



The regional government of Galicia against the preparation of illegal magistral formulas

Judgment of the High Court of Justice of Galicia of 8 May 2019

Background

This judgment refers to a sanctioning proceeding against a healthcare center located in Galicia (a Spanish autonomous region) initiated by the Department of Health of such region. The healthcare center was charged with the commission of a serious infringement under the Spanish Legislative Decree 1/2015 consisting on the prescription and preparation of magistral formulas in breach of the applicable regulations. The origin of the proceeding is a complaint made by a patient of the healthcare center to whom a treatment for alopecia was prescribed and supplied (as a magistral formula) without the necessary indications regarding its composition.

The sanctioning activity of the regional government of Galicia

During the course of the inspections carried out by the authorities in the premises of the healthcare center, several magistral formulas in bulk were found. Such magistral formulas were divided and introduced in small packages that were delivered to the patients. The authorities, considering the serious risk to the public health of this practice, seized the magistral formulas found in the center. Such seizure was decided after confirmation that the magistral formulas were (i) initially prepared for specific patients but indistinctly used for others, (ii) impersonally prescribed without a prior medical diagnosis; and (iii) packaged without the direct supervision of a pharmacist. Likewise, the authorities found that the healthcare center

was not authorized for the preparation, packaging and labelling of magistral formulas.

In sum, the Department of Health of the regional government of Galicia understood that the systematic production of medicines in a health center cannot be done under the umbrella of the regulations applicable to magistral formulas. Magistral formulas may only be used to cover specific needs of individually named patients and always require a prior medical prescription.

Statute of limitations

The Court overrode the sanction imposed to the healthcare center. This was done for merely procedural reasons and despite the fact that the legal arguments alleged by the regional authorities to sanction the healthcare center were not questioned. In particular, the Court pointed out that the regional authorities concluded the sanctioning proceeding two days after the maximum legal term; a delay that inexorably resulted in the action being barred by limitation.

In sanctioning proceedings, authorities must pay attention not only to the substance of the case but also to applicable deadlines. If a sanctioning proceeding is concluded once the applicable legal term has elapsed, such proceeding shall be barred by limitation. However, such expiry shall not prevent the authorities to initiate another sanctioning proceedings for the same facts if the initial infringement is not affected by prescription.