



## The door is open to holding the distributor responsible for damage caused by a product sold with incomplete instructions for use

*Judgment of the Provincial Court of León, of 29 November 2013, number 459/2010*

### Background

A patient suffered an episode of rejection and intolerance to the medical device 'Bio-Alkamid' (reticulated prosthetic polymer of poly-alkylamide), therefore it was necessary to extract it. The leaflet did not contain sufficient information about the possibilities of extraction.

This patient suffered damages and lodged a complaint against the companies responsible for the marketing of such product in order to obtain compensation for the damages suffered. The Court of First Instance found the defendants guilty.

### Leaflet's insufficient information

Both the Judge of First Instance as well as the Provincial Court found that the leaflet contained omissions regarding the possibilities of extraction of the product and considered that the information on the leaflet was incomplete. However, neither the Judge nor the Provincial Court qualified the product as defective despite this information gap, as they understood that the product was simply not tolerated or was rejected by the patient.

On this basis the courts decided not to apply the regime provided in Law 22/1994, on Civil Liability for the Damages Caused by Defective Products (LRPD), and they applied the regime provided in Law 26/1984, for the Defense of Consumers and Users (LGDCU).

In our opinion, it is surprising that the Court found the product not defective in spite of recognizing that the information was incomplete, since it is settled case-law of the Supreme Court that products that are not accompanied by due instructions for their correct use are defective.

According to this judgment, with which we do not agree, a door is open to the fact that the mere distributor or seller of a product which causes damages, and the instructions of which are incomplete may be held responsible for the damage even if it is able to identify the manufacturer.

### Consequences of applying one or the other law

In the case analyzed in the judgment, the first consequence of applying the LGDCU was that the defendants could not exempt themselves from the responsibility under the mere fact of being simple distributors of the product, which would have been possible applying the LRPD. Under the LRPD, in line with the EU Directive on product liability the distributor could avoid a claim by identifying the manufacturer.

Other consequences of applying the LGDCU instead of the LRPD is that the maximum period to claim responsibility varies as well as the top amount payable, and that claims regarding moral damages are permitted.