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> Historically, product recall insurance has had an efficacy exclusion - a significant gap in coverage for pharmaceutical companies.

Pharmaceutical Product Recall insurance

A new approach to efficacy cover

Recall risk in pharmaceuticals is especially severe: medicines impact patient safety and operate under strict regulatory scrutiny, making recalls among the industry's highest impact operational and financial risks.

When a pharmaceutical product is recalled, often, it is due to safety or efficacy issues.

The difference between safety and efficacy issues

Safety related recall	Efficacy related recall
A safety-related recall happens when a product could be directly harmful, for example, due to sterility issues, contamination with toxic substances or undeclared allergens.	An efficacy-related recall is when a product simply doesn't work as expected.

Addressing efficacy-related recall risk

Historically, product recall insurance excluded efficacy failure, leaving a major protection gap for pharmaceutical companies. Liberty's new Pharmaceutical Product Recall wording specifically addresses that gap. Efficacy-related recalls can now be insured under a dedicated sub-limit, giving manufacturers critical, targeted protection against losses arising from efficacy failures.

Understanding efficacy

What is efficacy?

Efficacy relates to the ability of a drug or treatment to achieve the expected therapeutic effect. In simple terms, efficacy refers to whether a product does what it says it is going to do.

How is efficacy determined?

Efficacy is measured and monitored throughout the entire lifecycle of a drug:

- **Pre-market**: Pharmaceutical companies must provide regulators with extensive clinical trial data demonstrating that the medicine is effective.
- **Post- market**: Pharmaceutical companies and regulators continuously monitor products to ensure they consistently perform as expected. This includes:
  a. **Pharmacovigilance**: collection and analysis of adverse event reports from patients and healthcare professionals.
  b. **Ongoing stability programs**: manufacturers are required to test their products regularly to confirm that the medicine's efficacy remains within specifications throughout its shelf life.
  c. **Regulatory oversight**: Regulators may conduct their own testing and reviews to verify that products on the market meet efficacy standards. They also monitor scientific literature to identify and respond to global trends or concerns.

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When does an efficacy-related recall occur?

When post-market monitoring reveals that a product already being sold is therapeutically ineffective or fails to deliver its intended therapeutic benefit.

In these cases, the product is not recalled for being toxic or physically harmful. Instead, the danger stems from its therapeutic failure. This lack of efficacy is what can lead to patient harm, such as treatment delays, misdiagnosis, the worsening of a disease, or other severe health complications.

Examples of efficacy related product recalls

Sunscreens

Several sunscreen brands were recalled because the actual Sun Protection Factor (SPF) was lower than advertised. Sunscreens are designed to protect the skin from the harmful UV rays, which are a known cause of skin cancer. The SPF number on a product indicates how effectively it filters UV radiation. For example, when applied correctly, an SPF 30 sunscreen filters about 97% of UVB rays, while an SPF 50 sunscreen filters about 98%.

Although this difference seems minor, a lower SPF rating results in greater exposure to UVB rays. In this situation, the sunscreen itself was not physically harmful to apply. The potential for bodily injury arose entirely from the product's lack of efficacy—its failure to provide the advertised level of sun protection.

Broken tablets

An investigation launched in response to customer complaints determined that some batches contained broken or cracked tablets.

While ingesting a fragment of a tablet is not toxic or physically harmful, it directly leads to the patient being underdosed. By not receiving the full intended dosage, the product's efficacy is compromised, which can lead to treatment failure.

Loss of potency

Ongoing stability testing for an antibiotic revealed its potency was declining faster than expected. Before reaching its official expiration date, the amount of active ingredient in the medication had fallen below the minimum required specifications.

In this scenario, the lower-potency antibiotic is not toxic to ingest. The risk comes from its lack of efficacy; its reduced strength means it may no longer be effective at treating a patient's infection. This can lead to treatment failure, resulting in a worsening of the infection.

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