



LS Prime® Feature: Product Shortage Coverage



Shortages of critical life science products have become front page news. The unavailability or rationing of anesthetics, cardiovascular treatments, cancer medicines and other life sustaining products have led to action by both the FDA and Congress. Intense media scrutiny and governmental action arising from product shortages present new challenges for life science companies.

One such challenge is the growing threat of litigation. Even a temporary shortage of a product may force life science companies to defend against claims seeking to hold them liable for injury resulting from the unavailability or rationing of their products. Whether or not such claims against life science companies are successful, responding to lawsuits and managing through such shortages can be a lengthy and very costly process.

Unfortunately, traditional product liability policies generally do not address claims alleging injury to patients due to the unavailability or rationing of a product. Because such claims do not allege that the product caused the injury—a coverage condition in such policies—even the policyholder's defense costs will not be covered. This creates a serious coverage gap for life science companies that could result in significant uninsured loss.

How Is LS Prime® Different?

Damages and Defense: Unlike other life science liability policies, LS Prime® Product Shortage Coverage responds to third party claims of injury due to the unavailability or rationing of a life science product. Even though a court may ultimately refuse to sanction a product shortage claim, coverage is available for the defense of these potentially costly cases.

Policyholder Expenses: In addition to the threat of litigation, life science companies faced with a product shortage often incur significant first party costs to address public concern over the shortage. LS Prime® reimburses the policyholder for expenses such as responding to the FDA, monitoring customers' health conditions throughout the shortage and locating stolen or counterfeited product.

Who Needs This Coverage?

- Biotech/biologics manufacturer
- Pharmaceutical Manufacturer
- Contract Manufacturing organization (CMO)
- Manufacturer of Medical Devices
- Manufacturer of Medical Device Components

How Does This Coverage Work?

Added by endorsement to an LS Prime® (a non-admitted) liability policy, Product Shortage Coverage offers policyholders the option to purchase one or both of the following coverage subparts:

1. Product Shortage Loss Liability—third party insurance that addresses damages and defense expenses associated with claims alleging bodily injury resulting from a product shortage
2. Shortage Management and Medical Monitoring Expense—first party insurance that reimburses the policyholder for expenses incurred to respond to the FDA, monitor customers' health conditions throughout the shortage, and even locate stolen or counterfeited product.

Life Science Product Shortage Claims Examples:

Since the following claims examples involve injury due to the absence or rationing of a product—not injury due to product use or exposure—they would not have been covered under a typical products liability policy.

Pharmaceutical and CMO Liability Claim:

A pharmaceutical company specializing in chemotherapy treatment hired a large contract manufacturer (CMO) to produce its drug. Contamination discovered during the manufacturing process resulted in a product recall and a halt in production. A cancer patient had progression of her disease, possibly hastening her death, because she could not complete treatment with the pharmaceutical company's chemotherapy drug, and it was too late to begin a new treatment protocol. The patient's family filed suit against the pharmaceutical company and the CMO alleging wrongful death resulting from the drug shortage. LS Prime® Product Shortage Loss Liability insurance would pay to defend the suit and the damages awarded, up to the coverage limit.

Shortage Management and Medical Monitoring Expense:

Due to production problems a drug firm was temporarily unable to produce a drug approved for use in children with a metabolic disorder. No alternative drug was available to treat the disorder. The drug firm reported the shortage to the FDA, and contacted the families of the children to advise them of the temporary shortage. The firm recommended weekly blood tests for the duration of the shortage as medically necessary to monitor any change in the children's condition. The children's medical insurance would only cover monthly tests. The drug firm paid for the weekly tests. LS Prime® Shortage Management and Medical Monitoring Expense would reimburse the firm for expenses necessarily incurred to prepare and issue communications regarding the product shortage, and the cost of the weekly blood tests.

Counterfeited Drug Expense:

While prescriptions for a firm's generic drug continue to increase, the Drug Enforcement Agency (DEA) restricted production of the active pharmaceutical ingredient (API) required to make the end product. The drug firm was unable to meet market demand, and notified the FDA of the potential for a shortage of this drug. When news of the shortage became public, profiteers began to distribute counterfeit product containing no API under the drug firm's label. The drug firm initiated an investigation into the illegal activity to halt the distribution of these false products under its label. LS Prime® Shortage Management Expense would cover the costs incurred by the drug firm to investigate and stop the counterfeiting activity.

Medical Device Shortage Wrongful Death Claim:

Shortly after an outbreak of a particularly contagious and deadly strain of influenza, the company that manufactures the test kits used in diagnosing this virus was unable to ramp up production to meet the swelling global demand. An individual became sick and visited his physician, who was unable to test for the virus due to the shortage of test kits. The patient was sent home without being tested. A week later the patient was admitted to the hospital where he died. A lawsuit was filed alleging that the shortage of the insured's test kits delayed the start of the patient's treatment, significantly reducing the treatment's effectiveness, and ultimately resulting in the patient's death. LS Prime® Product Shortage Loss Liability insurance would pay to defend the suit and the damages awarded, up to the coverage limit.

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