# Pharmaceutical Antitrust

*Contributing editors*
**Marta Giner Asins and Yann Anselin**

2017

GETTING THE DEAL THROUGH

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## Pharmaceutical regulatory law

### 1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

Royal Decree-Law 1/2015 of 2 July 2015, which approved the consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices (hereafter the Medicines Act), entered into force on 25 July 2015 and has repealed the former Medicine Act 29/2006, which itself had replaced the Medicines Act of 1990. The Medicines Act governs the authorisation, pricing and financing, marketing, and pharmacovigilance of pharmaceutical products. The procedure of authorisation, registration and dispensation of industrially manufactured medicines for human use is further regulated by Royal Decree 1345/2007.

The Medicines Act regulates price intervention of medicines that are financed by the National Health System (NHS). Although manufacturers are in principle free to determine the prices of their products, the prices of medicines that are reimbursed by the NHS and dispensed in Spain are fixed by the government as maximum prices. Pharmacies, wholesalers and pharmaceutical companies are required to provide the necessary information to allow reimbursement by the pharmacies to wholesalers and pharmaceutical companies of the difference between the regulated price and the free price when medicines included in the NHS financing system are dispensed in Spain through a private prescription. Royal Decree 271/1990 on the reorganisation of price intervention of human medicines further develops the procedure for setting the industrial price of medicines.

Royal Decree 177/2014 regulates the reference price system and homogenous group system. The reference price system is relevant for the financing of medicines, in that it determines the maximum price at which medicines are financed by the NHS. The homogeneous group system is relevant for the dispensation of medicines, in that it determines the price relevant for the application of dispensation and substitution obligations imposed on pharmacists. Royal Decree 177/2014 also regulates certain information systems in connection with the financing and pricing of medicines and medical devices.

The main regulatory body in charge of enforcing the Medicines Act is the Spanish Agency for Medicines and Sanitary Products (AEMPS). The AEMPS is responsible for the evaluation, authorisation and registration of medicines and medical devices in Spain and its main objective is to ensure that the authorised medicines marketed in Spain meet the fundamental criteria of efficacy, safety, quality and accurate information. The AEMPS functionally belongs to the Ministry of Health (MH).

The AEMPS develops a wide range of activities within the framework of medicine evaluation and authorisation for human and animal use: clinical trials, authorisation, continuous monitoring of medicine safety once medicines are on the market, quality control, authorisation and inspection of pharmaceutical companies, supervision of medicine supplies and its supply to the public, certification, control and supervision of medical devices, combating illegal and counterfeit medicines and medical devices, monitoring safety procedures for cosmetics and hygiene products, and providing all relevant information to the public and healthcare professionals.

The Directorate General for the Basic Portfolio of NHS Services and Pharmacy of the MH decides on the inclusion of a medicine in the NHS and manages the reference price system.

The Interministerial Price Commission for medicines of the MH is responsible for fixing prices of medicines.

The 17 Spanish regions have competencies in health and are responsible for the provision of public healthcare services and the enforcement of the regulation governing wholesale and supply, advertising and promotion, etc.

### 2 Is there specific legislation on the distribution of pharmaceutical products?

Royal Decree 823/2008 sets the margins of wholesalers and pharmacies, as well as certain deductions and discounts applicable to the dispensation of human medicines. Royal Decree 1416/1994 establishes the main rules concerning the advertising of medicines for human use.

Royal Decree 870/2013 regulates the distance sales, through websites, of non-prescription medicinal products for human use.

### 3 Which aspects of this legislation are most directly relevant to the application of competition law to the pharmaceutical sector?

Articles 94 et seq of the Medicines Act, which govern the intervention of pharmaceutical prices by the government, are the most relevant provisions for the application of competition law in the pharmaceutical sector since they are at the origin of the parallel trade phenomenon that has given rise to a proliferation of cases before the European Commission (EC) and the EU Courts (GSK Spain), the national competition authority and the Spanish courts, as will be detailed below. Prices fixed at an artificially low level provide a strong incentive to wholesalers (and even pharmacies) to export medicines into higher-price countries, such as the UK, the Netherlands or Germany.

Articles 67 et seq of the Medicines Act concerning wholesale distribution are also relevant, in particular since wholesalers have relied on them to claim a right to be supplied by pharmaceutical companies.

The provisions of the Act regulating marketing authorisations, the limits to their withdrawal from the market or the NHS, or the obligation to keep the market supplied are also likely to become relevant following the EU's precedent set in the *AstraZeneca* case. In general, the high level of regulation and intervention is relevant to the application of the competition rules, since, together with the NHS's purchasing power, it led the Spanish Competition Authority for Markets and Competition (CNMC) for many years to conclude that pharmaceutical companies are not necessarily dominant, even where their market shares in a given product are high. Although in more recent decisions the authority found that regulation does not necessarily exclude dominance, it nevertheless took this circumstance into account in assessing the existence of an objective justification to allegedly abusive conducts. Legal limitations on advertising and promotion of medicinal products are also relevant to the application of the competition rules and set the framework for voluntary codes of conduct in the industry.

## Competition legislation and regulation

### 4 Which legislation sets out competition law?

The Spanish Competition Act 15/2007 (SCA) and its implementing Regulation 261/2008 establish the essential provisions of national competition law. The EU's competition rules, in particular articles 101 and 102 of the TFEU, are cumulatively applicable to any case that is liable to affect trade between member states of the EU.

The prohibition of anticompetitive agreements is enshrined in article 1 of the SCA, which mirrors article 101 of the TFEU. Article 2 of the SCA prohibits any abuse by one or more undertakings of their dominant position in all or part of the Spanish market and mirrors article 102 of the TFEU. A peculiarity of Spanish law is the possibility of considering acts of unfair competition that distort the conditions of competition in the market as a separate infringement of the SCA, apart from the possibility of pursuing such infringements before the commercial courts under the Unfair Competition Act. Thus, article 3 of the SCA prohibits acts of unfair competition that affect the public interest by distorting free competition. In a decision of 23 January 2014, the CNMC found that the offer by generic producers of discounts to pharmacists above the maximum level permitted by law could infringe article 3 of the SCA, although it dismissed the case on the facts, since no such discounts had actually been offered.

The Spanish merger control regime applies to any concentration in which at least one of the two following circumstances is met:

- a market share of at least 30 per cent is reached or exceeded as a consequence of the concentration in the relevant national product or services market or in a geographical market defined therein. However, even if this threshold is met, the transaction is exempted from the merger control regime when the total turnover in Spain of the target does not exceed €10 million in the last financial year, provided that the individual or combined market share of the parties is below 50 per cent in any of the affected markets in Spain; or
- the aggregated turnover in Spain of all the companies involved in the transaction in the last financial year exceeds the amount of €240 million, provided that at least two of the companies involved have an individual turnover in Spain of at least €60 million.

These thresholds are only triggered if the transaction does not have a 'Community dimension' pursuant to the EU Merger Regulation. When the relevant thresholds are met, a filing to the CNMC is mandatory before the transaction is closed (a notification can be made from the moment there is a concentration project or agreement).

Spanish law only provides for criminal sanctions for antitrust infringements as regards bid rigging in public tenders, which could become relevant in hospital and other public tenders in the pharmaceutical sector. The corresponding provision of the Criminal Code has, however, not yet been enforced in practice. Since October 2015, companies that have participated in bid-rigging cartels in public tenders may be excluded from future tenders under the public procurement rules.

### 5 Which authorities investigate and decide on pharmaceutical mergers and the anticompetitive nature of conduct or agreements in the pharmaceutical sector?

In Spain, the central competition authority is the CNMC, which was created by Act 3/2013. The CNMC is the result of a merger, as of 7 October 2013, of the former Competition Authority (CNC) with the regulatory agencies of the network industries (telecommunications, energy, postal, railroad, broadcasting and airlines). The CNMC has two separate decision-making chambers that are in charge of antitrust and regulatory issues, although cases that are relevant to both sections are heard by the Plenary Chamber. Investigations in the area of antitrust are carried out by the Directorate of Competition, which concludes its investigations with a proposal to the Council. The Competition Chamber of the Council then makes a final decision on the case. Regional competition authorities are also competent to investigate and decide on anticompetitive practices (when their scope and effects are limited to the territory of the respective region), although their practical relevance is more limited. Spanish commercial courts are also empowered to apply EU and national competition law regarding anticompetitive practices or abuses of a dominant position.

The CNMC is the only competent body to investigate and clear mergers in the pharmaceutical industry. It has the power to adopt final decisions in merger proceedings, either prohibiting or authorising proposed transactions (with or without conditions). The government may only intervene exceptionally against a decision prohibiting a merger or making its clearance subject to conditions, provided the Minister of Economy decides to refer such cases to the Council of Ministers. In such cases the Council of Ministers has the power to amend the CNMC's decision on relatively broad grounds of public interest, such as national security, public health or the environment. Since the current SCA entered into force in 2007 the government has only used its powers on one occasion (*Antena 3/La Sexta* case). The CNMC analyses whether the proposed transaction may hinder the maintenance of effective competition in the market. The substantive test under the Spanish competition regime is therefore virtually equivalent to the 'significant impediment of effective competition' test under the EU Merger Regulation.

Judicial appeals against resolutions of the Council of the CNMC may be lodged before the Spanish National Court.

### 6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

The resolutions of the CNMC may order the cessation of the prohibited conduct; the imposition of specific conditions or obligations, be they structural or behavioural; the removal of the effects of the prohibited practices contrary to the public interest; and the imposition of fines. By way of example, in 1998, the Spanish competition authority imposed fines on various pharmaceutical companies for rigging public vaccine tenders and ordered the companies concerned to cease their collusive practices. In a 2004 decision, it held that the recommendation of the association of pharmaceutical wholesalers (Fedifar) to their members to uniformly react to the introduction of a new pricing scheme by Pfizer amounted to a collective recommendation prohibited by article 1 of the SCA and ordered them to cease that practice, although no fines were imposed.

Infringements of the SCA are classified as minor (including submission of incorrect, misleading or false information, procedural infringements), with a fine of up to 1 per cent of the undertaking's total turnover; serious (infringement of substantive competition rules), with a fine of up to 5 per cent of the total turnover; and very serious (including cartels and the abuse of a dominant position when it is committed by an undertaking that operates in a recently liberalised market, has a market share near monopoly or enjoys special or exclusive rights), with a fine of up to 10 per cent of the total turnover. In addition to these sanctions, a fine of up to €60,000 may be imposed on the legal representatives of the company or on the persons that comprise the management bodies that have participated in the agreement or decision. In May 2016, the CNMC imposed for the first time fines on four executives of adult-diaper manufacturers and their association for participating in a cartel to fix the prices of adult-diapers financed by the NHS and sold through the pharmacy channel. The CNMC may also impose periodic penalty payments of up to €12,000 per day to oblige undertakings to comply with a decision.

A leniency regime was for the first time included in the SCA of 2007 and entered into force in February 2008. This leniency regime offers both total immunity and a reduction of fines in cartel cases, and regulates the procedures for exemptions and reductions of the amount of fines. In June 2013, the CNC published guidelines on its leniency programme.

### 7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Any victim of an anticompetitive agreement or conduct by a pharmaceutical company would be entitled to claim damages before the commercial or civil courts, both in follow-on or stand-alone damages actions based on the general provisions of the Spanish Civil Code. In the case of horizontal agreements, typically cartels, both direct and indirect purchasers have standing to claim damages. In a judgment of 7 November 2013 in the *Sugar* cartel case, the Supreme Court recognised that the infringing parties may invoke the passing-on defence against any such claims by direct purchasers. Nonetheless, the burden of proof in that respect is on the infringing party, which will have

to prove that not only the excessive price, but the entire 'damage' (ie, including possible lost profit due to a loss of market share, etc), has been passed on to the next level.

**8 May the antitrust authority conduct sector-wide inquiries? If so, have such inquiries ever been conducted into the pharmaceutical sector and, if so, what was the main outcome?**

The CNMC is competent to launch sector-wide inquires. To date, no sector-wide enquiries have been conducted into the pharmaceutical sector. However, in October 2015 the CNMC published a study on the retail distribution of pharmaceutical products, which analysed the restrictions of competition stemming from the current regulatory framework (eg, restrictions concerning the number of pharmacies, the distance between them) and proposed several measures to increase competition. The CNMC also published a report on the Draft Royal Decree Law that approves the consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices (the future Royal Decree Law 1/2015), and a report on the Draft Royal Decree on financing and pricing of pharmaceutical and healthcare products. In November 2016, the CNMC published a report on the Draft Royal Decree implementing the new Patent Act. The Report analyses possible anticompetitive use of patents, particularly in the pharmaceutical sector, through collusive practices (patent settlements) or unilateral conduct (patent thicket, product hopping, abuse of litigation, abuse of regulatory proceedings, etc) and invited the legislator to take these practices into account in designing a patent system that reconciles promotion of innovation and defence of competition.

**9 To what extent do non-government groups play a role in the application of competition rules to the pharmaceutical sector?**

Under the Spanish Civil Procedure Act, legally constituted consumer and user associations have standing to defend the rights and interests of their members and of the association in court, as well as the general interests of consumers and users. Trade associations and consumer groups also have standing to file complaints before the CNMC and have the right to be consulted on the approval of any new regulation.

The Spanish Association for the Pharmaceutical Industry (Farmaindustria), Fedifar and the Spanish Federation of Pharmacists have in the past filed complaints before the Spanish competition authority against alleged anticompetitive practices or abuses of a dominant position. The European Association of Euro-Pharmaceutical Companies has also brought complaints against pharmaceutical companies related to parallel trade issues.

## Review of mergers

**10 Are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?**

Mergers between two pharmaceutical companies are analysed on a case-by-case basis. If the specific features are relevant for the competition analysis they will be taken into account. Certain aspects have been referred to widely: with respect to entry barriers, the most important for the manufacturing and marketing of medicines is pharmaceutical regulation, as well as patents and the procurement of raw materials, among others. In addition, the strong countervailing buyer power is also relevant since the Spanish public authorities, in particular the NHS, are the main customers of pharmaceutical companies.

**11 How are product and geographic markets typically defined in the pharmaceutical sector?**

The CNMC has adopted the same approach as the EC when assessing the market definition in the pharmaceutical sector. Regarding product market definition, the CNMC has in general defined it on the basis of the third level of the ATC classification that allows for a regrouping of pharmaceuticals based on their therapeutical indication, although on occasion it has relied on other ATC levels, including ATC5. In a decision of 13 February 2014, in the context of a possible abuse of a dominant position by Pfizer, the CNMC defined the market based on the fourth ATC level, following the EC's more recent practice to define relevant markets more narrowly in abuse cases. In accordance with the EC's practice, the geographic market is usually defined as national because of its regulation.

**12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?**

The criteria to be taken into account in merger reviews under the SCA include the economic efficiencies derived from the concentration, and, in particular, the contribution that the concentration may make to improving the production or marketing systems, and to business competitiveness, and the extent to which these efficiencies are transferred to the intermediate and ultimate consumers, specifically in the form of a larger or better supply and of lower prices.

**13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?**

When assessing mergers, the Spanish competition authority analyses whether a product and geographical overlap may hinder the maintenance of effective competition in the market. The first elements taken into account when analysing a merger are the structure of the relevant markets and the position of the parties therein. However, under certain circumstances, high market shares are not necessarily equivalent to a hindrance of effective competition in the market and concentrations resulting in high market shares have been authorised in a number of cases (for instance, in July 2016, the CNMC authorised a concentration between two manufacturers of radiopharmaceuticals, giving rise to market shares of 70 to 80 per cent).

Other elements taken into account when analysing a merger are the existence of actual or potential competitors inside or outside the national market, the possible alternatives for suppliers and consumers and their access to supply sources, the existence of barriers to entry into the market, the evolution of supply and demand, the negotiating power of supply and demand and their capacity to compensate the position of the parties to the transaction in the market, and the economic efficiencies derived from the operation, in particular the contribution of the merger to the development of production or marketing systems, the competitiveness of the industry and the proportion in which those efficiencies are transferred to consumers through a better or wider offer and lower prices.

**14 When is an overlap with respect to products that are being developed likely to be problematic? How is potential competition assessed?**

In order to identify overlaps, the CNMC usually considers actual market shares. An example of potential competition overlaps can be found in the telecommunications sector, where the Spanish competition authority opposed Telefónica's acquisition of Iberbanda, given that the latter was developing a competing technology.

**15 Which remedies will typically be required to resolve any issues that have been identified?**

Remedies may be either structural or behavioural, although as in the EU the CNMC has a certain preference for structural remedies. The CNMC closely monitors the compliance by the parties with any remedies that have been made binding on them and, indeed, the remedies as such most usually include reporting obligations to the CNMC on the compliance with the conditions imposed.

A (rare) example of a concentration in the pharmaceutical sector authorised subject to conditions is the *Cofares/Hefame* case, a concentration of two wholesalers active in the distribution of pharmaceutical and para-pharmaceutical products in Spain and controlled by cooperatives of pharmacies. The Spanish competition authority held that minimum purchase obligations of the members of the two pharmacy cooperatives and minimum membership terms amounted to a barrier to entry for new wholesalers. The potential threat to competition was high given the large market share that the merged entity would have. Thus, the merger was approved under the conditions that the minimum purchase requirement was lowered from 30 per cent to 25 per cent, and the minimum term of membership was reduced from five years to one year.

**16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?**

The acquisition of one or more patents or licences would be considered as a concentration for merger control purposes, provided that a turnover can be attributed to the asset in question.

## Anticompetitive agreements

**17 What is the general framework for assessing whether an agreement or practice can be considered anticompetitive?**

Article 1(1) of the SCA prohibits all agreements, collective decisions or recommendations, or concerted or consciously parallel practices, that have as their object, have, or potentially have the effect of preventing, restricting or distorting competition in all or part of the Spanish market. Agreements that would otherwise be caught by article 1(1) of the SCA may be exempted if they generate efficiencies that benefit consumers, do not impose restrictions that are not indispensable for the attainment of these efficiencies and do not eliminate competition on the relevant market. Pursuant to the SCA, EU block exemption regulations also apply in the national context (ie, to agreements that do not affect trade between member states). Although article 1 of the SCA closely mirrors article 101 of the TFEU, it differs from the latter in that it explicitly prohibits 'conscious parallel practices', a form of concerted practice that has also been developed in the ECJ's case law. The Spanish competition authority defined this practice in its 2001 decision in *Laboratorios Farmacéuticos* as 'a harmonised behavior by various market participants that is not the result of an express or tacit agreement, but the result of carrying out their respective actions with the purpose of avoiding disharmony'. In the *Vaccines* case of 1998, the CNMC relied on mere incidental evidence for its finding of a concerted bid-rigging practice. In October 2015, the CNMC closed proceedings against several pharmaceutical companies and the Spanish Federation of Health Technology Companies for alleged information exchanges and price-fixing agreements, without deciding on the substance, since the alleged infringements were time barred. In a decision of 12 January 2016, the CNMC dismissed a complaint by a regional health authority against the Ministry of Health, Farmaindustria and several pharmaceutical companies, in relation to an alleged concerted practice not to participate in a tender organised by the regional authority to select pharmaceutical products to be dispensed in pharmacies in case of prescription by active substance and certain measures taken by the Ministry against the initiative of that authority. According to the CNMC, the conduct of the Ministry of Health fell outside the scope of competition law since the Ministry acted as a public authority and the conduct of the pharmaceutical companies could be explained by the legal uncertainty concerning the legality of the tender organised by the regional health authority, the competence of which to organise such a tender had been challenged by the Spanish government before the Constitutional Court.

With regard to collective recommendations, in its 2009 decision *Productos Farmacéuticos Genéricos*, the CNMC fined four pharmaceutical associations for making collective recommendations in an attempt to harmonise the economic behaviour of pharmacists against Laboratories Davur. However, in a judgment of 24 October 2014 the Supreme Court quashed this decision, holding that the communications sent by the associations to pharmacists were not aimed at harmonising their behaviour in relation to certain price cuts announced by Davur, but essentially provided information on the legislation in force and an interpretation of the legal criteria to determine which product pharmacists are required to dispense (not the cheapest product but the one with the 'lowest price' included in Annex 5 to Order 3997/2006). In a 2009 decision, confirmed by judgment of the Supreme Court of March 2015, the CNC found that a regional health authority and the Council of Official Associations of Pharmacists had infringed article 1 of the SCA by agreeing that the Official Associations of Pharmacists would establish which pharmacies would supply, in rotation, public and private medico-social centres, which amounted to market sharing. In monitoring the compliance with the 2009 decision, the CNMC found in a decision of September 2014 that certain medico-social centres were implementing a system of rotating shifts between the pharmacies supplying them, but held that the implementation of this system was the result of a unilateral decision of the centres, therefore being outside the scope of article 1 of the SCA. In a decision of November 2016, the CNMC found that there was no evidence of a concerted practice between pharmacies of the Murcia Region, through the Official Association of Pharmacists of that Region, to establish a similar system of rotating shifts, but also ordered the investigatory body to continue monitoring, since other possible forms of coordination between pharmacies had not been analysed during the investigation and the regional legislation in force promoted the adoption of agreements between pharmacies.

**18 To what extent are technology licensing agreements considered anticompetitive?**

Technology licensing agreements are assessed under Commission Regulation (EU) No. 316/2014 of 21 March 2014 on the application of article 101(3) of the TFEU to categories of technology transfer agreements (TTBER), which is applicable mutatis mutandis to article 1 of the SCA. The TTBER provides a general exemption for two-party technology transfer agreements involving patents, know-how or software copyrights if the parties' market share in any relevant product market or technology market does not exceed 20 per cent (combined, for competitors) or 30 per cent (each, for non-competitors). However, the TTBER exemption generally does not apply to agreements that include restrictions on price, limits on output, market-allocation provisions, or restrictions on the licensee's ability to conduct research or exploit its own technology.

**19 To what extent are co-promotion and co-marketing agreements considered anticompetitive?**

There are no precedents of co-promotion and co-marketing agreements analysed by the CNMC. While co-promotion agreements are less problematic from an antitrust perspective because the parties are usually not competitors in the manufacturing of the product in question, co-marketing agreements may give rise to horizontal price fixing or market sharing and should, therefore, be carefully assessed. Nevertheless, following the *Johnson & Johnson/Novartis* decision of the EC, co-promotion agreements might be found to infringe article 1 of the SCA or article 101 of the TFEU if they are entered into by an originator and a generic producer to delay generic entry.

**20 What other forms of agreement with a competitor are likely to be an issue? Can these issues be resolved by appropriate confidentiality provisions?**

Of particular concern to the CNMC since the entry into force of a new Competition Act in 2007 have been the activities of industry associations, and many decisions imposing fines have been adopted. They relate to information exchange schemes – which must not lead to an exchange of individual, non-historic data, but rather limit themselves to the exchange of aggregated historical data – collective recommendations, such as those condemned in the above-mentioned *Fedifar* and *Davur* decisions (the latter was quashed by the Supreme Court); and codes of conduct, which must not limit competitive behaviour, such as advertising, beyond what is indispensable to achieve legitimate deontological objectives. In its decision of 23 January 2014 (*Especialidades farmacéuticas genéricas*) the CNMC found that the declarations made by the president of a generic manufacturer association from his personal Twitter account, concerning generic producers who offered aggressive price reductions to the NHS, were not capable of significantly affecting competition, given their limited reach and short duration. The recent judgment of the Supreme Court in the *Davur* case, as well as other judgments that annulled decisions of the competition authority on collective recommendations in other sectors, might lead the authority to raise the standard for a finding of an illegal collective recommendation.

**21 Which aspects of vertical agreements are most likely to raise antitrust concerns?**

Any limitation of parallel trade in vertical agreements is likely to raise competition concerns. After GSK Spain notified a dual-pricing scheme to the EC in 1998, the ECJ held on appeal, on the one hand, that any limitations of parallel trade, also in the pharmaceutical industry, were restrictions of competition 'by object', and, on the other, that the Commission had been wrong to reject the exemption sought by GSK for that restriction under article 101(3) of the TFEU. The litigation at EU level was accompanied by a myriad of cases before the Spanish competition authority and the administrative courts, which were eventually all

**Update and trends**

After the CNMC's *Pfizer* decision of 19 January 2017 and potential appeals against it by parallel traders, it is likely that parallel trade will remain a hot topic in the Spanish pharmaceutical sector.

decided in favour of GSK. Following these precedents, pharmaceutical companies started adopting free-pricing systems instead of the usual supply quota systems operated under the *Bayer-Adalat* case law of the European Courts. Under these schemes the manufacturers only set one free price, which applies to any situation not leading to a reimbursement under the public price intervention scheme described above. Thus, if a medicine is financed by the NHS and dispensed in Spain, the regulated price set by the state will apply, while medicine exports are subject to the (higher) free price set by the manufacturer.

The EAEPC and a Spanish wholesaler complained against this new pricing scheme to the CNC, which dismissed these complaints, holding that there was no dual pricing and therefore no restriction of competition. On appeal, the Spanish National Court quashed these decisions in two judgments of 2011 and 2012, holding that the scheme limited parallel trade and therefore had to be assessed pursuant to the *GSK Spain* case law of the ECJ, which qualifies agreements restricting parallel trade as restrictions of competition by object. It also held, however, that under the same case law, the agreements might qualify for exemption under article 101(3) of the TFEU, but that the CNMC had to pronounce itself in this respect. The 2011 and 2012 judgments of the Spanish National Court were confirmed by the Supreme Court in two judgments of 3 December 2014 and 4 March 2016. In particular, in the judgment of 3 December 2014 the Supreme Court rejected that there had not been an 'agreement' for the purposes of article 101 of the TFEU between Pfizer and its wholesalers, since Pfizer had concluded supply contracts with each wholesaler, which included the 'free pricing' provisions. According to the Court, these clauses have as their main object to impede or restrict parallel exports of pharmaceuticals into other member states of the EU. The ruling recalls that the judgment of the Spanish National Court rests on the ECJ's ruling in *GSK Spain*, where the Court held that the application of different prices to financed medicines dispensed in Spain and higher prices to exported medicines, amounted to a restriction of competition contrary to article 101(1) of the TFEU. Further to the Supreme Court's judgment of 3 December 2014, in March 2015 the CNMC started infringement proceedings against Pfizer in relation to a possible restrictive practice consisting of establishing supply contracts liable to impair parallel trade. In its decision of 19 January 2017, the CNMC held that the pricing system established by Pfizer does not infringe Article 1 SCA. First, the CNMC found that Pfizer did not establish a dual pricing system with the object of restricting parallel trade, but only set a free price, which is then replaced by the regulated price when the requirements for the application of the latter are fulfilled. According to the CNMC, Pfizer's behaviour is not an autonomous behaviour, due to state intervention, and cannot therefore be deemed to infringe competition law. Secondly, the CNMC found that the GSK case law cannot be applied by analogy to the Pfizer's case, since the applicable legal framework is different. According to the CNMC, the establishment of a dual pricing system by GSK was the result of a voluntary decision by GSK, who made an extensive interpretation of the legislation then in force that required the application of the regulated price to all financed medicines sold in Spain (independently of where they were dispensed). In the new legal framework that entered into force in January 2000 – in which the regulated price no longer applied to all sales of financed medicines in Spain, but only to sales of financed medicines actually dispensed to patients in Spain – the establishment by Pfizer of different prices for the same medicine merely complied with the applicable legislation, which implicitly introduced the existence of two different prices for the same product.

Similarly, in a judgment of 7 December 2015, the Provincial Court of Madrid held that the *GSK Spain* case law was not applicable to the free-pricing system of a pharmaceutical company, essentially arguing that the legal framework of the Medicines Act had changed since the *GSK Spain* case and that the scheme did not amount to dual pricing, but rather was the result of a unilateral decision of the pharmaceutical company. In the same judgment, the Audiencia Provincial held that the restructuring of the distribution system of that pharmaceutical company, which resulted in a reduction in the number of wholesalers, was objectively justified since it pursued the objective of increasing efficiency and therefore could not be held abusive, even assuming that the company were dominant.

**22 To what extent can the settlement of a patent dispute expose the parties concerned to liability for an antitrust violation?**

No cases have been decided yet, but the CNMC is likely to apply the same principles developed in the EC's *Lundbeck* decision, confirmed by the judgment of the General Court of 8 September 2016 (ie, agreements whereby an originator company makes payments or gives other benefits to generic companies for delaying the launch of a generic challenging the originator's patent (reverse payment patent settlement) may be deemed to infringe article 1 of the SCA or article 101 of the TFEU). In a decision of 18 June 2014 (*Citicolina*), the CNMC dismissed for lack of evidence an anonymous complaint against a pharmaceutical company for delaying and impairing generic entry by means of, inter alia, payments made to potential competitors in exchange for not entering the market. In the same decision, the CNMC ordered the Competition Directorate to monitor future developments in the market and, in particular, the granting of marketing authorisation of the active substance at issue and the actual marketing of the authorised products.

**23 Are anticompetitive exchanges of information more likely to occur in the pharmaceutical sector given the increased transparency imposed by measures such as disclosure of relationships with HCPs, clinical trials, etc?**

Taking into account, in particular, the type of data to be published, the level of aggregation and the frequency of publication, transparency obligations assumed by pharmaceutical companies should not raise competition concerns.

## Anticompetitive unilateral conduct

**24 In what circumstances is conduct considered to be anticompetitive if carried out by a firm with monopoly or market power?**

Under article 2 of the SCA, any abuse by one or more undertakings of their dominant position in all or part of the national market is prohibited. Dominance is not in itself prohibited, but if an undertaking holds a dominant position it has a special responsibility to ensure that its conduct does not distort competition. Abusive behaviour consists mainly of exclusionary conduct (predatory pricing, exclusive dealing, refusal to supply, tying) and exploitative abuses (excessive pricing, discrimination between customers). In its 2003 *Cofarca* decision, the CNMC fined a cooperative of pharmacists for abusing its dominant position in a regional market of wholesale distribution of medicines by imposing minimum purchase obligations on its members. In December 2015 the CNMC initiated infringement proceedings against IMS Health for a possible infringement of article 2 of the SCA and article 102 of the TFEU through the establishment of contractual conditions with Spanish pharmaceutical wholesalers that would allegedly impair or impede the entry of new competitors in the market. In February 2017, the CNMC initiated infringement proceedings against Aspen and its Spanish distributor Deco Pharma, for alleged abusive practices by Aspen (refusal to supply and application of excessive prices) and an alleged agreement between Aspen and Deco Pharma to limit distribution.

**25 When is a party likely to be considered dominant or jointly dominant?**

The market share is the first element analysed when assessing dominance together with other factors, such as the market shares of competitors, historical volatility of such market shares, entry barriers, countervailing buyer power and the level of regulation, a key element in the pharmaceutical sector.

For many years, the Spanish competition authority has held that in view of the heavy regulatory burdens and in particular the intervention of prices by the public authorities and the buyer power of the NHS, pharmaceutical companies are not in a dominant position even if their market share in a given product market is clearly above 50 per cent. These findings have been made in the context of complaints against manufacturers for refusing to supply extraordinary quantities of pharmaceuticals to wholesalers. More recently, the authority no longer seems to exclude

the possibility of dominance. In particular, in the *Sedifa-Grufarma* case, the CNC stated that the fact that the activity of pharmaceutical companies is regulated and their ability to act may be limited in certain aspects does not impede a possible finding of dominance (which was not established in the case at issue). In the *Pfizer/Xalatan* case, the CNMC found that Pfizer held a dominant position because of the exclusivity granted by the patent on the latanoprost active substance.

**26 Can a patent holder be dominant simply on account of the patent that it holds?**

As indicated, in the *Pfizer/Xalatan* case, the CNMC found that Pfizer held a dominant position because of the exclusivity granted by the patent on the latanoprost active substance. However, a patent holder should be held dominant only if no substitutes of the product in question exist on the relevant product market. In the above-mentioned judgment of 7 December 2015 the Provincial Court of Madrid refused to find dominance based only on ownership of a patent.

**27 To what extent can an application for the grant or enforcement of a patent expose the patent owner to liability for an antitrust violation?**

There are no precedents in Spain where an application for a grant of a patent has been considered as an abuse. In the *Pfizer/Xalatan* decision of 13 February 2014, the CNMC closed the proceedings initiated against Pfizer in relation to the prolongation of the Xalatan's patent, holding that no infringement of article 2 of the SCA and article 102 of the TFEU had been proved. In its reasoning the CNMC referred to the *AstraZeneca* judgment (C-457/10), although it did not expressly invoke the differences between Pfizer's and AstraZeneca's respective conducts to conclude that Pfizer's conduct was not abusive. The CNMC also seems to have taken into account the fact that Pfizer did not send communications to Spanish authorities and generic producers concerning the prolongation of its patent, it only initiated judicial proceedings against one generic producer that it then withdrew and generic products were marketed in Spain during the period of the patent's prolongation. Interestingly, the CNMC's investigation was prompted by an investigation of the Italian competition authority concerning essentially the same product and similar practices, which, however, terminated with an infringement decision confirmed by the Italian State Council.

Regarding the enforcement of patents by bringing actions for patent infringement, in the 1998 *Wellcome* case (R 315/98), the Spanish competition authority found that the criminal proceedings for patent infringement initiated by Wellcome against the generic producer Combino Pharm and the company that manufactured generics on behalf of Combino Pharm were aimed at protecting alleged patent rights that Wellcome deemed infringed by these two companies. It found that this practice could not be deemed as an unfair competition act by reason of the publicity given by the press to the proceedings at issue and in any event did not appreciably affect competition contrary to the public interest. In the 2011 *Novartis* decision, the CNC closed proceedings against Novartis for an alleged abuse of a dominant position by bringing an action for patent infringement against the generic company Actavis, which it subsequently withdrew. The CNC held that Novartis' legal suit and request for preliminary measures could a priori seem excessive or disproportionate in light of Actavis' conduct (Actavis had obtained marketing and price authorisation for a generic product), but there were no indications of an abusive exercise of the right to judicial protection, to the extent that Novartis' withdrawal of the legal suit was not the result of an agreement or settlement between the parties.

**28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?**

There are no decisions of the Spanish competition authority on life-cycle management strategies. However, the *AstraZeneca* judgment (C-457/10) is likely to be followed as a precedent. The above-mentioned *Pfizer/Xalatan* case also provides a first example of the CNMC's position towards practices aimed at prolonging patent protection.

**29 May a patent holder market or license its drug as an authorised generic, or allow a third party to do so, before the expiry of the patent protection on the drug concerned, to gain a head start on the competition?**

Given that Spanish regulation imposes prescription by active substance, obliges pharmacists to dispense the medicine with the lowest price and therefore excludes originator drugs if they do not match the lowest price, there are no incentives for a patent holder to license or market such generics before the expiry of its patent.

**30 To what extent can the specific features of the pharmaceutical sector provide an objective justification for conduct that would otherwise infringe antitrust rules?**

For many years, the Spanish competition authority and courts have recognised that the specific features of regulation may exclude the existence of dominance on the part of pharmaceutical companies, although more recently in the *Sedifa-Grufarma* case the CNC did not exclude the possibility of dominance on this basis. However, in the same case the CNC held that the allegedly abusive conduct – refusal to supply to certain wholesalers – should be assessed taking into account the legal and economic context, in particular, the partial liberalisation of the price of medicines following the 2006 Medicines Act, which prompted a restructuring of the pharmaceutical companies' distribution networks for efficiency reasons. The CNC finally held that even assuming dominance, the conduct at issue was not abusive since it was objectively justified by this restructuring aimed at increasing efficiency. In its decision of 19 January 2017, the CNMC relied on the state's intervention on prices of medicines to come to the conclusion that Pfizer's pricing system did not infringe article 1 SCA.

**31 Has national enforcement activity in relation to life cycle management and settlement agreements with generics increased following the EU Sector Inquiry?**

So far there has been no increase in these types of cases following the EU Sector Inquiry.

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