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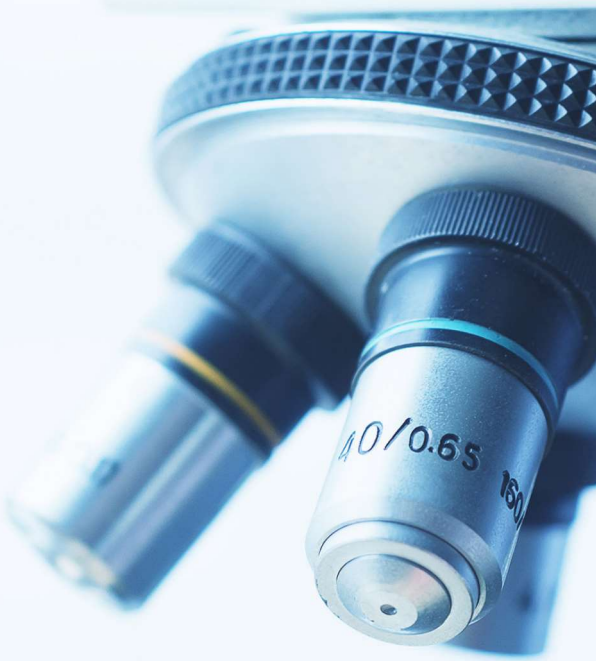

Spain: Law & Practice and Trends & Developments

Anna Gerbolés, Joan Carles Bailach, Claudia Gonzalo and Juan Martínez
Faus Moliner Abogados

SPAIN

Law and Practice

Contributed by:
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Faus Moliner Abogados

Faus Moliner Abogados is a modern boutique law firm based in Barcelona that specialises in advising the pharmaceutical industry and companies that operate in the life sciences sector. The firm was founded in 1997 and currently has 15 members. It focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. The firm advises pharmaceutical and healthcare clients, large companies and smaller biotech start-ups, and is frequently called upon to advise public authorities on matters such as draft legislation. It combines legal skills and specialisation with a practical and business-oriented manner of practising law. Since its foundation, Faus Moliner has been recognised in several international publications as the market leader in pharmaceutical law in Spain.

The authors appreciate the collaboration of Sergio Miralles of Intangibles Legal and Pablo Mansilla and Laia Rull of Faus Moliner.

Authors

Anna Gerbolés is a senior associate at Faus Moliner and specialises in pharmaceutical and food law. Her experience in these sectors includes the provision of legal advice on regulatory issues and the advertising of medicinal products, medical devices, food products and other borderline products. Since becoming part of the Faus Moliner team in 2021, she has been providing highly specialised advice to companies operating in the life sciences sector. Anna is a member of the Barcelona Bar Association.

Joan Carles Bailach is a senior associate at Faus Moliner and specialises in market access, pricing and reimbursement, commercial contracts and pharmaceutical and life sciences law. He has regularly advised national and international companies on these matters since joining the firm in 2019. Joan Carles is a member of the Barcelona Bar Association, the Section of Health Law, and the Young Advocacy Group of the Barcelona Bar Association.

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Faus Moliner Abogados

Claudia Gonzalo is a senior associate at Faus Moliner, specialising in pharmaceutical and healthcare regulations. She has experience in advising national and international companies ion regulatory matters, public procurement, and corporate transactions and contracts. Claudia has a master's in public economic law and an executive MBA in pharmaceutical, biotechnological and medical device companies, and is a member of the Spanish Compliance Association.

Juan Martínez is a senior associate at Faus Moliner 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. Since becoming part of the Faus Moliner team in 2017, he has been providing highly specialised advice to companies operating in the life sciences sector. Juan is a member of the Barcelona Bar Association.

Faus Moliner Abogados

Rambla de Catalunya 135
08008
Barcelona
Spain

Tel: +34 93 292 21 00
Email: bcn@faus-moliner.com
Web: www.faus-moliner.com

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Faus Moliner Abogados

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Key Legislation

The following legislation and regulations govern medicinal products and medical devices in Spain:

- Law 14/1986, General on Public Health;
- Royal Legislative Decree 1/2015, which approves the consolidated version of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices;
- Law 10/2013 on pharmacovigilance and on the prevention of the entry into the legal supply chain of falsified medicinal products;
- Law 16/2003, of 28 May, on the cohesion and quality of the National Health System;
- Royal Decree 192/2023, which regulates medical devices;
- Royal Decree 1616/2009 on active implantable medical devices (partially repealed);
- Royal Decree 1662/2000 on "in vitro" diagnostic medical devices;
- Royal Decree 824/2010 on pharmaceutical companies, manufacturers of active ingredients, foreign trade of medicines and investigational medicinal products;
- Royal Decree 1090/2015, which regulates clinical trials, the Ethics Committees for Research and the Spanish registry for clinical trials;
- Royal Decree 967/2020, which regulates observational studies with medicinal products for human use;
- Royal Decree 1345/2007, which regulates the authorisation, registry and dispensation conditions of medicinal products for human use prepared industrially for human use;
- Royal Decree 782/2013, which regulates the distribution of medicinal products;
- Royal Decree 1416/1994, which regulates the advertising of medicinal products;
- Royal Decree 870/2013, which regulates online sales to the public of non-prescription medicinal products;
- Royal Decree 577/2013, which regulates pharmacovigilance of medicinal products for human use;
- Royal Decree 1015/2009 on access to medicinal products in special situations;
- Royal Decree 271/1990, which regulates the prices of medicinal products reimbursed by the National Health System;
- Royal Decree 177/2014, which regulates the reference price system and homogeneous groups of medicinal products in the National Health System and information systems on reimbursement and prices of medicinal products and medical devices;
- Royal Decree 823/2008, which establishes the margins, deductions and discounts corresponding to the distribution and dispensation of medicines for human use;
- Royal Decree 1718/2010, on medical prescriptions; and
- Royal Decree 477/2014, which regulates the authorisation of medicinal products for advanced therapies not prepared industrially.

Regional authorities (Spain is divided into 17 autonomous regions) may also enact and enforce regulations that are applicable at their level, particularly concerning pharmacy offices or healthcare provision.

Furthermore, there is a self-regulatory framework established by trade associations that enforce their own codes of good practices. These codes have a binding effects on their members, and primarily govern advertising and interactions

with healthcare organisations, healthcare professionals and patients' organisations.

Regulatory Authorities

At a national level, the regulatory authorities responsible for applying and enforcing regulations on medicinal products and medical devices are mainly the Ministry of Health (MOH) and the Spanish Agency for Medicines and Medical Devices (AEMPS).

Among other things, the MOH is responsible for drafting and implementing the rules on pricing and reimbursement of medicinal products financed by public funds, while the AEMPS is responsible for the issuance of marketing authorisations for medicinal products in Spain, which includes overseeing the authorisation process through national, mutual recognition and/or decentralised procedures.

At a regional level, regional regulatory authorities enforce regulations in the abovementioned areas. Moreover, as financing for reimbursing medicinal products comes from the budgets allocated to the autonomous regions in Spain, these regions participate in the MOH committee responsible for evaluating applications concerning the pricing and reimbursement of medicines.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Decisions of regulatory bodies are subject to challenge through both administrative appeal and judicial review. In some cases, the administrative appeal is mandatory, and it must be filed within one month from receiving notice of the decision.

After administrative proceedings, the interested party may go to court within two months of receiving notice from the decision.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Medicinal Products

Article 8.1 of Royal Legislative Decree 1/2015 distinguishes between four types of medicinal products:

- medicinal products for human and veterinary use that are industrially manufactured, or in the manufacture of which an industrial process is involved;
- magistral formulae;
- officinal preparations; and
- special medicinal products (eg, vaccines and other biological medicinal products, advanced therapy medicinal products, radiopharmaceuticals, homeopathic medicinal products or medicinal gases).

In relation to prescription and dispensing conditions, Royal Legislative Decree 1/2015 contemplates the same classification set forth in Article 70 of Directive 2001/83/EC.

Medical Devices

Two special categories of medical devices are subject to specific regulations:

- implantable medical devices; and
- "in vitro" diagnostic medical devices.

2. Clinical Trials

2.1 Regulation of Clinical Trials

In Spain, clinical trials of medicinal products are mainly regulated by Royal Legislative Decree 1/2015 and Royal Decree 1090/2015. Clinical

trials of medical devices are governed by Royal Decree 192/2023 and Circular 7/2004 on clinical investigations with medical devices. Moreover, the AEMPS has issued the Document of Instructions for the conduct of clinical trials in Spain.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Medicinal Products

To initiate a clinical trial of medicinal products, the following will be required:

- a favourable opinion issued by a Research Ethics Committee with Medicines (CEIm) in Spain;
- prior authorisation by the AEMPS, after a scientific and ethical evaluation in accordance with Regulation (EU) No 536/2014; and
- a written agreement between the sponsor and the sites.

The authorisation procedure by the AEMPS is divided into two parts:

- Part I of the Assessment Report is evaluated by the AEMPS and an Ethics Committee; and
- Part II is evaluated only by an Ethics Committee, and refers to aspects such as subject recruitment, insurance, etc.

Based on the above, the AEMPS issues a decision that could result in authorisation, authorisation with conditions, or rejection.

Medical Devices

Two different situations can be distinguished for clinical trials involving medical devices:

- trials of medical devices without CE marking for conformity assessment have identical requirements to clinical trials of medicinal products; and
- trials of medical devices that have CE marking and are used in accordance with their instructions for use and within the approved intended purpose when the CE marking was issued require a favourable Ethics Committee opinion and a written agreement between the sponsor and the sites. The AEMPS approval is exempted.

If the AEMPS approval is required, the sponsor must submit the documentation described in Chapter II of Annex 15 of Regulation (EU) No 2017/745. The AEMPS shall evaluate the documentation submitted and decide to either authorise or reject the clinical trial.

If the AEMPS approval is not required but patients will undergo procedures beyond those applied under normal conditions of use, and these procedures are invasive or burdensome, the sponsor shall communicate this to the AEMPS through the database for clinical investigations with CE-marked medical devices (NEOPS).

2.3 Public Availability of the Conduct of a Clinical Trial

The Spanish Registry of Clinical Studies (REec) is a public database containing information on all clinical trials of medicinal products authorised by the AEMPS in Spain as of 1 January 2013. It can be accessed through the AEMPS website.

The sponsor must publish the results of the clinical trial, whether positive or negative, preferably in scientific journals, before disclosure to the general public, as well as in the REec.

For medical devices, there is currently no publicly available database.

2.4 Restriction on Using Online Tools to Support Clinical Trials

The decentralisation of clinical trials (including the use of online tools for monitoring purposes) began with the COVID-19 pandemic, when the AEMPS amended its Document of Instructions to introduce exceptional measures regarding:

- patient visits for ongoing clinical trials during the pandemic;
- access to trial medication;
- the transfer of patients between sites; and
- the procedure for obtaining patients' informed consent.

In view of the positive experience acquired, it has been considered convenient to facilitate the use of these decentralised aspects in clinical trials beyond the COVID-19 pandemic period.

2.5 Use of Data Resulting From Clinical Trials

Provided that it is not aggregated or anonymised, the resulting data from clinical trials is recognised as a special category of personal data and is therefore subject to restrictive guarantees by the personal data protection regulations applicable in the EU (GDPR) and Spain – ie, Law 3/2018, on the Protection of Personal Data.

Generally, personal data resulting from clinical trials may not be transferred to a third party or an affiliate situated in a country that does not provide an adequate level of protection, without complying with the provisions of Chapter V of the GDPR. In such cases, the sponsor must adopt one of the safeguards set out in Article 46 of the GDPR.

In those cases where there is an intention to use participants' data in future research, that future processing must be grounded in one of the lawful bases set forth in the GDPR.

2.6 Databases Containing Personal or Sensitive Data

Provided that no data analysis that could assimilate it to a clinical investigation is conducted, the creation of a database containing personal or sensitive data (eg, patient registries) is subject to the GDPR and Law 3/2018.

In this regard, it will be necessary to obtain the patient's informed consent prior to its entry in the database, or to rely on another lawful basis for the processing of the data (Article 6.1 of the GDPR), plus a valid exception to the prohibition of processing health data (Article 9.2 of the GDPR).

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

Products are classified as medicinal products or as medical devices on a case-by-case basis. The application of medicinal product legislation is preferable, due to the level of development, safety and greater consumer protection it offers compared to legislation for other products.

According to Directive 2001/83/EC, a product shall be classified as a medicinal product if it achieves its intended effect by means of a pharmacological, immunological or metabolic action (medicinal product by function), or if it is presented as having therapeutic properties typical of medicinal products (medicinal product by presentation). Those are alternative conditions, meaning that a given substance or combination

will be considered a medicinal product if either or both definitions apply to it.

The AEMPS is responsible for attributing the status of medicinal product to a substance in Spain. This can occur within the framework of a national marketing procedure or subsequently within the scope of the market surveillance functions of the AEMPS.

However, in the centralised procedure, it is the European Medicines Agency (EMA) that determines whether a substance is a medicinal product. Moreover, the EMA has the power to intervene in disputes arising during decentralised authorisation procedures.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

The granting of a marketing authorisation (MA) for biologic products is not subject to any obligations other than those for an MA in general. Most biologic medicinal products have to be authorised by the European Commission through the centralised procedure.

Advanced therapy medicinal products (which can also be biologic products) that are non-industrially manufactured are regulated by Royal Decree 477/2014, which sets out that their individual use and manufacture must be authorised on a case-by-case basis.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Medicinal Products

The MA of a medicinal product is valid for an initial period of five years. The marketing authorisation holder (MAH) may apply for a marketing authorisation renewal, pursuant to Article 27 of Royal Decree 1345/2007, at least nine months before expiration.

Once renewed, the MA will be valid for an unlimited period of time, unless the AEMPS requires an additional five-year renewal based on duly justified pharmacovigilance-related reasons. An MA shall be revoked if the product it refers to is not marketed for three consecutive years.

In addition, Royal Decree 1345/2007 imposes an obligation to keep the market duly supplied. In practice, each October the MAHs shall declare whether they intend to market the product during the following year. If they do not do so, they will be deemed to have requested a suspension of the validity of the MA.

Royal Decree 1345/2007 also empowers the AEMPS to keep MAs in force for reasons of public health interest, such as the creation of a treatment gap, either in the market in general or in the pharmaceutical provision of the National Health Service (NHS). This could contravene the provisions of Directive 2001/83/EC, which allows marketing cessation if notified two months in advance.

Medical Devices

The certificate of conformity for medical devices issued by the Notified Bodies is valid for a maximum of five years in line with provisions set out at the EU level.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Medicinal Products

The AEMPS is in charge of granting MAs in Spain, which are regulated by Royal Decree 1345/2007. Some provisions of such Royal Decree also affect medicines authorised by the

European Commission pursuant to the centralised procedure.

The AEMPS shall authorise a specific product if it:

- fulfils the established quality requirements;
- is safe under normal conditions of use;
- is effective in the therapeutic indications;
- is correctly identified; and
- provides the patient with the necessary information.

The positive therapeutic effects of the medicinal product shall be assessed under a risk-benefit perspective.

The key stages of the authorisation procedure are as follows:

- submission of the application to the AEMPS;
- validation and acceptance of the submission;
- issuance of the evaluation report; and
- resolution of the application and granting, where appropriate, of the MA.

The maximum period to notify the applicant of the resolution of the authorisation procedure is 210 calendar days.

The main requirements for the different types of variations of MAs of medicinal products are regulated in Royal Decree 1345/2007, in respect of the elements to be submitted by the MAH for each type of variation (ie, Types IA, IB and II, and extensions).

Applications for variations must be submitted to the AEMPS, which has 30 days to approve or deny Type IA and Type IB variations, and 60 days for Type II variations.

Transfers of MAs require prior authorisation by the AEMPS. The application is to be conducted through the RAEFAR platform, where the data and documentation supporting the proposed transfer must be uploaded.

Medical Devices

Medical devices are divided into four classes (III, IIb, IIa and I), depending mainly on 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, medical devices must bear a "CE" marking of conformity when they are placed on the market in Spain, which provides evidence of the device's conformity with the applicable requirements. The evaluation and variation approval of medical devices are governed at EU level in accordance with Regulation (EU) 2017/745.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Medicinal products cannot be placed on the Spanish market without obtaining an MA. Exceptionally, uses not covered by an MA outside a clinical trial might be permitted in three situations regulated by Royal Decree 1015/2009:

- compassionate use;
- off-label use; and
- access to foreign products.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Medicinal Products

Royal Decree 577/2013 imposes the following main pharmacovigilance obligations on MAHs:

- respect the good practices on pharmacovigilance published by the AEMPS;
- have an adequate pharmacovigilance system;
- have a suitably qualified person responsible for pharmacovigilance in both the EU and Spain;
- submit periodic safety reports to the EMA;
- have a risk management system for each medicinal product;
- notify and record suspected adverse reactions;
- monitor scientific literature worldwide;
- carry out post-authorisation studies of efficacy and safety; and
- perform a continuous evaluation of the risk-benefit parameters of the medicinal product.

The MAH shall conduct post-authorisation efficacy studies required by member states or the European Commission in the following circumstances:

- as a condition of the MA, where questions about the efficacy of the medicinal product arise that can only be resolved after the medicinal product has been placed on the market; and
- subsequent to the granting of an MA, where knowledge of the disease or clinical methodology indicates that previous assessments of efficacy may need to be significantly revised.

Products subject to additional monitoring requirements must include a black inverted triangle in their package leaflet and data sheet, accompanied by the sentence “this medicine is subject to additional monitoring”.

Medical Devices

Manufacturers, authorised representatives, importers or distributors of medical devices must notify the AEMPS of:

- any malfunction or alteration of the characteristics of the product, as well as any inadequacy of the labelling or instructions for use that could lead to death or serious damage to health; and
- any reason of a technical or health-related nature linked to the characteristics or performance of a device that has led the manufacturer to take systematic action on devices of the same type.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

EU Level

The EMA assesses each individual request for access to documents submitted in accordance with Regulation (EC) No 1049/2001, and its policy on access to documents.

EU case law supporting access to documents has noted that the companies involved usually fail to give any concrete evidence of how the release of the contested documents would undermine their commercial interests. Documentation requests could be rejected if the affected party demonstrates that disclosure could undermine their commercial interests, which has to be analysed on a case-by-case basis.

As per medical devices, the EU is currently deploying the European database on medical devices (EUDAMED), which will be composed of six modules related to:

- actor registration;
- unique device identification (UDI) and device registration;
- notified bodies and certificates;
- clinical investigations and performance studies;
- vigilance and post-market surveillance; and

- market surveillance.

National Level

The AEMPS processes access to public information requests in accordance with Law 19/2013 on Transparency.

In general terms, there is no public database listing pending authorisations. It is possible to request the number of pending applications for a given active substance, which is usually granted on a non-name basis.

If the authorisation has been granted, there is a public database named "CIMA" where information relating to authorised medicinal products is made available to the public. There are no provisions on access where an application has been refused.

In all scenarios, the dossier and expert reports are confidential (Article 15 of Royal Decree 1345/2007).

3.8 Rules Against Illegal Medicines and/or Medical Devices

Medicinal Products

Directive 2011/62/EU amending Directive 2001/83/EC, as regards the prevention of the entry into the legal supply chain of falsified medicinal products ("Falsified Medicines Directive"), introduced the following measures:

- MAHs are obliged to place two safety features on the packaging of most prescription medicines and some over-the-counter medicines in the EU – a unique identifier (a two-dimension barcode) and an anti-tampering device;
- manufacturers shall upload the information contained in the unique identifier for a medicinal product to a central EU repository;
- new responsibilities for wholesalers and a definition of brokering activities, as well as new responsibilities for brokers; and
- an obligatory logo that will appear on the websites of legally operating online pharmacies and approved retailers in the EU.

Medical Devices

The legal framework in force is less developed when dealing with counterfeit medical devices.

The main measure to check medical devices is the CE mark, which is used to show compliance with the essential requirements for safety. Therefore, users are encouraged to verify that the CE mark is authentic and supported by the appropriate certification from the manufacturer.

Another measure to limit counterfeit medical devices is the European Medical Device Nomenclature (EMDN), which is the nomenclature of use by manufacturers when registering their medical devices in the EUDAMED database and provides an additional layer of traceability.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

EU Level

The Falsified Medicines Directive introduces EU-wide rules for the importation of active substances. In practice, imports may occur only if they are accompanied by written confirmation from the competent authority of the exporting country attesting that the standards of good manufacturing practice and control of the manufacturing site are equivalent to those in the EU. This requirement is waived for certain third countries listed by the Commission.

National Level

Royal Legislative Decree 1/2015 and Royal Decree 824/2010 regulating foreign trade establish border measures to tackle counterfeit medicinal products and medical devices. Furthermore, Circular 1/2015 sets out that authorisation for the import of finished medicinal products must be requested by the importing pharmaceutical laboratory or by the laboratory holding the MA, in accordance with the MA for the medicinal product.

Please see **6. Importation and Exportation of Pharmaceuticals and Medical Devices** for more detail.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Medicinal Products

Any manufacturer of medicinal products or products under investigation, or any manufacturer that is involved in any of the processes that this may entail (ie, fractionation, packaging and presentation for sale) (Article 63 of Royal Legislative Decree 1/2015), shall be considered as a manufacturing pharmaceutical laboratory and authorised by the AEMPS. This authorisation shall be required even if the medicinal product is manufactured exclusively for export.

Obtaining the authorisation requires:

- applying to the AEMPS specifying the medicinal products and pharmaceutical forms to be manufactured or imported, as well as the place, establishment or laboratory where they are to be manufactured or controlled;
- having suitable and sufficient premises and technical and control equipment for the activity intended to be carried out; and
- having a technical director, manufacturing manager and quality control manager with sufficient qualifications.

The AEMPS will validate that the formal requirements of the application are correct within a maximum period of ten days. Subsequently, it will carry out an inspection at the corresponding facilities. The AEMPS will then issue the authorisation resolution, which will be communicated immediately to the autonomous regions. The maximum period for notification of the resolution is 90 days from the date of receipt of the application by the AEMPS. The validity of this authorisation is indefinite, unless revoked.

Medical Devices

Companies engaged in the manufacture, importation, grouping or sterilisation of medical devices, and the facilities involved, require a prior operating licence from the AEMPS.

The AEMPS will review the applications submitted and notify the resolution within three months of the application. The AEMPS shall refuse, suspend or revoke operating licences when the documentation provided or the corresponding inspection reports do not guarantee that the appropriate facilities, means, procedures and personnel are available to carry out the respective activities or when the conditions under which the licence was granted, its modifications or revalidations are not maintained.

Operating licences shall be valid for a period not exceeding five years.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Medicinal Products

Wholesalers and contract warehouses are subject to prior authorisation by the autonomous region in which the warehouse is domiciled. This authorisation will detail the distribution activities for which the entity is authorised in accordance with the European format. Such entities shall also notify the AEMPS of the start of their activities.

Royal Decree 782/2013 establishes that a prior assessment of applications for authorisation will be carried out to verify that the entities have the appropriate personnel, material and operational means to guarantee the correct development of their activity and that the entity is capable of providing a quality service in its field of action. In addition, a physical inspection of the premises where the distribution activity will be carried out.

The maximum period for notification of the resolution is 90 days from the date of receipt of the application by the competent health authority. Once this 90-day period has elapsed without notification of the resolution, the applicant may consider their application to have been accepted.

The validity of these authorisations is indefinite. However, the Administration may suspend them in the following circumstances:

- if it is found that the entity does not fully, effectively and continuously carry out all the distribution activities for which it has been authorised, one year after the authorisation is granted; or
- when it no longer meets the requirements that were taken into account to grant said authorisation or fails to comply with the legally established obligations.

Medical Devices

Distributors engaged in the sale of medical devices must make a prior notification of the commencement of activity to the health authorities of the autonomous region where the registered office of the company is located and of the autonomous region where the warehouse or warehouses are located. This notification shall contain:

- identification of the distribution establishment;
- the types of products it distributes or sells; and
- identification and qualification of the responsible technician, when applicable.

In addition, if the distributor places the product on the market, it must be registered in the AEMPS Marketing Register prior to the start of its activity.

5.2 Different Classifications Applicable to Pharmaceuticals

Please see **1.3 Difference Categories of Pharmaceuticals and Medical Devices.**

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The importation and exportation of medicinal products and medical devices is governed by Royal Legislative Decree 1/2015 (in particular, Articles 72 and 73 relating to exports) and Royal Decree 824/2010.

The AEMPS applies and enforces regulations regarding the import, export and intra-Community trade of medicinal products and medical devices. In the exercise of its duties, the AEMPS has issued the following guidelines:

- Circular 1/2015, which sets forth the procedures that must be completed for requesting authorisation from the AEMPS for imports/exports prior to international trade controls;
- Circular 1/2015 on the foreign trade of medicines; and
- Circular 2/2012 on the prior notification of shipments of medicines to other member states.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

Medicinal Products

Any individual or legal entity can apply for an import licence from the AEMPS if it complies with Article 63 of Royal Legislative Decree 1/2015. Requirements to obtain the import licence are the same as those listed for the application for manufacturing authorisations – please see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices** for more detail.

Medical Devices

The importation of medical devices is subject to obtaining a prior licence from the AEMPS covering the premises where importation activities are performed.

Importers of medical devices established in Spain and placing Class I or custom-made medical devices must be included in the registry of responsible persons. Also, the distribution of remaining medical devices requires a prior notification for commercialisation, which must include information regarding the premises, activities, type of products and responsible technician.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The importation of medicinal products and medical devices is subject to a prior licence issued by the AEMPS, as referred to in **6.2 Importer of Record for Pharmaceuticals and Medical Devices.**

Moreover, importers of medical devices established in Spain and placing class I or custom-made medical devices must be included in the registry of responsible persons, and the distribution of remaining medical devices requires a prior notification for commercialisation.

The AEMPS issued extraordinary import authorisations for medical devices during the COVID-19 crisis; please see **11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19.**

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Imports of healthcare products are controlled by the Pharmaceutical Inspectorate at customs, which will verify that the products comply with the requirements established in applicable Euro-

pean legislation, and that the importer has an operating licence.

Ministerial Order SPI/2136/2011 lays down the procedures for health control at the border by the Pharmaceutical Inspectorate and regulates the computerised pharmaceutical inspection system for border health controls. Annex I contains a non-exhaustive list of the headings subject to control. The products are classified according to the CN code, according to Council Regulation (EEC) No 2658/87.

6.5 Trade Blocs and Free Trade Agreements

The import authorisation referred to in **6.2 Importer of Record of Pharmaceuticals and Medical Devices** is not required if the product originates from another EU country (intra-Community trade) or from Norway, Iceland or Liechtenstein, by virtue of the Agreement on the EEA recognising the free movement of goods between the contracting parties, signed in Porto on 2 May 1992. In this case, a distribution licence is sufficient. For more information on distribution requirements, please see **5.1 Wholesale of Pharmaceuticals and Medical Devices.**

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Medicinal Products

Medicinal products supplied to the NHS have a maximum ex-factory price (PVL) set by the MOH. Spain has always been said to follow a "cost plus" system, under which the maximum PVL should respond to the cost of the product plus a given profit margin. This is what Royal Decree 271/1990 contemplates in accordance with the provisions of Directive EEC 89/105 relating to the transparency of measures regulating the pricing of medicinal products for human use.

As a matter of practice, the price-approval process entails a negotiation with the authorities, where the cost and the profit margin are not really the variables that are considered. Companies should be prepared for prices mainly to be determined by the following two issues:

- a comparative pharmaco-economic evaluation of the medicine in which the advantages of the new product should be quantified; or
- the price of the product in other EU member states.

Companies must also be ready for the authorities to consider other issues, such as the activities performed by the company in Spain (R&D, manufacturing, etc) and the relationship with a local company through a co-marketing or licensing arrangement.

The margin corresponding to the distribution of industrially manufactured medicinal products is regulated in Article 1 of Royal Decree 823/2008. For presentations of medicinal products whose PVL is equal to or less than EUR91.63, the margin is set at 7.6% of the wholesaler's selling price excluding taxes ("wholesaler price"). If the PVL is higher than EUR91.63, then the wholesaler's margin is fixed at EUR7.54 per package.

The margin for retail pharmacies is regulated in Article 2 of Royal Decree 823/2008, as follows:

- 27.9% of the retail price excluding taxes ("retail price") for those medicines whose PVL is equal to or less than EUR91.63;

- EUR38.37 per package for those medicines whose PVL is higher than EUR91.63 and equal to or lower than EUR200;
- EUR 43.37 per package for those medicines whose PVL is higher than EUR200 and equal to or lower than EUR500; and
- EUR48.37 for those medicinal products whose PVL is higher than EUR500.

The proceeding may start ex officio (for new medicinal products) or at the request of an applicant (eg, for medicinal products with a previous decision of non-reimbursement).

If the proceeding starts ex officio, the applicant may submit any documentation it deems appropriate, including the value dossier, within ten business days from the date the applicant receives the letter from the MOH informing that the pricing and reimbursement proceeding has begun. This period may be extended up to 15 business days.

If the proceeding starts at the request of the applicant, the applicant may submit any documentation it deems appropriate jointly with the request for initiation of the proceeding. Pricing and reimbursement proceedings are completed once the MOH issues a ruling with its decision on the reimbursement of a medicinal product.

Medical Devices

The reimbursement of medical devices is regulated in Royal Decree 9/1996 and Royal Decree 1030/2006, which establish the proceeding to reimburse medical devices and the criteria to be considered for the establishment of a maximum price.

According to Royal Decree 9/1996, only certain types of medical devices may be reimbursed, and this does not include products that are advertised to the general public. Annex I and Annex II of this Royal Decree include a list of medical devices that shall be reimbursed (eg, bandages, gauze, catheters, urine collection bags).

Royal Decree 1030/2006 refers to surgical implants, external orthoprostheses for use in hospitalised patients and external orthoprostheses for outpatient use (eg, wheelchairs).

7.2 Price Levels of Pharmaceuticals or Medical Devices

Spanish law does not allow the MOH to reference prices internationally. However, in practice, external reference pricing is a relevant factor influencing price rulings in Spain. The fact that this practice has no legal basis hinders traceability on how exactly the MOH proceeds regarding international prices.

It seems that the MOH requests the MAH to provide information about pricing in other EU countries, and that EU prices operate as a cap for Spanish prices. Prices in Spain are rarely fixed above the price of the same medicinal product in other EU countries.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Please see **7.1 Price Control for Pharmaceuticals and Medical Devices.**

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Until 2023, the cost-benefit assessment (HTA) of medicinal products was carried out in so-called “Therapeutic Positioning Reports” (IPTs). These IPTs included a therapeutic evaluation section and an economic evaluation section. HTA was

carried out jointly by the AEMPS, the MoH and the autonomous regions.

According to Law 10/2013, these reports will have a "scientific-technical" basis and will be binding but not mandatory. In 2020, the MOH approved the Plan for the Consolidation of IPTs ("the Plan"), which reviewed the whole HTA process in Spain and consolidated IPTs as a key element of such HTA. However, a judgment of the Spanish National High Court in 2023 ruled that this Plan had been issued without following the established procedure for drafting laws and regulations. Consequently, a joint clinical and economic evaluation cannot be conducted in Spain. Since this ruling, the IPTs being carried out by the AEMPS do not include an economic evaluation section.

In relation to medical devices, the criteria for inclusion are more explicitly conditioned to the requirement of efficiency. In this sense, Law 16/2003 establishes that a prior assessment will be required for the inclusion of new technologies in the NHS. The requirements established by Law 16/2003 for this evaluation include the need for the new technologies to provide an improvement in terms of safety, efficacy, effectiveness, efficiency or proven usefulness compared to other available alternatives.

A new Royal Decree is expected to be issued in 2024 to fully regulate the HTA procedure for medicinal products and medical devices in Spain.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Royal Legislative Decree 1/2015 governs the prescription and dispensing of medicinal products. The general rule is that prescription in the NHS should be done in the most appropriate way for the benefit of patients, while protecting the sustainability of the system.

Prescriptions are made by active ingredient. Prescription by trade name will be possible if the principle of greater efficiency for the NHS is respected and for medicinal products considered as non-substitutable.

When the prescription is made by active substance, the pharmacist shall dispense the lowest-priced medicinal product in the so-called "Homogeneous Groups", which are lists of products that may be substituted.

Generics and biosimilars have different substitution regimes. Biological medicinal products are non-eligible for substitution, with the general rule being that the pharmacist must dispense the medicinal product prescribed by the doctor. Exceptionally, when the prescribed medicinal product is not available in the pharmacy due to shortages or when there is an urgent need to dispense it, the pharmacist may replace it with a generic medicinal product. In any case, it must have the same composition, pharmaceutical form, route of administration and dosage.

According to Article 1 of MOH Order SCO/2874/2007, biological products shall not be substituted when dispensed without the express authorisation of the prescribing doctor.

To achieve greater efficiency for the NHS, the MOH can establish "singular reserves" for the dispensing of some medicinal products. When deciding on the reimbursement of a medicinal product, it is common for the MOHto stipulate that some medicinal products may only be dispensed in NHS hospitals, rather than in retail pharmacy offices.

No special rules apply to the prescription and dispensing of medical devices.

8. Digital Healthcare

8.1 Rules for Medical Apps

In Spain, there are no specific rules for medical apps, medical devices software or mobile health apps. If a particular software qualifies as a medical device, its regulatory framework will apply.

Some of the most common "health apps" (eg, medication reminders, pregnancy tracking, remote patient monitoring, telemedicine) may qualify as a medical device or an in vitro diagnostic medical device, and shall be CE marked. Guidance in this regard has been provided at EU level, by the Medical Device Coordination Group (MDCG) established by Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

In general terms, apps that do not perform an action on data or perform an action limited to storage, archiving, communication or simple search do not qualify as medical device software. The fact that the app alters data for embellishment purposes does not render it a medical device either, but altering data or its representation for medical purposes might. Apps that are not for the benefit of individual patients will also not qualify as medical device software; this excludes software or apps intended to aggregate population data, provide generic diagnostic or treatment pathways, serve as scientific literature, templates, models, etc.

8.2 Rules for Telemedicine

Telemedicine or teleconsultation services are not specifically regulated in Spain.

The Spanish Code of Medical Ethics does provide some guidance on what is permitted in the field of telemedicine. According to Article 23 thereof, the use of telematic means or other non-face-to-face communication systems aimed at aiding decision-making within the professional scope complies with medical ethics if the identification of those involved is unambiguous, confidentiality is ensured, and communication channels guarantee maximum available security.

Law 44/2003, on the organisation of the health professions, establishes that the exercise of health professions shall be carried out in full technical and scientific autonomy, subject only to the limitations set out by law and to the principles and values set out in the applicable regulatory and deontological framework. Therefore, there is a consensus that physicians can perform telemedicine services if they consider it appropriate from a scientific and technical point of view and in light of the ethical regulations.

8.3 Promoting and/or Advertising on an Online Platform

In essence, advertising on the internet is held to the same standards and requirements as advertising through traditional channels.

The advertising and promotion of medicinal products and medical devices is subject to the general rules on advertising contained in General Law 34/1988 on advertising and in Law 3/1991 on Unfair Competition. For medicinal products, Royal Decree 1416/1994 must also be followed, and the advertising of medical devices is regulated by the general regulatory framework for medical devices.

As regards advertising directed to healthcare professionals through the internet, it is noteworthy that companies must use valid channels

within a context that is basically scientific or professional. Those channels must be intended exclusively for healthcare professionals authorised to prescribe or dispense medicinal products. These need to identify themselves in order to have access to the information. Companies can also establish a healthcare professional status verification system. Furthermore, a company will be liable for the content of the websites accessed through links from its own website.

8.4 Electronic Prescriptions

Electronic prescriptions are regulated by Royal Decree 1718/2010, which establishes a system for electronic prescriptions made in the context of the healthcare services of the National Health System and in private medical practice.

8.5 Online Sales of Medicines and Medical Devices

Only online sales of non-prescription medicinal products are permitted, and under the conditions set out in Royal Decree 870/2013. Moreover, the AEMPS has issued a Q&A document on the online sale of medicinal products. At a regional level, Aragon and Catalonia have issued specific guidelines governing the online sale of medicinal products.

There is currently no specific regulation governing the online sale of medical devices. However, such sales are permitted and are subject to the basic rules and requirements for sale outlined in the general regulatory framework for medical devices (ie, RD 192/2023, RD 1662/2000 and 1616/2009).

8.6 Electronic Health Records

There are no specific rules for patients' electronic health records other than the general requirements set out in Royal Decree 1093/2010, the GDPR and Law 3/2018; please see **2.5 Use of Data Resulting From Clinical Trials** and **2.6 Databases Containing Personal or Sensitive Data.**

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The main laws applicable to patents in Spain are Law 24/2015 on Patents and Royal Decree 316/2017.

The requirements to obtain a patent in Spain are that the invention must be new in a field of technology (novelty), involve an inventive step and be susceptible to industrial application.

Among others, Article 5 of Law 24/2015 excludes the following as being non-patentable, under certain conditions:

- inventions for which the commercial exploitation would be contrary to public order or morality principles (eg, processes for cloning human beings);
- methods for treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body – however, it is possible to patent products for use in any such methods, in particular substances, compositions, apparatus or instruments;
- the human body, at the various stages of its formation and development, and the simple discovery of one of its elements – however, it is possible to patent an element isolated from the human body or otherwise produced by a technical process, including the sequence or partial sequence of a gene, even if the

structure of that element is identical to that of a natural element; and
- a mere DNA sequence, without indicating any biological function.

9.2 Second and Subsequent Medical Uses

The first medical use of a substance or composition already known may be patentable per se. The second or a subsequent medical use of a substance or composition already known for use in the treatment of another disease (second medical indication) may be patentable if the second or subsequent use is new and inventive.

9.3 Patent Term Extension for Pharmaceuticals

For medicinal products, it is possible to extend patent rights through a supplementary protection certificate (SPC). This confers the same rights as those conferred by the patent and is subject to the same limitations and obligations. The rules applicable to SPCs are contained in Regulation (EC) 469/2009, amended by EU Regulation 933/2019, which introduces the exception known as the "SPC manufacturing waiver".

An SPC starts from expiry of the relevant patent. Its duration is the period between the patent application filing date and the date of first marketing authorisation of the relevant medicinal product in the EU up to a maximum of five years. An SPC can be extended once by a period of six months if there is a paediatric investigation plan for the medicinal product (eg, Regulation (EC) 1901/2006 on medicinal products for paediatric use).

SPCs are granted on a product basis. Each product requires a separate SPC, even if they are all covered by the same patent.

9.4 Pharmaceutical or Medical Device Patent Infringement

A patent is infringed when there is an unauthorised use of the invention protected by the patent during its validity. Patent infringement can occur directly and/or indirectly.

Direct infringement occurs when there is an unauthorised use of the patented invention through:

- manufacturing, offering for sale, marketing or using a product that constitutes the patented invention, or importing or possessing such a product for any such purposes;
- using a procedure that constitutes the patented invention, when the person using the procedure knows or can be reasonably expected to know that the use is prohibited without the patent holder's consent;
- offering for sale, marketing or using a product directly obtained from a procedure that constitutes the patented invention, or importing or possessing such a product for any such purposes; and
- exporting a product that is the subject matter of a patent in Spain or that has been obtained through a process protected by a patent in Spain. This has been considered by courts as an act of marketing, and is therefore an infringement of a patent in Spain.

Indirect infringement occurs when a person makes unauthorised use of a patented invention by giving or offering to give to other person(s) the means to put the patented invention into practice, if:

- the means are an essential element of the patented invention; and
- the other person(s) to whom the means are offered knows or can be reasonably expected

to know that it is possible to put the patented invention into practice through such means, and they intend to do so.

The mere application for a MA of a medicinal product does not constitute a patent infringement per se, but it can be a relevant factor if the patent holder demonstrates that the infringing activity is imminent. In case of litigation of innovators v generics, the parties usually exchange letters prior to initiating ligation and the generic operator undertakes not to launch its product prior to a certain date to try to avoid the arguments of the patent holder that the launch is imminent.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The main defences to a patent infringement action include the following.

Research Exemption

Patent rights do not extend to acts carried out for experimental purposes relating to the patented invention. In particular, patent rights are not infringed by acts relating to performing the studies and trials necessary to obtain an MA for medicines in or outside Spain, and the practical requirements arising from them, including the preparation, obtaining and use of the active substance for these purposes.

The Bolar exception (a special case of the experimental use exception) relates specifically to experiments and trials, both pre-clinical and clinical, conducted to seek regulatory approval for a generic or similar bio-equivalent medicinal product.

IP Exhaustion

A patent holder cannot claim infringement against acts relating to a product that has been commercialised in the EEA by the patent holder or with their consent (patent exhaustion), unless there are legitimate grounds for the proprietor to oppose the marketing of the product.

Other Exemptions

Further exemptions include:

- stockpiling and manufacturing for export under the conditions set forth in Regulation (EU) 2019/933;
- acts done for strictly private and non-commercial purposes; and
- the extemporaneous preparation in a pharmacy of a medicine for an individual according to a medical prescription, or acts relating to a medicine so prepared.

9.6 Proceedings for Patent Infringement

A patent holder can bring actions to defend its patent in the competent Spanish courts. The following remedies, among others, are available:

- cessation action to stop the infringing activity;
- compensation for damages caused by the infringement; and
- seizure of the infringing articles and the means used for the infringement.

Interim relief can also be requested through a preliminary injunction application.

Pre-trial discovery proceedings to gather facts necessary to prepare the claim on the merits are available.

9.7 Procedures Available to a Generic Entrant

The generic entrant may file an action seeking the nullity of the patent/s expected to be enforced against the product intended to be commercialised. The defendant in such proceedings would normally file a counterclaim seeking the declaration of infringement.

The generic entrant may also file an action seeking a judicial declaration of non-infringement of a given patent by its product. Prior to the filing of the action, the interested party shall request the patent holder to give its opinion on the enforceability of the patent against the industrial exploitation that the applicant is carrying out on Spanish territory or against the serious and effective preparations that it is making for that purpose.

If no decision is made after one month or if the applicant is unsatisfied with its reply, the interested party will be entitled to bring an action for the declaration of non-infringement. This option is not available to those already sued for patent infringement.

There is no requirement under Spanish law for any prior legal action for the generic entrant regarding patents that may be infringed.

Patent linkage in MA procedures is prohibited under EU law.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

The ordinary legal tool used to tackle counterfeiting is the Spanish Criminal Code. Infringement committed knowingly is punishable with a fine and/or imprisonment (six months to two years). In serious cases, higher penalties may be imposed, namely higher fines and imprisonment of two to four years, temporary closing of the production plant or establishment concerned (up to five years) or even permanent closing thereof, and disqualification from exercising the profession related to the infringement.

Regulation (EU) No 608/2013 took effect throughout the EU in January 2014 and provides that patent owners may file an application to have Customs watch for imports of goods that infringe registered patents.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Law 14/2011 on Trademarks offers the trade mark holder a series of actions to defend the exclusivity it holds over the name and/or logo that is the subject matter of the protection. If the medicinal product or medical device is branded with a sign that infringes a valid trade mark, the holder of said mark will be entitled to file infringement actions against the entity responsible for the product or device.

Remedies include the cessation of the activity and damages. Contrary to patent law enforcement, the trade mark holder will not be able to impede the re-commercialisation of the same product or device with a different brand (unless the infringed right is a 3D trade mark or a registered design for protecting the shape of the product – see **10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices**).

The trade mark holder may oppose the importation of non-infringement product from non-EU countries based on its trade mark rights since Spanish law limits the defence of exhaustion to the territories of the EU.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The right of industrial designs may be a source of protection regarding the shape of the medicinal products and medical devices – specifically the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture and/or materials of the product itself and/or its ornamentation.

In order to be protectable, designs must be new and possess individual character. These conditions are established and defined at both EU and national levels: at the EU level, they are established in Articles 6 and 7 of EU Regulation 6/2002, while at a national level they are regulated in Articles 5 and 6 of Law 20/2003 on the Legal Protection of Industrial Design.

3D trade marks may be registered, but shapes that are imposed by reasons of a technical order or by the nature of the goods themselves or that may affect the intrinsic value of the goods cannot be registered as a trade mark.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Spanish legislation (Articles 17.3 and 18.1 of Royal Legislative Decree 1/2015 and Article 7 of Royal Decree 1345/2007) does not include any material difference from regulatory data protection regulations in the EU (Article 11.14 of Regulation (EC) 726/2004 and Article 10.1 of Directive 2001/83/EC).

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

In the context of the COVID-19 pandemic, Royal Decree-Law 21/2020 and Law 2/2021 were enacted to temporarily regulate the home delivery of hospital-prescribed and/or dispensable medications. Under these regulations, regional authorities were empowered to establish appropriate measures for the non-face-to-face dispensing of medicinal products, ensuring optimal care by delivering, if necessary, medicinal products at healthcare centres, authorised healthcare establishments for dispensing medications near the patient's home, or at the patient's own home.

Consequently, several regional authorities adopted resolutions, guidelines or other legal instruments to regulate home delivery activities. For example, Catalonia issued a Resolution in June 2020 authorising the home delivery of hospital medicinal products, as well as the "Document of Good Practices for the Delivery of Outpatient Dispensed Hospital Medication" in April 2021. Andalusia entered into a collaboration agreement with the Andalusian Council of Pharmacists' Associations in March 2021, enabling and regulating the home delivery of hospital medicinal products.

11.2 Special Measures Relating to Clinical Trials

The Document of Instructions for the conduct of clinical trials in Spain was updated in March 2020 to allow special measures; please see **2.6 Databases Containing Personal or Sensitive Data** for more detail.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The EMA has created a specific expedited procedure for the approval of medicines, which is characterised by significantly shorter timeframes for the review and approval process. The AEMPS has not adopted additional requirements, measures or exceptions in connection with national proceedings.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

Within the context of the COVID-19 pandemic, the AEMPS has established a temporary and abbreviated procedure for the certification of medical devices that are essential to answer the needs caused by the pandemic (namely, medical devices such as surgical masks and surgical gowns). In addition, Order SND/326/2020 established special measures for the granting of prior operating licences for facilities and for the commissioning of certain medical products without CE marking on the occasion of the health crisis caused by COVID-19.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Because of the COVID-19 crisis, the AEMPS issued extraordinary import authorisations for medical devices that do not comply with some of the marketing requirements for medical devices (such as authorisation for products without CE marking or for importers without import licences).

11.6 Drivers for Digital Health Innovation Due to COVID-19

Telemedicine services were already in use before the COVID-19 pandemic but their use became widespread during this period.

The MoH issued information notes providing guidance to health centres on how to manage COVID-19 cases telematically (Technical document "Management and home care of Covid-19", dated June 2020) and encouraging medical centres to promote telephone and telematic consultations, leaving the need for a face-to-face assessment to the discretion of the professional after an initial telephone assessment.

Also in 2020, the Medical Association of Catalonia published a document named "Deontological considerations in relation to information, consent and virtual consultation during the COVID-19 pandemic", and the Madrid Medical Association issued a document providing guidance on the use of telemedicine services because of the pandemic.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

There is no intention to issue compulsory licences for COVID-19-related treatments or vaccines.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions have been introduced in existing or new provisions regarding COVID-19 vaccines or treatments.

11.9 Requisition or Conversion of Manufacturing Sites

During the COVID-19 pandemic period, many companies offered their technology to Spanish authorities to manufacture respirators, masks, protective equipment and hydroalcoholic gel. For example, Spanish car manufacturer "SEAT" dedicated itself to the production of emergency respirators.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Under Royal Decree-Law 7/2020, measures to make public procurement more flexible were adopted to ensure the immediate availability of goods and services urgently needed to respond to the pandemic. Royal Decree-Law 7/2020 stipulated that all public contracts to address COVID-related needs would be processed through the emergency procedure. This procedure was already regulated in public procurement law, but because of Royal Decree-Law 7/2020, COVID-19 was accepted and established as a general criterion for justification for processing public contracts through the emergency proceeding.

Trends and Developments

Contributed by:
Anna Gerbolés, Joan Carles Bailach, Claudia Gonzalo and Juan Martínez
Faus Moliner Abogados

Faus Moliner Abogados is a modern boutique law firm based in Barcelona that specialises in advising the pharmaceutical industry and companies that operate in the life sciences sector. The firm was founded in 1997 and currently has 15 members. It focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. The firm advises pharmaceutical and healthcare clients, large companies and smaller biotech start-ups, and is frequently called upon to advise public authorities on matters such as draft legislation. It combines legal skills and specialisation with a practical and business-oriented manner of practising law. Since its foundation, Faus Moliner has been recognised in several international publications as the market leader in pharmaceutical law in Spain.

The authors appreciate the collaboration of Sergio Miralles of Intangibles Legal and Pablo Mansilla and Laia Rull of Faus Moliner.

Authors

Anna Gerbolés is a senior associate at Faus Moliner and specialises in pharmaceutical and food law. Her experience in these sectors includes the provision of legal advice on regulatory issues and the advertising of medicinal products, medical devices, food products and other borderline products. Since becoming part of the Faus Moliner team in 2021, she has been providing highly specialised advice to companies operating in the life sciences sector. Anna is a member of the Barcelona Bar Association.

Joan Carles Bailach is a senior associate at Faus Moliner and specialises in market access, pricing and reimbursement, commercial contracts and pharmaceutical and life sciences law. He has regularly advised national and international companies on these matters since joining the firm in 2019. Joan Carles is a member of the Barcelona Bar Association, the Section of Health Law, and the Young Advocacy Group of the Barcelona Bar Association.

Contributed by: Anna Gerbolés, Joan Carles Bailach, Claudia Gonzalo and Juan Martínez,
Faus Moliner Abogados

Claudia Gonzalo is a senior associate at Faus Moliner, specialising in pharmaceutical and healthcare regulations. She has experience in advising national and international companies ion regulatory matters, public procurement, and corporate transactions and contracts. Claudia has a master's in public economic law and an executive MBA in pharmaceutical, biotechnological and medical device companies, and is a member of the Spanish Compliance Association.

Juan Martínez is a senior associate at Faus Moliner 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. Since becoming part of the Faus Moliner team in 2017, he has been providing highly specialised advice to companies operating in the life sciences sector. Juan is a member of the Barcelona Bar Association.

Faus Moliner Abogados

Rambla de Catalunya 135
08008
Barcelona
Spain

Tel: +34 93 292 21 00
Email: bcn@faus-moliner.com
Web: www.faus-moliner.com

Contributed by: Anna Gerbolés, Joan Carles Bailach, Claudia Gonzalo and Juan Martínez,
Faus Moliner Abogados

Life Sciences in Spain: an Introduction

General pharma legislation

The Ministry of Health (MOH) opened a public consultation on the first draft of the law that will amend the current Royal Legislative Decree 1/2015. The document published by the MOH shows that the reform that is being considered will have the following three principal axes.

Public financing of medicines

The MOH document refers to adopting new measures to rationalise pharmaceutical expenditure and promote rational use of public funds. In this regard, it is proposed to modify the reference price system by introducing elements that increase competition and value the contributions that represent an incremental benefit in the use of medicines. The document envisages modifying the system of the co-payment of medicines, with the purpose of protecting the persons that are more in need. The document does not refer to whether the co-payment system may also be used as an instrument that may help in modulating the demand of certain products. The document also announces measures to apply additional pressure to the industry by stating that quarterly contributions may also apply to medicines dispensed in healthcare centres.

COVID-19 and the impact of new technologies

The pandemic created great challenges related to the availability of medicinal products and medical devices. In this sense, the MOH aims to consolidate the non-presential dispensing of medicines for hospital dispensing and telepharmacy in the National Health System.

Implementation of EU law

The text published by the MOH proposes to make the necessary amendments to incorporate the amendments and definitions of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro medical devices into Spanish law.

The process to approve this new law will be lengthy; the government is expected to provide a first draft law around Q4 2024.

Pricing and reimbursement

The MOH has publicly announced its intention to issue a new Royal Decree regulating the financing and pricing of medicinal products. However, the recently published Annual Regulatory Plan for 2024 does not include this Royal Decree as a priority for this year and is expected to be adopted in 2025.

This regulation would regulate the inclusion of medicinal products in the pharmaceutical provision, the establishment of special reserves and special financing conditions, the system for revising the minimum ex-factory price (PVL), the inclusion of new indications, and the exclusion of medicines from the pharmaceutical provision, among other matters.

In March 2024, the MOH opened a public consultation on the first draft of the Royal Decree regulating the procedure for the selective financing of medical devices for non-hospitalised patients and determining the margins corresponding to their distribution and dispensation. The objectives of this regulation are twofold:

- to set the retail price of financed medical devices and the margins corresponding to the activities of wholesale distribution and dispensing to the public; and
- to update the content of pharmaceutical provision by including new medical devices, altering them and excluding those that are not marketed.

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Faus Moliner Abogados

Health technology assessment

The MOH has launched a public consultation on the draft Royal Decree on health technology assessment. The aim of this regulation is to regulate the procedure for the evaluation of medicines and medical devices.

This new Royal Decree responds to the need to address the Spanish National High Court (*Audiencia Nacional*) ruling of 2023 that annulled the Therapeutic Positioning Reports Consolidation Plan ("IPT Consolidation Plan"). This IPT Consolidation Plan established the procedure to be followed to carry out the clinical and economic evaluation of medicines and their content. The National High Court ruled that the IPT Consolidation Plan had been issued without following the established procedure for drafting laws and regulations. For this reason, a regulation with the status of Law or Royal Decree is required to establish the procedure/content of the health technology assessment reports.

The Director General of Pharmacy of the MOH recently publicly announced that the draft Royal Decree has already been drawn up. The draft is expected to be published in a Public Hearing in the coming months, so that citizens can make contributions and suggestions on the text.

Advertising of medicinal products and medical devices

The MOH has recently commenced the public consultation phase for the draft Royal Decree governing the advertising of medical devices. This draft encompasses several elements, such as streamlining the process for obtaining prior approval for the public promotion of medical devices, introducing a requirement for a responsible declaration in advertising specific devices, and prohibiting hospitality in promotional meetings except for professional-scientific events. It also explicitly bans off-label promotion and offers detailed guidelines on permissible and prohibited content in advertisements directed to the public.

In April 2023, the MOH invited all interested parties to make their proposals regarding the preparation of the draft bill amending Royal Decree 1416/1994 on the promotion of medicinal products for human use. The interested parties submitted the proposals in May 2023, and the new draft law is currently under preparation.

According to the public consultation call initiated by the MOH on the amendment of the regulation, the new proposed draft bill is aimed to address the need to tackle digital advertising, the use of social media and audiovisual means, the necessity of addressing the distribution of competencies between the state and autonomous communities, and the inclusion of obligations for accessibility in advertising for individuals with sensory disabilities.

Cannabis

In February 2024, the MOH launched a public consultation on the draft Royal Decree that is expected to establish the conditions for the elaboration and dispensation of magistral formulae based on standardised cannabis preparations. According to the MOH, although there are already industrial medicinal products with cannabis as an active ingredient, there is an expectation that cannabis in other presentations will improve the symptoms and quality of life of certain patients.

The aim of this regulation is to establish the criteria for the elaboration of magistral formulae as a way of guaranteeing the correct dosage, stability and processing of these substances, and the limitation of their formulation to cases in which

there is a monograph with technical specifications in the National Formulary. The consultation also includes, as an objective, the establishment of therapeutic indications and conditions for the preparation, prescription and dispensing of magistral formulae.

Transparency and confidentiality of prices of medicinal products

One of the hottest topics is the debate on transparency and confidentiality of the price and conditions of medicinal products in Spain.

Following freedom of information requests from citizens, several court rulings have been issued in 2023–2024 obliging the MOH to provide access to the price and reimbursement conditions of certain medicinal products. These rulings are not final and have been appealed. A Supreme Court ruling is expected in the coming years.

So far, the MOH has maintained a firm stance in defence of the confidentiality of this information, arguing that providing access to it would be detrimental to its ability to negotiate with pharmaceutical companies when setting prices for medicinal products. Therefore, making the price and reimbursement conditions of medicinal products public would reduce the negotiating capacity of the MOH and damage the economic sustainability of the NHS.

Despite this, in an appearance before the Health Commission of the Spanish Parliament (*Congreso de los Diputados*) in January 2024, the new Minister of Healthtook a clear position in favour of transparency in the price and conditions of medicinal products. However, at the inauguration of CEFI's Course on Pharmaceutical Law in March 2024, the General Director for the Common Portfolio of NHS Services and Pharmacy spoke in favour of the advantages of confidentiality in this area, stating that confidentiality increases the MOH's bargaining power when negotiating with pharmaceutical companies and generates savings for the NHS.

Spanish recovery and resilience plan

At its meeting on 17–21 July 2020, the European Council agreed to create Next Generation EU, a temporary recovery fund in additional to the EU multi-annual budget for 2021–2027. Such funds are envisaged to be used to tackle the consequences of the COVID-19 pandemic and boost economic recovery. To access these resources, member states were required to design "recovery and resilience plans" to be evaluated by the European Commission (EC).

Spain presented its first version of its "recovery and resilience plan", which includes several references to the pharmaceutical sector under the section "strengthening of the capabilities of the National Health System". Later, the Spanish government published a document outlining all the strategic projects related to health that it wants to promote with the Next Generation funds – the "PERTE for Cutting-edge Health".

One of the most noteworthy measures of this plan is to create a public-private capital company to develop new advanced therapy medicinal products in Spain. In March 2024, the Spanish government approved the agreement authorising public participation in the creation of the first commercial company for advanced therapies with public-private capital in Spain. It will be promoted because of a shareholders' agreement to be formalised between the Ministry of Science, Innovation and Universities and two pharmaceutical companies.

Contributed by: Anna Gerbolés, Joan Carles Bailach, Claudia Gonzalo and Juan Martínez,
Faus Moliner Abogados

The new company will be owned 51% by the private partners and 49% by public investment from the Ministry of Science, Innovation and Universities. It is expected to mobilise an initial public-private contribution of more than EUR74 million, EUR36,685,000 of which will be provided by the Spanish government and EUR38,182,346 of which will be made up of private capital contribution, contributed equally by the private shareholders. In addition, the Carlos III Health Institute (a public institution devoted to scientific investigation) will collaborate in the contribution of scientific knowledge and participate in the company's scientific and technological decision-making bodies. In the near future, the Spanish government is expected to make an additional contribution of up to EUR71 million, so that the new company could mobilise up to EUR220 million, with a total public contribution of EUR107 million.

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