Ireland

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GENERAL PRODUCT OBLIGATIONS

Basic laws

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

Consumer products

The General Product Safety Regulations 2004 (GPSR) prohibit the placing of unsafe goods on the market. The GPSR places obligations on both producers and distributors to ensure that goods placed on the market are safe and do not pose a risk to consumers.

Under the GPSR, producers cannot place a product on the market unless the product is safe and such products are accompanied with appropriate warnings to consumers and instructions for use. Producers must provide consumers with all relevant information relating to the product to allow consumers to assess the risks associated with the products. Producers include the manufacturer of a product, the manufacturer's representative, the importer of the product, or other professionals in the supply chain, in so far as their activities may affect the safety properties of the product. Once the product has been placed on the market, the producer must monitor the product to be informed of any risks posed by the product and to take appropriate action if necessary, such as product recall or withdrawal and warning consumers.

Distributors must ensure that any products they supply to consumers are safe products. After the product has been placed on the market, the distributor must monitor the safety of the product and has a duty to inform:

- the enforcing authority, which in Ireland is the Competition and Consumer Protection Commission (CCPC); and
- the consumer and the producer of any defects or risks posed by the product on becoming aware of such risk or defect.

They must also keep and provide the CCPC with documentation necessary to trace the origin of the product and cooperate with the CCPC in any action it takes.

Commercial products

Ireland has separate legislation (not derived from the EU) covering the safety of products intended for commercial use, principally section 16 of the Safety, Health and Welfare at Work Act 2005 (SHWAWA), which is enforced by the Health and Safety Authority (HSA). Manufacturers, importers and other suppliers are required to ensure, so far as is reasonably practicable, that the products are safe and without risks to health at all times when they are being used or maintained. They must also arrange for the carrying out of appropriate testing and examination to ensure products are safe.

Sector-specific safety legislation

There are various regulations governing certain types of products and that implement EU Directives, for example medical devices, medicinal products, electrical items, cosmetics, vehicles and toys.

Tort law

General principles of negligence also apply in determining liability under tort law. Designers, assemblers, installers, repairers and suppliers of the product or the component parts owe a duty of care in relation to the placement of defective products on the market.

Contract law

Under contract law (the Sale of Goods Act 1893 and the Sale of Good and Supply of Services Act 1980), goods must be fit for their purpose and be of merchantable quality. If the defect is drawn to the buyer's attention before the contract is made, or if the buyer examines the goods before the contract is made and that examination ought to have revealed such defect, there is no implied condition as to merchantable quality. In a business-to-business situation, these implied terms can be excluded where it is fair and reasonable to do so.

Product Safety and Market Surveillance Package

The European Commission's proposed Product Safety and Market Surveillance Package will have increased obligations for manufacturers, importers, distributors and national authorities to improve product safety in the EU and strengthen market surveillance activities.

Traceability requirements

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

Consumer products should be supplied with details of the name of the product, address and relevant product reference or batch marking.

More detailed traceability requirements are set out in sector specific legislation. For example, the General Food Law Regulations 2007 (as amended) and the Food and Feed Hygiene Regulations 2009 (as amended) (which give effect to European Regulation (EC) 178/2002) contain requirements for extensive traceability systems throughout the supply chain. This must include documentation showing the origin and destination of the food (traceability at all stages) and identifying those that have supplied food to the food business operator or those that have been supplied with food by the food business operator (FBO). FBOs must also be able to show traceability of suppliers of food and packaging.

There is also a requirement for traceability within the supply chain of medical devices, as set out in the Medical Devices Regulation (Regulation 2017/745) and the in vitro medical devices Regulation (2017/746). These Regulations have a staggered transitional period. The obligations for distributors will apply with the full application of the Medical Device Regulation after three years (May 2020) and full

application of the Regulation on in vitro diagnostic medical devices after five years (May 2022).

The proposed Product Safety and Market Surveillance Package will require economic operators to make available any documentation that the market surveillance authorities require, including information that enables the precise identification and tracing of products.

Non-compliance penalties

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

Consumer products

The range of penalties varies and can include administrative fines and criminal prosecution. A summary conviction (an offence tried by a judge without a jury) typically amounts to no more than a fine of €3,000, three months' imprisonment, or both. Most often, criminal proceedings will be instituted against the corporate entity rather than individuals.

In some sector-specific areas, indictable offences (an offence tried by judge and jury) can apply. Other enforcement powers include seizure of the goods, and prior to taking legal proceedings recourse options include the issuing of suspension notices (temporarily suspending the supply or marketing of the products that are believed to be in breach of product safety requirements) and issuing notices requiring products to be marked with clear and comprehensive warnings. The authorities may also issue withdrawal notices, requirements to warn and recall notices, details of which are set out in more detail below.

Commercial products

Penalties for contravention of safety requirements relating to commercial products under the SHWAWA range from a fine up to €5,000, a maximum imprisonment term of 12 months, or both, for summary convictions. Indictable offences are punishable by a fine not exceeding €3 million, a maximum of two years' imprisonment, or both. Other enforcement powers are also available to the HSA (see question 19).

REPORTING REQUIREMENTS FOR DEFECTIVE PRODUCTS

Government notification

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?

Consumer products

The GPSR requires producers and distributors to immediately inform the competent authorities of the member state in which the products in question are, or have been, marketed or otherwise supplied to consumers where they 'know or ought to know' that a product they have marketed is unsafe and does not satisfy the health and safety requirements that the product should satisfy (the general safety requirement).

The requirements to notify, in general, concern notification of information regarding defects or newly discovered risks, irrespective of whether any incident, injury or damage has yet occurred.

Commercial products

There are currently no Irish statutory requirements requiring notification of defective commercial products to the authorities. The SHWAWA places an obligation on employers to report accidents and dangerous occurrences to the HSA. See the rules referred to in question 5 for specific sectors.

Where products have been tested or certified by a third party, it is possible there may be a contractual obligation incorporated into the agreement requiring the manufacturer or its representative to inform the body concerned.

Notification criteria and time limits

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

Consumer products

Notification is required if the consumer product is known to have risks that are not compatible with the health and safety requirements that the product should satisfy. The relevant authority should be notified immediately once it is known that a product is unsafe.

Food and drink

Obligations to inform the Food Safety Authority of Ireland (FSAI), the relevant authority in Ireland responsible for the monitoring of food on the Irish market, are governed by the General Food Law Regulations 2007 (as amended) and the Food and Feed Hygiene Regulations 2009 (as amended) . An FBO must notify the FSAI if it believes that the food placed on the market is unsafe. A food product is considered unsafe if it is considered to be injurious to health or unfit for human consumption.

Medical devices

The Health Products Regulatory Authority (HPRA) is the competent authority for medical devices in Ireland and has the responsibility of coordinating and recording details of incidents reported to them under the auspices of the vigilance system for medical devices.

The Medical Devices Directive 93/42/EEC places a mandatory obligation on manufacturers to report all incidents that occur in Ireland to the HPRA. An 'incident' is defined as:

> *an event that causes or has the potential to cause unexpected or unwanted effects involving the health and safety of patients, users or other persons.*

Incidents that meet the following three criteria must be reported to the HPRA.

An event has occurred

Typical events, for example, might include the following:

- device malfunction;
- unanticipated side effects;
- interactions with other substances or products; and
- inaccurate labelling.

Events could also include the outcome of an inspection or test or the receipt of scientific information.

The device is suspected to have a contributory cause of an incident

In assessing this criteria, the manufacturer should consider the opinion of healthcare professionals, the results of the preliminary results of their own investigations and any evidence of similar previous incidents. The HPRA recommend that manufacturers err on the side of caution when considering this criteria.

The event led, or might have led, to one of the following outcomes

- Death of a patient, user or other person; or
- serious deterioration in state of health of a patient, user or other person.

Upon becoming aware that one of its devices has contributed to an incident, a medical device manufacturer must report the incident within the following timelines, based on the nature of the incident:

- serious public health threat: report immediately, but not later than two calendar days after awareness;

- death or unanticipated serious deterioration in state of health: report immediately, but not later than 10 calendar days after awareness; and
- other: report immediately, but not later than 30 calendar days after awareness.

On 5 April 2017, two new European Regulations on medical devices were adopted and entered into force on 25 May 2017:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; and
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

The new regulations strengthen the regulatory framework relating to medical devices including the pre-market assessment of devices, post-market surveillance and the transparency of data. The new rules will only apply after transitional periods of three years after entry into force for the Regulation on medical devices (May 2020) and five years after entry into force for the Regulation on in vitro diagnostic medical devices (May 2022).

The HPRA is in the process of drafting a detailed implementation plan for the two Regulations.

Medicinal products

The Medicinal Products (Control of Placing on the Market) Regulations 2007 (as amended) state that a person must not place a medicinal product on the market unless authorised to do so. Manufacturing and marketing authorisation applications must include descriptions of the arrangements for the withdrawal or recall from sale, supply or exportation of any medicinal product to which the authorisation relates.

Notification to the HPRA for recalling classes of medicinal products can range from 24 hours for more serious risks, to within five days for less serious risks. For guidance, see the HPRA Guide for Recall of Medicinal Products for Human and Veterinary Use.

Cosmetics

Under the Cosmetic Products Regulations 2013, it is prohibited to place a cosmetic product on the market that is liable to cause damage when applied under normal conditions of use or conditions of use that are reasonably foreseeable. If the product does not adhere with the requirements set out in the Regulation, notification must be made to the HPRA.

Electrical equipment:

The European Union (Making Available on the Market of Electrical Equipment Designed for Use within Certain Voltage Limits) Regulations 2016 require that electrical products placed on the market must have been constructed in accordance with the principles of good engineering practice in safety matters and do not endanger the safety of persons, domestic animals or property. If manufacturers have reason to believe that an endangerment is likely, they must inform the CCPC.

Motor vehicles

Under the Road Vehicles Type-Approval Regulations 2009, manufacturers must ensure that, prior to placing new vehicles on the market, they must ensure that the vehicles are manufactured to prescribed safety and environmental standards. Manufacturers are responsible to the National Standards Authority of Ireland and the Road Safety Authority of Ireland (RSA), for all aspects of the approval process and for ensuring conformity of production.

Toys

Under the European Communities (Safety of Toy) Regulations 2011 (as amended), it is prohibited to place a toy on the Irish market unless it is safe, has a CE mark (the CE mark on a product is an indication that the product meets the essential safety requirements of the relevant directives) and complies with essential safety requirements. If not, then notification must be made to the CCPC.

Competent authority

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

For most consumer products, the appropriate authority for notifications in Ireland is the CCPC. For contact details, see www.ccpc.ie.

If the product is supplied across the EU, one single application can be made and the relevant national authorities will be informed of this. These authorities may forward the information notified to them to the EU authorities for the purposes of the Safety Gate – the rapid alert system for dangerous non-food products (RAPEX), RASFF (Rapid Alert System for Food and Feed) or other rapid alert systems in Europe for pharmaceuticals and medical devices, or for the purposes of information-sharing systems pursuant to other EU legislation.

Other bodies that monitor market safety of certain products include the following:

Medical devices	Health Products Regulatory Authority
Cosmetics	Health Products Regulatory Authority
Pharmaceuticals	Health Products Regulatory Authority
Food	Food Safety Authority of Ireland

Notification information

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

The information required generally relates to the nature of the defect, the product affected and the action being taken to prevent the risk. Information enabling a precise identification of the product or batch of products in question, a full description of the risk that the products in question present, all available information relevant for tracing the product and a description of the action undertaken to prevent risks to consumers should also be provided when notifying the competent authority. Failure to comply with these requirements is a criminal offence.

Medical devices

When notifying the HPRA of an incident, a manufacturer must complete the 'Manufacturer's incident report form', which can be downloaded from the HPRA website and can also be obtained in the European Commission Guidelines on Medical Devices Vigilance system MEDDEV 2.12-1.

Medicinal products

When reporting a quality defect to the HPRA, the following information must be provided:

- the exact name of the medicinal product;
- the product marketing authorisation number (PA/VPA/EU Number), if any;
- the product dosage form (eg, tablets) and strength (eg, 75mg);
- the batch or lot number;
- the expiry date;
- the name of the marketing authorisation holder;

- where you obtained the product (eg, the wholesaler or pharmacy name, and their address);
- an exact and full description of the suspected defect (be as specific and as detailed as possible);
- your name, address and contact details, including telephone numbers; and
- the date on which you are reporting the quality defect.

Marketing authorisation holders, manufacturers and wholesalers should use the Quality Defect Report Form to report quality defects to the HPRA. This form is available on the HPRA website.

Obligations to provide updates

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

Distributors and producers should provide as much information as possible to the authorities when first requested to do so. If the information initially provided is incomplete, distributors and producers should provide further and complete information as soon as possible. As distributors and producers have a duty to cooperate with the authorities and to minimise risk to consumers, failure to provide the required information may amount to an offence under Irish law. The authorities also have formal enforcement powers to require the provision of additional information and records if they require it in order to investigate a breach of product safety legislation or to decide whether to use their enforcement powers to, for example, serve safety notices. Market surveillance authorities will have new and expanded powers under the proposed EU Regulation on Market Surveillance of Products. The draft regulation requires economic operators to make available on request any documentation or information that the surveillance authorities require.

Penalties

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

Failure to comply with the GPSR can result in a summary conviction to a fine not exceeding €3,000, or to imprisonment for a term not exceeding three months, or to both.

Under food law, penalties range from a fine not exceeding €5,000 or three-month imprisonment for summary convictions, to a fine not exceeding €500,000 or a maximum three-year imprisonment for convictions on indictment. Motor-vehicle offences carry summary and indictable offences, ranging from a fine of up to €5,000 or six-month imprisonment for summary offences, to a fine of up to €100,000 or a maximum of 12-month imprisonment term. Offences relating to electrical equipment range from, on summary conviction, a fine not exceeding €5,000 or a maximum six-month imprisonment, to a fine not exceeding €500,000 or a maximum of two years' imprisonment for indictable offences. Offences relating to toys can comprise, on summary conviction, a fine not exceeding €5,000 or a maximum of six months' imprisonment, to a fine not exceeding €500,000 or a maximum of two years' imprisonment for indictable offences.

Public disclosure

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

The GPSR states that protection of professional secrecy will not prevent a company from disclosing to the CCPC information that is relevant to ensure the effectiveness of market monitoring and surveillance activities. The CCPC has a duty to ensure that the information received remains confidential.

The CCPC may make available to the public information relating to the risks to consumer health and safety posed by products, in particular information on product identification, the nature of the risk and the measures taken. If information is disclosed by the CCPC, which by its nature is confidential, other than information relating to the safety properties of any product that is disclosed in order to protect the safety and health of consumers, this will constitute an offence by the CCPC.

Under the Freedom of Information Act 2014 (FOIA), any person may request information from the authorities on a product safety matter. The original provider of the information has no right to prevent its disclosure. The authorities have discretion as to whether to release information that is provided in confidence or that could prejudice a person's commercial interests.

The FOIA recognises that in many circumstances it may be inappropriate for a public body to disclose the information that it holds. The FOIA therefore contains a number of exemptions that protect information from potential disclosure. Of particular relevance to product safety notifications and recalls are those exemptions relating to 'investigations', 'law enforcement' and 'information provided in confidence'.

Use of information in prosecution

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

If a criminal prosecution were to ensue, it is likely that the information notified would be used in these proceedings.

PRODUCT RECALL REQUIREMENTS

Recall criteria

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

Consumer products

While the Irish legislation does not lay down any specific legal criteria to ascertain the form of action to take, the GPSR states that the producer of consumer goods must be prepared to take appropriate action, where necessary, to avoid risks. This includes withdrawal of the product, issuing warnings to consumers or, as a last resort, recalling the product. As the precautionary principle is incorporated into the GPSR, corrective action may be justified even if a risk cannot be ascertained with sufficient certainty.

Under the RAPEX risk assessment, risks can be classified into four headings: serious, high, medium and low risks, with each respectively requiring immediate action, rapid action, some action and generally not requiring action from a market perspective, but rather a change in the design, quality control or manufacturing process.

Food

If an FBO believes that food placed on the market is unsafe, there is an obligation under the applicable Food Regulations to withdraw the food, inform the FSAI of the initiation of proceedings to withdraw the food, inform consumers of the reasons for withdrawal and ensure the food is withdrawn from the market. FBOs must also pass on relevant information to trace a food or cooperate in actions taken by producers, processors or manufacturers. The FSAI's Product Recall and Traceability Guidance Notes state that FBOs must take two steps to ensure compliance with their legal obligations – planning and management. Producers and distributors must develop a recall or withdrawal policy, stating clearly the objective of the recall and the senior management's endorsement of the policy and commitment to provide the resources to effect the policy.

The policy should be in place prior to the development of a recall plan. This recall plan must be reviewed and tested.

Medicines and medical devices

Manufacturers of medicinal products are obliged to report details of adverse reactions associated with the use of their product to the HPRA and to report any defect that could result in a product recall.

The HPRA has three classes of product recall:

- Class 1 recalls relate to quality defects of medicinal products that are potentially life-threatening or could cause serious risk to health;
- Class 2 recalls relate to quality defects that could cause illness or mistreatment, but are not Class 1 recalls; and
- Class 3 recalls relate to quality defects not likely to pose a significant hazard to health, but have been initiated for other reasons. If the nature of the quality defect is one that does not warrant a recall, healthcare professionals can be alerted to the issue and bring the product defect to their attention. This is known as a caution in use notification.

In relation to medical devices, the European Commission's MEDDEV 2.12/1 Rev 8, sets out guidance on the medical device vigilance system, including field safety corrective action.

Motor vehicles

If the vehicle presents a risk to road safety, public health or environmental protection, the manufacturer must inform the authorities that granted the vehicle approval of the recall and propose the set of remedies to neutralise the risk.

Commercial products

For commercial products, the duty in section 16 of the SHWAWA may comprise taking reasonably practicable steps to recall or modify products if this is necessary to prevent risks of injury. Again, there are no specific legal criteria to determine thresholds of risk requiring such precautions.

The common law of negligence is also relevant as it may comprise a duty to take reasonable steps to warn users or to prevent use of consumer or commercial products until they can be modified or replaced. This duty may apply even where the risk arises only where the product is incorrectly maintained or used.

Consumer warnings

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?

Under the GPSR, as an initial step, the manufacturer of a product determines whether or not a product is deemed to be unsafe and the appropriate course of corrective action to take to inform consumers. This can be achieved by issuing a warning, withdrawing the product from the market or issuing a product recall. If the CCPC is not satisfied with the course of action being taken, it can request that the producer provide the consumers with the relevant information or take other corrective action concerning the product.

Recall notices

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

Recall notices should include the following information:

- product recall date;
- the product's specific identification details (description of product, product's name, product's model numbers, date codes, serial numbers, tracking labels and stock-keeping unit numbers);
- description of action being taken;
- description of the product's hazard, including details of the product's defect and the type of hazard;
- details of the recalling company's name and identification of the manufacturer and significant retailers;
- the recalling company's contact details;
- picture of recalled product;
- the amount of products sold or affected in the region;
- the remedies on offer for consumers that have purchased a product that has been recalled, for example replacement or repair; and
- how consumers can check whether their product is included in the recall and how to return the product.

Medical devices and medicinal products

The HPRA regularly publish safety notices, targeted toward healthcare professionals, and relating to the safety and quality of medical devices. Medical device manufacturers, or their representatives, also issue field safety notices in relation to actions they are taking with respect to products that are already on the market.

All safety and field safety notices, included those relating to the recall of devices, are published on the HPRA website and are available at the time of publication on request to devicesafety@hpra.ie.

The Market Compliance section of the HPRA compliance department is responsible for coordinating all aspects of medicinal product recalls in Ireland. The HPRA will work closely with companies to ensure that recall communications are issued in a timely manner and with the required content.

Media

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

While there is no recommended form of media, the typical advertising channels used are advertisements in the local media and the press, in-store notices, web postings, emails and use of social media. The CCPC also maintains the details of recalled products on its website. The form of advertising used will depend on the seriousness of the risk involved, the type of product that is affected and the group of consumers likely to be affected. As part of the notification procedure to the enforcement authority, the producer or distributor may wish to state their course of corrective action, which could set out the proposed means of communication to consumers.

A plan of the proposed action has to be submitted to the relevant regulatory authority as part of the notification process. If the enforcing authority does not consider the approach to communication of information to users and others to be adequate, additional or alternative forms of corrective action can be requested.

In some sectors, there will be involvement by the regulator in the chain of communication. For vehicle recalls, the RSA can address and send letters directly to registered vehicle owners. The FSAI and the HPRA can also publish their own alerts.

Time frame

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

While there is no time frame or target set out in Irish legislation, generally, a recall will be deemed to be satisfactory once the product has been recalled in its entirety (100 per cent recalled). Enforcing authorities are likely to request update reports as to the success rate of any corrective

action that is taken. The enforcing authority may require additional measures to be adopted, including repeat recall notices if they consider the response to corrective action to have been unsatisfactory.

Repair and replacement

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

There is no positive obligation on a producer conducting a recall to offer to repair, replace or pay compensation as part of its corrective action programme. Unless the items in question are of low value or perishable, manufacturers generally tend to offer repair, replacement or refund of products.

Rights of recovery for any loss or damage relating to the product simply ceasing to be usable will largely be against the seller from whom the consumer directly purchased the products (unless he or she has suffered injury or property damage when a claim in that regard against the manufacturer or importer into the EU may be made). Whether or not the seller can obtain recourse for the costs of repair or replacement and such like, from the manufacturer or others in the supply chain, is an issue that will be determined by reference to the terms of the relevant supply contracts.

Consumer products

The buyer has statutory remedies under Sale of Goods legislation, the Consumer Protection Act 2007 and the (Certain Aspects of the Sale of Consumer Goods and Associated Guarantees) Regulations 2003. The buyer has a statutory right to a remedy. Legal rights include a right to have the product repaired or replaced. If this is not feasible, then the buyer has a right to have the purchase price refunded.

Commercial products

Subject to the express or implied terms governing quality in the contract of sale, the owner of a commercial product that has been recalled may be able to reject the product, if not already accepted, and reclaim the purchase price as well as additional losses incurred. More usually, though, the owner will be deemed to have accepted a product already in use, and the owner's rights will consist of a claim for damages for breach of warranty against the immediate seller. The damages would comprise the loss to the owner flowing directly and naturally resulting in the ordinary course of events from the breach of warranty.

In the event of the immediate seller being liable to the owner, the seller may, depending on the relevant contractual terms, be able to recover the losses from others in the supply chain.

Penalties

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

See question 3.

AUTHORITIES' POWERS

Corrective actions

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?

Consumer products

The enforcing authority may serve withdrawal notices to prohibit a person from supplying a product without the authority's consent. The notice may also require the person on whom it is served to take action to alert consumers to the risks that the product presents. If a product is already on the market, such a notice may only be served in circumstances where the action of the producer or distributor concerned is considered to be unsatisfactory or insufficient. The authorities also have power to serve a 'requirement to warn'. This can dictate the form and manner of publication warnings to consumers.

Recall notices may be used in situations where the enforcement authority has reasonable grounds for believing that a product is dangerous and that it has already been supplied or made available to consumers. Such notices require the person on whom they are served to use reasonable endeavours to organise the return of the product from consumers. Such notices can only be used by enforcing authorities in situations where another type of voluntary action would not suffice to prevent the risks posed by the product and the action taken by the person on whom the notice is to be served is deemed to be inadequate or insufficient, unless the risk is serious and deemed to require urgent action.

Medical devices and medicinal products

In terms of medical devices, article 14b of Directive 93/42/EEC, article 13 of IVD Directive 98/79/EC and article 14 of AIMD Directive 90/385/EEC allows for necessary and justified transitional action in relation to a product or group of products, limiting the availability of such products in order to ensure that public health requirements are observed.

With respect to medicinal products, the HPRA Quality Defects and Recall (QDR) Group will investigate quality defects on a case by case basis, which can result in product recalls, the issue of communications to healthcare professionals or in other actions requested a company. A significant part of the QDR's role is to ensure that a plan of timely corrective actions is put in place at the manufacturing site to prevent a recurrence of the defect.

The Medicinal Products (Control of Manufacture) Regulations 2007 (SI No. 539) relate to the recall of medicinal products, and the relevant requirements of Directives 2003/94/EC and 2001/83/EC as amended by directive 2004/24/EC are transposed in the Medicinal Products (Control of Manufacture) Regulations 2007.

Commercial products

The HSA may issue enforcement notices in respect of unsafe products. An 'improvement notice' may be used to require a manufacturer or other supplier to provide warnings or safety information. A prohibition notice may be used to stop the supply of a product.

The European Commission's proposed Regulation on Market Surveillance of Products will extend beyond consumer products, allowing enforcing authorities to deal with potential product risks, irrespective of the intended end user. The draft Regulation provides for market surveillance authorities to carry out risk assessments and to inform economic operators (manufacturers, distributors, importers) of the corrective action that must be taken and the period in which it must be taken.

Government warnings

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

It is common for the authorities to publish alerts on unsafe products (see question 15). Generally, this will be done in association with manufacturers or others responsible for recalls, and will reiterate warnings and other advice issued voluntarily by them. However, the authorities are not permitted to issue press releases or call for a recall or other action unless they do so in cooperation with manufacturers or other responsible persons, or they act within the limits and procedural frameworks of the GPSD, Safety Gate or other European notification frameworks and the enforcement powers above.

Government recalls

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

Yes, if an enforcement authority has been unable to identify any person on whom to serve a consumer product recall notice or the person on whom such a notice has been served has failed to comply with it, then the authority may itself take such action as could have been required by a recall notice. If a product poses a risk and the economic operator cannot be ascertained or does not take appropriate corrective action, the market surveillance authority can take 'all necessary measures', including recall.

Costs

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?

Enforcing authorities may recover any costs or expenses they reasonably incur in carrying out the actions stipulated in a consumer product recall notice and that have not been complied with by the person on whom the recall notice was served. Apart from this, administrative and other costs are not recoverable. In any proceedings for forfeiture of products, or for criminal prosecutions for the original supply of unsafe products, the court will generally order the parties to pay the authorities' legal and other costs.

The EU Regulation on the Market Surveillance of Products proposes that market surveillance authorities may charge fees to economic operators that wholly or partly cover costs of the activities of the market surveillance authorities, including testing or risk assessment.

Challenging decisions

23 | How may decisions of the authorities be challenged?

As a statutory body with statutory functions, the CCPC is an entity whose decisions are capable of being challenged by way of judicial review.

However, judicial review remedies are discretionary in nature and such a challenge is generally a remedy of last resort. Therefore, any other remedies available against decisions of the CCPC should be exhausted in the first instance. This would include any statutory appeals, complaints or remedies under the product safety legislation governing the CCPC's investigation or the CCPC's governing legislation.

As well as being discretionary in nature, judicial review is also quite limited in scope. The courts will be principally concerned about the manner in which the CCPC has exercised its relevant powers in making the decision rather that the merits of that decision, and the courts will not act as a court of appeal. In addition, unless flagrantly illegal, administrative decisions of public bodies, like the CCPC, are presumed to be lawful and valid for all purposes unless and until it is set aside by the courts. (It is for this reason that a stay on the impugned decision (akin to an interlocutory injunction) is also often sought in judicial review proceedings.) On this basis, the possible grounds for seeking judicial review of an administrative decision are also limited.

These are the following:

- the decision was unlawful because the CCPC did not comply with the principles of natural justice or constitutional justice in making its decision (also known as fair procedures), namely the right to be heard in a decision-making process affecting you and the rule against bias;
- the decision was unlawful because the CCPC acted outside of its jurisdiction (or ultra vires). It is a fundamental principle of administrative law that a public body may only do what it is empowered or required to do by statute, whether expressly or by necessary implication, and must also act in accordance with its statutory functions and duties; or
- the decision was unlawful because it was unreasonable. Administrative decisions must be rational, evidence-based and proportionate. However, it is well settled that the courts will not intervene with the decisions of public bodies on grounds of unreasonableness or irrationality unless satisfied that:
  - there was no relevant material before it that could reasonably have given rise to the impugned decision;
  - it wholly failed to take into account relevant material or took into account irrelevant considerations; or
  - the impugned decision flies in the face of fundamental reason and common sense.

Lastly, it is important to note that an application for leave to apply for judicial review must be made promptly, and within three months from the date when the grounds first arose. The court has, in very limited circumstances, the power to extend the deadline.

The GPSR permits any person aggrieved by a direction made by the CCPC, within 21 days of receipt of the direction, to appeal to the circuit court in the circuit where the person carries on business.

IMPLICATIONS FOR PRODUCT LIABILITY CLAIMS

Repercussions for court proceedings

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?

While the publication of a safety warning or a product recall could potentially be viewed by members of the public as an admission of liability, ultimately, the decision of liability will rest with the trial judge, taking into account all facts and circumstances of each case brought before it. The ECJ decision in *Boston Scientific Medizintechnik GmbH and Others* (2014) held that where a product belongs to the same group or production series of products that had a potential defect, such a product may be classified as defective. There was no need to show that the product in question had such a defect. Furthermore, in relation to the question of whether a risk of failure could constitute a defect, the court held that for products that carry a high risk (such as pacemakers) the potential lack of safety would constitute a defect.

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

Disclosure of documents is generally required by procedural rules in the Irish courts, and parties may be required to reveal documents that assist their opponents' cases. The usual rules as to document discovery apply to any documents (including electronic documents) that are created in the course of investigations, notifications to the authorities and recall communications. However, communications with lawyers and documents created for actual or contemplated litigation purposes may be protected from disclosure by legal privilege.

UPDATE AND TRENDS

Key developments of the past year

26 Are there any emerging trends or hot topics in product recall litigation in your jurisdiction?

In the area of white collar crime, there is an increasing trend of bringing enforcement action against officers of a company as well as prosecuting the company. This can extend to product safety enforcement actions.

The recently introduced Multi-Party Actions Bill 2017 seeks to introduce a type of class action in Ireland that may have an impact on the manner in, and ease with which, claimants can pursue cases sharing common issues of fact or law. Future multi-claimant product liability personal injury actions may benefit from these provisions, which are substantially aimed at introducing procedural efficiency and cost saving in these cases. The Bill was introduced by a non-governmental party so it remains to be seen whether it will get majority support in parliament.

A current draft European Commission Directive (the Representative Action Directive) proposes a new type of class action litigation that would allow a 'qualified entity' to take action on behalf of consumers.

It is unclear yet what impact the UK leaving the EU will have on product liability and safety in Ireland. There will be a potentially negative impact on the coordinated withdrawal of products on the island of Ireland if the UK no longer participates in Safety Gate.

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