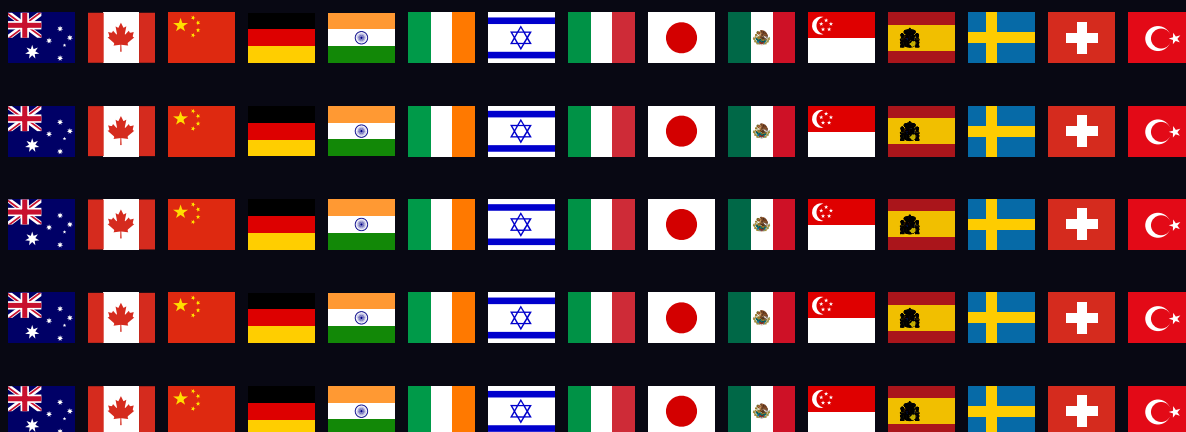


LIFE SCIENCES

Spain



Life Sciences

Quick reference guide enabling side-by-side comparison of local insights, including into organisation and financing; authorisation of providers; advertising; data protection, privacy and digitisation; collaboration with healthcare professionals and patient organisations; competition law; pricing and reimbursement; and recent trends.

Generated 06 December 2022

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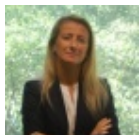
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UPDATE AND TRENDS

Key developments of the past year

Contributors

Spain



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ORGANISATION AND FINANCING OF HEALTHCARE

Organisation

How is healthcare in your jurisdiction organised?

Healthcare in Spain comprises private and public healthcare.

Public healthcare services are provided under the Spanish National Health System (NHS). This system was brought into existence by Law 14/1986 (the Spanish Health Law). The NHS is a decentralised multi-layered system coordinated by the central government and managed by regional governments of each autonomous community (except the autonomous community of Ceuta and Melilla, whose healthcare management and provision are conferred on the public entity INGESA). This means that each autonomous community has its own healthcare scheme for the provision of healthcare services within its region's territory. Regarding the kind of healthcare services under the NHS, they are divided into two healthcare levels, primary and specialist care. While primary care covers the basic healthcare services throughout primary healthcare centres, specialist care deals with healthcare issues of more complexity through specialist care centres and hospitals.

Whereas the central government holds competencies on coordination, setting basic principles, foreign health affairs and policy-making on medicines, among others, the regional governments of each autonomous community are responsible for the managing of healthcare services, providing healthcare services, health planning and matters on public health concerning their territory (in line with the distribution of competencies established in article 149 of the Spanish Constitution). As provided in article 50 of the aforementioned Law 14/1986, a public health service institution is established in each autonomous community, which comprises all healthcare centres, services and facilities of the region's territory. At a lower level, local councils are competent to rule on health and hygiene by cooperating in the management of public services.

The minimum portfolio of healthcare services to be provided is the same throughout the Spanish jurisdiction, but each autonomous community may increase the type of services offered above the minimum required. This is not very common, but it is legally possible.

Regarding private healthcare, in accordance with article 38 of the Spanish Constitution, article 89 of the cited law 14/1986 recognises freedom of enterprise in the health sector. However, providing healthcare services under a private scheme will require an authorisation granted by the government of the autonomous community concerned.

Law stated - 29 October 2021

Financing

How is the healthcare system financed in the outpatient and inpatient sectors?

Whereas public healthcare in Spain is a non-contributory benefit mainly financed by taxes and included in the general budget of each regional autonomous community (besides two additional funds, the Cohesion Fund managed by the Ministry of Health and the Programme Temporary savings in Temporary Disability), private healthcare is financed under a fee-for-service scheme.

The beneficiaries of public health services in Spain are those who hold Spanish nationality and foreigners residents in Spanish territory, according to article 3(1) of Law 16/2003 . It is important to note that being a beneficiary of public health services in Spain does not mean those healthcare services are always free of charge, especially for irregular migrants. This situation requires a further legal analysis on a case-by-case basis.

Law stated - 29 October 2021

Basic structures

What are the basic structures of the provision of care to patients in statutory and private care?

Public healthcare in Spain comprises primary care, specialist care, pharmaceutical benefits, complementary benefits and health information and documentation services, as established in Annex I of Royal Decree 63/1995 (organisation of services of the NHS). The structure of healthcare services may differ in each regional autonomous community, where in some of them the structure is centralised, such as Madrid, Castilla y León and Castilla-La Mancha, and in others it is deconcentrated (not to be confused with decentralised), such as Cataluña. In the latter case, the provision of healthcare services to patients is normally undertaken by public entities and non-profit organisations. The structure of each autonomous community requires independent analysis.

The structure of the provision of private healthcare services in Spain from a functional point of view depends on what the company wants to specialise in. In essence, it may be the same: primary care and specialist services. Each private healthcare provider may decide which portfolio to offer to their patients. Healthcare workers are hired under private employment laws from healthcare professionals duly registered under their professional associations.

Law stated - 29 October 2021

HEALTHCARE SERVICES

Authorisation

What steps are necessary to authorise the provision of health services, and what law governs this?

According to article 29(1) of Law 14/1986 (Spanish Health Law), health centres, services and facilities, irrespective of their nature, require prior administrative authorisation to operate in Spain, as well as for any modifications that may be established regarding their structure and initial regime. The Royal Decree 1277/2003 sets out the basis for the authorisation procedure, and the regional health authorities of the autonomous communities authorise the installation, operation, modification and closure of all health centres, services and facilities located in their respective territory. Each autonomous community may have its own regulation developing the aforementioned Royal Decree 1277/2003 and the procedure to grant the authorisation. Taking the autonomous community of Catalunya as an example, Decree 151/2017 establishes the requirements for obtaining the authorisation for the provision of healthcare services in its territory, which varies depending on whether the health centre facilities are newly created or existed previously.

Law stated - 29 October 2021

Structure

Which types of legal entities can offer healthcare services?

Public Healthcare services can be provided by public entities or non-profit organisations. This will depend on each autonomous community's healthcare structure. The most common deconcentrated structures for public healthcare providers are a public company, consortium, public business entity or non-profit organisations governed and funded by public entities.

Regarding private healthcare services, according to the constitutional freedom of enterprise principle, the law does not require a specific type of legal entity, so for any kind of business any of the following are acceptable: limited liability companies, but also cooperatives of healthcare professionals and non-profit organisations. Depending on the system

decided on in each autonomous community, private healthcare providers may enter into a concertation agreement with regional healthcare authorities.

Law stated - 29 October 2021

Services of foreign companies

What further steps are necessary for foreign companies to offer health services?

The law does not provide a specific procedure for foreign companies that offer health services. Once the subsidiary company is incorporated in Spain, the regulation is the same whether the holding is based in Spain or abroad.

Law stated - 29 October 2021

ADVERTISING

Legislation

Which legislation governs advertising of medicinal products to healthcare professionals?

As established in article 5(1) of Law 34/1988 (the Spanish Advertising Law), the advertising of medicinal products may be regulated by its special rules or subject to the prior administrative authorisation regime. Law 14/1986 (the Spanish Health Law) and the Royal Decree-Law 1/2015 (guarantees and rational use of medicines and healthcare products) contain some legal provisions regulating this advertising (eg, article 102 and 78, respectively), and Royal Decree 1416/1994 governs advertising of medicines for human use: part of it concerns to advertising of OTC medicines for the general public, and some other sections govern the advertising of medicinal products to healthcare professionals.

On the other hand, the advertising of medicinal products to healthcare professionals in Spain also relies on industry self-regulation instruments from both a European and national dimension.

Law stated - 29 October 2021

Main principles

What are the main rules and principles applying to advertising of medicinal products aimed at healthcare professionals?

Generally, the advertising of medicinal products in Spain should comply with the general principles of Law 34/1988 . The main principles for the advertising of medicinal products aimed at healthcare professionals are the principle of veracity, scientific nature and transparency (see article 78 of Royal Decree-Law 1/2015). The principle of veracity means that the information provided to healthcare professionals will adjust to the authorised technical and scientific conditions of the product. In this sense, the information must be rigorous, well-founded, objective and, in any case, misleading. In regard to the scientific nature principle, the information for the promotion of medicinal products will be strictly scientific. In the case of reports or articles financed by the pharmaceutical industry, this circumstance must be specified in the publication. With regard to the transparency principle, as established in article 78(4) of the cited Royal Decree-Law 1/2015 , prizes, scholarships, subsidies or any contribution to meetings, congresses, study trips and similar events by any person (natural or legal) related to the manufacture, elaboration or distribution of medicinal products will be made public. If those products are aimed at healthcare professionals, these activities will be of scientific nature. When organising events related to the previous activities, the source of financing the funds obtained will be stated.

Royal Decree 1416/1994 sets forth that advertising aimed at people empowered to prescribe or dispense drugs must provide the technical-scientific information necessary for its recipients to be able to judge for themselves the therapeutic value of the drug, and, at a minimum, must include:

- the essential information about the product according to the data contained in the technical sheet, including at least: name of the drug, qualitative and quantitative composition, complete clinical data, incompatibilities, instructions for use or handling, name and address of the authorisation holder;
- its prescription and dispensing regime;
- the different presentations of the product, where appropriate, and the dosage or pharmaceutical form; and
- the sale price to the public and the conditions of the pharmaceutical provision of the National Health System, where appropriate.

Article 25 of the aforementioned Royal Decree 1416/1994 sets the obligation to inform the health authorities of the autonomous community government about advertising aimed at healthcare professionals, providing a copy of the documents that contain the advertising.

Law stated - 29 October 2021

Advertising of medical devices

Is the advertising of medical devices to healthcare professionals regulated as rigorously as advertising in the pharmaceuticals sector? What are the main differences?

Generally, the advertising of medicinal devices in Spain should comply with the general principles of Law 34/1988 (the Spanish Advertising Law). The advertising of both medical devices and medicinal products aimed at healthcare professionals is regulated by Royal Decree-Law 1/2015 . In the case of medical devices, the *lex specialis* is Royal Decree 1591/2009 and Royal Decree 1616/2009 . The advertising of medicinal devices to healthcare professionals is not regulated as rigorously as advertising in the pharmaceutical sector.

Both require that the information comprised in the advertising is limited to scientific and technical specifications.

Law stated - 29 October 2021

DATA PROTECTION, PRIVACY AND DIGITISATION IN HEALTHCARE

Digitisation

What are the legal developments regarding digitisation in the healthcare sector and industrial networks or sales channels?

There are several legal developments regarding digitisation in the healthcare sector. Among others, it is worth mentioning the Digital Health Strategy presented by the Spanish government at the end of 2020. This strategy aims at providing health solutions deploying infrastructures that allow healthcare professionals to use data to promote the health and well-being of citizens. Second, the chamber of deputies is discussing the adoption of a legal instrument to promote telemedicine and a boost to the use of new technologies in primary care. Finally, the electronic health record system allows citizens and healthcare professionals access to the most relevant clinical documentation. Documentation is available in electronic support anywhere while assuring citizens that the consultation of their data is restricted to an authorised person.

Law stated - 29 October 2021

Provision of digital health services

Which law regulates the provision of digital health services, and to what extent can such services be provided?

In Spain, there is no specific regulation for digital health. This is because laws governing clinical records admit both analogical and digital recording, and apply to both. There is a common regulation for clinical records and clinical information (and also for informed consent) that governs all Spanish jurisdictions, but some autonomous communities have developed their own specifications in the framework of common and basic Spanish regulation.

Law stated - 29 October 2021

Authorities

Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation? Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

The Spanish Data Protection Agency (AEPD) is the public body responsible for ensuring compliance with the data protection regulations in Spain. The protection of personal data is a fundamental right laid down in article 18(4) of the Spanish Constitution and regulated by the European Data Protection Regulation (GDPR) and the Spanish Data Protection Law (LOPDGDD). These legal texts concern professionals operating in the healthcare sector, as well as clinics, hospitals and institutions. Law 41/2002 also covers the data protection aspects of a patient's medical history and complements the basic legislation on data protection. The AEPD and other regional data protection agencies have issued guidance for data protection and privacy in the healthcare sector.

Law stated - 29 October 2021

Requirements

What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

Personal data concerning health has special protection under European Union and national law. This means that additional conditions must be met for its treatment in accordance with the data protection legal framework. The basic principles that healthcare providers must comply with are confidentiality, data accuracy, patient's consent and duty of information. Article 34(1)(l) of the LOPDGDD obliges all healthcare centres that are legally obliged to maintain patient medical records to appoint a data protection officer. Healthcare professionals who carry out their activity on an individual basis are exempted from such obligations.

Law stated - 29 October 2021

Common infringements

What are the most common data protection and privacy infringements committed by healthcare providers?

The most common data protection and privacy infringements are the breach of the duty of information to the patient, the transmission of a patient's data to third parties without the patient's consent, recording the patient's data on

another medical record, not taking the proper security measures, failure to obtain patient consent when necessary, or providing a document to a patient for signing with data from another patient.

Law stated - 29 October 2021

COLLABORATION

Legislation

Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sectors?

As in many other European countries, the approach preferred by Spain has been industry self-regulation. Despite there being legislation at both European and national levels that touches upon this relationship, there is no specific law in Spain regulating collaboration between the pharmaceutical industry and healthcare professionals. The most significant provision in this sense is enshrined in article 4 of Royal Legislative Decree 1/2015 . The first section of the cited article establishes that, apart from the incompatibilities in the exercise of public activities, healthcare professionals able to prescribe medicines are incompatible with any kind of direct economic interests derived from the manufacture, elaboration, distribution, intermediation and commercialisation of medicines and health products. There are some exceptions to the aforementioned for the participation of research centre personnel under the public administrations. Industry self-regulation is the model adopted by Spain, relying on codes such as that issued by the European Federation of Pharmaceutical Industries and Associations (EFPIA) or the National Trade Association of the Spanish-based Pharmaceutical Industry (Farmaindustria) . There is no difference between the law applicable to inpatients and outpatients.

Law stated - 29 October 2021

Collaboration with healthcare professionals

What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

The industry self-regulating model adopted by Spain relies on codes of conduct issued by the pharmaceutical industry. Those codes are based on communitarian and national law, from medicinal products to data protection law, advertising to antitrust law, and the main ethical principles, such as patient first, independence, integrity, respect and transparency. Regarding independence, one should mention article 4(6) of Royal Legislative Decree 1/2015 . This precept prohibits the direct or indirect offer of any type of incentive (bonuses, discounts or gifts) by anyone who has a direct or indirect interest in the production, manufacture and marketing of medicines to health professionals (or their relatives and people in contact with them) involved in the prescription cycle, dispensing and administering medicines.

Law stated - 29 October 2021

Collaboration with patient organisations

What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

There is no specific regulation on this matter. The collaboration of the pharmaceutical industry with patient organisations relies mainly on industry self-regulation codes, such as those issued by EFPIA or the Farmaindustria) .

*Law stated - 29 October 2021***Common infringements**

What are the most common infringements committed by pharmaceutical manufacturers regarding collaboration with healthcare professionals?

Among the most common infringements are the irregular payments to healthcare professionals intended to promote the prescription under a false umbrella of funding research, training or education for public professionals.

*Law stated - 29 October 2021***Collaboration on medical devices**

Is the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as collaboration in the pharmaceuticals sector?
What are the main differences?

This is not as rigorously regulated as collaboration in the pharmaceutical sector. Royal Legislative Decree 1/2015 establishes general provision but this collaboration, and specific Royal Decrees for medical devices (general), in vitro diagnosis and active implantable devices, govern the way they can collaborate (incentives to prescription are prohibited, the sponsoring of scientific meetings is allowed but under certain circumstances, and there are some special rules for exhibitions). Most of these conditions are also developed in industry self-regulation codes such as the one issued by the Spanish Federation of Healthcare Technology Companies (FENIN) for medical devices, or Farmaindustria for medicines, respectively.

The main difference is that in pharmaceuticals it is mandatory to publish any payment to any healthcare professional through a transparent website managed by Farmaindustria. This obligation no longer exists in the medical devices market (where payments to health professionals for consultancy, lecturing, research, training or any other similar activity are not transparent).

*Law stated - 29 October 2021***COMPETITION LAW****Authority enforcement**

Are infringements of competition law by healthcare providers pursued by national authorities?

Competition laws do not apply to public healthcare providers as long their services are considered as a part of the social security system, which are considered services of general interest by the European Union.

Private healthcare providers fall under the European Union and national antitrust legal framework. In this sense, healthcare providers in Spain can be prosecuted by the European Commission and national competition authorities if breaching internal market rules. As enshrined in article 61(1) of Law 15/2007 (the Spanish antitrust law), any natural or legal person whose actions undermine legal provisions of the cited law could be eligible for prosecution by the competent competition authority. In 2018, the regional competition authority of Andalusia issued Resolution S/01/2018 imposing sanctions on a private hospital located in the south of Spain for a total amount of €5.33 million for anticompetitive behaviour (abusive pricing and exclusive dealing).

Law stated - 29 October 2021

Private enforcement

Is follow-on private antitrust litigation against healthcare providers possible?

Yes, any case of unfair competition between private healthcare providers can be claimed before the Spanish courts of justice.

It is also possible to bring follow-on actions and claim damages against healthcare providers by relying on a prior decision of a competition authority or court judgment declaring an infringement.

Damages can be sought for follow-on actions relating to bilateral, multilateral or unilateral antitrust infringements.

The legal basis for bringing a follow-on action is provided for under civil law (article 1902 of the Spanish Civil Code) and antitrust law (article 72 of Law 15/2007 and article 32(5) of Law 3/1991).

Law stated - 29 October 2021

Anti-corruption and transparency

What are the main anti-corruption and transparency rules applicable to healthcare providers?

There is no regulation on this matter specifically for healthcare providers. However, healthcare providers who belong to the public sector must comply with general transparency legislation applicable to the public sector. Private healthcare providers may be subject to general transparency laws depending on the legal form adopted (eg, private foundations), not because of their activities in healthcare, but their legal form.

Law stated - 29 October 2021

PRICING AND REIMBURSEMENT

Price regulation

To what extent is the market price of a medicinal product or medical device governed by law or regulation?

First of all, it is important to mention that for the commercialisation of a medicine in Spanish territory it will be essential to process the offer of the same to the NHS. It will proceed, in the same way thus, if there are substantial variations in the authorisation conditions of the medicine. NHS can decide whether to finance it or not, and if not (or in the meantime), then the price can be freely established but must be notified to the Health Ministry.

Royal Decree-Law 1/2015 regulates the public financing of medicines in Spain. In this sense, the cited law establishes the regime for setting and reviewing industrial prices and distribution and dispensing margins. The main criterion for setting the price relies on the assessment of the therapeutic utility of the medicinal product and medical device and the degree of innovation. The price of medicines and medical devices financed by the NHS subject to prescription is set by a resolution of the Ministry of Health or the central government of Spain, prior to the resolution of the Interministerial Price Commission, in which the central government and some regional governments of the autonomous communities (rotatory) participate.

Pharmaceutical laboratories can freely establish prices for those medicines and medical devices not financed by the NHS, with a prior notification to the Health Ministry. The Ministry is entitled to revise those prices and make objections on a public interest basis.

Law stated - 29 October 2021

Negotiations between manufacturers and providers

Must pharmaceutical and medical device manufacturers negotiate the prices of their products with public healthcare providers?

It is important to distinguish between PVP (retail price) and PVL (maximum industrial price of medicinal products).

Whereas PVP applies to medicines sold in pharmacy offices (shops for the public in general), this may not be subject to negotiation; it is a fixed price and it cannot be modified or negotiated. PVP is fixed by the Health Ministry.

For PVL (also called industrial price) we must distinguish financed price from purchasing price. The financed price (fixed by the Ministry of Health) for PVL is a maximum price and is for wholesalers, so this means that it can be negotiated with healthcare providers or dealers at a lower rate when they negotiate to purchase.

Hence, they cannot negotiate the PVP; they are not obligated to negotiate PVL but they can be 'invited to' by the purchasers. If they negotiate PVL, it will always be under the maximum price fixed as PVL, never above.

Law stated - 29 October 2021

Reimbursement

In which circumstances will the national health insurance system reimburse the cost of medicines?

Only medicines that make significant contributions are financed by the NHS. Specifically, according to article 92 of Royal Decree-Law 1/2015, the selective financing of medicines is based on the following criteria:

- seriousness, duration and the after-effects of the different pathologies the medicine is supposed to treat;
- specific needs of certain groups;
- therapeutic and social value of the drug and its incremental clinical benefit, considering its cost-effectiveness ratio;
- rationalisation of public spending for pharmaceutical services and the budgetary impact on the NHS;
- the existence of alternative medicines or therapies for the same pathologies at a lower price or lower cost of treatment; and
- the degree of innovation of the medicine.

Law stated - 29 October 2021

Price adjudication

If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

At the time of writing, the competent authority is the General Directorate of Common Portfolio of Services of the National Health and Pharmacy System, which comes under the Ministry of Health of the Spanish government. They issue the financing resolution after the resolution of the Interministerial Commission on Drug Prices.

Law stated - 29 October 2021

Discount

Are manufacturers or distributors of medicinal products statutorily obliged to give a discount to health insurance schemes or third parties?

No.

Law stated - 29 October 2021

UPDATE AND TRENDS

Key developments of the past year

Is there any legislation expected in the near future that will have a major impact on the current legal environment for medicines or medical devices?

Recent developments include:

- introducing biosimilar medicines;
- adapting Spanish regulation on medical devices to European Regulation (which is directly mandatory); and
- advanced therapies pricing.

* The information in this chapter was accurate as at 29 October 2021.

Law stated - 29 October 2021

Jurisdictions

	Australia	Clayton Utz
	Canada	Stikeman Elliott LLP
	China	East & Concord Partners
	Germany	Ehlers Ehlers & Partner
	India	LexOrbis
	Ireland	Matheson
	Israel	S Horowitz & Co
	Italy	CMS Cameron McKenna Nabarro Olswang LLP
	Japan	Anderson Mōri & Tomotsune
	Mexico	OLIVARES
	Singapore	Drew & Napier LLC
	Spain	Roca Junyent
	Sweden	Cirio Advokatbyrå AB
	Switzerland	Wenger Vieli Ltd
	Turkey	Gün + Partners