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Drug war intensifies for COVID-19

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The pandemic has entered yet another phase, with the Omicron variant wreaking havoc across the globe. The high infection rate of this new cause for concern, in India, has also triggered a 'war of medical opinions' between the Indian Council of Medical Research (ICMR) and the Drugs Controller General of India (DCGI). Pharma majors are churning out viable treatment options at a feverish pace, in a bid to become the most widely accepted drug listed in COVID-19 treatment protocols. Merck's Molnupiravir is one such drug that is embroiled in a 'safety vs efficacy' contest. Let's investigate further.

Molnupiravir, the oral antiviral drug developed by Merck and its partner Ridgeback Biotherapeutics, that received DCGI approval for the treatment of mild to moderate COVID-19 in India, is being opposed by the Indian Council of Medical Research (ICMR) due to safety concerns. Priced at Rs 1,399 for the full five-day course, the drug is claimed to be one of the cheapest antiviral coronavirus therapies during the pandemic. A repurposed COVID-19 drug, originally developed to treat influenza, it is meant for mild or moderately ill COVID-19 patients who are at risk of developing a serious illness. The pill, if administered during the first five days after contracting the infection, has the potential to prevent serious illnesses.

A host of pharma companies including Hetero, Sun Pharma, Natco and Dr. Reddy's Laboratories have rolled out the oral therapy. Approved by the UK's drug regulator and recently by the US Food and Drug Administration, the pills are projected to be a game-changer in COVID-19 treatment. Even the Drugs Controller General of India (DCGI) granted permission for restricted use of molnupiravir for treatment of adult patients with SpO2 93 per cent, and who have a high risk of progression of the disease.

However, ICMR has come up with a word of caution and has flagged certain side effects. The question remains - are these drugs required for the Indian market when on the one hand a sizable population has been vaccinated while on the other, the new variants are losing steam, according to the latest trends.

The ICMR gave a thumbs down to Merck's Molnupiravir, the antiviral drug that received approval for emergency use by the DCGI. Prof. Balram Bhargava, ICMR Director General, has been voicing safety concerns of Molnupiravir. The drug, according to Dr Bhargava, could trigger abnormalities in foetus development apart from other side effects such as damage to muscles and cartilages.

All for the drug

Leading health experts treating coronavirus patients across the country believe that the COVID antiviral drug molnupiravir is reducing hospitalisation by 30-50 per cent, as well as the severity of the disease. Countering what Dr Bhargava said, some sections of the experts said the benefits of the drug outweigh potential risks.

According to Dr Deepak Talwar, Senior Consultant & Chairman, Metro Respiratory Centre, Pulmonology & Sleep Medicine, physicians have to keep in mind the patient profiles while prescribing any drug. He says, “We have to use the available therapy rather than counting its side-effects, that too which are potential, but not known.”

Agreeing with Dr Talwar, Dr Dhruva Chaudhry, President-Elect ISCCM, Editor in Chief, Critical Care Communications, a Nodal Officer for COVID-19 at PGIMS Rohtak and Head of the Pulmonary and Critical Care Medicine opines, “While approving, the FDA, as well as DCGI, have gone through the safety data of the drug. Only once satisfied this drug has been approved. Even in the phase-3 clinical trials Molnupiravir, which demonstrated a significant reduction in the risk of hospitalisation or death with no observed safety concerns when compared to the placebo group."

Dr Vasant Nagvekar, an infectious diseases consultant at Lilavati Hospital and member of the COVID task force, has prescribed it to 30 patients since its availability in the market. Molnupiravir, according to him, should be administered as soon as possible after a diagnosis of COVID-19 has been made within five days of symptom onset.

Dr S K Jindal, Medical Director and Sr Consultant Pulmonology at Jindal Clinics Chandigarh; Former HOD, Pulmonology Medicine, PGIMER, Chandigarh opines, “Side-effects of mutagenicity does not matter, if the drug is indicated for certain patient profiles, for a treatment course of five days.

As new variants of the virus continue to emerge, it is crucial to expand the country’s arsenal of COVID-19 therapies using emergency use authorisation, while continuing to generate additional data on their safety and effectiveness. According to Patrizia Cavazzoni, Director of the FDA’s Centre for Drug Evaluation and Research, Molnupiravir is restricted to situations where other FDA-authorised treatments for COVID-19 are inaccessible or aren’t clinically appropriate and will be a useful treatment option for some patients with COVID-19 at high risk of hospitalisation or death.

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