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India Won't Add Merck's COVID-19 Pill To National Treatment Protocol, Citing Safety Concerns

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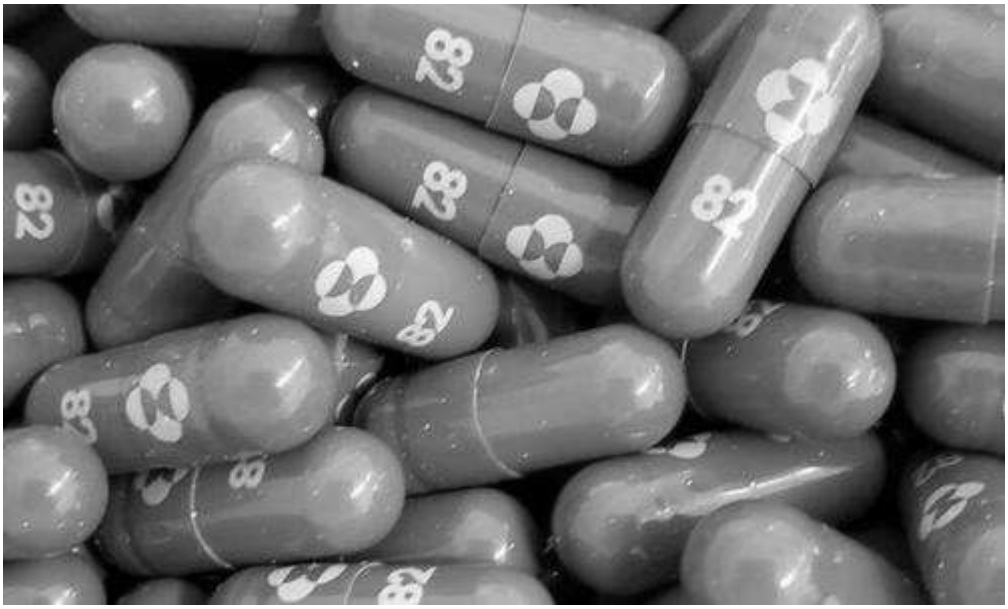
Authored by Katabella Roberts via The Epoch Times,

India's top health research body announced on Wednesday that it won't be adding Merck's COVID-19 antiviral pill molnupiravir to its national treatment protocol, citing concerns over its safety.



The state-run Indian Council of Medical Research (ICMR) said it had become aware of "major safety concerns" that prompted the decision, despite India's drug regulator in December approving the drug for emergency use.

It comes after France in December also canceled its order for the drug, developed by Merck and Ridgeback Biotherapeutics, following disappointing trial data suggesting its drug was markedly less effective than previously thought.

> ***"Molnupiravir has major safety concerns including teratogenicity, mutagenicity, muscle and bone damage. If this drug is given, contraception must be done for three months as the child may have problems,"*** ICMR Director-General Balram Bhargava told local media on Wednesday.

Bhargava noted that the United States Food and Drug Administration (FDA) issued an emergency use authorization for Merck's COVID-19 pill based on 1,433 patients with a 3 percent reduction in moderate disease when given in mild cases.

Members of the FDA's Antimicrobial Drugs Advisory Committee in November voted 13 for and 10 against the emergency use authorization for molnupiravir, agreeing with the idea that the drug's benefits outweigh its potential risks, including concerns about potential birth defects.

However, "we must remember that this drug has major safety concerns," Bhargava said, adding that the drug causes teratogenicity, or the ability to cause defects in a developing fetus, mutagenicity, or permanent transmissible changes in the structure of genetic material of cells, cartilage damage, and can also be damaging to muscles.

Moreover, Bhargava said contraception would also have to be given to individuals who take the drug—regardless of whether they are male or female— because "the child born could be problematic with teratogenic influences."

> ***"The WHO has not included it, the UK has not included it as of now. As of now, the current recommendation stands that it is not part of the national taskforce treatment,"*** Bhargava said.

However, Bhargava said that experts will continue to discuss the potential use of the treatment in the country, where virus case numbers are currently surging.

Molnupiravir is intended for use at home by adults with mild to moderate COVID-19 who are at high risk of developing severe disease. The drug is taken orally in pill form, twice a day for five days, within five days of symptoms onset.

Both FDA staff scientists and Merck have suggested the drug should not be recommended during pregnancy. Company studies in rats showed that the drug caused birth defects when given at very high doses. FDA staffers concluded the data "suggest that molnupiravir may cause fetal harm when administered to pregnant individuals."

Merck says that there is "no available human data on the use of molnupiravir in pregnant individuals to evaluate the risk of major birth defects, miscarriage or adverse maternal or fetal outcomes."

Around 13 Indian companies, including Cipla, Sun Pharma, and BDR, are manufacturing molnupiravir.

Indian multinational pharmaceutical company Dr. Reddy's Laboratories was set to roll out a generic version of the oral antiviral medication starting from next week at an extremely affordable treatment rate of 1,400 rupees ($18.84), 37 times cheaper than in the United States.

The Epoch Times has contacted Dr. Reddy's Laboratories and Merck for comment.