

RANK	SCORE
12	2.95
11 (2021)	

Eisai Co, Ltd

Stock exchange: TSE • Ticker: ESALY • HQ: Tokyo, Japan • Employees: ~10,000

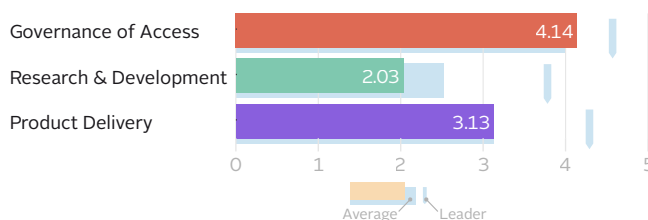
PERFORMANCE IN THE 2022 INDEX

12th place. Eisai has an average performance. The company has an average performance in access strategies for products on the market. Eisai engages in R&D for priority diseases, but the majority of late-stage pipeline projects do not have an access plan. It performs well by having processes in place to ensure the continuous supply of medicines in LMICs.

Governance of Access: 10th place. Eisai has an average performance in this area. It has a clear access-to-medicine strategy that is integrated into its overall corporate strategy, although the strategy does not fully extend across its pipeline and portfolio. It also has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index, but it shares the outcomes of its access-to-medicine activities for only a subset of initiatives.

Research & Development: 14th place. Eisai has a below average performance in this area. It has an average-sized priority pipeline, but only applies access plans to a small number of

How score was achieved



late-stage candidates. It has an average performance in R&D capacity building.

Product Delivery: 13th place. Eisai has an average performance in this area. It has access strategies in place for most of its products in upper-middle and lower-middle income countries. The company engages in high-quality supply chain capacity building but has a comparatively poor performance in terms of health systems strengthening and manufacturing capacity building.

OPPORTUNITIES FOR EISAI

Ensure all late-stage R&D projects have comprehensive access plans. Eisai has a structured process in place for R&D access planning that encompasses some projects in the pipeline. The company has access plans in place for 14% of late-stage projects analysed. These plans are for projects developed in partnership with DNDi. Eisai can apply access plans to all projects in the pipeline from Phase II onwards, for example, lecanemab for Alzheimer's disease.

Expand registration of epilepsy medicines. Eisai has one of the largest portfolios of on-patent antiepileptic products among the companies in scope. Its antiepileptic perampanel (Fycompa®) is currently not registered in any of the ten countries in scope with the highest burden of epilepsy. The company can register this product in those countries, including Guyana and Haiti.

Expand access strategies to reach populations in low-income countries. For its breast cancer treatment eribulin (Halaven®), Eisai deploys equitable access strategies and patient assistance programmes in at least two lower-middle income countries. The company can expand such strategies to low-income countries and other countries with a high burden of breast cancer, such as Armenia, Papua New Guinea and Morocco.

Expand supply chain capacity building to more disease areas. Eisai has one existing supply chain capacity building initiative that meets all Good Practice Standards, focusing on neglected tropical diseases. The company can work with local partners to expand its capacity building efforts to more diseases the company focuses on, such as epilepsy, in countries that have a high burden of disease, including Uganda.

CHANGES SINCE THE 2021 INDEX

- Established a pharmaceutical sales subsidiary in Vietnam.
- Signed the Kigali Declaration, the successor to the London Declaration, in June 2022, positioning neglected tropical diseases as an important area of focus.
- 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, in collaboration with more than 20 leading pharmaceutical companies.
- Supported a project led by CA Medlynks which aims to build a new structure for the efficient testing framework for COVID-19 in Kenya through the setup of PCR testing laboratories, along with procurement of equipment necessary for testing and training of screening technicians.
- Expanded the long-term donation programme of diethylcarbamazine tablets to combat lymphatic filariasis in Nepal.

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.

SALES AND OPERATIONS

Business segments: Pharmaceutical business and other business.

Therapeutic areas: Oncology and neurology.

Product categories: Innovative medicines.

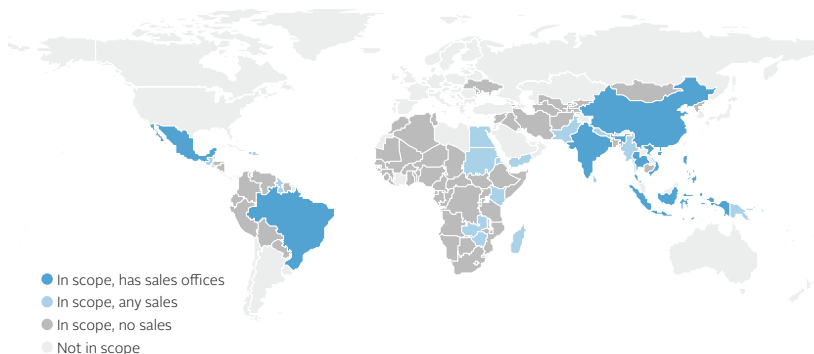
M&A news: Eisai acquired Arteryx Inc. in April 2022.

Eisai's products are sold in 33 out of 108 countries in scope of the Index. Eisai has sales offices in 8 countries, and sells via suppliers and/or pooled procurement in an additional 25 countries.

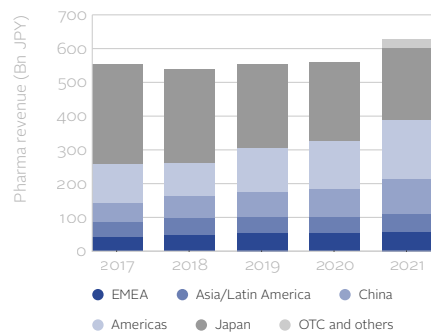
Revenue by segment (2021) – in JPY

Pharmaceutical business	626.28 bn
Other business	129.95 bn
Total	756.23 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

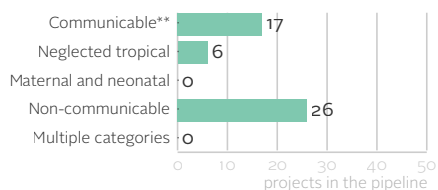
PIPELINE for diseases in scope

Eisai has a total of 49 R&D projects in scope with 23 of these projects targeting priority diseases. The other 26 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on malaria (13 projects). Of the projects targeting other diseases, the focus is on Alzheimer's disease (6) and oncology (18). Fourteen R&D projects are in late-stage development that target either a priority disease (3) or address a public health need in LMICs (11).^{*} Evidence of access planning was in place for 14% of these projects: one targeting a priority disease and one addressing a public health need in LMICs.

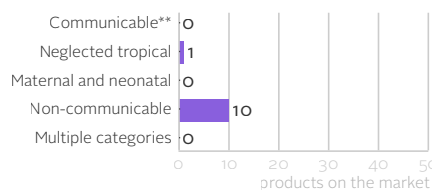
PORTFOLIO as selected for analysis by the Index

Eisai has 11 medicines in scope, six of which are on patent. 18% of the medicines (2) are on the WHO EML. The off-patent medicines (5) mainly target mental health (2). One product targets the neglected tropical disease lymphatic filariasis and one further product is for cardiovascular diseases. The on-patent medicines mainly target epilepsy (3) and oncology (2). In addition, one product is for Alzheimer's disease.

49 projects in the pipeline



11 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	10	9	1	1	2	0	0	23
Addresses needs of LMICs*			3	3	4	4	1	15
Other projects in scope			8	3	0	0	0	11

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	0	6			6
off patent	2	3			5
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other [†]				0	0

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

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

Eisai Co, Ltd

GOVERNANCE OF ACCESS

RANK 10

SCORE 4.14

Has an access-to-medicine strategy with measurable objectives. Eisai has an above average performance. Its strategy is fully integrated within the overall corporate strategy and states a commitment to long-term sustainability solutions, including affordable pricing. It covers some of the therapeutic areas in which the company is involved, including Alzheimer's disease and cancer. The highest responsibility lies directly with the board.

Provides evidence of financial and non-financial access-related incentives at the executive level.

Eisai performs well. It incentivises its in-country managers, including country-level corporate officers or regional managers, to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives, linked, for example, to initiatives aiming at eliminating neglected tropical diseases (NTDs).

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

Eisai performs average in transparency of access activities. It discloses its commitments, measurable goals, objectives and targets for improving access to

medicine in countries in scope of the Index. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, although it does so in a centralised manner in its Value Creation Report and directly on its website, including outcomes of activities supporting the elimination of NTDs such as lymphatic filariasis.

Performs above average in responsible promotional practices.

Eisai's sales agents are not solely incentivised on sales volume targets. Sales agent incentives are set at the individual, team and country levels. It does not publicly disclose 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), unless required by local regulations. The company has a country-specific policy limiting transfers of values to healthcare professionals.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

Eisai performs strongly, demonstrating evidence of all components looked for by the Index: fraud-specific risk assessment, a continuous

system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates), formal processes to ensure third-party compliance with company standards and country risk-based assessments. 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.

Eisai publicly shares support of the Doha Declaration on TRIPS and Public Health, highlighting that Article 31b (covering the use of compulsory licences) provides balance between the protection of both IP and public health under appropriate circumstances. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Eisai, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 14

SCORE 2.03

Access planning processes encompass some projects in the pipeline. Eisai has a structured process in place to develop access plans during R&D. The process is intended to be applied to a subset of R&D projects (both in-house and collaborative) for diseases in scope of the Index.

An average-sized priority R&D pipeline compared to peers, with 33% (1/3) of late-stage candidates supported by access plans.

Eisai has 23 projects including three late-stage candidates in its pipeline that target a priority product gap. The company's priority pipeline focuses mostly on malaria. Of Eisai's three late-stage candidates targeting a priority product gap, there is evidence of an access plan for one. This access plan for fosravuconazole as a treatment for patients with eumycetoma is in partnership with the Drugs for Neglected Diseases *initiative* (DNDi).

Many projects address a public health need in LMICs,* with 9% (1/11) of late-stage candidates covered by access plans.

In this analysis, Eisai has 11 late-stage R&D projects 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 concern clinical trials in countries in scope of the Index and/or are first-in-class molecules. The projects mainly focus on cancer and Alzheimer's disease. Eisai provides evidence of an access plan for one of the late-stage candidates. This plan concerns registration preparation in countries in scope of the Index.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development.

However,

Eisai does disclose fully disaggregated R&D investment data to Policy Cures Research.

One of the two R&D capacity building initiatives included meets all Good Practice Standards.

Eisai'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. Notably, Eisai partners with Seeding Labs to improve access to laboratory equipment for the scientific community in countries in scope of the Index. This initiative meets all GPS.

*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.

PRODUCT DELIVERY

RANK 13

SCORE 3.13

Public commitment not to enforce patents in countries in scope. Eisai publicly pledges to neither file for nor enforce patents in all Least Developed Countries and LICs. This commitment applies to infectious diseases, neglected tropical diseases and maternal and neonatal diseases.

Publicly discloses information on patent status. Like most of its peers, Eisai publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Eisai discloses patent information such as filing date, grant number, grant date and jurisdiction.

Is an average-performing company in terms of sharing intellectual property assets with third-party researchers. Eisai engaged in one new IP-sharing agreement with third-party research institutions or drug discovery initiatives established during the current analysis period that meets 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. Eisai does not engage in voluntary licensing for products in scope of the Index. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

No evidence of filing for registration its new product in any country in scope. Eisai did not disclose evidence of filing for registration its new product in any of the top ten high burden countries. Among old products, its most widely filed product, eribulin (Halaven®), indicated for breast cancer, has been filed for registration in 31 countries within scope of the Index, including three high burden disease countries, such as Morocco and Pakistan. Eisai filed two of its seven products assessed in one LIC.

Eisai is not eligible for assessment of supranationally procured products.

Has access strategies for the healthcare practitioner-administered product in scope of this analysis. Eisai performs above average in this area. The company provides examples of access strategies which consider affordability in both a UMIC and an LMIC for the only product assessed, including efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay. For example, Eisai obtained national reimbursement in China for eribulin (Halaven®), a breast cancer medicine as well as implemented

a patient assistance programme to reach additional patients. In India, Eisai company has a licensing agreement with Viatris to allow second brand manufacturing and increase access in the country. The company provides evidence of how patient reach has been increased through these approaches in India.

Has access strategies for its self-administered products for some countries in scope for this analysis. Eisai has an average performance in this area. The company provides examples of access strategies in UMICs and LMICs for all three products assessed, including efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay. For example, Eisai implemented the lenvatinib (Lenvima®) Easy Access Program (LEAP) in the Philippines, which offers two free boxes for every purchase of one box (of the same dose) to all patients regardless of their income since May 2017. The company provides evidence of how patient reach has been increased through these approaches.

Two manufacturing capacity building initiatives included for analysis. Neither manufacturing capacity building initiative included for analysis meets all Good Practice Standards (GPS). Eisai's performance is below average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all GPS than what is average for this indicator. In one of the included initiatives, since 2013 Eisai has built and improved pharmaceutical manufacturing capacity of an Indian local manufacturer, Saurav, to supply diethylcarbazine for lymphatic filariasis elimination.

The one supply chain capacity building initiative included for analysis meets all Good Practice Standards. Eisai's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all GPS than what is average for this indicator. NTD Supply Chain Forum is a multi-partner initiative that aims to deliver the drugs of neglected tropical diseases for donations from the first to last mile and tracks progress and logistics improvement of operations in countries in scope of the Index.

Three health systems strengthening initiatives included for evaluation. None of the three health systems strengthening initiatives included for analysis meet all GPS. Eisai's performance is below average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all GPS than

what is average for this indicator. One example of an initiative included for evaluation is the partnership with CA Medlynks Kenya and the government of Meru County to construct a screening framework for COVID-19 in Kenya.

Has engaged in piloting one inclusive business model but has not shown evidence of its involvement in scaling up any existing inclusive business models that meet all inclusion criteria. Eisai performs below average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. The One-stop Online Service Platform: Yin Fa Tong in partnership with JD Health is a joint venture that aims to create a new solution that provides medical, health, and lifestyle services specifically for the elderly, especially those with dementia and their families.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Eisai is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient (API) suppliers/produces in-house APIs, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Eisai has a policy for reporting SF medicines to national health authorities and the WHO within 24 hours to seven days. It provides evidence of shortened reporting time frames for cases which only require visual inspection to be confirmed based on the Risk Evaluation Committee.

Donates in response to expressed need and monitors delivery. Eisai has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations.

Publicly commits to the achievement of elimination, eradication or control goals in one structured donation programme for neglected tropical diseases or malaria. Since 2013, Eisai publicly commits itself to eliminating lymphatic filariasis by donating diethylcarbazine tablets in 25 countries in scope of the Index for an unlimited period of time.