Jordi Faus – Founding Partner, Faus & Moliner Abogados

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Faus & Moliner Abogados is a Spanish law firm that has been specializing in pharma and life sciences law since 1997. Founding partner Jordi Faus explains how having a comprehensive knowledge of the industry has become the firm's competitive edge. He discusses the push for regulatory innovation among European regulators, the industry, and public healthcare systems, the growing influence of patients, and

the improvement in Spain's clinical trial environment.

What is the underlying philosophy behind your firm, Faus & Moliner Abogados? Why did you decide to specialise in the pharma and life sciences industries?

The firm was born with the philosophy of doing things differently, searching for a new way of practicing law. We were facing the classic specialisation of law firms by categories like civil law, tax law, family law, employment law, and so on. What we tried to do is get away from that model and be a law firm for the pharmaceutical and life sciences industries, providing advice and support to navigate matters related to our clients' core business. This allowed us to get a full grasp of the environment where our clients operate, the economics behind the industry, as well as the regulatory, social and political environment. We have been rewarded with a very strong position in the market because the firm knows who is who and the expectations of our clients.

Moreover, we conduct a knowledge-based operation in a complex and heavily regulated industry that must consider international treaties, European laws, national laws, and regional regulations, all of which have evolved in the last 25 years.

I stress to our team that it is important to understand not only the economic, social and political environment, but also the history of pharmaceutical law; this allows you to understand why things are done a certain way in today's industry. The evolution of the rules is key. In 2018, together with Professor José Vida from the Carlos III University, we worked on the first treaty of pharmaceutical law (*Tratado de Derecho Farmacéutico*), a very comprehensive publication explaining the rules that the Spanish government has set at various times.

Our firm always tries to challenge classical barriers, the idea that things are done a certain way and cannot change. Something an official tells you might not be written into a law, so we must go to the root of it.

Another typical barrier is that you are never supposed to litigate against regulatory bodies like the European Medicines Agency (EMA), or the Spanish Agency of Medicines and Medical Products (AEMPS). Of course, no one wants to litigate, it is something to be avoided as much as possible. Nevertheless, while it is not the best option and no one wakes up wanting to litigate, it is true that some important milestones have been achieved through litigation. Like it or not, litigation helps build a body of rules that facilitate the betterment of patients' lives, the activity of companies, and even the activity of the administration because it can bring rigour to the process.

Since you chose to specialise in the pharma and life sciences industries, who would you say are your biggest competitors? Are they big multinational law firms with life sciences departments?

Yes, they are competitors in a sense. But these firms are under the pressure that a bigger structure puts on partners and associates, whereas we have a smaller operation that can better cope with that pressure. Large law firms do have people specialised in life sciences but, at least until today, I have not seen one European firm with a dozen lawyers specialised in the industry; many times they are part of other departments such as intellectual property. On the contrary, we are 100 percent devoted to the industry.

In your experience, how comprehensive is the legal knowledge of regulators and government? Are they up to the task?

They have very strong legal departments, for sure. For instance, the legal department at the EMA is led by Stefano Marino, a bright lawyer that used to work for the industry and knows both sides well. However, it is true that you can find a lack of legal support at intermediate levels of the structure of regulatory agencies. For example, I am not sure that the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) has strong legal support in its day-to-day activities.

Within Spain, AEMPS certainly has a robust legal department, and the Ministry of Health and payers have state attorneys that are dedicated to supporting them in the event of litigation.

Just like industry, regulators and governments are navigating uncharted waters with the arrival of personalised medicine and the biologics boom. Who is driving the regulatory changes that will allow healthcare systems to cope with this new reality?

It is a combination of both, at least in Europe where any regulation must take into account two fundamental things: healthcare-related matters (the safety, efficacy and quality of products) and the sustainability of the system, how to ensure that medicines are available for patients.

Regulators, the industry and people in charge of the public healthcare systems are all pushing for regulatory innovation. In that regard, I think that the European Commission’s (EC) work is interesting because, not being affected by day-to-day budgetary pressure, they are able to look at things from a broader perspective; they are very much interested in securing Europe as a place where public health is heavily protected and a robust industrial sector flourishes. At least in the last 25 years, the ideas coming from the EC have pushed in this direction.

The big challenge in today’s world is how to harmonise the pressure for access from patients – who demand that new drugs are available as soon as they come out, many of which are lifesaving or address an unmet medical need – and the uncertainty of new products, along with the impact on a country’s finances. There are many competing interests.

Something we have seen recently is that the position of patients is growing in importance, demanding what we call individual patient rights. Like it or not, we will have a debate about this because, in all modern constitutions, the right to life is considered a fundamental right. What does that mean? Does it mean that you have a right to exist, or does it mean that you have a right to a

treatment that will save your life? For public systems, does the system have the obligation to pay for those treatments? These issues raise interesting ethical debates.

In Spain, there are precedents that recognise the right of patients to have access to certain drugs based on the protection of fundamental rights, which may be enforced via special, faster procedures.

What would you say to foreign companies that look to the EU market for market access and find a layered and decentralised environment where they must deal with a European regulator, national regulators, and, in many cases, regional authorities?

For the purpose of getting regulatory approvals, the system is straightforward; the EMA has very clear procedures. A non-European company knows that the door of entry to the EU market is the EMA and that they will assess the quality, efficacy and safety of your product. EMA approvals are valid in all EU member states.

The challenge for companies in terms of market access is securing that the product is approved for reimbursement by the different national health systems. That part will remain a national matter, although countries will have to consider European procedural rules and directives, including some that ensure there is no discrimination in favour of local companies.

Also, let us not forget that market access decisions have become increasingly complex. The industry is now facing situations where payers want to have risk-sharing mechanisms, volume-based contracts or deferred payment systems.

Another interesting aspect is the evolving relationship between companies, payers and hospitals. Nowadays, companies understand that they may add value by collaborating in the diagnosis of diseases, the follow up of patients, the gathering of data, keeping patients away from hospitals, and so on. This, of course, raises many legal issues.

What is the situation around risk-sharing agreements in Spain?

At least in Spain, in this area we are seeing very frank and open collaboration between payers, regions and the industry. The new systems generate challenges for everyone, indeed, including physicians that must collect data, but this situation will only improve because the European health data space will be a reality one day, things will be easier to manage for physicians will see the

advantages of artificial intelligence tools. In terms of who wins and who loses, at least from my experience, I have not seen any important dispute in connection with the implementation of any risk sharing agreement.

What are the main issues being brought up by the firm's clients in Spain?

A lot of our most recent work has to do with market access. Another area on which are are very active is public procurement and innovative schemes as regards the relationship between companies, hospitals and payers.

Another hot topic nowadays is the transparency of prices. We have heard a lot about it in the context of the European Union's vaccine contracts during the pandemic; it is an area where you must find a balance between transparency and negotiation power. I am not an economist, but I have read plenty of literature about the economics of transparency and it appears to be a generally accepted conclusion that the more transparent the prices are in any given market, the higher the prices because companies are more reluctant to grant discounts.

It is logical and fair that the public wants to know how the government is spending its money, so the system must give information to the public, but I am not sure if it is necessary to go into specific details if this harms the negotiation power of the authorities.

Another hot topic is competition law applied to the pharma sector as there have been important cases of excessive pricing in Europe.

Is there any talk about exploring the possibility of national tenders in Spain?

We have not seen movement towards national tenders, no. The regional structure of the Spanish healthcare system is very strong.

Despite being a Big 5 European pharma market, Spain seems to punch above its weight in clinical trials. What are some of the reasons behind this?

That is a very good question because, indeed, the clinical trials environment in Spain has improved a lot in the last years. Spain has become a very attractive country for clinical trials. There are several factors behind this, first, the country has an extremely good healthcare system, one that

has contributed to Spain having one of the top five life expectancy rates in the world. The system is open to projects and initiatives. Also, the regulatory tools have helped because we now have a system where you can have one ethics committee approval that is valid throughout the whole country. Regional authorities have been active in developing reasonable templates for agreements. We do plenty of work in clinical trial agreements and have seen a positive evolution.

Has market access followed the improvements in the clinical trials environment?

The Spanish Ministry of Health is currently working on an amendment to the law and market access, pricing and reimbursement procedures are topics they wish to address. The draft of the new law will probably see the light soon. On the other hand, the mere fact of talking about these matters has already resulted in some procedural improvements in Spain.

Is this amendment a process that is repeated often in Spain?

Not necessarily. I began working with a law that dated back to 1990, the next big change came in 2006 which is when the law we are working with today was passed, although it was reorganised and put together into a single text in 2015. This is a once in a generation opportunity to improve legislation. Our firm has presented a document with recommendations and we are proud to say we have been doing this on our own, with the objective of sharing our independent views on some very relevant matters, and without getting instructions from any of our clients.

Is there anything else you would like to add regarding the firm?

I would like to add that the firm is very active in matters related to environmental, social, and corporate governance (ESG), as well as with issues related to compliance and promotion of drugs. Also, we have an important practice in both litigation and arbitration. The latter is a fantastic tool to solve commercial disputes between companies. Spain was a market where, traditionally, many products were marketed under licence or co-marketing agreements, and we also have a lot of experience in connection with these agreements.

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