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Generic possibilities from Bristol-Myers AIDS drug pact

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Indian drug-makers wanting to make AIDS drug atazanavir will now be able to do so, following a licensing agreement signed by multinational pharma firm Bristol-Myers Squibb (BMS) and UN-backed Medicines Patent Pool (MPP). Atazanavir, marketed by BMS under the Reyataz brand, is used in the second-line treatment of HIV/AIDS.

The agreement, announced on Thursday, will allow manufacturers worldwide to produce more affordable versions of atazanavir, and to combine atazanavir with other medicines, to make treatment easier and more accessible in developing countries, said Greg Perry, Executive Director of MPP. Generic drug-makers, many of which are in India, will be able to access the technology to make the drug, and export it to 110 countries.

The scope of the agreement covers over 88 per cent of the HIV/AIDS affected people in developing countries, said MPP.

GENERIC PARTICIPATION

BMS has existing agreements on this drug with Pune-based Emcure and Gurgaon-based Ranbaxy, besides multinationals Mylan and Aspen. These agreements cover only about 50 countries.

The latest MPP agreement more than doubles the countries covered, and allows for more players to make the drug, said Sandeep Juneja, MPP's business development director, adding that he will talk to Emcure to join the new agreement.

BMS' atazanavir costs about $412 per patient per year. Where generically-similar versions are available, the price is over $250 per patient per year.

As more companies participate, the resulting competition will further drive down medicine prices, ultimately benefitting patients, he told *Business Line*, speaking from Geneva.

Citing data from international humanitarian organisation MSF (Médecins Sans Frontières), another MPP representative said BMS' atazanavir costs about $412 per patient per year, in countries eligible for BMS price discounts. But where generically-similar versions of the medicine are available (sub-Saharan Africa and India), the price is lower, at over $250 per patient per year.

In the past, Indian generic makers including Aurobindo, Shasun, Laurus, Hetero and Shilpa Medicare have dipped into the patent pool on various HIV drugs.

ROYALTY PAYMENTS

Under the agreement, a technology transfer package will be provided to sub-licensees to facilitate the manufacture of atazanavir. While royalties are not applicable in the vast majority of the countries and are waived for all paediatric products, any royalties collected under this licence agreement will be reinvested in local HIV/AIDS groups in those countries, MPP said.

Generic drug-makers producing chemically-similar versions of BMS' atazanavir will pay royalties to MPP if they are in markets were patents are granted, Juneja explained. But in India, where the patent application is pending, there will be no royalty till a patent is granted, he added. Patents allow innovators 20 years of exclusivity to make and sell their innovative product.

The MPP agreement is its first on a WHO-preferred second-line therapy. The WHO estimates there will be over 1 million people on second-line treatment by 2016, and many more will need access to these therapies.

"Second-line treatment is increasingly important as people living with HIV around the world develop resistance to their current regimens," said Margaret Chan, WHO Director-General.

MPP focuses its negotiations on WHO-recommended medicines to expand access to HIV treatment. Its previous agreements include those with Gilead Sciences and ViiV Healthcare (a joint venture of GlaxoSmithKline, Pfizer and Shionogi) to expand access to WHO-preferred first-line treatments for adults and children.

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