Regulatory Non-Damage BI
Case Studies Europe

These case studies are based on real events at the manufacturing plants of pharma companies and demonstrate how EQuIP, Munich Re's Non-Damage BI cover would have responded.

Case I: Pre-emptive suspension and revocation of licence resulting in loss of revenue and ultimately insolvency

What happened?

During a routine regulatory inspection by the MHRA cross product contamination was detected at a sterile manufacturing facility and a statement of GMP non compliance was issued to the owner of the facility. Manufacturing was suspended voluntarily by the owner in order to remediate the problem but the regulator also revoked the site's manufacturing license meaning that the facility would also have to be formally re-approved to recommence production.

Impact

The remediation work required was extensive and the company's turnover was not large. Although its other manufacturing site was unaffected the company had insufficient cashflow to remediate the site. It was forced into administration and its assets were purchased by a major customer who depended on the facilty for key products in its range.

Case II: Pre-emptive suspension resulting in loss of revenue and product shortages

What happened?

A European manufacturing plant which produced a range of vaccines for 90 countries suspended production voluntarily when GMP compliance issues regarding quality standards were detected with two of its key vaccines. World-wide shipments of the affected vaccines were put on hold and production suspension lasted approximately twelve months whilst analysis of the root cause was completed. The local regulator ANSM were advised. Already distributed vaccines were not affected.

Impact

Product shortages occurred and the company was forced to re-allocate its existing compliant vaccine supplies. Revenues were impacted as the existing stock was insufficient to cover customer demand.

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Case III: Pre-emptive Suspension due to malicious tampering resulting in loss of revenue

What happened?

The company, a contract manufacturer, operates several plants which manufacture capsules for a number of major pharmaceutical customers. During QC procedures a number of out of place capsules were discovered in batches at one of the company's French facilities which produced 2bn capsules per annum for its customers. The local regulator ANSM was notified and the company closed the plant voluntarily to investigate. ANSM subsequently issued a notice of suspension. Investigations concluded that the problems arose from malicious tampering and not any form of manufacturing process failure. A criminal complaint was filed with the French police.

Impact

The site was closed for approximately 7 months. As a result of the suspension the company suffered a lossof approximately $21m in revenue. A number of its customers experienced delays and shortages and one company was forced to delay the launch of a new product with potential reputational impact.

What EQuIP, Munich Re's Non-Damage BI solution would have covered in these examples:

- **Loss of Gross Margin** incurred by the companies as the result of the closure of their affected sites provided such closure pre-empted action by the relevant regulator including where the compliance failure was as the result of malicious tamper

- **On-going Loss of Market Share** once production was re-established at the affected site (up to maximum indemnity period of Policy)

- **Direct Associated Expenses** including **Remediation Costs** provided that such expenses and costs reduced the overall loss by enabling a faster re-start of production