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HISTORIC JUDGMENT RENDERED BY THE PARIS COURT IN A FRENCH CLASS ACTION

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SUMMARY

The Paris Court has ruled against Sanofi in the Depakine case on the class action initiated by an association.

According to a parliamentary report dated 11 June 2020, only twenty-one class actions have been brought to court since the mechanism came into force in France on 1 October 2014 (in consumer matters). Until recently, only decisions on procedural issues and decisions dismissing the cases have been rendered.

The decision rendered on 5 January 2022 is the very first decision to rule on the merits against a professional entity subject to a class action. The class action in this case was introduced on the grounds of the provisions of the Public Health Code resulting from the law dated 26 January 2016.

In a nutshell : The Paris Court has ruled against Sanofi in the Depakine case on the class action initiated by an association.

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As a reminder, under French law, the entity filing the claim is not the class but a licensed association. Furthermore, class action allows all persons suffering damage caused by a fault related to the production, supply or delivery of a health product to be compensated. Established by

the law of 18 November 2016, the provisions of Articles L. 1143-1 et seq. of the Health Code provide for two phases of the action:

- initially, a judgement to determine the extent of the defendant's liability: in this phase, the judge must assess the admissibility of the action and the liability of the defendant. The judge will base his decision on the submissions made by the claimants, and he will decide whether to hold the defendants liable for their actions. The judge will also determine: (i) the criteria for compensation; (ii) how to define the class of consumers to which the defendant may be liable; and (iii) how to inform the members of this class of the judgment. Pursuant to the French consumer code, the court will decide on the appropriate measures to inform the class members of the existence of the judgement on liability. Once this information is provided, each member of the class has the opportunity to come forward to opt into the action.
- and then a second phase of enforcement of the judgement and individual compensation.

Class Action Complaint: The Association for the support of parents of children suffering from anticonvulsant syndrome (*Association d'aide aux parents d'enfants souffrant du syndrome de l'anticonvulsivant* – APESAC) represents many families where mothers took medical treatment for their epilepsy, including the drug Depakine (whose active ingredient is valproic acid or sodium valproate) and its derivatives (Depakine Chrono, Micropakine, Depakote and Depamide), during their pregnancy.

The association filed a class action against the laboratory Sanofi-Aventis France by writ of summons dated 2 May 2017. Sanofi in turn summoned the National Office for Compensation for Medical Accidents (*Office national d'indemnisation des victimes de affections iatrogènes, des infections nosocomiales et des accidents médicaux* – ONIAM) and its insurer, the company Allianz Global Corporate & Specialty SE.

The decision: In a judgement dated 5 January 2022, the Paris Court - after dismissing the claims relating to the inadmissibility of the allegations, the request to set aside a judicial expert opinion carried out in the context of the criminal proceedings, the demand for a stay of proceedings pending the criminal decision and a request for the reopening of the proceedings - ruled in particular that:

- Sanofi had was at fault for not fulfilling its duty of care and its duty of information in regard to children exposed before 22 May 1998 to the drug Depakine and its derivatives, between 1984 and January 2006 for congenital malformations and between 2001 and January 2006 for neurodevelopmental disorders. While recognizing that there was a scientific consensus that these drugs are among the best in the world for treating epilepsy in patients, the court stated that, according to the scientific literature, the possibility of causing malformations in children exposed in utero with respect to anomalies in the closure of the neural tube (the primitive nervous system of the embryo) could be qualified as a probable causal link as of 1984. As regards major malformations, this causal link could be qualified as probable between 1990-

1992. Concerning a possible causal link between behavioral disorders, particularly autism spectrum disorders, and prenatal exposure to valproate, a probable causal link between 2008-2009 was upheld by the court. Thus, the court considered that the laboratory should have, as early as 1984, requested the modification of the package insert for the drug Depakine and its derivatives from the national drug safety agency in order to provide clear and precise information to health professionals in accordance with the latest scientific data. This led the agency to reject the first two requests as insufficiently substantiated, before accepting the modifications in January 2006 and April 2015.

- Sanofi produced and marketed a defective product for children exposed to Depakine and its derivatives between 22 May 1998 and January 2006 for congenital malformations and between 2001 and January 2006 for neurodevelopmental disorders. The court considered that the presentation of the drug in the patient information leaflet did not contain the necessary information regarding the possible adverse effects of the drug, notably that there was a particularly serious possibility of causing malformations in children exposed in utero and that there was a risk of developmental and cognitive disorders, until the request to modify the leaflet in January 2006. The Court concluded that, from 22 May 1998 to 25 January 2006 inclusive regarding the possibility of causing malformations in children exposed in utero and from January 2001 to 25 January 2006 inclusive regarding the risk of developmental and cognitive disorders, the product did not present the safety guidelines that could legitimately be expected and that the contested drug was defective.

The Court went on to set out the criteria to be eligible to take part in the class action and ruled that users were entitled to a 95% loss of opportunity to choose a less dangerous therapeutic alternative.

It also ruled that claimants may opt into the class within 5 years. The Court ordered extensive publicity of the judgement in numerous French daily and weekly newspapers and ordered Sanofi and Allianz to pay a provision of 120,000 euros to cover future costs incurred in setting up the second phase of compensation under the class action procedure.

Finally, it rejected a request for a deposit of 400,000 euros with the Caisses des dépôts et consignation.

It is worth noting that the Orleans Court of Appeal, in a judgment dated 20 November 2017, and the Court of Cassation, in a decision dated 27 November 2019, had already established the defective nature of Depakine due to the lack of information in the leaflet insert for pregnant women.

Each member of the class now has the opportunity to come forward to opt into the action.

By joining the group, the members of the class give the association initiating the class action the mandate to negotiate the appropriate level of compensation. In this case, the compensation could reach up to tens of millons of euros.

Following the judgment on liability, the association may negotiate and agree with the defendant on the amount of compensation within the limits set by the judge. A settling defendant is then required to distribute the agreed upon compensation for the losses suffered to the members of the class who opted in. The judge that ruled on the liability must then approve the settlement, or partial settlement, reached between the parties and accepted by the members of the group concerned. Assuming that no settlement is reached between the parties, the judge is responsible for ruling on the compensation.

The class action procedure is terminated either by judgements of liquidation of damages, when necessary, or by the declaration of the dismissal of the action.

Our comments: Not only is this the very first decision to sentence a professional entity subject to a class action but it is also the first decision on the merits regarding the liability of a health product. It took almost five years to reach this first instance decision and it will take several more years before a final decision on compensation is rendered according to Sanofi's liability. It is only then, and in the absence of mediation, that the constitution of the class and its subsequent compensation can take place.

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