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By ***Cesar Rodrigues*** on ***Aug 27, 2015***

How prepared are pharma for Latin America's pricing storm?

"Perfect Storm" is a popular term to describe a situation in which several seemingly separate events take place at the same time and place, causing an aggregated effect beyond the sum of their individual impact. I cannot find a better term to describe what is happening now in the pricing environment of pharmaceuticals, in Latin America.

Price control is a tradition in Latin American countries, as old as the market

itself. The difference now is that governments must go beyond controlling, and squeeze prices as much as they can. The main reason is the lack of options the health authorities have to make new drugs accessible and affordable for the population.[1]

Latin America is suffering from the same trends as more mature markets, with skyrocketing prices for innovation and strong pressures on the healthcare systems to do more with less.[2]

Now, should these new drugs necessarily have higher prices? This is a huge discussion but there is a reason for them. New drugs are becoming more and more niched, with narrower indications and it does not matter if they will sell 100 thousand or 100 million units, the investments in R&D remain the same, roughly US $2.6 billion per new molecule.[3] This means the innovation expenses will be spread among fewer units, causing the unit cost to increase. Then, prices must be higher to keep margins and provide return on investment for the shareholders.

The question is: who will pay for these more expensive and better medications? Latin American governments are facing a tremendous challenge, since they have to work with both developing and developed country issues of limited health budgets and an aging population that will demand modern and basic drugs at the same time.

The goal of providing "universal healthcare" coverage, as demanded by the World Health Organization (WHO)is a hurdle, since the priorities are far more basic than new drugs.

WHO defines'universal healthcare' as

> "...(to) ensure that all people obtain the health services they need without suffering financial hardship when paying for them. (led by) a strong, efficient, well-run health system that meets priority health needs through people-centered integrated care (including services for HIV, tuberculosis, malaria, non-communicable

diseases, maternal and child health)."[4]

In most Latin America countries, private health insurers traditionally do not reimburse medications. The sector operates with tight margins, for example in Brazil, the average return on assets (ROA) was 3.55% for the HMO sector.[5] This does not leave much room to include costly medications without jeopardizing profitability - and increasing policy prices would not be an easy move.

That WOULD leave the bill to be paid by patients and their families - the out-of-pocket market. But again, the families can no longer afford more medication expenses. As examples, in Chile and Mexico, out-of-pocket already corresponds to 89% and 82% of total pharmaceuticals expenses respectively.[6] Thus, patients and their families are at the limit of purchase capacity to pay for medications.

Eventually some governments and private payers will have to fund the newer meds for at least part of the population – at least for those who can obtain them through legal actions. This is a slightly perverse situation where the people that can afford lawyers and win the "right" to free medications are taking funds from the rest of the population. This is the triumph of individual over the public and the opposite of "universalization".

The solution Latin American governments have found to this challenge is squeezing prices as much as possible.

Storm #1: International Reference Pricing

Brazil was the pioneer in Latin America in the practice of setting pharmaceutical prices by referring to the ones practiced in other countries. The "Resolution 2", issued in March 2004, defined the rules for determining the price of a new medication.

If a new product is recognized as having robust evidence of superiority versus the standard available therapy, external reference pricing should be applied. If no significant advantage versus existing therapies is seen by CMED (Câmara

de Regulação do Mercado de Medicamentos), the price regulation authority, the new product will have a comparable price to that therapy. The basket of countries that is the price source for referencing is composed by: Australia, Canada, France, Greece, Italy, New Zealand, Portugal, Spain, United States and country of origin. The new medication price in Brazil will be equal to the lowest among the countries referenced. The reference basket should change in the near future: Greece and New Zealand could be left out, and one Latin American country may be included.

Colombia is another important country that adopted international reference pricing, in 2012. In this case, the country wanted to decrease prices for products already on the market - those that had the biggest impact on the public health budget. Thus, Colombia created a basket composed of 17 countries, namely Argentina, Australia, Brazil, Canada, Chile, Ecuador, France, Germany, Mexico, Norway, Panama, Peru, Portugal, Spain,UK, United States and Uruguay. The new price of the product is the one in the "third quartile". That is, the prices of a product are collected in the 17 countries and sorted from highest to lowest. The product in Colombia will have a price close to country number 12 or 13. The results of this measure were impressive: some products that already underwent the exercise saw price drops up to 90%.

The Colombian Ministry of Health declared the savings achieved due to new price regulations was US $230 million as of May 2015.

These are only two examples; but other countries have moved or are moving toward employing reference pricing:

- **El Salvador:** in 2013 collected pharmaceutical prices in Argentina, Bolivia, Brazil, Ecuador, Uruguay and Central American countries and applying an obscure formula achieved an average price decrease of 35%;
- **Ecuador:** the "Decreto 400" determines that new pharmaceuticals with therapeutic advantages will undergo international reference pricing, having as basket-countries the ones in MERCOSUR and ALBA. Price will be the average of the 3 lowest.
- **Panama:** in his first speech the new president promised to implement the

same price regulations adopted by Colombia.

- **Argentina & Venezuela:** Minister of Health known to perform “informal international price reference” and request clarifications if a given product appears to be too expensive when compared to another country.

When one looks at reference baskets, it becomes clear that our countries are referencing one another - which has the potential to create a downwards spiral - pulling prices to lower levels continuously.

Storm #2: Sharing Price Information

Every time a country alliance, federation, pact etc. meets in Latin America, health is a key area. When discussing how to provide universal access to health for the population, as directed by the World Health Organization, the topic of pharmaceutical prices comes to the table.

So at Mercosur, CARICOM, UNASUR, Comisca, ALBA, Alianza del Pacificoetc meetings, countries realize they pay different prices for the same medications and propose to share price information of government purchases. This is not the same as reference pricing which is based mostly on list prices. Here we talk about the prices actually paid by governments after negotiations or tenders, which can have substantial discounts. If my neighboring country paid “x” for a given product, why am I going to pay “3x”? This information is not readily available anywhere and some federations start to build price databases. UNASUR, the Union of the South American Nations, decided three years ago to build an electronic price database with the objective of optimizing procurement. Each member country would input the prices paid for medications and there would be fresh, instant information to negotiate better deals. Although in subsequent meetings this project was confirmed as a priority, little progress has been achieved.

In 2014, the countries of the Pacific Alliance (Mexico, Colombia, Peru and Chile) signed an agreement to exchange information on the prices paid for medications by each government. At the meeting, the Colombian president Juan Manuel Santos declared: “ Why are we doing this? To be able to lower

health costs, the costs of medications for our citizens".

Another piece of this puzzle: in 2012, the International Development Bank approved a budget of US $500,000 for Mexico, Colombia and Ecuador to build a "pharmaceutical price observatory". This amount would be matched by US $300,000 from the 3 countries and aimed to exchange price information to promote decrease in health expenses.

Storm #3: Countries Joint Purchases

The practice of gathering demand needs from several countries and performing a mega-tender giving much more bargaining power is an effective one.

The best known is PAHO's (Pan American Health Organization) annual vaccines tender that started 35 years ago. It gathers vaccines to immunize 15 million people and attracts 31 manufacturers. Whoever offers the lowest price wins the right to sell vaccines to 41 Latin American countries, taking a major chunk of business[7].

Not only significant discounts are achieved, but also the contract signed with the winners ensures PAHO will always have the lowest price in the globe.

The fight against non-communicable, chronic diseases is now WHO and PAHO's highest priority. Regional consolidated tenders for anti-hypertensive, anti-diabetic drugs should be the next wave and prices will drop further. Some joint tenders already exist, such as COMISCA (Comité de Ministros de Salud de Centroamérica). Gathering supply needs from Belize, El Salvador, Honduras, Nicaragua, Costa Rica, Panama and Dominican Republic and performing one single tender has worked and provided savings of US $ 22 million in 2010. And others will come soon: during the June 2015 meeting of MERCOSUR Ministers of Health, it was decided that they would pursue pooled (joint) purchases in order to achieve greater bargain power in their medication purchases.

Storm #4: Retailers Consolidation

Pharmacy chains used to do business in one country and sometimes only in a particular area of a larger country. This allowed a pharmaceutical company to negotiate in isolation with each client, with more bargaining power.

Now you take a country like Brazil, where about 8 years ago a drugstore chain based in Sao Paulo opened a store in Fortaleza, Ceara in the northeast, just to see it boycotted by local players and local government. Now the pharmacy chains are invading each other's territories, competition has become more fierce and there is more pressure for better commercial conditions.

The same is happening across countries: in Brazil, Drogaria Onofre chain was bought by the CVS from the US. The Chilean chain Ahumada acquired FASA (from Peru). Socofar-Cruz Verde (Chile) bought the Colombian chain Farmasanitas and also Fischel/CEFA in Costa Rica. Last but not least, US' mega-chain Walgreens acquired Farmacias Benavides, from Mexico.

What does this mean? These are professional, well-run retailers who oftentimes have better information and are better organized than the pharma companies themselves. It is reasonable to think that they could try to negotiate regional deals, obtaining better prices, better discounts, squeezing pharmaceutical companies margins. And that's probably not the whole story - the same may start to happen for health insurance plans (HMOs), after all, United Health (US) has merged with Amil, one of the biggest Brazilian HMOs.

Raincoat, Umbrella and Plywood on the windows

I will stop with these four storms, although one could argue that there are others on the way: take biosimilars for instance. The difference here is that the company that owns the branded biological has the choice of lowering the price or not.

The four storms are arriving at different paces - but at some point they will merge and we must be prepared.

What experience has taught us is that when prices are cut in Latin America, volume will not compensate & sales will fall. The increased demand was not

enough to maintain sales, neither in the payers segment nor in the out-of-pocket market. In the payers' case, they try to avoid savings going down the drain by allowing greater access to that product – they keep the number of patients on the medication unchanged. As for the out-of-pocket, our countries mostly have "price-inelasticity", since the demand is often concentrated in the classes of higher purchase power. If your product costs US$ 100 per month and suffers a price cut of 50%, the additional volume (or patients) will not increase 100%. Worse, the price cut will trim your margin more than the sales itself as well. To leverage the out-of-pocket market, some companies have been experimenting with "internal tiered pricing" - charging differentiated prices for patients with different income levels. However, this has proved to be very tricky and brings many risks.

What can we do? Here are some ideas that are proving to be worthwhile:

1) Get access to payers, public and private, to keep your product relevant

If you have a product that is mostly in the out-of-pocket segment and is taking a big price cut, you must try to increase your sales mass as much as possible. The way out is getting access to large cohorts of patients, which can only be achieved through payers. And the name of the game for payers is Value - thus, you will have to develop a strong Market Access culture that unites all areas of the company (market access, medical, marketing, sales and so on).

2) Implement price corridors to minimize international reference pricing damage

For those who have responsibility for multiple countries, it is critical to have some level of price uniformity across them, even if this will hurt competitiveness in smaller countries with low price levels. What you cannot allow is to have this small country with very low price become reference for a bigger country and hurt overall business. Looking at Latin America, Ecuador comes as a good example of a small country with pharmaceutical prices frozen for many years - and decreasing - becoming reference to a larger market (Colombia), causing price cuts and jeopardizing business there.

3) Know pricing regulations in great detail

If you do not know every word of the price regulations, you will probably lose money by allowing price erosion that otherwise could be avoided. Sometimes even how the company manages a new product registration will make a difference. In some countries, if you register a product as line extension it will be priced based on the existing product. If you apply with a new registration dossier, you may be able to set a new and better price.

4) Get strategic pricing professionals

The new pricing environment calls for a professional that goes beyond following the regulations and calculating official price increases. You need professionals that find pricing opportunities, understand the impacts of neighboring countries' prices, are familiar with pricing studies, can dialogue with the pricing function at headquarters and have a good understanding of health economics principles. Unfortunately, most marketers nowadays do not care much about this “P” - pricing is not sexy. So you need someone else in charge.

5) Mind the margin

As prices drop you better pay much more attention to the lines between “Gross Sales” and “Net Sales”. Pharma has always been somewhat careless with commercial conditions, since margins were comparably higher than in many other industries. This is no longer the case, so you need to go in great depth on all types of discounts, rebates, promotional allowances etc. Do you really know the cost-to- serve for every client? Do you have P&Ls per client? If not, it is time to start doing your homework. In industries with slim margins (beverages, consumer goods) there is the role of Revenue Manager who is in charge of maximizing Net Sales by close control of the gross-to-net elements. Few pharmaceutical companies have this role yet.

6) Foster dialogue with government and have “one voice” as an industry

Easier said than done... but possible. The Colombian pharmaceutical industry

associations were able to achieve good dialogue with the government and could prevent major mistakes in the new regulations.

To close, I will quote Epicurus, the Greek philosopher, who wrote: “the great navigators owe their reputation to the tempests and storms”.

I hope this article helps you prepare for the “Perfect” one.

About the Author

Cesar Rodrigues has more than 25 years of experience in the pharmaceutical business having worked in Merrell Lepetit, HMR, Aventis and Sanofi, in Latin America and global functions.

He currently acts as Expert Marketing Associate to Heutagus Corporate Education.

Marketing is his main expertise, in a wide range of markets: OTC, prescription, vaccines and specialty products. His areas of focus include advertising, sales force effectiveness, marketing excellence, digital, CRM, segmentation & targeting and portfolio strategy.

Nowadays, his emphasis is on market access and pricing, in his viewpoint the most important challenges for the future of health.

Cesar has a post-grad in marketing from the Fundação Getúlio Vargas Business School (Brazil) and has recently completed a health economics seminar in the University of York (UK).

He has lived and worked in the US, Panama and Mexico and now resides in São Paulo, Brazil with his wife Elaine and daughter Julia.

References

1. I make a distinction on the terms "accessibility” and "affordability”. When

we talk about payers, we will use "accessible" to describe their ability to make the medications available to the population. "Affordable" will be used to describe patients' ability to pay themselves for the product (out-of-pocket).

2. Consider as an example Sovaldi (sofosbuvir), the breakthrough hepatitis C treatment, which has a list price of US$1,000 per 400 mg pill and a 12-week treatment course of $84,000.

3. http://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/

4. June 2nd 2015:
http://www.who.int/features/qa/universal_health_coverage/en/

5. Desempenho Economico-Financeiro de Operadoras de Plano de Saude Suplementar - V.Vieira Silva & E. Loebel - Anais do Encontro de Gestao e Negocios - EGEN2014

6. Health at a Glance 2013 - OECD

7. The PAHO Revolving Fund for Procurement of Vaccines &. Immunization supplies. 2014 Georgia Tech Conference on Health and Humanitarian Logistics – June 2014, Mexico City