

RANK	SCORE
19 [▲]	1.46
20 (2016)	

Astellas Pharma Inc.

Stock Exchange: Tokyo Stock Exchange • Ticker: 4503 • HQ: Tokyo, Japan • Employees: 17,202

PERFORMANCE

Rises 1 place to 19th. Although it has made notable improvements, such as joining the TB Alliance, Astellas placed comparatively poorly in every Technical Area.

Management: Falls 2 places to 20th. While some activities are guided by access-related goals, the company continues to lack an overall access-to-medicine strategy. Newly joined Access Accelerated.

Compliance: Rises 5 places to 12th. One of only two companies who report having all components of an internal control framework looked for by the Index.

R&D: Rises 6 places to 11th, with strengthened R&D commitments, and a higher proportion of projects carried out in collaboration.

Pricing: Holds 19th position for its continued lack of equitable pricing strategies for any of its marketed products for priority countries.

Patents: Falls 1 place to 14th, despite new engagement with Pat-INFORMED. It is affected negatively by a lack of transparency in remaining areas.

Capacity: Falls 7 places to 17th, for failing to demonstrate initiatives which meet all good practice standards looked for by the Index.

Donations: Rises 3 places to 16th. Remains in last quartile. Does not have any structured donation programmes in place, nor does it disclose evidence of *ad hoc* donations.

OPPORTUNITIES

Develop a process to establish access plans for R&D projects during development.

Astellas lacks a clear process for establishing access plans for R&D projects during development, instead it considers access on an *ad hoc* basis. It can improve in this area by publicly committing to develop access plans for R&D projects for diseases in scope with a clear timeline. It could consider the unique requirements for each of these projects. This includes developing access plans for projects such as its Phase III clinical candidate, gilteritinib, a potential oral treatment for leukaemia.

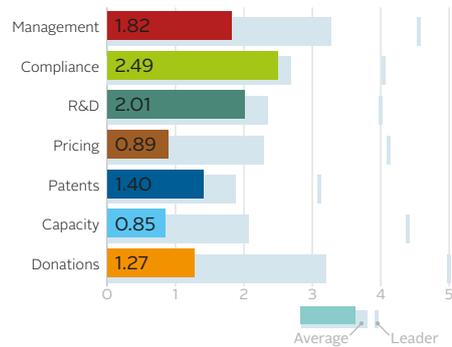
Develop access plans for key cancer products. Leuprorelin acetate (Eligard®) is a patented, first-line treatment on the 2017 WHO Model List of Essential Medicines (WHO EML) for the management of advanced prostate cancer. There is currently no evidence of any access plans for this product. The company could consider the application of, for example, equitable pricing strategies to support accessibility of this product.

Establish an overarching access strategy. Astellas can consolidate its access approaches into an overall strategy and clearly align it with its corporate strategy. The company could take this as an opportunity to incorporate its position on access to health into concrete objectives to improve access to medicine in low- and middle-income countries, and to expand access planning across their pipeline.

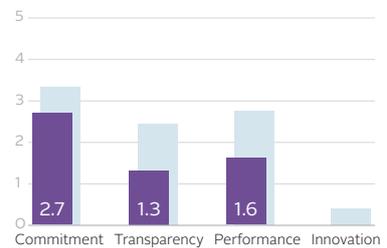
Strengthen processes to minimise the risk of non-compliance. Astellas can establish formal processes to ensure third-party compliance with the company's standards of anti-corruption and ethical marketing. Astellas can also provide non-sales based incentives for sales agents. Removing the emphasis on sales targets is recognised as a mechanism for reducing the impact of unethical marketing on, for example, rational prescribing.

Establish a clear and public post-trial access policy. Astellas' approach to post-trial access is broadly defined and carried out on a case-by-case basis. By developing a clear stance and protocol on post-trial access, and committing to register all new products in the countries where clinical trials for these products have taken place, it can expand access to medicine and ensure post-trial access for clinical trial participants.

Performance by technical area



Performance by strategic pillar



CHANGE SINCE 2016

- Joined Access Accelerated with its Action on Fistula programme in Kenya. 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.
- Joined the Drugs for Neglected Diseases initiative's (DNDi) NTD Drug Discovery Booster to accelerate the development of early-stage projects for Chagas disease and leishmaniasis through compound library sharing.
- Joined the UN Shot@Life campaign in 2017 by supporting the measles campaign in Latin America.

PIPELINE for diseases and countries in scope

Comparatively small pipeline: 25 R&D projects (all medicines) for diseases in scope.

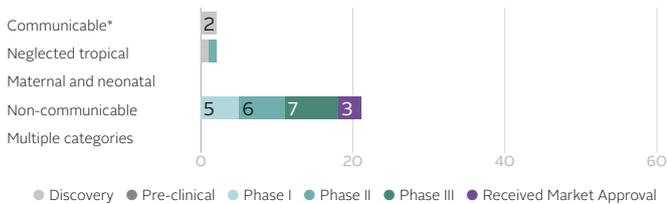
Clinical candidates: 19, including praziquantel for the treatment of schistosomiasis in children and ipragliflozin for type I diabetes mellitus.

Regulatory approvals: 3, including extended-release quetiapine for the treatment of bipolar affective disorder.

R&D focus: non-communicable diseases (cancer and diabetes mellitus).

Access provisions: for 4 projects, most commonly applied through access-oriented partnerships.

Projects in the pipeline: 25



Astellas developed new paediatric praziquantel formulations for the Paediatric Praziquantel Consortium. This project aims to provide access to schistosomiasis treatments for children, more than 30 years after praziquantel entered the market.

Projects for R&D priority targets with access provisions: 4



Of Astellas' 25 R&D projects, four are supported by access provisions: e.g., paediatric praziquantel has plans for not-for-profit pricing and non-exclusive voluntary licensing. One of its 17 late-stage projects has provisions.

PORTFOLIO for diseases and countries in scope

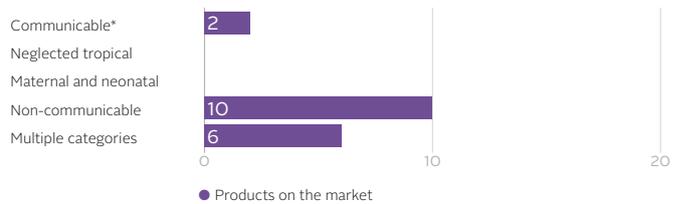
Comparatively small portfolio: 18 products (all medicines) for diseases in scope.

Portfolio focus: non-communicable diseases (hypertensive heart disease and epilepsy) and communicable diseases (viral hepatitis C).

Essential medicines: 44% of Astellas' medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).

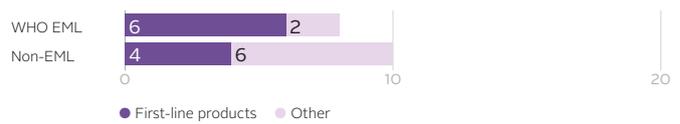
First-line treatments: 56% of Astellas' medicines have first-line indications for diseases in scope.

Products on the market: 18



Astellas's portfolio includes products such as micafungin (Mycamine®) for the treatment of invasive fungal infections, including those secondary to HIV/AIDS, in patients of all ages.

Essential medicines with first-line indications: 6



67% of Astellas' medicines are listed on the WHO EML and/or as first-line treatments: e.g., leuprorelin acetate (Eligard®) and the antibiotics doxycycline (Unidox®) and amoxicillin/clavulanate (Flemoclav®).

BUSINESS CONTEXT

One business unit: Pharmaceuticals, with five main therapeutic areas (urology, oncology, immunology, nephrology, and neuroscience).

M&A news: 2016 acquisition of Ganymed Pharmaceuticals, specialising in oncology. 2017 acquisition Ogeda SA, a clinical-stage drug discovery company for women's health. 2018 acquisition of Universal Cells, with a pipeline focused on stem cell technology; acquisition of

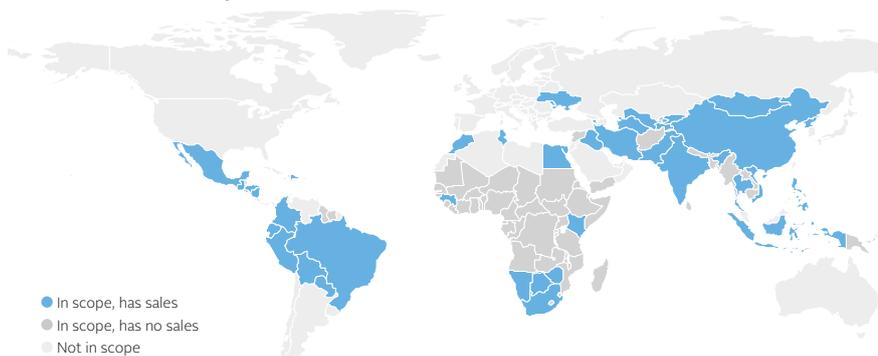
Mitobridge, a start-up focused on discovering and developing small-molecule therapeutics that enhance mitochondrial function.

Presence in emerging markets: In 2018, Astellas has sales in 39 countries in scope; six less than in the 2016 Index.

Sales by segment (2017) - JPY

Pharmaceuticals business	1,311,665 MN
Total	1,311,665 MN

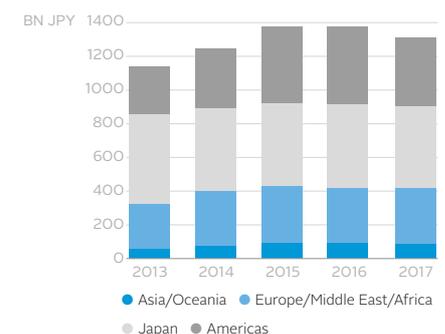
Sales in countries in scope



Statistics relate only to diseases and countries in scope.

* Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
** See Appendix IV for definition.

Sales by geographic region



Astellas Pharma Inc.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 20 SCORE 1.82

Lacks overarching access-to-medicine strategy; responsibility for access lies at the executive level. Astellas does not have an overarching access-to-medicine strategy, but shows evidence of some activities guided by access-related goals. For example, it aims to discover, develop and provide innovative medicines for patients, supported by its goal to improve access to health. The highest level of responsibility for access sits with its Corporate Social Responsibility Committee, which reports to a board-level committee.

No evidence of access-related incentives for employees. Astellas does not disclose details of how it incentivises employees (financially and non-financially) to perform on access-related issues. It is one of only two companies which do not demonstrate evidence of such incentives.

One of 16 companies working on impact measurement. Astellas measures and monitors progress and outcomes of access-to-medicine activities, for example its Action on Fistula initiative. It also publicly reports on its commitments and performance information. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Discloses who it engages with, incorporates local perspectives into strategies. Astellas publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, or its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 12 SCORE 2.49

Does not report processes for ensuring third-party compliance with standards. Astellas has a code of conduct relating to ethical marketing and anti-corruption, that is aligned with WHO Guidelines. It provides compliance training for employees. The company performs relatively poorly when it comes to enforcing compliance measures and non-sales incentives. It does not provide evidence of having formal processes in place to ensure compliance with standards by third parties. Further, expected performance for

sales agents is based solely on sales targets.

Internal control framework meets all Index criteria. Astellas has all the components looked for by the Index for an effective internal control framework to ensure compliance. Namely, it reports that it regularly conducts fraud-specific risk assessments. It also has a monitoring system in place to track compliance, it conducts audits involving both internal and external resources—which also apply to third parties. Astellas also demonstrates evidence of having procedures to segregate duties, so that decisions are checked by another party.

Below average transparency regarding access-related practices. Astellas publicly discloses its policy positions on access-related topics (e.g., its policy statement on access to healthcare, which includes its position on intellectual property). The company does not disclose political contributions in countries in scope. It publicly discloses its memberships of relevant organisations but does not disclose whether it provides financial support. It publicly discloses its position on Patient Organisation Engagement. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 11 SCORE 2.01
PROJECTS: 25 IN CLINICAL DEVELOPMENT: 19

Publicly commits to R&D to meet public health needs. Astellas has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on public health targets. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Astellas has one of the smallest pipelines in the Index with 25 projects. For diseases in scope where priorities exist, Astellas is active in four projects; all four target priority R&D gaps.

Access provisions in place for 6% (1/17) of late-stage candidates. Astellas does not have a clear process in place to develop access plans during R&D. Instead, it considers access on a case-by-case basis. To date, Astellas has project-specific access provisions in place for one of its late-stage R&D projects. This project is being conducted in partnership as part of the Pediatric Praziquantel Consortium.

No policy for post-trial access. Astellas does not have a policy for ensuring post-trial access to treatments for clinical trial participants. Instead, it takes a case-by-case approach to post-trial access, mostly for participants on clinical trials for cancer products. Astellas does not disclose a commitment to registering newly approved products in all countries where clinical trials for these products have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 19 SCORE 0.89

PRODUCTS: 18

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 0

Does not publicly commit to equitable pricing or report a commitment to file to register new products in scope. Astellas 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.

No new products in scope filed for registration in the majority of priority countries. Astellas 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 HIV/AIDS and neonatal sepsis and infections, is registered in one out of 21 possible priority countries. It also does not publicly share the registration status for any of its products.

No products have equitable pricing strategies targeting priority countries. Astellas' overall performance is below average compared to peers in equitable pricing. The company does not demonstrate evidence of having equitable pricing strategies in place.

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

PATENTS & LICENSING

RANK 14 SCORE 1.40

Publicly discloses detailed information on patent statuses. Like most of its peers, Astellas

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. Astellas does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Shares some IP assets with 3rd-party researchers. Compared to its peers, Astellas shares some IP assets with third-party researchers developing products for diseases in scope. This includes four shared with neglected disease drug discovery initiatives, such as the Medicines for Malaria Venture (MMV) and the TB Alliance. The assets shared include molecule libraries and research data.

Public commitment not to enforce patents in countries in scope. Astellas 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 and low-income countries.

CAPACITY BUILDING

RANK 17 SCORE 0.85

Three initiatives included for evaluation.

Astellas has three 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; Astellas submitted 17.

Focused on enhancing local manufacturing.

Astellas has initiatives which meet inclusion criteria in two areas of capacity building: manufacturing and health system strengthening. Most of its initiatives are in manufacturing, but it performs best in health system strengthening with its Action on Fistula initiative in Kenya.

One initiative meets most good practice standards. None of Astellas's included initiatives meet all the good practice standards looked for by the Index. Its health system strengthening initiative meets most standards, but falls short on ensuring good governance structures are in place.

Does not provide evidence of reporting substandard or falsified medicines to relevant authorities. Astellas has procedures for the prevention and handling of counterfeit medicines. However, it does not provide evidence that it systematically reports cases of substandard or falsified medicines to relevant authorities and/or WHO Rapid Alert.

PRODUCT DONATIONS

RANK 16 SCORE 1.27

STRUCTURED DONATION PROGRAMMES: 0

Has a policy for responding to emergencies or humanitarian crises. While Astellas did not make such donations during the period of analysis, it has policies in place to respond directly to need, which are aligned with international guidelines. The company tracks the delivery of the product until received by end user.

No donation programmes covering diseases and countries in scope. Astellas does not have any structured donations programmes that were active during the period of analysis in any countries in scope.

BEST PRACTICES

Three companies incorporate framework of strict guidelines to reduce non-compliance.

GLOBAL

Astellas, GSK and Novartis stand out for their comprehensive internal control frameworks.