APRIL 10, 2019 • 1 MIN READ

Product liability in Canada

AUTHORS

 Sylvie Rodrigue

 Grant Worden

In Canada, the sale of pharmaceuticals and medical devices is regulated by Health Canada under the Food and Drug Act and Regulations and related legislation (Canadian Food Inspection Agency Act, SC 1997 c.6; Consumer Packaging and Labelling Act, RSC 1985, c. C-38; Consumer Packaging and Labelling Regulations, C.R.C., c. 417; Natural Health Products Regulations, SOR/2003-196; Cosmetic Regulations, C.R.C., c. 869; Medical Devices Regulations, SOR/98-282). Product liability is governed by common law principles in all provinces except Québec, where it is governed by civil law, under the Civil Code of Québec, and in certain circumstances the Québec Consumer Protection Act. Product liability claims are typically framed as actions in tort in common law provinces or extra-contractual liability in Québec, though they may also be framed as claims in contract. Typical tort/extra-contractual liability-based claims include negligent design, negligent manufacture, and breach of a duty to warn. Breach of warranty is the most common claim based in contract.

In Québec, pharmaceuticals and medical devices are also subject to an extra-contractual regime specifically applicable to safety defects (e.g., defects in design or manufacture, poor preservation, or the lack of sufficient indications as to risks and dangers, or ways to avoid them), and two applicable contractual regimes: a general regime relating to contractual undertakings, and a specific regime relating to the guarantee of quality of a sold property (i.e., that it is free of latent defects).

At common law, product liability claims—including those relating to pharmaceuticals and medical devices—are assessed against a negligence standard, rather than a strict liability standard. To succeed in a claim for negligence, a plaintiff must establish the following:

- that the defendant(s) owed a duty of care to the plaintiff;
- that the defendant(s) breached that duty;
- that the plaintiff suffered damages; and
- that those damages were caused by the defendant's breach of their duty of care to the plaintiff.

Negligence may be alleged against any party in the distribution chain of a pharmaceutical product or medical device. The standard of care against which a defendant’s actions will be assessed is the use of reasonable care in the circumstances. Relevant factors include the defendant’s position in the distribution chain. For example, manufacturers will typically be held to a higher duty of care than retailers.

To succeed in establishing extra-contractual liability in Québec, a plaintiff must typically prove fault, injury and causation on a preponderance of evidence. In product liability cases relating only to an alleged safety defect—including pharmaceuticals and medical devices—the plaintiff must establish the safety defect (i.e., the product did not offer the expected levels of safety), an injury, and a causal link between the two. A claim in extra-contractual liability may be instituted against the manufacturer of the product, the distributor of the product, and any supplier (wholesalers or retailers), all of whom are held to the same standard.

In contractual cases where the guarantee of quality applies, the plaintiff must establish the following:

- that the defect renders the product unfit for its intended use or diminishes the product's usefulness to a point where the buyer would not have bought it or paid so high a price;
- that the defect existed at the time of the sale;
- that the defect was hidden; and
- that they were not aware of the defect at the time of the sale.

This guarantee of quality applies equally to all parties in the distribution chain.

Standard of proof for causation

In Canada's common law provinces, the standard of proof for determining causation in negligence claims is the 'but for' test: a plaintiff must establish, on a balance of probabilities, that the plaintiff would not have suffered damages 'but for' the defendant's breach of its duty of care.

In Québec, the standard of proof is the preponderance of evidence. In extra-contractual cases relating to an alleged safety defect, once the plaintiff proves the existence of the safety defect, the injury and the causal link, the burden shifts to the defendant to rebut the presumption that it knew of the safety defect. In contractual cases under the regime relating to the guarantee of quality of a sold property, the plaintiff benefits from the presumption that the alleged defect existed at the time of the sale, and the presumption the seller knew of the defect.

Specific defences

The defences available to manufacturers of pharmaceuticals and/or medical devices are the same as those available to manufacturers of other products sold in Canada, such as:

- expiry of the relevant limitation period;
- failure to prove the elements of the alleged cause of action;
- voluntary assumption of risk;
- product misuse or alteration;
- contributory negligence; and
- intervening act.

In the case of failure to warn allegations, a defendant pharmaceutical or medical device manufacturer can also rely on the 'learned intermediary' defence (i.e., the warning was directed to and adequate for the trained professional who dispensed the product to their patient).

In Québec, defences available to the defendant in circumstances where the burden shifts to the defendant (e.g., knowledge of the defect is presumed) include that the plaintiff knew of the defect, or could with reasonable diligence have known of the defect, or could have foreseen the injury. Other defences include the following:

- proof of the victim's fault;
- the state of knowledge at the time that the product was manufactured, designed or distributed was such that the existence of the defect could not have been known and the defendant was not negligent in providing the information once it became known (eg, by new scientific developments or knowledge); or

- the injury was caused by an unforeseeable event.

‘Regulatory compliance defence’

Canadian courts, including Québec courts, do not recognise compliance with regulatory requirements as a bar to liability. However, while regulatory compliance will not displace the requirement to act with reasonable care in the circumstances, in common law provinces it may be relevant to determining the applicable standard of care and whether the defendant breached its duty of care to the plaintiff.

Market share liability

Market share liability has not been recognised in Canadian law, other than in the context of specific statutes that provide for market share liability for tobacco manufacturers. For other products, including pharmaceuticals and medical devices, if a plaintiff cannot establish a link between their damages and the defendant’s allegedly wrongful conduct, their action will not be successful.

In Québec, if all pharmaceuticals taken by the plaintiff are found to contain safety defects causing injury, all defendants will be found liable, even if the proportion of injury caused by each product is difficult or impossible to ascertain.

General statute of limitation period

Limitation periods are creatures of statute, and the time for commencing actions varies from province to province. Typically, limitation periods relevant to product liability claims range from two to six years, with shorter periods applying to claims against government entities. Limitation periods commence when the act giving rise to the claim occurred, and may be extended to when the plaintiff’s claim became reasonably discoverable (i.e., when the plaintiff knew or ought to have known of the constituent elements of their claim). Limitation periods do not run while a plaintiff is a minor (except in Québec, unless the plaintiff is an unborn child) and/or incapable of commencing a proceeding due to physical or mental incapacity, and are ‘tolled’ (frozen) on the commencement of a class action.

Information against manufacturers

As a federal agency, Health Canada is subject to the Access to Information and Privacy Act (ATIP). Canadian citizens and permanent residents of Canada may submit requests for information under ATIP by submitting a request online at https://atip-aiprp.apps.gc.ca/atip/welcome.do. Under the Act, the head of the government agency receiving the ATIP request (e.g., Health Canada) is required to determine whether documents that are responsive to the request: (1) contain third party trade secrets, or scientific or technical information supplied to Health Canada that is treated consistently in a confidential manner by the third party; (2) could result in material financial loss or gain, or prejudice the competitive position of a third party; or (3) could interfere with contractual or other negotiations of a third party. If any of these conditions are met, the receiving agency must provide the affected third party (e.g., the pharmaceutical or medical device manufacturer) with notice of the request for information and the agency’s intention to disclose responsive documents. The third party is then given the opportunity to make representations to the agency as to why the record, or part thereof, should not be disclosed.

Available damages

Canadian law recognises claims for general damages (i.e., damages for 'pain and suffering'), similar to "moral damages" in Québec, and compensatory damages (e.g., out-of-pocket expenses related to the plaintiff's injury, loss of employment income, etc.). Claims for punitive damages are also recognised, but are rare and are limited to situations where a defendant's conduct is determined to be "high-handed, malicious, arbitrary or highly reprehensible." The goal of a punitive damages award in Canada is to attain the policy goals of deterrence, retribution and condemning reprehensible behaviour, and not to compensate the plaintiff. When granted, Canadian punitive damages awards are typically far smaller than those awarded in the United States.

Canadian law also recognises claims for restitution (e.g., disgorgement of the defendant's revenues or profits under the common law "waiver of tort" theory) and claims for aggregate damages (i.e., monetary damages assessed at a class-wide level). These types of claims are most often advanced in the context of product liability class actions.

In Québec cases, an award for punitive damages can only be granted if specifically provided for by law—for example, when there is a charter violation by the defendant, or in certain circumstances as provided under the Québec Consumer Protection Act.

Medical monitoring claims have been certified as common issues in Canadian class actions, but Canadian courts have not yet determined whether they are available and, if so, in what circumstances. However, in Québec, in cases of bodily injury, a judge may reserve the right of the victim to apply for additional damages if the course of his or her physical condition may not be determined with sufficient precision at the time of the judgment, for a period of up to three years.

Maximum limit on damages

General damages are capped by a trilogy of 1978 decisions of the Supreme Court of Canada including Andrews v. Grand & Toy Alberta Ltd., [1978] 2 S.C.R. 229 (SCC), with the cap indexed to inflation; as of the end of 2018, the cap is approximately C$380,000. Aside from the general damages cap, there is no limit on the amount of damages that may be awarded against one manufacturer.

Trial

Product liability trials are typically heard by judges, though civil jury trials are available in all provinces except Québec.

Disclosure obligation

Disclosure obligations are governed by the Rules of Civil Procedure in each of Canada's common law provinces, and by the Code of Civil Procedure in Québec. In the common law provinces, litigants are typically required to produce all documents in their power, possession or control that are relevant to any matter at issue in the action. They are also required to list relevant documents that are being withheld from production on the basis of privilege, and to state the basis of the claimed privilege. Recognising the scope and complexity of electronic discovery, many provinces allow parties to delineate the scope of production through a discovery plan that is either negotiated or settled by court order.

In Québec, parties obtain document production through requests made either orally during the pre-trial examination of the opposing party's witness, or in writing in advance of the pre-trial examination. Documents may not be withheld on the basis of relevance, though relevance objections may be made at the time of production, to be determined by

the Court at trial or subject to court approval during a pre-trial hearing. Overbroad requests may be challenged and adjudicated by the Court prior to production. As in the common law provinces, documents may be withheld on the basis of privilege.

Potential changes to legal regime

There have been no recent material discussions regarding potential changes in the legal regime for liability for pharmaceuticals.

This piece was originally published in *The In-House Lawyer*.

To discuss these issues, please contact the author(s).