Developing Strategies for Developing Countries

With the progress of HIV/AIDS treatment, the practice of making drugs available to developing countries has undergone a sea change. Anne V. Reeler and Joseph Saba review the lessons learned and propose a new model for doing business with these emerging economies.

**Prior to the HIV/AIDS epidemic, it was generally accepted that, because of their high prices and the lack of healthcare infrastructure, many high-tech patented drugs could not be made available in developing countries. High prices were justified because of the research costs involved and the need for return on investment; consequently, most of the pharmaceutical industry took a “one size fits all” approach and kept their drugs at the same price in all markets.**

This model has been challenged profoundly by HIV/AIDS. The research-based industry has undergone ten turbulent years of lawsuits, activism and international pressure to make life-saving drugs available at low cost in developing countries. Most, if not all, of the research-based industry has complied with these expectations for HIV/AIDS drugs.

There is now an expectation that drugs, whether for life-threatening conditions or for chronic diseases, should be available and accessible in emerging economies and developing countries. Improvements in the delivery mechanisms for the newer drugs have been so substantial that patients no longer require hospitalization but can take life-saving oral drugs at home. Many of these life-saving drugs, however, are still too expensive. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement initially established 20-year patents on pharmaceutical products, but a provision allowed emerging economies to produce (or threaten to produce) generic versions of patented drugs through compulsory licensing. Countries are supposed to seek approval from the patent holder, but this requirement can be waived in cases of national emergency or extreme urgency.1

Some governments have also used parallel importing, which means that governments are able to buy (generic) drugs from the cheapest source globally, but TRIPS does not address this.

**Emerging economies vs Big Pharma**

The real question for the research-based industry is what to do with emerging economies that may have some purchasing power but are unable to provide for the entire population. The track record is one of conflict and lawsuits. Both compulsory licensing and parallel imports have been used by governments of emerging economies. The Government of South Africa passed a law in 1997 to use both options and was sued by a group of pharma companies in 1998.2 The US was initially supportive of the lawsuit, but, under international pressure, later withdrew its support. After three years the companies gave up the lawsuit, having achieved nothing but a great deal of damage to their reputations.

Brazil is another example of an emerging economy where the government has fought, and won, the battle for generics. In 2001 the dispute was between the Brazilian and the US governments. The Government of Brazil used a Brazilian law that stipulates that all
foreign drug companies will lose patent rights in Brazil if they have not started local production of the drug within three years. The US government complained to the World Trade Organization and the case led to a vote in the UN Human Rights Commission. The Commission called on all nations to refrain from any measure that would limit access to medical technologies used for pandemics such as HIV/AIDS. The US government later withdrew the case. Earlier this year Thailand announced that it was going to issue compulsory licensing for a number of antiretrovirals, including Abbott’s Kaletra, as well as for products such as blood thinning drugs. Abbott threatened to withdraw all products from the Thai market but the World Health Organization intervened; as a result, the list price of Kaletra was reduced to $1000 (less than the cost of the generic version) per year, compared to $2200 before the intervention. Again, the research-based industry lost the battle. The other noteworthy aspect of this case is that the threat of compulsory licensing is no longer limited to HIV-related drugs but is now spilling over into other therapeutic areas.

Governments are morally obliged to provide drug access for the whole population, particularly when the drugs are life-saving. What happens when a substantial proportion of the population, those that lie between the very poor and the very rich, have no access to a life-saving drug and a company refuses to lower the price? The gap will be filled, often by the generics industry (Figure 1); it may be addressed through compulsory licensing (as seen in the cases of Thailand and Brazil), or there will be an interpretation of patent rights that allows for generic competition, as is the case with Novartis in India. While governments may also have local trade reasons for this licensing (they may, for example, wish to build their own drug industries), lack of access is clearly the driving factor. It is unlikely that pharma will ever win these battles with governments; companies may be handing over future markets to the generics industry.

**Not “business as usual”**

The examples above illustrate how difficult it has been for the research-based industry to do business in emerging economies. And yet this is where the future lies. Pharmaceutical markets in Europe and the US have limited growth potential because of government ceilings on health expenditure. Future market growth will be in Asia and Latin America, where purchasing power and populations are growing.

However, it cannot be business as usual in these emerging markets. Most pharma companies have traditionally refused to lower their (list) prices, but some have given donations to these countries. There remains a large middle segment of these populations that cannot afford full price, that is not covered by social reimbursement and that is not poor enough to qualify for humanitarian donations. This ‘middle ground’ vacuum is a potential customer base that is capable of generating relevant sales — but not at the full price (Figure 1).

So what can companies do in emerging markets? First of all, there is a need to build relationships with governments and try to understand some of the public health issues that governments face in these growing populations. There are healthcare infrastructure issues and difficulties in reaching rural and poor patients. Companies should be seen as partners in addressing the needs of such patients, rather than as “the enemy.” Secondly, most will remember the old common sense principle of charging what the market can bear. Using a differentiated set of prices based on different income levels within each market is a well-known principle in other industries, so why not use it in the pharmaceutical

**Figure 1: Accessibility of life saving drugs based on price–volume ratio.**

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**Figure 2: Model showing number of patients accessing a given drug at different price levels.**

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industry? There is no doubt that companies would reach a much larger volume of customers in emerging markets by identifying creative access strategies such as this.

Engaging governments in a dialogue around specific diseases is key in developing countries. Companies should reach out to key opinion leaders in governments and in academia and work with them to raise awareness amongst healthcare providers and the public about a given disease. In parallel, it is critical to segment the market and determine appropriate cost levels based on affordability as well as the coverage of third party payers, such as social security and private health insurances.

In short, pharma companies cannot conduct “business as usual” in emerging economies — they should consider taking a new approach that combines public health concerns, relationship building with governments and creative commercial strategies that make their products available to different segments of the population according to affordability. It would be useful to use the lessons from the HIV years, and create a win/win situation for governments, patients and companies.

Notes
1. In December 2005, members of the World Trade Organization (WTO) approved measures to make it easier for poorer countries to obtain cheaper generic versions of patented medicines. The decision transformed the 30 August 2003 ‘waiver’ into a permanent amendment of the WTO Agreement on TRIPS. The waiver sets aside a provision of the TRIPS Agreement that could hinder exports of pharmaceuticals manufactured under compulsory licences to countries that are unable to produce them.

THE THREE-STEP APPROACH

Building a strategy for doing business with developing countries, using an evidence-based market segmentation that takes into account patient income and purchasing power, requires a validated three-step approach.

First, the application of an affordability model that uses a unique mixture of statistical methods, income data, disease epidemiology, public health principles and in-depth knowledge of health infrastructure barriers to calculate what proportion of the population would be able to access a given drug at various price levels. The shape of the price/volume or cost/volume curve varies greatly based on country income and purchasing power. Figure 2 shows the percentage of the population that is able to afford a certain price/cost level in three countries with different levels of income.

The second step is to determine the strategies and operations to implement the approach. For instance, if a drug will be made available to three different income groups of patients at three different levels of cost to the patient, there needs to be a strategy of price discounting or non-price discounting that allows all patients of the population to access the drug. This approach is easier than it appears as public health organizations are used to segmenting populations for the delivery of public health interventions. Strategic considerations include keeping the list price, how to determine income levels of patients and how to operationalize this assessment, how to involve an existing distributor networks, customs and tax considerations and so on.

The third step consists of reaching out to the government and key stakeholders in the countries. The reduction in cost to the end-user should be used to build a closer relationship with the governments and key opinion leaders and to become a partner in providing access to patients in a given disease area. Such activities may include raising public awareness or training health professionals. It may also result in collaborations with the government on how and under which circumstances a given drug can be accepted for the national reimbursement list.

The picture may be different in each country but the three steps in the strategy are applicable to most developing countries.

About the Authors

Dr Anne Reeler is a medical anthropologist with 20 years’ experience in design and implementation of programmes to improve access to drugs and health care in developing countries. Her experience spans different organizations including the World Health Organization, UNAIDS, The Economic and Social Commission for Asia and the Pacific as well as research projects in the field. She is a co-founder and chief technical officer of Axios International (France).

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