

| RANK       | SCORE       |
|------------|-------------|
| <b>18=</b> | <b>1.77</b> |
| 18 (2016)  |             |

# Daiichi Sankyo Co. Ltd.

Stock Exchange: Tokyo Stock Exchange • Ticker: 4568 • HQ: Tokyo, Japan • Employees: 32,791

## PERFORMANCE

Holds 18<sup>th</sup> place, with a continued lack of an overarching access-to-medicine strategy, and a weak performance in the Capacity Building, Pricing, Manufacturing & Distribution, and Product Donations. However, the company has made key gains in areas such as Patents & Licensing and R&D.

**Management:** Rises 1 place to 19<sup>th</sup>. Lacks a coordinated access-to-medicine strategy and responsibility for access governance is not at board level.

**Compliance:** Falls 3 places to 18<sup>th</sup>. Its internal control framework performs poorly against peers e.g., lacking procedures to segregate duties.

**R&D:** Rises 2 places to 7<sup>th</sup>. Has access plans in place for 38% of its late-stage projects, despite lacking a process for access plans during R&D.

**Pricing:** Falls 4 places to 17<sup>th</sup>. Weak commitments to ensure equitable pricing and registrations, with no new products filed for registration in the majority of priority countries.

**Patents:** Rises 7 places to 12<sup>th</sup>. Improves transparency with a public commitment not to file patents in countries in scope, and new disclosure of patent status via Pat-INFORMED.

**Capacity:** Falls 8 places to 19<sup>th</sup>. Two included initiatives focused on manufacturing, which fail to meet all good practice standards.

**Donations:** Rises 1 place to 17<sup>th</sup>, with no structured donation programmes, but working with trusted partners to make *ad hoc* donations.

## OPPORTUNITIES

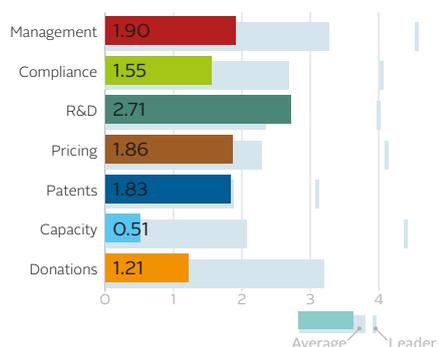
**Establish an overarching access strategy.** Daiichi Sankyo can consolidate its various access approaches into an overall strategy, clearly aligning it with its corporate strategy and assigning board level responsibility for it. The company can focus on priority countries, and develop appropriate mechanisms, e.g., through equitable pricing and licensing strategies, for ensuring its products reach those most in need. Daiichi Sankyo is one of three companies in scope that does not have such a strategy.

**Develop a process to establish more access plans for R&D projects.** Daiichi Sankyo can develop a clear approach to establishing access provisions for R&D projects during development that takes into account the specific considerations necessary for each project. It can develop this approach for both in-house and collaborative projects for all diseases in scope, with a clear timeline for developing, refining and executing access provisions to ensure broad and rapid access. This includes developing access provisions for projects such as its late-stage vaccines for measles and DTaP-IPV-Hib.

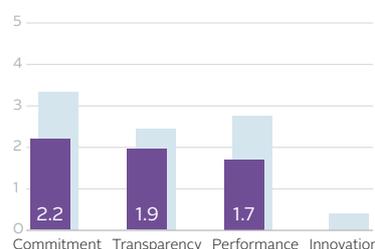
**Strengthen compliance framework.** Daiichi Sankyo can strengthen its framework to ensure compliance by incorporating additional processes to mitigate the risk of non-compliance with ethical standards. For example, it can develop a fraud-specific risk assessment, a monitoring system for compliance and procedures to segregate duties. The company could expand its existing auditing mechanism to third parties it engages with in countries in scope. It can apply formal processes that help to ensure third-party compliance with the company's standards.

**Review incentive structures.** Daiichi Sankyo can strengthen its access governance by providing access-specific incentives (financial or non-financial) for staff at all levels. Alongside this, Daiichi Sankyo can decouple sales incentives from sales targets to better incentivise responsible practices. Removing the emphasis on sales targets is recognised as a mechanism for reducing the impact of unethical marketing on, for example, rational prescribing. Removing an emphasis on sales targets is recognised as a mechanism for reducing the impact of unethical marketing on, for example, rational prescribing.

## Performance by technical area



## Performance by strategic pillar



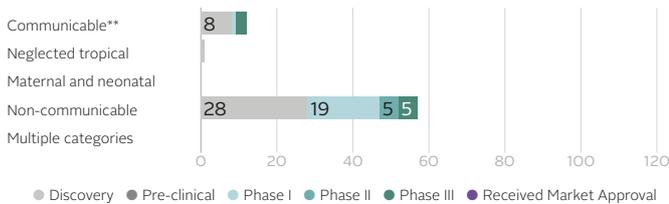
## CHANGE SINCE 2016

- Established a new global code of conduct for marketing in 2016 and a policy for anti-bribery and anti-corruption in 2017.
- Joined Access Accelerated with two initiatives in Tanzania and China. It has also committed to measure impact and share results publicly via Access Observatory.
- Discloses public commitments to not file or enforce patents in sub-Saharan African countries (except South Africa), Least Developed Countries, low-income countries and some middle-income countries.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Launched new Access to Healthcare policy in April 2018, establishing a strong commitment to conducting R&D for diseases and countries in scope.

**PIPELINE** for diseases and countries in scope

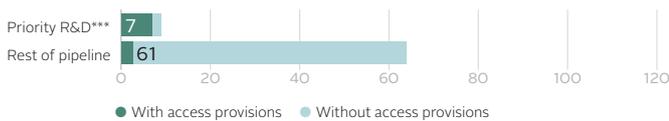
**Mid-sized pipeline:** 73 R&D projects for diseases in scope (66 medicines; 4 preventive vaccines; 3 diagnostics).  
**Clinical candidates:** 36, including a preventive vaccine for measles and a preventive vaccine for *Haemophilus influenzae*, pertussis and tetanus.  
**Regulatory approvals:** 0 for diseases in scope.  
**R&D focus:** non-communicable diseases (cancer and kidney diseases) and communicable diseases (diarrhoeal diseases and tuberculosis).  
**Access provisions:** for 10 projects, most commonly registration strategies.

**Projects in the pipeline: 73\***



Daiichi Sankyo's late-stage pipeline includes three diagnostic tests for Genoscholar®, in collaboration with the Nipro Corporation. These tests can detect tuberculosis including pyrazinamide- and multidrug-resistant tuberculosis infections.

**Projects for R&D priority targets with access provisions: 7**

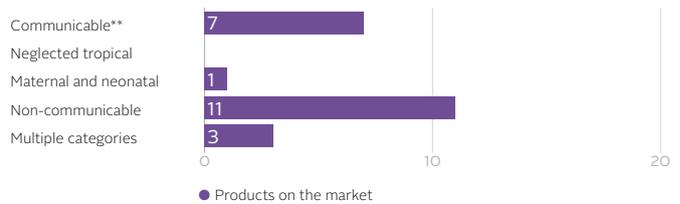


Of Daiichi Sankyo's 73 R&D projects, ten are supported by access provisions: e.g., two malaria projects have equitable pricing and non-exclusive voluntary licensing plans. Six of its 16 late-stage projects have provisions.

**PORTFOLIO** for diseases and countries in scope

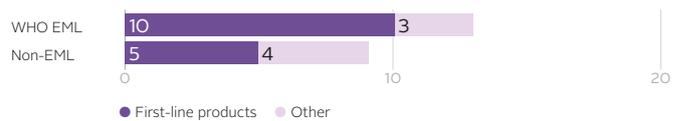
**Comparatively small portfolio:** 22 products for diseases in scope (19 medicines; 3 preventive vaccines).  
**Portfolio focus:** communicable diseases (lower respiratory infections) and non-communicable diseases (ischaemic heart disease).  
**Essential medicines:** 59% of Daiichi Sankyo's medicines and vaccines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).  
**First-line treatments:** 68% of Daiichi Sankyo's medicines and vaccines have first-line indications for diseases in scope.

**Products on the market: 22**



Daiichi Sankyo's portfolio includes products such as the antibiotics amoxicillin/sulbactam (Trifamox®), panipenem/betamipron (Carbenin®) and meropenem (Ropenem®) for the treatment of lower respiratory infections.

**Essential medicines with first-line indications: 10**



82% of Daiichi Sankyo's medicines and vaccines are listed on the WHO EML and/or as first-line treatments: e.g., tranexamic acid (Transamin®) for the treatment of postpartum haemorrhage and paclitaxel (Panataxel®).

**BUSINESS CONTEXT**

**Three business units:** Pharmaceuticals; Vaccines; and Over-the-Counter Medicines. Its pharmaceutical business has two therapeutic areas (oncology; and cardiovascular and metabolic diseases) and its vaccine portfolio covers traditional childhood vaccines, including for diphtheria, tetanus, pertussis, measles, mumps and rubella (including four combination vaccines).

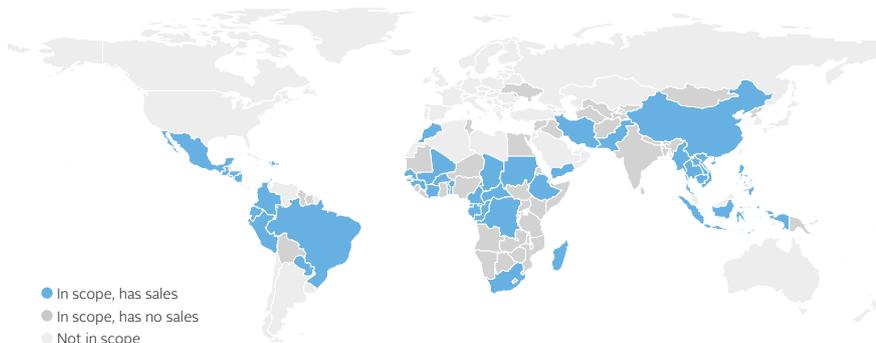
**M&A news:** 2017 consolidation of Kitasato Daiichi Sankyo Vaccine subsidiary into wholly owned subsidiary via acquisition of shares from The Kitasato Institute, a private research institute in Japan.

**Presence in emerging markets:** In 2018, Daiichi Sankyo reports sales in 43 countries in scope; one less than in the 2016 Index.

**Revenue by segment (2017) - JPY**

|                  |                   |
|------------------|-------------------|
| Pharmaceutical   | 884,907 MN        |
| Healthcare (OTC) | 72,943 MN         |
| Others           | 2,344 MN          |
| <b>Total</b>     | <b>960,194 MN</b> |

**Sales in countries in scope**

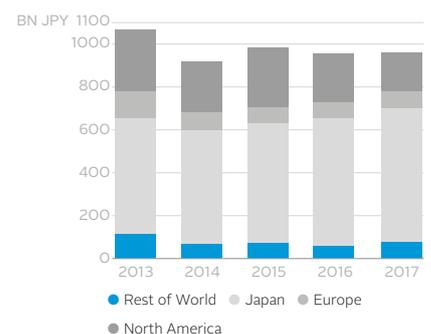


Statistics relate only to diseases and countries in scope.

\* Figure excludes three projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

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

**Revenue by geographic region**



# Daiichi Sankyo Co. Ltd.

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 19 SCORE 1.90

**Lacks an overarching access-to-medicine strategy; responsibility for access lies at executive level.** Daiichi Sankyo does not have an access-to-medicine strategy but shows evidence of some activities guided by access-related goals. For example, it operates mobile healthcare clinics in Tanzania. Access is discussed by its Global Management Committee, which entails executive leadership.

**Financial and non-financial access-related incentives in place for employees.** Daiichi Sankyo 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 rewards and awards.

**One of 16 companies working on impact measurement.** Daiichi Sankyo measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on its commitments and performance information. For example, for its initiative on mobile healthcare clinics in Tanzania, the company reports the rates of infants receiving measles vaccinations and mothers undergoing prenatal checkups. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

**Limited transparency about stakeholder engagement.** Daiichi Sankyo performs relatively poorly when it comes to the disclosure of its stakeholder engagement. Daiichi Sankyo 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. Neither does it report incorporating local stakeholder perspectives into the development of access strategies.

### MARKET INFLUENCE & COMPLIANCE

RANK 18 SCORE 1.55

**Does not report processes for ensuring third-party compliance with standards.** Daiichi Sankyo has a code of conduct and policy relating to ethical marketing and anti-corruption: namely, it has a global anti-bribery and anti-cor-

ruption policy. It provides compliance training for employees. The company performs relatively poorly when it comes to enforcing compliance measures and non-sales incentives. It does not provide evidence of having formal processes in place to ensure compliance with standards by third parties. Further, expected performance for sales agents is based solely on sales targets.

**Internal control framework lacks Index criteria.** Daiichi Sankyo's internal control framework for ensuring compliance meets one of the criteria looked for by the Index. This is an auditing and review mechanism (that performs evaluations once every three years). However, it does not report that this mechanism applies to third parties. Daiichi Sankyo does not report conducting fraud-specific risk assessments, nor does it demonstrate evidence of a monitoring system in place to track compliance, or evidence of having procedures to segregate duties, to ensure decisions are checked by another party.

**Average transparency regarding access-related practices.** Daiichi Sankyo publicly discloses its policy positions on access-related topics (e.g., its policy on intellectual property rights and access to medicine). It does not have a policy prohibiting political contributions in countries in scope, but states that no such contributions occurred during the period of analysis. The company publicly discloses its membership of relevant organisations for access, but not its financial contributions to such organisations. It shares its policies for responsible engagement for employees' interactions with healthcare professionals. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

### RESEARCH & DEVELOPMENT

RANK 7 SCORE 2.71

PROJECTS: 73 IN CLINICAL DEVELOPMENT: 36

**Publicly commits to R&D to meet public health needs.** Daiichi Sankyo 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 by following external targets including the United Nations Sustainable Development Goals. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Daiichi Sankyo has a mid-sized pipeline in the Index with 73 projects. For diseases in scope where priorities exist, Daiichi Sankyo is active

in 15 projects; nine of these target priority R&D gaps.

**Access provisions in place for 38% (6/16) of late-stage candidates.** Daiichi Sankyo does not have a clear process in place to develop access plans during R&D. Instead, Daiichi Sankyo considers access on a case-by-case basis. To date, Daiichi Sankyo has project-specific access provisions in place for six of its late-stage R&D projects. Of these, three are being conducted in partnership, all with the Nipro Corporation for GenoScholar® diagnostic tests for tuberculosis.

**No policy for post-trial access.** Daiichi Sankyo does not have a policy for ensuring post-trial access to treatments for clinical trial participants. Additionally, it does not disclose a commitment to registering newly approved products in all countries where clinical trials for these products have taken place.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 17 SCORE 1.86

PRODUCTS: 22

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 8

**Does not publicly commit to equitable pricing or report a commitment to file to register products in scope.** Daiichi Sankyo does not commit to filing its newest products for registration in countries in scope within one year of first market approval. Neither does it publicly commit to implementing equitable pricing strategies. However, it does have equitable pricing strategies for some products in scope of the Index.

**No new products in scope filed for registration in the majority of priority countries.** Daiichi Sankyo 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). Its most widely registered product, for hypertensive heart disease, is registered in two out of 12 possible priority countries. It also does not publicly share registration information for any of its products.

**36% of products have equitable pricing strategies targeting priority countries.** Daiichi Sankyo's overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 36% of its products for diseases

in scope. These strategies apply to an average of 10% of priority countries. One of these strategies, for asthma and chronic obstructive pulmonary disease (COPD), applies both inter- and intra-country pricing.

**Globally consistent recall guidelines for countries in scope but no processes to track products.** Daiichi Sankyo 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 12 SCORE 1.83

**Publicly discloses detailed information on patent statuses.** Like most of its peers, Daiichi Sankyo 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.** Daiichi Sankyo does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

**Does not report newly sharing IP assets with 3<sup>rd</sup>-party researchers beyond existing agreements.** Daiichi Sankyo reported existing agreements with product development partnerships such as the Drugs for Neglected Diseases initiative (DNDi) and the Medicines for Malaria Venture (MMV). During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

**Public commitment not to enforce patents in countries in scope.** Daiichi Sankyo commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in some Least Developed Countries, low-income countries, and in a subset of lower-middle income countries and upper-middle income countries.

## CAPACITY BUILDING

RANK 19 SCORE 0.51

**Two initiatives included for evaluation.** Daiichi Sankyo has two 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; Daiichi Sankyo submitted 13.

**Two initiatives aimed at enhancing local manufacturing.** Daiichi Sankyo's initiatives which meet

inclusion criteria are in manufacturing capacity building. The initiatives are active in China and Vietnam. It did not disclose initiatives which meet inclusion criteria in any of the other areas of capacity building.

**Initiatives meet inclusion criteria only.** Neither of Daiichi Sankyo's initiatives meet all the good practice standards looked for by the Index. This includes not setting clear, measurable goals that aim for long-term sustainable improvements.

**Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe.** Daiichi Sankyo states that it reports cases of substandard or falsified medicines to relevant authorities. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.\*

## PRODUCT DONATIONS

RANK 17 SCORE 1.21

STRUCTURED DONATION PROGRAMMES: 0

**Has policy for responding to emergencies or humanitarian crises.** Daiichi Sankyo donated medicines on the request of relief agencies. For example, during the period of analysis, it donated cancer medicines in Armenia upon request from Americares. The company discloses that such *ad hoc* donations are aligned with the requirements of local regulatory standards. It also monitors the delivery of the product until received by end user.

**No donation programmes covering diseases and countries in scope.** Daiichi Sankyo does not have any structured donations programmes that were active during the period of analysis in any countries in scope.

## BEST & INNOVATIVE PRACTICES

No best or innovative practices were identified for this company in this Index.

\*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.