Court of Justice of the European Union
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Press and Information

Advocate General's Opinion in Case C-219/15
Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH

Advocate General Sharpston considers that bodies monitoring the quality system of manufacturers of medical devices may be liable to patients for failure to fulfil their duties arising from EU product safety rules

If such a body is put on notice that a medical device may be defective, it is under a duty to take all necessary measures to determine whether its certification of that device may stand

In December 2008, Ms Elisabeth Schmitt had silicone breast implants, made by the French company Poly Implant Prothèse, fitted in Germany (18). In 2010, the French authorities found that the company had been using low-grade industrial silicone to manufacture those implants (20). As a result, and following medical advice, Ms Schmitt had her implants removed in 2012 (20).

Ms Schmitt subsequently brought an action before the German courts seeking to obtain € 40 000 by way of compensation for non-material damage and a declaration opening the way to further compensation for any material damage that she may suffer in the future because of the defective implants (20). Since the manufacturer had become insolvent, Ms Schmitt brought the action against TÜV Rheinland LGA Products GmbH, a German company responsible for auditing the manufacturer's quality system in its capacity as 'notified body' for the products in question under the Medical Devices Directive[1]. (18-20).

Hearing the case on appeal, the Bundesgerichtshof (Federal Court of Justice, Germany) has asked the Court of Justice questions regarding the nature of the duties incumbent on notified bodies as well as the scope of their liability towards patients if they fail to perform these duties adequately (22).

In her Opinion delivered today, Advocate General Sharpston notes that, although the Directive imposes primary liability for the product's compliance on the manufacturer, it does not prevent this liability from being extended to other actors (33-34). She points out that the Court has already recognised [2] that national legislation may impose liability on importers for specific obligations arising from EU product safety rules (37-38).

In this regard, she observes that if a Member State may impose such liability on importers, who occupy a relatively minor role in ensuring product safety, it must also be entitled to do so as regards notified bodies which have a crucial role in this area (38-39). In these circumstances, the Advocate General takes the view that **such bodies may be liable to patients and users for a culpable failure to fulfil their obligations resulting from EU product safety rules** provided that the principles of equivalence[3] and effectiveness[4] are respected (39).

As for the nature of duties incumbent on notified bodies, Advocate General Sharpston considers that, in the normal course, a manufacturer can be assumed to be operating in accordance with its approved quality system and that a notified body may also proceed upon that assumption (51).

[1] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1).
[2] Case C-40/04 *Yonemoto*.
[3] The principle of equivalence requires that a national procedural rule be applied without distinction, whether the infringement alleged is of EU law or national law, where the purpose and cause of action are similar.
[4] The principle of effectiveness requires that a national procedural rule does not render the application of EU law impossible or excessively difficult.

Such a body is therefore under no general obligation to inspect devices, examine the manufacturer's business records or carry out unannounced inspections (51).

However, **if a notified body is put on notice that a medical device may be defective, it is under a duty to exercise the powers available to it under the directive in order to determine whether its certification of that device may stand (54 & 59).** In this context, having regard to its scientific expertise, it is up to the body in question to choose the way in which it intends to act and the precise steps it wishes to take provided that it exercises due care and diligence at all times (57).

Finally, having regard to the risk of serious economic repercussions of her proposed solution, the Advocate General suggests that the Court limit the temporal effect of its ruling (60).

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 European Union law or the validity of a European Union 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.

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