The Pharma Legal Handbook

Spain

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs

PHARMA BOARDROOM

Spain

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Spain.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with Faus Moliner Abogados, a leading spanish law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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Faus Moliner Abogados is a modern boutique law firm, specialised in dealing with legal matters typical of the pharmaceutical industry and other companies which operate in the "life sciences" sector. Faus Moliner, which was founded in 1997, focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. The firm advises pharma and healthcare clients, acts on behalf of large companies and smaller biotech start-ups, and is frequently called upon to advise public authorities on matters such as draft legislation.

The Firm decided to pursue this specialisation route because its founding partners were convinced that they would be able to create more value for clients if they not only offered solid legal skills, both theoretical and practical, but also a deep knowledge of the social and economic environment of the sector in which their clients operate.

The Firm combines legal skills and specialization with a practical and business-oriented manner of practicing law. This allows Faus Moliner Abogados to offer innovative solutions and at the same time to provide adequate responses to the cases which are entrusted to us. Nowadays, the Firm is formed by ten lawyers all of them specialized in the "life sciences" sector.
Since its foundation in 1997, Faus Moliner has been the market leader in the area of pharmaceutical law in Spain as recognized in several international publications.

THE AUTHORS

EDUARD RODELLAR

Eduard Rodellar, a partner, is a member of Faus Moliner since 1998. He has wide experience in providing legal assistance on a great variety of matters typical of the pharmaceutical industry and other companies operating in the life sciences sector, especially in the areas of mercantile and procedural law. He is specialized in clinical trials and data privacy. Mr. Rodellar has a Law Degree from the University Pompeu Fabra, a Master's degree in Legal Practice from the Barcelona Bar Association and a Master's degree in Business, Tax and Legal Advice from ESADE.
Languages: Spanish, Catalan, English and French

JUAN MARTÍNEZ

Juan Martínez is a senior associate of the firm and regularly advises national and international companies on litigation and arbitration procedures. He specialises in conflicts related to contracts, unfair competition, product liability and regulatory matters. Mr. Martínez has Law Degree from the University of Granada, and a Master of Legal Practice with a specialization in International Business Law at the Garrigues Studies Center
Languages: Spanish and English.

ANNA GERBOLÉS

Anna Gerbolés is a senior associate of the firm, with experience in advising national and international companies on the regulation of the pharmaceutical and food sectors, advertising of medicinal products, healthcare and food products; as well as litigation. Anna has a Bachelor's Degree in Law from the University of Barcelona, an LL. M. in Professional Legal Practice from the University Pompeu Fabra and a Graduate Diploma in Quality Control and Food Safety Legislation, from the Autonomous University of Barcelona.

LAIA RULL

Laia Rull, a junior associate, specializes in the regulation of pharmaceutical law and healthcare sector. Ms. Rull has a Law Degree from University Pompeu Fabra, a Master's degree in Professional Legal Practice from UPF - Barcelona School of Management and a Diploma in Legal Studies from the University of Oxford.
Languages: Spanish, Catalan and English

LLUIS ALCOVER

Lluis Alcover, a senior associate, is specialized in corporate and M&A, regulation of the pharmaceutical and healthcare sector, market access and financing of medicinal products. He regularly advises national and international clients in the areas of the activities described. Mr. Alcover has a Law and Economics Degree from the University Pompeu Fabra, and a Master's degree in Business, Tax and Legal Advice from ESADE Barcelona and a Management Development Plan (PDD) from ESADE Madrid.
Languages: Spanish, Catalan and English.

SANTIAGO TOMÁS

Santiago Tomás is a senior associate of the firm, with experience in advising national and international companies in the areas of public procurement, regulatory matters of the pharmaceutical and healthcare sector, corporate transactions and commercial contracts. Santiago has a Bachelor's Degree in Law by University Pompeu Fabra of Barcelona and a Master's Degree in Tax Advice and Management by ESADE Business and Law School of Barcelona.
Languages: Spanish, Catalan and English.

JOAN CARLES BAILACH

Joan Carles Bailach, an associate, is specialized in pharmaceutical law. Mr. Bailach has a Law Degree from the University Pompeu Fabra, a Political Science and Administration Degree from the University Pompeu Fabra, Master's degree in Professional Legal Practice from UPF - Barcelona School of Management, and a Master's degree in Economic criminal law & Compliance from UPF - Barcelona School of Management.
Languages: Spanish, Catalan and English

Faus Moliner

Leading law firm in life sciences in Spain

Rambla Catalunya 135
08008 Barcelona

+34 93 292 21 00
bcn@faus-moliner.com

www.faus-moliner.com

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The main regulatory authorities in Spain are:

- The Spanish Ministry of Health ('Spanish Ministry of Health'), which is the department of the central Spanish government responsible, among others, for drafting and implementing the rules on pricing and reimbursement of medicinal products that are financed through public funds in Spain.
- The Spanish Medicines Agency of Medicinal Products and Medical Devices (i.e. Agencia Española de Medicamentos y Productos Sanitarios – 'AEMPS'), which is also part of the central Spanish government, is responsible, among others, for granting marketing authorizations for medicinal products in Spain through the national, mutual-recognition, or decentralized procedures foreseen in the European regulations and with jurisdiction over medical devices and cosmetics as well.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

The Spanish current regulatory framework regarding authorization, pricing and reimbursement of medicinal products, including biologicals, and medical devices includes (i) Royal Decree-Legislative 1/2015, approving the revised text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices ('Spanish Law on Medicinal Products'), (ii) Royal Decree 1345/2007 on authorization of industrially manufactured medicinal products, (iii) Royal Decree 271/1990, Royal Decree 83/1993, Order of 17 December 1990 and Order of 6 April 1993 on price and reimbursement, and (iv) Royal Decree 177/2014 establishing the Reference Price System. Likewise, Royal Decree-Law 8/2010 (amended by Royal Decree-Law 9/2011), establishes different mandatory discounts on the ex-factory price of the medicinal product when such medicinal product is dispensed or administered to patients through public funding.

The Spanish current regulatory framework regarding authorization, pricing and reimbursement of medical devices includes (i) Spanish Law on Medicinal Products, (ii) Royal Decree 1591/2009, on medical devices, (iii) Royal Decree 1616/2009, on active implant medical devices, and (iv) Royal Decree 1662/2000, on "in vitro" diagnostic medical devices.

3. What are the steps to obtaining authorization to develop, test, and market a product?

Any person or entity that wishes to manufacture medicinal products or medical devices in Spain, must be previously authorized as manufacturer by the AEMPS, in compliance with the provisions contained in Royal Decree 824/2010 or Royal Decree 1591/2009, as the case may be.

A medicinal product can be placed in the Spanish market if it previously holds a marketing authorization obtained by one of the following procedures: **(i)** national procedure, mutual-recognition procedure, or decentralized procedure at the AEMPS; or **(ii)** centralized procedure at the European Medicines Agency ('EMA')

As regards medical devices, please note that they are divided in four classes (III, IIb, IIa and I), ranked mainly considering the level of invasiveness of the device, the part of the body it is in contact with and the duration of such contact. Except for custom-made devices, all medical devices must bear a CE marking of conformity when they are placed in the market in Spain. The CE marking evidences conformity of the device with the requirements of the applicable laws. For class I devices, such conformity shall be evaluated and declared under the exclusive responsibility of the manufacturer. For class IIa, IIb and III devices, the declaration of conformity requires an evaluation of the device by a notified body (the AEMPS in Spain or any other notified body of another European Union member state). Additionally, for class IIa, IIb and III devices, a communication must be made to the AEMPS the first time that a person places a medical device for distribution or use in the Spanish market.

Furthermore, testing of medicinal products or medical devices must be carried out in accordance with clinical investigation rules, which are mainly contained in Royal Decree 1090/2015 regulating clinical trials.

4. What are the approximate fees for each authorization?

Fees for services provided by the AEMPS are approved on an annual basis. Current fees were approved by Law 22/2021 on the budget for 2022. A list of the services provided by the AEMPS and the corresponding fees may be found at: https://www.aemps.gob.es/industria-farmaceutica/tasas/relaciontasas/?lang=en

AEMPS's services/fees include, among others, the following:

- Fee for the evaluation, authorisation and registration of a new medicine for human use (no generic): 21,576.3 Eur
- Fee for the evaluation, authorisation and registration of a new generic medicine for human use: 8,776.68 Eur
- Authorisation of a new pharmaceutical laboratory: 6.156,58 Eur
- Authorisation and/or certification for medicines warehouses under customs control or supervision: 1,366,31 Eur
- Individual inspection activities in Spain, unless a complaint has been made or it is requested by a representative association of consumers: 5,208.19 Eur

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

The marketing authorization of a medicinal product is valid for an initial period of five years. At least nine months before expiration of period, the marketing authorization holder may apply for a marketing authorization renewal, pursuant to article 27 of Royal Decree 1345/2007. Together with the renewal application, the applicant must pay the relevant fees (EUR 2,437.84)

and provide a consolidated version of the registration dossier including evaluation data contained in suspected adverse reactions reports and periodic safety update reports, as well as all the variations introduced since the marketing authorization was granted.

Once renewed, the marketing authorization will be valid for an unlimited period, unless the AEMPS requires an additional five-year renewal based on duly justified pharmacovigilance-related reasons.

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

The authorization of both a brand-name medicinal product and a generic medicinal product follow the same legal process. There are only minor differences as regards the fees to be paid to the AEMPS (as explained in **Chapter 1, Question 4**) and as regards the application documentation since the authorization procedure of a generic medicinal product does not require the applicant to provide pre-clinical tests and clinical trials results (bioequivalence studies must be provided instead of).

The law does not contemplate any difference for local manufacturers vs foreign-owned manufacturers when it comes to the authorization procedure for medicinal products.

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

There is no specific regulation for combination products in Spain. Please note that biologics are considered as medicinal products and, thus, subject to the same rules.

A combination product comprising both a medicinal product and medical device may be authorized as a medicinal product, e.g., an injectable medicinal product that comes in a pre-filled syringe; such product may be authorized as a medicinal product (although the syringe itself may be authorized as a medical device). It is also possible that a combination product comprising both a medicinal product and medical device is authorized as medical device, e.g. a medical device incorporating as an integral part a substance which, used separately, may be considered as a medicinal product (Judgement of the European Court of Justice in the Case C-527/17 Boston Scientific v Deutsches Patent).

The AEMPS has the final decision on the classification of any such combination product.

8. How is compliance with regulations monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

The AEMPS as well as the Health Authorities of the Autonomous Regions (Spain is divided in 17 Autonomous Regions) are in charge of monitoring compliance with the applicable regulations in Spain. As the regulatory regime applicable in Spain is based in EU legislation and guidelines, it is aligned with the European Medicines Agency expectations and requirements.