

RANK	SCORE
<b>3</b>	<b>3.93</b>
7 (2021)	

# AstraZeneca plc

Stock exchange: LSE • Ticker: AZN • HQ: Cambridge, United Kingdom • Employees: 83,100

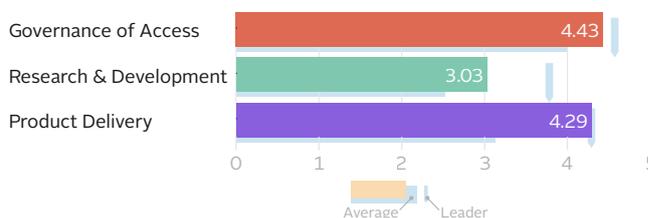
## PERFORMANCE IN THE 2022 INDEX

3<sup>rd</sup> place. AstraZeneca ranks among the top three companies in the Index. The company performs well in all three Technical Areas, particularly in its approach to patent transparency and sharing of intellectual property assets. It has strengthened its performance in R&D access planning, as well as manufacturing and supply chain capacity building.

**Governance of Access:** 2<sup>nd</sup> place. AstraZeneca has a strong performance in this area. It has an access-to-medicine strategy integrated into its overall corporate strategy and a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index. It also incentivises its senior executives, the CEO and in-country and regional managers to perform on access-to-medicine goals.

**Research & Development:** 6<sup>th</sup> place. AstraZeneca performs well in this area. It has a structured access planning process in place and applies this to nearly all late-stage candidates. Although its priority pipeline is small compared to its peers, it has the largest pipeline for non-communicable diseases of

How score was achieved



the companies. Furthermore, it performs well in R&D capacity building.

**Product Delivery:** 1<sup>st</sup> place. AstraZeneca leads in this area. In all product categories, it applies tailored access strategies across different country income classifications. It also excels in its approach to access strategies for supranationally procured products. The company has shared the highest number of intellectual property assets to third-party researchers. Furthermore, the company has piloted both new and scaled-up existing inclusive business models and it engages in many high-quality capacity building initiatives across all fields.

## OPPORTUNITIES FOR ASTRAZENECA

**Improve the quality and geographic coverage of access plans.** AstraZeneca has project-specific access plans in place for almost all late-stage R&D candidates. These plans focus mostly on registration in the emerging markets of Brazil, India and China. In its plans, the company can include more access components such as equitable pricing and licensing. Furthermore, it can expand the geographic coverage of these plans to focus more on low-income countries. For example, the access plan for nirsevimab, indicated for the prevention of respiratory syncytial virus, can be expanded to include more than five countries in scope of the Index.

**Bring equitable pricing initiatives to scale.** Through the Healthy Heart Africa (HHA) initiative, the company identifies different levels of ability to pay and affordability in markets to inform its pricing model. AstraZeneca can consider expanding the pricing model of HHA to other countries in sub-Saharan Africa that are not part of the programme yet, such as those with the highest burden of hypertensive disease, including the Central African Republic. The company can apply the HHA model to cover more therapeutic areas such as diabetes and oncology.

**Expand access to its diabetes medicine, dapagliflozin (Farxiga/Forxiga®), through non-exclusive voluntary licensing and/or equitable pricing.** The company has an access strategy for dapagliflozin across upper-middle income countries, lower-middle income countries and low-income countries, including one of the countries with the highest burden of disease for diabetes. AstraZeneca can provide evidence of implementing access strategies in other countries with high burdens of disease such as Sri Lanka, Kiribati and Micronesia for example via equitable pricing and/or non-exclusive voluntary licensing agreements.

**Expand access to cancer products such as osimertinib (Tagrisso®), through equitable pricing and/or non-exclusive voluntary licensing.** The company has equitable access strategies in place in UMICs and LMICs. The company can provide evidence of expanding access to the product in LICs and countries where the burden of the disease is highest, such as China, Armenia and Thailand.

## CHANGES SINCE THE 2021 INDEX

- Created a dedicated vaccines and immune therapies unit for COVID-19 vaccine and antibody treatments and the existing portfolio for respiratory viral disease.
- Initiated two global training programmes — Parexcel and UNIFY — to expand the pool of under-represented principal investigators and clinical research coordinators.
- Supplied more than two billion doses of COVID-19 vaccine (Vaxzevria) to LMICs at not-for-profit through private licensing agreements.
- Supplied its COVID-19 vaccine (Vaxzevria) through the COVAX facility.
- Initiated new partnerships with the UK Royal Academy of Engineering to strengthen healthcare innovation across Africa.
- Expanded the Healthy Heart Africa (HHA) programme to Senegal, Côte d'Ivoire, Rwanda and Nigeria. This initiative aims to improve access to end-to-end hypertension management and was recently expanded to more therapeutic areas such as diabetes.
- Joined the Access to Oncology Medicines (ATOM) Coalition, a new global initiative that aims to improve access to essential cancer medicines in LMICs.

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.

## SALES AND OPERATIONS

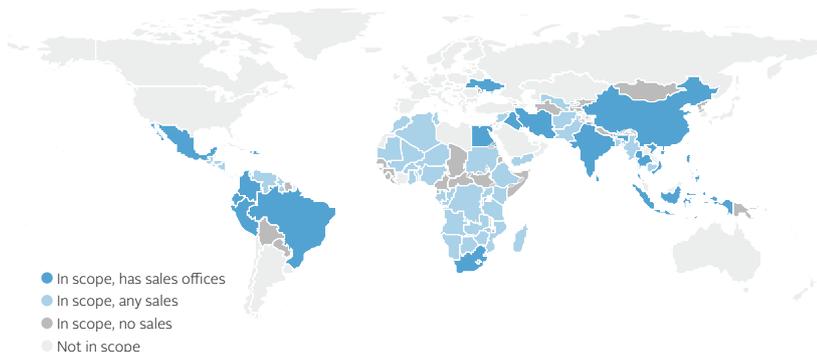
**Business segments:** Pharmaceutical  
**Therapeutic areas:** Biopharmaceuticals (including cardiovascular, immunology, metabolism, renal and respiratory), oncology and rare diseases.  
**Product categories:** Innovative medicines and vaccines.  
**M&A news:** AstraZeneca acquired Alexion Pharmaceuticals in July 2021 for USD 13.3 billion.

AstraZeneca's products are sold in 62 out of 108 countries in scope of the Index. AstraZeneca has sales offices in 19 countries, and sells via suppliers and/or pooled procurement in an additional 43 countries.

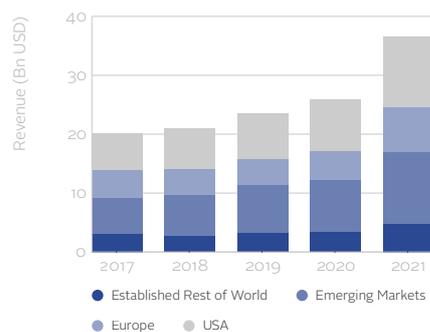
**Revenue by segment (2021) – in USD**

Pharmaceutical	37.42 bn
<b>Total</b>	<b>37.42 bn</b>

### Sales in countries in scope



### Sales by geographic region



## SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

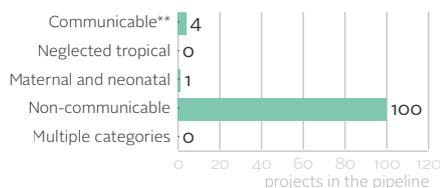
### PIPELINE for diseases in scope

AstraZeneca has a total of 105 R&D projects in scope with four of these projects targeting priority diseases. The other 101 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on COVID-19 (three projects). Of the projects targeting other diseases, the focus is on oncology (62). Twenty-five R&D projects are in late-stage development that target either a priority disease (3) or address a public health need in LMICs (22).<sup>\*</sup> Evidence of access planning was in place for 96% of these projects: three targeting a priority disease and 21 addressing a public health need in LMICs.

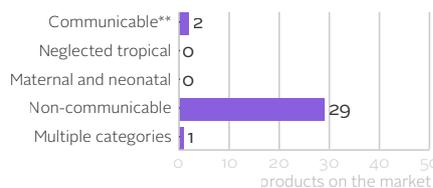
### PORTFOLIO as selected for analysis by the Index

AstraZeneca has 30 medicines in scope, 25 of which are on patent, and two vaccines. 22% of these medicines and vaccines (7) are on the WHO EML. The off-patent medicines target mainly non-communicable diseases (NCDs) such as hypertensive heart disease (2), asthma (2) and cancer (1). The on-patent medicines also mainly target NCDs, such as diabetes mellitus (8), cancer (8), and different respiratory diseases (7). In addition, the portfolio includes a COVID-19 vaccine and an influenza vaccine.

### 105 projects in the pipeline



### 32 products as selected for analysis by the Index<sup>†</sup>



### Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other <sup>***</sup>	Total
Targets established R&D priorities	0	0	0	2	0	2	0	4
Addresses needs of LMICs <sup>*</sup>			5	13	5	4	0	27
Other projects in scope			24	34	13	3	0	74

### Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	3	22			25
off patent	3	2			5
Vaccines	1	1			2
Contraceptives	0	0			0
Diagnostics			0		0
Other <sup>†</sup>				0	0

<sup>\*</sup>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.  
<sup>\*\*</sup>Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.  
<sup>\*\*\*</sup>Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).  
<sup>†</sup>Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.  
<sup>‡</sup>Other includes vector control products.

# AstraZeneca plc

## GOVERNANCE OF ACCESS

RANK 2

SCORE 4.43

**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 dedicated 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 incentivises select senior executives and in-country managers to perform on access to medicine with financial and non-financial rewards and the CEO has access-related incentives linked to its ESG performance. For example, AstraZeneca's "Contribution to society KPI" measures progress on annual and long-term targets and includes "Access to healthcare" as one of three pillars of sustainability.

### 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 2025 targets for improving access to healthcare in countries in scope. It facilitates accountability and transparency by consistently sharing the outcomes of its access to healthcare programmes, including its Healthy Heart Africa and Healthy Lung initiatives, in a centralised manner within its ESG Report.

### Performs above average in responsible promotional practices.

AstraZeneca's sales agents are not solely incentivised on sales volume targets. The company, however, does not disclose the level at which sales incentives are set. AstraZeneca 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 has policies on third party engagement, which can limit compensation and govern contributions and other items to healthcare professionals under certain circumstances.

### 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 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, including contract language and training on the AstraZeneca Code of Ethics. 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.

AstraZeneca publicly shares support of the Doha Declaration on TRIPS and Public Health, but expresses reservations on its provisions, namely on the use of compulsory licensing. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, AstraZeneca, like all other member companies in scope of the Index, is by default connected to this activity.

## RESEARCH & DEVELOPMENT

RANK 6

SCORE 3.03

### Access planning processes encompass all projects in the 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 (both in-house and collaborative) for diseases in scope of the Index. In general, AstraZeneca begins developing access plans for R&D projects in Phase II/III of clinical development.

### A small-sized priority R&D pipeline compared to its peers, with access plans in place for 100% (3/3) of the late-stage candidates analysed.

AstraZeneca has four projects, including three late-stage candidates in its pipeline, that target a priority product gap. These focus mostly on coronaviral diseases. Of AstraZeneca's three late-stage candidates targeting a priority product gap, all have evidence of access plans. These include commitments to register in countries in scope of the Index. Furthermore, the plan for the COVID-19 vaccine (Vaxzevria) includes manufacturing, procurement and distribution agreements with

CEPI and Gavi and a licensing agreement with Serum Institute of India (SII) to supply one billion doses for LMICs.

### Many projects address a public health need in LMICs,\* with 95% (21/22) of late-stage projects covered by access plans.

In this analysis, AstraZeneca has 22 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 of the Index and/or are first-in-class molecules. These projects target several diseases including cancer and kidney diseases. AstraZeneca provides evidence of access plans for 21 of these projects. These plans focus mainly on registration preparation in countries in scope of the Index.

### Publicly discloses disaggregated R&D investment data by phase of development.

However,

AstraZeneca does not disclose disaggregated R&D investment data to global health organisations.

### Three of the five R&D capacity building initiatives included meet all Good Practice Standards.

AstraZeneca's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, AstraZeneca's collaboration with the Cancer Research and Clinical Trials Centre (CRCTC) builds R&D oncology capacity in Vietnam through treatment development, medical research and continuous medical education. This initiative meets all GPS.

\*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.

## PRODUCT DELIVERY

RANK 1

SCORE 4.29

**Public commitment not to enforce patents in countries in scope.** AstraZeneca publicly pledges to neither file for nor enforce patents in a subset of Index countries. This commitment applies to 80 countries in scope of the Index, of which all Least Developed Countries and LICs in scope, and a subset of LMICs and UMICs. In sub-Saharan Africa, all countries are part of the commitment beside Ghana, Kenya, Nigeria and South Africa. The policy covers all products in the scope of the Index and publicly discloses the list of countries.

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

**Performs above average in terms of sharing intellectual property (IP) assets with third-party researchers.** AstraZeneca engaged in 14 new IP-sharing agreements with third-party research institutions or drug discovery initiatives established during the current period of analysis that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

**Uses licensing agreements to enable generic supply.** AstraZeneca has private, voluntary licensing agreements in place for one product, its COVID-19 vaccine (Vaxzevria). Details of these agreements are not publicly available.

**Filed to register new products in ten countries in scope on average.** AstraZeneca filed two out of nine newer products in a subset of high burden disease countries. Among new products, its most widely filed is acalabrutinib (Calquence®), indicated for leukaemia, filed in 23 countries in scope of the Index, including Ecuador and Ukraine among the top ten high burden disease. Durvalumab (Imfinzi®) has been registered in 22 countries within the scope of the Index, five of which are high-burden countries (China, Republic of Moldova, Thailand, Ukraine and Vietnam). None of its products assessed are filed for registration in any LIC.

**Has access strategies for its supranationally procured product in scope of this analysis.** AstraZeneca leads in securing access for its product procured supranationally. For the product assessed in this category, the COVID-19 vaccine (Vaxzevria), it demonstrates access strategies both in countries eligible for supply from such procurers and in countries that procured the vaccine outside the supranational agreement. The company provides evidence of an additional access strategy to increase patient reach. Evidence of patient reach is available.

**Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis.** AstraZeneca performs above average in this area compared to other companies. For all five products assessed, the company provides examples of access strategies which consider affordability in UMICs and LMICs. It makes efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay and additional financing mechanisms. For example, AstraZeneca set a direct distribution system for healthcare centres in Uganda to ensure supply stability and price reduction of goserelin acetate (Zoladex®). Evidence of an increase in patient reach in Uganda is provided.

**Has access strategies for the majority of its self-administered products for countries in scope of this analysis.** AstraZeneca has an above average performance in this area. For three of the five products assessed, the company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC). It makes efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay and patient assistance programmes. For example, AstraZeneca has secured public reimbursement of osimertinib (Tagrisso®) in Egypt, where patient reach has increased.

**All five manufacturing capacity building initiatives included for analysis meet all Good Practice Standards.** AstraZeneca is a leader in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, AstraZeneca has conducted a full technology transfer to Siam Biosciences for its COVID-19 vaccine (Vaxzevria).

**All five supply chain capacity building initiatives included for analysis meet all Good Practice Standards.** AstraZeneca is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, in the United for Health Partnership with the Egyptian Government, AstraZeneca provides support and education to governmental pharmacists through a structured programme that involves supply chain management training and scholarships.

**Four of the five health systems strengthening initiatives included meet all Good Practice Standards.** AstraZeneca's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, AstraZeneca's new initiative PUMUA aims to build capacity for asthma care in Africa through infra-

structure, awareness programmes and training of stakeholders along the patient journey.

**Has engaged in scaling up two and piloting two inclusive business models.** AstraZeneca performs above average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. As part of the One Young World Lead2030 programme, AstraZeneca has awarded funding to BIVE, a model that facilitates access to timely, high quality and affordable private health-care services for more than 19,000 Colombian people, the majority being low-income coffee farmers.

**Performs above average in terms of ensuring continuous supply of medicines in LMICs.** AstraZeneca is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient (API) suppliers/produces in-house APIs, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

**Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days.** AstraZeneca has a policy for reporting SF medicines to national health authorities within five days. It provides evidence of shortened time frames for reporting cases which only require visual inspection to be confirmed and aims to report within three working days when packaging is sufficient to assess the case.

**Donates in response to expressed need and monitors delivery.** AstraZeneca 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 until they reach the patient.

**Has no long-term donation programmes for neglected tropical diseases or malaria that are eligible for analysis under this indicator.** However, AstraZeneca 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.