Sun Pharmaceutical Industries Ltd

HQ: Mumbai, India • Ticker: SUNPHARMA • Stock exchange: NSE • Nr. of employees: 41,000+

COMPANY SUMMARY

Sun Pharma enables access and product availability through its manufacturing network, spanning 43 sites worldwide, and its presence across many low- and middle-income countries (LMICs). The company has successfully filed or registered products in 63 countries in scope, with the ten products selected for this assessment having been prioritised by Sun Pharma for registration in lower-middle and upper-middle income countries. Sun Pharma expands access to its products by engaging in competitive tenders by governments and hospitals to ensure availability in the public sector, while adhering to local pricing policies and competitor-based pricing strategies in the private sector. However, only six of the ten assessed products are covered by an access strategy, and the company submitted no examples of access strategies covering any low-income countries. The company has signed licensing agreements that allow the company to market generic versions of treatments for HIV and COVID-19, but no specific information is provided regarding the countries where Sun Pharma has registered these products. Sun Pharma uses several strategies to reduce the risk of product shortages, including demand forecasting and buffer stock maintenance. Sun Pharma reports one adaptive late-stage R&D project for a fixed dose combination of extended-release tablets treating type 2 diabetes.

Main therapeutic areas
Anti-infectives; cardiology; dermatology; diabetology; gastroenterology; gynaecology; nephrology; neurology; oncology; ophthalmology; orthopaedic; psychiatry; respiratory; urology.

Business segments*
Active pharmaceutical ingredients (APIs); Emerging Markets; Indian Branded Generics; US Business; Rest of the World; Others.

Product categories
APIs; branded generics; consumer health; innovative specialty medicines; generics.

Sales presence**
Sun Pharma reports sales in 49 countries in scope.

OPPORTUNITIES FOR SUN PHARMA

Engage further in adaptive R&D and strengthen access planning for products in the pipeline.
Sun Pharma's extended release fixed-dose combination of dapagliflozin/glimepriride/metformin, indicated for people with type 2 diabetes, demonstrates the company's capability to adapt products and simplify dosage regimens. Sun Pharma can further apply this expertise to adapt other products. For example, for the antiretroviral products in its pipeline, it can adapt products to be more suitable for population groups, such as children. It can also develop its access plans for its R&D projects to ensure they consider barriers to access, such as affordability and supply.

Expand access to essential cancer products, such as doxorubicin
In line with the company's sustainability 'focus area' of product accessibility and responsible pricing, Sun Pharma can use access strategies to increase the affordability and supply of essential cancer medicines in its portfolio. For doxorubicin, indicated for the treatment of different types of cancer, including non-Hodgkin lymphoma, the company can use access strategies that include elements to address affordability issues for patients paying out of pocket. Sun Pharma can apply such strategies in Myanmar, the country with the highest out-of-pocket healthcare spending in South-East Asia, where the company has registered the product.

Leverage manufacturing presence to address access-to-medicine gaps.
Sun Pharma can leverage its large manufacturing network and expand operations in countries where access gaps are prevalent. Drawing upon its experience using its South African manufacturing site to supply essential HIV treatments to neighbouring countries, Sun Pharma can expand the reach of its medicines to further countries in Africa, particularly low-income countries, by leveraging its manufacturing capabilities in South Africa and Nigeria.

Expand registration of in-licensed products as a sublicensee.
Sun Pharma is a sublicensee for a dolutegravir licensing agreement facilitated by the Medicines Patent Pool for the paediatric formulation (10mg scored, dispersible). Yet, the company has not registered this product in any country in scope. The company can file for registration in countries within the scope of the licence,*** prioritising countries with high disease burdens – particularly those where the company has previously successfully registered another project.

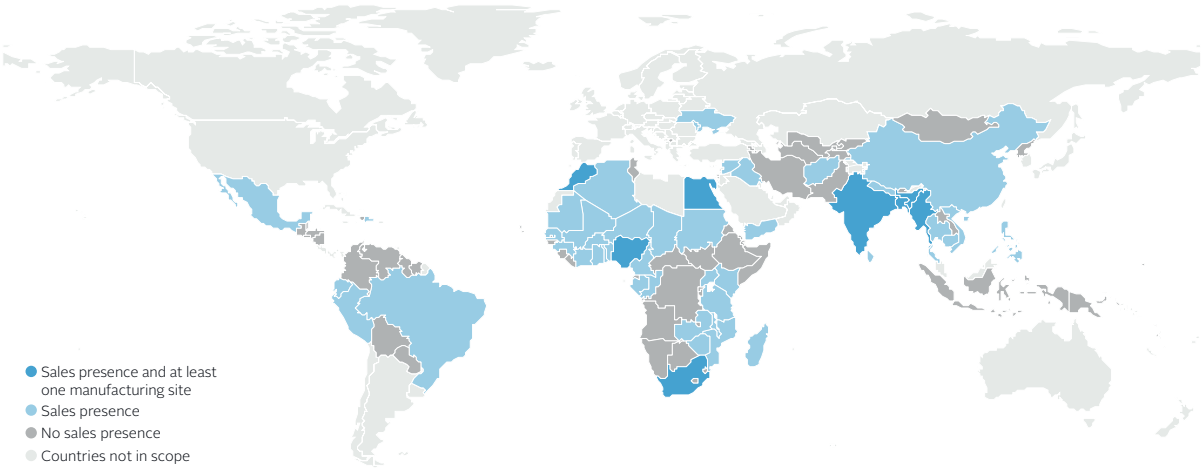
*Sun Pharma also reports the following segments: Global Specialty and Global Consumer Healthcare business.

**Refers to countries in which sales are conducted through suppliers, pooled procurement and/or the company sales offices. As Sun Pharma did not verify its company presence, this data was sourced from the public domain and previous submissions for the 2021 AMR Benchmark.

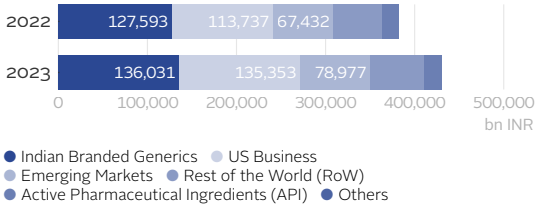
***The licence for dolutegravir paediatric formulation covers 102 countries within the scope of this Programme.

COMPANY PRESENCE & REVENUE

Sales and manufacturing presence in countries in scope

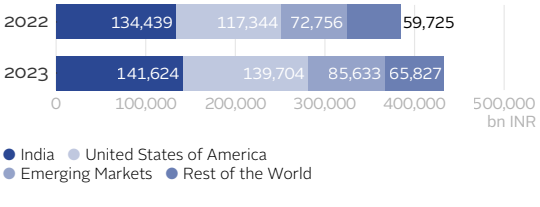


Revenue by business segment*



Indian Branded Generics · US Business · Emerging Markets · Rest of the World (RoW) · Active Pharmaceutical Ingredients (API) · Others

Revenue by region*

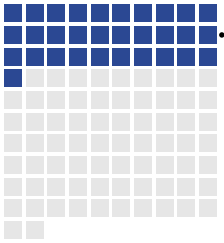


India · United States of America · Emerging Markets · Rest of the World

PORTFOLIO & PRODUCTS ANALYSED

Products in scope from the company's portfolio

Out of the 102 products in scope of this analysis,** Sun Pharma has at least 31 products within its portfolio.***



31+ products
These target a range of disease categories, namely cancer, bacterial infections, mental health disorders, asthma, chronic obstructive pulmonary disease (COPD), and cardiovascular disease.

Product is in Sun Pharma's portfolio
Product is not in Sun Pharma's portfolio***

Products selected for assessment

Of the in-scope products that Sun Pharma 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
Abacavir/lamivudine (ABC+3TC)	HIV
Atorvastatin	Ischaemic heart disease
Carbamazepine	Epilepsy
	Bipolar affective disorder
Doxorubicin	Cancer
Fluoxetine	Unipolar depressive disorders
	Anxiety disorders
Gemcitabine	Cancer
Gliclazide	Diabetes mellitus
Metoprolol	Hypertensive heart disease
	Ischaemic heart disease
Sumatriptan	Migraine
Tranexamic acid	Maternal haemorrhage

*Financial year (FY) 2022 covers April 2021 – March 2022. FY 2023 covers April 2022 – March 2023. The company reports the revenues from its Global Consumer Healthcare and Global Speciality businesses as part of the listed business segments.

**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.

***Sun Pharma verified that the ten products selected for assessment are included in its portfolio. However, the company did not confirm which of the 102 products in scope are in its wider portfolio. Thus, the analysis relies on data from Sun Pharma's India catalogue and India Product list accessed on 14 June 2023.

EXPANDING ACCESS

EA1. ACCESS-TO-MEDICINE STRATEGY

Sun Pharma reports a general commitment to expanding access, but does not present evidence of an overarching access-to-medicine strategy. The company places emphasis on product accessibility and responsible pricing as crucial aspects of its sustainability focus, as highlighted in its Environment, Social, and Governance (ESG) strategy. Additionally, Sun Pharma has stated its commitment to provide uninterrupted access to quality-assured medicines. However, there is limited information available about the scope of this commitment, such as the countries and products covered.

Under Sun Pharma's ESG strategy, the corporate social responsibility (CSR) division reports directly to the board of directors. However, it is unclear whether the CSR committee or the board holds ultimate responsibility for access to medicine. Furthermore, the company does not disclose measurable and time-bound objectives for its access-to-medicine commitments, nor does it outline specific strategies for achieving sustainable access and expanding patient reach. Establishing such objectives and strategies is critical for guiding Sun Pharma's access-to-medicine efforts and demonstrating the importance of access in the company's long-term growth.

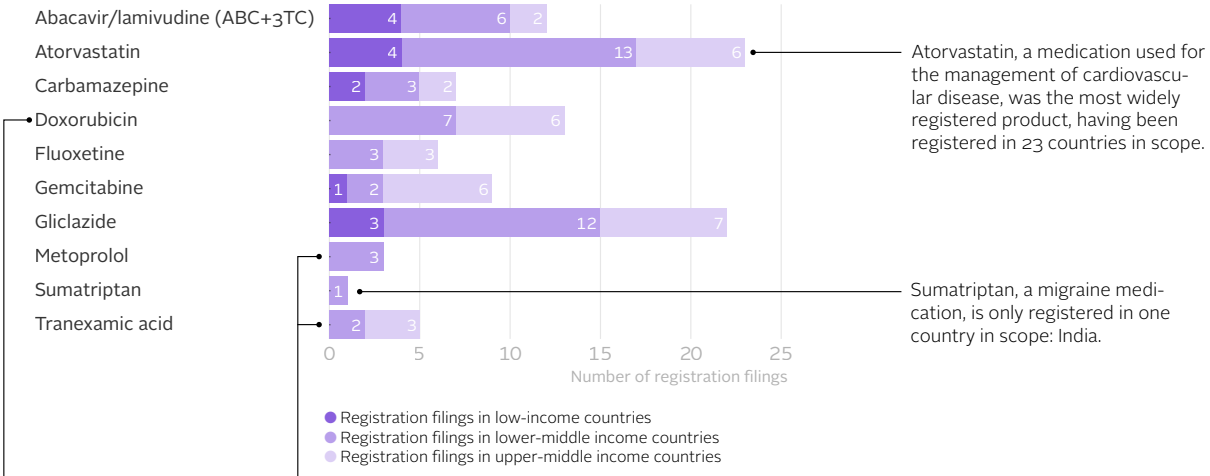
EA2. PRODUCT REGISTRATION

Sun Pharma has filed to register or successfully registered at least one product within its entire portfolio in 63 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. Sun Pharma has filed at least one of these products in a total of 42 out of the 63 LMICs (67%) where it has pre-existing regulatory filings.* This shows 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 23 countries. Out of the ten products, only five are registered in at least one low-income country, where significant gaps in access to essential medicines are prevalent.**

For a variety of its products, the company engages in mechanisms designed to facilitate wider registration in LMICs. Several of the company's products have been registered through the World Health Organization (WHO) Collaborative Registration Procedure (CRP) for WHO Prequalified products in multiple countries in the AFRO region*** and the Philippines. These products include HIV medicines abacavir/lamivudine and dolutegravir/lamivudine/tenofovir disoproxil fumarate. Additionally, a few of the company's products (outside the product scope of this analysis) have been recommended for approval by ZaZiBoNa.†

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

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

EXPANDING ACCESS

EA3. EXPANDING ACCESS AND PRICING STRATEGIES

In the country-specific examples provided by Sun Pharma, six out of the ten products selected for assessment are covered by an access strategy in the public and/or private market. Across the assessed products, Sun Pharma reported access strategies in lower- and upper-middle income countries, with no examples of access strategies for low-income countries. Based on the examples of in-country access strategies submitted for analysis, the company primarily participates in government and hospital tenders, which can facilitate access to its products within the public sector. However, the company only provides evidence of patient reach for two of the ten products, and it does not provide evidence of forecasting patient reach for any of the ten products.

In the private sector, Sun Pharma adheres to local pricing policies and employs competitor-based pricing strategies to determine the pricing of its products. Examples of access strategies submitted for atorvastatin, gliclazide, and metoprolol show that the company sets prices for its products based on local pricing policies, including the respective external reference pricing system implemented in each country.

For carbamazepine, fluoxetine and gemcitabine, Sun Pharma reports implementing access strategies in both the public and private sectors of LMICs in scope.

In Morocco, the company engages in government and hospital tenders to supply carbamazepine within the public sector. It also supplies the product in the Moroccan private sector, where it sets prices using competitor-based pricing. The company reports evidence of cumulative patient reach in five countries, including Morocco, where it supplies the product carbamazepine. Collectively, Sun Pharma estimates that approximately 523,000 patients were provided access to carbamazepine in five countries in scope between April 2020 and April 2023.

Sun Pharma adopts a similar strategy for fluoxetine and gemcitabine, participating in public sector tenders in countries in scope, while also supplying the private market – setting prices based on the competitor landscape. For fluoxetine, the company participates in public sector tenders in several countries in scope; this includes Kenya, which was selected as a specific country example. However, it emphasises that participation in tenders is not the primary strategy it employs to expand access. In the Kenyan private market, Sun Pharma employs competitor-based pricing strategies to supply the products. While the company provides evidence of the cumulative number of patients reached in five countries in scope where it supplies fluoxetine, including Kenya, it remains unclear whether the pricing strategies employed by the company ensure access to affordable prices for all patients across the income pyramid.

For gemcitabine, Sun Pharma reports engaging in public sector tenders in Thailand, as well as supplying the private market. However, the company does not provide any estimates regarding the number of patients reached through these efforts. It remains unclear whether Sun Pharma considers affordability when setting prices for the private sector, especially for individuals that pay out of pocket. Although the company reports implementing a patient support programme for gemcitabine in Thailand, there is a lack of available information regarding the programme's details and its effectiveness in ensuring access for patients within the country.

For three assessed products, abacavir/lamivudine, doxorubicin, and tranexamic acid, Sun Pharma did not report access strategies, indicating the company may not be taking steps to ensure the availability and affordability of these products in countries in scope. Additionally, while evidence was provided for improving the availability and affordability of sumatriptan, it was not specific to any country within the programme's scope.

FIGURE 2 **How many products are covered by an access strategy?**
For each of the ten products selected for assessment, Sun Pharma 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)	No country-specific access strategy					
Atorvastatin	Bangladesh (LMIC)		●			
Carbamazepine	Morocco (LMIC)	●	●	●*		
Doxorubicin	No country-specific access strategy					
Fluoxetine	Kenya (LMIC)	●	●	●*		
Gemcitabine	Thailand (UMIC)	●	●			●
Gliclazide	Sri Lanka (LMIC)		●			
Metoprolol	Nepal (LMIC)		●			
Sumatriptan	No country-specific access strategy					
Tranexamic acid	No country-specific access strategy					

For these products, Sun Pharma provides evidence of implementing initiatives aimed at improving access to diagnostics and education materials in countries in scope. While such strategies can play a critical role in improving patient outcomes and ensuring continuity of care, there is currently no evidence suggesting they can improve affordability.

*Sun Pharma provided aggregated patient reach for carbamazepine and fluoxetine, and as such, the country-specific patient reach estimates are unknown.

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

EXPANDING ACCESS

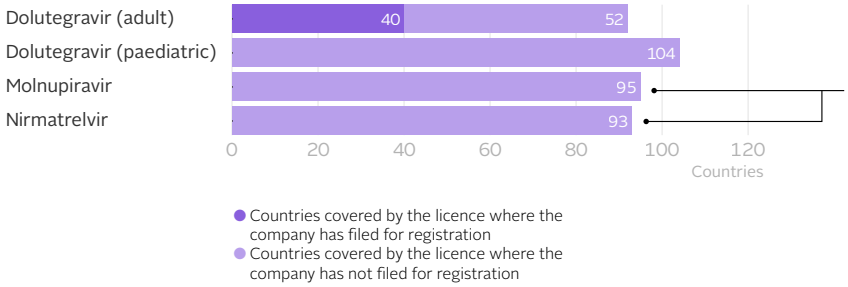
EA4. ENGAGING IN LICENSING ACTIVITIES

For Sun Pharma, five in-licensed products were selected for assessment: dolutegravir (paediatric) and dolutegravir (adult), indicated for the treatment of HIV; carbetocin, indicated for maternal haemorrhage; and molnupiravir and nirmatrelvir, indicated for COVID-19.

Sun Pharma was granted a non-exclusive voluntary licensing agreement (NEVL) for dolutegravir (paediatric) and dolutegravir (adult) facilitated through the Medicines Patent Pool (MPP). For the paediatric dose and formulation, the company did not report where this product was registered and as a result, the impact of this NEVL in countries in scope is unknown. For the adult dose and formulation of dolutegravir, the company reports that it is a global supplier with 40 registrations in LMICs;* however the company provided neither details on the specific countries where the product is registered, nor details of the impact of this licence on improving the affordability of this product.

Sun Pharma is currently engaged in one exclusive licensing agreement with Ferring Pharmaceuticals to distribute carbetocin, indicated for prevention of post-partum haemorrhage. This formulation is stable at room temperature and therefore offers advantages for use in LMICs over the current first-line treatment oxytocin (which requires refrigeration). Sun Pharma has only been granted co-marketing rights for heat-stable carbetocin in India, exclusively within the private market. The product was approved and launched in India in June 2021, and it was co-marketed with the originator company Ferring Pharmaceuticals. The company did not report further details on the licensing agreement, including whether the agreement has increased the number of patients receiving heat-stable carbetocin in India.

FIGURE 3 **Registration filings of Sun Pharma's in-licensed products****
This figure shows the number of LMICs in scope where Sun Pharma 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.***



Sun Pharma was granted two NEVLs for COVID-19 antivirals – molnupiravir and nirmatrelvir. The nirmatrelvir agreement was facilitated through the Medicines Patent Pool (MPP). These agreements were made after the COVID-19 vaccines were rolled out, which reduced the demand for these products. Consequently, the company has not filed these products for registration in any LMICs within scope. However, the company did report that molnupiravir is currently under review with WHO for prequalification (PQ) and the company retains the right to register and supply these products, should the need arise.

EA5. IMPROVING PRODUCT AVAILABILITY

Sun Pharma's manufacturing network comprises 43 manufacturing sites globally, including 29 finished dosage manufacturing sites and 14 API manufacturing facilities. The company reports that its large manufacturing network, with facilities in multiple countries, provides increased flexibility that enables it to effectively service the markets in which it operates, thereby leading to improved product availability. The company reports that it operates several finished dosage manufacturing sites located in LMICs in scope, including in Bangladesh, Egypt, Nigeria and South Africa.

Through the company's manufacturing presence in South Africa, Sun Pharma reports supplying antiretrovirals (ARVs) to neighbouring countries in southern Africa. It also reports supporting the HIV/AIDS Treatment Programme of the Ministry of Health of Morocco by making ARVs available in this country. Sun Pharma supplies medicines such as antibiotics and antihypertensives in South Africa and Nigeria.

Sun Pharma has stated that it undertakes technology transfers between its own manufacturing sites specifically pertaining to the transfer of product processes and analytical methods from one site to another within the same region in India. However, the details regarding these technology transfers and their impact on improving product availability within the region are currently unknown. Sun Pharma does not disclose being involved in technology transfers with external stakeholders and/or partnerships to develop or enhance local manufacturing in countries in scope.

*Sun Pharma did not disclose which specific 40 LMICs these are. The correspondence of the countries with the Programme's geographic scope therefore cannot be verified.

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

***The company did not provide registration data for the carbetocin licensing agreement.

SUPPLY & QUALITY

SQ1. DEMAND PLANNING AND DATA SHARING

Sun Pharma reports implementing demand forecasting in order to plan for short-, mid- and long-term requirements and to schedule production, using a forecasting system that operates up to 12 months in advance. It also reports that its demand planning teams work closely with sales teams to ensure adequate planning aligned with sales forecasts. In the financial year 2021-2022, Sun Pharma reported that it had maintained regular communication with the Indian government since the beginning of the COVID-19 pandemic providing updates on information such as sales, stock status and raw material status of key medicines.

However, there is no publicly available information indicating whether Sun Pharma engages in data sharing activities with external stakeholders from other countries, or beyond the context of COVID-19, to align supply and demand of its products.

SQ2. DELIVERY PERFORMANCE

Sun Pharma reports having systems in place to monitor and review internal delivery performance. However, it has not reported any information about what these systems consist of and/or how they are employed. The company states that it proactively communicates with stakeholders in case of delivery delays. However, no further details were provided regarding its communication strategies or other measures taken in such situations.

Furthermore, Sun Pharma does not report details about how successfully it fulfils its supply commitments to national and international procurement agencies. Additionally, the company does not publicly report its processes to ensure the consistent and timely delivery of quality-assured products to LMICs.

SQ3. STOCKOUTS AND SHORTAGES MITIGATION

Sun Pharma has implemented some strategies to promote a continuous supply of products and mitigate the risk of shortages and stockouts.

The company reports maintaining a buffer stock of critical components such as raw materials, excipients, APIs and finished products. It has also stated that supply chain continuity, along with a focus on inventory optimisation, is a top priority for the financial year 2023. However, no information was provided regarding strategies to optimise inventories or conduct audits of the company's stock. Additionally, it is not clear in which LMICs in scope the company holds stocks or if it has taken any steps to decentralise stocks of critical components.

To reduce supply risks, Sun Pharma reports sourcing critical items from multiple suppliers and states that it evaluates alternative suppliers for critical or non-substitutable raw materials. In 2021-2022, Sun Pharma reported sourcing 61% of its direct procurement from local suppliers with the aim of strengthening its supply chain, improving operational flexibility and reducing costs.

Furthermore, the company has established a Strategic Procurement Committee to identify potential supply risks and implement mitigation measures. The company also reports coordinating with various stakeholders, including clearing and forwarding agents, who are responsible for ensuring that the company's products are cleared through customs. Ultimately, coordination with various stakeholders helps to ensure the overall availability of products.

Sun Pharma produces APIs, both to fulfil its product requirement and supply other manufacturers. This approach has the potential to reduce the company's dependence on third-party suppliers and ensure a reliable supply of APIs. With a portfolio comprising around 380 APIs manufactured across 14 sites (nine of them located in India) and supplied to over 60 countries, Sun Pharma has significant API capabilities. However, the company did not provide specific details on its approach to scaling up API production in response to surges in demand in LMICs, thereby preventing stockouts and shortages.

FIGURE 4 **What steps is Sun Pharma 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	●

Sun Pharma has manufacturing sites in LMICs in scope, suggesting the company likely maintains regional stocks. However, it does not disclose specific strategies to expand or decentralise its stocks.

Sun Pharma reports its percentage of procurement sourced from local suppliers. However, it does not provide a definition of local suppliers nor the location of its local sourcing approach.

Sun Pharma reports using multiple upstream suppliers for critical items. However, it does not report a specific strategy to qualify alternative suppliers.

SUPPLY & QUALITY

SQ4. MANUFACTURING QUALITY ASSURED PRODUCTS

Sun Pharma reports that its own and third-party manufacturing sites maintain a quality management system consistent with international good manufacturing practice (GMP). This includes tracking of corrective and preventive actions (CAPA), mitigating adverse drug events, field alert reporting, and a recall process.

The company does not publicly disclose the number of manufacturing sites that have received approval from at least one stringent regulatory authority (SRA) or NRAs operating at maturity levels 3 or 4.* However, it states that an undisclosed number of its manufacturing facilities are certified by international regulatory bodies, including the FDA (US); EMA (Europe); MHRA (UK); TGA (Australia); SAHPRA (South Africa); BfArM (Germany); ANVISA (Brazil); MFDS (South Korea) and PMDA (Japan). The company is engaged in the WHO prequalification programme, whereby relevant manufacturing sites are assessed in line with WHO GMP.

The company reports that it conducts audits of all its manufacturing sites, contract facilities and vendors, and assesses third-party suppliers and new vendors for compliance with its Supplier Code of Conduct and regulatory requirements. The company states that its vendor performance is tracked regularly, for which it uses a scorecard mechanism.

During the period of analysis, the company received official requests for corrective action from SRAs related to non-conformities with cGMP. In December 2022, the FDA (US) issued a warning letter concerning significant GMP violations for finished pharmaceuticals at the company's Halol** site in India and placed the Halol site on Import Alert 66-40, with 14 products exempted from import alert, subject to certain conditions. In April 2023, a consent decree correspondence/non-compliance letter was issued by the FDA (US), and the company must implement corrective actions at its Mohali*** site before releasing further final product batches into the United States. In 2022, Health Canada also issued non-compliant ratings to Sun Pharma's Halol** , Mohali***, and Paonta Sahib† sites. The company reports that it is taking the required corrective steps.

SQ5. SAFEGUARDING QUALITY & SAFETY OF MARKETED PRODUCTS

Sun Pharma reports that it has a policy to address complaints concerning potentially substandard products, including a system for recalling products from the market and alerting appropriate authorities within the required timelines by providing a recall return card and a destruction certificate. However, the company did not provide further details of the policy.

The company takes steps to tackle the risk of substandard and falsified medicines. For instance the company uses 'Track and Trace' technology, which works to ensure the authenticity of its products. However, it is unknown whether this system is applied in LMICs.

Sun Pharma's product packaging contains important information such as the safe use of products, the sourcing of ingredients, and guidance on appropriate storage conditions. The company reports that for every product, the necessary storage conditions are outlined, and the sourcing plant address is provided.

FIGURE 5 **Depth and breadth of quality-assurance strategies**
This table shows the types of strategies Sun Pharma 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 reports efforts to harmonise compliance processes as part of its quality practices, but it does not provide concrete evidence on whether it implements specific strategies to limit variability in manufacturing processes between sites.

While the company reports implementing a 'Track and Trace' technology, it is unknown whether this system is applied in LMICs.

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

**Halol Baroda Highway Halol, Gujarat India, 389350.

***Unit 1 Plot A-41, Sez Industrial Area, Phase Viii A, Mohali, Punjab, 160071 India.

†Paonta Sahib District Sirmour-Village Ganguwala, Himachal Pradesh India 173025.

RESEARCH & DEVELOPMENT

RD1. ADAPTIVE R&D

Sun Pharma has one adaptive R&D project in its pipeline to develop a product that is better suited for LMIC settings. During the period of analysis, the company provided an example of a late-stage (phase II and beyond) adaptive R&D project. This project, currently in Phase III of clinical development, is a fixed dose combination (FDC) of extended release dapagliflozin, glimepiride and metformin for the treatment of type 2 diabetes mellitus. Extended-release FDC tablets simplify dosage regimens and reduce dosage frequency, thus improving adherence and patient outcomes. This is advantageous for both patients and health systems, especially in resource-limited settings.

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.

For the one example of adaptive R&D submitted, the company provided evidence of an access plan. This access plan consists only of filing the product for registration in one country in scope, specifically India. Whilst registration is a necessary first step to ensure availability in a country, there is no evidence that the company's access plan for this product considers other components conducive to access, such as affordability and supply.

FIGURE 6 **Example of an adaptive R&D project in Sun Pharma's pipeline**

International Nonproprietary Name (INN)	Disease in scope	Development stage	Partner(s)	Description of the adaptation	Evidence of an access plan
Dapagliflozin/glimepiride/metformin extended release FDC	Diabetes mellitus	Phase III	N/A	Extended release fixed-dose combination	Registration plans in India