Raúl Díaz-Varela – Chairman, Kern Pharma

The market share of biosimilars in Spain has been increasing but the returns on investment have decreased steadily

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Kern Pharma's chairman and Grupo Indukern CEO, Raúl Díaz-Varela, explains the new strategic direction of the Spanish generics player, how their partnership with Celltrion to commercialise biosimilars has evolved, and analyses the main developments shaping the country's generics industry, including regulatory changes and pricing policies. In addition, he comments on Kern Pharma's sponsorship of professional sports and how they help the company improve its products,

Last time we spoke with you, in 2018, Grupo Indukern was celebrating its 55th anniversary, had managed to partner with Celltrion to commercialise their biosimilars in Iberia, and was looking to expand into Mexico and the United States. How has the company evolved since then?

The group's changes since the last time we spoke are fairly easy to explain, we wanted to concentrate our efforts in the health space, so we divested our chemicals API business and Grupo Indukern kept Kern Pharma and Laboratorios Calier for animal health. The transaction occurred virtually during the pandemic, which was a big undertaking.

Our current focus is to continue investing in expanding the group's geographical presence, seeking new agreements in Europe rather than South America as we did before. The reason for choosing European markets is competitiveness since many countries in South America have a heavy presence of Indian and Chinese generic companies. On the other hand, most of the generics we develop follow European patent timelines which meant that Kern Pharma was usually a latecomer in

Latin America. Today, the company has been adding more out-licensing deals than before, focusing on partners rather than specific markets.

When we discuss generics, we must acknowledge that chemical-based products are not as promising as they used to be five years ago because most of the relevant products losing patent protection are biosimilars or linked to a medical device. Nevertheless, we are still launching products in diabetes and cardiovascular, but the number has decreased significantly and the size of the target is smaller; there are no more atorvastatin- or esomeprazole-type products outside of the hospital setting. For that reason, we have been fostering our collaboration with Celltrion to commercialise their biosimilar products in Spain, Portugal and Andorra.

Speaking about Kern Pharma's partnership with Celltrion, how do you assess the biosimilars market in Spain?

Spain has been working on a new generic and biosimilars plan for a long time but we did not support the first draft because our belief [Kern Pharma and ASESEG's] is that both categories must be separated. If both types of products are to be bundled together, they should be only hospital-based generics since they resemble biosimilars more than those sold in pharmacies.

In our view, there should be two different plans but, at the end of the day, no plan was finalised and the industry remains operating under 2015 rules which strongly impacted the generics market.

The biosimilars market in Spain resembles that of hospital-based generics; during the pandemic, we have said that it does not make sense to always have tenders in the hospital setting, jeopardising the supply chain. It has become evident that price erosion has developed much faster than anyone could have expected, especially in some of the latest launches like adalimumab [disease-modifying antirheumatic monoclonal antibody] where it was clear that seven players coming to the market at the same time was not the best scenario; the price fell 90 percent in a matter of weeks. Celltrion has a particular approach of trying to be different and is trying to provide added value biosimilars, often called bio-betters. Innovators, naturally, are looking to extend patent protection by adapting or mixing their products, which is the case of Humira.

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How different is the regulatory framework for biosimilars compared to generics, which must include at least a 40 percent discount from the originator drug?

Most of the first biosimilars have a price reduction of 18-25 percent from the original product, but since the cost of production is higher than generics, it is difficult to succeed unless you have a really high volume.

We must navigate a first price reduction after which, following a decrease of the reference price or the originator's lowering of the price, a second reduction happens. Companies must be present in all tenders possible and contact with private or public hospitals; at the end, it is the responsibility of commercial entities to put forward the best offer. However, since Spain has a decentralised healthcare system, the price on one region has a disproportionate effect on another. Some products have already reached rock bottom of their price and companies have exited the market.

Can you walk us through the impact of the COVID-19 pandemic on the company and the market?

2020 was a tough year and 2021 a better one. The dynamics of the market depend on the specific product, but in general terms we have had to postpone product launches we had targeted for the last couple of years. We also had to be very flexible adapting the production of different products more in need (such us products for ICU treatment and sedation) and reduce some production plans on products not in demand (allergy, cough and cold, etc.)

In general terms, Spain was lucky because, having such a strong manufacturing base, the availability of products continued throughout the pandemic thus avoiding the shortages seen in neighbouring countries; the country has at least six large manufacturing plants with more than 1000 employees.

Adding to the challenges related to fewer patients being diagnosed and doctors being harder to reach, we must add the difficulty of explaining to our employees that we work in an essential industry, and they had to keep coming to work. The most challenging time was January of this year due to the high number of infections related to the Omicron variant. All in all, our industry cannot complain because we are essential and fortunate enough to have a job to do.

Spain recently unveiled an investment mechanism to employ EU funds in the reindustrialisation of its pharmaceutical industry and the improvement of the public healthcare system. How do you evaluate the opportunities ahead?

I remain optimistic about the prospects of the generics industry in our country. If we look at the European Union’s pharmaceutical strategy, it is clear that the system will change in the following years, benefiting companies that produce locally in the continent. Some aspects, such as only looking at price when evaluating medicines, must change soon so that aspects like local manufacturing and proximity and safety of the supply chain are taken into account.

Regarding the recent investment plan approved by Spain’s central government [PERTE Salud de Vanguardia], I believe that is a missed opportunity because I do not see any evolution in the way political personalities are looking at our industry; they have to change to allow companies to become more profitable while we are helping the system be sustainable.

It is quite strange that, for example, innovative companies behind COVID treatments and vaccines have seen their revenue multiply while other producers, such as Kern Pharma, that produce many of the essential medicines that have been used to treat the same patients have faced such price pressure.

Of course, representing one of the largest generics producers in Spain, I am not entirely objective but that does not make our concern less valid. Everyone must bear in mind the new challenges of 2020: much higher API, logistics, energy and labor costs; we are talking about an increase of production costs of 5-6 percent while medicine prices have remained the same. When we did our first analysis of the situation, we found that of the 380 “essential products”, 93 percent were below10 euros and almost 70 percent of those are 3 euros or less. The country fought a pandemic with products that cost very little but paid undisclosed amounts for vaccines and other treatments. There is lack of balance.

The Kern Pharma brand might be familiar to professional athletes and sports fans interested in cycling. Can you comment on the company’s strategy to sponsor a professional cycling team and other events?

There are different approaches to that type of sponsorship and investment. Kern Pharma uses its name to sponsor a professional cycling team which is essentially a marketing tool that we felt coincided with our institutional identity.

At the same time, the activity has been a good opportunity to promote our sport-related brand (Finisher). We use the opportunity to improve our products by working with the athletes to understand their performance, even modifying dosage and formulations.

Kern Pharma has been supporting many sporting events but has concentrated more on sports that push athletes to the limit such as marathons, triathlons and cycling; sports that push athletes to perform for at least 3-4 hours.

To conclude, what makes Kern Pharma the partner of choice for executives and investors interested in the Spanish generics industry?

With that many competitors it is not easy to differentiate yourself, but we always say that Kern Pharma has a comprehensive portfolio in different categories; we will always have something for everybody. We have GMP facilities with different technological capabilities that are compatible with the most rigorous regulations. With over 30-40 partners in Europe, we are used to cooperating with a wide range of companies and projects.

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