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Drug exporters under pressure

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Latest development in the US government policies related to tax, quality and price in pharmaceuticals sector are being watched with concern by the Indian pharma companies that export drugs to US. President Donald Trump had repeatedly made statements over reducing drugs prices and increasing drug manufacturing in US.Scott Gottlieb has recently taken over as Trump administration's new FDA commissioner.

The India pharma companies, which are already under pressure due to some quality related issues raise by US FDA, are facing uncertainties over what steps Gottlieb takes to implement the Trump formula of price reduction and domestic manufacturing and how they will affect them.

Gottlieb is known as a conservative health policy expert with deep ties to the pharma industry. He told the US Congress sub-committee that he would soon share a 'drug competition action plan' which aims at expediting approval of generic drugs that lack competition and making it difficult to steeply increase prices of the off patent drugs due to lack of competition. Actually, FDA does not play any direct role in pricing but he intends to do that indirectly by facilitating entry of lower cost alternatives leading to competition and also speeding up approvals for older generics.

Although some of his statement is a relief to Indian companies to some extent, issues like possible imposition of Border Adjustment (BAT) is surely matter to worry for them. There is a talk of imposition of BAT, tax on imported drugs, to encourage domestic production in US. It is expected to affect the pricing of Indian drugs in US and when Trump administration is contemplating steps towards price reduction any hike in price, even due to the tax, may affect the prospect of the Indian companies.

This is really a matter of concern for Indian companies since they export drugs worth over USD 4 billion to US. However, one factor in favor of Indian companies is that for US market also export from India is important since they supply 40% of generic drugs consumption in US. In monetary terms, Indian companies export drugs worth almost 10% of 70 to 80 billion US generic drug market.

For the Indian companies which are already facing the uncertainties over the issues of BAT, subsequent pricing and competition, there is one more area to be concerned about and that is quality of products.

USFDA has focused on the quality aspect and in last few months some Indian companies have received warning letters from USFDA for not following manufacturing standards at the production units.

In a USFDA blog, Mary Lou Valdez, Association Commissioner for International Programme, USFDA, has said that quality is a challenge for Indian pharma sector and has initiated actions accordingly. Out of the total 42 Good Manufacturing Practices (GMP) related warning letters issued by USFDA last year nine were addressed to Indian companies. It is probably the result of doubling of FDA inspections of pharma company sites since 2012.

Edelweiss securities in its report apprehends that the number may go up even further as FDA would inspect 190 facilities that it had not in earlier five years. India has 572 US FDA compliant plants, the highest outside US.

Indian pharma companies are likely to face the quality issue even at the domestic front also. In view of the Medical Council of India's direction to medical practioners to prescribe only generic drugs, Doctors' associations in Telangana and elsewhere have expressed least confidence in the efficacy and quality of generics. There is no proper regulatory system to continuously monitor the quality and efficacy, doctors have pointed out.

While watching the developments in USFDA, the Indian companies will have to focus on quality standards to compete in US market, as well as to spread the government's generic drug movement with the country to help domestic customers.