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Advocate General's Opinion in Case C-338/24 | Sanofi Pasteur

Liability for Vaccines: AG Medina suggests that the unconditional application of a ten-year expiry period in the case of progressive injuries is contrary to the Charter

Time-limits to bring an action in such cases begin to apply when the victim's medical condition stabilises (ceases to evolve)

LF, a French employee, received Sanofi Pasteur's Revaxis vaccine against diphtheria, tetanus and poliomyelitis on 20 March 2003. From 2004, she developed a range of persistent ailments which, after a 2008 muscle biopsy, were attributed to an element contained in the vaccine. An expert report found, on 20 September 2016, that her condition had stabilised and that it could not be concluded that her illness was causally linked to the vaccination.

LF sued Sanofi Pasteur, pursuing both fault-based liability and liability for defective products. The national courts, however, dismissed her claims as time-barred, a view largely upheld on appeal, until the Court of Cassation set aside the appellate judgment on 5 July 2023, holding that, for progressive injuries, the limitation period begins only when the damage is stabilised. The case now lies before the Rouen Court of Appeal, the referring court.

The referring court seeks guidance from the Court of Justice concerning the Product Liability Directive. ¹

In today's Opinion, Advocate General Laila Medina takes the view that the **Product Liability Directive allows an injured person to sue a manufacturer under ordinary national fault-based rules, provided the claim is not confined to the product's defect alone**. Producers can be found at fault, for example, if they keep a product on the market after learning it is unsafe or ignore warnings about its risks.

The Advocate General then examines the setting of a time limit for bringing proceedings. She examines **the unconditional application of the ten-year expiry period** established in Article 11 of the Product Liability Directive to all injured persons. She finds that, its application **without consideration of the particular circumstances of those persons suffering from a progressive disease whose illness has not stabilised before expiry of that period, does not respect the essence of the right to an effective remedy guaranteed by the EU Charter of Fundamental Rights** ("the Charter").

Finally, the Advocate General observes that Article 10(1) of the Product Liability Directive must receive an autonomous, uniform interpretation across the Union, because the provision itself does not defer to Member State law for fixing the starting date of the limitation period. Linking the three-year limitation period to the injured person's "awareness" therefore has to be understood in a way that lets the injured person prove every element required — damage, defect and causal link — in order to obtain full compensation. **While an early manifestation date may suffice for non-progressive injuries, victims of progressive diseases cannot assess the nature and scope of their loss until medical evidence shows that their condition has stabilised.**

Starting the clock earlier would either deter timely actions or force them to sue piecemeal, undermining effective

judicial protection and producing divergent outcomes under national procedural rules. To safeguard the directive's consumer-protection aim and the Charter right to an effective remedy, **the limitation period may not begin before the stabilisation date, defined as the moment at which the victim's medical condition ceases to evolve.**

NOTE: The Advocate General's Opinion is not binding on the Court of Justice. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of EU law or the validity of an EU act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

Unofficial document for media use, not binding on the Court of Justice.

The [full text](#) of the Opinion is published on the CURIA website on the day of delivery.

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¹ [Council Directive 85/374/EEC](#) of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.