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With regulatory action rising, drug makers opt for larger covers

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Faced with a rise in the cost of compliance owing to regulatory action by the US Food and Drug Administration (FDA), Indian pharmaceutical companies are now turning to insurance firms for larger product-liability cover. Even smaller pharma companies, in the nascent stages of drug discovery, are purchasing these covers, insurance executives said.

According to a recent report by global credit rating agency CRISIL, stricter norms by the FDA will lead to higher compliance costs for Indian companies and it will remain high over the medium term. The report noted that the cost of compliance for drug makers has doubled over the past five years.

Tapan Singhel, managing director and CEO of Bajaj Allianz General Insurance, said there was a financial bearing to expand abroad for the pharma companies with the FDA regulations. He said compliance has become a bigger issue for these companies and hence, they are opting for pharma liability covers.

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"Higher growth brings complex risks and stricter regulations with it. Therefore, it is essential for the pharmaceutical companies to have insurance solutions that respond to changes in market conditions and emerging risks," Singhel added.

Adding to this, Ursula Waldhausen, chief executive senior underwriter, Allianz Global Corporate & Specialty, said the global exposure for Indian drug makers was increasing, given the rise in worldwide distribution of their products.

"This implies that the risks faced by these companies are no longer restricted within India. Today, they have a substantial exposure in foreign countries, especially in the US and the European Union. Stricter norms in these countries and instances of heavy losses in the past call for a comprehensive global liability cover for these companies," she explained.

In the past few years, there had been a rise in regulatory action by the FDA against Indian drug makers. Actions included not just drug recall but also enforcements such as warning letters and import alerts. The US is the largest export market for Indian pharmaceutical companies.

Bajaj Allianz said it would focus on risk management of these companies and offer solutions to ensure they were adequately covered. Bajaj Allianz General Insurance, along with Allianz Global Corporate & Specialty's Pharmaceuticals Global Practice Group, said they have the financial strength to provide major capacity and the worldwide resources to provide immediate help in case of claims.

Product liability covers are the most risky in the sector. With risks of faulty drugs and products recalls that can cause a financial and reputational damage to the drug maker, the industry is rushing to insurers for larger covers, protecting them against major costs rising out of fines and recalls. Insurers said there has been a 15-20 per cent rise in the prices of these covers.

Sanjay Datta, head of underwriting and claims at ICICI Lombard General Insurance, said apart from bigger pharma companies that have been taking product liability covers, smaller firms are also showing interest in these covers, especially from a US exposure point of view. The Indian pharmaceutical market was worth $6 billion in 2005 and grew to $18 billion in 2012. The sector is estimated to be a $35-70 billion market by 2020.

Sushant Sarin, senior vice-president (commercial lines and broking) at Tata AIG General Insurance, said mid-size and large companies buy pharma liability covers.

"The driver here is not the size, but that they export generics to the US. They take a product liability cover also because the retail chains abroad where these medicines are sold ask Indian manufacturers to purchase such covers," said Sarin. He added that a product recall cover is taken along with a product liability cover so that the cost of recall also gets covered.

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