

Healthcare and Competition Newsletter

Europe and Spain: 2024 and first quarter of 2025

1. PHARMACEUTICAL SECTOR IN EUROPE

In recent years, the pharmaceutical sector has been subject to increasing scrutiny by competition authorities, particularly in relation to anti-competitive practices that may distort the market and inhibit innovation. The European Commission has stepped up its monitoring and, in this context, there have been a significant number of decisions involving both mergers and infringement proceedings.

To recap the most recent developments, in January 2024, the European Commission published a report entitled *“Update on the application of competition law in the pharmaceutical sector”*¹, which provided a comprehensive analysis of the decisions taken by the Commission in the field of competition in the years 2018 to 2022. The report highlights that, during the period analysed, the Commission adopted a total of 26 decisions for infringements of competition law in the pharmaceutical sector, resulting in fines totaling more than €780 million, in addition to commitments accepted by the companies to remedy their anti-competitive behaviour. These decisions cover a wide range of anti-competitive behaviours, including the abuse of patent procedures (such as the strategic filing of patents with little or no real innovation), pay-for-delay agreements, disparagement campaigns against competing products and the imposition of excessive prices for off-patent medicines.

¹ Report from the Commission to the Council and the European Parliament, of 21 January 2024, regarding the update on competition enforcement in the pharmaceutical sector (2018-2022). COM(2024) 36 final. Available at: [2023Report-EN- ISC review 10.11 final comments CLEAN.docx](#)

In particular, the report highlights the growing number of investigations over the last decade into denigration or disparagement practices among competitors in the pharmaceutical sector. Such conduct essentially consists of disseminating misleading or inaccurate information intended to undermine confidence in rival products –whether vis-à-vis health authorities, professionals in the sector or directly to the general public– with the aim of limiting their entry or continued presence on the market.

INFRINGEMENTS OF COMPETITION LAW THROUGH DISPARAGEMENT CAMPAIGNS

In the field of competition law, companies that hold a dominant position in the market have a special responsibility under Article 102 of the Treaty on the Functioning of the European Union (“TFEU”). According to the case law of the Court of Justice of the European Union (“CJEU”), this responsibility implies, among other obligations, not to impede, by conduct which is not based on merits, the development of effective and undistorted competition in the common market (Judgement of the CJEU, 9 November 1983, *Nederlandsche Banden-Industrie-Michelin v Commission*, Case C-322/81).

Consequently, although a company with a dominant market position may legitimately compete by promoting and advertising the qualities and characteristics of its own product, it may not disseminate misleading messages or disparage a rival product by creating false perceptions about its material characteristics, safety or effectiveness, as such communications may be capable of misleading healthcare professionals and generating market exclusionary effects (Judgement of the General Court of the European Union, 1 July 2010, *AstraZeneca*, Case T-321/05).

The CJEU took this position in its Judgment *Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato* (Judgement of the CJEU, 23 January 2018, Case C-179/16), in which it established that the dissemination of false or ambiguous information for anti-competitive purposes may constitute an infringement of Article 101 TFEU if it forms part of a restrictive agreement that adversely affects the functioning of the market.

At European level, in 2024, attention in the pharmaceutical sector focused particularly on investigations into Vifor Pharma and Teva Corporation, whose disparagement practices were confirmed by the European Commission. Both cases are notable not only for the high profile of the companies involved and the media coverage they have generated, but also for their ability to establish the limits of lawful commercial discourse in the European pharmaceutical market.

Vifor Pharma (Case AT.40577)

One of the most representative cases of abuse of a dominant position in the pharmaceutical sector in 2024 was that involving Vifor Pharma. The European Commission opened this investigation after receiving a complaint from Pharmacosmos, which accused Vifor of launching a disparagement campaign based on the dissemination of misleading information about the safety profile of the drug Monofer. The products in question –Ferinject (Vifor) and Monofer (Pharmacosmos)– belong to the distinct segment of high-dose intravenous iron products, which the European Commission distinguishes from other iron products due to their clinical profiles, therapeutic indications, administration methods and prices.

According to the European Commission, Vifor used its dominant market position to develop a communication campaign aimed at inducing healthcare professionals to believe that the administration of Monofer entailed serious health risks and that its safety profile was substantially inferior to that of Ferinject. According to the decision, Vifor disseminated two types of messages in this campaign: (i) that Monofer was associated with the safety risks historically attributed with *iron dextran IV compounds* (HMW); and (ii) that Monofer caused more frequent hypersensitivity reactions compared to Ferinject².

The Commission analysed Vifor's internal and external communications, its documents and company reports, which stated, among others, that: *"Ferinject is not a dextran, so if you want to avoid dextran toxicity, use Ferinject"*³; *"what we want our customers to believe: Not all IV iron therapies are the same, and Ferinject is the leader in iron therapy with a superior benefit-risk profile"*⁴. Among the documents and communications examined, the Commission also found materials and studies sponsored by Vifor⁵, whose conclusions, according to Vifor, proved that Monofer caused hypersensitivity reactions four times more often than Ferinject or proved that Monofer was indeed a dextran.

The European Commission analysed whether the conduct: (i) consisted of disseminating objectively misleading information (i.e. inaccurate or incomplete information that could confuse its recipients and could be capable of discrediting a competing product); (ii) was capable of producing exclusionary effects; and (iii) was not objectively justified.

First, the European Commission established that Monofer is not an iron dextran and therefore confirmed that the messages disseminated by Vifor were objectively misleading. According to the Commission, Vifor was aware that it lacked an adequate scientific basis for associating Monofer with *"dextran toxicity"* and that the claims derived from its studies (which demonstrated this possible association) were also clinically irrelevant, which Vifor omitted and ignored in its communications⁶.

Secondly, the Commission confirmed that these messages could have had exclusionary effects on the market because, due to their inaccuracy, the incomplete way in which they were presented and the exaggerations used, they were capable of misleading healthcare professionals by suggesting that Monofer was a dextran or a derivative and by disseminating that Monofer was more dangerous for patients than Ferinject⁷.

² Decision of the European Commission, of 22 July 2024, relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union (TFEU). Case AT.40577 - VIFOR (IV iron products) ("**Decision of the Commission, AT.40577 - VIFOR**"), paragraph 92. Available at: <https://competition-cases.ec.europa.eu/cases/AT.40577>

³ Decision of the Commission, AT.40577 - VIFOR, paragraph 97.

⁴ Decision of the Commission, AT.40577 - VIFOR, paragraph 106.

⁵ Neiser S, Wilhelm M, Schwarz K, Funk F, Geisser P and Burckhardt S, *"Assessment of dextran antigenicity of intravenous iron products by an immunodiffusion assay"*, Port J Nephrol Hypert 2011; 25(3): 219-224 and Neiser S, Koskenkorva T, Schwarz K, Wilhelm M and Burckhardt S, *"Assessment of Dextran antigenicity of intravenous iron preparations with enzyme-linked immunosorbent assay (ELISA)"*, Int. J. Mol. Sci. 2016, 17, 1185.

⁶ Decision of the Commission, AT. 40577 - VIFOR, paragraph 150.

⁷ Decision of the Commission, AT.40577 - VIFOR, paragraphs 189, 199 and 217.

However, despite finding this anti-competitive conduct, Vifor was not sanctioned by the European Commission. Vifor and Pharmacosmos reached a confidential commercial agreement which the Commission took into consideration in closing the case with commitments and without imposing a sanction on Vifor. Among the commitments made, Vifor undertook to carry out a communication campaign to rectify and correct the effects of the misleading messages, accepted a ban regarding medical communications on the safety of Monofer in the EEA for a period of 10 years, and to establish internal mechanisms to analyze promotional communications.

Teva Copaxone (Case AT.40588)

Another significant case in 2024 was that of Teva, whose decision was very recently published by the European Commission. The pharmaceutical company was fined €462.6 million by the European Commission for abuse of a dominant position (Article 102 TFEU) in the market for *glatiramer acetate* (an active ingredient used in the drug Copaxone (Teva) for the treatment of multiple sclerosis). According to the Commission, the infringement involved two types of anti-competitive conduct: (i) abusive manipulation of the patent system, and (ii) a systematic campaign to discredit a competing medicine.

Regarding the abuse of the patent system, the European Commission concluded that Teva filed multiple divisional patent applications with the European Patent Office with content that largely overlapped or covered minor aspects of the medicine. Furthermore, when competitors attempted to challenge these patents in court to facilitate the entry of generic versions, Teva strategically withdrew the main applications, leaving the divisional applications open. According to the Commission, this tactic forced competitors to initiate legal proceedings against essentially identical patents, creating legal uncertainty that, in practice, artificially delayed the entry of similar generic medicines in the market, for example through interim measures⁸.

Furthermore, the Commission also considered that Teva had carried out a systematic disparagement campaign against a competing medicine, Synthon GA, which contained *glatiramer acetate* (GA), the same active ingredient as Copaxone. GA is composed of four amino acids in a stable proportion, although the order in which they are arranged is random. According to the Commission, although this randomness creates certain structural differences between the medicines, the health authorities consider that these differences are clinically irrelevant and that the two medicines (Synthon GA and Copaxone) are clearly therapeutically equivalent⁹.

Despite this, the Commission found that Teva disseminated misleading information about the safety, efficacy and therapeutic equivalence of Synthon GA compared to Copaxone. This disparagement campaign included several messages intended to raise doubts among healthcare professionals and national authorities responsible for setting prices and reimbursements for medicines, and its main

⁸ Decision of the European Commission, of 31 October 2024, relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union (TFEU). Case AT.40588 - Teva Copaxone ("**Decision of the Commission, AT.40588 - TEVA**"), paragraph 1418. Available at: <https://competition-cases.ec.europa.eu/cases/AT.40588>

⁹ Decision of the Commission, AT.40588 - TEVA, paragraph 1538.

objective was to slow down and prevent the entry of the rival product in several EEA Member States¹⁰. In particular, Teva (i) emphasized clinically irrelevant molecular differences between Copaxone and Synthon GA; (ii) alluded to risks associated with the use of other substances related to GA; and (iii) questioned the scientific validity of the GATE study as a basis for establishing therapeutic equivalence between the two medicines¹¹.

The European Commission found that this conduct had exclusionary effects on the market¹², which had a direct impact on public health budgets, since once these practices ceased and competitors finally gained access to the market, the prices of treatments containing GA fell by up to 80%.

The Vifor and Teva decisions are the first decisions of the European Commission concerning the denigration of competing products and demonstrate a clear objective to eliminate such practices, especially in sensitive sectors such as the pharmaceutical sector. These decisions make one crucial point clear: in order to understand an abuse of a dominant position, disparagement is not limited to providing objectively false information about a competing product or company, but can also include any alarmist or misleading communication, ambiguous messages, an incomplete or subjective presentation of scientific studies, or raising concerns about the safety of competing products without supporting evidence, provided that these are likely to influence the behaviour of healthcare professionals or competent authorities.

COLLUSION IN THE PHARMACEUTICAL SECTOR

An interesting aspect of the European Commission recent activity is the publication of its decision in case [AT.40636 - SNBB](#), in November 2024, concerning SNBB, an active ingredient essential for the production of the medicine Buscopan and its generic versions.

In this case, the European Commission sanctioned six pharmaceutical companies, suppliers of SNBB, for entering into bilateral and multilateral agreements to fix minimum sales prices and allocate market shares, with the aim of stabilizing prices worldwide and preventing their decline in various EEA markets.

Such practices are particularly harmful to the pharmaceutical sector, as they can distort the prices of essential medicines and thus increase the costs of pharmaceutical products for both consumers and public health systems.

The fines imposed on the operators were significant. With the exception of C2 Pharma, which applied for leniency and was exempted from paying a fine, and Transo-Pharm, which was the second operator

¹⁰ Decision of the Commission, AT.40588 – TEVA, paragraphs 1461 to 1469.

¹¹ Decision of the Commission, AT.40588 – TEVA, paragraph 1543.

¹² Decision of the Commission, AT.40588 – TEVA, paragraph 1478.

to apply for leniency and received a reduced fine of €98,000, the penalties imposed by the Commission on the remaining operators ranged from €537,000 to €10,401,000¹³.

ONGOING INVESTIGATIONS

In March 2024, the European Commission opened an investigation against Zoetis Inc. and Zoetis Belgium S.A. for possible abuse of a dominant position following the discontinuation of Ranevetmab, a monoclonal antibody for canine osteoarthritis that Zoetis acquired together with the acquisition of the pharmaceutical company Nexvet Biopharma in 2017 ([AT.40734 - Zoetis - Librela](#)).

The purchase of Ranevetmab by Zoetis was subject to a licensing agreement granting Virbac, a French animal health company, exclusive rights to commercialize it outside the United States and Canada. Two years after the acquisition, Zoetis decided to discontinue the production of Ranevetmab and, as a result, the drug developed by Zoetis also targeting canine osteoarthritis, Librela, became the first monoclonal antibody to be authorized for this indication by the European Commission.

This is the first case in which the Commission has investigated the termination of a product intended for marketing by third parties, which could indicate its willingness to use Article 102 TFEU to address *killer acquisitions* beyond the usual scope of merger control.

EU MEMBER STATES

Sanctions imposed by the Belgian Competition Authority for a category management agreement

In April 2025, the Belgian Competition Authority (BCA) imposed fines on three pharmaceutical manufacturers for an agreement deemed restrictive of competition in category management relating to over-the-counter (OTC) medicines sold in pharmacies¹⁴.

Category management agreements are, in principle, common and accepted strategies in retail distribution, whereby a supplier designated as a “*category captain*” assumes responsibility for the overall marketing of a product category, including products of competitors, influencing aspects such as promotion and placement at the point of sale¹⁵.

However, in this case, the BCA identified practices that, in its view, exceeded the legal limits of such agreements and constituted an infringement of Article 101 TFEU. The investigation revealed that the companies involved (Johnson & Johnson Consumer, Boehringer Ingelheim and Haleon), despite

¹³ Decision of the European Commission, of 19 October 2023, relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union (TFEU) and Article 53 of the EEA Agreement. Case AT.40636 – SNBB. Available at: <https://competition-cases.ec.europa.eu/cases/AT.40636>

¹⁴ Press Release of the Belgian Competition Authority, of 24 April 2025. “*The Belgian Competition Authority sanctions Johnson & Johnson Consumer, Boehringer Ingelheim and Haleon in relation to an anti-competitive category management arrangement for the placement of OTC medicines in pharmacies*”. Available at: https://www.belgiancompetition.be/sites/default/files/content/download/files/20250424_Press_release_16_BCA_0.pdf

¹⁵ Communication from the Commission, 2022/C 248/01. Guidelines on vertical restraints. Chapter 8.2.7. Category management agreements, paragraphs 385 to 388. Available at: [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022XC0630\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022XC0630(01))

being competitors in the supply market, agreed to systematically exclude products from third-party competitors from the design and implementation of planograms, exclusively favouring their own products with preferential shelf space in pharmacies. In addition, the BCA determined that the parties agreed on joint monitoring mechanisms to control the implementation of the agreement in a significant number of establishments. According to the BCA, such conduct was intended to limit effective competition in the market.

This procedure is particularly relevant as it is a matter with few precedents in European competition law. The Belgian Authority emphasized that its decision sets a clear benchmark on the limits applicable to this type of agreement, pointing out the risks of distortion that may arise when category management is used as a tool to restrict market access and competition.

MERGER CONTROL OPERATIONS ANALIZED BY THE EUROPEAN COMMISSION

In the field of business mergers, during 2024, the European Commission approved a total of seven mergers in the pharmaceutical sector¹⁶, reflecting the continued dynamism of this sector.

In July 2024, the Commission approved without commitments the acquisition of Aenova by Kühne Holding ([M.11571 - KÜHNE HOLDING / AENOVA](#)), a German company specializing in the manufacture of finished pharmaceutical products and dietary supplements, as well as the joint acquisition of Uriach and Ineldea by Intermediate Capital Group (ICG) and Holding Uriach ([M.11532 - ICG / HOLDING URIACH / URIACH / INELDEA](#)). This transaction involved granting ICG 30% of the capital of Uriach, giving it joint control of the Spanish company specialized in OTC pharmaceutical products, and the acquisition of Ineldea, which develops food supplements and personal care products.

In August 2024, the joint acquisition of Immedica Pharma Holding AB by KKR and Impilo ([M.11609 - KKR / IMPILO / IMMEDICA](#)) was also approved without commitments. Immedica is a Swedish company specialized in the marketing of medicines for rare diseases and care specialized products. The transaction was assessed under the simplified procedure as it did not give raise to competition concerns. In addition, the Commission also approved the acquisition of Vantive, the renal care division of Baxter International, by the Carlyle group ([M.11732 - CARLYLE / VANTIVE](#)) in November 2024, without commitments. The transaction was assessed primarily on the basis of the markets affected by the supply of renal replacement therapy products, and the Commission concluded that it would not reduce competition or create significant barriers to new competitors due to the limited presence of the companies involved in the relevant markets.

Among the most notable transactions highlighted by the European Commission in 2024, is the acquisition of Catalent by Novo Holdings ([M.11486 - NOVO HOLDINGS / NOVO NORDISK / CATALENT](#)), approved without commitments in December 2024, with a value of \$16.5 billion. This

¹⁶ NOVO HOLDINGS / NOVO NORDISK / CATALENT (M. 11486); CARLYLE / VANTIVE (M. 11732); KKR / IMPILO / IMMEDICA (M. 11609); KÜHNE HOLDING / AENOVA (M. 11571); ICG / HOLDING URIACH / URIACH / INELDEA (M. 11532); ICG / HOLDING URIACH / URIACH / INELDEA (M. 11532); OTPP / NORDIC CAPITAL / ADVANZ PHARMA (M.11512).

transaction aimed to increase the production capacity of *semaglutide*, the active ingredient in the drugs Ozempic and Wegovy, with the addition of three Catalent plants in Italy, Belgium and the US, which will be operated by Novo Nordisk. The Commission concluded that this transaction did not pose significant risks to competition due to the presence of sufficient competitors in the market.

Finally in 2025 were approved without commitments, in January, the acquisition of Opella Healthcare SAS by CD&R Fund XII, L.P. ([M.11813 - CD&R / OPELLA](#)), in February, the acquisition of IFF Pharma Solutions segment by the French company Roquette ([M.11592 - ROQUETTE / IFF PHARMA SOLUTIONS](#)) and, in May, the acquisition by Carlyle Group Inc. and SK Capital Investment VI, Ltd. of Bluebird bio, Inc. ([M.11935 - CARLYLE / SK CAPITAL PARTNERS / BLUEBIRD](#)), which is primarily engaged in the development and commercialization of gene therapies. According to the Commission, these transactions also did not pose significant risks to competition due to the lack of significant overlaps between the companies involved.

2. PHARMACEUTICAL SECTOR IN SPAIN

In January 2024, the CNMC decided not to initiate infringement proceedings against Igualatorio Médico Quirúrgico Colegial, Sociedad Anónima de Seguros (IMQ) ([S/0640/18 - CCM OFTALMOLOGÍA](#)), for the alleged violation of Articles 1 and 2 of the Spanish Law 15/2007, of 3 July, on the Defense of Competition (“LDC”) and to close the proceedings. The CNMC considered that there was insufficient evidence to prove that an infringement had been committed in relation to the amendment of IMQ's Internal Regulations (under which IMQ policyholders could not be treated at non-affiliated centers belonging to competing entities). The CNMC concluded that IMQ did not hold a dominant position in the market and, furthermore, established that the amendment did not constitute a restrictive practice of competition or an abuse of a dominant position, as it was a decision that only affected the conditions for the provision of healthcare services to its own insured members.

In November 2024, the CNMC initiated an infringement procedure against the General Council of Official Colleges of Pharmacists of Spain (CGCOF) and eleven Official Colleges of Pharmacists (COF), after receiving a complaint from Luda Partners, S.L., a company that develops digital applications for pharmaceutical logistics ([S/0009/23 - PHARMACEUTICAL LOGISTICS | CNMC](#)).

The proceedings were initiated on the grounds that the CGCOF had recommended that pharmacists use certain digital applications (CisMED and FarmaHelp) to control drug shortages. According to the CNMC, the collective recommendation could have affected competitors developing similar applications, such as the complainant, LudaFarma.



On the other hand, in January 2025, the CNMC decided not to initiate infringement proceedings in case [S/0006/24 - COUNCIL OF DENTAL AND STOMATOLOGICAL ASSOCIATIONS 2](#). In this case, the General Council of Dental Technicians of Spain (CGCP) reported the General Council of Official Associations of Dentists and Stomatologists (CGCOD) for practices that allegedly limited the freedom of patients to choose their dental technician. However, the CNMC recalled that, according to the decision of 17 December 2015, in case [S/0299/10 - COUNCIL OF DENTAL AND STOMATOLOGICAL ASSOCIATIONS](#), Articles 12 and 70 of the Spanish Code of Dental Ethics and Professional Conduct (now Articles 18 and 76) were not considered inherently contrary to Article 1 of the LDC, but rather that the conduct sanctioned in 2015 consisted of agreements signed to implement a collective strategy of recommendations to coordinate the actions of dentists. Therefore, the authority concluded that there was insufficient evidence to proceed with disciplinary proceedings and decided to close the case.

In March 2025, the CNMC initiated several infringement proceedings, notably in the pharmaceutical sector. [S/0014/23 - CLUB SANDOZ](#) investigates a possible exchange of sensitive commercial information between the pharmaceutical companies Sandoz Farmacéutica S.A., Bexal Farmacéutica S.A. and Bluetab Solutions, S.L., regarding orders for Sandoz/Bexal generic medicines placed by certain pharmacies (through the supplier Alliance Healthcare España, S.A.), without their knowledge or consent.

In the same month, the CNMC initiated proceedings [S/0008/25 - SANITAS-GENERALI AGREEMENT](#) against Sanitas and Generali for alleged practices contrary to Article 1 of the LDC, following a period of confidential information gathering. The CNMC is now investigating whether, through the agreement signed by the companies in October 2022 (under which Sanitas took over the management of Generali's customer care services and their payment to hospitals), the insurers fixed the prices and commercial conditions of Generali's customer policies (the consumers affected by the agreement), as well as whether they established clauses that could limit competition between the two insurance companies, not only in relation to these consumers but also in relation to other markets outside the agreement.

Finally, also in March 2025, the CNMC ruled that Hermandad Farmacéutica del Mediterráneo (HEFAME) had committed a very serious infringement of Article 62.4.c) of the LDC by certifying the breach of the commitments made in the merger operation [C/1340/22 - HEFAME/COFARCU | CNMC](#), within the framework of surveillance file [VC/1340/22 - HEFAME/COFARCU | CNMC](#) ([SNC/DC/010/25 - HERMANDAD FARMACEUTICA DEL MEDITERRANEO | CNMC](#)). Once the infringement procedure was initiated, HEFAME acknowledged its responsibility and paid the corresponding penalty, benefiting from a 40% reduction in the fine.

MERGER CONTROL OPERATIONS ANALIZED BY THE CNMC

During 2024 and the first quarter of 2025, the CNMC approved seven merger operations in the pharmaceutical sector, six of which were authorized in the first phase without the imposition of commitments and one in the first phase with the imposition of commitments. In February 2025, it also agreed to initiate a second phase of a merger control process.

In February 2024, the CNMC authorized, in the first phase and without commitments, the acquisition of sole control of Shanghai Raas Blood Products CO., Ltd by Haiyingkang (Qingdao) Medical Technology CO., Ltd ([C/1444/24 - HAIYINGKANG-QINGDAO- / SRAAS](#)); in July 2024, the creation of the joint venture Terafront Farmatech, S.L. by Laboratorios Farmacéuticos Rovi, S.A., Insud Pharma, S.L., and Innverté Economía Sostenible SICC, SME, S.A. ([C/1484/24 - ROVI / INSUD / INNVIERTE / TERAFRONT FARMATECH JV.](#)); in December 2024, the acquisition of sole control of Healthtech HTBA Holding, S.L. by Miura Private Equity S.G.E.I.C., S.A. ([C/1512/24 - MIURA PARTNERS SGEIC / HEALTHTECH HTBA HOLDING](#)); in February 2025, the acquisition of sole control of Mifamurtida de Takeda Pharmaceuticals International AG by Esteve Pharmaceuticals, S.A. ([C/1527/25 - ESTEVE / TAKEDA'S MIFAMURTIDA BUSINESS](#)), and the acquisition of sole control of Bruges Asistencial, S.A. and Synlab Diagnósticos Globales, S.A.U. by Eurofins Clinical Testing Services Spain Holding, S.L. ([C/1533/25 - EUROFINS/SYNLAB ESPAÑA](#)); and in March 2025, the acquisition of sole control of Stamina Topco B.V. and Synthon B.V. by Skio Bidco B.V. ([C/1542/25 - BIDCO / STAMINA TOPCO](#)).

In June 2024, the merger between MCH and CASP in their beauty and wellness retail businesses in Spain, with the integration of the Arenal and Druni brands ([C/1456/24 - CASP- MCH / DRUNI / ARENAL](#)), was also approved in first phase, but with commitments. The transaction affected the perfumery, cosmetics, drugstore and parapharmacy market, and the Competition Directorate considered that the resulting market share in some municipalities, combined with the lack of competitive pressure, could pose risks of price increases, deterioration in quality or a reduction in brand quality. Therefore, with the aim of ensuring the maintenance of effective competition, the CNMC approved the operation with structural¹⁷ and behavioural¹⁸ commitments.

On the other hand, in February 2025, the CNMC agreed to initiate the second phase of the merger control process of [C/1501/24 - CURIUM / IRAB](#). The transaction under review, consisting of the acquisition of Institut de Radiofarmàcia Aplicada de Barcelona, S.L. by Curium Pharma Holding Spain, S.L.U. will be assessed in the second phase by the CNMC, as it concluded that such concentration gives rise to significant horizontal overlaps. The CNMC has confirmed that the parties have combined market shares of over 60% in the domestic market for the manufacture and marketing of PET radiopharmaceuticals for the diagnosis of prostate cancer.

3. NEW SPANISH REGULATION IN THE PHARMACEUTICAL SECTOR

The pharmaceutical sector faces a constantly evolving legal environment, especially in a global context characterized by geopolitical instability and challenges arising from the health and economic

¹⁷ Among the commitments made are the divestment of a Druni retail establishment, whereby the buyer of the divested asset undertakes to operate it for a minimum period of three years, and Arenal's commitment to divest itself of Maremor.

¹⁸ The parties to the merger undertake not to establish or acquire control over any additional retail outlets selling perfumery, cosmetics, drugstore and parapharmacy products in the municipalities most affected during the divestiture period and the following two years.

crisis. The European Union and Member States have stepped up their legislative efforts to ensure that companies operate within a fair competitive framework, promoting innovation and ensuring that the citizens have access to effective and affordable treatments.

In Spain, in December 2024, the Council of Ministers approved the Pharmaceutical Industry Strategy 2024-2028¹⁹, recognizing the strategic nature of the pharmaceutical sector. This Strategy was, in turn, presented by the President of the Spanish Government to the CEOs of 16 major pharmaceutical companies on 12 February 2025.

One of the most significant developments in this context is the Preliminary Law on Medicines and Healthcare Products, the draft of which was published in April 2025, which seeks to update and modernize the existing regulatory framework. This new legislative text will introduce several key reforms that will affect both the pharmaceutical industry and consumers, as it is aimed at improving access to medicines at different stages of the medicine life cycle²⁰.

With regard to competition law, the main new features of the Preliminary Law on Medicines and Healthcare Products include the modification of the Spanish reference price system²¹ and the modification of the system for prescribing and dispensing medicines.

While the current reference price system aligns the prices of equivalent medicines with the lowest price (without allowing price differentiation between equivalent medicines), the current reform proposes (i) a selected price system²², and (ii) a reference price system²³. Under the selected price system, the Ministry of Health will use information on drug prices provided by the marketing authorization holders or their representatives to propose homogeneous groups of interchangeable drugs. For each group, a proposal will be made that includes: the drug with the lowest price, a group of drugs with selected prices and another group with non-selected prices²⁴.

Meanwhile, the modification of the reference price system, to which public funding for medicines will be subject, seeks to propose sets of prices that will include all medicines (with the same anatomical-

¹⁹ The Pharmaceutical Industry Strategy 2024-2028 was presented by the Government in December 2024 and was drawn up by the Ministries of Health, Finance, Industry and Tourism, and Science, Innovation and Universities, in addition to various pharmaceutical industry associations. Available at: <https://www.sanidad.gob.es/gabinete/notasPrensa.do?id=6585>

²⁰ The Draft establishes three fundamental phases in the life cycle of medicines: a first phase in which the medicine is still under regulatory protection and/or patent, and in which the key element is to guarantee access to innovation in the healthcare system; a second phase, when the periods of protection expire and it is possible to market medicines that do not require full development because they are based on other medicines (generics), and which lead to price reductions; and a third phase, in which, after a period of competition between developers, the number of manufacturers decreases and the price is very low.

²¹ To be further developed by the future Royal Decree on the Price and Financing of Medicines (page 10 of the Executive Document of the Preliminary Draft of the Law on Medicines and Healthcare Products. Available at: https://www.sanidad.gob.es/areas/farmacia/legislacion/docs/Anteproyecto_de_Ley_Medicamento.pdf

²² Preliminary Draft of the Law on Medicines and Healthcare Products, article 115.

²³ Preliminary Draft of the Law on Medicines and Healthcare Products, article 114.

²⁴ Prices not selected refer to medicines that are not included in the list of prices selected for financing by the National Health System.

therapeutic-chemical classification) financed by the National Health System, in which a maximum price range (the reference price) will be determined.

On the other hand, the pharmaceutical provision system and the intervention in the prices of medicines and healthcare products are developed in Title IX of the Preliminary Draft. In general, it is established that medicines and healthcare products shall be prescribed by their Spanish Official Name (DOE) or International Non-proprietary Name (INN) of the active ingredient, although it is also possible to prescribe them by their trade name, provided that this is accompanied by the active ingredient. In this regard, when patients go to a pharmacy to obtain their medicine, various scenarios may arise²⁵:

- i. If the medicine has other “*equally dispensable*” medicines²⁶ and the prescription is for the active ingredient, the professional must dispense the medicine with the lowest price, provided that the patient does not express any preference.
- ii. If the prescription is for a medicine and an active ingredient, and the patient requests a medicine other than the one prescribed (but with the same active ingredient), if this medicine is within the selected price range, the pharmacy professional will dispense the medicine chosen by the patient without charging the price difference.
- iii. If the patient requests a different medicine (same active ingredient) that is outside the price range, the pharmacy professional will dispense the medicine and charge the difference between its price and the price of the lowest-priced medicine in the homogeneous group.

The CNMC conducted a study on the wholesale market for medicines²⁷ in May 2022 and, in April 2024, following the announcement by the Ministry of Health on the proposed reform of the Law on Medicines Guarantees, the CNMC's *blog* published an article echoing the proposals contained in the aforementioned study, which included:

*“We proposed **modifying the current drug pricing system** (which does not allow price differentiation between branded drugs and generic or biosimilar drugs) **and replacing it with a flexible system**, in which drugs can have different prices (whether branded, generic or biosimilar). This flexibility would encourage the development and entry of new players into the generics and biosimilars market and would be key to promoting effective competition in the pharmaceutical sector.*

*The CNMC also proposed other **changes to drug prescription and dispensing policies** to maximise the impact of the measure. We suggest that pharmacists inform consumers about the*

²⁵ Preliminary Draft of the Law on Medicines and Healthcare Products, article 99.

²⁶ Same active ingredient and therefore suitable for homogeneous grouping.

²⁷ Study on the wholesale distribution market for medicines (E/CNMC/002/17) published by the CNMC on 24 May 2022. Available at: <https://www.cnmc.es/expedientes/ecnmc00217>

alternatives and prices available on the market, in order to empower them and increase their choice.” (CNMC blog)²⁸.

With the publication of the Preliminary Draft of the Law on Medicines and Healthcare Products, the CNMC blog has published new recommendations²⁹, including that the prescription and dispensing of medicines should allow pharmacists to propose several alternatives (rather than always having to offer the cheapest option), while proposing to reform the reference price system so that, in practice, it does not determine the prices of medicines but is more flexible, as well as expanding the reference sets of the reference price system, among other measures.

In this context, the National Association of the Pharmaceutical Industry and four other associations and federations in the sector, through their joint statement³⁰, have expressed concerns about these measures, arguing that the price control strategy could discourage innovation and affect the competitiveness of the Spanish pharmaceutical industry at the international level.

However, we must remember that this text is only a preliminary draft and is therefore subject to a legislative process that must pass through the Spanish Parliament. This means that the proposal could undergo substantial changes before becoming a law. Consequently, it will be necessary to wait for the final version of the legislative text to make more accurate assessments of its effectiveness and the real impact it will have on the pharmaceutical industry and the healthcare system.

²⁸ CNMC blog; “La salud es lo primero: más competencia entre medicamentos para reforzar el sistema sanitario” [Health comes first: more competition between medicines to strengthen the healthcare system], of 22 April 2024. Available at: <https://blog.cnmc.es/2024/04/02/salud-competencia-entre-medicamentos-para-reforzar-el-sistema-sanitario/>

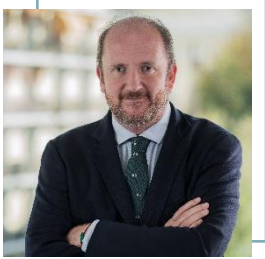
²⁹ CNMC blog; “Competencia saludable en el mercado de medicamentos” [Healthy competition in the medicine market], of 15 April 2025. Available at: <https://blog.cnmc.es/2025/04/15/competencia-saludable-en-el-mercado-de-medicamentos/>

³⁰ Joint statement by the Spanish Association of Generic Medicines, the Spanish Association of Biosimilars, the National Association of the Pharmaceutical Industry, the General Council of Pharmaceutical Colleges of Spain and the Federation of Pharmaceutical Distributors. Available at: <https://www.farmaindustria.es/web/prensa/notas-de-prensa/2025/04/10/posicionamiento-conjunto-ante-el-anteproyecto-de-ley-de-los-medicamentos-y-productos-sanitarios/>

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