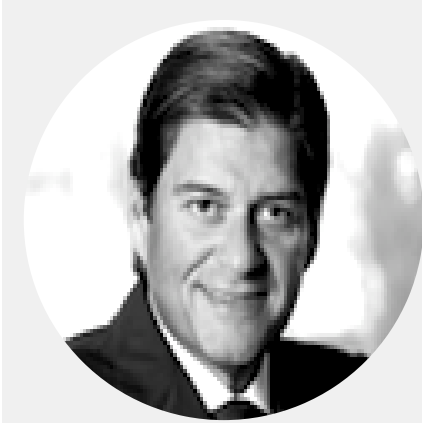


Interview: Raúl Díaz-Varela, CEO, Kern Pharma, Spain



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Raúl Díaz-Varela is the CEO of Kern Pharma and has served as president of Spain's generics association AESEG since 2008. He speaks to us about the challenges facing generic companies, and Kern Pharma's own strategies for growth through in-licensing and local partnerships in Europe and Latin America.

What are your goals as president of AESEG, having recently started your fourth term in this role?

When I started as President of AESEG six years ago, my goal was to build up a stable structure within the organization. Six years later, I can say that generics have done quite well due to patent cliffs and the number of molecules that were going to expire. But there have been many regulation changes that have negatively impacted the entire market, and price reduction of expired brands to the same price as generics does not allow generics to be differentiated in the market, which stifles growth. Therefore our main target is to allow generics to be cheaper than off-patent brands.

Today, generics are only used as a tool to reduce the prices of branded products. We can get some introduction through mandatory prescription by INN, which does inform consumers more about generics but it is not enough. In terms of products, generics in Spain are suffering the same problems that multinationals experienced many years ago; the number of products is still decent but the size of the market that these products have has shrunk. Therefore if we cannot get decent market share, our capacity for market growth is limited. This is in combination with the heavy price reductions that were implemented not only for generics but the whole market, leaving less room

for growth. We are still growing but not at the pace that we wanted, especially given that we are bringing so many new products into the market.

How is Kern Pharma innovative?

We are innovative in that we handle most of our own development and we are vertically integrated. Since we belong to a family-owned group that already had activities in the veterinary and API sectors, we have very good sourcing capabilities of API and we know the patent situation very well. Kern Pharma has its own development, production and commercialization, and as a vertically integrated company we consider ourselves capable of bringing new products into the market. In some areas we have been innovative in the sense that as a relatively new company we were the first to launch new molecules into the market and in some cases related to new technologies, sometimes based on pre-filled syringes or with controlled substances hard to acquire. While we participate in some areas of innovation, our main target is to bring as many products to market as possible, largely in the generics area. In that sense we were also innovative that we invested great effort to have a broad portfolio even as a young company in the beginning. Today, Kern Pharma has more than 150 generics and 400 presentations in the market.

What is Kern Pharma's market share?

In terms of value, Kern Pharma has about 7 percent in the generic market, and 1.3 percent of the total market. But we have also always considered strong positioning in units as a key factor as well, especially in Kern Pharma's early days. The company ranks third in the generic market and fifth in the total market in terms of units. That means every pharmacy in Spain recognizes the Kern Pharma brand. This really helped us at the beginning when the company was still largely unknown. Our investment in units has paid off in terms of helping obtain recognition as an important player in the pharmacy sector.

Kern Pharma is involved with a very wide range of therapeutic areas. How are you able to manage so many different indications?

It is clear that the generic market has moved from a GP/prescription market to a market focused on pharmacies. We do not consider ourselves as specialists in promotion at the doctor level although we still visit GPs and some specialty areas. Consequently, Kern Pharma has always focused on targeting pharmacies. That is the only way to manage such a large portfolio. Occasionally we still experience difficulties because it is not easy to launch more than 25 products per year. Sometimes we just launch products or place them into the market but we do not have time to promote them as they should be promoted. Thus, we place more effort into having a broader portfolio and we serve

our patients and pharmacists better by having one of the biggest portfolios in Spain with a focus in a few key therapeutic areas.

In light of recent pricing reforms, how have you convinced pharmacists to prescribe Kern Pharma products over other brands?

Kern Pharma has always communicated the same ideas and has always done so in the same manner. We have had a very stable team that has been with us for almost 15 years since we started promoting generics. We have always concentrated on using the same approach, providing pharmacists with as many products as they need with the best service possible, and always being one of the first to launch a new generic and provides a level of personal relationship to the pharmacist. I always say to our sales team that Kern Pharma can only differentiate itself from other generic companies by personal relationship. Today it is difficult to differentiate on pricing or portfolio (although we have one of the biggest) but creating trust on a personal level with pharmacists can make Kern Pharma stand out. Kern Pharma has always respected its promises and helped pharmacies to work this new market together.

Kern Pharma's production plant here in Terrassa is among the top five nationally in terms of number of units produced. How much does this plant contribute to the sales growth of the organization?

We always put great effort into having our own very competitive production. Generics are also based on economies of scale and it is important to have a competitive position in the production area. There are other models and companies that do not focus so much on their own production, but we consider this as a strategic perspective of Kern Pharma and that is why we continue reinvesting in new areas and facilities and sometimes in new technologies as well. We consider having our own production to be a big advantage. In terms of reputation, customers feel confident in our system of quality and how we work when they come to visit our facilities. This is especially true when we can demonstrate our capacity for both producing our own products and for third parties of very well-known companies; we maintain the same quality system and competitiveness. Furthermore, we place great emphasis on volume to remain competitive.

This high quality at an affordable price could indeed serve as a real competitive advantage for many Spanish pharmaceutical and chemical companies.

We consider ourselves similar to other Mediterranean European countries that have also had good capabilities in the past to compete in the global market like Turkey or Greece. Spain really is at the top in that respect as we still have competitive costs in labor and general production levels, as the

productivity of the Spanish plants is quite high. This is also true of multinationals with factories in Spain. There is a system and environment for training that helps to develop this competitive ecosystem for production.

We have always told our government that they should emphasize industry more. Luckily, the crisis has forced everyone to rediscover the country's industrial strengths. For a while, it seemed like housing and infrastructure were the only areas reasonable for investment. Today, everybody in Spain understands that the healthcare sector is an important part of the economy, not only in terms of being a strong industry, but also because it comprises nearly 20 percent of Spain's total R&D expenditure. As a sector primarily clustered in the Madrid and Cataluña regions, the pharmaceutical industry can be a competitive engine of economic growth in Spain.

What are the current and future markets that will serve as Kern Pharma's biggest strengths?

The company employs different strategies for different regions. For example, when we started 15 years ago many of the European markets were already significantly developed in generics, and this created some difficulty. In fact, we did not have such a big portfolio until after almost a decade of activity. In this regard, Kern Pharma experienced success in Portugal, which is also slightly behind in generics like Spain. We have been successful in licensing some products to third companies for whom we were able to develop prior to other companies, but our primary European strategy involves licensing out our own products with their brands and producing them for a certain period of time. Outside Western Europe, we have enjoyed good presence in Russia, although recent regulation there plus emphasis on local production has made business harder in Russia. Kern Pharma has also tried other markets like Turkey to varying degrees of success, and for a period of time the company has had strong presence in Colombia and Venezuela. We have also been present in Brazil through some agreements with third parties, supplying some of our products to Eurofarma. We are also looking at new markets like Peru and the Dominican Republic. Kern Pharma does some spot business in other markets, but licensing in Europe and in local presence in South America remain as the primary strengths.

With your strong international presence, what does Kern Pharma have to offer that is unique?

As an independent company we can offer similar companies to cooperate and exchange or in-license products. Compared to big multinationals in generics with their own direct presence, Kern Pharma normally works in those countries with other independent, family-owned companies. In

that respect we can offer a big portfolio of products to other companies that have a similar position. Locally, they can compete with the bigger companies, but internationally we all need to support each other in order to develop some of the market together. We still think of ourselves as being international but small. In our other two businesses, we have almost 70 percent of turnover outside Spain; here we only have 25 percent and therefore still have lots to develop.

Where can we expect to find Kern Pharma in another few years?

Kern Pharma will have a bigger international presence and we will probably enter other close-by areas of activities. Our OTC business is still fairly small but we can develop it, as well as non-reimbursed prescribed products. Kern Pharma has also invested in medtech, but not as part of the portfolio yet. We will continue to pursue new opportunities into biosimilars as well. We have already launched one biosimilar product in Portugal and we hope to bring more activity to that area. Our presence in hospitals will also be increasing. In five years, generics will still be the main driver but there will be other areas of activity; I do not consider Kern Pharma as a pure generic company but rather a pharmaceutical company with different areas of interest.

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