LIABILITY FOR DEFECTIVE MEDICAL DEVICES

A note on the liability for defective medical devices in the UK, including as derived from EU law. The types of liability discussed are statutory liability under product liability laws, liability in tort (negligence), liability in contract and breach of product safety regulation.

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SCOPE OF THIS NOTE

This practice note discusses the liability for defective medical devices in the UK, including as derived from EU law. The types of liability that are discussed are:

- Statutory liability under product liability laws.
- Liability in tort (negligence).
- Liability in contract.
- Breach of product safety regulation.

This note only briefly discusses the general principles of product liability law as it relates to medical devices. Other useful resources include Practice notes:

- *Product liability and safety: overview*, in which product liability law in general is discussed more substantively
- *Product safety crisis management: when product safety concerns arise* which considers what to do when a product safety issue arises, including carrying out corrective actions, such as product recalls.
- *How should a product liability claim be handled?* which provides information on how to conduct a product liability claim.
- *How can an in-house lawyer help to mitigate product safety issues and product liability claims?*, which covers strategies that can be used by an in-house lawyer in an attempt to try and minimise the likelihood of product liability claims arising.
- *Product liability and safety in the EU: overview.*
- *Product liability and safety in the UK (England and Wales): overview.*

SOURCES OF LIABILITY FOR DEFECTIVE MEDICAL DEVICES IN THE UK

In the UK the following sources of law create liability for defective medical devices:

- EU Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products (Product Liability Directive), which establishes a product liability regime in the EU. This is implemented into UK law by the Consumer Protection Act 1987 (CPA). (see *Statutory Liability under the CPA*).
- The tort of negligence (see *Negligence claims in relation to defective devices*).
- Contract law, which can include reference to the Sale of Goods Act 1979 (SGA) or the Consumer Rights Act 2015 (CRA), depending on the type of the contract at issue and its timing (see *Contract claims in relation to defective devices*).

In most instances, product liability offences create civil liability. However, criminal offence provisions exist for breach of product safety laws.

Criminal offence provisions are increasingly being relied on by UK regulators in a climate where enforcement of product safety and product liability laws is being more carefully scrutinised at an EU-wide level.

INTERACTION BETWEEN THE LIABILITY REGIMES FOR DEFECTIVE MEDICAL DEVICES IN THE UK

The separate mechanisms of liability all work together in the UK.

The strict liability regime under the CPA supplements the general law of tort and contractual claims. Pleadings in tort will be governed by the applicable principles of the common law which overlap with those that arise under the CPA. Actions brought in contract may be supplemented by relevant statute, as noted above.

In practice, it is common for claimants to bring actions under a combination of the above three mechanisms. These parallel actions are often used by claimants to seek to avoid statutory compensation caps or other restrictions associated with certain causes of action.

Interaction of liability regimes with regulatory regime

Any of the abovementioned liability claims in respect of medical devices will almost certainly, at least indirectly, call into question the regulatory compliance of the device subject to litigation. Furthermore, liability arises directly from failure to adhere to regulatory regimes, in respect of criminal offences.

The touchpoints between the liability and regulatory regimes are complex, but can include some of the following areas:

- Compliance with the regulatory regime, while not a complete statutory defence, can be useful in defence of a product liability claim under any of the abovementioned mechanisms (see *Defences under the CPA*).
- Breach of regulatory regimes can in and of itself give rise to criminal liability (see *Criminal liability for failure to comply with regulatory regime*).

MAJOR LEGISLATIVE REFORM

The EU's medical devices regulatory regime underwent significant reform in May 2017. For further discussion, see *New EU regulatory regime for medical devices*.

Statutory liability under the CPA

Strict liability offences

The CPA creates strict liability civil offences for defective products. Section 2(1) of the CPA states that producers, a person putting their name or trade mark on a product and the EU importer "shall be liable for the damage", "where any damage is caused wholly or partly by a defect in a product".

In *Centre hospitalier universitaire de Besançon v Thomas Dutrueux, Caisse primaire d'assurance maladie du Jura (Case 495/10)*, the European Court of Justice (ECJ) as the final interpreter of EU law (from which the UK law is derived) held that the Product Liability Directive does not affect any rights that a party injured by a medical device may have under a special system of liability existing under a national law.

Criminal offences

Producers, suppliers and importers of medical devices, including individuals and body corporates, may also be subject to criminal sanction under criminal offence provisions under the CPA in the UK.

It is an offence for a person to fail to comply with the requirements of the safety regulations made under the CPA (*section 12, CPA*). Those safety regulations include the *Medical Devices Regulations 2002 (SI 2002/618)* (as amended) (MDR UK), which constitute the UK's implementation of the EU-wide regime for medical devices:

- Directive 93/42/EEC concerning medical devices (MDD).
- Directive 90/385/EEC on active implantable medical devices (AIMDD).
- Directive 98/79/EC on in vitro diagnostic medical devices (IVDMD).

A person guilty of this offence is liable to imprisonment for up to six months or an unlimited fine (*section 12(5), CPA*).

The impact of Brexit to this regime remains to be seen.

SCOPE OF THE CPA

What are medical devices?

The CPA defines products which can be subject to a product liability claim broadly, as "any goods or electricity" which "includes a product which is comprised in another product, whether by virtue of being a component part or raw material or otherwise".

This definition encompasses medical devices. which are defined (under the MDR UK) as:

> "any instrument, apparatus, appliance, software, material or other article used alone or combined for humans to: diagnose, prevent, monitor, treat or alleviate disease; diagnose, monitor, treat, alleviate or compensate for an injury or handicap; or investigate, replace or modify the anatomy or a physiological process; or control conception."

Under this definition "medical device" goes significantly beyond the general meaning of that term and covers the most basic types of medical equipment such as wheelchairs or walking aids as well as the most sophisticated medical instruments and machinery. It also expressly includes software in some instances as shown by the decision of the ECJ in *Snitem and Philips France (Case 329/16)*, which held that prescription support software which enabled doctors to obtain relevant information relating to a patient (contraindications, drug interactions and dosage limits) constituted a medical device for the purposes of the MDD.

PARTIES TO CLAIMS FOR DEFECTIVE MEDICAL DEVICES UNDER THE CPA

Potential claimants

Patients

Under section 5(1) of the CPA, "any person who suffers death, personal injury or any loss to property as a consequence a defect in a product may seek compensation for that damage".

Theoretically, any individual patient or other person injured by a defective device may therefore commence a proceeding under the CPA.

In practice, multiple claimants frequently bring joint actions in relation to a single device, or even in respect of a sub-type of a device. Consequently, the European Commission in 2013 issued a non-binding recommendation for all member states to adopt a collective class action procedure. However, the UK chose to maintain the existing system of group litigation orders provided by the Civil Procedure Rules (see *Practice Note, Class/collective actions in the UK (England and Wales): overview*). This mechanism is frequently used in medical device litigation in the UK.

Insurers

The rights of the above claimants often devolve to insurers under health insurance policies which indemnify affected individuals for medical costs caused by the defective device.

The ECJ case of *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt: Die Gesundheitskasse and Betriebskrankenkasse) (Cases C503/13 and C504/13)* (Boston Scientific) confirmed this practice. In that case a health insurer was allowed to pursue a claim against a manufacturer of defective pacemakers and defibrillators for the costs to replace those defective devices (see *Proving the existence of a defect in a medical device and Damages under the CPA*).

Potential defendants

Producers, suppliers or importers

Section 2(2) of the CPA imposes liability for a defective product on a large class of potential defendants, including:

- The "producer" of the device, which includes "the person who manufactured it" or "the person who won or abstracted it" or "the person who carried out [the relevant industrial process]".

- "Any person who, by putting his name on the product or using a trade mark or other distinguishing mark in relation to the product, has held himself out to be the producer of the product", which is commonly referred to as the "deemed manufacturer".
- "Any person who has imported the product into a member State from a place outside the member States in order, in the course of any business of his, to supply it to another".
- "Any person who supplied the product".

Ordinarily, claimants will pursue the manufacturer of the device as a priority. In a situation where the producer has not, or cannot, be identified or, is otherwise unable to be pursued (such as in the case of an overseas entity), claimants often pursue the importer second to the deemed manufacturer. Where none of these defendants are available to be pursued, claimants can rely on section 2(3) of the CPA to pursue the supplier of the product.

Under section 8(1) of the Product Liability Directive, the imposition of any form of liability on any other party does not absolve producers, suppliers and importers of their strict liability. This is reflected in section 2(5) and 2(6) of the CPA, which establishes that liability under its provisions is joint and several.

Based on the above it is possible for claimants to maintain proceedings against those entities in addition to claims in a separate proceeding against, for instance, a notified body or a health professional (as below).

Notified bodies

The medical devices regulatory regime requires that member states designate "notified bodies" to provide product safety certification (CE mark) for medical devices under each regime. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is the competent authority that designates notified bodies.

In the UK there are presently four approved notified bodies. Brexit threatens to jeopardise the position of the current UK notified bodies to certify products for the EU. At the time of publishing, it is likely that immediately post-Brexit UK notified bodies will be unable to certify products for the EU market, but will be able to validly certify products for the UK market (under UK's new UKCA mark).

Such notified bodies generally cannot be subject to claims brought under the CPA and courts in the UK have been slow to hold regulatory authorities negligent for failure to carry out their obligations (see *X v Bedfordshire CC [1995] 2 AC 633*).

However, the ECJ case of *Schmitt v TÜV Rheinland LGA Products GmbH Case (Case-219/15)*. confirms the potential for liability of notified bodies for defective medical devices under common law. In that case, the German claimant contended that the notified body, TUV Rheinland, had failed to take necessary steps to discover the fraudulent use of sub-standard silicone in breast implants. More particularly, it was claimed that the surveillance methods it had employed, which were restricted to yearly announced inspections, were inadequate, and that more comprehensive and unannounced inspections would have enabled TUV Rheinland to uncover the fraud.

Following a referral from the German Federal Court of Justice, the ECJ declined to set out the precise obligations that had been imposed on TUV Rheinland in the circumstances but did hold that notified bodies were under an "obligation to act with all due diligence." It also ruled that they could be held liable under the laws of member states for failing to comply with that obligation. On remittal, the German Supreme Court ultimately held that TUV Rheinland had not contravened its obligations. However, in the latest iteration of this litigation in France, the Cour de Cassation confirmed the possibility of such liability (see *Mrs X and others v Company TÜV Rheinland LGA Products GmbH and others Judgment No. 610 of 10 October 2018 (15-26.093)*).

The new EU medical devices regime more expressly specifies the obligations of notified bodies vis-à-vis medical devices and substantively increases their level of accountability for injuries caused by such devices. Under the new regime, as with the old, notified bodies must have appropriate liability insurance for their conformity assessment activities, unless liability is assumed by the member state or the member state is directly responsible for the conformity assessment (see *New EU regulatory regime for medical devices*).

Doctors, hospitals and healthcare institutions

The CPA does not provide for liability of a doctor or health care professional who simply recommends use of a defective product, or for any vicarious liability on the part of the hospital or healthcare institution at which those professionals worked. This is confirmed by the defence in section 4(1)(b) of the CPA, which states that there will be "no liability where the person proceeded against did not at any time supply the product to another".

Liability may be imposed, however, where the healthcare professional or institution actually supplies the device in the course of providing treatment under section 2(3) of the CPA if the other potential defendants cannot be identified or pursued.

Additionally, healthcare professionals are under a duty to be aware that a medical device being recommended for treatment may be defective, as a corollary of the doctor's duty of disclosure, and could be found liable in negligence for their failure to do so (see *Montgomery v Lanarkshire Health Board [2015] SC 11 [2015] 1 AC 1430; Webster (A Child) v Burton Hospitals NHS Foundation Trust [2017] EWCA Civ 62* and *Practice note, Claims in negligence: an overview*).

Directors and executive officers

The PIP silicone breast implant litigation in Europe demonstrates the possibility of holding individuals (in that case the founder of the manufacturer and its executive officers) criminally liable for damage caused by defective medical products. French criminal law takes a comparatively interventionist approach to misconduct in healthcare, but the case does provide a precedent for such liability elsewhere. It would appear, however, that such liability requires proof of fraudulent or reckless conduct rather than (even gross) negligence. For further discussion of directors' civil and criminal liability, see *Practice notes, Overview of directors' health and safety responsibilities* and *Directors' liability: relief from liability*.

More conventionally, directors or other officers may be liable for failure to comply with regulatory requirements (see *Regulatory enforcement action*).

GENERAL PRINCIPLES ON "DEFECT" UNDER THE CPA

Meaning of defect

Section 3(1) of the CPA states that there is a defect in a product "if the safety of the product is not such as persons generally are entitled to expect". It states "safety" will include "risks of damage to property, as well as...risks of death or personal injury".

For the purposes of determining the content of that expectation, section 3(2) provides that the following must be taken into account:

- "The manner in which, and purposes for which, the product has been marketed, its get-up, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product.
- "What might reasonably be expected to be done with or in relation to the product".
- "The time when the product was supplied by its producer to another".

The CPA expressly includes a defect being inferred from the fact that "the safety of the product supplied after that time is greater than the safety of the product in question". However, in *Gee and others v DePuy International Ltd [2018] EWHC 1208 (QB))* (DePuy Pinnacle Metal on Metal Hip Litigation), Andrews J stated that, in determining whether that level of safety was achieved, a court is entitled to have regard to everything subsequently known about the device (at paragraph 84). That is irrespective of whether that information was available at the time it was put on the market or only came to light subsequently. Andrews J justified that approach on the basis that a claimant would otherwise never be able to establish that a product, the lack of safety of which only comes to light years after it was first marketed, was defective at the time of its initial circulation.

This approach to the law has particular relevance to products like medical devices which, by their very nature, may only reveal a defect after their marketing and subsequent widespread use. The approach also closely circumscribes the role of the so-called "developmental risks" defence provided for by section 4(1)(e) of the CPA (see *Defences under the CPA*).

When the defect came into existence

The existence of a defect is to be determined at the time that the product first goes into circulation, subject to the above exclusion of an inference of defect as in the *DePuy Pinnacle Metal on Metal Hip Litigation*.

Evidence of harm does not itself establish the existence of a defect

The English courts have set a precedent that the presence of harm in and of itself does not prove the existence of a defect.

The *DePuy Pinnacle Metal on Metal Hip Litigation*, is the most recent decision which provides guidance on the meaning of defects for the purposes of product liability claims and actions in relation to medical devices in particular. It was claimed that the evidence that people who had metal-on-metal hip (MOM) prostheses inserted needed to have them replaced established the existence of the defect. In that respect, the claimants relied on the analysis of Burton J in *A v National Blood Authority [2001] 3 All ER 289*. The presiding judge, Andrews J, rejected that proposition and criticised the reasoning underlying it as "circular". That was because it involved reasoning backwards from the harm (or incidence of harm) to find a defect in a normal characteristic of the product, even though that harm may have occurred without the product being defective. Andrews J further noted that it ignored entirely the central question of the expectation of safety that persons generally were entitled to have of the product. On that question, Andrews J stated that the public was not entitled at the material time to expect that a MOM hip would not shed metal debris, even though such debris could cause ARMD (an adverse reaction to metal wear debris generated by their prostheses) in some of those in whom it was implanted (*at paragraph 133*). It followed that the alleged incidence (or predicted incidence) of ARMD in a small minority of patients, even if established, did not turn a known risk which might eventuate in normal use into a defect as defined.

Inherent aspect of a medical device can be defective in certain circumstances

DePuy Pinnacle Metal on Metal Hip Litigation also establishes that there might be certain circumstances when an inherent attribute of a device might be regarded as a defect, if it falls below the standard of safety that persons are generally entitled to expect.

In that case, the claimants pled that DePuy's MOM prostheses had "an abnormal potential for damage, compared with existing established non-MoM total hip replacement prostheses." and relied on epidemiological and statistical evidence to attempt to prove this (see *Epidemiological or statistical evidence to establish elevated risk*). Andrew J, acknowledged that all hip prostheses were known to release debris into the joint such that that inherent aspect of their function could be considered a defect under the CPA. However, the judge stated that, where the incidence of the harm caused by that aspect, either in nature or degree, is abnormal, then the product may be regarded as falling below the standard of safety that persons generally are entitled to expect (*at paragraph 112*). In such a case, the defect is the abnormal potential for harm. More particularly, it is whatever it is about the condition or character of the product that elevates the underlying risk beyond the level of safety that the public is entitled to expect.

Proving the existence of a defect in a medical device

The case law on strict liability claims regarding medical devices appears to give rise to at least four ways in which claimants might establish a defect's existence:

- Expert evidence to demonstrate that an aspect of a medical device's design, engineering or production gives rise to a defect.
- Statistical or epidemiological evidence showing that an aspect of the device gave rise to a risk beyond what the public was entitled to expect.

- The device was part of a production series or "batch" with an established or accepted defect.
- A claimant may rely on circumstantial evidence to establish a link between a product and abnormal harm, a more controversial mechanism of proof

Expert evidence of a design, engineering or production fault

The possibility of establishing a defect in this manner is shown by the serial litigation concerning hip implants (though not that in respect of *DePuy*) and breast implants produced using sub-standard silicone. In the latter cases there was no issue that a defect actually existed (see most recently *Mrs X and others v Company TÜV Rheinland LGA Products GmbH and others Judgment No. 610 of 10 October 2018*).

This approach is generally regarded as the simplest means of proving defect.

Epidemiological or statistical evidence to establish elevated risk

In the *DePuy Pinnacle Metal on Metal Hip Litigation*, both DePuy and Andrews J accepted (that, according to the generally accepted understanding of section 3(1) of the CPA, the claimant's case could be proved by adducing quantitative evidence which purported to show the MOM hip prostheses had higher failure rates than non-MOM prosthesis case (*at paragraph 137*). The judge stated that framing the question in this way was consistent with section 3(1) of the CPA because the public was entitled to expect that the MOM prostheses would not have a much greater risk of failure in the first ten years after implantation than the expected failure rate.

In deciding ultimately not to accept the evidence adduced because it was "unsound", Andrews J made several important statements regarding this form of evidence which demonstrate the fundamental difficulties that must be confronted by any claimant who chooses to rely on statistical and epidemiological evidence to establish a defect in a medical device.

Andrews J stated that the existence of multiple confounding factors, such as age and sex, body mass index, asymmetric surveillance and the impact of "outlier" surgeons reduced the effectiveness of the data. The judge observed that those confounding factors could not be quantified, because there was no data on which such a calculation could be performed. As such, the confounding factors prevented any robust conclusion being drawn from that evidence, even if it otherwise suggested a significantly higher failure rate for MOM prostheses (which it did not). Andrews J reached that conclusion even though the data was taken largely from the National Joint Registry, a centralised government repository of joint replacement outcomes. Another two factors had artificially increased the number of revisions carried out in relation to MOM prostheses (*at paragraph 455*). Firstly, "the panic engendered by the media reports" after the MHRA issued public guidelines about MOM prostheses increased revision rates by a significant, but immeasurable, extent. Secondly, the enhanced surveillance regime and the decision by some surgeons not to follow the MHRA guidelines led to more MoM hips being revised within ten years than would have been revised had they been monitored in the same way as other hip replacements (*at paragraph 492*).

Batch liability

The ECJ decision of Boston Scientific establishes the existence of so-called "batch liability" for defects in medical devices.

In considering whether devices which were part of a group, some of which might contain the fault, meant they all had a "defect" for the purposes of the Product Liability Directive it stated that:

> "where it was found that such products belonging to the same group or forming part of the same production series have a potential defect, it is possible to classify as defective all the products in that group or series, without there being any need to show that the product in question is defective" (at paragraph 41).

The basis for the finding was that the public would have legitimate grounds for questioning the safety of a product that had exactly the same characteristics as other products that have been proven to have a significantly higher than normal risk of failure.

The ECJ's decision fails to make it clear whether this concept of batch liability extends to general consumer products, or is limited to medical devices or indeed specific medical devices only. It also is unclear what is required to apply the batch liability principle, for example, whether one defective product in a batch of thousands would suffice.

A national court might nevertheless be reluctant to apply the concept of batch liability to a medical device where the existence of a defect within it can actually be ascertained. In such a situation, there would be a basis for reasoning that the ECJ's decision is to be confined to the types of devices with which it was concerned.

Circumstantial evidence suggesting abnormal harm

This mechanism of proof is from the ECJ of *N.W. et al. v. Sanofi Pasteur MSD, (Case621/15)* (Sanofi). In that case the court circumstantial evidence concluded that a claimant had discharged its onus of proof in circumstances where that evidence provided the most plausible explanation and the product did not offer the safety expected (*at paragraph 41*).

There are several reasons why reliance on this mechanism of proof might be less robust than others:

- The *Sanofi* decision from which the principle arises is about a pharmaceutical product, namely, a vaccine, rather than a medical device. However, the similarities between the way in which pharmaceuticals and medical devices are used and operate in practice suggests that reasoning in the context of product liability will often be interchangeable. The ECJ's decision may have broader implications for medical devices because there is likely to be less of a developed medical and scientific literature about a particular device, or even a sub-type of such a device, then there is about something that is so pervasively used like a vaccine.

- The decision concerned the existence and operation of rebuttable presumptions in the French law of civil procedure, which might conflict with the civil procedure rules of other jurisdictions.

- The ECJ's decision is more concerned with causation rather than with proof of the existence of a defect. In the *DePuy Pinnacle Metal on Metal Hip Litigation*, for instance, Andrews J accepted that this was the primary focus of the decision but the judge also stated that the ECJ's reasoning was relevant to the question of how to show that a product has a defect (*at paragraph 128*).

Notwithstanding the above, Andrews J pointed out in the *DePuy Pinnacle Metal on Metal Hip Litigation*, that this approach to proof of defect is essentially an alternative way of using evidence to establish that the product has potential to cause damage so abnormal that the public would not consider it safe (at paragraph 129).

CAUSATION

General principles applicable to medical devices

The ECJ's decision in *Sanofi* establishes that, because the Product Liability Directive does not prescribe any general approach to causation in product liability cases, national courts are free to set their own rules as long as they do not undermine any aspect of the strict liability regime.

In the UK, the CPA also does not set out any general approach to questions of liability.

Absent an express alternative, the common law's "but for" test applies.

In the context of strict liability for defects in medical devices, the question would therefore be whether, "but for" the proved defect, would the damage have occurred?

The application of such a test may be straightforward where the established defect is some aspect of the device's manufacture, engineering or design.

In the *DePuy Pinnacle Metal on Metal Hip Litigation*, Andrews J observed that there is an added layer of complexity with this formulation where the defect in question is an **abnormal or increased risk** that a device will fail prematurely. The complexity arises because the alleged damage will be the costs and injuries that the claimant incurs as a consequence of that abnormal or increased risk, most notably the costs associated with a revision or replacement operation. However, because the defect is the **abnormal or increased** that those costs and injuries might be incurred, the test for causation must also factor in the possibility that the claimant would have incurred them anyway. Simply asserting that, but for the increased or abnormal risk, the costs would not have been incurred does not take account of the underlying or normal risk that the damage may have occurred in any event.

Without deciding the point, Andrews J suggested that the question could be answered by reference to the magnitude of the increased or abnormal risk. For instance, the judge accepted that if it was proved that the risk of failure was double the usual risk, then the claimant would establish causation (*at paragraph 186*). However, Andrews J also stated that this approach was not the only way that causation might be proved.

Can causation be established where a patient does not consent to a remedial procedure?

Defective medical devices, and implanted defective medical devices in particular, may pose a unique problem for the legal principles of causation where a patient is offered a remedial procedure to prevent the manifestation of an increased risk. If a patient chooses to undergo that procedure the harm suffered will clearly include the costs associated with it (see discussed under *Damages under the CPA* below). However, the difficulty arises where the patient chooses not to undergo the procedure and the risk then eventuates.

Prima facie, the position would be governed by Article 8(2) of the Product Liability Directive which stipulates that the liability of the producer may be reduced or disallowed when, having regard to all the circumstances, the damage is caused both by a defect in the product and by the fault of the injured person (this provision is reflected in section 6(4) of the CPA). The patient's decision not to undergo the remedial procedure in any given case may conceivably be "fault" for the purposes of Article 8(2).

Such a result would perhaps be appropriate in cases like *Boston Scientific* where, although not insignificant, the remedial procedures required to replace the medical devices were relatively straightforward and carried low levels of risk. However, in other cases the remedial procedure may be highly complicated and associated with significant levels or mortality and morbidity. Procedures to explant cardiac valves or aortic stents, for instance, can carry a mortality of up to 70%. In such a situation, it may be difficult to characterise the patient's decision not to undergo the procedure as "fault" under Article 8(2). More generally, it may be that a court in the UK, where significant deference is paid to the doctrines of patient autonomy and informed consent, would be slow to find that a patient was at fault in any situation only because of a decision not to undergo a remedial procedure (see *Chester v Afshar [2004] 1 AC 134; Montgomery v Lanarkshire Health Board [2015] SC 11 [2015] 1 AC 1430*).

Causation can be established without medical or scientific evidence

The ECJ's decision in *Sanofi* establishes that where the medical and scientific evidence is equivocal or absent on the existence of a causal relationship between the defect and the harm suffered, then a claimant can rely on other forms of evidence, such as circumstantial evidence, to establish causation.

In such a case, a court will be required to resolve the evidence given by the expert medical or scientific witnesses actually called in the proceedings. Given the probability that there will be conflicts in that evidence on the critical point, the ECJ's ruling in *Sanofi* may then be relied on by claimants.

On one view, this makes proof of causation easier for claimants because they are not required to overcome the evidential hurdle of demonstrating that medical or scientific research supports the asserted causal relationship. On the other hand, the ECJ also emphasised that a court is not required to accept the alternative evidence, cases must instead be determined on an individual basis. That is, there was no place for irrebuttable presumptions and the onus of proof remains on claimants.

Another view is that courts in other member states do not necessarily need to follow Sanofi because the ECJ's decision was concerned only with whether the French approach to causation was consistent with the Product Liability Directive. In that connection, reference may be had to the decisions of the ECJ in *Commission v France [2002] ECR 1-3827, Commission v Greece [2002] ECR 1-3879* and *Gonzalez Sanchez v Medicina Asturiana SA [2002] ECR 1-3901*. Those decisions collectively suggest that the strict liability regime, with its specified number of defences, sets a maximum level of consumer protection under which member states are granted autonomy to develop their own laws, including their own rules of civil procedure.

DEFENCES UNDER THE CPA

The CPA sets out several statutory defences to a product liability claim, including:

- The defect is attributable to compliance with a regulatory requirement

  The defect must be **caused** by compliance with a regulatory requirement. Conversely, compliance with all regulatory compliance obligations (pre-authorisation and post-authorisation procedures) in relation to a medical device is **not** a statutory defence (as opposed to claims in negligence, where such matters would go to breach of duty). However, the recent ECJ case of *DePuy* did indicate that it is a useful factor for the defence to refer to in making their case (*at paragraph 101*).
- There was no supply of the product to another (or such a supply was not in the course of business or with a view to profit).
- The defect did not exist at the time of supply. This means that mere advice concerning a medical device will not be actionable (see *Doctors, hospitals and healthcare institutions*). Where the defect entails an increased or abnormal risk of device failure and consequential damage, the defect will be present at the time of supply even where the specific device in question does not itself ever contain the defect.
- The statute of scientific and technical knowledge at the relevant time was not such that the producer might be expected to have discovered the defect (so-called called "development risks" or "state of the art" defence).

Development risks defence

A defendant can defend a product liability claim in relation to a defective medical device on the ground that, due to the state of scientific or technical knowledge at the "relevant time", the defect could not have been discovered (*section 4(1)(e), CPA*).

The ECJ confirmed in *Commission v United Kingdom (Case C-300/95)* that this is an objective test. Given that there is a defect in a product if its safety is not such as persons generally are entitled to expect, the test is whether the facts informing that expectation were known, or knowable, on the state of scientific and technical knowledge at the time of circulation.

However, in *DePuy Pinnacle Metal on Metal Hip Litigation*, Andrews J stated that, in determining whether the public expectation of safety was achieved for the purposes of identifying a defect, a court is to have regard to "everything subsequently now known" about the device irrespective of whether that information was available at the time it was put on the market or only came to light subsequently (*at paragraph 84*).

This appears to mean that the issues about the state of the scientific and technical knowledge at the time of a medical device's first circulation are not relevant to the initial question of whether there is actually a defect. Any scientific and technical knowledge that subsequently emerged after circulation can be used to answer that question. The issues about the existing state of knowledge only arise at the stage of considering whether the development risks defence can be relied on.

In that respect, it should be noted that one of the concerns prompting the recent reform of medical devices regime in the EU, is that the existing authorisation regimes permit circulation of medical devices despite a comparatively sparse scientific and technical knowledge about the risks they pose. Once those directives come into full effect (subject to Brexit in the UK), it is to be expected that the breadth of scientific and technical knowledge at the time

of a medical device's circulation will necessarily increase as authorisation procedures become more rigorous. In turn, that will commensurately make it more difficult to establish the development risks defence.

DAMAGES UNDER THE CPA

Section 5(1) of the CPA conforms with the Product Liability Directive in stating that a producer is liable for "damage caused by death or personal injuries" or "any loss of or damage to any property (including land)".

On its face then, the strict liability regime does not contemplate the award of damages resulting from **the prevention of** death or personal injuries. It also does not permit recovery for damage to the product itself (see section 5(2) of the CPA).

Complexities consequently arise where damages are sought in respect of implanted defective medical devices in which the defect is the increased or abnormal risk of the device's failure.

In those cases, the damages sought will invariably include the costs associated with the prevention of death or personal injuries. However, the broadening of the damages provisions to allow recovery in those circumstances may expose producers to an indefinite or open-ended liability. That is particularly because the CPA (departing from the Product Liability Directive) does not impose a statutory cap on damages that may be recovered in product liability claims.

Damages for increased or abnormal risk of device failure

In *Boston Scientific*, the claimants sought recovery for the costs of the procedures to remove the defective devices and to replace them with new devices. In relation to the defective pacemakers, the manufacturer had already agreed to pay for the costs associated with replacements where the patient's cardiologist had deemed that that replacement was necessary. However, in relation to the defibrillators, the manufacturer's advice had only been to consider deactivation of the magnetic switch. Despite this, some patients who had had the defective defibrillator implanted had gone through explantation or reinsertion procedures. The insurance company that brought the proceedings claimed those costs, as well as the costs in relation to replacement of the pacemakers, even though it was arguable that explantation of the defibrillators had not been necessary.

In considering these claims, the ECJ set out an expansive conception of "damage" for the purposes of the strict liability regimes. More particularly, it stated that compensation may be awarded "to eliminate harmful consequences and to restore the level of safety which a person is entitled to expect". It followed that, regarding the defective pacemaker, damages could be awarded to cover the entire replacement of the defective product including the costs of the associated surgical procedures.

In so holding, the ECJ did not explain how such a ruling is to be reconciled with Article 9 of the Product Liability Directive which, like section 5(2) of the CPA, precludes recovery for damage to the product itself. With regard to the defibrillators, the ECJ accepted that it was not clear whether or not the relevant claimants needed to undergo the remedial procedures. It therefore referred that question back to the national court, although it did note that such claimants were vulnerable to a high risk of damage if the defibrillator was actually to fail.

Combined with its conclusion on batch liability , the ECJ's ruling on damages would seem to significantly increase the scope for the imposition of damages against producers of medical devices. The existence of a defect in one device in a batch may expose the producer to the potentially open-ended costs of its "harmful consequences." That would appear to include not just the remedial procedure and its associated costs, but also the sequelae of any such procedure including ongoing complications.

Given that morbidity and mortality associated with ex-plantation exponentially increases within the patient groups who generally receive medical devices, the financial implications for the producers of these devices and their insurers may be considerable. In that respect, it should be re-iterated that in several jurisdictions (including the UK) there is no cap on damages that can be awarded under the CPA for product liability.

Damages where patient does not have remedial procedure

A further complexity may arise where a patient does not, or cannot, undergo a remedial procedure or treatment intended to ameliorate or obviate the damage caused by a medical device. This is an issue that may initially be encountered in the context of causation (see *Causation*). However, its implications will also need to be considered in the award of damages. The point will be especially relevant in two circumstances namely where:

- Owing to the magnitude of morbidity or mortality associated with the remedial procedure, the patient decides not to undergo that procedure.
- A medical professional advises that a patient, because of their morbidity or mortality, should not have the procedure.

In either case, if the risk was to manifest and the patient was to die or to be injured, doctrines of contributory negligence or voluntary assumption or risk would have difficult application. Consistently with *Boston Scientific*, the patient's injuries or death in those circumstances may be compensable "harmful consequences" of the defect. Once again, the deference that courts in the UK show to patient autonomy in the content of informed consent and medical decision-making might compel the rejection of any mitigation of damages in this situation.

Costs of medical monitoring

The costs of ongoing medical monitoring and surveillance is another potential aspect of a producer's liability for damage caused by a defective medical device. In some jurisdictions in the USA, "medical monitoring" has been treated as a discrete tort which can be invoked where a patient has been exposed to a risk (for instance, a carcinogenic substance). However, the implication of the ECJ's decision in Boston Scientific is that it may be an independent head of damages in circumstances where a medical device's defect is its increased or abnormal risk of failure. That will be the case where ongoing medical reviews, examinations or investigations are necessary to ensure that that abnormal or increased risk does not actually materialise. The costs of that monitoring and surveillance would seem to come within the ECJ's formulation of damages needed "to eliminate harmful consequences and to restore the level of safety which a person is entitled to expect".

NEGLIGENCE CLAIMS IN RELATION TO DEFECTIVE DEVICES

A product liability claim in negligence with respect to a defective medical device will give rise to the same issues as those that present themselves under the CPA. However, unlike the CPA which requires no such proof, the claim will also require the claimant to demonstrate fault on the manufacturer's part. The need to prove breach of duty is why claimants generally prefer to proceed under the strict liability regime. However, pleading in negligence means that the CPA's time bar can be avoided and different rules of civil procedure, particularly relating to discovery, may also apply.

Perhaps most significantly, however, a greater range of parties can be joined in common law actions. With regard to medical devices, this latter point was shown in *Schmitt v TÜV Rheinland LGA Products GmbH Case C-219/15* where the ECJ permitted negligence proceedings to proceed against a notified body for its alleged failure to properly discharge its surveillance obligations in relation to silicone breast implants.

Common law actions can also be brought in relation to types of conduct not covered by the CPA, most notably negligent advice given in relation to a medical device where there was no actual supply (see *Doctors, hospitals and healthcare institutions*). For discussion of general principles of negligence to product liability claims, see *Practice notes, Product liability and safety: overview* and *How should a product liability claim be handled?* For a discussion of the general principles of negligence see *Practice note, Claims in negligence: an overview*.

CONTRACT CLAIMS IN RELATION TO DEFECTIVE DEVICES

Where a claimant only seeks to obtain compensation for damage to the product itself, which is expressly excluded as a head of damage under the CPA, a contractual claim may be the most appropriate avenue of redress (see *Practice note, Damages for breach of contract: an overview*). With respect to medical devices, the most likely

scenario in which such a claim may arise is where a manufacturer supplies defective devices to an importer or distributor. In that case, reliance may be placed on the terms implied into the contract by the SGA or CRA. Most particularly, under section 14 of the SGA or 9 of the CRA the devices supplied must be of "satisfactory quality."

This phrase has a broader meaning than "defective" (see *Practice note, Supply contracts: overview: Statutory framework*). There may also be circumstances in which a consumer seeks damages in relation to a defective product itself, particularly where the device is a complex and expensive piece of medical equipment or machinery. The consumer's action is governed by the SGA or CRA, depending on the contract in question and its timing (see *Practice note, Consumer Rights Act 2015: overview*). In all contracts relevant to medical devices, there are limits on the extent to which product liability can be restricted or excluded (see *Practice note, Product liability and safety: overview*).

Criminal liability for failure to comply with regulatory regime

Producers, deemed manufacturers, importers and suppliers of medical devices can be subject to criminal sanctions for failure to comply with mandatory regulatory obligations under the medical devices regulatory regime or the general consumer products regulatory regime.

The EU has a robust regulatory regime in respect of medical devices, provided for currently under the MDD, AIMDD and IVDMD.

The regime provides for authorisation and surveillance processes. A medical device can only be authorised where its producer, supplier or importer is able to demonstrate its quality, safety and efficacy to a notified body. Where the notified body is satisfied that those attributes exist, it may verify the medical device by way of the CE mark.

The only explicit reference to product liability in the MDD, AIMDD and IVDMD is found in Annex XI (6) to the MDD which states that "[t]he [notified body] must take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly" (see *Notified Bodies*).

As noted above, section 12 of the CPA makes it an offence to contravene the regulations with a penalty of up to six months imprisonment in addition to financial penalties.

Furthermore, regulation 9 of the General Product Safety Regulations 2005 (*SI 2005/1803*) (GPSR) imposes the general requirement on "producers and distributors" of all products, including medical devices, to engage in post-authorisation surveillance. It also imposes the requirement that those entities co-operate with designated authorities (which is the MHRA in relation to medical devices in the UK) and comply with its rules.

The MHRA creates the following sets of post-marketing obligations on producers of medical devices:

- To hold and disclose information about a device.
- To report adverse incidents when such incidents occur.
- To take "field safety corrective actions" where deemed necessary.

In setting out the precise requirements in each of those respects, the MHRA adopts the European Commission's, *Guidelines on a medical devices vigilance system* (MEDDEV 2.12/1 rev.8, 2013). To ensure compliance with these requirements, Part VII of the MDR gives the MHRA powers of enforcement, investigation and suspension.

Supplementing these statutory provisions, a person may alternatively be held liable under the general provisions of the criminal law for conduct in relation to a defective medical device. That was demonstrated in 2013 in the context of medical devices when a French criminal court imposed custodial sentences on the founder of Poly Implant ProthEese (PIP) and four of its executives after it was found to have knowingly used sub-standard silicone in the production of breast implants that were distributed throughout the EU.

Furthermore, factual circumstances, including in particular the liquidation of the manufacturer or the supplier might mean that claimant parties pursue the notified body for failure to properly discharge its responsibilities under the applicable directive. The possibility of all those avenues of claim has been shown by the serial litigation

concerning defective silicone breast implants in France where the claimants maintained a proceeding against the notified body, TUV Rheinland, after the manufacturer and supplier had been liquidated (see *Notified bodies*).

OBLIGATION TO HOLD AND PROVIDE INFORMATION ABOUT A MEDICAL DEVICE

The MHRA requires producers and distributors of medical devices to hold and produce information about a medical advice. That includes information produced before market authorisation, such as data or documents pertaining to the conformity assessment procedure. It also includes information relating to post-market issues, such as adverse incident reports or any other information relating to a medical device's defect. The MHRA is empowered to request or seize and detain any such information to prosecute, or for the purposes of, criminal proceedings. However, the Enterprise Act 2002 also requires the MHRA to treat information that it obtains from a producer or distributor in the course of its regulatory powers as confidential.

OBLIGATION TO REPORT ADVERSE INCIDENTS TO DESIGNATED BODY

Producers and distributors of medical devices must report all adverse incidents in relation to their devices to the MHRA. There is no general definition of the phrase "adverse incident" or of when an adverse incident is deemed to have occurred. It depends on the nature of the medical device concerned. Consequently, the MHRA has currently published nine "device specific" guidance notes which describe when manufacturers must report adverse incidents. The medical devices which have these individual guidance notes are:

- Biological and mechanical surgical heart valves.
- Coronary stents.
- Intraocular lenses.
- Breast implants.
- Inferior vena cava filters.
- Joint replacement implants.
- Neurostimulators.
- Cardiac ablation catheters.
- In vitro diagnostic (IVD) blood glucose meters.

For medical devices that do not fall within these device specific notes, regard must be had to MEDDEV 2.12/1 rev.8 as to what an adverse incident is and when it occurs. To assist producers and distributors of medical devices that do not have the benefit of device specific notes, MEDDEV 2.12/1 rev.8 suggests that three general criteria must normally be fulfilled for an adverse incident to have taken place:

- "An event has occurred", such as a malfunction or deterioration in the characteristics or performance of the device.
- "The device is suspected to be a contributory cause of the incident". In assessing the link between the device and the incident, MEDDEV 2.12/1 rev.8 states that the producer or distributor should take account of:
  - the opinion, based on available evidence, of healthcare professionals;
  - the results of its own preliminary assessment of the incident;
  - evidence of previous, similar incidents; and
  - other evidence it holds.
- The event led, or might have led, to either the death, or serious deterioration in health, of a patient, user or other person.

MEDDEV 2.12/1 rev.8 suggests that, in the assessment of whether these criteria are fulfilled, there should be a predisposition to report rather than not to report.

OBLIGATION TO TAKE FIELD SAFETY CORRECTIVE ACTIONS

MEDDEV 2.12/1 rev.8 provides that, as part of ongoing quality assurance or an investigation at the manufacturing site, a manufacturer or distributor might identify a failure of a device to perform according to its specification. Where such a failure might lead to death or serious deterioration in the state of health of a person, then the manufacturer or distributor must initiate a field safety corrective action (FSCA).

MEDDEV 2.12/1 rev.8 states that a FSCA is an action taken by a manufacturer or distributor to reduce a risk of death or injury associated with the use of a medical device. Such actions, whether associated with direct or indirect harm, should be reported and should be notified, both to the regulatory authority and to recipients and users of the medical device, through a field safety notice (FSN).

Issuing of a field safety notice

A FSN is a communication sent by the manufacturer or distributor (or its appointed representative) in relation to an FSCA. The European Commission has produced a template FSN which is publicly available on its website and which the MHRA has endorsed. *The MHRA has also issued its own guidance entitled Producing and distributing effective field safety notices*. In summary, the FSN should contain the following nine elements:

- A clear title, with "Urgent Field Safety Notice" followed by the commercial name of the affected product.
- Specific details to enable the affected product to be easily identified.
- A factual statement explaining the reasons for the FSCA.
- Advice on any actions to be taken by the user or recipient of the medical device.
- A request to pass the FSN to all those who need to be aware of it.
- A request for the details of any affected devices that have been transferred to other organisations.
- A request that the recipient of the FSN alerts other affected persons or organisations.
- Confirmation that the MHRA has been advised of the FSCA.
- A contact point for customers.

All FSNs issued in the UK should be accompanied by the MHRA's FSN flyer (the purpose of which is to emphasise the importance of the FSN).

Recalls, exchanges, revisions and withdrawals

MEDDEV 2.12/1 rev.8 provides that the FSCA set out in the FSN may include any of the following:

- The return of a medical device to the supplier.
- Device modification.
- Device exchange.
- Device destruction.
- Retrofit of device.
- Advice given by manufacturer regarding the use of the device and the follow up of patients.

It is the responsibility of the manufacturer or distributor to determine what FSCA is appropriate in the circumstances. However, before publishing the FSN, the manufacturer or distributor must send it to the MHRA for assessment.

The MHRA will then make a determination of whether the proposed FSCA is appropriate. At that point, the MHRA may approve the FSN and the FSCA or ask for further information about the medical device, the defect or any aspect of the FSCA. If the MHRA disagrees with the FSCA proposed or the content of the FSN provided to it, then it might exercise its own powers under Part VII of the MDR to:

- Issue warnings.

- Publish restriction notices.
- Revoke a medical device's marketing authorisation.

NEW EU REGULATORY REGIME FOR MEDICAL DEVICES

The MDD, AIMDD and IVDMD were repealed by the Regulation ((EU) 2017/745) of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR 2017) and Regulation ((EU) 2017/746) of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVDMR 2017) on 25 May 2017.

However, to allow adjustment to the new regimes, the new regulations will only apply after a transitional period which is three years after entry into force for the MDR 2017 (spring 2020) and five years after entry into force for the IVDMR 2017 (spring 2022). Most of the substantive changes introduced by the MDR 2017 and the IVDMDR2017 do not directly affect liability for defective medical devices, although the regulatory regimes will always form the background to liability issues (see *Relationship between authorisation regimes and liability claims*).

As such, the MDR 2017 and the IVDMR 2017 will:

- Impose stricter pre-market control for high-risk devices through a new pre-market scrutiny mechanism and the establishment of a pool of experts at the level of the European Commission.
- Alter the criteria for designation and processes for oversight of Notified Bodies.
- Include aesthetic or plastic surgical devices as medical devices.
- Implement a new risk classification system for in vitro diagnostic medical devices.

The MDR 2017 and the IVDMR 2017 may also have a more direct impact on liability for defective medical devices through their attempts to strengthen post-market surveillance requirements. It appears that the chief mechanism by which this is to be achieved is through the development of the European database on medical devices (Eudamed). The objective of Eudamed is to integrate the different electronic systems of national bodies to collate and process information regarding devices on the market, including in relation to vigilance and market surveillance.

It may therefore be the case that at least some of the regulatory aspects raised by defective medical devices will be determined centrally rather than by designated bodies like the MHRA. Another change directly relevant to liability for defective medical devices is that, under the MDR 2017, where damage is caused by such a device, a manufacturer's authorised representative is to be jointly and severally liable. Of course, any such changes are subject to the outcome of Brexit.

LIST OF ABBREVIATIONS

AIMDD: Directive 90/385/EEC of 20 June 1990 on active implantable medical devices

Boston Scientific: Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt — Die Gesundheitskasse and Betriebskrankenkasse) (Cases C503/13 and C504/13)

CPA: Consumer Protection Act 1987 (UK)

CRA: Consumer Rights Act 2015 (UK)

DePuy Pinnacle Metal on Metal Hip Litigation: Colin Gee and others v DePuy International Ltd [2018] EWHC 1208 (QB)

FSCA: field safety corrective action

FSN: field safety notice

GPSR: General Product Safety Regulations 2005 (*SI 2005/1803*)

IVDMR 2017: Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices

IVDMD: Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices

MDR 2017: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

MDD: Directive 93/42/EEC of 14 June 1993 concerning medical devices

MDR UK: Medical Devices Regulations 2002 (*SI 2002/618*) (as amended)

MEDDEV 2.12/1 rev.8, 2013: European Commission's, Guidelines on a medical devices vigilance system

Product Liability Directive: Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products

Sanofi: *N.W. et al. v. Sanofi Pasteur MSD, C621/15*

SGA: Sale of Goods Act 1979 (UK)