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Important fine to an investigator that promoted a clinical trial without administrative approval

The Judgment of the Superior Court of Justice of 19 December 2013 confirms a fine of 120.000 Euros imposed by the Autonomous Region of Madrid

Background

As a result of an anonymous complaint made before the Spanish Agency of Medicinal Products and Medical Devices (AEMPS in Spanish), an infringement procedure was initiated against a physician claiming that he had carried out a clinical trial, acting as sponsor and principal investigator, without obtaining prior approval, without having received a favorable ruling from the CEIC, and having obtained the informed consent of the patients by providing them with information that was not accurate. The Autonomous Region of Madrid imposed a fine of 216.003 Euros. The judgment confirms the fine.

Differences between a trial and an observational study

The core of the discussion before the Court was establishing whether the study of Dr. Soriano was a trial or a prospective observational study. The judges analyzed in detail the differences between both concepts; and they came to the conclusion that when a medicine is used under conditions different from those that are set forth in its SmPC one cannot speak of a post-authorization observational study. In this sense, the judgment points out that in an observational study medicines must be prescribed in accordance with the normal conditions of clinical practice, and that according to the rules governing these studies such normal conditions are those established in the marketing authorization.

Before reaching this conclusion, the judgment establishes that a medicinal product used under conditions different from those authorized becomes a medicinal product under investigation; reproducing thus the provisions of Royal Decree 1015/2009. Therefore, it is convenient that those who use medicinal products under conditions different from those authorized adjust strictly to legal rules and handle with the utmost care any activity that might be considered as clinical investigation. As the judgment says neither the medical practice nor the professional freedom of prescription of the physician protect, under any circumstances, the performance of unauthorized clinical trials.

Off label use

On the other hand, the judgment is a wake-up-call for those who favor the use of medicinal products under not authorized conditions. The judgment refers to this use recalling the provisions of Royal Decree-law 16/2012 regarding the sustainability of the National Health System, highlighting that the prescription of medicinal products and medical devices must be made in the most adequate way in benefit of the patients and that off label use must be authorized previously by the commission responsible for the therapeutic protocols in each Autonomous Region.

The Court also recalls that this applies even if the medicinal product is used in the approved indications but with a dosage different from the one authorized.