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OVERCOMING CHALLENGES AND EXPANDING THE HEALTHCARE MARKET IN BRAZIL

by
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KANTAR HEALTH

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+ INTRODUCTION

Brazil is the second largest private healthcare market in the world, just behind the United States. More than 50 million people, or about 25% of the population, have a private health plan, according to the National Regulatory Agency for Private Health Insurance and Plans (*Agência Nacional de Saúde*, ANS). On the other hand, Brazil also offers free and open healthcare assistance for its entire population (Public Healthcare System or *Serviço Único de Saúde*, SUS) in addition to the private healthcare system. Fifty-four percent of healthcare spend comes from the private sector. At 46%, the proportion of government expenditure on health is much lower than other countries, such as the UK (83%), Canada (70%), and Argentina (61%).

The private healthcare system follows a strict law, supervised by ANS. Every two years, the agency issues minimum mandatory coverage lists that determine all of the procedures, medicines and technologies that must be covered by health plans so beneficiaries have access to the latest, top-of-the-line technologies.

ACCESSING HEALTH

Health is a major concern in Brazil and one of the biggest challenges for the government. When the Ministry of Health conducted a survey to certify the quality of the public healthcare system, the system received a mean rating of 5.5, on a scale of 0-10, by its users. Among the system's problems, users mentioned the delay in getting medical consultation, lack of equipment and specialized professionals, and lack of appropriate sites for performing certain procedures. All of these difficulties feed the demand for private health services.

Brazil has an agency to assess new technologies, CONITEC (National Commission on Technology Incorporation in the Public Healthcare System), which analyzes what will or will not be incorporated into the public healthcare system. The commission almost invariably has been slow to analyze new treatments. The root of this problem is that the government invests too little in health, less than 3.5% of the gross domestic product (GDP) – which is less than many neighboring countries – and there is no expectation of changing this scenario in the coming years.

PHARMACEUTICAL INDUSTRY: STILL GROWING

Despite the economic crisis that Brazil is currently experiencing, the domestic pharmaceutical market keeps growing and should be the fourth largest in the world by 2016. The sector registered a double-digit growth in the last five years, according to the Union of the Pharmaceuticals Industry of the State of São Paulo (Sindusfarma). In 2014, the sector's revenues were R$65.8 billion, a 13.3% increase over 2013. In the same period, sales in the generic industries were R$16.25 billion, a growth of 18.5% from 2013.

In the competition for the foreign market, Brazil still has a long way to go. Although the domestic market is valued at US$20 billion, exports account for only US$1.5 billion and place the country 27th in foreign trade. The total value of the German market, which leads in exports, surpasses US$60 billion, three times more than Brazil.

Generic drugs accounted for 23.7% of the revenues of the 10 largest pharmaceutical companies operating in Brazil, according to the survey of the Brazilian Association of Generic Drugs Industries (PróGenéricos), which examined market data between January

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2014 and January 2015. Generics and biosimilars lower cost by about 30% because some of the original drugs have very high costs. They offer an opportunity for the domestic industry to develop in an area where it is undeveloped: the production of medicines. If Brazil can achieve adequate production of biosimilars, it can open doors in other countries for exportation.

CHALLENGES OF CLINICAL RESEARCH

Clinical research is another area with huge growth potential in Brazil. Clinical research activities in Brazil are concentrated in Phase III studies, which are carried out in large and varied numbers of patients to determine the outcomes (risk and benefit) of the active principle of formulations in the short and long terms. According to the National Health Surveillance Agency (Anvisa), about 60% of clinical research in Brazil is in this category.

The development of clinical studies is directly related to the country's ability to produce and develop new drugs. In Brazil, 80% of clinical research studies for development of new drugs are conducted by multinational companies. In addition, only 4% of the total of these studies are dedicated to Phase I clinical trials, that is, those in which active principle of a new drug is first tested in humans.

But Brazil has much more to offer, especially in early development studies (Phase I and II) because it has extraordinary natural resources that could be used for the development of new drugs. Also, the huge variety of the population provides an excellent scenario for research.

One of the impediments to further developing clinical research in Brazil is the complexity and slowness of approval of clinical research. A clinical research project has must be approved by local institutional review boards (IRBs) and by National Health Council (Conep) and Anvisa, which can take more than a year. In the United States and Europe, this period takes two to three months.

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Q & A

Evidências-Kantar Health team members Otávio Clark, CEO and team leader; Valeria Clemente, market access and projects director; and Luiz Fernando Feijó, clinical research director, sat down to talk about the issues facing Brazil's pharmaceutical industry.

HOW ARE MARKET DYNAMICS SHAPING THE PHARMACEUTICAL INDUSTRY IN BRAZIL?

VC: Brazil has the second largest private healthcare market in world, behind only the United States, but access to healthcare in Brazil is slightly different. That's because our private health plans are not complementary to the public healthcare system (SUS), but supplementary. This means that the two systems have some points of intersection, things that both have in common, but they also have points that differ.

Brazil is very new to this part of public technology assessment, and our health agencies should be politically independent agencies. What I find necessary is that the technologies should be evaluated so we can know whether their incorporation is feasible, in both the public and the private healthcare systems. This would be ideal and effective. However, the scenarios are different, and the industries in the access area set up their structures so that they can finance their products.

OC: The big issue we have to think of is that we have a large private market that accounts for 25% of the population and have a public market that accounts for 75% of the population. The incorporation of new technologies in the public market has been difficult and slow, and this is mainly due to the lack of government budget to do so.

WHAT DO GLOBAL COMPANIES NEED TO DO TO TAP INTO THE BRAZILIAN MARKET?

VC: They need to have a partner, a local consultant who understands the country's rules and regulations and make this connection with the stakeholders. This partner must be ethical and trustworthy, so these companies can speed up the entry process in Brazil. Understanding the country's situation is essential to accelerating a company's activity curve.

LFF: Brazil is a very attractive location. We have over 205 million inhabitants and a huge genetic variety. So the supply of "human material" is fantastic. Also, we have top-notch professionals dealing with well-designed and competent research, and we have specialized centers. Despite all difficulties that we have at the moment, if some adjustments are made, we can expand quickly. Furthermore, companies that have an interest in Brazil must seek to know more about local settings and obstacles. Brazil has many particularities and peculiarities, so it is necessary that these companies look for a local partner who has understanding of the Brazilian situation and how things are conducted here, including legislation and regulations, so the researches can be well developed.

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THE MARKET HAS BEEN GROWING STRONGLY OVER THE PAST DECADE AND CONTINUES TO SHOW GROWTH. WHAT ARE THE MAJOR DRIVERS OF THIS GROWTH?

VC: Health has a great emotional appeal, and it is a basic need of every citizen. So, in addition to this fundamental context, awareness of health and treatment needs is the engine of this growth. I don't see that we can have great restrictions, even with Brazil's current situation. Somehow the industry is creative and can find strategies to meet this huge market's needs.

IN TERMS OF HEALTHCARE SPENDING, WHERE DOES BRAZIL FOCUS ITS INVESTMENTS, AND WHAT ARE THE GAPS?

VC: The largest investment in Brazil is done through the private healthcare system: approximately 50% of investment comes from this area, which comprises a quarter of the population. The government invests in programs for diseases with high prevalence, such as AIDS, hepatitis, diabetes and asthma.

But to invest in health the government should prioritize the niches in Brazil, which is in line with what the pharmaceutical companies want. The government can't provide even primary care for the population. We have a huge lack of equipment, specialized professionals and even adequate locations to perform some procedures. Another major problem is the lack of investment in medical education, with integrated and specialized training programs. It is necessary to have an intelligent management for Brazil's reality, to rank the needs and priorities, and to educate the health professionals.

OC: We have a lot of inequities. While some regions have almost everything available to assist various patients, others have almost nothing and suffer from a huge lack of resources. For example, we have a lack of radiotherapy equipment in the public healthcare system in Brazil, so the government created a program in 2012 to buy this equipment, but so far none have been bought. Besides, we don't have enough technicians to operate the equipment.

DOES CLINICAL RESEARCH HAVE RESOURCES AND SPACE TO GROW IN BRAZIL?

LFF: A lot! In Brazil clinical research needs to grow so we can have more – and better – local data. This is due to the type of drugs that are developed, especially targeted therapies, where population characteristics are essential in the process. In addition, we need to further develop basic scientific training so the whole country can advance its scientific expertise, and in being more connected in the direction and development of global clinical research. If we don't participate in the development process, we can't participate in directing it.

Companies may have simpler needs, but in the end it has to follow an international, much more complex process that doesn't apply to our reality at the time of using a medication.

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Q & A

If we don't master the scientific process of these data and research, we won't control their outcomes. We can develop products using European or American models, but that will not suit our reality.

This is the main process: to have the autonomy to drive the scientific process for our needs. It involves the knowledge on how to conduct this process and the understanding of what the local needs are. We will only learn how to technically conduct research by doing it and acting on it, so we need to learn from international models, and then merge the two aspects (international and national) to produce technologies that are important for us Brazilians.

HOW CAN CLINICAL RESEARCH BE EXPANDED IN BRAZIL?

LFF: To expand it, first we need a series of actions where the government, the scientific community and the population actually work together.

The scientific community must learn how to differentiate. Brazil has many qualified people, but some old and entrenched concepts still hinder wider development, and we need to cross these boundaries so this sector can grow and renew. To regulate the clinical research, we need the scientific community to work together with public agencies that rule this process so we can evolve it. We can't wait 12 months to approve a research protocol in a regulatory center, while in the United States it takes around 30 to 45 days. This prevents the development of research in Brazil.

The optimization of this process is essential for the country to develop its research. This streamlining of the process as a whole is important. But for that, we need a collective desire to adjust it. What we have at the moment are individual desires, which don't interact to reach a greater good, and we need them to be able to act synergistically.

DO THESE DIFFICULTIES IN THIS PROCESS PREVENT BRAZIL FROM ATTRACTING MORE FOREIGN INVESTMENT?

LFF: This is the biggest impediment of clinical research growth in the country. We have real examples from various industries that tried to conduct research in Brazil, and invested a lot of capital, but due to the complexity and slowness of the whole process and to bureaucratic problems, were discouraged to continue. Thus, the country loses a very large annual investment, loses the inclusion in research, and loses scientific development. When research is conducted in Brazil there is an acceleration of the technology incorporation process, which benefits the population.

+ ABOUT THE AUTHORS

OTÁVIO CLARK, CEO AND TEAM LEADER

Oncologist with fellowship in Evidence-Based Oncology and Research Methods at H. Lee Moffitt Cancer Center & Research Institute, in Tampa, Florida (USA). He is a household name in Brazil on matters regarding evidence-based medicine, pharmacoeconomics, health technologic assessment and market access.

VALERIA CLEMENTE, MARKET ACCESS AND PROJECTS DIRECTOR

Pediatrician at Hospital Infantil Candido Fontoura, with post-graduation in Hospital Administration and in Management and Health Economics. Her aim is to maintain the high performance and engagement of the team as well as to seek innovative and strategic partnerships with multiple stakeholders.

LUIZ FERNANDO FEIJÓ, CLINICAL RESEARCH DIRECTOR

Radiotherapist graduated from University of São Paulo (USP), with a Masters in Radiotherapy from University of Campinas (Unicamp). He has experience in clinical research and worked in various reference centers in oncology as well as large pharmaceutical companies. He leads a team of pharmacists, nurses and physicians dedicated to developing clinical research.

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WHY KANTAR HEALTH

Kantar Health is a leading global healthcare consulting firm and trusted advisor to many of the world's leading pharmaceutical, biotech and medical device and diagnostic companies. It combines evidence-based research capabilities with deep scientific, therapeutic and clinical knowledge, commercial development know-how, and brand and marketing expertise to help clients evaluate opportunities, launch products and maintain brand and market leadership.

Kantar Health deeply understands the influence of patients, payers and physicians, especially as they relate to the performance and payment of medicines and the delivery of healthcare services. Our advisory services, built on a solid foundation of market research and data, span three areas critical to bringing new medicines and pharmaceutical products to market – commercial development, clinical strategies and marketing effectiveness.

Kantar Health operates in more than 40 countries and employs more than 600 healthcare industry specialists and practitioners, including a high number of medical doctors, epidemiologists, PhDs, PharmDs and pharmacists, and biologists, biochemists and biophysicists. We work across the product lifecycle, from preclinical development to launch, and are experts at bringing multiple stakeholders together to advance the commercialization of pharmaceutical products. Our team acts as catalysts to successful decision making in the life sciences industry, helping our clients prioritize their product development and portfolio activities, differentiate their brands and drive product success post-launch. Kantar Health is part of Kantar, the data investment management division of WPP.

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