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The stability of Peru's economy in recent years has provided amply opportunity for multinational pharmaceutical companies to invest in the country. Augusto Rey de la Cuba, executive director of ALAFARPE (Asociación Nacional de Laboratorios Faramcéuticos de Perú), discusses intellectual property issues and investing in research in the country.

Can you introduce yourself and ALAFARPE to our readers?

ALAFARPE is an association for research-based companies in Peru founded in 1953, of which we currently have 21 members. The organization is one of four associations in Peru, three of which are specialized in pharmaceuticals. ALAFARPE exists primarily to protect intellectual property and promote research in the industry. We take care of all situations related to the international pharmaceutical industry as they relate to our member companies. Occasionally we work with other associations to help promote health products in Peru.

What have been the most significant milestones in recent times?

There is a lot to do in Peru in the pharmaceutical area. The government has been in the process of creating a law for pharmaceutical products that deals directly with quality and safety since 2009. There has been some progress made, but nothing has been set in stone. Six years later, we are still trying to implement this law. ALAFARPE is working with DIGEMID to alleviate this situation. The health sector in Peru still needs to grow significantly to gain more access to medicines. Fortunately

the growth of Peru's economy has been stable in recent years, and healthcare has been growing even faster. Importers and local manufacturers alike have access to both the private and public markets.

What are the biggest challenges your member companies face today?

Implementing this new law is of course one of our biggest challenges. Because of the growth of the market, there are also some problems with counterfeit medicines, although nobody has been prosecuted for selling unapproved medicines in Peru as of yet. The demand for new registers has grown rapidly and the authorities do not have the capacity to keep up with that demand. ALAFARPE has been helping the government in this regard by updating registers, which sometimes takes up to four years to complete. Renewal of registers is also a priority.

The implementation of a rule for biologics and biosimilars is also key for our members. ALAFARPE is currently working on such a law to be implemented in 2015, whereas countries like Chile, Mexico and Colombia have already passed such a law in their respective countries. Peru also does not have any rule that requires generics to demonstrate their bioequivalence to originators.

Medicines for the treatment of cancer, diabetes and HIV/AIDS are also grossly exaggerated for custom duties and taxes. Since 2011, there have been no new products approved for appropriate prices according to the health authorities' lists, so patients not receiving true benefits due to overpriced medicines.

Some of these problems are symptomatic of all pharmaceutical associations in Peru. False products or products with adulterated dates of expiration are only found in public hospitals, and the quality of these products is widely unknown. We still need to put some directives in place for this to change.

What is the perception of the added value that innovation brings in Peru?

The government only looks at price rather than quality. This is a big problem. Patients want quality, and they need to be treated with good products. Patients at public hospital usually do not know what treatments they are being given. Associations look for good quality products. But with Peru's lack of price control, which our constitution does not permit, the free market means that prices are slightly higher than the average Peruvian can afford. If the health budget is to grow, the environment for market access needs to be more reasonable.

What is your assessment of the R&D environment in Peru?

In the last few years, Peru has become a good place for investigation. The Instituto Nacional de Salud (INS) is actually in the process of implementing a new law the approval of clinical trials in Peru. These are undoubtedly good for the patients, doctors, and the government because of taxes. If these opportunities are not present in Peru, our member companies will go to other Latin American markets with better rules, such as Colombia or Brazil. ALAFARPE is committed to ensuring this situation improves. At the moment, only about seven or eight of ALAFARPE's member companies are engaging in clinical research in Peru, and some CROs are also present here with their own research.

How would you rate the regulatory environment in Peru for approval and reimbursement?

The regulatory standards in Peru are generally high. However, for us to become truly competitive we need to implement the law I referred to earlier. For example, Chile has a bioequivalence stamp for products, and Peru has nothing like this. Some government campaigns claim that generics manufactured here are bioequivalent, but then the health authorities are unable to prove this. As an industry we must improve our capacity for quality.

What is the split between locals and multinationals in terms of market share?

Local companies control between 50 and 60 percent of the market. Research-based companies do not sell to the government on public bids. They only do direct sales because of the price. ALAFARPE's member companies simply cannot compete with local prices or the prices of Chinese or Indian companies present in Peru. There is a system in Peru for corporate bids in which the Ministry of Health, EsSalud, and the national army buy medicines together annually in an attempt to improve prices.

What impact has Peru's numerous recently-implemented bilateral treaties had on the industry?

The impact of this was definitely better for local companies, who saw their market cap increase significantly. These treaties have provided a good opportunity for local manufacturers to sell to the United States, assuming their quality is approved by the US FDA. Furthermore, Peru is a member of the Pacific Alliance and the TPP, which also helps with trade issues. Nonetheless, there is still a lack of data protection for biologics. This does not depend solely on ALAFARPE, but it is one of the sensitive items that is discussed within the association.

Traditionally, Peru has relied on its commodities for growth. How do you sense a move to a knowledge-based economy?

I think that in the pharmaceutical sector, local companies will improve their quality for which there will be a higher demand. In the 1990s, almost all ALAFARPE members had facilities in Peru because multinationals were obliged to do so. When the government administration changed, these companies moved to some other countries. Normally they had one production facility in the region, occasionally exporting from the US and most of the time from Mexico, Colombia or Brazil where they have facilities. Peru is simply too small; multinationals only have commercial offices here.

Could multinationals find other ways to invest in infrastructure in Peru?

This does happen in some cases, in which global companies buy local companies. For example, Abbott bought Recalcine. This provided with the American conglomerate with a facility in Peru without having to invest in a new one.

What is your vision for the future?

There are many opportunities to grow. Sistema Integral de Salud (SIS) is a new opportunity in which there will be more opportunities for access to health products for Peruvian citizens. We believe this will continue to grow the market. ALAFARPE simply asks for quality!

What are the most important priorities on your agenda in the coming years?

The implementation of the law for quality is my number one priority, as well as to help DIGEMID with the process. Peru has all the standards necessary to be competitive with patents. We want all components of the market to have the same standards. The message is all about standards and respect for intellectual property.

Where will the industry be in 2020?

In that time I hope the industry will most importantly have a stronger and more transparent relation with the government. They understand that we are part of the same environment, working together. This is not always so easy for them to understand. By improving our relation, we can help the government create better access to medicines, as well as demonstrating that clinical trials for any product is good to have in Peru. ALAFARPE also wishes for more multinationals companies to come and invest in Peru.

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