



Note from the Co-chairs of the Human Rights Working Group:

The HRWG has discussed the complex question of Access to Medicines. There are clearly very many barriers preventing the world's poorest and most disadvantaged achieving their rights to adequate healthcare. Under the UN Guiding Principles for Business and Human Rights many of these fall under governments' duty to protect. The attached Good Practice Note illustrates a number of different ways in which responsible businesses can support the UN goals in this area. As the note points out, different companies place emphasis in different areas, and indeed some of the approaches such as separating activities from the commercial business or integrating activities into mainstream business are, at least in part, contradictory. However the HRWG considers that the examples given may be of assistance in considering which approach is best in a particular circumstance. In putting the position of companies in a wider perspective, the paper "Poverty, disease and medicines in low and middle-income countries: the roles and responsibilities of pharmaceutical corporations" by Klaus.M. Leisinger, a member of the HRWG may be of help (available at: <http://www.novartisfoundation.org/mandant/apps/publication/index.asp?MenuID=270&ID=612&Menu=3&Item=46.1&Act=search&cboTheme=1&MasterId=146>).

Human Rights, Access to Medicines, and the Pharmaceutical Industry¹

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The Universal Declaration of Human Rights encapsulates the most widely accepted normative standard for the "right to health": "[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services."² Within the International Covenant on Economic, Social and Cultural Rights, signatory nations also recognize a more comprehensive standard: "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."³ The right to health, however, is not exclusively confined to the realm of state actors. The United Nations Economic and Social Council has recognized that actions by "individuals, groups, or corporations" may violate obligations to respect and protect the right to health.⁴ Similarly, the Universal Declaration charges "every individual and every organ of society" to promote human rights and secure their universal recognition and observance.⁵ Therefore,

¹ Grateful acknowledgment is given to all those who were interviewed and/or commented on this Good Practice Note, as well as UN Global Compact Advisor and Good Practice Project Leader Prof. Chip Pitts.

² Universal Declaration of Human Rights art. 25.1, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III), at 76 (Dec. 10, 1948).

³ International Covenant on Economic, Social and Cultural Rights art. 12, G.A. Res. 2200A (XXI), U.N. Doc. A/6316 (Dec. 16, 1966) [hereinafter ICESCR].

⁴ U.N. Econ. & Soc. Council [ECOSOC], *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment No. 14*, ¶¶ 50-51, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000) [hereinafter General Comment No. 14].

⁵ Universal Declaration, *supra* note 2, pmbl.

although governments bear the primary duty for the realization of the right to the highest attainable standard of health for their citizens, everyone has a role to play, with realization of human rights requiring a multifaceted solution involving a variety of public and private actors. The question for corporations in this rights-conscious international legal order is whether they have a responsibility not only to respect the right to health, but also to take some degree of affirmative action to support the right to health.

Within the pharmaceutical industry, the “right to health” debate usually centers on access to medicines. But with the shortfall in essential drug access occurring primarily in developed and least-developed nations, access to medicines raises not only right-to-health concerns, but also the fundamental human right principles of equality, transparency, and non-discrimination.⁶ With millions of people lacking access to basic health services and resources, and with many tropical diseases being historically neglected from an R&D standpoint, the human rights of the particularly vulnerable – those without even minimal basic access to health care or those suffering from neglected diseases – are of special concern.

Pharmaceutical companies are perceived as uniquely positioned to lend a helping hand in addressing adverse right-to-health impacts due to their specialized role as the sole societal actors that produce innovative medicines to remedy illnesses and improve peoples’ quality of life. Drawing on their specific health expertise, many pharmaceutical companies have made commitments to make positive contributions towards supporting the right to health, aspiring to reach beyond merely avoiding infringing on human rights. For example, many companies have mobilized to improve access to medicines by helping to provide adequate health care, by helping to build health care infrastructure, and by developing medicines to address neglected diseases occurring primarily in the developing world. Although access-to-medicines was once a hostile policy discussion arising from the industry’s fight to uphold its intellectual property (“IP”) rights when the South African government took steps to address its HIV/AIDS crisis in the late 1990s and early 2000s, the debate has largely cooled and increasingly shifted to a pragmatic, solutions-based interaction between governments, the pharmaceutical industry, and health-care NGOs. As a result, a surprisingly diverse range of industry strategies for improving access to medicines has arisen from this gradual evolution of the access-to-medicines and right-to-health discussions over the past decade.

This Good Practices Note aims to clarify the most effective business-friendly strategies that have emerged to date for the pharmaceutical industry to improve realization of the right to health, including both access to medicines and the related fundamental human rights principles of equality, transparency, and non-discrimination. This Note draws on interviews conducted by the author with pharmaceutical industry executives and partner NGOs from mid-2010 through early 2011. It details the current context for improving access to medicines, presents the most effective and forward-thinking strategies identified thus far for the pharmaceutical industry to continue its progress in making access to medicines for all a reality, and identifies the benefits that pharmaceutical firms have realized through access-to-medicines action. Interviews with

⁶ See, e.g., General Comment No. 14, *supra* note 4, at ¶¶ 50-51; Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines, pmb1, § 5, in The Secretary-General, *Interim Report of the Special Rapporteur: The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, annex, transmitted to the General Assembly, U.N. Doc. A/63/263 (Aug. 11, 2008).

health-oriented NGOs helped to provide perspective on the obstacles for improving access to medicines and background on the evolution of the access-to-medicines discussion. The Note aspires to provide inspiration for pharmaceutical companies as to what they can do to support the right to health.

A. CONTEXT

Governments are the primary duty-bearers of human rights: they have the primary obligation to respect, protect and fulfill human rights, including upholding the right of everyone to the enjoyment of the highest attainable standard of physical and mental health⁷. The UN Human Rights Council unanimous endorsement of the Guiding Principles on Business and Human Rights for implementing the UN "Protect, Respect and Remedy" Framework solidly reaffirmed the corporate responsibility to respect as the global standard for all business enterprises. This responsibility implies that business should avoid infringing on the human rights of others and should address adverse human rights with which they are involved. In order to meet the responsibility, the Principles stipulate that enterprises need to have in place certain policies and processes to know and show that they are respecting human rights. These include a policy commitment to respect human rights; a human rights due diligence process; and processes to enable the remediation of adverse human rights impacts. These are also the key basic elements underlying all human rights-related good business practice.⁸ Within the scope of access-to-medicines, the Guiding Principles are a particularly valuable reference point for streamlining human rights programs and policies in line with the standards for human rights due diligence and processes to address any adverse impacts, given the wide-ranging effects of access-to-medicines initiatives on not only the right to health, but also the human rights principles of equality, transparency, and non-discrimination. In confronting these human rights challenges, the pharmaceutical industry has been increasingly expected to improve access to medicines for three primary rationales:

- Perceived influence: The pharmaceutical industry, by virtue of its reliance on IP protection to develop new drugs, is necessarily dependent on states to grant patents and enforce them for their duration. Given the industry's business relationship with government health ministries and political involvement in maintaining exclusive IP rights, which can price lower income individuals out of the pharmaceutical market, some argue that pharmaceutical companies' position of influence helps create a moral obligation to increase access to those who cannot afford the drugs.
- Perceived complicity: The pharmaceutical industry, because of its reliance on IP protection, has a strong interest in obtaining and maintaining a strong regime of IP rights throughout the world. Attempting to enforce or strengthen these intellectual property rights often has the external effect of depriving access to those who cannot afford drugs priced in accordance with the exclusive patent right. This creates a perception of complicity in depriving people of medication, unless pharmaceutical companies take other steps to minimize this loss.

⁷ ICESCR, *supra* note 3, art. 12.

⁸ U.N. Hum. Rts. Council, *Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises*, annex, U.N. Doc. A/HRC/17/31 (Mar. 21, 2001).

- Perceived capacity: Pharmaceutical companies are the only societal actors that fulfill the role of developing and producing innovative medicines to remedy illnesses and improve patients' quality of life. Expertise in developing medicines, delivery mechanisms, and familiarity with health care infrastructure help create a perception that pharmaceutical firms are well-positioned to act to remedy a wide array of access-to-medicines challenges.

Pharmaceutical sector action for improving access-to-medicines, however, presents a unique set of risks to the industry's business model because of the IP-dependent context in which the pharmaceutical industry operates:

- Developing pharmaceutical drugs is an extraordinarily expensive undertaking, and the industry relies on patent protection and regulatory data exclusivity to prevent generic drug firms from reverse-engineering innovative drugs and competing in the marketplace without bearing any of the initial R&D outlay.
- Because pharmaceutical R&D is extremely expensive, drug development is typically targeted at diseases where R&D investment will generate a return. Tropical diseases where the vast majority of sufferers have little or no ability to pay have therefore been historically neglected.
- Of the drugs currently available to treat diseases faced by citizens of developing or least-developed countries, the vast majority are *not* patented in those countries. Furthermore, patents are not a barrier to access when generic drugs are available, including in those countries where even the most recent innovative drugs are unpatented. Often, even generic drugs are too expensive for the citizens and governments of developing and least-developed countries, requiring access-to-medicines solutions that are not IP-focused.
- Even when drugs are affordable (or donated), a minimum level of health care infrastructure must exist in order for a nation's citizens to obtain access to those drugs. For example, HIV/AIDS patients must take their antiretrovirals (ARVs) on a regular schedule, which therefore requires a consistent supply of ARVs and consistent medical attention. When the health care infrastructure fails or patients are non-compliant, positive health outcomes cannot occur, and partial treatment may actually breed stronger drug-resistant strains of disease.
- Supply chain security,⁹ another form of health care infrastructure, is also often lacking. Product diversion undermines viable pharmaceutical markets, and reduces incentives for access-to-medicines activity. Procedural safeguards can help identify suspicious stock-outs and detect counterfeit drugs, which in turn will prevent product diversion away from the intended patients and reduce the chances of patient harm and firm liability.

B. RECENT TRENDS IN PHARMACEUTICAL INDUSTRY ACCESS-TO-MEDICINES ACTION

⁹ Supply chain security is paramount for ensuring that donating drugs (or drugs sold at discounted prices) reach the intended patients. Often, donated or discounted drugs intended for patients in developing countries are sold (diverted) by intermediaries in the supply chain for a profit. Where these drugs are re-imported into countries where a pharmaceutical firm has a profitable market and sold to patients who would otherwise purchase at market prices, the result is that a firm's access-to-medicines efforts may undermine its profits in main markets.

Pharmaceutical industry interviews revealed a lack of consensus in terms of specific strategies for increasing access to medicines. Despite their diversity of specific strategies, however, all firms clearly enunciated the need for a cohesive internal vision for approaching access-to-medicines – whichever combination of strategies is ultimately employed. Given that pharmaceutical action to increase access to medicines often acts in the context of government gaps in areas of the world with weak institutions, simplifying the overall approach is crucial. Rather than maintaining a portfolio of programs designed and implemented in a vacuum, firms reported that defining a reasonable set of objectives and tailoring access-to-medicines activity around achieving those objectives will generate improved results, even if firms do not agree on the specific strategies implemented. Streamlining access-to-medicines strategies will better enable firms to (1) identify their comparative advantages for action, (2) design complementary and sustainable access-to-medicines programs, (3) identify unused or underutilized resources, and (4) motivate non-industry actors to play their role in increasing access to medicines.

Although pharmaceutical firms tend to agree on the need for a cohesive overall approach, the most forward-thinking trends in specific access-to-medicines strategies vary widely simply because firms often have differing core competencies, unique comparative advantages for acting to increase access to medicines, and diverse pressures from internal and external stakeholders. Thus, individual access-to-medicines strategies remain dependent on the unique contexts of health needs and the particular circumstances of individual firms. For example, the limiting factor resulting in deprivation of access to needed drugs can occur at many stages along the spectrum from initial R&D efforts (or lack thereof) to patient treatment:

- The needed drugs do not exist
- The needed drugs do exist, but are not affordable
- The needed drugs do exist and are affordable, but health care infrastructure is insufficient to make the drugs available

Various firms, meanwhile, often have differing core competencies and stakeholder influences that would lead each to approach these access problems in different manners:

- Conducting R&D to create new drugs is usually within the core competency of any given firm, although certain firms may have particular advantages in developing drugs or vaccines for certain neglected diseases.
- Firms with extensive experience in designing treatments and monitoring care for chronic diseases may have comparative advantages in acting to strengthen health care infrastructure in developing countries.
- Internal and external stakeholders (directors, shareholders, employees, doctors, patients, etc.) may exert a variety of pressures on a firm to engage primarily in a narrow range of philanthropic activity, such as donating drugs or conducting pro bono R&D, while leaving NGOs do most of the on-the-ground work in access-to-medicines projects.
- Alternatively, internal and external pressure may lead a firm towards greater “hands-on” involvement in access-to-medicines. This may involve directly sending employees to provide care, conduct studies, train health care personnel, and build physical health care infrastructure in developing countries.

The following trends represent the current vanguard in pharmaceutical industry strategies for increasing access to medicines. Respecting the various fact-specific contexts in which firms act

to increase access to medicines, these trends are presented solely to stimulate reflection and evaluation rather than for recommendation. Indeed, these strategies often contradict each other, as the factors playing into firms' decisions to engage in these strategies have been highly context-dependent.

Most Recent and Effective Industry Access-to-Medicines Strategies:

- **Emphasize Human Resources and Capacity Building**
- **Intra-Industry Partnerships**
- **Increase Market Segregation**
- **Think Long-Term: Transform the “One Size Fits All” Business Model**
- **Distance Access-to-Medicines Activity from Business Considerations**

➤ **Emphasize Human Resources and Capacity Building**

Access-to-medicines is certainly no longer just an IP debate, which it appeared to be at times in the late 1990s and early 2000s. Solving access-to-medicines problems requires an understanding of the functional barriers to access, including but absolutely not limited to the need for drug availability. Trained health care workers are needed to detect and take early action against contagious outbreaks of tuberculosis and other tropical diseases. HIV/AIDS and other chronic diseases like diabetes require not only patient lifestyle adjustments, but also consistent health care and drug supply. Because basic health care resources and services are severely lacking throughout much of the developed world, action to raise this baseline level of access contributes immensely to improving equality of care and assisting those who are particularly vulnerable. In general, more specialized and targeted access-to-medicines programs can occur only with at least a basic platform of health care infrastructure. Pharmaceutical firms have found it difficult to temper expectations for their access-to-medicines programs by citing lack of health care infrastructure without actually taking affirmative action themselves to improve it. Although industry concerns exist regarding an appearance of self-interest in training potential future customers, these concerns have not tended to generate negative perception. Rather, capacity building has usually been met with great appreciation, and it has occurred through a variety of approaches:

- Active training, either directly or with the aid of a partner NGO,¹⁰ of local villagers to become health care personnel capable of detecting disease and organizing the people and materials necessary for care – particularly with regards to chronic disease.

¹⁰ Such NGOs are often infectious disease institutes or disease-specific organizations. For example, the Zimbabwe AIDS Prevention Project and AIDS Care China are relatively localized and disease-specific organizations, which send project teams out into the field to educate and train health workers. Faith-based groups are also very active in the field, such as the Churches Health Organization of Zambia (CHAZ). Larger NGOs, such as Millennium Promise and Family Health International, both of which sponsor a vast array of health projects, may be valuable partners and resources given their pre-existing partnership networks of smaller on-the-ground NGOs and health ministries.

- Active training, either directly or with the aid of a partner NGO, of government health personnel to maintain a functional health ministry. This involves not only hands-on health care training, but also policy design and managing drug supply chains.
- Firms with less of a comparative advantage in health care personnel training may choose to heavily rely on NGO partners to run the human-resources side of access-to-medicines projects, or simply donate a percentage of revenue or profits gained from developing country sales to help develop infrastructure and capacity.

➤ **Intra-Industry Partnerships**

Access-to-medicines activity is usually a resource-drain on pharmaceutical firms. Although it can lead to forming commercial relationships with government health ministries and occasionally result in positive public recognition, rarely does it promise significant future income. Traditional access-to-medicines programs have tended to match one pharmaceutical firm, one NGO, and one government health ministry per project. Greater cooperation between pharmaceutical firms, however, can reduce redundant research and operations, as well as match complementary competencies and enable pooling of resources to achieve larger objectives. Such cooperation, however, may run the risk of frustrating free-market-type efficiencies in designing and implementing access-to-medicines programs. Cooperation will also prevent firms from claiming sole responsibility for successes. Firm-firm partnerships can be applied in numerous contexts:

- Pro bono R&D: pharmaceutical R&D is remarkably expensive. When R&D is targeted towards diseases not occurring in the developed world, the drugs ultimately developed are unlikely to be rainmakers for their firms. Accordingly, there are increased incentives for cooperation and pooling resources for finding treatments and vaccines for malaria, tuberculosis, and other neglected diseases. Although many firms have established separate philanthropic foundations that engage in R&D, intra-industry cooperation for pro bono R&D has grown more frequent given the costs involved in R&D and the corresponding desire to reduce redundant R&D efforts.¹¹ R&D cooperation has primarily occurred in the forms of formal R&D joint ventures and patent-pooling, although comparatively informal information sharing between firms and outside researchers is increasing.
- Collaborative project implementation: when engaging in large-scale projects, individual firms have a greater opportunity to contribute firm-specific advantages in resources or competencies for which NGOs may not be sufficient partners. Within such projects, each individual firm may have complementary products or services that will result in a much more comprehensive project than a piecemeal system of smaller firm-NGO joint venture projects.

¹¹ Recently established R&D collaborations are usually disease-specific organizations. For example, the Medicines for Malaria Venture seeks build a strong pipeline of antimalarial compounds through collaboration with various pharmaceutical firms, national health institutes, and universities. ViiV Healthcare is a joint R&D effort aimed at improving development of HIV/AIDS medications, drawing on the drug pipelines of both GlaxoSmithKline and Pfizer. Pharmaceutical patent pooling is also starting to take hold, such as with the Medicines Patent Pool, which recently spun off from UNITAID.

➤ **Increase Market Segregation**

Tiered pricing in least-developed countries and developing countries has become a powerful strategy for increasing access to medicines. Over the past decade, firms have overcome initial resistance to generate segregated markets between countries with great success, enabling developing countries to gain access to medicines that under a more universal pricing policy would fall within the global market's deadweight loss. Current concerns with effectively segregating markets include:

- **Limiting intermediaries:** the more hands that drugs must pass through to reach patients, the more the drugs will ultimately cost, which undermines the benefits gained through tiered pricing. Strong governmental and political willingness to increase access to medicines plays a significant role in limiting middlemen and keeping prices low when pharmaceutical firms directly supply government health ministries. If political will or reliable government are lacking, some firms have preferred to bypass government health ministries and instead distribute drugs through on-the-ground NGOs when implementing access-to-medicines projects.
- **“Best price” agreements:**¹² as pharmaceutical firms act to increase access-to-medicines not only within the developing world, but also throughout needy populations in developed countries, “best price” agreements restrict firms from charging tiered prices in an increasingly broad range of circumstances. Should “best price” agreements be interpreted to include differential pricing in developing country markets, firms will not be able to offer low prices in those markets without undermining their profitable markets. If these provisions are used to lower prices in important markets, “best price” agreements may include carve-outs permitting access-to-medicines activity for firms to continue offering differential pricing.
- **Tiered pricing *within* a national market:** although firms have had great success in establishing segregated markets between countries, segregating market segments within national markets has proven more difficult. Because income gaps in developing countries are often wide, the profit-maximizing price in those markets may often cater to the most wealthy individuals and perhaps even exceed the price offered in developed countries. Should better intra-national market segregation develop, firms would be able to increase access to medicines in developing countries without foregoing profit from sales to wealthier internal market segments, eliminating or reducing conflicts of interest between pharmaceutical business interests and access-to-medicines activity. Intra-market segregation will require greater political willingness and monitoring on the part of government health ministries and drug wholesalers. Trustworthy NGOs, however, may also play a strong role in distributing drugs and helping to prevent low-price consumers from re-selling their drugs at a profit and undermining the firm's higher-price markets.

➤ **Think Long-Term: Transform the “One Size Fits All” Business Model**

¹² Governments often require that pharmaceutical firms contracting to supply drugs to government health care programs (e.g., Medicaid) pay a rebate if they charge a price higher than the “best price” charged to a non-government program. This creates a disincentive for a pharmaceutical firm to offer discounts, since it lowers the price charged to large government health care programs as well.

Developing countries are expected to account for forty-eight percent of pharmaceutical market growth as soon as 2013,¹³ giving firms ample motivation for cultivating a presence in those markets. Recognizing this future growth opportunity, some firms are gradually incorporating access-to-medicines activity into their core business plans. Treating access-to-medicines activity at least partially as a business investment may permit firms to make greater contributions than a purely philanthropic outlook would. Because most of these emerging markets have universal health care programs run by government health ministries, these ministries are future (and probably current, but small) customers. Establishing contacts and executing access-to-medicines projects with these ministries can therefore simultaneously improve access to medicines while laying the groundwork for strong, long-term relationships with future large-scale customers. Furthermore, early interactions with government ministries can inform firms of how governmental decisions are made, both at the policy level and in terms of making purchasing decisions. Incorporating access-to-medicines activity into business plans requires a significant shift away from the “one size fits all” market approach to R&D, sales, and distribution, however:

- Develop a product portfolio for emerging markets: developing countries, even powerful ones, continue to face health care challenges that do not occur in the developed world. Although certain firms with particular drug specialties (e.g., HIV/AIDS antiretrovirals) may see their products become profitable in emerging markets as incomes gradually rise, the most powerful early-movers in these markets will need to develop new products that will specifically address diseases and health care problems unique to those countries. Many emerging markets, such as India, Brazil, China, and Russia, are large enough to merit tailored strategic approaches. Because of the high cost of pharmaceutical R&D and the current low incomes in these economies, however, firms cannot count on quickly recouping R&D costs. Countries that provide reliable health care infrastructure and maintain strong regimes of IP rights will foster an environment that may enable pharmaceutical firms to begin targeted R&D comparatively earlier than other countries. Advances in achieving intra-national market segregation might also accelerate targeted R&D investment, as governments could ensure that most of its population would have access at reasonable prices, while eliminating or reducing the market deadweight loss would enhance firms’ return on R&D. Currently, though, patience is essential.
- Adjust the pricing paradigm: emerging markets are not on a level playing field with developed markets. Firms incorporating access-to-medicines activity within their core business plans indicated a strong need to adopt different pricing paradigms for different markets. Pricing for emerging market portfolios should tend to shift from a ‘low volume – high margin’ towards a ‘high volume – low margin’ approach. Several factors may inform the appropriate price point, including median incomes, sufficiency of health care infrastructure, and security of the drug supply chain. Catering to only the wealthy consumers in emerging markets is less likely to result in the desired strong customer relationships with government health ministries, given political interests in increasing access to health care to as much of the population as possible. Preferential pricing in developing countries, however, may undermine a pharmaceutical firm’s profitable markets if drugs are re-sold internationally. Firms will need to maintain effective market

¹³ David Campbell & Mandy Chui, IMS Health, Pharmerging Shake-Up: New Imperatives in a Redefined World 5 (2010).

segregation between countries in order to maintain separate developing country and developed country business models. Political will may distinguish which countries are appropriate hosts for tiered pricing, and those which are not.

- Create appropriate management incentives: although developing countries will soon account for half of pharmaceutical market growth, they will still only generate approximately twenty percent of sales by 2020.¹⁴ Incorporating access-to-medicines into a core business plan is a long-term commitment, and without proper management incentives, access-to-medicines activity is likely to remain ancillary to the core business. Incentivizing early-stage future market positioning may require redefining management metrics, for example by increasingly tying compensation to market share or volume gains instead of quarter-by-quarter profitability.

➤ **Distance Access-to-Medicines Activity from Business Considerations**

Opposing the trend of incorporating access-to-medicines activity into core business plans, an equally important recent trend has attempted to distance access-to-medicines activity as far as possible from business concerns. Justifications for distancing access-to-medicines activity mirror the potential problems that firms must navigate when they choose to incorporate access-to-medicines activity into their core business plans, and they include:

- Inherency of conflict in resource allocation: when access-to-medicines and core business intersect, there is a foreseeable pressure to redirect resources away from access-to-medicines projects and towards projects that will generate profit in the shorter-term. Taking action to increase access-to-medicines should mean affirmatively acting to increase access-to-medicines – and not merely when it is convenient. Separating access-to-medicines projects from the core business, for example by setting up private foundations, establishing joint ventures, or by partnering with NGOs, assures that immediate bottom-line considerations will play as little a role as possible in increasing access to medicines. Long-term, as current access-to-medicines projects gradually become profitable, firms currently separating core business and access-to-medicines projects may reevaluate the role that bottom-line profitability should play, especially if it would result in increased access-to-medicines activity. For now, separating (as opposed to incorporating) these competing interests provides stability, even if it reduces the potential for greater access-to-medicines investment by not treating it as a long-term investment in the core business of pharmaceutical firms.
- Perception of self-interest: although incorporating access-to-medicines into a firm's core business plan strengthens incentives for increasing access to medicines, this alignment may fail to give competing priorities their due consideration. Projects designed to increase infrastructure or to develop new drugs for neglected diseases may no longer appear benevolent; rather, they become a form of market manipulation and development. Preferential pricing, if implemented for business reasons, could be undermined by firms deciding to prematurely raise prices to generate potentially higher returns, which may impair access to medicines. Keeping access-to-medicines a philanthropic activity (though perhaps with long-term strategic benefits) reduces these concerns. Although

¹⁴ PricewaterhouseCoopers, *Pharma 2020: The Vision 1* (2007).

access-to-medicines activity has shifted from the crisis management of the late 1990s to pragmatic solutions-based action over the past decade, many firms are very hesitant to pollute their access-to-medicines programs with hints of self-interest.

- **Undermining current relationships:** Trust and goodwill between firms, NGOs, and governments are often necessary for access-to-medicines projects to be effective. Given how painstakingly the current levels of trust and goodwill have been built up over the past decade, contaminating these projects with self-interested business considerations may cast a pall not only over the projects themselves, but also over current relationships between pharmaceutical firms, government health care ministries, and NGOs.

C. ADVANTAGES OF A COHESIVE APPROACH TO ACCESS-TO-MEDICINES

Although there is little consensus in the latest trends of specific access-to-medicines strategies, all firms emphasized the need to develop a cohesive internal vision for access-to-medicines initiatives. The Guiding Principles on Business and Human Rights, with emphasis on human rights due diligence in identifying, preventing, and mitigating adverse impacts, provide a baseline for developing such an approach. Adopting a cohesive approach may generate significant benefits within the firm and strengthen access-to-medicines activity in the following ways:

➤ Positive Impact on Business Identity

In many respects, “doing good” is good business for an industry in the business of improving and saving lives. Firms willing to strategically apply their resources to tackle human rights challenges and save lives across the globe are more likely to foster positive, dynamic business environments. Internally, employees are likely to be more motivated and more creative when their work has a positive impact beyond the traditional short-term business considerations. A positive business identity will also assist in attracting the best and brightest employees.

Although taking action to increase access to medicines may generate some positive outside perception, pharmaceutical product differentiation limits the potential for the development of an “access-friendly” market for drugs. The majority of benefits arising from an access-friendly, positive business identity do not come externally, but usually are generated internally when a company incorporates its human rights and access-to-medicines action into its business identity. This particular alignment of potential benefits helps reduce motivation for engaging in the pharmaceutical equivalent of “greenwash.” The strongest benefits occur when overall respect and support for human rights and achieving results in increasing access to medicines are incorporated into a company’s DNA.

➤ Consistency Between Message and Action

Communicating substantive access-to-medicines accomplishments may effectively respond to criticism that industry is part of the access-to-medicines problem and not part of the solution.

Inconsistency between a company's access-to-medicines message and its actual activity, however, risks increasing the perception that industry is in fact part of the problem. A cohesive strategy to achieve increases in access to medicines is more likely to focus on opportunities to act, instead of articulating reasons to not act. For example, citing a lack of infrastructure as the primary barrier to access to medicines does not generate any potential for a positive solution. By comparison, acting to improve infrastructure through direct or indirect means (and communicating this action) actually targets a solution and harmonizes with the firm's message of being access-friendly. With a large-picture approach towards developing a cohesive portfolio of access-to-medicines initiatives, a firm can more effectively tailor its message to its substantive action, and vice versa.

Coherent and consistent communications regarding access-to-medicines achievements also enables a company's ability to engage external and internal shareholders. With accurately informed stakeholders, stakeholder feedback on access-to-medicines activity will help the company to make better choices and remain sensitive to perspectives that the company may not fully appreciate, particularly those in local communities where access-to-medicines projects are implemented. In turn, this increased dialogue may help the company to build trust and empathy while approaching complex right-to-health problems in a more effective, holistic manner.

➤ **Tailoring Action to Best Opportunities To Act**

A well thought out access-to-medicines strategy will aid a firm in discerning its best and most efficient opportunities to act. A company may find that it is most efficient for it to engage problems simply by doing what it does best (e.g., conducting HIV/AIDS research, educating health care personnel in chronic disease care, etc.) and applying those resources towards improving access to medicines. But where this practice would generate unproductive or redundant results, firms should consider next-best alternatives that offer an optimal balance of effectiveness in increasing access and retaining a strong link to a core competence of the company.¹⁵ For example, a firm that specializes in developing vaccines might find that other firms are collaborating comprehensively on a vaccine for malaria, and recognize that engaging in similar research would be redundant. Instead, its access-to-medicines resources might be better spent developing a vaccine for tuberculosis or training health care personnel in vaccine administration and policy. A cohesive access-to-medicines strategy clarifies this process. Although the possible permutations are endless, two such optimizations tend to recur:

- In an industry predicated on R&D, developing drugs, vaccines, and treatments that address neglected diseases is often within the core competency of a company, and often addresses a pressing need in increasing access to medicines. With no shortage of neglected diseases plaguing developing countries, a firm will almost always be able to conduct needed R&D, whether into HIV/AIDS, malaria, tuberculosis, or perhaps into relatively rarer diseases if other firms have preempted the more prevalent lines of research.

¹⁵ For example, the Global Business Coalition on HIV/AIDS, Tuberculosis and Malaria is a collaboration of approximately 200 companies. Many of the GBC's members are not necessarily active on the ground in fighting disease, but do contribute relevant know-how, technology, and resources within the GBC's network approach to confronting health challenges.

- When conducting R&D would unproductively duplicate other firms' efforts, or where drugs, vaccines, and treatments exist to address diseases in underserved areas, acting to improve health care infrastructure by leveraging the special knowledge and experience of ensuring a steady supply chain and administering patients may provide a greater benefit than additional R&D. For example, firms specializing in HIV/AIDS drug development and health care management have found that their experience treating HIV/AIDS often translates well to caring for other diseases requiring day-to-day lifestyle adjustments, such as diabetes or even preventing water-borne illnesses, which can require simple, daily prevention efforts. These diseases tend to pose remarkably high health risks because they receive only a fraction of the attention that HIV/AIDS, malaria, and tuberculosis do.

➤ **Ability to Identify Supplemental Low-Cost Options for Action**

A potentially vast array of resources is available within pharmaceutical companies to employ at little or no cost within their cohesive approaches to access-to-medicines. Simply by empowering capable parties to act who do not independently possess sufficient resources to increase access to medicines, a company may be able to make a strong contribution by employing dormant or little-used resources. Three such potential situations where a company may play an effective catalyst role are illustrated:

- Bright scientists motivated to address access to medicines exist in academia, public health institutions, private health practice, and other locations and professions. To the extent that a company has available equipment, laboratory space, or other resources particularly suited to an outside project, inviting outside scientists to work on site may, with proper communication and precautions, be a low cost way of contributing to increasing access to medicines simply by empowering capable individuals to act.
- Companies possess a wealth of IP rights. To the extent that a company can accurately foresee that certain IP will never generate significant revenue, it may not make sense to exclude outsiders from using it to address access-to-medicines. With proper communication and precautions, permission to use IP may be a low cost way of contributing to increasing access to medicines by empowering capable parties who do not possess sufficient resources to act independently. Constructing patent pools may provide a desirable amount of control over the use of a company's IP, while contributing IP to an independently managed patent pool may ensure similar oversight while decreasing possible perception of self-interest on the part of the donor company.
- Similarly, patented drugs frequently have little or no potential for generating revenue in developing countries where these drugs may nonetheless have potential for creating a significant beneficial impact. With proper communication and precautions regarding the strength of IP rights, limitations on uses of licensed IP, and distribution of any generated profits, granting voluntary licenses to local private or government pharmaceutical manufacturers may increase access to these drugs while lowering access-to-medicines spending and nearly eliminating perceptions of self-interest on the part of the licensor firm. In addition, cooperation with local manufacturers will help build health care infrastructure and capacity, giving governments in these countries the ability to play an increasingly autonomous role in realizing their obligations towards realizing the highest attainable standard of health.