



Obtaining adequate informed consent is essential in order to prevent liabilities

Judgment of the High Court of Justice of La Rioja, of 17 October 2011, on the liability of the Administration for damage caused by the administration of a medicine

Background

Last month an interesting judgment of the High Court of Justice of the region of La Rioja was made public. This judgment stresses once more the importance of adequately documenting the informed consent of the patient with the aim to prevent the possible claim for liabilities for damages caused by the administration of a medicine.

In particular, the court ruled on the claim of a patient that wanted to be indemnified by the healthcare Administration of La Rioja against a movement disorder supposedly caused by the administration of a medicine.

Requirements for the indemnity

The court starts by reminding that three necessary requirements must be fulfilled in order to be able to claim the Administration's liability for the damages caused as a consequence of the administration of a medicine in a public healthcare centre: (i) the existence of an actual damage, (ii) the existence of a cause-effect relation between the administration of the medicine and the damage and (iii) the illegality of the injury, that is, that the subject is not under the legal obligation to bear such damage.

The basic criterion to determine whether we are dealing with a damage that the patient has no obligation to bear is the "lex artis" criterion. This criterion implies that healthcare personnel

is not under the obligation to achieve a positive result for the patient, but to act with the diligence and the caution required by the circumstances of the case taking into account the current scientific knowledge.

The informed consent is an essential element of the "lex artis"

The court considers that in order to comply with the "lex artis" rule it is necessary that the healthcare personnel informs the patient about the diagnosis of the disease, the prognosis that may be expected from the treatment as well as the risks of the treatment, in such a way as to allow the patient to freely choose from the possible options including the option of not undergoing any surgery or treatment.

The judgment is also interesting as to the assessment of the proof on the relation of causality between the intake of the medicine and the damage suffered: the court modulates the burden of proof which falls on the plaintiff and it deems that the causal link has been proven since the Administration against which the claim was brought was not able to offer a satisfactory explanation for what happened.

The absence of the informed consent of the patient together with the causal relationship between the medicine and the ailments of the patient lead the court to conclude that he has suffered an indemnifiable moral damage as his right to self-determination regarding his healthcare was frustrated.