



## Publishing the data generated by off-label use does not imply that an unauthorised clinical trial is being carried out

*Judgment of 20 July 2016 of the Supreme Court of Justice of Galicia*

### Background

The Department of Health of Galicia imposed a fine of €120,000 on a medical practitioner in such region of Spain for having prescribed growth hormones to several patients in order to treat specific neurological pathologies for which said medicinal product had not been evaluated or authorised. The decision of the regional administration was supported by the fact that, in the past, the medical practitioner had requested authorisation to undertake a clinical trial on the use of the medicinal product on such pathologies, which had not been granted, as well as by the fact that he published the results of the treatment on individual patients. These circumstances, in addition to the fact that the regional administration of Galicia believed that the number of patients treated was not compatible with the exceptional nature applicable to the off label use of medicinal products, led the administration to conclude that, under the rules that provide for the special uses of medicinal products, the medical practitioner was in fact conducting an unauthorised clinical trial using said medicinal product.

### The administration must demonstrate that the medical practitioner effectively behaved as accused

The medical practitioner appealed to the Supreme Court of Justice of Galicia, which ruled that a fine cannot be imposed based merely on inferences and suspicions, and, therefore,

annulled the fine. In particular, the court blamed the Department of Health of Galicia for failing to identify the clinical trials that had allegedly been carried out by the medical practitioner, agreeing with the reasoning employed in the expert reports submitted by the appellant, which stated that the exceptional nature of off-label uses is not dependent on the number of patients treated, but on the fact that there is no authorised therapeutic alternative to treat the pathologies in question. In this regard, the court asserted that the mere fact that the medical practitioner had published the results of his patients' treatments with this medicinal product did not necessarily imply that an interventionist study, such as a clinical trial, was being conducted.

### The off label use of a medicinal product should be decided by the medical practitioner

Furthermore, the judgment sets out that our regulations allow medicinal products to be used in therapeutic situations other than those authorised, provided that the medical practitioner responsible for the patient deems that doing so is appropriate; in other words, when it is justified by the patient's needs. This is a call for attention which should not be disregarded given that recently we have seen various initiatives organised by regional administrations with a view to promoting off label uses of certain medicinal products based exclusively on economic criteria.