

**Juan Luis Fernandez Balaguer  General
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Juan Luis Fernández Balaguer, general manager of Laboratorios Combix, the Spanish affiliate of Zydus Cadila, shares the milestones achieved by the company since joining the group and its promising future as one of two European operations. Having formerly served as president of AESEG, he then goes on to offer expert insights into the generics environment of the market and what changes must be made to create a more sustainable competitive landscape for all pharmaceutical players.

How has Combix developed since being acquired by Zydus Cadila?

Before the acquisition in 2007, Combix was a very small company, a result of a joint venture between several pharmaceutical companies, with approximately EUR 2 million in turnover. Having been in France since 2003, Zydus Cadila was looking to launch its operations into the Spanish market and this was the beginning of Combix as we know it today.

I had the opportunity to join the company in 2009 with two key objectives; register products of the mother company in the market and to transfer products for which the cost of goods could be improved. We realized there was a big gap in the portfolio. In the pharmaceutical industry having one or two very successful brands is enough, however, when speaking about generics, we must be able to offer everything to the pharmacies. Large companies can have up to 500 or even 600 product lines and at this moment we have around 50 or 60. Therefore, portfolio completion has always been a way to gain market access for the company.

As of today, Combix has been growing very steadily and we have reached a turnover of EUR 15 million. Compared to major players in the market, we are still a modest company, nevertheless, we are focused on competition and Combix is here to remain. We are constantly moving forward, developing, and looking for new business opportunities.

What are your expectations for the company moving forward into 2019?

The generics market is growing at 4.5 percent but still, the penetration for the sector is relatively low at approximately 42 percent of units sold and 24 percent of total sales revenue. In a healthy market, the penetration in value should be around 40 percent, so we see that the sector is still undervalued and the potential role that the generic industry can play in reducing the bill to the public healthcare system has still not reached its full potential.

Many patents for big products will be expiring between 2019 and 2025 and we want to be a first mover here. The market is projected to grow five percent, therefore, my goal for 2019 is to achieve 20 percent growth. Having high aspirations is key for Combix.

What is the strategic importance of Spain for the operations of Zydus Cadila?

In the European region, the group has two affiliates; France and Spain. Out of Cadila's global operations, Europe accounts for just over two percent and Spain just under one percent. However, it is necessary to keep in mind that the group turnover is over EUR two billion and over EUR one billion in sales comes from the US, where Cadila has enjoyed great success.

In the European context, Spain is a very mature market where all the major players are also present. Both France and Spain are retained markets, which means we must work pharmacy to pharmacy and even patient by patient. In spite of this, through perseverance, we are motivated to ensure the importance of the European and Spanish market in the activities of Cadila.

What are the primary growth drivers of the Combix portfolio?

In the past, antibiotics were the drivers but today the main areas have adapted to the living habits of western society; cholesterol, hypertension, diabetes, central nervous system, etc. These are all very important but of course so are the oncological products. These drugs are now consuming 25 percent of expenditure from the healthcare system. Society is getting older and as life expectancy increases, it is complementary that the incidence of these diseases is increasing.

Additionally, because the lifestyle has changed in regard to the increased consumption of sugar, we see diabetic drugs becoming the new blockbusters in terms of demand. Many gliptins will go off patent and create a big market opportunity. Lastly, as a generics company, our primary product is in the cardiovascular area, atorvastatin, which helps compensate for the modern high-fat diet.

How is Combix's portfolio developing outside of the generics area?

Very recently, we have incorporated OTC products into our portfolio as they are synergetic with generics. We have launched a variety of products such as medical devices and including food supplements which are related to chronic diseases like arthritis. With a combination of medication, supplements and medical devices, we can help to improve the quality of life for these patients.

What do you see as the biggest challenge for generic players in Spain?

Spain is the only market in the European community where the price of the reference and generic drugs are the same; something neither player is happy about. In this regard, when generic drugs have introduced the price of the reference product is dropped, doctors are accustomed to prescribing a certain brand and do not feel the need to change. Therefore, the question becomes what right do generic products have to exist in the market?

In my personal opinion, this is something the healthcare stakeholders are not handling well. My first suggestion is to analyze other European countries where the market penetration of generics is

higher and their contribution to the health system is stronger. Some differentiation in the generics should exist; in the past, there was a positive discrimination law that even at an equal price, generics should prevail as the primary recommendation. This gave some tailwind to the evolution of generics and from 2010 to 2015 when the sector had growth from 5 to 10 percent. This was then removed, and the generic penetration dropped, now the situation of generics in Spain is not as it should be.

There have been discussions that this discrimination will be reinstated, even at High Court political level, we revived the support from the majority of the senators but so far there has seen no movement. Another possibility would be to create a more favorable reimbursement scheme for generic products. In the end, there are many solutions to the issue, but what is unacceptable is to keep the pricing of generic and reference products the same – we have a right to fair competition.

With these barriers in place, we understand that in order to gain some market share from a small segment, we must first to market, provide excellent service to pharmacies, and continue to push generics as a concept within health. From the health authority point of view, generics only exist to reduce the price of drugs after their patents expire. However, if we are not given space in the market, we cannot continue to invest in launching new products that reduce the price of drugs. A fair regulation must be established in order to protect the return on investment that is needed to sustain our contribution to Spain's healthcare system.

What message do you have to deliver to health authorities about the generics sector?

I would like to see faster approval of dossiers to reduce the entry barriers for generic products. The sooner generics can enter the market, the better they can benefit the public budget by reducing the cost of goods. Intellectual property is also very important, and patents must be respected, but once they expire and the innovator has had their opportunity to make a profit, the generics should be given their chance. Otherwise, the social contract of competition is broken.

What is your opinion on what many consider to be the fragmentation of the Spanish market over the country's 17 autonomous communities?

In my opinion, the only true fragmentation that exists is in the tendering system of Andalusia. The other communities are simply the logical differences that exist within the regions, which in reality are limited. Out of Andalusia, I do not believe there is a real fragmentation in this context.

However, the Andalusian tendering system creates a break in the market in such a way that it is very difficult to work in both Andalusia and the rest of the country. The fragmentation is not good as many companies are then forced to choose which market they will work in. In the case of Combix, we used to make one-third of our sales in Andalusia region, but we decided to remain in the rest of Spain.

How does Combix attract the investments of Zydus Cadila globally to Spain?

It is very important to showcase to opportunities for growth in the Spanish market. Combix presents plans and analyzes the internal portfolio of Cadila to identify the opportunities that exist for the products in Spain. Every three months we present the affiliate's evolution and strategies to highlight the possibilities that exist here.

What are your strategic priorities for Combix in the upcoming years?

Being at EUR 15 million today, I have the ambition to reach EUR 50 million in turnover for the medium term. The potential in the market exists, and I believe that if we take advantage of all our opportunities and work strategically, Combix can reach this goal by 2025.

What motivates you to work in the challenging sector of Spanish generics?

Although this is not a comfortable area to be in, it is a special one. I have been in the pharmaceutical industry for 30 years, starting in 1988, and have seen a lot of changes in both the industry and the country. Through my time in large organizations like Sandoz and service as president of AESEG (Spanish Association of Generic Medicines), I learned that every day you have to reinvent yourself and constantly grow. I love this industry because the generic sector is an area that works towards the improvement of the lives of patients. There is a strong commitment to health and despite challenges like competition and market share, I am proud to know the contribution to society that generics have.

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