MARSH | Munich RE

NDBI PHARMA IQ: PROTECTING LIFE SCIENCES COMPANIES FROM REGULATORY INSPECTION ACTIONS

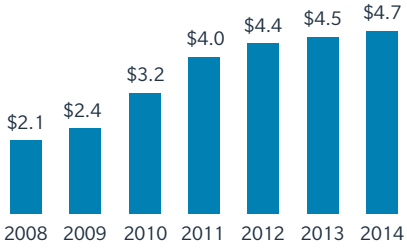
Life sciences companies have incurred approximately $8 billion in uninsured losses over the last 12 years as a result of manufacturing shutdowns emanating from regulatory actions imposed on their facilities. But traditional property insurance business interruption policies are designed to respond only in the event of physical damage to insured properties. NDBI (Non-Damage Business Interruption) Pharma IQ — available only from Marsh and jointly developed with Munich Re — provides a unique combination of risk transfer and risk consulting services to help address this critical risk. With built-in risk assessment services from Marsh Risk Consulting (MRC) and robust income disruption coverage, NDBI Pharma IQ can help you limit the impact of regulatory actions, including preemptive closures, and more quickly return to normal operations.

GROWING SCRUTINY, COSTLY INTERRUPTIONS

The US Food and Drug Administration (FDA) and its international counterparts are more closely scrutinizing life sciences manufacturing processes through planned and unplanned (or "for cause") inspections. This increased scrutiny is reflected in the agency's rapidly growing annual budget, which has more than doubled since 2008 (see Figure 1).

US Food and Drug Administration Annual Planned Budget (Billions)

Source: FDA



DEFINING, DESIGNING, AND DELIVERING SOLUTIONS TO YOUR MOST CRITICAL RISKS

A unique risk solution to protect against non-damage business interruption, NDBI Pharma IQ includes risk consulting services as part of the paid premium, to help life sciences companies assess and limit the impact of regulatory interruptions. Key features of the policy include:

- Coverage for up to 10 locations.
- $10 million in aggregate annual limits.
- A $1 million deductible.
- 60 hours of consulting services from Marsh Risk Consulting.

If during a site inspection a regulator identifies failure to comply with current good manufacturing processes (cGMP), it can:

- Issue a formal warning letter citing conditions in violation of cGMP, requiring a written corrective action plan and prompt implementation.
- Refuse to approve the manufacture of any new products at the affected site until it is remediated.
- File a consent decree, if the regulator remains unsatisfied, to suspend manufacturing and distribution of noncompliant operations.

Often, a company will preemptively suspend operations prior to a more severe action by a regulator. This can enable the organization to begin remediation and demonstrate a proactive response to avoid additional regulatory intervention.

The financial impact of these interruptions can be high, especially for companies that rely heavily on a single product, manufacturing facility, or supplier. The costs of such regulatory actions are not generally covered by traditional property, business interruption, and contingent business interruption insurance policies, but NDBI Pharma IQ is specifically designed to respond to such events.

ROBUST BUSINESS CONTINUITY PROTECTION

Unlike traditional property, business interruption, and contingent business interruption policies, NDBI Pharma IQ provides coverage for income disruption and/or contingent operating expenses incurred as a result of:

- The suspension of manufacturing due to a regulator's order.
- Voluntary preemptive suspension of manufacturing to prevent an imminent action by a regulator.

NBDI Pharma IQ provides a cost-effective way for a company to better understand its supply chain exposure while providing protection for up to 10 specified manufacturing locations (if located within a defined regulatory agency (DRA) country), including those owned by third-party suppliers. The policy provides reimbursement for loss of gross margin, remediation costs, and extra expenses associated with removal, destruction, and replacement of defective products.

RISK MANAGEMENT SERVICES

Risk transfer is just one tactic that a company can use to manage supply chain risk. That's why NDBI Pharma IQ includes risk assessment and quantification services, supported by MRC's forensic accounting, business continuity, and property risk experts. This unique benefit will enable you to assess your organization's supply chain exposures to potential regulatory actions, more effectively plan and manage those exposures, build resiliency in your supply chain, and make more informed risk transfer decisions.

Following our initial assessment, the experts at MRC can — for an additional cost — use our proven approach to help you:

- Assess the maturity of your supply chain risk management program by comparing it against best practices in strategy, organization, resources, and other factors.
- Use data and analytics to map your supply chain and prioritize interdependent risks and single points of failure.
- Define or optimize your supply chain risk management governance structure.
- Develop a process to monitor critical suppliers.
- Provide additional NDBI exposure analyses.
- Improve your NDBI risk insurance program.

In the event of a regulatory action that triggers NDBI Pharma IQ, our dedicated life sciences claims advocates can help you position your organization to achieve the best claims outcome possible. And you can rely on MRC's Forensic Accounting and Claims Services (FACS) Practice to help you measure your loss and any extra expenses incurred as a result of the regulatory action to ensure timely and effective recovery.

WHY MARSH AND MUNICH RE?

With strong insurance market relationships and diverse backgrounds in product manufacturing, underwriting, and other critical disciplines, Marsh's Global Life Sciences Practice has the knowledge and expertise you need to succeed. We understand your most critical risks and can help you develop insurance and risk management strategies to address them. Our clients include:

- 70% of the top 50 global pharmaceutical manufacturers.
- 44% of the top 50 global biotechnology manufacturers.
- 50% of the top 10 contract research organizations.

With its strong balance sheet, a superior A+ rating and extensive operations worldwide, Munich Re offers premium risk transfer solutions (through appropriate insurance companies) and has the expertise and capacity to deal with a wide range of different risk events by providing:

- Tailor-made solutions to meet clients' specific needs.
- Innovative solutions for the risks which have not been addressed or sufficiently addressed by the insurance market.
- Significant capacity for traditional lines.

These capabilities can be strategically deployed to benefit the key risk needs of pharmaceutical manufacturers, such as in the joint development of NDBI Pharma IQ by Munich Re Corporate Insurance Partner.

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