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Two Basic Freedoms of Pharmaceutical Companies Regarding the Sale of Medicines in Spain: Freedom to Set Prices and Freedom to Contract

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Freedom of enterprise is one of the pillars of the current economic model, not only under Spanish law, but also under EU law. Article 38 of the Spanish Constitution expressly recognises the freedom of enterprise. Furthermore, this principle has been recognised by the European Court of Justice as an autonomous general principle of the European Union.[1]

This basic freedom of enterprise undoubtedly encompasses the freedom (at least, in principle) of market operators to organise the sale of their products; more specifically, the freedom to set the price of their products and to enter, or not, into commercial relationships with clients.

However, this generally acknowledged principle has not been free from controversy when applied to the pharmaceutical sector. Indeed, the questions of whether pharmaceutical companies are free, in principle, to set the prices of their medicines and to select their wholesalers have become two of the most interesting topics of discussion in the pharmaceutical sector in Spain in recent years. Some stakeholders in the pharmaceutical sector have actively tried—so far, unsuccessfully—to contest such freedoms, as well as any commercial policy designed under the scope of such freedoms, both before the Spanish and the EU authorities and courts.

This article attempts to support, on the basis of acknowledged principles of law (including EU law), the lawfulness of commercial policies based on the partial and reasonable exercise of the freedom to set prices and select wholesalers.

Freedom to determine medicine prices

Freedom to determine medicine prices versus government intervention in medicine pricing

As mentioned, one of the basic consequences of the constitutional freedom of enterprise is that market operators are free to set the prices of their products.

However, this is not always the case in the pharmaceutical sector. Indeed, Member States retain the power to set the prices of medicines (as recognised, among others, by Directive 89/105[2]—the "Transparency Directive"). In exercising this power, a number of EU Member States (including Spain, as we will see in this article) fix these prices. However, as a limitation on the fundamental freedom of enterprise, such governmental price intervention must be absolutely exceptional and clearly limited to its justified object and scope.

The Preamble to the Transparency Directive recognises that Member States have adopted price intervention measures in the case of medicines based on public interest grounds:

> "Whereas Member States have adopted measures of an economic nature on the marketing of medicinal products *in order to control public health expenditure on such*

1 "[T]he case law of the Court of Justice indirectly recognises the importance of safeguarding free enterprise when applying competition rules of the Treaty" (*Bayer AG v Commission of the European Communities* (T-41/96 R) [1996] E.C.R. II-381). European Court of Justice case law has also recognised the freedom to exercise an economic or commercial activity (*J Nold Kohlen und Baustoffgrosshandlung v Ruhrkohle AG* (C-4/73) [1977] E.C.R. 1 and *SpA Eridania-Zuccherifici Nazionali SpA and Societa Italiana per l'Industria degli Zuccheri SpA Minister of Agriculture and Forestry, Minister for Industry, Trade and Craft and Zuccherifici Meridionali SpA* (C-230/78) [1979] E.C.R. 2749) and freedom to contract (*Sukkerfabriken Nykobing Limiteret v Landbrugsministeriet* (151/78) [1979] E.C.R. 1 and *Spain v Commission of the European Communities* (C-240/97) [1999] E.C.R. I-6571).

2 Directive 89/105 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems [1989] OJ L40/8.

> *products*; whereas such measures include direct and indirect controls on the prices of medicinal products as a consequence of the inadequacy or absence of competition in the medicinal products market and limitations on the range of products covered by national health insurance systems;
>
> Whereas *the primary objective of such measures is the promotion of public health by ensuring the availability of adequate supplies of medicinal products at a reasonable cost*." (Emphasis added.)

Thus, the Transparency Directive considers price intervention legitimate insofar as it promotes public health by ensuring the availability of adequate supplies of medicines at a reasonable cost.

In this context, reference must be made to "Recommendation VI" of the G10 High Level Group for Innovation and Provision of Medicines (commonly known as "G10"), which was set up by the European Commission ("the Commission") with a view to promoting the internal market for pharmaceuticals and states that:

> "[T]he Commission and Member States should secure the principle that a Member State's authority to regulate prices in the EU should *extend only* to those medicines purchased by, or reimbursed by, the State. *Full competition should be allowed for medicines not reimbursed by State systems or medicines sold into private markets*." (Emphasis added.)

The underlying principle of Recommendation VI is again that only policy objectives of primary importance justify government intervention in pricing. In particular, in the G10's view, the *financial stability of health care and social security insurance schemes* are prioritised objectives.

Recommendation VI was expressly supported by the Commission in the Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions COM(2003) 383 final (dated July 1, 2003), which indicates how the Commission considers that the G10 Recommendations could be taken forward. With regard to Recommendation VI, the Commission recognised that:

> "[T]he Commission fully supports the G10 Medicines Group's conclusions that, *as a matter of principle*, medicines which are neither purchased nor reimbursed by the State should be opened to full competition." (Emphasis added.)

Fully aligned with the Transparency Directive and Recommendation VI, the case law of the Spanish Constitutional Court expressly establishes that limitations on constitutional freedoms are only legitimate insofar as they pursue *objective public interest goals* that are the object of similar protection under the Spanish Constitution[3]. As we will see below, the need to protect public health—by ensuring that patients in Spain have adequate access to medicines—and the need to control public healthcare expenditure may be considered as essential public interest objectives, the protection of which may justify the restriction of the freedom of pharmaceutical companies to set prices in every instance.

Scope of Spanish government intervention

The key legal provision dealing with Spanish government intervention in the pricing of medicines is art.90 of Spanish Law 29/2006 of July 26, 2006 on Guarantees and Rational Use of Medicines and Medical Devices ("art.90" and the "Guarantees Law", respectively).

In this context, art.90[4] acknowledges that pharmaceutical companies are free to determine the prices of their medicines. However, it also states that, where the conditions for government intervention (i.e. reimbursement with public funds and dispensation in Spain) are met, pharmaceutical companies become obliged *ex lege* to replace the freely-determined price by the intervened price, unilaterally established by the Spanish health authorities. Pursuant to art.90, where intervention requirements are met, price intervention is coercively imposed ex post by the authorities, thus superseding the prior free determination of prices by the pharmaceutical companies.

The freedom of enterprise principle has highlighted the recent evolution of the wording of art.90, from a previous broader scope of intervention to greater pricing freedom.[5]

3 Spanish Constitution, art.43.

4 Guarantees Law art.90 is drafted in terms essentially similar (but not identical) to those of art.100 of Law 25/1990 on Medicines (the "Medicines Law"), which was repealed and replaced by the Guarantees Law in July 2006.

5 The Spanish legislator's main objective was *to limit coercive intervention in pricing to certain medicines*, or, in other words, to limit the scope of the Government's intervention in pricing. This objective—increased price liberalisation—was already clear under art.100, as amended by Law 55/1999. In light of a written Statement of the General Directorate for Pharmacy and Health Products (*Dirección General de Farmacia y Productos Sanitarios*) dated February 14, 2000, and of the Preamble of Royal Decree 725/2003, which develops art.100 of the Medicines Law, there is no doubt that the Spanish regulator was trying to introduce further price liberalisation. In particular, the Statement contains opinions that are of unquestionable interpretation value. For instance, it is stated, quite clearly, that:

The current wording of art.90 is the result of an amendment of the Medicines Law in December 1999, subsequently confirmed by the Guarantees Law in 2006. This amendment was specifically sought by the Spanish legislator to partially liberalise the Spanish pharmaceutical market by both: (i) returning the right to set prices to the pharmaceutical companies according to free market rules; and (ii) limiting the scope of government intervention in pricing to certain medicines.

As stated, art.90, while acknowledging the right of pharmaceutical companies to freely determine the price of their products, also establishes exceptions to this general freedom: the prices of medicines that are: (a) reimbursed with public funds; and (b) dispensed in Spain, are subject to government intervention. Therefore, the requirements that set the boundaries of the intervened market are as follows:

- a *budgetary requirement* (the medicines are eligible for reimbursement with specific public funds), which constitutes the basic, but not exclusive, *rationale* for government price intervention; and
- a *geographic requirement* (dispensation in Spain[6]), as the objectives sought by government price intervention are only achieved when the medicine is put at the disposal of patients in Spain.

Therefore, the goals pursued by the Spanish legislator when drafting art.90 (and Royal Decree 725/2003[7]) would include, quite legitimately, not only the achievement of budgetary objectives (financial stability in the Spanish health system), but also, and most importantly, the coverage of social and healthcare needs by increasing the range of beneficiaries of the Government's pricing intervention. In this regard, pricing intervention in connection with medicines listed for reimbursement implies that all patients in Spain—and not only the beneficiaries of the Spanish healthcare system—may benefit from the (lower) intervened prices (in connection with reimbursable medicines).

Main practical requirement to apply free prices and intervened prices: information on dispensation in Spain

There is no doubt that, in order to apply the pricing schemes contemplated under art.90, pharmaceutical companies operating in Spain must know whether the medicines they sell fulfil the two above-mentioned criteria for government intervention. While there is no difficulty in determining whether the first requirement for government intervention is fulfilled (i.e. whether a medicine is listed for reimbursement), pharmaceutical companies do not know beforehand whether medicines sold at wholesaler level will be subsequently dispensed in Spain. Therefore, in order to be in a position to correctly apply the Spanish pricing regime (as laid down by art.90), pharmaceutical companies need to know whether the medicines sold to wholesalers are subsequently dispensed in Spain.

When obliging pharmaceutical companies to charge (and wholesalers to pay) the intervened price at the wholesalers' level (if dispensation takes place in Spain), art.90 is in fact imposing certain obligations on wholesalers to provide information about dispensation in Spain. The provision of information on dispensation in Spain by wholesalers is a must for intervened prices to be correctly applied and, thus, for art.90 to be complied with.

Such information could be obtained by pharmaceutical companies through specially designed public (i.e. administrative) means, which would imply the intervention of the public authorities, as contemplated by Spanish Royal Decree 725/2003.[8]

Royal Decree 725/2003 has been challenged before the Spanish courts. The Spanish Supreme Court has dismissed two appeals[9] and expressly stated that Royal Decree 725/2003 complies with EU and Spanish legislation.[10]

"[T] he 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 the medicines that are not to be dispensed in the Spanish territory are freely priced".

6 Under Royal Decree 725/2003, dispensation is defined as the placement of medicines at the disposal of patients in Spain by duly authorised pharmacies or pharmacy services in hospitals or in other health establishments. Other sale transactions involving medicines (e.g. wholesale transactions with medicines) engaged in by pharmacists do not qualify as dispensation. Unless otherwise indicated, references made in this article to pharmacies will also be deemed to include "pharmacy services located in hospitals or in other health establishments".

7 See fn.5.

8 Royal Decree 725/2003 imposes the obligation on pharmaceutical companies and wholesalers to provide certain information to the health authorities, and grants 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 government price and subsequently re-sold to pharmacies, pharmacy services, and other wholesalers.

9 Judgments of the Supreme Court of June 20, 2005, appeal no.106/2003 and of June 21, 2005, appeal no.109/2003.

10 With regard to obtaining dispensation information, the Spanish Supreme Court has held that:

To the best of our knowledge, no further claims against Royal Decree 725/2003 are pending.

Regrettably, in spite of some attempts, the administrative system based on Royal Decree 725/2003 has not been successfully put into operation to date, and, five years later, it is not certain that pharmaceutical companies will be able to rely on this mechanism to gather appropriate information about dispensation in Spain.

Another option open to the pharmaceutical companies to obtain the legally required information on dispensation in Spain is through the appropriate private (contractual) means. These mechanisms are not necessarily alternative and could be cumulative.

There is no doubt that pharmaceutical companies may also obtain information on dispensation in Spain by expressly imposing the obligation on wholesalers to directly evidence dispensation in Spain as a prerequisite for benefiting from the intervened price. This interpretation has already been endorsed by the Spanish courts.[11]

In any case, antitrust and data privacy laws require that the type and level of information to be shared between pharmaceutical companies and their wholesalers must be very clearly and narrowly defined; more specifically, it should not go beyond that strictly required by art.90 (or any other mandatory legal provision).

Compatibility with Article 81 of the European Community Treaty

This section purports to show the compatibility of a pricing policy based on art.90 with Art.81 of the EC Treaty, which prohibits anti-competitive collusive behaviour.

The concerns that art.90 raises are mainly due to the risk of an art.90-based pricing policy being considered as a "dual pricing policy" (along the lines of the *Glaxo Wellcome* Decision[12]). We will briefly outline below some of the arguments which, in our view, clearly support the compatibility of an art.90-based pricing policy with Art.81 EC.

In our opinion, pricing policies based on art.90, or Recommendation VI, where pharmaceutical companies freely determine the prices for their medicines and these prices are subsequently coercively replaced with the intervened prices (if the criteria for governmental intervention are met), would not entail "dual pricing", as this concept should be understood under EU competition law.

- Undoubtedly, *the freely-determined price would be first set by the pharmaceutical company* (irrespective of the final destination of the medicine). Moreover, the determination of this free price is a private act and a normal expression of the constitutional freedom to set prices. Obviously, this unilateral and freely-determined price would be subject to ordinary antitrust assessment and, thus, could not be abusive (e.g. predatory, excessive or discriminatory).

In contrast, the intervened price, which is only applicable if the criteria for government price intervention are met, is exclusively determined and imposed by the Spanish health authorities. Thus, the replacement of the free price with the intervened price is not a result of the pharmaceutical companies' voluntary conduct, but rather the result of compulsory action of the Spanish authorities.

In summary, art.90, *in conjunction with Recommendation VI of G10*, provides for the coexistence of a free price (for which the pharmaceutical company is accountable) and an intervened price (for which only the Spanish State is accountable; but not the pharmaceutical company).

- *The Spanish health authorities determine the intervened price*. Although the administrative procedure for determining the intervened price

> "[T]he Royal Decree . . . establishes *certain information obligations on the economic operators in the sector and the Ministry* of *Health* and . . . *obtaining the said information is, if not indispensable, most convenient in order to ensure the effective fulfilment of Article 100(2) of the Spanish Medicines Act*, so that an appropriate destination for the medicines with intervened industrial prices is ensured." (Emphasis added.)

11 Judgment no.14, appeal no.567/2003, April 7, 2004, Court of First Instance of Valencia, expressly states that:

> "[I]t is clear from this that, in order to apply intervened prices, two requirements must be met: that it is a case of medicines financed by the Social Security, and that their dispensation occurs in Spain. This being so, in accordance with the abovementioned Article [art.100], it must be stated that the conditions established by [pharmaceutical company] are fully compatible with the Spanish legislation, and, *since in order to apply intervened prices it must be known whether the medicines supplied to its wholesalers comply with the requirement of dispensation in the Spanish territory, the requirement to evidence such compliance must be included within the scope of the legal requirements, which excludes its consideration as a unilateral and illegal condition.*" (Emphasis added.)

12 Decision of 8 May 2001 relating to a proceeding pursuant to Art.81 of the EC Treaty Cases: IV/36.957/F3-*Glaxo Wellcome* (notification), IV/36.997/F3-*Aseprofar and Fedifar* (complaint), IV/37.121/F3-*Spain Pharma* (complaint), IV/37.138/F3-*BAI* (complaint), IV/37.380/F3-*EAEPC* (complaint) [2001] OJ L302/1.

in Spain begins with an application submitted (at the request of the health authorities) by the pharmaceutical companies, and although such application contains the pharmaceutical company's initial price proposal, the administrative decision taken is not a "negotiated" decision. The pharmaceutical company is neither allowed to freely determine the terms of the application or of the price proposal, nor to base such a price proposal on all the costs related to the relevant medicine. On the contrary, the Spanish health authorities have dictated express instructions[13] establishing the restrictive criteria for selecting the type (and amount) of costs which may be taken into account in the determination of the intervened price, as well as the form and contents of the application.

After the application has been submitted, the Spanish health authorities (unilaterally) establish the intervened price and, subsequently, notify it to the pharmaceutical company.

- *The Spanish health authorities may also coercively amend*, at any moment, *an already determined intervened price*. In contrast, the pharmaceutical company can only apply price increases in very limited circumstances and in accordance with strict time constraints, and in any case they are subject to the Spanish health authorities' prior approval.

The fact that the intervened price in Spain is clearly determined by the Government is further evidenced by the fact that the Spanish health authorities have made ample use of their power to amend prices *ex officio,* and have repeatedly and unilaterally reduced the intervened price of medicines. Some examples of such coercive reduction of intervened prices are:

> — Royal Decree-Law 12/1999 introduced an *ex-lege* reduction of industrial prices of medicinal products. Article 1.1 of this Royal Decree-Law states the following:
>
> "The . . . price of the medicinal products . . . shall be reduced, from 15 September 1999, by the percentage resulting from the following formula: % reduction = 10.31 - (30.518,26 / industrial price + 5.027,03)."
>
> — The Inter-ministerial Commission for Prices of Medicinal Products decided, in May and June 2001, *to reduce by 15 per cent* the price of certain medicinal products (belonging to "homogeneous groups"—groupings of bio-equivalent medicines—and provided that they meet certain conditions). The reduction was notified to the corresponding companies as a *fait accompli*.
>
> — The Ministerial Order of December 27, 2001 introduced a price reduction applicable to the non bio-equivalent medicinal products used in the calculation of the "reference price", and establishes that the prices of such medicines must be equal to the relevant "reference price".
>
> — Act 16/2003 of May 28, 2003, introduced new rules regarding the prescription and dispensing of medicines with a direct impact on their prices.

In particular, Act 16/2003 amended art.94.6 of the Medicines Act and established a new definition of reference medicines groupings (each of which comprises all medicines with the same active substance, provided that at least one generic product exists) and a new method for the calculation of the "reference prices", which shall be the average of the three lowest-priced medicines belonging to each of relevant groupings. Prices of generic medicines are, subsequently, automatically reduced to the reference price.

Under this system, pharmacists are bound to replace any medicine prescribed by a doctor with a generic product (with identical medical composition, pharmaceutical form and dosage form) if the former has a price higher than the "reference price". Therefore, whenever a generic exists, the pharmacist must dispense the generic product to patients in Spain instead of the medicine prescribed by a doctor. If there is no substitutive generic product, the pharmacists must dispense the prescribed product and charge only the reference price, and the pharmaceutical company must compensate the wholesalers or, as the case may be, pharmacists, for the difference.

In short, this new regime implied, in practice, that pharmaceutical companies were forced to lower prices of branded medicines in order to match the prices of

13 Spanish Royal Decree 271/1990, art.3:

> "In order to calculate the cost, the following variables shall be taken into account, which directly influence the former: the level of activity, evolution of costs and sales volumes of the company, sales forecasts for the new specialty and the repercussion in structural costs of the manufacture of the new product. *Corporate profit for each specialty shall be set as a percentage*, determined by a technical report on the economic-financial situation of the company: *such percentage shall be comprised within a band established by the Delegate Government Commission for economic affairs*, taking as benchmark the economic condition of the pharmaceutical industry as a whole and the economic policy forecasts." (Emphasis added.)

generics so that their products could continue to be dispensed by Spanish pharmacists.

— Royal Decree 2402/2004 imposed, among other measures, a further reduction of industrial prices of all reimbursed medicines by 4.2 per cent in 2005 and 2 per cent in 2006,[14] provided that the resulting industrial price shall not fall below €2.

— Finally, and most recently, art.93 of the Guarantees Law, which establishes a new reference price system, includes various provisions directly affecting—in practice, reducing—the price of medicines. Among others:

- Article 93.3 of the Guarantees Law provides that the prices of (reference) medicines that do not have equivalent generics for substitution purposes (i.e. identical dosage and form), *may not exceed the reference price*.
- Article 93.6[15] of the Guarantees Law establishes that the current price of medicines (with respect to which no generic has been approved in Spain) shall be *automatically reduced by 20 per cent* after 10 years if there is a generic approved in an EU country.

In light of the above, it is out of question that the (initial) intervened price (as well as any amendment thereof) *is coercively and indisputably imposed* by the Spanish health authorities on the pharmaceutical companies.

• The fact that the Spanish health authorities determine the prices to be applied by pharmaceutical companies in Spain has been expressly acknowledged by the President of the Court of First Instance of the European Communities (the "CFI"). In this regard, the decision of the President of the CFI of June 3, 1996 (*Bayer AG v Commission of the European Communities* (T-41/96R))[16] expressly acknowledges that:

> "(55) A situation of that kind is particularly likely to cause serious damage to the applicant in the context of the pharmaceutical industry, which is distinctive in that prices and methods of financing are fixed or controlled by national health services, thereby giving rise to large disparities in the prices for a single medicinal product in the various Member States. *In this case, the applicant has no control over its prices in the exporting countries, Spain and France, where the prices of Adalat products are fixed by the competent authorities* at a level which is currently, on average, some 40 per cent lower than prices charged in the United Kingdom, as both parties agree." (Emphasis added.)

Similarly, the judgment of the CFI (*Bayer* [1996] E.C.R. II-381[17] in this case recognises that, "[i]n most Member States, the price of Adalat is directly or indirectly fixed by the national health authorities". Furthermore, the judgment of the CFI in *Glaxo*[18] at [133] states that:

> "At no point, however, does the Commission examine the specific and essential characteristic of the sector, which relates to the fact that *the prices of the products in question, which are subject to control by the Member States, which fix them directly or indirectly at what they deem to be the appropriate level*, are determined at structurally different levels in the Community and, unlike the prices of other consumer goods to which the Commission referred in its written *submissions and at the hearing, such as sports items or motor cycles, are in any event to a significant extent shielded from the free play of supply and demand*." (Emphasis added).

Additionally, the Spanish Competition Tribunal[19] has (repeatedly) acknowledged that intervened prices in Spain are coercively established by the health authorities.[20]

> "(57) In that context, the Commission's assertion that the applicant had the possibility of itself taking action over parallel imports to the United Kingdom by reducing the prices charged by Bayer UK to a competitive level must be tempered by the fact that *the applicant does not itself determine the prices charged in the exporting countries, where they are fixed by the public authorities*. . . (60) . . . it should be remembered that the prices currently charged by Bayer UK, which are higher than *those fixed by the Spanish and French authorities*, are in any case subject to indirect control in the United Kingdom by the competent authorities, as the Decision states (paragraph 151)." (Emphasis added.)

14 The Single Additional Provision of Royal Decree 2402/2004 stated that:

> "1. *The ex-factory price of medicines . . . shall be reduced* over the two years following the date on which this Royal Decree enters into force, by 4.2% in 2005 and by 2% in 2006." (Emphasis added.)

15 "The price of medications in respect of which no generic drug has been authorised in Spain, ten years after the decision to publicly finance the medication was adopted, or eleven in the event that a new indication should have been authorised, *shall be reduced by twenty per cent*, provided that any Member State of the European Union which, without being subject to exceptional or interim industrial property regulations, should have implemented the relevant European legislation, should have authorised a generic drug with a price lower than the medication of reference in Spain." (Emphasis added.)

16 Decision of the President of the CFI, *Bayer AG v Commission of the European Communities* (T-41/96 R) [1996] E.C.R. II-381:

17 *Bayer* [1996] E.C.R. II-381. This judgment was confirmed by the judgment of the ECJ of January 6, 2004 *Bundesverband der Arzneimittel Importeure eV v Bayer AG* (Joined cases C-2/01 P and C-3/01 P) [2004] E.C.R. I-23.

18 *GlaxoSmithKline Services Unlimited v Commission of the European Communities* (T-168/01) [2006] 5 C.M.L.R. 29.

19 Currently, the National Competition Commission.

20 Decisions of the TDC: *Laboratorios Farmacéuticos* (R-488/01), December 5, 2001; *Cofares/Organon* (R-547/02), September 22, 2003; *Spain Pharma/Smithkline* (R-558/03),

As the purpose of state intervention is to keep prices low, intervened prices tend to be significantly lower than freely-determined prices (indeed, intervened prices are actually fixed by reducing the corresponding free prices). However, the gap existing between the freely-determined prices and the intervened prices is not attributable to the pharmaceutical companies, as, according to a basic principle of law, private companies may not be held liable for state conduct. On the contrary, pharmaceutical companies may only be liable for the freely-determined prices.

Whilst this means that two different prices may apply, this is not "dual pricing" in the classical antitrust sense. EU competition law prohibits *free* "dual pricing", not a difference in prices resulting from the fact that an intervened price is coercively imposed when the conditions for pricing intervention are met. Consequently, if a pharmaceutical company unilaterally determines the free price of its medicines based on fair and objective market criteria, that business decision is absolutely legitimate and should not be considered anti-competitive conduct.

Freedom to select clients

Basic freedom to select clients

As mentioned in the introduction, a direct consequence of the constitutional freedom of enterprise is that market operators are free to decide how to organise the commercialisation of their products, and, in particular, to choose to whom they sell their products.

Again, in the pharmaceutical sector, such freedom to choose clients is restricted. The first type of restrictions derives from antitrust law. In this respect, the selection has to be made on certain objective and non-discriminatory criteria, as in any other economic sector. For the sake of brevity, we will not refer to the ordinary antitrust restrictions applicable to all economic sectors.

The second type of restrictions is specific to pharmaceutical law. As discussed with respect to pricing, this type of restriction on clientele should only be acceptable to the extent that they are aimed at protecting other prioritised public interest goals, such as public health.

December 3, 2003; and *Comercial Farmacéutica/Pfizer* (R-643/05), April 21, 2005.

Spanish legislation, aligned with Directive 2001/83,[21] which sets out the Community Code on Medicines for Human Use (as amended by Directive 2004/27[22] (the "Code Directive"), contains two types of restrictions: one based on the objective suitability (*idoneidad*) of the client, and the other based on the need to ensure appropriate and continued supplies to the market.

Suitability of the clientele

Pharmaceutical companies may not sell their medicines to any market operator, but only to those that are duly licensed to acquire (and subsequently sell) medicines. The rationale behind this restriction is that medicines are very sensitive products from a health perspective, and as such their commercialisation and manipulation must be controlled. Only those operators meeting the necessary technical, logistical and operative conditions for dealing with medicines may undertake such commercialisation activities, and only once they have obtained the relevant licence. In Spain, as in other EU countries, both pharmaceutical wholesalers and pharmacies are authorised to purchase medicines and, subsequently, to sell them (either to other wholesalers or pharmacies, in the case of wholesalers; or to the public, in the case of pharmacies).

Therefore, pharmaceutical companies are *free to commercialise their products through wholesalers or directly to pharmacies*. This basic freedom is acknowledged both by Spanish and EU regulations, as we will see below.

Guarantees Law

Article 68.1 of the Guarantees Law[23] (and ancillary regulations[24]) confirms the freedom of pharmaceutical companies to organise the commercialisation of their products to pharmacies (the only entities authorised to supply medicines to the patients), as they deem most suitable: either directly or through wholesalers, "[d]istribution of authorised medicines shall be carried out *through wholesalers or directly by the* holder of the marketing authorisation" (emphasis added).

21 Directive 2001/83 on the Community Code relating to medicinal products for human use [2004] OJ L311/67.
22 Directive 2004/27 amending Directive 2001/83 on the Community Code relating to medicinal products for human use [2004] OJ L136/44.
23 In line with art.77 of the repealed Medicines Law.
24 Royal Decree 2259/1994, art.1.2.

This assessment has been confirmed by the Spanish health authorities,[25] which expressly recognised that, as under Spanish law[26] the commercialisation of medicinal products through wholesalers is free and voluntary:

> "[A] pharmaceutical company may, if it so decides, go without or not use the services of intermediary wholesalers, and directly meet the demand of duly authorized pharmacies with respect to its medicinal products."

Code Directive

In different terms, but exactly with the same purpose, Art.77.3 of the Code Directive recognises the freedom of pharmaceutical companies to engage in wholesale activities (thus allowing direct sales to pharmacies): "[p]ossession of a manufacturing authorization shall include authorization to distribute by wholesale the medicinal products covered by the authorization".

The answer given by Competition Commissioner Neelie Kroes on behalf of the Commission on January 29, 2007 with respect to a question concerning planned changes to the distribution of Pfizer's products in the United Kingdom further sustains this interpretation, "[t]herefore, *pharmaceutical companies have the choice to distribute their products themselves, or to rely on wholesalers, or both*" (emphasis added).

In view of the above, it is more than clear that pharmaceutical companies are allowed to directly sell their medicinal products to pharmacies (without the participation of wholesalers) or with the mediation of wholesalers. While it is generally accepted that pharmaceutical companies may engage in direct sales to pharmacies, the fact that pharmaceutical companies may decide to, totally or partially, suppress the involvement of wholesalers has given rise to heated debates in Spain.

Wholesalers are strongly opposed to the suppression of their involvement, and are increasingly active in seeking legal arguments to challenge—so far, unsuccessfully—the above-mentioned right of pharmaceutical companies (to go without wholesalers). Wholesalers would like to find some support in a particular (and, in our opinion, biased) interpretation of certain legal provisions aimed at guaranteeing the adequate and continued supply of medicines to the market.

25 Letter from the Director General of Pharmacy and Medical Devices (*Director General de Farmacia y Productos Sanitarios*), addressed to a given pharmaceutical company, and dated January 17, 2004.

26 At that time, art.77.3 of the repealed Medicines Law.

Need to ensure adequate and continued supplies to the market

Guarantees Law

By way of introduction, art.2.1 of the Guarantees Law (essentially the same as art.3.1 of the repealed Medicines Law) states that pharmaceutical companies (as well as importers, wholesalers and pharmacies, among others) are obliged to supply the medicines requested from them, "in the terms stated in the applicable laws and regulations". Article 2.2 of the Guarantees Law goes on to state that the entities:

> "responsible for the manufacture, distribution, sale and supply to the public of medicines and medical devices must respect the principle of continuity in the rendering of the [supply service] to the community."

As regards pharmaceutical companies, these legal provisions are developed by art.64 of the Guarantees Law, which expressly vests in pharmaceutical companies the primary obligation to keep the market adequately supplied. The term "market" should be understood as referring to pharmacies as the only establishments authorised to supply medicines to patients, who are, in turn, the exclusive beneficiaries of the market supply obligation. On that basis, *pharmaceutical companies are not obliged to supply to any specific wholesaler, but exclusively to ensure that the needs of pharmacies are covered* (through the means they consider most appropriate) at all times.

However, wholesalers have insistently claimed that they are entitled "by law" to purchase from pharmaceutical companies, in order to be able to ensure a continuous supply to the community. This would mean, in practice, that each and every pharmaceutical company would be indefinitely obliged to meet orders from any company holding a wholesale licence. If this exceptional interpretation prevailed, the above-mentioned freedom of pharmaceutical companies to organise the commercialisation of their products would simply disappear. Pharmaceutical companies would become "prisoners" for life and bound to meet orders from any holder of a wholesale licence. Obviously, such a drastic elimination of the freedom of enterprise may not prevail; especially when Art.77.3 of the Code Directive grants pharmaceutical companies a clear right, but not an obligation, to use wholesalers as intermediaries. As already indicated, the existence of this right has been expressly confirmed by Commissioner Kroes.

Article 81.2 of the Code Directive

This conclusion is, in our view, also supported by Art.81.2 of the Code Directive, as amended[27]:

> "The holder of a marketing authorisation for a medicinal product *and the distributors of the said medicinal product* actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products *so that the needs of patients in the Member State in question are covered*." (Emphasis added.)

Article 81.2 of the Code Directive obliges:

> "the holder of a marketing authorisation for a medicinal product *and the distributors of the said medicinal product* actually placed in the market in a Member State . . . *within the limits of their responsibilities*,"

to appropriately and continuously supply the holder's medicines.

In our opinion, taking into account that: (i) pharmaceutical companies are free to organise the commercialisation of their medicines as they deem most appropriate; and that, furthermore, (ii) the commercialisation of medicines through wholesalers is free and voluntary for pharmaceutical companies, the supply obligation set forth under Art.81.2 is not imposed on each and every wholesaler with respect to each and every medicine. On the contrary, such obligation should be limited to the wholesalers' responsibilities related to the supply of each particular medicine ("within the limits of their responsibilities"). Therefore, the supply obligations do not apply to all wholesalers, but only to those "distributors" chosen by the pharmaceutical company for the supply "of the said medicinal product". Thus, wholesalers operating in Spain *not* selected by a pharmaceutical company to commercialise its medicines in the Spanish market are considered relieved from such supply obligation.

The second part of Art.81.2 states that the aim of this provision is undoubtedly to ensure "that the needs of patients in the Member State in question are covered". Appropriate and continued supplies must be guaranteed in order to achieve this objective. Therefore, insofar as these needs are adequately covered, pharmaceutical companies should under no circumstances be deemed bound by any supply obligation towards wholesalers. In contrast, we believe that pharmaceutical companies, who seek to improve the security and efficiency of their wholesale supply systems, by placing the products on the market through a rationalised number of wholesalers, are acting in line with this Article.

Conclusions

- Pharmaceutical companies have the right to freely establish the price of their medicines, unless they are required by law to replace such free prices with a government price. If so, the potential coexistence of those two prices (one decided by the company, and the other decided by the Government) does not entail "dual pricing" for antitrust purposes.
- Pharmaceutical companies have the right to select wholesalers, subject (as in any other economic sector) to ordinary antitrust rules.

27 See Directive 2004/27 [2004] OJ L136/44.