

COMPANIES HAVE LITTLE CHOICE, BUT TO INVEST IN BRINGING COMPLIANCE PROCESSES UP TO SPEED: CRISIL USFDA norms to push up costs for Indian pharma

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Stricter norms by American drug regulator the USFDA will lead to higher compliance costs for Indian pharmaceutical companies, although these enforcements are not country specific but more on account of "cultural differences", said a report by global credit rating agency Crisil.

The companies have little choice, but to invest in bringing compliance processes up to speed, it said, adding so (warnings letters/import alerts may impact both current revenues and fu-

pipeline) will be far higher. In general, the cost of compliance of drug makers has doubled over the past five years. About 30 per cent or \$4 billion worth of India's pharmaceutical exports are to the USA.

India remains a location of significant importance to the FDA as it has the largest number of FDA-approved drug manufacturing plants with over 150 formulation facilities and is also the second-largest pharmaceutical supplier to the US market in terms of volume of generic drugs.

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COST OF COMPLIANCE



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an pharmaceutical companies, though not country specific, are mainly on account of issues such as cultural differences and attitude of employ-

ees, it said. However, going forward, Crisil said, it expects the cost of compliance to rise as drug makers adapt to a stricter regime.

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the USA, while mid-sized players such as Torrent Pharma, IPCA Laboratories, Glenmark Pharma and Alembic Pharma account for the balance, according to the ratings agency.

Crisil said it believes that large Indian pharmaceutical companies have the financial flexibility to bear the increased cost of compliance and remain competitive in the USA, which constitutes more than 50 per cent of their overall revenues.

The top 10 Indian pharmaceutical companies by revenues account for more than 70 per cent of the total formulation exports to the USA. These players continue to maintain a strong financial risk profile marked by healthy cash accruals, strong network, moderate gearing and surplus liquidity.

"Nevertheless, India continues to enjoy a rising share of ANDA approvals compared to other countries. As on date, the top 10 Indian pharmaceutical companies account for more than 800 ANDA filings," the report indicated.

The credit risk profiles of the large Indian pharmaceutical companies are, therefore, expected to remain strong over the near term.

Regulatory