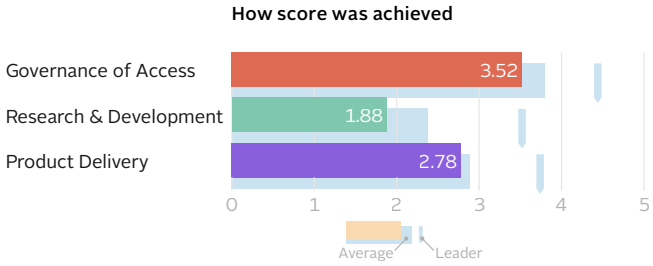
RANK	SCORE
14	2.62
12 (2022)	

Eisai Co, Ltd

Stock exchange: TSE • Ticker: ESALY • HQ: Tokyo, Japan • Employees: 11,067

PERFORMANCE IN THE 2024 INDEX

14th place. Eisai performs below average. It engages in Research & Development for priority diseases, but many of its late-stage pipeline projects do not have an access plan. It has increased engagement in health system strengthening initiatives but has a below-average performance in Governance of Access.



OPPORTUNITIES FOR EISAI

Ensure all late-stage R&D projects have comprehensive access plans. Eisai has a structured framework for access planning. However, it only has access plans in place for one of its 18 (6%) late-stage R&D projects. By implementing its systematic framework for access planning, the company can ensure the coverage of all pipeline projects from Phase II onwards. For example, it can develop access plans for farletuzumab ecteribulin (FZEC), which is in Phase II trials for multiple cancers, including ovarian and endometrial.

Expand geographic scope of technology transfer initiatives. Eisai engages in technology transfer initiatives for the active pharmaceutical ingredient of its lymphatic filariasis treatment diethylcarbamazine citrate (DEC) in India and for its oncology and epilepsy treatments eribulin (Halaven®), lenvatinib (Lenvima®), perampanel (Fycompa®) and rufinamide (Inovelon®) in Mexico and Brazil. The company can engage in further technology transfer initiatives in additional countries, for example in Southeast Asia or Africa.

Expand access to innovative products. Eisai has access strategies in place for its products targeting non-communicable diseases; however, it lacks coverage in low-income countries. The company can expand access through expanding registration and engaging in equitable access strategies, for key products such as eribulin (Halaven®), indicated for breast cancer.

CHANGES SINCE THE 2022 INDEX

- Since 2022, Eisai's access-to-medicine strategy covers all therapeutic areas the company is involved in.
- In 2023, Eisai received FDA approval for lecanemab-irmb (LEQEMBI®), a treatment for Alzheimer's disease.
- Eisai Vietnam launched a Dementia and Alzheimer awareness campaign in September 2023 to address misconceptions about Alzheimer's disease.
- Eisai has committed JPY 625mn to support the third phase of the Global Health Innovative Technology Fund (GHIT Fund) from FY2023 to FY2027, aimed at accelerating the development of medicines for infectious diseases in developing countries. This follows its previous contributions totaling JPY 1bn to the first two phases of the GHIT Fund.

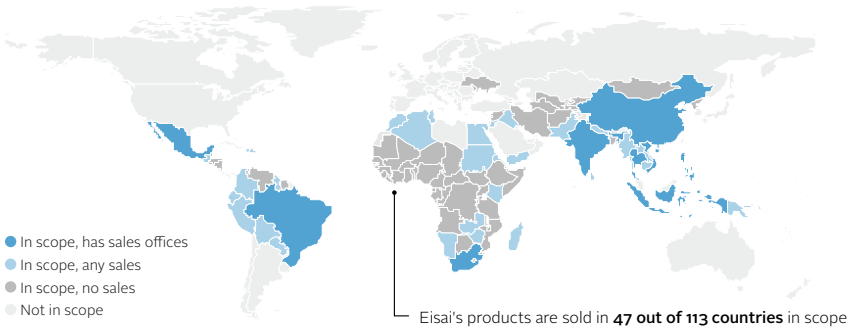
Eisai Co, Ltd

SALES AND OPERATIONS

Therapeutic areas: Oncology, neurology, tropical diseases
Product categories: Innovative medicines
M&A news: In 2024 Eisai absorbed KAN Research Institute, Inc.

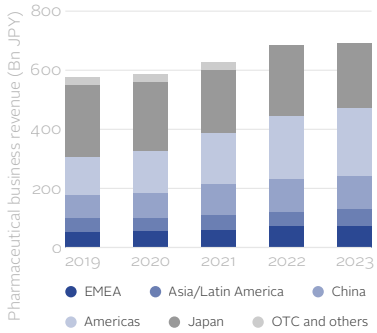
Revenue by segment (2023) – in JPY	
Pharmaceutical business	691.46 bn
Other business	50.29 bn
Total	741.75 bn

Sales in countries in scope



Eisai's products are sold in **47 out of 113 countries** in scope of the Index. Eisai has sales offices in 9 countries and sells via suppliers and/or pooled procurement in an additional 38 countries.

Sales by geographic region

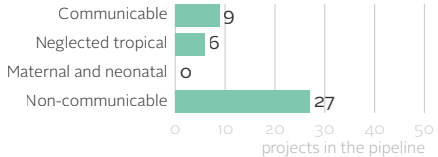


SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

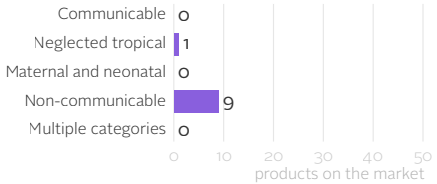
PIPELINE *for diseases in scope*
Eisai has 42 R&D projects in scope, 15 of which target priority diseases, including malaria (8), Chagas disease (3) and leishmaniasis (2). The remaining 27 projects target other diseases in scope, including cancer (21), Alzheimer's disease (5) and epilepsy (1). Of the 42 R&D projects, 18 are in late-stage development, with evidence of access planning for 6% (1/18) of these.

PORTFOLIO *as selected for analysis by the Index*
Eisai has 10 medicines in scope, 2 of which are listed on the WHO EML. Most of its medicines are on patent (7) and treat non-communicable diseases, such as cancer (3), epilepsy (2) and Alzheimer's disease (2). Eisai has 1 neglected tropical disease medicine that treats lymphatic filariasis.

42 projects in the pipeline



10 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	5	8	0	2	0	0	0	0	15
with access plan				1	0	0	0		1
Other projects in scope			10	9	4	0	3	1	27
with access plan				0	0	0	0		0

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines *on patent*	0	7			7
off patent	2	1			3
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other				0	0

Eisai Co, Ltd

GOVERNANCE OF ACCESS RANK 14 SCORE 3.52

14th place. Eisai has a below-average performance in this Technical Area. The company's patient reach process for diethylcarbamazine tablets (for treating lymphatic filariasis) covers some countries in scope of the Index. The underlying methodology details are not publicly available and the resulting patient reach numbers are not regularly published. Further, each country where Eisai operates has its own incentive compensation plans, with some individual-level targets for its sales agents.

The highest responsibility for access lies directly with the Board. Eisai incentivises its senior executives and in-country managers, including country-level corporate officers or regional managers, to act on access to medicine with financial and non-financial rewards. The CEO has long-term access-related incentives, linked, for example, to initiatives aimed at eliminating neglected tropical diseases (NTDs).

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy covers all therapeutic areas in which the company is involved, including Alzheimer's disease and cancer. Eisai publicly discloses its commitments to access to medicine, along with some company-specific measurable targets, goals and objectives. Reporting is mostly clear, linked to these goals, centrally available, and updated regularly in its Value Creation Report.

Shows comparatively strong commitment to responsible business practices. Eisai sets individual, team and country-level targets for sales agents, and incentives are not solely based on sales volume. Further, each country where Eisai operates has its own incentive compensation plans. For example, in Vietnam, it considers both sales and non-sales incentives. Eisai commits to ensuring ethical interactions with healthcare professionals in its Compliance Handbook. It also declares that transfers of value to healthcare professionals (e.g., payments for speaking at symposia) 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 robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Eisai performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessments. Eisai also has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

Eisai publicly supports the Doha Declaration on TRIPS and Public Health. It states that compulsory licensing provides a balance between protecting intellectual property (IP) and public health in appropriate circumstances.

Fulfils some criteria across 2 processes for measuring and reporting patient reach. For its process for diethylcarbamazine tablets (for treating lymphatic filariasis), which covers some countries in scope of the Index, Eisai provided the underling equation, metrics and assumptions directly to the Index. The resulting patient reach numbers are not published regularly, meaning no improvements could be demonstrated. The process has a measurable patient reach goal but no associated health outcomes goal was identified.

RESEARCH & DEVELOPMENT RANK 15 SCORE 1.88

15th place. Eisai has a below-average performance in this Technical Area. The company has an average-sized pipeline with developments for non-communicable and priority diseases, although the number of priority projects has fallen. It has an access planning framework from Phase II onwards, but it only has access plans in place for one of its late-stage candidates. It does not publicly disclose disaggregated R&D investment data, and the company has some R&D capacity building activities.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company does not make a public commitment addressing its systematic approach to access planning for LMICs.

Average-sized priority R&D pipeline, compared to peers, with access plans in place for 50% (1/2) of the late-stage candidates. Priority R&D pipeline of 15 projects, including 2 late-stage projects that target a priority gap. The company focuses on various priority areas, including malaria, Chagas disease and leishmaniasis. Of Eisai's 2 late-stage candidates targeting a priority product gap, 1 (50%) has evidence of an access plan in place. This plan includes registration preparation and is a partnership with an access-oriented organisation.

Average-sized pipeline, compared to peers, addressing other diseases in scope, with 0% (0/16) of late-stage projects covered by access plans. The company has 16 late-stage R&D projects targeting other diseases in scope that have not been established as a priority by global health stakeholders. The projects target cancer, Alzheimer's disease and epilepsy. Eisai does not provide evidence of access plans for any of its 16 late-stage projects.

Eisai 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).

One of the two R&D capacity building initiatives included for analysis meets all Good Practice Standards (GPS). In this initiative, Eisai provides equipment to Seeding Labs. In turn, this organisation provides this equipment to research institutions in LMICs.

Eisai Co, Ltd

PRODUCT DELIVERY

RANK 13 SCORE 2.78

13th place. Eisai performs below average in this Technical Area. The company has access strategies in place for its products and reports on the outcomes of these strategies. However, it lacks coverage in low-income countries. Eisai shows an increase in engagement in health system strengthening initiatives, with more included initiatives now meeting all Good Practice Standards. However, it does not show evidence of new intellectual property sharing agreements.

Eisai registers newer products* in 4 countries in scope on average. It registers 66% of products assessed in at least 1 of 10 countries with the highest disease burden. The company's donepezil (Aricept®), indicated for Alzheimer's disease, is most widely registered, totalling 37 countries in scope, including 8 of the 10 countries with the highest disease burden. The company reports engaging in mechanisms to facilitate registration, for example, the WHO Collaborative Registration Procedure for WHO Prequalified finished pharmaceutical products (FPPs).

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

One healthcare practitioner (HCP)-administered product covered by access strategies, with patient reach tracked and reported. For its product eribulin (Halaven®), indicated for breast cancer, Eisai provides evidence of access strategies in one UMIC and LMIC, but not in any LICs. In China (UMIC), the product is included in the National Reimbursement Drug List. In India (LMIC), where patients mainly pay out of pocket, Eisai implements a patient assistance programme based on annual income, demonstrating an effort to consider patients' ability to pay. The company has high-level goals to increase access to its products and provides evidence of the number of patients reached, as well as some details on the approaches for measuring this.

Access strategies for self-administered products in a few countries, which are supported by information on outcomes. For all 3 products selected for analysis, Eisai provides evidence of access strategies in UMICs and LMICs, but not in any LICs. It shows some efforts in ensuring access and affordability of its products. However, there is room for improvement in considering the different payers' ability to pay and expanding the strategy to all 3 country income classifications. For the LMIC examples, the company demonstrates efforts to improve product affordability for patients who pay out of pocket by applying discounts or implementing patient assistance programmes. The company has high-level goals to increase access to the products and provides evidence of the number of patients reached, as well as some details on approaches for measuring this.

Eisai publicly commits not to file for or enforce patents for some products in countries in scope. This applies to some products in all least developed countries and LICs and covers infectious diseases, neglected tropical diseases and maternal and neonatal diseases.

Publicly discloses product patent status for countries in scope. Like most peers, Eisai 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.

Eisai does not engage in non-exclusive voluntary licensing for products in scope.

The 2 manufacturing capacity building initiatives included for analysis meet some GPS. Despite not meeting all GPS, Eisai supports Grupo Biotoscana, now acquired by Knight Therapeutics Inc., to manufacture 4 oncology and neurology products to supply in Latin American countries. Eisai transferred technology for eribulin mesylate (Halaven®), lenvatinib (Lenvima®), rufinamide (Inovelon®) and perampanel (Fycompa®).

Both supply chain capacity building initiatives included for analysis meet all GPS. In 1 initiative, Eisai is a member of the Pharmaceutical Supply Chain Initiative which audits suppliers and builds capacity across multiple areas such as ethics, human rights, health and safety, environment, and governance and management systems.

Three of the five health system strengthening initiatives included for analysis meet all GPS. For example, since 2013, Eisai has stationed staff in India and Myanmar to support efforts in eliminating lymphatic filariasis. In 2023, Eisai staff supported a mass drug administration programme in Myanmar, conducting socialisation with patients and raising awareness about hygiene practices to reduce transmission.

Eisai remains engaged in an existing IP-sharing agreement with a public research institution to accelerate drug development. In 2020, Eisai shared a target-specific compound set with Universidad Nacional de La Plata to accelerate drug discovery for Chagas disease. However, the company has not entered into any new agreements during the period of analysis.

Fulfils most criteria for ad hoc donations. Eisai has policies and supply processes to rapidly carry out ad hoc donations in response to expressed need, with delivery monitored to ensure donations reach patients. However, it does not make commitments, publicly or otherwise, to adhere to the most recent WHO Guidelines for Medicine Donations.

Eisai publicly commits to continue long-term donation programme to support the elimination of lymphatic filariasis. Its programme is active in 25 to 26 countries in scope, with the company pledging to donate diethylcarbamazine citrate (DEC) tablets for an unlimited period until lymphatic filariasis is eliminated.

Fulfils all criteria for mechanisms to ensure continuous supply in LMICs. For example, Eisai manufactures diethylcarbamazine citrate (DEC) tablets at its own site in India to supply to lymphatic filariasis elimination programmes in Nepal, Malaysia, Sri Lanka, Zambia and Zimbabwe. Eisai also supported an Indian manufacturer to supply the active pharmaceutical ingredient (API), aiming to reduce cost and sustain supply.

Eisai has a policy for reporting substandard and falsified medicines in countries in scope. It reports cases to both WHO Rapid Alert and/or national or local regulatory authorities within 24 hours to 7 days. The company provides evidence of shortened reporting timeframes for cases that only require visual inspection for confirmation based on the company's Risk Evaluation Committee.

Eisai operates an inclusive business model supporting access to treatments for dementia, including Alzheimer's disease, in 1 country in scope. The model was launched in 2022 in partnership with Thai Life Insurance. Partners are designing insurance products, raising awareness and creating a national network for dementia care and research. The model plans to expand to an additional 5 countries in scope, including India, Vietnam and the Philippines.

*Products that received their first marketing authorisation within the last 5 years.