PERFORMANCE IN THE 2021 INDEX

11th place. Eisai has an average performance across all technical areas of the Index. It shows a strong performance in its approach to structured donation programmes, but its performance in responsible business practices is average.

Governance of Access: 8th place. Eisai is a middle-performing company in this area. It has an access-to-medicine strategy that is clearly linked to a business rationale but is not embedded in its overall corporate strategy.

Research & Development: 10th place. Eisai has an average performance in this area. Half of its priority R&D projects are covered by an access plan, but none of the projects that address a public health need in LMICs are covered by an access plan.

Product Delivery: 10th place. Eisai has an average performance. The company has newly shared one IP asset with third-party researchers. It has access strategies in place for some of its products but these are mainly focused on middle-income countries. It applies multiple mechanisms to ensure continuous supply and has a strong structured donation programme to achieve elimination of lymphatic filariasis.

OPPORTUNITIES FOR EISAI

Expand registration for epilepsy medicines. Eisai has one of the largest patented antiepileptic portfolios in scope. Its antiepileptic perampanel (Fycompa®) is currently registered in one out of ten countries with highest epilepsy burden. It can file for registration for these antiepileptics, including rufinamide (Inovelon®), which is currently not registered in any of those countries, in all ten countries with highest epilepsy burden. These include countries such as Nigeria, Tajikistan, Angola, Mozambique.

Apply access planning process to all R&D projects. Eisai has a structured process in place that encompasses some projects in the pipeline and starting in Phase II of clinical development. It has specific access plans in place for some late-stage projects. These plans are for projects developed in partnership with DNDi. The company can expand its access plans to all late-stage R&D projects in the pipeline. It can develop access plans for lenvatinib (Lenvima®) (multiple indications) for treatment of cancer.

Expand access strategies to reach low-income country populations. Eisai deploys access strategies in Asian countries for different products such as eribulin (Halaven®) for breast cancer and donepezil (Aricept®) for Alzheimer’s disease that consider affordability. These practices can be expanded to more low-income countries and other geographic regions with a high burden of breast cancer outside Asia, such as Ukraine, Armenia, Moldova and Morocco.

CHANGE SINCE THE 2018 INDEX

• Shares chemical libraries with the Global Antibiotic Research & Development Partnership (GARDP) to screen for novel compounds with antibacterial activity.
• New projects access planning process to all projects in R&D pipeline.
• Supports the clinical development of novel antibiotics via the AMR Action Fund.
• Reports fewer products falling under the commitment not to file for patents.
• Launched a new initiative in China via a partnership with JD Health on information on current care for people with Alzheimer’s disease and caregivers.
• Supports the Association for Aid and Relief, Japan (AAR Japan) programme, in Sudan on awareness of early diagnosis and treatment among mycetoma patients and caregivers, in remote areas working with the Kharoutum University Mycetoma Research Center (MRC).
• Joined the COVID-19 Therapeutics Accelerator.

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

Eisai’s products are sold in 30 out of 106 countries in scope. Eisai has sales offices in 7 countries, sells via suppliers in 5 countries and via pooled procurement into 18 additional countries.

Revenue by segment (2019) – JPY

- Pharmaceutical business: 577,267 bn
- Other business: 118,355 bn
- Total: 695,622 bn

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Eisai has a total of 52 R&D projects featuring an average-sized priority R&D pipeline compared to its peers: 22 projects. Remarkably, over 40% of Eisai’s R&D projects target priority diseases. The other 30 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on malaria (10 projects). Of the projects targeting other diseases in scope, the focus is on oncology (21).

13 R&D projects are in late-stage development that target either a priority disease or address a public health need in LMICs. Evidence of access planning was in place for 15% of these projects: 2 targeting a priority disease but none addressing a public health need in LMICs.

PORTFOLIO as selected for analysis by the Index

Eisai has 10 medicines in scope, 6 of which are on patent. 20% of these medicines (2) are on WHO’s EML. The off-patent medicines (2) target mainly mental health. One product targets the neglected tropical disease lymphatic filariasis (LF) 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.

Access strategies were analysed for 4 products on Eisai’s portfolio – nationally procured HCP-administered (1) and self-administered products (3).

52 projects in the pipeline

- Communicable: 16
- Neglected tropical: 6
- Maternal and neonatal: 30
- Non-communicable: 0
- Multiple categories: 0

10 products as selected for analysis by the Index

- Communicable: 0
- Neglected tropical: 1
- Maternal and neonatal: 0
- Non-communicable: 9
- Multiple categories: 0

Breakdown of projects*

- Targets established R&D priorities: 10
- Addresses needs of LMICs*: 0
- Other projects in scope: 0

Breakdown of products

- Medicines on patent: 6
- Meds off patent: 4
- Vaccines: 2
- Diagnostics: 0
- Other: 0

*52 diseases and 217 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.
Eisai Co, Ltd

GOVERNANCE OF ACCESS

Has an access-to-medicine strategy with measurable objectives and a business rationale. Eisai has an average performance. It has an access strategy embedded in its human health care philosophy and states a commitment to long-term sustainable solutions including affordable pricing. The strategy covers some of the therapeutic areas in which the company is involved, including Alzheimer’s disease and cancer. The highest responsibility for access lies indirectly with the board, namely with a senior executive.

Provides evidence of financial and non-financial access-related incentives at executive level. Eisai performs well here. 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 well in transparency regarding access activities. It discloses its commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope, related, for example, to its business plan EWAY 2025. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, including through the IFPMA Global Health Progress platform.

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Has an average performance in responsible promotional practices. Eisai’s sales agents are not 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), unless required by local regulations, nor does it disclose a policy limiting such transfers.

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PUBLIC HEALTH

Access planning processes encompass some projects in 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 for diseases in scope. Eisai begins developing access plans for R&D projects in Phase II or earlier of clinical development. The process is for both its in-house and collaborative R&D projects.

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An average-sized priority R&D pipeline compared to peers, with access plans in place for 50% of the late-stage candidates. Eisai has 22 projects including four late-stage candidates in its pipeline that target a priority product gap. The company focuses mostly on malaria. Of Eisai’s four late-stage candidates targeting a priority product gap, there is evidence of an access plan for two. These plans for (fosravuconazole) Nailin® are in partnership with DNDi.

Some projects address a public health need in LMICs*. The company does not disclose evidence of access plans for these projects. In this analysis, Eisai has nine 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 and/or are first-in-class molecules. Most target cancer.

Policy to ensure post-trial access; commits itself to registering trialed products. Eisai has a policy for ensuring post-trial access to treatments for clinical trial participants. However, this policy is not publicly available. This policy covers a subset of clinical trial participants on a case-by-case basis. Once a product is approved, Eisai commits itself to registering newly approved products in all countries where clinical trials for these products have taken place. The policy does not consider affordability for the wider population in the country where the trial(s) took place.

Two R&D capacity building initiatives included for evaluation. Eisai performs below average in this indicator. The company submitted two initiatives aimed at building R&D capacity, which were both included for analysis but did not meet all Good Practice Standards. For example, Eisai collaborates with scientists in Cameroon on drug discovery projects through WIPO Re:Search.

PRODUCT DELIVERY

Public commitment not to enforce patents in countries in scope. Eisai publicly pledges to neither file for nor enforce patents. This commitment applies to Least Developed Countries and low-income countries.

Publicly discloses detailed 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. This information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date, jurisdiction, publication number and publication date.

Shares some IP assets with third-party researchers. Eisai has newly shared some IP assets with third-party researchers developing products for diseases in scope. This includes four IP assets shared with research institutions and the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. Assets shared include molecule libraries.

No use of non-assert or licensing arrangements. Eisai does not engage in voluntary licensing arrangements for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Filed to register some new products in the majority of high burden countries. Eisai has filed 30% 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). For example, eribulin (Halaven®), for breast cancer has been filed for registration (registered in five high burden countries in scope, including Myanmar and Morocco).

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

Has access strategies for the healthcare practitioner-administered product in scope of this analysis. Eisai has average performance in this area. The company pro-
vided examples of access strategies which consider affordability in both an UMIC and a LMIC for the only product assessed. It makes efforts to reach additional patients using equitable pricing strategies. For example, in India, for eribulin (Halaven®), for breast cancer, the company applies intra-country pricing strategy through the patient assistant programme "Hope to Her" where the co-payment is set at several tiers in accordance with the income level and health insurance availability of the patients, ranging from the full price to free of charge depending on the condition, while strengthening the health system via healthcare practitioner trainings. The company is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for its self-administered products for some countries in scope for this analysis. Eisai performs average in this area. The company provides examples of access strategies which consider affordability in both UMICs and LMICs for two of the three products assessed. It makes efforts to reach additional patients through equitable pricing strategies. For example, in Philippines, for the donepezil (Aricept®), a medicine for Alzheimer, the company participates in tenders, offers discount to senior citizens and has a patient assistance programme in place to increase affordability and access for patients. The company is able to provide evidence of how patient reach has been increased through the approaches used.

Two manufacturing capacity building initiative included for evaluation. Eisai performs below average in this area. The company submitted four initiatives, of which two met all criteria for inclusion. The initiatives, which included technology transfers of diethylcarbamazine (DEC) for the treatment of lymphatic filariasis in India and of cancer medicine eribulin (Halaven®), lenvenitib (Lenvima®) and antiepileptic drugs rufinamide (Inovelon®) and perampanel (Fycompa®) in Brazil and Mexico, did not meet all Good Practice Standards as Eisai did not sufficiently demonstrate that outcomes are measured.

One supply chain capacity building initiative included for evaluation. Eisai performs below average in this area. The company submitted the maximum of five initiatives, of which one met all criteria for inclusion but not all Good Practice Standards. Eisai participates in the NTD Supply Chain Forum, improving adequate supply of donated DEC tablets for the treatment of lymphatic filariasis to the WHO and the countries’ Mass Drug Administration programmes. Eisai does not sufficiently demonstrate how the initiative aims for sustainability or that it is measuring outcomes.

Four health system strengthening initiatives included for evaluation. Eisai performs below average in this area. The company submitted the maximum of five initiatives, of which four met all criteria for inclusion i.e., they address local needs; have local partners; mitigate risk of conflict of interest; are guided by clear goals and objectives and (plan to) measure outcomes. For example, since 2013 Eisai supports an educational mycetoma awareness programme in Sudan, which focuses on the importance of early diagnosis. Nearly 1500 people living in rural areas participated in the awareness activities and patients who are diagnosed as mycetoma received treatments and surgeries. None of the initiatives met all Good Practice Standards, as Eisai does not sufficiently demonstrate in what ways the initiatives aim for sustainability or integration in the local health system.

Has not engaged in the development and implementation of inclusive business models. Compared to peers, Eisai 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.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Eisai performs well in this area, taking multiple steps to ensure the continuous supply of its medicine in countries in scope of the Index. Like other companies, Eisai works together with distribution partner DKSH to improve wider location access and product tracking information in South East Asia. For the distribution of DEC for the treatment of lymphatic filariasis, Eisai uses the NTDeliver system, sharing information with WHO and other pharmaceutical companies as well as the global health organisations which are taking important roles for the delivery to the community.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope in less than 10 days. Eisai has a policy for reporting SF medicines to national health authorities and WHO within 24 hours to 7 days. It distinguishes reporting time frames for cases which only require visual inspection to be confirmed based on the Risk Evaluation Committee.

Donates in response to an expressed need, but does not monitor delivery to end user. Eisai reports that it ensures ad hoc donations are carried out in response to an expressed need. However, it does not monitor the delivery until the end user as the monitoring system differs for each subsidiary company. For example, it donated medicines to Indonesia in 2016 in response to an earthquake and tsunami.

Publicly commits to achieving elimination, eradication or control goals in its structured donation programme for NTDs. One structured donation programme for NTDs was included for analysis where elimination, eradication or control goals are possible. Eisai publicly commits itself to eliminating lymphatic filariasis by donating diethylcarbamazine citrate (DEC) in 24 countries in scope of the Index since 2013.

§ 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.