

**In a blow to parallel trading of pharmaceuticals, the National Competition Authority clears the dual-pricing system applied by PFIZER (case S/DC/0546/15 PFIZER/COFARES).**

On 19 January 2017 the Spanish Competition Authority (SCA) issued a decision clearing PFIZER of antitrust charges and blessing PFIZER's dual pricing system (SCA Decision).

In 2009, the SCA decided (First Decision) to close the antitrust investigation against COMPAÑÍA FARMACÉUTICA ESPAÑOLA, S.A. (COFARES), a wholesale distributor, and PFIZER. The investigation started following a complaint filed by SPAIN PHARMA, S.A. (SPAIN PHARMA) reporting the existence of an agreement by means of which PFIZER prevented COFARES from exporting PFIZER's pharmaceutical specialties to other EU States and established a dual-pricing system on the basis of geographic destination of the pharmaceuticals.

The First Decision was challenged by SPAIN PHARMA before the Appeal Court (AC). The AC partially upheld the appeal and annulled the First Decision ordering the SCA to continue the investigation in order to ascertain whether or not PFIZER had acted restrictively by setting a dual-pricing system which in effect enabled a discounted price for Social Security financed pharmaceuticals being marketed in hospitals or pharmacies in Spain; whereas pharmaceuticals not financed by the Social Security and not being marketed in hospitals or pharmacies in Spain, would *de facto* be subject to a higher price.<sup>1</sup> The AC Judgment was confirmed by the Supreme Court.<sup>2</sup>

The SCA then had to reconsider the matter, in compliance with the AC's judgment. The SCA Decision starts by considering the legislative evolution of regulated prices of pharmaceuticals in Spain. In summary:

- Prior to 1997 the Pharmaceuticals Act stated that each pharmaceutical would be subject to regulated cap pricing.
- After 1997, the Pharmaceuticals Act was amended so that regulated cap pricing would affect pharmaceuticals *financed by Social Security funds or State funds dedicated to health*.
- After 1999 the Pharmaceuticals Act was further amended so that regulated cap pricing would affect pharmaceuticals *sold within the national territory* and financed by Social Security funds or State funds dedicated to health.

In November 2004, PFIZER announced that it would undercut wholesalers and sell to pharmacies directly. This move caused an uproar amongst wholesalers and an agreement was ultimately reached with ministerial blessing as a result of which PFIZER adopted a dual pricing system based on the principle that (i) initial pricing of pharmaceuticals sold to distributors is the price freely set by PFIZER (as opposed to the regulated cap price); (ii) once it has been proved by the wholesaler that the specific pharmaceutical has been sold in Spain, the initial price is adjusted downwards to meet the regulated cap price. The SCA Decision assesses the legality of the latter system.

The SCA Decision considers that the essential element of the *illegal* dual pricing, *i.e.*, the voluntary establishment of two different prices depending on the destination of the pharmaceuticals in order to restrict their parallel trade, would not concur in this case. In this case, the logic of the envisaged dual pricing addresses the issue that a regulated cap price applies to publicly financed products being sold in Spain. PFIZER must be allowed to fix its own price freely, consistently with the general principle of freedom of enterprise; only when (as an exception to the general rule) pricing is not free regarding certain products, then PFIZER must adjust to the regulatory obligations on pricing.

The SCA further reasons that the *ad hoc* national regulation explains and promotes the dual pricing system. The regulated cap prices are always below the free prices in three of the European countries taken as reference, *i.e.*, Germany, UK and the Netherlands: expecting PFIZER to enable exportation at

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<sup>1</sup> Judgment of the Appeal Court of 13 June 2011, appeal number 450/2009.

<sup>2</sup> Judgment of the Supreme Court of 3 December 2014, appeal number 4792/2011.

the regulated cap prices would be tantamount to conferring extraterritorial effects to the national regulated cap pricing system.

The SCA also dismisses the analogy between the dual pricing system applied by PFIZER and the dual pricing system at stake in the GLAXO case (ECJ Judgment of 6 October 2009, cases C-501, 513, 515, 519/06 P), where the ECJ regarded agreements seeking to restrict parallel trade as restrictive by object. That case stems from the commercial policy by GLAXO, back in 1998, to apply a differentiated or dual pricing to pharmaceuticals depending on whether those pharmaceuticals were going to be marketed in Spain or were destined for exportation. The SCA distinguishes the facts in the GLAXO case from those in the PFIZER case on the following grounds:

- When GLAXO introduced its dual-pricing policy the regulated cap pricing in Spain applied to publicly financed pharmaceuticals (the law had not yet been amended to further limit cap pricing to [publicly financed pharmaceuticals] *sold in Spain*). The SCA reasons that the regulatory framework in the GLAXO case back in 1998 was different, so that (it can be implied from the SCA's reasoning) GLAXO had some commercial freedom, not available to PFIZER in 2005, not to discriminate between pharmaceuticals sold in Spain and those sold for export. GLAXO's decision to establish a dual pricing system based on whether pharmaceuticals were sold in pharmacies and hospitals in Spain was a voluntary decision, not based on a regulatory obligation.
- The above is compounded by the fact that GLAXO required information to wholesalers on which pharmaceuticals had been exported, which provided GLAXO with sensitive commercial information of each wholesaler (which, according to the SCA, could enable GLAXO to condition or tailor its commercial policy *vis-à-vis* each distributor). Conversely, PFIZER designed a system which complied literally with the regulatory requirements and does not require knowledge of the pharmaceuticals exported.

Consequently, the SCA Decision considers that the 2005 PFIZER dual pricing policy is not contrary to competition.

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