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Health activists concerned over Cipla-Merck deal for HIV drug

Demand clarity on the pricing of Raltegravir 400 mg tablet in India

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Concerns have surfaced over Indian pharma major Cipla striking an India-specific strategic deal with US-based Merck and Co for a critical HIV drug Raltegravir with health activists demanding clarity on the pricing of the drug.

The agreement allows Cipla to have a non-exclusive licence to market, promote and distribute MSD's (Merck's trade name) Raltegravir 400 mg tablet under a different brand name in India. But activists are questioning pricing ramifications of the deal considering Raltegravir is patented in India since 2006 and with the patent not expiring before 2022, open generic competition on this medicine is blocked.

"The licence deal is a huge

Bitter pill

■ The deal allows Cipla to market, promote and distribute Merck's Raltegravir 400 mg tablet under a different brand name in India

■ Raltegravir is patented in India till 2022 and open generic competition on this drug is blocked

■ The deal is a huge disappointment as it doesn't allow competition among multiple producers that could lead to 90% price reduction of the drug



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decreases we've seen for other HIV medicines in India and other developing countries. India's Health Ministry should pursue a compulsory licence on Raltegravir to allow broad competition so that affordable generic versions of this drug are available," Leena Menon of Médecins Sans Frontières said. MSF added it was not up to companies to decide on a reasonable price or terms for a drug. "The government must decide whether or not such marketing arrangements between Indian and large foreign pharma firms undermine or improve access to medicines at affordable prices," Menon argued.

Raltegravir is an important HIV medicine used to treat patients who have failed first and second line anti-retroviral treatment. It was among the first HIV medicines to be patented in India.

Middle-income countries currently pay over \$5,000 per patient per year for Raltegravir with MSF alone paying over \$1,700 per patient per year for Raltegravir in treatment programmes in India.

"Any licensing deal concerning a drug patented in India is liable for scrutiny of the government. MSD is bound to submit a copy of its licensing agreement to the Patents Office to come clean on anti-competitive provisions in the agreement, if any. If MSD doesn't submit the agreement voluntarily, the government can ask for it," said activist Gopa Kumar. While the terms of the deal

between Merck and Cipla haven't been made public, activists say the company statements indicate the agreement is not a licence to open up production and supply of a generic version of Raltegravir. "It's a deal that will allow Merck to use Cipla's marketing and distribution network in India to sell its patented product under a different brand name. There's no clarity on price. Merck and Cipla must declare terms of the deal so stakeholders can independently assess the agreement for any restrictive conditions, if any," MSF activists said.

Activists also demanded that the process of pursuing a compulsory licence for Raltegravir should be continued by India. India has around 2.3 million HIV positive people and 1.3 lakh are reported to be on anti-retroviral treatment.

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