

COUNTRY PROFILE SPAIN

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Legal System

Spain is a parliamentary monarchy with a civil law system which is rooted in Roman law and whose main characteristic is that its central principles are codified into a referable system, which is the predominant source of law. Spain is a Member State of the European Union.

The Spanish Constitution is the highest legal norm in Spain. Under article 9(3), it guarantees the principle of normative hierarchy. The hierarchy established by the Spanish Constitution of 1978 is the following: (1) Spanish Constitution, (2) European Union law (regulations and directives), (3) International treaties, (4) Laws enacted by the General Courts: Organic laws (Leyes Orgánicas) and Ordinary laws (Leyes Ordinarias), (5) Norms with the force of law enacted by the executive power – Government: Royal Decrees-Laws (Reales Decretos - Leyes) and Royal Legislative Decrees (Reales Decretos Legislativos), (6) Regulations (Reglamentos): delegated orders and ministerial orders. [1]

The legislative process of Spain consists of the following stages: [2]

- Firstly, a bill (Proyecto de Ley) is proposed by the Government and approved in the Council of Ministers (Consejo de Ministros). Then the bill is passed onto Congress for approval. A proposal of law (Proposición de Ley) can be proposed by Congress or Senate.
- Secondly, the bill or the proposal of law is then sent to the Commission for review, where the Commission studies the text of the bill or proposal in sections and prepares a brief about the text. The text will then be discussed and voted on a Plenary Session.
- Once the text is approved by the Congress, the bill or proposal of law is submitted to the Senate, where the Senate approves, amends or rejects the bill or proposal. If the Senate rejects the text (by absolute majority), the Congress may override the Senate's veto by approving the text with an absolute majority. The Congress must accept or reject any amendments made by the Senate by a simple majority. In general, Congress has greater power than the Senate in the legislative process.
- Finally, the approved text is sent to the King, who must approve the law within 15 days, then promulgate it and order its publication. However, this is a formal requirement (not substantive).

Health Care System

Spain has a publicly funded health system. Publicly funded health care is financed with general revenue raised through state, provincial and municipal taxation. Therefore, the Spanish state grants its people the right to health services by relying mostly on the public sector (71%). Hence, this system of financing healthcare results in a universal national health service: every Spanish citizen is guaranteed healthcare, as the costs are covered mostly by the state. The remaining 29% is privately funded through "voluntary" payments. These Out-of-pocket payments fund most of the private healthcare sector in Spain. Moreover, there are possibilities within the Spanish private market to opt for private insurance. In order to do so, individuals must pay premiums to private Spanish insurance companies; these companies then provide aid for funding private healthcare. Further, those individuals working in the public sector have the option of obtaining "public servant insurance", which also helps to fund their private healthcare services [3].

The central government takes care of the legislation regulating universal healthcare, the pharmaceutical supply and the general coordination. They offer a basic benefit package to every Spanish citizen [4]. However, the central government has decentralized competences and powers to the autonomous communities, allowing them to choose the insurer for their population as long as it conforms to the national framework [5]. Furthermore, the autonomous communities can choose the territory within which their healthcare policies cover and redistribute the capital to extend upon the basic national package [6]. The third line of power exists within the local governments, who

have advisory role to the autonomous communities and take care of the sanitary division [7]. Spain's sanitary facility access is determined to be at 100%, showing the efficiency of Spain in the devolution of tasks [8]. This devolutionary system aims to reduce bureaucratic inefficiencies and creates a system tailored to the individuals' needs of each autonomous community. Even though this system functions efficiently, it creates disparities within the Spanish healthcare coverage. For example, some autonomous communities do reimburse, for example, sex-change operations or morning-after-pill, whereas others do not.

In order to create additional transparency within the National Health System, the central government issues a cost-containment package covered by the publicly allocated capital. This package consists of primary care, specialized care, pharmaceutical benefits and complementary benefits (prosthesis, orthopaedic products, etc.). Given the fact that this package is clearly defined, some health benefits are implicitly excluded from coverage, such as certain mental health treatments, dental care (although Navarre and Basque country do include this), sex-change treatments (covered only in Andalucía), regular health checks, or plastic surgery [9]. This general care package aims to create equality throughout the healthcare state; however, as previously mentioned, the devolution of political control creates a slight disparity between each autonomous community's healthcare coverage [10].

The National Health System is configured as a coordinated set of health services from the Central Government Administration and the autonomous communities that integrate all healthcare functions and benefits for which public authorities are legally responsible [11]. The main healthcare competences of the State are: general bases and coordination of the healthcare; foreign healthcare and relations and international healthcare agreements; legislation and authorization of medicines and healthcare products; administration of the National Management Institute of Healthcare; and Medicines poly. The main healthcare competences of the autonomous communities are: healthcare organization, public health and Management of Health Services [12].

The regulations of the actions to enable exercise of the right to health protection are set out in a set of regulations with the rank of Act: General Health Act (1986), which the right to health care was defined as universal and decentralised NHS; Act on the Cohesion and Quality of the National Health System (2003); Act on Guarantees and Rational Use of Medicines (2006); General Health Act (2011) and Royal Decree-Law on Emergency Measures for the Sustainability of the National Health System and Improvement of Quality and Safety (2012).

Constitution

The Spanish Constitution (1978) creates three levels of government: Central, seventeen Autonomous Communities and Municipal Governments (Article 137).

Article 43 of the Spanish Constitution of 1978 establishes the right to health protection and healthcare for all citizens:

(1) The right to health protection is recognized.

(2) It is incumbent upon the public authorities to organize and watch over public health and hygiene through preventive measures and through necessary care and services. The law shall establish the rights and duties of all in this respect.

(3) The public authorities shall foster health education, physical education and sports. Likewise, they shall facilitate adequate utilization of leisure [13].

Treaty Ratifications [14]

	Signed	Ratified	Acceded
International Convention on Economic, Social and Cultural Rights (ICESCR)	28 th September 1976	27 th April 1977	-
Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)	17 th July 1980	5 th January 1984	-

Convention of the Rights of the Child	26 th January 1990	6 th December 1990	-
Indigenous and Tribal Peoples Convention (ILO Convention 169)	-	-	-
International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families	-	-	-
Convention on the Rights of Persons with Disabilities, New York, 13 December 2006.	30 th March 2007	3 rd December 2007	-
European Convention of Human Rights	24 th November 1977	4 th October 1979	-
Constitution of the World Health Organization	28 th May 1951	28 th May 1951	-

Overview of Relevant Provisions

Indicators	National Legislation	National Regulation
Government Commitment Mandatory Language	<p>The Spanish health policy's main objective is the right to health protection and healthcare for all the citizens [15].</p> <p>This objective is reflected in the Spanish national law and in the Spain's international Treaty ratifications.</p> <p>With regards to national law, the objective is reflected in Article 43 and section 149 of the Spanish Constitution. Additionally, the regulations of the actions to enable exercise of the right to health protection are set out in a set of regulations with the rank of Act: the General Health Act (1986), Act on the Cohesion and Quality of the National Health System (2003), the Act on Guarantees and Rational Use of Medicines (2006), the General Health Act (2011) [16].</p> <p>Apart from the Spanish national law, Spain signed and ratified the following international conventions, which all include a right to health and health protection: International Convention on Economic, Social and Cultural Rights; the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW); Convention of the Rights of the Child; Convention on the Rights of Persons with Disabilities; European Convention in Human Rights; and the Constitution of the World Health Organization.</p> <p><i>See Government Commitment Overview for further legislation details.</i></p> <p>http://www.boe.es/boe/dias/1997/04/26/pdfs/A13450-13452.pdf</p>	<p>Royal Decree-Law on Emergency Measures for the Sustainability of the National Health System and Improvement of Quality and Safety (2012). http://www.boe.es/boe/dias/1997/04/26/pdfs/A13450-13452.pdf</p>

<p>Sustainable Financing State Reimbursement scheme</p>	<p>The Spanish health system of financing healthcare results in a universal national health service: every Spanish citizen is guaranteed healthcare, as the costs are covered mostly by the state [17].</p> <p>For further details see <i>Healthcare section</i> and <i>Sustainable Financing Overview section</i>.</p>	<p>Royal Decree 83/1993, of 22 January, on the selection of drugs for the purpose of funding by the National Health System is regulated [3]. Royal Decree 16/2012, of 20 April, on urgent measures to ensure sustainability of the National Health System and improve the quality and safety performance.</p>
<p>Rational Selection Essential medicines framework</p>	<p>The selection of medication can be described, as 'arbitrary' in Spain, where no guideline exists or it is not followed. Alternatively, doctors and hospitals follow the recommendations set by pharmaceutical companies. This is in contrast to other countries, which have an Essential Medicines list that classifies the basic necessary medication for prominent diseases such as tuberculosis, HIV and malaria. There is no positive reimbursement list and even though a negative reimbursement list was introduced, pharmaceutical companies reacted to this change by switching to other similar drugs, which were still covered [18].</p>	
<p>Affordable Prices Availability of generics</p>	<p>In Spain, the main goal of the distribution of medication is access for all patients to the medicines they need in a timely and appropriate manner, conforming to a sustainable long-term provision. The objectives of sustainability and efficiency attach great importance to the promotion of generic medicines. Promotion of generic medicines has been working for many years, but it started later than in the neighbouring countries. Therefore, the same level of use has not been achieved yet in Spain. Nevertheless, there is a reference price system enabling the setup of a maximum price for all medicines containing the same active ingredient and having the same route of administration once the innovator's patent protection has expired and a generic version has been launched. In the first half of 2010, the generic medicines market experienced significant growth in units, reaching a public market share of 26.02% per prescription. A plan was implemented which emphasised provision of information and education to citizens:</p> <ul style="list-style-type: none"> • Provision by pharmacies of information to citizens and generic medicines. • The provision of information and training to health professionals on the quality, safety and efficacy of the medication. 	

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| | <ul style="list-style-type: none"> • The streamlining of the marketing authorisation procedure and decision-making process on the public financing [19]. | |
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Government Commitment Overview:

Official translation:

Spanish Constitution:

Section 43 of the Spanish Constitution of 1978 establishes the right to health protection and healthcare for all citizens: "(1) The right to health protection is recognized.

(2) It is incumbent upon the public authorities to organize and watch over public health and hygiene through preventive measures and through necessary care and services. The law shall establish the rights and duties of all in this respect.

(3) The public authorities shall foster health education, physical education, and sports. Likewise, they shall facilitate adequate utilization of leisure."

Section 149: "1. The State shall have exclusive competence over the following matters: (...) 16. External health measures; basic conditions and general coordination of health matters; legislation on pharmaceutical products."

Original text:

Sección 43 de la Constitución Española de 1978 establece el derecho a la protección de la salud y la atención sanitaria para todos los ciudadanos:

"(1) Se reconoce el derecho a la protección de la salud.

(2) Corresponde a los poderes públicos organizar y tutelar la salud pública y la higiene a través de medidas preventivas y mediante la atención y los servicios necesarios. La ley establecerá los derechos y deberes de todos al respecto.

(3) Los poderes públicos fomentarán la educación sanitaria, la educación física y el deporte. Asimismo, facilitarán la adecuada utilización del ocio."

Sección 149: 1. El Estado tiene competencia exclusiva sobre las siguientes materias: (...) 16 medidas de salud externos; Bases y coordinación general de la sanidad; Legislación sobre productos farmacéuticos .

Author Translation:

Law 14/1986 of 25 April, General Health [19]

This law has the objective to regulate all the actions necessary to make the right to health protection effective as recognized and stated in Article 43 of the Constitution.

Original text:

Ley 14/1986, de 25 de abril, General de Sanidad.

La presente Ley tiene por objeto la regulación general de todas las acciones que permitan hacer efectivo el derecho a la protección de la salud reconocido en el artículo 43 y concordantes de la Constitución.

International Covenant on Economic, Social and Cultural Rights: [20]

- Spain, by signing and ratifying it, "undertakes to take steps [...] to the maximum of its available resources, with a view of achieving progressively the full realization of the right to health, including particularly the adoption of legislative measures, [...] without discrimination of any kind." (Article 2). The Covenant also recognizes the "right of everyone to the enjoyment of the highest attainable standard of physical and mental health." (Article 12.1).

Convention on the Elimination of All Forms of Discrimination against Women [21]

By becoming a State Party, Spain "shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning." (Article 12)

Convention on the Rights of the Child [22]

By becoming a State Party, Spain recognizes “the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health”; it “shall strive to ensure that no child is deprived of his or her right of access to such health care services.” (Article 24)

Convention on the Rights of Persons with Disabilities [23]

By becoming a State party, Spain “recognizes that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability. States Parties shall take all appropriate measures to ensure access for persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation.” (Article 25)

European Convention of Human Rights [24]

As a Member State of the Council of Europe, Spain shall be “convinced that everyone’s right to life is a basic value in a democratic society [...] and for the full recognition of the inherent dignity of all human beings. Moreover, as Member State of the Council of Europe, Spain shall recognize the right to life (Article 2).

The **Charter of Fundamental Rights of the European Union** when implementing European Union law binds Spain. Article 35 of the Charter provides that “Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union’s policies and activities [12].”

By accepting to become a member of the **Constitution of the World Health Organization**, Spain has “a responsibility for the health of its peoples which can be fulfilled only by the provision of adequate health and social measures [25].”

Observations:

In order to fulfill the right to health protection enriched in the Spanish Constitution (Article 43), the national Ministry of Health and Social Policy (MSPS) holds authority over certain strategic areas, such as pharmaceuticals’ legislation and as a guarantor of the equitable functioning of health services across the country. The highest body for SNS coordination is the CISNS, comprising the 17 regional ministers of health, chaired by the national minister.

Sustainable Financing Overview:

Author Translation:

Law 16/2003 of 28 May on Cohesion and Quality of the National Health System [26]

Article 10 Financing

1. Benefits are established by this law’s financial responsibility of the regions under transfer agreements and the current financing system , notwithstanding the existence of a third party obligor . The Autonomous Communities shall be allocated to the financing of these minimum benefits under Law 21/2001 of 27 December. Systems guarantees provided by this law are also the financial responsibility of the autonomous communities.

2. Adequacy to finance benefits and guarantees established in this law are determined by the resources allocated to the regions as established in Law 21/2001 , of 27 December , and according to the principle of institutional loyalty, in terms of Article 2.1.e) of the Organic Law 8/1980 of 22 September, Financing of the Autonomous Communities.

3. According to the previous section, the inclusion of a new provision in the catalog of benefits of the National Health System shall be accompanied by a financial report containing the assessment of the positive or negative impact which might result . This report is submitted to the Council of Fiscal and Financial Policy for analysis in the context of the principle of institutional loyalty.

Article 16 Provision pharmaceutical

Pharmaceutical benefits comprising medicines and health products and the set of actions designed to ensure that patients receive them appropriately in regards to their clinical needs, in

the precise dose according to your individual requirements, for the appropriate period of time and at the lowest possible cost to themselves and the community.
This provision shall be governed by the provisions of Law 25/1990 of 20 December on Drugs, and the regulations on health and other applicable products.

Original text:

**Ley 16/2003, de 28 de mayo, de cohesión y calidad del Sistema Nacional de Salud.
Artículo 10 Financiación**

1. Las prestaciones que establece esta ley son responsabilidad financiera de las comunidades autónomas de conformidad con los acuerdos de transferencias y el actual sistema de financiación autonómica, sin perjuicio de la existencia de un tercero obligado al pago. Las comunidades autónomas deberán destinar a la financiación de dichas prestaciones los mínimos previstos en la Ley 21/2001, de 27 de Diciembre. Los sistemas de garantías que prevé esta ley son asimismo responsabilidad financiera de las comunidades autónomas.
2. La suficiencia para la financiación de las prestaciones y de las garantías establecidas en esta ley viene determinada por los recursos asignados a las comunidades autónomas conforme a lo establecido en la mencionada Ley 21/2001, de 27 de diciembre, y de acuerdo con el principio de lealtad institucional, en los términos del artículo 2.1.e) de la Ley Orgánica 8/1980, de 22 de septiembre, de Financiación de las Comunidades Autónomas.
3. De acuerdo con el apartado anterior, la inclusión de una nueva prestación en el catálogo de prestaciones del Sistema Nacional de Salud se acompañará de una memoria económica que contenga la valoración del impacto positivo o negativo que pueda suponer. Dicha memoria se elevará al Consejo de Política Fiscal y Financiera para su análisis en el contexto de dicho principio de lealtad institucional.

Artículo 16 Prestación farmacéutica

La prestación farmacéutica comprende los medicamentos y productos sanitarios y el conjunto de actuaciones encaminadas a que los pacientes los reciban de forma adecuada a sus necesidades clínicas, en las dosis precisas según sus requerimientos individuales, durante el período de tiempo adecuado y al menor coste posible para ellos y la comunidad.
Esta prestación se regirá por lo dispuesto en la Ley 25/1990, de 20 de diciembre, del Medicamento, y por la normativa en materia de productos sanitarios y demás disposiciones aplicables.

Rational Selection Overview:

Author Translation:

Law 28/2009 of 30 December, on guarantees and rational use of medicines and health products (modification of Law 29/2006 of 26 July) [27]

Public funding of medicines and health products

Article 88 Principle of territorial equality and coordinated procedure

1. It is recognized the right of all citizens to obtain drugs on an equal footing throughout the National Health System, without prejudice to the measures aimed at rationalizing the prescription and the use of drugs and health products that the Autonomous Communities can adopt in the exercise of their competences.

A point to note, however, would be that illegal immigrants are not titled to the "full" healthcare package. Spain has made steps in guaranteeing the right to health for these immigrants, but they still do not have the right to reimbursed dental and mental healthcare.

Original text:

Ley 28/2009, de 30 de diciembre, de garantías y uso racional de los medicamentos y productos sanitarios (modificación de la Ley 29/2006, de 26 de julio)

La financiación pública de los medicamentos y productos sanitarios

Artículo 88 Principio de igualdad territorial y procedimiento coordinado

1. El derecho de todos los ciudadanos a obtener medicamentos iguales en todo el NHS, sujetas a las medidas de racionalización de la prescripción y uso de medicamentos y productos sanitarios que pueden tomar el ejercicio Comunidades Autónomas se reconoce sus habilidades.

Un punto a destacar, sin embargo, sería que los inmigrantes ilegales no se titulan al paquete de asistencia sanitaria "completa". España ha dado pasos para garantizar el derecho a la salud de estos inmigrantes, pero todavía no tienen el derecho a la asistencia sanitaria reembolsado dental y mental.

Affordable Prices and Availability of Generics Overview

Author Translation:

Royal Decree 782/2013, of 11 October, on the distribution of medicinal products for human use [28]

2. This Royal Decree shall apply, provided that they are located in Spain, to:
- a) The drug distribution entities, which are:
 - i. The wholesale distribution warehouses, warehouses wholesalers onwards.
 - ii. Contract stores.
 - iii. Drug stores under customs supervision or control.
 - b) Entities engaged in drug trading, also known as brokers

Original text:

Real Decreto 782/2013, de 11 de octubre, sobre distribución de medicamentos de uso humano.

2. Este real decreto será de aplicación, siempre que se encuentren ubicadas en España, a:
- a) Las entidades de distribución de medicamentos, que son:
 - i. Los almacenes mayoristas de distribución, en adelante almacenes mayoristas.
 - ii. Los almacenes por contrato.
 - iii. Los almacenes de medicamentos bajo control o vigilancia aduanera.
 - b) Las entidades dedicadas a la intermediación de medicamentos, también conocidos como brókeres.

Translations found in this template were made by the authors.

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