

Teva Pharmaceutical Industries Ltd

Generic medicine manufacturer

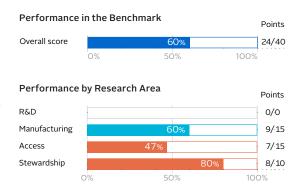
Stock exchange: NYSE • Ticker: TEVA • HQ: Petah Tikva, Israel • Employees: 40,216

PERFORMANCE

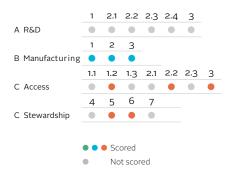
Teva performs above average overall in its evaluated Research Areas when compared to the other generic medicine manufacturers in scope. **Responsible Manufacturing:** Middle-performing. Reports environmental risk-management strategy for own sites; tracks compliance with limits at own sites.

Appropriate Access: Middle-performing. Files some of its relevant products (off-patent generic medicines) for registration in access countries. Reports some strategies to expand access and ensure continuous supply of its relevant product.

Stewardship: Performs well. It does not promote antibacterial and/or antifungal medicines to healthcare professionals. It adapts packaging for patients.



How Teva was evaluated



OPPORTUNITIES FOR TEVA

Ensure compliance with antibacterial discharge limits at suppliers sites by tracking and publicly disclosing progress and results specific to antibacterials for all sites. Teva can set limits and quantify discharge levels to track compliance at all suppliers's sites, as it does at its own sites, and publicly disclose the results. Teva reports the goal to audit half of all supplier sites by end of 2030. Teva can also publish information on how it manages environmental risk related to antibacterial manufacturing. The company currently publishes limited information.

Expand registration of antibacterial and antifungal medicines. Teva can expand registration of its antibiotics and antifungals listed on the 2021 WHO EML, such as cefalexin, colistin and nystatin, to more countries, including low-income countries.

Ensure continuous supply of antibacterial and antifungal medicines. Teva mitigates against shortage risks, e.g., by maintaining a flexible safety stock management process and keeping buffer stocks. It can implement several strategies to mitigate against shortage risks in access countries, e.g., build local manufacturing capacity and transfer technology into access countries.

Expand adaptations to brochures and packaging to consider more patient needs. In order to support the appropriate use of its antibacterial and/or antifungal medicines by patients, Teva adapts brochures to take account of local languages. It can further adapt its brochures and packaging to consider literacy levels, paediatric use, environmental conditions and patient adherence to treatment.

CHANGES SINCE 2020

- In its 2020 Environmental, Social and Governance (ESG) Progress Report, Teva publicly commits to meet existing AMR Industry Alliance commitments to minimise antimicrobial discharges from its own operations and supply chain by 2030.
- Teva pledged an unknown amount to the AMR
 Action Fund

SALES AND OPERATIONS

Therapeutic areas: Migraine/headache/pain, Neurodegenerative conditions and movement disorders, Oncology, Respiratory
Business segments: North America, Europe, International Markets
Product categories: Biosimilars, Generic medicines, Innovative medicines

M&A since 2020: None in the antibacterial and/or antifungal sectors

Net revenues by business segment



Net revenues by region



PORTFOLIO for pathogens in scope

Comparatively large portfolio: At least 137 products: 115 antibacterial medicines; 22 antifungal medicines

Off-patent/generic medicines: 10 of 137 were selected for analysis* (amoxicillin [A], azithromycin [W], cefalexin [A], ciprofloxacin [W], clotrimazole [F], colistin [R], daptomycin [R], ethambutol [T], isoniazid [T], nystatin [F])

AWaRe medicines**: 21 Access group; 43 Watch group; 5 Reserve group Anti-TB medicines**: 4

Products on the market



Antibacterial vaccine
 Antibacterial medicine
 Antifungal medicine

PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT

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

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

B.1 Environmental risk-management for own sites and plans implementation at supplier sites

Teva reports a strategy to minimise the environmental impact of wastewaters and solid waste from antibacterial manufacturing at its sites, including audits every three years. It reports setting discharge limits in the receiving environment for all antibacterials manufactured at its sites, based on PNECs to limit AMR, as recommended by the AMR Industry Alliance. Discharge levels are quantified using a mass balance approach. It reports 22 of 32 sites have quantified discharge levels and 10, or 31%, are compliant with discharge limits.

Teva started requiring third-party suppliers of antibacterials to follow similar standards. It reports a goal to audit 50% of all >250 suppliers by the end of 2030.*** It does not yet require suppliers to set discharge limits or quantify dis-

charge levels.

Teva expects external public and private waste treatment plants to comply with its general environmental standards. There is limited information on the requirements Teva makes of external private and public waste-treatment plants, in terms of audits and antibacterial discharge limits and levels.

3.2 Publicly discloses some information on environmental risk management and quantifying discharge levels at own sites

Teva publishes some components of its environmental risk-management strategy. It is a member of the AMR Industry Alliance, which publishes a list of recommended antibacterial discharge targets. Teva publicly commits to quantifying discharge levels at 20 of its 34 own sites that manufacture antimicrobials by the end of 2020. The levels themselves are not pub-

lished. Teva also does not publish: (1) the results of environmental audits, whether conducted at its own sites, the sites of suppliers or external private and public waste-treatment plants; or (2) a list of these suppliers and plants.

B.3 System in place to maintain production quality for own and suppliers' sites; regulator requested official corrective action

Teva reports that its own sites and suppliers have a system to maintain high-quality antibacterial production consistent with international GMP standards. This includes periodic risk-based audits and tracking of corrective and preventive actions. There is limited information on whether Teva requires its suppliers to audit their own suppliers. In January 2020, an FDA drug quality inspection identified non-conformities with cGMP at one Actavis site (a Teva subsidiary in Davie, FL, USA) producing antibacterial drug

^{*} See Appendix VII for information about eligibility criteria for products.

^{**} Listed on the 2019 WHO EML.

^{***}After period of analysis, Teva reported that the number of suppliers is updated

products, resulting in an official request for corrective action. Teva reports that the oral antibacterial products manufactured at this site were not impacted by the observations and that the site is taking corrective actions.

C APPROPRIATE ACCESS & STEWARDSHIP - ACCESS

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

Teva is not eligible for indicators: C.1.1, C.1.3, C.2.1 and C.2.3. For more information, see Appendix VII.

C.1.2 Filed to register off-patent/generic medicines in 3 access countries on average

Teva has an average performance, filing three of its 10 relevant off-patent/generic medicines for registration in three access countries on average. Its most widely filed relevant product is the antibacterial azithromycin, filed in 19 access countries. Two of its relevant products are filed in less than ten access countries. One of its relevant product (azithromycin) is filed for registration in seven LICs.

C.2.2 Some strategies to expand access to off-patent/generic medicines

Teva has an average performance, with access strategies reported for three of its ten relevant off-patent/generic medicines. It aims to expand

access in access countries through donations and tenders. In 2020, Teva, together with its partners, reports having donated more than 17 mn units of antibiotics and antifungals to access countries. In Malawi, Teva is partnering with Global HOPE and Direct Relief, to donate antibiotics for pediatric immunosuppressed cancer patients. The initiative aims to treat 4,000 new patients in Malawi over the next five years. Teva participates to the GDF and IDA Foundation global tenders for tuberculosis, to provide linezolid to all GDF eligible countries.

C.3 Some strategies to ensure continuous supply

Teva has an average performance, with strategies reported in three of four areas assessed. Teva mitigates against shortage risks by maintaining a certain volume of products ready to donate. Teva has a flexible safety stock management process within its Enterprise Resource

Planning (ERP) system. It reports keeping buffer stocks. Teva does not report capacity building and technology transfer initiatives. To mitigate against substandard and falsified products, Teva directly donates its medicines to certified partners and uses security features such as serialisation.

C APPROPRIATE ACCESS & STEWARDSHIP - STEWARDSHIP

Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

C.4 Educational Stewardship Activities
There is no information regarding Teva's involvement in AMR-related educational programmes
aimed at healthcare professionals and it is
therefore not eligible for this indicator as there is
no conflict of interest mitigation to be assessed.

C.5 Does not promote its antibacterial and/ or antifungal medicines

Teva performs strongly in sales practices. It does not deploy any sales agents to promote its antibacterial and/or antifungal medicines to healthcare professionals. Since Teva does not develop or use marketing materials for antibacterial and/or antifungal medicines to promote such medicines to healthcare professionals, the company is not eligible to be assessed on marketing materials.

C.6 Makes one type of brochure and/or packaging adaptation to facilitate appropriate use by patients

Teva adapts packaging to facilitate the appropriate use of azithromycin, linezolid and pyridoxine by patients. Teva is middle-performing in this measure, taking account of language. The packaging contains information translated into English, Spanish, French and/or Portuguese.

C.7 AMR Surveillance

As a generic medicine manufacturer, Teva is not assessed in this indicator nor does it report any involvement in AMR surveillance activities.