Product Liability for Medical Devices

Anne Ware and Grant Castle examine the product liability regime in Europe and provide guidance on how companies can protect themselves from claims.

Here we set out the European product liability regime as it applies to medical devices and examine key cases that indicate how the legislation is likely to be interpreted. Despite the fact that the strict liability regime has been in existence for many years, numerous issues have yet to be resolved and there continues to be a lack of harmonisation between the EU member states. We highlight a number of these issues and briefly discuss steps that the European Commission is taking to resolve them. We then discuss specific medical device aspects of product liability. Since the majority of product liability cases refer to labelling and information accompanying devices, we focus on device vigilance, safety reporting obligations and the importance of ensuring that product labelling reflects the developing safety profile of the products. Finally, the article provides some general guidance on how companies can protect themselves from product liability claims.

Product liability law

Product liability law in the EU has existed in various forms for many years. As it has evolved, the legislation has become more and more pro-consumer, making it easier for those injured by products to obtain compensation. Older legal regimes often co-exist with more recent ones, and it is not unusual for lawyers to bring product liability claims that rely on a number of legal doctrines. For this reason, we will briefly discuss the potential liability of companies under the three core regimes: liability in contract, fault or negligence liability and strict product liability.

Liability in contract

The oldest regime is liability in contract, which usually requires a contractual relationship between the injured party and the producer or supplier of a product. A number of contractual terms relating to the quality of goods and liability for injuries caused by those goods may be implied by law, which gives consumers some protection in the event that there is no written contract. The problem with this regime is that consumers can usually only take action against their direct supplier, which would often be a physician, hospital, clinic or other supplier of medical devices or diagnostic procedures. The problem is that these groups may not be responsible for the manufacture of the product or the injury caused, and may also not have the financial resources of a manufacturer.

Fault or negligence liability

Manufacturers, or anyone else in the supply chain of a medical device, may be held responsible if their negligent acts or omissions injure a patient. Manufacturers may be negligent if they fail to (i) conduct adequate research or quality control; (ii) provide adequate warnings; or (iii) take appropriate postmarketing action to deal with safety concerns involving their products. Notified bodies performing conformity assessment of devices may be negligent to the extent that they fall below the standards expected of a reasonably competent body. A medical professional may be negligent, for example, if they inappropriately prescribe a device or negligently insert an implantable device.

The negligence of an individual or company is judged against the standard of what constitutes ‘reasonable’ conduct, assessed against the ‘state of the art’ at that time. In essence, the state of the art comprises the legal, regulatory, professional, or scientific industry standard applicable at the relevant time. Courts will assess whether the conduct of the manufacturer of a device, or anyone involved in the supply or use of a device, has fallen below what would be reasonably expected of that individual or organisation. What constitutes ‘reasonable’ conduct would depend on the magnitude of the associated risk, the likelihood and consequences of any injury and the practicality and costs of taking avoiding or corrective action.

The problem facing consumers seeking compensation under negligence liability is that, for highly technical products, it is difficult to prove (i) unreasonable conduct, and (ii) that this conduct caused the injury that is the subject of complaint. There are often multiple risk factors, causes and mechanisms which may contribute to a patient’s injury. For this reason, the strict product liability doctrine was created.

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Strict liability

Directive 85/374/EEC, the product liability directive, has created what was intended to be a harmonised strict liability regime across the EU. The intention was that manufacturers, or importers of products, would compensate an injured party where a defect in a product had caused injury without the injured party having to show negligence. The focus is shifted from the actions of companies and individuals onto the product itself. Without the need to prove fault, it becomes irrelevant whether a manufacturer took all reasonable steps to avoid injury or damage, or whether its actions were consistent with current industry practices or standards.

Under the directive, a ‘producer’ shall be liable for damage ‘caused by a defect in its products’. In defining the term ‘producer’, the directive seeks to ensure that an injured party will always have someone within the European Economic Area (EEA), which includes the 25 EU member states, plus Norway, Iceland and Liechtenstein, against whom they can bring a claim. The term includes any manufacturer of finished products, raw materials or parts within the EEA; importers of products from outside the EEA; and any person who places their name or mark on a product (which would include companies selling own-branded products). It also includes any intermediate suppliers of products, which could include distributors, retailers, healthcare professionals and their employers. However, intermediate suppliers are only liable under the directive if they fail to identify any other ‘producer’ further up the supply chain within a reasonable period.

Defect

The directive provides that a product is defective when it:

- does not provide the safety which a person is entitled to expect, taking all the circumstances into account;
- a) The presentation of the product;
- b) The use to which it could reasonably be expected that the product would be put; and
- c) The time when the product was put into circulation.

Defectiveness is measured against an objective standard, ie the expectation of the public at large. It is irrelevant whether an individual claimant considered a device to be defective. It depends on the general expectations of the relevant consumers and a risk:benefit analysis. The courts consider several issues. They will assess the level of public knowledge that a product is dangerous: a claimant could not seek compensation if he or she was cut by a knife, since the average person understands that knives are inherently sharp and dangerous. With complex products, however, it is more difficult to ascertain what the expectation of the public should be.

A key issue with medical devices and pharmaceutical products is whether the way in which the product is presented, including information and warnings given by the producer, provides consumers with adequate understanding of its inherent dangers. The courts will also consider the uses that would be reasonably expected for a product, including possible misuses, abuses and reuses of it, and, again, what warnings and instructions have been provided by the producer. A device will not become ‘defective’ simply because a newer, safer product is introduced.

The leading case on the issue of ‘defect’ concerns Hepatitis C litigation in the UK. One hundred and ten claimants who had contracted Hepatitis C as a result of blood transfusions brought compensation claims against the UK National Blood Authority. The authority had routinely tested for Hepatitis B since the 1970s. It had become known that another agent was causing post-transfusion hepatitis. At that stage, little was known about the agent causing this infection, other than it was not Hepatitis A or Hepatitis B. In 1988, the US corporation Chiron identified Hepatitis C, but commercial tests for the virus were not available until 1990 and they were not introduced in the UK until 1991. The claims against the authority were made by patients who had contracted Hepatitis C between the implementation of the directive in the UK in March 1988 and 1 September 1991, when testing for Hepatitis C began in the UK.

The English court applied a very strict test for defectiveness in this case. It concluded that the relevant level of safety was not what the public actually expected, but what the public was entitled to expect, what it called their ‘legitimate expectation’. This may or may not exceed what the public actually expects. The court appears to have diverged from the text of the directive by applying what is, in essence, a subjective test for the courts. It concluded that blood, by its nature, was not the kind of product that should carry any risk. This could be contrasted with other products, such as guns, knives, poisons, tobacco and medicines, all of which have known risks and/or side effects. The public is entitled to expect that blood would be free from infection, irrespective of whether this was what they actually expected. Judgment was given for the claimants and damages were paid by the authority.

It will be interesting to see how other jurisdictions deal with issues of this type.
Proof and causation

Once a claimant has identified a defect in a product, he or she must also prove that they have been injured and that there is a causal link between the defect and the injury. The injured person has the burden of proof, not the defendant company.

In *Foster v Biosilk*, a claimant sought compensation for injury caused by a ruptured breast implant. Her lawyers argued that the fact that the device had ruptured proved that the product was defective. The courts disagreed, holding that a claimant had to indicate a specific defect and identify how it had occurred, e.g., what is a design or a manufacturing fault.

Causation is usually the greatest stumbling block for claimants pursuing claims for medical devices or pharmaceutical products. This is illustrated by a case involving third generation oral contraceptives. In *XYZ & Others v Schering Health Care*, 99 women lost a claim that third generation oral contraceptives carried an increased risk of venous thrombosis embolism (VTE) when compared to the second generation equivalents. At the end of a three month hearing involving evidence from ten epidemiologists, the court was not able to provide a definitive answer on the issue of causation. However, the judge considered that this was unnecessary, as he should simply assess issues as a matter of probability. He was unable to identify, as a matter of probability, any increased risk of VTE from third generation contraceptives relative to the second generation products. While there was an increased risk of VTE of about 1.7 times in those taking oral contraceptives, this appeared to be the same for both the second and third generation.

To prove a product was defective because of a failure to warn about a risk, claimants must show that: (i) the product caused the damage for which there was a failure to warn; and (ii) that the product caused the damage in their particular case (individual causation).

There is little case law on the issue of defective labelling, and it has been considered that any failure to warn for an injury that a product causes may render it defective. However, a recent French case casts some doubt on this strict interpretation. In *Ferring v Mauduit*, a patient treated for hemorrhagic rectocolitis with Ferring’s mesalazine product, Pentasa, suffered serious kidney damage. The patient had been treated between 1994 and 1997 and the injury occurred prior to France’s implementation of the directive. However, the court assessed the defendant company’s civil liability in light of the provisions of the directive.

During the case it became apparent that there was a consensus that the injury was linked directly to Pentasa, but the state of scientific and medical knowledge about this was extremely limited. Ferring had taken expert advice and consulted the relevant regulators about whether it should include a warning in its labelling for this potential adverse event, but there was no consensus about the need to warn. The French court held that the company was not liable for the claimant’s injuries. In reaching this conclusion, the French court seems to have applied a ‘negligence-type’ test to the issue of defective warnings. This would appear to be contrary to the wording of the directive. It reflects a sensible interpretation and approach, however, and one would hope that this would be the attitude of courts in other jurisdictions.

Defences

Article 7 of the directive contains a number of possible defences which are explained below.

The producer did not put the product into circulation

It is relatively common for medical devices to be custom-made or prepared within hospitals. The question under these circumstances is whether such devices would be viewed as being put into ‘circulation’.

A Danish case suggests that this defence would not be available. In *Veelfeld v Arhus Amtskommune*, a Danish hospital prepared a kidney for transplantation using defective fluid. This rendered the kidney unusable and the intended recipient sued for compensation. The hospital argued that the kidney had been prepared for internal use by the hospital and therefore had not been put into circulation. The courts disagreed, arguing that this exemption should be interpreted narrowly in order to provide consumers with the maximum level of protection under the directive.

The defect causing the damage came into being after the product was put into circulation by a producer

Producers may avoid liability if they can show that the defect that injured the claimant was caused by some other entity within the supply chain, for example by incorrect handling, storage or use of a device.

An example where this defence was successfully raised originates from the Netherlands. In *Nico v Fisher Farma*, a patient taking GlaxoSmithKline’s (GSK) Seroxat (paroxetine) developed permanent and painful erections. GSK had included a warning of such adverse events in a small num-
ber of cases for some time. The product used by the claimant, however, had been parallel imported from France by Fisher Farma, which had inserted outdated Dutch labelling. In this case, the Dutch court considered that Fisher Farma was not a ‘producer’ of the product, so it could not be liable under the strict liability doctrine established by the directive. We consider that the court erred in this respect since it could have been the producer by virtue of its identification as the parallel importer of the product. However, the Dutch court found Fisher Farma liable under a separate type of liability, negligence.

**The product was not manufactured for profit-making sale**

In the Veedfald case, the hospital that had used the defective fluid to clean the kidney argued that, as a government hospital, it had not manufactured the product for profit-making sale. There was no direct economic link and no economic purpose for the supply of the kidney to the patient. The Danish court dismissed this argument on the basis that the hospital was not a charitable body and that it was irrelevant whether the kidney was to be supplied using public funds.

**Development risks defence**

Under the directive, EU member states can adopt an optional defence of ‘development risks’. This allows producers to argue that the state of scientific and technical knowledge, at the time the product was put into circulation, was not such as to enable the defect to be discovered. Not all member states have adopted this defence. A producer must be able to demonstrate that it would not have been possible for them to identify the defect at the time it marketed the product. This is a high standard of proof. Claimants’ lawyers and their experts will trawl the medical and scientific literature to prove that a producer should have been able to identify a defect. As discussed below, the courts to date have interpreted the defence restrictively.

In *A and Others v National Blood Authority*, the authority tried to argue that the development risks defence applied, on the basis that it was impossible to identify the agent causing Hepatitis C at the point when the infected blood was supplied to the claimants. The court dismissed this argument, stating that the authority had been aware that the product was contaminated and could cause an infection, even though it could not identify the infective agent.

In a Dutch case, *Scholten v Sanquin Blood Supply Foundation*, a patient received a blood transfusion during surgery in 1996 and subsequently contracted HIV. The foundation had conducted an HIV test before using the blood, which had been negative. Subsequently, the blood was retested using this and another HIV test, both of which gave negative results. A third test gave a questionable result, but this test had not been approved at the time of the operation. The court ruled that the patient was entitled to expect blood to be HIV-free and that the product had therefore been defective. However, the foundation was able to rely on the development risks defence because it had not been able, or required, to use the new test at the time of the transfusion.

**Other possible defences**

Two other defences exist under Article 7 of the directive. First, it is a defence to argue that, in the case of a manufacturer of a component of the final product, the defect is attributable to the design of the product or to the instructions given by the product manufacturer. Secondly, it is a defence to argue that the defect is due to compliance with mandatory regulations issued by public authorities.

**Liability issues**

Once a plaintiff has shown that a product is defective and proved that the defect has caused an injury, the producer is liable in damages. The producer’s liability is not reduced if the injury is caused by both a defect in the product and a third party act or omission. However, it may be possible to reduce the level of liability if the injured party is responsible for, or contributed to, his or her injury.

**Limitation**

It is also worth noting that liability will expire after a certain period. Under the directive, an injured person has three years to seek compensation from the date on which they first became aware of the damage, the defect and the identity of the producer. In addition, the producer’s liability expires ten years from the date on which the product was put into circulation.

There have been a few cases that have considered the issue of limitation. In the English case of *Horne-Roberts v SmithKline Beecham*, a claimant, seeking compensation for injury alleged to have been caused by the MMR (measles, mumps, rubella) vaccination, brought an action against Merck, based on an error in identifying the batch number for the relevant product. After proceedings had commenced, the claimant realised the error and attempted to sue the correct manufac-
turer, SmithKline Beecham. However, this was after the ten year long-stop period. The English courts were obliged to consider whether or not to allow substitution of the defendant. The court held that the claimant should be given a ‘reasonable length of time’ to commence proceedings and exercised its discretion to allow the defendant to be substituted after the ten year period had expired.

(Editor’s note: the European Court of Justice (ECJ) is currently considering similar issues in a case involving a claim for injury alleged to have been caused by another vaccine. This case is likely to provide additional clarity on courts’ discretion to allow cases to proceed after the ten year long-stop period. In C-127/04 Pending Case, Master Declan O’Byrne, the plaintiff mistakenly sued Aventis Pasteur MSD, rather than the producer of the vaccine, Aventis Pasteur SA. The ten year limitation period had expired before the mistake was realised. The UK courts requested clarification from the ECJ, which has yet to rule. In advice that will be presented to the court, an advocate general suggested that there may be some discretion to allow the case to proceed, since Aventis Pasteur MSD failed to identify Aventis Pasteur SA as the producer within a reasonable time. The advocate general’s opinion is not binding on the ECJ, but the court follows his advice in about 70% of cases.)

**Divergent implementation and directive reform**

It should be noted that, whilst member states have implemented the directive by way of national legislation, the product liability regimes at national level cannot be described as entirely uniform. This is due to two factors: the derogations permitted by the directive and the product liability regimes which pre-existed the directive in some member states.

In their implementing legislation, Greece and Portugal omit Article 4 of the directive which requires the injured party to prove the causal relationship between the defect and the damage suffered. Most member states have included the development risks defence in their implementing legislation, but it is not available in Finland or Luxembourg, and available within certain parameters in both France and Spain.

Certain member states place a cap on the level of damages available to consumers. Germany’s *Produkthaftungsgesetz* (the German national law implementing the directive) has a financial ceiling of €85 million for a producer’s overall liability for cases arising from the same defect. In some member states, there has been a tension between the directive and the pre-existing product liability laws. Some member states have special industry-specific systems which run parallel to the directive, such as Germany’s *Arzneimittelgesetz* (Drug Law), which governs personal injuries arising from pharmaceutical products.

The issue of pre-existing product liability law is demonstrated by the case of *Sanchez v Medicina Asturiana*. Ms Sanchez received a blood transfusion from a medical centre owned by the defendants and claimed to have been infected with Hepatitis C. She sought compensation under both the previous Spanish legislation and the Spanish law implementing the directive. The Spanish courts referred the case to the ECJ for guidance. The ECJ ruled that the directive is a maximal harmonisation directive, expressly preventing consumers from taking advantage of any greater degree of protection afforded by an existing national general product liability regime. Ms Sanchez could not, therefore, recover compensation under the earlier Spanish law.

The European Commission is taking steps to reform the directive. In July 1999, a Green Paper was published, followed by a 2001 Report on the Responses. Studies have been commissioned on both the practical impact of the directive in member states, and the economic impact of possible removal of the development risks defence. An expert working group was set up by the commission in 2004 to consider reform and a formal report is expected in 2006.

**Medical device liability issues**

As outlined above, medical devices can be defective in a number of ways. Defects may arise by virtue of inadequate manufacturing, design or storage of a product. However, the vast majority of defects arise by virtue of inadequate instructions for use or warnings for products, or statements made during the marketing or promotion of devices.

**Adequate warnings**

A frequent question is whether adequate warnings can render an ‘unsafe’ device ‘safe’. If you bring to the attention of the relevant users or consumers risks associated with the device can they make appropriate treatment decisions? What constitutes an adequate warning? This is a difficult issue, and is ultimately a question of fact in each case. There will be a significant number of ethical, legal, regulatory and business aspects to any product’s labelling. For example, the safety profile of a product can often be a benchmark of its commercial success. On the other hand, lawyers and those

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**Legal Feature**

Although member states have implemented the directive, some have omitted certain parts or have their own systems running in parallel.

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Can an adequate warning render an ‘unsafe’ device ‘safe’?
considering potential product liability issues will favour labelling that affords a company the maximum possible protection from potential claims.

Legal requirements
As a minimum, companies should always ensure that they comply fully with applicable legal requirements and standards. The essential requirements for product labelling, information and warnings are found in the annexes to the relevant medical device directives\(^\text{16}\). The directive relating to *in vitro* diagnostic (IVD) medical devices and the directive relating to medical devices each provides that it is an essential requirement for a device to be accompanied by the information necessary to use it safely and properly, taking into account the training and knowledge of the potential users. As far as practicable and appropriate, this information should be on the device itself. If this is not practicable, the directives give manufacturers some flexibility to include information on the packaging and/or instructions for use supplied with the device. The label must contain any particular operating instructions, warnings and/or precautions to take when using the device. The instructions for use must contain warnings and ‘detailed’ procedures for using the device.

The directive relating to implantable devices provides that such a device must be accompanied by information, constituting the instructions for use, allowing the physician and, where appropriate, the patient to use the device, its accessories and software correctly. If appropriate, the instructions for use must also enable certain risks, in connection with implantation of the device, to be avoided. The instruction leaflet must include details allowing the physician to brief the patient on the contra-indications and the precautions to be taken.

European standards
Medical device manufacturers are permitted to rely on various standards that would assist them in complying with these essential requirements. Compliance with relevant European standards raises a presumption of conformity with the relevant essential requirements, but it is important to note that this presumption is rebuttable. In particular, compliance with a standard does not necessarily mean that your company’s labelling and/or instructions for use are not defective. A claimant’s lawyer could argue that, despite compliance with the relevant standards, the labelling of a product is still inadequate.

The essential requirement under the directives is that manufacturers take into account the likely users of a medical device, and this is reflected in some of the standards. For example, European standard EN 591:2001\(^\text{17}\) contains standards for instructions for professional use of IVDs. This allows manufacturers of IVDs to provide information as a user manual, built-in software, audio or video recording or other electronic means. It requires warnings and precautions related to any special, unusual risks relating to the installation, operation, maintenance, transportation or disposal of a device, any known interferences and uses not recommended by the manufacturer.

Professional use
European standard EN 375:2001\(^\text{18}\), for information accompanying IVD reagents for professional use, requires that suitable instructions for use be displayed on the relevant container or provided with the equipment. However, manufacturers may include a reference to instructions provided by other means: ‘[i]mmediate access of the user to the complete instructions for use can be ensured by means of an electronic databank (Internet) or a free of charge return telefax system.’ Warnings must also include ‘risks resulting from misuse which may reasonably be anticipated’.

Patient use
There are a number of key differences where instructions for use accompany IVDs-testing. European standard EN 376:2002\(^\text{19}\) requires that devices for self-testing must be accompanied by instructions for use, which must be easily understood and applied. In practice, companies should attempt to generate labelling that would be intelligible to a reasonably educated nine-year old. These instructions for use must include any special warnings and precautions, including risks resulting from misuse which may be reasonably anticipated. The key difference here between professional-use and self-testing IVD instructions is that there is no option to use any form of electronic media for self-testing devices.

Reducing liability
While product liability risks can never be entirely eliminated, there are a number of measures that manufacturers can put in place to reduce these risks.
Device vigilance
The most important of these is to ensure that the company fulfils its device vigilance obligations. It should create systems to collect and report information about adverse incidents occurring with its products and to take appropriate corrective action, all within the relevant regulatory timelines. Manufacturers should prepare and rehearse crisis management and recall plans to deal with the possibility that a product recall is required. These should be regularly updated, at least annually.

Contractual liability
Manufacturers should ensure that they enter into contractual arrangements with their suppliers and customers that exclude liability for injury (where legally appropriate) and ensure compensation or indemnity in the event that the manufacturer suffers loss due to that party’s negligence or supply of defective products or components.

Document management
Manufacturers should also be conscious of the way in which they communicate internally about safety issues. In the event of a claim, it is likely that adverse incident reports for a product and/or relevant internal correspondence will be discloseable to the claimant’s lawyers. Manufacturers will need to consider, document and discuss emerging safety issues with their products and the corrective actions that a company might take. However, the company should avoid doing so in an emotive, ill-considered manner. They should also limit the use of e-mail correspondence on such issues, where possible. It is tempting to use e-mail as an alternative to telephone conversation, and people tend to use e-mail to express views that they would otherwise not express in formal memoranda or reports. By their nature, e-mails are easily transmittable and it is common for them to become far more widely circulated than the original author may have anticipated.

As a general rule, companies should put in place guidelines for employees dealing with safety-related and/or product liability issues. A useful guide is to assume that an interested third party is reading everything that they produce over their shoulder.

Interactions with regulators
If, following a review of adverse incident reports, a company feels that a change in labelling is required, it should implement this as expeditiously as possible. Unfortunately, from a product liability perspective, labelling changes often require regulatory, or at least notified body, approval. This can result in delay. During this review period, the company may still be strictly liable for injury caused by a failure to provide adequate warnings. However, prompt corrective action will reduce this risk and liability for negligence.

International labelling
The medical device directives allow member states to require user information to be provided in the relevant national languages, regardless of whether a device is for professional or other uses. Some member states, like Germany, Norway and Luxembourg, have exemptions that allow for English language labelling where devices are for professional use. However, not all member states have such exemptions. This means that a company must theoretically include instructions for use in over 20 languages if it intends to market a product throughout the EEA. It can either do so on the basis of individual national labelling or attempt to produce a form of labelling that includes all relevant languages. In practice, however, many manufacturers limit the languages they include to five or six. These will often be English, French, German, Italian, Spanish, and possibly Portuguese. This approach is associated with an inevitable degree of product liability risk, and companies must assess the likelihood of product liability claims against their product before omitting labelling in particular languages.

The other key issue from an international labelling perspective arises from differences in labelling from jurisdiction to jurisdiction. The fact that different operating companies or partners may market products in different jurisdictions, with separate applicable laws and product liability risks, often results in labelling variations from one jurisdiction to another. Where possible, these differences should be avoided or reduced, since this may be used to try and demonstrate that a company has been negligent and/or that labelling in at least one of the jurisdictions is defective. Claimants’ lawyers are becoming increasingly focused on differences between labelling when pursuing product liability claims.

The situation in the US
Despite everything that has been said in this article, product liability risks in Europe remain modest. The strict liability regime under the directive has been around for many years now, but there...
have been relatively few cases. Product liability risks in the US, however, cause serious concern. In that jurisdiction, it is negligent per se to fail to report adverse incidents. If labelling becomes inadequate as a result of this failure, the company will be liable for resulting injuries. Moreover, under product liability laws in many states, a violation of a criminal law is likely to result in the award of punitive damages. If a company fails to report correctly, there is a real risk that a jury will be asked to award a level of damages that is deemed to punish the company. Punitive damages are often very significant.

Even though these risks are primarily US risks, it is important to note that a company’s performance of device vigilance in Europe can affect products sold in the US. There are small but clear differences between the adverse incident reporting requirements for devices in Europe and the US. In general, more adverse incidents are reportable under US law than in Europe. It is therefore crucial that companies implement procedures and systems that ensure the sharing of all relevant safety data within a time frame that allows the parties to fulfil their reporting obligations and take appropriate corrective action.

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