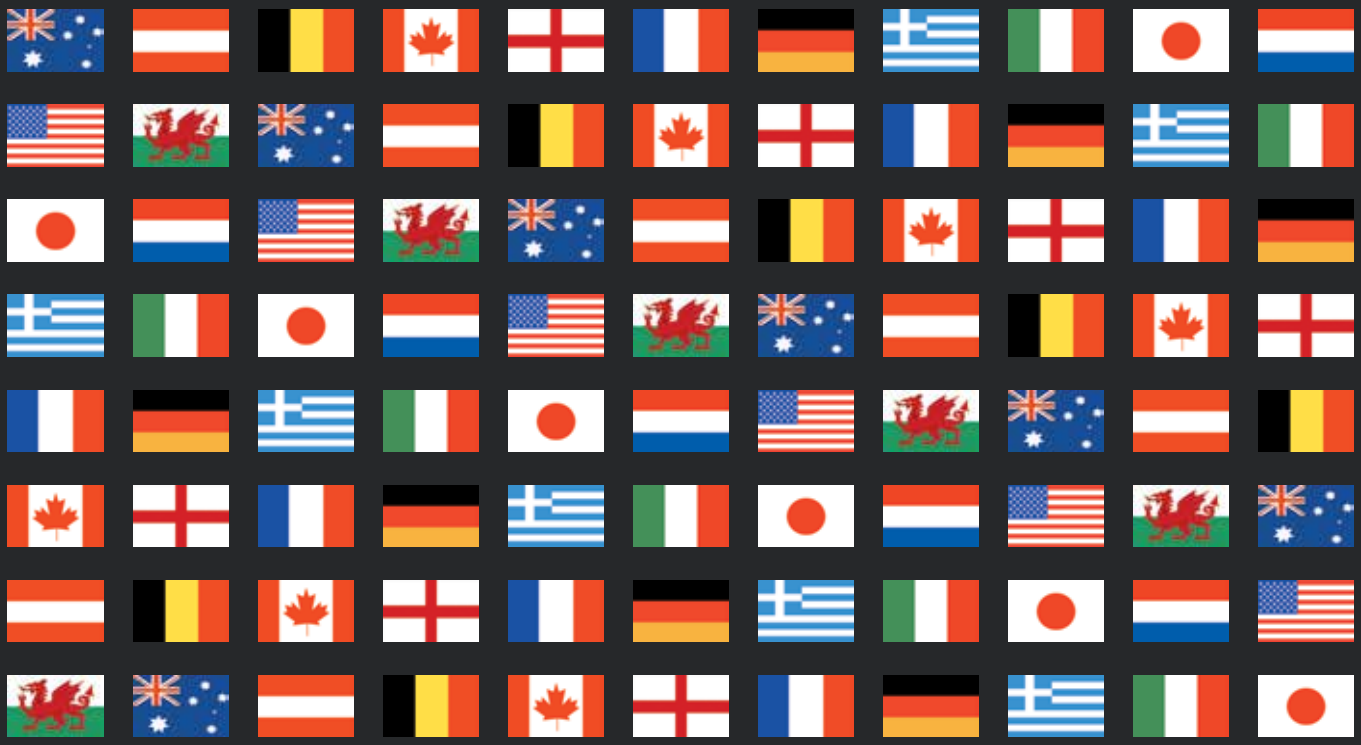
Product Recall

Contributing editors
Alison Newstead and Harley V Ratliff



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GETTING THE DEAL THROUGH

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Product Recall 2016

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Austria

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

In Austria, as in other EU member states, product safety requirements are governed by EU directives, EU regulations and various types of national legislation. The main rules at a national level regarding product safety are found in the Product Safety Act of 2004 (PSG 2004) (BGBl I No. 16/2005), which implements the EU General Product Safety Directive 2001/95 (Directive 95/2001 EC) into national law. The PSG 2004 is now the primary source of product safety regulations and requires that producers shall not place products on the market unless they are safe and are provided with appropriate warnings and proper instructions for their use. Furthermore, the PSG 2004 also functions as a subsidiary law, when products are not covered by more specific legislation and thereby sets minimum product safety requirements.

Such legislation exists for various categories of products, like drugs (AMG) (BGBl No. 185/1983), medical devices (MPG) (BGBl No. 657/1996), food (LMSVG) (BGBl I No. 13/2006), chemical products (ChemG 1996) (BGBl I No. 53/1997) and building products (BauPG) (BGBl I No. 55/1997).

Apart from EU directives, which are usually implemented into national law, there are also EU regulations like the EU General Food Regulation (Regulation EC No. 178/2002) or the EU Regulation on Medicinal Products (Regulation EC No. 726/2004). These are directly applicable in the member states and are therefore binding for manufacturers and importers without further need of adaptation into national legislation.

2 What requirements exist for the traceability of products to facilitate recalls?

For consumer products, the PSG 2004 gives examples of how manufacturers and importers can ensure that a product recall or a withdrawal from sale will be executed sufficiently. These include measures like an appropriate designation that enables the identification and traceability of the respective product and its manufacturer. Furthermore, it imposes a duty on distributors (ie, others in the supply chain) to keep and provide the documentation that is required to trace back products.

Upon special request of the competent authority, heads of medical services and supervisory medical personnel shall provide information of official observations, if they have reasonable doubt in connection with accidents or an illness that a product does not comply with the safety requirements of the PSG 2004.

Some sector-specific legislation contains more detailed regulations. For example, the LMSVG requires that producers guarantee the traceability of food, feed, food-producing animals and any other starting product that is intended to be processed to food, at all stages of the supply chain (production, processing and distribution).

Also, the special provisions on drugs, medical devices, building products and chemical products set out stricter rules than the PSG 2004, as they require labelling of the product or packaging with, at least, the name and the address of the producer.

3 What penalties may be imposed for non-compliance with these laws?

Disobedience of product safety regulations can result in serious consequences, including criminal prosecution that may lead to imprisonment in severe cases or penalties of up to €100,000. Furthermore, the competent authority can undertake unilateral measures to ensure the enforcement of the law, including a ban on sales, mandatory product recalls, confiscation of suspicious goods, or imposing extensive information duties on the manufacturer or importer. These governmental powers are explained in greater detail at question 19.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

The competent authorities must be notified without undue delay if manufacturers, importers or distributors become aware (or should become aware through their ordinary conduct of business) of the information that a product they market may not comply with the safety requirements of the PSG 2004 and, therefore, may pose a risk to consumers. Furthermore, the PSG 2004 imposes an obligation on all health protection and safety prevention federal executive bodies and statutory accident insurance institutions to report to the competent national minister, if they assume through official observation that a product may not fulfil the safety requirements of the PSG 2004. There are again more specific notification requirements for highly regulated products like drugs, food or chemical products.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

The main criterion for all products is that it is not regarded as safe anymore (ie, it is not meeting the respective safety requirements) and is therefore creating a hazard to consumers. There are indications in the sector-specific laws mentioned above that help the addressee to detect such a threat. Upon becoming aware of that information, he or she shall immediately and without undue delay inform the competent authority. There are no certain time limits in place that would determine a timely notification. In fact, this would be decided on the given circumstances of each case.

6 To which authority should notification be sent? Does this vary according to the product in question?

Notifications have to be sent to the competent authority. That does not mean that there is one competent authority in place for all product safety issues. Rather, depending on the product and the circumstances, there is a multitude of authorities on federal and provincial levels. The competent highest-ranking authority for products falling into the scope of the PSG 2004 is the Federal Minister of Labour, Social Affairs and Consumer Protection. In addition to that, the provincial governors are responsible for matters of market surveillance in that area. In practice, the person subject to the law can choose either of the competent authorities to fulfil its notification obligation, for the reason that the authorities themselves are obliged to coordinate their work and cooperate on all matters.

For the above-mentioned specially regulated products, the determination of the competent authority might be a more complex task. For example, the main authority for medical products according to the AMG is the Federal Office of Healthcare Security. In addition to that, several federal agencies and commissions and the Federal Minister of Health assist the main authority. Therefore, for the purpose of readability, the relevant authorities in that respect shall be defined herein as the 'competent authority'.

7 What product information and other data should be provided in the notification to the competent authority?

Austrian statutes do not provide particular requirements with regard to the details of the information that has to be submitted to the competent authority. As a general rule, the person obliged to notify the respective competent authorities could use the guidelines published by the European Commission (Commission Decision of 14 December 2004, 2004/905/EC) to ensure the effectiveness and comprehensiveness of its notification.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

Manufacturers, importers or distributors shall cooperate with the competent authorities to avoid hazards and risks to consumers. That means they have to provide information to the authorities, including product documentation, certificates or any other material that is needed to properly assess the risk of a product. Additionally the addressee shall answer enquiries of the authorities and shall provide product samples for further examination. As this duty is permanent and extensive, the manufacturer, importer or any other distributor is encouraged to provide updated and consistent information to the authorities; otherwise the authorities would have the right to take unilateral measures, if such acts are necessary to obtain the relevant information (see question 19).

Under the AMG, even more extensive duties apply. Every alteration to the data that was necessary for the registration of a certain pharmaceutical product has to be reported to the Federal Office of Healthcare Security. In addition, every severe side effect of a drug, especially lethal incidents, has to be reported immediately to the competent authority.

Similar obligations arise from the MPG, affecting healthcare professionals and persons with a licence to use and operate medical products.

A special provision applies to producers and distributors of toxically chemical products. If they become aware of the fact that a toxic product was wrongfully distributed or lost, they shall promptly notify the competent authority.

9 What are the penalties for failure to comply with reporting obligations?

Failure to meet the reporting obligations of the PSG 2004 is regarded as an administrative offence and is penalised with a fine of up to €3,000 or a subsidiary imprisonment if the fine is uncollectable. Again, depending on the product, higher fines could apply. For example, the fine for contravention of the AMG reporting obligations can be up to €7,500.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

Commercially sensitive information that comes to the knowledge of the competent authorities through the procedures set out in the PSG 2004 shall not be disclosed to the public unless it is necessary, after weighing the overall circumstances, to ensure the safety and health of consumers.

11 May information notified to the authorities be used in a criminal prosecution?

Information or facts provided to the authorities as part of the notification duties shall only be used for the enforcement of the PSG 2004 and shall therefore not be used over the course of criminal prosecution. In addition to that, the PSG 2004 explicitly refers to the statutory right to refuse self-incrimination. Following the word of the law, a person can choose not to testify, if the answer to a question would lead to criminal prosecution, direct financial disadvantages or would harm the reputation of that person. However, the criterion of financial disadvantage does not apply here, and, in addition, commercially-sensitive information is excluded from the right to refuse self-incrimination.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

Austrian statutes do not provide for specific criteria that would constitute a mandatory product recall. The main duty of manufacturers, importers and other distributors is to avoid any hazards or risks arising from their product. A proper risk assessment is therefore essential to take appropriate measures to ensure that goal.

As a consequence, the level of risk will directly affect the intensity of corrective actions that have to be taken. The principle of proportionality would be used to assign the right measure. A product recall as a matter of 'last resort' will therefore only be required in cases of high risk, meaning cases of the increased possibility of potential physical harm or even threats to the life of consumers. In minor, or less severe cases (ie, property damage only), other measures, like additional effective warnings, alteration of user manuals or the withdrawal of the product from sale may be reasonable enough to ward off any hazards from the customers.

If, however, the addressee fails to properly react to the danger or hazards from a product, the authorities would have the option to take unilateral measures, which may lead to mandatory product recalls. Again, a product recall would be regarded as a matter of 'last resort' and may only be imposed if other, less substantial, measures would fail to combat the respective risk.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

Manufacturers, importers and distributors have the statutory duty to monitor their products upon introduction to the market in order to detect hazards and dangers arising from their products timely and efficiently. It has been seen in a recent decision that the Austrian Supreme Court interprets the extent of this duty very broadly and obliged persons would therefore be well advised to ensure the effectiveness of their product-monitoring procedures.

According to the law, a manufacturer shall, first and foremost, notify the competent authority if it becomes aware that the respective product may be dangerous (ie, not meeting the safety requirements anymore). This is especially important for distributors of pharmaceutical products, as they are not allowed to disclose any information to the public without informing the Federal Office of Health Security beforehand. From that point the authorities will cooperate with the manufacturer, importer or distributor (whatever the case may be) to set coordinated measures. The principle of proportionality comes into effect, meaning that the authority should choose the least severe means to accomplish the intended objective. As set out in question 12, a public warning to product users may be sufficient in less substantial cases, whereas a product recall may be necessary if there is a potential danger of physical harm to customers.

However, cooperation with the competent authorities does not exclude the affected party from its duty to fulfil the respective product safety requirements. Even when a notification has been sent to the authority, the addressee will take appropriate and suitable measures, especially in the case where the supervisory body does not explicitly order any corrective action.

14 Are there requirements or guidelines for the content of recall notices?

The Federal Ministry would be authorised to set minimum requirements on the execution of product recalls by issuing an ordinance. Notwithstanding, there is no such ordinance in effect at present. As a second option, the relevant competent federal minister could, if the manufacturer, importer or distributor fails to comply with the safety requirements (ie, if he or she is not taking appropriate measures) charge the affected party with the obligation to conduct a proper and efficient recall. In this case, the minister could issue a scheme that would in practice set out specifically the content of such a recall notice and would determine the media that has to be used.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

Again, there are no specific statutes stipulating the use of certain media that must be used for a recall. The warning must be communicated in an appropriate and suitable way, in order to ensure its effectiveness, which means the chosen media will reach the affected customers comprehensively. For example, if the product in question is distributed nationwide, it is very likely that a nationwide publishing media channel would be used to reach the respective consumers.

In addition to that and as mentioned in the previous question, the competent authorities could impose the duty to conduct a mandatory recall, which will in most cases include the order to use specific media to publish the recall scheme.

Update and trends

In 2013 the European Commission issued a proposal for a new EU Regulation on Consumer Product Safety (COD 2013/0049). The planned regulation should repeal the General Product Safety Directive currently in place and provide a common and coherent framework for product safety and market surveillance in the EU. Despite intensive negotiations and efforts from all parties involved, the legislative process is currently on hold. This is mainly due to planned provisions on an obligatory designation of origin for the products. Whereas one group of EU member states argues that this may not be an issue for product safety at all; another group insists on the implementation of such rules. As by now, it is not foreseeable, when or if this disagreement will be resolved. However, if such a regulation will be enacted, yet another set of rules will apply to businesses operating within the common market.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

There are no specific targets or time periods at which a product recall is deemed to be sufficient. Rather, as already explained in detail, a product recall would then be regarded as successful if the manufacturer, importer or distributor can state that he or she has exercised duty of care in an appropriate and suitable way.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

Product safety regulation does not include rules on the reimbursement of costs incurred by the buyer of a recalled product. Rather, legislators regard this issue solely on the basis of contractual product warranties and the liability for defective products under tort law. Therefore a buyer could claim remedies like the reimbursement of the costs or the repair of a certain product under the conditions of the Austrian Civil Code, as he or she has the right to a product free of defects. The question as to what extent the manufacturer has to pay damages that are caused by the defect of the product has to be examined under tort law rules.

In practice, however, virtually all product recalls that have been facilitated to date included a procedure on the reimbursement of costs to the customer to warrant the effectiveness of the recall.

In addition, the provisions of the Product Liability Act (PHG) establish a system of strict liability on the manufacturers of defective products that lead to the damage or harm of objects and persons. Affected persons could therefore claim compensation for damages arising from a defective product. According to warranty law, it is furthermore possible to ask for the replacement or repair of the defective product itself.

18 What are the penalties for failure to undertake a recall or other corrective actions?

If manufacturers, importers or distributors fail to facilitate a prompt and efficient recall, which has been ordered by the competent authorities in accordance with the provisions on unilateral measures, they shall be subject to administrative penalties. These can lead to fines of up to €25,000 or subsidiary imprisonment if the fine is not collectable.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

Competent authorities have the ability to take unilateral measures if they are necessary to warrant a high level of health protection and security. As voluntary measures of the manufacturer, importer or distributor will have priority, the competent authority will therefore only act if the obliged person fails to comply with the respective safety requirements (ie, taking no or insufficient action). Measures taken by the authorities will furthermore meet the principle of precaution and proportionality. Therefore the authorities could act before a threat is evidently proven but will only do so by using the least severe means to ensure its purpose.

Particularly mentioned in the PSG 2004 are the following corrective actions:

- the obligation to amend or add user manuals, or the attachment of identification marks on the packaging;
- the obligation to add appropriate warnings and user guidance to avoid the realisation of hazards, in accordance with the urgency of the threat;
- the obligation to publish warnings or other urgent information on media channels suitable to reach respective consumer groups;
- orders and prohibitions with regard to matters of marketing of products;
- the determination of certain quality requirements, through declaring national or international norms to be mandatory;
- the obligation to certify the compliance with certain testing requirements;
- prohibitions or restrictions imposed on the distribution of products (eg, sale only to a selected group of persons);
- prohibitions or restrictions with regard to the export of products;
- requiring the immediate and efficient withdrawal of a product placed on the market from sale and, if necessary, destruction by appropriate means; and
- requiring the facilitation of an immediate and efficient recall of a product placed on the market, the publication of such a recall scheme in selected and suitable media channels and, if necessary, destruction with appropriate means.

This list, though extensive, is non-exhaustive. The federal minister will take such measures by issuing an ordinance, or, if such means address individuals, by issuing a decree directed to that individual.

In addition to that, the supervisory market surveillance bodies have the potential to take preliminary measures without issuing an ordinance or decree and without any prior proceedings (eg, a ban on sales, confiscation of goods and attachment of warnings to the product) if one or more of these requirements are fulfilled:

- a threat to the life or health of humans has been proven by a national or foreign official certified testing institution or by an hereto authorised civil engineer;
- there is the profound suspicion that the use of a product poses a serious threat to the life or health of humans;
- the distribution of a product is obviously contradictory to a measure imposed through the procedure as set out before; and
- the product in question was already subject to a measure imposed in an EEA member state and has been notified through the RAPEX system (ie, the EU rapid exchange system for consumer protection).

The supervisory bodies will only impose such temporary measures for the purpose of warding off an impending danger and will immediately notify the provincial governor thereof. As mentioned, these temporary measures lack a proper prior procedure. Therefore, the provincial governor will immediately issue a decree to ensure the legality of a measure and to open up the possibility for the addressee to appeal the decision (see question 23).

20 Can the government authorities publish warnings or other information to users or suppliers?

In extreme cases (ie, the manufacturer, importer or distributor does not take any measures to fulfil its safety requirements) the competent authorities have the ability to take unilateral measures as mentioned above, to ward off any risks to the public. If it is essential to ensure the safety of human life and health, the provincial governor may publish a warning to reach affected consumer groups by using appropriate media channels.

According to the PSG 2004, the public must be informed about dangerous products and especially about mandatory product recalls and other imposed unilateral measures, by appropriate means. The Federal Ministry of Labour, Social Affairs and Consumer Protection uses its website (www.bmask.gv.at/site/Konsumentenschutz/Produktsicherheit) to publish information about product recalls and product safety. Consumers have the ability to report any suspicious product with the help of an online application form that can be found at www.bmask.gv.at/site/Konsumentenschutz/Produktsicherheit/Melden_Sie_gefaehrliche_Produkte.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

As already set out in detail, the law gives preference to voluntary measures of manufacturers, importers or distributors. Only if the obliged party does not take any measure to avoid risks would the competent authority take unilateral measures, which may include an ordered, mandatory product

recall, to be facilitated by the addressee of the order. If the obliged party does not comply with that order, the competent authority would ultimately have the power to organise and facilitate a product recall as a matter of last resort. In reality, however, there has not been a single incident so far in which the competent authority would have used that power.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

It is explicitly stated that the costs of warnings that have been published in accordance with the procedure set out in question 20 have to be reimbursed by the distributor of the product. However, this is of little practical relevance, as the Austrian broadcasting companies are obliged to provide free broadcasting time to ward off dangers from the public. A second provision can be found on the costs that arise from the conduction of product examinations. The Federal Minister of Labour, Social Affairs and Consumer Protection could issue a decree, ordering the respective party to reimburse these costs, only if it is proven that the respective product does not meet the safety requirements of the PSG 2004.

23 How may decisions of the authorities be challenged?

As mentioned above, the execution of the power of authorities will be in the form of decrees. If, in the case of temporary measures explained in question 19, a decree has not been released within one month of the unilateral actions, the measure will be regarded as repealed and therefore no longer exists.

An addressee can appeal against a decree imposing measures like a mandatory product recall, or other measures mentioned in question 19, within two weeks with the competent local independent administrative senate.

Decisions over the appeal issued by the independent administrative senate may be subject to a separate appeal, by either the competent federal minister or the affected party, which subsequently can lead to a decision in favour or against the will of the addressee.

From next year, the respective independent administrative senates will be substituted by the new institution of administrative courts, who will follow similar rules with regard to the appeal of decrees.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

Austrian Civil Procedure Law does not have statutory rules of evidence but rather leaves the decision to the discretion of the court. Therefore, a safety warning or a product recall would not automatically prove the negligence of the producer. Nevertheless, the issuing of a safety warning or the facilitating of a product recall or a product withdrawal could indicate a certain wrongdoing of the manufacturer or importer and will therefore be most certainly used by the plaintiff to argue against the defendant.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Austrian civil litigation does not provide for a pretrial discovery stage. Therefore a party cannot be forced or compelled to disclose any of the documents in its possession. This means that each party in a lawsuit can decide whether to bring documents, information, evidence, etc, in front of the court. Therefore the plaintiff has to weigh its chances with the material available to it at the time, before the suit is filed.

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