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LIFE SCIENCES INDUSTRY COVID-19: KEY RISKS AND POLICY IMPLICATIONS



The COVID-19 pandemic is an unprecedented crisis with virtually no point of reference in modern history. Organizations are struggling to cope with the constantly evolving situation. The life sciences industry is no exception. It has been experiencing a volatile situation, with developments creating new threats and opportunities at the same time.

In order to support our clients and make them aware of the potential implications of the pandemic under various insurance policies; we have attempted to capture some scenarios to explain how these policies will react and what could be the key actionables for the same.

The advisory is an inclusive, but not an exhaustive list of recommendations. While we have provided coverage positions in general, we would like to emphasize that insurers and underwriters would take a view based on policy level terms, conditions and warranties agreed upon initially.

Property Risk Issues



Voluntary / government-ordered shutdown of plant if infected person enters it

The insured is advised to notify the insurer(s) about the incident/situation as a potential loss situation and seek their opinion.

Exceeding sum insured of stocks

With restricted transportation services, stocks may have piled up at plants, warehouses, etc, thereby exceeding the sum insured of stocks. Insured must promptly inform the insurer(s) and seek an endorsement for an increased value. It would also be helpful to maintain a healthy CD balance with the insurer as a backup, although backdated endorsements may not be agreeable by insurers.

Temporary shutdown / Restarting post temporary shutdown of plants/warehouses

The insured must promptly notify the insurer(s) and seek their concurrence.

Change in risk provision

Under any of the following circumstances the insurance ceases to attach as regards the property affected unless the insured, before the occurrence of any loss or damage, obtains the sanction of the company signified by endorsement upon the policy by or on behalf of the company.

If the trade or manufacture carried on be altered, or if the nature of the occupation of or other circumstances affecting the building insured or containing the insured property becomes unoccupied and so remains for more than 30 days.

Marine Risk Issues



FOB exports: Extension of duration under the FOB clause and shut out cargo clause

Insured is advised to take an extension under the FOB clause, where arrival of the vessel is delayed. In case the contract of carriage is terminated and hence the cargo is not shipped, then the cargo must be returned and no extension on the FOB clause is

required. The return journey from the port has to be insured. In the event that the vessel has arrived and the cargo has not been loaded, an extension is required under the shut out cargo clause.

Accumulation of cargo in port/ airport/ transporter's godown/CFS due to lockdown and resultant congestion. In such cases, the schedule of cargo movement is stretched, thereby challenging the limit under the policy

It is recommended that insured informs the insurer and seek their concurrence for an increase in the location limit.

Change of voyage (rerouting / temporary storage) due to COVID restrictions

If the insured is aware of any such change in the voyage, then the same should be informed to the insurer and concurrence to be taken. It is also recommended that an extension be taken from the Indian insurer under the duration clause.

Termination of contract of affreightment (domestic /export/import) before the cargo reaches its destination

It is advised that insured informs the insurer about this situation and takes concurrence from insurer for continuity of cover under the cargo policy.

Cargo is stuck at the destination seaport, airport or railway siding due to lockdown. (Policy taken by insured's buyer or supplier)

In such a situation, extension of duration has to be taken from the supplier's insurance policy. If an extension is not possible, insured should arrange for fire and burglary policy with the local insurer when cargo is lying in the port beyond the duration period. It is also advised to take that a tail end risk cover from local insurer.

Cargo is stuck at destination seaport, airport or railway siding due to lockdown. - (Policy taken by insured)

If such a situation arises, insured needs to take a separate fire and burglary policy while the bond exists. The transit leg post debond is recommended to be covered under the cargo policy.

Liability Risk Issues

The potential claim scenarios in Liability can be broadly classified as direct claims and indirect claims

Direct claims: Claims lodged by the affected parties against the insured. Direct claims would

include direct contracting / being directly infected by COVID-19 and/or sustained a mental anguish/ emotional distress because of COVID-19 due to the alleged wrongful acts of insured. For instance, claims arising out of wrongful employment practices would classify as direct claims.

Indirect claims: Claims lodged by the affected parties against the insured, not due to direct contracting of COVID-19, but have occurred due to institutional/governmental actions, distressed economic climate and functioning remotely under stressful circumstances due to COVID-19.

Insurers as well as reinsurers have incorporated COVID-19 /infectious diseases exclusions under various liability policies that could potentially negate a cover that was otherwise admissible under normal circumstances. Clincial trial policies usually do not have COVID-exclusion but it is important to note that the policy will pay only for side effects caused as a direct result of an administered drug.

As a matter of abundant caution, we recommend that you intimate circumstances to your insurer and seek their advice on coverage.

Your Marsh relationship manager would assist you in drafting necessary intimation to your insurer so that in the event of any doubt, your intimation may help insurer to review your current state and advise you on coverage confirmation.

Trade Credit



The pandemic has led to financial stress in the lifesciences industry and there are risks associated with non-payment of accounts receivables. In view of the current situation, some insurers have extended the timelines for reporting an overdue account or for seeking an extension of a due date. As a matter of abundant caution, we recommend that the insured maintain close touch with its buyer's financial health. In case the insured is informed or aware of any adverse information about its buyers, it is advisable that the insured intimates insurer and seeks confirmation of their position.

Risk Management

It is recommended that lifesciences companies consider the below aspects of their operations and take prescribed measures to maintain business continuity.

Availability of Work Force

- Corporates may assess the need for the non-critical workforce and classify business activities as critical (that need to be completed during lockdown) and others.
- It is recommended to assess the availability of critical work force due to absenteeism increase mainly due to travel restriction, containment zones and illness. Accordingly, corporates can collaborate with service providers to explore ways to introduce remote health and care services.
- With limited work force, it is advised to ensure that the focus on regulatory compliance with FDA/CGMP norms are not diluted. Similarly it is advised to ensure that fire protection system and security system are not compromised considering limited work force.
- With limited workforce, the maker-checker control should be active particularly during the shift change.
- It may also be beneficial to carry out route planning for people and vehicular movement in view of social distancing.

Contractor Management

- It is recommended to assess availability of trained contract manpower.
- Further, contractor access to plant or office operations should be restricted.
- Mandatory sanitization and thermal screening is advised if contractors need to access plant or warehouse.

Sanitization of Workforce and Place

- Training of workforce for social distancing and sanitization should be provided.
- It is recommended to develop procedures with respect to COVID-19, which states the additional steps that need to be taken to ensure sanitization; including routinely cleaning all frequently touched surfaces, discouraging workers from using other's belonging, use of PPE, social distance, etc.

- Sanitization and thermal screening of personnel who enter and exit work premises must be carried out; usage of masks and gloves while in the premises must be made mandatory.
- Additional infrastructural changes may be required to ensure provision of contactless sanitization - adequate stocks of PPE, sanitizers and disinfectants, sourcing tools helping social distancing.
- Communication media in the form of posters and banners that encourage hygiene at the entrance to workplaces and in areas where they are likely to be seen should be placed.
- Sanitization should not be restricted to personnel but should be extended to the parcels, couriers, vehicles, in-bound materials, etc.
- Scheduled maintenance activity such as HEPA filters must be prioritized.
- Quality checks of material received (including external material covering checks for contamination) should be undertaken.

Work From Home



- It is advisable to document a policy pertaining to work from home, if not already done. Key focus should be on being secure and productive while being connected remotely. It is imperative to maintain the three basic pillars (confidentiality-integrity-availability) of information security.
- Non-essential travel (domestic/ international) must be restricted and flexible working arrangements should be promoted.
- Emergency toll-free numbers to handle any crisis that may come up should be communicated to all employees.

- Effective planning for IT infrastructure and equipment with updated software patches should be carried out.

Supply Chain Risk Management

- Shortage of raw materials/API/ solvent due to dependency on other countries to complete BOMS/batch size processing should be addressed.
- Products affected by possible shutdowns at suppliers - and suppliers' suppliers - or logistics interruptions in Asia (especially China) must be identified.
- Potential expiry of materials must be assessed; they should also be monitored for re-assessments and quality certificates.
- Non-availability of local transportation for dispatch of material and finished goods must be assessed.
- Additional stress on companies for clinical trials may also be assessed.

Change Control

The scope of a change control program covers a broad set of possibilities of risk, including changes to product formulation or design, upgrades to facilities, utilities, equipment and computer systems, manufacturing instructions, operating procedures, test methods and specifications, any new raw materials as well as any changes in policy.

Change control is one of the most critical elements in the pharmaceutical industry. Inadequate change control procedures may end up creating a huge risk of non-compliance not only from a regulatory and qualification perspective, but also from a risk management perspective. In the present scenario, many companies have started manufacturing sanitizers and disinfectants. This change introduces flammable liquids at site which is the key raw material for manufacturing of sanitizers. With introduction of flammable liquid, severity of fire hazard increases considerably thus impacting the risk mitigation measures and insurance rating as well. Hence any such changes should be managed carefully with proper evaluation informing all stakeholders.

Marsh Risk Consulting can perform offsite services for property, marine cargo and business interruption loss

control program. These services include:

- Virtual Risk Inspection.
- Risk Financing Optimization.
- Review of Property Loss Control Policies and Procedures.
- Risk Profile.
- Natural Hazard Desktop Review.
- Interdependency and BI Study.
- Marine Claims Analysis.

Claims Management



In view of constraints due to the ongoing pandemic, claims management through the traditional method of physical site inspections and documents has become challenging. Insurers and surveyors are gradually adapting to the idea of processing files based on digital documents and engaging in discussions virtually. There are unique ways that can be adopted by insureds to fulfil the requirements for both, ongoing claims as well as new claims reported during the lockdown. We recommend that the insured intimate any claims or circumstances that may result into a claim to its insurer in a timely manner. We also advise the insured to reach out to its Marsh relationship manager who will assist in the co-ordination with insurers for all aspects related to insured's claims.

Lifesciences Industry Team

The Marsh India LifeSciences Industry Team has been setup to support our clients and colleagues with industry specific knowledge, experience and expertise to structure solutions that address the life sciences industry's insurance and risk management requirements in the optimum way.



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