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Spanish court orders the administration to bear the damages caused by the erroneous price reduction

Miquel Montaña (Clifford Chance) · Friday, May 6th, 2011

On 23 February 2011 the Administrative Chamber of the “Audiencia Nacional” handed down an interesting judgment ordering the Administration to bear the damages caused by the erroneous price reduction of EVOPAD®, a medicament marketed by JANSSEN-CILAG comprised of Galantamine. The facts of the case may be summarised as follows:

The Ministry of Health reduced by 20 % the price of EVOPAD® on the grounds that a generic of Galantamine was marketed in the United Kingdom. It should be clarified that according to Article 93.6 of the Spanish Medicines Act, medicaments for which no generics have been marketed in Spain 10 years after they were included in the reimbursement system, or 11 years when a new indication has been approved, must reduce their price by 20 % if a generic has been launched in another European Union member state with a lower price. As mentioned, the Ministry of Health reduced the price of EVOPAD® on the grounds that a generic had been launched in the United Kingdom. However, during the proceedings JANSSEN-CILAG proved that, in fact, the product launched in the United Kingdom was not a generic, but a product marketed by JANSSEN-CILAG under a different trademark. Therefore, the Court concluded that the Ministry of Health had erroneously reduced the price and ordered the Administration to compensate JANSSEN-CILAG for the damages caused by the price reduction.

In addition, in the same judgment the Court annulled the inclusion of Galantamine within the “price reference” system, on the grounds that a product cannot be included within the “price reference” system when no generics of said product have been marketed, as was the case. In this regard, the Court followed the same line as its previous judgment of 9 December 2010, already discussed on this blog, which radically changed the Court’s own previous case law on this point.

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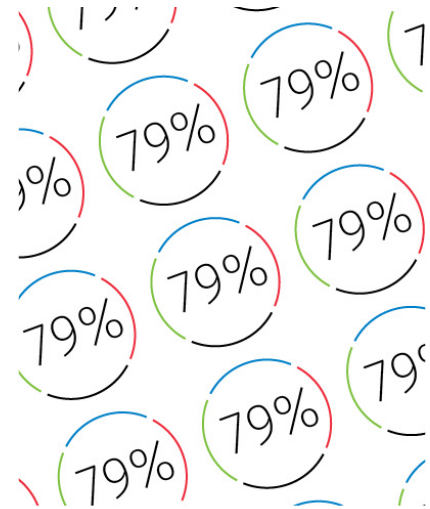
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