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13 Indian firms set to boost India's anti-Covid arsenal with a pill

The Subject Expert Committee in its meeting recommended the use of this drug to treat high-risk patients.

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Thirteen Indian [companies](#) can now manufacture and market oral antiviral drug Molnupiravir developed by Merck and Ridgeback Biotherapeutics after the country's drug regulator granted approval for restricted use under emergency situations for Covid-infected adults in high-risk category.

The approval for Molnupiravir assumes significance, as it can become an affordable oral treatment for Covid. The drug targets the part of the virus called ribonucleic acid polymerase, which has not changed much even after mutations in the Omicron variant.

The drug inhibits replication of the Sars-CoV-2 virus and has already been approved by the UK MHRA on November 4 and the US Food and Drug Administration on December 23, recommending it for adult patients who have at least one risk factor for developing severe illness.

The Central Drugs Standard Control Organisation (CDSCO) received 22 applications for manufacturing and marketing Molnupiravir in the country, of which 13 have submitted their clinical trial reports to the regulator.

The Subject Expert Committee (SEC), in its meeting on Monday, recommended the use of this drug to treat high-risk patients. The recommended dose is 800 mg twice a day for 5-days for treatment of adult patients with SpO2 over 93 per cent and who have high risk of progression of the disease, including hospitalisation or death.

The CDSCO has, however, noted that the drug should be sold only by retailers under prescription of medical specialists.

Soon after, [companies](#) like Torrent Pharma, Sun Pharma, Cipla, Hetero, Dr Reddy's Laboratories (DRL) rushed in to announce that they would soon launch the drug in India. Sun Pharma said it aims to make the drug available in a week's time. However, none of them disclosed the pricing.

Kirti Ganorkar, the chief executive officer of India Business, Sun Pharma, said, "in line with our consistent efforts to accelerate access to new drugs for Covid-19 treatment, we will make Molxvir available to patients at an affordable price. We are also in the process of launching a toll-free helpline to ensure the availability of Molxvir to doctors and patients across India. Our endeavour is to make the product available in a week's time".

FIRST-OF-A-KIND PILL
Companies that can now make and market Molnupiravir in India. Brand name in brackets

1. Dr.Reddy's Laboratories, Hyderabad (MolFlu)
2. Natco, Hyderabad
3. MSN, Hyderabad
4. Hetero, Hyderabad (Movfor)
5. Optimus, Hyderabad
6. Aurobindo, Hyderabad
7. Mylan, Hyderabad
8. Strides, Bengaluru (Stripiravir)
9. Emcure, Pune
10. Cipla, Mumbai (Ciplmolnu)
11. Sun Pharma, Mumbai (Molxvir)
12. Torrent, Ahmedabad (Molnutor)
13. BDR, Ahmedabad

Aman Mehta, the executive director - India, Torrent Pharmaceuticals, said that Molnupiravir would be an important addition to our healthcare system's 'ammunition' in the fight against Covid-19. His company will launch it under the brand name Molnutor.

Hetero will launch it as Movfor — a 40 capsule pack (200 mg) that will be marketed by its associate company Hetero Healthcare. It will make the drug in Telangana and Himachal Pradesh.

Earlier this year, Dr Reddy's entered into a non-exclusive voluntary licensing agreement with Merck to manufacture Molnupiravir and supply it to India and over 100 low and middle income countries (LMICs).

In a first-of-its-kind collaboration in the Indian pharmaceutical industry, a Dr Reddy's-led consortium of pharma companies, like Torrent Pharmaceuticals, Emcure Pharmaceuticals, Sun Pharma, and Cipla, collaborated to jointly sponsor, supervise and monitor the phase III clinical trial in India, and presented its findings to the SEC.

Between March and April, these five [companies](#) had individually entered into non-exclusive voluntary licensing agreements with Merck Sharp Dohme (MSD) to manufacture and supply molnupiravir.

"Dr. Reddy's will soon launch its Molnupiravir capsules 200 mg under the brand name Molflu across India. As a vertically integrated company, Dr Reddy's is able to manufacture the active pharmaceutical ingredient (API) as well as the formulation for Molnupiravir, and has made adequate capacity preparations to ensure that it is able to help patients in India as well as patient populations in need around the world," the company said.

Rehan A Khan, the managing director, MSD - India Region, said that the company was pleased to work with the voluntary licensing and manufacturing partners to expand the access to Molnupiravir.

Read our full coverage on Coronavirus

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