

RANK	SCORE
<b>17</b>	<b>2.20</b>
16 (2021)*	

# Daiichi Sankyo Co, Ltd

Stock exchange: TSE • Ticker: 4568 • HQ: Tokyo, Japan • Employees: 16,033

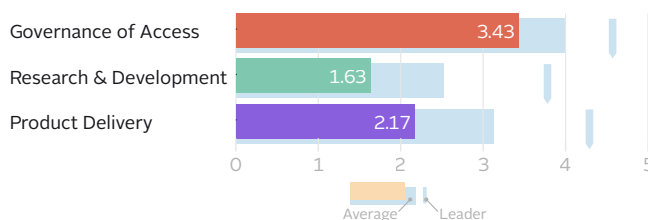
## PERFORMANCE IN THE 2022 INDEX

17<sup>th</sup> place. Daiichi Sankyo is in the lower ranks across all Technical Areas. It has a weak performance in responsible promotional practices and implementation of compliance controls. Furthermore, the company lacks access strategies for the majority of its products assessed. However, it performs well in health systems strengthening.

**Governance of Access:** 15<sup>th</sup> place. Daiichi Sankyo performs below average in this area. It has an integrated access-to-medicine strategy, but it provides very little information related to responsible promotional practices and lacks some compliance controls, namely a continuous system to monitor activities, fraud-specific risk assessment and a country risk-based assessment to mitigate the risk of non-compliance in countries in scope of the Index.

**Research & Development:** 18<sup>th</sup> place. Daiichi Sankyo performs poorly in this area. It has a general access planning process in place and applies this to a subset of pipeline projects. The company has an average-sized priority pipeline and has

How score was achieved



access plans in place for most late-stage candidates. However, it does not engage in R&D capacity building.

**Product Delivery:** 17<sup>th</sup> place. Daiichi Sankyo performs poorly in this area. The company has a strong commitment not to enforce or file patents in the majority of the countries in scope (including low- and lower-middle income countries). It applies a few access strategies, yet only in upper-middle income countries. It has shown evidence of technology transfer initiatives and high-quality health systems strengthening initiatives yet does not engage in supply chain capacity building.

## OPPORTUNITIES FOR DAIICHI SANKYO

**Ensure that governance structures do not vary across subsidiaries.** Daiichi Sankyo's current governance structures related to responsible promotional practices and substandard and falsified medicines vary by subsidiary. It can ensure that such governance structures apply across all subsidiaries. This includes its approach to decoupling of sales targets from sales volume, policies that address responsible interactions with and appropriate payments to healthcare professionals and policies that address the timely reporting of confirmed cases of substandard and falsified medicines to health authorities.

**Develop a structured access planning framework and ensure all late-stage R&D projects have comprehensive access plans.** Daiichi Sankyo can continue to improve access planning by developing a structured access planning framework. The company has access plans in place for 75% of late-stage R&D projects. It can apply access plans to all projects in the pipeline from Phase II onwards.

**Improve access to patented cardiovascular products on the WHO Model List of Essential Medicines (EML).** Daiichi Sankyo has two patented products on the WHO EML, edoxaban (Lixiana®), indicated for ischaemic heart disease and stroke, and amlodipine/olmesartan medoxomil (Azor®/Sevikar®), for hypertensive heart disease. The company has an equitable access strategy for edoxaban that covers UMICs. Daiichi Sankyo can further expand access to both this product and to amlodipine/olmesartan medoxomil via registration, equitable pricing and/or non-exclusive voluntary licensing in lower-income countries and high burden countries such as the Republic of Moldova.

## CHANGES SINCE THE 2021 INDEX

- Appointed a Head of Access to Healthcare who is responsible for improving access to healthcare and addressing and resolving issues related to access.
- Incorporated improving access to healthcare as a materiality in its current mid-term plan.
- Established an Emerging and Re-emerging Infectious Diseases Research Special Team (EReDS) to address emerging and re-emerging infectious diseases.
- Participated in the AMR Action Fund, which was established to support the clinical development of new antimicrobial agents and to achieve a sustainable antimicrobial market, with a total contribution of USD 20 million.
- Implemented a general access planning framework for a subset of its R&D pipeline.
- Launched two new initiatives in Nepal and Zimbabwe to address breast and cervical cancer care and awareness.
- Signed a joint research agreement and will share its compound libraries with the non-profit public-private partnership Medicines for Malaria Venture (MMV) to screen compounds against new *Plasmodium* biological targets.
- Signed a joint research agreement with the non-profit public-private partnership Drugs for Neglected Diseases initiative (DNDi) to screen compounds against *Trypanosoma cruzi*. Daiichi Sankyo provided a library of 35,000 compounds.

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.  
\*In the 2021 Index, dense ranking was used. In the 2022 Index, standard

competitive ranking is used. Therefore, a direct comparison with Daiichi Sankyo's previous rank is not possible.

### SALES AND OPERATIONS

**Business segments:** Healthcare (OTC) products, prescription drugs and other.

**Therapeutic areas:** Cell therapy, central nervous system diseases, oncology, rare diseases, vaccines and other disease areas.

**Product categories:** Consumer health products, generic drugs, innovative medicines and vaccines.

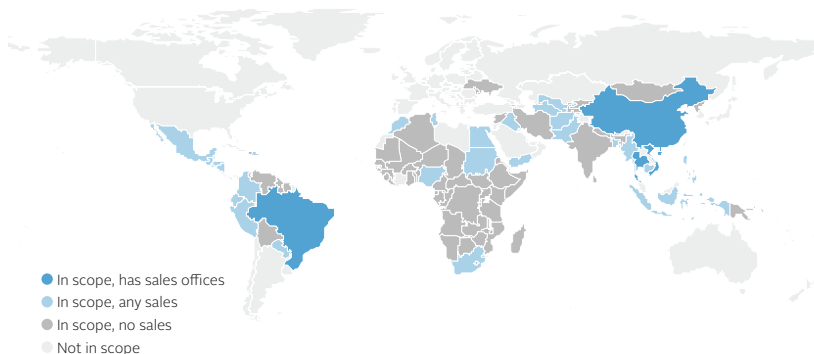
**M&A news:** None since May 2020.

**Daiichi Sankyo's products are sold in 35 out of 108 countries in scope of the Index.** Daiichi Sankyo has sales offices in four countries, and sells via suppliers and/or pooled procurement in an additional 31 countries.

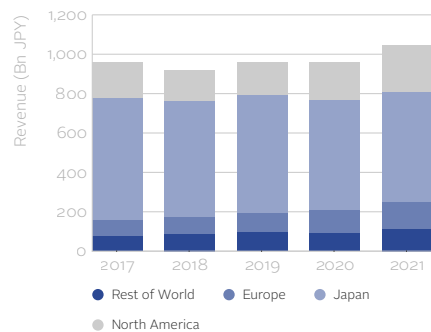
#### Revenue by segment (2021) – in JPY

Prescription drugs	977.98 bn
Healthcare (OTC) products	64.70 bn
Other	2.20 bn
<b>Total</b>	<b>1,044.89 bn</b>

#### Sales in countries in scope



#### Sales by geographic region



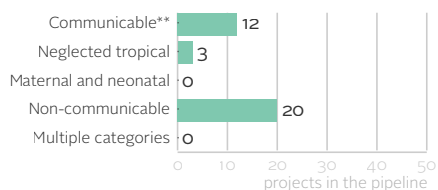
### SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

#### PIPELINE for diseases in scope

Daiichi Sankyo has a total of 35 R&D projects in scope with 16 of these projects targeting priority diseases. The other 19 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on lower respiratory infections (three projects), Chagas disease (2), malaria (2) and tuberculosis (2). Of the projects targeting other diseases, the focus is on oncology (15).

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).<sup>\*</sup> Evidence of access planning was in place for 75% of these projects: one targeting a priority disease and two addressing a public health need in LMICs.

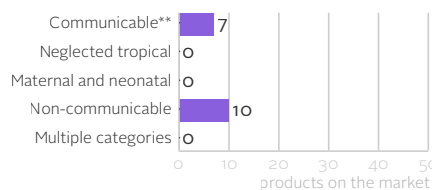
#### 35 projects in the pipeline



#### PORTFOLIO as selected for analysis by the Index

Daiichi Sankyo has 12 medicines in scope, nine of which are on patent. 33% of these medicines (4) are on the WHO EML. In addition, the company markets three diagnostics and two vaccines. The off-patent medicines target mainly non-communicable diseases (NCDs) such as hypertensive heart disease (1) and ischaemic heart disease (1), and a communicable disease, lower respiratory infections (1). The on-patent medicines mainly target NCDs, such as hypertensive heart disease (3), ischaemic heart disease (2) and cancer (2). Daiichi Sankyo's preventative vaccines target tetanus and pertussis. The diagnostics in scope are for tuberculosis (3).

#### 17 products as selected for analysis by the Index<sup>†</sup>



#### Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	11	3	0	0	1	0	1	16
Addresses needs of LMICs <sup>*</sup>			3	2	1	0	0	6
Other projects in scope			4	5	3	1	0	13

#### Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	2	7			9
off patent	2	1			3
Vaccines	2	0			2
Contraceptives	0	0			0
Diagnostics			3		3
Other <sup>†</sup>				0	0

<sup>\*</sup>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. <sup>\*\*</sup>Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index. <sup>\*\*\*</sup>Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics). <sup>†</sup>Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. <sup>‡</sup>Other includes vector control products.

# Daiichi Sankyo Co, Ltd

## GOVERNANCE OF ACCESS

RANK 15

SCORE 3.43

**Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy.** Daiichi Sankyo performs well. Its strategy is focused on expanding medical access to oncology products, with a key theme of the strategy being "how to deliver oncology products around the world". The strategy covers some of the therapeutic areas the company is involved in, but mainly focuses on oncology products. The highest responsibility for access is indirectly with the board, with its Global Management Committee.

**Provides evidence of financial and non-financial access-related incentives at the executive level.** Daiichi Sankyo performs well. It 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.

**Publicly discloses outcomes of a subset of its access-to-medicine activities.** Daiichi Sankyo

performs average in transparency of access activities. It publicly discloses its commitments, objectives and targets related to improving access to medicine in countries in scope of the Index, namely with its capacity building initiatives. It shares the outputs of a subset of its capacity building initiatives, although it does so in a centralised manner directly on its website.

**Performs below average in responsible promotional practices.** Daiichi Sankyo's policies governing promotional practices vary by subsidiary. It does not publicly disclose whether sales agents are solely incentivised on sales volume targets and not other targets, nor the level at which sales incentives are set. It does not disclose whether it shares information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities), nor does it disclose a policy limiting such transfers.

**Has some compliance controls to ensure that**

**governance efforts are not undermined by non-compliant or corrupt activities.** Daiichi Sankyo performs below average, demonstrating evidence of some components looked for by the Index: audits and formal processes to ensure third-party compliance with company standards. There is no evidence, publicly found or disclosed to the Index, of a continuous system to monitor activities, fraud-specific risk assessment or country risk-based assessment. 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.** Daiichi Sankyo publicly shares a general statement on the Doha Declaration on TRIPS and Public Health, but expresses reservations on its provisions, stating that the use of compulsory licensing should be carefully exercised. As a member of the industry association, Daiichi Sankyo, like all other member companies in scope of the Index, is by default connected to this activity.

## RESEARCH & DEVELOPMENT

RANK 18

SCORE 1.63

**Access planning processes encompass some projects in the pipeline.** Daiichi Sankyo has a 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 for diseases in scope of the Index.

**An average-sized priority R&D pipeline compared to peers, with an access plan in place for its late-stage candidate.** Daiichi Sankyo has 16 projects, including one late-stage candidate, in its pipeline that target a priority product gap. These projects target several diseases. Daiichi Sankyo's late-stage candidate is supported by an access plan.

**Some projects address a public health need in LMICs,\* with 67% (2/3) of late-stage candidates covered by access plans.** In this analysis, Daiichi Sankyo has three late-stage R&D projects in its pipeline 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. Daiichi Sankyo provides evidence of access plans for two of these projects.

**Does not publicly disclose R&D investment data disaggregated by disease category, prod-**

**uct type or phase of development.** However, Daiichi Sankyo does disclose fully disaggregated R&D investment data to Policy Cures Research.

**No R&D capacity building initiatives included for evaluation.** There is no evidence — in the public domain or disclosed to the Index — of R&D capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Daiichi Sankyo's performance is below average in this area.

## PRODUCT DELIVERY

RANK 17

SCORE 2.17

**Public commitment not to enforce patents in countries in scope.** Daiichi Sankyo publicly commits to neither file for nor enforce patents. This commitment applies in sub-Saharan African countries (with the exception of South Africa), Least Developed Countries and LICs, and in a subset of LMICs and UMICs.

**Publicly discloses information on patent status.** Like most of its peers, Daiichi Sankyo publicly discloses the patent statuses for small mole-

cules in scope via the Pat-INFORMED database. It discloses patent information such as filing date, grant number, grant date and jurisdiction.

**Performs above average in terms of sharing intellectual property (IP) assets with third-party researchers.** Daiichi Sankyo engaged in three new IP-sharing agreements with third-party 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.** Daiichi Sankyo does not engage in voluntary licensing for products in scope of the Index.

\*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.

**Filed to register one new product in one country in scope.** Daiichi Sankyo did not disclose evidence of filing for registration any of its new products in any of the top ten high burden countries. Its most widely filed product, edoxaban (Lixiana®) indicated for stroke prevention among other uses as an anticoagulant, has been filed for registration in 12 countries within the scope of the Index, including three high burden disease countries (China, Indonesia and Vietnam). None of its eligible products are filed for registration in LICs.

**Daiichi Sankyo is not eligible for assessment of supranationally procured products.**

**Has an access strategy for a country in scope of the analysis for its healthcare-practitioner-administered products.** Daiichi Sankyo performs below average in this area. The company provides data on access strategies for the cancer drug trastuzumab deruxtecan (ENHERTU®) applied in two UMICs. Evidence of patient reach is not available.

**Has few access strategies for its self-administered products for some countries in scope for this analysis.** Daiichi Sankyo performs below average in this area. The company provides examples of access strategies in UMICs for four of the five products assessed, including efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay. For example, the company secured national reimbursement of one product and provides evidence of meeting national payer price expectations. Patient reach is provided for two access strategies in UMIC countries, but the company does not provide examples in LMICs or LICs for any of the products.

**One of the two manufacturing capacity building initiatives included meets all Good Practice Standards.** Daiichi Sankyo'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. In the initiative that meets all GPS, which was active from 2002 until 2020, the company worked to strengthen Vietnam's capacity to produce vaccines through the POLYVAC project.

**No supply chain capacity building initiatives included for analysis.** There is no evidence — in the public domain or disclosed to the Index — of supply chain capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Daiichi Sankyo's performance is below average in this area.

**All three health systems strengthening initiatives included for analysis meet all Good Practice Standards.** Daiichi Sankyo's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average but an average number of initiatives meet all GPS for this indicator. For example, through the company's new initiative in Nepal, Daiichi Sankyo expands screening services and improves resident knowledge about breast and cervical cancers through screening camps and public awareness activities. This initiative meets all GPS.

**Has no inclusive business models that meet all inclusion criteria.** There is no evidence that Daiichi Sankyo has engaged in the piloting or scale-up of any inclusive business models that aim to meet the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. Daiichi Sankyo performs below average in this area.

**Performs above average in terms of ensuring continuous supply of medicines in LMICs.** Daiichi Sankyo does not show evidence of its involvement in supply chain capacity building initiatives meeting inclusion criteria for evaluation.

However, the company does have 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 transfers technology to local manufacturers in LMICs.

**Has procedures in place for reporting substandard and falsified (SF) medicines for several countries in scope of the Index in less than ten days.** Daiichi Sankyo provides evidence of reporting SF medicines to relevant national health authorities within five days depending on the region. The company reports aiming at reporting within three days if the case presents a serious risk. Depending on the subsidiary, it provides evidence of shortened time frames for reporting cases which only require visual inspection to be confirmed.

**Donates in response to expressed need and monitors delivery.** Daiichi Sankyo has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it shows some evidence of monitoring the delivery of donations.

**Has no long-term donation programmes for neglected tropical diseases (NTDs) or malaria that are eligible for analysis under this indicator.** Daiichi Sankyo is not engaged in any structured donation programmes for NTDs or malaria where elimination, eradication or control goals are possible and that are eligible for analysis under this indicator.