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Defective Products: Managing a Product Recall in the UK and Beyond


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Introduction

As many businesses have discovered to their cost in recent years, the consequences of placing an unsafe or defective product on the market can be devastating. In addition to the potential criminal penalties and civil claims (including group actions), frequently in multiple jurisdictions, the business will face the often significant costs of recalling the affected products, and inevitable damage to its reputation and brand.

In this chapter, we set out the legal framework governing product safety and recall in the UK and provide practical guidance on managing a recall, both in the UK and other affected jurisdictions, so as to minimise legal liability and reputational damage.

The General Product Safety Regulations 2005

The main regulatory regime governing product safety and recall in the UK is set out in the General Product Safety Regulations 2005 ("**GPSR**"). These Regulations impose criminal liability on producers and distributors of unsafe products and require them to take corrective action (including, in some cases, recall) to mitigate risk to consumers created by their products.

The GPSR apply to all products that are not subject to sector-specific regulations (products subject to a specific regime include medicines/medical devices, food and drink, toys and cosmetics). Where any relevant matter is not addressed by a sector-specific regime, the GPSR "*fill the gap*". For example, some sector-specific regimes do not include an express power for the regulator to require a producer to recall unsafe products for which it is responsible. In such cases, the regulator can invoke the general power to order recalls set out in the GPSR.

The GPSR are implemented and enforced jointly by the Trading Standards offices of local authorities and by the Office for Product Safety and Standards ("**OPSS**"). As set out below, these bodies have the power to prosecute companies for placing unsafe products on the market and, in some circumstances, to require them to recall the products (or take other measures to mitigate the risk posed by the products).

The GPSR gave effect to the European General Product Safety Directive (2001/95/EC). Although the purpose of the GPSR was to implement EU law, they have always been part of the UK's domestic law and therefore remained in force post-Brexit.

General safety requirement

Producers

The main obligations under the GPSR are imposed on "*producers*" of products. "*Producer*" is defined broadly so as to include not only the manufacturer of the product (if it is established in the UK) but also: (i) any other business which presents itself as the manufacturer by putting its name, trade mark or other distinctive mark on the product; and (ii) any business which reconditions the product. Where the manufacturer is not established in the UK, "*producer*" is taken to mean: (i) any representative of the manufacturer in the UK; or (ii) if the manufacturer is not represented in the UK, the importer of the product into the UK; and (iii) any other professionals in the supply chain, insofar as their activities may affect the safety of a product.

The core requirement is that producers must not place any product on the market unless it is a safe product (Regulation 5). A safe product is defined broadly in Regulation 2 as one which, under normal or reasonably foreseeable conditions of use, does not present any risk or only the minimum risk compatible with the product's use.

There is a presumption that the general safety requirement is met where the product conforms to either: (i) any applicable specific health and safety requirements laid down by UK law; or (ii) a voluntary national standard of the UK, or a standard adopted by an international standardising body, which has been recognised by the UK government.

In many cases, it will be clear whether or not a product is unsafe but, in others, the complicated definition provided by Regulation 2 might allow room for uncertainty. Regulation 2 requires a range of factors to be considered in determining whether a product is unsafe, including:

- The characteristics of the product including its composition, packaging and instructions.
- The presentation of the product, its labelling, any warnings and instructions for use.
- The effect of the product on other products.
- Whether it poses a risk to vulnerable consumers, such as children and the elderly.

In addition, Regulation 6(3) provides that one factor in assessing whether or not a product is safe is "*reasonable consumer expectations concerning safety*". This underlines the point that different levels of risk will be acceptable in respect of different types of product.

There is a distinction in the GPSR between unsafe products that pose a "*serious risk* […] *requiring rapid intervention*" and those that do not. Severity of risk is determined through a structured risk assessment (discussed in more detail below). This distinction was, prior to 2021, primarily relevant to the government rather than producers, since the government was required to share information on products posing serious risks via the European RAPEX system. Following the end of the Brexit transitional period in December 2020, the UK no longer participates in RAPEX (we return to this below). However, the question of whether or not the risk posed by a product is "*serious*" is also relevant to producers (and distributors) because this may affect the speed with which they are expected to notify the authorities (as discussed below).

Under the GPSR, the very fact of placing an unsafe product on the market is itself a criminal offence. It is an offence of strict liability subject only to the defence of due diligence, which is discussed below. The maximum penalty is a fine not exceeding £20,000 or imprisonment for a term not exceeding 12 months, or both.

The local trading standards office and OPSS (as the relevant prosecuting authorities) will always have a discretion whether or not to prosecute. Our experience is that the authorities will normally choose not to prosecute where the producer is a reputable business and is seen to be taking responsible measures to address the risk created by the product. However, the fact that an offence will often already have been committed by the time the defect is discovered provides the authority with a helpful enforcement tool should the producer not take what the authority considers to be the required remedial action, or fail to do so in the way the authority wishes it to, or within its desired timetable.

Distributors

The equivalent obligation placed upon a distributor is not to supply (or possess for supply or offer or agree to supply) a product that it knows (or should have presumed on the basis of the information in his possession and as a professional) is a dangerous product.

In practice, it is more difficult for a prosecutor to establish that a distributor has committed an offence than it would be in respect of a producer. This is because it is necessary to prove knowledge or implied knowledge on the part of the distributor that the product was unsafe (whereas, for a producer, there is no such requirement). The maximum penalty is the same as for a producer: a fine not exceeding £20,000 or imprisonment for a term not exceeding 12 months, or both.

Duty to notify

One of the most difficult judgments to make in practice is when to notify the enforcement authority that a product is (or may be) unsafe. After a producer (or distributor) first becomes aware of a potential problem it will want to carry out tests, which can be time consuming, to determine: (i) whether there is in fact a safety defect; and (ii) if there is, the extent of the problem, before deciding on a course of action. There may be some uncertainty as to whether or not the product is unsafe and, even if it clearly is, a producer will usually want to establish the risk it poses and, crucially, how many units of the product have been supplied, where and to whom. As explained in more detail below, the most effective recalls in our experience are those in which the producer is able to supply the enforcement authorities with this relevant information and explain what steps it is taking.

Regulation 9, however, requires that once the producer or distributor knows that the product is unsafe (i.e. that it poses risks to the consumer that are incompatible with the general safety requirement), they must notify the enforcement authority "*forthwith*". The European Commission has in the past issued Guidelines to producers and distributors which interpret the obligation to notify forthwith to mean that notification should be made as soon as relevant information has become available and, in any event, (i) within 10 days, or (ii) immediately and not later than three calendar days where a serious risk is identified. These Guidelines were never legally binding and, post-Brexit, they are no longer applicable in the UK. However, no equivalent guidance on the timing of notifications has yet been produced by the UK authorities and we anticipate that in practice the authorities' expectations will continue to accord with the previous Guidelines.

It is relevant to note, in this context, that the form that producers must fill in when notifying the regulator of an unsafe product requires them to submit details of not only the safety defect itself but also the number of units affected and the corrective measures they are taking. It is permissible to leave some fields blank when submitting a notification but the level of detail required by the form nonetheless underscores the tension between the expectation, on the one hand, that the producer will notify the regulator "*forthwith*" and, on the other, that its notification will include details of its plan for resolving the issue (which can require a significant amount of investigation and thought).

Failure to notify in accordance with Regulation 9 is a criminal offence and it is committed by a producer or distributor where it is proved that it ought to have known that the product posed risks to consumers that are incompatible with the general safety requirement and failed to notify "*forthwith*". In our experience, some latitude is given and the enforcement authorities tend to focus on ensuring proper steps are taken to counter the risk, rather than on prosecuting companies for failing to submit a notification during the period in which they were still investigating the issue. However, the position might be different if a consumer has been injured before the authorities are notified. In such circumstances, the risk is that the matter will be viewed with the benefit of hindsight and it will be more difficult for the producer/distributor to show that they ought not to have known the product posed a risk. There is, therefore, always some risk in delaying notification.

As noted above, because of the different expectations regarding speed of notification, a company that has determined that a product is unsafe will need to undertake a further assessment to determine whether or not the risk is "*serious*". The EU RAPEX risk assessment methodology is endorsed by the UK government's Code of Practice for product recalls (discussed in more detail below). This methodology involves consideration of various factors including:

- The severity of injury that could be caused by the product.
- The probability of an injury occurring.
- Whether or not the hazard is likely to affect particularly vulnerable people.
- Whether the danger is obvious or addressed by adequate warnings/safeguards.

Obligation to recall unsafe products

A producer which discovers it has placed an unsafe product on the market is not, automatically, required to recall the product. The relevant obligation placed on a producer by Regulation 7(3) is to:

> "*adopt measures commensurate with the characteristics of the products which he supplies to enable him to*
> *(a) be informed of the risks which the products might pose, and*
> *(b) take appropriate action including, where necessary to avoid such risks, withdrawal, adequately and effectively warning consumers as to the risks or, as a last resort, recall*".

Therefore, the onus is on the producer to decide upon the appropriate course of action, taking into account the characteristics of the products, the nature of the risk and the nature of the consumers. However, the enforcement authorities do have the power to require the producer to take steps if they consider its actions to be insufficient to deal with the risk.

The enforcement authorities have the power under the GPSR to serve upon a producer or distributor a variety of safety notices including:

- Suspension notices (Regulation 11). These prevent the producer/distributor, for the period of the notice, from placing the product on the market or supplying it. This type of notice is appropriate where the authority needs time to organise its own safety evaluation of the product.

- Requirements to mark or warn (Regulations 12 and 13). These notices are appropriate where the authority considers the product could pose risks in certain circumstances. The notices ensure the producer/distributor either marks on the product or provides warnings with the product.
- Withdrawal notice (Regulation 14). This prohibits the producer/distributor from placing the product on the market or supplying it. This is an extreme step and will be taken only if an enforcement authority considers (i) that the product poses a serious risk (requiring urgent action), or (ii) that the action being taken by the producer/distributor to remedy the problem is insufficient.
- Recall notices (Regulation 15). These enable the enforcement authority to require a producer/distributor to recall a product. It is a power of last resort and may only be used where other action provided for under the Regulations would be insufficient. Unless the product poses a serious risk (requiring urgent action), a recall notice can only be issued if the action taken by the producer/distributor is unsatisfactory or insufficient and the authority has given not less than 10 days' notice of the recall. It is very rare indeed for a recall notice to be imposed on a reputable business, since they almost invariably recall dangerous products voluntarily at an early stage.

Contravention of any of these notices is a criminal offence with maximum penalties of a fine not exceeding £20,000 or imprisonment for a term not exceeding 12 months, or both.

Defence of due diligence

In relation to each of the offences referred to above, it is a defence for the producer/distributor to show (on the balance of probabilities) that it took all reasonable steps and exercised all due diligence to avoid committing the offence.

Although the burden of proof is only to the civil standard of the balance of probabilities, in practice it is a difficult defence to establish because it requires the corporate entity not only to prove the existence of suitable systems and procedures but, in addition, that the corporate entity sought to ensure that the system was, in practice, followed correctly. Thus, though the existence of a rigorous regime of safety testing, quality control and inspection might indicate a company has taken reasonable steps – at a structural level – to avoid marketing an unsafe product, demonstration that these rules have been consistently complied with – at a practical level – is also required.

Impact of Brexit / Potential Divergence of UK and EU Law

As noted above, whilst the purpose of the GPSR was to implement the EU General Product Safety Directive, the Regulations are part of the UK's domestic law and have therefore remained in force after the end of the Brexit transitional phase on 31 December 2020. That said, prior to January 2021 the GPSR were tied into the EU-wide system of product safety regulation that is no longer recognised in the UK and a number of changes were made to reflect this. For example:

- Prior to January 2021, a product would be presumed to be safe where it conformed with applicable European safety standards as well as UK standards. The reference in the GPSR to European standards has now been removed.
- The GPSR definition of "*producer*" previously included manufacturers established anywhere in the EU or an importer of products into the EU. The definition is now limited to entities within the UK that manufacture or import products.
- The GPSR previously referred to the Rapid Alert ("**RAPEX**") system (now also called the EU Safety Gate) through which competent authorities in different EU Member States share information about products that pose a serious risk. The UK no longer participates in RAPEX and the GPSR have been amended to remove references to it.

Notwithstanding the various changes referred to above, the UK rules on product safety and recall remain effectively the same as in all EU Member States that have implemented the General Product Safety Directive 2001 into their national law. However, if relevant aspects of EU or UK law were to change in future, that could lead to divergence.

Long before Brexit, the European Commission had begun planning reform of the General Product Safety Directive. There was a consultation between 2009 and 2011, following which a draft new Regulation on Consumer Safety was published in 2013. This Regulation would, if enacted, have retained most of the important features of the existing regime but with some additional requirements, including clearer rules for marking products to assist in any recall.

Ultimately, the draft Regulation published in 2013 was never passed into law and in June 2021 the European Commission published a new draft Regulation. This is currently being considered and is not expected to become law until 2023 at the earliest. The new draft Regulation includes a number of changes that seek to modernise and strengthen the existing law, including:

- Expressly requiring assessments of product safety to take account of new technologies such as artificial intelligence and software updates and to ensure products include cyber security features where appropriate.
- The creation of a "Consumer Safety Network" to facilitate co-operation between competent authorities in different Member States in relation to joint surveillance and testing; tracing, withdrawal and recall of dangerous products; and regulatory enforcement.
- The potential for higher penalties to be imposed at Member State level (the draft Regulation refers to fines up to a maximum of 4% of an offending company's annual turnover. Whilst this is expressed as a maximum, the creation of any link between a fine and annual turnover has the potential to lead to much higher fines over time, particularly for larger companies).
- Standardisation of the remedies available to consumers in the event of a recall, through the creation of a right to receive a repair, replacement or refund.

The new draft Regulation (when and if it is enacted within the EU) will not, of course, be legally binding in the UK. However, the UK government would, at that stage, have to decide whether to amend the GPSR to reflect the changes. If it chose not to do so, important distinctions would begin to exist between UK and EU law, which would add a further complication for companies that discover they have placed unsafe products on the market, and may need to undertake a recall, in multiple European jurisdictions.

In the meantime, the UK government has also begun to review the GPSR, both (i) to assess whether the existing law (as a legacy of EU membership) remains appropriate, and (ii) to take account of developments including technological advances, changes to traditional supply chains and the environmental agenda. The UK government has yet to publish any detailed proposal for a change to the law.

With both the UK and EU in the process of reviewing and updating their product safety laws, the potential for divergence over the coming years is clear.

Handling a Product Recall Effectively

In our experience, there are a number of important steps that a producer can take to minimise the negative impact of having to recall unsafe products.

Many of the steps outlined below are endorsed by the government's 2018 Code of Practice ("Supporting Better Product Recalls"), which includes guidance on the types of measures that companies are expected to have in place to enable them to effectively withdraw/recall products where necessary.

Planning ahead

In most cases, it is possible to plan ahead and have mechanisms in place to deal with product safety issues quickly and decisively when they arise.

The Code of Practice states that all UK producers, importers and distributors should have a written Product Safety Incident Plan ("**PSIP**"). Such a plan is expected to include, amongst other things: (i) information on products and customer traceability; (ii) a plan for monitoring product safety; (iii) a plan for notification of the relevant authorities; (iv) a risk assessment procedure; and (v) a mechanism for deciding upon appropriate corrective action.

Other steps companies can take in advance include: (i) selecting an incident management team (the membership of which may have to be adjusted depending upon the exact nature of the issue that arises); and (ii) preparing template communications to be issued to consumers, regulators, other companies in the supply chain and, in some cases, the media.

Assembling an incident management team

A producer's written procedure for dealing with product safety issues should include assembling an incident management team to handle the issue as soon as it arises. The membership of the team may vary depending upon the affected product and the nature of the defect but it will generally include:

- A manager with sufficient seniority to make decisions about how to handle the issue; to engage confidently with the regulator; and, where the product has been placed on the market in multiple jurisdictions, to coordinate teams in each jurisdiction to lead a united response.
- Individuals with a detailed technical knowledge of the relevant product.
- Representatives from the company's legal team and insurance/risk management teams.
- Communications specialists (to assist in crafting messages to be delivered to stakeholders including the regulator, consumers and other companies in the supply chain as well as any public statements).
- Where appropriate, individuals responsible for the supply chain who can liaise with suppliers to investigate the source of any defect.
- Individuals with experience of dealing with the regulator.

In smaller companies (which will generally not have specialist communications, legal and other teams) it may well be that the same individuals occupy more than one of these roles.

Deciding on the appropriate corrective action

The first, and most important, tasks of the incident management team will be to identify the nature of the issue and decide what corrective action is required.

The team will need to review the information received by the company (whether via customer complaints or notifications from other businesses in the supply chain) and work with technical experts on the product in order to identify: (i) the nature of the apparent defect; (ii) its potential consequences; (iii) how many units are (or may be) affected; and (iv) what point in the supply chain the affected units have reached.

Using this initial information, the team should undertake a careful risk assessment in order to ascertain the level and extent of the risk posed by the defective product. This is a crucial step since the severity of the risk is likely to underpin all subsequent decisions. For example, the outcome of the risk assessment will determine:

- Whether or not the product is "*unsafe*" for the purposes of the GPSR and, therefore, whether or not there is an obligation to notify the regulator.
- If the product is unsafe, whether the risk it poses is "*serious*". As explained above, this may affect the speed with which the producer is expected to notify the regulator.
- What corrective measures may be most appropriate to mitigate the risk. These steps can include one or more of the following:
  - Stopping future sales.
  - Issuing warning notices (either directly to consumers or via advertisements).
  - Withdrawing affected products from the supply chain.
  - Implementing corrective measures (e.g. arranging for affected products to be repaired "in the field" without being recalled).
  - Recalling affected products that have reached consumers.

Corrective action should be proportionate and so, in general, the greater the risk, the more extensive the steps that will be required to mitigate it. In practice, however, matters may be more complicated. The producer may determine, for example, that whilst the risk is very serious there is no need to recall the product because it has only reached a handful of consumers who can be contacted directly. At the other end of the scale, a producer may decide for reputational reasons to undertake a full recall in response to a very small risk (or even where there is no risk at all and the product is merely defective rather than unsafe).

The GPSR do not mandate the use of any particular risk assessment methodology. However, the Code of Practice recommends use of the EU RAPEX methodology (referred to above) and notes that this is the methodology used by the regulator. The Code of Practice pre-dates the UK's withdrawal from RAPEX but we anticipate that this would still be seen by regulators as an appropriate methodology. The Code acknowledges that other methodologies may be appropriate, including: "*nomograph risk assessment*" (which uses similar inputs to the RAPEX methodology but follows a more mathematical approach and shows the results graphically); and a Chemical Safety Assessment using guidance published by the European Chemicals Agency (pre-Brexit the Agency was responsible for authorising the use of chemicals in the UK under REACH (the regulation on the registration, evaluation, authorisation and restriction of chemicals) – those responsibilities have now transferred to the Health and Safety Executive).

Whichever methodology is followed, it is important to keep the risk assessment under review (and, if necessary, repeat it) as more information becomes available.

The risk assessment should be documented so that the producer can show, if challenged at a later date, that its approach was based upon a careful and objective evaluation of the information available at the relevant time.

In many cases, the outcome of the risk assessment will not necessarily point to just one course of action. There will often be a range of options available and selecting one will require

judgment. It is important, therefore, that the producer's incident management plan identifies who should make the decision as to which option to follow and the timescale in which that decision should be taken.

Engagement with the regulator

The goal for the producer is, generally, to persuade the regulator to adopt a "*hands-off*" approach and allow the producer to implement whatever corrective measures it considers necessary with minimal interference. Inevitably, the regulator is more likely to take this approach if it is satisfied that the producer understands the scope of the issue and has a robust plan in place to address it. The producer will, therefore, want to be able to provide as much information as possible to the regulator when it first makes contact to notify the regulator of the safety issue. As explained above, there is almost always a tension between this and the legal obligation to contact the regulator immediately. How that tension is resolved will vary from case to case.

Whatever point the company has reached in its own investigation when it contacts the regulator, its communications with the regulator must be carefully crafted to provide the relevant information and to show that the issue is being dealt with competently. The usual approach is for a senior manager to lead the dialogue with the regulator, having been fully briefed by technical experts, legal advisors and other members of the incident management team. It is often helpful to anticipate questions the regulator may have, and to prepare a script for dealing with these.

The GPSR require producers to submit written notifications in respect of unsafe products but, in our experience, it is almost always helpful for a senior manager to speak to the regulator at the same time as the formal notification is submitted, in order to establish a dialogue and address any immediate questions.

Coordinating recalls in multiple jurisdictions

Producers who place the same product on the market in more than one country will be faced with the added complexity of coordinating a response in multiple jurisdictions which may be subject to different product safety laws.

As part of its incident management plan, a company should ideally: (i) determine which country should take the lead in coordinating a multi-jurisdictional response; and (ii) have incident management teams (including lawyers able to advise upon local law requirements) in each relevant jurisdiction.

Where different product safety laws and standards apply, a company may be able to justify (from a legal perspective) taking a different approach in different countries (e.g. recalling an unsafe product and providing a replacement in countries where it is required by law to do so; but only issuing a warning notice to consumers, explaining how the original product can be used safely, in others). Whilst this may be justifiable from a legal perspective, it can lead to extremely negative publicity and brand damage, and the company will need to factor that risk into its decision-making.

Even within the EU (and, at least for the now, the UK) where product safety laws are effectively identical, there are still differences between the practical approaches taken by regulators in different jurisdictions. For example, some regulators expect to receive very early notifications of unsafe products, whereas others are slightly more relaxed on timing and prefer to receive more detailed information as to the nature of the risk and the plan for addressing it. Some regulators are more likely than others to take a hands-off approach and allow the company to implement its measures without disturbance. It is important for the incident management team in the lead country to engage with legal/regulatory experts in each jurisdiction in order to understand these differences and take account of them in decision-making. Despite the differences in expectations between different regulators, the right approach (almost without exception) will be to provide exactly the same information at exactly the same time to all regulators.

Within the EU, producers are able to use the General Product Safety Directive Business Application (also known as the Business Alerts Gateway) to notify regulators in multiple jurisdictions simultaneously. This can be a helpful tool but it should not prevent the producer from making direct contact with each regulator by telephone (or whatever channel is most appropriate in each jurisdiction).

Communication with consumers

How a producer will communicate with consumers will depend upon the nature of the safety issue and the steps being taken to mitigate it. At one end of the scale, the producer may be informing consumers that a non-urgent repair is required and that they will be contacted about it in due course. At the other end of the scale, the producer may be informing consumers of a full recall to avoid a serious risk to safety (potentially relating to a product they are already using). In all events, however, it is crucial that communications are carefully drafted and controlled to ensure that the relevant information needed to avoid the risk is communicated, whilst limiting brand damage in so far as possible.

The Code of Practice provides detailed guidance on what information should be included in communications with consumers and how it should be presented.

Various different channels may be available for contacting consumers:

- In some cases, it will be possible to target individual consumers who have purchased affected products (e.g. where they have purchased online or have provided contact details for warranty purposes or for a loyalty scheme).
- In other cases, it will be possible to target most potentially affected consumers with a reasonable degree of accuracy (e.g. via the company's website, social media or trade magazines).
- Where it is difficult or impossible to target only affected consumers, it will be necessary to cast the net more widely using one (or often all) of: (i) notices at point of sale in shops; (ii) advertising in newspapers, radio and television; and (iii) communications via the company's website and on social media.

The regulator will expect the producer to justify its approach by showing the basis on which it is confident that it will be able to contact all potentially affected consumers.

Product recall and liability insurance

Producers may have the benefit of insurance that will cover some or all of the costs of recalling products and/or the cost of civil claims they may receive from consumers or other businesses in the supply chain.

These policies will frequently require, as a condition precedent to cover, that insurers are notified at a very early stage of any matter that may lead to a claim under the policy. For this reason, it is important for the incident management team to include representatives from the company's insurance/risk management team and for the incident management plan to include details of how to contact insurers and what information to provide.

Insurance policies can also include terms requiring the company to seek insurers' agreement before taking various steps. This can give rise to timing issues where, for example, a company is required by law to take steps (such as notifying the regulator and beginning to communicate with consumers immediately) but it is not possible to obtain express consent from insurers within the necessary timescales. In those circumstances, the best approach is almost always to keep insurers fully informed (so that they have the chance to raise any objections) but not to delay any step that is required by law, or required to mitigate the risk posed by the product, whilst waiting for express agreement.

Civil claims

Unsafe and defective products can, inevitably, lead to civil litigation. A producer may face claims from consumers who have been injured or suffered property damage (or who merely wish to recover the cost of the unusable product) and from other companies within the supply chain (e.g. distributors who have been required to offer refunds to consumers). The producer may also have its own claims to pass on some or all of the liability it incurs (e.g. claims against suppliers who are responsible for providing defective components).

It is outside the scope of this chapter to comment on civil claims, except to note that it is important that they are considered at an early stage and that appropriate steps are taken to preserve the company's rights. The appropriate steps will often include: (i) carefully tracking details of costs incurred in the recall so that the quantum of any claim against a supplier can be properly evidenced; (ii) retaining an appropriate number of affected units of the product for evidential purposes; and (iii) carefully reviewing the contractual terms in place with suppliers and distributors.

How to decide when a recall can come to an end

The final responsibility of the incident management team is generally to decide when it is appropriate to close the recall. In practice, it is usually not possible to recover 100% of affected products and a judgment must be reached on when all reasonable steps have been taken. This decision will be informed by factors such as: (i) how confident the company can be that its communications have reached all or most consumers (even if those consumers have not acted on them); and (ii) whether the lifecycle of the product makes it unlikely that it would now be used.

Whilst the company does not, strictly speaking, require approval from the regulator to close a recall, it will almost always be appropriate to liaise with the regulator to explain the rationale for closing the recall and seek its view in order to minimise the risk of criticism at a later stage.

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