TÜV Rheinland's legal woes over PIP will strengthen NBs sector
16 July 2015
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Now that TÜV Rheinland, the notified body of the French company found to have fraudulently manufactured and sold breast implants with inferior grade silicon content, has been cleared of any wrongdoing in the French appeal courts, what are the knock-on effects for device companies and NBs?

To recap, on 2 July the Aix-en-Provence Court of Appeal reversed a judgment handed down by the Toulon Commercial Court on 14 November 2013 against TÜV Rheinland in connection with Poly Implant Prothèse's breast implants. In doing so, the court dismissed the claims brought by foreign distributors of PIP implants as well as over 3,000 persons who had joined the case.

In a statement for *Clinica*, TÜV Rheinland said it has, at all times, fulfilled its duties as an NB responsibly and in compliance with all applicable laws and regulations. The court's 2 July verdict was in line with a "long series of positions taken in favor of TÜV Rheinland by courts and authorities to date." In ongoing disputes, the NB says it is confident that the courts will continue to deal with these disputes and will come to the same conclusion.

TÜV Rheinland has suffered as a result of PIP's fraudulent activities (as have the women concerned), and its relief at being cleared in courts is shared by the wider EU notified bodies sector. Director of TEAM-NB (the European Association of Notified Bodies for Medical Devices) Françoise Schlemmer told *Clinica*: "It's a good step in the right direction, in that it helps to define the role of each of the stakeholders."

She continued: "Manufacturers are responsible for their products, and we [NBs] are responsible for assessments." In the current medical device directives, NBs are not instructed to focus on detecting intentional fraud, which can be (and was in the PIP case) concealed from the NB, she said. And a 2-3 day-per-year audit can hardly be expected to detect such illicit activities.

That is also the point of TÜV Rheinland, which reiterates: "The NB's role in the manufacturer's conformity assessment is not designed to protect against intentional fraud. By way of its complex and large-scale fraud, PIP deceived all parties involved – most importantly the patients, but also the health authorities and TÜV Rheinland. The fraud committed by PIP was not noticeable by TÜV Rheinland and could not be detected with the means the law provides to an NB."

The TEAM-NB director agrees, saying: "We must keep these things separate – ie 'who is liable for what'." By extension, seeking to make NBs liable for such matters as intentional fraud committed by a client would necessitate liability insurance at levels that would threaten the survival of the NBs themselves – a far-fetched and counterproductive idea in every conceivable aspect.

As the EU Council resumes its own deliberations on the proposed EU Medical Devices Regulation (MDR) in September, and later brings the European Parliament back to the debating table, those deciding the future role of NBs may do well to reflect on and factor in

TÜV Rheinland's recent experiences in its court disputes. The key details from the Aix-en-Provence judgement, as communicated to *Clinica* by the NB itself, include:

* TÜV Rheinland's mission did not consist, at the time of certification, in verifying on products whether the manufacturer indeed used the materials declared, or in carrying out tests, but only in making sure of quality management and design of the product on the basis of documents and assurances submitted by PIP;

* TÜV Rheinland complied with the provisions of the EU directives in the scope of certification;

* under Annex II to the Directive 93/42/EEC, NB's are not obliged to take samples of the products or carry out tests [in this case, on marketed prostheses];

* in light of the stratagem of PIP's managers, it was not at all possible for TÜV Rheinland, which was not entitled to carry out a search, to discover the replacement of the [correct brand] Nusil gel with the [inferior grade] PIP gel, regardless of the investigations it may have made, notably because of falsified accounts, the use of Nusil gel during the audits , the "cleaning up" in plants of any material related to the manufacture of the PIP gel, the concealment of the barrels containing products forbidden for medical use and the strict instructions given to the staff; and

* through periodical audits compliant with the Directive, TÜV Rheinland indeed used the appropriate means to comply with its obligations and it cannot be blamed for any fault or negligence in the scope of the mission that had been entrusted to it.

The timing of the recent court case and its findings are significant given the soon-to-resume MDR deliberations at EU trialog level. They come not without irony, given that the PIP affair's initial revelations poured much fuel on the fire that back in 2012 was already being lit under the EU medical device regulatory system by those claiming it was not fit for purpose.

Summer is yet upon us, but for some in the sector, autumn surely can't come too soon.

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