THE DIRECTIVE 85/374/EEC ON DEFECTIVE PRODUCTS: ITS INTERPRETATION BY THE EUROPEAN COURT OF JUSTICE

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Abstract

This paper focuses on the interpretation of the European Court of Justice concerning substantive aspects of the Directive 85/374/ECC of July25, 1985, on liability for defective products. Therefore, this work will deal with the interpretation of some aspects regarding the essence of products liability: The concept of defect and the extent of damage covered by this liability. In addition, a number of issues needing of interpretation are analyzed, such as: The meaning of putting a product into circulation, the right to information of the consumer in order to prove the causation of damage, and finally the problems that arise in cases where the producer is exempt from liability.

Keywords: *Liability, product liability, strict liability, producer liability, defective products.*

1. Introduction. Principle of complete harmonization

As it is known, products liability is governed by the Directive 85/374/EEC of July 25, 1985, on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products. In essence, this Directive concerns liability of the producer for the damage caused by defective products. It imposes "strict liability"[1], without fault, on the liable subject, the producer, where a defective product causes injuries to a person or damage to property.

It is settled case-law that Directive 85/374 seeks to achieve, in the matters regulated by it, completed harmonization of the laws, regulations and administrative provisions of the Member States[2]. To this respect, the European Court of Justice (ECJ) has held that reference in Article 13 to the rights which an injured person may rely on under the rules of the law of contractual or non-contractual liability cannot be interpreted as giving the Member States the possibility of maintaining a general system of product liability different from that provided for in the Directive[3]. Differently, it must be interpreted as meaning that the system of producer liability put in place by

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[1] As it noted by the ECJ, that is expressly stated in the second recital in the preamble to the Directive. It is also apparent from the enumeration of the matters to be proved by the injured person in article 4 and from the cases in which the producer's liability is excluded in article 7 (see Case C 402/03 *Skov Æg v Bilka Lavprisvarehus A/S and Bilka Lavprisvarehus A/S v Jette Mikkelsen and Michael Due Nielsen* [2006], paragraph 19).

[2] See Case C 52/00 *Commission v France* [2002], paragraph 24; Case C 154/00 *Commission v Greece* [2002], paragraph 20; Case C 183/00 María *Victoria González Sánchez v Medicina Asturiana SA* [2002], paragraphs 24-29 and *Skov and Bilka*, paragraph 23. Concerning the intention to harmonize completely at Community level article 11 of the Directive, see Case 358/08, *Aventis Pasteur SA v OB* [2009], paragraph 37.

[3] *Commission v France*, paragraph 21, *Commission v Gree*ce, paragraph 17, *González Sánchez*, paragraph 30 and *Skov and Bilka*, paragraph 39.

the Directive does not preclude the application of other systems of contractual or non-contractual liability based on other grounds, such as fault or a warranty in respect of latent defects[4]. Likewise the reference in Article 13 to the rights conferred to an injured person under a "special liability system" existing at the time when the Directive was notified, must be construed as referring to a specific scheme limited to a given sector of production[5].

Nevertheless, as is apparent from the 18th recital in the preamble, it is also settled case-law that it does not seek exhaustively to harmonize the field of liability for defective products beyond those matters[6]. In accordance with this statement, the ECJ has ruled that Directive 85/37 brings about complete harmonization only so far as the producer's liability and damages covered by the Directive, among other aspects, are concerned[7].

2. Interpretation concerning the elements that determine liability product

After the promulgation of the Directive 85/374, the ECJ has ruled on several issues concerning its interpretation. Some of them, in recent days, regarding the scope of the Directive, such as the class of liable person, concept of defect and the damage covered by it.

2.1. Concept of liable person

Article 1 of this Directive imposes the defective product liability on the producer of the product in question, as it has been defined in Article 3. The reasons why it appeared appropriate to hold the producer liable have been summarized by the ECJ. So, it is recalled that the choice of allocating liability to producers in the legal system established by the Directive was made after weighing up the parts played by the various economic operators involved in the production and distribution process. To this respect, it was considered that the fact of imposing liability on the supplier, although would make it simpler for an injured person to bring proceedings, first, there would oblige those subjects to insure such liability, resulting in products significantly more expensive. Second, it would lead to a multiplicity of actions brought by the suppliers, back up the chain as far as the producer. All, while in the great majority of cases, the supplier does not influence the quality of the products it sells[8].

Since this Directive, as it has been said before, seeks a complete harmonization in the matters covered by it, the determination in Article 1 and 3 of the class of persons which can be considered liable must be considered as exhaustive[9]. Therefore, in *Skov and Milka* the ECJ holds that the Directive precludes a national rule which transfer to the supplier the liability imposed

[4] See *Commission v France*, paragraph 22, *Commission v Greece*, paragraph 18, González *Sánchez*, paragraph 31, and *Skov and Bilka*, paragraph 47.

[5] See *González Sánchez*, paragraph 32, and Case C-310/13 *Novo Nordisk Pharma GmbH v. S.* [2014], paragraphs 20 and 21.

[6] See Case C 285/08 *Moteurs Leroy Somer v Société Dalkia France, Société Ace Europe* [2009], paragraphs 24 and 25; Case C 495/10 *Centre hospitalier universitaire de Besançon v Thomas Dutrueux, Caisse primaire d'assurance maladie du Jura* [2011], paragraph 21.

[7] See *Centre hospitalier universitaire de Besançon*, paragraphs 26-30 and *Moteurs Leroy Somer*, paragraphs *30-32*, respectively. In addition, regarding the consumer's right to obtain information on the adverse effects of the defective product, see *Novo Nordisk Pharma GmbH*, paragraphs 24 and 25.

[8] See *Skov and Bilka*, paragraphs 27-29.

[9] See *Skov and Bilka*, paragraph 33 and Case C 127/04, *Declan O'Byrne v Sanofi Pasteur MSD Ltd and Sanofi Pasteur SA* [2006], paragraph 35.

by its regulation on the producer, beyond the cases listed exhaustively in Article 3(3) [10]. Reversely, in the same judgment it is recalled that the Directive allows a national rule under which the supplier is answerable for the fault-based liability of the producer for a defective product, since Article 13 does not preclude the application of other systems of contractual or non-contractual liability based on other grounds, such as fault[11].

Likewise, since the Directive brings about complete harmonization only so far as the producer's liability for defective product is concern, Member States are allowed to establish a system of strict liability for suppliers different from that laid down under the Directive, only on condition that it does not adversely affect the system established by the latest [12].

It follows that the liability regulated by the Directive only may be imposed on the producer, as defined in Article 3 (1): The manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part. And it is only in the cases exhaustively listed in this Article 3 that other persons can be considered as a producer: Any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer (Article 3(1), any person who imports into the Community (Article 3 (2) and, where the producer or the importer cannot be identified, the supplier who does not inform the injured person of the identity of the producer or of the person who supplied him with the product (Article (3)[13].

In the context of determining the liable person under the Directive, the question of the substitution of the defendant when this is not the producer becomes significant. This question involved two separate references to ECJ as to the same case in the main proceedings. To this respect, in *O'Byrne,* the ECJ rules that it is for national law to determine the conditions in accordance with which one party may be substituted for another when an action is brought against a company mistakenly considered to be the producer. However, in light of considerations made above, the national court which examines the conditions governing such a substitution "must ensure that due regards is had to the personal scope of the directive, as established by Article 1 and 3 thereof"[14]. It follows that the subject who substitutes the defendant must be a producer as defined by this Article.

In *Aventis Pasteur,* as to the same case where the victim mistakenly brought an action against a defendant who was not the producer, the ECJ, having regard to the fact that the defendant was the supplier of the defective product, recalls that where the producer cannot be identified, the supplier of the product is treated as the producer, unless he informs the injured person, within a reasonable time, of the identity of the producer or of his own supplier according to Article 3 (3)[15].

As was pointed out by the ECJ, this latest provision should be understood as referring to the situation in which, taking into account the specific circumstances of the case, the victim "could not reasonably have identified the producer of that product before exercising his rights against its supplier". To this respect, it was stated that the mere fact that the supplier of a product

[10] See *Skov and Bilka*, paragraph 37 and 45.
[11] See *Skov and Bilka*, paragraphs 47 and 48.
[12] See *Centre hospitalier universitaire de Besançon,* paragraphs 26-30
[13] See *O'Byrne*, paragraphs 36 and 37.
[14] See *O'Byrne, paragraphs* 34, 38 and 39.
[15] *See Aventis Pasteur*, paragraph 54.

denies being its producer does not suffice for that supplier to be treated as having informed the injured person of the identity of the producer or its own supplier. On the other hand, the condition relating to the supply of such information within "a reasonable time" involves that the supplier informs the injured person, "on its own initiative and promptly, of the facts referred to above. In any case, it is for national court to determine if the supplier fulfills these requirements[16].

2.2. Concept of defect

The definition of defect is given by Article 6 of the Directive, according to which a product is defective "when it does not provide the safety which a person is entitled to expect". With this purpose, all circumstances must be taken into account, including: (a) The presentation of the product (b) its reasonably expected use; and (c) the time when the product was put into circulation.

Recently, the ECJ has ruled on the circumstances under which a product can be considered as defective in Joined Cases *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt and others*[17]. The question referred to the court was, in essence, whether Article 6(1) allows to classify as defective certain products, belonging to the same group or forming part of the same production series and having all of them a potential defect, without any need to establish that the product in question has such a defect. In this judgment, the Court rules on two related cases concerning implanted medical devices, such as a pacemaker and a cardioverter defibrillator. As we will see, the specific nature of the defective products, medical devices implanted in the human body, was relevant for its ruling.

In deciding this question, the ECJ considered the concept of defect by reference to the Directive itself and, therefore, gave guidance on the parameters to consider a product as defective. The Court, making reference to the definition of defective product (Article 6 of the Directive) and to the sixth recital of the preamble, states that the effect of that recital was that the "assessment must be carried out having regard to the reasonable expectations of the public at large". This expectations, according the Court, must be assed taking into account a number of factors, *inter alia*, "the intended purpose, the objective characteristics and properties of the product in question and the specific requirements of the group of users for whom the product is intended".

For products such as those at issue in the main proceedings, implanted medical devices, the ECJ noted that, given its function and the particularly vulnerable situations of patients using them, the safety requirements which those patients were entitled to expect were "particularly high". Moreover, taking into account these factors, the Court understood that in the cases at issue, where it is found that such products belonging to the same group or forming part of the same production series have a potential defect, it is possible to classify all products in that group or production series as defective, without the need to show that any specific product was defective.

As it has been said above, in adopting this decision the Court seems to have taken into account the specific nature of these products, implantable medical devices, and the specific risks arising from them. However, the Court does not limit its

[16] *See Aventis Pasteur*, paragraphs 55-59.

[17] See Joined Cases C-503/13 and C-504/13, *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt and others* [2015].

decision to these particular products. Therefore, the same solution can be applied, under the same circumstances, to products, other than implanted medical devices.

2.3. Recoverable damages

As it is noted by the ECJ, unlike the terms "product", "producer" and "defective product", for which the Directive provides express definitions (Article 2, 3 and 6 respectively), the term "'damage'" is not defined in the Directive. Neither Article 9 nor Article 1 of the Directive, to which Article 9 refers, contains any explicit definition of the term "damage"[18].

Therefore, Article 9 only indicates the various heads of damage covered by the Directive. Under this Article, those damages are limited to:

Damage caused by death or by personal injuries;

Damage to, or destruction of, any property other than the defective product itself, with a lower threshold of €500[19], provided that the property is ordinarily intended for private use or consumption, and was used by the injured person mainly for his or her private use or consumption.

In *Henning Veedfald v Århus Amtskommune*, given the difficulty in specifying the nature of the damage in the case at issue, the national court referred the question whether the Community Law imposes any requirement as to define the expressions '"damage caused by death or by personal injurie" and "'damage to, or destruction of, any item of property other than the defective product itself" provided for in Article 9 of the Directive[20].

The Court held that **it is for Member States to determine the precise** content of those two heads of damage. Nevertheless, full and proper compensation for persons injured by a defective product must be available for both kind of damages referred in the preceding paragraph, since it is settled case law that application of national rules may not impair the effectiveness of the Directive[21]. In essence, that means that it is for Member States to define these two heads of damages, in order to determine if in a particular case a damage is resulting from death or personal injury or damage to property. But a Member State may not restrict the material damages which are recoverable under these two heads of damages in accordance with Article 9 of the Directive[22].

In recent days, the ECJ has provided guidance on the damages which constitutes "damage caused by death of by personal injuries" according to Article 9 of the Directive. The particular question referred to the Court was whether the costs of an operation to remove and replace the defective medical device constitute damage caused by personal injuries covered by this provision, in the specific circumstances of the joined cases *Boston Scientific* above mentioned. The ECJ has adopted a broad interpretation of the concept of this head of damage, stating that it relates "all that is necessary to eliminate harmful consequences and to restore the level of safety which a person is entitled to expect". This interpretation is based both on the objective of protecting consumer health and safety pursued by this Directive in

[18] See Case 203/99, *Henning Veedfald v Århus Amtskommune* [2001], paragraph 25.

[19] According to the principle of full harmonization imposed by the Directive 85/374, Member States cannot decide against the minimum threshold of €500 (see Commission *v France* [2002] and *Commission v Greece* [2002].

[20] See *Henning Veedfald*, paragraph 11. In this case, the damage consisted of the loss of a kidney that had been removed from a donor for transplantation. The kidney was prepared by the hospital through flushing with a perfusion fluid designed for that purpose. This fluid proved to be defective, making the kidney unusable for any transplant.

[21] See *Henning Veedfald*, paragraph 27.

[22] See Henning *Veedfald*, paragraps 28-29.

accordance with the first and sixth recitals of the Preamble, and the causal relationship between the defect and the damage suffered.

It means that costs for replacing defective medical devices only constitute damage caused by personal injuries covered by the Directive as long as the replacement is necessary to restore the safety the injured person is entitled to expect. In other case, the compensation for this head of damage will cover only those costs which are necessary to overcome the defect. In any case, it is for national courts to determine what measure is necessary in a particular case, "bearing in mind the abnormal risk of damage to which it subjects the patients concerned".

Therefore, in the concrete cases at issue, as to the defective pacemaker, the Court finds that the costs for the replacement of such device, including the costs of the surgical operations, constitute damage caused by personal injuries covered by the Directive. But the Court holds that this finding may be different in the case of the defective cardioverter defibrillators, since it was apparent that the magnetic switch of those medical devices should simply be deactivated. In any case, as it was said above, it is for national court to decide this.

Finally, as it has been said above, since the Directive 85/374 does not seek to harmonize products liability beyond the matters regulated by it, the harmonization does not cover compensation for damage excluded from its scope. That is the case, *inter alia*, of compensation for damage to an item of property intended for professional use and employed for that purpose. In *Société Moteurs Leroy Somer v Société Dalkia France and Others*, the national court asks, in essence, if this Directive precludes the interpretation of domestic law according to which the injured person can seek compensation for this type of damage under a system of strict liability corresponding to that established by its regulation[23]. After stating that compensation for this type of damage is not one of the matters regulated by this Directive, and therefore is not covered by its scope, the Court held that nothing in its wording leads to the conclusion that Community Law deprive Member States of the power to provide a system of liability which corresponds to that established by that Directive[24].

3. Other issues needed of interpretation

Beyond those elements which determine the scope of the Directive 85/374, there are other provisions interpreted by the ECJ which complete a general approach in respect of product liability across the EU.

3.1. Limitation in time of the right of compensation

Article 11 of the Directive states that Member States must provide in their legislation that the rights conferred under its regulation shall be extinguished after a period of 10 years from the date on which the producer put into the circulation the defective product. This 10 years period only can be interrupted when the injured person has instituted proceedings against the producer. To this respect, the 10th recital in the preamble to the Directive states that "a uniform period of limitation for the bringing of action for compensation is in the interests

[23] See *Société Moteurs Leroy Somer*, paragraph 14. In the case at issue, a generator installed in a hospital in Lyon caught fire due to the fact that the alternator manufactured and put into circulation by "Moteurs Leroy Somer" overheated. Dalkia France, which was responsible for the maintenance of this installation, and its insurer, paid compensation for the material damage caused to hospital by that accident and then brought an action against Moteurs Leroy Somer, to obtain reimbursement of the payment made by them.

[24] See *Société Moteurs Leroy Somer*, paragraphs 27-31.

both of the injured person and of the producer".

As it is noted by the ECJ, the purpose of this Article is to place a time-limit on the rights conferred by the Directive on the victim and, it is apparent from its Preamble, to satisfy the requirements of legal certainty in the interests of the parties involved. Therefore, as we will see later when examining the putting into the circulation of the product as the starting date of that period, the establishment of the time-limits within which the action for compensation must be brought must satisfy objective criteria[25].

According to the ECJ, this harmonization contributes, first, to the general aim expressed in the preamble of the Directive, consisting of putting an end to the divergences between Member States which entail differences in the degree of protection of consumers. Second, seeks to limit the liability of the producer to a reasonable length of time, taking into account a number of factors, such as, the gradual aging of products, the increasing strictness of safety standards and the constant progressions in the state of science and technology. In addition, bringing up the opinion of the Advocate General, the Court invokes the need not to restrict technical progress and to maintain the possibility of insuring against risks connected with this specific liability, given the burden this liability represents for the producer[26].

In a context in which the action laid down by the Directive must be brought within the 10-year period, the issue related to the substitution of one defendant for another after the expiration of that period becomes relevant. In *Aventis Pasteur* the question referred by the national court was whether the Directive allowed this substitution although the person named as a defendant in the first place did not fall within the scope of the Directive. Bearing in mind the *rationale* for limiting in time the right of compensation, the ECJ hold that Article 11 precludes the application of a rule of national law which allows the substitution of one defendant for another during proceedings in a way which "a producer", as defined by the Directive, is sued after the expiry of the period prescribed by that Article[27].

According to the court, an outcome to the contrary would involve, first, to accept that this period could be interrupted for a reason other than the institution of proceedings against the producer as prescribed by Article 11. And, second, a lengthening of the limitation period with regard to such a producer. The latter would be inconsistent with the harmonization intended by the Directive and with the legal certainty this provision seeks to grant this subject in the context of the liability established by that Directive. To this respect, the Court recalls the importance of the principle of legal certainty in rules that entail financial *consequences*, in order that those concerned may know precisely the extent of their obligations[28].

In addition, the ECJ gave clarifications to guide the referring court in giving judgment in the main proceedings of reference, where the person named as a defendant before the expiration of the 10 years period was a wholly-owned subsidiary of the producer. To this respect, this Court appoints that it is for the national court to assess whether the product was put into circulation by the producer. So, where the national court notes that fact, first, Article 11 does not preclude national court from

[25] See *O'Byrne,* paragraph 26.
[26] See *Aventis Pasteur,* paragraphs 40-43.
[27] See Aventis Pasteur, paragraphs 43-44
[28] See Aventis Pasteur, paragraphs 45-47.

holding that the parent company, "producer" as defined by the Directive, can be substituted for that subsidiary. Second, the supplier of the product can be treated as the producer, in particular for the purposes of Article 11, where the latest cannot be identified, unless he informs the injured person, within a reasonable time, of the identity of the producer of his own supplier in accordance with Article 3(3)[29]. Where the conditions provided for in this provision are met, the supplier should be treated as a "producer" and, therefore, the proceedings instituted against him will interrupted the limitation period laid down in Article 11[30].

3. 2. Meaning of "putting the product into circulation"

The Directive does not define the concept of 'put into circulation', which is referred to in several provisions of the Directive 85/374. Primarily, in Article 7(a) dealing with the circumstances where the producer will be exempt from liability and Article 11, which places a time-limit on the exercise of the rights conferred by this Directive on the injured person. Secondarily, this term is also used in other provisions: In Article 6.1 (c), dealing with the circumstances to assess the safety expectations of the products to be considered defective, and in Article 17, as the reference date for determining the temporal scope of application of the Directive.

As to the concept of "putting into circulation" referred to in Article 7 of the Directive, in *Henning Veedfald* the ECJ hold that the producer may himself exempt from liability because the product has not been put into circulation, primarily, in cases "in which a person other than the producer has caused the product to leave the process of manufacture". In accordance with this approach, the Court considered that this exception also covers the use of a product contrary to the producer's intention (where the manufacturing process is not yet complete) and use for private purposes. In this context, regarding the concept referred in the Article 7, the Court considered that the cases exhaustively listed by this Article, by which the producer may exempt himself from liability, "are to be interpreted strictly" in order to protect the interests of the victims[31].

In the case at issue, the producer of the defective product , a hospital, produces and uses the product in the course of provinding a medical service. Bearing in mind this situation, the Court held that a defective product is put into circulation when "it is used during the provision of a specific medical service" , although the product did not leave the sphere of control of the service provider [32]. This case is different from that on which a service provider, in the course of providing a service, uses defective equipment or product of which it is not the producer. [33] In the latter case, as it is

[29] See Aventis Pasteur, paragraphs 50-54.

[30] See. Aventis Pasteur, paragraph 60. As to the conditions for the application of article 3 (3), see 1.1. Concept of liable persons.

[31] Cf. *Henning Veedfald*, paragraphs 24 and 25.

[32] In this case, as it was mentioned before, a kidney, previously removed from the donor from transplantation was, rendered unsable for any transplant due to that kidney was prepared through "flushing" with a fluid designed by the hospital for this purpose with proved defective. The defendant hospital denied liability on the grounds that the product had not been put into circulation.

[33] See *Centre hospitalier universitaire de Besançon*. In the case at issue in the main proceedings, a patient suffered burns during surgery carried out in public hospital. The burns were caused by a defect in the temperature-control mechanism of a heated mattress on which he had been laid. The defendant claimed that the Directive 85/374 prevented application of the principle deriving from the case-law, whereby a public hospital is liable even without

apparent from ECJ case law, damage to the recipient of the services does not fall within the scope of the Directive 85/374. Therefore this Directive does not prevent a Member State from applying rules which impose strict liability on a service provider, provided that it does not adversely affect the system established by Directive 85/374[34].

The concept of "putting into circulation" referred to in Article 11 was interpreted in *O'Byrne v. Sanofi Pasteur.* In this context, taking into account the purpose and the aim of this Article explained above, the Court held that a product is put into circulation "when it leaves the production process operated by the producer and enters a marketing process in the form in which it is offered to the public in order to be used or consumed". The ECJ considered that, generally, it is not important in that regard that the product is sold directly by the producer to the user or to the consumer or that the sale is carried out as part of a distribution process involving one or more operators, as Article 3 (3) of the Directive makes apparent[35].

It must be noticed that in the case of reference in the main proceeding, one of the links in the distribution chain was closely connected to the producer, since the distributor of the defective product was a wholly-owned subsidiary of the latter[36]. To this respect, the Could considered that it is necessary to determine whether the subsidiary entity was in reality involved in the manufacturing process of the product or it acts simply as a distributor of depository for the product manufactured by the parent company. In any case, it is for the national courts to establish this aspect, having regard to the circumstances of each case and the factual situation of the matter before them[37].

3.3. Exemption of liability

Since the Directive imposes a system of "strict liability" on the producer, this subject cannot avoid that liability by the mere fact of proving he has acted without fault. Nevertheless, in accordance with the principle of a fair apportionment of risk between the injured person and the producer laid down in the seventh recital in the preamble, Article 7 sets out a number of facts exonerating him from liability[38].

The case law of the ECJ has interpreted some of these circumstances, in addition to that which allows the producer to be exempt from liability when he did not put the product into circulation, analyzed before. In particular, this Court has ruled on the exonerating circumstances laid down in Article 7, paragraphs (c) and (e).

Article 7 (c) of the Directive exempts the producer from liability when the producer proves that "the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business". As to the exemption from liability where an activity has no economic or business purpose, the ECJ has ruled that it does not extend to the

fault for damage caused to users as a result of the failure of products or equipment used in connection with their treatment.

[34] See *Centre hospitalier universitaire de Besançon,* paragraphs 27, 30 and 39.

[35] See *O'Byrne v. Sanofi Pasteur,* paragraphs 26 and 27. See also paragraph 32.

[36] In the case of reference, the producer of the defective product, an antihaemophilus vaccine, had sent it to a distributor, which was a wholly-owned subsidiary of the producer. Then, the vaccine was sold by this distributor to the Department of Health of United Kingdom and delivered directly to a hospital nominated by the Department of Health.

[37] See *O'Byrne v. Sanofi Pasteur,* paragraphs 29 and 30.

[38] See Case C 300/95, *Commission of the European Communities v. United Kingdom of Great Britain and Northern Ireland* [1997], paragraph 24.

case of a defective product which has been manufactured and used in the course of a providing a service (in the case of reference, a medical service) which is entirely financed from public funds and for which the user is not required to pay any consideration. To this respect, this Court appoints that this activity "is not a charitable one" which could therefore be covered by the exemption from liability provided for in this provision[39].

On the other hand, Article 7 (e), in connection with Article 15.1 (b), allows Member States to decide whether in its legislation the producer can be exempt from liability when "the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered" (the so called, "development risks"). The ECJ makes several observations as to the wording of this provision. The Court states, first, that this provision does not refer to the practices and safety standards in use in the industrial sector in which the producer is operating, but "at the state of scientific and technical knowledge, including the most advanced level of such knowledge at the time when the product in question was put into circulation". Second, that it does not contemplate the subjective knowledge of a producer but "the objective state of knowledge of which the producer is presumed to have been informed". Finally, it is considered implicit that the relevant knowledge must have been accessible at the time when the product in question was put into circulation[40].

3.4. Proof concerning the causation of damage

As it is known, Article 4 of the Directive places the burden of proof on the victim or injured party as to the damage, the defect, and the causal relationship between these two elements.

Although the Directive does not define the standard of proof and how evidence is gathered, some Member States have imposed on the producer the obligation to provide useful documentation and information related to the defective product to the victim. The question is if the principle of complete harmonization brought by the Directive would prevent Member States from adopting this provision.

According to the ECJ, it should be noted that, as a matter of principle, the consumer's right to obtain information on the adverse effects of a product provided for by national legislation is excluded from the scope of the Directive 85/374 and, therefore, it would not be affected by the principle of complete harmonization of the matters covered by it. But, as it is noted by this Court, in reaching a decision, it would be necessary to ascertain if this provision would be capable of undermining the allocation of the burden of proof as delimited in Article 4. To this regard, the Court holds that it does not bring about a reversal of the proof as delimited by the Directive and does not introduce any change in the circumstances listed in Article 7 under which the producer can be exempt from liability. It follows that the Directive does not preclude national legislation under which the consumer has a right to require the producer to provide him with such an information[41].

In the case at issue, the Court avoids the question referred by the national court for preliminary ruling concerning the interpretation of Article 13 of the Directive, since that question becomes irrelevant once found that the right to information is outside the scope of it.

[39] See *Veedfald*, paragrpahs 21 and 22.
[40] See *Commission v United Kingdom*, paragraphs 25-29.
[41] See *Novo Nordisk Pharma GmbH*, paragraphs 25 -31.

3. Conclusions

Ever since the Directive 85/374 concerning liability for defective products was adopted, the ECJ has been called on to deliver a number of judgments on its interpretation. ECJ case law provides a catalogue of cases on product liability, a number of them in recent days in the field of medicine (pharmaceutical products and medical devices). Certainly, the case law of this Court does not put an end to all the questions arising from the application of the Directive but it decisively contributes to clarifying and elaborating the basic principles of product liability across the European Union.