The Challenges of Providing Affordable Healthcare in Emerging Markets – The Case of Brazil

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Emerging markets are in the midst of implementing major healthcare reforms. These reforms, however, are much more challenging than in industrialized countries, due to the profound social inequalities common in these markets. Brazil, for example, with one of the highest levels of income inequality in the world, has experimented with a wide range of initiatives to make healthcare more affordable, including the increasing use of generic drugs. This study will discuss the patent/generics debate and how multinational pharmaceutical companies rely on emerging markets to provide a soft lending from the inevitable patent expiration of many of their blockbuster drugs.

INTRODUCTION

Can Emerging Markets Provide a Soft Landing?

As the pharmaceutical industry considers how to find a soft lending from the inevitable patent expiration cliff, there is a main hope: emerging markets. Emerging markets are considered to be the main hope of major pharmaceutical companies as a large number of their most important medicines lost market exclusivity without enough products in the pipeline to replace them.

Roughly 80% of the world's population live in emerging markets and many of them are not treated today, or at least are not receiving the healthcare they need.

Growth in China, India, Brazil and other developing economies would revive the industry, as rising living standards, ageing population and increased incidence of diseases such as cancer and diabetes are fueling higher healthcare spending. China alone is forecast to provide more than a third of global growth in pharmaceutical spending between 2012 and 2019, as Beijing aims for universal health insurance coverage by 2018 (Financial Times, December 2015). This would increase China's share of global sales from 8 to 15 percent over the same period, surpassing the top five European markets combined, according to the IMS Institute for Healthcare Informatics. To some extent, this new world has begun to materialize. Take Sanofi, France's biggest drug maker, for example, which has increased revenues from emerging markets by a fifth since 2010, even as revenues from the developed world have stalled. Emerging markets accounted for a third of sales in 2010 – well ahead of the U.S. and Europe as Sanofi's biggest geographic division. Others, including Bayer of Germany and GlaxoSmithKline of the U.K., have been making similar strides in Asia, the Middle East, Africa and Latin America (Financial Times, October 2014).

Yet the general upward trend masks pockets of volatility, as drugmakers grapple with local healthcare and regulatory systems that vary widely in their structure and maturity. GlaxoSmithKline $350,000 fine from Chinese authorities in September 2013 for "massive and systemic" bribery of doctors to boost sales highlighted the potential pitfalls in chasing rapid growth in unfamiliar and often opaque markets (Financial Times, December 2015).

In India, meanwhile, multinational pharmaceutical companies have been waging a running battle over intellectual property, as regulators have opened some patent-protected medicines to low-cost generic production by local manufacturers such as Cipla and Sun Pharma. Novartis, the Swiss multinational pharmaceutical company, saw its best-selling drug, Glivec for leukemia, denied patent protection by the Indian Supreme Court last year. Health activists have welcomed such rulings as a step towards more affordable access to medicines. Some industry leaders, however, accuse India of using public health as a pretext for giving domestic drugmakers a free ride on western innovation. Should other emerging markets take a similar stance, the intellectual framework underpinning the pharmaceutical industry would be in jeopardy and the risk for western drugmakers will be that the developing world will gradually begin to look more like a threat than an opportunity and the hope for the soft lending from the edge of the patent cliff will vanish (Financial Times, October 2014).

THE PHARMACEUTICAL INDUSTRY AND THE PATENT SYSTEM

The pharmaceutical industry views the patent system as essential to its business model. Under the basic concept of this patent system, an inventor is entitled to a limited monopoly for a period of time, typically twenty years. Such exclusivity permits high prices during the patent term and the consequent profit incentives provide the basis for the pharmaceutical industry to invest in the very costly development process that is necessary to bring new medicines to market. When a patent expires, the price normally falls as generic competitors enter the market.

Many emerging market countries, however, view patent law quite differently and deliberately decided to deny patent protection to pharmaceutical products. These countries believe that access to pharmaceutical products is so important that they should not be patented. In its 1970 patent law, for example, India excluded medicines from patent protection and chose to provide low-cost drugs for its people at the expense of eliminating incentives to create new products. This law was one of the reasons that the Indian generic drug industry was able to evolve to make and market copies of drugs still on patent in wealthier countries. India has become a major international supplier of drugs to countries where these products can be marketed legally because they have not been patented locally (The Economist, November 2014).

Also, a number of countries had "compulsory licensing" provisions. Compulsory licensing is a TRIPS (Trade Related Aspects of Intellectual Property Rights) flexibility that defines a legal process under which governments can authorize use of a patented technology even over the patent holder's objection. In practice, however, compulsory licensing has rarely been formally granted; rather, governments have used the threat of granting a compulsory license as a way to negotiate lower prices for the drugs (Bird, R. C. (2014).

Brazilian Government and Compulsory Licenses

In October 1999 Brazil issued a presidential decree that allowed compulsory licensing during national emergency situations, such as the AIDS epidemic. In February 2007, former Brazilian president Luiz Inacio Lula da Silva issued a "compulsory license" that bypasses the patent of the HIV drug Sustiva (efavirenz), which is marketed by Merck & Co. as Stocrin in developing countries. His decision came a day after the Brazilian government rejected Merck's offer to sell the drug at a 30% discount, or $1.10 per pill, the same price Thailand pays for Sustiva (de Mello e Souza, A., 2008).

The compulsory license allowed Brazil to manufacture or buy generic versions of sustiva, effectively overturning its patent protection. It is estimated that the country saved $30 million in 2007 alone by

purchasing generic efavirenz and would cut $237 million from its HIV/AIDS drug bill through 2016, when the patent right would expire (de Mello e Souza, A., 2008).

The WTO and Compulsory Licenses

Under the TRIPS agreement countries belonging to the World Trade Organization (WTO) must grant exclusive patent rights on medicines, but also retain the rights to grant compulsory licenses that legally authorize the production of lower-cost, generic versions of patented drugs in exchange for royalties. Breaking the monopoly of patent-holders is only allowed, within limits, when a country faces an emergency health issue, such as an HIV epidemic. TRIPS also states that products made under compulsory licenses must be "predominantly" for the supply of the domestic market, which limits the quantity of generic medicines that can be exported between WTO member countries. However, in December 2005, the WTO amended its intellectual property rules to permit countries that lack a strong pharmaceutical industry to import generic medications for HIV and other high-priority communicable diseases from countries that produce them under compulsory license, like Brazil for example (de Mello e Souza, A., 2008).

In recent years, Brazil has repeatedly managed to get steep price reductions on drugs from multinational pharmaceutical companies by threatening to break patents, although 2007 marks the first time that the country actually broke such a patent. In July 2005, Abbott agreed to keep the price of Kalestra (lopinavir/ritonavir), a top-selling protease inhibitor (PI), at current levels for the next six years in return for Brazil not to break Abbott's patent. However, the Brazilian Health Minister dismissed the agreement and said the country would continue to negotiate for a lower price or country manufacturers would break Kalestra's patent and sell the drug for a highly reduced price (Bird, R. C. 2010).

Finally, an agreement was reached in October 2005 with Abbott lowering the price in order to protect the drug's patent. Brazil is in continuous talks with the drug companies that manufacture nine of the 17 antiretroviral drugs used in the country free treatment program, while the other eight are already produced in local laboratories and are not patented. It is evident that pharmaceutical companies prefer to lower their prices in order to retain control over the Brazilian market rather than lose it completely.

Brazilian Domestic Companies Lack the Skills …

A fact that cannot be overlooked is that Brazilian domestic companies and public laboratories still lack the skills, technology and research capacity of multinational pharmaceuticals companies (MPCs). For example, Far-Manguinhos, a public laboratory, has been instrumental in developing the government's AIDS programs. It has not only produced cheap anti-retroviral drugs (ARVs), but has also helped to contribute to local knowledge by using reverse engineering techniques to produce versions of ARVs not protected under TRIPS. However, this industrialization process has reached "a major stumbling block" because the number of domestic firms that are able to receive and implement the technologies is limited (Cassier & Correa, 2012). Furthermore, there will always be a need for new AIDS drugs that generic manufacturers are unable to produce, because patients develop immunity and treatment regimens need adjustment (Shadlen, M., 2013).

THE BRAZILIAN PHARMACEUTICAL MARKET

Besides attracting foreign investment from several sectors, Brazil's 200 million plus population presents very attractive prospects for pharmaceutical companies from all over the world. The Brazilian pharmaceutical industry, comprised of 270 companies, is the eighth largest pharmaceutical market in the world and the largest market in Latin America. In 2016, the Brazilian pharmaceutical market is estimated to reach US$ 25.1 billion, 35 percent of Latin America sales. The health sector as a whole represents 9 percent of the Brazilian GDP and employs directly 47,000 people (IMS Health, 2014). Government purchases represent 50 percent of the market for medical equipment, more than 90 percent of the vaccines and 25 percent of all drugs, according to the Brazilian Ministry of Health. Total sales of drugs since 1975 have been increasing on average 14 percent a year in Brazil – the annual growth rate in the U.S. was only

9 percent during the same period. Demand for pharmaceutical products will increase still further when the government makes good on campaign promises to provide medical treatment for free and easily available to more people through medical posts, health units, and health centers in rural areas (Frost & Sullivan, 2013).

Nearly 20 percent of the companies operating in the Brazilian market are foreign, accounting for approximately 75% of all pharmaceutical sales. So, foreign firms have a rather large chunk of the market even though foreign investment in the drug industry accounts for only 4% of all foreign investment in Brazil. Most of the international firms are from the U.S. and Europe, with the majority of the world's largest pharmaceutical companies being represented. Foreign companies account for approximately 75 percent of the internal market. Major local manufacturers are also well represented in the Brazilian pharmaceutical market (Frost & Sullivan, 2013).

The Public Healthcare Services and the Private Sector

Public healthcare services, in conjunction with the private sector, work under contract with the government and it is estimated that healthcare coverage is now about 75 percent. Much of the work being carried out by the current government to improve healthcare services is focusing on the poorest sections of the population in areas such as combating vitamin deficiencies and reducing child mortality rates (IMS, 2013).

Over 75 percent of the financing for the public sector comes from the Brazilian treasury, with the remainder provided by the states and municipality, in other words, much of the healthcare burden rests on the public sector.

THE CHALLENGES OF PROVIDING AFFORDABLE HEALTH CARE IN BRAZIL

Brazil's size as a country makes the provision of affordable healthcare for all citizens a difficult commitment for the government to fulfill. Despite its classification as the 7th richest country in the world in terms of nominal Gross Domestic Product, (World Bank 2013) Brazil has been described as a country that exhibits profound social inequalities. According to figures from the UK's Department for International Development Health Resource Center, across Brazil there is a 63.4 percent degree of income inequality (Amon, P., 2014). The scale of the difference is highlighted by the fact that the median income of the wealthiest 10 percent of the Brazilian population remains 30 times greater than that of the poorest 40 percent (Amon, P., 2014).

Resolving these inequalities is made more difficult by the fact that the population is growing and ageing rapidly. According to the Population Division of the Department of Economic and Social Affairs of the United Nations, between 1950 and 2010, the Brazilian population grew from 54 million to 188 million (Amon, P., 2014). Despite an expected overall slowing down of the population growth rate after 2013, by 2050 the Brazilian population could be as high as 253 million. Furthermore, while those aged 65 and over represented only three percent of the population in 1950, they will represent nearly a fifth by 2050 (Amon, P., 2015).

This population growth is unprecedented and, consequently, the majority of the people does not have the healthcare with the quality they need. In the last decade or two, a large number of Brazilians is moving out or poverty and entering the market for consumer goods such as apparel, appliances, automobiles, etc., and, of course, healthcare. The private sector can handle the 10 percent of the population that already treats healthcare as another consumer good but cannot make a dent in the influx of poor people that does not treat healthcare as a consumer good but as a public good (Financial Times, October 2014).

The provider of public goods such as healthcare is the government but in the case of Brazil, with its growing and ageing population, the government can no longer afford to pay the high prices of patented medicines and has decided that the best way to alleviate the healthcare burden is through the use of generic drugs.

Generics Law

Possibly the greatest impact on the local pharmaceutical industry was the introduction of the Generics Law in 1999. The regulations in the law aimed to control the implementation of the Generics Law by establishing technical standards and norms, defining concepts of bioavailability and bioequivalence, setting the criteria for licensing aimed to increase competition and variety in the supply of medicines in the market, to improve the quality of all medicines, to reduce prices, and to improve access of the population to treatments.

The law created a new category of drugs (generics) where previously there had been only similar and originator products. Drugs classified as generics are defined as those that are interchangeable with the reference medicine or innovator product; that is, they prove "bioequivalence" (the demonstration of identical composition of active ingredients, pharmaceutical dose and form) and have comparable "bioavailability" (the degree or rate at which a drug is absorbed or becomes available at the site of physiological activity after administration) when studied under the same experimental design (Elias P. & Cohn, A, 2010). Generics can be produced only once a patent has expired or a waiver of a patent has been granted, and must comply with safety, efficacy and quality tests according to Brazilian Non-Proprietary Name standards. The generic option provides a generally cheaper – between 40-45% lower than the original product and better quality option to the consumer, due to the long-term existence in the market, and their well-known brand names (Chetley, R., 2014).

The Generics Law and Multinational Pharmaceutical Companies

While multinational pharmaceutical companies benefited from the introduction of the patent law, they suffered greatly from the introduction of the Generics Law. According to IMS information, some MNC pharma companies experienced up to an 80% loss in revenues because of the introduction of the Generics Law. As a result, many began to shift their business strategies and began to sell off old off-patented product lines and to focus primarily on innovative-patented products (Grabowski, H., 2011).

Brazilian companies, on the other hand, benefited greatly from this new market in part because they were prepared for the transition to the new IP regime and the introduction to generics due to the drawn out debates in Congress over these issues. The law benefited many small local companies who were able to produce drugs cheaper and take advantage of their good relations with distributors and pharmacists as well as large sales force. As a government spokesperson noted, the generics law benefited the smaller labs, many of which are Brazilian; they now were able to produce these drugs at a much lower cost. In fact, he states, "we now have a group of cheaper drugs that have the same quality and efficacy as the much more expensive branded drugs. This has cut into the sales of the multinational pharmaceutical companies, and that's why they resist accepting the generics" (Grabowski, H. 2011, p. 8).

Furthermore, some national privately owned companies indicated that, due to the new IP legislation, the opening up of the economy, and the health regulations, they were diversifying their business strategies; increasing exports to Latin America, the United States and Europe; investing in types of R&D, including into new molecules, delivery systems, formulations, and indications; and diversifying from similar into generics production (Grabowski, H. 2011).

According to the president of the Brazilian Generic Drugs Industry Association, Odnir Finotti, "The strong growth of generic drugs in Brazil (and globally) is due to the combination of equal quality products with prices around 50% lower than brand products" (The Economist, May 2012, p. 15).

The good news, Finotti added, is that Brazil's market still has plenty of space to develop. The current expiration of patents, for example, could boost the development of new generic drugs. Another reason for Brazil significant generic-drug growth may be the global economic crisis that began in 2008. "During times of insecurity, patients search for lower-priced drugs to continue their treatments or even start a treatment that otherwise would not be started if generics were not available," concluded Finotti (The Economist, May 12, p. 16).

In Brazil, patent expiration could lead to the transfer of approximately $444 million to the generic-drug market between 2011 and 2017 according to São Paulo based Pró Genéricos, whose members

include large generic-drug laboratories operating in Brazil. The association aims to help increase access to generic drugs by promoting the expansion and consolidation of the market in the country.

Brazilian law requires that the price of generic drugs be at least 35% lower than brand-name drugs and that public health care professionals prescribe solely generic drugs to patients, considering the limited income of most Brazilians (IMS Health, 2012).

The market share of generic drugs in Brazil corresponds to nearly 20% of the country's total domestic sales of drugs in units. In European countries the national market share of generic drugs varies from 35% to 60%. In the U.S., a 20-year old consolidated market, share in volumes is currently around 60%, according to IMS health. In the U.S., generic drugs are discounted as much as 8% compared with branded drugs (IMS Health, 2013).

Association data show that around 25 blockbuster-drug patents will expire by the end of 2016, leading to optimistic generic-drug industry projections. It is estimated that market-share growth in units for 2017 will grow at more than 20% based on the production of new generic drugs following innovator-drug patent expirations. Trade officials expect generic drugs to account for more than 22% of Brazil's overall market share by 2018 (IMS Health 2013). In this case, the country could become one of the largest generic-drug markets in the world.

Pharmaceutical Promotion

The pharmaceutical industry is motivated by profit and it is the quest for ever larger sales and profits that determine how the industry promotes its products in most countries, especially in developing and emerging markets. Physicians and consumers are strongly influenced by pharmaceutical promotion, with all too predictable results: doctors prescribe irrationally and consumers develop grossly distorted ideas about the value of modern medications. We would not be realistic if we were to say that MNCs are operating in the developing and emerging markets primarily for the welfare of those countries – they are not missionaries, they are businessmen (Melrose, 2015). In China, for example, poorly paid doctors can still top up their salaries by taking bribes from drug companies or receiving payments for speaking on their behalf at promotional events. A Shanghai doctor can double his monthly salary by accepting two or three speaking engagements, according to the compliance officer of one western pharmaceutical group (Financial Times, December 2015).

The international Federation of Pharmaceutical Manufacturers Associations (IFPMA) claims that information from the industry "provides prompt, detailed and accurate information for the benefit of both doctor and patient" (Chetley, R., 2014, p. 70). Benefits may sometimes indeed occur to doctors and patients, but if so they are distinctly secondary outcomes. Far too often, the only benefits from advertising go to the drug companies. The main reason for advertising is to increase sales and profits and to achieve these objectives the truth might have to be bent or broken. As a former Abbott medical director pointed out: "The incidence of disease cannot be manipulated and so increased sales volumes must depend, at least in part, on the use of drugs unrelated to their real utility or need" (Chetley, R., 2014, p. 90).

Cost Breakdown for Advertising Costs

Expenses for advertising and promotion in emerging markets generally account for between 20 to 30% of sales. Yudkin, R., (2013) estimated that pharmaceutical companies were spending twice as much per doctor on promotion in Brazil and other emerging markets as they spend in Britain. About half the money spent on promotion goes toward salaries and other expenses associated with the companies' detailers or sales representatives. These are the men and women who are paid to travel from office to office promoting their companies' products. Whereas in the west there is about one detailer to every 10 or 20 doctors, in emerging markets the ratio is usually 1:5. Early in 2011 a Brazilian senator, who was also a physician, found that he was visited on 18 out of 21 working days by a total of 69 detailers. They left him a total of 452 free samples of drugs and 25 gifts (Ledogar, A., 2013).

The IFPMA maintains that detailers play "an essential role in linking the research laboratory with the physician" (Health Horizons, 2005). THE IFPMA Code of Pharmaceutical Marketing Practices states that these people "must be adequately trained and possess sufficient medical and technical knowledge to

present information on their company's products in an accurate and responsible manner" (International Federation of Pharmaceutical Manufacturers Association, 2009, p.6). However, doctors, and their patients, would probably be better off if the detailers paid them fewer visits. Often detailers are poorly trained and ill-informed. A Brazilian detailer worked in the mornings as a clerk for his country medical association and in the afternoons as a detailer for one German and one American pharmaceutical company. He had no medical or pharmacology training and felt that his job was to promote the products as "the best" without having any idea of their real usefulness (Melrose, K., 2015).

Detailers are often only concerned with selling their products. In Salvador, Brazil, a Hoechst detailer was observed trying to persuade a doctor that Lasix (furosemide) was a good drug to use for children who had kwashiorkor or marasmus. These are diseases that result from severe protein deficiency and one of their manifestations is edema or swelling throughout the body. Lasix which is a diuretic or "water pill" is used to eliminate excess fluid in the body. When it was pointed out to the detailer that the swelling might go down if Lasix was used but the child would be killed, the detailer responded "Well, the child is going to die anyway" (Muller, K., 2012, p. 21).

As in every country, printed promotional material is also heavily used in Brazil. During a six-month period in 2011 all advertisements delivered to four internists in the city of Pelotas, Brazil, were collected and examined. There were over 350 pieces ranging from full reports of clinical trials to unsubstantiated claims without any references. Many of the pieces employed faulty experimental design, analysis and presentation of results in order to impress upon doctors the quality of the drugs being advertised. And many health care providers, busy with large number of patients, rely, almost exclusively, on promotional material to keep up with new developments in their field (Victoria, G., 2012).

Detailing, sampling and the provision of printed material are not the only methods of promotion: doctors are literally wined and dined and "gifted." In major areas such as São Paulo, Rio de Janeiro and Brasilia, doctors are entertained lavishly at famous hotels and restaurants and invited for free weekends in well-known resorts. Pharmacists, hospitals and doctors are rewarded by multinationals with gifts like televisions, video cassettes, nursery room equipment, air conditioners, office furniture and many others (Chetley, R., 2011; Muller, K., 2014). In March 2012, one multinational firm organized symposia in major Brazilian cities to celebrate twenty years of its antimicrobial drug. These venues were five star hotels and doctors were treated to sumptuous meals (Tan and Tanchoco, 2013). However, it is not only the multinational companies that are guilty of such sumptuous spending; domestic companies are known for giving expensive gifts like cars and refrigerators to class A doctors who have what is known in the trade as a "prescription following" (Melrose, K., 2015).

Promoting Medicines to the Consumer

Drug promotion in developing and emerging markets such as Brazil is not confined to only health professionals; consumers are also heavily targeted. A former president of the Brazilian Association of Pharmaceutical Companies (ABIFARMA) estimates that advertising expenses for over-the-counter drugs may reach 40 percent of the drugs' cost (Health Action Information Network, 2011). Mass media promotion in Brazil in April 2010 alone came to about $3 million while ads for medicines and other health products account for about 10 percent of total revenues in the Brazilian print media (Tan, M., L. 2012).

Consumers in Brazil and other emerging market countries are the victims of aggressive advertising to induce consumption and self-medication. Drugs are promoted as a way of obtaining happiness, with television ads making the response to drugs appear instantaneous and magical. At health and beauty fairs the public is given free samples and literature normally reserved for doctors (Greenhalgh, T. 2012). One particular popular radio station in São Paulo pours out a stream of pharmaceutical commercials that are heard all over Brazil (Haak, H., 2012). One Latin American "drug promotion expert" saw discrepancies in the information that companies supply in different countries as part of normal business practices: "if your competitor claims five indications for his product, you claim at least six. And if he discloses three adverse reactions, you are senseless if you disclose more than two" (Melrose, K., 2015, p. 73). One of the

pharmaceutical executives that Braithwaite (2011, pp. 25-6) interviewed for his book, *Corporate Crime in the Pharmaceutical Industry,* argued along similar lines:

In countries like Brazil our product has to compete with 20 pirate competitors. Now these people promote the product for every infection imaginable. They therefore get better sales than we who developed the product … Of course our Brazilian manager then wants us to expand the indications too.

Evidence indicates that like physicians in emerging market countries, doctors in other countries also rely heavily on the drug companies for their information (Lexchin, J., 2012). A study in Brazil concluded that the main sources of information of the medical profession are directly or indirectly linked to the promotional activities of private companies (United Nations Centre on Transnational Corporations, 2012).

The WHO's Ethical and Scientific Criteria for Pharmaceutical Advertising

Although The World Health Organization (WHO) established the "Ethical and Scientific Criteria for Pharmaceutical Advertising" in 1968, the work of people like Ledogar (1975) in the mid-1970s made it clear that there was one set of promotional standards for the developed world and a different set for the other countries. Consequently, the 1980 World Health Assembly (WHA) decided to authorize the development of a code of pharmaceutical marketing practices that could be used in every country. Finally a revised "Ethical Criteria for Medicinal Drug Promotion" was approved by the 44th WHA in 1995. The revised ethical criteria constitutes of general principles for ethical standards in drug promotion and advertising, regarding medical representatives, free samples, symposia, post-marketing studies, packaging and labeling and information for patients. Of particular note is the additional suggestion that countries without a well-developed regulatory agency that approves labeling should be provided with "information consistent with that approved by the drug regulatory authority of the country from which the drug is imported or other reliable sources of information with similar content" (World Health Organization, 1995). However, the revised criteria are general principles only and have no legal force – there were no provisions for either monitoring compliance with the code of enforcement of its provisions (Ledogar, A., 2010). The code, to begin with, is only applied after the ads have appeared. There is no requirement for pre-clearance of ads before they are used. Regulatory agencies in Latin America have filed over 500 complaints of violations of the code. Even when the complaint was upheld, there was such a long delay that the offending companies may have been able to complete the advertising runs as planned before the ads were withdrawn (Muller, K., 2012).

Dispensing of Drugs in Brazil

Another idiosyncrasy in the Brazilian and Latin American pharmaceutical market is that prior to 1978, most all drugs, except controlled substance, could be purchased over the counter. . For customers who did not know which drug would be most effective for their illness the pharmacist would make his or her recommendation and sell the medicine. In reality the pharmacist was the health care provider to families who either did not have health insurance or could not afford a visit to a medical doctor. The most popular pharmacists had a good number of loyal customers who considered them even better than medical doctors and usually spread the word among their relatives and friends. Some pharmacists became so busy that they would only "consult" during certain hours of the day. In 1978 a law was passed that established a prescription only category of drugs but the pharmacists continued prescribing medicines to their "patients," including antibiotics (Nascimento, A., 2012).

Cross-Sectional Study of 166 Pharmacists in Santa Catarina, Brazil

The way antibiotics are prescribed and dispensed in Brazil reveals another interesting idiosyncrasy of that market. Antibiotics are drugs widely used in prophylaxis and treatment of a great number of diseases. However, their use must be carefully controlled, as acquisition in pharmacies, often without medical prescription, is elevated. Rauber et al. conducted a cross-sectional study of 166 pharmacists in October 2013, in the State of Santa Catarina, Brazil. While 15 percent of the respondents replied that antibiotics dispensation only occurred under medical prescription, a relatively large number of pharmacists (85 percent) said they dispensed them without prescription. Among the diseases for which the pharmacists

said they oversaw sales of antibiotics without medical prescription were throat infection (29 percent), urinary tract infection (12 percent), ear infection (11 percent) and sinusitis (8.4 percent). The responses indicate that the respondents' main symptoms indicating antibiotics were: high fever (23.6 percent), formation of throat plaques (16.2 percent), presence of pus (7.5 percent) and sore throat (6.4 percent), among others. Further results showed that the three antibiotics most frequently sold in the dispensing pharmacies, without medical prescription, were amoxicillin, cephalexin and the combination of sulfamethoxazole with trimetropine (Martins & Martins 2014).

The large number of interviewees (pharmacists) who reported dispensing antibiotics without medical prescription is of particular concern. According to author (Nascimento-Carvalho, 2014), this practice should be addressed, since the majority of acute respiratory infections are of viral etiology and therefore do not benefit from the use of antibiotics. According to the author, these drugs provide only slight benefits for acute otitis media in children, yet can significantly increase the occurrence of adverse effects associated with their use. The study also showed that pharmacists with a heavier workload, and those who underestimated the physicians' qualification to prescribe and overestimated their own qualifications, were the ones who most frequently dispensed medicines without medical prescriptions. In contrast, pharmacists who stressed the importance of their duty in rationalizing the consumption of drugs, required medical prescriptions more frequently.

If the desired outcome is to provide quality health care, pharmacists should bear in mind that the official recommendation concerning their role is to identify mild or moderate diseases, whose symptoms are self-limited and for which they can dispense medicines that do not require medical prescriptions, while advising the patient to consult a medical doctor if symptoms persist beyond a few days (World Health Organization, 2014).

CONCLUSION

Healthcare has become a top priority for the Brazilian and other emerging market governments as they seek to redress social inequality within the country. Funding ambitious health care programs represents a major challenge, however, owing to the demands of a large population and continuous economic uncertainty. As the cost of health care is rising, generics have been identified as a useful tool to expand health care coverage; as these products are cheaper than branded medicines, they allow the government to better allocate its limited resources to serve all the segments of the population.

The shift to generics creates opportunities for international companies that market such products, but also presents them with challenges, as the legislation concerning generic medicines is still evolving. There are likely to be developments in this area to tighten up legislation, however, and in many cases the requirements for bioequivalence will necessitate the running of additional clinical trials as proof of a product's suitability to be classified as generic.

The manufacturers of branded products are also carefully monitoring Brazil's healthcare situation, as the emphasis on essential medicines has seen the government begin to challenge their patents. The recent success of the Brazilian government in maintaining its strong stance with the industry over the pricing of AIDS treatment is likely to encourage it to take additional measures to make medicines affordable for other conditions as well. Thus, the affordability of a particular medicine will become a crucial factor for its success in the Brazilian market and, most probably, in most emerging markets as well.

Strengths of the Study

This study's focus on emerging markets seems to be very timely since close to 80 per cent of the world's population live in emerging markets (Financial Times, 2014), and, specifically, the focus on Brazil is important because of its rapidly developing economy, ageing population and social inequality makes it possible for valid findings to be used as a proxy in dealing with similar economies. Furthermore, given the current economic climate in most countries, and the concern of governments on being fiscally judicious on their expenditures to obtain the best possible public value, the study of the provision of

affordable healthcare stands to not only contribute to the literature, based on the significance of findings, but also contribute to the development of implementation frameworks and replicable best practices.

Suggestions for Further Research

This study could be greatly improved by conducting interviews with healthcare stakeholders such as medical doctors, pharmacists, insurance companies, hospitals and patients to determine, from their perspective, how efficient the present Brazilian healthcare system is and what their suggestions are for improvement.

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