COMMENTARY

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French Supreme Court Clarifies Surveillance Obligations of Notified Bodies

IN SHORT

The Situation: In a recent decision, the French Supreme Court clarified the surveillance obligations of notified bodies—independent entities accredited by an EU Member State's national health authority to determine whether a product to be placed on the market meets certain standards—regarding medical device manufacturers.

The Outcome: The Court ruled that, in the face of evidence indicating a potential noncompliance of the manufacturer, the notified body was required to take specific measures to fulfill its role.

Looking Ahead: Notified bodies should be aware of the requirements laid down by the French Supreme Court, which add to the new requirements under the Medical Device Regulation.

The French *Cour de cassation* (Supreme Civil Court) recently issued a series of rulings regarding the responsibility of a notified body. The cases concerned the surveillance obligations of a notified body regarding the manufacturer of PIP breast implants.

After the Court of Appeals of Aix en Provence ruled in favor of the notified body, TÜV, and its subsidiary TRLP, the *Cour de cassation* overturned the appellate decision and judged that the notified body was under a surveillance obligation. In the face of evidence indicating that the medical device may not comply with the requirements laid down in Directive 93/42 of June 14, 1993, concerning medical devices, the notified body should inspect the medical devices, inspect the manufacturer's records on the supply of raw material, and carry out unannounced inspections.

> In the face of evidence indicating that a medical device might not be compliant, the notified body must take all steps necessary to fulfill its due diligence obligation.

Surveillance Duty of Notified Bodies

Under European medical device regulations, medical devices require a conformity assessment procedure, which, depending on classification of the device, may require the involvement of a notified body. Upon request of the manufacturer, the notified body carries out an audit to assess the manufacturer's quality system. In addition, for class III medical devices such as breast implants, the notified body examines the design of the product. If the notified body is satisfied that the manufacturer and product comply with the relevant requirements, it issues a CE certificate.

Annex II of Directive 93/42 provides for surveillance, which must be undertaken by notified bodies to ensure that the manufacturer fulfils the obligations imposed by the approved quality system. In particular, notified bodies must be supplied with all necessary information by the manufacturer and authorized to carry out inspection, including unannounced ones.

The European Court of Justice's preliminary ruling in Case C-219/15 (*Schmitt v. TUV Rheinland*)

concluded that Directive 93/42 does not impose a general obligation on the notified body to carry out unannounced inspections, examine devices, and/or examine the manufacturer's business records. However, in the face of evidence indicating that a medical device might not be compliant, the notified body must take all steps necessary to fulfill its due diligence obligation.

Following the ECJ *Schmitt* decision, the *Cour de cassation* ruled that since the notified body's subcontractor, TRLP, had stated that it had checked PIP's raw material records as part of its surveillance mission, TÜV/TRLP should have carried out additional investigations to comply with its obligations as a notified body under Directive 93/42. Such investigations may have led the notified body to establish that the quantities of Nusil brand silicone gel acquired by the manufacturer were clearly disconnected with the number of breast implants effectively sold.

Extracontractual Liability

Consequently, the *Cour de cassation* held that the court of appeals' decision—which ruled that the notified bodies could not be found responsible—lacked legal basis. The *Cour de cassation* considered that the lack of review of PIP's raw material records was faulty (or implicitly that the audit was insufficient, since TÜV/TRLP failed to review documentation that they had identified). Such negligence amounted to a violation of Article 1240 (former article 1382) of the French Civil code, which applies to extracontractual liability and provides that "Any act whatever of man, which causes damage to another, obliges the one by whose fault it occurred to compensate it."

While the decision of the *Cour de cassation* is final on the law, the case was remanded to another appellate court for a new review of the facts, taking into account the *Cour de cassation*'s finding of law.

Therefore, this decision creates a serious risk that a notified body could be held liable for damages sustained by distributors and patients. This in turn would have a significant impact on the business model of notified bodies. Given that the medical device industry is facing a major bottleneck in retaining notified bodies for review of their conformity assessment, this will put additional strain on an already stretched system.

Criminal Liability of a Manufacturer's Managers and Employees

Judicial decisions were also issued on the criminal side: two managers and two employees of the manufacturing company were found criminally liable on various counts of fraud toward the notified body. Ultimately, they were ordered to pay damages to the victims in compensation for their material and physical losses, including emotional distress (*préjudice d'anxiété*) (Cass. Crim., 11 sept. 2018, n° 16-84.059).

THREE KEY TAKEAWAYS

1. The French *Cour de cassation* concurs with the European Court of Justice in placing notified bodies under "surveillance obligations" that require extra care and additional measures in the face of evidence of potential noncompliance.
2. The notified body's liability was triggered when it stated that it audited the clients' raw material records but failed to identify a significant discrepancy.
3. The French *Cour de cassation*'s decision may have additional impact on the difficulties that notified bodies and the medical device industry as a whole are currently experiencing.


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