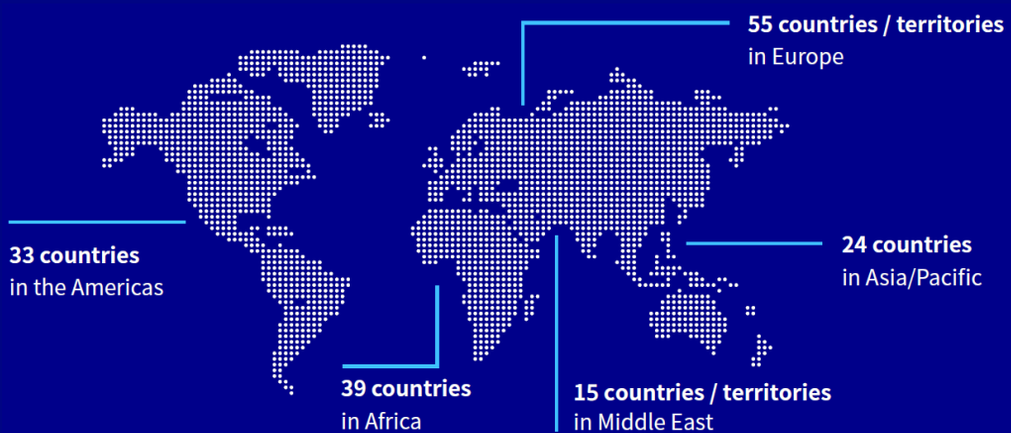
Manufacturing, Trade and Equitable Global Access to COVID-19 Vaccines and Therapeutics

To help ensure equitable global access to the Pfizer-BioNTech COVID-19 vaccine and the Pfizer oral COVID-19 treatment, **two conditions** had to be met for each: **a price that all countries can afford** and **reliable manufacturing to enable broad global distribution.**

COVID-19 Vaccine: Working to Reach Everyone, Everywhere

By the end of 2021, within 13 months of the Pfizer-BioNTech Vaccine receiving its first authorization+, we had shipped **more than 2.6 billion vaccine doses to 163 countries and territories around the world**, including:



As of January 2024, Pfizer and BioNTech have shipped **more than 4.9 billion vaccine doses to 183 countries and territories around the world**.

This includes more than **1.8 billion vaccine doses provided to 112 low- and middle-income countries**.

Partnering to Advance Access to COVID-19 Therapeutics

Medicines Patent Pool (MPP).

Voluntary license (VL) agreement with MPP to share intellectual property for our oral COVID-19 treatment to help enable qualified manufacturers produce and distribute generic versions.

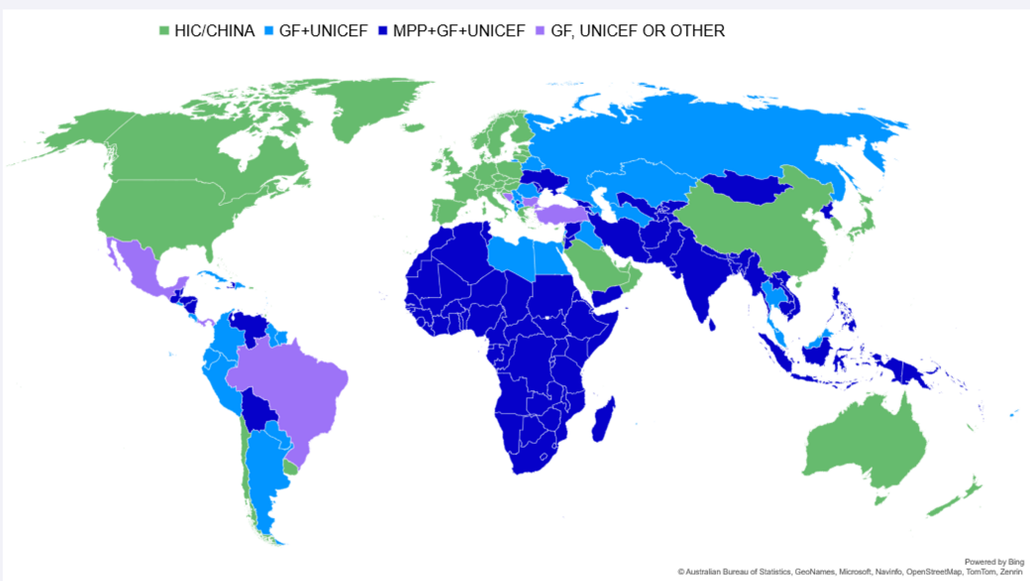
The VL covers **95 low- and middle-income countries**, accounting for 53% of the world's population.

UNICEF Supply Agreement.

Agreement with UNICEF to supply up to 4 million treatment courses to **137 low- and middle-income countries**, subject to local regulatory authorization or approval.

Global Fund (GF) Supply Agreement.

Agreement to supply the GF with up to 6 million treatment courses to **132 eligible low- and middle-income countries**, subject to local regulatory authorization or approval.



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*.

Global Impact: Expanding Access

- Pfizer adopted a **tiered pricing policy** for our COVID-19 portfolio during the pandemic. We remain committed to helping ensure equitable access around the world and we will **continue to work closely with governments and partners** to supply the COVID-19 vaccine and therapeutic in alignment with demand.

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

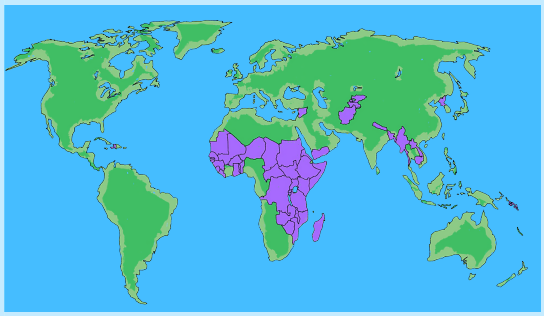
V10 February 2024

+ UK MHRA authorization for temporary supply under Regulation 174 of the Human Medicines Regulations 2012, 02 December 2020.
*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: Pfizer has had other agreements in place to help facilitate access to our oral COVID-19 therapeutic in China.

An Accord for a Healthier World

Pfizer announced **Accord for a Healthier World** to support access for both the COVID-19 vaccine and oral treatment, in addition to all medicines and vaccines for which Pfizer holds global rights, 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 help get medicines and vaccines to patients who need them in these countries.



www.pfizer.com/accord

Manufacturing and Supply Chain: Speed, Complexity and Collaboration for Scale Up

We relentlessly focused on efficiency to help scale up, for example **reducing production timelines for our COVID-19 vaccine from 110 to 60 days.**

Looking forward, we will continue to adjust our production to align with changes to demand.

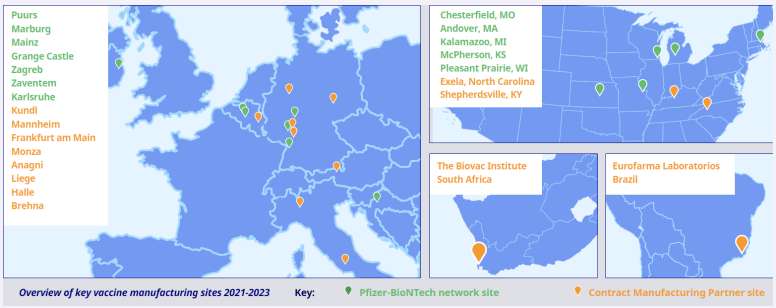
The Pfizer-BioNTech COVID-19 Vaccine requires:

- **280 components from 86 suppliers in 19 countries**
- **~10-15 unique raw materials**
- **40 individual quality control tests for each finished batch.**

The supply chain for our oral COVID-19 treatment involves:

- More than **60 materials** from
- **20 supply points**, and
- Partners across **10 countries.**

During the pandemic, the Pfizer-BioNTech global **COVID-19 vaccine supply chain** and manufacturing network spanned **four continents**, including more than **20 facilities**.



During the pandemic, we also leveraged multiple internal and external manufacturing sites worldwide to meet demand for our **oral COVID-19 treatment**.

In addition, as part of the COVID-19 therapeutic's voluntary license, MPP signed **sublicences with multiple generic manufacturers worldwide**.

We **selected partners** via a rigorous process based on several factors, including: quality, compliance safety track record, technical capability, capacity availability, workforce training levels, and prior working relationship.

Steps involved in a **tech transfer process for a new facility** include **on-site development, equipment** installation, engineering and process qualification tests, and regulatory approvals.

As we **transition to traditional commercial models**, close partnerships with governments, international health leaders, and global manufacturers will help optimize supply and access to patients worldwide.

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 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 of raw materials and equipment. Trade bottlenecks – such as export restrictions and tariffs – add uncertainty, cost and delay to both manufacturing and patient access. Voluntary approaches to tech transfer should be supported. Once in place, manufacturing depends on a sustainable commercial environment and policy outlook.

Strengthen Health Systems.

Governments and international organizations should ensure health systems can support absorption of new vaccines and therapeutics. This includes infrastructure to support vaccine delivery, and systems in place to prescribe and supply therapeutic to eligible patients at first sign of infection or at first awareness of an exposure, without requiring patients to be hospitalized.

Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 6 months through 11 years of age. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

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; and 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.