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.

Regulatory Overview

Pharmaceuticals

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

Legislation

The main Spanish legislation for medicinal products includes:

- Law 14/1986, General on Public Health.
- Royal Legislative Decree 1/2015, which approved the consolidated text of the Law 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.
- Royal Decree 1345/2007, which regulates the authorisation, registration 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 (NHS).
- Royal Decree 782/2013, which regulates distribution of medicinal products.
- Royal Decree 1416/1994, which regulates advertising of 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.

The above legislation applies in Spain only. EU legislation also applies in Spain, including:

- Regulation (EC) No 726/2004.
- Directive 2001/83/EC.
- Regulation (EC) No 141/2000 on orphan medicinal products.
- Regulation (EC) No 1394/2007 on advanced therapy medicinal products.
- Regulation (EC) No 536/2014 on clinical trials on medicinal products for human use.

Spanish regional authorities can also adopt rules applicable at their level, mainly in the context of organising the dispensing of medicines to patients at health care centres and hospitals.

Trade associations have adopted codes of good practice that regulate, among other matters, interactions with health care professionals, health care organisations and/or patient organisations by their members (*see below, Regulatory Authorities*).

Regulatory Authorities

The main regulatory authorities in Spain are the:

- *Ministry of Health*, part of the central government and responsible for, among other things, drafting and implementing the rules on pricing and reimbursement of medicinal products financed by public funds.
- *Medicines Agency*, part of the central government and responsible for, among other things, granting marketing authorisations for medicinal products in Spain through the national, mutual recognition and/or decentralised procedures.

Public funds used to finance reimbursement of medicinal products come out of the budget of the 17 autonomous regions in Spain. Therefore, the regions participate in the Ministry of Health committee that assesses applications for the pricing and reimbursement of medicines.

The relevant authorities of the 17 regions draft and implement rules in their regions. These relate to pharmacy offices or institutions, health services and hospital co-ordination. In relation to pharmaceutical products, the regions only have implementing powers.

Self-regulatory systems apply to companies that are members of self-regulatory associations such as the:

- *Farmaindustria association*, for medicinal products.
- *Fenin association*, for medical devices.
- Anefp association, for OTC products, cosmetics and personal care products.

These associations draft and implement their own codes of conduct, mainly relating to advertising products and interaction between the industry, health care organisations, professionals, and patients.

Even if companies are not members of these associations, the codes of conduct and other self-regulations may impact on their businesses. Under Spanish law, legal rules must be interpreted and applied in a manner consistent with the social environment where they are intended to have effect. Therefore, competent authorities might refer to relevant codes of conduct as an expression of the prevailing social environment.

Spanish regulation does not provide a general definition of pharmaceutical or medicinal products but defines the following specific product categories: medicinal products for human or veterinary use, medical devices, cosmetics, and personal care products.

The category of medicinal product falls within the definition of "pharmaceutical product" contained in the general EU definition of medicinal product in Directive 2001/83/EC, that is, either:

- A substance or combination of substances having properties for treating or preventing diseases in human beings.
- A substance that may be used in or administered to human beings or animals, with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Biologicals

2. Briefly outline any additional or alternative regulation of large molecule (biological) medicines, and discuss how combination products and gene therapies are classified and regulated in your jurisdiction.

Although there is no specific law on biologicals, combination products or gene therapies, general laws on medicinal products include certain provisions for them.

A marketing authorisation application for a biosimilar product must usually include the results of adequate clinical trials or preclinical studies showing, among other matters, the similarity of the biosimilar product with the reference biological product. Biological products are subject to additional pharmacovigilance monitoring requirements and must be prescribed by doctors, who must indicate the brand name of the product. The prescribed product can only be substituted with a doctor's authorisation.

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

Gene therapy medicinal products fall within the concept of "advanced therapy medicinal products", the authorisation of which is subject to EU regulations. However, as a distinctive feature of these products, some gene therapy medicinal products might occasionally and specifically be prepared for use in a hospital, under the direct supervision of a health care professional according to a customised prescription for a particular patient. In these cases, the medicinal product does not need a regular marketing authorisation, but its manufacture and defined use must be approved by the competent Spanish authorities.

Products designed to administer medicinal products are considered separately, unless they are marketed together. For example, if a medical device and a medicinal product are arranged in a single combination which cannot be reused, this is classified as a medicinal product (for example, prefilled syringes for administering insulin, or sprays with the medicinal product incorporated in them). However, medical device requirements relating to safety and functionality apply to these products.

For commercial presentations where a medicinal product and a device for its administration are independently arranged, each element is subject to its relevant regulations (for example, syrup with a measuring spoon, and a vial with a syringe).

Medical devices incorporating a medicinal product in a complementary manner are only subject to the medical device regime, provided that the medicinal product only has an effect on the human body complementary to the effect exerted by the medical device (for example, bone cement with antibiotics, catheters with heparins, or condoms with spermicide). This also applies if the medical device only incorporates part of the medicinal product or a medicinal product derived from human blood or plasma.

For medical devices incorporating advanced therapy medicinal products (which includes gene therapies), the product complexity requires special analysis. Irrespective of the medical device's function, the pharmacological, immunological or metabolic action exerted by the cells or tissues are the main action of the combined product. Therefore, these products are considered special medicinal products within the scope of Regulation 1394/2007 on advanced therapy medicinal products.

Medical Devices and Health Care IT

> 3. Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of medical software, health care IT, e-health (such as mobile health apps), or laboratory diagnostic testing kits?

The main Spanish regulation on medical devices is:

- Royal Legislative Decree 1/2015.
- Royal Decree 1591/2009 on medical devices.
- Royal Decree 1616/2009 on active implant medical devices.
- Royal Decree 437/2002, setting out the criteria to grant licences to custom-made medical device manufacturers.
- Royal Decree 1662/2000 on in vitro diagnostic medical devices.

Medical devices are divided into four classes (III, IIb, IIa and I), ranked mainly according to the invasiveness of the device, the part of the body it is in contact with, and the duration of 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 applicable laws.

For class I devices, evaluation and declaration of conformity is the manufacturer's responsibility.

For class IIa, IIb and III devices, the declaration of conformity requires an evaluation of the device by a notified body (the Medicines Agency, or the relevant notified body of an EU member state).

In addition, for class IIa, IIb and III devices, the Medicines Agency must be notified when a medical device is placed on the Spanish market for the first time.

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

There are no specific regulations on medical device software or mobile health apps, but they are included in standard provisions for medical devices. The regulatory regime for medical devices also applies to software medical devices. The key issue is whether the software falls within the definition of a medical device.

Some common health apps (for example, medication reminders and info, pregnancy tracking and info, remote patient monitoring, telemedicine and so on) may qualify as a medical device or an in-vitro diagnostic medical device, and therefore must be CE marked in line with medical device regulations. These regulations do not provide much detail on this qualification and guidance has been provided at EU level (*Medical Device Co-ordination Group, Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 - IVDR*).

Generally, apps that do not perform an action on data, or perform an action limited to storage, archival, communication or simple search do not qualify as medical device software. An app altering data for embellishment purposes does not make it a medical device but altering data or its representation for medical purposes might do so.

Apps that are not for the benefit of individual patients do not qualify as medical device software. This includes software or apps intended to aggregate population data, provide generic diagnostic or treatment pathways, or serve as scientific literature, templates, models, and so on.

If the software or app is used to collect data on a medicinal product in a patient support programme (through planned contact with patients), regulations on observational studies also apply. Therefore, use of the software must be consistent with the terms in the protocol governing the patient support programme.

Pricing, Government Funding and Reimbursement

National Health Care System

4. What is the structure of the national health care system, and how is it funded? Explain briefly how medicines are introduced into that system.

The NHS is based on the principles of universality, free access, equity and fairness of financing (*Article 2, Law 16/2003*). This aligns with Article 43 of the Spanish Constitution, which establishes the right to health care as a basic principle that requires action by all public administrations.

Some measures by the Spanish government during the economic crisis of 2008 to 2014 affected universal access to health care. This basically consisted of imposing some conditions on access to health care benefits. Co-payments by patients were also redefined (*see Royal Legislative Decree 16/2002*). The Constitutional Court declared these limits valid but many regions declared the right to health care as universal in their territory and the matter became very controversial. In July 2018, Royal Decree Law 7/2018 on Universal Access to the NHS restored universality to the NHS.

The NHS is mainly financed from general taxation. The NHS is usually classified as a gatekeeper system, where primary care physicians authorise access to speciality care, hospital care and diagnostic tests. Most hospitals offering public health are publicly owned, with some exceptions.

The NHS co-exists with mutual funds for civil servants, mutual funds for accidents and occupational disease, and private insurance.

With respect to market access, Spain has two initial stages at national level:

- Granting of marketing authorisation by the Medicines Agency (or recording products approved under the EU centralised procedure in the Medicines Agency registry) (*see Question 9*).
- A resolution on pricing and reimbursement by the Ministry of Health (*see Question 5 and Question 6*).

There is then a regional phase. The regions have an important role in market access because, even though the Ministry of Health decides which therapies are financed, the regions allocate the budget to finance them. The regions can also establish specific procedural rules on how patients access reimbursed products.

Alternative pricing and reimbursement rulings, such as payment based on results, are increasingly popular. They can be approved by the Ministry of Health in its pricing and reimbursement resolutions, or negotiated between companies and hospital or regional authorities. Such payment systems play an important role in pricing and reimbursement decisions and in purchasing decisions from hospitals, especially for medicinal products with high uncertainty or high budgetary impact.

Price Regulation

5. How are the prices of medicinal products regulated?

A marketer cannot freely set the prices of medicinal products that are reimbursed (*see Question 6*), as this requires 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 setting the price of a reimbursed medicinal product involves negotiating the price with the public authorities.

In addition, unless the medicinal product is subject to the reference pricing system, companies must grant a discount on the maximum ex-factory price for the product approved by the authorities.

A product is subject to reference pricing if either:

- A generic or biosimilar of the product exists, even if it is not substitutable.
- Its active substance has been in the EU market for more than ten years and there are other medicinal products in the Spanish market (other than the original brand product and its licensees) with the same active substance.

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

Medicinal product substitution rules also apply. This uses the concept of homogeneous groups of reimbursed products with the same active substances, dosage, composition, and route of administration, that are essentially interchangeable. Pharmacists must supply the product that has the lowest price in its homogeneous group.

In relation to clawbacks, an agreement between Farmaindustria and the government was in place until June 2020, which contemplated chargebacks paid by pharmaceutical companies if pharmaceutical expenditure exceeded the agreed ratio of real GDP growth. Farmaindustria and the government are negotiating to extend this agreement.

HTA is important in pricing and reimbursement decisions and market access. HTA occurs first at national level, in the context of IPTs (*see above*). Subsequently, the regions and hospitals may do their own HTA, to decide whether to finally include the medicinal product in clinical practice.

Reimbursement

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

Under Royal Legislative Decree 1/2015, the criteria used by the Ministry of Health to decide 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 alternatives for the same illnesses.
- Degree of innovation of the product.

The Ministry of Health must also consider the cost-efficiency ratio of the product, based on the Therapeutic Position Report (IPT) prepared by expert groups from the Medicines Agency, the Ministry of Health and the regions.

In 2020, the Permanent Pharmacy Commission of the NHS Interterritorial Council approved a Plan to Consolidate Pharmaceutical IPTs. This Plan, presented in November 2020 by the Ministry of Health General Pharmacy Directorate, aims to review the health technology assessment (HTA) process and consolidate IPTs as a key element of HTA. It includes two major action lines:

- Setting up a new pharmaceutical evaluation network called REvalMED to co-ordinate the IPT process. REvalMED will consist of a therapeutic evaluation group (led by the Medicines Agency), an economic evaluation group (led by the Ministry of Health) and therapeutic area specialists mainly appointed by the regions.
- Improving IPT methodology. This will include health economic evaluations and be based on guidelines of the Group for the Evaluation of Innovations, Standardisation and Research in Drug Selection (GENESIS) of the Society for Hospital Pharmacy (SEFH). Under GENESIS, the IPT criteria will be mainly defined by the incremental cost-effectiveness ratio and budget impact.

The pricing authorities can also consider the product's contribution to the Spanish economy, and return mechanisms proposed by the marketer (discounts, price reviews, and so on).

Once the Ministry of Health decides to reimburse a certain medicinal product, the patient obtains the medicine from a pharmacy and, if applicable, pays the pharmacist a set co-payment.

The pharmacy then charges the sale price of the medicinal product (the maximum ex-factory price approved by the Ministry of Health) (*see Question 5*) to the government of the region where it is established, plus the margin set by law for the wholesaler and for the pharmacy, less the amount paid by the patient.

If medicinal products are administered to patients in public health care centres and hospitals, the products are not paid for by patients but financed from the centre's own budget.

Clinical Trials

7. Outline the regulation of clinical trials.

Legislation and Regulatory Authorities

Clinical trials with medicinal products in Spain are mainly regulated by Royal Legislative Decree 1/2015 and Royal Decree 1090/2015.

The Medicines Agency enforces regulation on clinical trials. It has issued a document with instructions on the *practical aspects of conducting clinical trials in Spain*.

It has also issued, with the relevant ethics committees, a memorandum detailing the *procedure for authorising clinical trials with medicinal products in Spain*, defining the roles of the Medicines Agency and the ethics committees.

Both documents are subject to periodic review by the Medicines Agency.

Codes of conduct approved by Farmaindustria and Fenin apply to payments made to health care professionals and organisations for their participation in clinical trials, since this is a form of interaction with pharmaceutical companies.

Authorisations

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

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

Authorisation must be obtained by the sponsor or the legal entity to which the sponsor has delegated this task, and entitles the sponsor to perform the trial according to the approved protocol.

The investigator or even the institution where the trial will take place can be the sponsor. There can also be more than one sponsor. All co-sponsors assume the sponsor's responsibilities, unless they decide otherwise in a contract detailing their responsibilities. A sponsor must be established in an EU member state or appoint a legal representative established in the EU.

Details of the regulatory approval pathway are set out in the memorandum detailing the *procedure for authorising clinical trials with medicinal products in Spain*.

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 trial 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 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 Medicines Agency has issued a guideline for the *correct preparation of a patient information sheet and informed consent form*.

Trial Pre-Conditions

Before a clinical trial can start, the sponsor must 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 trial.

The minimum insured amount is EUR250,000 per trial subject. The maximum insured capital per trial and per year is EUR2.5 million. However, when the sponsor and principal investigator are the same person and the trial is conducted in a health centre belonging to the public health administration, the administration can take other measures apart from insurance it deems appropriate to guarantee against risks resulting from the trial, with the aim of promoting research. In any case, liability to study participants cannot be limited.

The studied medicinal product must be supplied by the sponsor free of charge.

Procedural Requirements

The sponsor must report the following to the Medicines Agency and to the ethics committee:

- The start and end dates of the trial.
- Any temporary suspension of the trial.
- Any serious breaches of the trial protocol or of Royal Decree 1090/2015 that occur in Spain.
- All suspected unexpected adverse reactions associated with the investigational product.

- Any important information that could adversely affect the safety of the trial subjects or the conduct of the trial, and file an annual safety report.

The sponsor must also:

- Publish the results of the trial, whether positive or negative and preferably in scientific journals, before they are disclosed to the non-healthcare public. A summary of the results must also be published in the *Spanish Clinical Studies Registry*. The use or disclosure of participants' data must comply with confidentiality and data privacy regulations (*see Question 17*). Information that can identify trial subjects must not be included.
- Keep the clinical trial master file on record for at least 25 years after the end of the trial.

If the Medicines Agency believes on justified grounds that the requirements in the applicable regulations are no longer met, it can do any of the following:

- Revoke the authorisation of the trial.
- Suspend the trial.
- Require the sponsor to modify any aspect of the trial.

Suspension or revocation can also be ordered based on a justified request from the sponsor.

Transparency and Reporting Requirements

When research work or investigations on medicinal products directed to the scientific community are published, it must state the funds obtained by the author(s) for or through the conduct of the clinical trial and the funding source (*Royal Decree 1090/2015*).

The Farmaindustria and Fenin codes of conduct require their members to publish, on a yearly basis, all payments to health care professionals and health care organisations to perform clinical trials. This disclosure must be made by each company on an aggregate basis and include all amounts under the Research and Development Transfers of Value category. Costs related to meetings that are clearly related to R&D activities can also be included in this category.

The sponsor has various reporting obligations (*see above, Procedural Requirements*).

A report with a summary of the trial results must be sent to the Medicines Agency and to the ethics committee within one year after the global end date of the clinical trial (or within one year after an early termination of the trial).

Manufacturing and Distribution

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

Application

Industrial manufacturing of medicinal products in Spain requires authorisation from the Medicines Agency. The application is normally electronically submitted to the 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 authorisation from the Medicines Agency.

Any entity can apply for a manufacturing authorisation, provided that it complies with Article 63 of the Law on Guarantees and Rational Use of Medicines and Royal Decree 824/2010 on pharmaceutical laboratories.

For controlled drugs or drug precursors, Law 4/2009 on drug precursors must also be complied with. Law 4/2009 develops and complements the applicable EU law, including Regulation (EC) 273/2004 on drug precursors, Regulation 111/2015 on trade in drug precursors between EU and third countries and Commission Delegated Regulation (EU) 2015/1011.

A manufacturing authorisation is required for both total and partial manufacture and for the various process of dividing up, packaging and presentation (*Article 63, Law on Guarantees and Rational Use of Medicines*). Therefore, authorisation is required for the manufacturer and all entities performing activities in the manufacturing process.

Manufacturing authorisations are granted to manufacture the medicinal products and pharmaceutical forms described in the authorisation application (*Article 10, Royal Decree 824/2010 on pharmaceutical laboratories*), not for any type of product.

Distribution activities for medicinal products requires authorisation from the health authorities of the regions. Exceptionally, for warehouses under customs supervision, authorisation is granted by the Medicines Agency (*Article 68, Law on Guarantees and Rational Use of Medicines*).

Conditions

To obtain a manufacturing authorisation, an applicant must:

- Submit to the Medicines Agency a description and technical report on the medicinal products that it intends to manufacture, and a description of the premises where quality control of the medicinal products will be performed.
- Have sufficient and adequate premises and technical and control equipment to manufacture the medicinal products.
- Have a duly qualified technical director (qualified person), persons responsible for manufacturing and 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 can be assumed by a technical director.

Conditions to obtain authorisation to distribute medicinal products in Spain may differ, depending on the type of authorisation. Such conditions are set out in Article 66 and following of the Law on Guarantees and Rational Use of Medicines and Royal Decree 782/2013 on distribution of medicinal products. They include having competent personnel and suitable and sufficient premises, equipment and facilities to ensure adequate conservation and distribution of the products.

Health authorities (for example, the Medicines Agency and regional authorities) can undertake periodic inspections of manufacturers and distributors (and facilities where they perform their activities) to ensure compliance with applicable law, good manufacturing practices (GMP) and good distribution practices (GDP). After the inspection, the manufacturer and/or distributor may receive a certificate of GMP/GDP compliance.

Restrictions on Foreign Applicants

There is no specific restriction on a foreign applicant obtaining a manufacturing authorisation, if it has adequate manufacturing premises in Spain and fulfils the other general conditions.

Key Stages and Timing

After the application is submitted, Medicines Agency will review the documentation and may request further information.

The Medicines Agency will then inspect the manufacturing sites and may raise objections or request further information.

The Medicines Agency will then issue a decision to grant or deny the application. Although the law sets a period of 90 days to issue a decision, in practice the Medicines Agency issues the decision around 180 to 270 days after the application is submitted.

Fees

The Medicines Agency fees are listed on its *website*.

Authorisations, Variations, and Renewals

Manufacturing authorisations are granted for an indefinite period. However, the holder and its manufacturing sites and operations must comply with the authorisation conditions.

A manufacturing authorisation includes details of the premises where the manufacturing activity is to be performed, the terms of the manufacturing activity, the products (and their pharmaceutical form) to be manufactured and the qualified technical director (*Article 10, Royal Decree 824/2010*).

Manufacturers can submit variations to the manufacturing authorisation (*Article 11, Royal Decree 824/2010*). Such variations must be electronically submitted to and approved by the Medicines Agency. An amendment of the manufacturer's details does not need to be approved by the Medicines Agency, but manufacturers must inform the Medicines Agency of such changes so that it can update the authorisation.

Before approving any variation, the Medicines Agency can carry out inspections to confirm that the manufacturer complies with all applicable conditions required for the variation.

A manufacturing authorisation can be totally or partially suspended or revoked if the manufacturer no longer complies with any condition in the authorisation (*Article 12, Royal Decree 824/2010*).

Monitoring Compliance and Imposing Penalties

The Medicines Agency and the regional authorities can monitor manufacturer and distributor compliance with the conditions in their authorisations, and their general compliance with the laws on manufacturing or distributing medicinal products (including GMP and GDP).

Manufacturers and their manufacturing sites or premises where distribution activities are performed are subject to inspections by the Medicines Agency and/or regional authorities.

Failure to comply with the legal requirements for manufacturing and/or distributing medicinal products can result in fines (*Article 110 and following, Law on Rational Use of Medicines and Medical Devices*) and, depending on the case, civil and/or criminal liability.

The amount of the fine depends on the case. Fines range from:

- EUR6,000 to EUR30,000 for minor infringements.
- EUR30,001 to EUR90,000 for serious infringements.
- EUR90,001 to EUR1 million (or five times the value of the infringing products) for very serious infringements.

The following penalties can also be imposed:

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

If an infringement procedure is initiated against a manufacturer and/or distributor, they can first contest the decision at administrative level. Once an administrative procedure is concluded, an appeal can be submitted to the Spanish courts.

A health authority can inspect manufacturing facilities when it deems necessary, by itself or through the health departments of the relevant regions. Manufacturers and distributors must collaborate with inspectors and provide them with access to any premises, facility, equipment or documents necessary to verify compliance with their obligations (*Law on Guarantees and Rational Use of Medicines and Medical Devices, Royal Decree 824/2010 and Royal Decree 782/2013*).

Marketing

Authorisation Procedure

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

Application

The Medicines Agency grants marketing authorisations in Spain, under the national procedure, the mutual recognition or the decentralised procedure.

Marketing authorisations granted by the 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 EU procedure.

The application must include at least the following information:

- Name or corporate name and domicile or registered office of the applicant and, if applicable, of the manufacturer, DNI/NIE or CIF (tax identification number).
- Name of the medicinal product.
- Qualitative and quantitative composition of all the components of the medicinal product, including its international nonproprietary name (INN), and its equivalence with the official Spanish name (DOE).
- Evaluation of the risk that the medicine could entail for the environment.
- Description of the manufacturing method.
- Therapeutic indications, contraindications and adverse reactions.
- Posology, pharmaceutical form, form and route of administration and expected shelf life or period of validity.
- Indications on the precautionary and safety measures to be adopted when storing the medicinal product, when administering it to patients and when disposing of residual products.
- Description of the manufacturer's control methods.
- Results of pharmaceutical (physicochemical, biological or microbiological), preclinical (toxicological and pharmacological) and clinical tests, with corresponding detailed summaries and expert reports.
- A summary of the applicant's pharmacovigilance system, including details of the qualified person.
- A risk management plan.
- A declaration by the applicant that clinical trials conducted outside the EU comply with ethical principles and standards of good clinical practice.

- Technical data sheet or summary of product characteristics (SmPC) in accordance with the model approved by the EU, a mock-up of the design and contents of the outer packaging and the immediate packaging, and the package leaflet.
- A document certifying that the manufacturer is authorised in its country to manufacture medicinal products.
- Copies of the following, where applicable:
    - the marketing authorisation obtained in another EU member state or in a third country, with the technical file and a summary of the safety data;
    - the technical file proposed by the applicant or approved by the competent authorities of the EU member state; and
    - details of any decision to refuse authorisation, in the EU or in a third country, and the reasons for the decision.
- Documentary evidence that the manufacturer of the medicinal product has verified through audits that the manufacturer of the active substance complies with GMP principles and guidelines.

The application and accompanying information must be submitted using the EU Common Technical Document (CTD), following the guidelines published by the European Commission, *Volume 2 B, Note for applicants, Medicinal products for human use, Submission and content of the dossier, Common Technical Document (CTD)*.

This implies the need to present the documents in five modules:

- Module 1 contains administrative data specific to the European Community.
- Module 2 contains clinical and non-clinical quality summaries.
- Module 3 provides chemical, pharmaceutical and biological information.
- Module 4 contains non-clinical reports.
- Module 5 contains clinical study reports.

This presentation follows a common format for all International Conference on Harmonization (ICH) regions: the EU, US and Japan.

Exceptions

In the following exceptional circumstances, the Medicines Agency can authorise the use or distribution of medicinal products that do not have a marketing authorisation in Spain:

- Compassionate use in patients with a disease that is chronic or severely debilitating or considered life threatening, and who cannot be satisfactorily treated with an authorised medicinal product. The medicinal product must be the subject of a marketing authorisation application or be undergoing clinical trials. There are two forms of compassionate use:
    - individual access authorisation for a specific patient; and

    - temporary authorisation outside a clinical trial, for medicinal products at an advanced stage of clinical research to support a marketing authorisation, or for which marketing authorisation has been requested, provided their use is foreseen for a significant group of patients.

- Use of medicinal products under unauthorised conditions, if there are no authorised therapeutic alternatives for a specific patient respecting, where appropriate, restrictions on the prescription and/or dispensing of the drug and the therapeutic protocol of the health care centre. The responsible physician must justify in the patient's clinical history the need to use the medicinal product, inform the patient of its possible benefits and risks, and obtain their consent to its use.
- Use of medicinal products authorised in other countries (not complying with the definition of compassionate use), if there is no medicinal product authorised in Spain with the same composition (or it is in a pharmaceutical form that does not allow treatment of the patient) that is a suitable alternative for that patient. In this situation, the unauthorised medicinal products can be accessed in either of the following ways:
    - a request for individual access for a specific patient, by the health department of a region or a hospital management; or
    - the Medicines Agency approves a protocol imposing conditions for use of the medicinal product, when its need is foreseen for a significant subpopulation of patients and subsequent use by hospitals applying that protocol.

      The Medicines Agency can also temporarily authorise the import of foreign medicinal products not authorised in Spain, due to shortages.

- Temporary authorisation of the distribution of unauthorised medicines, in response to the supposed or confirmed spread of a pathogenic or chemical agent, toxin or nuclear radiation capable of causing harm.

Authorisation Conditions

The Medicines Agency will grant 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 to the patient's health or public health, from a risk-benefit perspective.

Marketing authorisations are granted to a specific individual or entity for a specific medicinal product, and cover all activities related to placing the product on the market (including advertising). However, all facilities in

which medicinal products are stored (even temporarily), repackaged, relabelled or manufactured and companies developing related activities must also hold specific authorisation.

The following medicinal products are subject to specific regulation:

- Blood-derived medicines and vaccines: each batch of finished product is subject to prior authorisation/ certification, which implies a review of the production and control protocols and, if necessary, analytical tests considered appropriate.
- Radiopharmaceutical medicinal products.
- Medicinal gases.
- Advanced therapy drugs.

Traditional herbal medicinal products must be registered in the register of traditional herbal medicinal products managed by the Medicines Agency. There is a simplified procedure for traditional herbal medicines meeting the following requirements:

- Having indications exclusively appropriate for traditional herbal medicines which, due to their composition and purpose, are intended and designed for use without the control of a physician.
- Administered according to a specific dosage or posology.
- Preparations for oral, external or inhalation use.
- The period of traditional use has elapsed, which is at least 30 years, at least 15 of which have been use in the EU.
- The information on traditional use is sufficient, in particular the product is proved not to be harmful under the established conditions of use, and the pharmacological action or efficacy can be deduced from experience in traditional use.

For homeopathic medicines, if they have an approved therapeutic indication, they must follow the usual procedure to obtain marketing authorisation. If not, there is a special simplified procedure if the following requirements are met:

- Oral or external route of administration.
- No particular therapeutic indication on the label or in any information relating to the medicine.
- Their degree of dilution guarantees the safety of the medicine. In particular, that the preparation does not contain more than one part per 10,000 of mother tincture, nor more than one hundredth part of the lowest dose eventually used in allopathic medicine of those active principles whose presence in an allopathic medicine implies an obligation to present a medical prescription.

Conditional authorisations can be granted subject to certain obligations in exceptional situations (*see below, Key stages and timing*). Otherwise, the regulations only refer to imposing conditions in a marketing authorisation on the prescription of the medicine (based on its indications, safety and effectiveness), by classifying it as prescription or non-prescription (OTC medication). Prescription drugs can in turn be classified as renewable or non-renewable prescription drugs, special prescription drugs (including narcotic and psychotropic drugs) or restricted prescription drugs (for use only by hospital services).

Where applicable, price and reimbursement proceedings are initiated automatically after the granting of the marketing authorisation and their outcome determines whether the product is included in the NHS (reimbursed) and its maximum price (*see Question 5 and Question 6*). They do not impact on the obtaining of a marketing authorisation, but to effectively initiate marketing of the product, it is essential to prepare the offer to the NHS before marketing authorisation is granted.

Key Stages and Timing

After an application is submitted to the Medicines Agency, it will check and accept the application and issue an evaluation report.

The Medicines Agency will decide the application and issue, where appropriate, a marketing authorisation for the product. The maximum period in which to notify the applicant of the outcome of the application is 210 calendar days after the application is submitted.

In exceptional circumstances, the Medicines Agency can authorise a medicinal product based on an application with incomplete preclinical or clinical data, if the applicant can justify on objective and verifiable grounds that it cannot provide complete data on efficacy and safety under normal conditions of use of the product, for any of the following reasons:

- The cases for which the medicinal product is indicated occur so rarely that the applicant cannot reasonably be required to provide detailed evidence.
- The current state of scientific development does not permit the provision of complete information.
- Commonly accepted principles of medical ethics prohibit collection of this information.

In these circumstances, authorisation granted by the Medicines Agency is reviewable annually and subject to the applicant complying with the following conditions as appropriate:

- Carrying out within a deadline imposed by the Medicines Agency a programme of studies, whose results will be the basis for a new evaluation of the product's risk/benefit ratio.
- Classifying the medicinal product as subject to medical prescription and, if necessary, authorising its administration under strict medical control only, if possible in a hospital.
- Including available information in the SmPC explaining the limitations of the data, and in the package leaflet and any other medical information document, emphasising that, in certain aspects, there is no conclusive data available yet.

Fees

The Medicines Agency fees are listed on its *website*.

Effect of Authorisation and Related Protections

Marketing authorisation holders benefit from a data exclusivity period, during which an applicant for a generic medicinal product cannot refer to the reference medicinal product's clinical data (the results of pre-clinical tests and clinical trials) (*Royal Legislative Decree 1/2015*). This period lasts for eight years from the approval of the first marketing authorisation for the reference product by the authorities in any EU member state (not necessarily Spain). Once this eight-year period has expired, the applicant for a marketing authorisation for a generic is not required to provide the results of pre-clinical tests and clinical trials.

Once a generic is authorised using the results of pre-clinical tests and clinical trials for the reference product, the generic cannot be marketed until the expiry of ten years from the first marketing authorisation of the reference product in the EU (marketing exclusivity period).

The marketing exclusivity period of ten years can be extended by one additional year up to a maximum of 11 years if, during the first eight of those ten years, the holder of the marketing authorisation for the reference product obtains approval for a new indication(s) with significant clinical benefits compared to existing therapies.

In addition to patent rights (which have a duration of 20 years), marketing authorisation holders can benefit from supplementary protection certificates for medicinal products. They can be granted for a period equal to the period between the date on which the application for a basic patent was filed and the date of first marketing authorisation in the EU, reduced by five years, up to a maximum duration of five years.

Authorisations, Variations, and Renewals

A marketing authorisation has an initial period of five years. Renewal is for an indefinite term, unless pharmacovigilance reasons justify it being subject to further renewals.

A marketing authorisation can be modified on request of its holder to the Medicines Agency. Depending on the content and scope of the intended modification (variation), it can be classified into the following categories:

- Type IA minor variations, with only minimal or no impact on the quality, safety or efficacy of the medicinal product. They are covered by Annex II, paragraph 1 of Regulation (EC) No 1234/2008.
- Type II major variations which, without being a line extension, may impact on the quality, safety or efficacy of the medicinal product and are covered by Annex II, paragraph 2 of Regulation (EC) No 1234/2008, as well as transfers of ownership of marketing authorisations.
- Line extension, extension of a marketing authorisation, or extension, as indicated in Annex I, paragraphs 1 and 2 of Regulation (EC) No. 1234/2008.
- Type IB minor variation, which is not a minor variation type IA, not a major variation type II, and not a line extension.

Type IA and IB minor variations only need to be notified to the Medicines Agency. Type IA variations must be notified within 12 months following implementation of the modification. Type IB variations must be notified before they are implemented. The Medicines Agency has a 30-day period to accept or refuse the variation and, if no response is given within this period, the variation is deemed accepted.

For type II major variations the marketing authorisation holder must apply with the information listed in Annex IV of Regulation (EC) No. 1234/2008, following the instructions that the Commission and/or the Medicines Agency may impose.

A line extension of a marketing authorisation is evaluated following the procedure followed by the initial marketing authorisation. The line extension will be granted a new marketing authorisation.

A transfer of a marketing authorisation is subject to authorisation by the Medicines Agency. Variations of the marketing authorisation that are due to the transfer are governed by the procedure for modifications of a marketing authorisation.

The Medicines Agency can suspend, revoke or modify a marketing authorisation in any of the following circumstances:

- The medicinal product is considered harmful.
- It turns out not to be therapeutically effective.
- Based on safety data, the medicinal product has an unfavourable risk-benefit ratio.
- The medicinal product does not have the authorised quantitative or qualitative composition, quality guarantees are not complied with, or the required quality controls are not executed.
- The data and information in the documentation are incorrect or do not comply with the applicable regulations.
- The manufacturing method used by the manufacturer does not comply with that in the authorisation.
- For any other cause, which involves a foreseeable risk to public health and safety.
- In any other case the European Commission has agreed to.

The procedure is initiated by the Medicines Agency hearing the interested party, after which a resolution is issued and notified within six months.

Monitoring Compliance and Imposing Penalties

The Medicines Agency and regional authorities can monitor compliance with marketing authorisations.

Failing to comply with a marketing authorisation can result in a fine. The amount of the fine depends on the case, between EUR6,000 and EUR1 million, or up to five times the value of the goods or services that are the object of the infringement in the most serious cases, when direct damage or a serious and direct risk to public health has been caused.

The following penalties can also be imposed:

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

The applicable regulations do not provide the possibility to bar individuals or entities from receiving authorisations. However, marketing authorisation holders with their own or subcontracted facilities to store their medicines in

Spain must be authorised as marketing authorisation holders of medicinal products with a warehouse (*see below, Release Requirements*). Such authorisation can be suspended or revoked if the company and/or its premises cease to comply with the requirements in the applicable regulations.

Protection of Confidential Information

The documentation and expert reports submitted with a marketing authorisation application are confidential (*Royal Decree 1345/2007*).

Once a medicinal product has been authorised, the Medicines Agency will publish the decision on the marketing authorisation, the technical data sheet, package leaflet and Medicines Agency assessment report, after deleting any information of a commercially confidential nature (*Royal Legislative Decree 1/2015*).

In some cases, a third party has requested information on the date when a marketing authorisation application was filed but the Medicines Agency refused to grant this information on confidentiality grounds. However, the courts stated that providing such information did not involve disclosing confidential information.

Release Requirements

Pharmacovigilance obligations (*see Question 10*) and advertising requirements apply (*see Question 16*).

Marketing authorisation holders with their own or subcontracted facilities to store their medicines in Spain must be authorised as a marketing authorisation holder of medicinal products with a warehouse (this is included in any pharmaceutical manufacturing or importing authorisation they have).

To obtain authorisation as a marketing authorisation holder of medicinal products with a warehouse, the applicant must:

- Apply to the Medicines Agency, specifying the medicines for which it has marketing authorisation that are going to be stored.
- Have premises, technical and control equipment and appropriate and sufficient means for the correct storage and distribution at its disposal, which meet the legal requirements for preservation of the medicinal products.
- Have permanently and continuously available a responsible technician (qualified person), to carry out the marketing authorisation holder's obligations relating to the storage and distribution of the medicinal products, according to the applicable GDP.

Using third parties or wholesalers to distribute medicinal products must be included in the authorisation as a marketing authorisation holder of medicinal products with a warehouse or a manufacturing authorisation.

All these subcontracted entities and facilities in Spain must also have relevant authorisation (for example, as a wholesaler).

Pharmacovigilance

10. What pharmacovigilance obligations and other commitments apply after a company has obtained marketing authorisation? Are there further conditions on how the medicinal product is distributed and made accessible to patients?

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

- Following good pharmacovigilance practice for the pharmaceutical industry, as published by the Medicines Agency.
- An adequate pharmacovigilance system, including a master file and undertaking periodic audits.
- A suitably qualified person responsible for pharmacovigilance in the EU.
- A contact person for pharmacovigilance in Spain.
- Submitting periodic safety reports to the EMA.
- 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 on the medicinal product.
- Carrying out post-authorisation studies of efficacy and/or safety required by the competent authorities.
- Performing a continuous evaluation of the risk-benefit parameters of the medicinal product.

The marketing authorisation holder must perform all post-authorisation safety and efficacy studies required by the Medicines Agency or the European Commission. Post-authorisation safety studies can be required:

- As a condition of the marketing authorisation. The marketing authorisation will state, if necessary, deadlines for compliance.
- After granting a marketing authorisation, if doubts appear about the safety of an authorised medicinal product. If this concerns more than one medicinal product, the Medicines Agency, after consulting the European Pharmacovigilance Risk Assessment Committee, will invite the marketing authorisation holders concerned to jointly conduct a single study.

Post-authorisation efficacy studies can be required:

- As a condition of the marketing authorisation, when questions about the efficacy of the medicinal product arise that can only be resolved after marketing of the medicinal product. The marketing authorisation will state, if necessary, deadlines for compliance.

- After granting a marketing authorisation, when knowledge of the disease or clinical methodology indicates that previous efficacy assessments may need to be significantly revised.

The requirement to conduct such studies is based on the situations stipulated by the European Commission. The *list of medicines under additional monitoring* published by the EMA includes medicines for which the marketing authorisation holder must carry out a post-authorisation safety study.

Marketing authorisation holders must also comply with certain obligations to prevent shortages. They must guarantee a continuous supply of their medicines in the national market and hold a minimum stock of their products, to ensure supply to pharmacies and hospital pharmacy services. However, no explicit rules define the criteria to determine minimum stock. Therefore, this obligation must be understood as a duty to meet demand for the product in the Spanish market.

This duty involves an additional obligation to promptly inform the Medicines Agency about any possible abnormal restrictions, interruptions, or problems in the supply of their medicines which they are aware of.

There are additional notification obligations for the:

- Export of medicines outside the EU, which must be notified to the Medicines Agency according to its circular letter 1/2015 on foreign trade of medicinal products.
- Parallel trade of certain medicinal products listed by the Medicines Agency as critical products, according to its circular letter 2/2012 on the prior notification of medicinal product shipment to other member states.

The obligation to guarantee a continuous supply can only be suspended temporarily with prior authorisation from the Medicines Agency. A final ending of the supply and cancellation of the marketing authorisation must also be authorised by the Medicines Agency.

Abridged Procedure

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

A marketing authorisation applicant need not provide the results of pre-clinical and clinical trials if it can show 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 scientific documentation, provided that the product's active substances have had a well-established medical use for at least ten years in 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 an already authorised medicinal product, the applicant can rely on the pre-clinical and clinical documentation of the authorised medicinal product with the permission of its marketing authorisation holder.

Foreign Marketing Authorisations

12. Are foreign marketing authorisations recognised in your jurisdiction?

Marketing authorisations issued by authorities in another EU member state can be recognised in Spain through the mutual recognition procedure set out in the EU regulations.

The marketing authorisation holder must request the reference member state to prepare an assessment report on the medicinal product or update an existing assessment report. The reference member state will prepare or update the assessment report within 90 days of receipt of a valid application.

The assessment report and the approved SmPC, labelling and package leaflet must be sent to the concerned member state(s) (in this case, including Spain) and to the applicant.

Within 90 days of receipt, the concerned member states (including Spain) will approve the assessment report, SmPC and the labelling and package leaflet, and inform the reference member state accordingly. The reference member state will record the agreement of all parties, close the procedure and inform the applicant accordingly.

If a concerned member state refuses to approve the assessment report and the SmPC on grounds of a potential serious risk to public health, it must give a detailed explanation for this to the reference member state, the other concerned member states and to the applicant. Points of disagreement will be referred to the *co-ordination group*, where all member states must use their best endeavours to agree the action to be taken. They must allow the applicant to make their view known orally or in writing. If, within 60 days of notification of the points of disagreement, the member states reach agreement, the reference member state will record the agreement, close the procedure and inform the applicant.

Each concerned member state (including Spain) must adopt a decision complying with the approved assessment report, the SmPC and the labelling and package leaflet, within 30 days of acknowledgement of the agreement.

Under Royal Decree 1015/2009, the use of drugs authorised in other countries but not authorised in Spain can be authorised by the Medicines Agency in exceptional circumstances when certain conditions are met (*see Question 9, Exceptions*).

Parallel Imports and Cross-Border Trade in Medicines

13. Are parallel imports of medicinal products into your jurisdiction allowed? What are the general requirements for imports of medicinal products into your jurisdiction? Are particular foreign markets or products favoured?

Under Royal Decree 1785/2000, parallel imports are allowed into Spain from other EU member states, subject to the following requirements:

- The medicinal product must have a marketing authorisation, both in the country of origin and in Spain.
- The parallel importer must obtain prior authorisation from the Medicines Agency.
- The labelling and leaflet of the product must comply with Royal Decree 2236/1993.
- The parallel importer must have authorisation to manufacture medicinal products in Spain if it carries out, in Spain, any repackaging and relabelling of the imported product (otherwise, the importer must have authorisation in Spain to carry out wholesale activities).

IP rights cannot be used to oppose parallel imports. However, before marketing a medicinal product parallel imported into Spain, the importer must notify this to the holder of the marketing authorisation for the medicinal product in Spain and provide, if requested, a sample of the repackaged product to be marketed.

Other imports (medicinal products imported into Spain from outside the EU) must be authorised by the Medicines Agency. Imports are authorised for a period of one year and can be made in several batches.

For finished medicinal products, authorisation to import them must be obtained from the Medicines Agency by the importing pharmaceutical laboratory or the marketing authorisation holder, in accordance with the marketing authorisation.

For intermediate or bulk products, import authorisation is requested by the manufacturing or importing laboratory in accordance with the marketing authorisation.

Each imported batch of finished product is subject to a complete qualitative analysis, a quantitative analysis of at least all the active ingredients, and all other tests or checks necessary to ensure the quality of the medicinal products complies with the marketing authorisation. This analysis must be carried out in an EU member state. The importer's qualified person must issue a certificate for each imported batch before its release.

Importers who carry out the required analyses to import medicines or investigational medicinal products from third countries and their facilities must obtain a manufacturing authorisation from the Medicines Agency (*see Question 8*).

Restrictions on Dealings with Health Care Professionals

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

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 (*Article 4.6, Royal Legislative Decree 1/2015*).

This prohibition does not apply to offering stationery or items for the practice of medicine or pharmacy, provided their price does not exceed EUR10.

This prohibition applies to offers made to both private and public practitioners.

For sponsorship of scientific meetings, Royal Decree 1416/1994 only allows sponsoring events of a professional and scientifical character in the following ways:

- Direct or indirect offering of hospitality to attending health professionals must be moderate and subordinate to the main purpose of the meeting, and cannot extend to non-health professionals.
- Prizes, scholarships, contributions and subsidies to meetings, congresses, study trips and similar events must relate to activities of a scientific nature, to recipients that are clinically practising physicians or their associated entities.

For the publication of works or studies and presentations at meetings, congresses and similar events, funds obtained for them and their source of financing must be stated. This obligation extends to the means of communication through which they are made public and which obtains funds by or for their publication.

In addition, the codes of conduct of several industry associations (such as Farmaindustria and Fenin) impose on their members further rules on dealings with health care professionals (public and private practitioners). For example, the Farmaindustria and Fenin codes of conduct establish rules on, among other matters:

- Entering into consultancy agreements with health care professionals.
- Delivery to health care professionals of informational and educational materials, items of medical utility, samples and gifts of a limited value.
- Sponsorship of the attendance by health care professionals at third party or company organised educational events.

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

Spanish law does not require payments by companies to health care professionals or other interactions between companies and health care professionals and organisations to be publicly disclosed. However, the Farmaindustria

code of conduct requires its members to publish each year on their websites certain information on interactions with health care professionals and organisations. This publication must:

- Identify each health care professional or organisation individually (in case of health care professionals, companies must state that this data is disclosed according to the code and Spanish data protection regulations).
- Specifically disclose the amount of payments for service agreements and sponsorship of attendance at educational events. This applies to payments made to both public and private health care professionals.

There are no specific anti-bribery regulations for the life sciences industry. However, breach of the above regulations can be a serious administrative infringement under Article 111.2.(c) 27 and 28 of Royal Legislative Decree 1/2015, which sanction:

- Directly or indirectly offering any type of incentive, bonus, prohibited discounts, premiums or gifts, by anyone with a direct or indirect interest in the production, manufacture and marketing of medicines, to health care professionals, on the prescription, dispensing and administering of medicines, or to their relatives and people living with them.
- Health care professionals accepting, on the prescription, dispensing and administering of medicines reimbursed by the NHS, or their relatives and people they live with, any type of incentive, bonus, prohibited discount, premium or gift, made by anyone with a direct or indirect interest in the production, manufacture and commercialisation of medicines.

Serious infringement can incur fines between EUR30,001 and EUR 90,000, and publication of the infringement in the Spanish Official Gazette.

Additionally, bribery acts are sanctioned by the general rules of the Criminal Code. It defines a bribe as either:

- The offer of a price, a gift or a favour in exchange for an authority or public official to perform or omit an act inherent to their position, or to unjustifiably delay an act that must be performed in the exercise of their professional duties.
- Promises, offers or grants to the directors, administrators, employees or collaborators of a commercial company, of an unjustified benefit or advantage, of any nature, as consideration to unduly favour the offeror or a third party over others in the acquisition or sale of products, the contracting of services or, more generally, in any type of commercial relations.

If the bribe is aimed at a public official (for example, health care practitioners in the public health care system), the bribery is punishable with a prison sentence of three to six years, a fine from (the exact amount of the fine is fixed by the judge on a case-by-case basis) and disqualification from the affected commercial activity for a period of nine to 12 years.

If the bribery is aimed at a private or commercial operator (for example, a private practitioner), the bribery is punishable with a prison sentence of six months to four years, disqualification from the affected commercial activity for one to six years and a fine of three times the value of the benefit or advantage.

However, only in the most serious cases, in which irrefutable proof of the bribery is provided, could such actions be punished under the anti-bribery provisions of the Criminal Code, and not as administrative infringements of the regulations on promotion of medicinal products and interactions with health care practitioners.

Selling Restrictions

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?

The sale of medicinal products to the public can only be carried out by duly authorised pharmacies. This applies to over-the-counter (OTC) and prescription-only medical products.

Only medicinal products with a valid marketing authorisation can be placed on the Spanish market (*Royal Legislative Decree 1/2015*).

Medicinal products can only be distributed by:

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

The distribution regime is the same for OTC and prescription-only medical products.

Selling prescription medicines online is strictly forbidden. However, under Royal Decree 870/2013 online sales of OTC medicinal products are permitted by a pharmacy open to the public (that is, an actual physical pharmacy authorised to operate as such).

A pharmacy website 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 intending to sell OTC medicinal products online must notify this to the relevant Spanish authorities, at least 15 days before starting it.

The term OTC product includes both:

- Medicinal products not subject to medical prescription and for which advertising is permitted. These are known in Spain as EFP (*Especialidad Farmacéutica Publicitaria*).

- Other products not technically considered a medicinal product (such as personal care products or cosmetics). These products are not subject to distribution through the authorised entities referred to above, nor to public sale through authorised pharmacies.

Advertising and Promotion

16. What restrictions apply to the advertising and promotion of medicinal products and the provision of samples, and how are adverts and promotional activity regulated?

Legislation and Regulatory Authority

The rules on advertising medicinal products are set out in:

- Law 34/1988 on advertising.
- Law 3/1991 on unfair competition.
- Royal Legislative Decree 1/2015.
- Royal Decree 1416/1994.
- Instruction 6/1995 from the Ministry of Health.

Some regions (Madrid and Catalunya) have adopted further guidelines on certain advertising matters.

Some industry associations have adopted codes of conduct that regulate, among other matters, interactions with health care professionals (*see Question 14*), health care organisations and patient organisations.

Responsibility for enforcing advertising rules (other than under industry codes of conduct) lies with the health authorities of the regions and the courts.

Industry codes of conduct are enforced by industry association self-regulatory bodies in agreement with Autocontrol, a Spanish association acting as an independent tribunal in advertising self-regulation matters. For OTC products, the Spanish association Anefp can also act as an independent tribunal for companies that submit their cases to it.

Autocontrol and Anefp can also provide supervisiory services on promotional materials before they are distributed. Companies can ensure that they comply with advertising rules before disclosure of promotional materials.

Whether a particular communication, material or information is deemed promotional is determined by its real purpose, which is the promotion of the prescription, dispensing, sale or consumption of a medicinal product. It is not solely determined by the activity or channel where it is distributed (a wide range of different types of support have been considered promotional materials).

Certain activities are in all cases considered promotion addressed to health care professionals, such as medical visits, reminder advertising (mainly consisting of desktop items), providing medical samples, incentives, sponsoring scientific events, and so on.

The following among others are not considered promotional, due to their exclusively informative nature:

- The labelling and package leaflet of a medicinal product.
- Correspondence with health care professionals necessary to answer a specific question about a specific medicinal product, accompanied where appropriate by a non-advertising document.
- Specific information on notable facts such as a change of packaging, information on side effects, sales catalogue and price list.
- Information related to human health or diseases, provided that no reference is made, even indirectly, to a medicinal product.

Restrictions

Advertising prescription-only medicinal products and/or public financed medicinal products to the general public is prohibited.

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 SmPC or leaflet of the medicinal product.

Advertising medicinal products that have not obtained a marketing authorisation and a relevant price resolution is not allowed.

Advertising medicinal products does not need to be approved in advance by a regulatory or industry authority. However, companies placing advertisements directed to health care professionals must send a copy of the advert to the health authority of the 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.

Promotional materials addressed to the public (therefore, only referring to OTC medicinal products) must comply with the following principles:

- Identification, meaning that the materials must evidently be recognised as promotional and specify that the object of the promotion is a medicinal product.
- Veracity and objectivity, meaning that all information in the promotional material must be consistent with the SmPC.
- Faithfulness, meaning that the content and forms of dissemination of the material cannot be addressed to bring discredit, denigration or disparagement of a person or company, its products or services, or trade

marks or other distinctive signs. Comparative advertising addressed to the public suggesting that the effects of a medicinal product are the same or superior to the effects of another is prohibited.

- Promoting the correct and rational use of medicinal products, meaning that the materials must include references determined by the Ministry of Health to prevent abuse of non-prescription medicinal products, and include essential information to promote the rational use of medicinal products.

Promotional materials addressed to health care professionals must also generally comply with these principles. However, there are some differences in their application.

The principle of veracity and objectivity requires materials addressed to health care professionals to include concrete information not required for materials addressed to the public, such as:

- The name and address of the marketing authorisation holder.
- Essential information on the product, dosage and available pharmaceutical presentations.
- Dispensation and prescription regime of the product.
- Price and financing conditions.
- Treatment estimated cost.
- Date of last revision of the promotional material.

Also, in contrast with promotional materials addressed to the public, it is arguable that materials addressed to health care professionals can rely on information in the SmPC and also on data derived from scientific literature.

The principle of faithfulness does not prohibit comparative advertising addressed to health care professionals. However, comparisons can only be made between medicinal products of comparable safety and efficacy and equivalent therapeutic effect.

The principle of promoting the rational use of medicinal products does not require, for materials addressed to health care professionals, a particular reference to promote the rational and correct use of the medicinal product, in contrast to materials addressed to the public.

Internet Advertising

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

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

There are no special rules applicable for social media channels. The Farmaindustria code of conduct refers to social media channels and states that companies are responsible for training their employees and collaborators to prevent

them sharing inappropriate content. The code also advises companies to incorporate internal policies to self-regulate use of social media by their employees and collaborators.

Data Privacy

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

Sensitive Patient Data

Processing sensitive patient data typically requires obtaining (usually in writing) the patient's prior explicit consent. However, consent is not necessary when:

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

In these cases, the patient must still previously be informed, explicitly, precisely and unequivocally, of all the aspects listed in Article 14 of Regulation (EU) 679/2016 (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 (*see Question 7*) 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 according to the applicable data protection laws. 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

Reporting adverse events (*see Question 10*) must comply with the applicable data protection laws. If sensitive patient data is collected for this purpose, the data subject must be informed about the terms of the processing but no consent is needed.

If the processed data is anonymised, it is not considered personal data and therefore the data protection laws do not apply.

Transfers of Data

International transfers of patients' personal data from Spain to recipients in countries outside the European Economic Area can be made without authorisation from the Spanish Data Protection Agency, provided that the data processing complies with the General Data Protection Regulation and Law 3/2018 on data protection, and either:

- The recipient is located in a country declared of adequate level by the European Commission.
- The data controller/processor has offered adequate guarantees which include, among others, a transfer under standard contractual clauses approved by the European Commission, binding corporate rules, and so on.

Otherwise, the data controller/processor can only transfer patients' personal data if any of the conditions in Article 49(1) of the General Data Protection Regulation is met (as a rule, if the prior explicit and informed consent of the clinical trial participant has been obtained).

Transfers of patients' personal data to Spain must also comply with the General Data Protection Regulation and Law 3/2018 on data protection.

Packaging, Labelling and Tracking

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 Medicines Agency is in charge of approving the text and others features of packaging and labelling of medicinal products (including their amendments) authorised in Spain through the national procedure.

For medicinal products that have received marketing authorisation from the European Commission, the 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 be easily readable, clearly comprehensible and indelible, and include the following:

- The name of the product.
- An accurate summary of the products' characteristics.
- The batch and unit numbers, allowing for individual identification.

- Any other required symbols, such as the symbol for being subject to medical prescription, as referred to in Annex IV of Royal Decree 1345/2007.
- Any excipients that must be declared under EU regulations and regulatory guidelines.
- All information listed in Annex III of Royal Decree 1345/2007, which distinguishes between information on the outer packaging and in the inner packaging.

The information that must be included on the outer packaging can be summarised as follows:

- Name of the medicinal product, consisting of the name followed by the strength and pharmaceutical form and, where appropriate, an indication of the intended recipients, whether infants, children or adults.
- Qualitative and quantitative composition, in active ingredients per unit of administration.
- Pharmaceutical form and content in weight, volume or administration units.
- Form of administration and route of administration.
- Warning: "Keep out of the reach and sight of children".
- Special warnings, when the medicinal product requires them.
- For medicines containing radionuclides, conditions of transport of dangerous goods.
- For medicinal gases, technical specifications, conditions of supply and transport and, if applicable, the corresponding symbols.
- Expiration date clearly expressed (month and year).
- Special precautions for conservation, if any.
- Special precautions for disposal.
- Name and address of the marketing authorisation holder and, if applicable, the name of its local representative.
- The National Code for Medicinal Products.
- Manufacturing batch.
- For medicines not subject to prescription, their indications.
- Prescription and dispensing conditions.
- Symbols, acronyms and legends described in Annex IV of Royal Decree 1347/2007.
- Box or blank space to indicate the prescribed dosage, duration of treatment and frequency of use or intakes.
- NHS seal coupon, when applicable.
- For drugs that must bear security devices (as listed on the Ministry of Health and Medicines Agency websites), a two-dimensional barcode, and the product code and serial number in visible characters.

Serialisation

The packaging of most prescription-only medicinal products (except those specifically exempt from this requirement) and a limited number of OTC medicinal products must bear the safety features (a unique identifier and an anti-tampering device) indicated in EU Commission Delegated Regulation (EU) 2016/161 and Royal Decree 1345/2007.

The Ministry of Health and the Medicines Agency publish on their websites updated information on medicines marketed in Spain that must carry these safety features.

A unique identifier is a sequence of numeric or alphanumeric characters unique to a pack of a medicinal product, enabling verification of its authenticity and identification of the individual pack. It consists of:

- A code allowing identification of at least the name, common name, pharmaceutical form, strength, pack size and pack type of the medicinal product.
- A numeric or alphanumeric sequence of up to 20 characters, generated by a deterministic or non-deterministic randomisation algorithm (serial number).
- A national reimbursement number or other national number identifying the medicinal product.
- Batch number.
- Expiry date.

A unique identifier must be encoded by the manufacturer in a two-dimensional barcode that is machine-readable. The manufacturer must also print in human-readable format the product code, serial number and national reimbursement number.

An anti-tampering device allows verification of whether the packaging of a medicinal product has been tampered with.

Such obligations apply to the manufacturer, but the marketing authorisation holder must ensure compliance as it is ultimately responsible for the product.

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 National Code of Medicinal Products assigned by the Medicines Agency.

To ensure access to the information for blind or visually impaired 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.

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".

The packaging of most prescription-only medicinal products (except those specifically exempt from the requirement) and a limited number of OTC medicinal products must bear a unique identifier and an anti-tampering device (*see above, Serialisation*).

Product Safety, Quality and Liability

Regulators and Product Recall

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

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 consumers or users 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 (*Article 13, 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 (*Article 51, Royal Decree 1/2007*).

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

The main regulatory authority on the technical aspects, safety and surveillance of medicinal products is the Medicines Agency. Regional authorities can also perform necessary controls to ensure that the products comply with applicable regulations.

The specific procedure for product recall of medicinal products is mainly regulated by Royal Legislative Decree 1/2015 and Royal Decree 1345/2007.

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

Under Royal Decree 1345/2007, the marketing authorisation holder must notify any action taken to recall a batch or full line of a medicinal product from the market to the:

- Medicines Agency.
- Regional authorities.

- Authorities of all countries where the product has been distributed.

There is no specific deadline to carry out this notification, but it must be done within an appropriate period, given the circumstances of each case and the reasons for the recall.

In addition, among other obligations, the marketing authorisation holder must also:

- Comply with its pharmacovigilance obligations (*see Question 10*).
- Observe the conditions under which the marketing authorisation was granted, in addition to the general obligations in the legislation.
- Submit periodic safety reports established by regulation, to keep the safety file updated. This also applies, in particular, to the information addressed to health care professionals included in the product's technical sheet and the information on the leaflet.
- Make the results of clinical trials public, regardless of whether their conclusions are favourable (*see Question 7*).
- Collaborate in control programmes and guarantee the suitability of the products on the market.

Medicinal Product Liability Law

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 medicinal products is in Articles 128 to 146 of Royal Decree 1/2007.

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 contract law (based on non-compliance of the goods or services, or non-performance or defective performance of the contract) or non-contractual liability.

The product liability regime in Royal Decree 1/2007 requires the claimant to prove a defect in the medicine, that it has suffered damage, and a causal link between the defect and the damage.

To establish a causal link between the defect and the damage, the claimant must provide clear and substantial evidence of the link, and the damage must be an appropriate and sufficient result of the defect.

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

Disputes over liability can be settled by agreement between the parties. There is no obligation for such settlements to be made public.

Liable Parties

22. Who is potentially liable for defective medicinal products?

Under the product liability regime in Royal Decree 1/2007, liability for a defective medicinal product is borne by the producer, that is:

- The manufacturer or importer into the EU of a finished product, raw material or component part of the finished product.
- An "apparent producer" of the product, that is, any person who, by putting their name, trade mark, or other distinguishing feature on the product (whether on its container, packaging or other protective or presentational component) presents themself as its producer.

Any producers responsible for the same damage are jointly and severally liable to the injured party. However, the producer who responded to the injured party can file an action for recovery against the other responsible producers, according to their participation in the damage.

If the producer cannot be identified, the supplier of the product (the distributor or retail supplier) is treated as the producer, unless it informs the injured party within three months of the identity of the manufacturer or the person who supplied the product to it. This rule has been clarified by a judgment of the European Court of Justice of 2 January 2009 (*Case C-358/08*) and judgments of the Spanish Supreme Court of 21 January 2020 and 20 July 2020.

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

Under Royal Legislative Decree 1/2015, manufacturers of medicinal products must take out civil liability insurance or an equivalent financial guarantee to cover damage to health derived from medicinal product safety problems.

In case of undue off label use of medicinal products, a physician may be subject to general contractual and tort liability applicable in the case.

Defences

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

Under the product liability regime in Royal Decree 1/2007, the producer is not liable if it can prove that the product is not defective because it provides the safety which legitimately could be expected from it, taking all circumstances into account, including the time when the product was put into circulation, its presentation and the use to which it could reasonably be expected to be put.

The producer is also not liable if it can prove any of the following:

- It did not put the product into circulation.
- In the circumstances, 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 a professional or entrepreneurial activity.
- The defect is due to the product being manufactured in accordance with existing mandatory rules.
- The state of scientific and technical knowledge at the time the product was put into circulation did not allow for the discovery of the defect. However, this is not a valid defence for liability for medicinal products, food or foodstuffs.

The producer of a part 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 injury) caused by identical products with the same defect is limited to EUR63,106,270.96.

Product liability derived from Royal Decree 1/2007 cannot be excluded or limited contractually. Any clause intended to exclude or reduce such liability is ineffective against the injured party.

Product Liability Claims

24. How can a product liability claim be brought?

Limitation Periods

The statute of limitation to bring proceedings to recover damages caused by a defective product 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 liable party is known to the injured party. This period can be interrupted by the injured party by filing a claim before the courts or through an extrajudicial claim, or through an act of acknowledgment by the liable party.

In any case, the right to claim the recovery of damages as provided in the product liability regime of Royal Decree 1/2007 expires ten years after the defective product was placed on the market. The only way to stop this expiration date is to start legal proceedings.

Class Actions

Class actions for product liability claims are allowed but not common in Spain.

Article 11 of the Civil Procedural Code 1/2000 allows for collective legal proceedings. 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 persons who suffer damage.

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

Product liability claims are most commonly brought in Spain by individual lawsuits.

Remedies

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

An injured party has the right to receive compensation as an economic indemnity for damage caused by a defective product.

The product liability regime in Royal Decree 1/2007 extends to personal injury (including death) and to property damage (if the damage is to goods for private use or consumption that are mainly used by the injured party for those purposes). This can include economic and consequential damage.

Moral damage, damage to commercial property or property intended for professional use and damage to the product itself are not recoverable under Royal Decree 1/2007. The injured party can claim compensation for such damage under general civil and commercial law. Moral damage can be recovered under general civil law.

Punitive damages cannot be recovered under Spanish law. Only compensatory damages are available. However, the courts have some discretionary powers in awarding compensatory damages, and the defendant's conduct can be expected to have some impact on the amount of damages awarded.

Local Establishment, Representation and Residency Requirements

26. What local requirements apply to businesses and individuals (such as the person responsible for releasing a product onto the market) acting within or in relation to the jurisdiction?

An applicant for a marketing authorisation for a medicinal product must be established in the EU or have a local representative based in the EU.

A marketing authorisation holder established in another EU member state can appoint a local representative in Spain to carry out distribution activities (usually, a legal representative and a local representative are the same).

Marketing authorisation holders must have on a permanent and continuous basis a suitably qualified person responsible for pharmacovigilance in the EU. This person must reside and carry out their activities in the EU and is responsible for establishing and maintaining the pharmacovigilance system. The marketing authorisation holder must notify the name and contact details of the responsible person to the Medicines Agency and the EMA.

Reform

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

New Royal Decrees are planned to reform the reimbursement and pricing regulations (including on reference pricing and homogenous groups). According to announcements and consultations by legislative authorities, they mainly aim to:

- Allow reference pricing groups for medicines with the same active principle but 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.

A new Royal Decree is planned to reform Royal Decree 1015/2009, which regulates access to medicinal products in special situations. The Ministry of Health has started a public consultation to obtain feedback from subjects and organisations potentially affected. The reform mainly aims to:

- Differentiate between access to unauthorised medicinal products and access to medicinal products that are authorised but not effectively marketed for different reasons.
- Clarify under what conditions these medicines are available.
- Establish use or non-use recommendations for access to medicinal products under unauthorised conditions.
- Regulate use of the magistral formulation in special situations.

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