STATEMENT

Delivering equitable access in pandemics: Biopharmaceutical industry commitments

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The 77th World Health Assembly (WHA) marks the deadline for the conclusion of a pandemic agreement and amended International Health Regulations (2005) that seek to make the world better prepared for the next pandemic.

In response to the threat of future global pandemics, the biopharmaceutical industry developed a set of commitments for equitable access to essential medical countermeasures in future pandemics. Demonstrating the commitment of the private sector to prioritize the needs of all individuals and communities affected in a pandemic, companies are prepared to leverage their individual expertise and resources to address the challenges posed by pandemics and ensure that no one is left behind. This represents a significant step forward in promoting equity and inclusivity in the distribution of vital resources.

Achieving equitable access to medical countermeasures requires a comprehensive solution and should not be based on linking access to pathogen samples and sequence data to benefit-sharing obligations. It is critical to preserve the innovation ecosystem and research incentives that were effective in the fight against COVID-19. Scientists need rapid access to pathogens and data without conditions in order to quickly develop safe and effective countermeasures to save lives.

Equitable Access Commitments in the pandemic agreement

Building on the commitment contained in the Berlin Declaration, we support that the pandemic agreement creates a broad multistakeholder Partnership for Equitable Access to which companies can voluntarily associate through their adoption of a range of Equitable Access Commitments, which would be legally binding and enforceable through contracts.

Companies could independently adopt one or more of the following Equitable Access Commitments in periods in between pandemics and/or during pandemics based on what each company could best contribute in view of its circumstances, such as its size, location, technology platform, research and development pipeline, or manufacturing capabilities.

<u>In pre-pandemic time</u>, commitments to commence, continue, or enhance:

- → Basic or applied research and development (R&D) on vaccines or therapeutics against pathogens of pandemic potential, including through the use of novel technologies such as artificial intelligence, supercomputing, and robotics;
- → Novel platform technologies, with the goal of having multiple platforms ready for a pandemic and exploring collaborations with relevant public and private entities, especially in low-income countries (LICs) and lower-middle-income countries (LMICs);
- → Geographically diverse and comprehensive clinical trial sites and networks, including through expanding clinical research sites in underserved areas;
- → Manufacturing and/or distribution capacity for relevant therapeutics or vaccines, including through public and/or private partnerships, supply agreements, or voluntary technology transfer agreements, in support of globally enhanced manufacturing and fill/finish capacity;
- → Financial and technical support to LICs and LMICs for capacity building for pandemic preparedness and response, including genomic, environmental, or laboratory disease surveillance; establishing or enhancing clinical trial capacity; strengthening and retention of the health workforce; strengthening regulatory systems; or running additional laboratory capacities that might be relevant.

<u>After a pandemic is declared</u>, commitments to:

- → Reserve a percentage of real time production volume of a relevant therapeutic or vaccine for equitable distribution on the basis of public health risks, needs, and demand. This could include a portion expected as a donation to LICs and/or a portion negotiated under equity-based tiered pricing with the lowest tiers dedicated to LICs and LMICs. In the case of a Repurposed Medicinal Product, attention should be taken to ensure security of supply for care of patients who continue to need the product for its existing indications and uses;
- → Rapid scale-up of production and distribution capabilities, where possible in geographically diverse locations. This may include enhancing the availability of raw materials, active pharmaceutical ingredients, or consumables for the manufacturing of relevant therapeutics or vaccines, and may be done in collaboration with relevant WHO programs;
- → Leverage voluntary license and technology transfer partnerships to ensure that their innovative medical countermeasures reach patients, with special attention to the needs of LICs and LMICs;
- → Establish, enhance, and prioritize research efforts to identify candidate vaccines as well as new and/or repurposed therapeutics relevant to the pandemic;
- → Make its library of molecules available to relevant third parties on fair conditions for the purpose of developing a relevant therapeutic or vaccine;

- → Lend financial and technical support to LMICs for capacity building to support research, manufacturing, or supply for relevant therapeutics or vaccines;
- → Collaborate with the WHO and others on treatment guidelines for relevant audiences to optimize delivery and administration of relevant therapeutics or vaccines.

Enablers

The pandemic agreement provides a unique opportunity to establish a comprehensive system for better and more equitable pandemic preparedness and response. For the Partnership to deliver on its mission, four enablers are of particular importance:

- → All countries, but specifically those governments of countries with manufacturing facilities, commit, through the pandemic agreement, to allow for unrestricted exports of pandemic medical countermeasures, manufacturing inputs, and raw materials.
- → Strong regulatory systems and the use of regulatory strategies ensure the accelerated availability of pandemic vaccines and treatments, in line with the G7 100 Days Mission. Internationally harmonized and streamlined approvals will be instrumental in improving equitable access. Member states need to facilitate distribution of donations by ensuring that such products are approved for use in that Member State, including through WHO Emergency Use Listing, prequalification, or based on reliance on approval by a stringent regulatory authority.
- → Unconditional access to pathogens and relevant data and recognition of the pandemic agreement as a Special International Instrument (SII) in accordance with the Nagoya Protocol, thereby mitigating the delays caused by national access and benefit-sharing laws.
- → Inclusive governance through a Partnership where WHO has a central role but also encompasses all stakeholders that will contribute to the implementation of the agreement, including industry, in roles appropriate to their capacity and expertise.

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