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Spain

Jordi Faus, Lluís Alcover & Joan Carles Bailach
Faus Moliner

Abstract

Spain is a very attractive market for pharmaceuticals within the European Union ("EU"). However, it is also a very regulated market, and the decisions are taken by different authorities at different levels. This is why market access can appear complex. In the following chapter, we will seek to explain the most significant rules that must be taken into account in order to understand the process of pricing and reimbursement in Spain.

Market introduction/overview

In 2021, the pharmaceutical market in Spain reached €20.9 billion, of which €8.4 billion correspond to the hospital market, and €12.5 billion to products dispensed through retail pharmacies. Growth was around 7%, with expenditure in hospital products exceeding 6.8% over 2020, whilst growth in retail pharmacies was 7.2%.[1] In 2022, YTD figures (until March 2022) show a 5.1% increase in the hospital market with respect to the same period of 2021 and a 7.1% increase of the retail market with respect to the same period in 2021.[2]

According to data of Farmaindustria (the association of the Spanish innovative pharmaceutical industry), the Spanish pharmaceutical industry is the most productive sector of Spain (double the industry average): it is one of the leaders in exports (exceeding €14.9 billion per year); and by comparison with other sectors in Spain, it has a higher concentration of stable, qualified and diverse employment (94% of its workers are permanent, 62% have university studies, and 52% are women).

As regards demographics, in December 2021 (last gross data available), 47.3 million inhabitants lived in Spain, with a gross birth rate of 7.9 births per 1,000 inhabitants and an average maternal age of 32 years. Life expectancy at birth reached 83.7 years. Since 2017, Spain has the classical pyramid of population of a developed country where the number of deaths increases more than the number of births. Data from Instituto Nacional de Estadística ("INE")[3] show that steady growth in births may be expected during the next 10 years at rates that may be near 0.5% but with a decline in population of almost 50,000 persons each year. The percentage of the population aged 65 years and over may reach 25% in 2033, and the number of persons that are dependent on others will continue increasing up to almost 60% in 2033.

In relation to the Spanish healthcare system, Article 43 of the Spanish Constitution establishes the right to healthcare as one of the basic principles that must inspire action by all public administrations, and this has been interpreted to recognise universal access to healthcare.[4] However, measures taken by the Spanish Government during the economic crisis that Spain suffered from 2008 to 2014 have affected such universal access to healthcare, setting forth some limits as regards the condition of beneficiaries of the system.[5]

These limits consisted basically in the establishment of some prerequisites in order to access healthcare benefits, such as: contributing to the Spanish Social Security System; having an authorised residence in Spain; holding pensioner status in the Social Security System; or being the beneficiary of any other periodic Social Security benefit, including unemployment benefits and subsidies. Those who have exhausted their benefit or unemployment subsidy and appear registered in the corresponding office as a jobseeker will also have access. Other than that, the measures taken determined that nationals of Spain, or of any EU Member State, the European Economic Area ("EEA") or Switzerland residing in Spain, and foreigners holding an authorisation to reside in Spanish territory, may hold the status of insured provided they can prove they do not exceed an income limit determined by regulation.[6]

Put into practice, these measures imply that a certain proportion of the population does not have access to the healthcare provision. This matter has been very controversial in Spain in recent times, resulting in fact, in contradictory judgements from Spanish courts. While the Constitutional Court of Spain declared that these limitations to healthcare provision access were valid, many regions in Spain avowed that the right to healthcare is universal in their territory. Many of the restrictions resulting from Royal Decree-Law 12/2016 were reversed by another Royal Decree-Law adopted on 27 July 2018 on Universal Access to the National Health System ("NHS").[7]

During the year 2019 (last data available), 1,391 presentations of medicinal products were included in the provision of the NHS.[8] Furthermore, Spain is a market with numerous innovative therapies included within the provision of the NHS.

In Spain, market access has two stages: (i) the granting of the marketing authorisation ("MA") by the regulatory agency (Spanish Agency of Medicines and Medical Devices, "AEMPS") or the inscription at AEMPS registry of products approved under the EU centralised procedure; and (ii) the resolution on pricing and reimbursement by the Ministry of Health ("MOH"). AEMPS also intervenes to some extent in the pricing and reimbursement procedure by issuing a so-called Therapeutic Positioning Report ("IPT", for its acronym in Spanish), on which the MOH relies when deciding on pricing and reimbursement.

Furthermore, an aspect that must be taken into account is that Spain is a decentralised country and regions play a large role in market access. Even though the MOH decides which therapies are financed, the regions allocate the budget for financing such therapies. This means that in the case of high budgetary impact products, companies must expect access to the market to be subject to agreements with regional authorities (or sometimes with local hospitals) regarding the conditions under which the product will be available in such region or hospital.

Pharmaceutical pricing and reimbursement

Regulatory classification

According to Article 19 of the Spanish Law on Medicinal Products (Royal Legislative Decree 1/2015), when AEMPS authorises a medicinal product, it will determine whether the product is subject to medical prescription or not.

The same Article establishes that certain medicinal products, when they meet certain conditions, will always be subject to medical prescription. This is the case for those medicines that may present a risk, either directly or indirectly (even under normal conditions of use), when they are used without medical supervision. The same happens with those medicinal products that are used frequently under abnormal conditions of use, and this may involve,

directly or indirectly, a risk to health. Spanish law also sets forth that those medicinal products that contain substances (or preparations based on these substances) whose activity and/or adverse reactions must be studied in more depth, must also be classified as subject to a medical prescription. The same applies to those medicinal products that are parentally administered.

AEMPS may also establish some subcategories for medicines that can only be dispensed under medical prescription. This will apply to products subject to a special medical prescription regime, or to products that can only be dispensed by certain means (such as medicinal products for hospital use). It is also relevant to note that the MOH may also establish restrictions as regards the prescription, dispensing and financing of some medicinal products within the NHS. These may include the need to go through a special visa procedure before the patient gets a given product under reimbursement by the NHS. Under Spanish law, the regions are not entitled to lay down local measures restricting the prescription, dispatching or financing of medicines or devices that have been accepted for reimbursement at a national level.

AEMPS may classify as medicinal products that are not subject to medical prescription those that are destined for processes or conditions that do not require an accurate diagnosis, or those whose toxicological, clinical or use evaluation data and route of administration do not require medical prescription. These medicines will be dispensed by a pharmacist who will inform, advise and instruct about their correct use.

Spanish law also contemplates the classification of medicines between brand medicinal products, generic medicinal products, biologic medicinal products or biosimilar medicinal products.

Article 2 of the Spanish Law on Medicinal Products (Royal Legislative Decree 1/2015) defines generic medicinal products as any medicinal product that has the same qualitative and quantitative composition in active ingredients and the same pharmaceutical form, and whose bioequivalence with the reference medicine has been demonstrated by adequate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active ingredient will be considered the same active ingredient, unless they have considerably different properties in terms of safety and/or efficacy. Biosimilar products are not defined under Spanish law, although there exist provisions under which all biological products are considered non-eligible for substitution without the prior approval of the prescribing doctor.

Under Spanish law, the distinction between over-the-counter medicines and non-prescription medicines does not exist, because the law only distinguishes between prescription and non-prescription medicines.

Who is/who are the payer(s)?

Spain's Autonomous Regions pay for all healthcare services from their own budgets and, subject to certain conditions that may derive from European and Spanish rules on public procurement, they enjoy a large degree of autonomy to decide how they purchase the goods and services they may require in order to provide healthcare services to patients.

The MOH is the department of the central government responsible for approving reimbursement of medicinal products. As explained, the public funds that may be used to finance this reimbursement come out of the budget of the 17 Autonomous Regions into which Spain is divided. Because of this, the regions participate in the specific committee at the MOH responsible for assessing applications for deciding on the maximum ex-factory price ("PVL") for reimbursed products. This committee is called the Interministerial Committee for the Price of Medicines ("ICPM").

This generates a complex situation where the basic content of the pharmaceutical provision is set forth at state level (because the MOH makes the decision on pricing and reimbursement) but where the Autonomous Regions are responsible for the financing of these medicines without being allocated a specific budget for each medicinal product, and having to administer their budget and complying with the basics of the pharmaceutical provision.

On the other hand, products that patients obtain at retail pharmacies are subject to co-payment rules under which the patient must pay part of the price of the product. The co-payment percentage depends on the type of product and also on the type of patient.

What is the process for securing reimbursement for a new pharmaceutical product?

The reimbursement process starts *ex officio* and it is compulsory, meaning that the marketing authorisation holder ("MAH") does not have the right to say that it is not interested in reimbursement and that it will launch the product right away. Under Article 92 of the Spanish Law on Medicinal Products (Royal Legislative Decree 1/2015), the MAH must go through this process so that the MOH decides whether the product shall be reimbursed and covered by the NHS or not.

In Spain, the process regarding pricing and reimbursement of a medicinal product that is centrally approved begins when AEMPS gives final clearance to the packaging materials that are to be used in Spain. Once AEMPS has approved the final packaging materials of the product, it shall record this decision and notify it to the MAH and to the General Directorate for Pharmacy and Medical Devices, which is the body within the MOH competent to rule on reimbursement. As explained, the reimbursement process then starts *ex officio*. The General Directorate for Pharmacy and Medical Devices shall send a letter to the MAH or to its local representative, informing it that the process has begun and granting the company a period between 10 and 15 working days to make any submission it deems convenient on the reimbursement of the product.

Under the law, the process to decide on pricing and reimbursement may take up to 180 days. Furthermore, the authorities usually request additional information, and these requests may stop the clock of the procedure. In practice, companies may well expect the reimbursement approval to run for a minimum of six months. Occasionally, procedures have taken up to a year.

Who influences the decision?

The most important decision-maker in the reimbursement process is the central government. The MOH, through the General Directorate for Pharmacy and Medical Devices and the ICPM, decides on reimbursement and then on price. In theory, the General Directorate for Pharmacy and Medical Devices is the first to decide on whether the product is reimbursed or not, and the ICPM then decides on the maximum reimbursed price. In practice, however, the two procedures run in parallel and overlap because the decision of the General Directorate for Pharmacy and Medical Devices regarding reimbursement is also based on the price that the ICPM would set for the product. The General Directorate for Pharmacy and Medical Devices, on the other hand, takes care of process management, preparing the rulings that the ICPM shall adopt; it is also the *de facto* leader of the negotiations with the MAH, and coordinates the work carried out by evaluation teams who handle the dossiers prior to the meeting of the ICPM.

AEMPS has a major role in the reimbursement process when issuing its IPT. In 2020, a network called REvalMED was set up and has become responsible for the coordination

of the whole IPT process from late 2021 onwards. REvalMED comprises a therapeutic evaluation group (led by AEMPS), an economic evaluation group (led by MOH) and therapeutic area specialists. Within REvalMED, AEMPS still retains significant power, especially with respect to the therapeutic evaluation of the product; however, this power is shared with the General Directorate for Pharmacy and Medical Devices of the MOH, which has increased its influence on the IPT process, mainly with respect to the economic evaluation. Moreover, the Autonomous Regions have a remarkable role in this decision because they are funding the dispensing of the product to the patient. This is also why three of the Autonomous Regions are members (on a rotating basis) of the ICPM. At present, representatives of all other Autonomous Regions may participate as observers at all ICPM meetings. Autonomous Regions also have a relevant role within REvalMED, providing input to the therapeutic and economic teams led by AEMPS and the General Directorate for Pharmacy and Medical Devices, respectively, and appointing "expert reviewers" that will be entitled to review and provide comments on IPTs drafts before their approval.

On the other hand, whilst the central Spanish legislature and government have exclusive competence to enact legislation on medicinal products, the Constitutional Court has established in several cases that this applies to the rules related to the evaluation, approval and surveillance of medicinal products, but not necessarily to the rules relevant to how individual patients may get access to medicines.[9] This is essential because the Autonomous Regions are thus competent to establish the specific procedural rules that may apply to how the patients may get access to reimbursed products.

It is also worth noting that other relevant stakeholders may include doctors, medical and hospital pharmacy societies and patient associations, who may try to exercise some influence. Anyhow, the procedure is bilateral, and between the interested company and the MOH. Other entities (including associations, competitors, etc.) do not have legal standing to intervene as interested parties, nor do they have the right to make allegations. Regarding the right of access to the information provided by the interested company, we refer to the "Confidentiality and transparency" section below.

What pharmaceutical products are eligible/ineligible for reimbursement?

Under Article 92 of the Spanish Law on Medicinal Products (Royal Legislative Decree 1/2015), the inclusion of a medicinal product in the financing of the NHS is decided according to a selective funding system and taking into account general objective and published criteria, more precisely, the following:

a) the seriousness, duration and sequels of the pathologies for which the product is approved;
b) the needs of special groups of people;
c) the therapeutic and social utility of the product as well as its incremental clinical benefit, taking into account its cost and effectiveness;
d) the need to limit and rationalise public pharmaceutical expenditure and the impact of the medicinal product on the NHS;
e) the existence of medicines already available and the existence of other alternatives for the same illnesses, which have a lower price; and
f) the degree of innovation of the product.

This being said, Royal Decree-Law 16/2012 introduced new rules stating that, when deciding on whether a product must be accepted for reimbursement or not, the MOH shall also specifically consider:

a) The impact that financing such product may have on the public budget.
b) A cost-efficiency analysis. For the purposes of this analysis, the MOH shall rely on an IPT for "*Informe de Posicionamiento Terapéutico*" in Spanish) that the Coordination Group of REvalMED shall approve, and on the opinion of the Advisory Committee on Pharmaceutical Coverage. Any studies that the MAH may present may also be considered.
c) The innovation of the product: whether it provides an indisputable therapeutic advance for altering the course of an illness or easing the course of such illness; and its prognostics, results or contribution to the NHS.
d) The contribution of the product to Spain's gross domestic product. This is awkward because it could indicate that local manufacturing or development operations have an influence on pricing and reimbursement; something which would be entirely contrary to EU law principles.
e) The return mechanisms that may be proposed by the MAH (discounts, price reviews). This is the result of the increasing relevance that risk-sharing schemes are currently having in Spanish practice; many companies, especially for high-budgetary-impact products, are required to offer specific arrangements to obtain reimbursement. These may be in various forms, including caps on the number of units that will be reimbursed by the NHS and chargebacks in the event that some established therapeutic results are not achieved.

The medicines that are directly excluded from the pharmaceutical provision are: those that are not subject to medical prescription; medicinal products that are not addressed at healing a concrete illness; and products that are considered cosmetics, dietetics, mineral waters, elixirs, dentifrices and other similar products. Spanish law also specifies that those medicinal products that are indicated for syndromes or illnesses of minor severity, and those that do not respond to current therapeutic needs, shall also be excluded from the pharmaceutical provision.

What is the relationship between pricing and reimbursement?

Under Spanish law, the ICPM determines the maximum price for the units of the products that are reimbursed by the NHS. The MOH will also take note of the so-called "notified price". The notified price is the price at which the MAH intends to market the product if it is not reimbursed by the NHS. This may apply to products that are not eligible for reimbursement and also to units of reimbursed products that are marketed outside the NHS (i.e., private patients or products that wholesalers may parallel-export from Spain to other EU Member States). The MOH, when receiving notice of the notified price, may only oppose to it on the grounds of protecting public interest. Further, it is worth mentioning that due to a recent modification of the Spanish Law on Medicines and Medical Devices (Royal Decree-Law 7/2020), the MOH may now establish maximum retail prices for non-reimbursed products sold in Spain (including non-prescription medicinal products) that might be needed for the protection of public health in the context of exceptional health crisis (such as the COVID-19 crisis). The only condition that the law imposes on the MOH is that its decisions must be based on objective factors and must be transparent. The fixed prices will remain valid throughout the duration of the exceptional circumstances that motivated the administrative intervention.

Finally, it is noteworthy to mention that the decision on financing a product does not have to affect all the therapeutic indications of such a product. It is viable that only certain indications of products are financed. In these cases, it is customary for MOH to make prescription of these products subject to a visa system.

How are drug prices set?

As regards setting the price of medicinal products, Spain has always been said to follow a "cost plus" system, under which the maximum PVL should respond to the cost of the product plus a given profit margin. This is what Royal Decree 271/1990 contemplates in accordance with the provisions of Directive EC 89/105.

The cost of the product is to be determined through the analytical application of the "Complete Cost", including R&D, manufacturing costs, and allocations corresponding to commercial and administration costs. In determining the Complete Cost, three groups of variables are established: variables that are considered; variables that are not considered; and variables that are subject to intervention and may be limited:

a) Variables that are considered:
   - Level of activity of the company.
   - Evolution of costs of the company.
   - Evolution of sales of the company.
   - Sales estimates.
   - Impact that manufacture of the product may have on overhead costs of the company.

b) Variables that are not considered since they are treated as unjustified or unnecessary costs:
   - Overvaluation of active substances in comparison with market prices.
   - Excessive royalties (trademarks or technology).
   - Promotion or advertising expenses that are not adequate to the characteristics of the product.
   - Expenses that are not necessary to the normal development of the activities of the company.

c) Variables that are subject to intervention and may be limited by the Government Delegate Commission for Economic Affairs:
   - "R&D".
   - Promotion and publicity.

Under Order of 17 November 1990, R&D expenses are not subject to any limitation. Therefore, R&D expenses may be incorporated into the cost of the product if they are justified, and prior deduction of all public aids granted to the company under R&D programmes. The R&D percentage that may be incorporated to the cost of the product is the equivalent of the percentage that the total expenses of R&D represent of the company's total sales.

As to promotion and advertising expenses, they may only be incorporated into the cost of the product within a range of 12–16% of such cost.

As regards the profit component, the rule is that the target profit of each company shall be within a range of 12–18% on capital allocated to exploitation, including own resources (share capital, update and revaluation accounts, reserves, and others) and external resources with financial cost.

Finally, we note that alternative pricing and reimbursement rulings, such as payment based on results, have become increasingly popular in the last years, particularly for medicinal products with a high budgetary impact and with an important R&D component such as CAR-T medicinal products. In this respect, on 22 October 2019, an information system[10] to support the collection and processing of health outcomes (the so-called "VALTERMED") was officially presented by the MOH.

Issues that affect pricing

As a matter of practice, it has always been known that the price-approval process entails

a negotiation with the authorities where the cost and the profit margin are not really the variables that are considered.

Companies should be prepared for prices mainly to be determined by the following two issues:

a) A comparative pharmaco-economic evaluation of the medicine in which the advantages of the new product should be quantified.
b) The price of the product in other EU Member States.

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

It should be noted that under the Spanish Law on Medicines and Medical Devices (Royal Decree-Law 7/2020), the authorities, when dealing with the price-approval process, must take into account the criteria mentioned above when discussing reimbursement approval. It is also true that in the case that a similar product is commercialised in the Spanish market, the authorities may use it in order to determine the price. The price of any competing product inside Spain will undoubtedly serve as a reference for the MOH when discussing the price of a new product.

Finally, it also relevant to highlight that IPTs, which will start including economic evaluations, are expected to significantly increase their influence on pricing and reimbursement negotiations going forward.

What is the process to appeal a decision?

Companies may file an administrative appeal against the decision taken by the ICPM once this is notified. The appeal must be filed within one month of the date on which the decision is considered to have been notified. These decisions are notified electronically, and companies have a period of 10 days to download the notice once they receive the alert that it is ready to be downloaded.

If the administrative appeal is rejected, the company may file a court action seeking a declaration that the ICPM acted wrongly. However, in pricing and reimbursement cases, the chances of a court action being successful are rather limited given that the MOH has wide discretionary powers on these matters. In general, companies have more chances of being successful at the administrative appeal level if they are able to provide evidence of some major mistake in the administrative decision.

In February 2022, the High Court of Justice of Madrid issued a judgment regarding a ruling of the MOH pursuant to which the reimbursement of a medicinal product was denied on the basis of "cost-effectiveness and budgetary criteria, and the existence of alternatives at low cost". The MAH challenged this decision on the grounds that it lacked sufficient statement of reasons, as it did not explain which studies had been conducted leading to the conclusions, nor did it provide cost-effectiveness data. In support of its claims, the MAH requested the court to appoint an independent expert that concluded that the medicinal product "is a unique, and [...] innovative product" and constitutes a "more beneficial alternative to plasma". Plasma was the lower-priced therapeutic alternative on which the MOH relied to deny reimbursement. The court assessed the expert report as required by law (in accordance with the logical and reasonable rules of evaluation) and concluded that its reasoning was convincing. On the basis of the above, the court ruled that the MOH must re-examine the medicinal product's dossier. On the basis of this judgment, we believe that the administration cannot resort to "technical discretion" in an indiscriminate manner. Whenever solid and substantiated data support different conclusions to those reached by the MOH, companies

may rely on such data to defend their position both before the administration and the courts. These data should be introduced in the relevant proceedings by way of expert reports, which may be issued by experts appointed by the court or by a party.

Finally, we note that courts cannot rule on the reimbursement of a medicinal product. For this reason, the effect of the judgment of the High Court of Madrid was the recommencement of the reimbursement proceeding before the MOH. This being said, it is important to highlight that the MOH, when re-examining the case, is bound by the Court ruling and, therefore, the MOH is not permitted to deviate from the Court's considerations and conclusions.

The administrative appeal does not suspend the application of the decision taken by the ICPM. The suspension may be requested when filing the administrative appeal and this request must be answered within one month. In this case, failure to respond by the MOH acts in favour of the appellant, because in such event the suspension is deemed granted. Afterwards, however, the MOH may lift such suspension when deciding on the substance of the appeal. In order for the suspension request to have any chance of success, the applicant must provide evidence that the immediate entry into force of the ICPM's decision will result in irreparable harm. Thus, the threshold is rather high, and this is why we normally consider that the chances of succeeding in a request for suspension are rather low.

One issue that often arises when dealing with administrative procedures in Spain refers to the general climate, and whether companies that are strict in enforcing their rights, and even file administrative or court appeals, may suffer some sort of negative reaction by the MOH. Our opinion, based on over 20 years of experience dealing with these matters, is that neither AEMPS, nor the MOH nor the ICPM penalise companies for defending their position – provided this is carried out under general good faith principles. In some cases, special diplomacy may need to be exerted to ensure that the position of the company is not misinterpreted – it is important to play fair – however, in general terms, it is not something to be too concerned about.

Reference pricing

It is also crucial to bear in mind that in Spain, the public financing of medicines is subject to a reference price system. Once a generic version of a medicinal product is approved, or even in other circumstances if no generic exists in Spain but the main active ingredient of a product has been generally available in the EU for the last 10 years, the MOH may make it subject to a reference price, which will apply to all financed product presentations having the same level 5 of the Anatomical Therapeutic Chemical ("ATC") Classification System of the World Health Organization and identical administration route.

The reference price is the maximum price that the Spanish authorities will pay for these products when they are prescribed and dispatched through an official prescription at a pharmacy. Such price is fixed on the value represented by the lowest cost of the treatment per day of the presentations of the medicinal products included in each group. The reference price system, as an instrument designed to guarantee the sustainability of the public pharmaceutical provision, uses the appearance on the market of competing products at the same ATC 5 Classification to establish a maximum price for the dose necessary for a day of treatment with this substance, which is the maximum price that the NHS will satisfy when the presentations with this substance are dispensed or administered to the patient charged to public funds.

Whether reference price groups must be created with presentations having the same "active substance" or the same "ATC 5 Classification" has been a controversial matter in Spain since

2014. While Article 98 of the Spanish Law on Guarantees and Rational Use of Medicines (Royal Decree-Law 1/2015) used to unambiguously contemplate that reference price groups had to be created with product presentations having "the same active substance", it was not unusual for the MOH to conform groups with presentations having the same ATC 5 Classification rather than the same active substance. This way of acting of the MOH led to many claims before Spanish courts where companies argued that the MOH was inadequately including product presentations with different active ingredients in the same reference pricing group. In 2017, the Supreme Court declared that if the MOH wanted to include two product presentations in the same reference price group on the basis of the ATC 5 Classification, the MOH had to provide sufficient evidence that the active ingredients of the two presentations were the same; otherwise, such presentations could not be included in the same group. This 2017 Supreme Court decision was followed by many others with the same rationale. In view of these court rulings, the MOH changed its criterion and in 2020, it updated many reference price groups following the active-substance-criterion. However, shortly after this decision, Article 98 of the Spanish Law on Guarantees was amended to specifically contemplate the ATC 5 level criterion to conform reference price groups. In general terms, when a medicinal product is included in the reference price system, one can expect a 40–50% reduction in the price of the reference/s product/s (the price of generics is likely to be within this range).

Between 2019 and 2022, Spanish courts ruled on several cases related to reference pricing.

A first group of cases revolve around the interpretation of the requisites laid down in Spanish law for the creation of reference price groups. In October 2019, the National High Court (*Audiencia Nacional*) of Spain had the chance to rule on an interesting case regarding the creation of reference groups when no generic or biosimilar exists in Spain.[11] In that case, the plaintiff was the MAH of an exenatide product with two presentations (an immediate release formulation and a delayed release formulation). The plaintiff claimed that the MOH inadequately created a reference price group with both presentations because such presentations were, in fact, the same medicinal product. The Court did not share this view, and resolved that the creation of the group had been correctly carried out by the MOH because the two presentations were to be considered different products for reference price purposes. The Court supported its position with the fact that the two presentations had separate MAs and were commercialised under different trademarks. The Court did not consider the fact that the two presentations were part of the same global MA for data protection purposes. An appeal against this judgment was presented to the Supreme Court. On 1 October 2020, the Supreme Court admitted the appeal and clarified that the controversial matter that was sufficiently relevant to be submitted to the Supreme Court was "whether a reference price group may be created exclusively with presentations of the same medicinal product that, despite being commercialised under different names/trademarks, are owned by the same company". On 28 June 2021, the Supreme Court dismissed the appeal and confirmed that, indeed, a reference price group may be created exclusively with presentations of the same medicinal product that are commercialised under different names/trademarks but owned by the same company. The Supreme Court considered that the fact that the presentations are marketed by the same company is irrelevant for the purpose of forming a reference price group because the law does not give any relevance to this circumstance.

A second group of judgments refer to matters related to the challenging of already-formed reference price groups. In this group, we find particularly interesting a judgment of the National High Court in October 2019, which discussed the test that should be carried out to determine whether the commercialisation of a product is economically viable after the price

reduction operated by its inclusion in a reference price group.[12] The Court considered that such test should compare the PVL with the actual commercialisation and manufacturing costs of the product, and disregard any profit margin. Although the Court finally refused the plaintiff's arguments on the basis that the plaintiff did not provide sufficient evidence about the costs associated to the product, the message conveyed by the Court is relevant to the extent that it expressly recognises that a product may be deemed economically inviable if the plaintiff can prove that its PVL falls below its manufacturing and commercialisation costs. As a final comment, we note that in the recent past, Spanish courts have usually been reluctant to accept this type of economic rationale when companies challenge the inclusion of its products in reference price groups.

A third group of judgments refer to cases where plaintiffs argued that the MOH was inadequately conforming reference price groups on the basis of the ATC Classification System. Such cases, however, have become moot because, as mentioned, the law was changed with effect as from 1 January 2021 to contemplate that reference price groups must be created with presentations having the same ATC 5 Classification rather than the same active substance.

Finally, we note that on 3 March 2020, the Spanish Government approved a resolution pursuant to which it was declared that orphan medicinal products with no therapeutic alternative (or with a therapeutic alternative but providing a significant benefit with respect such alternative) would not be subject to the reference price system.

In 2021–2022, there have been three rulings regarding the subjection of orphan medicinal products to the reference price system.

First, on 2 December 2021, the National High Court issued a judgment of great importance on this matter following an appeal lodged by Farmaindustria against the 2019 Order updating the reference price system. The ruling stated that Regulation 141/2000 on orphan medicinal products prevails over national regulation; that Article 98(2) of Royal Legislative Decree 1/2015 is an obstacle to the fulfilment of the objectives of European regulation; and that, therefore, Article 98(2) of Royal Legislative Decree 1/2015 should not be applied with respect to orphan medicinal products. Article 98(2) of Royal Legislative Decree 1/2015 is the main rule in Spain regarding the reference price system and states that all presentations of reimbursed medicinal products (regardless of whether they are orphan or not) with the same ATC 5 level and identical route of administration are subject to the reference price system. This judgment of the National High Court did not mention the Resolution of 3 March 2020. However, and with all necessary caveats, it seems reasonable to conclude that, according to the judgment, orphan medicinal products should be excluded from the reference price system unconditionally, as required by Regulation 141/2000's primacy over Spanish national law. This judgment of the National High Court was not appealed and, therefore, it became final.

Second, in February 2022, the Supreme Court issued two judgments that essentially ratified the validity of the 3 March 2020 Resolution. As per the Supreme Court, it is not correct to state that orphan products shall not be, in general, subject to the reference price system. As per the Court, the general rule shall be that orphan medicinal products are subject to the reference price system as any other medicinal product ex Article 98(2) of RDL 1/2015, which, according to the Court, does not contravene Regulation 141/2000. Only those orphan products that comply with the provisions of the 3 March 2020 Resolution (i.e., products with no authorised therapeutic alternative or, if such alternative exists, products that provide a "significant clinical benefit" against the alternative) may be excluded from the reference price system after the corresponding administrative proceeding contained therein.

As a result of these rulings, there is some uncertainty in Spain with respect to the regime of orphan products to the extent that there are two contradictory judgments: one of the National High Court (which is final); and two of the Supreme Court. We shall wait and see how this matter settles.

Compulsory discounts

For many products, compulsory discounts or chargebacks apply. The general rule in this respect is that products for which no generic competition exists will be subject to a discount of 7.5% on their maximum PVL (4% in the case of orphan drugs). If a product has been on the market for more than 10 years, the discount will apply even if there is no generic competition, unless the product is still covered by product patent protection in any EU Member State.

Annual reviews

The MAH of products with a high budgetary impact might expect that decisions on pricing adopted by the ICPM will be subject to annual review, which may be triggered *ex officio* by the MOH. Actual sales of the product being greater than the sales forecast submitted by the company during the price and reimbursement proceeding is one of the reasons that may trigger an *ex officio* price review. In this regard, we note that on 5 June 2020, the High Court of Justice of Madrid confirmed that the price reduction of a product, due to a 15% deviation between the forecasted and actual sales of such product, was in accordance with the law.

From January 2021 until April 2022 (last period with available information),[13] the ICPM has reviewed the price of 53 products. Such reviews ended with 42 price increases and 11 price reductions.

As one may expect, the *ex officio* annual review procedure will aim to lower the price of the product. Within the procedure, the MOH shall grant the company a period of 10 working days to file documents and allegations in support of its position.

May patients have access to an approved drug while the pricing and reimbursement process is still open?

Under Royal Decree-Law 1/2015, a medicinal product that has received an MA valid in Spain cannot be placed on the market in Spain until the pricing and reimbursement process has been completed. However, under Royal Decree 1015/2009, in these situations the product may be available for patients under the rules that apply to products for which a valid MA exists in Spain but which are not commercially available.

These rules allow access to the product if the prescribing doctor, under their own responsibility, considers that the use of such product is indispensable for the treatment of an individual patient because no other equivalent product is available in Spain. An equivalent product is one having the same composition and the same pharmaceutical form. The patient – or the patient's representative – must consent in writing the prescription, after having been informed about the benefits and risks of the treatment, and the written approval of the management direction of the healthcare centre where the patient is treated must be obtained. The law also states that: prior administrative approval from AEMPS for each individual case must be obtained; the prescribing doctor must respect any special restrictions resulting from the protocols approved at the healthcare centre; and they must also report to AEMPS the results of the treatment and any suspected adverse events.

The units of the product supplied under either of these routes can be charged to the healthcare centre requesting such medicinal product. The price is fixed by the importer normally after negotiation with the pharmacy service of the healthcare centre. The common practice is to stick to the "international" price of the product. However, there are some caveats to this: first, as a matter of practice, it is not uncommon that some units provided under this route are supplied free of charge. At present, there is no legal obligation to do so in Spain, but this is not uncommon. Second, if the product is for a patient who has previously participated in a clinical trial with this product in Spain, and the sponsor continues to receive information from the doctor/healthcare centre as regards the treatment results of such patient, then the supply must be free of charge until the product is effectively marketed in Spain after receiving all relevant approvals (Article 31 of Royal Decree 1090/2015 on clinical trials).

We note that Royal Decree 1015/2009 is under review, and it is likely to be replaced in the near future. A public consultation with respect this initiative was run in December 2020–January 2021 with the objective to inform all relevant stakeholders and citizens and to invite them for feedback. The need to differentiate the regimes (currently unified under Royal Decree 1015/2009) applicable to access to non-authorised products and to access to authorised but not commercially available products has been identified as one of the topics expected to be addressed with the reform.

What happens with products for which reimbursement is denied?

Up until very recently, there was a consensus in Spain in the sense that if the MOH decided to deny reimbursement, the MAH could still place the product on the market for patients or hospitals who wish to acquire the product at the notified price. The only regulatory requirements would be two. First, to inform AEMPS about the fact that the product would be commercially available. Second, for hospital use products purchased by hospitals, approval is required from the regional authorities where the hospital is located and are granted as per the process determined by each region.

This consensus has been in danger since May 2019 when the General Director of Pharmacy issued a report stating that medicines for which a ruling expressly denying reimbursement has been adopted cannot be paid for by hospitals or regional authorities. This report is now the subject of major controversy. Our position is that it is null and void because the General Director of Pharmacy is not competent, under Royal Decree 1047/2018, which defines their authority, to issue a report that creates a new category of products (those for which a ruling expressly denying reimbursement has been adopted), and which is drafted under terms that restrict the ability of the regions and of hospitals to purchase those products, and the right of patients to have access to them.

Furthermore, we sustain that Article 17.6 of Royal Decree 1718/2010 states that hospitals may buy products that are not reimbursed subject to some special approvals and procedures handled by the regional healthcare services. The report states that Article 17.6 of Royal Decree 1718/2010 refers to medicines not included in reimbursement by the NHS, but not medicines that have expressly received a resolution of no reimbursement. We think that there is no passage of Royal Decree 1718/2010, or of any other law or regulation in Spain, that supports the idea that when Royal Decree 1718/2010 refers to medicines not included in the reimbursement of the NHS, it intends to differentiate between products that are not reimbursed because the law excludes them from reimbursement and those that are not reimbursed because a ruling expressly denying reimbursement has been adopted. This is a case where the general principle of law *ubi lex non distinguit nec distinguere debemus* applies (no differences should be made when the law does not establish them).

In 2019, a Spanish Court had the chance to rule on a significant case regarding the payment by regional authorities of medicinal products for which a ruling expressly denying reimbursement had been adopted.[14] In this case, the plaintiff (a minor patient with a severe genetic disease) claimed against the decision of a regional authority that refused to pay for the treatment that the doctor had prescribed. The plaintiff alleged that the refusal of the regional authority to pay for the treatment constituted a violation of its fundamental rights, including the "right to life", the "right to equality" and the "best interest of the child". The defendant regional authority argued that no fundamental rights were infringed and that there were no reasons to justify the payment of a product that the MOH had decided not to reimburse. The Court ruled in favour of the plaintiff and required the regional authority to pay for the treatment after recognising that the position of the regional authority infringed the right to equality of the patient (other patients in other Spanish regions were receiving the product free of charge) and the best interest of the child. The Court did not accept any violation of the right to life. As a final note, we point out that although this judgment does not specifically refer to the report of the General Director of Pharmacy mentioned above, it provides for a solution that is contrary to that of the report.

In March 2020, the High Court of the Basque Country issued an interesting ruling that recognised that denying a patient access to a treatment (even if such treatment is not reimbursed nor authorised in Spain but is authorised in the US) may violate the right to life of such patient if such denial poses a significant risk for the patient's life. In 2020–2022, Spanish courts have ruled on several cases regarding access to non-reimbursed medicines. In all cases, as occurred with the 2019 case outlined in the preceding paragraph, the Court ruled in favour of the plaintiffs (patients) after recognising that the conduct of the administration being sued amounted to an infringement of the right to equality of such patients: patients in the same exact situation were treated differently without any objective reason. A ruling of a Canary Court issued in September 2021 deserves to be highlighted because it insists on the idea that denying a patient access to a treatment may constitute a violation of the right to life in certain occasions.

Finally, we note that in May 2022, the MOH issued a report[15] describing the pricing and reimbursement procedure where the MOH insisted on the idea that public entities should only purchase medicinal products that the MOH has decided to reimburse. Although this document has no legal value, it shows the position of the MOH in this very delicate matter. Our position remains the same: we strongly advocate in favour of the right of public hospitals and regions to purchase medicinal products even if such products are not reimbursed by the NHS.

Confidentiality and transparency

Companies involved in a pricing and reimbursement procedure may need to disclose confidential information to Spanish authorities. Spanish law, in this respect, contemplates that the MOH may request the company to provide information about technical, economic and financial aspects related to the product and to the activities of the company. Article 97 of the Spanish Law on Medicinal Products (Royal Legislative Decree 1/2015) states that all information that the authorities may obtain from the company in these procedures is confidential. Moreover, under Article 52 of Law 7/2007, which is the general law on public employees, all civil servants are obliged to act in conformity with the law and to abide by the principle of confidentiality.

The decisions of the MOH on pricing and reimbursement are acts of public authority, taken in the ordinary course of its activity, and as such they are subject to the rules on transparency

and freedom of information contained in Law 19/2013 on Transparency, Access to Public Information and Good Government. Under Law 19/2013, any person, without the need to prove any special interest, might have access to documents that a public authority has created in the ordinary course of its activity, and the reasons for which such access may be denied are rather limited.

Until 2019, in cases where the Spanish Transparency Council received complaints against the MOH denying access to pricing and reimbursement rulings, it used to decide that the MOH should deliver these rulings to the party that had requested them, only not disclosing those parts of the ruling the transparency of which could cause unfair or disproportionate damage to the company. In these decisions, the Spanish Transparency Council took this position relying on the fact that Spanish law contemplates that the information that a company provides to the MOH when applying for pricing and reimbursement of a drug is confidential.

Between 2019 and 2022, the Spanish Transparency Council has had the chance to rule on several matters regarding access to pricing and reimbursement rulings. The position of the Spanish Transparency Council on this matter has been rather erratic during this period. On the one hand, the Spanish Transparency Council has issued several resolutions ordering the MOH to disclose copies of the rulings whereby the MOH accepted to reimburse certain products and fix their PVL. On the other hand, the Spanish Transparency Council has adopted the contrary position in other cases. In this respect, in September 2019 the Spanish Transparency Council denied the right of a citizen to have access to the price and reimbursement ruling of a medicinal product (and, therefore, to its PVL) on the basis that such access would damage the legitimate interests of the company. In this case, the Spanish Transparency Council assessed the value of keeping the PVL confidential from a public interest point of view, claiming that if prices were not confidential in the EU, they would tend to be fixed at a level that could be low for richer countries but too high for countries with less economic capacity, thus making access to certain products difficult.

On another note, it is worth pointing out that the information that the MOH makes public when uploading the minutes of the meetings of the ICMP on its website has increased since mid-2019.

In view of the foregoing, it is clear that both the administrations and the bodies in charge of settling claims arising from requests for access have a significant challenge ahead in order to find the right balance between the protection of commercial, economic and strategic information of companies and the principle of transparency that should govern the activity of the public administration.

In addition to the above, it is relevant to consider that under Spanish rules on public procurement, public contracting bodies are under an obligation to make public the main terms of any contract they enter into with any supplier of any good or service. In the event that the public contracting body understands that such publication may harm legitimate private or public interests, it may only redact the documents and avoid publishing some data after having obtained permission to do so from the Spanish Transparency Council (which will probably be reluctant to agree to not publishing information on the prices at which a hospital is buying a given product).

Between 2019 and 2022, the Spanish Transparency Council has also had the chance to rule on several cases regarding requests to disclose supply prices offered to hospitals. The position of the Spanish Transparency Council in this matter, again, has been erratic. On the one hand, the Spanish Transparency Council has ruled in favour of a citizen who requested

the disclosure of a list of all the medicinal products purchased by four specific hospitals from 2016 to 2018 (including units and prices paid for them by the hospitals) and also in favour of another citizen who requested access to the quantities of certain products (and their price) purchased by Spanish hospitals in 2018. On the other hand, the Spanish Transparency Council has issued decisions whereby disclosure requests have been denied. In this respect, the Spanish Transparency Council ruled against the disclosure of the "annual expenditure of hospitals in Madrid for three specific medicinal products" on the basis that the disclosure would harm the economic and commercial interests of the companies and would distort competition in the market. In some rulings, the Spanish Transparency Council relied on Law 1/2019 on Commercial Secrets to support the denial to release information on unit prices. It is also relevant to mention that during 2019–2022, the Spanish Transparency Council has issued four Interpretative Criteria (1/2019, 2/2019, 3/2019 and 1/2020) on how to evaluate access requests. Regarding access to pricing and reimbursement rulings, the Interpretative Criterion 1/2019[16] on how to evaluate whether disclosing certain information may cause harm to economic and commercial interests is particularly relevant. In this document, the Spanish Transparency Council states that when the requested information qualifies, in whole or in part, as a business or commercial secret under the terms of Law 1/2019 on Commercial Secrets[17] or is affected, in whole or in part, by a declaration of confidentiality contained in a law or established under the terms of the law, access must be denied by application of the limit of protection of economic and commercial interests established in Article 14.1.h of Law 19/2013 on Transparency, Access to Public Information and Good Government.

With respect to the position of the Spanish courts, the judgments published in the period 2019–2021 do not provide for clear and unequivocal criteria on this matter and, as occurs with the Spanish Transparency Council, their position has been rather erratic. In this respect, the three most recent rulings regarding access to price and reimbursement rulings (April 2020) and disclosure of supply prices offered to hospitals (May 2020 and March 2021) reached different conclusions. On the one hand, one judgment annulled a resolution of the Spanish Transparency Council that required the disclosure of the reimbursement terms of a new product on the basis that the MOH had not heard the affected company. The court recognised the right of the affected company to be heard and indicated that the process before the MOH should be started again from the beginning. On the other hand, the other judgment (May 2020) confirmed a resolution of the Spanish Transparency Council that ruled in favour of the disclosure of the price for medicinal products paid by Spanish public authorities during 2018. This judgment was appealed and annulled. A Spanish court ruled (March 2021)[18] that providing such information would violate the guarantee of confidentiality established in Article 97 of Royal Legislative Decree 1/2015. In addition, this judgment of March 2021 recognised that providing this information would affect the economic and commercial interests of the pharmaceutical companies that market them.

Finally, we note that in March 2021 the Supreme Court issued an important judgment confirming that if there is a risk that disclosure of a document undermines the protection of commercial interests of a third party, the Spanish Transparency Council (and not only the institution that initially receives and denies an access request) must consult with such third party before granting access to the document. The Supreme Court further stated that if the Spanish Transparency Council does not know the identity of such third party and does not have any data that allows such identification (this may happen when the institution that receives the access request at first does not consult with the third party before denying access), then the Spanish Transparency Council must order the proceeding to be resumed at

the point where the institution that received the access request (e.g., the MOH) should have consulted such third party.

Policy issues that affect pricing and reimbursement

The general political environment in Spain has affected the pricing of medicinal products. Over the last few years, budget constraints have been constant, and authorities have been strict and careful as regards pricing decisions.

It is relevant to mention that in late 2015, Farmaindustria reached an agreement with the Spanish Government (the "Farmaindustria Agreement") under which pharmaceutical expenditure was not to grow more than real GDP growth. The agreement contemplated chargebacks to be paid by pharmaceutical companies in the event that the expenditure exceeded the agreed ratio. The agreement also contemplated that if the expenditure exceeded the agreed ratio, special measures to rationalise the use of medicinal products may be adopted. These measures, in essence, would imply barriers for prescription of high-budgetary-impact drugs.

The Farmaindustria Agreement was fully effective until 30 June 2020. Since then, Farmaindustria and the Spanish Government have been negotiating a new agreement. No agreement has been reached so far.

With respect to the implementation of the Farmaindustria Agreement, it is worth mentioning that at the end of 2021, the members of Farmaindustria made a claw-back payment of approx. €331 million. Such payment referred to the financial year 2019 when the agreement was still in force.

As regards more specific groups of medicines, we would also like to mention the special situation for rare disease medicines in Spain. In 2009, the Spanish MOH launched the Rare Diseases Strategy of the Spanish NHS. This Strategy was approved by the Interterritorial Council of the Spanish NHS, a committee on which the MOH sits together with representatives of all the Autonomous Regions. The Rare Diseases Strategy of the Spanish NHS was therefore a document supported by the central Spanish Government and also by all the Autonomous Regions. One of the objectives of the Strategy was to secure prompt access to treatments, and the recommendation to such effect was to shorten the periods for pricing and reimbursement approval once an orphan drug has obtained the relevant MA. This recommendation was confirmed when the Strategy was updated in June 2014.

Emerging trends

Amendment of Royal Legislative Decree 1/2015

In July 2022, the MOH opened a public consultation on the first draft of the law that will amend the current Royal Legislative Decree 1/2015. The document published by the MOH shows that the reform that is being considered will have three principal axes:

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

certain products. The document also announces measures of additional pressure to the industry by stating that quarterly contributions may also apply to medicines dispensed in healthcare centres.

b) *The experience of the pandemic and the impact of new technologies*
The pandemic has created great challenges related to the availability of medicinal products and medical devices. In this sense, the MOH aims to consolidate the non-presential dispensing of medicines for hospital dispensing and telepharmacy in the NHS.

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

The process to approve this new law will be lengthy. After this public consultation period, the Spanish Government will prepare a draft of the new law and it will be put to a Public Hearing so that contributions can be made. After this, the Government will send the draft law to the Spanish Parliament for the legislative amendment to be processed.

Stability Program 2019–2022

The Stability Program 2019–2022, submitted by the Spanish Government to the EU, refers to various measures aimed at obtaining savings in public expenditure of medicinal products dispensed in pharmacy offices. Furthermore, some proposals on hospital expenditure are expected to be formulated by the Government in the near future.

a) *Medicine selection processes at the national level*
The most relevant proposal among those announced in the Program is the introduction of a national medicine selection system for medicinal products dispensable in pharmacy offices. The objective of this measure is to allow the MOH to benefit from the margins currently received by pharmacies when dealing with these products. Recommendations in this area point towards a purchase model based on tenders, with only one bid per laboratory, at a uniform price, and with an invitation to tender at European level (rather than a national level). The proposed model takes inspiration from Andalusia's medicine selection system, but with corrective mechanisms such as the elimination of exclusive supply, or the use of the system only for medicinal products for minor pathologies and with high economic impact.

b) *A new reference price system*
The Program contemplates a review of the current reference price system. In this regard, the Government proposes a system considering therapeutic indications (ATC 4) and active ingredients (ATC 5). The Program does not contemplate the introduction of an "avoidable co-payment system" that would allow patients to choose between branded and generic products by paying a higher price for the branded product if the patient wanted to do so.

c) *Decision-making and sustainability*
The Government proposes specific measures on the application of cost-effectiveness criteria in decisions related to reimbursed products, such as the introduction of a pharmacoeconomic evaluation method for medicinal products, and the measurement of health outcomes.
The Program also foresees the performance of *ex officio* reviews of the prices of products for treating chronic diseases with a high impact on the NHS. The need to reach sustainability agreements with the industry is also stressed in the Program. In this regard, the Program endorses the agreement already subscribed with Farmaindustria regarding this matter and shows a strong position in favour of its renewal.

d) *Measures to monitor prescriptions and expenditure*
Although this is a matter that mainly falls within the scope of the Regional Authorities' competences (and therefore not the central government's), the Program includes the following proposals: (a) the implementation and improvement of protocols for the supervision and follow-up of prescriptions; (b) the enhancement of electronic prescription and incentive systems; (c) the introduction of periodic control systems over certain kinds of medicinal products or groups of patients to mitigate consumption variations; (d) the interoperability of databases from different authorities; and (e) the development of educational plans aimed at the general public. All of the above seem reasonable measures, provided they do not inappropriately interfere with the freedom of the physician to prescribe the medicinal product that he or she deems appropriate.

Action Plan to promote the use of generic and biosimilar products[19]

In September 2019, the Interterritorial Council of the Spanish NHS (a committee on which the MOH sits together with representatives of all the Autonomous Regions) approved a draft of an Action Plan to foster the use of generic and biosimilar products. Subsequently, the MOH published the Plan for public consultation and asked all relevant stakeholders to submit observations and proposals with respect to the Plan. Such observations will be assessed in the Interterritorial Council of the Spanish NHS and, afterwards, the MOH will publish a revised version of the Plan.

As specifically stated in the Plan, its main and general objective is to foster the use of generics and biosimilar products (the so-called "regulatory" medicinal products) by facilitating the price and reimbursement proceeding for such products. Other specific objectives contemplated in the Plan include reducing the time elapsed between the authorisation of a generic or biosimilar and its inclusion in the reimbursement, increasing the competitiveness of the pharma sector, promoting the generic and biosimilar industry, increasing the use of generics and biosimilars in the NHS and enhancing the level of information regarding generics and biosimilars.

For the achievement of these objectives, the Plan proposes specific actions in the following areas: (a) reimbursement; (b) Pharmacotherapeutic Guide of the NHS; (c) prescription; (d) dispensation; and (e) information and training.

The publication of the Plan has generated a lot of interest and many stakeholders have actively submitted observations and proposals to the MOH.

Plan for the Consolidation of Pharmaceutical IPT

In 2020, the Permanent Commission of Pharmacy of the Interterritorial Council of the Spanish NHS approved the Plan for the Consolidation of Pharmaceutical Therapeutic Positioning Reports. This Plan, which was presented in November 2020 by the General Directorate for Pharmacy and Medical Devices of the MOH, reviewed the whole health technology assessment ("HTA") process in Spain and consolidated IPT as a key element of such HTA. The Plan included two major action lines that have already been implemented. First, the set-up of a new pharmaceutical evaluation network called REvalMED, responsible for the coordination of the IPT process. Second, improvement of the methodology of IPTs. Such methodology includes health economic evaluations, based on guidelines developed by the Group for the Evaluation of Innovations, Standardisation and Research in Drug Selection ("GENESIS") of the Spanish Society of Hospital Pharmacists ("SEFH"). As per GENESIS, the therapeutic positioning criteria are mainly defined by both the incremental cost-effectiveness ratio and budget impact.

Spanish Recovery and Transformation Plan (*Plan de Recuperación, Transformación y Resiliencia*)[20]

At its meeting of 17–21 July 2020, the European Council agreed to create Next Generation

EU, a temporary recovery fund additional to the EU multiannual budget for 2021–2027. Such funds are envisaged to be used to tackle the consequences of the COVID-19 pandemic and boost economic recovery. To access these resources, Member States were required to design "recovery and resilience plans" to be evaluated by the European Commission ("EC").

Spain presented its first version of its "recovery and resilience plan" in January 2021 and sent it to the EC in April 2021. The plan includes several references to the pharmaceutical sector in its 18th component (page 161) under the section "strengthening of the capabilities of the National Health System".

The 18th component contemplates funds amounting to €1,069 million and includes two subsections: "reforms"; and "investments". Both the reforms and the investments are listed but not described in detail. With respect to the reforms, we highlight Sec. C 18.R5, which contemplates "the approval of a national plan to rationalise the use of medicinal products and to promote sustainability", including measures such as the "reform of the regulatory framework for medicines and medical devices to introduce elements to foster competence and to facilitate access to new treatments". In this regard, the Spanish Government's Annual Regulatory Plan[21] (a document that includes legislative and regulatory initiatives to be submitted for approval during 2022) envisages the amendment of Royal Legislative Decree 1/2015 to incorporate new perspectives related to the public financing of medicines and the rational use of medicines.

With respect to investments, we outline Sec. C 18.15, which foresees "the approval of a national plan to rationalise the use of medicinal products and to promote sustainability".

Other trends

The rules contained in Royal Decree 271/1990 have been under review for a long time now. At the end of 2015, the Spanish MOH was working on a Royal Decree project that would have governed reimbursement of medicines, but which was never approved. In 2019, the MOH finally formed an Advisory Council on Pharmaceutical Coverage of the NHS, and works on the renovation of these rules may be expected to resume soon.

Successful market access

Pricing and reimbursement procedures in Spain entail a great deal of negotiation. As in any negotiation, defining a strategy will be of great importance. When doing so, companies must not forget that budgetary constraints in Spain are important, so they must be ready to be confronted with incredibly strong positions by the authorities that intervene in the process.

Successful market access depends on many aspects; however, the basics in order to access pharmaceutical provision are: to prove additional therapeutic value over the existing medicines that are already being financed (for which the IPT will be essential); and to be open to entering into risk-sharing agreements with the MOH.

* * *

Endnotes

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Law Professor at Carlos III University of Madrid, chapter 22 of the *Tratado de Derecho Farmacéutico* by Jordi Faus and José Vida (*Thomson Reuters Aranzadi*, 2017).

5. Those measures were established by means of Royal Decree 16/2012, of urgent measures to guarantee the sustainability of the Spanish NHS and improving the quality and security of the provisions contained within it.
6. This limitation was later annulled by the Constitutional Court of Spain in its judgment of 21 July 2016.
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Jordi Faus
Tel: +34 93 292 21 00 / Email: jfaus@faus-moliner.com

- Graduated in Law, Autonomous University of Barcelona, 1986.
- Diploma in Advanced Legal European Studies, College of Europe, Bruges (Belgium), 1987.
- Executive Management Programme at IESE, 2003.

Jordi Faus has been practising law for over 30 years. In 1997, he founded Faus Moliner, a Spanish boutique law firm specialised in legal matters typical of the pharmaceutical industry and of other companies that operate in the life sciences sector. Faus Moliner has been recognised as the leading firm in pharmaceutical and life sciences law in Spain by various Spanish and international publications.

Jordi Faus is the author of several publications on pharmaceutical and EU law. His works include *Pharma, a journey through the pharmaceutical industry* (2008) and the *Pharmaceutical Law Treaty* co-authored with Professor José Vida (2017).

Lluís Alcover
Tel: +34 93 292 21 00 / Email: lalcover@faus-moliner.com

- Graduated in Economics, Pompeu Fabra University, 2010.
- Graduated in Law, Pompeu Fabra University, 2012.
- Master's degree in Business Tax and Legal Advice, ESADE, 2014.
- Executive Management Programme, ESADE, 2017.

Lluís Alcover joined Faus Moliner in 2017 coming from PwC, where he worked for four years as part of the transactions legal team (M&A). Lluís Alcover has experience in investment operations, restructuring and due diligence processes, drafting and negotiation of all types of commercial contracts, as well as in regulatory matters affecting companies operating in the life science sector, including pricing and reimbursement proceedings.

Joan Carles Bailach
Tel: +34 93 292 21 00 / Email: jcbailach@faus-moliner.com

- Graduated in Political and Administration Sciences, Pompeu Fabra University, 2015.
- Graduated in Law, Pompeu Fabra University, 2017.
- LL.M. in Professional Legal Practice at UPF Barcelona School of Management, 2018.
- Master's degree in Economic criminal law & Compliance at UPF Barcelona School of Management, 2019.

Joan Carles Bailach has been practising law for over five years. He joined the team of Faus Moliner in 2019.

Faus Moliner

Rambla Catalunya 135, 08008 Barcelona, Spain
Tel: +34 93 292 21 00 / URL: www.faus-moliner.com

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