



LIFE SCIENCES & HEALTHCARE

SRS Advogados is a full-service, multi-practice law firm advising clients on all aspects of domestic, as well as international law.

Our lawyers are focused on their clients' business and have gained knowledge and experience advising large national and international corporate groups, financial institutions, as well as local and national authorities.

We are organised by specialist practice areas and sector groups. This dynamic structure allows the firm to combine a diverse range of legal experts within a group, all of whom have relevant sector knowledge and experience. Sector groups have an extensive understanding of areas in which our clients operate and assist clients in fulfilling their objectives. We know our clients' business and regard ourselves as an active and dynamic part of it.

The Life Sciences team at SRS Advogados provides assistance to the pharmaceutical and biotechnology industry in all stages of the life cycle of medicinal products, as well as to the medical devices industry.

The team also provide assistance to cell and tissue banks, having increasingly gained and developed expertise in this area.

The lawyers of the Life Sciences team have significant experience and in-depth knowledge of pharmaceutical and biotechnology companies since the early stage of their incorporation and set-up in Portugal, as well as in the I&D stage, including all legal aspects regarding clinical trials to be performed in Portugal, in particular filings of applications for authorisation to commence clinical trial agreements with medical institutions, trial centres and investigators.

Our experience also includes:

- > Legal assistance to protect IP rights, trademarks and patents, and all regulatory procedures required to obtain a marketing authorisation and other licensing procedures and, in general, all regulatory matters related with the life cycle of medicinal products
- > Pricing of medicinal products, state reimbursements and the establishment of distribution structures, as well as commercial practices, including discounts, promotions and events, and advice on legal regulations applicable to the sales and marketing of medicinal products in general, both in the pharmacy market as well as in the hospital market
- > Licensing of human cells and tissue banks and activities related with the donation, procurement, cryopreservation, storage and use of human stem cells and tissues
- > Advising university spin-outs and the financing of projects in that area

The Life Sciences team provides its services in alignment with the management/board of medical directors, compliance and regulatory directors and commercial directors of its client companies in order to:

- > Advise and implement clients' projects
- > Ensure full conformity with the legal rules governing the full life cycle of the covered areas
- > Prevent breach of applicable legal and regulatory rules
- > Ensure an efficient defence in proceedings involving the clients

Through the creation of SRS Global (Angola, Brazil, Macau, Malta, Mozambique, Portugal and Singapore), as well the creation of a strong network of international relationships with third parties, we aim to extend our experience, expertise and services globally so as to ensure that we can respond efficiently to complex issues with global implications.

AREAS OF FOCUS

- > Circulation within the EU, imports and exports to third countries, rules applicable to parallel imports
- > Clinical trials, preparation and revision of documentation, including informed consents and agreements with trials centres and investigators
- > Establishment of distribution channels, preparation of documentation, agreements and prices charts and general sales conditions
- > Financing of life sciences projects
- > Legal audits and legal training conferences, preparation of internal manuals with legal information and procedures regarding legal matters
- > Personal data bases, including health data bases, preparation of documentation to collect data and informed consents, approval by or registration at the National Personal Data
- > Procedures regarding pricing, prices revision, prices reimbursements and reimbursement agreements
- > Procedures regarding the life cycle of medicinal products in the hospital markets, public procurement procedures to select Portuguese NHS suppliers and procedures to supply products to the hospitals markets
- > Production license agreements, services agreements regarding production and supply of active substances
- > Promotions, samples, advertising and events
- > Protection committee
- > Protection of IP rights (trademarks and patents)
- > Regulatory procedures, MA and other authorisations
- > Review of the documentation regarding promotion and marketing

CONTACTS

The Curricula of the contacts can be seen in www.srslegal.pt



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