Interview: Leandro Pinheiro Safatle – Executive Secretary, Brazilian Drug Market Regulation Chamber (CMED)

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Leandro Pinheiro Safatle

, executive secretary of the Brazilian Drug Market Regulation Chamber (CMED) explains why pharmaceuticals was the only sector to have resisted the country's recent recession, the role that CMED has played in stabilizing the price evolution of medicines in Brazil, and the importance of increasing the regulatory framework's transparency.

Can you introduce the Brazilian Drug Market Regulation Chamber's (CMED) mission and importance within Brazil's Healthcare system?

CMED is a consortium of five ministries: the Ministries of Health, Budget, Industry, Justice, and Finance. Each and every one of these ministries plays an important role in helping CMED regulate the pharmaceutical market.

This rich and diversified composition means that CMED rules take into account the assistance, the competitiveness of the sector, the industrial promotion, the consumers and the good functioning of the whole sector.

While the Brazilian government regulates very few sectors, the pharmaceutical sector is one of them. The need to regulate this market stems from several information asymmetries and market

failures. For instance, medicines are both essential and credence goods *[drugs prescribers are not those paying them –Ed.]* and therefore their price elasticity is low. Because of these characteristics, the pricing adjustments do not function well. This is why many, if not most countries, regulate the prices of the pharmaceutical market.

Brazil uses price cap and referential price as regulation tools. These price regulation tools have allowed us to maintain the accessibility of medications by preventing prices to rise faster than inflation and reducing the average launch price in the market by 35 percent. Despite these price decreases, the overall Brazilian market's sales in value rose by 10 percent in the meantime. In fact, in the wake of the crisis, all the sectors constricted but two, including the pharmaceutical industry.

How do you explain why the pharmaceutical sector has been growing so quickly, despite the crisis?

[Featured_in]

In 2015, at the height of the economic crisis, pharmaceutical market was the fastest growing industrial sector of the Brazilian economy, growing 8.3 percent while all other sectors were largely declining. For instance the steel sector was declining by 22.5 percent. This situation was so exceptional, and remarkable that Harvard University reached out to CMED to better understand why the Brazilian pharmaceutical market had been so resilient and how it could inspire other industries.

Brazil is the only country in the world with a population of over 100 million inhabitants that has chosen the path of universal healthcare. In this regard, the coverage is so good in the public sector that even people with private health plans can use the public sector to get access to the treatments they need, including through legal actions [*called the judicialization of health – Ed].* The demand in the public sector being guaranteed by the Constitution, we understand why the latter has been growing despite the crisis.

On the other hand, the private demand also continued to grow despite the crisis. Private sector demand is driven by the increasing purchasing power of the population, as two years of recession is not enough to offset 25 years of prosperity while led dozens of millions of Brazilians to finally hold the financial means to access new treatments.

Interestingly, Brazil's situation is different than in Europe, where the main source of medicine expenditure is the government reimbursement, while in Brazil most of the medicine purchasing comes as out of pocket spending. When the people become wealthier, they consume more

medicines. Nevertheless, it is interesting to notice the most expensive cures are still provided by the SUS *[Brazil's public health system – Ed.]* and that is why the public demand for these products has remained constant regardless of the economic situation.

The government recently announced that public spending – including in healthcare – would be tied to inflation rate for the next twenty years. As a result, have you changed the way CMED work in terms of pricing?

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Despite the economic crisis, CMED has not changed its price setting criteria or model, even for the mandatory discounts required to sell in the public sector. The stability of the rules of CMED is very important to maintain predictability and visibility of the pricing processes for industry. Since the pharmaceutical sector is one of few Brazilian sectors to be regulated, we cannot take the risk to send the message to international companies that Brazilian rules may fluctuate according to economic performance. In fact we strive to make the pricing process totally transparent. In an attempt to do so, CMED publishes all its pricing review methods and seeks to hold public consultations with the participation of society as a whole and the regulated sector to adapt the regulations.

Between 1990 and 1998, there were no regulations on the prices. In the same period, the real prices of medication had more than doubled with high fluctuations in between as a result of a drop in sales. Since the CMED's creation in December 2000, stability has been brought to the market. The price of medication has decreased steadily the sales volume continuously growing at a double-digit rate until the crisis.

Do you use the same pricing criteria for orphan drugs as for others?

The pricing decisions for generic and innovative drugs have been separated. In the case of innovative drugs, CMED differentiates innovations with a therapeutic gain and innovation with no therapeutic gain.

As Orphan drugs have therapeutic gains we use the reference market's price as a benchmark. Brazil uses a total of nine reference markets including the US, Greece, Italy, France and Canada. In this sense, there is no difference between the method used to price orphan drugs and any other drug that shows therapeutic advantages in relation to drugs already existing in the Brazilian market.

Otherwise, there are cases where the external price search method cannot be used and CMED needs to move forward with its procedures.

For instance, we recently conducted our first ever complete cost-effectiveness study in Brazil to establish product ceiling price. Recalling that there are clear methodological differences between studies of cost effectiveness to decide the price of incorporation and ceiling price of medicine

Dengue virus vaccine was CMED's first example of complete cost-effectiveness study, as it was a first-in-class product that was not yet approved in one of our reference countries.

You were appointed two years ago, what are your main priorities?

Currently CMED's main objective is to move forward with the regulatory apparatus for the new challenges and promote transparency. CMED want to become fully transparent, and has recently decided it would list all the infringements to CMED's regulations and their corresponding penalties. For that purpose, we organized a public consultation in September, and one of the main outcomes is that companies selling their products at a higher price in Brazil than the set price will be fined.

I am also looking forward to establishing a set of rules that will prevent companies from unlawfully taking advantage of judicialization of health. [The government's budget is imbalanced by the numerous lawsuits against it as a result of the constitutional unavailability of some health products in Brazil –Ed.] Companies unlawfully benefitting from the judicialization of health will receive a penalty equivalent to the penalty addressed to companies selling their product above the authorized price.

With these measures CMED is not trying to harm the industry, rather make the market more transparent to ensure the sustainability of the healthcare system provided to over 100 million Brazilians. It is important that both the government and the companies are more transparent about their actions in Brazil. While only very few companies do not play by the rules in Brazil, we want to make sure we limit the possibilities for them to skirt laws because the few companies not respecting the Brazilian law also have a negative impact on the other players in the industry.

Finally, We intend to extend the range of tailored regulations to more parts of the pharmaceutical industry including OTC. By the end of the year I hope that we can launch a number of public consultations to that end.

Do you have a final message for our international readers?

Being the sixth largest market in the world, the Brazilian market is absolutely crucial to the global industry and still has tremendous growth potential. The growth demand appears to be sustainable

in the long term, although growth rates have slightly slowed down recently. Last but not the least, the world-class regulatory frameworks that CMED and ANVISA are putting in place truly contribute to make Brazil a more attractive country for foreign investors and healthcare companies and we will continue our efforts to ensure our regulations are perfectly aligned with the best standards in the world.

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