**Equitable Global Access to COVID-19 Treatments**

### Our commitment

Pfizer is committed to working toward equitable access to its oral COVID-19 treatment aiming to deliver safe and effective oral therapeutics as soon as possible and at an affordable price.

### To help ensure access, as of May 2023, we have:

- Initiated bilateral outreach to over 100 countries, and have now entered into agreements with many countries around the world.
- To support equitable access globally, during the pandemic, we are deploying a pricing structure with three tiers:
  1. high income
  2. upper middle income
  3. lower-middle income and low-income. Low- and lower-middle income countries pay a not-for-profit price.

### Partnering to advance access

- **Medicines Patent Pool.** Entered into a voluntary license agreement with the Medicines Patent Pool (MPP) to share intellectual property related to our oral COVID-19 treatment to help 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 for 95 low- and middle-income countries, accounting for 53% of the world's population.

### Collaborating with the WHO.

Pfizer is closely collaborating with the WHO and its partners in the Therapeutics pillar of the Access to COVID-19 Tools Accelerator (ACT-A), as well as other global health leaders, to help enable supply of its oral COVID-19 treatment to more low- and lower-middle income countries.

### UNICEF Supply Agreement.

Pfizer signed a supply agreement with UNICEF for up to 4 million treatment courses of its oral COVID-19 treatment for distribution to 137 low- and middle-income countries, subject to local regulatory authorization or approval.

### Global Fund.

Pfizer will supply the Global Fund (GF) with up to 6 million treatment courses of its oral COVID-19 treatment for supply to 132 Global Fund-eligible low- and middle-income countries in all regions of the world, subject to local regulatory authorization or approval.

### COVID Treatment Quick Start Consortium

The Consortium is implemented with Duke University, the Clinton Health Access Initiative (CHAI), COVID Collaborative and Americares, with support from Pfizer, Open Society Foundations, and the Conrad N. Hilton Foundation. Pfizer is providing both treatment courses and financial support to support the Consortium's efforts to accelerate COVID-19 testing and improve access to treatments in under-resourced parts of the world. To date, treatment courses have reached Ghana, Laos, Malawi, Rwanda and Zambia.

With the MPP, UNICEF and Global Fund agreements, every low- and middle-income country in the world, except China, now has the potential to access the oral treatment or a generic version through one or more of these pathways.*

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*This information is intended to support policy discussions with policy stakeholders.

V8 May 2023

1. U.S. FDA Emergency Use Authorization Statement: PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death. The emergency use of PAXLOVID is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.
An Accord for a Healthier World

Pfizer announced **Accord for a Healthier World** to support access for its oral COVID-19 treatment, in addition to its full portfolio of patented and off-patent medicines and vaccines, on a **not-for-profit-basis to 45 lower-income countries**.

Pfizer will also collaborate with governments and global health organizations to help remove barriers to access like diagnostics, training, storage and more to get its oral COVID-19 treatment and other medicines to patients who need them in these countries.

**Manufacturing Process and Lead Time**

We are constantly looking to improve our processes, shorten timelines. Through this work, we have developed an approach to enable short- and long-term supply to support global needs and will continue to adjust our production to align with a change in demand.

Successful development and production of our oral COVID-19 treatment 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 multiple internal and external manufacturing sites worldwide to meet demand for our oral COVID-19 treatment.

- **Pfizer sources our API and registered starting materials (RSMs) from multiple locations globally.**
- **The primary production sites for the nirmatrelvir drug product are in Freiburg, Germany and Newbridge, Ireland.**
- **The primary packaging sites for Paxlovid are in Ascoli, Italy and Newbridge, Ireland.**

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**

- **Harness the power of science**
  Manufacturers are engaged in unprecedented collaboration to support R&D and production, thanks in large part to intellectual property (IP) protections and other pro-innovation policies. IP protections are essential to speed up R&D, and facilitate sharing of technology and information to scale up manufacturing. Weakening IP for therapeutics would therefore negatively impact R&D needed to tackle pandemics and undermine at-risk investment in production, all without helping improve patient access.

- **Maintain a robust global network.**
  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.

- **Strengthen 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.

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"The sole country included in the category "other" is Palau, which has received COVID-19 vaccines and treatments from the United States under U.S. contracts with manufacturers. China: In March 2022, Pfizer reached an agreement with Meheco, a Chinese distributor, to import and distribute our oral treatment in China. In August 2022, Pfizer concluded an agreement with Huahai, a Chinese pharmaceutical manufacturer, to locally manufacture it on behalf of Pfizer for mainland China."