The PIP scandal – a never-ending story!

by Miriam Schuh

New proceedings against TÜV Rhineland – impacts on notified bodies of medical device manufacturers?

Retrospective court work on the scandal involving the faulty production of breast implants by the French manufacturer Poly Implant Prothèse (PIP for short), which filled more than 75% of its products with an industrial-grade gel that had not been licensed, is still ongoing. TÜV Rhineland, the notified body responsible for PIP at the time, is now after all threatened with being sentenced to pay compensation to damaged patients. The Paris Court of Cassation, as the supreme French court, has reversed a judgement made in the year 2015, in which liability on the part of the TÜV Rhineland was dismissed. Claims for compensation against TÜV Rhineland amounting to almost six million euros were thus rejected. Now, the question of liability is to be the subject of new proceedings before the court of appeal in Paris.

The ECJ too has meanwhile occupied itself with the question of the responsibility for liability of notified bodies. In a judgement of 16 February 2017, referring to the European directives for medical devices, IVD and active implants which are relevant until the new European regulations MDR / IVDR come into force, the ECJ argued that notified bodies such as TÜV Rhineland were not under a general obligation to subject medical devices to unannounced audits, or to test them themselves or inspect the business records of the manufacturers. It was rather the case that obligations of that kind did not arise until there were actual indications of defectiveness.

On the basis of this standard of review – which is to be applied in the opinion of the ECJ – the chance of obtaining compensation out of a liability claim against the certification bodies is dwindling fast. When all is said and done, it is not until there is evidence of plain ignorance regarding information indicating defective products or misconduct on the part of the manufacturer that notified bodies can be forced to accept liability of their own.

Whether or not there were any indications of this kind and whether or not they were overlooked are likely to be two of the issues to be considered in further proceedings against TÜV Rhineland. When the supreme court of France has made its judgement, the next round of those proceedings will begin.

Conclusion

The consequences of the PIP scandal, which was uncovered as long ago as 2012, thus continue to keep the industry in suspense. TÜV Rhineland, as the notified body responsible, must prepare itself for further juridical altercations. In general – also on the basis of the ECJ ruling of 16 February 2017 – notified bodies will in their own interests be well advised to exercise more care when supervising conformity assessment procedures. For a long time, moreover, the manufacturers of medical devices will continue to feel the effects of the scandal which is considered in the industry as one of the main reasons why the previously applicable directives have had to make way for the new regulations MDR and IVDR. MDR / IVDR compliance should be ensured as soon as possible. The transitional periods until they come into force are short. The MDR, for example, is due to come into force as soon as 25 May 2020.