AstraZeneca plc

Stock Exchange: XLON • Ticker: AZN • HQ: London, UK • Employees: 61,500

PERFORMANCE

AstraZeneca is one of the biggest risers in 2016, climbing eight positions into the top 10. It improves in multiple areas, including pricing, where it has a new affordability-based pricing strategy. It has extensively expanded and updated its access strategy, which it operationalises, e.g., through its Healthy Heart Africa programme. It takes a transparent approach to IP management, disclosing how and where it will enforce patents or issue licences, and disclosing patent statuses. It has several best and innovative practices: in pricing, patents and capacity building. In R&D, its relevant pipeline has grown, but with comparatively little movement and less collaborative R&D based on pro-access terms. It has breached civil laws and codes of conduct multiple times. It does not have a structured donation programme.

CHANGE SINCE 2014

- Launched its Healthy Heart Africa programme, which aims to reach 10 million hypertensive patients across Africa by 2025.
- Has more products with equitable pricing strategies than in 2014.
- Improves its accountability for its sales agents’ pricing practices, by providing pricing guidelines for all local sales agents.
- Provides volume-of-sales data for the first time.
- Still has no targets for registering new products in low- and middle-income countries.
- Is developing more products: including medicines for lower respiratory infections, asthma, chronic obstructive pulmonary disease and diabetes.
- Publishes the status of patents it holds in countries in scope.
- Publicly commits to not file for patents in a range of low-income countries, lower-middle income countries and upper-middle income countries.
- Improves in building manufacturing capacity, where it undertakes a relatively large number of capacity building activities (mainly in India and China).

OPPORTUNITIES

Monitor impact of Healthy Heart Africa programme and expand to other regions.
AstraZeneca can evaluate the impact of its hypertension-focused Healthy Heart Africa programme in Kenya and consider expanding it to other non-communicable diseases (NCDs) and countries/regions. It can use the lessons learned from this programme to update its overall access strategy.

Broaden IP access strategy to include NCDs.
AstraZeneca can expand the reach of programmes such as Healthy Heart Africa by licensing products for NCDs. For Healthy Heart Africa, this could include ticagrelor (Brilinta®), a first-line option for preventing atherothrombotic events. This could make AstraZeneca the first company to license a product targeting an NCD. A first step would be to explicitly include NCD products in its commitment to licensing.

Further expand partnerships with academia for R&D capacity building.
AstraZeneca can build on its growing focus on academic partnerships in the UK to include public research organisations in low- and middle-income countries. Such partnerships can be important for addressing local research capacity gaps.

Expand new equitable pricing strategy to more products and countries.
AstraZeneca can apply its new affordability-based pricing policy to more key products: such as its selective beta-2-adrenoreceptor agonists, used in the management of asthma and chronic obstructive pulmonary disease (COPD). These belong to a therapeutic class listed on the WHO Model Essential Medicines List (EML). The company can also extend its policy to more priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products): e.g., its equitable pricing strategy for budesonide (Pulmicort®) can be expanded to India, Bangladesh, Nigeria, and China.

Plan for access during R&D.
AstraZeneca can consider appropriate access provisions for all of its relevant products while they are still in the pipeline. This is important for key late-stage products, whether developed in-house or via research partnerships.
SALES AND OPERATIONS

AstraZeneca has one business segment, biopharmaceuticals, with activities in five main areas: respiratory disease; inflammation and autoimmunity; infection and neurosciences; oncology; cardiovascular and metabolic diseases. At the end of 2015, the company bought Takeda’s respiratory business for USD 575 mn. AstraZeneca has sales in 67 countries in scope.

PORTFOLIO AND PIPELINE

AstraZeneca has a mid-sized portfolio of relevant products, with 41 medicines and one preventive vaccine, and a mid-sized pipeline of 16 R&D projects that address the needs of people in countries in scope.

The majority of medicines in AstraZeneca’s portfolio target NCDs, with 18 medicines for hypertensive and ischaemic heart disease. It also has several medicines for diabetes, asthma and COPD. It has gained marketing authorization from the European Medicines Agency for several products since 2014: saxagliptin/dapagliflozin (Qtern®) for type 2 diabetes, the MEDI-550 vaccine for preventing pandemic influenza, and ceftazidime/avibactam (Zavicefta®) for complicated Gram-negative bacterial infections.

The focus of its clinical pipeline reflects its on-market portfolio: targeting lower respiratory infections, asthma, COPD and diabetes. It also has discovery-stage projects targeting Chagas disease, leishmaniasis, dengue, lymphatic filariasis and onchocerciasis, which target high-priority product gaps with low commercial incentive.

AstraZeneca conducts R&D for neglected tropical diseases with partners including the Liverpool School of Tropical Medicine and University College London. The company is also part of the new NTD Drug Discovery Booster.

AstraZeneca focuses on developing innovative medicines. It is developing medicines targeting lower respiratory infections caused by Staphylococcus aureus and respiratory syncytial virus, among others.

AstraZeneca has received EU-approval for ceftazidime-avibactam (Zavicefta®), a new combination antibiotic for Gram-negative bacterial infections. Phase III trial sites were conducted in high-burden countries.
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PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

Rank 5 Score 4.0

Improvements across all areas make AstraZeneca the biggest riser. AstraZeneca is the biggest riser in this area, climbing from 14th into the top five. It has improved in all areas and has an innovative approach to stakeholder engagement integrated into its Healthy Heart Africa programme.

Access strategy aligned with corporate strategy. AstraZeneca’s access strategy focuses on product deployment, affordability and on removing healthcare barriers in low and middle-income countries. This strategy is aligned with the company’s core business strategy; access to healthcare is one of the five pillars of the company’s sustainability framework, which is in turn integrated within the corporate strategy.

Healthy Heart Africa (HHA) programme newly launched. Initially launched in Kenya, Healthy Heart Africa aims to reach 10 million hypertensive patients across Africa by 2025; by establishing new partnerships; ensuring access to affordable anti-hypertensive medicines and services; and by developing local ownership.

Mature access management structures in place. AstraZeneca is transparent about its targets and about the progress it is making toward them. The company also has a dedicated incentive structure for encouraging senior management to achieve access-related targets.

► Innovation: approach to incorporating stakeholder insights. As part of its HHA programme, AstraZeneca has established a Global Advisory Board and Steering Committee that include both local and global stakeholders. These bodies fulfil an advisory role, identifying and discussing insights gathered, with the aim of improving the programme.

MARKET INFLUENCE & COMPLIANCE

Rank 10 Score 2.2

Falls three places due to breaches of corruption laws. AstraZeneca drops from 7th to 10th position. This is due to comparatively stronger performances from peers. AstraZeneca was found in breach of civil laws and codes of conduct three times in the period of analysis.

RESEARCH & DEVELOPMENT

Rank 10 Score 2.6

Falls three places. AstraZeneca is generally less active than in 2014; its relevant pipeline has grown, but with comparatively little movement and less collaborative R&D based on pro-access terms. Its rank also reflects changes in performance among its peers.

Commitment to R&D partnerships, but no policy. AstraZeneca makes a clear commitment to making its intellectual property, compounds and expertise available for free in a sub-set of countries in scope. This includes for projects targeting NTDs, TB and malaria. However, the company has no clear policy for ensuring these features or other access-oriented terms are systematically included in its R&D collaborations.

Sharing IP via the NTD Drug Discovery Booster. AstraZeneca shares intellectual property to support the development of treatments for leishmaniasis and Chagas disease via the NTD Drug Discovery Booster. In this project, funded by the Global Health Innovative Technology Fund (GHTF) and established in 2015, six companies provide plates of compounds on a monthly basis to help the Drugs for Neglected Diseases initiative develop new leads.

Access to Medicine Index 2016

Not transparent about marketing practices in countries in scope. AstraZeneca’s ethical marketing code also applies to third parties, and the incentives it offers to sales staff are not linked to sales targets. Nevertheless, the company’s disclosure around its marketing programmes and related payments only meets minimum legal requirements.

Publishes policy positions but lacks transparency on lobbying. AstraZeneca has published its policy positions relating to compulsory licensing, intellectual property, product counterfeiting and pricing in emerging markets. It is also transparent regarding its memberships of industry associations and about the board seats it holds. However, it does not disclose financial contributions.

Enforcement processes in place, but little insight into disciplinary measures taken. The company has clearly-defined enforcement processes and disciplinary measures in place. Although it states that it has taken disciplinary action following violations of its codes of conduct governing lobbying, corruption and marketing, it provides no further details.

Solid risk-based audit system. AstraZeneca has an auditing system that uses a mixture of internal and external measures, such as the Transparency International Corruption Perception Index. The scope of each audit is based on a market-specific risk assessment. In some cases, AstraZeneca audits its third parties.

Found in breach of civil laws and codes of conduct three times. AstraZeneca was found to have breached civil laws and codes of conduct three times during the period of analysis. Among others, it agreed to pay USD 46.5 mn in US, plus interest, to resolve allegations that it underpaid rebates owed under the Medicaid Drug Rebate Program.

Bigest riser in Pricing, Manufacturing & Distribution. AstraZeneca rose 11 places from 19th in 2014 to 8th in 2016. This is mainly due to its innovative approach to equitable pricing and the implementation of this approach to products and countries in the scope of the Index.
Significant increase in products with equitable pricing. Compared to 2014, AstraZeneca has significantly increased the number of its products with equitable pricing strategies, taking affordability into account for products focused on hypertensive heart disease, ischaemic heart disease and diabetes. However, only a third (31%) of its products have pricing strategies that target some priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products).

Registration behaviour lags behind advances in pricing. AstraZeneca does not provide evidence of disease-specific registration targets. It does not publish where its products are registered or the criteria it uses to decide where and when to register its products. The company has filed to register some (40%) of its newest products in just a few (6%) priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). While some of these products were first launched more recently (between 2012 and 2014), most were launched between 2000 and 2010.

Limited brochure & packaging adaptation to facilitate products’ rational use. For its Healthy Heart Africa programme, in East African markets, AstraZeneca has developed new artwork for felodipine (Plendil®), lisinopril (Zestril®) and lisinopril/hydrochlorothiazide (Zestoretic®), packs, to distinguish the HHA products from commercial products, which are also for sale in Kenya.

Best practice: intra-country equitable pricing for ticagrelor. AstraZeneca’s intra-country equitable pricing strategy for ticagrelor (Brilinta®) takes account of multiple socio-economic factors (such as disease burden, public financing, inequality, supply chain mark-ups and patient awareness) to target specific population segments of three priority countries: India, China, and Brazil. This strategy is particularly important as ticagrelor is a first-line therapy in the prevention of atherothrombotic events, is on patent, and AstraZeneca is the only manufacturer.

Innovation: analysis of populations’ abilities to pay. AstraZeneca has conducted an in-depth analysis of the abilities of different population segments in a sub-set of countries to pay for its products. This has shaped its new pricing policy and will continue to do so in the future. AstraZeneca has also created an Affordable Centre of Excellence and trains international staff on its new affordability approach.

PATENTS & LICENSING

Rises furthest due to clear new policies. AstraZeneca is the largest riser, climbing ten places, due to a suite of new commitments and a clear public position on patent filing, patent transparency, licensing commitment and trade policy.

New public commitment not to file patents. AstraZeneca publicly commits not to file for patents in a range of low-income countries, lower-middle income countries and upper-middle income countries that together cover 70% of countries within the scope of the Index.

New commitment to licensing, with clear exceptions. Although AstraZeneca has not yet licensed a product, it has now set out the situations where it would consider doing so. Its policy excludes licences for products for non-commensurate diseases in lower-middle income countries, includes products on the WHO EML, and permits supply to Least Developed Countries, low-income countries and lower-middle income countries.

Flexible acknowledgement of Doha. AstraZeneca publicly acknowledges and endorses the Doha Declaration on the TRIPS agreement and public health. It acknowledges that countries have the right to determine what constitutes a public health emergency.

Patent status disclosure. AstraZeneca publishes the status of all patents it holds for high-need products in the high-burden countries measured by the index, including publishing the patent type.

Best practice: Clarity in approach to IP management. AstraZeneca clearly states the countries where it holds patents, where it will not file for patents, where it is prepared to license, and for which products, and gives an indication of the terms.

CAPACITY BUILDING

Active in all areas of capacity building, targets local needs. AstraZeneca has improved its performance in capacity building. It is active in all areas but demonstrates key strengths in building manufacturing capacity and capacities beyond the pharmaceutical value chain. It takes an innovative approach, and targets local needs through many activities.

Focus on Kenya for strengthening supply chains and pharmacovigilance systems. AstraZeneca focuses on Kenya, through its Healthy Heart Africa programme, to build local supply chain management and pharmacovigilance capacity. The company targets the capacity-building needs of its NGO implementing partners through training and information sharing.

Strong approach to philanthropy that meets local needs. AstraZeneca’s approach to philanthropic activities is very strong; it targets local health needs, and is aimed at long-term improvements, while monitoring and evaluating pre-defined objectives. The company’s focus areas include public health initiatives, increasing disease awareness, health-related research, and addressing unmet health needs in under-served populations.

Best practice: manufacturing capacity building partnership in China. Rather than training individual manufacturers, AstraZeneca provides funding, training and other support to Tianjin University to build local manufacturing skills gaps. Via the university, the company’s expertise can be shared more widely, to help improve manufacturing safety standards at the industry level in China.

Innovation: building capacity through Healthy Heart Africa. In 2014, AstraZeneca launched its Healthy Heart Africa programme, targeting hypertension in Kenya. The programme’s broad scope of capacity building activities is innovative, including working with the Ministry of Health to develop national treatment guidelines, mobile-based training for health-workers, and targeted supply chain management support.

Innovation: scale-up of Young Health Programme. AstraZeneca has scaled up its Young Health Programme. The programme focuses on preventing non-communicable disease among adolescents. Since 2014, it has been scaled up in India and expanded to Kenya.

PRODUCT DONATIONS

Ranks last in the index due to low product donations. AstraZeneca has dropped four positions, from 11th to 15th. The company is not active in any structured donation programmes, but is active in ad hoc donations.

Complies with external guidelines. All AstraZeneca donations are covered within the AstraZeneca Global Guidance Procedure and Guidance Community Investment. The company’s guideline aligns with WHO and PQMD guidelines.

Engages in monitoring and auditing. AstraZeneca regularly audits its NGO partners, such asAmericares, to ensure that they are compliant with its regulations to ensure products are donated appropriately and as represented. The company also requires quarterly reports from partner organisations.

Involved in humanitarian aid programmes. AstraZeneca provided ad hoc donations for humanitarian aid via its partnerAmericares, and in response to natural crises such as typhoons in the Philippines.