Eisai Co. Ltd.

RANK | SCORE
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8 | ▲ 2.48
11 (2016)

**PERFORMANCE**

Rises 3 places to 8th, taking a place amongst the top ten companies of the Index. Eisai demonstrates particular strength in R&D, engaging in partnerships to develop a comparatively high number of projects that address R&D priorities, and in Donations.

**Management:** Falls 4 places to 12th lacking board-level responsibility for access and a clear stakeholder engagement process to incorporate local perspectives.

**Compliance:** Holds 3rd place, extending ethical standards to third parties, and providing non-sales based incentives for sales agents.

**R&D:** Rises 2 places to 6th, with a clear strategy for engaging in R&D to meet public health needs and 17 projects targeting priority R&D gaps.

**Pricing:** Holds 14th place. Below average performance in both registration and pricing with weak outward-facing commitments.

**Patents:** Falls 2 places to 11th, showing strong performance in IP-sharing but peers have broader geographic commitments not to enforce patents.

**Capacity:** Rises 3 places to 11th. Average performance with initiatives meeting most good practices standards but none meeting all.

**Donations:** Holds at 4th place. Maintains strong performance in donations with single strong programme committed to eliminate lymphatic filariasis.

**OPORTUNITIES**

**Expand process to establish access plans for R&D projects during development.** Eisai can improve its process to develop access plans by expanding this process to all projects for diseases in scope and consider the unique requirements needed for each project. It can also establish a firmer timeline for establishing access plans by Phase II of clinical development. This includes developing access plans for projects such as lenvatinib (Lenvima®), an oral medicine which was approved after the period of analysis for the treatment of liver cancer.

**Expand registration for epilepsy medicines.** Expand access by filing more epilepsy products for registration in countries in scope. Eisai’s products for epilepsy, perampanel (Fycompa®), rufinamide (Inovelon) and zonisamide (Zonegran®), have been filed for registration in three, zero, and one countries, respectively, out of 11 possible priority countries. Additional priority countries for registration can include, Dem. Rep. Congo, Ethiopia, Mozambique, Nigeria, Pakistan, Tanzania and Uganda.

**Expand access via voluntary licensing.** Eisai can consider terms for voluntary licences of its patented anti-epileptic perampanel (Fycompa®) and any future anti-epileptic medicines. While Fycompa® (perampanel) is not yet first-line or on the 2017 WHO Model List of Essential Medicines (WHO EML), the company is expanding its indications, including for partial onset seizures in children as young as four.

**CHANGE SINCE 2016**

- Established a process to develop access provisions, including equitable pricing strategies and patent waivers, for projects targeting neglected tropical diseases in countries in scope.
- Extended partnerships with Charles River Laboratories and the Broad Institute to continue developing projects in collaboration that target diseases in scope including malaria.
- Joined Access Accelerated with its Remember I Love You initiative in China. It has also committed to measure impact and share results publicly via Access Observatory.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Has publicly committed to the UN Global Compact since 2017.
**PIPELINE** for diseases and countries in scope

Mid-sized pipeline: 41 R&D projects for diseases in scope (40 medicines; 1 therapeutic vaccine).

**Clinical candidates:** 28, including eritoran for the treatment of influenza and two Phase II candidates for the treatment of Chagas disease and mycetoma.

**Regulatory approvals:** 1, perampanel (Fycompa®) for the treatment of partial-onset seizures.

**R&D focus:** non-communicable diseases (cancer and epilepsy), communicable diseases (malaria) and neglected tropical diseases (e.g., mycetoma).

**Access provisions:** for 15 projects, most commonly applied through access-oriented partnerships.

**Projects in the pipeline: 41***

![Bar chart showing projects in the pipeline by category]

Most of Eisai’s projects for communicable diseases are early-stage. However eritoran, which was previously examined as a possible therapy for severe sepsis, is being studied as a potential treatment for both influenza and Ebola.

**Projects for R&D priority targets with access provisions: 13**

![Bar chart showing projects for R&D priority targets with and without access provisions]

Of Eisai’s 41 R&D projects, 15 are supported by access provisions: e.g., fosravuconazole, a Phase II candidate for the treatment of mycetoma, includes a commitment to register in countries in scope. Three of its ten late-stage projects have provisions.

**PORTFOLIO** for diseases and countries in scope

Comparatively small portfolio: 15 products for diseases in scope (all medicines).

**Portfolio focus:** non-communicable diseases (epilepsy).

**Essential medicines:** 27% of Eisai’s medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).

**First-line treatments:** 33% of Eisai’s medicines have first-line indications for diseases in scope.

**Products on the market: 15**

![Bar chart showing products on the market by category]

Eisai’s portfolio includes products such as the antiepileptic drugs eslicarbazepine acetate (Zebinix®), rufinamide (Novelon®), zonisamide (Zonegran®) and valproic acid (Val.O.K.®).

**Essential medicines with first-line indications: 3**

40% of Eisai’s medicines are listed on the WHO EML and/or as first-line treatments: e.g., diethylcarbamazine citrate (DEC), for the treatment of lymphatic filariasis, and warfarin.

**BUSINESS CONTEXT**

- **Two business units:** Pharmaceuticals and other businesses. Its pharmaceutical business has three areas: prescription pharmaceuticals, consumer healthcare and generic medicines. Its prescription pharmaceutical business has two therapeutic areas: neurology and oncology.
- **M&A news:** No mergers or acquisitions since 2016.

**Revenue by geographic region**

- **Revenue by segment (2017) - JPY**
  - Pharmaceutical Business: 553,200 MN
  - Other Business: 46,800 MN
  - Total: 600,100 MN

**Sales in countries in scope**

Statistics relate only to diseases and countries in scope.

* Figure excludes two 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.

† Data not comparable due to changes in company reporting practices.
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Has a clear process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely projects for neglected tropical diseases. In general, Eisai develops access plans for R&D projects for neglected tropical diseases in early-stage development but does not have such clear timelines for other diseases. To date, Eisai has project-specific access provisions in place for three of its late-stage R&D projects. All three are being conducted in partnership with the Drugs for Neglected Diseases initiative (DNDi). The Global Health Innovative Technology Fund (GHIT) is also involved in one of the projects.

Policy to ensure post-trial access: commits 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. The policy is aligned with the standards set in the Declaration of Helsinki. Eisai commits to registering newly approved products in all countries where clinical trials for these products have taken place.

Does not commit publicly to equitable pricing or report a commitment to file to register new products in scope. Eisai 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. Eisai 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 epilepsy, is registered in three out of 11 possible priority countries. However, it publicly shares detailed registration information for a minority of its products.
20% of products have equitable pricing strategies targeting priority countries. Eisai’s overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 20% of its products for diseases in scope. These strategies apply to an average of 14% of priority countries. All of these strategies apply inter- and intra-country pricing; these take into account an average of six and four socioeconomic factors, respectively.

Globally consistent recall guidelines for countries in scope but no processes to track products. Eisai 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.

Publicly discloses detailed information on patent statuses. Like most of its peers, Eisai 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. Eisai does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope. It publicly states it would not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

Shares many IP assets with third-party researchers. Compared to its peers, Eisai shares many IP assets with third-party researchers developing products for diseases in scope. This includes ten shared with research institutions and neglected disease drug discovery initiatives, such as the Medicines for Malaria Venture (MMV) and the TB Alliance. The assets shared include molecule libraries and performing assays for drug discovery.

Public commitment not to enforce patents in countries in scope. Eisai commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries, low-income countries and Low Human Development Countries.

Eight initiatives included for evaluation. Eisai has eight 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; Eisai submitted 22.

Strong focus on strengthening local R&D capacity and health systems. Eisai has initiatives which meet inclusion criteria in all areas of capacity building, except pharmacovigilance. Most of these initiatives are focused on R&D capacity building and health system strengthening. Most of its health system strengthening initiatives are active in East Asia.

Most initiatives meet most good practice standards. None of Eisai’s included initiatives meet all the good practice standards looked for by the Index. While most of its initiatives have good governance structures in place, the standard it most commonly falls short on is monitoring the progress and outcomes of its initiatives.

Timely approach to confirming and reporting substandard or falsified medicines. Eisai provides evidence that it systematically confirms suspected cases of substandard or falsified medicines and then reports confirmed cases to relevant authorities or WHO Rapid Alert within the period recommended by stakeholders (maximum seven days for each, confirmation and reporting).

Has policy for responding to emergencies or humanitarian crises. While Eisai did not make any ad hoc donations during the period of analysis, it has policies in place to respond directly to need. The company discloses that such ad hoc donations are aligned with international guidelines (issued by WHO). The company tracks the delivery of the product until received by end user.

One donation programme covering diseases and countries in scope. Eisai’s programme is focused on neglected tropical diseases (NTDs). The programme is carried out in partnership with WHO and has been ongoing since 2013. Its NTD programme for lymphatic filariasis supplies diethylcarbamazine citrate (DEC) in 24 countries. As of June 2017, Eisai reports that over 1.1 billion tablets have been provided through WHO’s elimination programme.

Addresses long-term access by aiming to eliminate disease. Eisai commits to long-term structured donation programmes by aiming to eliminate the diseases targeted. For example, its DEC donation programme aims to eliminate lymphatic filariasis in 24 countries. It plans to supply DEC tablets continuously after 2020, until lymphatic filariasis is completely eliminated in all endemic countries where the treatment is needed.

Continued commitment to combat NTDs
GLOBAL
One of five companies running donation programmes to eliminate or eradicate NTDs.