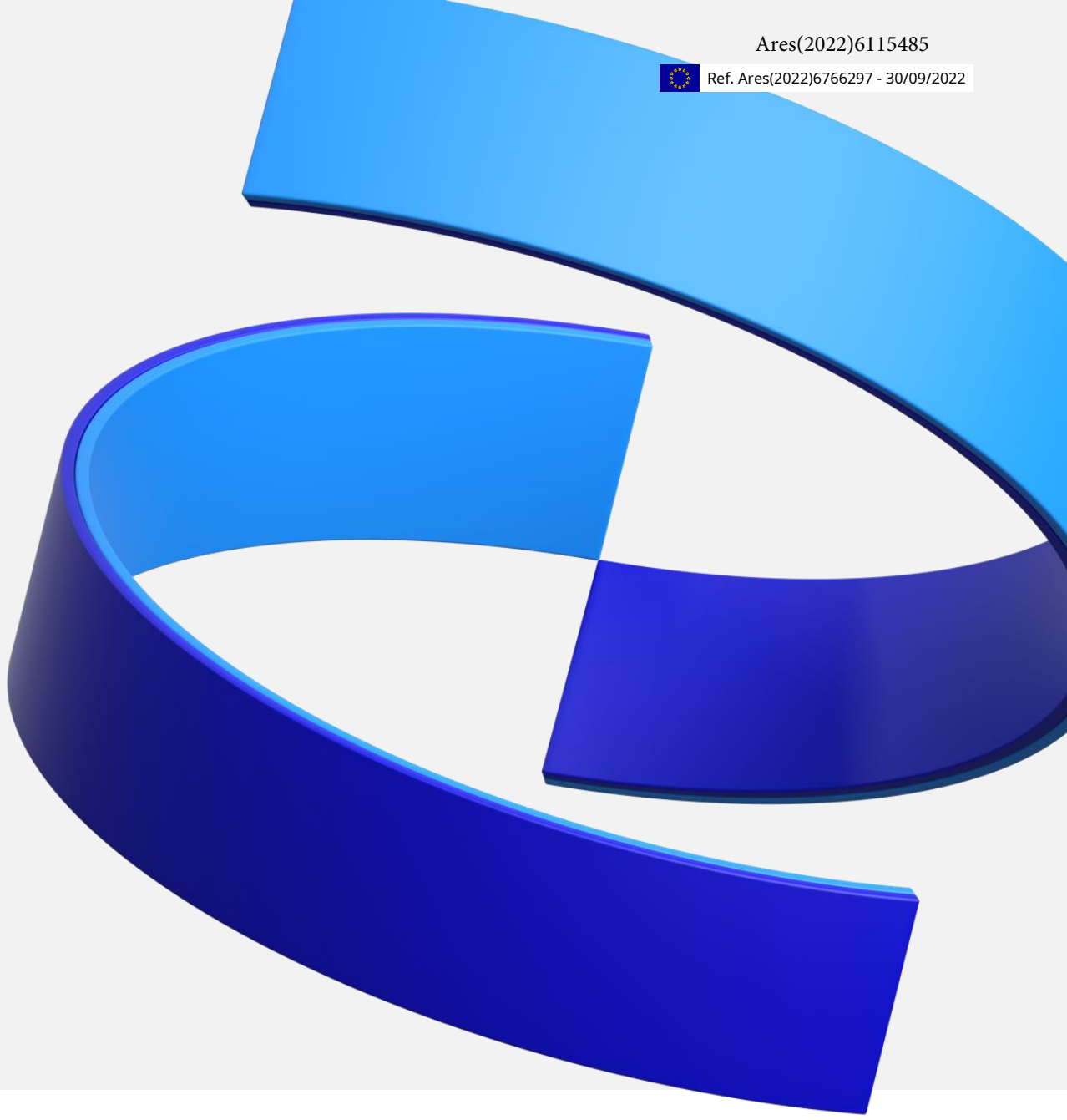
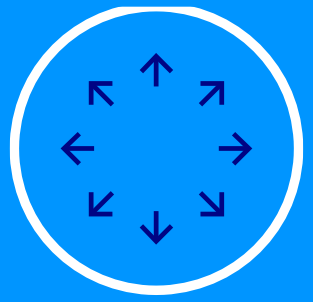
Supporting Manufacturing, Trade and Equitable Global Access to COVID-19 Vaccines



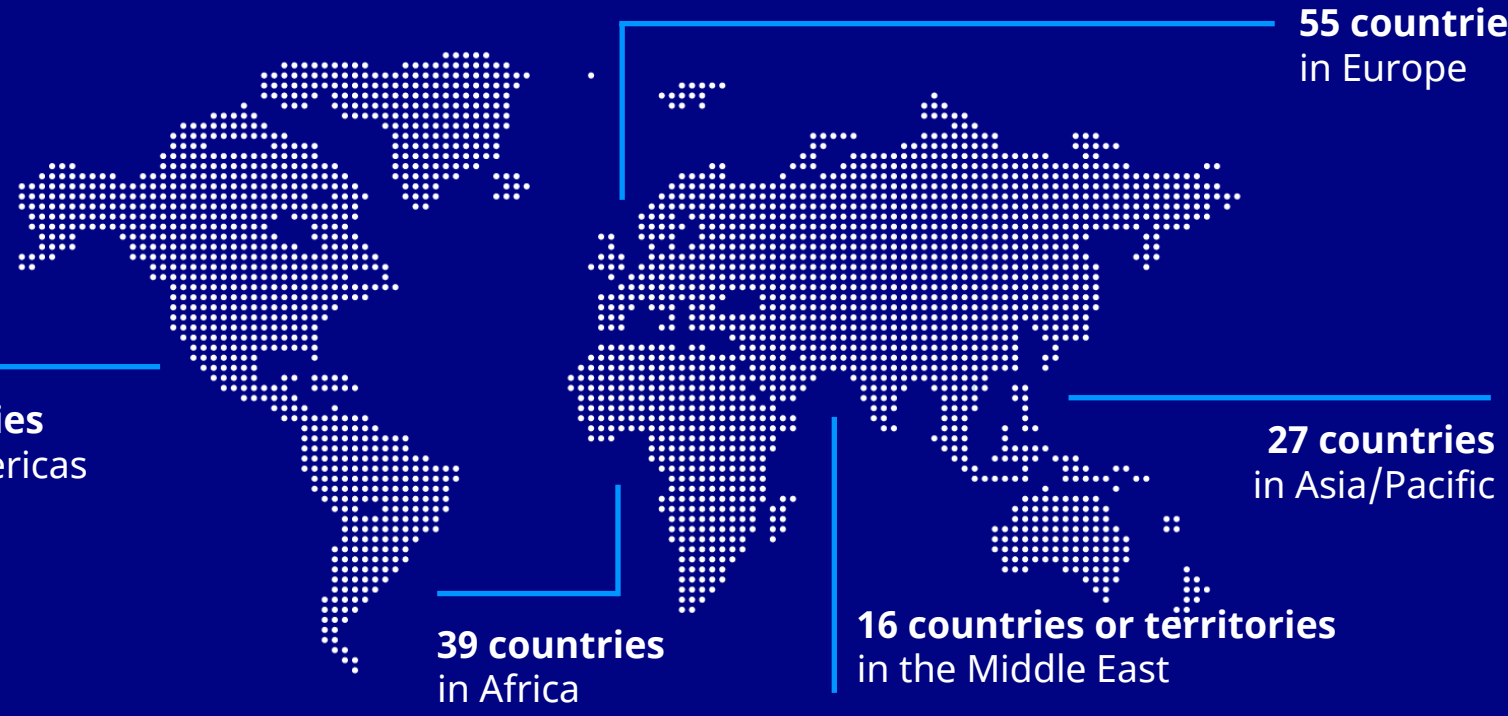
10 February 2022

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 COVID-19 Vaccine, which is based on BioNTech's proprietary mRNA technology, was developed by both BioNTech and Pfizer.



Together with our partner BioNTech, we are firmly committed to equitable and affordable access to the Pfizer-BioNTech COVID-19 vaccine to help bring an end to the pandemic for everyone, everywhere.

In 2021 Pfizer and BioNTech supplied more than 2.5 billion vaccines to patients globally.



Pfizer and BioNTech produced **3 billion** doses worldwide in 2021

We expect to produce **4 billion** doses in 2022

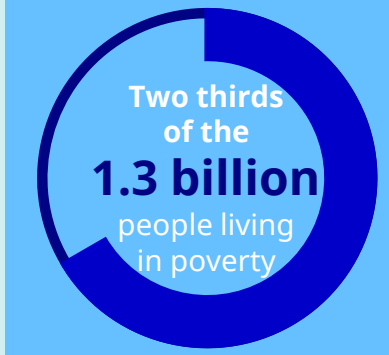
To date (10 February 2021) Pfizer and BioNTech have now shipped **more than 2.9 billion vaccines to 170 countries and territories around the world**.

Accelerating our efforts to reach vulnerable populations

- Pfizer and BioNTech have **pledged to provide 2 billion doses of our COVID-19 vaccine to low- and middle-income countries in 2021 and 2022** – at least 1 billion doses each year.
- **On 29 December 2021, Pfizer and BioNTech fulfilled this pledge for 2021**.
- As of 6 February 2022, more than **1.1 billion doses** have been delivered to 101 low- and middle-income countries towards this pledge.
- This includes more than 503 million doses – more than 40% of this supply - that have reached 57 low- and lower-middle-income countries.

Together with our partner BioNTech, we will continue to partner with governments and the global health community to supply **at least another 1 billion doses** to these countries in 2022.

Our equitable access strategy focuses on **low-income and middle-income economies** because approximately



are in middle-income countries

Lower-middle-income and **upper-middle-income** countries are currently home to

and 62%
of the world's poor

To advance equitable global access, Pfizer and BioNTech have

Established multiple **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.

Implemented a **tiered pricing policy:**

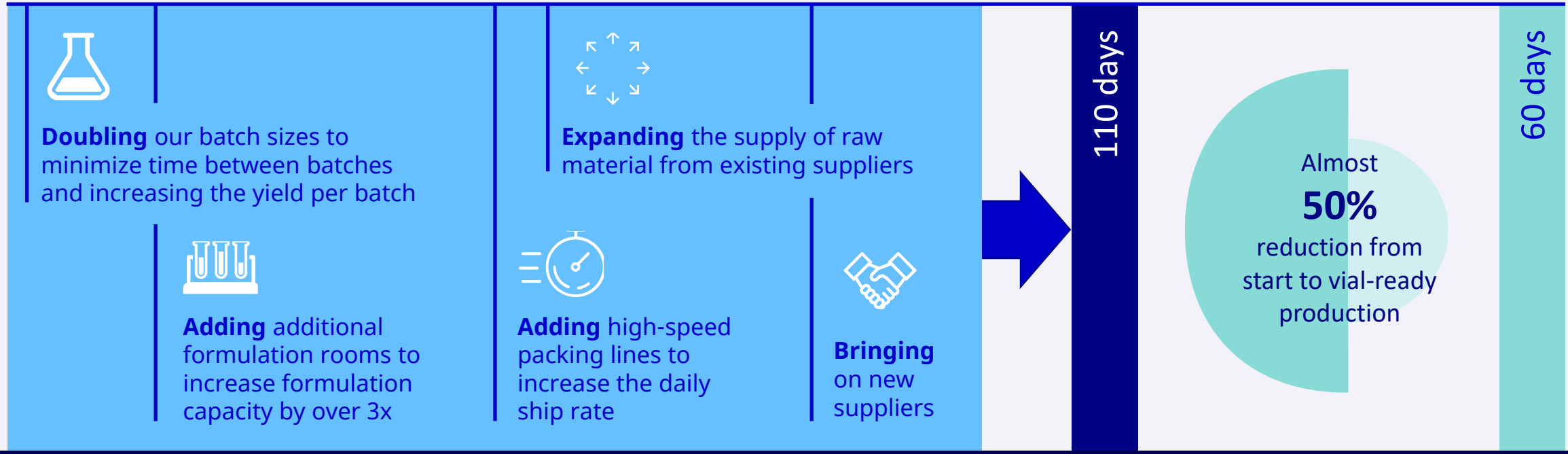
During the pandemic we are pricing our vaccine in a way that can help governments ensure that there is little to no out-of-pocket cost for their populations.

- 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.

Fundamental to our access strategy is work to globally scale up manufacturing.

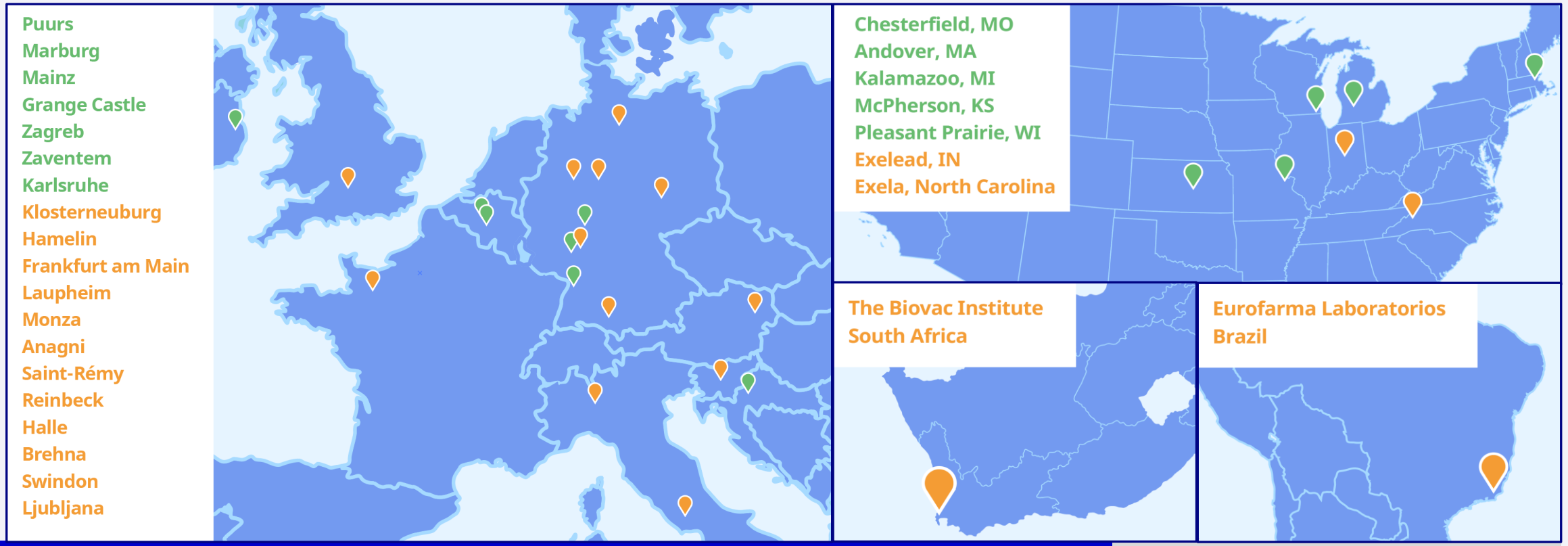
From the outset, Pfizer and BioNTech have taken a relentless focus on efficiency to enable us to quickly scale up manufacturing.

Reducing production timelines has been achieved by:



Pfizer and BioNTech have already achieved an almost **50% reduction** from start to vial-ready production time

Pfizer and BioNTech have formed an unprecedented number of manufacturing partnerships to build up scale.



The Pfizer-BioNTech global COVID-19 vaccine supply chain and manufacturing network now spans **four continents**, with more than **20 facilities**

Our scale up is backed up by rigorous selection and integration processes.

We select partners using a rigorous process based on:
quality, compliance safety track record, technical capability, capacity, highly trained workforce, project management abilities and a prior working relationship.

- *For example, it was key to identify partners with infrastructure to support freezer farms for ultra-cold temperature storage.*

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.

The average fill/ finish technology transfer takes up to three years from project kickoff.

This timeline has been expedited for the Covid-19 vaccine, with transfers ranging between five to 18 months.

Together with our partner BioNTech, we will continue to explore opportunities to bring on new partners to accelerate access to the COVID-19 vaccine

Despite the progress to date, there is more work to do. Policymakers should support open trade, invest in country readiness, drive innovation and strengthen regulatory cooperation to help ensure all doses manufactured reach people around the globe.

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.
- There is a critical role for governments to address this by:
  - Refraining from export restrictions;
  - Strengthening regulatory cooperation and capacity building;
  - Improving trade facilitation;
  - Eliminating tariffs.

The Pfizer-BioNTech vaccine requires[I]

280 components
from 86 suppliers
in 19 countries;

~10-15 unique raw materials[i]
and the same number of unique / specialized components

>40 individual quality control tests
for each finished batch.

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

Invest in country readiness

- Distributing vaccines rapidly and at national scale has no precedent in modern public health, and close coordination among all stakeholders is critical for ensuring the success of vaccination campaigns.
  - 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.

We are partnering with global health stakeholders to understand where the private sector can support the delivery of any COVID-19 vaccine. This includes:

- Working with the UPS Foundation to donate freezers to countries to help build out ultra-cold chain capacity.
- Partnering with Zipline to use drones to deliver vaccines requiring cold-chain storage to hard-to reach areas.

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.

- Governments should support the global IP framework, given its indispensable role in research and collaboration in areas of need:
  - for special populations (e.g. children),
  - tackling new variants,
  - developing further therapeutics, and
  - preparing for future pandemics.

Innovative Industry Response[I]

<12
Months of COVID-19 vaccine development until WHO Emergency Use Listing (EUL)

5
Who approved or authorized COVID-19 vaccines from IFPMA members

14
COVID-19 vaccines in clinical development from IFPMA members

357
Manufacturing and production deals for COVID-19 vaccines around the globe

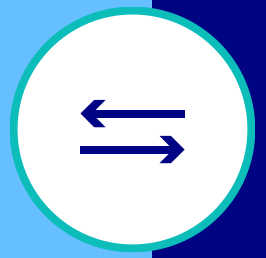
146
Manufacturing and production deals for COVID-19 therapeutics around the globe

I https://www.ifpma.org/covid19/

Strengthen regulatory cooperation

- The pandemic has highlighted the importance of robust and convergent regulatory standards for vaccines and other health products, the challenges of resource constraints, and the need for international cooperation in developing and applying those standards.
    - Countries should strengthen regulatory cooperation, share best practices across borders, and expand mutual and unilateral recognition policies, as appropriate.
    - Countries should also consider implementing formal capacity building programs and resource sharing.

Effective regulation boosts public trust in the safety of vaccines, and contributes to global supply chain resilience.



Throughout the pandemic, coherent and consistent regulations, and agile approaches from regulators have helped facilitate patient access.

Conversely, regulatory complexities and inefficiencies in certain markets have impeded supply chains and delayed patient access.

We are calling on policymakers to:

Support open trade

Vaccine manufacturing depends on a complex global network of supplies of 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

Countries face multiple issues for supply planning and delivery, including:

- Ability to absorb vaccine supply; limited ultra-cold-chain capacity or infrastructure; syringe supply.
- Other issues including workforce constraints and lower uptake rates due to hesitancy.

Enable innovation

Manufacturers are engaged in unprecedented collaboration to support R&D and manufacturing, thanks in large part to intellectual property and other pro-innovation policies.

Additional research and collaboration continue to be needed for special populations (e.g. children), tackling new variants and developing therapeutics.

Strengthen regulatory cooperation

Countries should strengthen regulatory cooperation, share best practices across borders, and expand mutual and unilateral recognition policies, as appropriate.

Countries should also consider implementing formal capacity building programs and resource sharing.