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International regulatory non-compliance is serious challenge to life sciences sector growth, discloses Deloitte survey

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Although the numbers are not available, the economic impact of non-compliance of international regulatory by the life sciences sector in the last five years is very high.

The non-compliance due to various reasons is a serious challenge to growth of the sector and is going to hold growth of companies.

"Nobody has counted it in numbers but it was needed to be computed and the opportunity loss cannot be counted," said Rohit Mahajan, Senior Director, and Nitin Bidkar, Director, Deloitte Touche Tohmatsu India Private Limited, while releasing the survey report 'Managing growth through better compliance management' here today.

Mahajan said about 50 plus companies were banned by the regulators from abroad for non-compliance so it can be very roughly guessed that the loss was somewhere around 5 to 7 % of the total revenue. The anonymous survey was done to assess the industry' preparedness for zero tolerance level of the regulators, to understand compliance culture and to capture behavior culture for compliance of the companies.

About 50 companies exporting products from among top life science 100 companies that included pharmaceuticals, medical devices, biotechnology, were approached for the survey and 33 responded. The survey was launched in August 2014. Deloitte concentrated on this area because of increasing monitoring by regulators abroad of Indian pharma sector and manufacturing facilities.

One of the main reasons for non-compliances has come out to be shortage of skilled staff as claimed by 64%, 55 percent of survey respondents have indicated that their compliance teams were not adequately trained to address regulatory requirements. Besides talent shortage, lack of an efficient internal control/ compliance system (61 percent of survey respondents), inadequate utilization of technology to identify red flags (45 percent), and lack of a zero tolerance approach towards noncompliance and malpractice (45 percent) were indicated as key contributors to noncompliance and malpractice in the sector.

Further, 30 percent of survey respondents said they had experienced noncompliance with GxP guidelines in the last two years. However, 45 percent said they had not experienced any type of noncompliance.

The Indian pharma sector is growing 15 to 20 % CAGR year on year and expected to be worth $55 billion by 2020 and majority of that revenue will be coming from exports, Bidkar said. He informed that in India there are 546 facilities approved by USFDA, 847 by UKMHPH and 1295 by WHO-GMP. Over 50 facilities were banned for non-compliances, he added.

In addition, "in the last two years, most regulatory bodies have introduced new areas of scrutiny beyond just testing drug efficacy, and now involve risk management and mitigation programs for R&D laboratories, manufacturing facilities and procurement functions. For compliance management professionals to familiarize themselves with these changes and become adequately trained in them requires time. In the interim, companies could be exposed to vulnerabilities arising from non-compliance," said Mahajan.

Industry was evolving, Mahajan pointed out, this was the transition issue that the sector was facing. Even developed countries faced this problem of transition. The only difference was that in India we were also in response, he added.

Both Mahajan and Bidkar denied the possibility of manipulation by respondents saying that they have not done any ranking of the companies on compliance and hence no industry or industry person would be interested in manipulating their responses. If fact, Bidkar said even industry wanted to know the realistic picture and where they stand. He informed that US and UK have begun the process of ranking the companies on compliance basis.

The survey report said around 48 percent of respondents confirmed that compliance strategy was not a key area earmarked for investment in their organizations, indicating that perhaps senior management did not consider this area as a high risk with serious consequences in the event of non-compliance.

"Organizations that view fraud risk management and compliance management as strategic activities, are able to identify instances of noncompliance and work towards mitigating such incidents. Unless the life sciences sector looks at compliance management strategically, it will not be able to make the necessary investments in tools and technology to build a robust control environment that can mitigate non-compliance," said Mahajan.

On detection of fraud, noncompliance and malpractice, 76 percent of respondents indicated relying on whistleblowing channels. Upon detection of fraud 85 percent of respondents said they launched an internal investigation by a specially appointed committee, while 82 percent confirmed that some form of disciplinary action was initiated as per existing policies and fraud and compliance risk management frameworks.

The survey report also discusses the key types of noncompliance observed in the sector along with providing a roadmap for organizations to build an effective compliance management system.