RANK	SCORE
7	3.51
6 (2021)	

Takeda Pharmaceutical Co, Ltd

Stock exchange: NYSE • Ticker: TAK • HQ: Tokyo, Japan • Employees: 47,347

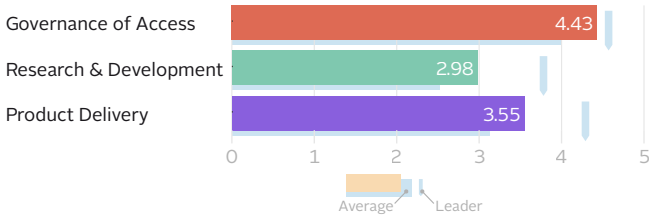
PERFORMANCE IN THE 2022 INDEX

7th place. Takeda ranks among the top ten countries in the Index. The company performs strongly in Governance of Access and engages in high-quality capacity building initiatives across all fields. Despite having a small pipeline, it also performs well in Research & Development, by applying comprehensive access plans to all late-stage pipeline candidates.

Governance of Access: 2nd place. Takeda performs strongly in this area. It has an integrated access-to-medicine strategy with direct board-level responsibility for access to medicine and incentives for its senior executives, including the CEO, and in-country and regional managers. It discloses outcomes of its access-to-medicine activities and has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index.

Research & Development: 7th place. Takeda performs above average in this area. It has a structured access planning framework and applies this to all of its late-stage pipeline candidates. The company also performs strongly in R&D capacity building. However, it has a small-sized priority pipeline compared to its peers.

How score was achieved



Product Delivery: 7th place. Takeda performs well in this area. It leads in applying access strategies for healthcare practitioner-administered products across all country income levels but it has a comparatively poor performance for sharing intellectual property assets, with no evidence of engaging in new agreements during the period of analysis. It has a strong performance in supply chain capacity building and health systems strengthening but shows average performance in building manufacturing capacity.

OPPORTUNITIES FOR TAKEDA

Expand the geographic coverage of project-specific access plans for non-communicable diseases. Takeda has comprehensive access plans in place for all late-stage R&D projects analysed. The company can increase the number of countries included in these plans. For example, the access plan for mobocertinib (Exkivity™) for lung cancer can be expanded to include more low- and lower-middle income countries.

Expand registration of cancer products. Takeda has four on-patent cancer medicines in its portfolio, including non-Hodgkin lymphoma treatment brentuximab vedotin (Adcetris®). This product has been filed in 21 countries in scope of the Index, including three countries with a high burden of non-Hodgkin lymphoma. The company can further expand the registration of this product, especially in countries where the burden of non-Hodgkin lymphoma is the highest, such as Myanmar, Afghanistan and Suriname.

Expand the use of tools to assess patients' ability to pay and determine differential prices to more products and countries. Takeda developed a sophisticated Patient Assistance Tool to assess individual patients' ability to pay. The company can apply this tool to more of its products, such as its lung cancer treatment brigatinib (Alunbrig®), in countries where the tool is already being applied for other products. The patient assistance tool and intra-country pricing strategies can be applied in more countries in scope with a high burden of lung cancer such as China and Thailand.

CHANGES SINCE THE 2021 INDEX

- The launch of Corporate Philosophy Dashboard, including the launch of the Growth and Emerging Market Transformation and Aspiration Dashboard which provides a framework of measuring progress against priorities included access metrics.
- Successful completion of an innovative digital authentication technology pilot in Kenya which will allow the authentication of Takeda products and now preparing for launch readiness in higher risk markets.
- Evaluating a novel field and rapid analytical technology based on time-domain nuclear magnetic resonance (TD-NMR) that has been adapted for testing biologics and vaccines counterfeit suspects to provide immediate results.
- Sought regulatory authorization for its dengue vaccine candidate (TAK-003). Takeda is participating in the EMA's first-ever parallel assessment of a medicinal product for use in the European Union (EU), and through the EU-M4all procedure for countries outside of the EU.
- Joined the Antimicrobial Resistance (AMR) action fund, which was established to support the clinical development of new antimicrobial agents and to achieve a sustainable antimicrobial market.
- Scaled up the Blueprint for Innovative Healthcare Access initiative concept to Nigeria in partnership with BIO Ventures for Global Health (BVGH) to build diagnostic and treatment capacity and in Uganda and Tanzania with the International Cancer Institute (ICI).
- Partnered with UNITAR and the local authorities of Rwanda and South Africa to launch the new Value-based Healthcare (VBHC) Hub, which facilitates locally led initiatives that will promote and advance the implementation of VBHC models in low-income and resource-limited settings.
- Takeda takes a co-leadership role in the Corona Accelerated R&D in Europe (CARE) programme.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

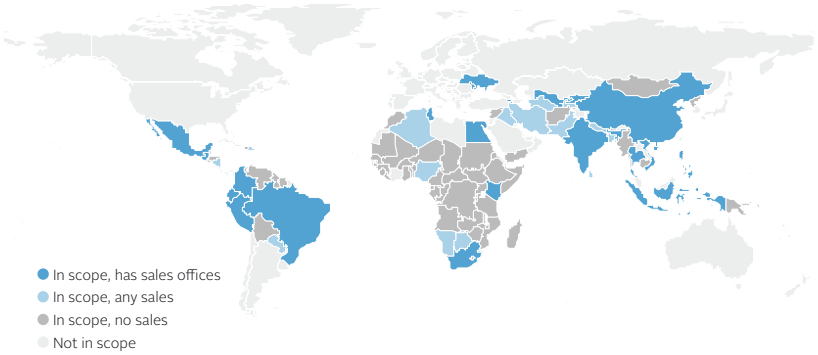
Business segments: Pharmaceuticals.
Therapeutic areas: Oncology, Rare Diseases, Neuroscience, Gastroenterology (GI) and Plasma Derived Therapies.
Product categories: Innovative medicines and vaccines.
M&A news: In March 2021, Takeda announced it would acquire Maverick Therapeutics for USD 525 million. Takeda acquired GammaDelta Therapeutics in November 2021.

Takeda's products are sold in 37 out of 108 countries in scope of the Index. Takeda has sales offices in 21 countries, and sells via suppliers and/or pooled procurement in an additional 16 countries.

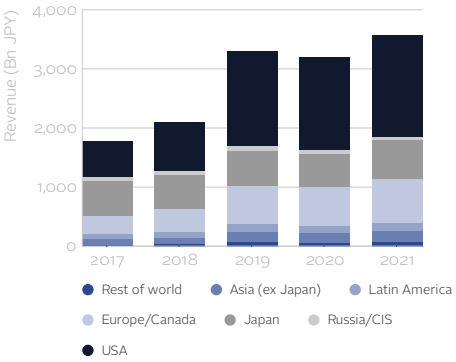
Revenue by segment (2021) – in JPY

Pharmaceuticals	3,569.01 bn
Total	3,569.01 bn

Sales in countries in scope



Sales by geographic region

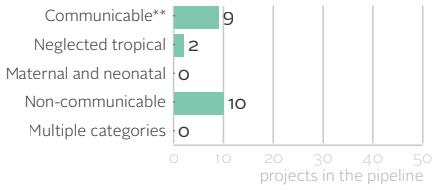


SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

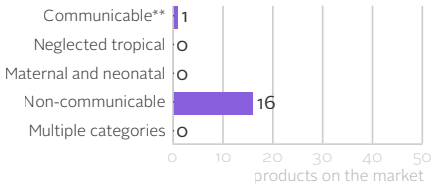
PIPELINE *for diseases in scope*
Takeda has a total of 21 R&D projects in scope with 11 of these projects targeting priority diseases. The other ten R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on coronaviral diseases (6). Of the projects targeting other diseases in scope, the focus is on oncology (7).
Four R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (3).* Evidence of access planning was in place for 100% of these projects.

PORTFOLIO *as selected for analysis by the Index*
Takeda has 16 medicines in scope, 12 of which are on patent, and one vaccine. 42% of these medicines (5) are on the WHO EML. The off-patent medicines target non-communicable diseases (NCDs) such as cancer (1), cardiovascular diseases (2) and kidney diseases (1). The on-patent medicines target NCDs (12) such as diabetes (5), cancer (4), cardiovascular diseases (2) and kidney diseases (1). Takeda's preventative vaccine targets lower respiratory infections.

21 projects in the pipeline



17 products as selected for analysis by the Index†



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	1	8	1	0	0	1	0	11
Addresses needs of LMICs*			1	0	2	1	0	4
Other projects in scope			3	3	0	0	0	6

Breakdown of products

		WHO EML	Non-EML	WHO EDL	Other	Total
Medicines	on patent	1	11			12
	off patent	3	1			4
Vaccines		1	0			1
Contraceptives		0	0			0
Diagnostics				0		0
Other‡					0	0

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in the clinical phase of development were included for this analysis.
**Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
***Other includes projects that have a technical lifecycle and projects that follow a different development cycle (e.g. diagnostics).
†Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
‡Other includes vector control products.

Takeda Pharmaceutical Co, Ltd

GOVERNANCE OF ACCESS

RANK 2 SCORE 4.43

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Takeda performs strongly. Its strategy, called The Corporate Philosophy, aims to increase sustainable access of innovative medicines globally and covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely the CEO of the Takeda Executive Team.

Provides evidence of financial and non-financial access-related incentives at the executive level. Takeda performs strongly. It incentivises its senior executives and in-country managers in Growth and Emerging Markets units to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives.

Publicly discloses outcomes of its access-to-medicine activities. Takeda performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its Access to Medicines Progress Report and its Annual Integrated Report.

Performs above average in responsible promotional practices. Takeda's sales agents are not solely incentivised on sales volume targets. Employee KPIs are based on company or global KPIs which are then passed onto the business unit or function. It does not publicly disclose information related to transfers of values to healthcare professionals (HCPs) in the bulk of countries in scope of the Index (e.g., payments for attending events or promotional activities), unless required by law or by local regulations. However, Takeda reports that it has standard operating procedures to control HCP engagement in all countries in scope of the Index and has implemented automation/digitalisation initiatives to increase controls around HCP activities.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Takeda performs strongly, demonstrating evidence of all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards which has recently been updated and enhanced. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health. Takeda publicly shares support of the Doha Declaration on TRIPS and Public Health, but expresses reservations on its provisions, stating that it does not view compulsory licensing as a sustainable solution and should only be use in exceptional circumstances and as a last resort. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Takeda, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 7 SCORE 2.98

Access planning processes encompass all projects in the pipeline. Takeda has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) in the company's pipeline. In general, Takeda begins developing access plans for R&D projects in Phase II or earlier of clinical development.

A small-sized priority R&D pipeline compared to its peers. Takeda has 11 projects, including one late-stage candidate in its pipeline that target a priority product gap. These projects focus on communicable diseases including coronaviral diseases, Zika, malaria, dengue, chikungunya and tuberculosis. There is evidence of an access plan for Takeda's late-stage candidate targeting a priority product gap. This plan for the dengue vaccine candidate (TAK-003) is currently undergoing regulatory review in the European Union through the EU-Medicines for all (EU-M4all) procedure which intends to facilitate patient access to essential medicines or vaccines that prevent or treat diseases of major public health interest. The plan considers innovative methods to ensure availability, affordability and supply.

Some projects address a public health need in LMICs,* with 100% (3/3) of late-stage projects covered by access plans. In this analysis, Takeda has three late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* These projects have clinical trials in countries in scope of the Index or the project is a first-in-formulation treatment. They focus on cancer and epilepsy. Takeda provides evidence of access plans for all three late-stage projects. These access plans mainly focus on registration preparation and continuous supply.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, Takeda does disclose fully disaggregated R&D investment data to Policy Cures Research.

All five R&D capacity building initiatives included for analysis meet all Good Practice Standards. Takeda leads in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. Takeda builds R&D capacity through the following initiatives:

- Strengthening clinical trial capacity in LMICs with BIO Ventures for Global Health.
- Clinical care and lab capacity building with Partners in Health, AMPATH, Foundation for Cancer Care Tanzania (FCCT) and Healthcare Partners for Access (HPA).
- Instrumental Access Program with Seeding Labs to strengthen local research and diagnostic capabilities.
- ReGRoW (Repurposing Grants for the Rest of the World) program with Cures Within Reach fosters repurposing research to address health inequities and improve access to medicines.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 7 SCORE 3.55

Public commitment not to enforce patents in countries in scope. Takeda publicly pledges to neither file for nor enforce patents. This commitment applies in Least Developed Countries and LICs.

Publicly discloses information on patent status. Like most of its peers, Takeda discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Takeda discloses patent information, including filing date, grant number, grant date and jurisdiction.

Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers. Takeda does not report on any new IP-sharing agreements with public research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

No use of licensing agreements. Takeda does not engage in voluntary licensing for products in scope of the Index. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Filed to register new products in seven countries in scope on average. Takeda did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among old products, its most widely filed is brentuximab vedotin (Adcetris®), for the treatment of non-Hodgkin lymphoma, is filed in 21 countries within the scope of the Index, including three high burden countries (Ecuador, Peru and Ukraine).

Takeda is not eligible for assessment of supranationally procured products.

Has access strategies for all its healthcare practitioner-administered products in scope of this analysis. Takeda is leading in this area. For the two products assessed, the company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC). It makes efforts to reach additional patients using tiered inter-country pricing strategies and intra-country pricing strategies through patient assistance programmes. For example, Takeda evidenced an increase in patient reach of 41% through patient assistance programmes for Adcetris in Thailand and the Philippines and the company developed a pricing strategy that considers patients' ability to pay for its oncology medicine leuprolide acetate (Enantone®) in Thailand. The product is listed on the National List of Essential Medicines and more than 75% of patients can access it. Takeda provides evidence of patient reach.

Has access strategies for its self-administered products for some countries in scope of this analysis. Takeda has an average performance in this area. The company provides examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC) for two of the five products assessed. It makes efforts to reach additional patients through pricing strategies that consider payers' ability to pay and patient affordability programmes (PAPs). For example, in Indonesia, for brigatinib (Alunbrig®) Takeda applies an inter-country tiered pricing strategy. In addition, it launched two projects: the Market Access Scheme programme in which patients get fixed price reductions based on their healthcare practitioner's discretion, and a PAP which provides further cost reduction based on a patient affordability assessment. Forecasted patient reach for the programme is available. In addition, the company provides evidence of how patient reach has been increased through the approaches used.

The one manufacturing capacity building initiative included for analysis meets all Good Practice Standards. Takeda's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. From 2017 until 2021, Takeda was involved in a partnership with Biological E. Limited in India where the company agreed to transfer technology to manufacture affordable combination vaccines for measles. This initiative meets all GPS.

All five supply chain capacity building initiatives included meet all Good Practice Standards. Takeda is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, Takeda's five-year partnership with the World Food Programme (WFP) aims to make health systems and public health supply chains more resilient and enhance targeted countries' ability to absorb and respond to health emergencies and pandemic preparedness. This initiative meets all GPS.

All five health systems strengthening initiatives included for analysis meet all Good Practice Standards. Takeda is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, Healthy Village aims to achieve "healthy villages" by reducing preventable deaths among mothers and children by strengthening training for 1,400 community health workers and providing approximately 500,000 people in local communities with healthcare-related knowledge and services to prevent disease and protect lives.

Has engaged in scaling up one inclusive business model but has not shown evidence of its involvement in piloting any new inclusive business models that meet all inclusion criteria. Takeda performs average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. Blueprint for Innovative Healthcare Access in Rwanda, Tanzania, Uganda and Nigeria aims to save and improve the lives of patients with cancer and other non-communicable diseases using a practical framework to sustainably strengthen healthcare systems at a local level and provide innovative affordability programmes.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Takeda is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient suppliers, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives in LMICs.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Takeda has a policy expecting reporting of SF medicines to national health authorities and the WHO within seven days. It provides evidence of shortened reporting timeframes for cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. Takeda has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations until they reach the patient.

Has no long-term donation programmes for neglected tropical diseases or malaria that are eligible for analysis under this indicator. However, the company is engaged in another structured donation programme: the Max Access Solutions whereby it donates ponatinib (Iclusig®) for chronic myeloid leukaemia in 17 countries since 2015.