IRMA, MARIA HIGHLIGHT PHARMA'S NEED TO BALANCE SUPPLY CHAIN

What Drug Manufacturers Should Watch in the Wake of Natural Disasters

When it comes to natural disasters, it’s not about if your supply chain will be impacted, it’s when.

For the life sciences industry, the consequences of supply chain disruption become a public safety concern. Like 1998’s Hurricane George, Hurricanes Irma and Maria have underlined this concern. Following the storms, the FDA announced that the U.S. will likely experience drug shortages due to the natural disasters’ residual impact on the drug manufacturing industry in Puerto Rico.

Nearly 10 percent of drugs prescribed in the U.S. are manufactured in Puerto Rico. Those include critically important products like treatments for cancer, HIV and rheumatoid arthritis. More than 50 medical device plants are located in Puerto Rico, manufacturing more than 1,000 types of medical devices and employing 18,000 people. Only a small fraction of the power to the island has been restored, suggesting many drug and device manufacturers may not be fully online. FDA Commissioner Scott Gottlieb told Reuters, “It’s unclear when they are going to be able to bring [production] up to full capacity.”

On Oct. 20, the FDA released a statement outlining efforts in conjunction with federal and local agencies to rebuild the island, monitoring more than 40 medical devices manufactured there and working alongside pharmaceutical and medical device makers to expedite the process of getting factories back up and running.

IMPACTS

Supply Chain
While many factories owned by large global pharmaceutical companies are running on generator power as backup, some of these plants may be the single manufacturer
of a certain device type. The FDA said it is working with about 10 manufacturers, especially those manufacturing critical blood-related medical devices, which fall within this camp.

Outcomes & Reimbursement
If providers don’t have access to the right drugs or devices, they could face adverse financial impacts including greater costs associated with delivering patient care through higher drug acquisition and personal costs. They may also have to prescribe an alternate drug that isn’t as effective. That leads to implications for the effectiveness of care and potentially a hit to quality metrics, which would impact reimbursement under value-based arrangements, including those taking place under the Medicare Access and CHIP Reauthorization Act (MACRA). Providers who might be up against a shortage should work to understand what that could mean for their ability to attract investors.

Business Continuity Risk
The revenue disruption also poses an audit risk for pharmaceutical and medical device companies. If a plant is destroyed or not operating at full capacity and providers are forced to turn to other suppliers for critical drug products, like cancer treatments, it could create a going concern or business continuity issues for a pharma or medical device company.

BDO INSIGHTS
For life sciences, natural disaster and supply chain risks are hardly new. According to the 2017 BDO Life Sciences RiskFactor Report, 81 percent of the top 100 companies on the NASDAQ Biotechnology Index cited natural disasters as a risk in their most recent shareholder filings. Almost all (97 percent) mentioned supply chain issues, including product availability and compliance with Good Manufacturing Practices. Both risks have been tracked every year of the report’s five-year history.

But Hurricanes Irma and Maria should serve as a stark reminder of the importance of disaster preparedness and supply chain balance. Many factories selected sites in Puerto Rico to take advantage of significant tax benefits, but the benefits of a reduced tax burden will no longer outweigh the supply chain risk associated with production that’s concentrated in a single area. Looking ahead, pharmaceutical and device manufacturers—even those that haven’t been directly impacted by the disruptions in Puerto Rico—would be wise to re-evaluate supply chain risk.

Start with a broad risk assessment. This should begin at the top level of the organization, with an analysis of the risk related to natural disasters throughout the drug and device manufacturing process, including analysis of supply chain, regulatory and reputation risks to which the company may be exposed. As natural disaster events persist, manufacturers should consider prioritizing these risk assessments. These assessments can help manufacturers start to address short- and long-term threats, and create and implement manageable changes and solutions within both their supply chains and their production processes.

Pharmaceutical and medical device manufacturers can also take proactive steps to make plants more secure. Infrastructure investments for hurricane and fireproofing or building remote storage, away from natural disaster-prone regions, will more than pay for themselves if and when catastrophe strikes.

Liability, property and equipment insurance can also help to protect against these events. Pharmaceutical and medical device manufacturers make large investments in specialized equipment and warehousing space. Whether it’s a small flood or a Category 5 hurricane, property and equipment insurance can minimize the impact to operations.

Pharma and device manufacturers should also ensure they are diversifying their suppliers and, perhaps most importantly, their production locations. This can help more adequately develop a supply chain able to withstand extreme weather. For investors in the space, conducting regular due diligence on supply chain risk is recommended.

During the first several weeks following a big storm, businesses that are properly covered by insurance are likely beginning to check off steps on their emergency preparedness checklist. Those that don’t have contingency plans, or who are noticing gaps in their path forward, should consider incorporating the next steps listed below for coping with disaster and picking up the pieces:

1. **Communicate with employees and external stakeholders.** Following the activation of an emergency preparedness program, it is critical to communicate with employees and business partners about their well-being, as everyone will be dealing with potentially significant, or even devastating, personal and professional issues.

2. **Review your insurance policy.** Even if a business does not suffer physical damage, it may have coverage for business interruption losses. For example, if a business’s customers or suppliers have been flooded and cannot receive the business’s goods or services, the insurance policy may include what is referred to as “Contingent Time Element coverage.” Non-physical damage coverage for business interruption losses can also include lack of access to facilities (e.g., road closures) and loss of utilities, among others.
3. **Maintain contemporaneous documentation.** To say that the hours and days after a disaster are hectic is an understatement. This is a trying time for businesses as they try to rebuild and recover. However, keeping careful records even during this time of disruption is critical. Preserving email traffic around current market conditions and cancellations of sales or impacted suppliers/customers is critical to a business interruption claim.

4. **Get the right team on your side.** A major property claim can take several months to resolve, and the complexity of the issues that may arise requires external experts to look out for a business’s interests while management focuses on what is important—rebuilding and recovering.

5. **Establish milestones for claim recovery.** Following a major catastrophe, resources are often stretched thin. It is important to create milestones and hold all members—from the adjusting team to internal stakeholders—accountable for achieving those goals.

A version of this article also appeared in *The Pharma Letter*.
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