

Responsible Investing Perspectives

ESG Viewpoint Pharma: Access to success in the developing world

Key summary

- The rapid growth of emerging economies and the developing world presents long-term opportunities for the major pharmaceutical companies.
- The industry has thus far encountered a mixture of success and disappointment due to not fully appreciating challenges in these growing markets, especially poor access to medicines and healthcare.
- Leading companies are now implementing novel, business-focused practices with the combined goal of delivering commercial success and sustainable social development in a world where two billion people still lack access to necessary health products.
- Over ten years of engagement, we have seen broad improvements in industry practices around access to healthcare provision in the developing world. A growing number of major companies have strong programs in place, but laggards remain.

Background

Advanced economies—the U.S., Europe and Japan—have traditionally been the drivers of revenue growth and profitability for the major pharmaceutical companies. As developed economies continue to constrain or cut back on healthcare funding, however, spending in developing economies is rapidly increasing. Medium-term healthcare annual growth forecasts in developed economies are in low single digits in percentage terms. Meanwhile, in major emerging markets nations—namely Brazil, Russia, India, China, Mexico and Turkey—growth is at or close to double digits.

- Nearly a third of the global pharmaceutical market will be from outside the advanced economies by the end of 2016—double the proportion from a decade ago.¹
- Pharmaceutical spend in the developing world (major emerging markets and other lower-income countries) overtook those of the European Union's five major economies (Germany, UK, France, Italy and Spain) in the early part of this decade.²
- The developing world will be a key contributor to global pharma sales growth in the coming years, with \$190 billion of new sales forecast to be accounted for by 2020.²

¹ Strategy & research "Pharma emerging markets 2.0"

² McKinsey & Co research "Pharma's next challenge"

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- **Goal:** Drive business growth and improve access to healthcare in developing countries
- **Engagement since:** 2007
- **Sectors involved:** Pharmaceutical

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In the next two decades, the middle class is expected to expand by another three billion people, almost exclusively from the developing world.³ Increasing prosperity and improving longevity has also resulted in a gradual shift from the traditional communicable diseases of low-income countries—such as tuberculosis, malaria and HIV/AIDS—to non-communicable diseases—such as diabetes, cancer and cardiovascular diseases—resulting in growing demand for treatments in these areas.

Barriers to success

Despite the broadly positive macro trends in the industry's favor, most pharmaceutical companies have experienced a mixture of success and disappointment outside of the major advanced economies. Our research and discussion with pharmaceutical companies and industry experts have identified some common pitfalls and difficulties:

- **Treating all developing world countries as a single homogenous entity.** This has led to go-to-market strategies that are ill-suited to the country. There has been a growing recognition that one-size-fits-all sales-oriented strategies are not adequate and need to be complemented by country-specific access to market-based strategies.
- **Underestimating the challenge of navigating local regulatory requirements.** Regulation and approval processes can be uniquely volatile and unpredictable. To overcome this, companies have increasingly developed local expertise through acquisition or hiring, an important step that takes time and effort to bear fruit.
- **Overcoming bribery and corruption.** Cash in envelopes are largely a thing of the past following the establishment of tough, extra-territorial legislation in the U.S. and UK. Facilitation payments to local officials and middle-men have morphed into consultancy contracts or other seemingly above-board arrangements. While not a focus of

this piece, business ethics is an area in which we have undertaken extensive engagement with pharmaceutical companies.

- **Weak intellectual property protection.** Less complex drug molecules and formula are under threat of being copied by local generics producers. However, the industry's ferocious defense of their Intellectual Property (IP) has done much reputational harm (such as in South Africa over antiretrovirals).
- **Poor access to healthcare infrastructure and service.** This is cited by the World Health Organization as one of the biggest barriers to improving health. It is wide ranging in nature and reflects the resource poor nature of many developing economies. This includes low quality and/or lack of: hospitals and clinics, doctors and nurses, diagnostic tools, manufacturing, sanitation and the distribution and supply of medication. It is also affected by broader societal issues such as poor standards of water, electricity, education and transportation.

This final point is a crucial obstacle but one difficult to overcome. It can often be beyond the ability of a pharmaceutical company—however big it may be—to singlehandedly overcome and resolve the issue of poor healthcare infrastructure. It requires a wide range of stakeholders bringing expertise, commitment and resources for healthcare development to be successful. Despite the rapid growth in healthcare spending in developing countries and potential business opportunities, there continues to be significant hurdles in creating a viable commercial business strategy. At a wider-level, failure to overcome these barriers has major implications for the achievability of healthcare targets and, ultimately, sustainable social development in a world where two billion people still lack access to health-related products they need.

Access to Medicine Index

A key player driving the industry's practices over the past ten years has been the Access to Medicine Foundation (ATM Foundation). This Dutch not-for-profit has analyzed the top 20 research-based global pharmaceutical companies and ranked them according to their efforts to improve access to medicine in developing countries. The first Access to Medicine Index (ATMI) was published in 2008 and a new index has followed every two years. The latest 2016 Index was released in November 2016.⁴

Refinements over the years to the analytical framework—which now includes close to 100 indicators on company performance related to 50 or so diseases in low income countries—has reflected the ever-evolving

practices within the industry. The Index is a useful and robust benchmark for companies, investors and stakeholders to compare a range of industry approaches to improve access to medicine.

As the Index gained traction with institutional investors, the ATM Foundation has started to collaborate more closely with the global asset management community. They have organized a series of engagement initiatives, including an Investor Statement, putting forward the view that access to medicine is a material issue to long-term shareholder creation. We are signatories alongside 56 other institutional investors.⁵ Over the past two years, we have met them on numerous occasions including at their office in Haarlem, Netherlands, and have developed a positive working relationship.

³ Ernst & Young, 2014

⁴ Access to Medicine Index

⁵ Investor Statement Access to Medicine Index http://www.accessmedicineindex.org/sites/2015.atmindex.org/files/investor_statement_atmf.pdf

Engagement action

Our engagement history with pharmaceutical companies on this issue is extensive, dating back to a May 2007 discussion with **AstraZeneca**. At that time, the Access to Medicine Foundation was consulting with the pharmaceutical industry on the methodology for the first Access to Medicine Index. In total, we have held 150 engagements with 27 companies since that time. This includes 19 of the 20 largest global pharmaceutical companies on the ATMI including **Pfizer**, **Novartis** and **GlaxoSmithKline (GSK)** (the only exception being Germany's Boehringer Ingelheim, which is privately held and issues no equity or bonds). Our engagement also touches emerging markets companies — some of which are major manufacturers of generic drugs such as **Ranbaxy Industries** and **Glenmark** — to increase awareness of these issues.

During this near decade of engagement with the industry's leading players, our most important recommendation has been for access to healthcare to be clearly driven by commercial imperatives and to be meaningfully integrated into the business' main strategy. From an initial starting point of reticence, we have seen many companies doing more to improve their approaches to access, with a range of new initiatives and innovations. There has been a slow but gradual shift from philanthropic approaches to focusing on delivering commercial opportunities and establishing new business models. Transparency and disclosures from companies on these areas have improved drastically.

- We significantly intensified our engagement with pharmaceutical companies in 2015, initiating an engagement program specifically on healthcare access. The objective was to leverage the knowledge we have developed — especially of leading industry practices — over the past decade and to encourage companies with weaker practices to learn from and adopt key approaches of the engagement program one-to-one engagement with nine pharmaceutical companies. This included discussions with companies we identified as having the most advanced practices (e.g., **Novartis**, **Novo Nordisk**) and those we were concerned over having the weakest practices. Three of ATMI's lowest ranked companies are Japanese (**Takeda Pharmaceutical**, **Daiichi Sankyo** and **Astellas**). We engaged with these companies, including sit down meetings with management in Tokyo.
- We initiated a collaborative engagement with the ATM Foundation and 40 other institutional investors representing \$5 trillion of assets. We contacted all 19 of the listed companies on the ATMI, calling for full cooperation with the data collection and submission for the 2016 Index. This also included intensive engagement with **Roche** following its refusal to submit data.

Assessment

Based on this engagement, we identified clear business-focused practices pharmaceutical companies should consider when operating in the largest emerging markets and lowest income countries. From our investor perspective, we consider these corporate practices to be material to shareholder value creation:

1. **Governance:** Senior management and board-level strategic oversight, commitment and accountability
2. **Performance:** Clear objectives supported by measurable, time-bound targets, which are regularly reviewed and monitored
3. **Pricing:** Sophisticated and intricate approach to inter- and intra-market equitable pricing to ensure different populations with varying levels of affordability can access treatments
4. **Capability advancement:** Contribution to the development of local healthcare infrastructure and supply chains with a transparent, long-term plan for cooperating with local stakeholders

Based on these four practice areas, we see three broad levels of company performance within the industry:

- **Leading:** These are companies with the most sophisticated and nuanced approaches to delivering their strategic goals in the developing world. All four areas of practices identified previously will be in place (or clear steps are being taken to achieve it). A wide range of products are available and there are pipelines of relevant treatments for developing countries. We see companies in this category taking key steps to overcome manufacturing, distribution and affordability challenges by implementing novel pricing models in cooperation with local partners to ensure patients across the wealth/poverty spectrum can receive medication — while still making a profit. Reporting and disclosures are transparent and detailed. Of 23 companies we assessed, we rate ten companies within this category.
- **Average:** These companies have implemented key steps and are making progress, but there are a number of important areas that still need to be addressed compared to industry leaders. Companies may have adopted sophisticated approaches but these can be limited to certain countries/regions and are yet to be adopted business-wide globally and on a global scale. Of 23 companies we assessed, we rate seven companies within this category.
- **Weak:** Those in this category are laggards and are yet to develop a sufficient level of internal expertise or capability to overcome the challenges of developing world markets. As a result, most of the approaches adopted have little link to the central business strategy and there is little focus on delivering genuine commercial success. Many in this category see their presence in the developing world as being driven by philanthropy and motivated by corporate social responsibility. Of 23 companies we assessed, we rate six companies within this category.

Pricing

Our discussions in the past two years with companies have focused in particular on pricing. This is an area in which we have seen some big steps taken. The underlying issue is that the affordability of western treatments is a key barrier in the developing world. Traditionally, this has resulted in global pharmaceutical companies predominantly targeting wealthy, urban patients (who pay out of their own pockets).

This has changed of late, with companies in the “Leading” category in particular establishing equitable pricing strategies that include affordability considerations. This has led to implementations of:

- inter-country equitable pricing (charging different prices for the same drug, for example, between Netherlands and India);
- intra-country equitable pricing (charging different prices for the same drug between different segments in the same country).

A number of leading companies such as **Gilead** commit to both and report specific details on performance.

Intra-country equitable pricing—which we consider to be particularly critical to establishing long-term success in a developing/emerging market—is based on different pricing tiers. We have seen a number of companies differentiate among the tiers in the following ways: packaging/branding, manufacturing and distribution.

For example, the lowest, poorest, rural tiers are accessed by keeping costs to a minimum through local or outsourced production, different packaging/brand name and distribution via development agencies and missionary groups. These steps are aimed at clearly differentiating one tier to the next and overcoming concerns of medications produced for poorer tiers being sold at lower prices to wealthier patients. This also means that companies can still have a presence across the country and establish the corporate brand along the socioeconomic spectrum. The business model at lower tiers seeks to break even or make a slim profit. Importantly, it also switches the corporate mentality and approach from a purely philanthropic activity to one that is delivering commercial opportunities.

Conclusion and next steps

Pharmaceutical companies are faced with a great opportunity to capitalize on the long-term growth potential in the developing world. There has been a realization among some that a blunt go-to-market approach rarely results in the desired commercial success and that a tailored approach is required to place themselves in a position to enjoy the improvements in the country’s economic fortunes.

Our engagement over the past ten years in this issue with the industry has driven the adoption of important practices. Our focus has primarily been on the largest companies in the industry but the challenge is to ensure that the wide range of players in the global healthcare market also adopt the innovative mind-set that we now see among the companies in the “Leading” category.

As a next step, we will consider the analysis and findings of the 2016 Access to Medicine Index. We will also engage companies

such as Roche on its plans in this area in the coming years. We will continue our dialogue with various stakeholders, including the ATM Foundation. The key objectives will continue to be establishing commercial success for companies in fast-growing developing markets and ensuring billions of the poorest people in the world have better access to an adequate standard of healthcare.

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