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.

Astellas Pharma Inc

Stock Exchange: Tokyo Stock Exchange • Ticker: 4503 • HQ: Tokyo, Japan • Employees: 16,243

PERFORMANCE IN THE 2021 INDEX

14th place. Astellas has an average performance. It shows a strong performance in its approach to compliance controls and health system strengthening, but has a small priority R&D pipeline and a few access plans. Its equitable pricing approach is average.

Governance of Access: 9th place. Astellas is a middle-performing company in this area. It has a robust set of compliance controls in place, but lacks a clear access-to-medicine strategy with measurable objectives and a business rationale.

Research & Development: 14th place. Astellas performs below average in this area. It applies a structured process to developing access plans during R&D. However, it has a small-sized priority R&D pipeline compared to peers and does not engage in R&D capacity building.

Product Delivery: 14th place. Astellas performs less well in this area. It applies access strategies to some of its products in some countries in scope and engages in multiple strong health system strengthening initiatives, but no supply chain and manufacturing capacity building initiatives were included for analysis.

OPPORTUNITIES FOR ASTELLAS

Consolidate its approach to access to medicine into an overall strategy integrated within its core business. Astellas can build an access strategy that is integrated within its corporate business strategy based on its public position on Access to Health. Such strategy should apply to all therapeutic areas in which the company is involved.

Apply newly established access planning process to all R&D projects. Astellas newly established an access planning process for all late-stage R&D projects for diseases in scope, but it has specific access plans in place for some late-stage projects. These plans are in partnerships or focus on registration. The company can expand its access plans to all late-stage R&D projects in the pipeline, such as zolbetuximab for cancer and micafungin (Micamine®) for neonatal infections and can include product delivery in low- and middle-income countries.

Strengthen post-trial access policy. Astellas can strengthen its post-trial access policy by allowing for continued affordable access to treatments for patients that take part in clinical trials following the close of these trials.

Expand access to innovative medicines for NCDs in more low- and middle-income countries. The company can increase affordability and supply through equitable pricing and/or non-exclusive voluntary licensing to products such as gilteritinib (Xospata®) for leukaemia and ipragliflozin (Suglat®) for diabetes.

CHANGE SINCE THE 2018 INDEX

• Newly demonstrates access-related incentives in place for senior level executives.
• Astellas Global Health Foundation provided support for NTDs with the END Fund in the Democratic Republic of Congo, from October 2019 to September 2020.
• Astellas Global Health Foundation provided a two-year grant to UNICEF Mothers and Babies in Good Care Initiative from December 2019.
• ACTION ON FISTULA™ supported by Astellas in 2019 increased number of programme outreach partners and exceeded targets set to 2020, performing 6,223 surgeries.
• Is creating a corporate-wide access to medicine strategy for 2021.

RANK SCORE

14 2.33
19 (2018)
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

**PIPEDLINE** for diseases and countries in scope

Astellas has a total of 24 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 6 projects. The other 18 R&D projects target other diseases in scope. Projects targeting priority diseases include schistosomiasis and Chagas disease. Of note is the paediatric formulation (children aged < 6 years) of praziquantel (Phase III). Of projects targeting other diseases in scope, the focus is on oncology (14 projects). 9 R&D projects are in late-stage development that target either a priority disease (2) or address a public health need in LMICs (7). Evidence of access planning was in place for 33% of these projects: 1 targeting a priority disease and 2 addressing a public health need in LMICs.

**PORTFOLIO** as selected for analysis by the Index

Astellas has 8 medicines in scope, 7 of which are on patent. 38% of these medicines (3) are on WHO’s EML. The off-patent medicine targets oncology. The on-patent medicines mainly target oncology (3). In addition, one product targets diabetes, one targets diarrhoeal diseases and one is an antifungal medicine. Access strategies were analysed for all 7 products on Astellas’ portfolio – nationally procured HCP-administered (3) and self-administered products (4).

Sales in countries in scope

The Astellas products are sold in 49 out of 106 countries in scope. Astellas has sales offices in 14 countries and sells via suppliers in 35 additional countries.

Sales by geographic region

**breakdown of projects**

- Communicable
- Neglected tropical
- Maternal and neonatal
- Non-communicable
- Multiple categories

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</table>

Breakdown of projects

- Paediatric formulation (children aged < 6 years) of praziquantel for treatment of schistosomiasis.
- Targets established R&D priorities
- Addresses needs of LMICs
- Other projects in scope

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<th>Projects on the market</th>
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</table>

**8 products as selected for analysis by the Index**

- Communicable
- Neglected tropical
- Maternal and neonatal
- Non-communicable
- Multiple categories

**Breakdown of products**

- Medicines on patent
- Medicines off patent
- Vaccines
- Diagnostics
- Other

- WHO EML
- Non-WHO EML
- WHO EDL

<table>
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</table>

- #projects in the discovery phases and/or other drug development phases were not included in this breakdown.

- *50 diseases and 271 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.

- †Product 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.
Astellas Pharma Inc

**GOVERNANCE OF ACCESS**

Does not have a clear access-to-medicine strategy with measurable objectives. Unlike most of its peers, Astellas does not have a clear strategy integrated within its overall corporate strategy. It has a general commitment to improve access to medicine, embedded within its public position on Access to Health. The highest responsibility for access lies indirectly with the board, with the Corporate Social Responsibility committee overseeing social activities, including access.

Provides evidence of financial access-related incentives at the executive level. Although Astellas does not have an access-to-medicine strategy, it incentivises some senior executives to perform on certain access-related factors with financial rewards. The CEO also has access-related incentives linked to its remuneration plan. Astellas does not, however, have such incentives in place for in-country or regional managers.

Publicly discloses outcomes of a subset of its access-to-medicine activities. Astellas performs well in transparency of access activities. It publicly discloses commitments, including contributing to the achievement of SDG3, its measurable goals, objectives, and targets for improving access to medicine in countries in scope. It shares outcomes of a subset of its access activities, for example its ACTION ON FISTULA™ initiative.

Has an average performance in responsible promotional practices. Astellas' sales agents are not solely incentivised on sales volume targets. The company, however, sets sales incentives at the individual level for agents. Astellas 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.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Astellas performs strongly here, demonstrating all components looked for by the Index: Fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure compliance with company standards by third parties.

Publicly supports the Doha Declaration on TRIPS and Public Health. Astellas publicly shares support of the Doha Declaration on TRIPS and Public Health with regard to the Least Developed Countries. It expresses reservations on the use of compulsory licensing and states that it does not believe IP protection is a primary factor in limiting access to health. It does not have a policy to dissent from industry association positions.

**RESEARCH & DEVELOPMENT**

Access planning processes encompass all projects in pipeline. Astellas has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope and includes both its in-house and collaborative R&D projects.

A small-sized priority R&D pipeline compared to peers, with access plans in place for 50% of the late-stage candidates. Astellas has six projects, including two late-stage candidates in its pipeline that target a priority product gap. The company focuses on various priority areas, including schistosomiasis and Chagas disease. Of Astellas’s two late-stage candidates targeting a priority product gap, there is evidence of an access plan for one. This plan is in partnership with the Pediatric Praziquantel Consortium, which includes the registration and access and delivery of paediatric praziquantel.

Some projects address a public health need in LMICs*, with 29% of these projects covered by access plans. In this analysis, Astellas has seven 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 have clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer. Astellas provides evidence of access plans for two of these projects. These plans focus on registration in LMICs.

Public policy to ensure post-trial access; commits itself to registering trialled products. Astellas has a public policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial participants, including participants with a life-threatening condition, but does not consider affordability for the wider population in the country where the trial took place.

No R&D capacity building initiatives included for evaluation. Astellas performs poorly in this area. The company submitted two R&D capacity building initiatives, but none met all criteria for inclusion.

**PRODUCT DELIVERY**

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

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

Does not report newly shared IP assets with third-party researchers beyond existing agreements. Astellas reported current agreements with product development partnerships such as the Medicines for Malaria Venture (MMV) and TB Alliance. During the period of analysis, beyond the 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-assent or licensing arrangements. Astellas does not engage in voluntary licensing nor has it issued non-assent declarations 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. Astellas has filed 17% 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).

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

Has access strategies for the majority of health-care-practitioner-administered products in scope of this analysis. Astellas performs below average in this area compared to other companies. The company provides examples of access strategies which consider affordability countries of all assessed income levels (UMIC, LIC, HIC) for one out of the three products assessed. It makes efforts to reach additional patients using equitable pricing strategies. 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.** Astellas has an average performance in this area compared to other companies. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for one of the four products assessed. It makes efforts to reach additional patients through the use of equitable pricing strategies. Astellas is able to provide evidence of how patient reach has been increased through the approaches used.

**No manufacturing capacity building initiatives included for evaluation.** Astellas performs poorly in this area. The company submitted two initiatives aimed at building manufacturing capacity, but none met all criteria for inclusion.

**No supply chain capacity building initiatives included for evaluation.** Astellas performs poorly in this area. The company submitted one initiative aimed at building supply chain capacity, which did not meet all criteria for inclusion.

**Four health system strengthening initiatives meet all Good Practice Standards.** Astellas performs above average in this area. The company submitted the maximum of five initiatives, of which four were included for analysis and met all Good Practice Standards: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a clear governance structure in place and aim for sustainability/integration in the local health system. Examples include:
- **UNICEF Mothers and Babies in Good Care Initiative in the Dominican Republic,** which started in 2019.
- **ACTION ON FISTULA™,** improving care for women with obstetric fistula in Kenya. Since its inception in 2014, more than 6,000 women have been treated through the initiative.

**Has not engaged in the development and implementation of inclusive business models.** Compared to its peers, Astellas 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 some mechanisms in place to ensure continuous supply in countries in scope of the Index.** Astellas shows average performance in this area, disclosing some strategies to ensure the continuous supply in countries in the scope of the Index. Astellas has safety stock regulations in place but did not report on policies to mitigate API shortages.

**Has a policy for reporting falsified medicines in countries in scope in less than 10 days.** Astellas has a policy for reporting falsified medicines within 10 days, to national health authorities and WHO Rapid Alert, but applies a separate process to substandard medicines. It can distinguish time frames for reporting for cases which only require visual inspection by experts to be confirmed and are not contingent upon laboratory analysis.

**Donates in response to an expressed need and monitors delivery.** Astellas donates medicines in response to an expressed need and monitors the delivery. Further details are provided under basis of confidentiality.

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