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US generic drug fee relief plan may benefit Indian companies

PTI ■ WASHINGTON

American health regulator FDA could consider bringing some relief in payment of fees to small generic drug makers, including those from India, if a newly proposed legislation is enacted.

With the US Food and Drug Administration proposing to hike the fees for generic drug-makers for next fiscal, concerns had been raised on the financial burden that the one-size-fits-all fee structure creates issues for the smaller units, which typically face cash crunch problems.

Congressman Robert Hurt introduced a legislation along with Congressman Phil Roe this month that seeks to level the playing field for generic drug user fees so that smaller manufacturers would be expected to pay fees that reflect the relative size of their firms compared to giants.

The Small Manufacturer Protection Act of 2013 would add new provisions allowing for waivers and refunds of user fees.

"The expectation that all manufacturers pay the same fees, regardless of their size, is unrealistic and should be adjusted to accommodate these smaller companies so they can continue to innovate, produce and compete," Hurt said in a statement.

While the fees collected by FDA garner the funding required for the agency to review generic drug submissions, failure to pay up results often results in stiff penalties.

For instance, failure to timely submit the annual facility payment means that FDA would not be able to receive new Abbreviated New Drug Applications or Prior Approval Supplements referencing these facilities until outstanding fees are paid.

The FDA is tight-lipped on the effect of the legislation. "The Administration does not have a position on this legislation," Sandy Walsh, an FDA spokeswoman, said in an e-mailed reply to queries in this regard.

India is the second largest drug exporter to the US. Indian drug-makers mostly specialise in manufacturing of generic versions of innovative drugs at a fraction of cost after their patent expiry and are estimated to command 10 per cent share in the US generic drug market.

"The bill does not discriminate between domestic and foreign companies. Thus, small Indian companies could benefit if the bill is enacted," Kurt Karst, Director at top US law firm Hyman, Phelps & McNamara told the news agency.

The US regulations require companies to pay user fees to supplement the costs of reviewing generic drug applications and inspecting facilities. For fiscal 2014, the new Abbreviated New Drug Application fee has been proposed to be fixed at $63,860, which is around 24 per cent higher than the existing $51,520. Similarly, the Prior Approval. Supplement fees for fiscal year 2014 (from October 1, 2013 to September 30, 2014) has been proposed to be hiked by 24 per cent to $31,930.

The steepest increase may be in Drug Master File fees, which has been hiked by 48 per cent to $31,460.

The annual facility fees for finished dosage forms have been increased by about 25 per cent. The domestic FDF facility fee has been revised to $220,152 and foreign FDF facility fee to USD 235,152.

However, the FDA has lowered the annual active pharmaceutical ingredient fees for both domestic and foreign API facilities.

Regulatory