Teva Pharmaceutical Industries Ltd

HQ: Tel Aviv, Israel • Ticker: TEVA • Stock exchange: NYSE / TASE • Nr. of employees: 37,000+

COMPANY SUMMARY

Teva demonstrates its commitment to access to medicine by integrating measurable and time-bound objectives into its business model and corporate strategy. These objectives are publicly reported and tied to the company's sustainability-linked financing framework, fostering accountability. While Teva's business model mostly focuses on high-income countries, the company's products are sold in approximately 40% of LMICs in scope, with the ten products selected for this assessment having been prioritised by Teva for registration in upper-middle income countries. To provide access to its assessed products, Teva employs various strategies, primarily in private markets across regions including sub-Saharan Africa. Teva reports using tender approaches in public markets. The company did not report strategies to increase access in public markets for the ten assessed products. The company has not been a sublicensee of voluntary licensing agreements within countries in scope. It leverages its manufacturing network to supply products globally, including in 39 LMICs where it has a sales presence. To ensure reliable product delivery and minimise shortages, Teva implements various strategies to ensure continuous supply of its products and to uphold quality standards, while making efforts to combat substandard and falsified medicines. Teva has not been assessed in R&D since it is not engaged in any adaptive R&D projects under the scope of this programme.

Main therapeutic areas
Anti-infectives; cardiovascular; central nervous system and pain; diabetes; gastrointestinal; immunology; mental health; oncology; respiratory.

Business segments
Europe; International Markets; North America.

Product categories
Active pharmaceutical ingredients (APIs); biosimilars; generic medicines; innovative medicines.

Sales presence*
Teva reports sales in 39 countries in scope.

OPPORTUNITIES FOR TEVA

Explore engagement in mechanisms to facilitate registration
Teva can explore engaging in mechanisms to facilitate the registration of eligible products, such as the WHO Collaborative Registration Procedure, regional Joint Assessments such as the ASEAN Joint Assessment, the African Regional Joint Assessment initiatives, the CARICOM Joint Assessment, ZaZiBoNa Collaborative Procedure, and Swissmedic MAGHP Procedure. For instance, for the ZaZiBoNa Collaborative Procedure, Teva could consider the inclusion of carboplatin, as well as analgesics, antibiotics, antineoplastic, and blood thinning agents.

Prioritise registration of essential medicines in more lower-middle and low-income countries
Across its entire portfolio, Teva has registered products in 44 countries in scope. For the subset of ten off-patent products selected for assessment, the company has filed for registration in ten upper-middle income countries and six lower-middle income countries. In line with its access target of increasing the number of registrations by 150% in LMICs** by the end of 2025, Teva can expand registration filings across a broader spectrum of countries. For example, it can file cisplatin, an essential medicine indicated for multiple cancers, for registration in lower-middle and low-income countries.

Improve access strategies for essential medicines to ensure affordability for low-income and vulnerable people.
Teva implements an access strategy for lisinopril in Nigeria, specifically targeting the private sector. This medicine treats hypertension, the most common cardiovascular disease in the country. In Nigeria, less than 10% of the population is covered by any health insurance, leading patients to heavily rely on out-of-pocket payments to access health care, which poses significant affordability issues. To expand equitable access and adequate supply for private sector patients, Teva can further strengthen its existing private market access strategy to better address ability to pay and local barriers to access. This approach could help low-income and uninsured patients gain access to essential medicines such as lisinopril.

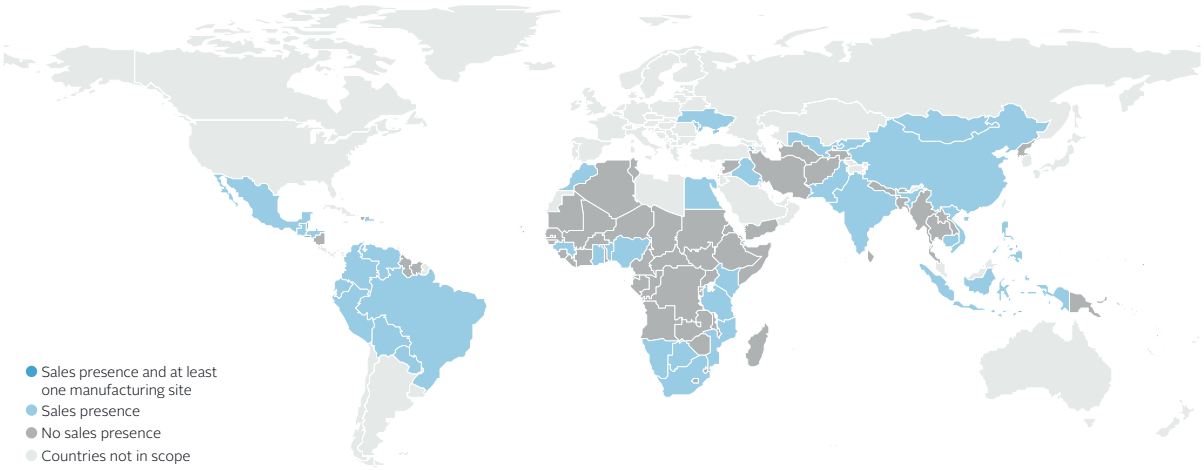
Expand access approaches to incorporate long-term sustainability
Teva has set targets to expand affordable access to medicines to underserved and vulnerable populations in LMICs** through donations and access programmes. Its partnership with Global HOPE to donate cancer medicines in sub-Saharan Africa serves as a strong starting point. Teva can consider expanding and strengthening its access programmes towards sustainable approaches and across more therapeutic areas. By working with local partners such as distributors and local organisations, the company can put in place sustainable access models that increase the availability and affordability of its essential products.

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

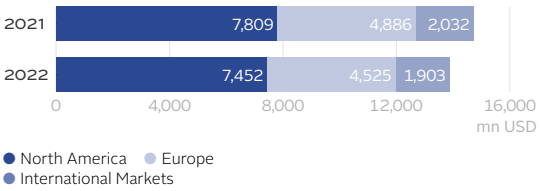
**Teva's definition of LMICs encompasses 127 countries following the 2020 World Bank classification as outlined within its sustainability-linked financing framework. This scope does not precisely match the Programme's country scope of 108 LMICs.

COMPANY PRESENCE & REVENUE

Sales and manufacturing presence in countries in scope



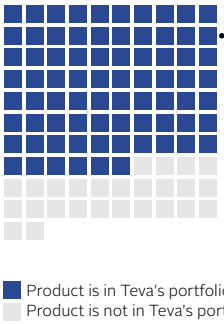
Revenue by business segment*



PORTFOLIO & PRODUCTS ANALYSED

Products in scope from the company's portfolio

Out of the 102 products in scope of this analysis,** Teva has 76 products within its portfolio. Teva's portfolio has a strong focus on non-communicable diseases (NCDs), particularly respiratory diseases and cancer, with 18 products for cancer, and 13 products for cardiovascular disease. Additionally, the company focuses on certain communicable diseases (CDs), including bacterial infections, for which it has ten antibiotics in scope.



76 products
These target a range of disease categories, namely NCDs (50); CDs (21); neglected tropical diseases (2); and reproductive, maternal and newborn conditions (6). Three products fall into multiple categories.

Products selected for assessment

Of the in-scope products that Teva 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
Azithromycin	Bacterial infection
Budesonide	Asthma
	Chronic obstructive pulmonary disease (COPD)
Capecitabine	Cancer
Carbamazepine	Epilepsy
	Bipolar affective disorder
Carboplatin	Cancer
Cisplatin	Cancer
Fluoxetine	Unipolar depressive disorders
	Anxiety disorders
Lisinopril	Hypertensive heart disease
Risperidone	Schizophrenia
	Bipolar affective disorder
Sumatriptan	Migraine

*Teva reports revenue by region in the same regions that represent the business segments. Financial year (FY) 2021 covers January - December 2021. FY 2022 covers January - December 2022.

**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

Teva integrates its access-to-medicine strategy within its business model and corporate strategy, indicating the company's commitment to addressing access to medicine in LMICs. This strategy is further supported by the company's Environmental, Social and Governance (ESG) strategy.

Teva conducted a materiality assessment in 2022 to inform its strategy, which includes commitments to quantify savings for health systems, implement initiatives such as access programmes for vulnerable populations and patients at the last mile in LMICs,* and establish donation and social business programmes. Teva sets measurable and time-bound objectives as part of its access strategy, which are publicly reported. These objectives and the reporting are tied to its sustainability-linked financing framework and sustainability-linked bonds, enhancing transparency and accountability for its access commitments. Among the objectives are targets to increase the cumulative number of new regulatory submissions by 150% in LMICs across six therapeutic areas** by 2025 (using a 2017-2020 baseline) and to increase product volume by 150% for certain access programmes in LMICs across the same therapeutic areas by 2025 (using a 2020 baseline). As per Teva's 2022 ESG Progress Report, it has accomplished 28% of this target, translating to 21 submissions. Teva announced a new strategy in 2023, which involves reallocating resources from generics to innovative medicines, focusing on high-value products. The impact on the product portfolio and access strategies is as yet unknown. The responsibility for Teva's ESG and access-to-medicine strategy lies with executive management, and oversight is provided by the Compliance Committee of the Board of Directors. The ESG steering committee governs the implementation of the strategy, ensuring accountability at the senior level, with the ultimate responsibility resting with the board of directors.

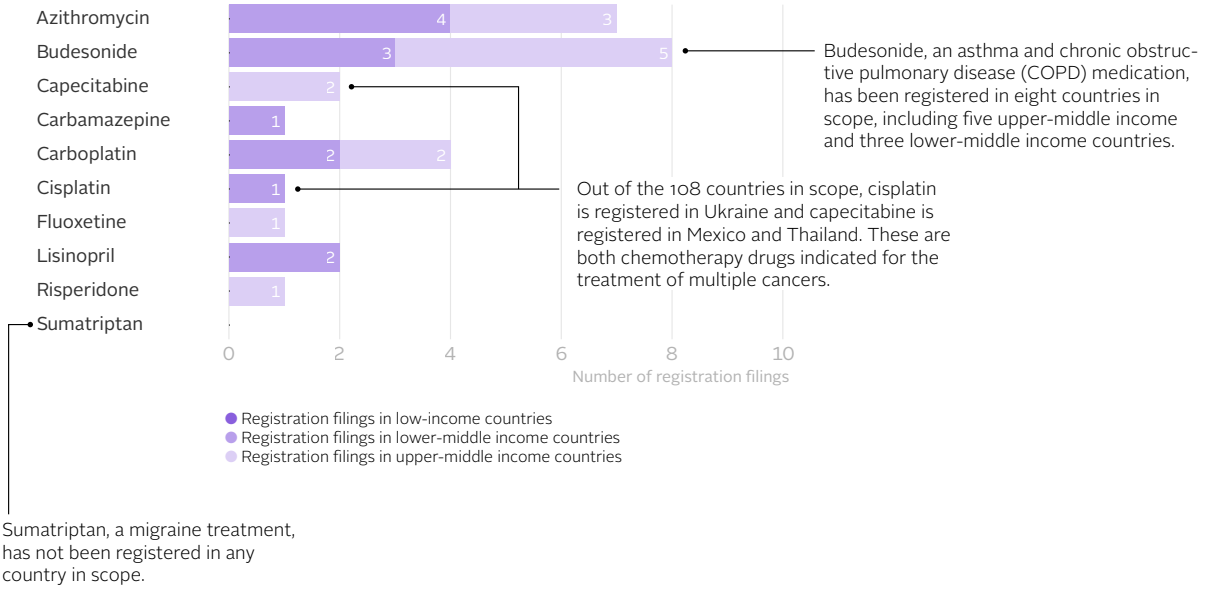
EA2. PRODUCT REGISTRATION

Teva has filed to register or successfully registered at least one product within its entire portfolio in 44 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. Teva has filed at least one of these products for registration in a total of 16 of the 44 LMICs where it has pre-existing regulatory filings.*** Teva's registration efforts for these ten products have primarily focused on upper and lower-middle income countries. The company has not filed any of these products in low-income countries.

Teva does not actively engage in mechanisms to facilitate registration, such as the World Health Organization (WHO) Collaborative Registration Procedure or regional joint assessments.

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.



*Teva's definition of LMICs encompasses 127 countries following the 2020 World Bank classification as outlined within its sustainability-linked financing framework. This scope does not precisely match the Programme's country scope of 108 LMICs.

**The six therapeutic areas are: cardiovascular diseases; oncology; respiratory diseases; diabetes; mental health; and pain/palliative care. This scope does not exactly coincide with the Programme's disease scope.

***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.

EXPANDING ACCESS

EA3. EXPANDING ACCESS AND PRICING STRATEGIES

For eight out of the ten products included in this assessment, Teva submitted an example of a strategy to expand access to that product in a specific country in scope. This included examples of access strategies in three upper-middle, four lower-middle, and one low-income country.

For six of these products, the examples consist of pricing strategies, with the majority exclusively focused on the private sector. For two of these products, Teva enables access through product donations. Additionally, the company provides evidence of the number of patients reached for all eight products, with evidence of forecasting patient reach provided for the two of them (carboplatin and cisplatin).

Among the six products with pricing strategies, Teva provides evidence of implementing different types of strategies for each of the six country-specific examples provided. These include a competitor pricing strategy, a transfer pricing model, and pricing strategies that follow local pricing policies in those specific countries. While Teva adheres to local control pricing policies imposed by governments, which aim to limit product prices, this may not be sufficient to make the prices affordable for all relevant payers.

For the other four products which follow local pricing policies, namely, azithromycin, carbamazepine, budesonide and capecitabine, Teva reports setting the price by referring to the pricing policies set by the local governments. Within the private market in South Africa, an upper-middle income country, Teva supplies budesonide, a treatment indicated for asthma and chronic obstructive pulmonary disease (COPD), at a price aligned with the government reference price, ensuring patients can access the treatment without making co-payments. In Thailand, an upper-middle income country, Teva supplies capecitabine within the private market, adhering to government pricing regulations that set the ceiling price. Teva has provided evidence of product volumes sold within private markets for the six assessed products.

For two products, cisplatin and carboplatin, Teva implements product donation programmes In Ghana, a lower-middle income country, the company collaborates with Direct Relief and Breast Cancer International to supply cisplatin through its breast cancer donation programme. Teva reports that approximately 400 women across two hospitals received treatment between January 2020 and March 2023. In Malawi, a low-income country, the company implements its Global HOPE Donation programme* in collaboration with Texas Children's Hospital and Direct Relief to provide carboplatin for children with cancer and blood disorders.

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

For each of the ten products selected for assessment, Teva 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**
Azithromycin	Uzbekistan (LMIC)		●	●		
Budesonide	South Africa (UMIC)		●	●		
Capecitabine	Thailand (UMIC)		●	●		
Carbamazepine	Ukraine (LMIC)		●	●		
Carboplatin	Malawi (LIC)			●	●	●
Cisplatin	Ghana (LMIC)			●	●	●
Fluoxetine	No country-specific access strategy reported					
Lisinopril	Nigeria (LMIC)		●	●		
Risperidone	Peru (UMIC)		●	●		
Sumatriptan	No country-specific access strategy reported					

For capecitabine and budesonide, Teva reports participating in tenders to supply the public sector. However, it is unknown whether the company secured and/or were awarded the tender in Thailand and South Africa.

For cisplatin and carboplatin, donation programmes were the only strategy employed by Teva to ensure access.

*The Global Hope Donation programme is active in other countries in scope, which are not covered under this assessment: Botswana, Ghana, Rwanda Tanzania, and Uganda.

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

EXPANDING ACCESS

EA4. ENGAGING IN LICENSING ACTIVITIES

During the period of analysis, Teva did not report engaging in any non-exclusive voluntary licensing agreements or exclusive licensing agreements within the geographic scope of the Programme.

EA5. IMPROVING PRODUCT AVAILABILITY

Teva's manufacturing network consists of 53 manufacturing sites and 25 R&D centres spread across 27 countries. While the specific LMICs where these sites are located are not disclosed by the company, Teva does report that the majority of its production capacity is located in Europe, India, Israel, Latin America and North America.* Out of the 53 sites, 16 specifically focus on active pharmaceutical ingredient (API) manufacturing. Teva recently announced a new strategy in 2023, indicating its intention to adapt its manufacturing footprint and reduce its number of sites to reach a range of 40 to 44 by 2027. It is uncertain whether the planned closures involve sites in LMICs in scope.

Teva utilises its manufacturing network to ensure product availability in the different markets in which it is present, therefore its operation of local manufacturing sites in LMICs in scope is limited. Teva aims to maximise its global manufacturing capabilities to meet the supply needs of different countries and regions. For instance, the company's sites in the Latin American and Asia-Pacific regions serve different LMIC markets. Teva also reports striving to simplify its network by creating clusters and specialised sites focusing on specific manufacturing technologies and products. This approach can help enhance efficiency in terms of lead times and cost optimisation.

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

*Teva. United States Securities and Exchange Commission. Form 10-K. Annual Report for the Fiscal Year Ended 31 December 2022.

SUPPLY & QUALITY

SQ1. DEMAND PLANNING AND DATA SHARING

Teva reports that is has established an internal system for forecasting and demand planning, both for its regular supply activities and for new product launches. This system includes a 24-month forecast which is shared with the company's manufacturing sites during its annual operational plan and adjusted accordingly on a monthly basis.

The company reports that in certain circumstances it collaborates with government agencies and authorities, disclosing information regarding stocks in order to fulfil local needs.

SQ2. DELIVERY PERFORMANCE

Teva uses a global logistics system to track the delivery of its finished goods, and plans to extend the coverage to APIs and raw materials. Teva reports measuring On Time in Full (OTIF) for every delivery and aggregating performance results to a monthly Key Performance Indicator, which is assessed globally. Additionally, the company reports having established last-mile tracking systems for product distribution within countries where delivery takes place, however, it is unknown whether this is also applied in LMICs. The company did not provide any specific examples of how it communicates with procurement agencies or the steps it takes to address issues that may impact product delivery.

SQ3. STOCKOUTS AND SHORTAGES MITIGATION

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

The company reports that it maintains buffer stocks of APIs, critical components and finished goods, alongside having a finished good stock policy in place. The company reports conducting weekly and monthly regional audits to identify and mitigate out-of-stock risks. Additionally, Teva reports having developed a special software for optimising global stocks. The company does not disclose holding regional stocks of finished goods in countries in scope, or taking steps to decentralise stocks of critical components, as it states leveraging its global network to meet supply needs in different locations.

The company reports implementing a dual sourcing policy in some instances, based on the risk profile and portfolio importance. Additionally, Teva states using a mix of global and local suppliers to promptly meet demand but does not report the proportion of locally sourced materials. The company also reports taking steps to maintain the availability of APIs and meet surges in demand. Teva operates a separate API business that produces over 350 APIs for both vertical integration and sale to third parties, while also outsourcing additional APIs from suppliers across Europe, Asia and the Americas. The company has an API department with dedicated teams that engage in prioritisation and risk mitigation. During the COVID-19 pandemic, Teva leveraged its API production and overall manufacturing capabilities to meet surges in demand. However, no specific examples of these steps were publicly disclosed. The company has also established a Critical Action Committee (CAC) to address emergencies related to drug or API shortages, in all countries where the company operates. There were no concrete examples provided to demonstrate how CAC has addressed shortages specifically in LMICs in scope.

To further meet product demand, Teva reports developing a global platform that facilitates fulfilling product demand in case of emergency needs, allowing the company to move available stocks to other locations.

FIGURE 3 **What steps is Teva 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	●

Teva reports implementing a dual sourcing policy in some instances.

Teva implements a global platform that allowed it to move 5,000 units of vincristine, a cancer treatment (not in scope of this Programme) from one market to another to address shortages.

SUPPLY & QUALITY

SQ4. MANUFACTURING QUALITY ASSURED PRODUCTS

Teva reports that all its manufacturing sites comply with the required regulatory standards, including current good manufacturing practices (cGMPs) and other standards set by organisations such as the International Council for Harmonization. These standards are enforced by regulatory authorities such as the FDA (US), EMA (Europe), MHRA (UK), PMDA (Japan), and NMPA (China). The company reports that most of its sites have stringent regulatory authority (SRA) approval from the EMA or FDA. Its remaining sites, located across Latin America, have been approved by national regulatory authorities (NRAs). Teva has not submitted any products to the WHO prequalification (PQ) programme, which exempts the company from site inspections by the WHO. No warning letters from the USFDA or non-compliance reports from the EMA were issued at Teva's sites in countries in scope during the period of analysis.

The company reports that it prioritises maintaining quality across all 53 of its manufacturing sites. To achieve this, Teva has implemented a quality management system (QMS) that enables continuous monitoring throughout the manufacturing process. Through this system, the company addresses any quality concerns and takes corrective and preventive measures when necessary. To ensure any quality related issues are addressed, the company monitors the execution of corrective actions on a monthly basis. The Senior Vice President of Global Quality and the Chief Quality Officer are ultimately responsible for quality compliance and for establishing, implementing and continuously improving Teva's QMS.

Teva utilises multiple methods to evaluate its third-party suppliers on GMP and compliance. This includes a certification programme used to assess third party suppliers on GMP, which considers suppliers' audit outcomes amongst other criteria. Additionally, Teva requires its suppliers to adhere to its Code of Conduct, which includes a requirement for suppliers to inform the company immediately of any significant inspection or regulatory issue with national or international authorities.

SQ5. SAFEGUARDING QUALITY & SAFETY OF MARKETED PRODUCTS

Teva implements strategies to maintain the quality and safety of its products. The company reports having strategies in place to combat falsified, substandard and/or unsafe medicines. The company's Anti-counterfeiting Policy aims to protect customers' safety and the integrity of the supply chain and applies to all aspects of the company's supply chain, including third-party manufacturers.* Teva Global Corporate Security focuses on product security and is responsible for enforcing these policies and managing supply chain security. When a falsified medicine is detected, the company alerts the appropriate health or regulatory authorities, along with any immediate trading partners that could have received the product. Additionally, the company engages in several partnerships to help address the risk of substandard and falsified medicines. Teva has established processes for managing crisis events, such as product recalls. These processes are applied globally, and in compliance with local laws and regulations. The company also works with local health authorities to address potential product recalls and take appropriate action to protect consumers.

The company works to keep its supply chain secure through implementing technologies and systems to mitigate the circulation of substandard and falsified medicines. For example, the company has implemented mechanisms to improve the traceability of its global shipments, including 'Real Time Tracking' to track its shipped products to increase supply chain visibility worldwide. This system enables the company to respond to any temperature and/or route deviations and ensures that customers maintain visibility of any deviations that may occur. However, no information is publicly available on whether the company makes efforts to disclose the source of finished products, including specifying the primary manufacturing plant, and disclosing product components and materials that are third-party sourced.

FIGURE 4 **Depth and breadth of quality-assurance strategies**

This table shows the types of strategies Teva 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 efficent 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	

Teva has set the goal to maintain 100% annual evaluations of identified high-risk third-party partners through its Third-Party Due Diligence tool, which screens for possible compliance risks using a database of publicly available information on compliance.

Teva reports the majority of its sites are approved by SRAs, while others have the approval of NRAs. However, it does not disclose any further details.

The company has an Anti-Counterfeiting Policy to mitigate the circulation of substandard and falsified products.

*Falsified medicines are included in the company's Anti-Counterfeiting Policy. Teva states that the terms "falsified" and "counterfeit" are used interchangeably when addressing this issue. The definition of falsified medicines used in this report can be found in the Appendix.

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