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

Equitable distribution was our North Star from day one. In order to ensure that every country that chooses the Pfizer-BioNTech COVID-19 vaccine can have access to it, two conditions had to be met: a price that all countries can afford and reliable manufacturing to enable broad global distribution.

To date (18 September 2022), Pfizer and BioNTech have shipped more than 3.8 billion vaccines to 181 countries and territories around the world, including:

- 55 countries/territories in Europe
- 45 countries in Africa
- 31 countries/territories in Asia/Pacific
- 17 countries/territories in Middle East
- 33 countries in the Americas
- 45 countries in the Americas

Pfizer and BioNTech have pledged to provide 2 billion doses of our COVID-19 vaccine to low- and middle-income countries. As of September 2022, have now delivered more than 1.5 billion doses to 112 low- and middle-income countries towards this pledge.

As Covid-19 remains a global threat to health, we will continue to work closely with governments and partners all around the world to supply doses in alignment with demand through our agreements with governments and international partners. This sits alongside our work to provide expertise and resources for novel approaches that can bring help to strengthen healthcare systems where greater support may be needed.

Supply Pathways:
- Direct supply agreements to governments.
- Direct supply agreement with COVAX for 40 million doses in 2021.
- Government donation programs – via COVAX & directly.
  - This includes 1 billion doses supplied to the US for donation to low- and lower-middle-income countries and the African Union.
- Targeted humanitarian donation programs.

Tiered Pricing Policy:
- During the pandemic we are pricing our vaccine in a way that can help governments ensure that there is little to no out-of-pocket cost for their populations.
  - The price for wealthier nations would be equivalent to the cost of a takeaway meal.
  - Middle income countries are offered our COVID-19 vaccine at half this price.
  - Low and lower-middle income countries are offered doses at a not-for-profit price.

With our industry partners, we also share the three priorities¹ to urgently advance vaccine equity:

- Support country readiness
- Support equitable distribution
- Continue to drive innovation

¹ This information is intended to support policy discussions with policy stakeholders. All statements and claims in this document are made by Pfizer. Plans and timing estimates are subject to change based on emerging data, regulatory guidance, and manufacturing and technical developments, among other risks. The Pfizer-BioNTech vaccine, which was developed using BioNTech’s proprietary mRNA technology, was developed by both BioNTech and Pfizer.

Pfizer and BioNTech produced 3 billion doses worldwide in 2021.

We have the capacity to produce 4 billion doses in 2022.
Fundamental to our access strategy is work to globally scale up manufacturing.

From the outset, Pfizer and BioNTech have taken a relentless focus on efficiency to enable us to quickly scale up manufacturing. Reducing production timelines has been achieved by:

1. Doubling our batch sizes to minimize time between batches and increasing the yield per batch.
2. Adding extra formulation rooms to increase formulation capacity by over 3x.
3. Adding high-speed packing lines to increase the daily ship rate.
4. Bringing on new suppliers.

We are also partnering to build up scale. The Pfizer-BioNTech global COVID-19 vaccine supply chain and manufacturing network now spans four continents and includes more than 20 facilities.

We select partners using a rigorous process based on several factors, including: quality, compliance safety track record, technical capability, capacity availability, highly trained workforce, project management abilities, 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.

Together with our partner BioNTech, we will continue to explore and pursue opportunities to bring new partners into our supply chain network to further accelerate access to the COVID-19 vaccine.

Recommendations for policymakers:

Support open trade. The vaccine 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.

Invest in country readiness. Vaccine deployment requires scale up of ultra-cold chain capacity, trained health care personnel, and more resilient health system infrastructure to broadly support delivery, particularly in low and lower-middle income countries. In addition, issues with demand and vaccine confidence are faced in some countries.

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), tackling new variants, developing additional therapeutics, and preparing for future pandemics.

2. Including plasmid DNA, nucleotides, capping agents, and lipids.

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