Compensation for personal injury and medical liability in the light of the recent case law of the EU Court of Justice

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When I was invited, some weeks ago, to give you an update on the European case law concerning personal injury, my first reaction was: "Well, what could I say?" There is no specific EU law and, thus, no specific EU case law on this topic.

I was then invited to focus on the recent European case law concerning medical liability and insurance law.

But medical liability as such is not regulated by EU law. It is a matter for national law, as stated by the European Court of Justice in two judgments concerning defective breast implants (the "PIP" scandal)[2].

Concerning insurance, the situation is different. As you certainly know, a large number of directives coordinated national laws, in particular on prudential supervision of insurance undertakings, with a view to creating a single European market in the field of insurance "sensu lato" (including insurance distribution). Some European judgments, already old, clarified specific aspects of this legislation but this case law is too technical to be presented at 9 o'clock in the morning and certainly too far from your topics of interest.

Legal expenses insurance is also influenced by European rules, one of them – the main one – granting to the insured person the right freely to choose a lawyer. According to settled European case law, this right is very broad and applies even when multiple insured persons suffered loss or damage as a result of the same event[3]. More recently, the Court of Justice decided, in a judgment of 14 May 2020, that this freedom of choice also applies to judicial and extrajudicial mediation proceedings[4].

A detailed European regulation has also been adopted concerning motor liability insurance, giving rise to European case law. This case law was in the meantime codified by the last directive of November 2021, in particular concerning vehicles

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[2] Judgments of 16 February 2017, *Schmitt*, C-219/15, and of 11 June 2020, *TÜV Rheinland*, C-581/18.
[3] Judgment of 10 September 2009, *Eschig*, C-199/08.
[4] Judgment of 14 May 2020, *Orde van Vlaamse Balies and Ordre des barreaux francophones and germanophone*, C-667/18.

usable as a means of transport but also as an industrial means (a tractor, for example).

One of the main trends of the general case law on motor insurance consists of the broad scope of protection for victims of traffic road accidents.

For example, the Court of Justice decided, in the *KBC Verzekeringen* judgment of 12 October 2023[5], that a cyclist using an electric bike, who died in an accident on the way to work, should not be considered as a "driver of a vehicle", but as a vulnerable road user within the meaning of Belgian rules on automatic compensation (no-fault liability).

In another judgment, the *Matmut* judgment of 19 September 2024[6], the Court of Justice also ruled, in a French case, that the passenger of the vehicle involved in an accident that caused personal injury to him cannot be automatically excluded from motor insurance cover on the grounds that this passenger had made a false declaration, when concluding the insurance contract (as policyholder), on the identity of the usual driver of this vehicle.

For the rest, except for specific aspects, insurance *contract* law has not been harmonised to date. That's why, even in cross-border situations, the law governing an insurance contract is always a national law, designated on the basis of the « Rome I » provisions on the law applicable to contractual obligations.

Should I therefore suggest you to open immediately your general meeting?

Certainly not. The absence of specific European legislation on personal injury, medical liability and insurance contract does not mean that European law and case law are irrelevant. EU general regulations have indeed an impact on these areas. And I would like to illustrate this with two regulations: the General Data Protection Regulation (the well-known « GDPR »)[7], on the one hand, and the Product Liability Directive, on the other hand.

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The GDPR is one of the "legal stars" of the last decade. Since May 2018, this regulation aims to protect individuals when their personal data are processed by

[5] Judgment of 12 October 2023, *KBC Verzekeringen*, C-286/22.
[6] Judgment of 19 September 2024, *Matmut*, C-236/23.
[7] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (*OJ L 119, 4.5.2016, pp. 1–88).*

private or public actors. Its scope is very broad, covering data processing in medical and insurance matters.

The GDPR establishes a set of "basic principles" (criteria) and "grounds" governing the lawfulness of all personal data processing.

It also imposes a higher level of protection for certain categories of personal data, the so-called "sensitive data". This means that the processing of such sensitive data is, in principle, forbidden, except in well-defined situations, for example when the data controller obtained prior "explicit, free and informed" consent of the data subject, or when the processing is justified by public interest purposes (linked, for example, to social security, social protection, healthcare management or administration of justice), and provided that the processing strictly complies with confidentiality rules.

Unsurprisingly, "sensitive" data include data relating to health.

Under the 1995 "Privacy" directive[8] which has been replaced by the GDPR, the Court of Justice broadly interpreted the concept of "health data", as covering "all aspects, both physical and psychological, of a person's health". This broad interpretation has been consolidated in the context of the GDPR by the recent *Lindenapotheke* judgment of 4 October 2024[9].

Lindenapotheke is a German pharmacy selling via the well-known online platform "Amazon Marketplace" medicines not subject to medical prescription. A competing pharmacy challenged this distribution practice, claiming that Lindenapotheke processed health data without obtaining, in all circumstances, a valid consent of the persons concerned.

One of the questions referred to the Court of Justice was whether data provided by a user of the online platform (a "customer") to Lindenapotheke should be considered as personal health data even when the online order is placed by the customer for someone else, like a relative (a family member), who may be unidentified since the medicines in question are not subject to a nominal prescription.

[8] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (*OJ L 281, 23.11.1995, pp. 31–50).*

[9] Judgment of 4 October 2024, *Lindenapotheke*, C-21/23.

In a nutshell, the Court of Justice replied "yes": "health data" include "all data capable of revealing by an intellectual operation of matching or deduction", information about an individual's state of health.

In the Court's view, even when the online order is placed by a customer for another person, conclusions could be drawn about this other person's state of health, by deducing his or her identity from other indications concerning, for example, the delivery address of the medicines which is mentioned in the order.

You may wonder why I mention this *Lindenapotheke* judgment concerning commercial practice of a pharmacy. In reality, this judgment is a clear example of the *preventive* approach of the Court of Justice in its interpretations of the GDPR, especially when sensitive data, such as health data, are concerned. As explicitly stated in the judgment, this approach is not based on the absolute certainty of a "privacy" infringement, but on the reasonable probability of such a risk. This judgment must therefore call for caution all professionals dealing with personal health data at a time when the development of artificial intelligence (AI) is enabling an increase in the number of "intellectual operations of matching or deduction".

The GDPR confers a number of rights to the person concerned. One of them is the right to access data held by the data controller.

The Court of Justice recently clarified this right in another German case opposing a dentist to one of her patients. The patient wished to obtain from the dentist a copy of his medical records, *free of charge*, in order to challenge the dentist's medical liability. But the dentist wanted the patient to pay for this copy, as provided for under German law.

In the *FT* judgment of 26 October 2023[10], the Court of Justice stated that the patient has the right, according to the GDPR, to obtain, free of charge, a first copy of his medical records, in view of an action for damages against the practitioner. National rules, such as the German one in this case, may not impose the cost of this first copy on a patient, even to protect the economic interests of practitioners.

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Regulation on liability for defective products is, of course, also relevant to the medical field and the compensation of personal injury. Until recently, this regulation, based on a no-fault liability rule, stemmed, at European level, from a

[10] Judgment of 26 October 2023, *FT (Copy of medical records)*, C-307/22.

directive adopted in July 1985[11], but this directive has been replaced by a new one, adopted in October 2024[12] and to be implemented in national laws by the end of next year.

A presentation of this new directive would be beyond the scope of my speech but this legislation deserves attention, because its adoption was motivated, in particular, by a political will to strengthen protection for victims of defective complex products, such as products linked to new technologies, including AI, which are more and more present in devices and products, in particular in medical ones.

But, so far, the only existing case law refers to the "old" directive of 1985 and I would like to briefly highlight a few European judgments that will, in my view, remain relevant under the new directive.

First of all, the *material* scope of this European legislation focuses on the notion of "products", namely "tangible movable goods resulting from industrial production". This includes defective medical and pharmaceutical products, but not defective services, unless the service defect stems from a defect in the product used to provide the service.

In an Austrian case, the Court of Justice ruled, in the *KRONE-Verlag* judgment of 10 June 2021[13], that a copy of a printed newspaper giving inaccurate health advice on the use of a plant that caused damage to a reader's health, does not constitute a "defective product" within the meaning of the directive, although this health advice was given via a product (a printed newspaper).

Of course, the plaintiff may challenge the liability of the "health adviser" or the newspaper on other grounds, such as fault or negligence. But in this case, and contrary to the no-fault liability regime established by the directive, the plaintiff will have to proof a fault or a negligence.

Concerning the *personal* scope of application of the directive, this regulation primarily focuses on the producer (the manufacturer of the product deemed to be defective).

The directive may also be invoked against any person who presents itself as a producer by putting its name, trademark or other distinctive sign (distinguishing

[11] 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 (*OJ L 210, 7.8.1985, pp. 29–33).*
[12] Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC (*OJ L, 2024/2853, 18.11.2024*).
[13] Judgment of 10 June 2021, *KRONE-Verlag*, C-65/20.

feature) on the product, or by consenting to another manufacturer to do so. The Court of Justice clarified this aspect in one Finnish case concerning a consumer who suffered damage caused by a defective coffee machine produced by Saeco, a Romanian subsidiary of the well-known Dutch Philips company. The coffee machine was branded both Saeco and Philips. But Philips denied any liability, claiming that the defective machine had been produced by Saeco solely.

In the *Fennia* judgment of 7 July 2022[14], the Court of Justice ruled that a legal entity like Philips, accepting their name, trademark or other distinctive sign to be put on the product in question, must be assimilated to a "producer", even if they have not taken part into the manufacturing of the product. In the Court's view, by such a consent (acceptance), Philips gave the impression of being involved in the production process and of assuming liability for it, in return for advantages obtained from their commercial association with the effective producer.

A similar "economic" approach was recently adopted in the *Ford Italia* judgment of 19 December 2024[15]. The case concerned an Italian buyer of a Ford vehicle produced in Germany but supplied (distributed) by Ford Italia in Italy. This car owner had been involved in a road accident in Italy. The airbag had failed to work, resulting in bodily injury. The Court of Justice ruled that, when the supplier's company name (Ford Italia) coincides, at least largely, with the vehicle's mark and the producer's name (Ford), this supplier must be treated in the same way as the producer and, consequently, be held liable for the defective vehicle.

In such a case, the Court of Justice is of the opinion that the supplier takes advantage from the reference to the trademark in question and must therefore be considered to present itself to consumers as responsible for the product's quality.

Some last words on the burden of proof. According to the directive, the plaintiff bears the burden of proving the product default (failure), the alleged damage and the causal link between these two elements. This burden of proof is often heavy for victims because they do not have equal access to information or evidence, compared to the professionals they are suing. This unbalanced situation is better taken into account in the new directive, but the Court of Justice meanwhile sought to address this imbalance by mitigating the burden of proof which lies with the plaintiff. Two judgments illustrate this.

The first case, a German one, concerned financial coverage of surgical replacement of pacemakers produced by an American company. These replacement operations had been recommended after quality control tests revealed

[14] Judgment of 7 June 2022, *Keskinäinen Vakuutusyhtiö Fennia*, C-264/21.
[15] Judgment of 19 December 2024, *Ford Italia*, C-157/23.

a risk of failure for devices of this kind. In the *Boston Scientific Medizintechnik* judgment of 5 March 2015[16], the Court of Justice ruled that, when a defect has been found in devices belonging to a given category or production series, it may be presumed that devices belonging to the same category or series are potentially affected by the same defect, without it being necessary for each plaintiff to establish concretely that "his" or "her" pacemaker is also defective.

A second and last judgment, the *W* judgment of 21 June 2017[17], also deserves to be mentioned.

This French case arose from the injection of a hepatitis B vaccine produced by Sanofi Pasteur to a French citizen (Mr W). A few months later, W was diagnosed with multiple sclerosis. Some years later, he died of this disease.

W, and subsequently his heirs, brought an action for damages against Sanofi Pasteur, relying on the case law of the French Cour de cassation, according to which proof of a vaccine defect and its causal link to the victim's damage may be based on "serious, precise and concordant presumptions", and not necessarily on absolute scientific certainties. In this case, W and his heirs alleged that the coincidence in time between the vaccination and the onset of multiple sclerosis, as well as W's lack of personal or family history of the disease, were such as to give rise to presumptions of a vaccine defect and a causal link between the injection of the vaccine and the onset of the disease.

The Court of Justice was asked by the French Cour de cassation to rule on the compliance of this French case law with the directive.

The Court of Justice pointed out that, while the directive places the burden of proof on the victim, however it does not govern the procedures for the administration and judicial assessment of such proof. These procedures are therefore a matter for national law, provided that they do not undermine the rule on burden of proof laid down in the directive.

In this case, the Court of Justice admitted that the French case law facilitates the victim's task in challenging the producer's liability. However, in the Court's view, this case law does not go so far as to reverse the victim's burden of proof, since the victim is still required to provide a body of elements capable of convincing the judge.

The Court of Justice added that, moreover, the producer's rights of defence must be taken into account by giving this producer the opportunity to present its own

[16] Judgment of 5 March 2015, *Boston Scientific Medizintechnik*, C-503/13.
[17] Judgment of 21 June 2017, *W e.a.*, C-621/15.

elements and defending arguments to cast doubt on the degree of plausibility of the elements and explanations put forward by the plaintiff.

I thank you very much for your attention and I wish you a pleasant conference and stay in Brussels.