

**HEALTHCARE &**

**LIFE SCIENCES**



**Yolanda  
Puiggròs  
Jiménez de Anta**

**Partner**

**In particular, the Healthcare & Life Sciences team deals with the following matters:**

## HEALTHCARE & LIFE SCIENCES

The Healthcare & Life Sciences Department offers advice to companies operating in the healthcare industry, ranging from providers of healthcare services and medical equipment to laboratories and distributors of pharmaceutical and healthcare products. It also provides advice to biomedical research centres and on research projects related to healthcare.

## A COMPLEX AND HIGHLY SPECIALISED SECTOR

The healthcare industry is unique in that any party looking to operate within it must ensure that they are familiar with applicable law and regulations, the agents involved and the complex relations between these and with the healthcare authorities, which must green-light the intended service, establishment or product before it can be provided, sold or made available. Interested parties must also be aware of how procurement processes work with the numerous entities that make up the Spanish National Health System and how to defend their interests in the event of fines or claims for liability.

## SPECIFIC ADVICE ON ALL FACETS OF THE WORK CARRIED OUT BY HEALTHCARE INDUSTRY AGENTS

The Healthcare Department at Roca Junyent offers advice on:

- Authorisation, registration and pricing of medicine funded by the Spanish Health System.
- Authorisation for pharmaceutical establishments and business licenses.
- Authorisation to market and sell healthcare products and cosmetics.
- Transfer of marketing authorisations.
- Suspension or withdrawal of authorisation to market and sell medicinal products.
- Market access for medicinal and healthcare products.
- Clinical trials.
- Shared risk agreements.
- Public and private agreements to supply medicinal and healthcare products to healthcare centres and pharmacies.
- Compliance with applicable law and regulations, codes of ethics and good practices.
- Advice to Drug Research Ethics Committees.
- Revision and adaptation of the sales proposals in accordance with the requirements of pharmaceutical or health product legislation, as well as the good practice codes of FARMAINDUSTRIA and FENIN at a national level, and of EFPIA and EUCOMED at a European level.
- Revision, consultancy and adaptation of the value transfer practices in accordance with the FARMAINDUSTRIA and EFPIA good practice codes.
- Revision, consultancy and adaptation of contracts and agreements with health professionals and clinical practice institutions.
- Revision, consultancy and adaptation of training proposals and scientific events in accordance with the recommendations of the good practices codes of FRAMAINDUSTRRIA and FENIN.
- Consultancy and drafting of internal codes of conduct.
- Revision, consultancy and drafting of contracts for drugs, health care products, medical equipment and diagnostic software.
- Training programmes for marketing departments and the sales network of companies related to the practices permitted and prohibited in the applicable codes of conduct, introducing the concept of compliance as a competitive advantage.
- Consultancy on the preparation and implementation of commercial compliance programmes for drugs and health care products.
- Drafting of informed consent sheets.
- Authorisation, registration and accreditation of healthcare centres.
- Procurement, contracting and other interactions and business between providers of healthcare products and the healthcare authorities or their agents.

- Specific advice on health law: informed consent, advanced directives, refusals to receive treatment, rights of healthcare system users, data protection, voluntary and obligatory medical discharges, etc.
- General advice on all aspects of the law governing hospitals, primary care and public health centres, laboratories and medical equipment companies.
- Medical liability and healthcare centre liability.
- Biomedical research: genetics, regulation of extraction conditions and use of cells and tissue.
- Cell and tissue Banks.
- Assisted reproduction.