Medicinal product regulation and product liability in Spain: overview

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A Q&A guide to medicinal product regulation and product liability law in Spain.

The Q&A gives a high level overview of key issues including pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability.

For information on pharmaceutical patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports, visit *Pharmaceutical IP and Competition Law in Spain: overview*.

To compare answers across multiple jurisdictions, visit the Medicinal product regulation and product liability *Country Q&A tool*.

The Q&A is part of the global guide to life sciences law. For a full list of jurisdictional Q&As visit *global.practicallaw.com/lifesciences-guide*.

Regulatory overview

1. What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

Legislation

The main Spanish legislation for medicinal products currently consists of:

- Law 14/1986, General on Public Health.
- Royal Decree 1/2015, on guarantees and rational use of medicinal products and 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 1345/2007, which regulates the authorisation, registry and dispensation conditions of medicinal products for human use prepared industrially.
- Royal Decree 271/1990, which regulates prices of medicinal products reimbursed by the National Health System.
- Royal Decree 8/2010, adopting extraordinary measures to reduce public expenditure.
- Royal Decree 782/2013, which regulates distribution of medicinal products.
- Royal Decree 1416/1994, which regulates advertising of medicinal products.
- Royal Decree 870/2013, which regulates online sales to the public of non-prescription-only medicinal products.
- Royal Decree 577/2013, which regulates pharmacovigilance of medicinal products for human use.
- Royal Decree 1015/2009, which regulates access to medicinal products in special situations.
- 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 price of medicinal products and medical devices.
- Royal Decree 618/2007, which regulates the procedure for establishing particular measures for prescription and dispensation of medicinal products.

The above legislation applies in Spain only, but certain EU legislation is also directly applicable in Spain. Spanish regional authorities can also adopt some rules that apply at their level, mainly in the context of organising the dispensation of medicines to patients at healthcare centres and hospitals. Spanish trade associations of different sectors of the pharmaceutical industry have also adopted or are adopting codes of good practices that regulate, among other matters, interactions with healthcare professionals by their members.

Regulatory authorities

The main regulatory authorities in Spain are:

- The Spanish Ministry of Health, which is the department of the central Spanish government responsible for, among other things, drafting and implementing the rules on pricing and reimbursement of medicinal products that are financed through public funds in Spain.
- The Spanish Medicines Agency, which is also part of the central Spanish government and is responsible for, among other things, granting marketing authorisations for medicinal products in Spain through the national procedure.

In addition, as the public funds used to finance reimbursement of medicinal products come out of the budget of the 17 regions into which Spain is divided, the regions participate in the committee of the Ministry of Health responsible for assessing applications relating to the price and reimbursement of medicines.

2. Briefly outline how biologicals and combination products are regulated in your jurisdiction.

Although there is no law addressed individually to biologicals or combination products, general laws regarding medicinal products establish certain specific provisions for these kinds of products:

- Biological products. The regulatory dossier for the marketing authorisation of biosimilar products must usually include the results of adequate clinical trials or preclinical studies evidencing, among other matters, the similarity of the biosimilar product with its biological product of reference. In addition, biological products:
    - are subject to additional pharmacovigilance monitoring requirements;
    - must be prescribed by doctors, who must indicate the brand name of the product. The prescribed product can only be substituted with the authorisation of a doctor.

- Combination products. The regulatory dossier for the marketing authorisation of products with a combination of active pharmaceutical ingredients (APIs) that are individually authorised, but that have not been combined for therapeutic purposes, must include the results of new clinical trials and preclinical studies relating to the combination, but does not need to include the documentation relating to each individual API.

3. Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of health IT issues and mobile medical applications?

The main Spanish regulation on medical devices is:

- Royal Decree 1/2015, on guarantees and rational use of medicinal products and medical devices.
- Royal Decree 1591/2009, on medical devices.
- Royal Decree 1616/2009, on active implant medical devices.
- Royal Decree 347/2002, which sets out the criteria for the grant of licences to medical devices' manufacturers.
- Royal Decree 1662/2000, on "in vitro" diagnostic medical devices.

Medical devices are divided in four classes (III, IIb, IIa and I), ranked mainly according to the:

- Level of invasiveness of the device.

- Part of the body it is in contact with.
- Duration of such contact.

Except for custom-made devices, all medical devices must bear a CE marking of conformity when placed on the market in Spain. The CE marking shows the conformity of the device with the requirements of the applicable laws. For class I devices, evaluation and declaration of conformity is the exclusive responsibility of the manufacturer. For class IIa, IIb and III devices, the declaration of conformity requires an evaluation of the device by a notified body (the Spanish Medicines Agency or the relevant notified body of an EU member state).

In addition, for class IIa, IIb and III devices, a communication must be made to the Spanish Medicines Agency the first time that a person places a medical device on the Spanish market.

Persons performing the manufacturing, importing, refurnishing or sterilisation of medical devices, as well as the premises where such activities are performed, require a prior authorisation granted the Spanish Medicines Agency (for custom-made devices an authorisation can also be required from regional authorities).

Pricing, state funding and reimbursement

4. What is the structure of the national healthcare system, and how is it funded?

The Ministry of Health is the department of the Spanish central government responsible for approving reimbursement of medicinal products. However, as the public funds used to finance the reimbursement of medicines come out of the budget of the 17 regions into which Spain is divided, the regions participate in the committee of the Ministry of Health responsible for assessing applications relating to the price and reimbursement of medicines.

5. How are the prices of medicinal products regulated?

Under Royal Decree-legislative 1/2015, the criteria to be taken into account by the Ministry of Health in deciding whether a product is reimbursed include:

- Seriousness, duration and consequences of the pathology treated.
- Needs of special groups of patients.
- Therapeutic and social use.

- Need to limit public pharmaceutical expenditure.
- Existence of other alternatives for the same illnesses.
- Degree of innovation of the product.

In addition, the Ministry of Health must also consider the cost-efficiency ratio of the product based on the Therapeutic Position Report prepared by the Spanish Medicines Agency. The pricing authorities can also consider the contribution of the product to the Spanish economy, as well as return mechanisms proposed by the marketer (discounts, price reviews, and so on).

A marketer cannot freely set the prices of medicinal products that are reimbursed, as this requires the prior approval from the Ministry of Health. If there are legitimate public health reasons, the Ministry of Health can also control the price of medicinal products that are not reimbursed.

Royal Decree 271/1990 states that the maximum ex-factory price of a reimbursed medicinal product should be equal to the cost of the product plus a given margin (12% to 18% on capital allocated to exploitation). However, in practice, the process of setting the price of a reimbursed medicinal product entails a negotiation of the price with the public authorities. In addition, companies must grant a discount on the maximum ex-factory price approved by the authorities.

Under the Spanish reference price system, products are subject to reference pricing if:

- A generic or a biosimilar exists, even if it is not substitutable.
- They have generic competition and have been in the market for more than ten years.

This means that the price of the products in the same reference pricing group are lowered to the level of the lowest product in the group.

The rules on medicinal products' substitution must be also taken into account. The system works under the concept of "homogeneous groups", which are groups of reimbursed products with the same active substances that are essentially interchangeable. Pharmacists must supply the product that has the lowest price within its homogeneous group.

6. When is the cost of a medicinal product funded by the state or reimbursed? How is the pharmacist compensated for his dispensing services?

Once the Ministry of Health has decided to reimburse a certain medicinal product, the patient withdraws the medicine from the pharmacy and, if applicable, pays to the pharmacist the co-payment, as established. The pharmacy then charges the selling price of the medicinal product (the maximum ex-factory price approved by the Ministry of Health) to the government of the region where it is established, plus the margin set out in the law for the wholesaler and for the pharmacy, less the amount paid by the patient. If medicinal products are administered to patients in

public healthcare centres and hospitals, the products are not paid for by the patients but financed from the budget of the centre itself.

Clinical trials

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

The performance of clinical trials with medicinal products in Spain is mainly regulated by Royal Decree-legislative 1/2015 and Royal Decree 1090/2015.

The Spanish Medicines Agency is the regulatory authority enforcing regulation on clinical trials. It has issued a document with instructions on the practical aspects of conducting clinical trials in Spain (available in English at *www.aemps.gob.es/investigacionClinica/medicamentos/ensayosClinicos.htm*).

Authorisations

To start a clinical trial with medicinal products in Spain, it is necessary to have:

- A favourable opinion from a Spanish ethics committee.
- An authorisation from the Spanish Medicines Agency.
- A written agreement between the sponsor and the site(s) where the trial is conducted.

The details of the regulatory approval pathway are laid down in a memorandum issued by the Spanish Medicines Agency (available in English at *www.aemps.gob.es/investigacionClinica/medicamentos/docs/memorandum-collaboration-AEMPS-ethics-committees-investigation.pdf*).

Consent

Trial subjects must freely give their consent before being included in a clinical trial. Consent must be given after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate. Minors' or incapacitated persons' consent must be given through their legal representatives. Consent must be given in writing. The principal investigator is normally in charge of obtaining informed consent from trial subjects.

The ethics committee must approve the process for obtaining consent from trial subjects and the patient information sheet or informed consent form. These documents must be in Spanish as a minimum.

The Spanish Medicines Agency has issued a guideline for the correct preparation of a patient information sheet and informed consent form (available in English at *https://www.aemps.gob.es/en/investigacionClinica/medicamentos/docs/annex8a-Ins-AEMPS-EC.pdf*).

Trial pre-conditions

Before a clinical trial can start, the sponsor must:

- Be established in one of the countries of the EU or have appointed a legal representative that is established in the EU.
- Hold civil liability insurance covering the sponsor, principal investigator, investigator's team and site against any claim brought by trial subjects for damages suffered due to the clinical trial. The minimum guaranteed amount is EUR250,000 per trial subject. The maximum insured capital per trial and per year is EUR2,500,000.

Procedural requirements

The sponsor must fulfil the following obligations:

- Keeping the clinical trial master file on record for at least 25 years after the end of the trial.
- Publishing the results of the clinical trial, whether positive or negative, preferably in scientific journals, before being disclosed to the non-healthcare public (a summary of the results must also be published in the Spanish Clinical Studies Registry).
- Supplying the studied drug free of charge.
- Reporting:
    - the start and end dates of the trial, as well as any temporary suspension of the trial and its results;
    - serious breaches of the protocol or of Royal Decree 1090/2015 that occur in Spain;
    - all suspected unexpected adverse reactions associated with the investigational product; and
    - an annual safety report and any important information that could adversely affect the safety of the trial subjects or the conduct of the trial.

Manufacturing

8.What is the authorisation process for manufacturing medicinal products?

Application

Industrial manufacturing of medicinal products in Spain requires an authorisation from the Spanish Medicines Agency. The application is normally electronically submitted directly to the Spanish Medicines Agency and must be in Spanish as a minimum (although scientific-technical documentation can be submitted in another language). Non-industrial preparation of compounded medicinal products at hospital and community pharmacies does not require the authorisation of the Spanish Medicines Agency.

Conditions

To obtain an authorisation for the manufacturing of medicinal products, an applicant must provide the Spanish Medicines Agency with:

- A description of and a technical report on the medicinal products that the applicant intends to manufacture, as well as a description of the premises where the quality control of the medicinal products will be performed.
- Evidence that the applicant has sufficient and adequate premises and technical and control equipment required for the manufacturing of the medicinal products that the applicant intends to manufacture.
- Evidence that the applicant has a duly qualified technical director (known as the "qualified person" under EU regulations) and persons responsible for manufacturing and for quality control and, in general, sufficient and adequate personnel to perform the manufacturing activities. If only small quantities or non-complex products are manufactured, the responsibilities for quality control may be assumed by a technical director.

Restrictions on foreign applicants

Although not specifically contemplated in the law, there is no legal restriction on a foreign applicant holding an authorisation for the manufacturing of medicinal products in Spain if it has adequate manufacturing premises in Spain and fulfils the rest of the conditions for the grant of the manufacturing authorisation in Spain.

Key stages and timing

The key stages in the process of obtaining a manufacturing authorisation are:

- Compilation of the documentation to be submitted to the Spanish Medicines Agency.
- Receipt and review of the documentation by the Spanish Medicines Agency.
- Compilation and submission of additional information requested by the Spanish Medicines Agency.
- Inspection of the manufacturing sites by the Spanish Medicines Agency.

- Submission of allegations and additional information with regards to any objections raised by the Spanish Medicines Agency as a result of the inspection of the manufacturing premises.
- Issue by the Spanish Medicines Agency of a resolution granting or denying the authorisation.

Although the law foresees a period of 90 days for the issue of the decision regarding the grant of the manufacturing authorisation, in practice the decision is issued by the Spanish Medicines Agency around 180 to 270 days after the submission of the application.

Fees

The fees charged by the Spanish Medicines Agency are listed on its website (*www.aemps.gob.es*).

Period of authorisation and renewals

Manufacturing authorisations are granted for an indefinite period. However, retaining a manufacturing authorisation is subject to the beneficiary and its manufacturing sites and operations fulfilling at all times the conditions for the grant of the authorisation.

Monitoring compliance and imposing penalties

The Spanish Medicines Agency and Spanish regional authorities can monitor manufacturers' continuous fulfilment of the conditions for the grant of their manufacturing authorisations and, in general, that they comply with the provisions of the law regarding manufacturing of medicinal products (including good manufacturing practice (GMPs)). For these purposes, manufacturers and their manufacturing sites are subject to inspections by the Spanish Medicines Agency and/or regional authorities a minimum of every three years.

Failing to comply with the legal requirements for manufacturing medicinal products can result in fines being imposed. The amount of the fine depends on the circumstances of the case. The following additional sanctions can also be imposed:

- Confiscation of the illicit profit that has been obtained.
- Publication of the infraction in the official journal of the relevant region, for serious or very serious infractions.
- Shutting down the activities of the company for up to five years, for very serious infractions.

Marketing

Authorisation and abridged procedure

9. What is the authorisation process for marketing medicinal products?

Application

The Spanish Medicines Agency has the authority to grant marketing authorisations in Spain, whether they result from a national procedure or from a mutual-recognition or decentralised procedure.

Marketing authorisations granted by the Spanish Medicines Agency are regulated by Royal Decree 1345/2007. Some provisions of the Royal Decree also affect medicines authorised by the European Commission under the centralised European procedure.

Authorisation conditions

The Spanish Medicines Agency will grant an authorisation if the product:

- Fulfils the established quality requirements.
- Is safe under normal conditions of use.
- Is effective in the therapeutic indications.
- Is correctly identified.
- Provides the patient with the necessary information.

The positive therapeutic effects of the medicinal product are assessed in relation to any risk for the patient's health or public health, from a risk-benefit perspective.

Key stages and timing

The key stages of the procedure are:

- Submission of the application to the Spanish Medicines Agency.
- Validation and acceptance of the submission.
- Issuance of the evaluation report.
- Resolution of the application, and issuance, where appropriate, of the marketing authorisation of the product.

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

Fees

The fees charged by the Spanish Medicines Agency are listed in its website (*www.aemps.gob.es*).

Period of authorisation and renewals

A marketing authorisation has an initial period of five years. The agreed renewal of the authorisation is for an indefinite term, unless pharmacovigilance reasons justify it being subject to further renewal approvals.

Monitoring compliance and imposing penalties

The Spanish Medicines Agency and regional authorities can monitor compliance with the marketing authorisation of the medicinal product.

Failing to comply with the marketing authorisation can result in a fine being imposed. The amount of the fine depends on the circumstances of the case. The following additional sanctions can also be imposed:

- Confiscation of the illicit profit obtained.
- Publication of the infraction in the official journal of the relevant region, for serious or very serious infractions.
- Shutting down the activities of the company for up to five years, for very serious infractions.

10. What commitments and pharmacovigilance obligations apply after a company has obtained marketing authorisation? Are there further conditions concerning how the drug is distributed and accessible to patients?

Royal Decree 577/2013 imposes the following obligations on a marketing authorisation holder:

- Respecting the good practices on pharmacovigilance for the pharmaceutical industry published by the Spanish Medicines Agency.
- Having an adequate pharmacovigilance system, including a master file of the system and undertake periodic audits.
- Having a suitably qualified person responsible for pharmacovigilance in the EU.
- Having a contact person for pharmacovigilance in Spain.
- Submitting periodic safety reports to the European Medicines Agency.
- Having a risk management system for each medicine.
- Notifying and recording suspected adverse reactions to the medicinal product in the Eudravigilance database.
- Monitoring worldwide scientific literature related with the medicinal product.
- Carrying out post-authorisation studies of efficacy and/or safety required by the competent authorities.

- Performing a continuous evaluation of the benefit-risk parameters of the medicinal product.

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

11. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

The applicant for a marketing authorisation need not provide the results of pre-clinical and clinical trials if it can demonstrate that the medicinal product is a generic medicinal product of a reference medicinal product that has been authorised for at least eight years in an EU member state. If a biological medicinal product similar to a reference biological medicinal product falls outside the definition of a generic medicinal product, appropriate pre-clinical and clinical trial results must be provided.

The applicant can also replace the pre-clinical and clinical trial results with appropriate documentation of scientific references, provided the active substances of the product have had a well-established medical use over at least ten years within the EU and are of recognised efficacy and an acceptable standard of safety.

If the medicinal product is of the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form as another medicinal product that has already been authorised, the applicant can rely on the pre-clinical and clinical documentation of the authorised medicinal product, with the permission of its holder.

12. Are foreign marketing authorisations recognised in your jurisdiction?

Under Royal Decree 1015/2009, the use of a medicinal product that has a foreign marketing authorisation requires prior approval from the Spanish Medicines Agency. Approval is subject to the following requirements:

- There is no other adequate medicinal product authorised in Spain.
- A doctor must justify the prescription in writing.
- The patient must consent to the prescription in writing, after having been duly informed.

Parallel imports

13. Are parallel imports of medicinal products into your jurisdiction allowed?

Under Royal Decree 1785/2000, parallel imports are allowed in Spain, but the following requirements must be met:

- The medicinal product in question must have a marketing authorisation both in the country of origin as well as in Spain.
- The company responsible for the parallel import must obtain prior authorisation from the Spanish Medicines Agency.
- The labelling and leaflet of the product must comply with the provisions of Royal Decree 2236/1993.
- The parallel importer must have an authorisation as a manufacturer of medicinal products in Spain if it carries out in Spain any repackaging and relabelling of the imported product (otherwise, the importer must have an authorisation in Spain to perform the activities of a wholesaler).

Intellectual property rights cannot be used to oppose parallel imports. However, before beginning the marketing of a product that has been introduced in Spain through a parallel import, the importer must notify the marketing authorisation holder of the medicinal product in Spain of its intention to carry out its marketing in Spain (providing, if requested, a sample of the reconditioned product to be marketed by the importer).

Restrictions on dealings with healthcare professionals

14. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

Under Article 4.6 of Royal Decree-legislative 1/2015, it is prohibited for any person with a direct or indirect interest in the production, manufacture and placing on the market of medicinal products to directly or indirectly offer any kind of inducement, bonus, discount, reward or gift to health professionals, their relatives or cohabitants,

In addition, the codes of conduct approved by several Spanish industry associations (such as Farmaindustria, the Spanish Pharmaceutical Association, and Fenin, the Spanish Medical Devices Association) impose on their members further rules regarding dealings with healthcare professionals. For example, the codes of conduct of both Farmaindustria and Fenin establish rules on, among other matters:

- The entering into of consultancy agreements with healthcare professionals.

- The delivery to healthcare professionals of informational and educational materials, items of medical utility, samples and gifts of a limited value.
- Sponsorship for the attendance by healthcare professionals to third party or company organised educational events.

Fenin's code of conduct prevents companies associated with Fenin from providing financial support directly to individual healthcare professionals to cover the costs of attendance at third-party organised educational events.

Spanish law does not require payments by companies to healthcare professionals or other interactions between companies and healthcare professionals to be publicly disclosed. However, the code of conduct of Farmaindustria requires its members to publish each year on their websites certain information regarding interactions with healthcare professionals. This publication must identify each healthcare professional individually, and specifically disclose the amount of payments for consultancy agreements, donations and sponsorships for attendance at educational events.

Sales and marketing

15. What are the restrictions on selling medicinal products? Are there specific regulations for the sale of medicinal products on the internet, by e-mail and by mail order?

Only medicinal products with a valid marketing authorisation can be placed on the Spanish market (Royal Decree-legislative 1/2015). Medicinal products can only be distributed by:

- Duly authorised manufacturers.
- Marketing authorisation holders and their local representatives (but only for the products that they manufacture or for which they hold a valid marketing authorisation).
- Wholesale distributors, depositories and importers.

However, the sale of medicinal products to the public can only be carried out by duly authorised pharmacies.

Selling prescription medicines online is strictly forbidden. However, Royal Decree 870/2013 establishes that online sales of over-the-counter (OTC) medicinal products on the internet is permitted if performed by a pharmacy open to the public (that is, by brick and mortar pharmacy holding an authorisation to operate as such). The website of a pharmacy that sells OTC medicinal products must comply with certain requirements, such as not including any tools for self-diagnosis or self-medication, and displaying the common EU logo for legally operating online pharmacies. A pharmacy that intends to sell OTC medicinal products on the internet must communicate that intention to the relevant Spanish authorities at least 15 days before the start of its activities.

Advertising

16. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

The rules on advertising of medicinal products are set out in:

- Law 34/1988, on advertising.
- Law 3/1991, on unfair competition.
- Royal Decree-legislative 1/2015, on guarantees and rational use of medicinal products and medical devices.
- Royal Decree 1416/1994, on advertising of medicinal products for human use.
- Instruction 6/1995 from the Ministry of Health.

In addition, some regions (Madrid and Catalunya) have adopted further guidelines on certain advertising matters.

Spanish industry associations have also adopted codes of conduct that regulate, among other matters, interactions with healthcare professionals, healthcare organisations and patient organisations.

Responsibility for enforcing advertising rules (other than those resulting from industry codes of conduct) lies with the health authorities of the Spanish regions and courts. The industry codes of conduct are enforced by industry associations' self-regulatory bodies in agreement with Autocontrol, a Spanish association that acts as an independent tribunal for advertising self-regulation matters.

Restrictions

The advertising of prescription-only medicinal products and/or public financed medicinal products directed to the general public is prohibited. However, non-prescription medicinal products that are not publicly financed (OTC medicinal products) can be advertised to the general public.

Advertising messages must be precise, balanced, honest, objective, based on adequate scientific evaluation, sufficiently complete, and conform to the Summary of Product Characteristics (SmPC) or leaflet of the medicinal product. Advertising of medicinal products that have not obtained a marketing authorisation is not allowed.

Advertising of medicinal products does not need to be approved in advance by a regulatory or industry authority. However, companies placing advertisements directed to healthcare professionals must send a copy of the advertisement to the health authority of the autonomous region where the company is located, as well as an annual index summarising all their advertising activities. The Ministry of Health can, in exceptional circumstances, make advertising of a specific medicinal product subject to a prior approval.

Internet advertising

Advertising activities on the internet are generally subject to the same requirements as advertising through traditional channels.

Advertising directed to healthcare professionals must be through valid channels intended exclusively for healthcare professionals. A clearly readable warning must be included, indicating that the information is intended exclusively for healthcare professionals and that therefore specialised training is required for the correct interpretation of the information. To prevent access by people that are not healthcare professionals, healthcare professionals should be required to identify themselves as such on the website before accessing the information.

Data protection

17. Do data protection laws impact on pharmaceutical regulation in your jurisdiction?

Sensitive patient data

The processing of sensitive patient data typically requires having previously obtained (usually in writing) the explicit consent of the patient. However, consent is not necessary when:

- A law authorises the processing of the data for reasons of public interest.
- The processing is necessary for the purposes of preventive medicine or diagnosis, medical care or treatment, or the management of healthcare services, and the data processing is performed by a healthcare professional or by another person with an equivalent obligation of secrecy.

The absence of the need of consent in these cases does not preclude that fact that the patient must previously be informed, explicitly, precisely and unequivocally, on all the aspects listed in Article 14 of Regulation (EU) 679/2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation).

Sensitive patient data is subject to a stricter protection regime and its processing requires appropriate security measures.

Clinical trials

A clinical trial can only be conducted when the ethics committee considers that the privacy rights of the trial subjects and the protection of their data are safeguarded in accordance with the applicable laws on data protection. The ethics committee must approve the process for obtaining consent from trial subjects, as well as the patient information sheet and informed consent form.

Pharmacovigilance

The reporting of adverse events must comply with the applicable data protection laws. This means that if sensitive patient data is collected for this purpose, the data subject must be informed about the terms of that processing, but no consent is needed. However, if the processed data is anonymised, it is not considered as personal data and therefore the data protection laws do not apply.

Packaging and labelling

18. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

The packaging and labelling of medicinal products in Spain is regulated by Royal Decree 1345/2007.

The Spanish Medicines Agency is the regulatory authority in charge of approving the texts and others features of the packaging and labelling of medicinal products (including their amendments) authorised in Spain through the national procedure. For medicinal products that have received a marketing authorisation from the European Commission, the Spanish Medicines Agency only plays a secondary role approving final mock-ups and the contents of the "blue box" in the packaging of the product.

Information requirements

Labelling on a medicinal product must comply with the identification and information requirements, including:

- Giving an accurate summary of the products' characteristics.
- Being easily readable, clearly comprehensible and indelible.
- Giving the batch and unit numbers, allowing for individual identification.
- Having any other required symbols, such as the symbol for being subject to medical prescription, among others.

Other conditions

Any text contained in the labelling/packaging must be in Spanish as a minimum. It can also be in other languages, as long as this contains the same information as the Spanish version.

The packaging of reimbursed medicinal products must bear the coding of the Spanish National Code of Medicinal Products assigned by the Spanish Medicines Agency.

To ensure access to the information for blind or visually disabled persons, the packaging must bear the necessary details for proper identification of the type of medicine, dose, and pharmaceutical form, printed in the Braille alphabet.

Product liability

19. Outline the key regulators and their powers in relation to medicinal product liability.

Article 13 of Royal Decree 1/2007 establishes that any entity involved in placing goods and services at the disposal of consumers and users must withdraw from the market, suspend marketing or recover from the consumer or user any goods or services that do not meet the necessary conditions or requirements, or which represent a foreseeable risk to personal health or safety on any other grounds.

Under Article 51 of Royal Decree 1/2007, the relevant public administration can order the precautionary or definitive withdrawal or recall of goods or services from the market on the grounds of health and safety.

The intentional or negligent supply of defective products can be a criminal offence under the Spanish Criminal Code, and the persons responsible for the crime can be liable for damages.

20. Are there any mandatory requirements relating to medicinal product safety?

Royal Decree 1345/2007 requires the holder of a marketing authorisation for a medicinal product to communicate any action taken to recall a batch from the market to the:

- Spanish Medicines Agency.
- Spanish regional authorities.
- Authorities of all countries where the product has been distributed.

There is no specific deadline to carry out the notification of recall of the medicine, but it must be done within an appropriate period, considering the specific circumstances of each case and the reasons why it was decided to recall the product from the market.

In addition, the owner of the medicine must submit periodic safety reports to keep the safety record of the product updated, as required to ensure an adequate understanding of the product. This applies in particular to the

information addressed to healthcare professionals included in the product's technical sheet and the information on the leaflet.

21. Outline the key areas of law applicable to medicinal product liability, including key legislation and recent case law.

The general regime on liability for defective medicines is established in Articles 128 to 146 of Royal Decree 1/2007. The actions available under Royal Decree 1/2007 do not affect any other right to damages, including moral damages, that the injured party may have under contractual liability based on the lack of conformity of the goods or services, non-performance or defective performance of the contract, or under any non-contractual liability.

The regime on liability for defective medicines places on the claimant the burden of proving the existence of the medicine's defect, the damage, and the causal link between the defect and damage. To establish the causal link between the defect in the product and the damages suffered, the claimant must provide solid and substantial evidence that supports that link, and the damages must be an appropriate and sufficient result of the defect.

Occasionally, the Spanish Courts may also accept that the causal link can be proven by presumptions or circumstantial evidence.

22. Who is potentially liable for defective medicinal products?

The responsibility for the defect is borne by the manufacturer or by the importer who introduces the product into the EU.

If the manufacturer cannot be identified, the supplier of the product (the distributor or retail supplier) is treated as the manufacturer, unless it informs the injured party of the identity of the manufacturer or of the person who supplied the product to it within three months. This rule also applies to imported products, if the product does not indicate the name of the importer (even if it indicates the name of the manufacturer).

However, the supplier of the defective product is liable towards the injured party as if it was the manufacturer if it supplied the product knowing that the defect existed. In such a case, the supplier may have a right of recovery against the manufacturer.

23.What defences are available to product liability claims? Is it possible to limit liability for defective medicinal products?

The manufacturer or importer is not liable if it can prove that either:

- It did not place the product into circulation.
- Given the circumstances of the case, it can be presumed that the defect did not exist when the product was put into circulation.
- The product was not manufactured for sale or for any other form of distribution with an economic purpose, and was not manufactured, imported, supplied or distributed in the context of a professional or entrepreneurial activity.
- The defect is due to the fact that the product was manufactured in accordance with existing mandatory rules.
- The state of scientific and technical knowledge existing at the time the product was placed into circulation did not allow for the discovery of the existence of the defect. However, this is not a valid excuse for liability for medicinal products, food or foodstuffs.

The manufacturer of a part that is integrated into a finished product is not liable if it can prove that the defect is attributable to the design of the product into which the part was integrated or to the instructions provided by the manufacturer of the finished product.

The overall civil liability of a manufacturer for damages (death and personal injuries) caused by identical products with the same defect are limited to a maximum of EUR63,106,270.96.

24. How can a product liability claim be brought?

Limitation periods

The statute of limitation for proceedings for the recovery of damages caused by a defective product initiated under Royal Decree 1/2007 is three years from the date the damages were suffered by the injured party, provided that the identity of the party liable for the damages is known to the injured party.

Class actions

Article 11 of the Spanish Civil Procedural Code 1/2000 allows for collective legal proceedings and establishes that legally constituted associations of consumers and users have standing in court to defend their rights and interests and those of their members, as well as the general interests of consumers and users, without prejudice to the individual legal standing of the persons who suffered the damages.

The General Attorney's Office also has legal standing to bring actions to defend the collective interests of consumers and users.

25. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

An injured party has the right to receive compensation in the form of an economic indemnity for the damages caused by a defective product.

The regime on product liability established in Royal Decree 1/2007 extends to personal damages (including death) but also to damages to property (if the damage is to goods for private use or consumption and that are mainly used by the injured party for those purposes).

Damages to the defective product itself are not recoverable under Royal Decree 1/2007. However, the injured party can claim compensation for such damages under general civil and commercial law. Moral damages can be recovered under general civil law.

No punitive damages can be recovered under Spanish law. Only compensatory damages are available. However, the courts have some discretionary powers in awarding compensatory damages and the conduct of the defendant can be expected to have some impact on the amount of damages awarded.

Reform

26. Are there proposals for reform and when are they likely to come into force?

The main proposals for reforms likely to come into force in Spain in the near future are new Royal Decrees reforming the current reimbursement and pricing regulations (including the current regulation on reference pricing and homogenous groups). The new Royal Decrees are in their early development stages but according to announcements and consultations made by legislative authorities they will mainly aim to:

- Amend the current regulation on the reference pricing system and homogenous groups to allow establishing identity between active principles on the basis of their anatomical therapeutic chemical (ATC) classification.
- Allow the creation of reference pricing groups for medicines with the same active principle but with a different administration device, dosage form or route of administration, provided they imply a clinical advantage for patient treatment.

- Increase the minimum ex-factory price for reimbursed medicinal products.

Online resources

W *www.aemps.gob.es/legislacion/portada/home.htm*

Description. The website of the Spanish Medicines Agency. Contains Spanish legislation on medicinal products and medical devices. Documents are normally updated. No English translations of documents are provided.

W *www.boe.es/legislacion/legislacion.php*

Description. The website of the Spanish Official Gazette. Documents are official and updated. No English translations of documents are provided.

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