

Legal News: Clarification on the starting point of the limitation period for product liability claims

In a widely published ruling handed down on 27 November 2019, the 1st Civil Chamber of the French Court of Cassation provided an important clarification on the starting point of the limitation period for product liability claims.

The judgment concerns a failure to provide sufficient information on the drug Dépakine (sodium valproate) produced by the pharmaceutical laboratory Sanofi-Aventis, one of the adverse effects of which is to cause foetal malformations (teratogenic risk) and for which the laboratory was indicted on 3 February 2020 for aggravated deception and involuntary injuries.

In this case, a woman suffering from epilepsy was treated with this drug and the treatment was continued even though she was contemplating pregnancy. At the end of 2002, she gave birth to a child with a general malformative syndrome. After an expert report issued almost 9 years later ruled out a genetic disease or chromosomal abnormality that caused the malformations and, on the contrary, linked them to the taking of the drug, the parents sued the pharmaceutical group.

The Orléans Court of Appeal, confirmed by the Court of Cassation, held the laboratory liable on the basis of the defective products regime because the package leaflet did not contain the information that, among the possible adverse effects of the drug, there was a teratogenic risk of particular seriousness, even though this risk was known in the medical literature at the time (the leaflet only called on the patient to "inform" her doctor in the event of pregnancy or desire for pregnancy and to "carefully monitor" the newborn).

It is of particular interest that the laboratory challenged the appeal judgment as it stated that the claimants' action was not time-barred.

As a reminder, an action for liability under the defective products regime is time-barred "*within three years from the date on which the claimant had or should have had knowledge of the damage, the defect and the identity of the producer*" (former article 1386-17 of the French Civil Code, now 1245-16 of the French Civil Code).

It was therefore necessary in this case to define the precise moment when the claimants became aware of the injury, of the defect (and necessarily of the link between the two) and of the identity of the producer.

The laboratory essentially argued that the parents were aware of these three elements on the day of their child's birth in 2002, or at the latest a few weeks later when three doctors had hypothesized a link between the malformations and the taking of Dépakine. Their action, initiated in 2013, was therefore, according to the applicant in the appeal proceedings, largely time-barred.

The Court of Cassation does not follow this reasoning and upholds the judgment of appeal in that it dismissed the appeal. Since the defect in the drug was related to the lack of information contained in its package insert, the Court held that the limitation period could only run from the date on which the claimants "*knew or ought to have known that they did not benefit from the information that Dépakine [...] could produce teratogenic effects*".

However, according to the Court, this information could not be obtained by the claimants in a sufficiently tangible manner until the expert's report was filed in 2011, i.e. less than three years before the initiation of their action, which was therefore not time-barred.

With this ruling, the Court of Cassation thus determines the claimant's "knowledge" of the defect and its link with the damage according to the degree of information available to the claimant. Such knowledge should not be hypothetical but sufficiently tangible or even certain, which may result in a considerable postponement of the starting point of the limitation period. The scope of the judgment is therefore far-reaching, in particular as regards actions for liability for defective products in connection with iatrogenic conditions for which diagnostic errors generally last several years.

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