Product Withdrawal And Crisis Management Insurance

Endorsement

Policy Period
Effective Date
Policy Number
Insured

Name of Company
Date Issued

This Endorsement applies to the following forms:

Coverages

Under Coverages, the following coverages are added:

Product Withdrawal Expenses For Life Science

Subject to all the terms and conditions of this insurance, we will pay for withdrawal expenses incurred by the insured as a result of a class 1 recall, provided that:

• such expenses are directly related to such recall;
• the recall is first reported to us by the insured in writing during the policy period; and
• coverage for the life science product is included in the products completed operations hazard.

All reports in connection with the same recall will be deemed to have been made at the time the first of those reports is made to us by any insured in writing.

We have no duty to investigate, defend or settle any claim, suit or other demand of any nature against any insured or any other person or organization.

We have no duty to investigate, defend or settle any claim, suit or other demand of any nature against any insured or any other person or organization.

No other obligation or liability to reimburse sums or perform acts or services is covered.
Crisis Management Service For Life Science

Subject to all the terms and conditions of this insurance, we will pay reasonable and necessary expenses incurred by the insured for crisis management service, provided that:

• such service is directly related to a class 1 recall;
• such recall is first reported to us by the insured in writing during the policy period;
• coverage for the life science product is included in the products-completed operations hazard; and
• the services are for the sole purpose of advising the insured how to reduce potential economic harm to the insured by maintaining and restoring public confidence in the insured or the product.

All reports in connection with the same recall will be deemed to have been made at the time the first of those reports is made to us by any insured in writing.

We have no duty to investigate, defend or settle any claim, suit or other demand of any nature against any insured or any other person or organization.

No other obligation or liability to reimburse expenses or perform acts or services is covered.

Limits of Insurance

Under Limits of Insurance, the following limit is added:

The most we will pay for the sum of withdrawal expense and crisis management service, to which this insurance applies, is $25,000 in any one policy period.

Product Withdrawal Expense and Crisis Management Service Exclusions

Banned Materials

This insurance does not apply to any withdrawal expenses or crisis management service expenses in connection with goods or products that have been distributed after any governmental organization has banned such goods or products (or any container, ingredient or part thereof) or declared them unsafe.

Known Defects

This insurance does not apply to any withdrawal expenses or crisis management service expenses in connection with any life science product which has a defect if such defect was known, or should have been known, by any insured prior to the:

• effective date of this insurance; or
• delivery of such life science product by any insured or any person or organization acting on any insured’s behalf.
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Product Withdrawal Expense and Crisis Management Service Exclusions (continued)

Waste Sites

This insurance does not apply to any withdrawal expenses or crisis management service expenses in connection with goods or products located at any premises, site or location which is or was at any time used for the handling, storage, disposal, processing or treatment of waste.

Willful Violation Of Law

This insurance does not apply to any withdrawal expenses or crisis management service expenses in connection with any willful violation of any statute, regulation, ordinance or other law, or any governmental directive or order.

The following section is added, but only with respect to the coverages titled Product Withdrawal Expenses For Life Science and Crisis Management Service For Life Science:

Conditions

Abandonment

There can be no abandonment of property to us unless we specifically agree to such abandonment in writing.

Duties In The Event Of A Class 1 Recall

A. The insured must give us immediate written notice upon discovery, or upon notification by a governmental organization, that a life science product, to which this insurance applies, is or may become the subject of a class 1 recall.

B. All insureds must immediately make every reasonable effort to stop any release, shipment, consignment or other distribution of any:

1. such life science product; and

2. kindred goods or products until it is determined that those goods or products are not subject to such recall.

C. As often as we reasonably require, any insured must:

1. permit us to inspect and make copies of records which support all withdrawal expenses or crisis management service expenses claimed.

2. cooperate with us in the investigation or settlement of any claim.

3. permit us to examine any person under oath, outside the presence of any other person and at such times as may be reasonably required, about any matter relating to this insurance or the claim, including any insured’s books and records. In the event of an examination, answers of the person we examine must be signed.
Conditions

Duties In The Event Of A Class 1 Recall (continued)

D. Within 90 days after any insured's report of a class 1 recall to us, the insured must provide to us a sworn written statement containing the following information:

1. a copy of any written notification from a governmental organization directing that the recall begin or documentation that supports your decision to voluntarily begin such recall;
2. a complete description and proof of the defect or situation, including the cause of the recall;
3. a listing that identifies the life science product, including batch or lot numbers, serial numbers and dates of manufacture; and
4. an itemized estimate of the withdrawal expenses and crisis management service expenses.

Loss Determination

In making any loss determination under this insurance we will utilize relevant sources of information, including:

• financial records and accounting procedures; and
• bills, invoices and other vouchers.

The amount of loss will be determined based on:

• withdrawal expenses and crisis management service expenses which exceed normal operating expenses; and
• other necessary expenses which reduce withdrawal expenses and crisis management service expenses that otherwise would have been incurred.

We will deduct from the total of such expenses the salvage value that remains of any property bought for temporary use in connection with the class 1 recall of a life science product.

Loss Payment

We will reimburse the insured for covered withdrawal expenses and crisis management service expenses within 30 days after we received the sworn written statement, as described under the condition titled Duties In The Event Of A Class 1 Recall, if all insureds have complied with all of the terms of this insurance, and we have reached agreement on the amount of loss.

No Benefit to Others

This insurance is for the benefit of insureds. No other person or organization may benefit directly from it.

Other Insurance For Product Withdrawal and Crisis Management Expenses

If any insured has other insurance covering loss which is also covered by this insurance, we will only reimburse the insured for the amount of loss, to which this insurance applies, in excess of the amount due from that other insurance, whether collectible or not.

Reduction of Expenses

All insureds must take all reasonable steps to minimize withdrawal expenses and crisis management service expenses.
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The following section is added but only with respect to the coverages titled Product Withdrawal Expenses For Life Science and Crisis Management Service For Life Science:

Definitions

Class 1 Recall

Class 1 recall means actions taken by, on behalf of, or at the direction of the insured to remove a life science product from the market because of a situation in which there is a reasonable probability that the use of, or exposure to, such product will cause serious adverse health consequences or death.

Such recall may be:

- a voluntary action initiated or requested by, or on behalf of, any insured; or
- required by any statute, regulation, ordinance, law or directive of any governmental organization.

Crisis Management Service

Crisis management service means professional service or advice provided by a crisis management service firm in connection with a class 1 recall.

Other Insurance

Other insurance means a policy of insurance or any type of self-insurance or other mechanism by which an insured arranges for funding of loss.

Withdrawal Expenses

Withdrawal expenses means that part of the following expenses which are reasonable, necessary and devoted exclusively to activities directly related to a class 1 recall of a life science product, to which this insurance applies:

- broadcast, electronic, printed, telecast and telephonic announcements, communications and notices;
- transportation and storage of such products or replacements thereof; or
- destruction and disposal of the products, including, but solely in connection with the foregoing:
  - overtime remuneration, transportation and accommodation of persons other than the insured's regular employees.
  - procurement, remuneration, transportation and accommodation of persons other than the insured's regular employees.

Withdrawal expenses does not include any:

- cost or expense to correct any defect;
- cost or expense of inspecting, adjusting or repairing any life science product or any other property;
Definitions

Withdrawal Expenses (continued)

• cost or expense of removing any such product from any other goods or products or from any other property;
• cost of the product, replacements thereof or of any other property;
• cost or expense of installing any replacement goods, products or other property;
• refund to any person or organization, including any cost or expense in connection with such refund; or
• cost or expense in connection with the realization, maintenance or recovery of market share, goodwill, reputation, revenue or profit.

All other terms and conditions remain unchanged.

Authorized Representative