RANK SCORE

18 1.94

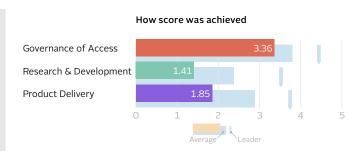
17 (2022)

# Daiichi Sankyo Co, Ltd

Stock exchange: TSE • Ticker: 4568 • HQ: Tokyo, Japan • Employees: 18,726

# PERFORMANCE IN THE 2024 INDEX

**18**<sup>th</sup> **place.** Daiichi Sankyo is in the lower ranks of all Technical Areas. It engages in health system strengthening initiatives; however, its Research & Development access plans and product access strategies are limited in geographic reach.



### **OPPORTUNITIES FOR DAIICHI SANKYO**

Develop a structured access planning framework and ensure comprehensive access plans for all late-stage R&D projects. Currently, the company has access plans for only 11% of its late-stage R&D candidates. By implementing a systematic framework for access planning, the company can ensure the coverage of all pipeline projects from Phase II onwards.

Establish direct board-level responsibility for access to medicine. Daichii Sankyo has an access-to-medicine strategy. The company appointed a Head of Access to Healthcare, who is responsible for reporting on access to medicine to the Executive Management Committee and the Board of Directors. To further progress, Daiichi Sankyo can ensure a member of the board is directly responsible for its access-to-medicine strategy.

Expand access to its innovative products. Daiichi Sankyo has access strategies in place for products in its portfolio, but these are limited to a select number of countries in scope. It can expand access to its products through increased registrations and/or equitable access strategies. For example, it can increase access to trastuzumab deruxtecan (Enhertu®), indicated for multiple cancer types, through registration and access strategies in countries where it has marketing rights or additionally through its strategic partnership to scale access.

### **CHANGES SINCE THE 2022 INDEX**

- Since July 2022, Daiichi Sankyo has launched two new health system strengthening initiatives focused on prevention of breast and cervical cancer. One initiative works with the Japanese Organization for International Cooperation in Family Planning in Kenya and the other with AMDA Multisectoral and Integrated Development Services in Honduras.
- In December 2022, President and CEO, Sunao Manabe, was appointed IFPMA Vice President.
- Donated medicines to global emergencies and poverty-stricken countries in 2022 in response to aid requests from Americares.
- Received approval in Japan for its mRNA COVID-19 vaccine (Daichirona®) in November 2024.

# Daiichi Sankyo Co, Ltd

#### SALES AND OPERATIONS

**Therapeutic areas:** Oncology, cardiovascular, vaccines, other disease areas

**Product categories:** Consumer health, generics, innovative medicines, vaccines

**M&A news:** In 2023, Daiichi Sankyo Co, Ltd divested its generics division, Daiichi Sankyo

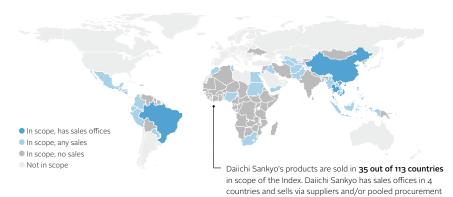
Espha, to Qol Holdings Co. Daiichi Sankyo absorbed its wholly owned subsidiaries, Daiichi Sankyo Propharma and Daiichi Sankyo Chemical Pharma, in 2023.

## Revenue by segment (2023) - in JPY

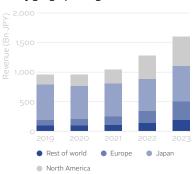
Prescription drugs	1,523.41 bn
Healthcare (OTC) products	75.90 bn
Other	2.38 bn

Total	1,601.69 bn

### Sales in countries in scope



### Sales by geographic region



### SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

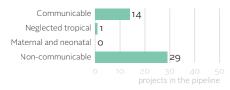
#### PIPELINE for diseases in scope

Daiichi Sankyo has 44 R&D projects in scope, 14 of which target priority diseases, including influenza (4), COVID-19 (3) and malaria (2). The remaining 30 projects target other diseases in scope, including cancer (26), respiratory infections (1) and measles (1). Of the 44 R&D projects, 18 are in late-stage development, with evidence of access planning for 11% (2/18) of these.

### PORTFOLIO as selected for analysis by the Index

Daiichi Sankyo has 17 products in scope, including 12 medicines, 3 diagnostics for TB and 2 vaccines for pertussis and tetanus. Of its medicines and vaccines, 5 are listed on the WHO EML; all 3 diagnostics are listed on the WHO EDL. Its medicines target a variety of communicable and non-communicable diseases, including cardiovascular diseases (6), cancer (3) and lower respiratory infections (2).

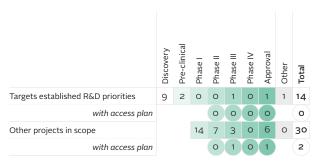
# 44 projects in the pipeline



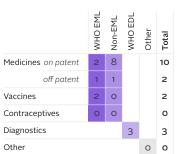
# 17 products in the portfolio



# Breakdown of projects



# Breakdown of products



# Daiichi Sankyo Co, Ltd

#### **GOVERNANCE OF ACCESS**

RANK 16

SCORE 3 30

16th place. Daiichi Sankyo performs below average in this Technical Area. The company provides evidence of a patient reach process that covers one product and some countries in scope of the Index and does not publicly provide the details of the underlying methodology. Additionally, no patient reach goals were identified for this process. Further, it only has a few sets of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

The highest responsibility for access lies indirectly with the Board. The company installed a Head of Access to Healthcare, who is responsible for reporting on access to medicine to the Executive Management Committee and the Board of Directors. Daiichi Sankyo incentivises its senior executives and in-country managers to perform on access to medicine with financial and non-financial rewards, as part of its CSR goals. The CEO also has access-related incentives.

integrated within the overall corporate strategy. Its strategy covers some of the therapeutic areas in which the company is involved, with a focus on its oncology products. Daiichi Sankyo publicly discloses its commitments to access to medicine, along with company-specific targets, goals and objectives.

Reporting is clear, linked to these goals, centrally

available and updated regularly in its Value

Creation Report and directly on its website.

Comprehensive access-to-medicine strategy

Shows comparatively moderate level commitment to responsible business practices. Daiichi

Sankyo's incentive compensation plans vary by subsidiary. For example, in one of the countries in scope of the Index, sales agents are not solely incentivised by sales volume. Incentives are also based on behaviour assessments, such as academic interaction, training and compliance. Further, the company has a global policy on ensuring ethical interactions with healthcare professionals. It offers guidance on establishing and documenting a legitimate need for interaction and declares that transfers of value to healthcare professionals (e.g., payments for speaking at events) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

Has a few sets of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Daiichi

Sankyo performs poorly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards. However, it does not disclose sufficient evidence publicly or to the Index of fraud-specific risk assessments and region or country risk-based assessments in countries in scope. Daiichi Sankyo has a code of conduct that guides ethical employee decision-making. No breaches in countries in scope were found in the period of analysis.

## Daiichi Sankyo publicly supports the Doha Declaration on TRIPS and Public Health.

However, it expresses reservations on some provisions of TRIPS flexibilities, namely compulsory licensing. The company states that compulsory licensing should be carefully used in situations like public health-related national emergencies.

Fulfils some criteria with its process for measuring and reporting the patient reach of 1 of its cancer medicines. The process covers some countries in scope of the Index and Daiichi Sankyo provides the underlying equation and metrics under an NDA. The resulting patient reach numbers are published regularly and demonstrate improvements. No associated patient reach and health outcomes goals were identified for this process.

# RESEARCH & DEVELOPMENT

RANK 1

SCORE 1.41

17<sup>th</sup> place. Daiichi Sankyo performs poorly in this Technical Area. It has a general access planning process in place, rather than a systematic framework. The company has pipeline projects targeting both priority and non-communicable diseases, but only has access plans in place for a small number of its late-stage candidates – which mostly focus on registration preparation in emerging markets. Furthermore, it does not publicly disclose disaggregated R&D investment data, nor does it engage in R&D capacity building activities.

General process in place to develop access plans during R&D. The process is intended to be applied to a subset of R&D projects in scope. The company does not make a public commitment addressing its approach to access planning for LMICS.

Average-sized priority R&D pipeline, compared to peers, with access plans in place for 0% (0/2) of the late-stage candidates. Priority R&D pipeline of 14 projects, including 2 late-stage projects that target a priority gap. The company focuses on various priority areas, including influenza, COVID-19 and malaria. Of Daiichi Sankyo's 2 late-stage candidates targeting a

priority product gap, neither have evidence of an access plan in place.

Large-sized pipeline, compared to peers, addressing other diseases in scope, with 13% (2/16) of late-stage projects covered by access plans. The company has 16 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cancer, respiratory infections and measles. Daiichi Sankyo provides evidence of access plans for 2 of its 16 late-stage projects, including registration preparation and post-trial access.

Daiichi Sankyo does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, it does disclose anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

No evidence of R&D capacity building initiatives that meet inclusion criteria.

# Daiichi Sankyo Co, Ltd

PRODUCT DELIVERY

RANK 18

SCORE 185

18th place. Daiichi Sankyo performs poorly in this Technical Area. It implements access strategies for its products; however, these are limited to upper-middle-income countries and lack data on their outcomes. The company does not register its products widely or show evidence of engaging in inclusive business models or supply chain capacity building initiatives. While it does not engage in new intellectual property sharing agreements, all health system strengthening initiatives included meet all Good Practice Standards.

Daiichi Sankyo registers newer products\* in 1 country in scope on average. It did not provide evidence of registering any products assessed in LICs. Additionally, it registers only 10% of products assessed in at least 1 of 10 countries with the highest disease burden. The company's edoxaban (Lixiana®), indicated for stroke prevention, is most widely registered, totalling 12 countries in scope. Daiichi Sankyo did not report participating in any mechanisms to facilitate registration.

Daiichi Sankyo is not eligible for assessment of supranational access strategies because it has no products in scope that are supranationally procured.

Access strategy in progress for one healthcare practitioner (HCP)-administered product, resulting in current lack of outcomes data. For trastuzumab deruxtecan (Enhertu®), indicated for multiple cancer types, Daiichi Sankyo provides evidence of a comprehensive access strategy in an UMIC. However, it lacks strategies in LMICs and LICs. In the UMIC example, the company has a clear and comprehensive strategy, working towards national reimbursement. To overcome affordability barriers prior to achieving public reimbursement, this strategy is complemented by a patient assistance programme. Daiichi Sankyo did not report outcomes, including patient reach, of the strategy, nor did it report its approaches for measuring and tracking future progress.

Access strategies for self-administered products are limited in geographic scope, with information on outcomes lacking. For 4 of the 5 products selected for analysis, Daiichi Sankyo provides evidence of access strategies only in UMIC examples and the data reported for these strategies is very limited. In general, the company applies a mix of strategies to set the price of its products, for most of which generic alternatives are on the market. For 1 product, edoxaban (Lixiana®), indicated for stroke prevention, it shares goals to further expand access in the public sector; for the other examples analysed, data on the outcomes, including patient reach, and plans for the strategy are lacking.

Daiichi Sankyo publicly commits not to file for or enforce patents for all products in the majority of countries in scope. This applies to all sub-Saharan African countries (excluding South Africa), all least developed countries and LICs, and a subset of LMICs and UMICs. However, the list of countries to which the commitment applies is not publicly available.

Publicly discloses product patent status for countries in scope. Like most peers, Daiichi Sankyo publicly discloses patent information for small molecules in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction.

Daiichi Sankyo does not engage in nonexclusive voluntary licensing for products in scope.

The 1 manufacturing capacity building initiative included for analysis meets all Good Practice Standards (GPS). Daiichi Sankyo partners with the Center for Research and Production of Vaccines and Biologicals, Vietnam to produce the Measles-Rubella vaccine from a seed stock provided by the company. The technology transfer was completed in 2018, but Daiichi Sankyo continues to provide ongoing manufacturing support.

No evidence of supply chain capacity building initiatives that meet inclusion criteria.

All 5 health system strengthening initiatives included for analysis meet all GPS. For example, Daiichi Sankyo financially supports Save the Children's efforts to improve the sexual and reproductive healthcare services and awareness among adolescents in 2 districts in Vietnam. In 2023, the initiative reached 2,500 adolescents through peer clubs at local high schools.

Daiichi Sankyo remains engaged in existing IP-sharing agreements with drug discovery initiatives to accelerate drug development. In 1 agreement, the company shared 35,000 compounds with the Drugs for Neglected Diseases Initiative to screen against Trypanosoma cruzi. However, Daiichi Sankyo has not engaged in new agreements during the period of analysis.

# Fulfils most criteria for ad hoc donations.

Daiichi Sankyo has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. For example, in October 2022, Daiichi Sankyo responded to aid requests from Americares, by donating medicines to global emergencies and poverty-stricken countries. The donation comprised 7 products, including 3 in scope, namely amlodipine/olmesartan medoxomil (Azor®), prasugrel (Effient®) and olmesartan medoxomil/amlodipine/hydrochlorothiazide (Tribenzor®). However, it does not make commitments, publicly or otherwise, to adhere to the most recent WHO Guidelines for Medicine Donations.

Fulfils most criteria for mechanisms to ensure continuous supply in LMICs. For example, to ensure sustainable supply in China and Latin America, Daiichi Sankyo holds meetings with its affiliates and manufacturing plants in Brazil and China to share risks and implement solutions.

Daiichi Sankyo has procedures in place at several of its subsidiaries for reporting substandard and falsified medicines in countries in scope. It does not have a global reporting policy yet, but provides evidence of reporting cases to national or local regulatory authorities within 5 days, depending on the region. Further, the company aims to report cases within 3 days if the case presents a serious risk. Depending on the subsidiary, it provides evidence of shortened timeframes for reporting cases that only require visual inspection for confirmation.

No evidence of inclusive business models that meet inclusion criteria.