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Aspects to be considered in the future regulation on public financing and prices of medicinal products

Judgment of the European Court of Justice, of 26 February 2015, and Report of 28 April 2015, of NCMC, on the Draft of the Revised Text of the Law on Guarantees

Drafting the new Royal Decree on financing and price of medicinal products is, without question, a complex process. The two documents to which we refer in this article bring valuable ideas that should be considered in future regulations.

Transparency

It is particularly convenient to talk about transparency. The Spanish National Commission for Markets and Competition (NCMC) points out in its Report that the procedure that is currently being followed for deciding about the inclusion of a product in the pharmaceutical coverage provides too much discretion to the decision on how the pre-selected criteria will be applied and the possible preference of some products over others.

In this regard, the NCMC criticizes the fact that the reasoned decisions of the prices fixed are not published. In our opinion, it would be convenient to at least ensure that those decisions are fully reasoned. So far, the only reasoning offered is a brief reference to an article of the Law. For instance, reimbursement is denied by simply pointing out that there are other therapeutic alternatives for the same diseases at a lower price or at lower cost per treatment. However, it is not explained which are these alternatives or how the cost of the treatment has been calculated in order to come to that conclusion, which may leave interested parties defenseless.

Europe, always Europe

On the other hand, the judgment in the Servier case recalls that the provisions of the Directive aim to ensure that any national measure controlling prices or public financing of medicinal products must meet the requirements set out by it. According to the Court, in order to ensure the effectiveness of the rule it is necessary that the interested parties are able to check that the decisions on this matters respond to objective criteria. Furthermore, the Court adds that the Directive seeks to obtain an overall picture of national agreements on price fixing, including all the criteria on which they are based. It also seeks to provide public access to such agreements for all the ones who intervene in the market of medicinal products.

In its judgment, the European Court recalls that the European Law requires for products coming from other Member States not to be discriminated against national medicinal products. In this regard, the NCMC noted in its Report that future regulations should review the reference of the contribution that medicinal products make to the gross domestic product, because it introduces in the system a "*possible discriminations based on the origin of products coming from an uncertain trajectory*".

Unilateral and unjustified termination of a license and supply agreement for medicinal products

Judgement of the Provincial Court of Madrid, of 17 December 2014, No 438/2014

Background

In 2008 two pharmaceutical companies signed a license and supply agreement for medicinal products, according to which the licensee assumed the obligation to purchase the product exclusively from the licensor for a period of 5 years. Furthermore, a penalty clause was included, according to which in case the licensee purchased the medicinal product from other suppliers the licensor would be entitled to request a compensation representing 100% of the value of the product not acquired from licensor.

Two years later, the licensee placed several orders for medicinal products from a third party and informed the licensor of its intention to terminate the contract. The licensor brought a lawsuit against the licensee requesting the corresponding compensation. The Court of First Instance ruled that the licensee had breached the contract and sentenced it to pay a fine of 1 million €, calculated according to the referred penalty clause, decision that was later confirmed by the Provincial Court.

Principle of relativity of contracts

The licensee claimed that it was entitled to freely terminate the contract arguing that when entering into the supply agreement the former shareholders of the licensee, who were engaged in the process of selling the company to a new owner, committed themselves to modify the license and supply agreements signed by the licensee in order to obtain a right of unilateral withdrawal in favor of the licensee. The Provincial Court understood that the "principle of relativity" of contracts should be applied. According to this Principle, contracts are only effective between the parties. The Court said that according to this principle, the former shareholders of the licensee cannot be asked to modify the terms of the license and supply agreement, as it is a different contract in which they were not a party. Moreover, the licensor was completely alien to this agreement between the shareholders sellers and the purchasers of shares from the licensee, and therefore such agreement could not possibly cause a prejudice to licensor.

Scope of the penalty clause

Alternatively, in case the free termination right was not recognized by the Court, the licensee asked for a reduction of the penalty clause arguing that it was disproportionate. However, the Provincial Court confirmed that violating the duration and exclusivity agreed between the parties are "total breaches" that prevent the penalty clause from being reduced. The Court also rejected the argument of non-proportionality of such clause, because it was freely and voluntarily agreed between the parties, two important companies in the industry under equal conditions.

In short, the judgment is a wake-up call against the temptation to give in to the rush and pressure that usually precede the signing of any contract. Assuming obligations whose content and scope are, sometimes, not entirely clear, could bring unnecessary risks.

The gifts handed out in a pharmacy do not escape from attention of the health authorities

Judgment of the Superior Court of Justice of Galicia of 29 January 2015

Background

In this judgment the Superior Court of Justice of Galicia ruled on the administrative appeal lodged by two pharmacists against the fine of 91.000 Euros that was imposed on them by the Galician Department of Health. The Galician health authorities imposed the abovementioned fine because the pharmacists had handed out gifts to clients who purchased medicinal products. Such conduct constitutes a serious offence under Spanish Law 29/2006, of 26 of July, on Guarantees and Rational Use of Medicinal Products and Medical Devices.

In their appeal the pharmacists argued, inter alia, that the decision of the Galician Department of Health violated the presumption of innocence, because, in their view, there was no evidence that gifts had been offered in relation to the promotion or sale to the public of medicinal products. They also claimed that the decision was against their right to entrepreneurial freedom established by the Spanish Constitution.

Analysis by the Court

Contrary to what was alleged by the pharmacists, the Court considered that there was enough evidence of the infringement, as the administrative file contained the results of private investigations, the affirmative statements of six witnesses as well as statements of the pharmacists themselves, who admitted having occasionally offered gifts when supplying medicinal products to their clients.

Regarding the classification of the infringement, the Court confirms that the Law is clear on qualifying it as a very serious offence, as this case falls under the prohibition of: "offering of inducements, gifts, prizes, competitions, bonuses or similar expedients as methods associated with the promotion or sale to the public of products of the products governed by this Law". It would have been interesting to know what were the gifts offered, in order to obtain a more in-depth knowledge of the criteria used by the health administrations when exercising their power to impose sanctions, but unfortunately the judgement does not offer any further details on this issue.

Concerning the argument of the pharmacists, who claimed that the imposition of this sanction constituted an infringement to their entrepreneurial freedom right, the Court declared that pharmacies are private health facilities of public interest. The Court established that even if the entrepreneurial freedom could be interpreted as affected, this is not contrary to the constitution, because in this case, the aim of this legal measure is not to impede competition, but to guarantee a rational use of medicinal products. The Court ends up fully dismissing the appeal.

The subject matter of this judgement is not new at all, but the reasoning of the Court is clear and concise and it serves as a reminder that even the promotional activities carried out in a pharmacy do not go unnoticed to the Public Administration.

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The parties must abide by the fiscal terms as specified in the agreements, regardless of who the taxable person is

Judgment of the Supreme Court, First Civil Chamber, of 19 January 2015

The Ministry of Defence sold several houses to the military men who occupied them. In the purchase agreements both parties agreed that all applicable taxes resulting from the change of ownership of the houses, would be borne by the buyers. The deeds specified that the sale was exempted from the value added tax (VAT) and, therefore, in accordance with tax regulations, each party proceeded to pay the Spanish Tax on Property Transfers.

After consulting with the tax authorities, it was concluded that the tax which should have been applied was the VAT instead of the Tax on Property Transfers. Therefore, the seller asked the buyers to pay the VAT in virtue of the agreement which established that the latter were bound to cover all taxes. For such purpose, the seller sent the buyers the relevant invoices, including VAT. The buyers challenged the passing on of the VAT and the courts ruled in their favour, considering that the seller had one year to pass the payment of the VAT on the buyers and such period was long exceeded.

The seller decided to file a civil claim requesting the buyers to reimburse the VAT that he had initially paid, in virtue of their agreement, reaching the Supreme Court who finally ruled in favour of the seller.

Binding power of the agreements

The Supreme Court considered that, although under VAT regulations the period to pass the payment of the VAT on had expired, that was not an obstacle for the seller to pass on the payment of a tax borne by the seller himself and that, in accordance with the agreement, it had to be satisfied by the buyer. In particular, the Supreme Court stated the agreements are binding between the parties, and that they cannot be exempted from their undertaken obligations just because it was initially assumed that the purchase agreement was subject to the payment of the Tax on Property Transfers and it was only afterwards when it was determined that the applicable tax was VAT.

Regardless of which ends up to be the tax applicable, the fact is that the buyers explicitly and unconditionally undertook the obligation to bear the taxes resulting from the purchase of the houses. In short, the Supreme Court makes the provisions from the agreement prevail over any administrative incidence.

In the light of this ruling, it would always be convenient to pay particular attention when specifying in the agreements the obligations assumed by each party, even if they might seem auxiliary obligations, as for instance in this case who must cover the taxes.