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Liability for defective medicinal products: adverse effects of vaccines and their causal link

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Certain elements of the system of liability for defective medicinal products are analysed in the wake of the recent judgment of the Court of Justice of the European Union of 21 June 2017 in Case C-621/15

1. Preamble

The liability of producers for harm caused by defective products manufactured or imported by them is regulated by EU law in 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. This Directive (subsequently amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999) was transposed into Spanish law by the Defective Products Liability Act 22/1994 of 6 July only to be subsequently recast together with other laws in the recast text of the Consumer and User Protection Act and other supplementary laws ("TRLGDCyU"), approved by Royal Legislative Decree 1/2007 of 16 November (arts. 128 et seq.).

The purpose of Directive 85/374/EEC is to lay down a system of producer liability for damage caused by a defect in his product [damage caused by death or personal injuries; damage to, or destruction of, any item of property other than the defective product itself, subject to a deduction of a lower threshold and provided that the item of property: (i) is of a type ordinarily

intended for private use or consumption, and (ii) was used by the injured person mainly for his own private use or consumption.

The main characteristic of this specific system of liability is that it is a strict (without fault) liability system, since the injured person seeking to obtain compensation for the damage caused will only have to prove the defect, the damage and the causal link between these.

As regards the persons liable, the Directive regards as a "producer" the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer. Similarly, and without prejudice to the liability of the producer, any person who imports into the EU a product for sale, hire, leasing or any form of distribution in the course of his business shall be liable as a producer.

Finally, the Directive also refers to the supplier of the product which causes damage as a consequence of being defective, making him liable unless he informs the injured person, within a reasonable time, of the identity of the producer, importer or of the person who supplied him with the product.

Moreover, art. 13 of the Directive expressly provides that such Directive shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified.

2. Medicine as a defective product

2.1 The concept of "product" within the Directive (and the TRLGDCyU) includes medicinal products, since "product" is defined as all movables. Therefore, producers of medicinal products are liable for the damage caused by defective medicinal products they manufacture or import.

According to art. 6 of the Directive, a "product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation". And adds that a "product shall not be considered defective for the sole reason that a better product is subsequently put into circulation". Art. 137 TRLGDCyU is expressed in the same vein, although it clarifies that "in any case, a product is defective where it does not provide the safety normally provided by the other items of the same series".

On the basis of this legal concept it follows that what is relevant is that the product exhibits a lack of safety with respect to persons or items of property, and not a lack of

fitness for the use intended. This is expressly stated in recital 6 of Directive 85/374/EEC. Consequently, many circumstances that, from a material and even extra-legal perspective, are considered to be defects are left out of the concept of defect.

The defect must be determined objectively, i.e., regardless of what the parties may have agreed under a contract. In fact, the use of the word "entitled" when referring to the safety to be expected reinforces this objective nature of the defect determination, since in this way the concrete expectations of a given consumer are excluded.

Furthermore, it is very important that both the Directive and Spanish legislation do not allude to the safety that is legally required of a product, but rather to the safety that one is "entitled" to expect of that product. In this way, it could be the case that a product, despite complying with all safety regulatory standards, could be considered defective, because consumers or users would expect greater safety than that actually provided.

2.2 The concept of defect having been constructed on the basis of the safety that one is entitled to expect from a product, it is logical that the first element to be taken into account when judging the expected degree of safety is the uses given when the product is presented to the public. Because the degree of safety on is entitled to expect from the medicinal product, which must be taken into account in assessing the possible defectiveness, is the degree of safety expected by the patient. This is true even if the medicinal product has been dispensed or prescribed by a doctor.

Presentation must be understood not only as the packaging of the product, but also the uses which may be incorporated into the product itself, or which may appear in its advertising or in specifications with instructions, descriptions, etc. Therefore, and in the present case, there is no doubt that the package leaflet for medicinal products plays an important role here.

The Community code relating to medicinal products for human use approved by Directive 2001/83/EC defines the package leaflet as "a leaflet containing information for the user which accompanies the medicinal product" (art. 1 (26)). And art. 15(3) of Royal Legislative Decree No 1/2015 of 24 July 2005 approving the recast text of the Medicinal Products and Medical Devices (Guaranteed Standards and Rational Use) Act provides that "the package leaflet, which shall be drawn up in accordance with the contents of the fact sheet, shall provide patients with sufficient information on the name of the active ingredient, identification of the medicinal product and its owner and instructions for its administration, use and preservation, as well as on adverse effects, interactions, contraindications, in particular the effects on the driving of motor vehicles, and other particulars to be determined by regulations in order to foster the most appropriate use and observance of the prescribed treatment, as well as the measures to be taken in the event of poisoning".

Unlike the fact sheet of a medicinal product (which is addressed to healthcare professionals), patients are the addressees of the package leaflet. For this reason, and in order to facilitate its comprehension by the patient, art. 15(3) of Royal Legislative Decree 1/2015 provides that "the package leaflet must be legible, clear, ensuring its comprehension by the patient and reducing technical terms to a minimum".

2.3 On the basis of the above, it is to be concluded that the fact that medicine has side effects, some of which may at times be very serious, does not necessarily mean such is a defective product; a product is not defective simply because it is dangerous. On the other hand, it will be defective if the level of danger of the product is not clearly indicated to the intended recipients.

As pointed out in Judgment no. 559/2011 of the Madrid *Audiencia Provincial* (Twenty-first Chamber) of 24 November, in the administrative authorisation procedure for the marketing of a medicinal product, the therapeutic benefits of the medicinal product in question for society in relation to possible adverse risks are taken into account "in such a way that when the benefits of a medicinal product are greater than the toxic or undesirable risks or effects of the same, the health authorities classify it as safe and suitable for marketing". Therefore, and as the Madrid *Audiencia Provincial* also pointed out in the aforementioned judgment, a medicinal product will not be defective simply because it is not "perfect" and produces adverse reactions or side effects, but because it undermines the degree of confidence or certainty about the risk that the product may entail. And this makes it necessary to analyse whether there is sufficient information on its side effects and contraindications.

3. Strict liability and the causal link between the defect and the damage

3.1 As has already been said, the key trait of Directive 85/374/EEC is that it sets out a system of strict liability, so that it is not necessary to show evidence of fault on the part of the producers, since art. 4 of the Directive stipulates that "the injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage".

3.2 The Court of Justice of the European Union ("CJEU") has recently made a pronouncement on the interpretation of the foregoing provision in its judgment of 21 June 2017 in Case C-621/15 (*W and Others v Sanofi Pasteur MSD SNC, Caisse primaire d'assurance maladie des Hauts-de-Seine and Carpimko*).

The questions referred for a preliminary ruling to the CJEU by the French *Cour de cassation* were raised in the course of proceedings concerning a citizen who was vaccinated against hepatitis B with a vaccine administered in three injections, after which he began to suffer from various ailments, following which he was diagnosed with multiple sclerosis, of which he died. His relatives sued the producer of the vaccines in the belief that the short period

between the vaccination and the appearance of the first symptoms of multiple sclerosis, in conjunction with the lack of any personal or family history of the disease, were such as to give rise to serious, specific and consistent presumptions as to the existence of a defect in the vaccine and as to there being a causal link between the injection of the vaccine and the occurrence of the multiple sclerosis. They relied in that regard on the case law of the *Cour de cassation*, according to which, in the area of liability of pharmaceutical laboratories for the vaccines they produce, proof of a causal link between the defect in the product and the damage suffered by the person injured can be derived from serious, specific and consistent presumptions, which falls within the remit of the court ruling on the merits in the exercise of its exclusive jurisdiction to appraise the facts.

According to the CJEU, art. 4 of Directive 85/374/EEC must be interpreted as not precluding national evidentiary rules such as those at issue in the main proceedings under which, when a court ruling on the merits of an action involving the liability of the producer of a vaccine due to an alleged defect in that vaccine, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that, 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, certain factual evidence relied on by the applicant constitutes serious, specific and consistent evidence enabling it to conclude that there is a defect in the vaccine and that there is a causal link between that defect and that disease.

However, the Court points out that the establishment in national legislation or by the courts of a Member State of a criterion according to which, once certain pre-determined facts have been established, the existence of the causal link between the defect and the damage will always be considered to be established, would give rise to an unrebuttable presumption, which would be contrary to the Directive. As the Court points out, "such a presumption would have the consequence that, even where the pre-identified facts are not, hypothetically, capable of establishing with certainty the existence of such a causal link, the producer would, in such a case, be deprived of all opportunity to adduce facts or put forward arguments, such as scientific arguments, in order to rebut that presumption, and the court would thus not have any opportunity to assess the facts in the light of that evidence or those arguments. In being so automatic, such a situation would not only undermine the principle set out in Article 4 of Directive 85/374 by which the victim has the burden of proof of the defect and the causal link, but would also risk compromising the very effectiveness of the system of liability introduced by that directive. The presence of one of the three conditions for engaging the liability of the producer under that directive would then be imposed on the court, without it even having the possibility of examining whether the other facts submitted to it for assessment in the case before it might not lead to the opposite conclusion".

It would also be contrary to the Directive to establish a rebuttable presumption - whereby the presence of pre-established elements would make it possible to consider that the causal link between that defect and the occurrence of the damage exists, unless proof to the contrary is provided by the producer of the medicinal product – because it would involve altering the burden of proof laid down in the Directive.

In conclusion, therefore, national courts must ensure that their specific application of those evidentiary rules does not result in the burden of proof introduced by art. 4 being disregarded or the effectiveness of the system of liability introduced by that directive being undermined.

3.3 It follows from all of the foregoing that the person injured by the medicinal product must provide proof of the causal link between the defective product and the damage, without room for any rebuttable or unrebuttable presumption to relieve him of the burden of proof.

In this regard, it is worth mentioning, in our country, the recent Judgment no. 259/2017 of the *Audiencia Nacional* (Judicial Review Division) (Fourth Chamber), of 17 May (ECLI: ES: AN: 2017:2181), which did not uphold a claim filed against the Public Administration and the laboratory for adverse effects of a vaccine. The reason for this determination was that the causal link between the damage and the vaccine was not deemed proven by the claimant to the satisfaction of the court.