

## **Lawfulness of free pricing models for pharmaceutical products in Spain: is there really an open debate?**

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Prices of pharmaceutical products are, and have traditionally been, subject to government control or intervention throughout the European Union, though with a varying degree of intensity depending on the country. These government controlled price schemes have led to significant distortions as regards the functioning of the pharmaceutical market. Distortions have also arisen around the legal assessment of certain legitimate practices -implemented by pharmaceutical companies, aimed at exercising the margin of freedom, if any, allowed by certain government control price regulations, such as the ones in force in Spain.

For a number of years we have been witnessing a singular phenomenon in the pharmaceutical sector in Spain: the reorganisation of the traditional supply systems for pharmaceutical products, aimed, precisely, at exercising the (limited) freedom left to pharmaceutical companies by applicable Spanish regulations.

Even though the particular features of the commercial models set by each pharmaceutical company concerned varies significantly, the common denominator is that all such models are based on one or both of the following pillars of any free market economy: (i) the freedom of

pharmaceutical companies to set the price of their products, if and when such price is not subject to government price control, and (ii) the freedom (at least, in principle) to enter, or not, into commercial relationships with clients.

In this article, we will focus on the legal assessment of free price aspects of those commercial models, which pose interesting challenges from a legal point of view. Indeed, the implementation by a number of pharmaceutical companies of the so-called “free price policies” has given rise to a major (and, sometimes, artificial) debate both in Spain and on side Spain.

The free price policies, which in many cases have been in force for several years, have been systematically contested by wholesalers and their associations. Until their introduction, wholesalers had benefitted from the application of artificially low prices (the government controlled prices) to all supplies of medicines from pharmaceutical companies, even in cases in which application of the government prices was not required by Spanish law. The implementation of free price policies meant the application of free market prices (determined by pharmaceutical companies), which are only replaced by government prices (government-set prices) in the case of medicines that meet the statutory intervention requirements.

In general terms, the outcome of challenges brought by wholesalers (either in the form of complaints filed before the antitrust authorities or of legal actions before the courts) has so far proved to be favourable to the thesis of the pharmaceutical companies<sup>1</sup>. However, there is still deep controversy surrounding this issue.

In this article, we will analyse the antitrust precedents in Spain upholding the lawfulness of commercial policies that are based on the -reasonable- exercise of the freedom to set prices. We will also review a recent court judgment (now under appeal) that has, to a certain extent, questioned some of the positions adopted in previous antitrust decisions.

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<sup>1</sup> The long list of “battles” surrounding free price systems is very revealing. At the end of this article, the reader will find a chart summarising the many judicial actions and antitrust complaints that have been brought to date, and their current status.

## What does “free price system” mean? What is the scope of government control in the price of medicines in Spain?

Before analysing the Spanish antitrust precedents concerning free price systems, it is worth taking a brief look<sup>2</sup> at the legal basis for a free price policy.

Article 38 of the Spanish Constitution recognises the “*freedom of enterprise within the framework of the market economy*”. The freedom of enterprise is also a principle of EU law, as has been widely acknowledged by the European Court of Justice.

One of the basic consequences of this general principle is that market operators are free to set the prices of their products. As a limitation to this constitutional freedom, price controls must be exceptional and must be construed narrowly and be strictly limited to an objective and justified scope.

Indeed, such freedom could be limited for reasons linked to the defence of other interests that are equally protected (such as the protection of human health or limiting public expenditure on medicines). The Spanish legislator has (correctly) acknowledged such freedom to set prices, and has considered that there is no reason to limit this freedom with respect to medicines that merely pass through Spain but do not finally benefit Spanish patients.

In this context, Article 90 of Spanish Law 29/2006 of 26 July on Guarantees and Rational Use of Medicines and Medical Devices (“**Article 90**” and the “**Guarantees Law**”, respectively), deals with government price control and impliedly acknowledges that pharmaceutical companies are free to determine the prices of their medicines while it states that, where the conditions for government price control are met (i.e., reimbursement with public funds and dispensation in Spain), pharmaceutical companies become obliged *ex lege* to apply the

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<sup>2</sup> The purpose of this article is not to assess all the legal and practical implications of a free price system, but rather, to provide an overall picture of free price systems with a view to facilitating the understanding of the precedents that will be analysed below. For a fuller legal analysis of these policies, on the basis of acknowledged principles of law (including EU law), please refer to “*Two basic freedoms of pharmaceutical companies regarding the sale of medicines in Spain: freedom to set prices and freedom to contract*” (Pérez Santos and Paz-Ares); ECLR volume 29: Issue 10 in 2008.

government price unilaterally established by the Spanish health authorities. This is the essence of Article 90.

The current wording of Article 90 is the result of an amendment of Article 100 of the former Law 25/1990 on Medicines (“**Article 100**” and the “**Medicines Law**”, respectively) passed in December 1999 by Law 55/1999, which was subsequently reiterated by the Guarantees Law in 2006. Although not identical, there is no significant difference between Article 90 and Article 100 as concerns the subject of the December 1999 amendment. The evolution of the wording of Article 100 was driven by the will of the Spanish legislator to apply the freedom of enterprise principle to the pharmaceutical sector, thus reducing the scope for government price control in medicine prices and returning the right to set prices to the pharmaceutical companies according to free market rules.

It is worth focusing, even if briefly, on the changes made to Article 100<sup>3</sup> in December 1999, as they are key to the assessment of the legality of free price systems:

Article 100.2 until its amendment in December 1999	Article 100.2 after the amendment in December 1999 (introduced by Act 55/1999)	Comparison
<p><i>“The Inter-ministerial Commission for Medicine Prices, ascribed to the Ministry of Health, under the provisions of the foregoing paragraph 1, shall establish the maximum industrial price with national character (“con carácter</i></p>	<p><i>“The Inter-ministerial Commission for Medicine Prices, ascribed to the Ministry of Health, implementing the provisions of the foregoing paragraph 1, establishes the maximum industrial price for each medicine which is dispensed</i></p>	<p><i>“The Inter-ministerial Commission for Medicine Prices, ascribed to the Ministry of Health, implementing the provisions of the foregoing paragraph 1, <del>shall</del> establishes the maximum industrial price <del>with national character</del> for</i></p>

<sup>3</sup> According to the official interpretation of Article 100 until December 1999 (set out in a letter issued by the Sub-secretary of the Ministry of Health dated 5 May 1998), price intervention applied to all medicines made available to wholesalers in Spain. Applying any other price (a free price) amounted to a breach of Article 100 as in force at that time. The pharmaceutical companies were not free to set prices. This official opinion appears word for word in the decision of the Spanish Competition Defence Court of 16 October 1998 regarding the adoption of interim measures in the *Glaxo* case (Case no. 29/98, *Glaxo*).

The wording of the amended Article 100 (as per Law 55/1999, which has been in force since January 2000) reflected this trend towards liberalisation. In the words of the General Directorate for Pharmacy and Health Products (*Dirección General de Farmacia y Productos Sanitarios*) issued on 14 February 2000 “*the intervention of the State is limited not only to authorised medicines, registered and financed with public funds, but also, among that group, only to those to be dispensed in the national territory*” and that “*this means that medicines that are not to be dispensed in the Spanish territory are freely priced*”.

Article 100.2 until its amendment in December 1999	Article 100.2 after the amendment in December 1999 (introduced by Act 55/1999)	Comparison
<i>nacional”) for each medicine which is financed with Social Security funds of Estate funds allocated to health”</i>	<i>in the national territory, financed with Social Security funds of Estate funds allocated to health”</i>	<i>each medicine <u>which is dispensed in the national territory</u>, <del>which is</del> financed with Social Security funds of Estate funds allocated to health”</i>

In short, government price control since January 2000 has been limited to medicines the cost of which is reimbursable with public funds and that are dispensed in Spain.

In essence, the free price policies implemented by pharmaceutical companies under Article 90 consist of them exercising the freedom to determine prices by applying to their products the price they freely set, which is mandatorily replaced by the government price if, and only if, the legal government price control requirements are met.

Regarding the practical implementation of these systems, while a pharmaceutical company knows in advance if its medicines are reimbursable (there must be an official resolution establishing the eligibility for public financing), it does not know if these medicines will be dispensed in Spain. Thus, obtaining information on dispensation in Spain is a “must” for these policies to be correctly applied. This requires the implementation of mechanisms that allow the pharmaceutical companies to obtain information from the wholesalers (as there are no public information sources) about their products that are dispensed in Spain.

### **Favourable antitrust assessment: remarks**

The positive assessment<sup>4</sup> of a free price policy under Article 101 of the Treaty on the Functioning of the European Union (“TFEU”) and Article 1 of Spanish Law 15/2007 of 3 July on the Defence of Competition (the “LDC”) is mainly based on the distinction between lawful free price policies and illicit dual pricing policies. The coexistence of two different prices under a free price policy does not entail “dual pricing” in the classical antitrust sense,

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<sup>4</sup> Vid. *supra*. “Two basic freedoms of pharmaceutical companies regarding the sale of medicines in Spain: freedom to set prices and freedom to contract”

as they are not attributable to the pharmaceutical company, but rather the result of the State's intervention or control in medicine prices.

This opinion has been widely contested, particularly by wholesalers and their associations, who claim that free price policies are contrary to Article 101 TFEU and Article 1 LDC. In particular, claimants state that: (i) the application of two different prices is attributable to an agreement between the pharmaceutical company and its wholesalers aimed at restricting parallel trade; and (ii) free price policies are equivalent to Glaxo's sales conditions implemented in 1998. They also allege that the practical implementation of these policies is anticompetitive, particularly, the obligation on wholesalers to inform the pharmaceutical company about whether the product has been dispensed in Spain.

From this perspective, all decisions of the Spanish Competition Authority (*Comisión Nacional de la Competencia* - "CNC") have expressly and repeatedly assessed free price policies positively. However, a judgment of the *Audiencia Nacional* ("AN") dated 13 June 2011 partially upheld an appeal against the decision of the CNC dated 21 May 2009 regarding the dismissal of a complaint filed by Spain Pharma ("AN Judgment"). In our opinion, there are solid grounds for the revocation of the AN Judgment in the cassation appeal proceedings (*recurso de casación*) pending before the Supreme Court.

### **CNC Decisions**

Three complaints against free price policies implemented by several pharmaceutical companies in Spain have been filed before the CNC based on an alleged infringement of Article 101 TFEU and Article 1 LDC<sup>5</sup>.

All of them have been dismissed by the CNC. We refer to the legal arguments made by the CNC in dismissing them and, in particular, the free price related arguments.

#### *CNC Decision of 21 May 2009 (the Spain Pharma decision)*

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<sup>5</sup> The CNC recently dealt with two additional complaints against new commercialisation policies implemented by pharmaceutical companies in Spain, based on (i) alleged concerted conduct to exclude certain wholesalers from the market, and (ii) an alleged abuse of a dominant position due to a refusal to supply certain wholesalers. Both complaints were dismissed.

The *Spain Pharma* decision analyses a complaint filed back in 2003 by a Spanish wholesaler (Spain Pharma) against a pharmaceutical wholesaler for conduct allegedly contrary to the former Article 81 of the European Community Treaty (“**EC Treaty**”) (current Article 101 TFEU), and Article 1 LDC. In the complaint it was argued that the supply agreement entered into between the pharmaceutical company and its wholesaler included a dual pricing system. The complaint was dismissed by the CNC decision of 21 May 2009.

The CNC did not find that the free price system was a dual pricing system. Rather, the CNC acknowledged that the free price system was a direct result of Spanish legislation, finding that under both Article 100 (in force at the time the complaint was filed) and Article 90, which replaced and superseded the former, “*prices of medicines are freely set, even if they are reimbursable with public funds, whenever they are not dispensed in the national territory*”.

The CNC further found that the implementation of a free price policy is a “*unilateral decision*” (vs. agreement) of the pharmaceutical company based on the application of Article 90.

On this basis, the CNC held that the pharmaceutical company:

*“has not established a dual price for its products depending on the destination of the products. It establishes a single price, which is changed for the intervened price once wholesalers evidence that the medicine has been dispensed in the national territory.”* (our translation)

It is also of note that, as highlighted by the CNC, the free price policy was notified to the European Commission (“**EC**”) and no further action was taken.

As mentioned, somewhat unexpectedly the *Spain Pharma* decision has been partially annulled by the AN Judgment, which is now pending appeal.

#### *CNC Decision of 18 September 2009 (the EAEPC Decision)*

In the *EAEPC* decision, the CNC dismissed a complaint filed on 19 October 2007 by the European Association of Euro-Pharmaceutical Companies (“**EAEPC**”) against six Spanish multinational pharmaceutical companies that were accused of implementing new supply systems that allegedly included dual pricing agreements with wholesalers, in breach of Article

81 EC Treaty as then in force. It was stated that there was no legal basis for this conduct, and that it constituted a barrier to parallel exports.

It was also alleged that the system for exchanging commercial information implemented by the defendants was anti-competitive.

The EAEPC further asked for interim measures consisting of temporarily suspending the new supply systems implemented by the defendants. The CNC did not grant the interim measures and the complaint was dismissed by the CNC Decision of 18 September 2009. This decision is now under appeal before the AN.

In dismissing this complaint, the CNC reinforced and further developed the legal grounds put forward in the *Spain Pharma* decision concerning the “core” of free price policies.

Similarly to the *Spain Pharma* decision, and after an investigation described by the CNC as “*exhaustive*” (the supply agreement between the defendants and the wholesalers was assessed), the CNC noted that:

*“we are not dealing with double pricing conduct; what stems from the information available is that the pharmaceutical companies freely set the prices of their medicines. This is the only price fixed by the companies.”*  
(our translation)

The CNC went on to assess government price control measures in the context of the principle of freedom of enterprise guaranteed by the Spanish Constitution. The CNC concluded that government price control, which is driven by public interest concerns, could not reasonably be extended to other territories as this would unjustifiably limit the freedom of the undertakings.

It is very significant that in the *EAEPC* decision the CNC expressly states that the Spanish legislation on medicine pricing has undergone significant amendments since the *Glaxo* case:

*“[T]he Spanish rules on price intervention of medicines have undergone significant changes since the Commission’s Decision [EC Glaxo Decision], and, under the current regulations, and under those applicable since 2000, it is evident that pharmaceutical companies are able to fix the prices of their medicines and they may do so, even if in certain cases, those of medicines financed by the Social Security and sold in Spain, the prices freely set must be compulsorily replaced by the price imposed by the Spanish authorities in accordance with the law.”* (our translation)



The *EAEPC* decision not only endorsed the inexistence of dual pricing, but also held that there was no indication that the exchange of information mechanisms implemented by the pharmaceutical companies restricted competition. The CNC did not find anything that led it to conclude that the systems put in place to verify dispensation in Spain were anticompetitive, since these information mechanisms were “blind” and handle aggregate and codified data in such a manner that pharmaceutical companies could not know the clientele of their respective wholesalers.

*CNC Decision of 17 February 2010 (the FEFE Decision)*

On 20 January 2008, FEFE (Spanish Federation of Pharmacists’ Associations) filed a complaint before the CNC against eight pharmaceutical companies for alleged anticompetitive conduct consisting of the implementation of a dual pricing system, contrary to Article 81 EC Treaty and Article 1 LDC. FEFE also claimed that certain ancillary or procedural aspects of the new supply policies implemented by the defendants had anticompetitive effects for pharmacists. Among others, FEFE referred to the procedure for verifying whether a given unit of a pharmaceutical product has been dispensed in Spain (and, therefore, whether government prices apply).

The complaint was dismissed by the CNC Decision of 18 September 2009, making the *FEFE* decision final.

The CNC reiterated the assessment made in the *Spain Pharma* and *EAEPC* decisions, but also expanded on the questionable value of the *Glaxo* precedent in order to assess free price policies:

*“The so-called ‘dual pricing’ system in the pharmaceutical sector has been the subject of decisions and judgments of both the Spanish and EU competition authorities and the ordinary courts. In this regard, the Commission decision in the Glaxo Wellcome case, and the subsequent CFI Judgment, invoked in the complaint, as well as the recent judgment of the European Court of Justice (ECJ) of 6 October 2009 reviewing the CFI’s judgment, conclude that this dual pricing system may infringe Article 101 TFEU (former 81). In that case, the pharmaceutical company Glaxo Wellcome had set out general conditions of sale whereby a maximum regulated price would apply to medicines that are dispensed in Spain and paid for by the public health system, and a free price set by the company in*

*the remaining cases. In the cases analysed in this complaint, as well as in the two previous precedents [EAEPC and Spain Pharma decisions], there is no indication of the fixing of a dual price from the commercial conditions agreed between the pharmaceutical companies and the wholesalers. The price fixed by the pharmaceutical companies is a single, free price, and when the pharmaceutical companies know which medicines have been financed by the public healthcare system, they apply the price fixed by the authorities as a maximum price. Thus, we are not dealing with general conditions of sale that impose different prices depending on the product's destination.*

*Furthermore, contrary to the complainant's allegations, it cannot be directly concluded from the case law that the dual pricing system is illegal because the ECJ judgment held that the conduct must be assessed within the legal and economic context of this sector (...)." (our translation)*

### **The AN Judgment**

After successive and repeated court and CNC decisions clearly confirming the lawfulness of a free price policy, there was nothing on the horizon to suggest that the courts would require the CNC to reconsider its previous rulings. As such, the AN Judgment is the first decision that does not confirm the lawfulness of free price policies.

The AN Judgment resolves on the appeal filed before the AN by Spain Pharma challenging the *Spain Pharma* decision. Although the complaint filed before the CNC had a wider purpose, Spain Pharma only challenged the decision of the CNC in connection with the dismissal of the complaint as far as the supply agreements were concerned.

The AN Judgment partially upheld the appeal, annulling the *Spain Pharma* decision insofar as it orders the closure of the proceedings, but it dismissed Spain Pharma's request that the supply agreements be declared null.

The AN "*does not express an opinion as to whether the agreements infringe Article 81 or if paragraph 3 applies, but only reviews the CNC's actions and the grounds on which it dismissed the complaint*" (our translation). The AN does not request the CNC to open sanction proceedings either. The AN Judgement only finds that the CNC's decision not to further investigate the case was mistaken, but does not necessarily prejudge the final assessment or make any binding statement as to the substantive analysis of the case. The AN Judgment is now under appeal before the Supreme Court.

In our view, the AN Judgment fails to assess relevant issues and takes for granted, with little legal support, certain premises which, in our view, are questionable. The following is a brief summary of a number of substantive grounds that confirm the weakness of the AN Judgment from a legal standpoint:

- *There is no “agreement” for the purposes of Article 101 TFEU and Article 1 LDC.* For Article 101 TFEU to apply, there must be an agreement between the pharmaceutical company and the wholesalers to implement the free price policy.
- The AN simply takes for granted that there is such an agreement, but there is no explanation as to why the CNC’s conclusion that the implementation of the free price policy is a “unilateral decision” of the pharmaceutical company, taken without the consensus of the wholesalers, is not upheld.

The AN considers that the fact that the CNC qualified the policy as “unilateral” entails that it is the result of a voluntary action of the pharmaceutical company. However, the fact that a conduct is voluntary does not necessarily mean that Article 101 TFEU and Article 1 LDC apply. The case law of the EU courts and the Spanish Supreme Court<sup>6</sup> has expressly established that purely unilateral measures adopted by pharmaceutical companies in their commercial relationships with wholesalers do not amount to an agreement for the purposes of Article 101 TFEU or 1 LDC. These provisions only apply when at least two parties have reached a consensus to adopt anticompetitive conduct. In this case there was no such consensus:

- The fact that the price policy is adopted within the context of the commercial dealings between the pharmaceutical company and its wholesalers does not necessarily mean that there is an agreement for the purposes of Article 101 TFEU or Article 1 LDC. The implementation of the policy is a unilateral decision of the pharmaceutical company.

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<sup>6</sup> In support of this interpretation, see the judgment of the CFI in *Bayer vs. Commission* (judgment of the CFI of 26 October 2000). This judgment was confirmed by the judgment of the ECJ of 6 January 2004 in *Joined Cases C-02/01 and C-03/01 (the Adalat case)*. Along the same lines, see the judgment of the Spanish Supreme Court of 19 June 2007 (appeal 9449/2004).

- The pharmaceutical company must put in place the necessary mechanisms to comply with the rules on government prices (where applicable). In particular, mechanisms must be established that allow the pharmaceutical company to know if its medicines are dispensed in Spain. In view of the failure of the administrative mechanisms designed for that purpose<sup>7</sup>, pharmaceutical companies must rely on private contractual mechanisms (within the framework of their supply relationships with wholesalers) to gather the information needed about dispensation in Spain. But the existence of an agreement for the purposes of Article 101 TFEU or Article 1 LDC cannot be inferred from this: from the moment when a pharmaceutical company decides to freely set prices, both the company and wholesalers must take all necessary measures to ensure that government prices apply when required by law.
- *There is no anticompetitive conduct.* Nor does the AN make any special effort to analyse the anticompetitive nature of the pharmaceutical company's conduct. Again, the AN takes for granted that the alleged agreement between the pharmaceutical company and its wholesalers is aimed at limiting parallel trade, exclusively based on the *Glaxo* case<sup>8</sup>.

The AN ignores the fact that the pharmaceutical company's commercial policy is not intended to restrict parallel exports, but is rather aimed at applying free prices for medicines whenever this liberty exists in accordance with the law. This commercial policy is supported by the freedom of enterprise principle enshrined in Article 38 of the Spanish Constitution.

- *Pharmaceutical companies' (limited) freedom to fix their prices.* The AN has (wrongly) understood that the CNC and the pharmaceutical company argued that the

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<sup>7</sup> Royal Decree 725/2003 of 13 June imposed an obligation on pharmaceutical companies and wholesalers to provide certain information to the health authorities and gave pharmaceutical companies the possibility to obtain, via certificates issued by the Spanish Ministry of Health, the information on the units of medicines sold to wholesalers at a government price and subsequently re-sold to pharmacies, pharmacy services or other wholesalers. Regrettably, attempts to put the administrative system based on Royal Decree 725/2003 into operation have so far been unsuccessful.

<sup>8</sup> EJC judgment of 6 October 2009 (accumulated cases C-501/06P, C-513/06P, C-515/06P and C-519/06P).

free price policy was an imposition of the pharmaceutical products government price control legislation. The AN devotes sterile efforts to attack such argument. This is not at all the position of the CNC or the pharmaceutical company. Neither of them tried to or justified the existence of an obligation to apply such a system, or that such a system was afforded an exemption under Article 101.3 TFEU.

Analysing whether one of the exemptions under Article 101.3 TFEU applies would only make sense in a scenario where the existence of two prices could be attributed to an agreement between the pharmaceutical company and the wholesalers (an agreement which, as explained, does not even exist). The AN has misunderstood the CNC and the pharmaceutical company's reasoning: the pharmaceutical company –in the exercise of the freedom of enterprise enshrined by the Spanish Constitution- is free to apply the price it freely determines for its pharmaceutical products. Only in those cases where the two statutory government price control requirements are met must the price freely decided by the pharmaceutical company be mandatorily replaced with the government price fixed by the Spanish authorities.

The premise on which the AN's reasoning is based, influenced by the *Glaxo* case, is erroneous. The AN considers that the Spanish legislation does not determine “*in any way*” the wholesale price of the pharmaceutical products that are “*not financed*” (it does not even refer to the pharmaceutical products “*not dispensed in Spain*”). Therefore, in the AN's opinion, the pharmaceutical company is not obliged to apply a different price (the free price) for those pharmaceutical products, but rather does so voluntarily. Indeed, it would be a contradiction in terms to be obliged to apply a free price.

This impairs the AN's ability to understand that the pharmaceutical company is free to determine the price of its pharmaceutical products (general rule), although such price will be mandatorily replaced with the government price when the legal government price control requirements are met (exception). The subject of debate is not whether the pharmaceutical company is or not obliged to implement the free price system. The pharmaceutical company is indeed not obliged to do so, as it is free to decide how to

organise its business. In the exercise of such freedom, the pharmaceutical company has unilaterally decided to sell its products at the market price. However, such freedom is limited by general interest reasons and for products that are financed with public funds and dispensed to patients in Spain: in these cases, the pharmaceutical company (and the wholesaler) is obliged to apply the government price coactively fixed by the Spanish health authorities.

- *Coerced vs. agreed prices.* The AN considers it immaterial (in spite of the fact that Spain Pharma, the CNC and the pharmaceutical company consider this to be a key issue) whether the pharmaceutical products' government price is agreed with or imposed by the authorities. The fact that the price is fixed by the authorities (and not negotiated with them) is an essential element to differentiate a free price policy from a dual price policy. We are not dealing with two prices that are freely decided by the pharmaceutical company (this being an essential condition for dual pricing to exist), but a single price established by the pharmaceutical company. The pharmaceutical company is subsequently obliged by law to replace (when the legal government price control requirements are met) its single price with another price that is coactively fixed by the authorities. The coexistence of the two prices is not the result of voluntary conduct attributable to the pharmaceutical company.
- *Free price policy vs. Glaxo policy.* Finally, the AN is not keen to analyse the striking differences between a free price policy and Glaxo's dual price policy. The outcome is that the AN wrongly considers that the *Glaxo* doctrine would be applicable to the case at hand. Among the numerous and significant differences, the AN only refers to the different legislation in force, which it then concludes is irrelevant. The reason for this is probably that it has not noticed the remarkable differences between the legislation in place at the time Glaxo implemented its policy and that in force following Law 55/1999.

Yet the different legislation is not the only difference. According to the *Glaxo* judgement, the agreement between Glaxo and the wholesalers provided for two contractual prices; however, under a free price policy, the pharmaceutical company

only establishes one price, which is coercively substituted by the government price when the legal government price control requirements are met. Furthermore, according to the *Glaxo* judgment, Glaxo's aim was to reduce parallel trade, while a pharmaceutical company's only aim under a free price policy is to apply the Spanish government price control rules correctly - not renouncing its freedom to set prices. In addition, Glaxo's policy requested information regarding the destination of the medicines, but under a free price policy the information is requested to determine if the government price control requirement of dispensation in Spain is met (no export information is required) so that the statutory pricing regime can be applied correctly.

In connection with the alleged similarities with the *Glaxo* case, we will finally refer to the Judgment of the Court of First Instance no. 5 of Talavera dated 10 December 2003, which noted that:

*“it is not enough, in order to declare such unlawfulness, to merely equate, as the defendant does, Glaxo Welcome's policy with [the pharmaceutical company's] policy, as this would be to grossly simplify the comprehensive analysis undertaken by the European Commission to reach such conclusion.”*

It now remains to be seen how the Supreme Court will settle the appeals filed (by the pharmaceutical company and the CNC itself) against the AN Judgement. In this connection, however, it is worth referring to some statements of the Supreme Court in a related matter. When dealing, back in 2005, with wholesalers claims against Royal Decree 725/2003<sup>9</sup>, the Supreme Court made it clear that, contrary to the claimants' opinion, what could distort competition would be precisely entering into competition in the international market with products acquired at a government price which is only justified in order to address specific needs of the Spanish population and budgetary system:

*“when discussing the claimant's arguments on the infringement of both EU and national rules, we must take into account the underlying interest, which is intimately linked to the subject of this process. It must be said that the purpose of this process is linked to the claimant's intent that no unnecessary obstacles - in their opinion - are imposed on the export of medicines at intervened prices.*

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<sup>9</sup> See footnote 7.

(...)

*We cannot fail to consider, as indicated on several occasions, that we are not dealing with export of freely priced products - which is not affected in any way by the measures contained in the Royal Decree - but with export of products at an industrial intervened price. This is also connected with the alleged infringement of Articles 81 and 82 EC Treaty, regarding anticompetitive agreements and abuse of dominant position. We must state that the claimants, in making this allegation, contradict their own arguments in an evident way. Even if this Court is not due to issue statements of economic nature or on economic principles, it is clear that entering into competition in the international market by selling, at higher prices, products acquired at an intervened price which is established to address the health needs of the Spanish population (...) is very unlikely to meet the free, fair competition rules established both under EU and under Spanish law. Thus, allegations of infringement of Articles 81 and 82 EC Treaty must be rejected” (Judgment of the Supreme Court of 20 June 2005, reiterated by Judgments of 21 July 2005 and 21 February 2006).*

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