7th place. AstraZeneca takes a place among the top ten companies of the Index. It shows a strong performance in governance and compliance and health system strengthening, but has a small-sized priority R&D pipeline with few access plans.

Governance of Access: 3rd place. AstraZeneca shows a strong performance in this area with an access-to-medicine strategy that is integrated within the overall corporate strategy and a robust set of compliance controls in place.

Research & Development: 6th place. AstraZeneca performs well in this area with a structured process to develop access plans during R&D. It commits itself to registering trialled products but has a small-sized priority R&D pipeline with a few late-stage projects covered by access plans.

Product Delivery: 6th place. AstraZeneca performs well in this area, with access strategies in place for certain products and markets. It has shared unpublished preclinical data for drug discovery and engages in multiple strong health system strengthening initiatives, but did not demonstrate evidence of inclusive business models with expectations to reach financial sustainability, as looked for by the Index.

OPPORTUNITIES FOR ASTRAZENECA

Bring equitable pricing initiatives to scale. In the frame of the Healthy Heart Africa (HHA) initiative, the company identifies different levels of ability to pay and affordability in markets. In Kenya it offers reduced prices for products in its HHA portfolio to public market and faith-based sector utilising input from local stakeholders and NGO partners. Additional price reductions were implemented for patients in informal settlements where communities are typically very low income/migrant populations who generally pay out of pocket for healthcare. AstraZeneca can consider expanding the pricing model of Healthy Heart Africa to other countries in Sub-Saharan Africa not part of the programme yet and it can be scaled to more therapeutic areas such as diabetes and oncology.

Apply access planning process to all R&D projects. AstraZeneca has a structured process in place to develop access plans during R&D for all diseases in scope starting in Phase II of clinical development. It has specific access plans for some late-stage projects. These plans focus on registration. The company can expand its access plans to all late-stage R&D projects in the pipeline and can include more elements of product delivery, such as equitable pricing and licensing, in its plans. It can for example develop an access plan for suvoravorxumab for S. aureus and expand the access plan for nirsevimab for RSV.

Increase access to diabetes portfolio. By increasing affordability and supply through equitable pricing and/or non-exclusive voluntary licensing, AstraZeneca can expand access to diabetes medicines in its portfolio such as dapagliflozin (Farxiga/Forxiga®), dapagliflozin/metformin (Xigduo®), saxagliptin/dapagliflozin (Qtern®) and saxagliptin/dapagliflozin/metformin (Qternmet XR®). The company has some access strategies in UMICs and LMICs and it can expand further to countries with high burden of diabetes such as Mexico, Myanmar, Sri Lanka and Lesotho.

CHANGE SINCE THE 2018 INDEX

• Launched an interactive tool, the Transparency Map, to share global data on sustainability topics, including access to healthcare.
• Expanded Healthy Lung initiative beyond Asia to eight countries in scope of the Index, including Mexico, Colombia and Egypt.
• Expanded Healthy Heart Africa to two new countries, Ghana and Uganda.
• Engaged in new ways of sharing IP, a public access Next Generation Sequencing Microbial Surveillance Toolbox for viral and bacterial genomes and an Open Innovation Program with unpublished, preclinical data sets shared ad hoc with research organisations.
• Started Project Heart Beats in December 2019, a collaborative initiative for acute coronary syndrome (ACS) in India.
• Expanded Young Health programme from five to nine countries in scope of the Index, with plans to develop initiatives in three more countries in partnership with UNICEF.
• New collaboration with Vietnam National Cancer Hospital to enhance cancer research capabilities.
• Launched Brazil Health Innovation Hub (InovaHC) in September 2019.
• Launched the Take CaRe of Me pilot in four Index countries in 2020, to improve end-to-end management of type 2 diabetes.
• 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

Business segments: Pharmaceuticals
Therapeutic areas: Oncology; Cardiovascular, Renal & Metabolism; Respiratory & Immunology
Product categories: Innovative medicines
M&A news: Announced in December 2020 to acquire Alexion for USD 39 billion.

AstraZeneca’s products are sold in 48 out of 106 countries in scope. AstraZeneca has sales offices in 19 countries and sells via suppliers in 29 additional countries.

Total revenue in USD
Pharmaceuticals 24.384 bn
Total Revenue by Segment 24.384 bn

Sales in countries in scope

Sales and operations

Product sales in USD

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope
AstraZeneca has a total of 79 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 4 projects. Remarkably, however, AstraZeneca has the third largest pipeline. The other 75 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on COVID-19 (3 projects). Of the projects targeting other diseases in scope, the focus is on oncology (42).

46 R&D projects are in late-stage development that target either a priority disease (4) or address a public health need in LMICs (42). Evidence of access planning was in place for 28% of these projects: 1 targeting a priority disease and 12 addressing a public health need in LMICs.

PORTFOLIO as selected for analysis by the Index
AstraZeneca has 34 medicines in scope, 26 of which are on patent, and 1 vaccine. 29% of these medicines and vaccines (10) are on WHO’s EML. The off-patent medicines target non-communicable diseases (NCDs) such as cardiovascular diseases (4) and pulmonary diseases (4). The on-patient medicines target NCDs such as diabetes (8), pulmonary diseases (6) and oncology (9). The company’s preventative vaccine targets the influenza virus.

Access strategies were analysed for 9 products on AstraZeneca’s portfolio – nationally procured HCP-administered (4) and self-administered products (5).

35 products as selected for analysis by the Index*

Breakdown of projects*

Breakdown of products

Nirsevimab a monoclonal antibody in collaboration with Sanofi, aims to provide prophylaxis for respiratory syncytial virus in infants with a single injection.

*50 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.
AstraZeneca plc

GOVERNANCE OF ACCESS
RANK 3
SCORE 4.32

Has an access-to-medicine strategy with measurable objectives, integrated within the overall corporate strategy. AstraZeneca performs strongly. It has an access to healthcare strategy integrated within its core business, beyond philanthropy. The strategy covers all therapeutic areas the company is involved in. The highest responsibility for access lies directly with the board, with a Board of Directors member responsible for sustainability, including access to healthcare.

Provides evidence of financial and non-financial access-related incentives at the executive level. AstraZeneca performs strongly. It incentives select senior executives and in-country managers to perform on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives linked to its ESG performance, including targets on access initiatives such as Healthy Heart Africa, for tackling hypertension and cardiovascular disease.

Publicly discloses outcomes of its access-to-medicine activities. AstraZeneca performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access to healthcare activities, including tackling hypertension in Africa with Healthy Heart Africa, for example in its Sustainability Data Summary.

Performs above average in responsible promotional practices. AstraZeneca’s sales agents are not solely incentivised on sales volume targets. More details on how the company addresses sales incentives for agents are unavailable. AstraZeneca 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, but has policies on third party engagement, which can limit compensation and govern contributions and other items to HCPs under certain circumstances.

PUBLIC COMMITMENT TO ACCESS

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

Publicly supports the Doha Declaration on TRIPS and Public Health. AstraZeneca publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on its provisions, namely on the use of compulsory licensing. There is no evidence of a policy, but the company states that it can dissent from industry association positions on these.

RESEARCH & DEVELOPMENT
RANK 6
SCORE 2.78

Access planning processes encompass all projects in pipeline. AstraZeneca 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. In general, AstraZeneca begins developing access plans for R&D projects in Phase II clinical development. The process is for both its in-house and its collaborative R&D projects.

Many projects address a public health need in LMICs*, with 29% of the late-stage projects covered by access plans. In this analysis, AstraZeneca has 42 late-stage R&D projects in its pipeline 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. AstraZeneca provides evidence of access plans for 12 of these projects. These access plans prioritise registration in countries in scope.

Policy to ensure post-trial access; commits itself to registering trialled products. AstraZeneca has a policy for ensuring post-trial access to treatments for clinical trial participants. However, this policy is not publicly available. It covers a subset of clinical trial participants who have a serious condition and no alternative treatments are available. Once a product is approved, AstraZeneca commits itself to registering it in all countries where clinical trials for the product 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 meet all Good Practice Standards. AstraZeneca performs above average in this area. The company submitted four initiatives aimed at building R&D capacity in Index countries, of which three were included for analysis and two met all Good Practice Standards. These initiatives include:

- AstraZeneca partnership with Hospital das Clinicas of the University of São Paulo Medical School to create InovaHC, a Health Innovation Hub within the Hospital das Clinicas.
- Advancing oncology research capability and capacity in Vietnam. For one initiative, the Wusi International Life Science Innovation Campus, AstraZeneca did not sufficiently demonstrate that the goals are aligned with its partner institutes.

PRODUCT DELIVERY
RANK 6
SCORE 3.29

Public commitment not to enforce patents in countries in scope. AstraZeneca publicly pledges to neither file for nor enforce patents. This commitment applies to any least developed countries and low-income countries and in a subset of lower-middle income countries and upper-middle income countries.

Publicly discloses detailed information on patent status. AstraZeneca publicly discloses on its website information relating to the status of its patents for almost all products in scope. This includes: brand name, nature of the patent, patent number, expiry date and jurisdiction.

Shares some IP assets with third-party researchers. AstraZeneca has newly shared some IP assets with third-party researchers developing products for diseases in scope. This includes many IP assets shared via AstraZeneca’s Open Innovation Program and with the research institution University Medical Center (UMC) Utrecht. Assets shared include unpublished preclinical stage data for drug discovery.†

† Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initiatives align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.
No use of non-assert or licensing arrangements. AstraZeneca does not engage in voluntary licensing nor has it issued any non-assert 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. AstraZeneca has filed 20% 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, durvalumab (Imfinzi®), indicated for bladder and lung cancer, has been filed for registration/registered in nine high burden countries in scope, including Colombia and Peru.

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

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. AstraZeneca has average performance in this area compare to other companies. The company provides examples of access strategies which consider affordability for LMICs and LMICs for three out of the four products assessed. It falls short to provide example for a LMC and a LDC for the other product. It makes efforts to reach additional patients using equitable pricing strategies. For example, in Mexico, for durvalumab (Imfinzi®), a treatment for bladder and lung cancer, the company applies equitable pricing strategy to list the product on the national list of essential medicine and has a patient assistance programme to increase access, 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 of this analysis. AstraZeneca has average performance in this area compare 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 five products assessed. For the other products, it falls short to provide example in LMICs and/or LMCs. It makes efforts to reach additional patients through the use of equitable pricing strategies. For example, in Kenya, for felodipine (Plendil®), the company offers a lower price in the public sector and faith based facilities as part of the healthy heart Africa programme. Additional reductions are implemented for patients in informal settlements where communities are typically low income/migrant populations who generally pay out of pocket for healthcare. The products reached nearly 70,000 patients.

One manufacturing capacity building initiative included for evaluation. AstraZeneca performs below average in this area. The company submitted two initiatives, of which one met all criteria for inclusion. The initiative, which ended in 2019, aimed to expand access to innovative medicines through training on quality standards and the transfer of pharmaceutical production technology in Iran. It did not meet all Good Practice Standards as it did not demonstrate how it is guided by clear goals and objectives or that outcomes are being measured.

No supply chain capacity building initiatives included for evaluation. AstraZeneca performs poorly in this area. The company submitted two initiatives aimed at building supply chain capacity, but none were included for analysis as they did not meet all criteria for inclusion.

Five health system strengthening initiatives meet all Good Practice Standards. AstraZeneca is one of the leaders in this area. The company submitted the maximum of five initiatives, which were all 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: - The Healthy Lung initiative, improving access to and quality of respiratory disease care. Since its launch in Asia, there has been a reported 27% uptake increase in respiratory screenings. - Healthy Heart Africa (HHA), tackling hypertension and the increasing burden of Cardiovascular Disease across Africa. To date, HHA has conducted approximately 14.9 million blood pressure screenings, trained over 7,200 health-care workers and supported more than 800 healthcare facilities to provide hypertension services.

Has not engaged in the development and implementation of inclusive business models as looked for by the Index during the period of analysis. Although it performs well in other areas, AstraZeneca 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. Four initiatives were submitted, but did not meet the Index criteria.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. AstraZeneca performs well in this area, taking multiple steps to ensure the continuous supply of its medicine in Index countries. In LUMICs, AstraZeneca forecasts demand, while in LDCs this is done through local distributors that report to AstraZeneca’s regional commercial organisation. AstraZeneca is running an Export Simplification project in 30 countries in scope of the Index by aggregating demand of these markets onto one central distribution hub in Europe. For all markets, the company has Business Continuity Plans in place for major brands and reviews the global variability in demand and supply to ensure sufficient safety stocks. AstraZeneca did not report which products this include.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope in less than 10 days. AstraZeneca performs strongly in this area. It has a policy for reporting SF medicines to national health authorities within 5 days. It distinguishes time frames for reporting for cases which only require visual inspection to be confirmed, aiming at reporting within 3 working days when packaging is sufficient to assess the case.

Donates in response to an expressed need and monitors delivery to end user. AstraZeneca has a policy in place to ensure ad hoc donations are carried out in response to an expressed need, and it monitors the delivery until the end user. For example, it donated AMP Rapid Test SARS-COV-2 IgG/IgM to Egypt in 2020 in response to the COVID-19 pandemic.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. AstraZeneca is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. However, it is engaged in another structured donation programme: the Cambodia Breast Cancer initiative whereby it has been donating anastrozole (Arimidex®) and fulvestrant (Faslodex®) to Cambodia since 2008.