

Interview: Osvaldo Ponchioli - CEO, OP Pharma, Italy



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Dr. Osvaldo Ponchioli, CEO of OP Pharma, discusses the expertise his company can offer to help navigate Italy's regulatory environment, the outlook for medium-sized generics companies in Italy and OP's plans for international expansion.

Dr. Ponchioli, you founded OP pharma in 1996 as a data management and generics company mainly offering regulatory services to the industry through its fast and efficient information retrieval system. What differentiates your company from other data management companies?

Our core business is the provision of an integrated solution for the complex regulatory requirements AIFA imposes on new products. We assist with all elements of product market authorization, including but not limited to communication and submissions.

We have also developed our own products, which do not conflict with those of our clients, and we have plans to move into the branded generics markets. We currently already have two products on the market but we tend to focus on product development for out-licensing; we do not deal with commercialization of our own products.

Our main offering is indeed our proprietary data management system, which we developed in-house and which is GMP approved. This is an integrated program that helps our clients manage documentation, and which provides automatic updates, maintains offline access and syncs

documents with their partners. This ensures that all changes are immediately apparent to all parties and everyone is up to date on the process.

Essentially, we facilitate the market authorization process. Our clients rely on us for fast and efficient market approval because the quicker their products are approved, the quicker they can be put on the market.

Generics companies require a dedicated system due to the sheer number of products they have in their portfolios. When OP Pharma started, we worked with pharma companies with maybe 10 or 15 products, and I remember that we started off using Microsoft Excel. With generic companies that have hundreds of products in their portfolio, this is now impossible. Our system helps keep track of administrative data as well as product documentation. We are the only company to offer this and this is what differentiates us from our competition.

What would you say is the secret to your success?

I have worked in the industry in both national and international pharmaceutical and consulting companies for my entire career, and during that time I have accumulated 35 years of experience. This means I have relationships throughout the industry, with pharma companies, regulatory authorities, and manufacturing companies. This has allowed us to build up a solid reputation for reliability and trustworthiness among the more significant players in the industry.

Another way I have bolstered this reputation is the safety features of our system. All documentation is shared on a single system but access to the system is regulated by many safety features, which only allow companies to access their own information. Security was a top priority in the design of our system, because our clients' trust is of utmost concern. Once a single mistake is made, this trust can be lost, so we need to be extremely careful not to lose the reputation we have painstakingly built up.

OP Pharma primarily caters to medium-sized generics companies. From your interactions with them, how would you rate the current business environment for these companies in Italy?

There has been a sea of change in the generics market in the past decade, which has been excellent news for my clients. Organic industry growth, following the patent expiry cliff in the 2000s and increasing pressure to cut healthcare budgets and costs, has been significant, and the Italian generics market has seen double-digit growth in the past decade. Generics companies have gotten very lucky and they have reaped the rewards of this industry development. The organic

growth of the generics market has naturally led to significant growth for both local and foreign generics companies in Italy

What is equally clear is that this growth is set to continue. Generics penetration is still low in Italy compared to other European countries, and given the unrelenting budget constraints, the generics market will only continue to grow, as these drugs represent a critical element of the solution to the problem of maintaining budget sustainability. The future is certainly bright for medium sized generics companies in Italy.

Regulatory complexity is still a major issue for the pharmaceutical industry in Italy but we have heard that AIFA has become more open and transparent over the last few years. Would you agree with this?

It is difficult to say if there has been concrete improvement. I remain quite pessimistic. There is still much room for improvement. The fundamental problem is that there is a power imbalance between the government and the pharmaceutical industry. If you look at how many companies actually appeal AIFA's decisions, it is indicative of how non-transparent the process still is. We have only seen one case.

The authorities are too focused on budget constraints and this is their main priority. Scientific evaluation, innovation, these are not prioritized as they should, and this is where the government comes into conflict with the industry. We understand the need for budget sustainability but this should not be achieved at the sacrifice of value and innovation.

The pharmaceutical industry is one which is traditionally dominated by a small number of multinational giants. However, in Italy, over 95 percent of the industry is actually SMEs and there is a notable group of Italian family businesses that has thrived. What do you think is the reason behind this?

It is true that there are a number of well-known Italian companies, which are family-owned, and they have seen great success. I attribute the success of a family-owned business mainly to the latest generation's affinity with the pharmaceutical industry. Not everyone has this, but the founders and sometimes, the successors and families of companies like Recordati and Menarini had a deep knowledge of the industry. Where they are able to pass this on to the next generation successfully, the company continues to do well. This in-depth, insider knowledge, accumulated over decades and combined with a long-term vision is what allowed them to build the companies to the successes that they are today.

However, this is a double-edged sword. Family-owned businesses have the critical weakness of continuity – they need to ensure that successive generations can manage the companies that they inherit. This is not always the case.

What is OP Pharma's five-year plan?

Currently, the business is still too centered around my experience and presence. I would want to gradually distance myself from it and begin to draw up handover plans. Concurrently, I would like to evolve the company by increasing our areas of competences and developing more products, among other things.

A core part of our strategy is international expansion. Traditionally we have remained primarily in Italy, however that is changing. Internationalization has become a trend borne of necessity among Italian companies during the crisis, and we are no exception. Although I do believe the generics market in Italy is still relatively underdeveloped and has significant room for growth, we will continue to focus on our regulatory services at home while building up a solid generics business abroad. Today, we are looking to expand aggressively into emerging economies in Asia, Latin America and the Middle East, as there is significant potential for our products there. As I mentioned earlier we currently have two products on the market in Italy, but are looking to expand our portfolio with high-potential drugs destined for emerging markets. Our strategy is to break into these markets and establish a solid presence and reputation locally, thereby building up a foundation generating enough revenue to support our entrance into more mature, difficult markets like Europe and the US.

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