Takeda Pharmaceutical Co., Ltd.

Stock Exchange: XTKS • Ticker: 4502 • HQ: Osaka, Japan • Employees: 31,168 (consolidated)

PERFORMANCE

Takeda is one of the biggest risers, moving 5 places to 15th. Its access-to-medicine strategy aligns with its overall business strategy. This is not yet coupled with a solid compliance system, as evidenced by cases of misconduct settled since 2014. Takeda has strong R&D commitments related to access to medicine, and shares IP for leishmaniasis and Chagas disease. It also improves in pricing, where Takeda has newly implemented equitable pricing strategies that differentiate between countries. It newly commits not to file for or enforce patents in sub-Saharan Africa. It has not yet established a structured product donation programme. It improves in capacity building, particularly for R&D and pharmacovigilance.

CHANGE SINCE 2014

- Has launched new access strategy supported by a centralised dashboard for tracking progress and performance.
- Has been handed the largest fine following a case of misconduct of all companies in scope during the period of analysis.
- Has improved its measures for ensuring clinical trials are conducted ethically and is more transparent with clinical trial data.
- Implements relevant inter-country equitable pricing strategies for the first time.
- Does not provide price or volume-of-sales information.
- Improves its accountability for its sales agents’ pricing practices.
- Newly commits to not filing for patents and to abandoning patents held in sub-Saharan Africa.
- Has improved its auditing processes related to its ad hoc product donations, which it applies to a limited selection of partners.
- Has supported local health services in Haiti through Access to Health Project Haiti, in partnership with Partners in Health and other stakeholders.

OPPORTUNITIES

Engage with stakeholders to act on commitment to voluntary licensing. Takeda has a new commitment to considering the use of voluntary licensing as a mechanism for addressing the affordability and supply of on-patent and pipeline products in lower-middle income countries. It can actively seek potential partners (including manufacturers, where relevant) to explore viable opportunities for turning this commitment into action.

Implement access plans as company expands its focus. As Takeda expands its pipeline and the geographic scope of its pharmaceutical business, it can implement detailed plans for ensuring successful new products are accessible upon market approval. This can include registration targets for products targeting diseases with high burdens in low- and middle-income countries and plans to ensure affordable pricing.

Ensure the long-term sustainability of its new access strategy. Takeda can strengthen the link between access and its corporate strategies to go beyond a philanthropic approach to improving access to medicine. This would ensure the long-term sustainability of its strategy, as the company moves ahead with an increased focus on access.

Expand use of equitable pricing strategies. Takeda can expand its commitment to equitable pricing, as well as its use, to more products, e.g., azilsartan (Azilva®), a first-line treatment for hypertensive heart disease. The company can also implement intra-country equitable pricing strategies in countries with high levels of inequality and/or high out-of-pocket spending.

Join efforts to combat antimicrobial resistance. Takeda has seven antibiotics that are on the WHO Model Essential Medicines List (EML), are used in clinical practice and are important for low-resource settings. The company can take action to increase access to these medicines, while ensuring their responsible use. Takeda can join global efforts to address antimicrobial resistance, for example by signing the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.
SALES AND OPERATIONS

Takeda’s core therapeutic areas are: gastrointestinal diseases, oncology, central nervous system diseases and cardiovascular and metabolic diseases. The company’s Ethical Drug Division accounts for its largest share of sales, derived from its small presence in the consumer healthcare market. In April 2016, Takeda announced the establishment of Teva Takeda Yakuhin Ltd, a joint venture between Takeda and Teva Pharmaceutical Industries. This step is intended to allow Takeda to focus on developing innovative medicines, as this separate entity will market the company’s off-patent medicines and focus on the generic medicine market. Takeda has sales in 29 countries within the scope of the Index.

PORTFOLIO AND PIPELINE

Takeda has a mid-sized portfolio of 50 products for diseases in scope and a mid-sized pipeline of 24 R&D projects that address the needs of people in low- and middle-income countries. Takeda’s relevant portfolio has a strong focus on non-communicable diseases (NCDs), covering diabetes, hypertensive and ischaemic heart disease and unipolar depressive disorders. The company is developing medicines and vaccines for seven communicable diseases, three neglected tropical diseases (NTDs) and five NCDs.

Takeda’s pipeline is approximately double the size it was in 2014. It has joined the new NTD Drug Discovery Booster, and several of its early-stage innovative projects for NCDs have qualified for analysis for the first time in 2016. Takeda has moved several products along its pipeline since 2014, and received regulatory approval in Japan for trelagliptin succinate (Zafatek®) for type 2 diabetes. Takeda is conducting multiple projects targeting high-priority product gaps with low commercial incentive.

Takeda participates in several R&D projects with the Global Health Innovative Technology (GHIT) Fund that require products be made available in relevant countries at reasonable prices or are licensed out royalty-free.

Takeda’s relevant pipeline concentrates on innovative medicines and vaccines. Its projects are mainly in early stages of development, targeting 17 diseases, with a focus on schizophrenia.

Most medicines in Takeda’s portfolio are for NCDs. It also has several broad-spectrum antibiotics for diseases in scope.

Takeda is adapting one product, for malaria, which targets the needs of people living in low- and middle-income countries.

**Pipeline projects**

<table>
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<tr>
<td>0</td>
<td>10</td>
<td>20</td>
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<tr>
<td>In partnership, with access provisions (ap)</td>
<td>In partnership, w/o ap</td>
<td>Not in partnership</td>
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Takeda’s relevant pipeline concentrates on innovative medicines and vaccines. Its projects are mainly in early stages of development, targeting 17 diseases, with a focus on schizophrenia.

**First-line treatments and essential medicines**

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<th>6</th>
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<th>15</th>
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<td>0</td>
<td>10</td>
<td>20</td>
<td>30</td>
</tr>
<tr>
<td>First-line &amp; on WHO Essential Medicines List</td>
<td>First-line only</td>
<td>On WHO EML only</td>
<td>Other</td>
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A comparatively high proportion of Takeda’s relevant products are listed on the WHO EML and/or as first-line treatments: e.g., azilsartan (Azilva®) and candesartan for hypertensive heart disease.

**Adaptive medicines and vaccines**

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<tr>
<td>0</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>Communicable</td>
<td>Non-communicable</td>
<td>Maternal and neonatal</td>
</tr>
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</table>

Most medicines in Takeda’s portfolio are for NCDs. It also has several broad-spectrum antibiotics for diseases in scope.
Takeda Pharmaceutical Co., Ltd.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT
RANK 16  SCORE 3.0

Rises three positions due to new access strategy. Takeda climbs from 19th to 16th position. This reflects the company’s inclusion of access in its business strategy and its new system for tracking access-related performance.

Access strategy aligned with overall business strategy. Takeda’s access strategy has been updated, drawing on the Access to Medicine Index methodology. Specific areas of focus within the strategy include vaccines, less developed healthcare markets and sub-Saharan Africa.

New centralised performance management system. Takeda has implemented a centralised access strategy dashboard. This dashboard reports on the overall implementation and progress of the company’s access initiatives. It also allows divisions to track the progress of key initiatives and escalate problems to leadership if needed.

Ad-hoc stakeholder engagement approach. Takeda does not have a structured approach to stakeholder engagement. Furthermore, the company does not publish information related to its stakeholder engagement.

MARKET INFLUENCE & COMPLIANCE
RANK 13  SCORE 1.8

Rises two positions despite large fine for misconduct. Takeda rises to 13th place, despite being the subject of the largest settlement in financial terms following a case of misconduct of any company evaluated. The company has a comprehensive, risk-based auditing system and enforces its procedures on third parties.

Marketing code in place, but performance incentives are sales driven. Takeda has a marketing code of conduct that aligns with industry standards. However, the company does not have performance incentives for its sales employees other than sales targets. Furthermore, it only provides general information about its marketing practices in countries in scope.

Low transparency regarding lobbying activities. Takeda declares it may make financial contributions to political organisations, public officials and candidates for public office where permitted by law. Takeda has shared its policy positions with the Index related to the TRIPs and the Doha Declaration. It has also disclosed information about its conflict of interest policy, but under a non-disclosure agreement.

Auditing system in place. Takeda has a risk-based auditing system for measuring compliance with its anti-bribery and anti-corruption measures and codes of conduct. For each country where it operates, audits are undertaken annually or every two years, depending on risk factors. Wherever issues are identified, an audit the following year is mandatory. The company also audits some third parties.

Enforcement procedures apply to third parties. Takeda employs a number of strategies to ensure that third parties adhere to relevant standards of behaviour, such as due diligence and monitoring. These include enforcement procedures to contract termination in cases of non-compliance.

Settlement for misconduct relating to unethical marketing. Takeda has been the subject of settlements in two instances since 2014. In the US, Takeda agreed to pay up to USD 2.4 bn to settle U.S. personal injury suits claiming that the company did not adequately warn about the cancer risk of one of its diabetes medicines. The company maintains that it acted appropriately.

RESEARCH & DEVELOPMENT
RANK 7  SCORE 2.8

Maintains performance in R&D. Takeda fell one position, but remains in the top ten. This fall is largely explained by improvements in the performances of its peers. The company maintained a strong performance across R&D. Its relevant pipeline almost doubled in size and its performance in product development, clinical trial conduct and data transparency also improved.

R&D commitments are oriented towards access. Takeda aims to deliver its pipeline to patients with unmet needs around the world. The company has a dedicated Access to Medicine Council with specific R&D aims.

No policy for R&D partnerships to include access plans. The company does not commit to ensuring access-oriented terms (e.g., registration targets or affordable pricing strategies) are systematically included in its research partnerships.

Comprehensive policy to ensure clinical trials are conducted ethically. Takeda has policies and takes measures to ensure its in-house and outsourced trials are conducted ethically. Its policies are strong: they include, alongside standard measures, the consideration of scientific requirements and research protocols and post-trial provisions.

High transparency around clinical trial data. The company upholds high standards of transparency concerning clinical trial data. This includes including providing scientific researchers access to patient-level data upon request, via clinicalstudydatarequest.com.

NTD Drug Discovery Booster. Takeda shares intellectual property for leishmaniasis and Chagas disease via the NTD Drug Discovery Booster. The company also shares intellectual property with partners such as WIPo ReSearch and Drugs for Neglected Diseases initiative.

PRICING, MANUFACTURING & DISTRIBUTION
RANK 16  SCORE 1.3

Rises four places due to performance in equitable pricing. Takeda moves from 20th to 16th, due to its implementation of equitable pricing strategies for the first time, as well as to its improved performance in registering products in high-burden countries.

Newly implements equitable pricing of products for high-burden diseases. Takeda implements equitable pricing strategies for products for diabetes, hypertensive heart disease and chronic obstructive pulmonary disorder (COPD). Only a few (2%) of Takeda’s products have equitable pricing strategies that target priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). These reach just a few corresponding priority countries.

Sets pricing guidelines for all sales agents. Takeda provides pricing guidelines to third-party wholesalers and distributors, but does not provide evidence that it monitors or audits their pricing practices.
Mixed performance in product registration. Takeda does not provide evidence that it sets disease-specific registration targets. It does not publish its criteria for making decisions about when or where to register its products, nor does it publish information about its products’ registration status. However, it has filed to register more than half (70%) of its newest products in a few priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). As most of these products were first marketed in 2010, the company can consider improving its registration in low- and middle-income countries.

Consistent recall guidelines. Takeda has globally consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. Takeda does not publish information on recalls.

Limited brochure and packaging adaptation for rational use. Takeda adapts its brochures and packaging materials to address local language and environmental needs, but does not consider literacy, demographic, or cultural needs.

PATENTS & LICENSING
RANK 17  SCORE 0.6

Among laggards, but new policy. Takeda had not published its patent filing and enforcement policy, the status of their patents, or their position on the Doha Declaration on the TRIPS agreement and public health during the period of analysis. However, there are positive future indications. It has a newly agreed IP policy, which includes a policy of not filing patents in sub-Saharan Africa, and a new preparedness to offer royalty-free licensing terms for supply to low-income countries and Least Developed Countries.

Waiving patent rights in sub-Saharan Africa. Takeda has not made its position on patents public, but it has disclosed to the Index that it will not file for new patents and will actively abandon existing patents in sub-Saharan Africa (except in South Africa).

No public disclosure of patent status. Takeda does not publish the status of its patents.

Commits to engaging in licensing in the future. Takeda does not engage in the non-exclusive voluntary licensing of its patented products. Takeda disclosed to the Index that it will offer royalty-free licences to manufacturers to supply Least Developed Countries and low-income countries.

Absence of competition-related breaches. Takeda was not found to have been the subject of breaches, fines or judgements relating to competition law during the period of analysis.

No public position on Doha Declaration. Takeda has not published its position on the Doha Declaration on the TRIPS agreement and public health.

CAPACITY BUILDING
RANK 10  SCORE 1.8

Showing significant improvements. Takeda is one of the biggest risers since 2014. The company has particularly improved in capacity building in R&D and pharmacovigilance. However, its performance is mixed: it disclosed no relevant supply chain management capacity building initiatives, and does not have a clear focus on local needs.

Strong in R&D capacity building. Takeda builds local R&D capacity through partnerships with and support of local research organisations in countries in scope, including China and Thailand. The company has a relatively large number of partnerships but it is unclear how it targets local skills gaps.

Improved performance in strengthening pharmacovigilance systems. Takeda voluntarily shares safety data with authorities in countries in scope. The company has activities to build local pharmacovigilance capacity in south-east Asia, through the International Society of Pharmacovigilance.

Building manufacturing capacity with a focus in Asia. Takeda commits to assessing and building capacity in countries in scope for in-house manufacturers only. The company undertakes a relatively small number of capacity building activities, focusing on in-house facilities in Asia (India and Indonesia).

Builds capacity outside the value chain in Haiti and Kenya. Takeda’s philanthropic strategy is relatively strong: it targets local needs and includes impact measurements, but does not routinely consider long-term impact. The company builds capacities outside the pharmaceutical value chain, focusing on local gaps in access to health services, in Haiti and Kenya.

PRODUCT DONATIONS
RANK 16  SCORE 1.7

Rises two places. While Takeda has not yet implemented a structured donation programme, it has risen from 18th to 16th position in this area. The company has tailored donation policies and strategies, and is involved in humanitarian aid programmes.

Respects WHO guidelines in product donations. Takeda has tailored its donation strategy, partly in line with the core principles of WHO Guidelines for Medicine Donations.

Donations monitored by partners. Takeda works with international organizations to make ad hoc donations. Third parties have the responsibility of ensuring that donations are made successfully and in compliance with local codes and laws. Takeda reserves the right to conduct independent audits of third parties and recipients.

Involved in humanitarian aid programmes. Takeda provided ad hoc donations for humanitarian aid, mostly via its partner Americares.

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