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SPAIN

Law and Practice

Contributed by:
Lluís Alcover, Eduard Rodellar, Laia Rull and Pablo Mansilla
Faus Moliner

Contents

Faus Moliner 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. Faus Moliner 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.

Authors

Lluís Alcover is a partner of Faus Moliner and specialises in corporate and M&A, regulation of the pharmaceutical and healthcare sector, market access and the financing of medicinal products. Lluís regularly advises national and international clients in these areas. 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. Lluís is a member of the Barcelona Bar Association.

Eduard Rodellar is a partner of Faus Moliner. Since becoming part of the firm's team in 1998, he has been providing highly specialised legal assistance on a great variety of matters in the pharmaceutical industry. He advises companies operating in the life sciences sector, especially in the areas of mercantile, procedural law, clinical trials and data privacy.

Laia Rull is an associate at Faus Moliner who specialises in pharmaceutical law. Since becoming part of the firm's team in 2022, she has provided highly specialised advice to companies operating in the life sciences sector. Her practice focuses on issues related to the regulation and advertising of medicinal products, as well as compliance matters. Laia is a member of the Barcelona Bar Association.

Pablo Mansilla is an associate at Faus Moliner who specialises in pharmaceutical law. Since becoming part of the firm's team in 2023, he has provided highly specialised advice to companies operating in the life sciences sector. His practice focuses on regulatory matters, clinical trials, data privacy and compliance. Pablo 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

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Key Legislation

The following legislation governs medicinal products and medical devices in Spain.

- General pharmaceutical legislation:
  - (a) Law 14/1986 (the *"General Law on Public Health"*)
  - (b) Law 16/2003, of 28 May, on the cohesion and quality of the National Health System; and
  - (c) Royal Legislative Decree 1/2015, which approves the consolidated version of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices.
- The authorisation, registration and distribution of medicinal products:
  - (a) Royal Decree 1345/2007, which regulates the authorisation, registry and dispensation conditions of medicinal products for human use prepared industrially for human use;
  - (a) Royal Decree 477/2014, which regulates the authorisation of medicinal products for advanced therapies not prepared industrially;
  - (b) Royal Decree 824/2010 on pharmaceutical companies, manufacturers of active ingredients, foreign trade of medicinal products and investigational medicinal products;
  - (c) Royal Decree 1785/2000 on the intra-community trade of medicinal products for human use; and
  - (d) Royal Decree 782/2013, which regulates the distribution of medicinal products.
- Medical devices:
  - (a) Royal Decree 192/2023, which regulates medical devices;
  - (b) Royal Decree 1616/2009 on active implantable medical devices (partially repealed); and
  - (c) Royal Decree 1662/2000 on in vitro diagnostic medical devices.
- Clinical studies, pharmacovigilance and access to medicinal products in special situations:
  - (a) Royal Decree 1090/2015, which regulates clinical trials, ethics committees for research on medicinal products and the Spanish registry for clinical trials;
  - (b) Royal Decree 967/2020, which regulates observational studies of medicinal prod-

ucts for human use;
(c) Royal Decree 577/2013, which regulates pharmacovigilance in relation to medicinal products for human use;
(d) Law 14/2007 on biomedical research; and
(e) Royal Decree 1015/2009 on access to medicinal products in special situations.

- Price, reimbursement and promotion:
(a) Royal Decree 271/1990, which regulates the prices of medicinal products reimbursed by the National Health System;
(b) Royal Decree 177/2014, which regulates the reference price system and homogeneous groups of medicinal products in the National Health System and information on the reimbursement and prices of medicinal products and medical devices;
(c) Royal Decree 823/2008, which establishes the margins, deductions and discounts corresponding to the distribution and dispensation of medicinal products for human use;
(d) Royal Decree 1416/1994, which regulates the advertising of medicinal products, and provisions established in Articles 38–40 of Royal Decree 1594/2009, which regulates medical devices (partially repealed by Royal Decree 192/2023); and
(e) Royal Decree 870/2013, which regulates online sales to the public of non-prescription medicinal products.

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

Furthermore, there is a self-regulatory framework established by trade associations (eg, Farmaindustria, Fenin and Aeseg) that enforce their own codes of practice. These codes of practice have a binding effect on their members and primarily govern advertising and interactions with healthcare organisations, healthcare professionals and patients' organisations. Although adherence to these trade associations or their codes of practice is not mandatory, authorities often reference them as a reflection of the current social reality and take them into account in practice.

Regulatory Authorities

At the national level, the main regulatory authorities responsible for applying and enforcing regulations on medicinal products and medical devices are the Ministry of Health (MOH) and the Spanish Agency for Medicines and Medical Devices (*Agencia Española de Medicamentos y Productos Sanitarios* AEMPS). Among other functions, the MOH is responsible for drafting and implementing the rules on pricing and reimbursement of medicinal products. The AEMPS is responsible for the issuance of marketing authorisations (MAs) for medicinal products in Spain, which includes overseeing the authorisation process through national, mutual recognition and/or decentralised procedures, amongst other matters.

At the regional level, regional regulatory authorities enforce regulations in the above-mentioned areas and enact rules within their scope of competence. Moreover, regions participate in the MOH's committee responsible for evaluating pricing and reimbursement applications for medicinal products. High-level co-ordination among all regional healthcare systems mainly occurs through the National Health Service (NHS) Interterritorial Council, which comprises the national Minister of Health and the 17 regional ministers of health.

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

Decisions of regulatory bodies may be challenged 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 of the decision; if no notice is received, the deadline is six months from the presumed rejection date.

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;
- official 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

Medical devices are classified into four classes (III, IIb, IIa and I), as are in vitro diagnostic medical devices (A, B, C and D). Devices are ranked considering their level of invasiveness according to Regulation (EU) No 2017/745 on medical devices and Regulation (EU) No 2017/746 on in vitro diagnostic medical devices. Additionally, medical devices can be categorised based on their intended purpose, following the classifications outlined in European regulations.

2. Clinical Trials

2.1 Regulation of Clinical Trials

In Spain, clinical trials with medicinal products are mainly regulated by Royal Legislative Decree 1/2015 and Royal Decree 1090/2015, whereas clinical investigations with medical devices are governed by Royal Decree 192/2023.

Moreover, the AEMPS has issued a document of instructions for the conduct of clinical trials with medicinal products in Spain and guidelines for conducting clinical investigations with medical devices, both of which are regularly updated.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Medicinal Products

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

- prior authorisation by the AEMPS, after a scientific and ethical evaluation in accordance with Regulation (EU) No 536/2014;
- a favourable opinion issued by an ethics committee for research on medicinal products (*comité de ética de la investigación con medicamentos* CEIm) in Spain; and
- a written agreement between the sponsor and the sites (clinical trial agreement; CTA).

The sponsor may select any CEIm within Spain to review the study and issue a favourable opinion. With respect to the CTA, there is no standardised template for all Spanish sites. In practice, each hospital/region usually has its own template. The sponsor may sign the CTA before obtaining the required authorisations (Article 17 of Royal Decree 1090/2015). In such cases, the CTA will become effective once both AEMPS and CEIm approvals are in place.

Medical Devices

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

- clinical investigations involving medical devices without European Conformity (*Conformité Européenne* CE) for conformity assessment, as well as those with CE marking used outside the scope of their intended purpose, require a favourable CEIm opinion, AEMPS approval and a written agreement between the sponsor and the sites; and
- clinical investigations involving 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 CEIm opinion and a written agreement between the sponsor and the sites – AEMPS approval is exempted.

In the first situation, 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 investigation.

Additionally, if patients will undergo procedures beyond those applied under normal conditions of use, and these procedures are invasive or burdensome, the sponsor shall notify this to the AEMPS through the database for clinical investigations involving CE-marked medical devices (NEOPS).

2.3 Public Availability of the Conduct of a Clinical Trial

The Spanish Registry of Clinical Studies (*Registro Español de Estudios Clínicos* REec) is a public database containing information on all clinical trials with medicinal products authorised by the AEMPS in Spain. 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 specific for Spain.

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 medicinal products;
- 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. In November 2024, the AEMPS published a guide

for the implementation of decentralised elements in clinical trials, providing a series of recommendations on procedures performed with online tools to support clinical trials, such as online recruitment, electronic informed consent and telemedicine for remote monitoring. The use of these online tools is subject to appropriate safeguards to ensure participant safety and protect their rights. For example, the patient information sheet must clearly detail any decentralised elements, identify potential additional risks, and specify the measures in place to protect patient privacy.

2.5 Use of Data Resulting From Clinical Trials

Provided that it is not aggregated or anonymised, the data resulting 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 (ie, the General Data Protection Regulation; 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, 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 for future research or outside the protocol of the clinical trial (secondary use), data processing must be grounded in one of the lawful bases set forth in the GDPR. Additional Disposition 17 of Law 3/2018 has established specific provisions for secondary use of health data. In this regard, the re-use of data from previous studies is considered lawful and compatible with clinical investigation purposes, provided that the new research is related to the scientific area of the original study for which consent was obtained. In such cases, the site or the sponsor must publish the information established by Article 13 of the GDPR in an easily accessible place on its website and notify the data subjects. In addition, a prior favourable report from a CEIm is required.

2.6 Databases Containing Personal or Sensitive Data

Databases containing personal data (eg, health data) are subject to the GDPR and Law 3/2018. In this regard, it is necessary to obtain the patient's informed consent prior to entering their data in the database, or to rely on another lawful basis for the processing of the data (Article 6.1 of the GDPR), as well as a valid exception to the prohibition of processing health data (Article 9.2 of the GDPR).

It is important to note that if a database involves the collection of information on medicinal products prescribed to patients, it may fall under the scope of observational studies involving medicinal products, as regulated by Royal Decree 967/2020, and thus be subject to the requirements established therein.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

Products are classified as medicinal products or medical devices on a case-by-case basis.

According to Directive 2001/83/EC and Royal Legislative Decree 1/2015, 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). These 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 a 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.

The AEMPS is also responsible for the qualification and classification of medical devices in Spain.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

The granting of an MA for biologic products is governed by the same obligations as for other medicinal products. Biosimilar medicinal products have to demonstrate comparability in efficacy, safety and quality through an abbreviated clinical and non-clinical development programme. Biological and biosimilar medicinal products developed by means of biotechnological processes, as described in Regulation (EU) No 726/2004, must be authorised by the European Commission through the centralised procedure. Other biological and biosimilar medicinal products may optionally undergo the centralised procedure or decentralised/national procedures.

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 by the AEMPS 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 MA 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, 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 (ie, sunset clause).

Once the MA is granted, Royal Decree 1345/2007 imposes an obligation on the MAH to keep the market duly supplied. In practice, each October the MAH 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 NHS.

This could contravene the provisions of Directive 2001/83/EC, which allows marketing cessation if notified two months in advance. In practice, AEMPS has adopted a rather strict position on this matter and is taking actions against companies that cease supplies or that are not able to meet market demand if they cause a therapeutic gap.

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. The validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment conducted in accordance with the applicable conformity assessment procedures.

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 the Royal Decree also affect medicinal products 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 from 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 about the resolution of the authorisation procedure is 210 calendar days.

The main requirements for the different types of variations of MAs of medicinal products (ie, types IA, IB and II, and extensions) are regulated in Royal Decree 1345/2007.

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 on the risk posed by the device, which is mainly determined according to its level of invasiveness, the part of the body it is in contact with and the duration of such contact, according to the classification rules of Annex VIII of Regulation (EU) No 2017/75. In vitro diagnostic medical devices can also be classified into

four classes (A, B, C, D), taking into account the intended purpose of the devices and their inherent risks, in light of the classification rules in Annex VIII of Regulation (EU) No 2017/746.

Except for custom-made devices, medical devices must bear the CE marking to be 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 the EU level in accordance with Regulation (EU) 2017/745.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Medicinal Products

Spain has two national exemption schemes, implemented under Article 5(1) of Directive 2001/83, which permit the importation of and patient access to medicinal products that do not have a valid MA in Spain – the so-called compassionate use and foreign use of medicinal products – both of which are regulated under Royal Decree 1015/2009 on access to medicinal products in special situations.

Compassionate use is allowed for patients with serious or life-threatening conditions when no authorised and commercialised alternatives are available; in such cases, the medicinal product must either be subject to an MA application or be part of a clinical trial. In practice, the AEMPS takes the view that, when a medicinal product already has a valid MA and is commercialised in Spain, no compassionate use programme can be opened for indications under investigation. This may raise issues in practice if companies wish to offer units of the commercialised product to be used for such unauthorised indication free of charge. Meanwhile, the foreign use regime enables the import of medicinal products approved in other countries but not yet authorised in Spain.

Both the compassionate use and the foreign use regimes require prior approval from the AEMPS, which manages these programmes with high efficiency through its website for medicines in special situations (*medicamentos en situaciones especiales* MSE), allowing physician and healthcare centres to submit requests for individual or group patient access. Furthermore, under Spanish law, such uses are carried out under the exclusive responsibility of the physician and require prior informed consent from the patient or their legal representative, a clinical report justifying the need for the treatment and approval from the healthcare centre where it will be administered. The price of the product concerned is fixed by the importer, normally after negotiation with the pharmacy service of the healthcare centre. In compassionate use cases, the AEMPS, hospitals and regional authorities frequently put pressure on the company to supply the product free of charge. However, for the time being, Spanish law does not require that the supply be free of charge.

Finally, off-label use of medicinal products is accepted when there are no authorised alternatives for the patient. Off-label use does not require AEMPS approval and may be accomplished under the healthcare provider's authority.

Medical Devices

Medical devices without CE marking, and those used outside of a clinical investigation or for conditions not included in the instructions for use, may be permitted under a compassionate use programme in accordance with the conditions established in Circular 7/2004 issued by the AEMPS. According to this Circular, the compassionate use of medical devices is car-

ried out under the exclusive responsibility of the physician and requires prior informed consent from the patient or their legal representative, a clinical report justifying the need for the treatment, approval from the healthcare centre where it will be administered and authorisation from the AEMPS.

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 the 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 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 medicinal product is subject to additional monitoring"*.

Medical Devices

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

- any malfunction or alteration of the characteristics of the device, as well as any inadequacy in 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

Medicinal Products

Royal Decree 1345/2007 establishes the confidentiality/transparency regime that the AEMPS must follow in MA procedures for new medicinal products. Article 15 of Royal Decree 1345/2007 guarantees the absolute confidentiality of MA applications and the expert reports attached to such applications.

Royal Decree 1345/2007 also requires that the AEMPS must have a public database with information on authorised medicinal products

in Spain. This database must include the evaluation report issued by the AEMPS during the authorisation procedure (or a link to the one issued by the EMA), as well as the summary of product characteristics (SmPC), the patient leaflet and any other relevant information (risk management of the product, usage restrictions, post-authorisation studies, etc).

All this information is included in a publicly accessible online database called CIMA (*Centro de Información de Medicamentos* Drug Information Centre), which incorporates all information regarding medicinal products authorised in Spain (through both the national and centralised procedures), as well as those whose MA has been revoked or temporarily suspended. This database does not display information on medicinal products with pending MA decisions or MA applications rejected by the AEMPS.

It is important to note that the activity of the AEMPS is subject to the provisions of Law 19/2013 on transparency and access to public information. This law states that any interested party may submit requests for access to public information. Based on this regulation, it is possible to request that the AEMPS report on the number of pending MA applications for a specific active substance.

Based on the authors' experience with such requests, AEMPS provides information regarding the number of pending MA applications for a given active substance, the submission date of such application, the validation date, the pharmaceutical form, the registration status and the anatomical therapeutic chemical (ATC) code. However, the AEMPS does not disclose details regarding the name of the medicinal product or the applicant company, arguing that this information is confidential and that its disclosure could affect the economic and commercial interests of the applicants, as it forms part of their regulatory strategy.

The same rationale applies to requests regarding MAs that have been rejected by the AEMPS. The names of medicinal products whose MAs have been denied, as well as the name of the applicant company, remain confidential.

Medical Devices

Finally, concerning medical devices, the AEMPS does not maintain a public database of all medical devices marketed in Spain. The AEMPS only publishes three specific lists of medical devices, indicating the date of notification, the trade name, the composition, the manufacturer and the distributor. These lists refer to:

- filler implants used for plastic, reconstructive and aesthetic purposes with CE marking marketed in Spain;
- medical devices considered platelet-rich plasma collection systems; and
- medical devices that were specifically used during COVID-19 and were found by the AEMPS to be non-compliant with regulations while on the market.

Additionally, Royal Decree 192/2023 created a registry for medical device distributors, requiring companies engaged in distribution activities to register. However, this registry is not yet operational. This Royal Decree also created the AEMPS Marketing Registry, where all medical devices placed on the market, except class I devices, must be registered. This registry is currently only operational for economic operators and is not public.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

Fast-track registration routes are available for AEMPS-listed strategic medicinal products. While not explicitly established by law, these mechanisms have been implemented in practice by the AEMPS. The AEMPS regularly publishes and updates the strategic medicinal products list on its website, which includes medicinal products that meet two key criteria: criticality (ie, importance of the therapeutic indication) and vulnerability (ie, availability of alternative treatments).

The list of strategic medicinal products includes clinically essential but under-represented treatments in Spain, particularly those containing World Health Organization (WHO) essential active ingredients and those selected by the Food and Drug Administration (FDA). It also includes medicinal products for which cancellation or suspension requests have been denied due to their critical healthcare impact, as well as those authorised through the mutual recognition procedure to address supply shortages.

Additionally, the list includes vulnerable medicinal products essential for national clinical practice. Products from the European List of Critical Medicinal Products that meet Spain's national criteria are also considered, along with those that have a high market concentration (over 70% share) and are manufactured nationally. Medicinal products still under market protection are excluded, as their availability is guaranteed through other mechanisms.

There are no fast-track registration routes in place for medical devices.

4.2 Regulatory Reliance

Spain embraces regulatory reliance, particularly within the European Medicines Regulatory Network. The AEMPS operates within the EMA-coordinated network, contributing to centralised and mutual recognition procedures for MAs.

Furthermore, the AEMPS adheres to the mutual recognition agreements (MRAs) established between the EU and third-country authorities concerning good manufacturing practice (GMP) inspections and batch certification for human and veterinary medicinal products. In this context, the AEMPS regularly publishes communications detailing the procedures to be followed in Spain in alignment with the MRAs.

5. Manufacturing of Pharmaceuticals and Medical Devices

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

Medicinal Products

Any manufacturer or importer of medicinal products, and those involved in processes such as fractionation, packaging and presentation for sale, must be authorised by the AEMPS (Article 63 of Royal Legislative Decree 1/2015). This authorisation is also required if the medicinal product is for export only. To obtain the authorisation, the manufacturer must:

- apply to the AEMPS through the website of the Spanish Agency for Medicines and Health Products (*Agencia Española de Medicamentos y Productos Sanitarios* LABOFAR), specifying the medicinal products and pharmaceutical forms to be manufactured or imported,

as well as the location and facilities where the manufacturing or control will occur;
- have suitable premises and technical and control equipment for the activity intended to be carried out; and
- have a technical director, manufacturing manager and quality control manager with sufficient qualifications.

The AEMPS will verify that the application meets the formal requirements within ten days and conduct an inspection at the facilities. The AEMPS will then issue the authorisation resolution, notifying the autonomous regions. The maximum time for notification of the resolution is 90 days from the receipt of the application. The authorisation is valid indefinitely, unless revoked.

Medical Devices

Companies engaged in the manufacture, importation, grouping or sterilisation of medical devices, as well as the facilities where these activities are carried out, require a prior operating licence from the AEMPS.

The AEMPS will review the submitted application and notify its decision within three months from the application date. Operating licences might be refused, suspended or revoked if the documentation provided or inspection reports do not guarantee that the appropriate facilities, means, procedures and personnel are in place. Operating licences are valid for a maximum of five years.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

Medicinal Products

In Spain, the distribution of medicinal products can be carried out by entities holding a wholesale distribution authorisation (WDA), or directly by the MAH or its local representative (LR). Notably, an LR that only purchases (acquires) and sells (invoices) the product, without physically handling it, is not required to hold a WDA. This distinction is important for two reasons. First, it highlights the priorities of the AEMPS regarding WDAs. AEMPS is primarily concerned with the physical flow of products and ensuring that any entity handling them holds the necessary regulatory permits. It places less emphasis on financial transactions, such as product ownership transfer and invoicing. Second, in practice, foreign MAHs often rely on an LR that does not physically handle the product.

Typically, the MAH appoints a Spanish company within its group as the LR, entrusting it with all responsibilities related to marketing the product, including invoicing hospitals. At the same time, the LR contracts a third-party logistics provider (3PL) to receive and physically deliver the product to hospitals. In such cases, ownership of the product usually transfers to the LR (from the MAH or another authorised entity) just before hospital delivery, allowing the LR to invoice under its VAT number. From a regulatory perspective, the 3PL must hold a WDA since it physically handles the product, whereas the LR does not require one.

Wholesalers and contract warehouses must obtain a WDA from the health authority of the autonomous region where the warehouse is

located. This authorisation will specify the distribution activities the entity is authorised to perform, in accordance with the European format. Additionally, these entities must notify the AEMPS before starting their activities.

To grant this WDA, the regional authority will verify that such entities have the appropriate personnel, material and operational means to guarantee the correct development of their activity, as well as the capability to provide a quality service. In addition, a physical inspection of the premises will be carried out. The regional authority must notify its decision within 90 days of receiving the application. If no decision is made within this period, the applicant can consider their application approved.

The authorisation is valid indefinitely. However, it may be suspended in the following circumstances:

- if 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 the entity no longer meets the requirements that were considered to grant such authorisation or fails to comply with the legally established obligations.

Medical Devices

Distributors and other entities engaged in the sale of medical devices must submit prior notification of the start of their activity to the health authority of the autonomous region where the company's registered office is located. They must also notify the health authority of the region where the warehouses are located, if they are in different regions. The notification must include:

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

In addition, the distributor must be registered in the AEMPS Marketing Register prior to the start of its activity. This register is currently in the design phase and is not operational. When the European Database on Medical Devices (EUDAMED) is fully functional, all devices, except custom-made medical devices, will be reported in the new Medical Device Market Register.

6.2 Different Classifications Applicable to Pharmaceuticals

Concerning the importer of record of pharmaceuticals and medical devices, please see **1.3 Difference Categories of Pharmaceuticals and Medical Devices**.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export 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 on the foreign trade of medicinal products; and
- Circular 2/2012 on the prior notification of shipments of medicinal products to other member states.

Parallel imports of nationally authorised medicinal products (ie, those which are distributed in Spain by an entity other than the MAH) are regulated by Royal Decree 1785/2000.

7.2 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 details.

Medical Devices

The importation of medical devices is subject to obtaining a prior licence from the AEMPS. Importers of medical devices established in Spain and class I or custom-made medical devices must be included in the registry of responsible persons.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

Prior authorisation is required for the importation of medicinal products into the EU customs territory, as established in Circular 1/2015. The duration of the import authorisation granted by the AEMPS depends on the type of medicinal product. For finished medicinal products, investigational medicinal products, those used in special situation programmes, advanced therapy medicinal products and hemoderivatives, import authorisations are valid for one year and may be carried out in several dispatches.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

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 European 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 combined nomenclature (CN) code, according to Council Regulation (EEC) No 2658/87.

7.5 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 for the European Economic Area (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**.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Medicinal Products

Reimbursed medicinal products have a maximum ex-factory price (*precio de venta laboratori* o; PVL) set by the Interministerial Committee for the Price of Medicines (ICPM), a committee of the MOH. The PVL is the maximum price for the units of the reimbursed product that will be reimbursed by the Spanish NHS. To determine the PVL, Spain has always followed a cost-plus system, under which the maximum PVL should correspond 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 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use. As a matter of practice, however, the price-approval process entails negotiation with the authorities, where the cost and profit margin are not the main variables considered. In the firm's experience, companies should be prepared for prices to be determined based on:

- a comparative pharmaco-economic evaluation of the medicinal product and its competitors; and
- the price of the medicinal 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 (eg, R&D, manufacturing) and any relationship with a local company through a co-marketing or licensing arrangement. Reimbursed medicinal products also have a so-called notified price, which is the price at which the MAH may market such reimbursed product outside the Spanish NHS (eg, units supplied on a patient-payment basis). The notified price is in fact free, although according to Article 94.4 of Royal Legislative Decree 1/2015, it must be notified to the MOH, who may oppose to it on the grounds of protecting the public interest. The notified price is, by definition, higher than the PVL.

Finally, the MOH is working on an update of the rules governing the price and reimbursement of medicinal products. At the end of 2024, the MOH launched a public consultation on this matter.

Medical Devices

Unlike medicinal products, the vast majority of medical devices used at NHS hospitals do not have a maximum PVL determined at the national level. Instead, the price of such products is determined/negotiated on a case-by-case basis in public procurement proceedings.

Furthermore, certain medical devices/products for non-hospitalised patients (eg, bandages, gauze, catheters, urine collection bags) have a specific reimbursement regime laid down in Royal Decree 9/1996, which includes determination of the maximum PVL at the national level. This Royal Decree is expected to be replaced in the near future by a new one that is currently being drafted by the MOH (a first draft was released in late 2024).

8.2 Price Levels of Pharmaceuticals or Medical Devices

As per Spanish regulations, the MOH is not allowed to reference international prices. International referencing was contemplated in the Law on Medicinal Products before 2012, but Royal Decree-Law 16/2012 of 20 of April removed any reference to this practice in 2012; subsequently, international referencing had no legal basis in

Spain, and the judgments of the Supreme Court of 28 October 2015 and 11 November 2015 confirmed this.

However, in practice, external reference pricing influences price rulings in Spain. The fact that this practice has no legal basis makes it quite difficult to identify precisely how the MOH factors in international prices, and the sources from which these prices are obtained. In any case, as per the firm's experience in dealing with the MOH, it has become clear that the MOH requests the MAH to provide information about how the medicinal product has been priced in other EU countries, and that EU prices operate as a cap for Spanish prices, meaning that prices in Spain are rarely fixed above the price of the same medicinal product in other EU countries.

In relation to medical devices, the current regulation does not provide for price comparisons with other European countries. However, it is important to highlight that the draft of the new Royal Decree on the financing of medical devices for non-hospitalised patients does mandate, as a requirement for obtaining public reimbursement, that the company marketing a device submit, along with the price request, documentation regarding the status and price of the medical device in the EU member states where it is marketed. Additionally, the offering company must provide information, if available, on the prices of similar medical devices marketed by the company, both in Spain and in other EU countries.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Medicinal Products

For the reimbursement of medicinal products, two hurdles must be overcome. First, the product must not be specifically exempt from reimbursement; such products include those that are not subject to medical prescription; are not designed to cure a specific illness; are considered cosmetics, dietetics, mineral waters, elixirs, dentifrices or other similar products; are indicated for syndromes or illnesses of minor severity; or do not meet current therapeutic needs.

Second, a price and reimbursement proceeding must be completed before the MOH, in which the decision to reimburse a given product is taken considering the following criteria (Article 92 of Royal Legislative Decree 1/2015): (i) the severity, duration and sequelae of the different pathologies for which the product is indicated; (ii) the specific needs of certain groups; (iii) the therapeutic and social value of the medicinal product and its incremental clinical benefits, taking into account its cost-effectiveness; (iv) the rationale for public expenditure; (v) the existence of medicines or other therapeutic alternatives for the same condition/s at a lower price or with a lower treatment cost; (vi) the degree of innovation of the medicine; (vii) the contribution of the product to Spain's gross domestic product; and (viii) return mechanisms that may be proposed by the MAH (discounts, price reviews).

It must be acknowledged that item (vii) in the foregoing list is rather peculiar, as it suggests that local manufacturing or development operations could influence price and reimbursement decisions, which would be entirely contrary to EU law principles. Nevertheless, in the authors' experience, this criterion is occasionally applied by the Spanish authorities.

Item (viii) in the foregoing list reflects the growing significance of risk-sharing schemes in Spain. Many companies, particularly those with high-budgetary-impact products, are required to propose specific arrangements to obtain reim-

bursement. These arrangements may take various forms, including caps on the number of units reimbursed by the NHS and charge-backs if predefined therapeutic outcomes are not satisfied.

Medical Devices

Royal Decree 1030/2006 and Ministerial Order SCO/3422/2007 regulate the process of updating the package of benefits provided within the NHS. The rules state that any new technique, technology or process cannot be included in the NHS's package of benefits unless it contributes effectively to the prevention, diagnosis or treatment of diseases; to the maintenance or improvement of life expectancy; to self-resilience; or to the elimination or reduction of pain and suffering. Moreover, an improvement in safety, efficacy, effectiveness, efficiency or usefulness over other currently available alternatives must be demonstrated.

Royal Decree 9/1996, as mentioned in the foregoing, is the relevant legislation for the reimbursement of specific devices/products for non-hospitalised patients. Under this legislation, the reimbursement of such products must be guided by the same criteria used for medicinal products.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Medicinal Products

Spanish law does not make any reference to cost-benefit analyses when it comes to the reimbursement of medicinal products. However, Article 92 of Royal Legislative Decree 1/2015 includes a reference to *"cost effectiveness"* as one of the criteria to be considered in reimbursement decisions. Cost-effectiveness ratios are commonly used in price and reimbursement proceedings, but unlike in other jurisdictions, no official cost-effectiveness threshold (eg, the maximum amount a decision-maker is willing to pay for a unit of health outcome) applies in Spain.

With respect to the type of economic evaluation to be performed, Spanish law provides no guidance. However, the Spanish National Health System's Advisory Committee for Pharmaceutical Financing (*Comité Asesor para la Financiación de la Prestación Farmacéutica del Sistema Nacional de Salud* CAPF) has recently published a guideline on this matter, which the MOH has informally confirmed will be used as a reference. In the guideline, it is stated that *"Cost-utility analysis (CUA) will be prioritized"* and that *"In cases where a CUA is not feasible, justifications must be provided, and a cost-effectiveness analysis (CEA) will be conducted"*.

Finally, in 2024, the MOH launched a public consultation for a new Royal Decree pertaining to health technology assessment within the framework of the NHS. This legislation, which has not yet been approved, will be the main legislation governing health technology assessment (HTA) in Spain. The first draft of the Royal Decree submitted for public consultation established that economic evaluations of health technologies *"will provide useful information for decision-making… through a robust evaluation that considers the value of the medical technology from the perspective of relative effectiveness, the social value of the medical technology, and the impact on health-related quality of life. This information will identify the efficiency of the new technology compared to available alternatives, as well as analyse its budgetary impact"*.

Medical Devices

As with medicinal products, Spanish law does not refer to cost-benefit analysis in the regulation of the reimbursement of services or technologies other than medicinal products. Royal

Decree 1030/2006, however, does specifically require that any new technique, technology or process that aspires to be eligible for reimbursement must *"bring about an improvement, in terms of safety, efficacy, effectiveness, efficiency or proven usefulness, over other currently available alternatives"*. Notably, this requirement is much stricter than the one applying to medicinal products in Article 92 of Royal Legislative Decree 1/2015, which states that *"cost effectiveness"* analysis *"shall be taken into account"*.

8.5 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 prescriptions in the NHS should be based on the active ingredient/s. Prescriptions based on trade name are possible if the principle of greater efficiency for the NHS is respected, and for medicinal products considered non-substitutable (eg, biological medicinal products). When the prescription is made based on the active substance/s, the pharmacist shall dispense the lowest-priced medicinal product in the so-called homogeneous groups – ie, lists of products available for substitution.

Further, it is worth mentioning that the MOH may impose *"singular dispensation reserves"* on medicinal products, under which the affected products may only be dispensed by NHS hospital pharmacy services – ie, not by community pharmacies.

Trends and Developments

Contributed by:
Joan Carles Bailach, Lluís Alcover, Laia Rull and Pablo Mansilla
Faus Moliner

Faus Moliner 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. Faus Moliner 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.

Authors

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.

Lluís Alcover is a partner of Faus Moliner and specialises in corporate and M&A, regulation of the pharmaceutical and healthcare sector, market access and the financing of medicinal products. Lluís regularly advises national and international clients in these areas. 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. Lluís is a member of the Barcelona Bar Association.

Laia Rull is an associate at Faus Moliner who specialises in pharmaceutical law. Since becoming part of the firm's team in 2022, she has provided highly specialised advice to companies operating in the life sciences sector. Her practice focuses on issues related to the regulation and advertising of medicinal products, as well as compliance matters. Laia is a member of the Barcelona Bar Association.

Pablo Mansilla is an associate at Faus Moliner who specialises in pharmaceutical law. Since becoming part of the firm's team in 2023, he has provided highly specialised advice to companies operating in the life sciences sector. His practice focuses on regulatory matters, clinical trials, data privacy and compliance. Pablo is a member of the Barcelona Bar Association.

Contributed by: Joan Carles Bailach, Lluís Alcover, Laia Rull and Pablo Mansilla, **Faus Moliner**

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

At the end of 2024, the Spanish Government approved its Pharmaceutical Industry Strategy 2024-2028 (the *"Strategy"*), a long-anticipated development for Spain's pharmaceutical sector.

The Strategy is a government action plan within the framework of the Recovery, Transformation, and Resilience Plan. With the involvement of four ministries (Health, Treasury, Industry and Tourism and Science, and Innovation and Universities), it aims to steer innovation towards addressing public health needs. The Strategy seeks to create a sector that not only contributes to the population's well-being but also enhances competitiveness, fosters economic development and ensures the sustainability of the National Health System (NHS).

The Strategy focuses on three key areas: equitable access to medicines, the sustainability of the NHS and promoting innovation and competitiveness in the pharmaceutical industry. The Spanish government aims to foster an ecosystem where innovation, production, access and sustainability are integrated.

One of the Strategy's key pillars is improving access to new medicines in Spain while managing the budgetary impact. A set of global measures is proposed to enable the system to adopt efficient access mechanisms and control pharmaceutical expenditure through more proactive monitoring of this spending.

The measures and actions included in the Strategy stem from the need to create a system for evaluating the efficiency of healthcare technologies, and for financing and pricing medicinal products, which will provide essential resources for Spain.

In parallel to building this evaluation system, the Strategy proposes other necessary changes to ensure quick and sustainable access to innovation, while also guaranteeing the supply of essential and strategic products within the NHS.

Among the measures, actions to improve timely access to medicinal products throughout their life cycle are included – specifically focusing on compassionate use and access between the stages of authorisation and decisions pertaining to pricing and reimbursement – without compromising price negotiations or sustainability. Additionally, the Strategy considers modification of the pricing and reimbursement procedure to provide, among other things, clear criteria, predict-

ability for stakeholders and clear rules regarding usage or non-usage during management.

Regarding the reference pricing system, the Strategy deems it necessary to introduce transparency and flexibility, thereby eliminating the current imbalances in the system and reducing the risk of associated supply problems. Finally, other actions are outlined related to the public procurement of medicinal products, the promotion of generic and biosimilar medicinal products and new economic return mechanisms to mitigate the impact of the growing budgetary expenditure dedicated to pharmaceutical services.

To implement these measures, the Spanish Ministry of Health (MOH) has been active in amending the regulations governing medicinal products and medical devices throughout 2024. It has also continued the reforms initiated by the previous government. Most of these regulations aim to provide a legal framework for realising the Strategy's objectives. These efforts have made 2024 a productive year for legislation, with many reforms expected to be finalised in 2025.

The main legislative amendments passed so far, and those expected to progress in 2025, are as follows.

General Pharma Legislation

The MOH opened a public consultation on the first draft of the law that will amend Royal Legislative Decree 1/2015(*"RDL 1/2015"*). The associated published document indicated that the proposed reform aimed to address three specific matters.

Public financing of medicinal products

The MOH document outlines new measures for rational pharmaceutical expenditure and rational use of public funds. It proposes modifying the reference price system by introducing elements that increase competition and value, representing an incremental benefit of the use of medicines. Additionally, the document suggests changes to the co-payment system to protect those in greater need, though it does not address whether co-payments could also be used to modulate demand for certain products. The document also announces measures to increase pressure on the pharmaceutical industry, including the possibility of quarterly contributions to medicines dispensed in healthcare centres.

COVID-19 and the impact of new technologies

The COVID-19 pandemic highlighted limitations in the availability of medicinal products and medical devices. The MOH aims to consolidate the non-presential dispensing of medicines and telepharmacy within the NHS.

Implementation of EU law

The MOH document also proposes amendments to incorporate Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro medical devices into Spanish law.

The government was expected to provide a first draft law around Q4 2024. However, the draft prepared by the MOH, including all its amendments, was leaked.

While acknowledging the caution merited when analysing a leaked (unofficial) draft, the text nonetheless reveals a more substantial reform than initially anticipated. The text provides interesting ideas in relation to the criteria for reimbursement of medicinal products and medical devices, measures to speed up access to medicinal products, innovative measures in rela-

tion to public procurement and measures aimed at guaranteeing the supply of essential and strategic medicinal products.

The official draft is expected to be published during Q1 2025, allowing all interested parties to submit comments or objections. Subsequently, the government will need to approve the final proposal and forward it to Parliament (Congress and the Senate) for debate and final approval. Further changes may be made during the parliamentary process. Final approval of the new law is not expected in 2025.

Pricing and Reimbursement of Medicinal Products

The MOH launched a public consultation on the draft Royal Decree on the pricing and reimbursement of medicinal products, which seeks to repeal Royal Decree 271/1990 and establish an updated regulatory framework.

This new regulation is intended to regulate the inclusion and exclusion of medicinal products from pharmaceutical provisions, establish special reserves and financing conditions, establish a system for revising the minimum ex-factory price (*precio de venta al público* PVL) and provide new indications, among other things.

Although this public consultation is very welcome, representing another step towards the much-needed revision of the regulations of the public funding of medicines, holding the consultation before the approval of the new RDL 1/2015 (and even before the official publication of its draft via a public hearing) is not, in the authors' opinion, the most appropriate approach. As explicitly stated in the consultation, the objective should be to implement the new RDL 1/2015. Logically, the public consultation and the drafting process for the Royal Decree should take place once RDL 1/2015, establishing the basic framework, has been finalised. Therefore, in the authors' view, conducting the public consultation after the publication of RDL 1/2015 publication would be more appropriate. It is expected that the draft of this new Royal Decree will be published during 2025.

Pricing and Reimbursement of Medical Devices for Non-Hospitalised Patients

A draft of the new Royal Decree on the financing of medical devices for non-hospitalised patients has also been published. This new Royal Decree aims to repeal Royal Decree 9/1996 and update the regulatory framework for these products.

The objectives of this regulation are twofold:

- to set the retail price of funded medical devices and margins for the activities of wholesale distribution and dispensing to the public; and
- to update the pharmaceutical provisions by including new medical devices and excluding those that are not marketed.

It is expected that this new Royal Decree will be approved during 2025.

Health Technology Assessment

The MOH published the draft of the new Royal Decree on health technology assessment (HTA) in August 2024. This new Royal Decree was a response to the judgment of the Spanish National High Court that declared void the *"Plan for the Consolidation of the Therapeutic Position Reports"*.

The MOH proposes the creation of an HTA system separate from the price and reimbursement system, such that health technology evaluations will be separated from the decision-making process.

A health technology evaluation includes evaluation of both clinical and non-clinical aspects, with the latter including economic, environmental, ethical and patient quality of life issues. The guidelines that will be used to prepare the evaluation reports will be developed later by the MOH.

Once completed, the positioning group will make a final assessment of the clinical and non-clinical evaluation reports for a given health technology, and issue a recommendation thereon that will provide a basis for decision-making in respect to reimbursement.

One element of the draft Royal Decree that has raised concerns at the national industry level is the obligation for health technology developers to provide the *"reliable costs of production, research and development, as well as the sources of financing to cover these costs, whether public or private"*, given the difficulty of obtaining such information – especially considering that research and production can be done in other countries.

This new Royal Decree is expected to be approved during 2025.

Cannabis

In October 2024, the MOH published a draft Royal Decree establishing the conditions for the elaboration and dispensation of the standardised magistral formulas of standardised cannabis preparations. The purpose is to establish the conditions for the prescription, preparation, dispensing and use of standardised cannabis-based magistral formulas.

This proposed Royal Decree stems from a mandate from the Health and Consumer Affairs Committee of the Congress of Deputies, which in 2021 requested the creation of a subcommittee to study experiences in the regulation of cannabis for medical use. One of the conclusions reached by the subcommittee was that there is a need to adopt measures to make standardised cannabis preparations available, to in turn address the needs of certain patients for whom authorised treatments have not been effective.

The MOH proposes to allow the use of standardised cannabis-based magistral formulas. These formulas would be prepared by hospital pharmacy services in response to a medical prescription, under the supervision of a pharmacist and in compliance with applicable good preparation practices.

The National Formulary, which contains standardised magistral formulas, will include monographs for the use of standardised cannabis preparations. These monographs will establish the uses and indications for these magistral formulas, allowing them to serve as alternatives when other therapeutic options have failed.

For now, the MOH intends for the monograph to cover four indications: chronic pain refractory to other treatments, spasticity related to multiple sclerosis refractory to other treatments, epilepsy refractory to other treatments and intractable vomiting refractory to other treatments related to chemotherapy in cancer patients. For these four indications, the use of cannabis would be authorised as a last-line treatment.

This Royal Decree is expected to be approved during 2025.

Advertising of Medicinal Products and Medical Devices

In April 2023, a public consultation on the new Royal Decree on the promotion of medicinal products for human use was launched. This

new regulation is intended to replace the current regulations, dating from 1996.

The proposed draft is aimed at addressing digital advertising, the use of social media and audiovisual modalities, the distribution of competencies between the state and regions and obligations for accessibility for individuals with sensory disabilities.

Regarding medical devices, the MOH published a draft Royal Decree governing the advertising of medical devices in March 2024. This draft encompasses several elements, such as streamlining the process for obtaining prior approval for the public promotion of medical devices, a new requirement for responsible advertising of specific devices and the prohibition of hospitality in relation to promotional meetings, except professional-scientific events. The draft also explicitly bans off-label promotion and offers detailed guidelines on permissible and prohibited content in advertisements directed at the public.

This Royal Decree is expected to be approved during 2025.

Transparency

One of the hottest topics at present is transparency and confidentiality in relation to the price and reimbursement conditions of medicinal products in Spain.

Following freedom of information requests from citizens, several court rulings were issued in 2023–24 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 defending the confidentiality of this information, arguing that disclosure thereof would be detrimental to its ability to negotiate with companies when setting prices for medicinal products, thus undermining the economic sustainability of the NHS.

Despite some messages from the MOH at the beginning of 2024 that point to a potential change in criteria, in reality the MOH's position remains unchanged. Indeed, the leaked draft of the new RDL 1/2015 reinforces the confidentiality of the price and reimbursement conditions.

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