84 State Street, Suite 940
Boston, MA 02109
TEL (617) 720-5557
FAX (617) 720-5665
www.bostoncommonasset.com
invest@bostoncommonasset.com

The investor's view on promoting access to medicines in the developing world

Thought Piece
September, 2012

"Access to medicines" describes the practice of making pharmaceutical products available to low-income patients, particularly in less developed countries.

The term derives from a long-standing struggle between social advocates, who want life-saving medicines made available cheaply throughout the world, and the pharmaceutical industry giants who control the drugs, and who try to provide attractive returns to shareholders. This conflict reached its apex at the turn of the twenty-first century, when inefficiencies in pricing and distribution of HIV/AIDS antiretroviral medications (ARVs) in sub-Saharan Africa bred uncalled-for suffering, and undermined pharmaceutical firms' social license to operate. The ensuing backlash and reputational damage to the industry spurred shareholders to urge company managements to rethink how they were addressing access to medicines. Since 2003, Boston Common Asset Management, LLC (Boston Common) has worked as a shareowner to urge these firms to align their thinking and practices with the needs of patients in the world's poorest regions, encouraging them to view underserved demographics as a growth opportunity, rather than a lost cause.

Major pharmaceutical companies typically practice a "blockbuster" business model, investing heavily in research and development (R&D) to treat major chronic conditions - such as high blood pressure and high cholesterol - that afflict the developed world. The blockbuster model typically doesn't well serve the world's poorest countries, where different diseases reign and patients can scarcely pay. In developing world markets, medicine manufacturers are now urged to turn their attention to the diseases specific to these regions, and to explore higher volume, lower margin business strategies that can provide new access to a large class of underserved consumers.

In Brief

- In response to investor and stakeholder demand, pharmaceutical companies are beginning to implement profitable strategies to make medicines available to low income demographics.
- Medicine manufacturers are re-imagining their business models to fit the healthcare needs of the developing world.
- Strategies such as voluntary licensing, patent pooling, adaptive R&D, and product development partnerships are options for addressing developing world diseases and cost hurdles.
- Boston Common Asset Management has encouraged the pharmaceutical companies in its portfolios to integrate access to medicines considerations into their core business strategies.

The investor's view on promoting access to medicines in the developing world

Thought Piece
September, 2012

Re-imagining business models in developing countries carries an inherent set of opportunities and risks.

The primary opportunity is the large pool of patients that stands to contribute meaningfully to pharmaceutical industry growth. As recently as 10 years ago, the access to medicines policies of most pharmaceutical companies were focused on the world's least developed countries (LDCs). This is expanding as the industry begins to establish strategies to target low income demographics in emerging market countries, where pharmaceutical sales are slated to reach $400 billion by 2020.[1] Companies that adapt their products, pricing, marketing, and distribution to these trends stand to benefit significantly.

Medicines designed for developing world distribution have historically targeted the three major pandemics: HIV/AIDS, tuberculosis, and malaria. However, neglected tropical diseases, such as worm parasites and elephantiasis, and chronic and non-communicable diseases like diabetes and asthma, are projected to comprise over 65% of the disease burden in low-and middle income countries by 2030.[2] Development of treatments to treat these diseases has significantly lagged demand, largely because the patients that suffer them have limited ability to pay the prices that would justify the R&D investment.

Responding to these opportunities, however, challenges many pillars of the pharmaceutical industry. One of these pillars is drug patenting. The blockbuster model relies on patent protection to insulate drug companies from competition from both branded and generic manufacturers, allowing them to recoup their significant R&D investments by keeping prices high. A second pillar has been to maintain consistent pricing across regions. Firms historically felt obliged to charge the same lofty prices for drugs in low and high income regions, in order to prevent "product diversion" - in which traders ship lower-priced drugs from LDCs to developed markets, undercutting pharmaceutical companies' developed market prices, and reducing the availability of medicines in the lowest income regions. Furthermore, because there are relatively few patients at the bottom of the income pyramid who can afford these marked-up prices, pharmaceutical companies often haven't thought carefully about how to distribute and deliver their drugs effectively in LDCs and emerging market countries, where patients may be more poorly educated and doctors and clinics lacking compared to the developed world.

In the last decade, pharmaceutical companies have experimented with and rolled out several strategies to address stakeholder concerns. When done right, these strategies serve the dual purpose of increasing patients' access to medicine and providing the companies with incrementally profitable sales.

"Tiered pricing," the simplest of these strategies, allows for medicines to be offered at different price points based on regional ability to pay. The Access to Medicines Index (AtMI), a cross-industry, multi -stakeholder initiative that benchmarks the performance of global pharmaceutical players in providing medicines to low-income demographics, outlines the criteria for an effective tiered pricing program. These criteria include setting medicine prices near marginal cost in low wealth regions, implementing mechanisms to minimize the risk of product diversion, and working with local distributors to ensure that price-adjusted products reach intended consumers. In February of 2009, for instance, pharmaceutical giant GlaxoSmithKline (Glaxo) announced that it would reduce prices for patented medicines in LDCs such that they would not exceed 25% of developed world prices. In tandem, Glaxo lowered prices in a small number of neighboring regions prone to product diversion to ensure that medicines would make their way through distribution chains as intended.

While these challenges are ongoing, we believe pharmaceutical companies are making progress toward addressing them and reimagining their role in the developing world.

[1] *Ben Hirschler, "Emerging Market Drug Sales Seen $400 Bln by 2020." Reuters. 28 Feb 2008.*

[2] *WHO. The Global Burden of Disease: 2004 update. Geneva: World Health Organization, 2004.*

The investor's view on promoting access to medicines in the developing world

Thought Piece
September, 2012

A "patent pool" is an association of pharmaceutical companies that agree to collectively cross-license their products.

Both sides have their criticisms over pricing. Companies continue to find it difficult to strike a balance between equitable pricing and profitability. Meanwhile, activists claim that even significant price cuts such as those implemented by Glaxo don't meaningfully increase affordability for the poorest patients. Furthermore, tiered pricing addresses distribution concerns without tackling the problem of R&D for neglected and chronic diseases. To effectively provide access to medicines, tiered pricing must be combined with additional strategies. In 2012, the Pugatch Consilium, a research consultancy, published a comprehensive study of strategies to encourage R&D for developing world diseases. Among those referenced are voluntary licensing, patent pools, and product development partnerships.

Through "voluntary licensing," patent holders issue licenses to a third-party, usually a generic manufacturer, to produce, market, and/or distribute their medicines, in exchange for a royalty fee. The idea is that generic makers may be able to manufacture and distribute a drug at a lower cost. To date, most voluntary licenses are issued for anti-retroviral medications (ARVs) - used to treat HIV/AIDS - and are issued to generic companies with permission to distribute them in LDCs and sub-Saharan Africa.

Patent pools provide a cost-effective and efficient venue for licensing multiple patents from several patent owners at once. This kind of non-exclusive voluntary licensing allows for multiple generic manufacturers to enter the marketplace, which drives competition and lowers prices for end consumers. Patent pooling additionally allows for the advancement of "adaptive R&D": research into new uses for existing medications. Adaptive R&D can yield benefits such as broadening the application of existing treatments to other diseases or demographic groups, and can lead to breakthroughs in "fixed dose combinations," or the simplifying of dosing regimens by combining multiple treatments into one unit of intake, such as a pill.

Two major patent pools currently exist. The Medicines Patent Pool was launched by UNITAID, an international organization for the purchase of treatments for the three major pandemics, in 2008, to support the production of medications for HIV/AIDS, malaria and tuberculosis. This pool has two contributors to-date, and, currently, it licenses to generic companies to produce non-branded versions of patented ARVs. The Pool for Open Innovation against Neglected Tropical Diseases (POINT) is another major patent pool. Launched by Glaxo in 2009, its aim is to support research among pharmaceutical companies and academic institutions into developing world diseases beyond the three major pandemics.

Finally, new cross industry associations are emerging to collaborate on access to medicines and innovation issues. Product Development Partnerships are non-profit enterprises comprised of branded and generic pharmaceutical companies, public and civic sector institutions, and academia. These groups work to develop solutions to neglected global health problems. The Global Funding of Innovation for Neglected Diseases (G-FINDER) survey counted 18 such Product Development Partnerships as of 2012. At the same time, intra-industry joint ventures are developing within the pharmaceutical arena. Glaxo and Pfizer launched ViiV Healthcare in 2009 to collaboratively pursue R&D in HIV/ AIDS treatments.

[3]Meir Perez Pugatch, Rachel Chu, David Torstensson, Assembling the Pharmaceutical R&D Puzzle for Needs in the Developing World, Pugatch Consilium, 2012.

The investor's view on promoting access to medicines in the developing world

Thought Piece
September, 2012

Boston Common's engagement with pharmaceutical companies has focused on how companies are integrating access and affordability issues into their core business strategy.

Since 2003, Boston Common has led the investor engagement with Glaxo, and have helped shape their thinking on access to medicines issues, in particular by urging them to apply many of the strategies detailed above. While Glaxo showed leadership in its establishment of POINT, we have urged it to additionally consider contributing to the Medicines Patent Pool. We used our voice as shareholders to encourage Glaxo's further penetration of emerging markets, and in 2010, the company created the Developing Countries and Market Access Unit, designed to expand the Glaxo product portfolio to fit regional disease profiles, thereby unlocking new demand in the developing world.

As with Glaxo, we have urged other pharmaceutical companies held in Boston Common portfolios to apply access to medicines considerations across the range of business activities, from initial risk assessment to marketing. In recent conversations with pharmaceutical companies, we have asked them to report on the impact and efficacy of their programs, to set key performance indicators by which their efforts can be measured, and to benchmark their progress against visible milestones, such as the Millennium Development Goals.

In meetings with company managements during the Spring of 2012, Boston Common representatives asked Novartis, Roche, and Glaxo to develop metrics and report on the effectiveness of the Product Development Partnerships of which they are members.

At the industry level, Boston Common has promoted access to medicines via multi -stakeholder initiatives that work to enhance broad sector performance on the issue. We assisted in developing the methodology behind the Access to Medicine Index, and continue to consult for the AtMI on its methodology and progress. As a member of the Interfaith Center on Corporate Responsibility, we have twice convened investors, advocates and corporations at roundtables to explore sustainable business models for pharmaceutical companies in emerging markets.

At Boston Common, we take a big picture approach to tackling society's critical challenges, and encourage company managements to do the same. In the long-term, the status of global health will be dictated by the ability of societies to provide diverse services to an expanded population. Within this context, distribution of medicines is but one piece of a broader "access to healthcare" objective. In addition to traditional therapy providers such as hospitals, pharmaceutical companies, and medical device manufacturers, we see tremendous opportunities in the fields of diagnostics and medical information technology. We look to healthcare services that will reduce medical waste, engage in proactive management, and increase the success rate and safety of treatments for patients as we pursue enhanced access to healthcare worldwide.

Boston Common Asset Management

is an investment manager and a leader in global sustainability initiatives. We specialize in long-only equity and balanced strategies and pursue long-term capital appreciation by seeking to invest in diversified portfolios of high quality, socially responsible stocks. Through rigorous analysis of financial, environmental, social, and governance (ESG) factors we identify what we believe are attractively valued companies for investment. As shareholders, we urge portfolio companies to improve transparency, accountability, and attention to ESG issues. Our focus is global; we manage U.S. and international portfolios to meet the needs of institutional and individual investors. We are independent, employee-owned, and field a seasoned, close-knit team of professionals.