ECJ decision could increase medical products claims

A recent ruling by the European Court of Justice (ECJ) on the Product Liability Directive could result in a rise in the number, and severity of, claims relating to defective products.

The ruling means that courts may be able to take a broad interpretation of what constitutes a defective product when considering claims for implantable medical devices.

An injured party need not demonstrate that a potential defect exists in their individual device where it can be shown that defect exists in a product of the same group or product series. The ECJ also ruled that damages should include the costs of replacement of the device if such an operation is necessary to overcome the defect.

This clarification by the ECJ removes obstacles to proving a product is defective. This has previously frustrated potential claimants from bringing an action under the Consumer Protection Act (CPA). There could be an upswing in the number of claims from patients of similar devices, as in the past the onus was on the claimant to provide the proof that a product was defective, which could be costly and time-consuming.

It is important to note that the Product Liability Directive and the CPA make the producer strictly liable. A producer is not just the manufacturer of the finished product but any component or person putting their name to it. The definition of producer also includes any importer bringing products in to the European Economic Area (EEA).

Medical device producer found liable

The company manufactured and sold pace makers and implantable cardioverter defibrillators.

They identified a defect in the pacemaker that could lead to premature battery depletion and a defect in the defibrillator that could affect its efficacy, both defects had potentially fatal consequences to their recipient.

In response the company made available replacement pacemakers free of charge and recommended deactivating the defibrillators magnetic switch.

The insurers of affected patients were claiming reimbursement of the costs from the producer relating to the surgical procedure of removing the implanted devices under the Product Liability Directive. These claims are regardless of the individual device not being shown to be defective.

The court ruled that when a medical device has a potential defect it is possible to classify all products of the same model as defective and there would be no need to show that each individual product is defective.

It also ruled that the costs relating to replacement necessary to overcome a defect constituted damage for which the producer is liable.

As a result, this ruling means that organisations dealing with these types of devices need to check to see if they could indeed be liable, and ensure that they have the correct insurance cover in place to protect them.

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