

BERLIN DECLARATION

BIOPHARMACEUTICAL INDUSTRY VISION FOR EQUITABLE ACCESS IN PANDEMICS

The innovative biopharmaceutical industry, having developed COVID-19 vaccines and treatments at record speed and in historic quantities, proposes to create a collaborative solution for more equitable rollout of vaccines, treatments and diagnostics for future pandemics. In particular, the innovative biopharmaceutical industry is willing to reserve an allocation of real-time production of vaccines, treatments and diagnostics for priority populations in lower income countries and take measures to make them available and affordable. To be successful, we call on other stakeholders to work together with industry to help make this proposal a reality and shape a future where everyone is better protected from the threat of pandemics.

COVID-19 has shown what the world needs to do to be better prepared for future pandemics. The innovative biopharmaceutical industry succeeded in developing and scaling up multiple high-quality, safe, and effective vaccines and innovative treatments against COVID-19 in historic record time, thanks to the intellectual property system. We developed and executed on access plans, and collaborated with partners all over the world to produce enough vaccines for every adult on the planet in 2021. However, whereas there is now broad acknowledgment that supplies of COVID-19 vaccines have outstripped global demand, lack of country readiness and absorption capacity leave highest risk populations in many countries vulnerable. Societies all over the world need to build pandemic preparedness into health systems, based on [the lessons learned during the response to COVID-19](#). Collectively, we need to consolidate and reinforce the actions that have worked well and define solutions to address the shortcomings. We aspire to respond even faster and partner to achieve greater equity from the outset of future pandemics, supporting the ambitions of the G7's 100 Days Mission.

In the future, we call on the G7, the G20 and all stakeholders in the global health community to play their part, to ensure that people in all countries have more equitable access to future pandemic vaccines, treatments and diagnostics ("pandemic VTDs¹") no matter where they live. Achieving equity requires actions from all relevant stakeholders, underpinned by sustained political support, as all countries must build the technical and health infrastructure, human resources and financial capacity to successfully vaccinate, test and care for their populations.

This Berlin Declaration draws on the lessons we have learned and sets out an approach for more equitable pandemic preparedness and response, based on commitments and contributions from a global collaboration of public, private and charitable sectors together with civil society. Critical for success is to ensure that pandemic VTDs reach those who need them most, no matter where they live, from the outset of future pandemics.

¹ "Pandemic VTDs" is used to denote the medical products – vaccines, treatments and diagnostics – developed, produced and delivered to work against pathogens with the potential to, or already causing a pandemic.

The industry proposes to reserve an allocation of real-time production for distribution to priority populations in lower income countries, as determined by health authorities during pandemics. During COVID-19, efforts to achieve equitable access were not fully realized because of inadequate upfront procurement financing and a lack of country readiness which still inhibits the vaccines from getting to every arm that needs it. For future pandemics, it is critical to ensure that all countries have the technical and health infrastructure, human resources, and financial capacity as well as political support to successfully vaccinate, test and care for their populations. Furthermore, the success of the proposal requires open borders and no trade restrictions.

We have learned that other foundational prerequisites of the future pandemic preparedness system are:

1. Robust pandemic plans to deliver pandemic VTDs and care to populations in all countries, as well as on-going healthcare, built on, and complementing progress towards Universal Health Coverage
2. Rapid detection and open sharing of pathogens and their information on emerging infectious diseases
3. Acceleration of R&D and regulatory pathways for delivering new pandemic VTDs
4. Optimized manufacturing scale-up and sustainable supply for the whole world, including de-risking mechanisms to support the R&D, manufacturing scale up, and procurement
5. Aligned, evidence-based prioritization of populations and VTD demand forecasts
6. Long-term political commitment and adequate funding to establish and maintain pandemic readiness as part of a resilient healthcare system

We are committed to working with governments and all stakeholders to help ensure that preparedness and response systems are put in place and maintained into the future, because we should be better prepared as none of us know where or when the next pandemic will emerge.

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IMPLEMENTATION PRIORITIES TO BUILD EQUITY INTO PANDEMIC PREPAREDNESS

The Berlin Declaration is reflected in a set of priorities of what the industry is committed to doing, and what is needed from governments and other key players to enable future success. With all stakeholders collaborating and playing their part, we can make sure that the efforts, investments, learnings and losses seen during COVID-19 are not in vain, but rather help shape a future where everyone is better protected from the threat of pandemics.

Our three implementation priorities focus on innovation, manufacturing scale up, and planning ahead for equitable access.

1. DRIVE INNOVATION IN ADVANCE OF THE NEXT PANDEMIC:

- **We (the innovative biopharmaceutical industry)** will build on the rapid development of innovative COVID-19 vaccines and treatments, working with regulators and other stakeholders to establish streamlined approaches to develop and deliver new quality, safe and effective vaccines and treatments even faster in the future.
- **Key enablers for success:**
 - Regulatory Authorities should define the best science-based regulatory strategies for ensuring the accelerated availability of pandemic vaccines and treatments, in line with the G7 100 Days Mission.
 - Health Authorities should increase clinical trial capability globally to support the rapid development of new treatments and vaccines.
- **Our researchers** will collaborate with academia, biotech and the public sector on cutting-edge science to build portfolios of candidate vaccines and treatments against priority pathogens in advance of the next pandemic, leveraging robust intellectual property protections.
- **Key enablers for success:**
 - Intellectual property rights should be respected since society depends on them to stimulate innovation and the scale up of supply.
 - Governments should ensure robust surveillance world-wide and guarantee the immediate and unhindered sharing of emerging pathogens and their associated data to all researchers, as any delays will slow the delivery of pandemic products.

2. AIM FOR FASTER MANUFACTURING SCALE-UP FOR HIGH VOLUME GLOBAL SUPPLY:

- **We support** collaborations, a geographically diverse sustainable manufacturing footprint and mechanisms for rapidly scaling-up supply in a future pandemic. We will build on existing manufacturing partnerships, business-to-business agreements set up in advance, ongoing capability development and voluntary licensing and/or early, voluntary technology transfer where this will facilitate rather than impede scale up and global supply.
- **Key enablers for success:**
 - Governments should commit to unrestricted trade and no export bans across the VTD supply chain and expedited processes for import and export during a pandemic to help support fast and efficient global distribution. Restrictions in place during COVID-19 undermined the ability to manufacture and deliver vaccines and treatments.
 - Predictable demand including from lower income countries would be important for supporting pandemic readiness, by ensuring sufficient and sustainable capacity between pandemics, especially for vaccine manufacturing.

3. PLAN AHEAD FOR AFFIRMATIVE EQUITABLE ACCESS AND DELIVERY OF PANDEMIC PRODUCTS:

- **We** support evidence-based prioritization and allocation frameworks when medical supplies are limited. For pandemic vaccines, priority groups identified by health authorities, such as health care workers and high-risk individuals, should be vaccinated first, regardless of the country they live in. For pandemic treatments, prioritization should be based on medical need and up to date clinical guidelines.
- **Companies** will reserve an allocation of real-time production for distribution to priority populations in lower-income countries, as determined by health authorities during pandemics.
- **Key enablers for success:**
 - Public health authorities need to define and rapidly update the priority populations and pandemic 'standard of care' in clinical guidelines, to enable rapid access and appropriate use of new products and help align global regulatory requirements.
 - The global community needs to set up strong, fully funded international procurement mechanisms for pandemic VTDs for lower-income countries that can forecast the demand and sign advanced purchase agreements with industry early in a pandemic. Each country should provide early visibility of its demand for different products.
 - Countries should avoid restrictive clauses in their procurement or contracting processes that could prevent biopharmaceutical companies from executing on equitable access priorities.

- **Each company** will take measures, in partnership with Governments, to help ensure that authorized pandemic vaccines and treatments are available and affordable in countries of all income levels, including via donations, not-for-profit supply, voluntary licenses or equity-based tiered pricing based on countries' needs and capabilities, or any other innovative mechanism as during COVID-19.
- **The industry** will work with partners to help ensure continuity and security of supply for **all** vaccines and treatments during future pandemics.
- **Key enablers for success:**
 - Long-term political commitment and adequate funding to establish and maintain pandemic preparedness within resilient healthcare systems.
 - Governments should invest in strengthening national health systems and global infrastructure, to deliver the UN 2030 Universal Health Coverage targets and develop the capabilities to protect the world against future pandemics. This includes National Pandemic Plans and the healthcare workers, infrastructure and supporting systems needed to deliver them.
 - No-fault compensation programs and liability protections are pre-requisites for rapid pandemic VTD deployment under emergency conditions.
 - Building trust in science and health literacy, public health institutions and vaccines remains critical to ensure population uptake. This requires coordinated action between all actors, including industry, to achieve sufficient confidence, demand-generation and uptake.