

## Europe *Spain*

# Causation-related factual evidence: ECJ judgment interpreted by Spanish National Court

### Introduction

Until recently, the Spanish courts had neither applied nor referenced the 21 June 2017 ruling by the European Court of Justice (ECJ) on the Hepatitis B vaccine. However, that changed in June and July 2019 when the Spanish National Court handed down judgments in two separate cases (for alleged damages following administration of an HPV vaccine), both of which referred to and interpreted the ECJ ruling. This article provides an overview of the conclusions reached by the National Court, as well as the potential implications of its interpretations of the 2017 ECJ judgment.

### The 2017 ECJ judgment summarised

By way of background, the European Court of Justice concluded in 2017 that when medical evidence neither establishes nor rules out the existence of a link between a vaccine's administration and the occurrence of a disease, the existence of a causal link between the defect attributed to the vaccine and the damage suffered by the victim could be considered to be established on presentation of certain predetermined causation-related factual evidence, that is when "solid, concrete and concordant evidence" concurs.

In the 2017 case, an expert report had concluded that the weight of the scientific literature did not clearly establish a direct relationship between the vaccine and the disease. However, such a relationship could not be ruled out, given the temporal coincidence between the administration of the vaccine and the onset of the disease. A scientific study supporting the association between the disease and the vaccine was also produced as evidence, along with a decision from the French administration.

### Background to the recent Spanish cases

Separate contentious-administrative actions were brought by two girls against the Spanish Ministry of Health and a manufacturer of HPV vaccines. Each plaintiff sought economic compensation for alleged suffering following administration of the vaccine. Both alleged adverse neurological adverse reactions that had not been mentioned in the patient

information leaflet nor in the summary of product characteristics of the vaccine.

The plaintiffs also alleged (i) the liability of the Spanish Ministry of Health for financing the vaccine and including it in the Spanish vaccination calendar, (ii) a lack of safety studies into the vaccine, (iii) the vaccine's ineffectiveness and (iv) lack of compliance by the laboratory with its pharmacovigilance obligations.

The plaintiffs' medical records did not evidence a causal relationship between the alleged diseases and the administration of the vaccine but did indicate that the onset of the alleged diseases happened after the administration of the vaccine. There was therefore an apparent temporal coincidence between the administration of the vaccine and the onset of the alleged diseases.

A large number of clinical trials, studies and papers by worldwide health authorities evidencing the safety and positive risk-benefit profile of the vaccine were filed in support of the lack of causal relationship.

An expert report issued by a neurologist evidenced (i) errors in the medical diagnoses and (ii) the absence of causal relationship on the basis that none of the following three criteria were met: temporal, biological and epidemiological. In relation to the temporal criteria, the expert concluded that the onset of the diseases was either too early or too late to be linked with the administration of the vaccine.

### The Spanish judgments in focus

Once it had reviewed the evidence, the National Court issued two 2019 judgments dismissing the actions brought by the plaintiffs on the basis that (i) some of the diseases were incorrectly diagnosed, (ii) the weight of the scientific evidence supported the vaccine's safety and positive risk-benefit profile of the vaccine and (iii) the expert report clearly ruled out a causal relationship between the alleged diseases and the administration of the vaccine.

In relation to the ECJ's June 2017 ruling, the National Court concluded the following (in both its 2019 judgments)

“Finally, the ECJ dated 21 June 2017 (Case C-621/15), provided by the plaintiff, does not obstruct the conclusion reached, since in this case the facts alleged in the lawsuit do not constitute “solid, concrete and concordant evidence” that would allow us to conclude that the vaccine suffers from a defect and that there is a causal relationship between the defect and the disease.”

So although temporal coincidence and the lack of any previous history of related diseases were argued, the National Court reasonably decided not to apply the ECJ judgment. This was because the evidence was not solid enough to conclude both that the vaccine was defective and that there was a causal relationship between the vaccine’s administration and the disease.

### Comment

The recent judgments issued by the Spanish National Court, interpreting the ECJ’s 2017 ruling offer helpful guidance in two areas, providing (i) criteria on what can be considered as solid evidence of defect and causal relationship and (ii) the premise used to justify the absence of a causal link between the administration of the vaccine and the onset of the diseases.

Where criteria on what constitutes solid evidence of defect or causal relationship is concerned, the only evidence produced in the two cases before the National Court was (a) an apparent temporal coincidence between the administration of the vaccine and the onset of disease and (b) the absence of any history of related disease in the plaintiffs prior to the administration of the vaccine in question.

Although both facts could have been considered as solid evidence, in light of the ECJ’s ruling, the National Court did not consider them to be solid enough to find the presence of either a causal relationship or a defect. This could be viewed as a positive outcome of the interpretation of the ECJ Judgment for manufacturers given that both judgments set a reasonable standard when interpreting facts and evidence.

On the other key issue – the premise used to justify the absence of any causal link – the Spanish National Court based its interpretation on a lack of solid evidence rather than on the premise that medical evidence ruled out the existence of a link between the administration of the vaccine and the occurrence of disease. This had also been the premise on which the ECJ’s 2017 ruling was based:

“(…) notwithstanding the finding that medical research neither establishes nor rules out the existence of a link between the administering of the vaccine and the occurrence of the victim’s disease”.

This raises two questions (i) what would the National Court have concluded if the evidence had been more solid and (ii) would solid evidence have been enough to discredit the weight of scientific evidence?

In our opinion, even if there had been more solid evidence, the National Court would have reached the same decision on the basis of the weight of the scientific literature and the expert report. This view is based on the fact that, prior to analysing the 2017 ECJ judgment, the National Court clearly ruled out the causal relationship based on the scientific evidence filed on behalf of the manufacturer.

For the moment, this first interpretation of the ECJ’s judgment is positive and suggests that a similar line of reasoning would be followed by the courts in future.



**Carolina Revenga.**

Counsel, Madrid

T +34 91 349 82 89

carolina.revenga@hoganlovells.com



**Jorge Etreros**

Associate, Madrid

T +34 91 349 82 07

jorge.etreros@hoganlovells.com