AstraZeneca plc

Stock Exchange: London Stock Exchange • Ticker: AZN • HQ: Cambridge, UK • Employees: 61,100

**PERFORMANCE**

Falls 2 places to 9th. AstraZeneca maintains a strong performance in 2018, notably in the application of advanced methods for determining prices for different population subsets. It falls two places in part due to a lack of impact measurements on its access approaches.

**Management:** Falls 6 places to 11th. It maintains strong governance and strategy, but fails to emulate peers in its commitment to measure the impact of its access initiatives.

**Compliance:** Falls 3 places to 13th. Reaches a settlement under the Foreign Corrupt Practices Act concerning improper payments to healthcare professionals in China.

**R&D:** Holds 10th place. Has the largest pipeline with a process for access-planning, but does not disclose project-specific access plans for its late-stage projects.

**Pricing:** Rises 4 places to 4th. Substantial increase in the coverage of the company’s portfolio with equitable pricing strategies.

**Patents:** Falls 4 places to 10th. Despite consistent performance in transparency, it lags behind leading performers in IP-sharing.

**Capacity:** Falls 6 places to 10th. Strong performance in health systems strengthening, but falls short on consistently monitoring progress and outcomes of initiatives.

**Donations:** Rises 4 places to 11th with the inclusion of structured donations programmes for breast cancer and cardiovascular diseases.

**OPPORTUNITIES**

**Strengthen planning for access for R&D projects.** AstraZeneca can improve its access planning process by applying it to more candidates across its entire pipeline and earlier in development (so that plans can be in place before Phase II). This can ensure more successful and rapid access.

**Expand intra-country equitable pricing approach.** The company’s Brazil Mosaic model of segmented intra-country equitable pricing is a best practice for others to follow. It is applied to products listed under the Faz Bem programme, including, for example, Candesartan (Atacand®), ticagrelor (Brilinta®) and rosuvastatin (Crestor®). AstraZeneca can consider expanding the model to other countries, with similar demographics, including China, India and Mexico.

**Expand access to key products through registration.** For example, AstraZeneca’s ticagrelor (Brilinta®) for ischaemic heart disease is an on-patent, first-line treatment product and registered in 6 out of 13 possible priority countries. Broader registration in more priority countries would help increase access to the product for more people in need, including Afghanistan, the Democratic Republic of Congo, Iran, Islamic Rep., Nepal and Pakistan.

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**CHANGE SINCE 2016**

- Implemented an intra-country tiered pricing model to evaluate the maximum population that could be reached based on cost of goods to determine if a sustainable affordability programme can be developed for particular markets.
- Expanded its Healthy Heart Africa programme beyond Kenya to include Ethiopia and Tanzania. It has also partnered with PEPFAR to integrate HIV and hypertension care in Kenya.
- Launched the Healthy Lung Asia programme in 2017 which focuses on improved awareness, prevention, and treatment of respiratory diseases in Asia.
- Published and incorporated its 5R framework (right target, patient, tissue, safety and commercial potential) for R&D into its Innovative Medicines and Early Development (IMED) Biotech Unit.
PIPELINE for diseases and countries in scope

Largest Pipeline: 218 R&D projects (all medicines) for diseases in scope. Clinical candidates: 90, including a monoclonal antibody for the treatment and prophylaxis of influenza type A and a monoclonal antibody for the prophylaxis of respiratory syncytial virus (RSV). Regulatory approvals: 7, including durvalumab (Imfinzi®) for the treatment of lung and bladder cancer. R&D focus: non-communicable diseases (cancer, diabetes mellitus and asthma).

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

Projects in the pipeline: 218*

Statistics relate only to diseases and countries in scope.

PORTFOLIO for diseases and countries in scope

Mid-sized portfolio: 44 products for diseases in scope (all medicines). Portfolio focus: non-communicable diseases (hypertensive heart disease, asthma and diabetes mellitus).

Essential medicines: 50% of AstraZeneca’s medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML). First-line treatments: 45% of AstraZeneca’s medicines have first-line indications for diseases in scope.

AstraZeneca’s portfolio includes products such as inhaled aclidinium bromide/formoterol fumarate (Duaklir®/Genuair®) and glycopyrrolate/formoterol fumarate (Bevespi Aerosphere®) for the treatment of COPD.

Of AstraZeneca’s 218 R&D projects, four are supported by access provisions. All four projects are in collaboration with DNDi, which incorporates access into partnerships. None of its 63 late-stage projects have provisions.

BUSINESS CONTEXT

One business unit: Biopharmaceuticals, with five main therapeutic areas (cardiovascular, renal and metabolism diseases; oncology; respiratory, inflammation and autoimmunity diseases; infection and vaccines; and neuroscience). M&A news: 2016 sale of small-molecule anti-infectives business and late-stage pipeline to Pfizer; divestment of its global anaesthetics portfolio outside the US to Aspen Global Incorporated (AGI). 2017 acquisition of Takeda’s respiratory business.

Presence in emerging markets: In 2018, AstraZeneca reports sales in 40 countries in scope; one less than in the 2016 Index. It reports that around 30% of its sales in 2017 came from emerging markets.

57% of AstraZeneca’s medicines are listed on the WHO EML and/or as first-line treatments: e.g., zolmitriptan (Zomig®), budesonide/formoterol (Symbicort®) and isosorbide mononitrate (Imdur®).

Revenue by segment (2017) - USD

Biopharmaceuticals Business  20,152 MN
Total  20,152 MN

Revenue by geographic region

Sales in countries in scope

*Figure excludes 4 projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

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

*** See Appendix IV for definition.
AstraZeneca plc

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT
RANK 11  SCORE 3.26

Has a strong access-to-medicine strategy with board-level responsibility. AstraZeneca is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals and aligns with its corporate strategies. The company aims to take a commercially sustainable approach to access. The strategy centres around expanding disease prevention, awareness, treatment and capacity building in areas with limited infrastructure. The highest level of responsibility for access sits with a board member.

Non-financial access-related incentives in place for employees. AstraZeneca has non-financial incentives in place to motivate employees to perform on access-related issues. These incentives are centred around providing a good working environment and delivering on performance.

Measures and monitors outcomes and progress; not impact. AstraZeneca measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, targets and performance information. For example, the company reports a target of reaching 25 million patients by 2025 through a variety of Health Systems Development programmes. However, it does not report measuring the impact of its initiatives.

Some transparency about stakeholder engagement. AstraZeneca publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with. Neither does it report on how it incorporates local stakeholder perspectives into the development of its access strategies. However, AstraZeneca publicly shares a specific policy for ensuring responsible engagement — in order to strengthen transparency and multi-stakeholder engagement (including with patient groups and other healthcare organisations aimed at improving patients’ lives) and comply with local regulations.

MARKET INFLUENCE & COMPLIANCE
RANK 13  SCORE 2.36

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. AstraZeneca has a code of conduct and policy relating to ethical marketing and anti-corruption, and provides compliance training for employees on an annual basis. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents’ rewards are not solely based on sales targets. Instead, it rewards other qualities, such as accountability and integrity in the workplace.

Internal control framework meets some Index criteria. AstraZeneca’s internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place, and it reports that it regularly conducts fraud-specific risk assessments. It also has a monitoring system for compliance. However, it did not demonstrate evidence of procedures to segregate duties, so that decisions are checked by another party.

Above average transparency regarding access-related practices. AstraZeneca publicly discloses its policy positions on access-related topics (e.g., its positions on intellectual property). It discloses political contributions in countries in scope. AstraZeneca publicly discloses its membership of relevant institutions to access, but does not disclose whether it provides financial support. The company also discloses its policies for responsible engagement through its Global Policy on Ethical Interactions. During the period of analysis, AstraZeneca did not publicly disclose its policy approach to payments made to healthcare professionals in countries in scope. Following the period of analysis, the company shared plans to disclose such payments, including countries in North Africa and Latin America.

RESEARCH & DEVELOPMENT
RANK 10  SCORE 2.05

PROJECTS: 218 IN CLINICAL DEVELOPMENT: 90

Commits to R&D to meet public health needs. AstraZeneca has made a specific commitment to R&D for diseases and countries in scope, but it is not publicly available. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale through its “S”R framework (to help ensure the right target, patient, tissue, safety and commercial potential). Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. AstraZeneca has the largest pipeline in the Index with 218 projects. For diseases in scope where priorities exist, AstraZeneca is active in eight projects; six of these target priority R&D gaps.

No access provisions; process in place for setting them. AstraZeneca has a general process in place to develop access plans during R&D. It is unclear whether this applies to all or some of the company’s R&D projects. Mainly, AstraZeneca develops access plans for R&D projects in Phase III of clinical development. To date, AstraZeneca does not have any project-specific access provisions in place for its late-stage R&D projects.

Policy to ensure post-trial access; commits to registering trialed products. AstraZeneca has a policy for ensuring post-trial access to treatments for clinical trial participants and has provided a detailed example of this policy in action in countries in scope. However, this policy is not publicly available. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, AstraZeneca commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION
RANK 4  SCORE 2.93

PRODUCTS: 44

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 26

Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope. AstraZeneca does not commit to filing its newest products for registration in countries in scope within one year of first market approval. However, it does publicly commit to implement inter-country equitable pricing strategies for a majority of its products for diseases in scope, including for future products. Its public commitments also apply to intra-country equitable pricing strategies.

Some new products in scope filed for registration in the majority of priority countries. AstraZeneca has filed 10% 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). However, it does not publicly share the registration status for any of its products.

60% of products have equitable pricing strategies targeting priority countries. AstraZeneca’s overall performance is average compared to
peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 60% of its products for diseases in scope. These strategies apply to an average of 19% of priority countries. Almost all of these strategies apply inter-country pricing; these take into account an average of three socioeconomic factors.

Has both globally consistent recall guidelines for countries in scope and processes to track products. AstraZeneca has guidelines for drug recalls that apply to all countries in scope. It has processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

Publicly discloses some information on patent statuses. AstraZeneca publicly self-discloses information relating to the status of its patents for products in scope, this includes: name of the medicine, nature of the patent, expiry date and jurisdiction. However, it does not include patent numbers.

No use of non-exclusive or licensing arrangements. AstraZeneca does not engage in voluntary licensing nor has it issued non-exclusive declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Does not report newly sharing IP assets with 3rd-party researchers beyond existing agreements. AstraZeneca reported existing agreements with product development partnerships such as the Drugs for Neglected Diseases initiative (DNDi). During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

Public commitment not to enforce patents in countries in scope. AstraZeneca commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies to most Least Developed Countries, low-income countries, and in a subset of lower-middle income countries and upper-middle income countries.

Nine initiatives included for evaluation. AstraZeneca has nine 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; AstraZeneca submitted the maximum.

Performs strongest in strengthening health systems. AstraZeneca has initiatives which meet inclusion criteria in three areas of capacity building: manufacturing, pharmacovigilance and health system strengthening. It performs strongest in health system strengthening, with programmes focused on non-communicable disease prevention and treatment.

Five initiatives meet all applicable good practice standards:
- Healthy Heart Africa (pharmacovigilance)
- Young Health Programme
- Healthy Lung Asia
- Phakamisa South Africa
- Healthy Heart Africa (health system strengthening)

AstraZeneca’s remaining included initiatives typically aim for sustainability and long-term improvements, but most commonly fall short on monitoring progress and outcomes.

Does not provide evidence of reporting substandard or falsified medicines within the recommended time frame. AstraZeneca has a policy for reporting cases of substandard or falsified medicines to local regulatory authorities. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.*

Product donations

Responds to emergencies, humanitarian crises and tracks delivery. AstraZeneca donated medicines to local regulatory authorities. For example, during the period of analysis, it donated the antibiotic meropenem (Merrem®) in response to paediatrician requests for a sepsis programme in Cambodia. The company discloses that such ad hoc donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with Americares and Direct Relief International to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Two donation programmes covering diseases and countries in scope. AstraZeneca’s programmes are focused on non-communicable diseases, namely cancer and cardiovascular disease. Both programmes are carried out in partnership with its long-term partners Americares and the Red Cross. Its breast cancer programme supplies anastrozole (Arimidex®) in Cambodia and has been ongoing since 2008. During the period of analysis, AstraZeneca reports that this has reached almost 800 patients.

No transition plans in place. AstraZeneca does not provide evidence that it considers longer-term access to donated products, for example, once a programme ends, or through transition planning.

* Defined as a recommended time frame through consultation with stakeholders during Index methodology development.

INNOVATIVE PRACTICES

New pilot programme considers more than just health

KENYA
Dunga Beach Biogas Project, that aims to reduce air pollution and improve respiratory health, also contributes to local economic and employment development.