

Teva Pharmaceutical Industries Ltd

Generic medicine manufacturer

Stock exchange: TASE; NYSE • Ticker: TEVA • HQ: Petah Tikva, Israel • Employees: 42,535

PERFORMANCE

Teva performs well overall in its evaluated Research Areas when compared to other generic medicine manufacturers in scope.

Responsible Manufacturing: Performs well. Reports environmental risk-management strategy for own sites, including ongoing risk assessments based on discharge limits.

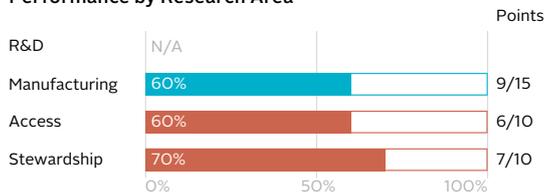
Appropriate Access: Middle-performing. Files for registration for its relevant products in access countries. It discloses strategies for pricing and to ensure supply including forecasting, global supply networks, and safety and strategic stocks.

Stewardship: Performs well. It does not deploy sales agents to promote its products. It translates packaging for three antibacterial medicines, but reports no further adaptations.

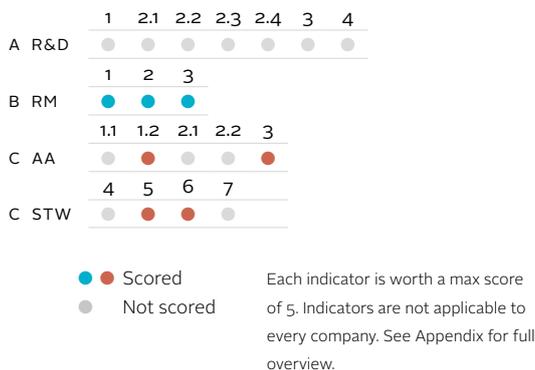
Performance in the Benchmark



Performance by Research Area



How Teva was evaluated



SALES AND OPERATIONS

Therapeutic areas: Neurology; Respiratory diseases

Business segments: North America; Europe; International Markets

Product categories: Generic medicines; Innovative medicines

Manufacturing & supply: Teva reports having 38 manufacturing sites that produce antibacterial APIs and/or drug products.

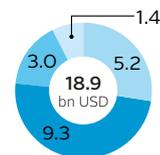
M&A since 2018: None in the antibacterial and/or antifungal sectors

Revenues by product (2018)



Total revenue

Revenues by region (2018)



- Europe
- North America
- International
- Other

PORTFOLIO for diseases in scope

Largest portfolio: At least 202 products (117 unique INNs): 172 antibacterial medicines; 26 antifungal medicines; 4 antibacterial and antifungal combinations

Essential medicines: 37% (74) products are on the 2019 WHO EML**

AWaRe medicines*: 34 Access group; 15 Watch group and 1 Reserve group

Anti-TB medicines*: 8 (incl. 1 Watch group, 2 Reserve group)

Products on the market



The number of products is based on data from public sources, IQVIA, and data submitted by the company. It may not account for Teva's entire portfolio.

* Listed on the 2019 WHO EML (Section 6).

** The number of products is based on data from public sources and IQVIA, and

data submitted by the company. It may not account for the company's complete portfolio.

OPPORTUNITIES FOR TEVA

Expand registration and ensure adequate supply antibacterial medicines to access countries.

Teva can file for registration and ensure adequate supply of antibacterial medicines on the 2019 WHO EML list within its current portfolio (e.g. the forgotten antibiotics cloxacillin, nitrofurantoin, phenoxymethylpenicillin, fosfomycin and trimethoprim) in more access countries.

Expand its set of strategies to ensure the continuous supply of its antibacterial and/or antifungal medicines.

Teva implements some strategies to prevent shortages and stockouts, such as demand planning and maintaining a certain volume of products ready to donate in order to mitigate shortages and stockouts. Teva can also exchange information with external stakeholders (such as government ministries of health) to align supply with demand and set up contracts with multiple suppliers.

Implement and monitor its environmental risk-management strategy, including discharge limits, at third-party suppliers and external private waste-treatment plants. Teva has an environmental risk-management strategy and auditing processes for its own manufacturing sites, including discharge limits. The company can ensure that these limits, as well as the strategy, extend fully to the sites of third-party suppliers and external private waste-treatment plants, including auditing and discharge-monitoring processes.

Further adapt brochures and packaging. Teva already adapts its packaging by taking account of language. It can also make brochure and/or packaging adaptations that take account of literacy levels, paediatric use, adherence to treatment and environment conditions to facilitate appropriate use.

CHANGES SINCE 2018

- Recently started the Teva Access Initiative and is collaborating with five NGOs (e.g. Stop TB Partnership, the Global Drug Facility (GDF) and the IDA Foundation) to address a sustainable medicine supply in access countries.
- Newly reports not deploying sales agents to promote its antibacterial and/or antifungal medicines and does not have marketing materials for such medicines.

PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT

As a generic medicine manufacturer (GMM), Teva is not evaluated in this Research Area.

However, the company reports investments of > USD 2.5 million in 2017-2018 in the development

of generic versions of antibacterial and antifungal medicines.

B RESPONSIBLE MANUFACTURING Evaluated: antibacterials manufacturing (APIs and drug products)

B.1 Environmental risk-management strategy for own sites

Teva reports a strategy to minimise the environmental impact of wastewaters and solid waste from antibacterial manufacturing at its sites, which includes audits. The company reports setting discharge limits for all antibacterials manufactured at its sites, based on PNECs to limit AMR (or more stringent PNECs), as published by the AMR Industry Alliance. It has used these limits to initiate risk assessments at a subset of its sites, with plans to cover the great majority of its antibacterial production by volume by the end of 2019.

Teva has not yet implemented its strategy with third-party suppliers of antibacterial APIs and/or drug products. It expects suppliers to follow its code of conduct, which includes only a general provision on appropriate management of API-containing waste. Teva expects external private waste-treatment plants to comply with its environmental standards, but there is limited information on how plants are audited. Teva reports not requiring wastewater plants to set antibacterial discharge limits.

B.2 Publicly discloses some information on environmental risk management

Teva publishes some components of its environmental risk-management strategy. Further, it is a member of the AMR Industry Alliance, which publishes a list of recommended antibacterial discharge targets. Teva does not publish: (1) the results of environmental audits, whether conducted at its own sites, the sites of suppliers or external private waste-treatment plants; (2) a list of these suppliers and waste-treatment plants; or (3) the levels of antibacterial discharge from its own sites.

B.3 Has system to maintain production quality for own and suppliers' sites; regulator requested official corrective action

Teva reports having a system to maintain high-quality antibacterial production, consistent with international GMP standards. This includes periodic risk-based internal audits and tracking of corrective actions. In July 2018, an FDA drug quality inspection identified non-conformities with cGMP at one Actavis site (a Teva subsidiary) producing antibacterial drug products, resulting in an official request for corrective action. The company reports that oral antibacterial products manufactured at this site were not impacted by the observations and that the site is taking corrective actions. The company reports requiring suppliers to abide by regulatory and company quality standards, auditing its suppliers as its sites and having the same expectations in terms of corrective action implementation.

C APPROPRIATE ACCESS & STEWARDSHIP – ACCESS

Evaluated: access activities relating to antibacterial & antifungal medicines & vaccines in 102 access countries***

C.1.1 Registering on-patent products

Teva was not eligible for this indicator as it does not have on-patent antibacterial or antifungal medicines or vaccines in its portfolio.

C.1.2 Filed to register relevant off-patent products† in 6.4 access countries on average

Teva is a middle-performing company when it comes to filing relevant off-patent products for registration. It has filed 14% of its products (1/7 antibacterial and antifungal medicines) for registration in access countries. Its most widely filed product in this analysis is the antibacterial linezolid, used for various conditions including pneumonia and skin infections. Teva has filed its version of this product for registration in approximately 50 access countries. Teva plans to file its other four antibacterial medicines and two antifungal medicines with highest volume sales in access countries during 2019-2020.

C.2.1 Pricing strategies for on-patent products

Teva was not eligible for this indicator, as it does not have on-patent antibacterial or antifungal medicines or vaccines in its portfolio.

C.2.2 Pricing strategies for off-patent products

Companies were not scored for this indicator as the available data was not sufficient for a comparative analysis. Teva does report that it donates six of its highest volume antibacterial and antifungal medicines (in terms of sales) to access countries via the US Donations Program and NGO partnerships with AmeriCares, Brother's Brother Foundation, Direct Relief International, Operation Blessings and Universal Heart.

C.3 Some strategies to ensure the continuous supply of relevant products

Teva is a middle-performing company, compared to other generic medicine manufacturers evaluated, when it comes to taking steps

to ensure the continuous supply of its relevant products to access countries. It discloses some strategies for achieving this aim. It uses an Enterprise Resource Planning (ERP) system for demand planning and maintains a certain volume of products ready to donate in order to mitigate shortages and stockouts. Teva recently started its Teva Access Initiative and is collaborating with five NGOs with the aim of enlarging its footprint and ensuring a sustainable medicine supply in more countries. To mitigate against falsified medicines reaching the supply chain, Teva's donated products go directly to its certified NGO partners and all EU Teva affiliates now implement product serialisation (as required by EU law). Teva also supplies five forgotten antibiotics‡ (benzylpenicillin, chloramphenicol, colistin, dicloxacillin and tobramycin) to some access countries.

C APPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP

Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

C.4 Educational stewardship activities

Teva is not eligible for this indicator as it reports no involvement in AMR-related educational programmes aimed at healthcare professionals (HCPs).

C.5 Does not promote its antibacterial and antifungal medicines

Teva engages in practices that aim to address the appropriate use of antibacterial and/or antifungal medicines. It is one of the two companies evaluated to report that it does not deploy any sales agents to promote such products. As Teva does not perform any promotional activities, it does not have marketing materials for such medicines.

C.6 Translates packaging materials to facilitate appropriate use

Teva adapts packaging to facilitate the appropriate use by patients of relevant products: namely its antibacterials azithromycin, linezolid and pyridoxine. These adaptations only take account of language needs. Their packaging contains information that is translated into English, Spanish, French and Portuguese.

C.7 Antimicrobial surveillance

As a GMM, Teva is not eligible for this indicator as GMMs have a limited role in AMR surveillance activities.

*** 102 low- and middle-income countries where better access to medicine is most needed. See Appendix VI.

† See Appendix VII.

‡ A set of older off-patent antibacterials that are not always marketed or available, due to economic reasons, lack of

awareness and lack of demand but are still considered effective as a treatment for bacterial infections. See Appendix VII for citation.