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HEALTH

Pfizer and Merck Covid-19 Pills Are Coming Soon in the U.S., but Other Countries Will Have to Wait

Drugmakers licensed pill formulas for low- and middle-income countries to generic drugmakers, who are now ramping up

Covid-19 testing at a refugee camp in the Democratic Republic of Congo; drugmakers Pfizer and Merck have licensed new Covid-19 treatment pills to generic manufacturers but there may still be delays in getting them to poor countries.

PHOTO: ALEXIS HUGUET/AGENCE FRANCE-PRESSE/GETTY IMAGES

By Jared S. Hopkins and Gabriele Steinhauser
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Promising Covid-19 treatment pills are likely to take longer to reach patients in low- and middle-income countries than in rich ones because of manufacturing and pricing obstacles, despite efforts by drugmakers to make them more available, drug-access advocates and public-health experts say.

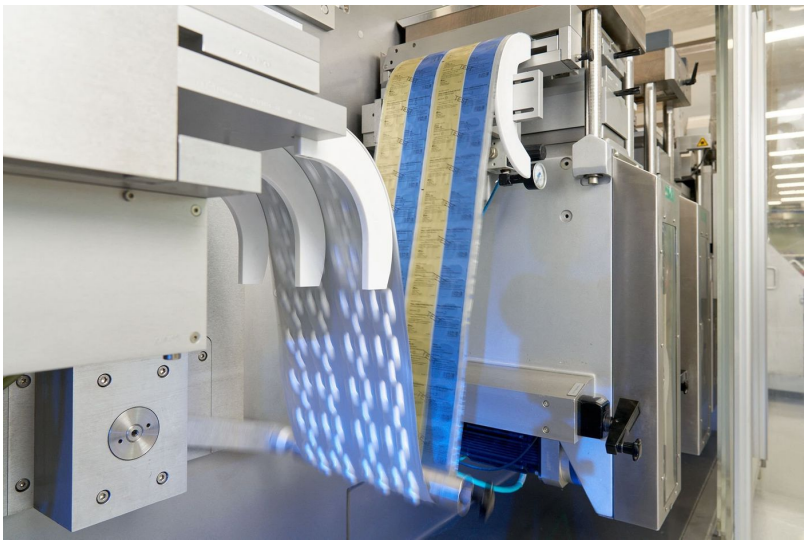
The pills promise to keep people who get infected from developing severe disease that requires hospitalization. They are already in use in the U.K. and nearing regulatory clearance in the U.S.

The medicines are set to play a central role in the world's fight against Covid-19 and could become even more important if, as some scientists fear, vaccines turn out to be less effective against the new Omicron variant. Researchers say the pills are likely to be less affected by Omicron's mutations than most leading Covid-19 vaccines.

Yet drug-access advocates and public-health experts express concern that the pills will arrive months later in poor countries and delay treating people, similar to the way the world's vaccination campaign has left many in poor countries unvaccinated after wealthy governments bought much of the early supply.

Pfizer Inc., PFE **-5.14%** ▼ as well as Merck MRK **0.11%** ▲ & Co. and its partner Ridgeback Biotherapeutics LP, licensed formulas for their treatments so generic drugmakers can produce them for poor countries. The companies say the deals will provide supply to governments that can't afford the more-than-$500 for a course of treatment that wealthy countries like the U.S. are paying.

The generic drugmakers, however, need several months to ramp up their manufacturing, and the prices they set may still be too expensive for certain poor countries.



Pfizer's new pill, Paxlovid, being manufactured in a German lab, is expected to receive Food and Drug Administration clearance in the U.S. as soon as this month.

PHOTO: PFIZER/AGENCE FRANCE-PRESSE/GETTY IMAGES

Adding to the challenges, advocates and experts say, most low-income countries lack adequate testing and diagnostic tools to identify patients early enough for the treatments to help.

"There's lots of logistics and training and community health literacy that has to happen in order for this to work well," said Brook Baker, professor at Northeastern University School of Law who works with the Access to Covid-19 Tools Accelerator, a World Health Organization-backed effort meant to ease access to Covid-19 vaccines, treatments and diagnostics.

Studies have found subjects needed to begin taking the pills within five or fewer days of developing symptoms, making it critical for doctors to quickly identify patients who will benefit.

Most people in poor countries have little-to-no access to Covid-19 testing and often get access only when they are already hospitalized. Of three billion tests reported world-wide, only 0.4% were done in low-income countries, according to the WHO. The organization estimates that just one in seven Covid-19 infections in Africa ever gets diagnosed.

A Covid-19 testing drive in Nairobi, Kenya, last year; many places in Africa lack access to Covid-19 testing and many cases go undiagnosed.

PHOTO: PATRICK MEINHARDT/BLOOMBERG NEWS

"The testing piece is just huge," said Rachel Cohen, North America regional executive director for the nonprofit Drugs for Neglected Diseases Initiative. "There's no possibility to treat people within the first three-to-five days of symptom onset if we don't have really dramatically scaled-up access to rapid diagnostics."

Both the Pfizer and Merck-Ridgeback drugs were found in separate clinical trials to reduce the risk of hospitalization and death for high-risk people with mild or moderate disease.

As treatments that can be taken at home, physicians and health experts say, the drugs could fill a big gap, especially for unvaccinated people or individuals who might not respond to shots because of compromised immune systems.

In contrast, antibody treatments cleared for use need to be administered by infusion or injection at a hospital or doctor's office and are largely unavailable in many poor countries.

Antibody treatments cleared for use in the U.S. are administered by injection or IV infusion, as at a treatment site in Pembroke Pines, Fla.

PHOTO: CHANDAN KHANNA/AGENCE FRANCE-PRESSE/GETTY IMAGES

Pfizer has said it can make about 80 million courses of its treatment, Paxlovid, by the end of next year. Merck says it can produce at least 30 million courses of its drug, molnupiravir, over the same period.

Most of the supply deals publicly announced have been for rich countries, including the U.K., which cleared molnupiravir for use in November. The U.S. has secured 10 million courses of Pfizer's drug and 3.1 million of the Merck-Ridgeback therapy.

Courses are expected to become available in the U.S. shortly after clearance by the Food and Drug Administration, as early as this month.

Generic versions of Pfizer's pill won't come to low- and lower-middle income countries until at least mid-2022, said Charles Gore, executive director of the Medicines Patent Pool, the United Nations-backed nonprofit that is coordinating manufacturing of the two antivirals with generic companies. That is because manufacturers still have to set up or repurpose production lines and governments have to approve the pills, Mr. Gore said.

The molnupiravir Covid-19 treatment pill from Merck & Co. and its partner Ridgeback Biotherapeutics is licensed to eight generic drugmakers in India.

PHOTO: MERCK

Merck has also licensed production of molnupiravir to eight generic drugmakers in India, whose versions could become available earlier.

One such maker, Dr. Reddy's Laboratories Ltd. RDY **-1.69%** ▼ , will start supplying molnupiravir early next year and produce up to 2.5 million courses of treatment a month by the second quarter, and about 20 million courses for all of 2022, said Marc Kikuchi, the company's chief executive for North America generics.

Dr. Reddy's can't make more supply sooner because it needs six months of manufacturing data to satisfy regulators around the world, he said.

Aurobindo Pharma Ltd. 524804 **1.64%** ▲ , also based in India, has so far manufactured enough molnupiravir to distribute for about 145,000 people and will have more supplies next year, a company spokesman said.

Industry experts estimate that competition among generic makers could push the cost of Covid-19 antivirals to as little as $10 a person. Drug-access advocates, though, say even that price remains too expensive for many people in poor countries, especially if the cost isn't covered by the government or donors.

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Dr. Reddy's said its version of molnupiravir hasn't been priced yet but will cost a fraction of Merck's U.S. price of about $700, a spokesman said. Aurobindo will price its generic

product according to volume and hasn't finalized a price yet, the Aurobindo spokesman said.

Complicating access to the drugs is that most upper-middle-income countries, including Brazil and Russia, where large parts of the population live in poverty, are prohibited under Medicines Patent Pool agreements from buying generic versions of the Merck-Ridgeback or Pfizer pills.

There also are efforts to help distribute the antiviral drugs to countries in need by the WHO'S ACT-Accelerator, which hosts the Covax program that has been supplying vaccines to developing countries.

How the distribution will proceed, including whether pills would be provided at no cost to the poorest, are still under discussion, according to Unitaid, an international agency that helps oversee treatment access under the WHO's ACT-A and has been seeking donations for it.

The WHO said in October that the ACT-A will need $3.5 billion from donors to help supply Covid-19 therapeutics until next September. So far it has received $39 million.

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