

RANK	SCORE
6	3.31
5 (2018)	

Takeda Pharmaceutical Co, Ltd

Stock Exchange: Tokyo Stock Exchange • Ticker: 4502 • HQ: Tokyo, Japan • Employees: 49,578

PERFORMANCE IN THE 2021 INDEX

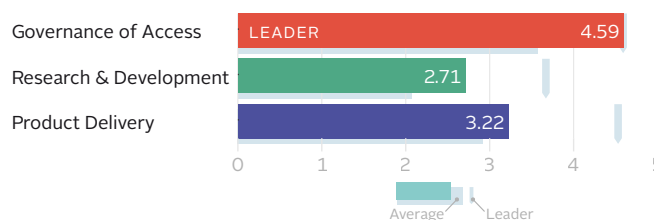
6th place. Takeda leads in Governance of Access, showing a strong performance in governance and compliance and health system strengthening. It has a small-sized priority R&D pipeline with a few late-stage candidates covered by an access plan.

Governance of Access: 1st place. Takeda leads in this area with a clear access-to-medicine strategy, embedded in its corporate strategy, and access-related incentives for the CEO.

Research & Development: 8th place. Takeda performs above average in this area. It has a small-sized priority R&D pipeline compared to peers with one late-stage project covered by a comprehensive access plan. It has an access planning process that encompasses all projects in pipeline. The company performs strongly in R&D capacity-building, with four initiatives meeting all Good Practice Standards.

Product Delivery: 7th place. Takeda has an above average performance in this area. It newly shared some IP assets with third party researchers. It has access strategies in place for

How score was achieved



some of its products in countries of all assessed income levels, yet there is no evidence of new products in scope filed for registration in the majority of high-burden countries. It applies a solid reporting policy to substandard and falsified medicines and discloses some strategies to ensure continuous supply in countries in scope. Yet, it does not provide evidence of ensuring continuous supply in the Least Developed Countries.

OPPORTUNITIES FOR TAKEDA

Strengthen registration approach. Takeda can register its products more broadly and take into account disease burden when looking to register its newest products, such as brentuximab vedotin (Adcetris®) for the treatment of non-Hodgkin's lymphoma, in countries in scope.

Establish project-specific access plans, particularly for NCDs. Takeda has access plans (registration and equitable pricing) for its one late-stage priority R&D project and for 57% of the late-stage R&D projects identified as having a clear public health benefit in countries in scope. Takeda demonstrates a strong access plan for its dengue vaccine candidate and can apply high quality access plans to all its late-stage R&D projects, such as pevonedistat for lung cancer, and TAK-607 for the complications of premature birth.

Expand price segmentation approach. Takeda developed a sophisticated Patient Assistance Tool to define intra-country pricing segmentation for some countries in scope. The company could apply this tool to more of its marketed products, such as brigatinib (Alunbrig®), in countries where the tool is already being applied for other products, and to more countries in scope with a high burden of lung cancer such as Vietnam, Myanmar and Moldova.

CHANGE SINCE THE 2018 INDEX

- Newly launched Blueprint for Innovative Healthcare Access, aimed at addressing access to treatment constraints for patients with non-communicable diseases (NCD), including supply chain management (in Kenya).
- Published a new Position on Access to Medicine with end-to-end access commitments.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Expanded partnership with Seeding Labs from 10 to 23 countries on the Instrumental Access Program (IAP) providing equipment and training.
- Partners with Last Mile Health to train community health workers in Malawi and Liberia.
- Shares chemical libraries to the Global Antibiotic Research & Development Partnership (GARDP) to screen for novel compounds with antibacterial activity.
- Partners with UNICEF to help strengthen health systems for children under five years and pregnant women in Angola, Guinea, Togo.

The term LMIC is used to denote all low- and middle-income countries in the 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.

SALES AND OPERATIONS

Business segments: Pharmaceuticals
Therapeutic areas: Gastroenterology; Rare Diseases; Plasma-derived therapies; Immunology; Oncology; Neuroscience
Product categories: Innovative medicines; Vaccines
M&A news: Completed acquisition of Shire (rare diseases) in 2019 for USD 62 billion. It divested its eye care business to Novartis in 2019 for USD 3.4 billion. Several primary care and OTC

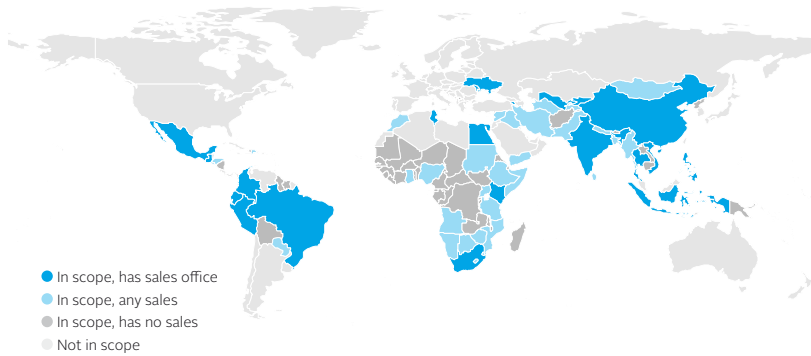
products were divested to different companies, including Stada, Acino, Hypera, Orifarm, Celltrion and Cheplapharm.

Takeda's products are sold in 53 out of 106 countries in scope. Takeda has sales offices in 21 countries, sells via suppliers in 21 countries and via pooled procurement into 11 additional countries.

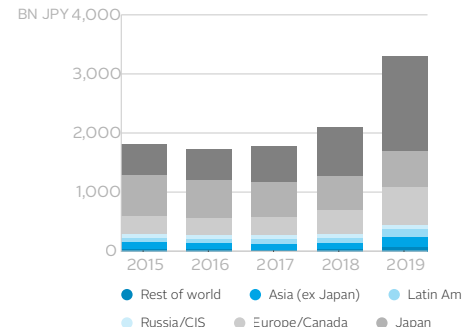
Revenue by segment (2019) – JPY

Pharmaceuticals	3,291.2 bn
Total	3,291.2 bn

Sales in countries in scope



Sales by geographic region



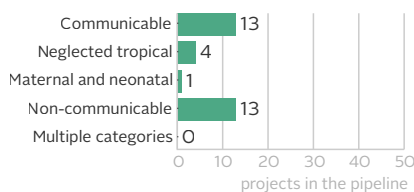
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Takeda has a total of 31 projects featuring an average-sized priority R&D pipeline compared to its peers: 16 projects. The other 15 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on communicable diseases, which includes a late-stage vaccine for dengue. Of the projects targeting other diseases in scope, the focus is on oncology (12).

8 R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (7).^{*} Evidence of access planning was in place for 63% of these projects: 1 targeting a priority disease and 4 addressing a public health need in LMICs.

31 projects in the pipeline

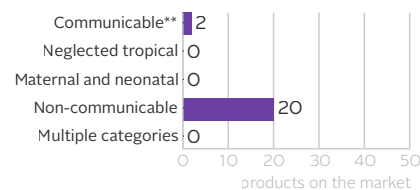


PORTFOLIO as selected for analysis by the Index

Takeda has 22 medicines in scope, 15 of which are on patent, and one vaccine. 19% of these medicines (4) are on WHO's EML. All six off-patent medicines target non-communicable diseases (NCDs) cardiovascular diseases (3), cancer, migraine and kidney diseases. The on-patent medicines mainly target NCDs (13) such as diabetes (6) and cancer (4), cardiovascular diseases (2), kidney diseases and mental health. In addition, one product targets lower respiratory tract infections. Takeda's preventative vaccine targets lower respiratory tract infections, as well.

Access strategies were analysed for 8 products on Takeda's portfolio – nationally procured HCP-administered (3) and self-administered products (5).

22 products as selected for analysis by the Index †



Breakdown of projects*

Dengue vaccine (TAK-003) indicated for children and adolescents (4 to 16 years) has demonstrated immunogenicity against all four serotypes of the dengue virus.

Takeda has the only project targeting preterm birth complications

	Pre-clinical	Phase 1	Phase 2	Phase 3	Approval	Total	W. access plans
Targets established R&D priorities	8	3	0	1	0	12	1
Addresses needs of LMICs*	0	3	3	4	0	10	4
Other projects in scope	0	2	3	0	0	5	

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	1	14			15
off patent	4	2			6
Vaccines	1	0			1
Diagnostics			0		0
Other				0	0

*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, 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.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

†Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

#Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Takeda Pharmaceutical Co, Ltd

GOVERNANCE OF ACCESS

RANK 1

SCORE 4.59

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Takeda performs strongly in this area. The strategy, the Access to Medicines Vision aiming at increasing sustainable access of innovative medicines globally, covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with the CEO.

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, meas-

urable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access-to-medicine activities, including in its Access to Medicines progress report.

Performs above average in responsible promotional practices. Takeda's sales agents are not solely incentivised on sales volume targets. Takeda, however, sets sales incentives at the individual level for agents. Except for Ukraine where it discloses to EFPIA[†] and one Brazilian state with such regulatory requirement, it does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities). However, Takeda reports that it has standard operating procedures to control HCP engagement in all countries in scope.

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 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.

Publicly supports the Doha Declaration on TRIPS and Public Health. Takeda publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on its provisions, namely it challenges the use of compulsory licensing, which it does not see as a sustainable solution. It states that it reserves itself the right to go further than the JPMA where it considers a need to increase access to medicine, in line with its corporate commitments.

RESEARCH & DEVELOPMENT

RANK 8

SCORE 2.71

Access planning processes encompass all projects in 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 for diseases in scope. In general, Takeda begins developing access plans for R&D projects in Phase II of clinical development. The process is for both its in-house and collaborative R&D projects.

A small-sized priority R&D pipeline compared to peers. Takeda has 16 projects, including one late-stage candidate, in its pipeline that target a priority product gap. Among these, the company has most projects for communicable diseases such as malaria. There is evidence of an access plan for Takeda's late-stage candidate targeting a priority product gap. This plan for a dengue vaccine (TAK003) includes a commitment to register the vaccine in dengue endemic areas, WHO prequalification, country tiered pricing strategies, and voluntary licenses.

Some projects address a public health need in LMICs*, with 57% of the late-stage projects covered by access plans. In this analysis, Takeda has seven 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.* Primarily, these projects are first-in-class molecules. Most target cancer. Takeda provides evidence of access plans for four of these projects. These plans prioritize registration in LMICs and equitable pricing for some projects.

Public policy to ensure post-trial access; commits itself to registering trialed products. Takeda has a policy for ensuring post-trial access to treatments for clinical trial participants, who meet criteria as defined in Takeda's Global Patient Access policy. Once a product is approved, Takeda commits itself to registering it in all countries where clinical trials for the product have taken place. This policy considers affordability for the wider population in

the country where the trial(s) took place.

Four R&D capacity building initiatives meets all Good Practice Standards. Takeda leads in this area. The company submitted the maximum of five initiatives, which all met all criteria for inclusion. Four initiatives met all the Good Practice Standards:[§]

- The African Consortium for Cancer Clinical Trials, strengthening cancer clinical trial and research capacity in low- and middle-income countries.
- Seeding Lab's Instrumental Access Program, providing training and equipment to scientists and universities in low- and middle-income countries.
- Mental Health Research and Care Delivery in low- and middle-income countries with Partners in Health.
- Cancer Research and Care Delivery in low- and middle-income countries with AMPATH Kenya, Foundation for Cancer Care Tanzania (FCCT) and Healthcare Partners for Access (HPA).

PRODUCT DELIVERY

RANK 7

SCORE 3.22

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 low-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, Takeda discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically

updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Shares some IP assets with third-party researchers. Compared to its peers, Takeda has newly shared some IP assets with third-party researchers developing products for diseases in scope. This includes five IP assets shared with research institutions, such as the Infectious Disease

Research Institute. Assets shared include molecule libraries and set of target-specific compounds at the discovery stage.

No use of non-assert or licensing arrangements. Takeda does not engage in voluntary licensing nor has it issued any non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

[†] Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, member companies are required to disclose payments made to healthcare pro-

fessionals, such as sponsorship to attend meetings or speaker fees, in European countries they operate in.

[§] Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initia-

tive goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.

No evidence of new products in scope filed for registration in the majority of high burden countries. Takeda did not disclose evidence of filing any of its most recently registered products in more than half of the top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). One of its most widely registered products, Brentuximab vedotin (Adcetris®) for the treatment Non-Hodgkin Lymphoma, is registered/has been filed for registration in 17 countries in scope including two high burden countries; Tanzania and Uganda.

No supranationally procured products. Takeda has no products eligible for scoring in this indicator.

Has access strategies for the majority of health-care practitioner-administered products in scope of this analysis. Takeda is leading in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for two out of the three products assessed. It makes efforts to reach additional patients using tiered inter-country pricing strategies and intra-country pricing strategy through patient assistance programs. For example, in the Philippines, for the oncology medicine, brentuximab vedotin (Adcetris®), the company partners with Axios to offer a patient assistance programme that assesses patient income and offers tailored solutions to increase access, while strengthening the health system by strengthening diagnostics capacity. The company forecasts an increase of 200% in patient reach by the programme in the next 4 years. Takeda is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for some of its self-administered products for countries in scope of this analysis. Takeda performs on average in this area. The company provides examples of access strategies which consider affordability 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 equitable pricing strategies and donations. For example, in Rwanda, Takeda applies an inter-country tiered pricing strategy and an approach to reduce distribution mark-ups to increase access to alogliptin (Nesina®) for patients across the income pyramid. The company is able to provide evidence of how patient reach has been increased through the approaches used.

One manufacturing capacity building initiative included for evaluation. Takeda performs below average in this indicator. The company submitted two initiatives, of which one initiative, a transfer of Takeda's measles and acellular pertussis vaccine technologies for the development of combination vaccines including diphtheria, tetanus and acellular pertussis (DTaP) and measles-rubella (MR) vaccine, met all criteria for inclusion but not all Good Practice Standards.^{||} Takeda did not demonstrate how the initiative aims for sustainability.

One supply chain capacity building initiative meets all Good Practice Standards. Takeda has an average performance in this area. The company submitted the three initiatives, of which one met the criteria for inclusion and all Good Practice Standards.^{||} Takeda's initiative aims to strengthen supply chain management in Meru County of Kenya, addressing data for decision making, coordination,

cash flow and capacity challenges.

Five health system strengthening initiatives meet all Good Practice Standards. Takeda is one of the leaders in this area. The company submitted the maximum of five initiatives, which all met all criteria for inclusion and all Good Practice Standards: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. Examples include:

- Partnership with Pan-African Heart Foundation and AMREF to provide chronic care programmes for diabetes mellitus and hypertension in Kenya. Since 2016, the initiative has screened over 200,000 people and trained more than 160 community health workers.
- Partnership with Last Mile Health to train community health workers in Malawi and Liberia, reportedly enabling nearly 200,000 women in Liberia to access family planning services since 2018.

Has engaged in the development and implementation of a new inclusive business model. Takeda has improved performance since 2018 when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope. It has developed one new model: the Blueprint for Innovative Healthcare Access, focused on non-communicable disease (NCD) care for local communities in Kenya and Rwanda.

The company has some mechanisms in place to ensure continuous supply in countries in scope of the Index.

Takeda is a medium-performing company in this area, disclosing some strategies to ensure continuous supply in countries in scope. For example, in 2017 Takeda implemented a new end-to-end Sales & Operations Planning System, aligning demand forecasts with supply and assess safe stock levels. Takeda is currently implementing this process in all countries where the company operates, including 12 countries in scope of the Index. Takeda did not provide supporting evidence on ensuring supply in Least Developed Countries.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope in less than 10 days.

Takeda has improved performance since 2018. It has a policy for reporting SF medicines to national health authorities and WHO within 7 days. It distinguishes reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to an expressed need, but does not monitor delivery to end user.

Takeda has a policy in place to ensure ad hoc donations are carried out in response to an expressed need; however, it monitors the delivery until the recipient healthcare organisation, not the end user. For example, it donated human albumin (Flexbumin®) in February 2020 in response to the COVID-19 outbreak in China.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. Takeda is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. However, it is engaged in another structured donation programme: the Max Access

Solution programme where it donates ponatinib (Iclusig®) for chronic myeloid leukaemia in 12 countries since 2015.

^{||} Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.