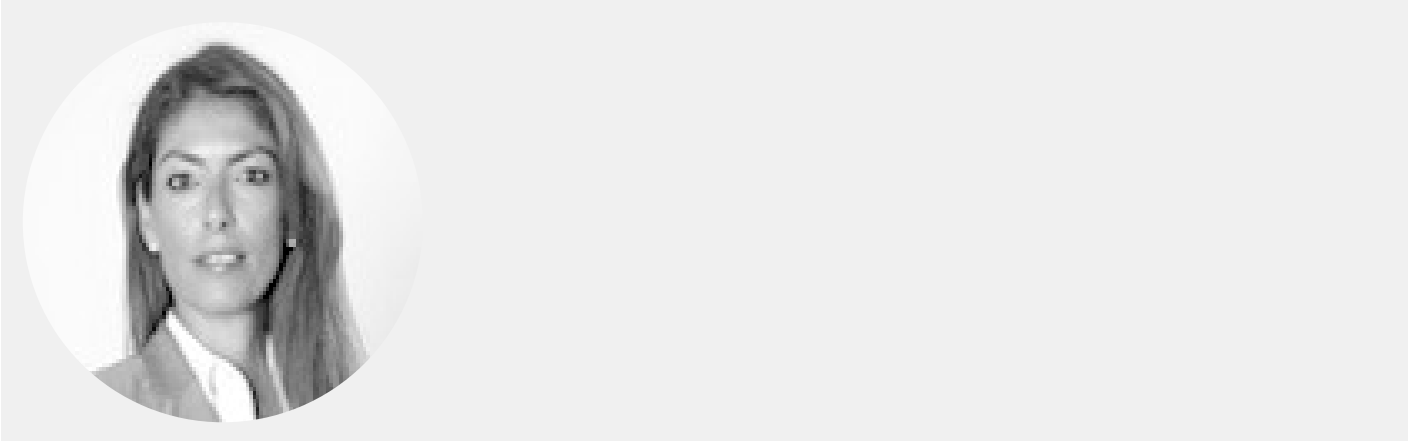
Interview: Ana Menéres, Managing Associate of Life Sciences, SRS Advogados, Portugal



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“The advantage of working in a law firm such as SRS Advogados is that it favors specialization in specific legal areas, such as life sciences, in order to meet the client’s needs. The regulatory aspects require study and preparation and are the main aspects of the legal advice of the life sciences industry,” states Ana Menéres, managing associate of Life Sciences, SRS Advogados, Portugal.

What is SRS Advogados’ positioning within Portugal’s life science industry?

SRS Advogados has been very active in working with pharmaceutical companies for many years. We are one of the most important players in the market in this sector as there are very few lawyers with this expertise and experience in this area in Portugal. As such, we work with some of the prominent pharmaceutical companies in the US, UK, France and Germany. More recently we have developed the market of biotech and startup companies.

Portuguese law is equivalent to other European countries’ regulatory law regarding pharmaceutical products as a result of the transposition of EU directives from 2001 in 2006. Since 2006, almost every year there have been changes in Portugal’s legal framework, so SRS has focused on helping clients to understand the changes. Every pharmaceutical product cycle is regulated in Portugal, from the start of clinical trials until the product is launched in the market, which is split between

inpatients (hospital) and outpatients (pharmacy), each with different rules. Additionally, each country has its own rules regarding prices and reimbursement. The EU does not have uniform regulation regarding prices. We cannot say that there is one market regarding pharmaceutical products, since each country has its own market. However, the regulatory rules are almost the same since they result from directives transposition, which also affects the regulation of clinical trials. In fact, economically each country is a different market because of pricing and reimbursement. In order to start a clinical trial, the authorization of the national agency is required and this takes a while. This has hindered the progression of clinical trials in Portugal.

You started your tenure here in 2011; what opportunities did you see in coming to this firm?

SRS Advogados is a law firm that has good clients in the pharmaceutical industry. There are only three or four law firms that work for this industry. SRS is one of them. In more recent times, we have gained new clients on a monthly basis because of the law firms' reputability in Portugal.

From your perspective, what are some of the ways the Portuguese healthcare system could be made more sustainable so that pharmaceutical companies are not losing out?

It is very simple. The pharmaceutical industry needs to know the rules of the game. The industry also needs transparency, particularly regarding the conditions that were requested to their competitors. This needs to be public, and it is not because there are agreements made with each company in private. These kinds of agreements are not illegal, but there is no transparency.

You said that since 2006 there have been many changes in the rules. What is the most important advice you give to clients in dealing with these changes?

The pharmaceutical industry needs to be informed and to request advice regarding the scope and effective consequences of each change in the law, in order to plan future investments or divestments.

Many multinationals in Portugal used to have R&D and manufacturing facilities years ago. How can you ensure that their R&D investments are safe?

There are no problems regarding safety. The pharmaceutical industry takes measures to ensure that their clinical trials are safe. The problem is that they take too long to get approved.

In respect to the safety of R&D investments, this is something that depends on the results of clinical trials.

What could be streamlined to make authorization faster?

The government could produce very clear opinions of the ‘DOs’ and ‘DON’Ts’, for example, regarding the procedure required for approval. They could employ more people to work on this, so that decisions are made more quickly. It is a problem that arises from the financial crisis; there are less people working in these agencies and decisions then take longer.

You said biotech was becoming increasingly part of your portfolio. How does SRS help its biotech clients obtain funding?

In order to obtain funding, it is crucial to obtain regulatory authorizations required for the approval of the final product or process, whatever the invention at stake is, and to launch it in the market. In accordance with our experience, biotech companies stand a chance to succeed with financing if they obtain a favorable opinion from the European Medicines Agency to start a clinical trial, and to obtain a favorable opinion from the Portuguese medicines agency INFARMED. Ultimately, financing depends on regulatory milestones being achieved.

How can Portuguese companies use tax credit to their advantage?

SRS has a tax department that provides advice to its clients in many matters, including tax incentives.

What are some of the ways that more international investments could be made in Portugal, through attracting either venture capital or business angel investors for biotech?

The biotech capacity of Portugal has been well promoted. Startup biotech businesses are always attending conferences and seminars, and AICEP and other Portuguese agencies as well as the Portuguese Government have succeeded in making Portugal an easy place to establish a company. There are many initiatives that promote entrepreneurship in Portugal. SRS Advogados works for companies’ incubators, who has organized many seminars and has been promoting a number of initiatives linked to the biotechnology business. Furthermore, there are many centers in Portugal that stimulate the creation of startups. SRS Advogados works for several start-ups in Portugal in the Life Sciences Department.

How can synergies be created through partnering or technology license, to foster more collaboration in the industry as a whole?

As lawyers, we should not be involved in that area. We deal with clients independently, and they tend to discover partnerships on their own. We just give legal advice. I think that pharma companies and small startup biotech companies know their needs well, and which partnerships are the most adequate.

How do you adapt to the individual needs of your varied clients?

It is important to have experience, and we have experience with many types of clients. Indeed, it is very different to work with a big pharmaceutical company compared to a small biotech startup. Historically, SRS Advogados and similar law firms in Portugal have always had a mix of national and international clients.

What are the advantages of being a small, independent law firm?

In Portuguese terms, SRS Advogados is not small. We are one of the five biggest in Portugal. The great advantage of independence is that we work with other international law firms. An important part of our life sciences legal activity is to give advice to international lawyers, with whom we work at other firms in case they need advice namely in regulatory affairs.

What makes SRS Advogados the strategic partner of choice?

Firstly, our know-how has been developed in legal advice from many years of experience. We are focused on the client's business and in achieving the client's goals. SRS Advogados also has a well-organized structure, capable of giving the legal support required in all areas.

What are your expectations for the pharmaceutical and healthcare industry in five years?

In recent years, there have only been a few products launched. In 2014, we are advising clients in launching new products. There are a number of drugs with patents ending. There was a period where no new products entered the market. Now we will hopefully have a period where new products enter the market. If governmental entities understand that and try to help biotech companies take less time to launch their products into market that would be very helpful. On the other hand, there are international launches of big pharmaceutical companies expected for 2014. We hope that trend continues.

What is the most important aspect of legal advice in the life sciences industry?

The advantage of working in a law firm such as SRS Advogados is that it favors specialization in specific legal areas, such as life sciences, in order to meet the client's needs. The regulatory

aspects require study and preparation and are the main aspects of the legal advice of the life sciences industry. Since we are a multidisciplinary law firm within the legal areas (not in other areas), we may render legal advice in all other legal areas as well.

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