



Trench
Rossi
Watanabe.

**LIFE SCIENCES &
HEALTHCARE**

trenchrossi.com

GROWING YOUR SHARE OF THE MARKET

The road can be long and difficult for healthcare companies. Take your next steps with world-class advisers.

Brazil's growing population has a huge appetite for innovative, safe and effective products. To attend the demand, local businesses are expanding and international healthcare companies are interested in alternatives for introducing products into Brazilian market.

Although there are opportunities, there are also challenges. The Brazilian regulatory framework is complex, highly regulated and subjected to conflicting interpretations. Licensing companies and the obtainment of marketing authorizations can be a time consuming procedure. Intellectual property rights are protected, but they require vigilance and a proactive strategy.

Trench Rossi Watanabe offers the legal, technical and commercial know-how you need to tap into and grow in the Brazilian market. We are a full-service law firm with experience and knowledge in all the traditional areas of law and in these specialty industries. Our lawyers represent domestic and international investors with equal ease.

We assist companies in the sectors of medicines, pharmaceutical inputs, medical devices, cosmetics and hygiene products, household sanitation products, foods and supplements, beverages, animal health products and agrochemicals.

We anticipate and address regulatory issues that may affect your operation and, whenever necessary, we assist with dealing with public agencies at the local, state and federal levels.

If controversy occurs, we can defend your interests through litigation or administrative procedures. We are experienced with product recalls and defending or pursuing charges of unfair business practices. In several cases, we have set precedents on how Brazil's health laws are interpreted.



HERE ARE WAYS WE HELP

- Advisory services for obtainment, modification, cancellation and transfer of product registrations before the National Health Surveillance Agency ("ANVISA") and before the Ministry of Agriculture, Livestock and Supply ("MAPA");
- Advisory services related to local and international inspections for Good Manufacturing Practices Certification;
- Assistance with matters involving Production Development Partnerships ("PDP's") and technology transfer agreements;
- Drafting and review of agreements related to manufacturing, distribution, co-marketing, among others;
- Advisory on clinical trial matters, including importation of investigational products, approvals before Research Ethics Committees and before the National Committee for Ethics in Research (CEPs and CONEP), drafting of agreements and of Informed Consent Forms, among others;
- Preparation of administrative defenses and appeals to be filed against ANVISA, MAPA and local health authorities;
- Advisory services related to the licensing of companies before ANVISA (Operating Authorization - AFE), before local health authorities (Operating Licenses - LF), and before MAPA;
- Advisory and litigation services related to matters involving the Chamber of Drug Market Regulation ("CMED");
- Comprehensive assistance with corporate transactions, in order to identify and solve possible regulatory issues;
- Advisory on compliance programs applicable to healthcare companies, considering the guidelines provided by industry associations and specific regulatory provisions;
- Advisory on public tenders and on waiver/unfeasibility procedures involving the industry.

DID YOU KNOW?

- We have participated in several meetings with ANVISA, CONEP and MAPA in order to discuss about innovative products and activities in order to obtain decisions that could benefit our client and in order to initiate discussions about the modification of the existing rules in view of new technologies;
- We monitor Public Consultations and the publication of new regulatory rules every day in order to maintain our client updated;
- We organize interdisciplinary discussions with our clients about legislative updates;
- We provide counseling advice to clients on legislation related to the cultivation and medicinal use of cannabis sativa.

AWARDS AND RECOGNITION

CHAMBERS LATIN AMERICA

In the 2016 edition, clients and peers praise Henrique Kruger Frizzo: "He deals with the Brazilian sanitary authority, ANVISA, and is excellent for regulatory matters."

ANÁLISE ADVOCACIA 500

The 2018 edition conducted an interview with more than 700 representatives of the major companies in Brazil. Trench Rossi Watanabe appears in all the 19 areas researched by the publication.

LATIN LAWYER 250

The 2018 edition recommends Trench Rossi Watanabe, highlighting the quality and expertise of our lawyers in most practice areas.

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