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Excessive Pricing in Pharmaceutical Markets - Note by Spain

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More documents related to this discussion can be found at

www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm

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Spain

1. The Spanish Competition Act - and in coherence with the art.102(a) of the Treaty for the Functioning of the European Union - explicitly prohibits the **abuse of a dominant position**[1], which **includes fixing excessive prices**. Moreover, and in line with the European Court of Justice, it is assumed that a price is abusive if *"it has no reasonable relation to the economic value of the product, whether the price cost margin is excessive or the price imposed is either unfair in itself or when compared to competing products.*

2. In cases of price abuse, article 25 of Law No.15/2007 establishes that the National Commission on Markets and Competition (**CNMC) shall act as consultative body on matters related to competition.** In particular, the CNMC may be consulted by the Legislative Chambers, the Government, Ministerial Departments, Autonomous Communities, Local Corporations, Professional Bodies, Chambers of Commerce and the business or consumer organisations. In any event, the CNMC shall issue an opinion, through a report, in the process of developing standards that affect its scope of competence (i.e. draft and proposal rules that affect competition, the provisions of current regulations, criteria for the quantification of compensations in antitrust practices, and so on).

3. On the other hand, regarding the collaboration and information duties, the CNMC can set additional ways of communication with other public authorities, either through formal or informal contacts. The former, described in article 39 of Law No 15/2007, involves the **formal request of information, and implies specific timelines and format.** The latter, which is the most useful one, comprises informal meetings or phone calls with the authorities as well as informal information exchange (through e-mails). So far, in sanctioning procedure as well as in mergers, the contacts with the involved entities (i.e. competitors, associations and affected parties) and authorities of the pharmaceutical sector (i.e. the Health Ministry, the Spanish Patent Office, and the AEMPS) have been carried out by formal request for information. However, in preliminary proceeding, these aforementioned entities and authorities have also been contacted in the framework of the informal procedure.

4. Outside pharmaceutical sphere, in the last ten years, the CNMC has resolved **several cases against exploitative price abuse**[2]. In those cases, the methodology used by the CNMC to determine whether a price is excessive and/or unfair, was to **compare on a consistent basis the prices in other similar markets such as the European countries**.

[1] Art.2 Law No 15/2007

[2] S/0157/09 ENTIDAD GESTION DERECHOS PRODUCTORES AUDIOVISUALES,EGEDA(https://www.cnmc.es/expedientes/s015709); S/0208/09 AISGE CINES(https://www.cnmc.es/expedientes/s020809); SACAN/0003/10 - EXPLOSIVOS CANARIAS (https://www.cnmc.es/expedientes/sacan000310); S/0220/10 SOCIEDAD GENERAL DE AUTORES Y EDITORES,SGAE(https://www.cnmc.es/expedientes/s0220109);S/0211/09 ENDESA INSTALACIÓN(https://www.cnmc.es/expedientes/s021109); S/0297/10 AGEDI/AIE (https://www.cnmc.es/expedientes/s029710); S/0446/12 ENDESA INSTALACIÓN (https://www.cnmc.es/expedientes/s044612); S/0460/13 SGAE – CONCIERTOS (https://www.cnmc.es/expedientes/s046013); S/0500/13 AGEDI/AIE RADIO (https://www.cnmc.es/expedientes/s050013).

This methodology has been approved by the European Court of Justice in different rulings such as in the Tournier Case[3].

5. Regarding sanctions or remedies against excessive pricing, all the restrictive conducts included in articles 1, 2 or 3 of Law No 15/2007 (collusive conduct, abuse of a dominant position and distortion of free competition by unfair acts respectively), infringements and fines have been typified and fixed in terms of a percentage of the total sales volume of the offenders.

6. On the basis of the offender's situation the abuse of a dominant position can be considered as a (i) serious and (ii) very serious infringement (when an undertaking that operates in a recently liberalised market, has a market share close to monopoly or which enjoys special or exclusive rights) and so the respectively maximum fines range from 5% to 10% of the total turnover of the infringing undertaking in the previous business year to that of the imposition of the fine.

7. During a sanctioning procedure, it is worth mentioning the flexibility of the system of conventional termination[4] (article 52 of Law No 15/2007), focused on the proposal on commitments by the alleged offender. This is a negotiation among the authorities and the parties, which can be adopted without the agreement of the rest of the interested parties in the proceeding.

8. With regard to precautionary measures, at any time during the sanctioning proceedings and without a deadline, the Law No 15/2007 makes the system flexible and expeditious for its agreement. Additionally, as all sanctions imposed by the application of Law No 15/2007 are published, the dissuasive and exemplary power of the resolutions that are adopted is reinforced.

1. THE CASE OF PHARMACEUTICAL MARKETS, PHARMACEUTICAL REGULATION AND PRICE REGULATION

1.1. The market

9. According to the legal framework for pharmaceutical products, it is substantial to highlight the particularities of this sector compared to other markets.

- Firstly, the pharmaceutical sector covers different products, such as medicines and medical devices, with different regulations. Despite the fact that both of them could be included and reimbursed by the National Health System (SNS) after meeting the criteria set out by the authorities, the ways for fixing the price of medicines differ from those of medical devices, there are different barriers to entry into these markets and consequently, different strategies for antitrust practices. When it comes to control and monitor the market, these aspects are challenges to the competition authority.

3 Sentence European Court of Justice 13 July 1989 C-395/87

4 Conventional Termination (art. 52 of Law 15/2007) implies the early termination of a sanctioning file, by the approval by the CNMC of commitments (adequate and binding) presented by the offenders that would solve competition problems detected effectively and rapidly. This procedure can only be used when certain conditions provided in the above-mentioned law.

- Regarding **medicines**, depending on the nature of the product (innovator, generic, biosimilar, orphan, pediatric, and so on) and the authorisation procedure (centralised or national procedure), there could be different incentives for companies: additional patents (supplementary protection certificate (SPC), secondary patents,…), data protection, market protection, market exclusivity for orphan medicinal products and rewards for paediatric medicinal products. Additionally, specifically in Spain, they could have free price or controlled price if they are reimbursed (called "reference price system"). However, this controlled price is a maximum price, which could be reduced by public tender for hospitals. Private hospitals have their own negotiations. Distribution and dispensation margins are fixed for reimbursed medicines and are set by a royal decree (they vary depending on the laboratory price fixed by the Health authority).
- Regarding the **medical devices**, they do not entail a specific authorisation for their commercialisation, but they do have a certification procedure (assessed by external certifying entity or by the own manufacture) that allows them to move freely all over the EEE. Moreover, they do not have any additional patent (SPC), data protection or market exclusivity as the medicines have. Consequently, in general terms, the incentives and the entry barriers are lower than in the case of medicines. Furthermore, these products could be sold for free or under a controlled price if they are reimbursed by the Public Health Administration. However, so far, they are not included in any "reference price system". A proposal for a new regulated system is currently in course. As well as medicines, medical devices could be obtained by public hospitals through public tenders. The fixation of the final price of the medical device implies that the different actors on the commercialisation process (manufacturers, distributors and pharmacies) could control their benefits based on the margins that they settle.

10. All these incentives and strategies are taken into account by the CNMC as a way to understand and investigate the affected market, independently on how it is defined.

11. In this sense, the CNMC acknowledges that market regulation might be necessary in this market in order to protect the public general interest. However, a proper understanding of how competition works is also key to avoid introducing or maintaining unjustified restrictions to competition that prevent or make it difficult to achieve greater efficiency in the functioning of this market and the use of public resources. With this objective in mind, the CNMC launched a market study on the pharmaceutical market in Spain, with the aim to identify potential improvements for competition in the regulatory framework.

1.2. Prices

1.2.1. Price regulation.

12. Spanish pharmaceuticals pricing systems are different depending on whether pharmaceuticals are publicly financed by the National Health System (SNS) or they are not. Spanish price regulation is contained in the Royal Legislative Decree 1/2015, of July 24.

13. In general, pharmaceutical laboratories are free to set the price for pharmaceuticals that are not financed by the SNS[5]. By contrast, publicly financed pharmaceuticals by the SNS are subject to strict regulation of prices. The Health Ministry is in charge of the **industrial price decision (fixing and revision)** for each medicine presentation, to be included or already included, in the National Health System (SNS).

14. There are mainly two different systems for setting the industrial price[6] of publicly financed pharmaceuticals, depending on whether they are (i) innovations -and then not exposed to competition from generics - (fixed price system), or (ii) they are off-patent pharmaceuticals (reference price system)[7]. Discounts on the retail price of financed pharmaceuticals are not allowed in any case.

Fixed price system.

15. In general, every financed pharmaceutical whose price is not determined by the reference price system -see below- (i.e. mostly innovative pharmaceuticals) will be included in the fixed price system.

16. The Inter-Ministerial Commission for Pharmaceutical Prices (CIPM) - dependent of the Ministry of Health, Consumption and Social Welfare, and formed by representatives of the Health, Economy and Finance Ministries and Autonomous Communities -, is in charge of the industrial price decision for each pharmaceutical. According to the law, this Commission has to make its decisions objectively and taking into account cost-effectiveness analysis and budgetary impact. In practice, the CIPM also takes into account other elements (like sales prevision, international prices, therapeutic gaps) to make its price decisions. Moreover, pharmaceutical prices can be revised in case of changes in therapeutic value, or in economic, technical or sanitary circumstances.

17. The criteria applied to fix prices are very general, leaving ample room for discretion, and prices are not revised following a regular schedule.

18. The CNMC is in charge of monitoring the market and the evolution of prices fixed by the CIPM and controlling the potential exclusionary practices from innovators and antitrust agreements (such as exclusivity distribution, pay for delay, secondary patents, and so on). The CNMC does not intervene in the price fixation process. Its supervisory role is developed once the medicines are marketed or issuing regulation reports during public consultation phase before approving new regulations.

5 Nevertheless, non-publicly financed pharmaceuticals can be subject to a regulated pricing system (notified prices) under some circumstances: pharmaceuticals that used to be financed by the SNS but have recently been removed from the public catalogue are obliged to join this system, and the rest of non-financed pharmaceuticals can do it voluntarily. According to the notified prices system, laboratories communicate its prices to the Ministry of Health, Consumption and Social Welfare, who can reject them on grounds of the general interest.

6 Pharmaceuticals' retail price is obtained by adding the regulated distribution margins to the industrial price.

7 The Royal Legislative Decree 1/2015 contains another pricing scheme for financed pharmaceuticals, called selected prices system, but as long as the CNMC knows, it has never been applied. It consists of the following: the Ministry of Health, Consumption and Social Welfare proposes a maximum price for a presentation, and the laboratories who are interested in it fix that price, becoming the only ones who can provide the presentation to the SNS for two years.

Reference price system.

19. Most off-patent pharmaceuticals are included in the reference price system. It is based on "reference groups" (each group contains every pharmaceutical presentation with the same active ingredient and route of administration). Reference price is the highest price that the SNS pays for pharmaceuticals included in reference groups. This price is calculated as the lowest cost per treatment and day of the pharmaceuticals contained in each reference group. Every year, reference groups and prices are updated.

20. There is a complementary system, based on *"homogeneous groups"*. Each homogeneous group is formed by pharmaceuticals with the same active ingredient, dose, content, pharmaceutical form and route of administration, which can be interchangeable. The lowest price of each homogeneous group is the maximum price paid by the SNS. The lowest price is updated each month.

21. This pricing scheme is applied to pharmaceuticals where commercial protection (the monopoly granted by the patent) comes to an end, and it is the mechanism by which generics[8] introduce price pressure on branded pharmaceuticals. This system allows the SNS and patients to obtain important savings and contributes to the sustainability of public finance, due to the fact that, when a branded drug enters the reference price system, its price equals that of the generics. As the minimum price of the group falls, it follows that the rest of pharmaceuticals get their price cut too.

Distribution margins.

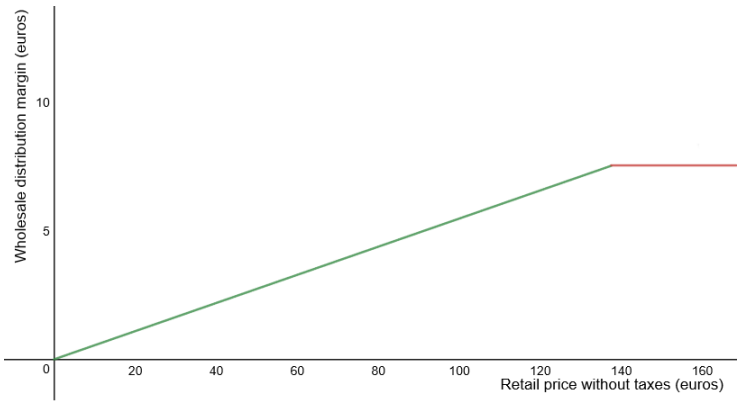
22. In Spain, distribution of pharmaceuticals is subject to regulation of commercial margins. This applies to all drugs, regardless whether they are financed or not by the SNS. Royal Decree 823/2008, of May 16, establishes the margins, deductions and discounts corresponding to the distribution and dispensation of pharmaceuticals for human use. The objective of said regulation is twofold: (i) to control public spending and (ii) to control excessive pricing at the distribution level.

23. The current margins for wholesale distributors and retailers are the following:

- Wholesale margins:
  - 7.6% of the wholesale price without taxes, if the industrial price is equal to or lower than 91.63 euros.
  - 7.54 euros per container if the industrial price is higher than 91.63 euros.

[8] In order to promote generics in Spain, there are currently some regulatory policies, like encouraging the use of INN (International Nonproprietary Names) prescription or the possibility for a pharmacist to substitute a prescribed pharmaceutical by an interchangeable one with lower price, under some circumstances. Between 2012 and 2015, there was a positive discrimination rule for generics (in case of equality of price between a branded name pharmaceutical and a generic, pharmacists had to dispense the generic presentation), but it was repealed.

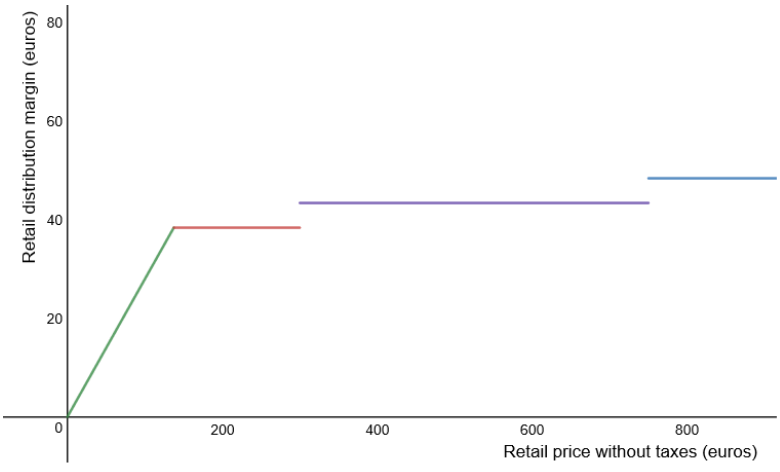
Figure 1. Wholesale distribution ranges of medicines



Note: The margins established for wholesale distribution act as maximums, since distributors can apply discounts to pharmacies, against their own margin, for volume and prompt payment. The possibility of establishing discounts to pharmacies therefore allows exerting some competitive pressure in the market for wholesale distribution of medicines to pharmacies.
Source: elaborated by the CNMC based on the Royal Decree 823/2008

- Retail (pharmacies) margins:
  - 27.9% of the retail price without taxes, if the industrial price is equal to or lower than 91.63 euros.
  - 38.37 euros per container if the industrial price is higher than 91.63 euros and equal to or less than 200 euros.
  - 43.37 euros per container if the industrial price is greater than 200 euros and equal to or less than 500 euros.
  - 48.37 euros per container if the industrial price is greater than 500 euros.

Figure 2. Retail distribution margins



Note: The Royal Decree also determines the contribution that pharmacies should make, depending on their sales, to the National Health System. Thus, the margin they obtain for dispensing medicines should be reduced according to a scale of deductions based on sales volume (the higher the sales volume, the greater the contribution to the National Health System becomes).
Source: elaborated by the CNMC based on the Royal Decree 823/2008

24. Margin regulation can take different forms, including regressive margins, proportional margins, flat rates and mixed forms, as is the case of Spain. As illustrated by the above figures, in the case of drugs with a retail price up to 91.63 euros, unit margins are set as a fixed percentage (%) of the sales price. For drugs beyond 91.63 euros, margins are set as a fixed amount per unit (with three different brackets in the case of retail margins).

25. While margins should remunerate distribution costs, it is not entirely clear whether unit distribution costs are constant per unit sold or proportional to the retail price of drugs. Depending on the cost structure, the Spanish model may make more attractive for wholesalers and retailers to sell drugs within a particular range of prices, where unit margins – relative to unit costs – are highest.

26. The CNMC is currently examining the Royal decree proposal of medical devices regarding the fixation of their margins on distribution and commercialisation.

1.2.2. Excessive pricing in the Spanish pharmaceuticals.

27. Within the pharmaceutical sector, given the complexity of the sector and the broad variety of cases, the Spanish Competition Authority ("CNMC") **does not have an automatic or specific protocol or screening method to** consider whether a price is excessive in the pharmaceutical sector. The assessment is done **case by case, due to the enormous variety of criteria that should be applied**: legal framework, nature of the illnesses, orphan and pediatric uses, number of patients to treat, treatment length, price of each dose and its dosage, other alternative therapies authorised in Spain and other countries, off label uses, different health care level uses, etc. Therefore, the use of a general method for excessive prices in pharma is not always possible because, in most cases, it is complicated to set a proper causality relationship between cost-effectiveness analysis and the price actually required.

28. A specific team from the CNMC daily reviews the information published by different websites and well-known bibliography, as a method to detect any trend toward higher prices. In addition to that, the Health regulators (specifically, the CIPM), also track the price evolution before and after the inclusion of a medicine in the National Health System ("SNS"). As a result of this screening process, the CNMC has found certain drugs that have shown upward price revisions, but this fact does not always correspond to anticompetitive behaviour. In the same way, the CNMC works in close collaboration with the Spanish Health Ministry and the AEMPS, to compare whether the reasons for these increases detected respond to objective and justified causes or if, on the contrary, they could be the result of anti-competitive practices.

29. In the last five years, although **the Spanish Competition Authority has not received any complaint against excessive prices situations in pharmaceutical products**, it has pursued several **antitrust investigations** in the pharmaceutical market regarding exclusionary conduct; focused on medicines and medical devices. At least 5 cases have been opened during that 5 year period, however only one (AIO cases) have been ratified by the court of first instance (National High Court).

- **Medical gases** case was initiated in July 2015 (classified information) by the CNMC, after having access to certain information related to possible anticompetitive practices in the market for the manufacture, distribution and sale of medicinal gases. This practice consisted in possible market sharing, price fixing and information exchange agreements in the framework of tenders for supply of medical gases in the national territory. Following the dawn raids carried out in July

2015 at the premises of Linde, Air liquide, Carburos Metálicos, Contse and Praxair, in January 2016 the CNMC opened a formal investigation against a total of ten companies (Linde, Air Liquide, Carburos Metálicos, Gasmedi, Praxair, Contse, Esteve,Teijin Healthcare, Oxigen Salud, Oximesa and Vivisol Ibérica) suspicious of anticompetitive practices, including alleged market-sharing and bid-rigging between 2012 and 2014. However, after the company's replies, only five firms (Linde, Air Liquide, Carburos Metálicos, Gasmedi and Praxair) were included since for the rest of them there was no strong evidence of their participation. Finally the Board found a plausible alternative explanation for the evidence gathered so the CNMC decided in July 12017 to close the investigation.

- **Glucose Test Strips case** was initiated in March 2013 (classified information) by the CNMC after a complaint from Pharmaceutical Free Trade Union of the Valencian Community (SLF-CV) against the Valencian Health Agency (AVS). A possible infraction was alleged by the AVS because of the supply agreement with glucose test strips (medical devices) signed in June 2012 between the Official Associations of Pharmacies of Alicante, Valencia and Castellón, pharmaceutical and distribution companies to benefit the Valencian Health Agency obtained lower prices in comparison with other Autonomous Communities. Following dawn raids carried out at the premises of certain laboratories and one Federation (Spanish Federation of Companies of Sanitary Technology (FENIN)), it was suspected the possible existence of rational indications exchanges of information and agreements for the setting of prices and other commercial conditions of these products, carried out within FENIN and several laboratories (Abbott Laboratories S.A.; Johnson & Johnson S.A.; Menarini Diagnósticos S.A.; Roche Diagnósticos S.L..; Bayer Hispania S.L). In September 2014 the Board initiated a sanctioning procedure, however despite the fact that the prohibited conducts had been accredited for the temporary period, due to the fact that limitation periods had been exceeded, the case was finally filed in October 2014.

- **Aspen case** was initiated in .January 2017 after receiving information from the Italian Competition Authority regarding the price increase for 6 medicines (up to 1,500% in Italy) without any ostensible cost justification jointly with threats of withdrawal them from the list of reimbursable medicines. In Spain, Aspen and its Spanish distributor caused a deliberate shortage to force the acquisition of these medicines via by non regulated prices (foreign medicines). Finally, in July 2017 the case was shelved by the Board due to loss of jurisdiction (Article 44 of Law No 15/2007) and the European Commission assumed the investigation in all Member States, except Italy.

- **AIO case** was initiated in 2014 in the framework of the leniency program requested by Arbora & Ausonia, S.L.U (A&A) and The Procter & Gamble Company(P&G) which helped to initiate dawn raids . A sanctioning file was opened against 15 companies of manufacture, distribution and dispensing of absorbent for the serious incontinence of the urine in adults (AIO) (medical devices) (A&A, P&G, P&G España, S.A, Arbora & Ausonia, S.L.U (A&A), domtar lux holdings, SARL, indas, SCA group holding B.V, SCA, Paul Hartmann España, S.L.U, Laboratorios Hartmann, S.A., Barna Import Medica, S.A., Ontex ES Holdco, S.A, Ontex peninsular, S.A.U, Ontex ID, S.A.U, Textil Planas Oliveras, S.A., Algodones del Bages, S.A.) as well as to the Spanish Federation of Companies of Sanitary Technology (FENIN). The presumed practice consisted in fixing both prices and conditions in the dispensation procedure in the retailed market for avoiding public

tender processes. In the Spanish market, these products are reimbursable and have regulated price (maximum price but not fix margins for distribution and dispensation). The original price of AIO was set in 1997 and it was only revised in 2010 by the parties as a way to encourage the public Administration to maintain the dispensation of this product through the pharmacy channel (fixed price) instead of participating in public tenders (where the price will really decrease in comparison with the proposed price). The case ended in May 2016 by sanctioning the pharmaceuticals and individuals, finning 4 executives who participated directly in the cartel (2 of which have been upheld by the court of first instance as well as the sanctions on the companies).

- **Pfizer /Cofares Case** was initiated in 2005 after a complaint from SPAIN PHARMA, S.A., alleging that PFIZER S.L.U. (PFIZER)and COMPAÑÍA FARMACÉUTICA ESPAÑOLA, S.A.(COFARES) had reached an agreement that prohibited COFARES from exporting medicines from Spain to other EU countries. Additionally, since 2001, PFIZER had established a double-price system (depending on the final destination of the medicine: national o EEE market), restricting the possibility of parallel exports. Despite the fact of that the case was closed by the Board based on the absence of evidence, Judicial review (in the first instance the National High Court in 2011 and finally the Supreme Court in 2014) appealed to reinitiate the case. After the reassessment by the CNMC, finally, on January 2017, the Board issued a resolution stating that it had not been proven that the price system applied by PFIZER, in the early 2000s, constituted a dual price system aimed at restricting parallel trade in the EU. Unlike Glaxo Case (double prices in the parallel trade), price system applied by PFIZER to their distributors derived from the modifications introduced in the Spanish regulation regarding the prices of medicines and not from an autonomous decision of each one.
- **EAEPC/Laboratorios Farmacéuticos** case was initiated by European Association of Euro-Pharmaceutical Companies (EAEPC) against Pfizer, Janseen-Cilag, Merck Sharp & Dohme, Lilly, Sanofi-Aventis and Novartis. Both the complainant and the arguments used by the complainant were the same as those used in Pfizer/Cofares case (dual price in parallel trade). After the resolution of the aforementioned case and its analogy, in August 2018, the CNMC issued the resolution alleging the same arguments.

30. Among these cases, only the Aspen case is a "formal" excessive pricing case. When the patent form the innovator expires, its price in the market usually decreases due to the entry of generics or biosimilars in the market. However, particularly in the Aspen case, after the patent expiration, the price of its five chemotherapy medicines increased between 300 % and 1500 %.

2. COMPETITION ENFORCEMENT AGAINST EXCESSIVE PRICING IN PHARMACEUTICALS

31. In Spain, the CNCM aims to provide a competitive environment and to promote efficient economic regulation throughout the diverse economic sectors, including the pharmaceutical sector. These accountabilities are carried out by the Competition Directorate and the Competition Advocacy Department respectively. Advocacy and antitrust enforcement are in charged with maintaining, securing and promoting

competition, in short and long term respectively. So both of them are indispensable tools to fight against excessive prices in the national market.

32. About sanctions and remedies, According to the national competition authority, excessive price-fixing is considered as one of the possible forms of abuse of a dominant position. In particular, article 2 of the Law No.15/2007 of the Defence of Competition (Competition Act), establishes that it could be included within the dominant position abuse; hence, this practice could be sanctioned as a serious or very serious infringement as aforementioned. Nevertheless, this type of abuse has not been identified and sanctioned recently in Spain in the pharmaceutical sector.

33. Regarding remedies, article 52 of the Law No.15/2007 authorizes the CNMC to resolve the termination of the sanctioning proceedings (conventional termination) in matters of agreements and prohibited practices when the alleged offenders propose commitments that resolve the effects on competition derived from the conduct covered by the proceedings and the public interest is sufficiently guaranteed. This formula was implemented in the IMS case, where the parties proposed different commitments to put an end to the antitrust clauses included in the contract with different distributors.