Takeda Pharmaceutical Co. Ltd.

Stock Exchange: Tokyo Stock Exchange • Ticker: 4502 • HQ: Tokyo, Japan • Employees: 32,691

PERFORMANCE

Rises further than all other companies, moving 10 places to 5th. Takeda has newly assigned responsibility for access to its CEO, with a raft of new policies, deepening its approach to equitable pricing, with a solid approach to Capacity Building.

Management: Rises 10 places, to 6th place with responsibility for the company’s access-to-health strategy newly assigned to the CEO. It demonstrates innovation with the development of the Cancer Alliance. Compliance: Rises 7 places to 6th place as its code of conduct applies to third parties, rewards for sales agents are not solely based on sales. R&D: Rises 1 place to 6th with a solid performance, but displaced by peers due to lagging slightly behind in priority R&D and access planning. Pricing: Rising 11 places to 5th; it has a large increase of products with equitable pricing strategies.

Patents: Rises 11 places to 6th, a leading company in IP-sharing, along with a new public commitment not to enforce patents in LDCs and new levels of patent disclosure. Capacity: Rises 3 places to 7th. Deepened approach to capacity building with a focus on strengthening health systems. Donations: Rises 2 places to 14th, with no structured donation programmes, but working with partners to ensure rapid delivery of products in emergencies and humanitarian crises.

OPPORTUNITIES

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, for example, leuprorelin acetate (Enantone®) and leuprorelin (Lupron), both 2017 WHO Model List of Essential Medicines (WHO EML) listed cancer products in the scope of the Index, in countries where the tool is already being applied for other products, and to more countries in scope.

Establish project-specific access plans for late-stage projects, particularly for non-communicable diseases. Takeda can establish project-specific access plans for all late-stage projects with a focus on its non-communicable disease projects, such as those targeting cancer. By ensuring that access plans are not only considered but established, it can address key barriers to access that normally restrict access in low- and middle-income countries.

Strengthen registration approach. Takeda has registered aloglitpin (Nesina®) for diabetes mellitus in five out of twelve possible priority countries. The company could file to register the product in more priority countries, for example, Afghanistan, Dem. Rep. Congo, Ethiopia, Tanzania and Uganda.

Strengthen commitments through transparency to public. Takeda has strong, clear commitments to conduct R&D for diseases and countries in scope and for providing post-trial access to clinical trial participants. However, these policies are not readily available. Takeda can publish these commitments, reinforcing its values to advance access to medicine through R&D.

CHANGE SINCE 2016

• Established a structured process to develop access provisions for R&D projects, with execution carried out by a designated R&D Access to Medicine Office.
• Joined Access Accelerated with multiple initiatives, most focused on cancer care. It has also committed to measure impact and share results publicly via Access Observatory.
• Launched its Chronic Care Program (CCP) in late 2016, focused on improving public awareness and equipping community and primary healthcare workers for detecting diseases such as diabetes and hypertension.
• Launched the Strengthening Health Systems through Technology in 2017 which focuses on introducing and adopting digital platforms to strengthen healthcare delivery and management in low- and middle-income countries.
• Publicly discloses its new commitments to either not file or not enforce patents for its medicines in Least Developed Countries.
• Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
PIPELINE for diseases and countries in scope

Mid-sized pipeline: 35 R&D projects for diseases in scope (30 medicines; 5 preventive vaccines).
Clinical candidates: 27, including preventive vaccines for Zika virus, norovirus and dengue.
Regulatory approvals: 1, brigatinib (Alunbrig™) for the treatment of metastatic lung cancer.
R&D focus: non-communicable diseases (cancer and schizophrenia) and communicable diseases (malaria).
Access provisions: for 10 projects, most commonly applied through access-oriented partnerships.

Projects in the pipeline: 35

Communicable* | 3
Neglected tropical | 4
Maternal and neonatal | 2
Non-communicable | 10
Multiple categories | 6

Projects for R&D priority targets with access provisions: 10

Priority R&D** | With access provisions | Without access provisions
Rest of pipeline | 22 | 2

Takeda's dengue vaccine for children and adolescents, TAK-003, has progressed from Phase II to Phase III and has demonstrated immunogenicity against all four types of dengue virus.

PORTFOLIO for diseases and countries in scope

Mid-sized portfolio: 42 products for diseases in scope (all medicines).
Portfolio focus: non-communicable diseases (hypertensive heart disease and diabetes mellitus) and communicable diseases (lower respiratory infections).
Essential medicines: 52% of Takeda's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 48% of Takeda's medicines have first-line indications for diseases in scope.

Products on the market: 42

Communicable* | 3
Neglected tropical | 1
Maternal and neonatal | 32
Non-communicable | 6
Multiple categories | 0

Essential medicines with first-line indications: 19

WHO EML | Non-EML | First-line products | Other
19 | 3 | 19 | 0

55% of Takeda's medicines are listed on the WHO EML and/or as first-line treatments: e.g., sumatriptan (Sitran®) for treatment of migraine and the antihypertensives azilsartan (Azilva®) and candesartan.

BUSINESS CONTEXT

Six business units: Four geographic business units - Emerging Markets, Europe & Canada, Japan, and the US; two therapeutic area business units - Oncology and Vaccines. Its portfolio of prescription drugs focus on: oncology; gastroenterology; neuroscience disorders; and vaccines.


Presence in emerging markets: In 2018, Takeda reports sales in 44 countries in scope; five more than in the 2016 Index.

Sales in countries in scope

Statistics relate only to diseases and countries in scope.

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

***See Appendix IV for definition.
Takeda Pharmaceutical Co. Ltd.

**PERFORMANCE BY TECHNICAL AREA**

### GENERAL ACCESS TO MEDICINE MANAGEMENT

**RANK 6**  
**SCORE 3.70**

Has a strong access-to-medicine strategy with board-level responsibility. Takeda is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals and aligns with its corporate strategies. The strategy capitalises on partnerships, and focuses on addressing unmet needs, through R&D, IP management, patient assistance programmes and capacity building. The highest level of responsibility for access sits with a board-level committee.

Financial and non-financial access-related incentives to reward employees. Takeda performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include financial bonuses and fellowship opportunities.

One of 16 companies working on impact measurement. Takeda measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments and performance information. For example, Takeda publicly committed to supply vaccines for infectious diseases such as dengue, Zika, norovirus and polio. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Discloses who it engages with, incorporates local perspectives into strategies. Takeda publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

### MARKET INFLUENCE & COMPLIANCE

**RANK 6**  
**SCORE 3.03**

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Takeda has a code of conduct relating to ethical marketing and anti-corruption, and provides regular compliance training for employees upon hire and on an annual basis. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents’ rewards are not solely based on sales targets. Instead, it rewards other qualities relating to accountability and integrity in the workplace.

Internal control framework meets some index criteria. Takeda’s internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has some processes aimed at mitigating non-compliance, addressed in its global monitoring policy. It has an auditing and review mechanism in place, and performs regular evaluations, that also apply to third parties. It does not demonstrate evidence of having fraud-specific risk assessment. It does, however, have a monitoring system to track compliance in the workplace, and procedures to segregate duties, so that decisions are checked by another party.

Below average transparency regarding access-related practices. Takeda publicly discloses its policy positions on access-related topics (e.g., it publicly supports TRIPS and the Doha Declaration). It does not have a policy prohibiting political contributions in countries in scope, but reports that it did not make such contributions during the period of analysis. It does not publicly disclose its financial support and membership of relevant organisations, nor its policies for responsible engagement. Further, Takeda does not publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

### RESEARCH & DEVELOPMENT

**RANK 6**  
**SCORE 2.80**

Publicly commits to R&D to meet public health needs. Takeda has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on internal targets and data from external sources related to global health needs. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Takeda has a mid-sized pipeline in the Index with 35 projects. For diseases in scope where priorities exist, Takeda is active in 13 projects; all 13 of these target priority R&D gaps.

Access provisions in place for 21% (3/14) of late-stage candidates. Takeda has a clear process in place to develop access plans during R&D. The process considers all R&D projects for diseases in scope. In general, Takeda begins considering and developing access plans for R&D projects from the discovery phase onward. To date, Takeda has project-specific access provisions in place for three of its late-stage R&D projects. Of these, one is being conducted in partnership with the Medicines for Malaria Venture (MMV).

Policy to ensure post-trial access; commits to registering trialed products. Takeda has a policy for ensuring post-trial access to treatments for clinical trial participants and has provided a detailed example of this policy in action in countries in scope. However, this policy is not publicly available. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Takeda commits to registering it in all countries where clinical trials for the product have taken place.

### DISTRIBUTION

**RANK 6**  
**SCORE 2.21**

Takeda measures and monitors product availability for 21% (3/14) of late-stage candidates. Takeda has a clear process in place to develop access plans during R&D. The process considers all R&D projects for diseases in scope. In general, Takeda begins considering and developing access plans for R&D projects from the discovery phase onward. To date, Takeda has project-specific access provisions in place for three of its late-stage R&D projects. Of these, one is being conducted in partnership with the Medicines for Malaria Venture (MMV).

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### PRICING, MANUFACTURING & DISTRIBUTION

**RANK 5**  
**SCORE 2.68**

PRODUCTS: 42

Covered by EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 4

Commits publicly to equitable pricing and reports a commitment to file to register new products in scope. Takeda commits to filing its newest products for registration in countries in scope within one year of first market approval, where possible. It publicly commits to implement inter-country equitable pricing strategies for a minority of its products for diseases in scope. This does not explicitly apply to future products. It also commits to implementing intra-country pricing strategies, albeit to only some of its products.

No new products in scope filed for registration in the majority of priority countries. Although Takeda newly commits to filing its newest products for registration in countries in scope within one year of first market approval, it has not filed any of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). It publicly shares some registration information for the minority of its products.

10% of products have equitable pricing strategies targeting priority countries. Takeda’s over-
all performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 10% of its products for diseases in scope. These strategies apply to an average of 22% of priority countries. All of these strategies apply inter-country pricing; these take into account an average of five socioeconomic factors. Takeda also applies equitable pricing strategies to one further product informed by a public health rationale.

Globally consistent recall guidelines for countries in scope but no processes to track products. Takeda has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

**PATENTS & LICENSING**

**RANK 6**  **SCORE 2.46**

Publicly discloses detailed information on patent statuses. Like most of its peers, Takeda publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

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

Shares many IP assets with 3rd-party researchers. Compared to its peers, Takeda shares many IP assets with third-party researchers developing products for diseases in scope. This includes 18 shared with research institutions and neglected disease drug discovery initiatives, such as MMV and the Drugs for Neglected Diseases initiative (DNDi). The assets shared include molecule libraries, patented compounds, processes and technologies.

Public commitment not to enforce patents in countries in scope. Takeda commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries.

**CAPACITY BUILDING**

**RANK 7**  **SCORE 2.35**

12 initiatives included for evaluation. Takeda has 12 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Takeda submitted 20.

Strong focus on strengthening health systems. Takeda has initiatives which meet inclusion criteria in all areas of capacity building, except manufacturing. It performs strongest in health system strengthening with most initiatives focused on non-communicable diseases such as cancer.

Four initiatives meet all applicable good practice standards:

- R&D Access to Medicines Employee Fellowship Program
- Accelerating Cancer Care in Sub-Saharan Africa
- Global Accelerating Cancer Care
- Chronic Care Program

Takeda’s remaining included initiatives typically have goals in place, but fall short on monitoring progress and outcomes.

Timely approach to reporting substandard or falsified medicines to relevant authorities. Takeda provides evidence that it systematically reports confirmed cases of substandard or falsified medicines to local regulatory authorities within the period recommended by stakeholders (maximum seven days).

Responds to emergencies and humanitarian crises and tracks delivery. Takeda donated medicines on the request of relief agencies. For example, during the period of analysis, it donated pioglitazone/metformin (Actosmet®) and pioglitazone (Actos), both used for the treatment of diabetes, through the Pharmaceutical and Healthcare Association of the Philippines (PHAP) Cares Foundation. The company discloses that such ad hoc donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with Americas and Direct Relief to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

No donation programmes covering diseases and countries in scope for products in scope. Takeda does not have any structured donation programmes that were active during the period of analysis in any countries in scope for products in scope.

**BEST PRACTICES**

R&D Employee Fellowship Program engages in longer-term projects

**HAITI, KENYA, AND TANZANIA**

Employee fellowship programme that enters long-term engagements with selected NGOs to support and build healthcare capacity in areas such as clinical care, epidemiology, training, R&D project management and supply chain.

Extensive sharing of IP assets with third-party researchers

**GLOBAL**

Sharing IP assets with third-party researchers developing products for diseases in scope of the Index.

Commits to registering new products in poorer countries in 12 months.

**GLOBAL**

Parallel dossier preparation to facilitate faster registration.

**INNOVATIVE PRACTICES**

Diverse stakeholders come together for The Cancer Alliance

**SUB-SAHARAN AFRICA**

Cross-sector partnership with local stakeholders – represents a new, regionally focused approach to integrate and improve the provision of cancer services.