

The Supreme Court is reluctant to allow criminal proceedings against failure to act by administrative authorities

Judgement of the Supreme Court, of 29 April 2015, on the financing of new treatments for Hepatitis C Virus (HCV)

This judgment rules on the criminal complaint filed by patients and relatives of persons who were affected by the hepatitis C virus on account of the obstacles they found to access new treatments against this pathology. Given that among the defendants there was a person with privileged jurisdiction, the initial assessment of the complaint in relation to this person was made by the Supreme Court.

Background of the case

As is generally known, when a new medicine obtains its marketing authorization the Ministry of Health must decide whether or not the product will be financed with public funds, and under what conditions. In the case of a product approved to treat HVC, the decision process lasted up to 10 months and, moreover, limitations to access to such medicinal product were approved.

The frustration in view of this situation, together with the high initial expectations, explain why a group of persons decided to bring criminal proceedings against certain authorities and public employees of the Ministry of Health, as well as against the pharmaceutical company which had obtained the marketing authorization. The plaintiffs accused them of several crimes including homicide, injuries and offences against moral integrity, omission of the duty to provide assistance, administrative malfeasance, and prices alteration.

The plaintiffs based these very serious accusations on the fact that the persons responsible within the Ministry refused to challenge, expropriate or impose a compulsory licence on the patent of the active ingredient. They also argued that, in their opinion, there was an infringement of the legal duty to set a price for such medicinal product which would make it available for patients.

Criminal proceedings must be the exception and the last resort

The Supreme Court rejected the complaint and considered that no prima facie evidence of a criminal offence had been submitted. The court claims that the possibility to take actions against a patent for reasons of public interest falls within the authority of the administration, but there is no legal obligation requiring it to act in this way.

On the other hand, regardless of its level of diligence, the court highlights that the Ministry provided early access to the medicinal product through various programs, and that there was no evidence that any regulation had been violated during the decision-making process regarding its financing.

The court concludes warning against the temptation to pursue these matters criminally, which, without underestimating the difficult situation of the affected parties, should be the last resort, and not the first response to delays in administrative procedures.