Cipla Ltd

HQ: Mumbai, India • Ticker: CIPLA • Stock exchange: NSE • Nr. of employees: 26,615

COMPANY SUMMARY

Cipla has a broad portfolio of off-patent medicines covering a diversity of therapeutic areas, and manufactures products at 47 sites across the world. The company's access efforts encompass its corporate social responsibility activities and its "Cipla Global Access" business, through which it collaborates with international organisations and procurement agencies to supply essential medicines to low- and middle-income countries (LMICs). Cipla registers its products across a variety of LMICs, including low-income countries. Cipla expands access to its products by engaging in competitive tenders by governments and hospitals, while adhering to local pricing policies and competitor-based pricing strategies in the private sector. Cipla has signed licensing agreements that allow the company to market generic products in LMICs to treat diseases such as HIV and COVID-19. Cipla implements forecasting mechanisms and promotes supplier diversity, among other strategies, to ensure continuous product supply and mitigate shortages. Cipla reports one example of an adaptive R&D project, consisting of a paediatric fixed-dose combination of four antiretrovirals, which can simplify dosage and improve treatment adherence.

Main therapeutic areas
Cardiovascular diseases; infectious diseases; metabolic disorders; oncology; respiratory diseases; dermatology; gastrointestinal; urology; central nervous system.

Business segments
New Ventures; Pharmaceuticals.

Product categories
Active pharmaceutical ingredients (APIs); biosimilars; consumer health products; generic medicines.

Sales presence*
Cipla reports sales in 26 countries in scope.

OPPORTUNITIES FOR CIPLA

Expand efforts to ensure product availability in sub-Saharan Africa.
Cipla has made a commitment to improve product availability by strengthening its local manufacturing presence, incorporating this commitment into its business strategy for the SAGA region.** Cipla can deliver on this commitment by expanding in-house manufacturing and by engaging in the transfer of skills to local manufacturers to develop and strengthen capacity for manufacturing products targeting high burden diseases in the region.

Continue to engage in adaptive R&D to develop products that address R&D priority gaps.
Cipla has partnered with the Drugs for Neglected Diseases initiative (DND*i*) to produce a 4-in-1 fixed-dose combination for the treatment of HIV in children. The company can continue to leverage its R&D expertise to adapt products targeting diseases with high burden in LMICs, where treatment options are ineffective or lacking, such as paediatric formulations.

Expand registration and affordability of essential cancer products.
Cipla can expand access to essential cancer products in its portfolio by pursuing broader registration filings in LMICs, particularly in high-burden and low-income countries. For cisplatin and carboplatin, indicated for various cancers including cervical cancer, Cipla can file for registration in LMICs with high cervical cancer burdens where it has previously registered other products in its portfolio including Botswana, Suriname, and Zimbabwe. Moreover, in the countries where these cancer treatments are already registered, Cipla can prioritise implementing access strategies, using approaches that include elements to address affordability, supply, and local barriers to access. Cipla can apply such strategies to expand access to cisplatin in Nepal, which is a country where Cipla has registered the product; cervical cancer is prevalent; and the majority of patients pay out-of-pocket.

Expand engagement in voluntary licensing agreements.
As a sublicensee in various licensing agreements, Cipla is following through on its commitments to register in-licensed products in LMICs in scope. Cipla can build on these efforts by continuing to register products like dolutegravir in more countries, especially to reach children and young women living with HIV. Having recently signed a non-exclusive licence for cabotegravir long-acting, used for HIV pre-exposure prophylaxis (PrEP), Cipla can ensure broad registration in countries with high HIV burden, once possible. The company can also explore engaging in additional voluntary licensing agreements across other therapeutic areas, including non-communicable diseases, when relevant.

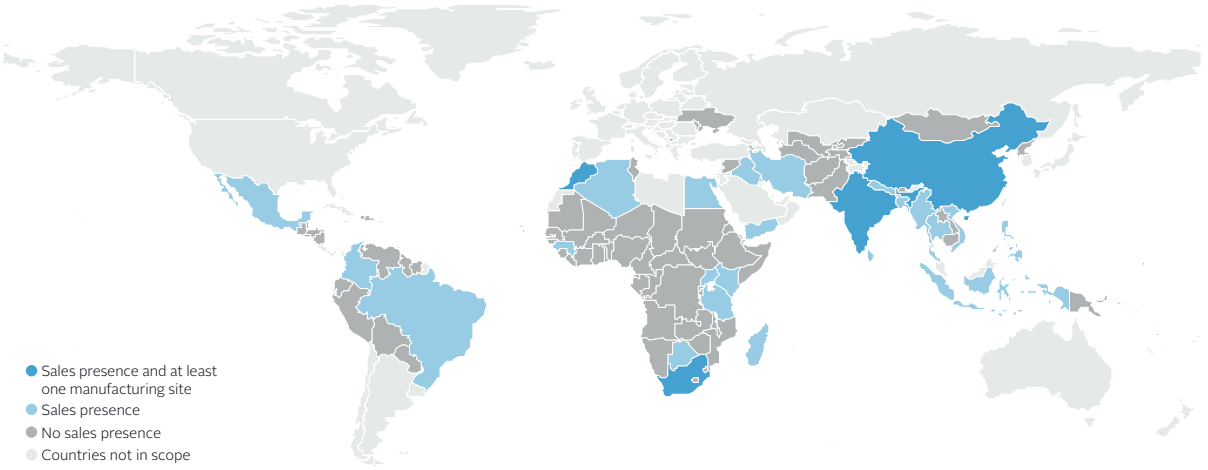
*Refers to countries in which sales are conducted through suppliers, pooled procurement and/or the company sales offices.

**South Africa, sub-Saharan Africa, and the countries covered by the Cipla Global Access business.

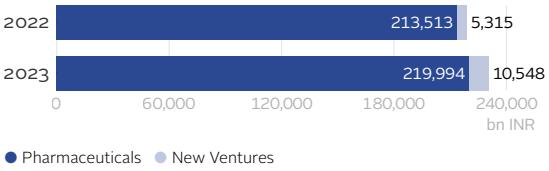
Cipla exclusively submitted data for the evaluation of themes EA2, EA3, EA4, RD1 and RD2. All other information was initially sourced from publicly available data and subsequently fact checked by the company.

COMPANY PRESENCE & REVENUE

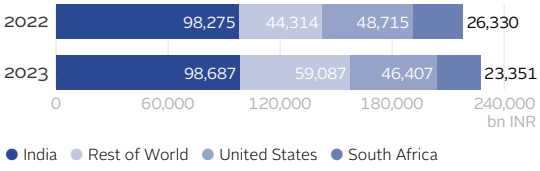
Sales and manufacturing presence in countries in scope



Revenue by business segment*



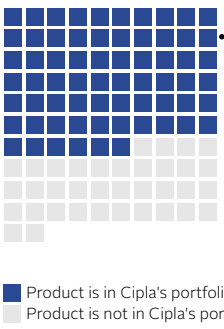
Revenue by region*



PORTFOLIO & PRODUCTS ANALYSED

Products in scope from the company's portfolio

Out of the 102 products in scope of this analysis,** Cipla has 66 products within its portfolio. Cipla's portfolio has a strong focus on non-communicable diseases (NCDs), as well as communicable diseases (CDs) including bacterial infections, HIV and hepatitis B and C.



66 products
These target a range of disease categories, namely NCDs (40), CDs (21), neglected tropical diseases (3) and reproductive, maternal and newborn conditions (4). Two products fall into multiple categories.

Products selected for assessment

Of the in-scope products that Cipla has in its portfolio, ten off-patent medicines were selected for analysis for the themes EA2 (product registration) and EA3 (expanding access and pricing strategies).

Product	Indication
Carboplatin	Cancer
Cisplatin	Cancer
Rituximab	Cancer
Telmisartan	Hypertensive heart disease
Formoterol/budesonide	Asthma
	Chronic obstructive pulmonary disease (COPD)
Salbutamol	Asthma
	COPD
Metformin	Diabetes mellitus
Nitrofurantoin	Bacterial infection
Abacavir/lamivudine (ABC+3TC)	HIV
Sofosbuvir	Hepatitis C

*Financial year (FY) 2022 covers April 2021 - March 2022. FY 2023 covers April 2022 – March 2023.

**The Generic & Biosimilar Medicines Programme's product scope includes 102 off-patent medicines, most of which are listed on the 22nd World Health Organization's Model List of Essential Medicines. Essential medicines are those that satisfy the priority health care needs of a population.

EXPANDING ACCESS

EA1. ACCESS-TO-MEDICINE STRATEGY

Cipla commits to ensuring access to its medicines globally and reports working towards improving their availability and affordability, but does not present evidence of an overarching access-to-medicine strategy. The company's Corporate Social Responsibility (CSR) division carries out its activities through the Cipla Foundation, the company's philanthropy arm, and focuses on five key areas: health, education, environmental sustainability, disaster response activities and skillset development. Additionally, through its "Cipla Global Access" (CGA) business, the company expands access to products, including those targeting HIV, tuberculosis, and malaria, by working with international and donor organisations to supply essential medicines in LMICs. CGA also collaborates with procurement agencies to identify reliable suppliers and ensure efficient delivery of medicines. While the board approves and monitors the company's CSR activities, Cipla does not report where the highest responsibility lies for ensuring access to medicine in LMICs. Moreover, the company identifies availability and affordability of its medicines as a high-priority topic in its recent materiality assessment, providing evidence of supplying medicines for affordable prices. For example, since 2001 it offers a one-dollar-a-day treatment for HIV patients in Africa. Although access considerations guide some of the company's activities, it does not disclose measurable and time-bound objectives for its access-to-medicine commitments, nor specific strategies to ensure sustainable access and expand patient reach.

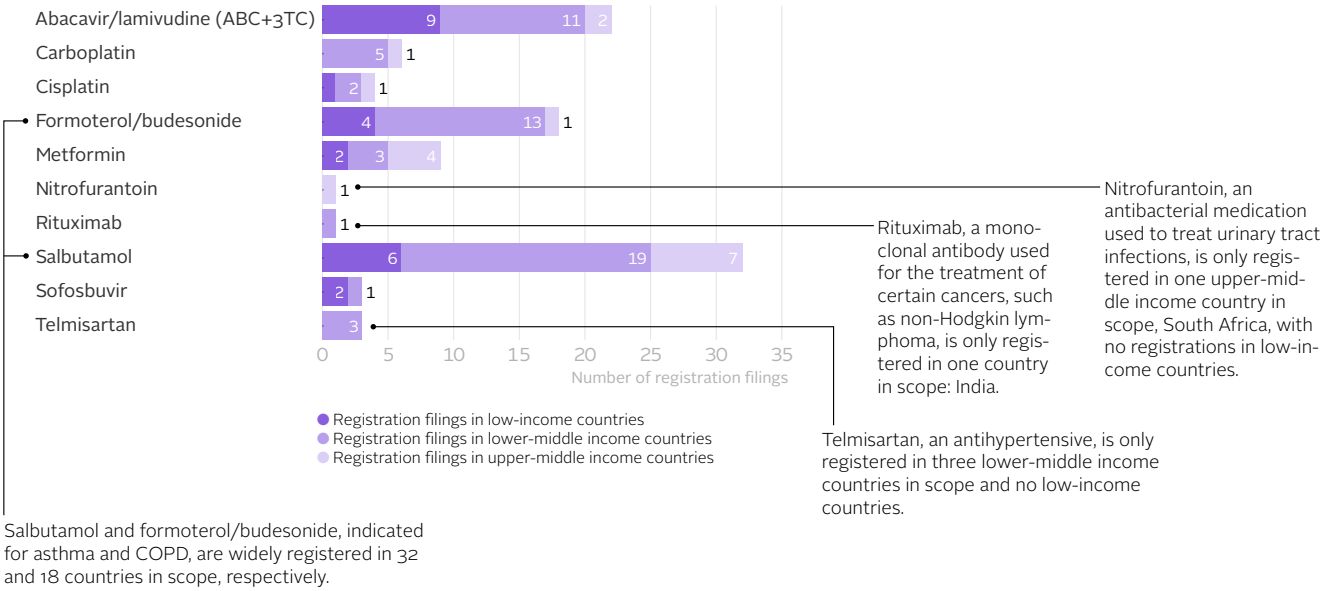
EA2. PRODUCT REGISTRATION

Cipla has filed to register or successfully registered at least one product within its entire portfolio in 61 LMICs in scope. This demonstrates the company's ability to register products with national regulatory authorities (NRAs) in LMICs in scope.

Of the products within the scope of the Generic & Biosimilar Medicines Programme, ten off-patent medicines were selected for assessment. Cipla has filed at least one of these products for registration in a total of 48 out of the 61 LMICs (79%) where it has pre-existing regulatory filings,* showing the company's capacity to register across a wide geographic area. These ten products have all been registered in at least one country in scope, with one product registered in a total of 32 countries. For low-income countries, the company registers the ten products selected for assessment in 14 out of the 15 low-income countries where it has pre-existing regulatory filings.* This is significant as in general regulatory filings in these countries are low, and significant gaps in access to essential medicines remain.** However, carboplatin, rituximab, telmisartan and nitrofurantoin were not registered in any low-income countries. The company engages in mechanisms designed to facilitate the registration of quality-assured products in LMICs. Several of the company's products have been registered in the AFRO*** region and Ukraine through the World Health Organization (WHO) Collaborative Registration Procedure (CRP) for WHO Prequalified products, including products to treat HIV, hepatitis C, malaria, soil-transmitted helminthiasis, maternal haemorrhage, and tuberculosis. Examples of such products are fixed-dose antiretroviral combinations abacavir/lamivudine and dolutegravir/lamivudine/tenofovir disoproxil fumarate to treat HIV, along with an emergency contraceptive method, levonorgestrel. Moreover, five of the company's products (outside the product scope of this analysis) have been recommended for approval by ZaZiBoNa.†

In April 2021, the company's subsidiary Cipla Quality Chemical Industries Limited (CiplaQCIL), based in Uganda, was approved to manufacture and distribute medicines to the Economic Community of West African States and ZaZiBoNa regions in Africa. In March 2023, the company announced it would be divesting its stake in CiplaQCIL. The impact of this divestment is unknown, however, Cipla reports that they have reached mutual agreements with CiplaQCIL for transition and technology support, ensuring business continuity for the near and medium term.

FIGURE 1 **Registration filings of ten products selected for assessment across income categories**
This figure shows the number of registrations for the ten off-patent products included in this assessment, categorised by whether the filing is in a low-, lower-middle or upper-middle income country.



*Refers to all the countries in scope where the company has previously filed for or successfully registered any of its products. This includes products that fall outside the scope of the Generic & Biosimilar Medicines Programme.

**Based on data analysed in the 2022 Access to Medicine Index and the 2021 Antimicrobial Resistance Benchmark.

***AFRO region includes countries including but not limited to: Botswana, Democratic Republic of the Congo, Ghana, Malawi, Mozambique, Namibia, Nigeria, Tanzania, Uganda, Zambia and Zimbabwe

†ZaZiBoNa process is a work-sharing initiative amongst national regulatory authorities (NRAs) in Zambia, Zimbabwe, Botswana, Namibia, South Africa, Democratic Republic of Congo, Tanzania, Malawi and Mozambique.

EXPANDING ACCESS

EA3. EXPANDING ACCESS AND PRICING STRATEGIES

Seven out of the ten products selected for assessment are covered by an access strategy in the public and/or private market. Cipla submitted examples of access strategies for its products in a range of country income classifications, with examples provided from three upper-middle income countries, one lower-middle income country and three low-income countries. For the country examples provided, the company primarily participates in government tenders to facilitate access to its products within the public sector. In the private sector, Cipla adheres to local pricing policies and employs competitor-based pricing strategies to determine the pricing of its products. However, the company only provides evidence of the number of patients reached for one product, and it does not provide evidence of forecasting patient reach for any of the ten products.

For one of the products, sofosbuvir, indicated for hepatitis C, the company participates in tenders to supply the product in the public sector in several countries; this includes Rwanda, which was selected as a specific country example. In Rwanda, the product is fully funded by the government, meaning that individual patients do not have to pay for their treatment.

For three of the ten products assessed (metformin, nitrofurantoin and salbutamol), Cipla reports implementing access strategies in both the public and private sectors within South Africa. In the public sector, the company supplies the three products via government tenders which are awarded based on the lowest pricing, and the entire cost is government funded. In the private sector, the company implements competitor-based pricing strategies. The resulting price is then submitted to the Department of Health, which approves the final price (the single exit price) at which the company sells the products. The product's price is covered by private insurance, either fully or partially, depending on the plans to which the patient is subscribed. Patients not part of a private scheme will pay out-of-pocket for their medicines, and it is unclear if the product is affordable for these patients. Furthermore, the success of these tender strategies remains uncertain due to the lack of evidence regarding the number of patients reached by such initiatives.

Cipla supplies abacavir/lamivudine (ABC + 3TC) in 20 countries, in which its access strategies are primarily focused on the public sector. Of these, Benin, a low-income country, has been selected as an example for this analysis. In Benin, the company supplies the product via participating in tenders issued by the government or by international agencies, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund). By engaging in supranational procurement, Cipla aims to expand access to affordable, quality-assured products while reducing commercial risks. The company supplies products below agency-set ceiling prices, with tender allocation based on factors including competitive pricing, delivery timeline and minimum procurement quantities. Cipla submitted patient reach data for abacavir/lamivudine (ABC+3TC), using the volume of tablets supplied as a metric for number of patients reached. In the period from April 2019 to July 2023, the company provided a total of 1.6 million tablets in Benin. Across the 20 countries it supplies, the company supplied 180 million tablets between January 2020 and April 2023.

For two of the ten products assessed, formoterol/budesonide and telmisartan, the examples of access strategies submitted – in Zambia and Madagascar, respectively – only cover patients in the private sector. In these countries, the price of each product is set based on the competitor landscape, and patients have to pay out of pocket. Furthermore, the company did not provide evidence of patient reach, therefore it is unclear if the company has ensured access to the two products in the countries where it operates.

FIGURE 2 **How many products are covered by an access strategy?**

For each of the ten products selected for assessment, Cipla was requested to provide one example of a country-specific access strategy covering that product. The company was asked to include examples from a minimum of three low-income countries (LICs) and three lower-middle income countries (LMICs). Further examples could come from upper-middle income countries (UMICs). The types of access strategies the company utilises for each product are outlined in this figure. Where details on country-specific access strategies were not shared, the company was not assessed.

International Nonproprietary Name (INN)	Country	Public market access/pricing strategies	Private market access/pricing strategies	Evidence of patient reach	Evidence of forecasting patient reach	Additional initiatives to improve affordability and availability*
Abacavir/lamivudine (ABC+3TC)	Benin (LIC)	●		●		
Carboplatin	No country-specific access strategy					
Cisplatin	No country-specific access strategy					
Formoterol/budesonide	Madagascar (LIC)		●			
Metformin	South Africa (UMIC)	●	●			
Nitrofurantoin	South Africa (UMIC)	●	●			
Rituximab	No country-specific access strategy					
Salbutamol	South Africa (UMIC)	●	●			
Sofosbuvir	Rwanda (LIC)	●				
Telmisartan	Zambia (LMIC)		●			

For three assessed products, carboplatin, cisplatin, rituximab, Cipla did not provide evidence of expanding access within LMICs in scope.

*For example: donations, public-private partnerships, or patient assistance programmes.

EXPANDING ACCESS

EA4. ENGAGING IN LICENSING ACTIVITIES

Five in-licensed products were selected for assessment: dolutegravir (adult) and lopinavir/ritonavir (paediatric), indicated for HIV; dulaglutide, indicated for type 2 diabetes; and molnupiravir and remdesivir, indicated for COVID-19.

Cipla was granted a non-exclusive voluntary licensing agreement (NEVL) for dolutegravir (adult) facilitated through the Medicines Patent Pool (MPP). The company has registered this product in 22 countries in scope, including Mozambique, Zambia and Zimbabwe, three of the ten countries with the highest disease burden for HIV. The company supplied approximately 25 million tablets in countries in scope and has supplied over one billion doses of the fixed dose combination (FDC) tenofovir, lamivudine, and dolutegravir globally.

The company has an exclusive licensing agreement with Eli Lilly to market and distribute Trulicity® (dulaglutide), a treatment for type 2 diabetes, in India.* Eli Lilly is responsible for manufacturing the product and is the primary marketing authorisation holder, with Cipla being the second. It was reported that 142,800 units of Trulicity® were sold from June 2022 to June 2023.

Examples of Cipla's licensing agreements

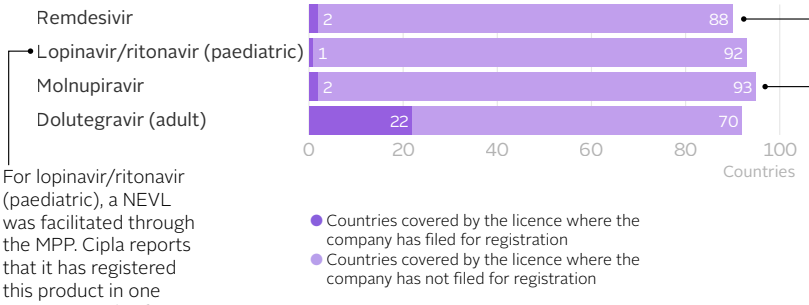
In March 2023, Cipla entered into a NEVL with ViiV Healthcare, facilitated by the MPP, for cabotegravir (CAB) long acting (LA) for HIV pre-exposure prophylaxis (PrEP) which will be manufactured in India and South Africa. An extended-release formulation of CAB, the first long-acting injectable for HIV PrEP, was approved in 2021. This extended dosing regimen, administered through a single injection every two months, offers a convenient alternative to daily oral medication, by reducing dosing frequency and improving treatment adherence and administration challenges in LMICs. The agreement allows three generic manufacturers to develop, manufacture, and supply generic versions in 87 countries in scope, prior to patent expiry of the original drug in 2031.

Cipla and ViiV Healthcare also signed an MPP licence for dolutegravir (paediatric), the terms of which also allows licensees to combine dolutegravir with other antiretrovirals to develop fixed dose combinations.

In December 2022, Cipla received approval from the Global Fund for abacavir, lamivudine and dolutegravir FDC for use in children.

FIGURE 3 **Registration filings of Cipla's in-licensed products****

This figure shows the number of LMICs in scope where Cipla has filed for registration or registered four in-licensed products out of the five selected for assessment, compared to the total number of countries covered by the licensing agreement.*



For lopinavir/ritonavir (paediatric), a NEVL was facilitated through the MPP. Cipla reports that it has registered this product in one country, South Africa.

Cipla was granted NEVLs for two COVID-19 products, molnupiravir and remdesivir. Several factors including clinical guidelines and widespread rollout of COVID-19 vaccinations reduced demand for these products and as a result both products were only registered in Thailand and Indonesia. However, the company retains the right to register and supply these products, should the need arise.

EA5. IMPROVING PRODUCT AVAILABILITY

Cipla's manufacturing network consists of 47 sites globally, with several sites located in LMICs in scope, including China, India, Morocco and South Africa. As part of its three-year (2020-2023) business strategy within its SAGA*** region, covering countries across the African continent, Cipla aims to improve product availability by strengthening its local manufacturing presence through expansions and optimisations of its existing sites and by developing new sites. As part of this strategy, it also states that it aims to maintain its focus in sub-Saharan Africa by growing and launching new products, including cardiovascular and respiratory therapies. For 2023-2024, the company reports that it aims to strengthen its private market position in the region and is planning new product launches targeting cardiovascular diseases and diabetes.

Cipla reports market growth in certain African countries. For instance, in South Africa, the growth appears to be driven by products in the private market, including those targeting neurological and respiratory diseases. Cipla has also reported a strong presence in Kenya, where it markets a branded fixed-dose antidiabetic medication, and it has entered the market in Ghana, following recent regulatory approvals.

In 2014, Cipla acquired a stake in Quality Chemical Industries Limited (QCIL) in Uganda, which has served as a hub to supply antiretrovirals (ARVs), antimalarials and hepatitis B products in the country and the region. However, in March 2023 it was announced that Cipla will divest its stake in QCIL, with the site ceasing to be a subsidiary of the company. Cipla and QCIL have established transition agreements for short and medium-term business continuity. The extent of Cipla's continued manufacturing and supply presence in the region remains uncertain. Furthermore, Cipla commissioned a new manufacturing site during 2021 - 2022 in Qidong, China to manufacture respiratory products for emerging markets.† The company recently reported growth in countries including Nepal and Sri Lanka.

Cipla does not disclose being involved in technology transfers or partnerships to develop or enhance local manufacturing in countries in scope.

*Cipla's Trulicity® licence with Eli Lilly was excluded from this analysis as Cipla is not the primary market authorisation holder and therefore not responsible for registering the product.

**Products may be available through other mechanisms without having been filed for registration by the company.

***South Africa, sub-Saharan Africa and Cipla Global Access.

†Cipla's definition of emerging markets covers the Latin American, North African, Middle Eastern, South Asian (excluding India) and the Pacific regions.

SUPPLY & QUALITY

SQ1. DEMAND PLANNING AND DATA SHARING

Cipla reports having an internal system for forecasting and demand planning. This includes both a 12-month rolling forecast process, and a long-term demand planning process that looks five years ahead to assess future need, to evaluate, and to build capabilities to meet demand. The company holds monthly planning meetings with its sales and supply chain teams to review the latest demand and supply updates and to take corrective actions. Cipla also reports it has integrated both its Production Planning and Detailed Scheduling system and its Integrated Business Planning system, helping the company improve its capacity utilisation.

While Cipla company reports communicating with critical vendors to ensure a continuous supply of its products, the company did not provide information about data sharing initiatives with external stakeholders such as government agencies and wholesalers to align supply and demand.

SQ2. DELIVERY PERFORMANCE

Cipla reports having a vendor engagement programme to support its vendors by assisting them in improving their performance, such as their On Time in Full (OTIF) scores. The programme seeks to reduce the risk of vendor disqualification and resultant supply chain disruption. The company reports that it uses OTIF to monitor internal delivery performance. During the fiscal year (FY) 2022-2023, it achieved 90% compliance for 21 vendors (as compared to a target of 85% for 20 vendors). In addition, it supported 18 vendors in improving their OTIF scores. For FY 2023-2024, it has set a compliance target of 85%. However, the company does not report how it meets its supply commitments to national and international procurement agencies. Cipla reports implementing tools for improving its supply chain responsiveness, such as a digital platform providing users with updates on purchase order statuses, and a mobile application providing access to supply chain Key Performance Indicators.

SQ3. STOCKOUTS AND SHORTAGES MITIGATION

Cipla has implemented multiple strategies to promote a continuous supply of its products and mitigate the risk of shortages and stockouts.

The company reports maintaining sufficient buffer stock and inventory of critical components. Cipla reports using stock norms ranging from two to 12 months in India, with some exceptions made for certain components. It also audits its stocks on a regular basis and secures quantities of active pharmaceutical ingredients (APIs) in advance. To mitigate shortages, the company applies a rolling 12-month open purchase order pipeline for key components. It also reports monitoring the risk of shortages and stockouts on a monthly basis and planning corrective or preventive actions accordingly. However, the company does not disclose the specific countries in which it holds stocks for regional supply, or where it has taken steps to decentralise stocks of critical components.

Cipla reports having diversified its sources for critical APIs, intermediates and key starting materials to reduce single source dependency. In line with this, the company has taken steps to de-risk its upstream supply by implementing an alternative vendor development strategy, which also aims to reduce costs and promote local manufacturing. It also reports implementing vendor reviews as a way to address logistical challenges and ensure uninterrupted raw material supply. In addition, for 2022-2023, the company reports having spent 62% of its total procurement budget on sourcing locally to the country of operation, including in India, South Africa and Uganda.

Cipla produces APIs both for its own use and for supplying customers in over 50 countries. It reports having supplied over 110 distinct APIs to third parties during 2022-2023, which include ingredients for gastrointestinal, central nervous system and respiratory therapies. It also states it will continue focusing on critical and high-demand APIs to ensure uninterrupted supplies to key customers. The company has transitioned its supply chain management strategy from a pull to a push strategy to manufacturing products in advance to reduce lead times and maintain sufficient stocks.

Cipla's additional approaches to prevent shortages and stockouts include placing advance orders with vendors and transporters, entering rate contracts with sea liners and booking cargo slots in advance.

FIGURE 4 **What steps is Cipla taking to mitigate stockouts and shortages?**
This table shows the approaches the company reports taking to ensure the uninterrupted supply of its products.

Approaches to mitigate stockouts and shortages	
Strategies to maintain sufficient stock for critical components, including buffer and safety stocks	●
Conducting regular audits of its stock	●
Disclosure of the frequency of stock auditing	
Holding regional stocks and/or making efforts to decentralise stocks of critical components	●
Strategies to promote third-party supplier diversity, such as establishing alternative sources of APIs, excipients and packaging materials	●
Implementation of sourcing strategies, such as procuring from local suppliers in LMICs	●
Evidence of a policy or approach for scaling up the production of APIs to quickly adapt to meet surges in demand, when applicable	●
Other initiatives to fulfil emergency orders and/or surges in demand	●

Cipla has implemented an alternative vendor development strategy, which aims to de-risk its upstream supply, reduce costs and promote local manufacturing.

Cipla states that they hold regional stocks in LMICs, however, it does not disclose specific strategies to expand or decentralise its stocks.

Cipla reports engaging in local sourcing in India, South Africa and Uganda.

SUPPLY & QUALITY

SQ4. MANUFACTURING QUALITY ASSURED PRODUCTS

Cipla reports that its 47 manufacturing facilities are current Good Manufacturing Practices (cGMP) compliant, in alignment with international regulatory authorities. It also reports that its sites have been inspected by Stringent Regulatory Authorities (SRAs) including MHRA (UK), EMA (EU), FDA (US), TGA (Australia) and by National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3) such as EDA (Egypt), and CDSCO (India). However, there is no publicly available information on which of the 47 manufacturing sites have approval from at least one SRA and/or NRA operating at ML3/4.* The company does participate in the WHO Prequalification programme and is subject to inspections by WHO.

Cipla has implemented various initiatives to standardise quality management across its manufacturing sites. For instance, the company has rolled out the Quality Metric Program (QMP), a compliance monitoring tool, in additional regions in Africa and emerging markets. QMP, is a governance programme used to track quality critical key performance indicators through the company's Quality Management System (QMS). Furthermore, Cipla has implemented several digitisation and automation projects to reduce variability and ensure consistency in quality control processes. For example, the company implemented a laboratory information management system and a software platform, 'TrackWise', at its sites in India and overseas to digitise and automate its QMS data. This platform aims to streamline operations and improve risk management, including management of Corrective Action and Preventive Action (CAPA) processes. This module of the QMS has already been implemented in several countries in scope, including South Africa and Uganda.

Cipla evaluates its vendors, suppliers, and contract manufacturing organisations on quality parameters to ensure compliance with cGMP requirements. The company has a supplier code of conduct to follow and performs annual supplier audits and event-based supplier engagement on compliance and QMS. To address gaps in cGMP practices, regulatory compliance, and audit readiness, the company has a vendor engagement programme and a 'Supplier Scorecard', which is a performance monitoring tool that evaluates supplier transactions on quality, delivery and cost parameters and approximately 1,100 suppliers have been assessed.

Cipla received a warning letter from the FDA (US) on 25 February 2020, regarding significant GMP violations for finished pharmaceuticals at its Goa site in India.** Cipla reported the site was reinspected in August 2022 and is working with the FDA to address the observations from the inspection.

SQ5. SAFEGUARDING QUALITY & SAFETY OF MARKETED PRODUCTS

Cipla implements strategies to ensure the quality and safety of its marketed products. The company discloses the number of annual recalls it receives and conducts a Health Hazard Evaluation for each recalled batch to assess the impact on public health. Additionally, it reports that it responds to regulatory audit observations within defined timelines. The company reported that if a falsified medicine is confirmed, it will promptly notify authorisation holders, customers, regulatory bodies and relevant authorities. However, the company does not disclose whether it has a policy to mitigate the circulation of substandard and falsified medicines.

In an effort to mitigate falsified and substandard medicines, the company has introduced an automated track and trace system with unique product serialisation for the EU, and primary packaging serialisation for US-bound products. Cipla reports automated tracking and tracing systems outside the EU and US.The company reports that for its products marketed in India, it provides details of the primary manufacturer plant and discloses third party sourced product components on the packaging.

FIGURE 5 **Depth and breadth of quality-assurance strategies**
This table shows the types of strategies Cipla implements to maintain the production of quality-assured products and to safeguard the quality and safety of products already in the market.

Quality-assurance strategies		
Manufacturing quality-assured products	Strategies to standardise quality management systems and compliance monitoring tools across all manufacturing sites	●
	Strategies to assesses third party suppliers on GMP compliance	●
	Disclosure of the number of manufacturing sites with approval from a stringent regulatory authority (SRA) or national regulatory authority (NRA) operating at maturity level 3 or 4 (ML3 or ML4)*	
Safeguarding quality & safety of marketed products	System for recalling products promptly and effectively and alerting the appropriate authorities in a timely and efficient manner	●
	A clear policy to mitigate the circulation of substandard and falsified medicines, including to which authorities and/or organisations the company reports encounters of substandard or falsified medicines	
	Evidence of concrete strategies to mitigate the risk of substandard and falsified medicines	●
	Efforts to disclose the source of finished products, including specifying the primary manufacturing plant and disclosure of product components and materials that are third-party sourced	●

The company also reports that its sites have been inspected by multiple SRAs and by NRAs operating at ML3*. However, outside of the company's API sites, there is no publicly available information on which of the company's 47 manufacturing sites have approval from at least one SRA and/or NRA operating at ML3/4.*

Cipla reports that its automated track and trace systems are implemented to other countries outside the EU and US.

*As benchmarked against WHO Global Benchmarking Tool (GBT).

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RESEARCH & DEVELOPMENT

RD1. ADAPTIVE R&D

During the period of analysis, Cipla had one adaptive R&D project in its pipeline, meaning the company was adapting a product to ensure it was better suited for LMIC settings. Cipla developed a granule-filled capsule containing a 4-in-1 paediatric fixed-dose combination (FDC) of ARVs (abacavir, lamivudine, lopinavir, ritonavir) for the treatment of HIV. The FDC is heat-stable and does not contain alcohol or inappropriate solvents. The HIV drug was developed in partnership with Drugs for Neglected Diseases initiative (DND*i*), Unitaid, Stellenbosch University, and Tygerberg Hospital and was approved by South African Health Product Regulatory Authority (SAHPRA) in June 2022. This product is currently awaiting approval from other regulatory bodies, such as the US FDA. It can be sprinkled on food without leaving an aftertaste, due to its granular texture and strawberry flavour. Additionally, by developing a new FDC, a complicated dosage regimen is simplified, which helps with treatment adherence. The development of this product has the potential to ease administration and improve outcomes in children living with HIV.

RD2. ACCESS PLANNING

The company does not disclose having an overarching policy or structured framework in place for systematically developing access plans during R&D for its adapted products.

However, for the one adaptive R&D project example in scope, Cipla has a comprehensive access plan in place. The product, Quadrimune, was developed in collaboration with product development partner DND*i*, who ensure that plans for equitable and affordable access are put in place during the drug development process. The product was approved in South Africa and dispatched to the Democratic Republic of Congo (DRC), as per temporary authorisation received for the DRC during the period of analysis. However, the company did not disclose further details on plans for registration in countries in scope.

To address affordability, the access plan includes transparent and publicly available details on pricing plans for South Africa. Cipla has committed to offering Quadrimune at ex-factory prices of USD 15 for 120 capsules for young children and infants. Ultimately, this commitment will price the drug USD 1 per day (USD 360 per year) for children weighing 10 to 13.9 kg. For younger children and infants, this price drops to USD 0.50 per day.

FIGURE 6 **Example of a late-stage adaptive R&D project in Cipla's pipeline**

International Nonproprietary Name (INN)	Disease in scope	Development stage	Partner(s)	Description of the adaptation	Evidence of an access plan
4 in 1 combination of ARVs (abacavir/ lamivudine/lopinavir/ritonavir)	HIV/AIDS	Approved	Drugs for Neglected Diseases initiative (DND*i*), Stellenbosch University, Tygerberg Hospital, Unitaid and others	New paediatric fixed dose combination with strawberry flavour and granules, which ease administration and improve adherence	Equitable pricing plan; Partnership with an accesss-oriented organisation; Approved in South Africa and temporarily authorised in the Democratic Republic of the Congo