Daiichi Sankyo Co, Ltd

Stock Exchange: Tokyo Stock Exchange • Ticker: 4568 • HQ: Tokyo, Japan • Employees: 15,348

PERFORMANCE IN THE 2021 INDEX

16th place. Daiichi Sankyo is in the lower ranks across all Technical Areas, with weak performance in R&D. There is a lack of evidence of access strategies and it has a poor performance in responsible promotional practices.

Governance of Access: 16th place. Daiichi Sankyo performs poorly in this area. The company does not have a clear access-to-medicine strategy with measurable objectives and a business rationale. The company conducts internal and external audits but does not demonstrate other components of compliance controls looked for by the Index.

Research & Development: 20th place. Daiichi Sankyo performs poorly in this area. It has no structured process for the development of access plans during R&D and does not publicly disclose a post-trial access policy. It has 11 priority R&D projects in its pipeline but does not report access plans for its late-stage candidates.

Growing opportunities for Daiichi Sankyo change since the 2018 Index

• Supports the clinical development of novel antibiotics via the AMR Action Fund.
• Launched a new initiative in Vietnam to promote the proper use of medicines with medication guiding tools through clinical pharmacists intervention from July 2019 to February 2020.

OCCUPATIONAL OPPORTUNITIES FOR DAIICHI SANKYO

Develop an access-to-medicine strategy and expand operations. Daiichi Sankyo can establish an access strategy that is integrated within its corporate business strategy building on its Group Policy on Access to Healthcare. Such a strategy can apply to all therapeutic areas in which it operates. It can also include risk mitigation of non-compliant or corrupt activities and a balanced scorecard approach for sales incentives, thus not solely promoting sales volumes as a performance target for its sales agents in countries in scope. In 2020 Daiichi Sankyo established a subsidiary in Vietnam, the fourth Index country where it now operates. It can expand operations to serve more countries in scope of the Index.

Develop an access planning process and access plans for all R&D projects. Daiichi Sankyo can develop a formal access planning process and accordingly develop access plans for all clinical Phase II projects, such as its diagnostic tests for Genoscholar®, its measles-mumps-rubella combination vaccine and for Valmetostat for leukaemia. Further, Daiichi Sankyo can develop and publish a post-trial access policy allowing for continued access to investigational treatments for clinical trial participants and can commit to registering the product in countries where clinical trials take place while ensuring affordability.

Improve access to patented products on WHO EML. Daiichi Sankyo has three patented products on patent which are on the 2019 WHO Model List of Essential Medicines (WHO EML). The company can further prioritise expanding access to these products, such as edoxaban (Lixiana®) for ischaemic heart disease and management of stroke and other blood clots, by increasing affordability and supply using mechanisms such as equitable pricing and/or non-exclusive voluntary licensing in countries in scope. The company should, e.g., take into account the different socio-economic levels and offer tailored pricing for different population segments.

Governance of Access

Research & Development

Product Delivery

How score was achieved

Average
Leader

Governance of Access 2.54
Research & Development 0.84
Product Delivery 1.9

NOTE: Governance of Access was scored from 1 to 5.

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: Prescription drugs; Healthcare (OTC) products; Other
Therapeutic areas: Oncology; Genetic/Orphan Diseases; Inflammation/Immunology; Cardiorenal Diseases; Neurology; Vaccines
Product categories: Innovative medicines; Generic medicines; Vaccines; Consumer health
M&A news: None since publication of the 2018 Index.

Sales in countries in scope

Daiichi Sankyo's products are sold in 34 out of 106 countries in scope. Daiichi Sankyo has sales offices in 3 countries and sells via suppliers into 31 additional countries.

Revenue by segment (2019) – JPY

- Prescription drugs: 911.3 bn
- Healthcare (OTC) products: 68.4 bn
- Other: 2.1 bn
- Total: 981.8 bn

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Daiichi Sankyo has a total of 33 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 11 projects. The other 22 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on tuberculosis (4 projects). Of the projects targeting other diseases in scope, the focus is on oncology (18). 6 R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (5). No evidence of access planning was in place for any of these projects.

PORTFOLIO as selected for analysis by the Index

Daiichi Sankyo has 11 medicines in scope, 9 of which are on patent and 3 vaccines. 36% of these medicines (4) are on WHO’s EML. In addition, the company markets 3 diagnostics. The off-patent medicines target ischaemic heart disease and lower respiratory tract infections. The on-patent medicines mainly target non-communicable diseases such as cardiovascular diseases (6), mental health and oncology. In addition, one medicine targets influenza. Daiichi Sankyo's preventative vaccines target pertussis and tetanus. The diagnostics in scope are for tuberculosis (3). Access strategies were analysed for 5 products on Daiichi Sankyo's portfolio – nationally procured self-administered products (5).

33 projects in the pipeline

- Communicable: 23 projects
- Neglected tropical: 9
- Maternal and neonatal: 0
- Non-communicable: 0
- Multiple categories: 0

Breakdown of projects*

- Pre-clinical: 22 projects
- Phase 1: 0
- Phase 2: 0
- Phase 3: 0
- Approval: 0
- Total: 22

17 products as selected for analysis by the Index*

- Communicable**: 8
- Neglected tropical: 0
- Maternal and neonatal: 0
- Non-communicable: 9
- Multiple categories: 0

Breakdown of products

- Medicines on patent: 9
- Off patent: 2
- Vaccines: 3
- Diagnostics: 3
- Other: 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.
Daiichi Sankyo Co, Ltd

**GOVERNANCE OF ACCESS**

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Does not have a clear access-to-medicine strategy with measurable objectives. Unlike most of its peers, Daiichi Sankyo does not have a clear strategy integrated within its overall corporate strategy. It has a general commitment to improve access to medicine, the Daiichi Sankyo Group Policy on Access to Healthcare. The highest responsibility for access is indirectly with the board, with its Global Management Committee discussing the access policy.

Provides evidence of financial and non-financial access-related incentives at the executive level. Although it performs poorly in access-to-medicine strategy, Daiichi Sankyo performs well here. It incentivises its senior executives and in-country managers to perform on access to medicine with financial and non-financial rewards, as part of their CSR goals. The CEO also has access-related incentives.

Does not publicly disclose outcomes of its access-to-medicine activities. Daiichi Sankyo performs below average in transparency regarding access initiatives. It publicly discloses its commitments, objectives and targets related to improving access to medicine in countries in scope, namely with its capacity building initiatives. It does not, however, share the outcomes of its access activities during the period of analysis.

Performs comparatively poorly in responsible promotional practices. Daiichi Sankyo’s sales agents are solely incentivised on sales volume targets. The company does not disclose the level at which sales incentives are set. 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), 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, with evidence of some of the components looked for by the Index audits (both internal and external) and it reports working on a compliance system for third parties it engages with in Brazil.

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 expressing reservations on its provisions, namely it challenges the use of compulsory licensing, stating it should be carefully exercised. There is no evidence of a policy to dissent from industry association positions on these.

**RESEARCH & DEVELOPMENT**

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No structured process for access planning reported. Daiichi Sankyo does not report a structured process to develop access plans during R&D. The company did not report a structured timeline for the development of access plans for its R&D projects.

A small-sized priority R&D pipeline compared to peers, with no access plans in place. Daiichi Sankyo has 11 projects, including one late-stage candidate, in its pipeline that target a priority product gap. The company focuses mostly on tuberculosis. There is no evidence of an access plan for Daiichi Sankyo’s late-stage candidate targeting a priority product gap.

Some projects address a public health need in LMICs*. The company does not disclose evidence of access plans for the late-stage projects. In this analysis, Daiichi Sankyo has five 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 have clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer.

No public disclosure of post-trial access policy. Daiichi Sankyo does not have a publicly available policy for ensuring post-trial access to treatments for clinical trial participants, nor did it disclose such a policy to the Index.

No R&D capacity building initiatives included for evaluation. Daiichi Sankyo performs poorly in this area. Companies could submit a maximum of five initiatives in this area. The company reported no information to the Index about R&D capacity building in Index countries.

**PRODUCT DELIVERY**

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Public commitment not to enforce patents in countries in scope. Daiichi Sankyo commits publicly to neither file for nor enforce patents. This commitment applies in all countries in scope.

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

Does not report newly sharing IP assets with 3rd-party researchers beyond existing agreement. Daiichi Sankyo reported existing agreements with product development partnerships such as the Drugs for Neglected Diseases Initiative (DNDI) and the Global Health Innovative Technology Fund. 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.

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.

No evidence of new products in scope filed for registration in the majority of high burden countries. Daiichi Sankyo did not disclose evidence of filing any of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). Its most widely registered product, edoxaban (Lixiana®) for ischaemic heart disease and stroke is registered/has been filed for registration in twelve countries in scope including El Salvador and Vietnam.

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

No healthcare-practitioner-administered products. Daiichi Sankyo has no products eligible for scoring in this indicator.

Has few access strategies for its self-administered products for some countries in scope for this analysis. Daiichi Sankyo performs poorly in this area. The company provides examples of access strategies which consider affordability only in LMICs for three out of the five products assessed. It makes efforts to reach additional patients through the use of both inter and intra country pricing strategy. For example, in Brazil it applies equitable pricing strategy for lurasidone hydrochloride (Latuda®), a treatment for bipolar affective disorder and schizophrenia.
to reach 12,000 patients. The company provided evidence of patient reach through this approach. It falls short to provide example in LMICs or LICs for any of the product.

Two manufacturing capacity building initiative included for evaluation. Daiichi Sankyo performs below average in this area. The company submitted the maximum of five initiatives, of which two met all criteria for inclusion, including a technology transfer of prasugrel (Effient®) in China for the treatment of stroke and a collaboration with the Center for Research and Production of Vaccines and Biologicals (POLYVAC) in Vietnam for the manufacturing of a measles-rubella vaccine. The initiatives did not meet all Good Practice Standards‡ as Daiichi Sankyo did not demonstrate that they were either guided by clear goals/objectives, aim for sustainability a long-term aims and are measuring outcomes in relation to manufacturing capacity.

No supply chain capacity building initiatives included for evaluation. Daiichi Sankyo performs poorly in this area, with no supply chain capacity building initiatives included for analysis. Companies could submit a maximum of five initiatives. The company reported no information to the Index about supply chain capacity building in Index countries.

One health system strengthening initiative meets all Good Practice Standards. Daiichi Sankyo has average performance in this area. The company submitted four health system strengthening initiatives, of which two were included for analysis. One initiative, clinical pharmacist intervention in Vietnam, promoting appropriate use of medicine through the development of medicine guidelines, met all Good Practice Standards i.e. addresses local needs, has local partners, mitigates risk of conflict of interest, is guided by clear goals and objectives, (plans to) measure outcomes, has a governance structure in place and aims for sustainability/integration in the local health system. For the other initiative, Mobile Healthcare Field Clinical Services in Tanzania, which reportedly increased the measles immunisation ratio among infants from 78% to 96%, Daiichi Sankyo did not provide sufficient evidence on how the initiative aims for sustainability and/or integration in the local health system.

Has not engaged in the development and implementation of inclusive business models. Compared to peers, Daiichi Sankyo performs relatively poorly when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid (which may include vulnerable populations) in countries in scope, with a long-term horizon. It did not report on any initiative.

The company has some mechanisms in place to ensure continuous supply in countries in scope of the Index. Daiichi Sankyo has average performance in this area, disclosing some strategies to ensure the continuous supply in countries in the scope of the Index. The company provides evidence of having a Sales & Operations Planning process in place at the headquarter level, which is aimed at aligning demand and supply, covering some countries in scope of the Index. The company reports that a multiple supplier approach for key APIs has been implemented or is being considered for implementation. The company did not provide evidence of ensuring supply to Least Developed Countries or communicating with governments on potential supply disruptions.

Has a case-by-case approach for reporting substandard and falsified (SF) medicines in countries in scope. Daiichi Sankyo provides evidence of reporting SF medicines to relevant national health authorities, on a case-by-case basis. It does not, however, require reporting to occur within the time frame of ten days looked for by the Index, nor does it distinguish timeframes for reporting cases which only require visual inspection to be confirmed.

Donates in response to an expressed need, but does not monitor delivery to end user. Daiichi Sankyo reports that it ensures ad hoc donations are carried out in response to an expressed need. However, it is unclear if it monitors the delivery until the end user, though it selects partners with a secure and reliable monitoring system.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. Daiichi Sankyo is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible.

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