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I Russia, Mexico, Brazil, Japan on radar; bid to cut US market risk Indian pharma scouts for new geographies under USFDA fire

ANIL SASI NEW DELHI, DECEMBER 25

HE sharp recovery in the US economy notwithstanding, India has kickedoff a desperate diversification plan that aims to leverage inter-country partnership pacts for gaining market access in new geographies that include countries such as Russia. Kazakhstan, Mexico, Brazil, Venezuela, Japan and those forming a part of the ASEAN bloc.

Coming at a time when India's drug exports are increasingly coming under regulatory fire in the United States — its biggest market that accounts for 25 per cent of the country's cumulative drug exports — the proposal firmed up by the department of pharmaceuticals also mentioned a clutch of other non-traditional markets that it would want to now focus on, including South Africa, Nigeria, Kenya, Saudi Arabia and the UAE.

Moreover, European countries such as Spain, Greece, Germany, France and Italy are also on this focus list that essentially aims



to counterbalance the heavy reliance currently on the US market for export of active pharmaceutical ingredients and niche formulations from the country.

The proposal, which has been presented by the department of pharmaceuticals in a deposition to the Parliamentary Standing. Committee on chemicals and fertilisers, comes at a time when major drug companies which are dominant players in the Rs 80,000 crore Indian pharmaceutical industry are struggling with quality problems repeatedly highlighted through punitive regulatory interventions by the US Food and Drug Administration (USFDA).

There is the also the

added problem of Indian drug companies witnessing a severe pressure on their pricing power in the conventionally lucrative US market, something that is evident in a Morgan Stanley analysis of 582 drugs sold in the US by six leading Indian pharmaceutical companies. The report shows that about 86.per cent of these drugs did not register any change in price during calendar years 2013 and 2014.

The market diversification plan also comes at a time when the Indian pharmaceutical exports registered their slowest growth in over a decade, surging a measly 1.2 per cent to \$14.84 billion last fiscal.

While the continuing

slowdown in the US is a prime reason, other hurdles include regulatory reverses in that market as well as intellectual property rights issues flagged by authorities in that country.

India's pharma exports are likely to miss the target of \$25 billion set for 2014-15, according to a government strategy paper issued earlier this year.

According to commerce ministry data, in 2012-13, the country's pharma exports totaled to \$14.66 billion.

The growth registered in 2013-14 was the slowest in nearly 15 years, the previous slowest growth having been clocked in 2009-10 when pharma exports grew by just 5.9 per cent

Regulator