THE PHARMACEUTICAL INTELLECTUAL PROPERTY AND COMPETITION LAW REVIEW

FOURTH EDITION

Editor
Daniel A Kracov

THE LAWREVIEWS

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PREFACE

Despite the industry's critically important response to the covid-19 pandemic, which saved millions of lives around the world, the attacks on industry – and science – continue. The pharmaceutical business is under unprecedented pressure – pricing is a constant focus of new legislation, patenting and business strategies are under continual scrutiny, and regulatory and compliance burdens are growing. Combine that complexity with the fact that pharmaceuticals are truly one of the most global industries, with many companies operating in dozens of countries with differing legal regimes and healthcare systems, and you have a 'perfect storm' for industry lawyers.

While there has been significant harmonisation in certain areas, the nuances of these local frameworks require careful attention from both a strategic planning and operational perspective in order to achieve business objectives across jurisdictions. Maximising the value of intellectual property can make the difference in deciding whether to pursue the development of an important new treatment, and in maintaining success in the marketplace. Similarly, a failure to carefully manage risks in dealings with competitors, such as generic and biosimilar companies, can result in huge civil and criminal liabilities. As companies are all too familiar, this is an area of significant enforcement activity around the world, with large fines being imposed and transactions thwarted if applicable legal constraints are not heeded. Moreover, the links between intellectual property, such as exclusivities, and drug pricing and affordability are a constant source of political scrutiny, as well as patient and physician concern.

Our objective in structuring this updated volume is to give practitioners in the field a one-volume introduction to these critical issues in an array of jurisdictions. It is hoped this book will reduce some of the burdens associated with bringing new treatments and cures to patients while achieving global business success. I would like to thank the authors for their renewed contributions to this edition of *The Pharmaceutical Intellectual Property and Competition Law Review*; they have produced what we believe is a very useful tool for managing global risks in this area.

Daniel A Kracov
Arnold & Porter
Washington, DC
August 2023

Chapter 9

SPAIN

Teresa Paz-Ares, Alfonso Gutiérrez and Ingrid Pi i Amorós[1]

I OVERVIEW

The pharmaceutical industry is a strategic industry in Spain, owing not only to the nature of its activity but to its invaluable economic contribution. It is particularly relevant considering its heavy investment in research and development (R&D).

The pharmaceutical industry, which was directly affected by the covid-19 pandemic, is (and will continue to be) at the forefront of discussions regarding R&D budgets and priorities, digital transformation, transparency, patent protection, access to innovative medicines and cost-reduction measures, among other things. Cost-containment measures will almost certainly continue to play a prominent role in the following years, with a special focus on the authorities fostering generics and biosimilars.

This chapter provides an overview of the current legal situation regarding the pharmaceutical industry in Spain, paying particular attention to the most recent developments from a regulatory, intellectual property and antitrust perspective. In most cases, both the regulations (and guidance and interpretation documents) issued by EU institutions and Spain's own state and regional regulations, with their peculiarities, are relevant for these purposes.

II LEGISLATIVE AND REGULATORY FRAMEWORK

i Pharmaceutical regulation

The main piece of legislation governing medical products in Spain is Royal Legislative Decree 1/2015, approving the revised text of the law on guarantees and the rational use of medicines and medical devices (the Guarantees Law). It sets out the general principles applicable to the authorisation, manufacture, labelling, distribution, pharmacovigilance, promotion, dispensation, pricing and reimbursement of medicines for human and veterinary use (including generics and biosimilars), and medical devices.

The Guarantees Law was originally enacted in 2006 and has been amended several times since its enactment, notably during the 2008 financial crisis to incorporate several cost-cutting and savings measures, and during the covid-19 pandemic.[2] In June 2022, the

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1 Teresa Paz-Ares, Alfonso Gutiérrez and Ingrid Pi i Amorós are partners at Uría Menéndez Abogados, SLP. The authors would also like to acknowledge the contributions of Alejandro Abad, François Doumont and Alberto Pérez, who participated in the preparation of this chapter.

2 At the end of June 2023, once the health crisis caused by covid-19 had been declared officially over by Spanish authorities, the Guarantees Law was amended to include the possibility of carrying out home dispensing of medicines and medical devices, which had taken place in some Spanish regions during the pandemic. However, this provision is subject to further regulatory development by these regions.

Minister of Health opened a public consultation on the modification and update of the Guarantees Law, requesting operators' views on modifying the reference price system and updating provisions on medical devices, advertising of medicines and telepharmacy, among others. However, no specific proposals have been published and the reform process, for the time being, seems to be at a standstill.

The general principles laid down by the Guarantees Law are further detailed by specific regulations, depending on the type of medicinal product and its life cycle, from the most basic clinical development to placement on the market, prescription, dispensation and use.[3] Public purchasing of pharmaceuticals is governed by Law 9/2017 on contracts with the public sector (the Public Procurement Law) and subject to the general principles for public financing set out by the Law on Guarantees and Royal Decree 1030/2006, of 15 September, which establishes the portfolio of common services of the National Health System and the procedure for its updating (Royal Decree on NHS common services).

The Spanish Medicinal Products and Medical Devices Agency (AEMPS) is the main body responsible for all technical and quality aspects of medical products, while economic aspects (particularly pricing and reimbursement) are dealt with by the General Directorate for the Common Portfolio of National Health System and Pharmacy Services (the General Directorate), which is part of the Ministry of Health, and the Inter-ministerial Drug Pricing Commission, which is responsible for price-fixing. The 17 regional governments and other public contracting authorities, including public hospitals, are also competent to negotiate and reach specific pricing agreements with drug marketers, subject to the provisions of Public Procurement Law, the Law on Guarantees and the Royal Decree on NHS common services.

Among other initiatives designed to encourage innovation in the pharmaceutical sector, a prominent role is played by the Plan Profarma. The main objective is to boost competitiveness within the pharmaceutical industry in Spain through modernising the sector and furthering investment in new industrial plants and new technologies for production, and fostering research, development and innovation.[4]

In 2021, the government launched a series of strategic economic recovery and transformation projects (referred to as PERTE), one of which envisages significant public and private investments in innovation in the health sector from 2021 to 2023. The implementation of these projects, however, is proving to be slower than expected.

Pharmaceutical companies operating in Spain that supply their pharmaceutical products (or medical devices) to the Spanish National Health System (SNS) are required to

3 For example, Royal Decree 1345/2007 on the procedure for the authorisation, registration and supply conditions of industrially manufactured medicinal products for human use; Royal Decree 1015/2009 on the availability of medicines in special situations (Royal Decree 1015/2009); Royal Decree 824/2010 on pharmaceutical laboratories, producers of active ingredients for pharmaceutical use and the international trade of medicines and investigational medicines; Royal Decree 177/2014 governing the reference price and homogeneous groups system within the national healthcare system and certain information systems concerning reimbursement and pricing of medicines and medical devices; and Royal Decree 477/2014 on the authorisation of non-industrial advanced therapy medicines.

4 The current Plan Profarma was approved by means of the Resolution of 10 December 2021 of the General Secretary of Industry and Small and Medium-sized Enterprises. While previous plans had a duration of four years, this new plan has a duration of only two years (2021 to 2022). The Plan Profarma for the following period (including 2023) has not yet been approved.

make a contribution to the SNS, calculated on the basis of the volume of sales to the SNS. By participating in the Plan Profarma, they may benefit from certain reductions (up to 35 per cent), according to a varying scale depending on their valuation within the Plan Profarma.

The legal criteria for the inclusion of a medicine in the public reimbursement system and the setting of its price also mention (among many other factors) the medicine's degree of innovation, but in practice it is usually only considered to be relevant in respect of real 'blockbusters' as opposed to, for instance, improvements or follow-on innovations.

From time to time, proposals are put forward in Spain seeking to improve and guarantee access to medicines (including orphan medicines or advanced therapies), focusing, among others, on shortening the assessment process and approval times. Some of these issues are addressed in the reform proposal of the EU pharmaceutical regulations announced by the European Commission in April 2023. It remains to be seen, however, when and in which terms this legislation will finally be approved.

ii Competition regulation

In the field of competition, the legal framework is two-fold insofar as both Spanish and EU rules can concurrently apply to potentially anticompetitive practices and mergers and acquisitions (one or the other, depending on which set of thresholds is met) that have a potential effect in Spain. The main applicable Spanish competition provisions (including merger control) are set forth in Law 15/2007 on the defence of competition (LDC), which is implemented by means of the Regulations on the Defence of Competition approved by Royal Decree 261/2008 (RDC).

Leaving aside rules governing state intervention in companies, the main applicable EU competition rules are Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU),[5] which ban, respectively, anticompetitive agreements between companies and abuse of dominance. These primary rules are supplemented by secondary law in the form of parliamentary and council legislation, as well as European Commission regulations and guidelines. Council Regulation (EC) No. 139/2004 on the control of concentrations between undertakings (Regulation 139/2004)[6] sets up the EU merger control regime.

EU and Spanish competition rules fully apply to the pharmaceutical industry to the extent that there is an economic activity. Nonetheless, the Court of Justice of the European Union (CJEU) has ruled, in a case concerning the SNS, that certain activities carried out by the state in the context of free universal healthcare services that are financed through social security contributions and other state funding do not qualify as economic activities for the purposes of applying competition rules.[7]

iii Patent and exclusivity regulation

Both Spanish and European patents (designating Spain) coexist in the Spanish patent arena. Spanish patents are governed by Law 24/2015 on patents and utility models (the Patents Law). In line with the requirements of the Agreement on Trade-related Aspects of Intellectual Property Rights, Spanish patents last 20 years as of the date of the application.

5 Official Journal of the European Union C-326, 26 October 2012, pp. 1–390 (consolidated version).

6 Official Journal of the European Union L-24, 29 January 2004, pp. 1–22.

7 Judgment of the Court of First Instance of 4 March 2003 in Case T-319/99 *FENIN v. Commission*, upheld by Judgment of the Court of Justice of 11 July 2006 in Case C-205/03 P *FENIN v. Commission*.

Spain has been party to the European Patent Convention (EPC) since 10 July 1986. In line with Article 65 of the EPC, the effectiveness of European patents in Spain is subject to a further requirement (currently foreseen in Article 155.2 of the Patents Law), specifically the filing with the Spanish Patents Office of the translation into Spanish of the relevant patent pamphlet within a three-month period of the date when the grant was published in the European Patent Gazette.

Supplementary protection certificates (SPCs) for medicinal products are granted by the Spanish Patents Office under Regulation (EC) No. 469/200.

The enforcement of Spanish patents, European patents designating Spain and SPCs are governed by both the Patents Law (with regard to specific patent issues, such as time periods, specific remedies, damages, amendments of claims during the proceedings and standing) and Law 1/2000 on civil procedure (for broader procedural matters, such as evidence, hearings and appeals).

In addition to the protection granted by patent legislation, the Commercial Court of Barcelona has also granted pretrial relief based on unfair competition law in two cases in which the patent's formal granting had not yet been published. These cases involve very specific circumstances in which the European Patent Office had already ordered that a patent be granted but needed several months to publish the patent's formal granting to fulfil internal administrative procedural steps. The Commercial Court ruled that launching generics before the patent's formal grant had been published was an act of unfair competition owing to undue hindering, since it de facto deprived the claimant from its patent rights.

The Guarantees Law grants the originator eight years of data exclusivity (during which no application for marketing authorisation of a generic or biosimilar can be sought) and two or three additional years of market protection (as generic drugs cannot be commercialised until 10 years after the date the initial authorisation of the reference medicinal product is granted, or 11 years if a new indication is approved during the first eight years).

Finally, in connection with orphan medicines, Regulation (EC) No. 141/2000 establishes a 10-year market exclusivity period during which no application for a marketing authorisation can be accepted for the same therapeutic indication and in respect of a similar medicinal product. This market exclusivity may be extended in the case of completion of a paediatric investigation plan.

In addition to this market protection, the exclusion of orphan medicines from the reference price system must also be taken into account (see Section II.i).

III NEW DRUGS AND BIOLOGICS – APPROVAL, INCENTIVES AND RIGHTS

i Drugs

Approval scheme

To be placed on the Spanish market, drugs must have obtained a prior marketing authorisation from the AEMPS, under the national, mutual recognition or decentralised procedures (or from the European Medicines Agency (EMA), under the centralised procedure) and be registered with the AEMPS's medicines registry.

The national authorisation procedure is regulated by Royal Decree 1345/2007. The authorisation process, following the principles established at the EU level, requires the

submission of a detailed application that covers all aspects of the medicine, the results of preclinical, clinical and pharmaceutical investigations, and relevant expert reports. The documentation is assessed by the AEMPS, which may request additional information.

The assessment of the positive therapeutic effects of the medicinal product will be considered in relation to any risk related to the quality, safety and efficacy of the medicinal product for the patient's health or public health, under a risk-benefit balance approach. The AEMPS then issues a reasoned report, which, if unfavourable, is sent to the applicant before a decision is taken.

In accordance with EU law, as implemented in Spain, the decision of the AEMPS must be issued within 210 calendar days of the submission of a valid application.[8] This term can be extended for three months (or exceptionally six months) if the applicant is requested to provide additional documentation. The authorisation will be valid for five years and may be extended for an indefinite period, subject to the risk-benefit ratio being reassessed.

Once authorised, the authorities must be notified before a medicine can be placed on the market for the first time. If, within three years after the authorisation is granted, the marketing authorisation holder does not actually place the product on the market or if, after it has been authorised, registered and marketed, it is no longer actually present on the market for three consecutive years, the authorisation for a medicinal product will be deemed to have expired. This 'sunset clause' does not apply, however, when health-related reasons so require, in which case the AEMPS will maintain the validity of the authorisation and may require the effective marketing of the product.

Under certain circumstances, the Spanish regulations also include exceptions to the above-mentioned procedure. In particular, unauthorised medicines can be supplied in special situations (e.g., compassionate use or foreign medicines use). These authorisations can be granted on a named-patient basis or under a general protocol applicable to a category of patients.

Pricing and reimbursement

Before marketing a prescription medicine, the pharmaceutical company must submit it to the national health authorities so that they decide on its inclusion in the reimbursed medicines system. The process to obtain a resolution for pricing and reimbursement is taken at a state level (the Ministry of Health).

The inclusion of a medicinal product in the reimbursement system by the SNS is made possible 'through a selective and discriminatory financing system' that takes into account general, objective and published criteria. Specifically, the following criteria are considered for the purposes of reimbursement decisions:

a the severity, duration and effects of the various pathologies for which the medicine is prescribed;

b the specific needs of certain patient groups;

c the therapeutic and social usefulness and the incremental clinical benefit of the medicine, taking into account its cost-effectiveness;

d the rationalisation of public expenditure on medicinal products and the budgetary impact the medicine's inclusion will have on the SNS;

8 It must be noted that the average time for a medicinal product to become available to patients from the time of authorisation by the competent regulatory authorities is significantly longer.

e the existence of medicines or other therapeutic alternatives for the same diseases with a lower price or lower treatment cost; and

f the degree of innovation of the medicine.

Pharmacoeconomic aspects of the product are considered in addition to the relevant cost-effectiveness and budgetary impact analysis, such as its contribution to the sustainability of the SNS if, for the same result, its contribution to the national gross domestic product is positive.[9] In this regard, the Permanent Pharmacy Commission of the SNS Inter-territorial Council approved in 2020 a 'Plan for the consolidation of therapeutic positioning reports of medicines in the SNS' to enhance the process for the assessment of the pharmacoeconomic aspects of these products within the SNS by, among other things, creating a medicines evaluation network (REvalMed SNS).[10]

Further, most of the regional health authorities perform their own – sometimes informal – cost-benefit assessment prior to allowing the use of new medicines. These factors continue to significantly delay the launch of innovative medicines.

A polemic issue that has given rise to extensive debate in Spain refers to the transparency and publicity of the procedure for setting the prices and reimbursement conditions of medicines.[11]

Finally, even though the existing regulation[12] is not crystal clear in this respect, in practice, the health authorities expected pharmaceutical companies to refrain from marketing

9 Once a product is listed for reimbursement, specific prescription, dispensation and financing conditions may be imposed on reimbursed products to ensure the rational use of the medicinal product within the scope of the Spanish National Health System (SNS); thus, for example, it is not uncommon to find medicines for which reimbursement by the SNS requires that they are dispensed in hospitals, while the summary of product characteristics contains no such dispensation restrictions.

10 'Plan para la consolidación de los Informes de Posicionamiento Terapéutico de los medicamentos en el Sistema Nacional de Salud, Comisión Permanente de Farmacia del Consejo Interterritorial del SNS', 3 February 2020, updated 8 July 2020.

11 The Spanish Transparency and Good Governance advisory body (CTBG), and some subsequent court decisions, have been resolving different matters concerning the balance between, on the one hand, the general right of the public to information and transparency, as enshrined in Law 19/2013 on transparency, access to public information and good governance (and at the EU level, regarding medicinal products, in Council Directive 89/105/EEC) and, on the other hand, the protection of business and commercial interests of marketing authorisation holders. The Ministry of Health stands for the need to maintain the confidentiality of information concerning the price of medicines as it allows 'each country to achieve the best possible price according to its circumstances', claiming that 'if there were no confidentiality at the European level, prices would tend to equalise in a single value that could be relatively low for the richest countries, but too high for those with less economic capacity', which 'could hinder access to patients in those countries with fewer resources' (see CTBG's Resolution 478/2019 of 26 September); however, the CTBG has not always upheld these arguments, ruling in some cases that certain documentation within the administrative files of a medicine's price setting, which is non-confidential or does not affect the economic interests of the marketing authorisation holder, must be provided to the applicants. Spanish courts have in some cases upheld arguments limiting access to certain information on the price of medicinal products on the basis of the exceptions provided for in the Law 19/2013 (e.g., the Administrative Chamber of the National High Court, in a judgment of 30 March 2021, relying on a report issued by the Ministry of Health).

12 Article 93 of Royal Legislative Decree 1/2015 (the Guarantees Law), Royal Decree 1416/1994 on the promotion of medicines and Royal Decree 1015/2009.

and promoting medicines until all the relevant pricing and reimbursement formalities have been completed. This restriction was also included in the Code of Ethics of the Pharmaceutical Industry.

However, on 30 June 2021, the High Court of Justice of the Basque Country region[13] ruled that the applicable regulations cannot be interpreted as prohibiting the promotion of medicines that hold a valid marketing authorisation, even if the competent authorities have not yet decided on their pricing and reimbursement.

Shortly after this judgment, the Spanish Pharmaceutical Industry (Farmaindustria) amended its Code of Ethics (September 2021) to expressly provide that medicines could be promoted from the moment of their authorisation, provided that the promotional materials indicate that price and reimbursement proceedings are pending.

Despite this, some regional health authorities continue to prevent pharmaceutical companies from promoting authorised medicines while price and reimbursement proceedings are pending and have started infringement proceedings against those that carried out promotion of those medicines relying on the Basque judgment and the Farmaindustria Code of Ethics. In particular, the Judgment of the High Court of Justice of Madrid (Contentious-Administrative Chamber) No. 621/2022 of 17 June 2022 ruled that the advertising of a medicinal product that was made before a decision on its financing had been obtained was contrary to the applicable laws. The discussion on this matter is therefore still open.

In April 2023, a new royal decree on the advertising of medicinal products was submitted to the general public for prior public consultation. However, no draft of this new proposal has been published, so it still remains to be seen whether new regulations will be enacted to provide clear rules on this issue and how it will evolve in practice.

ii Generic and follow-on pharmaceuticals

Simplified procedures are in place under Spanish legislation implementing Directive 2001/83/EC for generics of medicines that have been authorised in other jurisdictions for at least eight years (even if not authorised in Spain) and active principles that are regarded as having had a 'well-established use' in the European Union for 10 years and are known to be effective and safe.

The Guarantees Law sets out a simplified procedure for granting marketing authorisations for generic drugs. In particular, there is no obligation to provide the results of the required preclinical and clinical trials if it is proven that the medicinal product is a generic of a reference medicinal product[14] that is or has been authorised for a minimum of eight years in any EU Member State or by the EMA, even if the reference medicinal product is not authorised in Spain.

13 Judgment of the High Court of Justice of the Basque Country (Contentious-Administrative Chamber) No. 246/2021 of 30 June 2021.

14 To prove that a medicinal product is a generic of a reference medicinal product, according to the definition adopted in Spain following the implementation of Directive 2001/83/EC, the generic medicine must meet the following conditions: it has the same qualitative and quantitative composition of active ingredients; it has the same pharmaceutical form; and its bioequivalence with the reference medicinal product has been proved by bioavailability studies.

Generic drugs cannot be commercialised until 10 years after the date the initial authorisation of the reference medicinal product is granted, or 11 years if a new indication is approved during the first eight years.

Generics benefit from the *Bolar* exemption, which enables the activities aimed at obtaining regulatory approval and preparing the launch to start while the product still has patent protection (see Section IV.i).

iii Biologics and biosimilars

Under Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing the EMA, certain biological products, such as advanced therapy products, can only be authorised by the EMA under the centralised procedure. The authorisation of biosimilar is therefore carried out through a centralised procedure based on clinical, non-clinical and quality studies. These studies allow the extrapolation of indications, frequently, without carrying out additional analyses.

The simplified procedure used for the approval of generic drugs (see Section III.ii) can be followed for a biological product that is similar to a previously authorised biological product (as a reference product); however, where a biological medicinal product that is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products, owing, in particular, to differences relating to raw materials or differences in manufacturing processes of the similar and the reference biological medicinal product, the results of preclinical tests or clinical trials relating to these conditions must be provided.[15]

Biosimilars also benefit from the application of the *Bolar* exemption (see Section IV.i).

There is some controversy regarding the possibility of 'substituting' biological medicines for their biosimilars at hospitals.[16] The Order of the Ministry of Health SCO/2874/2007[17] states that, under Article 89.4 of the Guarantees Law, biological medicinal products may not be substituted at the time of dispensation without the express permission of the prescribing physician. The issue at stake is whether this regulatory provision exclusively applies to dispensation in street pharmacies or if it also affects hospital pharmacy services. After some hesitation, the AEMPS seems to support the later view;[18] however, future legislative developments or interpretive changes on this issue cannot to be ruled out.

In April 2019, the Permanent Pharmacy Commission of the SNS Inter-territorial Council approved a proposal for an action plan to promote the use of biosimilar and generic medicines.[19] This proposal incorporated a number of initiatives to foster the use of biosimilars

15 Article 17.4 of the Guarantees Law.

16 While some stakeholders (among others, several Spanish medical associations and Farmaindustria; see Farmaindustria's Statement of 8 February 2017 on the substitution of biological drugs) advocate that it is not possible to replace a biological medicinal product by its biosimilar at hospital pharmacies as these products hold the condition of 'individualised products' (subject to further monitoring) and substitution can only be decided by the prescribing physician (and not by the hospital pharmacy commission), other relevant actors, including regional health departments, public contracting bodies and scholars, claim that this substitution is perfectly legal, prioritising the ultimate objective of cost-reduction measures.

17 Also, the Information Note of the Spanish Medicinal Products and Medical Devices Agency (AEMPS) of 24 April 2009.

18 According to the information published by the AEMPS on its website on 4 April 2018.

19 Action plan to promote the use of market-regulated drugs in the SNS: biosimilar drugs and generic drugs, Permanent Pharmacy Commission of the Inter-territorial Council of the SNS, 11 April 2019, updated 24 September 2019.

and generics, sometimes allowing for positive discrimination in favour of these medicines (e.g., prioritising the initiation of the dossiers for inclusion of generics and biosimilars in the pharmaceutical reimbursement system, adopting prescription by active ingredient and introducing a clawback mechanism for pharmacy discounts). Implementation of this action plan, should it be the case, would require legislative amendments.

While this proposal has been welcomed by operators in generics and biosimilars, it has been heavily criticised by biological companies and, in general, full-fledge innovators and pharmacists' councils. This plan was closely analysed by the National Markets and Competition Commission (CNMC).[20] While the CNMC issued some recommendations and suggestions to improve this plan, it generally shared its orientation and ultimate objectives, reiterating that it is necessary and desirable to promote the widespread penetration of generic and biosimilar medicines in the Spanish market.

The plan, which was further updated in September 2019 to try to encompass the suggestions made by the CNMC, clearly shows that the Spanish authorities intend to encourage the development, authorisation, prescription and use of generic and biosimilar medicines to seek better efficiency in health economic resources. The plan was approved by the Permanent Pharmacy Commission in September 2020, but the final text has not yet been approved by the SNS Inter-territorial Council.

It remains to be seen whether the demands of many operators in the industry have been reflected in the approved plan. It seems that the plan might not be formally approved since, according to the health authorities, the actions to be carried out at a regional level are already being implemented, while the actions that would require further regulation will be addressed in the modification and update of the Guarantees Law.

Otherwise, biological medicines in Spain are generally subject to the same general requirements for manufacturing, advertising and sale as other medicines.

IV PATENT LINKAGE

The existence of one or more patents or SPCs that can be potentially infringed is not taken into account when granting marketing authorisation for generics or biosimilars (or during their inclusion in the SNS). The Guarantees Law and Spanish courts have clarified that these decisions are taken without prejudice to the rights granted by the industrial property legislation.

However, this does not mean that the patent or SPC holder cannot take any action during or after the administrative proceedings, especially in situations where there is a risk of imminent commercialisation by the manufacturer of generics or biosimilars. These measures normally focus on avoiding commercialisation before the expiry of the patent or SPC, as well as the inclusion of the original medicine in a price reference group or homogenous group, or both (which would lead to a reduction in its price).

20 INF/CNMC/059/19. Report on the Action plan to promote the use of market-regulated drugs in the SNS: biosimilar drugs and generic drugs, the National Markets and Competition Commission (CNMC), 27 June 2019.

i Granting the marketing authorisation to the generic or biosimilar product

Article 61.1 of the Patents Law contains the '*Bolar* provision', which states that the rights granted by a patent or SPC do not apply to studies and trials aimed at obtaining authorisation for medicines (in Spain or abroad), including preparing, obtaining and using the active ingredient for this purpose; therefore, none of these activities can be considered as infringement of a patent or SPC, provided that they are strictly aimed at obtaining the relevant marketing authorisation.

ii Inclusion of a generic or biosimilar in the reimbursement system of the SNS

Since the enactment of Royal Decree 177/2014, the inclusion of medicines in the reimbursement system of the SNS is a two-step procedure. Once the medicine is authorised, pricing and reimbursement proceedings start. As a first step, the Ministry of Health decides on its inclusion in the reimbursed medicines system; however, this inclusion will not be effective (and the medicine will not be included in the catalogue of medicines) until a further step is taken by the marketing authorisation holder, specifically the filing of a communication on its decision to commercialise (and the intended date of commercialisation) the medicine to the Ministry of Health (more specifically, to the General Directorate). The actual date of effective inclusion depends on the effective date of commercialisation being communicated.[21]

Patent actions during the non-effective inclusion period

For patent actions to be granted, patentees must at least evidence that there is a risk of imminent infringement. According to Spanish case law, the non-effective inclusion of a generic or biosimilar in the SNS does not entail per se an infringement of the relevant patent or SPC; however, during this period, originators should closely follow the factual situation to be in a position to file action when possible.

For these purposes, patentees normally send warning letters to the manufacturers of generics or biosimilars, informing them of the existence of the relevant patent or SPC and, in light of the response, infer its intention to commercialise the generic or biosimilar before the expiry of the patent or SPC.[22] Likewise, originators usually request the General Directorate to keep them updated on the status of reimbursement proceedings of the generic or biosimilar. In any event, under certain circumstances, there could be a risk of imminent infringement even before the date of effective inclusion in the SNS. In particular, when the manufacturer of generics or biosimilars is in a position to commercialise them considerably before the date of expiry of the relevant patent or SPC. It may occur in situations where the marketing authorisation is granted (or the financial information to establish the price is provided to the authorities) more than three years before the patent expires (owing to the impact of the sunset clause explained in Section III).

21 In particular, if the communicated date of effective commercialisation is between days one and 15 of the month, effective inclusion in the SNS will take place on day one of the following month, and if the (communicated) date of effective commercialisation is between days 16 to 31 of the month, effective inclusion in the SNS will take place on day one of the second subsequent month.

22 See, for example, the order of the Commercial Court of Barcelona of 29 December 2009; the judgment of the Court of Appeal of Barcelona dated 6 November 2010; the judgment of the Barcelona Court of Appeal of 22 January 2013; the order of the Court of Appeal of Barcelona of 16 June 2013; and the order of the Commercial Court of Barcelona of 30 May 2017.

This evidence can be completed by the responses by the manufacturers of the generic or biosimilar to the originator's warning letters referred to above (denying or not the commercialisation of the product before the patent or SPC expires). In this regard, objective case law factors would prevail over the subjective declarations of the generic or biosimilar companies.

Patent actions as of effective inclusion

After effective inclusion in the SNS, the commercialisation of the generic or biosimilar is imminent; therefore, as a general rule, there is an imminent risk of infringement.

iii Preliminary or final injunctions

Originators can request both preliminary and final injunctions. In particular, preliminary injunctions can be requested before or together with the claim and with or without hearing the defendant (cases where the originator must bear in mind the impact of the 'protective letters'). Requirements for the grant differ depending on the type of preliminary injunction.

Several types of preliminary or final injunctions have been granted by the Spanish courts, such as:

a the prohibition (or cease) of the commercialisation of the generic or biosimilar;
b restrictions to the transfer of the marketing authorisation (and the corresponding notification to the AEMPS); and
c notification to the General Directorate for Pharmacy Medical Devices that the generic or biosimilar product cannot be commercialised or prescribed (and its exclusion from the Spanish Prescription Nomenclator).

In connection with second-use patents, the communication by the manufacturer of generics or biosimilars to the practitioners that the product cannot be prescribed or provided for the specific protected use as well as the corresponding indication in the Spanish Prescription Nomenclator (to avoid generics or biosimilar being prescribed) can be requested.[23]

V COMPETITION ENFORCERS

The CNMC is the independent administrative agency responsible for applying Articles 101 and 102 of the TFEU, the LDC, the RDC and other applicable competition rules in Spain. Certain regional governments have their own competition authorities, which may intervene in relation to anticompetitive practices that have an effect only in their territories but lack merger control competence. The decisions of the CNMC and the regional authorities are subject to appeal before, respectively, the National Court of Appeal and the corresponding regional high court. They can also, eventually, be appealed to the Supreme Court.

Additionally, the European Commission is competent to apply EU competition rules in all Member States. It has exclusive jurisdiction under merger control rules where the concentration is deemed to have an 'EU dimension' within the meaning of Regulation 139/2004. Contrarily, competence for applying Articles 101 and 102 of the TFEU to practices 'affecting trade between Member States' is agreed upon with national competition

23 Order of the Court of Appeal of Barcelona dated 5 July 2016.

authorities through coordination within the European Competition Network (ECN). The European Commission's decisions are subject to appeal before the European General Court, the rulings of which may be challenged before the CJEU.

The CNMC comprises an investigative body (the Directorate for Competition), which is functionally independent from the decision-making body (the Competition Chamber of the Board). Regional authorities mirror this structure but some of them feature only an investigative body and rely on the Board of the CNMC for decision-making purposes.

The Directorate for Competition brings proceedings on its own motion, at the request of the Board or following a complaint filed by any person. In addition, a leniency programme allows cartel infringers to apply for immunity or reductions in fines in exchange for acknowledgment of liability and information on the infringement, as well as provides a publicly available whistle-blower tool.

In April 2021, Royal Decree-Law 7/2021 was passed. It reforms the Competition Act and implements into Spanish law the ECN+ Directive (EU) 2019/1. The amendments to the LDC:

a strengthen the investigation powers of the CNMC by empowering it to conduct interviews and clarifying the scope of its powers in relation to digital information;

b increase the maximum fines that may be imposed on companies;

c give the CNMC the ability to reject complaints on the basis of its enforcement priorities; and

d clarify that leniency applicants may avoid disqualification from public tenders.[24]

Before proceedings are formally opened, the Directorate for Competition can conduct an informal preliminary inquiry (no statutory deadline), during which companies' procedural rights are not fully guaranteed. Once the Directorate for Competition considers that there are sufficient signs of an infringement, it may open the formal procedure; otherwise, it may propose its closure to the Board, which in turn may accept it or order that the formal procedure be initiated instead. Following formal opening, the Directorate for Competition must complete its inquiry and submit a draft decision to the Board, and the latter must adopt and notify a decision within 24 months or it will expire.

The CNMC has broad investigative powers to carry out unannounced inspections at companies' premises or employees' domiciles, which allow its personnel to enter and seal any facilities (upon prior consent or court order), access, examine, seize, copy and retain any documents in any format, conduct interviews, request and record explanations on facts and documents. The scope for examination by the CNMC covers all documentation to which the company has access. This includes all forms of emails or documents that appear as unread or have been deleted, employees' systems and devices and information hosted on third-party servers. The obligation to comply with the inspection order applies to the whole corporate group insofar as there is a connection between the companies and the infringements under investigation.

The CNMC may impose administrative fines of up to a certain percentage of the infringer's worldwide total turnover (not only revenues from the products concerned) in the preceding year to the decision: up to 1 per cent for minor infringements, up to 5 per cent for serious infringements (e.g., most procedural breaches and gun jumping) or up to 10 per cent

24 Royal Decree-Law 7/2021 of 27 April. For more information, see Uría Menendez's newsletter on the subject.

for very serious infringements (including any abuse of dominance and all anticompetitive agreements, even between non-competitors). Time limitation periods are one year for minor infringements, two years for serious infringements and four years for very serious infringements, as of the moment they cease. Following the annulment of its former fining guidelines by the Supreme Court in 2015,[25] the CNMC is developing a new methodology that is still rather opaque.

Since 2016, it has been fairly common to find administrative consequences of competition infringements, especially cartels, in Spain. These consequences may also include fines of up to €60,000 for legal representatives and managers of infringing companies. Further, in several recent decisions,[26] the CNMC has availed of the public procurement provision, which allows for debarment of natural or legal persons from public tendering for up to three years in the case of a serious (or very serious) infringement. There is still uncertainty regarding the direct applicability of the debarment sanction imposed by the CNMC. In June 2023, the CNMC announced its intention not to only declare the application of the debarment sanction as a result of anticompetitive conducts, but also to set its duration and scope.

Regarding private enforcement, Articles 1 and 2 of the LDC entail the nullity of any agreement or conduct in breach thereof, as do Articles 101 and 102 of the TFEU, and provide grounds for a claim for damages before national commercial courts. Actions for damages have been boosted in Spain by the 2017 amendments to the LDC and Law 1/2000 on civil procedure, which implemented Directive 2014/104/EU.[27] There is a lot of private enforcement activity in sectors such as vehicles (trucks and cars), paper envelopes and milk purchasing. A potential landmark development in antitrust private litigation in Spain may be derived from the implementation into domestic law of Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC. There is uncertainty whether the national legislator will include antitrust damages claims brought by consumers into the scope of application of these representative actions.

Regarding intervention in economic sectors, the CNMC has endorsed the 2019 report on competition enforcement in the pharmaceutical sector issued by the European Commission in the context of the ECN.[28] Since then, it has carried out unannounced inspections at the premises of at least three laboratories in 2019, according to public press releases (including AbbVie, see Section VII). In 2021 and the first half of 2022, the CNMC reported several new inspections, none of which were in the pharmaceutical sector.

In line with the European Commission's resolution to curb exploitative price abuses by laboratories, the CNMC has proven ready to inquire into excessive pricing by bringing

25 Judgment of the Supreme Court of 29 January 2015 in Appeal 2872/2013.

26 Decisions of the CNMC of 13 February 2020 in Case S/DC/9626/18 *Radares Meteorológicos*, of 9 February 2021 in Case S/0644/18 *Radiofármacos* and of 7 July 2022 in Case S/0021/20 *Constructoras*.

27 Official Journal of the European Union L-349, 5 December 2014, pp. 1–19.

28 Report from the commission to the Council and the European parliament 'Competition enforcement in the pharmaceutical sector (2009–2017). European competition authorities working together for affordable and innovative medicines' (COM(2019) 17 final).

proceedings against Aspen, which were eventually closed when the European Commission took over.[29] In its Action Plan for 2021 to 2022, the CNMC confirmed this trend, with a particular focus on pharmaceutical products related to covid-19.

VI MERGER CONTROL

Under Spanish merger control rules, any change in the control structure by means of the merger of several companies, the acquisition of control by one or several companies over one or several companies, or the creation of a fully functional joint venture is an economic concentration.[30] If an economic concentration having an effect in Spain does not meet the thresholds to be considered of an 'EU dimension', it may be subject to notification to the CNMC,[31] in which case its implementation must be suspended until clearance.[32] Referral mechanisms between the Commission and national competition authorities are also in place.

In March 2021, the European Commission published new guidance[33] on the application of the referral mechanism set out in Article 22 of the EU Merger Regulation, allowing for mergers falling below national merger thresholds to be referred to the Commission. This includes mergers affecting, among other things, the pharmaceutical industry.

The European Commission used Article 22 and the guidance to claim jurisdiction over the review of a merger related to the pharmaceutical sector (biotech): the acquisition of GRAIL by Illumina.[34] In July 2022, the General Court confirmed the Commission's jurisdiction over this merger and in the process validated the Commission guidance.[35] In September 2022, the Commission prohibited the implemented acquisition of GRAIL by Illumina and on July 2023, the Commission issued a record fine of €432 million on Illumina and €1,000 on GRAIL for having breached the standstill obligation. The fine on GRAIL was symbolic since the Commission acknowledged that it was the first time that a target company had been fined for gun jumping.

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29 Decision of the CNMC of 20 July 2017 in Case S/DC/0601/16 *Laboratorios Aspe*n and decision of the European Commission in Case AT.40394 (Aspen and the European Commission agreed on commitments in February 2021).

30 'Control' means the possibility of exerting decisive influence, regardless of the legal grounds, on the market behaviour of a business with current market presence, or that can be reasonably expected to develop market presence in a reasonably timely manner, and to which a market turnover can be clearly attributed. The European Commission has considered this to be so in a case regarding the development, manufacturing and marketing rights in a pipeline drug that is already in Phase III (confirmatory) trials, along with related tangible assets, administrative approvals, clinical trial data and supply contracts, in the decision of the Commission of 18 December 2015 in Case M.7872 *Novartis/GSK (ofatumumab autoimmune indications)*.

31 There are two alternative notification thresholds in Spain: a market share is acquired or increased up to or over 30 per cent (50 per cent if the target's turnover in the preceding financial year did not exceed €10 million) in any product market either in Spain or in a geographic market defined within it; or both parties' combined turnover in Spain in the preceding financial year exceeded €240 million, and each of their turnover in Spain exceeded €60 million.

32 Failure to notify a concentration subject to review by the CNMC, and its execution before authorisation (i.e., gun jumping) are two separate serious infringements entailing fines of up to 5 per cent of the company's total turnover during the preceding financial year.

33 Communication from the Commission: Commission Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases (26 March 2021).

34 COMP/M.10188 *Illumina/GRAIL* (ongoing review).

35 Case T-227/21 *Illumina v. Commission*, 13 July 2022.

Interestingly, on the whole, the CNMC is not using this system as it is not permitted under the LDC. It decided not to join the referral made by other national authorities in the context of *Illumina/GRAIL*; however, it remains to be seen whether the General Court decision will affect that position.

Prior to formal submission, customary informal contacts are held with the CNMC to ensure filing is completed and potential concerns are clarified. Pre-filing contacts are not subject to a deadline, but their duration may range from around two to four weeks in straightforward cases to around four to five months if there are significant activity overlaps (horizontal) or there is an important presence in vertically related markets.

After formal submission, Phase I starts, and a decision must be issued within one month. By way of an exception, time limit to decide on a concentration during Phase I is shortened to fifteen business days, provided that the concentration is eligible for a simplified form which has been previously discussed in pre-notification with the Competition Directorate. If serious concerns are raised, Phase II is opened, which comprises an in-depth analysis, in practice, for up to three additional months.[36] If no decision is issued within these deadlines, the concentration is deemed authorised. Intervention by the government in prohibition or conditional approval Phase II cases is possible under certain circumstances but is very exceptional in practice.

In Spain, the latest mergers (in the first half of 2023) in the pharmaceutical sector were unproblematic and cleared in Phase I without remedies.[37]

The legal test for a concentration to be prohibited under Spanish rules (in the same way as under EU rules) is the 'significant impediment to effective competition' caused by either non-coordinated effects (i.e., post-merger reduction of the competitive pressure on either the merged entity or on the other remaining players in the market) or coordinated effects (i.e., increased likelihood of collusion among competitors or easier or more effective pre-existing collusion). To solve concerns raised by the CNMC, the notifying parties may offer remedies as a condition for authorisation. Structural remedies (essentially divestments) are usually preferable but behavioural remedies might be sufficient in the absence of significant overlaps.

In 2018, the CNMC had the opportunity to look into the marketing of pharmaceuticals and defined local markets for the wholesale distribution of medicines and health products to pharmacies encompassing areas of 120 to 150-minute drive radii (albeit analysing in practice the provinces in which the combined market shares exceeded 25 per cent and bordering provinces).[38]

Regarding finished doses, the CNMC uses the Anatomical Therapeutic Chemical (ATC) classification system of the World Health Organization as a reference for market

36 In practice, however, proceedings extend significantly beyond the three-month deadline because requests for information to the merging parties or to third parties automatically stop the clock. The offering of remedies entails an extension of 10 additional days in Phase I and 15 in Phase II.

37 Among others, CNMC decisions of 8 March 2023, in Case C/1372/23 *Chiesi/AMRYT*, of 8 March 2023 in Case C/1373/23 *Bavarian Nordic/Emergent Biosolutions (Business of vaccines for corporate travel)* and of 7 June 2023 in Case C/1388/23 *Cheplapharm/Zyprexa Business*.

38 CNMC decisions of 19 July 2018 in Cases C/0959/18 *Bidafarma/Socofasa* and C/0958/18 *Bidafarma/Zacofarma* and of 21 November 2019 in Case C-1054/19 *Cofares/Cofarta*. In *Cofares/Cofarta*, the CNMC did not authorise as ancillary to the acquisition of a distributor by a cooperative the pre-existing agreement between them, which was subject to tactic extensions for an indefinite duration, whereby the target would integrate its orders with those of the acquiring cooperative, and which contained an exclusivity purchasing commitment.

definition in line with the CJEU's case law, which sets ATC level 3 (i.e., therapeutic and pharmacological subgroups) as a departure point for selecting candidate products.[39] In 2018, the CNMC defined the market as narrowly as at ATC level 5 (i.e., molecular composition) for two orphan drugs with no close substitutes (of a national scope).[40]

Having said that, in April 2021, the CNMC issued a decision setting an important precedent (albeit not in merger control) in the application of competition law to the pharmaceutical industry.[41] In the context of market definition, the CNMC rejected a product market definition at ATC level 5 and confirmed that the basic principle to delineate pharmaceutical markets is the 'effective clinical practice' or therapeutic substitutability of each medicine.

Regarding future trends, 'killer acquisition' concerns over transactions involving pipeline products remain at the forefront of the European merger control debate in the context of a broader discussion about the consideration to be given to innovation (the *Illumina/GRAIL* merger being a prime example). The trend towards a higher degree of factual and economic analysis, which has also reached the CNMC, is anticipated to infuse the aforementioned discussion into Spanish merger control.

VII ANTICOMPETITIVE BEHAVIOUR

Intra-EU parallel imports by wholesalers used to take centre stage in Spanish pharmaceutical competition enforcement owing to the intervened prices for publicly financed drugs to be dispensed in Spain. After a series of decisions and judgments, the free-pricing policy implemented by some laboratories (according to which laboratory prices were automatically replaced by intervened prices when conditions established in the applicable regulation were fulfilled) was considered to be compatible with competition rules since the policy did not result from a restrictive 'dual pricing' policy of laboratories but rather from public intervention overriding their commercial freedom.[42]

In February 2021,[43] the CNMC fined two pharmaceutical companies €5.76 million for agreeing to share the market for supplying the radiopharmaceutical fluorodeoxyglucose, 18F-FDG, a drug used in radio diagnosis, as well as two of their managers. According to the decision, the conduct comprised an agreement to lose bids to supply radiopharmaceuticals to hospitals and assigned specific hospitals to each other. This case shows the continued interest of the CNMC in tackling collusion in public tenders.

In December 2022, the CNMC accepted binding commitments from a Spanish pharmaceutical and personal care company to terminate practices that amount to fixing the

39 Judgment of the General Court of 1 July 2010 in Case T-321/05 *AstraZeneca v. Commission*.

40 CNMC decision of 2 March 2018 in Case C-0925/18 *Recordati/Mylan*.

41 CNMC decision of 20 April 2021 in Case S/0027/19 *Inhaladores AstraZeneca*.

42 Decisions of the former National Competition Commission (CNC) of 29 May 2009 in Case 2623/05 Pfizer/Cofares and of the CNMC of 19 January 2017 in Case S/DC/0546/15 *Pfizer/Cofares* and of 30 August 2018 in Case S/DC/0608/17 *EAEPC v. Laboratorios Farmacéuticos* and corresponding appeals. On 22 April 2021, the National Court of Appeal has confirmed that there was no evidence that supported that Pfizer's pricing system (the 'free pricing system') constitutes an anticompetitive agreement. On 7 March 2023, the Spanish Supreme Court issued a ruling confirming the position of the CNMC and the National Court of Appeal, upholding the legality of the free pricing system.

43 CNMC decision of 9 February 2021 in Case S/0644/18 *Radiofármacos*.

online resale price of its skincare products.[44] In its press release, the CNMC warned other market players that they are closely looking into this type of infringement in the industry, particularly online. Regarding abuse of a dominant position, administrative and judicial practice has been brought in line with the CJEU's case law in respect of the definition of relevant markets for drugs below ATC level 3 (see Section VI) and the possibility of dominance not being excluded by the buying power of national health systems.[45] Two earlier precedents saw national markets for finished doses be delimited according to their therapeutic indication (i.e., ATC level 3),[46] while the possibility of descending to the mode of action (i.e., ATC level 4) was considered but deemed too narrow.[47] Abuse charges were deemed unfounded in both cases, so no in-depth analysis of dominance was carried out.

In 2021, the CNMC also dismissed two abuse cases. In the first, against AstraZeneca, the CNMC decided to take no further action against AstraZeneca regarding a complaint by a generic manufacturer for alleged abuse of dominant position consisting of predatory prices for the sale of one of its medicines. In addition to rejecting the market definition at ATC level 5 and confirming the importance of 'effective clinical practice', the CNMC further endorsed the 'meeting competition' defence, asserting that in general it is legitimate for dominant companies to equal the offers of its competitors so the customer may choose its preferred commercial option.[48]

In the second, against AbbVie,[49] the CNMC decided to take no further action against AbbVie regarding a complaint for alleged abuse of dominant position comprising the set-up of a commercial strategy of fidelity discounts offered to hospitals for the sale of one of its medicines. One of the key takeaways of this case is that the CNMC considered that AbbVie was not necessarily dominant despite a share well above 60 per cent owing to the rapid penetration of biosimilars (volatile market shares). The National Court of Appeal has traditionally held that intense public intervention and the significant bargaining power of the SNS in pharmaceutical markets make dominance unlikely.[50]

In 2022, the CNMC imposed a fine on Leadiant for excessive pricing of an orphan drug for cerebrotendinous xanthomatosis.[51] According to the CNMC, the price was 17 times the price of a prior and similar version of the same drug. The investigation was carried out in close cooperation with the Italian and Dutch competition authorities, which were probing Leadiant's prices in parallel. The CNMC decision additionally ordered to waive exclusivity on the sole active ingredient producer for this drug and to engage in a price negotiation with the Spanish Ministry of Health instead of importing it as a rare drug.

44 Case S/0049/19: *ISDIN* (initiated in November 2020).

45 Judgments of the General Court of 1 July 2010 in case T-321/05 *AstraZeneca v. Commission* (upheld by the judgments of the Court of Justice of 6 December 2012 in Case C-457/10 P *AstraZeneca v. Commission*) and of 12 December 2018 in Case T691/14 *Servier and others v. Commission*.

46 CNC decision of 9 June 2010 in Case S/0176/09 *Sedifa y Grufarma*.

47 CNC decision of 25 April 2011 in Case S/0228/10 *Novartis*.

48 CNMC decision of 20 April 2021 in Case S/0027/19 *Inhaladores AstraZeneca*.

49 CNMC decision of 20 April 2021 in Case S/0024/19 *AbbVie*.

50 Judgments by the National Court of Appeals of 14 February 2005 in Appeal 79/2002, of 17 July 2006 in Appeal 179/2004 and of 10 May 2007 in Appeal 56/2004. See also CNC decision of 16 January 2008 *Preparados Farmacéuticos*.

51 Case S/0028/20 *Leadiant*. The Dutch and Italian authorities sanctioned Leadiant for similar conduct with fines of €19.5 million in July 2021 and €3.5 million in May 2022, respectively.

Also in 2022, the CNMC imposed a fine on MSD for sham litigation against a new competitor at the time the exclusivity rights over MSD's contraceptive solutions were about to expire.[52] While the CNMC acknowledges the fundamental right for access to a judicial decision (and the right to lose in court), it considered that the timing and the manifestly ill-founded nature of the claims brought by MSD had the sole purpose of delaying the biosimilar solution offered by this competitor.

The recent developments brought about by the CJEU's rulings regarding pay-for-delay and other practices may make the CNMC open to taking a more fact-based stance; thus, for instance, prescribers and patients' inertia and switching patterns, as well as the companies' own perception of rivalry, may gain a foothold in market definition and dominance appraisal to the detriment of rigid categories based on the objective characteristics of the drugs, in line with cases such as *Servier*,[53] *Hoffmann-La Roche*[54] and *Generics*.[55] The light shed by these judgments may also lay the foundations for more targeted competition enforcement in the pharmaceutical sector. It can be argued that AstraZeneca for instance stems from the Servier case-law. For that matter, the CNMC's Strategic Plan for 2021–2026 as well as its Action Plan for 2021–2022, as adjusted to account for the covid-19 pandemic, clearly mention the pharmaceutical sector as the target of a sectoral supervision given its particular vulnerability to structural and conjectural circumstances (as can be seen in the current economic climate).

VIII OUTLOOK AND CONCLUSIONS

The Spanish pharmaceutical sector is mainly shaped by EU regulations, although with certain peculiarities and trends of its own, in particular with regard to the pricing and reimbursement system.

We can expect the Spanish authorities, in both the regulatory and competition fields, to continue promoting the use of generics and biosimilars, as one of the measures to contain health expenditures, although hopefully also allowing for a framework where innovation is still encouraged. In any case, under Spanish patent legislation (which can be combined in some cases with regulatory actions), originators will retain useful tools that lead to good protection of their investments. Further, transparency of public financing and pricing decisions, efficiency in the distribution of resources, home dispensing, guarantee of supply, market access and telemedicine will continue to be particularly relevant issues.

In June 2022, the CNMC published a study into the market for the wholesale distribution of medicines.[56] Despite its title, the study also offers an in-depth analysis of various aspects of the pharmaceutical industry other than wholesale distribution. In particular, it focuses on the pricing systems applied to prescription medicines (including generics and biosimilars), which are state-funded and are dispensed through pharmacies.[57]

52 Case S/0026/19 *Merck Sharp Dome*.

53 Judgment of the General Court of 12 December 2018 in Case T-691/14 *Servier and others v. Commission*.

54 Judgment of the Court of Justice of 23 January 2018 in Case C-179/16 *F Hoffmann-La Roche Ltd and Others v. AGCM*.

55 Judgment of the Court of Justice of 30 January 2020 in Case C-307/18 *Generics (UK) Ltd and others v. Competition and Markets Authority*.

56 E/CNMC/002/17 'Estudio sobre el mercado de distribución mayorista de medicamentos'.

57 The hospital channel is left out of the scope of the study.

To mitigate the competitive restrictions identified in the study and to achieve a more efficient regulation, the CNMC made a series of recommendations to the competent public authorities, such as:

a modifying the prescription and dispensation policies in pharmacies to foster competition between the original drug and generics and, as a result, patients' options;

b promoting the use of generics and biosimilars;

c reforming the national reference pricing system (from a maximum price model with a price cap to a model without a price cap, as in other EU Member States) to encourage actual pricing competition; and

d reforming and replacing the current system of margins for distributors based on price with a system based on the services provided and introducing a clawback system.

In any case, the impact of the new pharmaceutical regulation in the European Union, pending discussion and approval, and the legislative changes that may be further implemented in Spain will have to be closely monitored.

Regarding competition enforcement, the trend towards bolder intervention to curtail abusive commercial practices witnessed in other EU jurisdictions (including the European Commission) anticipates action will be taken in relation to excessive pricing and pricing in general as highlighted by the aforementioned study.

The clarifications in the CJEU's pay-for-delay rulings appear to have paved the way for national prosecution of hypothetical strategies aimed at foreclosing generics from the perspective of both anticompetitive agreements and abuse of dominance (the importance of the sector has already been highlighted in the CNMC's Action Plan for 2021–2022 and Strategic Plan for 2021–2026). In any event, a higher degree of sophistication in enforcement and more margin for fact-based and economic-driven analysis is to be expected in line with European developments, which in the field of merger control may translate into innovation theories of harm being the bone of contention.