

The International Comparative Legal Guide to:

Product Liability 2008

A practical insight to cross-border Product Liability work



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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

According to the Austrian system, product liability may arise out of the general tort law, the contract law and out of various specific liability regimes, such as the Genetic Engineering Act. Depending on the general concept behind the various regimes, product liability can be based on the concept of fault or strict liability.

Product liability based on the Civil Code contract provisions will only be of relevance if the purchase of a product does not qualify as a consumer transaction; otherwise the Product Liability Act applies (Produkthaftungsgesetz, BGBl No. 98/2001, as amended).

In addition, since the introduction of the Product Liability Act (PLA), which provides for strict liability, relying on general tort law will only make sense if the statutes of limitations provided by the PLA have already expired.

The PLA implements the European Directive 85/374/EEC on Liability for Defective Products (the Directive). As required by the Directive, the PLA contains a strict liability system and provides for stricter limits on recoverable damages, and also on the persons liable, as compared to the general tort system.

1.2 Does the state operate any schemes of compensation for particular products?

The Act concerning Compensation for Vaccination Damages (Impfschadengesetz, BGBl 371/1973) operates a compensation scheme for damages caused by certain vaccines. Recoverable are damages caused by vaccinations that are, among others:

- either recommended by the “mother-child-passport”;
- recommended by a regulation issued by the competent minister; or
- ordered by an administrative authority based on §17 of the Pandemic Law (Epidemiegesetz, BGBl 186/1950).

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

According to the PLA, the responsibility for a defective product is

placed on the manufacturer. The manufacturer could either be the entrepreneur manufacturing the product, importing it into the European Economic Area or marketing the product, if the latter fails to disclose the name of the actual manufacturer or importer in due time.

Under the tort concept, every person within the production and distribution chain could potentially be liable. Contrary to the regulations of the PLA, the supplier may even be liable, irrespective of whether the manufacturer can be identified.

Liability could also arise out of the breach of statutory or regulatory duties. In such a case, the person violating the relevant provision could be held liable: for instance, persons covered by the Food Safety and Consumer Protection Act (Lebensmittelsicherheit- und Verbraucherschutzgesetz, BGBl 13/2006) or the Product Safety Act (Produktsicherheitsgesetz 2004, BGBl 16/2005).

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The Food Safety and Consumer Protection Act (LMSVG) and the Product Safety Act regulate under which circumstances a product shall be recalled. According to the Product Safety Act, a product must be recalled if (i) the product under normal and reasonably foreseeable conditions of usage presents a risk, or (ii) does not have the minimum risk compatible with the product’s use considered to be acceptable and consistent with a high level of protection for the safety and health of persons. In addition, if food products violate the standards laid down in the LMSVG, the relevant authorities may also order a recall of the products.

1.5 Do criminal sanctions apply to the supply of defective products?

Persons placing for instance food products on the market, which cause damage to health can be held responsible under the Criminal Code (Strafgesetzbuch, BGBl 60/1974, as amended). The sanctions can be up to one year imprisonment or a financial fine up to 360 daily rates. The amount of the daily rate depends on the income of the person or turnover of the company. For products placed on the market contributing to the spreading of infectious diseases the fines are increased to two years imprisonment and, if a person dies, up to three years imprisonment. In addition, the criminal court may order that the relevant judgment be published in a newspaper. Also legal entities can now be prosecuted under criminal proceedings.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The claimant has to prove the damage, the defect, causation and that the product was placed on the market by the manufacturer. The defendant, if relying on the defence that the product was not defective when placed on the market, must prove that the defect that caused the damage did not exist at the time when the product was put into circulation, or that such defect came into being afterwards. In addition, the defendant may also prove that he was not the entrepreneur placing the product on the market and may nominate the actual person placing it on the market.

Under the tort concept, claimant must prove damages, causation, unlawfulness and, in addition, negligent conduct of defendant.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The test to be applied is the so-called “*conditio sine qua non*” test meaning that the question to be answered is: would the damages have occurred if the product had not been defective? If the answer is affirmative, no liability will exist. In general, it is not sufficient for the claimant to show that the product exposed claimant to an increased risk. However, if the event follows an established typical course, the Austrian courts consider it sufficient to prove causation by a *prima facie* evidence. This means that the claimant must simply convince the judge that according to general knowledge and understanding the event followed a general course and, therefore, it is more likely that the damage was caused by the defendant than by other means. The concept of *prima facie* evidence aims at reducing the burden of proof, but of course, this *prima facie* evidence can be counter evidenced by the defendant.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

The Austrian system does not recognise the concept of market-share liability. However, under certain circumstances joint and several liability could arise, namely if the damages cannot be attributed to one specific person or if two or three persons were intentionally working together to harm the injured person. This concept might perhaps apply to situations where it cannot exactly be established what product caused the harm, but it will definitely not apply when the claimant cannot even allege which product he has actually used.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

A product is defective in the meaning of the PLA if it does not provide the safety that a person is entitled to expect. Therefore, a failure to warn could be considered as a defect. The warnings must generally be of such a nature that the risks associated with the product must be described to the greatest possible extent. Any inconsistencies will be held against the party issuing the warning. In general, the concept applied is whether an average and well-informed consumer would have been reasonably warned about the risks. However, the court decisions in Austria are normally in favour of consumers.

If the product is intended to be used by professionals, the standard could be lower. However, if the manufacturer is aware that the professionally used product is also constantly used by consumers, for avoiding liability, the manufacturer should provide more detailed information.

There is no learned intermediary rule under Austrian law. Consequently, warnings given to physicians normally do not release a pharmaceutical company from providing sufficient warnings to patients. However, it must be specifically taken into account that certain warnings due to the lack of appropriate scientific proofs are not allowed to be included in the package leaflet. Therefore, in product liability cases the warnings provided in the summary of product characteristics as well as in the package leaflet must be seen as supplementing each other. According to at least one case in Austria, although certain information was not contained in the package leaflet, the manufacturer was not automatically held liable. The Supreme Court stated that the lower court must still establish whether the patient would not have taken the product although recommended by her physician. Therefore, for undermining causation, the learned intermediary defence can be tried.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the PLA the following defences are available:

- the manufacturer did not place the product on the market;
- the manufacturer can prove that the product did not have the defect causing damages at the time the product was placed on the market or the defect came into being afterwards;
- the product was not intended for sale;
- the manufacturer complied with specific mandatory regulations issued by public authorities when manufacturing the product;
- the state of scientific and technical knowledge at the time when the manufacturer placed the product on the market was

not such as to enable the existence of the defect to be discovered; or

- in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instruction given by the manufacturer of the product.

Under tort law, all defences are available that allow defendant to disprove causation, that the manufacturer was not violating any protective laws, etc.

- 3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?**

Austria has implemented the development risk defence as provided for in Article 7 of the Directive. Most legal scholars in Austria assume that this defence will be only available in rare cases, because of the case C-300/95, European Commission vs. the United Kingdom. Advocate General *Tesauro* stated that the state of scientific knowledge cannot be identified by relying on the views expressed by the majority of learned opinion, but by taking into account the most advanced level of research, which has been carried out at the relevant time. Consequently, publications in a Chinese local journal would still allow a manufacturer to rely on this defence; however, if the article was published in an English journal, the manufacturer could not rely on this defence any longer. Therefore, the requirements to be met are extremely high and it is doubtful whether any company could reasonably meet them.

- 3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?**

Compliance with regulatory and/or statutory requirements constitute(s) only a defence when the manufacturer was specifically ordered to comply with these standards. Compliance with “general” authorisations, such as marketing authorisations for medicinal products or with a CE marking in the medical devices fields does not constitute a defence under the PLA. However, this is a suitable defence under the general tort concept.

- 3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?**

If a judgment rendered between the same parties becomes valid, the claimant can generally not re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage again (some rare exemptions apply, e.g. the first judgement is based on fraudulent evidences). The principle “ne bis in idem” prevents a court from ruling again on an identical claim. The second judge must dismiss the claim if the new claim contains the same requests and is based on the same facts used in the old proceedings. Because a court’s decision is binding only between the involved parties, a different claimant can re-litigate any issues of fault, defect or causality. However, if the Supreme Court has for instance already decided that under certain circumstances a product was not defective, a lower court will generally follow this ruling.

Because fault, defect and causation are questions of law and not of facts, the same claimant can re-litigate these issues provided that he is relying on different facts.

- 3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?**

Manufacturers who only provide raw materials or a part of the finished product will only be held liable if their contribution caused the damage. The plaintiff can freely decide whether the plaintiff relies on the final manufacturer or on the person providing the raw material or parts of the finished product. However, such a claim could fail due to the fact that the final manufacturer is not required to provide the claimant with the name of such an intermediate manufacturer.

Of course there is a possibility to initiate subsequent proceedings if one court rules that the final manufacturer is not liable. Also, it is possible to interplead third parties. However, the ten-year statute of limitations must be met (i.e., an actual action against the third party must be filed in due time). Consequently, if ten years have already elapsed, a claim based on the PLA can no longer be filed. In such a case, the claimant must rely on the general tort concept which is more burdensome for the claimant.

- 3.6 Can defendants allege that the claimant’s actions caused or contributed towards the damage?**

The PLA allows that the liability of the manufacturer may be reduced if the damage is (partially) caused by the fault of the injured person or any other person for whom the injured person is responsible. The same principle also applies under tort rules.

4 Procedure

- 4.1 In the case of court proceedings is the trial by a judge or a jury?**

In civil court proceedings, the Austrian system does not know a jury system. The proceedings are handled by career judges.

- 4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?**

The judges will often invite technical experts to participate in the court hearings and to ask questions to parties and witnesses. Legally, the facts are assessed by the judge. In practice, the judge will often rely on expert opinions containing also a summary of facts recorded by the expert.

- 4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure ‘opt-in’ or ‘opt-out’? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?**

Currently, no group or class actions are permissible under the Austrian legal system. However, the Minister of Justice is

considering to implement some sort of group proceedings. A first draft was submitted to Parliament in Summer 2007, but was heavily criticised by the major stakeholders (e.g. for restricting the right to be heard before the court). It is expected that an amended draft will be re-submitted to the Parliament in the course of this year. The draft law, as it stands now, would provide for an “opt-in” option.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

In product liability proceedings, claims cannot be brought by representative bodies, such as consumer associations. However, also here the Ministry of Justice wants to allow such proceedings, where the consumer association can apply that one pending proceeding is classified as “model case proceedings” because the legal issues involved could be relevant for a huge amount of claims filed against the same defendant.

4.5 How long does it normally take to get to trial?

Austria does not have a pre-trial stage. After the claim is filed, the defendant normally has four weeks to respond. After the court has received the response, it normally takes one to two months for the first hearing to take place.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The Civil Procedure Code (Zivilprozessordnung, RGeB. No. 113/1895, as amended) does not provide for the court to try preliminary issues first. Under certain circumstances, the parties may request that, for instance, the judge first issues an interim award with respect to the merits, and only afterwards the amount of the damages to be awarded will be established.

4.7 What appeal options are available?

The first instance judgment can be appealed to the appellate court (there are certain restrictions, however, regarding disputes not exceeding EUR 2,000).

A further appeal to the Supreme Court is admissible if the matter in dispute relates to a matter of substantial or procedural law which is of utmost importance for the consistency or legal certainty of the law, or contributes to a further important development of the legal system. In general, no appeal to the Austrian Supreme Court is admissible if the matter in dispute does not exceed EUR 4,000.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

If a judge does not have the required technical and/or scientific knowledge, the judge can appoint an expert. In general, a judge will allow the parties to comment on the expert selected by the court. The expert is instructed to provide a written opinion on technical and scientific issues, and if so requested, he must also draw a conclusion and provide a thesis.

Parties are allowed to rely on their own experts. However, reports submitted by a party expert are not considered as expert opinions in

the meaning of the Civil Procedure Code and are, therefore, of lesser importance. Private expert opinions are normally used to undermine the court expert report because, for instance, the expert report did not discuss all the issues at stake or is not in line with the opinion of the parties. In general, private expert opinions are not submitted before the court appointed expert has rendered his/her opinion.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There is no pre-trial deposition proceeding in Austria. In general, no expert reports are exchanged before the trial has started.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

In Austria no discovery procedure is available. Consequently, the parties are not required to disclose any documents before the trial has started. However, if a party relies in the proceedings on a specific document, the document must also be given to the other party. In addition, if the document is considered a joint document, for instance, contracts signed by both parties, and it is in the possession of the other party, the possessing party must furnish the other party with this joint document. Only under very limited circumstances could a party legally enforce the provision of such documents. If such document is not provided, the judge will normally hold this against the refusing party.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

In general, alternative methods of dispute resolution are available, but are not relied upon in practice. Sometimes the so-called *Patientenanwaltschaft*, comparable to a patient ombudsman, intervenes on behalf of a patient and tries to achieve a settlement.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

The Civil Code as well as the PLA provide for statutes of limitations.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

With respect to time limits on starting proceedings, it must be distinguished between the relative statute of limitation period and the absolute statute of limitation period. The relative limitation period of three years begins to run from the day on which the claimant should have reasonably become aware of the damage, the defect and the identity of the manufacturer. Under tort rules, the absolute statute of limitation period will be 30 years after the incident of dispute occurred, under the PLA, this time period is reduced to 10 years. With respect to the latter, the starting point will be the day when the product was placed on the market.

Contractual warranty claims, such as a claims due to the delivery of products not suited for the agreed purpose, must be lodged within two years.

Only if raised by defendant, the judge must take into consideration the statute of limitation period and dismiss the claim. Under certain circumstances the time period provided for by law can be suspended, for instance, if the parties conducted settlement negotiations. However, such settlement negotiations must be concrete, meaning that there must be at least an exchange of different proposals (rather than one party alleging liability and the other party denying liability).

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Concealment or fraud does generally not affect the running of any time limit. However, because the time limit will only start to run from the actual knowledge of the damage and the person inflicting such damage, concealment will simply result in a later filing of the claim after the facts have surfaced.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Under the PLA the same remedies are available as in normal civil court proceedings, such as monetary compensation, declaratory relief, e.g. for all future damages. It would also be possible to file a cease and desist claim, but this is never done in PLA proceedings.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The tort law as well as the PLA cover both monetary and non-monetary losses. Compensation for personal injuries include, among others, the cost for medical treatment, loss of income, etc. Furthermore, damages can be awarded for suffering of pain due to the loss of a close relative. Damages awarded in Austria are much lower than in the United States. For instance, for a man whose arms and legs are paralysed, needs artificial respiration until he dies and he is completely aware of his situation, the Supreme Court awarded an amount of approximately EUR 218,000.

Mental damage as well as so-called disfigurement damages must also be compensated.

Damages to property are generally recoverable under all three regimes, but restricted under the PLA to damages exceeding EUR 500 (i.e., there is a deductible of EUR 500). Under warranty law, damages to the product itself are generally not recoverable, except for damages that have spread to the non-defective portion of a purchased product from a defective part.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Under the PLA such damages cannot be recovered because one of the requirements to be met by claimant is to prove that damages actually occurred.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

The Austrian legal system does not recognise punitive damages. A foreign judgment granting punitive damages would not be enforceable in Austria (violation of the *ordre public* principle).

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There are no caps on damages under the PLA.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

As mentioned above, Austria does not (yet) have the concept of group or class actions. Claims filed by infants need the approval by a judge and are filed on behalf of the infant by his/her legal representatives.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

The award is only binding between the litigating parties and so payment is only effected between the parties. The government/reimbursement institutions cannot claim any part of the damages awarded to an individual person. In practice, if a unfavourable decision is rendered for a company, sometimes the insurance bodies approach the company requesting to be compensated for the treatment costs.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

According to the Civil Procedure Code, the successful party is reimbursed for its necessary legal costs and court fees by the losing party. Recoverable costs will be calculated in accordance with the lawyers' tariff, which is based on the value of the claim.

7.2 Is public funding e.g. legal aid, available?

Legal aid will be granted to physical persons and, in limited circumstances, to corporations. However, the person getting legal aid must still pay the costs of the other party if the other party prevails. Legal aid consists of a waiver of court and expert fees and free representation by an attorney appointed by the bar association.

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid will only be granted if a party does not have sufficient

financial means to conduct the proceedings. In addition, the judge approving legal aid must evaluate whether the claim has sufficient prospect of being successful. Under certain circumstances, e.g. if the financial situation has favourably changed, the legal aid must be paid back.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Austrian attorneys are prohibited from working on a contingency fee or on a “no win - no fee” basis. It is admissible to agree on a bonus for successful work.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding of claims is permitted under Austrian law. In general, a request is sent to a private company asking for financial assistance, which will normally only be granted if the amount in

dispute exceeds a certain threshold. Based on the expected outcome, the compensation for the private financier is between 20% to 50% of the awarded amount.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Austria.

Due to the coming into effect of the Rome II-Regulation concerning the law applicable to non-contractual obligations the substantive law to be applied in an international context will be further clarified. In addition, it will be seen, if implemented at all, the proposals of the Ministry of Justice concerning model actions and group actions have an impact on product liability cases, especially if the product was widely used. Still some clarification is needed in the case of product liability and off-label use of medicinal products.



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FPLP’s life sciences team is unique to Austria, combining outstanding expertise and experience in the field. FPLP regularly represents national and multinational life sciences companies, in particular concerning pharmaceutical and food law. FPLP advises on all regulatory matters, in particular concerning market authorisations and advertising of medicinal products as well as the inclusion of pharmaceutical products into the list of reimbursable drugs. Another focus of FPLP’s life sciences practice is IP and competition matters including, in particular all aspects of patent law and protection, litigation, unfair competition and anti trust matters. Other areas covered by the life science team include borderline issues, medical devices and dietetic products.