Interview: Antonio Britto â?? Executive President, Interfarma, Brazil

â??Accessing medicines through legal actions comes at a very high cost for the Ministry of Health and does not stand a sustainable way to provide access to medicines.â?•

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Antonio Britto, the executive president of Interfarma, the main association gathering together local and international innovators in Brazil, provides insights into some of the hottest topics in Brazilâ??s pharmaceutical sector, including an assessment of the eye-catching growth prospects of the industry after years of political and economy turmoil, as well as the judicialization of health, technology transfers, and the necessity to build a new model for innovation access.

Amidst political and economic turmoil that saw the Brazilian economy contracting 3.8 percent in 2015 and 3.6 percent in 2016, the pharmaceutical industry stands as one of the only sectors of the Brazilian economy that has continued to grow and develop itself. How do you explain this specificity and what is your assessment of the growth prospects for innovators in Brazil moving forward?

The outstanding resilience displayed by Brazilâ??s pharmaceutical industry over the past few years is directly linked with one of the main shortcomings that still characterizes Brazilâ??s health system: a limited access to pharmaceutical products through the public health system. In a country where medicines purchasing comes as out of pocket expenses for around 76 percent of the Brazilian population, the recent economic crisis has had no impact on the growth of private pharmaceuticals sales, because patients cannot live without the medicines they need. When it comes to life-changing or life-saving medicines, Brazilians have no choice but to find new ways to access them and therefore choose to sacrifice other items of expenditures. In this regard, the private Brazilian market has proven being absolutely resilient to the crisis, and it continues to increase more rapidly than the global average, despite the fact that recent growth rates are less impressive than a few years ago.

In this context, the main issues faced by pharmaceutical companies relate to the public market; nevertheless, the working of Brazilâ??s institutional system has somehow diminished the negative impact of the economic crisis, as the government could not cancel ongoing multiple-year tenders. As a result, the Ministry of Health has so far been mainly focused on reaching a greater level of efficiency across the system and differing the payment of medicine-related bills â?? but no tremendous changes have yet occurred. Looking forward, we cannot overlook the fact that the past economic crisis has tremendously decreased budget availability, prompting the government to take a stance on public expenses, which naturally casts a shadow on public marketâ??s growth prospects. In the grand scheme of things, the Brazilian situation is no different to those in the US and other mature health systems, where public resources to finance innovation are becoming scarcer.

Overall, we expect that very good years are yet to come for pharmaceutical innovators, as Brazilâ??s exit from a two year recession period *[according to the IMF, the Brazilian GDP should rise by 0.3 percent in 2017 and 1.3 percent in 2018, e.d.]* should enable evermore growth rates to materialize in the upcoming years.

On the international stage, Brazil has been strengthening its leadership for regulatory matters, as ANVISA became in November 2016 a regulatory member of the International Conference on Harmonization (ICH) alongside the US FDA, the EU EMA, and other leading regulators. Looking at the domestic situation, what do you see as the main challenges that innovators face when bringing their products in Brazil?

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From a regulatory standpoint, the Brazilian context might seem quite disconcerting for a foreigner, as we have successfully solved crucial issues with regards to legal predictability, the respect of intellectual property, and the strength of our pharmaceutical market, but we still lag behind concerning several â??minorâ?• issues, such as registration timelines and red tape.

This discrepancy takes its roots into various reasons, the first of them being cultural: Brazilians love bureaucracy. Second, ANVISA was set up only 18 years ago and therefore still stands as a young regulatory agency, which moreover handles a very broad scope of responsibilities â?? ranging from food and beverages to tobacco, cosmetics, pharmaceutical products and medical devices â?? through only 2.500 employees, which is particularly limited in comparison to the USD FDAâ??s 15.000 staff.

Fortunately, ANVISA decided three years ago to operate a complete paradigm shift and started to review its own processes and reduce bureaucracy across the organization. Interfarma and ANVISA stand as steadfast allies in the fulfillment of this objective and our association has been offering strong support to our countryâ??s regulator.

On the other hand, ANVISAâ??s backlog of registration dossiers is still particularly substantial, and the agency will need some time before displaying approval timelines similar to those of the most advanced agencies in the world. However, the most important aspect in the eyes of Interfarma is that ANVISA is strongly committed to upgrading its processes and is definitely moving to the right direction. In this regard, we can already feel the great influence of the aforementioned ICH membership, as the latest regulations implemented by the agency are absolutely world class.

In some of the largest pharmaceutical markets in the world, the pharmaceutical industry, the regulators and the government maintain tense relationships. How would you rate the openness of Brazilâ??s stakeholders to work together?

A sound dialogue gathers together the main stakeholders of the Brazilian ecosystem, and the door is always open to discuss innovative solutions and collaborative approaches. Nevertheless, our countryâ??s recent political crisis has provoked frequent changes among all layers of our public system, which renders extremely complex to design and implement a sustainable long-term vision for our countryâ??s health system.

This aspect is particularly crucial as Brazil truly stands as a country that requires a clear 25-year vision to further moving forward. Day-by-day management will not allow us to face the huge challenges posed by our rapidly aging population, the evolution of our countryâ??s epidemiological profile, and the increasing prevalence of cancer or rare diseases, at the moment we definitely need to collectively look at the way the private and public sectors interact. In the current political context of our country, addressing these critical challenges seems to have been be put aside by decision makers, whose attention is monopolized by daily operations.

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During our recent interview with Minister of Health Barros, he highlighted the significant role of Partnerships for Productive Development (PDP) and technology transfers in building a more sustainable health system in Brazil. What is Interfarmaâ??s position on the broadening and further development of these PDPs?

The narrative and promises commonly associated with PDPs are probably more exciting than the tangible outcomes that they have already delivered to date â?? and this imbalance is mainly due to the way PDPs are managed. First, the government established more than 180 strategic technology transfers, which stands as a huge number for a country like Brazil. Furthermore, the current regulations stipulate that PDPs mandatorily include a public laboratory within the technology transfer. As you can imagine, Brazilâ??s public capacities are not able to integrate 180 technology transfers, which led us to the following situation: out of the 180 strategic technology transfers, 104 PDPs were signed but only three of them have actually completed the entire technology transfer process. In the meantime, around 25 PDPs have entailed the commercialization of products which are in reality produced abroad, while public laboratories only handle late-stage manufacturing. Finally, over 25 PDPs have already been canceled, and around 45 additional partnerships are currently under review.

As per Interfarma, we are not fundamentally opposed to PDPs and the outcomes they should bring to our country; however, we believe that there is an urgent need to review how PDPs are managed in the country. As a matter of fact, we hold tangible evidences that current policies are inefficient: first, our trade balanceâ??s keeps on worsening, while a large share of products sold to the government through PDPs display a higher price tags than in the previous free market setting, when several companies could fairly competed against each others *[PDPs usually entail exclusive, five-year supply contracts under which the Brazilian Ministry of Health agrees to only buy a given product from a single contracted supplier for a fixed sum of ten percent below a reference price, e.d.].*

In 2017 alone, the government established 83 new strategic technology transfers. Such a high number is highly questionable, while we moreover need to carefully assess whether the companies chosen actually hold the required technologies and whether public laboratories hold the means to integrate these transfers. In this regard, Interfarma position is that the government should concentrate its efforts on the most innovative technologies, i.e. the ones for which there is no free market setting. Second, we need to develop a model where Brazilian laboratories are actually able to receive all technology transfers prioritized by the government, and â?? finally â?? we must ensure PDPs are developed in legal and ethical ways that would bring real technological improvements to Brazil and/or decrease product prices in comparison to a free market situation.

The increasing numbers of lawsuits for access to medicines in Brazil â?? or â??judicialization of healthâ?• â?? is hotly debated. What is your assessment of this problem and how does it impact the pharmaceutical industry?

Brazilâ??s 1988 Constitution states that all citizens must access free healthcare, but our public system does not hold the financial resources to ensure that our entire population access all medicines and medical technologies available. In this regard, the judicialization of health is created by the gap between the level of access that our Constitution guarantees and that currently available through our public health system. In a country where 75 percent of patients do not holds the means to access the private healthcare market, it is understandable that families leverage this legal way to access the medicines they need.

On the other hand, this constitutional right is not limited to poor people, while judges moreover do not hold the technical capacities to assess the validity of claims. It makes no doubt that we must set valid and lawful health-related claims apart from fraud and criminal cases, and this variety of situations prompt me to use the term of *judicializations* of health rather than assuming all situations originate from the same needs and should lead to the same outcomes.

The judicializations of health have a huge impact on the entire Brazilian ecosystem. Accessing medicines through legal actions comes at a very high cost for the Ministry of Health and does not stand a sustainable way to provide access to medicines. To truly solve this issue, we are however left with no choice: we need to change our Constitution and define more clearly what are the responsibilities and rights of all citizens.

After more than ten years at the head of the association, what do you want to be seen as your legacy?

When I took over this position, Interfarmaâ??s modus operandi was to first and foremost address industry-specific topics and then â?? in a second phase â?? to communicate our associationâ?? position to external stakeholders. The vision that I have been instilling over the past ten years is that our industry cannot content itself with addressing issues that are only relevant to pharmaceutical innovators: we must go beyond defending our turf and truly discussing the national agenda of healthcare.

When the objective is to tackle the real problems affecting the health of our citizens, one however cannot operate in isolation, and engaging with patients, physicians, scientists, payers, and the government stands as the only way forward. In this context, we have implemented an aggressive policy of opening and started conducting comprehensive studies covering a broad spectrum of healthcare topics. Just to give you an idea, we launched â?? in September 2017 alone â??studies assessing the level of access in the oncology area, the evolution of federal budgets for healthcare, as well as an analysis of healthcare costs over the past two decades.

When you open the window and truly engage with all stakeholders of our countryâ??s health system, one quickly understands that many industry-specific debates have now become obsolete â?? and the word on everyoneâ??s lips is *access*. In Brazil as in other countries, there is a consensus about the necessity to maintain access to innovation, leaving pharmaceutical innovators and the government with the shared responsibility to build a new innovation model. We are at the dawn of a new era â?? this is not an assumption, this is a necessity.

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