147	302	175

Source(s): National Coordination Center for Medicines (Landelijk Coördinatiecentrum Geneesmiddelen), Industry Reports, Secondary Research

3.2 Company Filtration, Scoring Parameters and Weighted Scoring

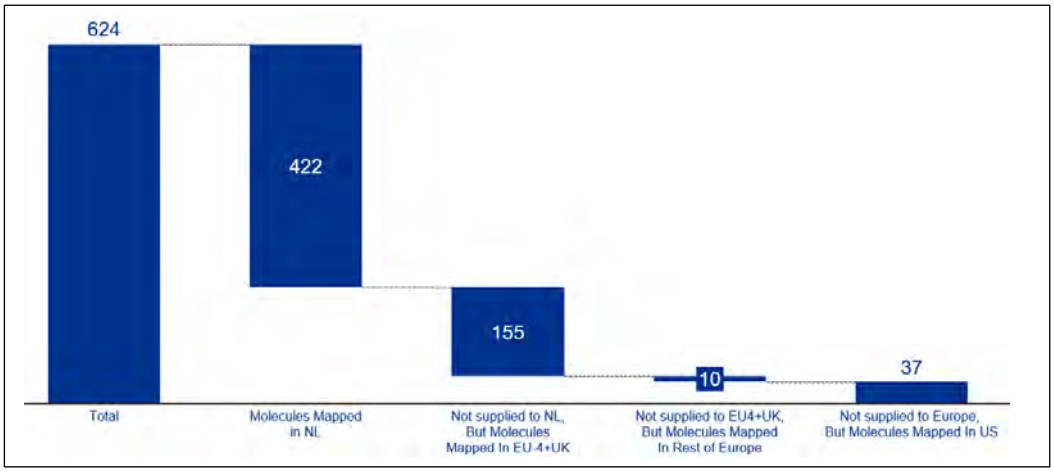
Methodology: The molecules from the Dutch critical medicines list were mapped leveraging Indian export data (API-FDF database) to identify the top 25 exporters based on 2020-2024 export values. These exporters were further evaluated for their supply of vital, critical, and essential molecules and scored on coverage, supply capabilities (Netherlands>EU4+UK>US), export values, and shortages of molecules.



Mapping of Medicines and Coverage Analysis (Formulations)

Methodology: The import-export data was cleaned and mapped to align with the Netherlands' critical medicines list. This process identified and categorized molecules by their presence in the Netherlands, EU5, and US markets, enabling detailed regional mapping and further exporter identification.

	Total	Vital	Essential	Necessary
Total Unique Molecules in Critical List	**624**	**147**	**302**	**175**
Molecules Mapped in Netherlands	422 (68%)	97 (66%)	212 (70%)	113 (65%)
Not Found in Netherlands, But Available in EU4+UK (France, Germany, Italy, UK, Spain)	155 (25%)	38 (26%)	74 (25%)	43 (25%)
Not Found in EU4+UK, But Available in Other European Markets (Rest of Europe)	10 (2%)	3 (2%)	2 (1%)	5 (3%)
Not Found in Europe, But Available in Other Regulated Markets (US)	37 (6%)	9 (6%)	14 (5%)	14 (8%)



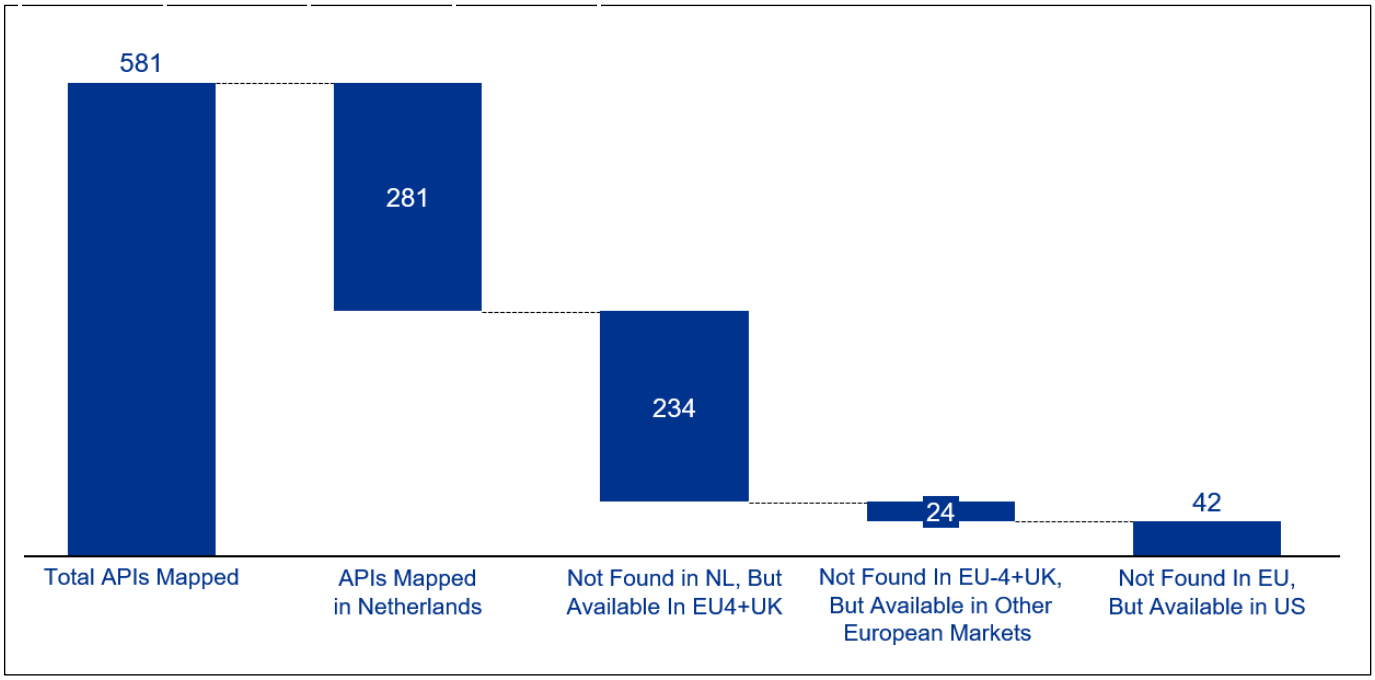
Based on the mapping process for formulations, 624 molecules were mapped from the critical list across the Netherlands (68%), EU4+UK+Rest of Europe (27%), and the US(6%)[a] thus helping with the process to identify potential suppliers.

Note(s): (a) The numbers may not add up to exactly 100% due to rounding errors.
Source(s): National Coordination Center for Medicines (Landelijk Coördinatiecentrum Geneesmiddelen), Industry Reports, APIFDF Data, Secondary Research, External Agency Analysis.

Mapping of Medicines and Coverage Analysis (APIs)

Methodology: A similar process was followed for Active Pharmaceutical Ingredients (APIs). Unique ingredients from the medicine list were separated, and the same methodology was applied. The import-export data was cleaned and mapped to align with the Netherlands' critical medicines list. This process identified and categorized molecules based on their presence in the Netherlands, EU4+UK, and US markets. This enabled detailed regional mapping and facilitated the identification of key exporters.

	Total	Vital	Essential	Necessary
Total Unique APIs in Critical List	**581**	**136**	**278**	**167**
APIs Mapped in Netherlands	281 (48%)	69 (51%)	123 (44%)	89 (53%)
Not Found in Netherlands, But Available in EU4+UK (France, Germany, Italy, UK, Spain)	234 (40%)	52 (38%)	120 (43%)	62 (37%)
Not Found in EU4+UK, But Available in Other European Markets (Rest of Europe)	24 (4%)	6 (4%)	15 (5%)	3 (2%)
Not Found in Europe, But Available in Other Regulated Markets (US)	42 (7%)	9 (7%)	20 (7%)	13 (8%)
Total Unique Molecules Mapped	**581 (100%)**	**136 (100%)**	**278 (100%)**	**167 (100%)**



Based on the mapping process for APIs, 581 APIs from the critical list were mapped across the Netherlands (48%), EU4+UK(40%), and US(7%)[(a)], thus helping with the process to identify potential suppliers.

Note(s): (a) The numbers may not add up to exactly 100% due to rounding errors.
Source(s): National Coordination Center for Medicines (Landelijk Coördinatiecentrum Geneesmiddelen), Industry Reports, APIFDF Data, Secondary Research, External Agency Analysis.

Section 4: Synthesis & Recommendations
4.1 Top Supplier Identification based on Shortlisting Process

The methodology for supplier selection and scoring was designed to ensure that the most reliable and capable suppliers are identified for critical medicines. This process involves evaluating suppliers based on several key parameters, each with specific weightages to reflect their importance. Here is an overview of the methodology:

1.Critical List Categorization (50%)

- **50% Vital coverage**: Higher weightage is assigned to companies providing vital medicines, as these are indispensable for life-saving treatments.
- **30% Essential coverage**: Companies supplying essential medicines, which are crucial for treating serious conditions, receive significant weightage.
- **20% Necessary coverage**: Necessary medicines, required for basic healthcare needs, are also considered but with a lower weightage.

2.Export Value (20%)

- Companies with higher export values are scored higher, as this indicates their manufacturing capabilities and capacity to meet demand.

3.Supply Capabilities (20%)

- Companies currently supplying to the Netherlands are scored highest, followed by those supplying to EU5 countries (Germany, France, Italy, Spain, UK), and then the US. This reflects the strategic importance and demand in these markets.

4.Shortages Molecules Coverage (10%)

- Companies with broader coverage of shortage molecules receive higher scores, highlighting their ability to address critical shortages and ensure the availability of essential medicines. This structured approach ensures that the selection process is comprehensive and prioritizes suppliers who can reliably meet the needs of the healthcare system, particularly in times of shortages.

Source(s): APIFDF Data, Secondary Research, External Agency Analysis.

Top 20 suppliers based on comprehensive filtration and scoring (Formulations)

Rank	Company	Vital medicines Coverage	Essential medicines Coverage	Necessary medicines Coverage	Export Value (2020-2024)	Supply Capability	Shortages Molecules Coverage	Final Score
1	AUROBINDO							
2	INTAS							
3	MYLAN							
4	ZYDUS							
5	DR REDDY'S							
6	LUPIN							
7	GLAND PHARMA							
8	CIPLA							
9	GLENMARK							
10	SUN PHARMA							
11	AMNEAL PHARMA							
12	MICRO LABS							
13	MACLEODS							
14	ALEMBIC							
15	TORRENT							
16	AJANTA PHARMA							
17	HETERO GROUP							
18	MSN GROUP							
19	STRIDES PHARMA							
20	GRANULES INDIA							

Scoring Legend	High	Medium	Low

These preliminary findings suggest that the top companies listed above have scope to supply a huge quantum of medicines from the list, based on the supplier shortlisting criteria.

- Top 5 players can supply 379 medicines (~60% of the mapped medicines from the critical list)
- Top 10 players can supply 435 medicines (~75% of the mapped medicines from the critical list).
- Top 20 players can supply 489 medicines (~80% of the mapped medicines from the critical list).

The top 20 companies can supply majority (~80%) of the critical medicines list. As we go further down, even though the coverage increases, one will find more niche suppliers with capabilities for fewer products.

Supplier Identification: Top 20 suppliers based on comprehensive filtration and scoring (APIs) (Similar Shortlisting Methodology as Formulations)

Rank	Company	Vital medicines Coverage	Essential medicines Coverage	Necessary medicines Coverage	Export Value (2020-2024)	Supply Capability	Shortages Molecules Coverage	Final Score
1	MSN GROUP							
2	CIPLA							
3	DR REDDYS							
4	AUROBINDO							
5	GLENMARK							
6	HETERO							
7	PIRAMAL GROUP							
8	MYLAN LAB							
9	TEVA							
10	SUN PHARMA							
11	DIVIS LAB							
12	BIOCON							
13	HARMAN FINOCHEM							
14	GRANULES INDIA							
15	CENTRIENT INDIA							
16	SMS GROUP							
17	JUBILANT GROUP							
18	SOLARA APS							
19	NECTAR LIFESCIENCES							
20	ATUL GROUP							

Scoring Legend	High	Medium	Low

These preliminary findings suggest that the top companies listed above have scope to supply a huge quantum of medicines from the list, based on the supplier shortlisting criteria.

- Top 5 players can supply 222 APIs (~40% of the mapped APIs from the critical list)
- Top 10 players can supply 283 APIs (~50% of the mapped APIs from the critical list).
- Top 20 players can supply 442 APIs (~55% of the mapped APIs from the critical list).

The top 20 companies can supply majority (~55%) of the critical medicines list. As we go further down, even though the coverage increases, one will find more niche suppliers with capabilities for fewer products.

Source(s): APIFDF Data, Secondary Research, Company Websites, External Agency Analysis.

4.2 Qualitative Insights from Industry Experts and Recommendations

Based on interactions with industry experts from regulatory, market access, and business development teams, the following insights were gathered. This covers the overall aspects of exporting medicines to the Netherlands and the EU – w.r.t regulations, distribution and logistics, and market-access related considerations as mentioned below:

Regulatory / Licensing / Quality Compliance

Distribution / Logistics/Market access

Considerations	Description	Key Implications
1. Complex Multi-Stage Licensing Approval Processes	• The licensing procedures in the EU involve complex multi-stage approval processes that require extensive clinical and bioequivalence data for certain complex generic products. • Furthermore, some member countries may require further mandates – for e.g. Documentation must be submitted in both local language and English. • Longer approval timelines – the average approval timeline usually ranges from 12 to 24 months but can extend in case of multiple queries for complex generics.	• Significant financial investment and compliance infrastructure costs • Extended time-to-market • Potential market entry barriers
2. Local Language Artwork and Labeling Compliance	• Compliance with artwork and labeling regulations in the Netherlands requires mandatory Dutch language packaging and adherence to strict EU packaging guidelines and detailed patient information leaflets.	• Additional artwork development costs • Language-specific packaging requirements
3. Long Waiting Periods for DCP Appointments	• Long waiting periods for Decentralized Procedure (DCP) appointments hinder timely regulatory filings, leading to longer approval timelines.	• Delayed market entry, increased costs due to prolonged approval processes.
4. Delays Due to Batch-Testing	• EU's requirement for analytical testing of each batch delays market entry by 2-3 months	• Delayed market entry, increased costs due to prolonged testing processes.
5. Cold Chain Management	• Strict cold chain management protocols must be followed to ensure product integrity. • Managing the cold chain for temperature-sensitive products like injectables, liquids, and biologicals involves complex transportation and distribution networks especially if multiple member states are involved.	• Increased transportation costs, product integrity risks, potential supply chain disruptions
6. Small-Volume Orders increases cost burden	• Individual country requirements may sometimes be relatively small, necessitating the consolidation of orders from multiple countries. • This can create logistical complexities, including increased consolidation complexity and higher logistics costs.	• Higher logistics costs, reduced economies of scale
7. Patent Extension Mechanisms	• Supplementary Protection Certificates (SPCs) can extend patent lifecycles by 5-7 years, creating a complex patent landscape. Data exclusivity provides 8-10 years of protection for originator drugs. • The European Commission reported that additional savings, on the 219 prescription medicines investigated, could have been as much as 20% higher if there had been no delays in generic entry to the market	• Delayed market entry, increased legal expenses, reduced market opportunities.

Note(s): (a) The considerations / challenges mentioned are based on our interactions with industry experts and may differ from case-to-case basis (depending on the nature of the product – e.g. oral solids, liquids, injectables, biosimilars, etc.
Source(s): Secondary Research, Expert Interviews.

Opportunities for Indian Generic Market to improve trade relationships in the Netherlands Market

1) **Major Patent Cliff Opportunity for Indian Generic Market**
   - 24 major blockbuster drugs worth €230 billion in annual sales will lose patent protection by 2030, creating a significant opportunity for generic drug manufacturers.
     - Key examples include arthritis drug Humira (€19.5 billion revenue) and cancer drug Keytruda (€19.3 billion revenue), with drug prices expected to fall by 50-60% after patent expiration, opening substantial market opportunities for Indian pharmaceutical companies.
   - Biologics will dominate this opportunity, comprising ~75% of the total revenue potential by 2030, with particular focus on biosimilars, immunomodulators, and monoclonal antibodies. The patent cliff presents a strategic entry point for Indian manufacturers to expand their global market presence, though companies need to prepare for complex IP landscapes and invest in R&D capabilities to ensure bioequivalence with original branded drugs.

2) **Supportive Regulatory Environment in the Netherlands**
   - The Netherlands has implemented pro-generic drug policies to contain rising healthcare costs, creating a favorable environment for generic drug exporters from India.
   - The regulatory framework in the Netherlands provides clear guidelines for drug approval, manufacturing standards, and post-market surveillance, ensuring a smooth entry for Indian generic drugs into the market.

3) **Recent Initiatives by Indian Local Agencies / Association bodies**
   - The Pharmaceuticals Export Promotion Council of India (Pharmexcil) plays a crucial role in promoting and facilitating the export of pharmaceutical products from India. Pharmexcil offers guidance on regulatory compliance, helping exporters understand and meet the requirements of different international markets.
     - Pharmexcil has sought a review of a new rule for drug exports that requires a product registration certificate from the importing country or Indian regulatory approval, aiming to streamline the export process and reduce regulatory burdens on exporters.
   - On the private side, organizations such as the Organization of Pharmaceutical Producers of India (OPPI), the Indian Pharmaceutical Alliance (IPA), the Indian Drug Manufacturers' Association (IDMA), and the Bulk Drug Manufacturers' Association of India represent majority of Indian pharmaceutical companies, that support exports by advocating for favorable policies, ensuring regulatory compliance, promoting research and development, and providing training and capacity-building initiatives, which collectively enhance the global competitiveness of Indian pharmaceutical companies

4) **Advancements in Indian Pharmaceutical Regulations and Compliance**

The Indian pharmaceutical industry has made significant strides in regulatory compliance and quality enhancements, making it an attractive market for exports to the Netherlands.

- The Production Linked Incentive (PLI) scheme has been implemented to boost domestic manufacturing and exports of pharmaceuticals, providing financial incentives to manufacturers based on their incremental sales and investments in production capacities.
- The government has mandated bioequivalence studies and stability data submission for drug manufacturing licenses, ensuring that generic drugs meet the same standards of quality, safety, and efficacy as their branded counterparts.
- The Central Drugs Standard Control Organization (CDSCO) has conducted risk-based inspections of drug manufacturing and testing firms, resulting in strengthened regulatory compliance and improved manufacturing practices.
- The Indian government has amended the Drugs Rules, 1945, revising Schedule M concerning Good Manufacturing Practices (GMP) requirements, effective from June 29, 2024.
- Mandatory barcodes and QR codes have been introduced on packaging labels of top 300 drug brands from August 1, 2023, to ensure better tracking and tracing of pharmaceutical products.

Note(s): (a) The considerations, challenges and opportunities mentioned are based on our interactions with industry experts and may differ from case-to-case basis (depending on the nature of the product – e.g. oral solids, liquids, injectables, biosimilars, etc.
Source(s): Secondary Research, Expert Interviews.

5) Cross-Government Interactions

- Bilateral trade talks between India and the Netherlands to strengthen trade in the pharmaceutical sector, focusing on vaccine raw materials and other pharmaceutical products is fostering better collaboration between both countries.
- Partnerships between National Institutes of Pharmaceutical Education and Research (NIPERs) in India and counterpart institutions in the Netherlands aim to foster research and development in the pharmaceutical sector.

Recommendations to Strengthen the Export Relationship between India and the Netherlands: A Comprehensive Policy Approach

1) Partner with Leading Indian Suppliers

- The top 10 identified Indian pharmaceutical companies in this report can supply 70% of critical medicines and are also key beneficiaries of government schemes.
- Engaging with companies such as Aurobindo, Intas, MSN, Cipla, and Dr. Reddy's can diversify and strengthen the Netherlands' supply chain.
- Additionally, partnering with organizations like GNH India, a leading pharmaceuticals distributor specializing in orphan drugs and providing a wide range of services, including contract manufacturing, clinical trial supplies, and temperature-controlled shipments, can ensure compliance with international standards and improve distribution efficiency.
- The Netherlands has successfully partnered with Indian suppliers in the past. Further diversification will enhance supply chain resilience and ensure a consistent supply of critical medicines.

2) Joint Inspections and Capacity Building

- Conducting joint Good Manufacturing Practice (GMP) inspections by Indian and EU regulators can build trust and reduce duplication. This approach has been successfully implemented by Japan's PMDA in collaboration with the US FDA. Enhancing collaborations through joint research, workshops, and training sessions can further strengthen relationships.
- The Netherlands has initiated discussions with Pharmexcil to engage key stakeholders in India, and a more collaborative approach can strengthen this relationship further.
- Both governments, through their respective regulatory agencies (e.g., CDSCO in India and the Medicines Evaluation Board (MEB) in the Netherlands, or EMA at the EU level), can organize joint workshops and training programs for industry professionals.
- These programs often cover topics like EU GMP requirements, pharmacovigilance, data integrity, and regulatory submission processes, helping Indian manufacturers better understand and comply with EU standards. Through diplomatic channels and trade forums, specific regulatory challenges faced by Indian exporters can be discussed with the Dutch and EU authorities.
- This can lead to clarifications, guidance documents, or potential adjustments in regulatory practices.
- In 2023, the Netherlands and India signed an MoU to enhance cooperation in healthcare, including pharmaceuticals. The agreement focuses on regulatory harmonization, joint research, and capacity building, marking the start of stronger trade relationships between both countries.

2) Simplify Market Access

- Advocating for pharmaceutical trade agreements between India and the EU can significantly reduce tariffs and non-tariff barriers, facilitating smoother trade relations.

Note(s): (a) The considerations, challenges and opportunities mentioned are based on our interactions with industry experts and may differ from case-to-case basis (depending on the nature of the product – e.g. oral solids, liquids, injectables, biosimilars, etc.
Source(s): Secondary Research, Expert Interviews.

- For instance, Australia's Free Trade Agreement (FTA) with India includes provisions that ease market access for pharmaceuticals, setting a precedent for similar agreements. Such agreements can help streamline regulatory processes, reduce costs, and enhance the availability of critical medicines in both regions.
- The EU-India Free Trade Agreement (FTA) negotiations have been ongoing but have faced delays due to various complexities. The Netherlands, as a key EU member, can play a crucial role in pushing for a faster resolution of these negotiations. By advocating for expedited discussions and addressing the sticking points, such as tariffs and regulatory standards, the Netherlands can help finalize the agreement more swiftly. This would not only benefit the pharmaceutical sector but also strengthen overall trade relations between India and the EU

3) Fast-Track Regulatory Approvals

- Implementing expedited pathways for critical drug development and review can significantly accelerate the availability of essential medicines. This process involves more frequent meetings with the FDA, rolling reviews, and eligibility for accelerated approval and priority review, ensuring that important new drugs reach patients sooner.
- Enhancing the local presence of regulatory support in India can benefit the Indian exporters. This can help navigate the complex regulatory landscape more efficiently, reducing delays in approvals and market entry. It can also lead to a more tailored guidance and support, helping exporters meet specific market requirements and improve their export strategies.
- Standardizing requirements across member states can reduce administrative burdens and speed up market entry by avoiding the need for multiple licensing processes for individual member states.
- Harmonizing packaging and labeling requirements across member states can simplify compliance for exporters by reducing the need for multiple versions of packaging.
- Streamlining appointment processes for DCP (Decentralized Procedure) approval and scientific advice can expedite market entry by reducing waiting times for regulatory appointments and ensuring sufficient slots for advice meetings. This is crucial as the demand for advice meetings often exceeds the available slots, impacting the timely introduction of new treatments.

4.3 Detailed Company Profiles of Top 10 Shortlisted Companies [a, b]

Aurobindo Pharma Limited

Business Overview

- Aurobindo Pharma Limited is an Indian biopharmaceutical company that manufactures generic formulations and APIs for various therapeutic areas, including CNS, cardiovascular, and oncology.
- The company's business segments focus on pharmaceuticals, including formulations, APIs, and specialty products, with expertise in both beta-lactam and non-beta-lactam APIs.
- Globally, Aurobindo has a significant presence in major markets like the US, EU, Canada, UK, Brazil, Japan, and Australia.
- In Europe, Aurobindo focuses primarily on France and Netherlands (through its subsidiary Aurex Pharma), also has a strong sales infrastructure in ten European countries.

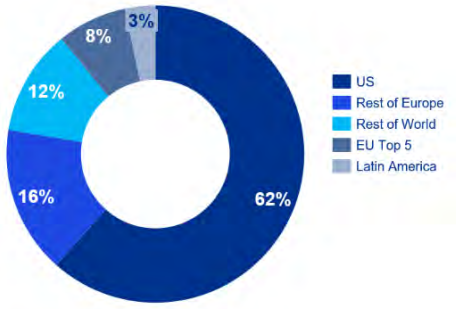
Key Facts

Headquarters: Telangana, India
Company Type: Public Company
Year Founded: 1986
Website: www.aurobindo.com

Portfolio Overlap with Critical Medicine List (#, %)

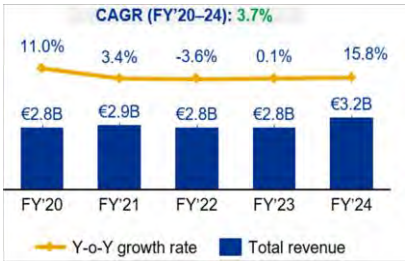
Total	181 (29%)
Vital	47 (32%)
Essential	90 (30%)
Necessary	44 (25%)

Export in Key Regions (Market share by Value – 2024)

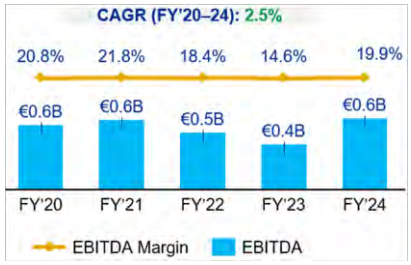


Key Financials[c,d]

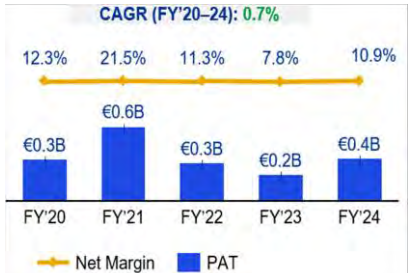
Revenue (€B) and YoY growth (%), FY20–FY24



EBITDA (€B) and EBITDA margin (%), FY20–FY24



Profit after Tax (PAT) (€B) & PAT margin (%), FY20–FY24



Manufacturing Capabilities

Aurobindo Pharma's extensive manufacturing network and regulatory approvals enable the company to cater to global markets and maintain a strong position in the pharmaceutical industry.

- Aurobindo Pharma has a substantial manufacturing capacity, with the ability to produce over 50 billion units of formulations and approximately 19,000 metric tons of APIs and intermediates annually.
- The company operates a total of 29 manufacturing facilities, many of which hold various regulatory certifications from international authorities.
    - In the United States, Aurobindo Pharma has a USFDA-approved orals facility in Dayton, New Jersey, and a USFDA-approved derma, inhaler, and transdermal facility in Raleigh, North Carolina; The company also has multiple USFDA-approved facilities in India.
    - Aurobindo Pharma's presence in Europe includes an EU GMP-approved oral products facility in Taizhou, China, and formulations facilities in Portugal that are EU GMP-approved. The company also has several EU GMP-approved facilities in India.
    - In India, Aurobindo Pharma operates 16 formulation facilities, many of which are approved by regulatory bodies such as USFDA, EDQM, WHO, and others.
    - The company's API manufacturing capabilities are supported by 13 facilities, including an EU GMP-approved facility in Hyderabad (CuraTeQ Biologics Private Limited); These API facilities hold multiple certifications from authorities like USFDA, EDQM, EMEA, UK MHRA, TGA Australia, WHO, ANVISA Brazil, and Japan PMDA.

Note(s): (a) The information provided is based on secondary and primary research; (b) Detailed definitions of key terms for the company profiles are mentioned in the appendix section; (c) Sourced financial information for Indian companies from publicly available data such as annual reports, regulatory filings from the Ministry of Corporate Affairs (MCA), stock exchange disclosures, press releases, direct company communications, proprietary databases, and industry reports; (d) Financial information based on latest available information and for year ending on March 31st. ;Source(s): Company website, Annual Reports, Industry Reports, Capital IQ, EMIS, VCC Edge, APIFDF Data, Secondary Research, External Agency

Intas Pharmaceuticals Limited

Business Overview

- Intas Pharmaceuticals Limited is engaged in the manufacture, marketing, and distribution of pharmaceutical formulations and APIs with a strong presence in neurology, psychiatry, and cardiology among other therapeutic areas.
- The company provides products in various therapeutic areas, such as neurology, psychiatry, cardiology, diabetology, urology, nephrology, and pain management.
- The company offers a diverse portfolio of biosimilars, plasma derived products, anti-infectives, NSAIDs, reproductive care products, injectable tonics, oral nutritional products, and therapies for cancer, infectious diseases, and acute medical emergencies.
- They have presence in India, the US, the UK (through Accord Healthcare), Europe, and other regulated markets, with ~70% of their revenue derived from India, the UK and Europe, and the remaining ~30% from the US, and the rest of the world markets.

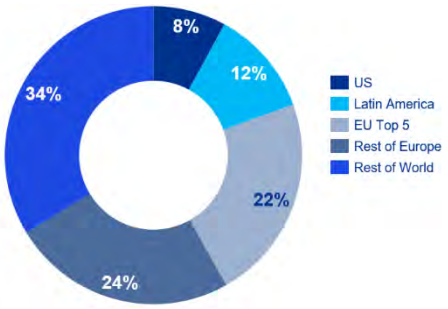
Key Facts

Headquarters: Gujarat, India
Company Type: Private Company
Year Founded: 1977
Website: www.intaspharma.com

Portfolio Overlap with Critical Medicine List (#, %)

Total	156 (25%)
Vital	31 (21%)
Essential	90 (30%)
Necessary	35 (20%)

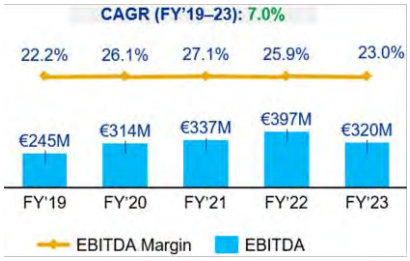
Export in Key Regions (Market share by Value – 2024)



Key Financials

Revenue (€M) and YoY growth (%), FY19–FY23

EBITDA (€M) and EBITDA margin (%), FY19–FY23



Profit after Tax (PAT) (€M) & PAT margin (%), FY19–FY23

Manufacturing Capabilities

- Intas Pharmaceuticals operates 17 manufacturing facilities, including 8 USFDA-certified plants (4 in Ahmedabad, 1 in Dehradun, 1 in the UK, and 1 in Mexico), 1 EUGMP-certified plant in Ahmedabad, 11 Indian regulatory body-certified plants across India, and 8 plants with other certifications in the UK, South Africa, Australia, Brazil, Gulf, Turkey, Spain, and Argentina.
- The company's manufacturing facilities in the UK under its subsidiary Accord Healthcare are approved by the Medicines and Healthcare products Regulatory Agency (MHRA).
- The company is developing a new highly automated Pharmez 2 facility in Ahmedabad and is expected to have an annual capacity of ~60M injectable units.

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Mylan Labs

Business Overview

- Mylan Pharmaceuticals Inc, part of Viatris Inc., operates extensively in the generics and specialty pharmaceutical sectors, addressing a variety of conditions from cardiovascular diseases to neurological disorders.
- The company has a strong presence in the anti-retroviral (ARV) segment, with around ~60% of its revenue derived from ARVs.
- The company derives most of its revenue from regulated markets like the US, Europe, Australia, Japan, they also have a substantial business in developing markets like Africa, LATAM and rest of the world.
- Mylan Labs sells products in regulated markets through its parent Viatris Inc, while sales in semi-regulated markets are institutional and tender based.
- In 2023, Mylan Labs announced the sale of its Indian API business and women's healthcare business for ~$1.2 B to focus on core areas and reduce debt at the parent level.
- The company derives most of its revenue from regulated markets like the US, Europe, Australia, Japan and emerging markets.

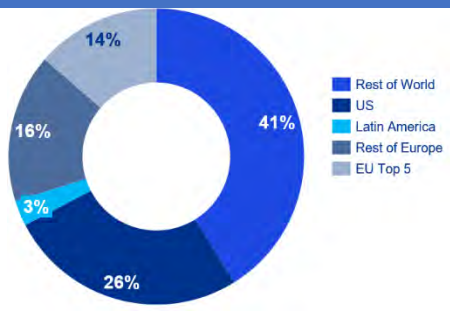
Key Facts

Headquarters: Telangana, India
Company Type: Private Company
Year Founded: 1984
Website: www.viatris.in

Portfolio Overlap with Critical Medicine List (#, %)

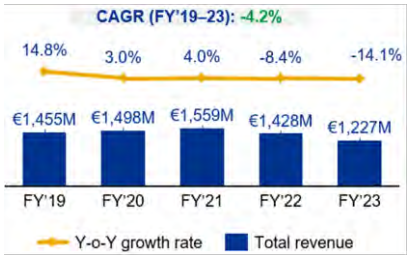
Total	179 (29%)
Vital	38 (26%)
Essential	99 (33%)
Necessary	42 (24%)

Export in Key Regions (Market share by Value – 2024)

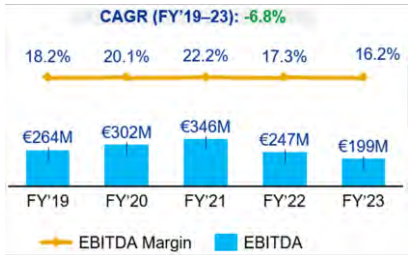


Key Financials

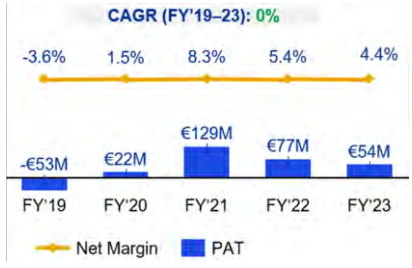
Revenue (€M) and YoY growth (%), FY19–FY23



EBITDA (€M) and EBITDA margin (%), FY19–FY23



Profit after Tax (PAT) (€M) & PAT margin (%), FY19–FY23



Manufacturing Capabilities

- Mylan Labs has 21 manufacturing facilities across India - 6 API facilities, 8 oral solid dosage facilities and 7 injectable facilities.
  - 16 of these, including all 6 API sites, are approved by the US-FDA.
- These include facilities for Active Pharmaceutical Ingredients (API), Oral Solid Dosage (OSD) forms, and injectables. Key locations include Hyderabad, Ahmedabad, and Sarigam.
- Several of these facilities are approved by regulatory bodies such as the USFDA and EU-GMP.
  - US-FDA facilities include their Nashik facility manufacturing tablets and capsules, and their Bangalore facility producing sterile injectables.
- The company's manufacturing network caters to key regulated markets like the U.S., Europe, Japan, Australia as well as emerging markets in Asia, Africa, Middle East, LATAM etc.
- Mylan Labs is one of the world's largest producers of ARV drugs; manufactured at various facilities, including the ones in Nashik and Bangalore.
- Other key drugs produced by Mylan in India include generic versions of medications for cardiovascular diseases, diabetes, and oncology, manufactured at their facilities in Hyderabad, Pithampur, and Hosur.

Note(s): (a) The information provided is based on secondary and primary research; (b) Detailed definitions of key terms for the company profiles are mentioned in the appendix section; (c) Sourced financial information for Indian companies from publicly available data such as annual reports, regulatory filings from the Ministry of Corporate Affairs (MCA), stock exchange disclosures, press releases, direct company communications, proprietary databases, and industry reports; (d) Financial information based on latest available information and for year ending on March 31st. ;Source(s): Company website, Annual Reports, Industry Reports, Capital IQ, EMIS, VCC Edge, APIFDF Data, Secondary Research, External Agency Analysis.

Zydus Lifesciences Limited

Business Overview

- Zydus Lifesciences Limited engages in the research, development, production, marketing, distribution, and sale of pharmaceutical products in India, the United States, and internationally.
- It operates through two business segments: Pharmaceuticals and Consumer Products
- It offers finished dosage human formulations, such as generics; branded generics; specialty formulations, including biosimilars and vaccines; active pharmaceutical ingredients; consumer wellness products; animal healthcare products; and products in the therapeutic areas of pain management, neurology, metabolic disorder, and liver diseases.
- The company was formerly known as Cadila Healthcare Limited and changed its name to Zydus Lifesciences Limited in February 2022.

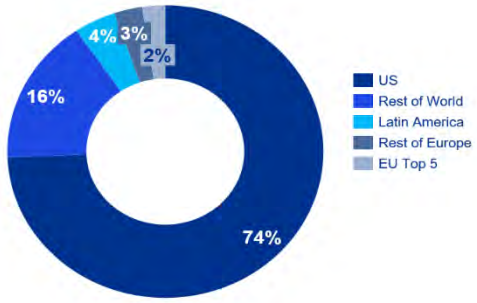
Key Facts

Headquarters: Gujarat, India	
Company Type: Public Company	
Year Founded: 1952	
Website: www.zyduslife.com	

Portfolio Overlap with Critical Medicine List (#, %)

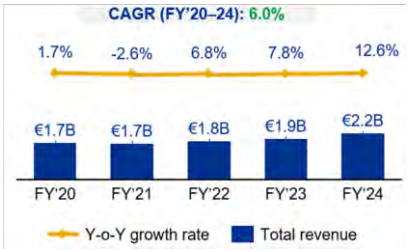
Total	163 (26%)
Vital	28 (19%)
Essential	84 (28%)
Necessary	51 (29%)

Export in Key Regions (Market share by Value – 2024)

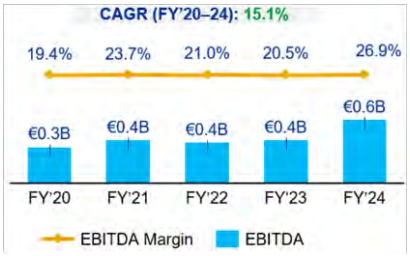


Key Financials

Revenue (€B) and YoY growth (%), FY20–FY24



EBITDA (€B) and EBITDA margin (%), FY20–FY24



Profit after Tax (PAT) (€B) & PAT margin (%), FY20–FY24

Manufacturing Capabilities

Zydus Lifesciences has a robust manufacturing capacity across various dosage forms.

- The company can produce approximately 24 billion tablet units, 6 billion capsule units, 240 million injectable vials, and 1,000 metric tons of APIs annually.

The company operates a total of 37 facilities, with 33 dedicated to finished dosage formulations and active pharmaceutical ingredients (APIs). These facilities are located across India and internationally, and hold various regulatory certifications:

- In India, Zydus Lifesciences has 35 production facilities spread across five states.
  - The company has manufacturing plants for various dosage forms in Ahmedabad, Gujarat, as well as finished dosage and transdermal facilities in Moraiya, Gujarat.
  - Finished dosage plants are also located in Baddi, Himachal Pradesh, and Sikkim.
  - The company operates an injectable facility in Vadodara, Gujarat, an API plant in Dabhasa, Gujarat, and a manufacturing facility in Goa.
- Internationally, Zydus Lifesciences has manufacturing facilities in the United States (Pennington, New Jersey), Portugal, Spain, and Brazil; with eight of the company's finished dosage sites and two of its API manufacturing plants are FDA-approved.
- Most of the facilities also hold EU GMP, Indian FDA, and approvals from TGA (Australia), DMA (Denmark), and WHO certifications.
- Zydus Lifesciences plans to invest INR 4,000 crore for capacity expansion, acquisitions in the US specialty market, and the development of its medical devices business, demonstrating its commitment to growth and diversification.

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Dr. Reddy's Laboratories Limited

Business Overview

- Dr. Reddy's Laboratories Limited operates across three major segments: Global Generics, Pharmaceutical Services and Active Ingredients (PSAI), and proprietary product development.
- With a diverse portfolio including generics, active pharmaceutical ingredients (APIs), biosimilars, and differentiated formulations, DRL has a robust presence across major markets such as North America, India, and Europe, with North America accounting for ~40% of its revenue in FY2023.
- In Europe, DRL has a solid presence and operates through subsidiaries such as Betapharm Arzneimittel GmbH in Germany and Dr. Reddy's Laboratories (UK) Limited.
- The company's key markets include the United States, India, Russia, other EU member countries, and emerging markets, with strategic expansions to tap into new therapeutic areas and markets.

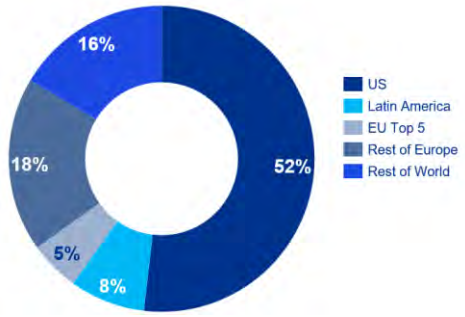
Key Facts

Headquarters: Telangana, India
Company Type: Public Company
Year Founded: 1984
Website: www.drreddys.com

Portfolio Overlap with Critical Medicine List (#, %)

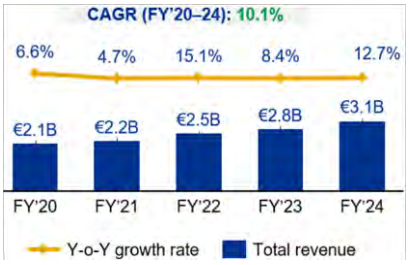
Total	120 (19%)
Vital	21 (14%)
Essential	69 (23%)
Necessary	30 (17%)

Export in Key Regions (Market share by Value – 2024)

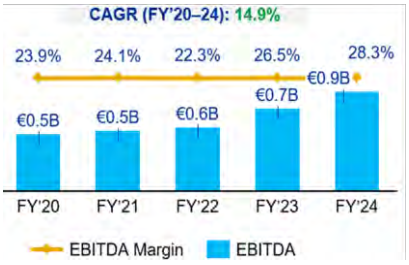


Key Financials

Revenue (€B) and YoY growth (%), FY20–FY24



EBITDA (€B) and EBITDA margin (%), FY20–FY24



Profit after Tax (PAT) (€B) & PAT margin (%), FY20–FY24

Manufacturing Capabilities

Dr. Reddy's Laboratories has a substantial manufacturing capacity and a strong presence in both API and formulation production.

- The company has the capability to produce annually over 250 APIs, with a total reactor volume of 4,100+ KL and 1,250 reactors across four sites.
- Dr. Reddy's produces 5,000+ metric tons of intermediates and 2,100 metric tons of APIs annually, with 90% of the APIs being forward integrated into generic formulations.

The company's manufacturing plants are located in various parts of India and the United States to cater to the company's global market requirements and ensure a consistent supply of high-quality products.

- In Hyderabad, Telangana, India, Dr. Reddy's operates four API plants, including the Bollaram Plant, and one formulations plant in Jeedimetla.
- The company also has two API plants in Andhra Pradesh, India, namely the Pydibhimavaram Plant 1 and the SEZ plant. Another API plant is in Peddadevulapally, Telangana, India.

Note(s): (a) The information provided is based on secondary and primary research; (b) Detailed definitions of key terms for the company profiles are mentioned in the appendix section; (c) Sourced financial information for Indian companies from publicly available data such as annual reports, regulatory filings from the Ministry of Corporate Affairs (MCA), stock exchange disclosures, press releases, direct company communications, proprietary databases, and industry reports; (d) Financial information based on latest available information and for year ending on March 31st. ;Source(s): Company website, Annual Reports, Industry Reports, Capital IQ, EMIS, VCC Edge, APIFDF Data, Secondary Research, External Agency Analysis.

Lupin Limited

Business Overview

- Lupin Limited is a leading global pharmaceutical company operating across segments like generics, branded generics, complex generics, APIs, biosimilars, and specialty medicines.
- It covers major therapy areas such as cardiovascular, diabetes, respiratory, anti-infective, gastrointestinal, CNS, and women's health. Lupin's business includes branded generics, generics, specialty medicines, and APIs, with a strong presence in the Indian Pharmaceutical Market and the US.
- It operates in >100 countries, with significant revenue from India and the US markets. Additionally, Lupin has a notable presence in the European Union, offering a range of products, including biosimilars like Etanercept.

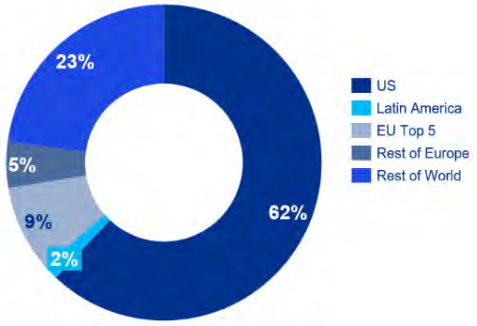
Key Facts

Headquarters: Maharashtra, India
Company Type: Public Company
Year Founded: 1968
Website: www.lupin.com

Portfolio Overlap with Critical Medicine List (#, %)

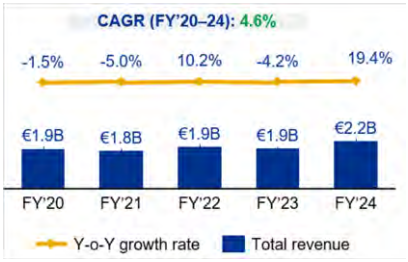
Total	104 (17%)
Vital	23 (16%)
Essential	48 (16%)
Necessary	33 (19%)

Export in Key Regions (Market share by Value – 2024)

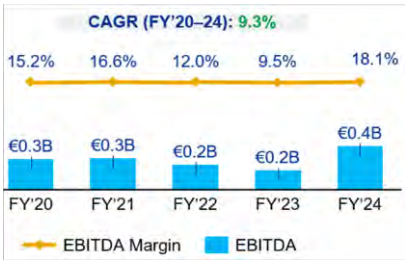


Key Financials

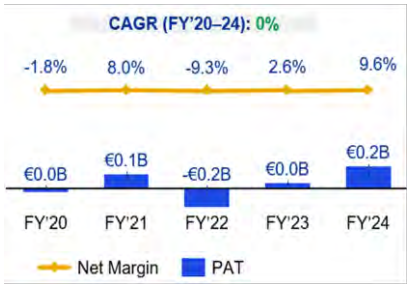
Revenue (€B) and YoY growth (%), FY20–FY24



EBITDA (€B) and EBITDA margin (%), FY20–FY24



Profit after Tax (PAT) (€B) & PAT margin (%), FY20–FY24



Manufacturing Capabilities

Lupin operates a total of 15 manufacturing facilities, with 11 of them being USFDA certified.

- These USFDA-approved facilities are located in Aurangabad, Ankleshwar, Mandideep, Tarapur, Nagpur, Goa, Indore, Pithampur, Sikkim (all in India), Somerset (USA), and Coral Springs (USA).
- Two of Lupin's facilities, one in Pune (Biotech Facility) and another in Aurangabad, have received EU GMP certification.
- Additionally, 12 of Lupin's facilities are ISO 14001 & ISO 45001 certified; These facilities are situated in Aurangabad, Ankleshwar, Mandideep, Tarapur, Nagpur, Goa, Indore, Pithampur, Sikkim, Visakhapatnam, Pune, and Dabhasa.
- Lupin has recently expanded its manufacturing capabilities by adding a high-potency product block at its Indore facility, an MDI plant also in Indore, a Pyrazinamide API block at its Visakhapatnam facility, and OSD formulations and injectables manufacturing at its Nagpur SEZ facility.

Lupin has a significant manufacturing capacity and a wide network of facilities across India and the United States.

- The company's annual manufacturing capacity includes 700m³ of reactors and 4B units of complex formulations.

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Gland Pharma Limited

Business Overview

- Gland Pharma Limited engages in manufacturing and sale of injectable formulations in India, the United States, Europe, Canada, Australia, New Zealand, and internationally.
- The company offers its products for various therapeutic categories, such as anti-malarial, anti-infectives, anti-neoplastic, blood related, cardiac, gastrointestinal, Gynaecological, hormones, Neurology/CNS, ophthalmic/otological, and other areas, as well as pain and analgesics, respiratory, and vitamins, minerals, and nutrients, and contract development services.

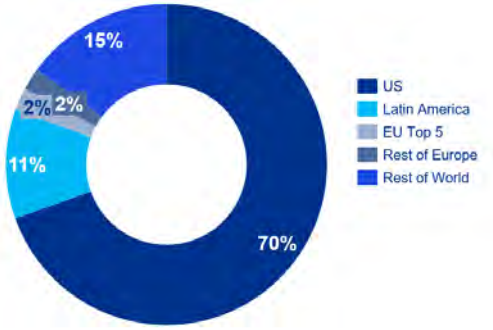
Key Facts

Headquarters: Telangana, India
Company Type: Public Company
Year Founded: 1978
Website: www.glandpharma.com

Portfolio Overlap with Critical Medicine List (#, %)

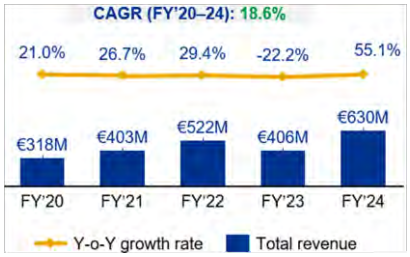
Total	109 (17%)
Vital	40 (27%)
Essential	56 (19%)
Necessary	13 (7%)

Export in Key Regions (Market share by Value – 2024)

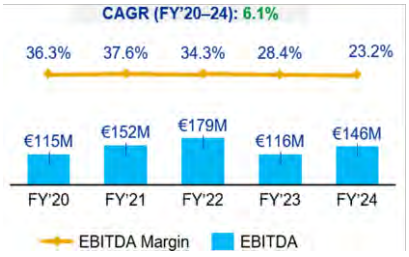


Key Financials

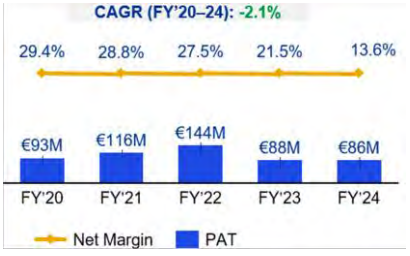
Revenue (€B) and YoY growth (%), FY20–FY24



EBITDA (€B) and EBITDA margin (%), FY20–FY24



Profit after Tax (PAT) (€B) & PAT margin (%), FY20–FY24



Manufacturing Capabilities

Gland Pharma operates a total of four formulation manufacturing facilities and four API manufacturing facilities:

- Gland Pharma's manufacturing facilities are certified by various regulatory bodies.
  - Multiple facilities, including their flagship sterile injectable facility in Dundigal, Hyderabad, and the Pashamylaram facility, are USFDA certified.
  - The oncology facility in Visakhapatnam has received EU GMP certification.
  - The Pashamylaram facility has been inspected and certified by the UK's MHRA.
  - Additionally, Gland Pharma's facilities are also certified by regulatory bodies such as ANVISA (Brazil), TGA (Australia), MCC (South Africa), and Health Canada.

Gland Pharma has a robust annual manufacturing capacity across its facilities for various pharmaceutical dosage forms:

- Injectables:
  - Vials: 383M units per year (Dundigal, Pashamylaram, and Visakhapatnam)
  - Lyophilized units: 79M units per year (Dundigal, Pashamylaram, Penems, and Visakhapatnam)
  - Ampoules: 180M units per year (Dundigal and Pashamylaram)
  - Pre-filled syringes: 60M units per year (Dundigal)
- Ophthalmic products:
  - Ophthalmic units: 45 million units per year (Dundigal)

Note(s): (a) The information provided is based on secondary and primary research; (b) Detailed definitions of key terms for the company profiles are mentioned in the appendix section; (c) Sourced financial information for Indian companies from publicly available data such as annual reports, regulatory filings from the Ministry of Corporate Affairs (MCA), stock exchange disclosures, press releases, direct company communications, proprietary databases, and industry reports; (d) Financial information based on latest available information and for year ending on March 31st. ;Source(s): Company website, Annual Reports, Industry Reports, Capital IQ, EMIS, VCC Edge, APIFDF Data, Secondary Research, External Agency Analysis.

Cipla Limited

Business Overview

- Cipla Limited engages in the manufacture, development, sale, and distribution of pharmaceutical products in India, the United States, South Africa, and internationally.
- The company operates through Pharmaceuticals and New Ventures segments, offering generic and branded generic medicines, vaccines, active pharmaceutical ingredients, and formulations for various therapeutic areas, such as MI, angina, heart disease, pulmonary disease, kidney failure, Alzheimer's disease, hypertension, arrhythmia, lipid abnormalities and diabetes, obesity, central nervous system, HIV/AIDS, respiratory, asthma, urology, oncology, cardio-metabolism, child health, infectious diseases and critical care, hepatitis, women's health, ophthalmology, and neuro psychiatry.
- Cipla's presence in Europe is bolstered by strategic alliances and the adaptation of products to meet the specific regulatory and commercial needs of the European market.

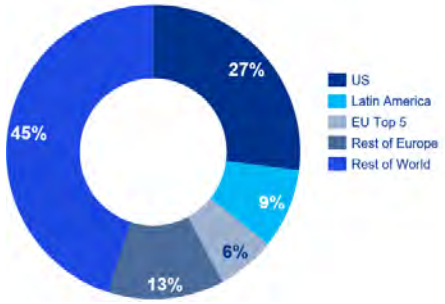
Key Facts

Headquarters: Maharashtra, India
Company Type: Public Company
Year Founded: 1935
Website: www.cipla.com

Portfolio Overlap with Critical Medicine List (#, %)

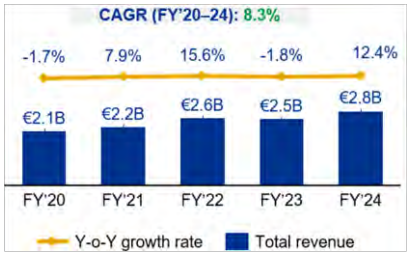
Total	106 (17%)
Vital	23 (16%)
Essential	52 (17%)
Necessary	31 (18%)

Export in Key Regions (Market share by Value – 2024)

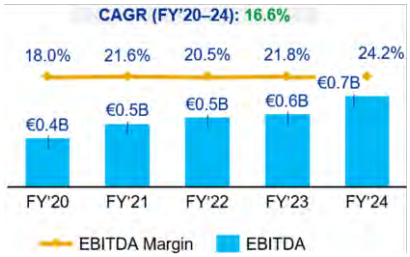


Key Financials

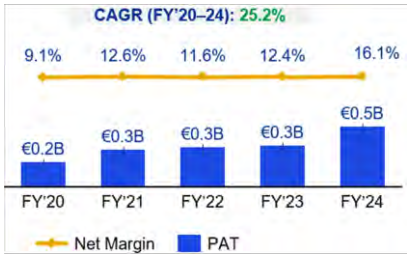
Revenue (€B) and YoY growth (%), FY20–FY24



EBITDA (€B) and EBITDA margin (%), FY20–FY24



Profit after Tax (PAT) (€B) & PAT margin (%), FY20–FY24



Manufacturing Capabilities

Cipla has 46 cGMP-compliant manufacturing facilities spread across five countries - India, the US, South Africa, China, and Uganda

- The company has four cGMP-compliant API manufacturing sites approved by major regulatory agencies, with a total API manufacturing capacity of over 1,000 MT.
- The manufacturing sites in India are located in Maharashtra, Goa, Madhya Pradesh, Karnataka, Himachal Pradesh, and Sikkim
- The company's manufacturing facilities have approvals from major regulators including India's Central Drugs Standard Control Organization, US's Food and Drug Administration (FDA), UK's Medicines and Healthcare Products Regulatory Agency (MHRA), World Health Organisation (WHO), South African Health Products Regulatory Authority, National Medical Products Administration, China, Therapeutic Goods Administration, Australia, and Brazil's National Health Surveillance Agency (ANVISA)

Annual Manufacturing Capacity and Production:

- Tablets, capsules, and oral liquids: 28.3B units (tablets and capsules) + 51.6M units (oral liquids)
- Aerosol pMDI, nasal spray, and respules: 129.1M units (aerosol pMDI) + 43.2M units (nasal spray) + 726.9M units (respules)
- Form fill seal eye drops and lyophilized injections: 0.7M units (eye drops) + 1.9M units (injections)
- APIs: >1,000MT

Note(s): (a) The information provided is based on secondary and primary research; (b) Detailed definitions of key terms for the company profiles are mentioned in the appendix section; (c) Sourced financial information for Indian companies from publicly available data such as annual reports, regulatory filings from the Ministry of Corporate Affairs (MCA), stock exchange disclosures, press releases, direct company communications, proprietary databases, and industry reports; (d) Financial information based on latest available information and for year ending on March 31st. ;Source(s): Company website, Annual Reports, Industry Reports, Capital IQ, EMIS, VCC Edge, APIFDF Data, Secondary Research, External Agency Analysis.

Glenmark Pharmaceuticals Limited

Business Overview

- Glenmark Pharmaceuticals Limited develops, manufactures, and sells generics, specialty products, and OTC pharmaceutical products in India, North America, Latin America, Europe, and internationally.
- The company provides branded and generic formulations in the therapeutic areas of dermatology, respiratory, oncology, cardiology, diabetic, gynecology, gastroenterology, and anti-infective in the dosage forms of complex injectables and biologics, oral solids, liquids, topical products, drops, and respiratory/MDI/DPI/nasal sprays.
- The company also has a strong pipeline of specialty and innovative products, including treatments for multiple myeloma and other cancer.
- Glenmark Pharmaceuticals and its fully owned US subsidiary Ichnos Sciences together have formed an alliance 'Ichnos Glenmark Innovation' to use different modalities, technologies and combined expertise to treat cancer.

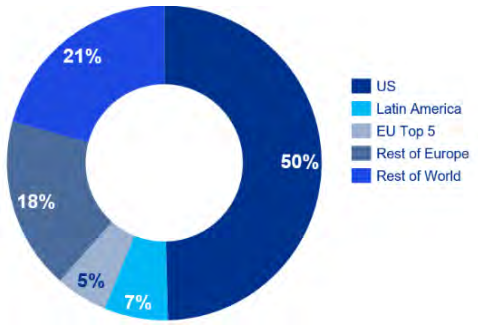
Key Facts

Headquarters: Maharashtra, India	
Company Type: Public Company	
Year Founded: 1977	
Website: www.glenmarkpharma.com	

Portfolio Overlap with Critical Medicine List (#, %)

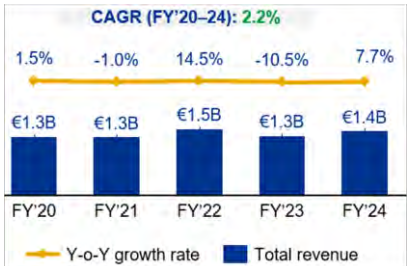
Total	95 (15%)
Vital	13 (9%)
Essential	45 (15%)
Necessary	37 (21%)

Export in Key Regions (Market share by Value – 2024)

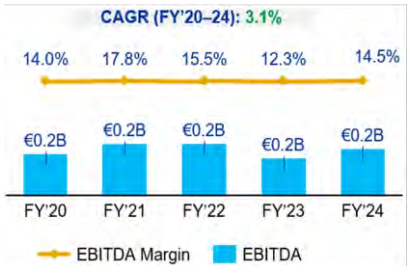


Key Financials

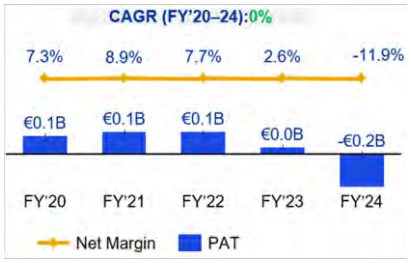
Revenue (€B) and YoY growth (%), FY20–FY24



EBITDA (€B) and EBITDA margin (%), FY20–FY24



Profit after Tax (PAT) (€B) & PAT margin (%), FY20–FY24



Manufacturing Capabilities

Glenmark has 12 cGMP-compliant manufacturing facilities globally, with their market reach spanning North America, Europe, Latin America, Asia, Africa, and CIS/Russia

- These are located in India (Goa (3 facilities), Baddi, Nalagarh, Sikkim, Nashik, Aurangabad, and Indore), the US (Monroe), the Czech Republic (Vysoke Myto), and Argentina (Buenos Aires).
- US FDA Approved: 5 facilities (Monroe (US); Goa, Baddi, Indore, Aurangabad (India)).
- EU GMP Approved: 1 (Vysoke Myto (Czech Republic))
- Other Regulatory Approvals: Facilities in Goa, Baddi, Nalagarh, Buenos Aires, Nashik, Indore, and Aurangabad are approved by CDSCO, WHO-GMP, ANVISA (Brazil), UK MHRA, RU-GMP, ISO 14001:2015, ISO 45001:2018, and others.

Annual Manufacturing Capacity and Production:

- Oral solids: ~11b tablets/capsules annually (~92% production in India (Goa, Baddi, Sikkim, Nashik, Indore, and Aurangabad), rest in Monroe, US (~6%), and Vysoke Myto, Czech Republic (~2%)
- Oral liquids: ~120M units (Baddi, Nalagarh, Nashik (India))
- Semi-solids: ~185 M units (including tubes, sachets, ointments, creams), with facilities in Goa, Baddi, Nalagarh, Nashik, and Indore
- Injectables: ~22-27M units (Most production in US and Argentina (Monroe and Buenos Aires respectively)
- Inhalation products and other specialized formulations: 25-30 Mn ampules, 11 Mn MDIs, 8.4 Mn nasal sprays, and 0.6 Mn topical (Monroe (US) and Aurangabad (India))

Note(s): (a) The information provided is based on secondary and primary research; (b) Detailed definitions of key terms for the company profiles are mentioned in the appendix section; (c) Sourced financial information for Indian companies from publicly available data such as annual reports, regulatory filings from the Ministry of Corporate Affairs (MCA), stock exchange disclosures, press releases, direct company communications, proprietary databases, and industry reports; (d) Financial information based on latest available information and for year ending on March 31st. ;Source(s): Company website, Annual Reports, Industry Reports, Capital IQ, EMIS, VCC Edge, APIFDF Data, Secondary Research, External Agency Analysis.

Sun Pharmaceutical Industries Limited

Business Overview

- Sun Pharmaceutical Industries Limited, a generic pharmaceutical company involved in developing, manufacturing and marketing formulations and APIs.
- Its business is broadly categorized into five segments — India-branded generics, US formulations (generics and speciality branded products), emerging markets (formulations), ROW business, and APIs.
- The company has a diversified presence across ~100 regulated and semi-regulated markets with >60% of its business driven by branded formulations business segments in India and the US
- The company offers formulations in various therapeutic areas, such as cardiology, psychiatry, neurology, gastroenterology and diabetology. It also provides APIs such as warfarin, carbamazepine, etodolac, and clorazepate, as well as anticancers, steroids, peptides, sex hormones, and controlled substances.

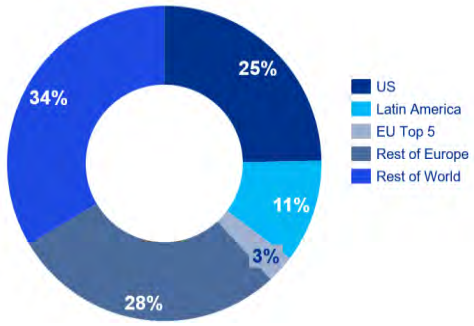
Key Facts

Headquarters: Maharashtra, India
Company Type: Public Company
Year Founded: 1983
Website: www.sunpharma.com

Portfolio Overlap with Critical Medicine List (#, %)

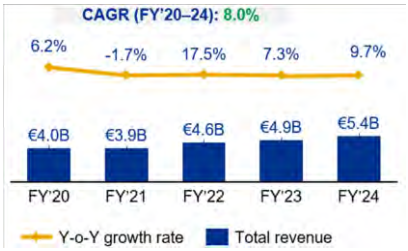
Total	100 (16%)
Vital	25 (17%)
Essential	51 (17%)
Necessary	24 (14%)

Export in Key Regions (Market share by Value – 2024)

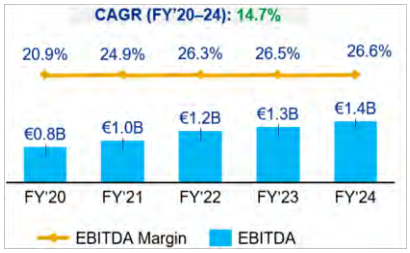


Key Financials

Revenue (€B) and YoY growth (%), FY20–FY24



EBITDA (€B) and EBITDA margin (%), FY20–FY24



Profit after Tax (PAT) (€B) & Net margin (%), FY20–FY24

Manufacturing Capabilities

Sun Pharma operates 41 manufacturing facilities worldwide, including 27 finished dosage facilities and 14 API facilities.

- Finished dosage facilities are located in India (13), US (3), and one each in Canada, Japan, Hungary, Israel, Bangladesh, South Africa, Malaysia, Romania, Egypt, Nigeria, and Russia.
- API facilities are located in India (9), Australia (2), and one each in Israel, USA, and Hungary.
- Their facilities are approved by global regulatory agencies such as USFDA, UK MHRA, EMEA, among others.
- Sun Pharma has the capability to manufacture a variety of dosage forms including orals, creams, ointments, injectables, sprays, and liquids.
- They have over 380 Active Pharmaceutical Ingredients (APIs) in their portfolio, supporting complex formulations.

Note(s): (a) The information provided is based on secondary and primary research; (b) Detailed definitions of key terms for the company profiles are mentioned in the appendix section; (c) Sourced financial information for Indian companies from publicly available data such as annual reports, regulatory filings from the Ministry of Corporate Affairs (MCA), stock exchange disclosures, press releases, direct company communications, proprietary databases, and industry reports; (d) Financial information based on latest available information and for year ending on March 31st. ;Source(s): Company website, Annual Reports, Industry Reports, Capital IQ, EMIS, VCC Edge, APIFDF Data, Secondary Research, External Agency Analysis.

MSN Laboratories Private Limited

Business Overview

- MSN Laboratories Private Limited (MSN Labs) operates in the Active Pharmaceutical Ingredients (API) and Finished Dosage Formulations (FDF) segments, with a focus on complex generics and specialty products.
- The company's therapeutic focus areas include oncology, cardiovascular, central nervous system, gastrointestinal, and anti-diabetic segments.
- MSN Labs has a global presence in over 65 countries, with subsidiaries and offices in the United States, Europe, Latin America, and Asia; The company derives a significant portion of its revenues from regulated markets such as the US and Europe.
- In recent years, MSN Labs has made some acquisitions to expand its geographic reach and product portfolio.
    - In 2020, the company acquired a majority stake in Novadoz Pharma, a US-based generic pharmaceutical company.

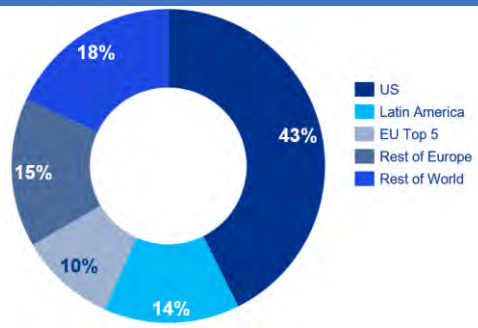
Key Facts

Headquarters: Telangana, India
Company Type: Private Company
Year Founded: 2003
Website: www.msnlabs.com

Portfolio Overlap with Critical Medicine List (#, %)

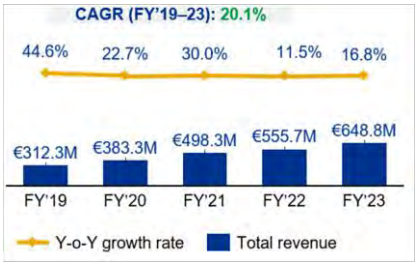
Total	93 (16%)
Vital	19 (14%)
Essential	48 (17%)
Necessary	26 (16%)

Export in Key Regions (Market share by Value – 2024)



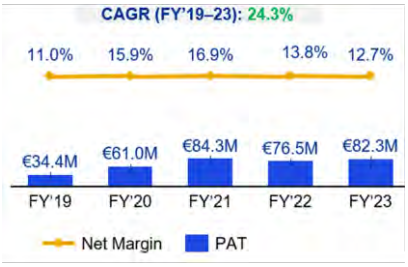
Key Financials

Revenue (€B) and YoY growth (%), FY19–FY23



EBITDA (€B) and EBITDA margin (%), FY19–FY23

Profit after Tax (PAT) (€B) & PAT margin (%), FY19–FY23



Manufacturing Capabilities

- MSN Laboratories operates a total of 20 manufacturing facilities across India. This includes 14 facilities dedicated to Active Pharmaceutical Ingredients (APIs) and 6 facilities focused on finished dosage formulations (FDFs). These facilities are primarily located in and around Hyderabad, Telangana.
- In terms of regulatory compliance, several of these facilities are approved by the United States Food and Drug Administration (USFDA) and the European Medicines Agency (EU GMP), although specific numbers of each were not provided.
- For APIs, MSN Laboratories has a combined reactor capacity of 6551 KL across its 14 facilities, with 1618 reactors installed and plans to add more capacity. The company produces over 450 different APIs, covering various therapeutic categories such as oncology medicines and prostaglandins.
- On the finished dosage front, the 6 formulation plants have the capability to produce a wide range of products, including tablets, capsules, ampoules, and lyophilized vials. The annual production capacity stands at over 5 billion capsules or tablets.

Note(s): (a) The information provided is based on secondary and primary research; (b) Detailed definitions of key terms for the company profiles are mentioned in the appendix section; (c) Sourced financial information for Indian companies from publicly available data such as annual reports, regulatory filings from the Ministry of Corporate Affairs (MCA), stock exchange disclosures, press releases, direct company communications, proprietary databases, and industry reports; (d) Financial information based on latest available information and for year ending on March 31st. ;Source(s): Company website, Annual Reports, Industry Reports, Capital IQ, EMIS, VCC Edge, APIFDF Data, Secondary Research, External Agency Analysis

Hetero Labs Limited

Business Overview

- Hetero Labs Limited (HLL) (the flagship company of the Hetero Group) is a major producer of Active Pharmaceutical Ingredients (APIs) and generic formulations, operating in >140 countries with 30 years of industry experience.
- The company supplies a significant portion (40%) of the global demand for Anti-Retroviral (ARV) APIs and Finished Dosage Forms (FDFs) used in HIV/AIDS treatment.
- HLL offers ~500 products in APIs and formulations across 20 therapeutic areas; Key therapeutic segments include Antiretroviral, Antihypertensive, Antiviral, and Antipsychotic.
- Major markets served are India and the US (~60% of the business), they also cater to other regulated markets such as Europe and rest of the world markets (South Africa, UAE).

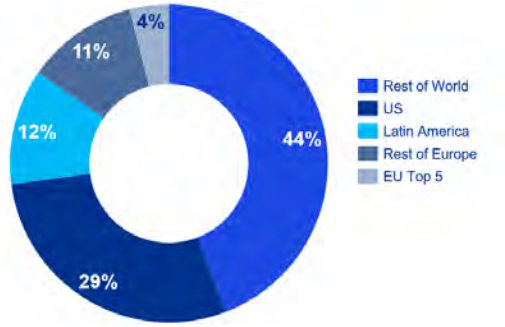
Key Facts

Headquarters: Telangana, India	
Company Type: Private Company	
Year Founded: 1993	
Website: www.hetero.com	

Portfolio Overlap with Critical Medicine List (#. %)

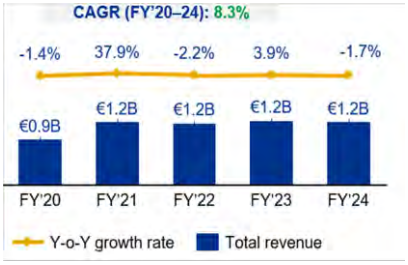
Total	69 (12%)
Vital	4 (3%)
Essential	42 (15%)
Necessary	23 (14%)

Export in Key Regions (Market share by Value – 2024)

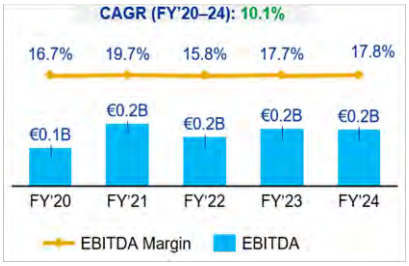


Key Financials

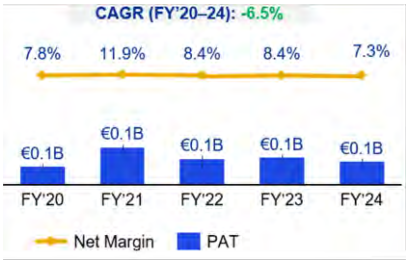
Revenue (€B) and YoY growth (%), FY20–FY24



EBITDA (€B) and EBITDA margin (%), FY20–FY24



Profit after Tax (PAT) (€B) & PAT margin (%), FY20–FY24



Manufacturing Capabilities

- Hetero Labs Limited (HLL) operates over 36 manufacturing facilities across India, USA, China, Russia, Egypt, Mexico, Indonesia, and Saudi Arabia.
- The company's key manufacturing capabilities include API SEZ complex in Visakhapatnam with 1,000+ reactors and an installed capacity of 36,878 MT per annum, as well as the largest Finished Dosage SEZ facility.
- HLL can produce 54 billion tablets, 7 billion capsules, 180 million injectables, and 23 million liquids annually.
- The company's biosimilars facilities have a bioreactor capacity of 10 KL, producing 135 batches, 750 million PFS, 600 million vials, and 120 million vaccine doses per annum.
- Hetero's manufacturing facilities adhere to cGMP and regulatory requirements, with continuous investments in upgradation and advanced technology adoption.

Note(s): (a) The information provided is based on secondary and primary research; (b) Detailed definitions of key terms for the company profiles are mentioned in the appendix section; (c) Sources financial information for Indian companies from publicly available data such as annual reports, regulatory filings from the Ministry of Corporate Affairs (MCA), stock exchange disclosures, press releases, direct company communications, proprietary databases, and industry reports; (d) Financial information based on latest available information and for year ending on March 31st. ;Source(s): Company website, Annual Reports, Industry Reports, Capital IQ, EMIS, VCC Edge, APIFDF Data, Secondary Research, External Agency Analysis.

Piramal Pharma Limited

Business Overview

- Piramal Pharma Limited (PPL) operates as a pharmaceutical company in North America, Europe, Japan, India, and internationally; Piramal Pharma Limited is a part of the Piramal Group, a global business conglomerate.
- PPL includes Piramal Pharma Solutions (PPS), an integrated Contract Development and Manufacturing Organization (CDMO), Piramal Critical Care (PCC), a Complex Hospital Generics business, and the India Consumer Healthcare business selling over-the-counter products.
- The company operates across major therapy areas including critical care, consumer healthcare, and contract development and manufacturing (CDMO).
- The company has a significant geographic reach, with a presence in >100 countries; Major revenue is derived from markets in North America, Europe, and Asia

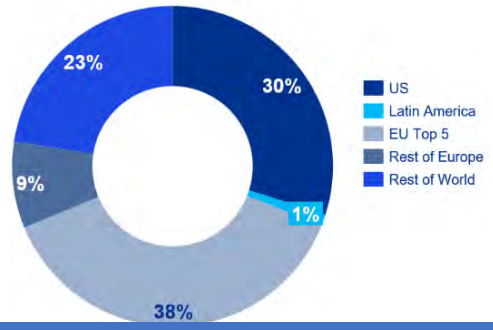
Key Facts

Headquarters: Maharashtra, India	
Company Type: Public Company	
Year Founded: 2020	
Website: www.piramalpharma.com	

Portfolio Overlap with Critical Medicine List (#, %)

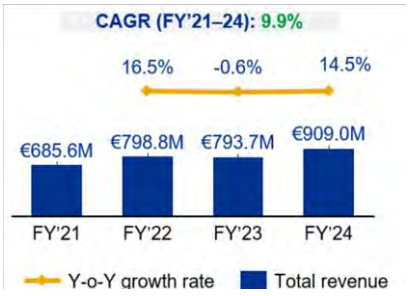
Total	32 (6%)
Vital	8 (6%)
Essential	12 (4%)
Necessary	12 (7%)

Export in Key Regions (Market share by Value – 2024)

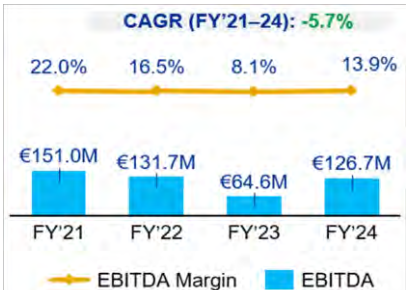


Key Financials

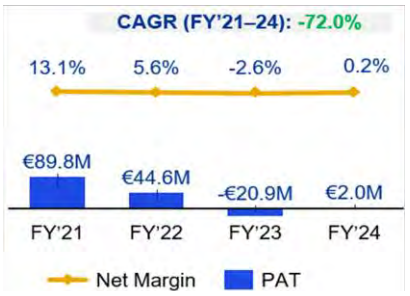
Revenue (€M) and YoY growth (%), FY21–FY24



EBITDA (€M) and EBITDA margin (%), FY21–FY24



Profit after Tax (PAT) (€M) & PAT margin (%), FY21–FY24



Manufacturing Capabilities

Piramal Pharma has extensive and diversified manufacturing capabilities across multiple dosage forms, spread over its global network of 15 facilities.

- 8 facilities in India, 4 in the US, 1 in Canada, 2 in the UK
- USFDA approved facilities (6): Pithampur, Lexington, Sellersville, Digwal, Riverview, Aurora
- EU approved facilities (3): Pithampur, Morpeth, Grangemouth
- WHO-GMP approved facilities (3): Mahad, Turbhe, Ennore

Annual Manufacturing Capacity Details:

- Oral solid dosage forms: Capacity to produce ~3B tablets per year.
- Injectable formulations: Facilities equipped to manufacture vials and lyophilized vials.
- Liquid, cream, and ointment formulations: Manufacturing capabilities for these dosage forms.
- Active Pharmaceutical Ingredients (APIs): API manufacturing reactor capacity exceeds 1200 KL; Specialized manufacturing capabilities include high potency APIs, peptide APIs, and antibody-drug conjugates.
- Piramal Critical Care (PCC) is a business unit of Piramal that focuses on the manufacturing and distribution of complex hospital generics with a portfolio comprising of ~35 hospital-focused products in the areas of inhalation anesthesia, injectable anesthesia, pain management, and intrathecal therapy.

Note(s): (a) The information provided is based on secondary and primary research; (b) Detailed definitions of key terms for the company profiles are mentioned in the appendix section; (c) Sources financial information for Indian companies from publicly available data such as annual reports, regulatory filings from the Ministry of Corporate Affairs (MCA), stock exchange disclosures, press releases, direct company communications, proprietary databases, and industry reports; (d) Financial information based on latest available information and for year ending on March 31st. ;Source(s): Company website, Annual Reports, Industry Reports, Capital IQ, EMIS, VCC Edge, APIFDF Data, Secondary Research, External Agency Analysis.

Teva Pharma India Pvt. Ltd.

Business Overview

- Teva India, a subsidiary of Teva Pharmaceutical Industries Ltd., has been operating in India for more than 20 years.
- The company produces a wide range of generic medicines, active pharmaceutical ingredients (APIs), and specialty medicines for various therapeutic areas such as neurology, respiratory, and oncology.
- Teva India serves both domestic and international markets, exporting products to North America, Europe, Asia-Pacific, the Middle East and Africa, Latin America, and Russia and Eastern Europe, significantly contributing to Teva's global supply chain.
- Teva acquired Regent Drugs Limited, a subsidiary of the JK Group, in July 2003 for around $10 million. This gave Teva an API manufacturing plant in Gajraula and a small R&D unit in Faridabad.

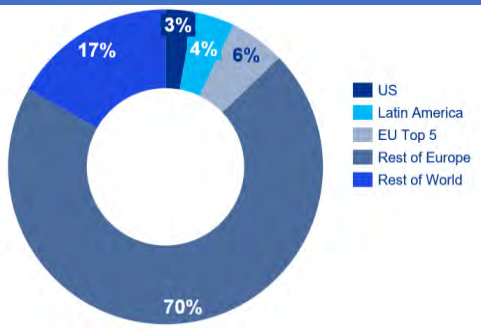
Key Facts

Headquarters: Maharashtra, India
Company Type: Private Company
Year Founded: 2000
Website: www.tevapharm.in

Portfolio Overlap with Critical Medicine List (#, %)

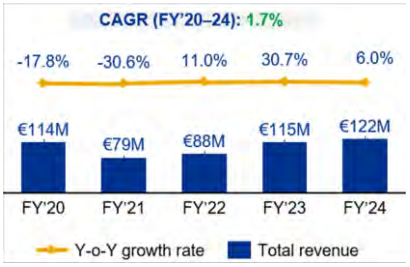
Total	25 (4%)
Vital	4 (3%)
Essential	17 (6%)
Necessary	4 (2%)

Export in Key Regions (Market share by Value – 2024)

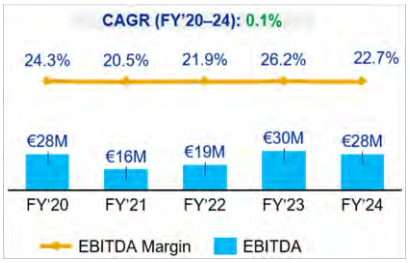


Key Financials (Global)

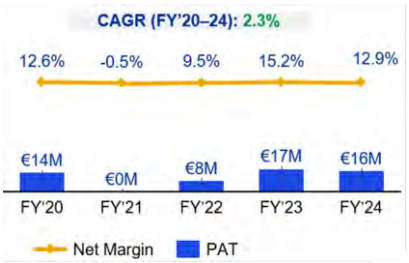
Revenue (€M) and YoY growth (%), FY20–FY24



EBITDA (€M) and EBITDA margin (%), FY20–FY24



Profit after Tax (PAT) (€M) & PAT margin (%), FY20–FY24



Manufacturing Capabilities

Teva India has five manufacturing plants located in Gajraula (Uttar Pradesh), Malanpur (Madhya Pradesh), Ambernath (Maharashtra), and two additional plants in Goa.

- API Plants: Three API manufacturing plants are located in Gajraula, Malanpur, and Ambernath.
- Finished Dosage Form (FDF) Plants: Two plants in Goa focus on producing pharmaceutical formulations.
- USFDA: Several facilities are certified – for e.g. the Gajraula was FDA approved in 2005.
- EU GMP: The API plants in Gajraula, Malanpur, and Ambernath meet EU Good Manufacturing Practices.
- Other Certifications: Facilities are also certified by WHO GMP, UK MHRA, TGA Australia, AFSSAPS, KFDA, and the German Ministry of Health.

Annual Capacity:

- Finished Pharmaceutical Formulations: The Goa plants have an annual production capacity of 7.2B units, which includes 150 licensed generic and specialty medicines.
- API Production: The facilities in Gajraula, Malanpur, and Ambernath contribute significantly, producing 40 APIs and advanced intermediates such as statins, sartans, and antifungal agents.

Note(s): (a) The information provided is based on secondary and primary research; (b) Detailed definitions of key terms for the company profiles are mentioned in the appendix section; (c) Sources financial information for Indian companies from publicly available data such as annual reports, regulatory filings from the Ministry of Corporate Affairs (MCA), stock exchange disclosures, press releases, direct company communications, proprietary databases, and industry reports; (d) Financial information based on latest available information and for year ending on March 31st. ;Source(s): Company website, Annual Reports, Industry Reports, Capital IQ, EMIS, VCC Edge, APIFDF Data, Secondary Research, External Agency Analysis.

Appendix

Company Detailed Profiles Definitions and Notes:

1. **Portfolio Overlap with Critical Medicine List (#, %):**
   This term refers to the number and percentage of a company's products that overlap with the critical medicine list, based on historical export data from 2020-2024 obtained from the APIFDF database. The overlap is further categorized into vital, essential, and necessary medicines. In cases where there is an overlap for both formulations and APIs, the overlap for formulations has been stated.

2. **Exports in Key Regions:**
   This term indicates the key regions outside India to which a company's products were exported, based on the 2024 export value from the APIFDF database. It is important to note that this data may vary from a company's internal data.

3. **Key Financials:**
   This term refers to the financial information of Indian companies sourced from publicly available data such as annual reports, regulatory filings from the Ministry of Corporate Affairs (MCA), stock exchange disclosures, press releases, direct company communications, proprietary databases, and industry reports. The financial information is based on the latest available data and for the financial year ending on March 31st. The definitions of the financial terms are as follows:
   - Revenue: The total income generated by a company from its business activities.
   - EBITDA: Earnings Before Interest, Taxes, Depreciation, and Amortization, which is a measure of a company's operating performance.
   - PAT: Profit After Tax, which is the net profit earned by a company after deducting all expenses, including taxes.
   - EBITDA Margins: The ratio of EBITDA to revenue, expressed as a percentage.
   - PAT Margins: The ratio of PAT to revenue, expressed as a percentage.
   - CAGR: Compound Annual Growth Rate, which measures the annual growth rate of a company's financials over a specified period. In cases where the base year value is negative, the CAGR has been reported as '0'.

   All financial figures have been converted to Euros based on historical exchange rates.

4. **Manufacturing Capabilities:**
   This term refers to a company's manufacturing facilities, capacities, and certifications, as sourced from company websites, industry reports, and primary interviews. It is important to note that the actual manufacturing capabilities may differ from the reported data due to various factors, such as recent expansions, upgrades, or changes in manufacturing processes.