

RANK	SCORE
16	2.46
14 (2021)*	

Astellas Pharma Inc

Stock exchange: TSE • Ticker: 4503 • HQ: Tokyo, Japan • Employees: 14,522

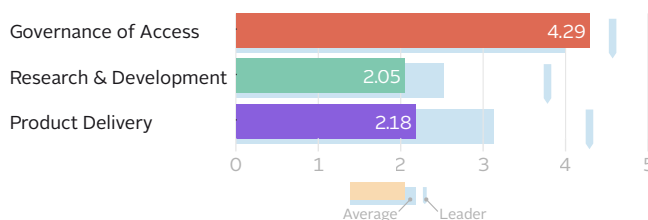
PERFORMANCE IN THE 2022 INDEX

16th place. Astellas performs below average, with a weak performance in Product Delivery, where it has a comparatively poor performance for its equitable access strategies. However, it has strengthened its R&D access planning processes.

Governance of Access: 8th place. Astellas performs well in this area. It has an access-to-medicine strategy that is integrated within the overall corporate strategy and a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index, but the responsibility of its access-to-medicine strategy lies indirectly with the board.

Research & Development: 13th place. Astellas has a below average performance in this area. It has a structured access planning process in place and applies this to all late-stage pipeline candidates. However, it has a small-sized priority R&D pipeline compared to peers and does not engage in R&D capacity building.

How score was achieved



Product Delivery: 16th place. Astellas performs below average in this area. It applies access strategies for two of its products in some countries in scope of the Index. The company newly engages in a high-quality supply chain capacity building initiative but lacks engagement in other areas such as manufacturing capacity building and inclusive business models.

OPPORTUNITIES FOR ASTELLAS

Establish direct board-level responsibility for access to medicine. Astellas has an access-to-medicine strategy. The Sustainability Advisory Panel, responsible for this strategy, reports to the CEO. Instead, the CEO can become a member of the Sustainability Advisory Panel, putting the responsibility for the access-to-medicine strategy at the board level.

Expand the geographic coverage of access plans to include more lower-middle and low-income countries. Astellas has access plans in place for all late-stage candidates. For example, it has access plans in place for zolbetuximab (IMAB362), indicated for oesophageal cancer, in six countries in scope of the Index. These are all upper-middle income countries. Astellas can increase the number of countries in scope of the Index included in R&D access plans and specifically focus on low- and lower-middle income countries with the highest burden of disease, such as Mongolia, Malawi and Zimbabwe.

Expand access to innovative medicines for non-communicable diseases. The company can increase affordability and supply through equitable access strategies and/or non-exclusive voluntary licensing to products such as gilteritinib (Xospata®) for leukaemia and ipragliflozin (Suglat®) for diabetes. These products can further be filed for registration in countries within the scope of the Index, especially where the burden of disease is the highest, such as Ethiopia and Bolivia for gilteritinib and Guyana, Sri Lanka and Suriname for ipragliflozin.

CHANGES SINCE THE 2021 INDEX

- Launched Corporate Strategic Plan in 2021 with Access to Health, including the implementation of its access-to-medicine strategy, as part of its sustainability strategic goal.
- The Astellas Global Health Foundation awarded a three-year grant to the Academic Model Providing Access to Healthcare (AMPATH) for a programme that will provide 400,000 people in Kenya with access to mental health programmes.

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.
*In the 2021 Index, dense ranking was used. In the 2022 Index, standard

competitive ranking is used. Therefore, a direct comparison with Astellas' previous rank is not possible.

SALES AND OPERATIONS

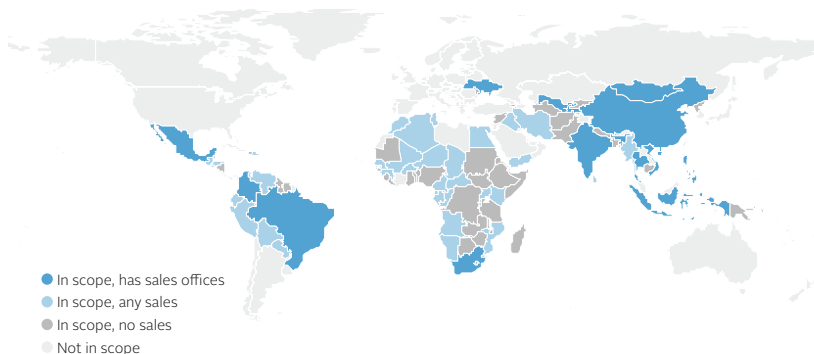
Business segments: Pharmaceutical
Therapeutic areas: Immunology, oncology and urology.
Product categories: Innovative medicines
M&A news: Astellas acquired its own shares and cancelled its treasury stock in March 2022 for JPY 29.4 billion.

Astellas' products are sold in 49 out of 108 countries in scope of the Index. Astellas has sales offices in 14 countries, and sells via suppliers and/or pooled procurement in an additional 35 countries.

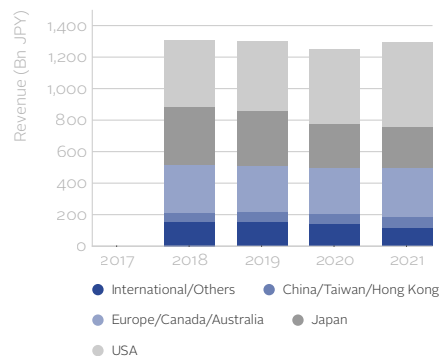
Revenue by segment (2021) – in JPY

Pharmaceutical	1,323.00 bn
Total	1,323.00 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

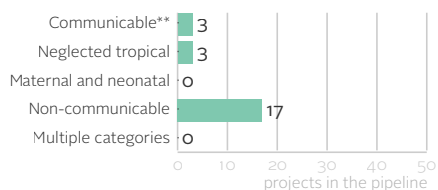
PIPELINE for diseases in scope

Astellas has a total of 23 R&D projects in scope, with six projects targeting a priority disease. The other 17 R&D projects target other diseases in scope. Projects targeting priority diseases include schistosomiasis, Chagas disease and leishmaniasis. Of projects targeting other diseases in scope, the focus is oncology (14 projects). Four R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (3).^{*} Evidence of access planning was in place for 100% of these projects.

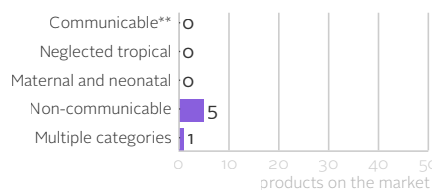
PORTFOLIO as selected for analysis by the Index

Astellas has six medicines in scope, four of which are on patent. 50% of these medicines (3) are on the WHO EML. The off-patent medicines target cancer (1) and HIV/AIDS (1). The on-patent medicines target cancer (3) and diabetes mellitus (1).

23 projects in the pipeline



6 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	4	1	0	0	1	0	0	6
Addresses needs of LMICs [*]			1	1	1	1	0	4
Other projects in scope			9	2	1	1	0	13

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	1	3			4
off patent	2	0			2
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.

Astellas Pharma Inc

GOVERNANCE OF ACCESS

RANK 8

SCORE 4.29

Has an access-to-medicine strategy with measurable objectives, integrated with the overall corporate strategy. Astellas performs strongly. It has an access strategy integrated across the company business as one of its strategic goals in its Corporate Strategic Plan. The strategy covers all therapeutic areas in which the company is involved. The highest responsibility for access lies indirectly with the board, with the Sustainability Advisory Panel overseeing social activities, including access.

Provides evidence of financial access-related incentives at the executive level. Astellas performs well. 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.

Publicly discloses outcomes of its access-to-medicine activities. Astellas performs strongly in transparency of access activities. It publicly discloses commitments on improving social sustainability, measurable goals, objectives, and targets for improving access to medicine in countries in scope of the Index, towards reduc-

ing premature deaths from non-communicable diseases by 2030. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities, including its response to COVID-19, in a centralised manner within its Access Accelerated initiative Year 4 Report.

Performs above average 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 of the Index (e.g., payments for attending events or promotional activities) unless required by local regulations, but it has a policy and guidance limiting such transfers at the global level, including in countries in scope of the Index.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Astellas performs strongly, demonstrating evidence of 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. 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. Astellas publicly shares support of the Doha Declaration on TRIPS and Public Health with regard to the Least Developed Countries. However, 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. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Astellas, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 13

SCORE 2.05

Access planning processes encompass all projects in the 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 (both in-house and collaborative) for diseases in scope of the Index.

A small-sized priority R&D pipeline compared to its peers. Astellas has six projects, including one late-stage candidate in its pipeline that targets a priority product gap. The company focuses on various priority areas, including schistosomiasis, Chagas disease and leishmaniasis. Astellas has an access plan in place for its late-stage candidate targeting a priority product gap. This plan is for the development of paediatric praziquan-

tel in partnership with the Pediatric Praziquantel Consortium.

Some projects address a public health need in LMICs,* with 100% (3/3) of late-stage candidates covered by access plans. In this analysis, Astellas has three 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 of the Index and/or are first-in-class molecules. Most target cancer. Astellas provides evidence of access plans for all three late-stage candidates.

These plans focus mainly on registration preparation in countries in scope.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Astellas does not disclose disaggregated R&D investment data to global health organisations.

No R&D capacity building initiatives included for evaluation. There is no evidence — in the public domain or disclosed to the Index — of R&D capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Astellas' performance is below average in this area.

PRODUCT DELIVERY

RANK 16

SCORE 2.18

Publicly commits not to enforce patents in countries in scope. Astellas publicly pledges to neither file for nor enforce patents in Least Developed Countries and LICs.

Publicly discloses 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. Astellas discloses patent information such as filing date, grant number, grant date and jurisdiction.

Is an average-performing company in terms of sharing intellectual property (IP) assets with

third-party researchers. Astellas 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

*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.

current Index cycle and meet all inclusion criteria for evaluation.

No use of licensing agreements. Astellas 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.

Filed to register new products in two countries in scope on average. Astellas did not disclose evidence of filing for registration any of its new products in any of the top ten high burden countries. Among old products, its most widely filed is enzalutamide (Xtandi™), for prostate cancer, filed in 40 countries in scope of the Index. The product reaching most LICs is micafungin (Mycamine®), used in HIV/AIDS complications, filed in six of the 27 LICs within scope of the Index.

Astellas is not eligible for assessment of supra-nationally procured products.

Has access strategies for some of the health-care-practitioner-administered products in scope of this analysis. Astellas performs below average in this area. For one of the two products assessed, the company provides evidence of pricing strategies considering some affordability factors for all assessed income levels (UMIC, LMIC, LIC). For example, Astellas applies a pricing strategy that considers relevant payers' ability to pay for micafungin (Mycamine®) in a UMIC. Patient reach is available for one product only in a UMIC.

Has access strategies for some of its self-administered products for some countries in scope for this analysis. Astellas performs below average in this area. For one of the three products assessed, the company provides examples of access strategies which consider affordability factors in countries of all assessed income levels (UMIC, LMIC, LIC). For example, Astellas applies a pricing strategy that considers relevant payers' ability to pay for enzalutamide (Xtandi™) in

the UMIC example provided. Evidence of patient reach is available for two products in UMICs.

No manufacturing capacity building initiatives included for analysis. There is no evidence — in the public domain or disclosed to the Index — of manufacturing capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Astellas' performance is below average in this area.

The one supply chain capacity building initiative included for analysis meets all Good Practice Standards. Astellas' 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. The Astellas Global Health Foundation partners with Academic Model Providing Access to Healthcare (AMPATH) to build ancillary support services including pharmaceutical supply chains, electronic health records and medical supplies to deliver mental health services in Kenya. This initiative meets all GPS.

One of the four health systems strengthening initiatives included meets all Good Practice Standards. Astellas' performance is below average in this area. The number of initiatives meeting all inclusion criteria is average but fewer initiatives meet all GPS than what is average for this indicator. The Astellas Global Health Foundation awarded a grant to the END Fund which works to deliver neglected tropical disease (NTD) treatments through mass drug administration mechanisms designed to control and eliminate NTDs in the Democratic Republic of Congo. This initiative meets all GPS.

Has no inclusive business models that meet all inclusion criteria. There is no evidence that Astellas has engaged in the piloting or scale-up of any inclusive business models that aim to meet the access needs of populations at the base of the income pyramid (including other underserved

populations) in LMICs. Astellas performs below average in this area.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Although there is no evidence of technology transfer initiatives that meet inclusion criteria for evaluation, Astellas does have a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, has a dual active pharmaceutical ingredient sourcing strategy for some products and is involved in supply chain capacity building initiatives. The company manages a buffer stock of relevant products in countries with Astellas warehouses and otherwise works to ensure that third parties have relevant stocks.

Has a policy for reporting substandard and falsified medicines in countries in scope of the Index in less than ten days. Astellas has a policy for reporting falsified medicines within ten days to national health authorities and the WHO, but applies a separate process to substandard medicines. It provides evidence of shortened 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 expressed need and monitors delivery. Astellas 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.

Has no long-term donation programmes for neglected tropical diseases (NTDs) or malaria that are eligible for analysis under this indicator. Astellas is not engaged in any structured donation programmes for NTDs or malaria where elimination, eradication or control goals are possible and that are eligible for analysis under this indicator.