Ares(2022)6115485

Equitable Global Access to COVID-19 Treatments

Ref. Ares(2022)6766297 - 30/09/2022

Oral therapeutics can play an important role in treating COVID-19, complementing vaccines and other therapeutic and social interventions. We have been working diligently to actively leverage our deep heritage in anti-infective development, as well as our remarkable research, scale, and capital resources, to create targeted treatments that may help those who contract the virus around the world.

Our commitment

Pfizer is committed to working toward equitable access to its oral COVID-19 treatment, PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets), for high-risk patients in need, aiming to deliver safe and effective oral therapeutics as soon as possible and at an affordable price.

To help ensure access, to date (01 April 2022), we have:

Initiated **bilateral outreach to over 100 countries**, and have now entered into agreements with multiple countries around the world.

Entered into an **agreement with UNICEF** to supply up to 4 million treatment courses to 95 low- and middle-income countries, pending authorization or approval.

Entered into a voluntary license agreement with the **Medicines Patent Pool (MPP)** to share intellectual property related to our oral COVID-19 treatment to enable qualified generic medicine manufacturers to produce and distribute generic versions of the treatment. This is one of the largest voluntary license agreements in the world.

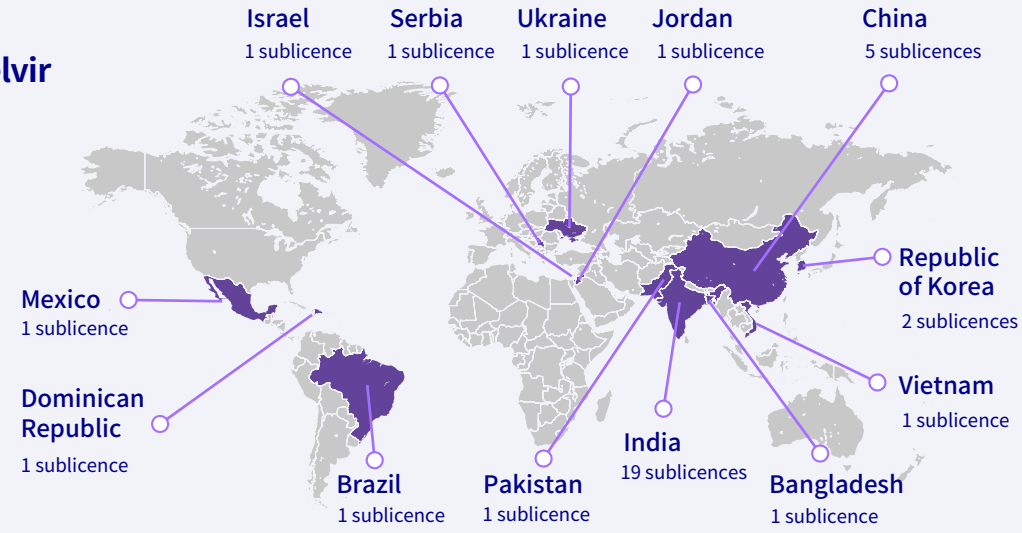
The voluntary license is intended to help improve access to COVID-19 treatments to 95 low- and middle-income countries, **accounting for 53% of the world's population**.

53%

The MPP has sub-licensed to **36 manufacturers from 13 countries**.

36 sublicenses signed with MPP for nirmatrelvir

(update 22 March 2022)



Tiered Pricing

To support equitable access globally, we are deploying a pricing structure with three tiers: **i) high income ii) upper middle income and iii) lower-middle income and low income.**

High and upper-middle income countries will pay more than lower income countries, but at values that are significantly discounted from our normal benchmarks during the pandemic. Low and lower-middle income countries will pay a not-for-profit price.

Manufacturing Process and Lead Time

We are constantly looking to improve our processes, shorten timelines and enhance the supply chain – including our internal and external network, raw material production and tableting capacity. Through this work, **we have already increased our 2022 production expectation from 50 million courses to up to 120 million**, pending global demand[1]. But we have never sacrificed – and will never sacrifice – product quality or patient safety to ensure expediency – safety and quality are at the heart of Pfizer's supply chain.

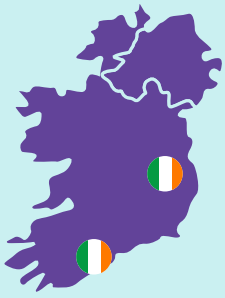
The number of steps involved in the manufacturing of PAXLOVID™ drives a relatively long lead-time of up to nine months. However, we have been working quickly to try to optimize this, in parallel with manufacturing, and are already at an average time of around seven months end-to-end. We continue to assess how this can be reduced further.

Successful development and production of PAXLOVID™ is dependent on a complex supply chain involving more than **60 materials** from **20 supply points** including internal Pfizer sites and **partners across 10 countries**.

Supply Chain

We are currently leveraging four key manufacturing locations worldwide to meet demand for PAXLOVID™, as well as multiple partners.

The primary production site making the drug product is based in Freiburg, Germany where we have extensive technical knowledge and specialized high-volume machines.



Ringaskiddy in Ireland is a primary site for active pharmaceutical ingredient (API) manufacturing. Ascoli (Italy) and Newbridge (Ireland) are also being leveraged for drug product manufacturing and co-packaging with ritonavir.

We are applying our deep heritage in developing oral treatments and the success from developing and scaling of our manufacturing process for the Pfizer-BioNTech COVID-19 vaccine to respond to this global pandemic.

Policy Considerations and Recommendations

Support Open Trade.
The manufacturing process depends on a complex global network of suppliers, competing for raw materials and equipment. Trade bottlenecks – including export restrictions, regulatory barriers, tariffs, and customs red tape – add uncertainty, cost and delay to both manufacturing and patient access.

Enable innovation.
Manufacturers are engaged in unprecedented collaboration to support R&D and manufacturing, thanks in large part to intellectual property (IP) protections and other pro-innovation policies. R&D continues to be needed for special populations (e.g. children), developing further therapeutics, and preparing for future pandemics.

Invest in resilient health systems.
Beyond manufacturing, governments and international health organizations need to ensure that systems are in place to prescribe and supply the therapeutic to eligible patients at first sign of infection or at first awareness of an exposure, without requiring patients to be hospitalized.

1 This does not include any courses manufactured by sublicensees through the agreement with the MPP.