

Life Science Companies and the Bill & Melinda Gates Foundation: Joint Communique

Commitments to expanded global access for COVID-19 diagnostics, therapeutics, and vaccines. Sep 30, 2020

COVID-19's existence anywhere poses a threat to communities everywhere. The health, social, and economic impacts can only be addressed through the collective actions of stakeholders across private, public, and philanthropic sectors in partnership with civil society. As organizations dedicated to improving and protecting global health, with our varied skills, roles, and resources, we remain committed to doing our part in ending this pandemic worldwide. Earlier this year AstraZeneca; Bayer; bioMérieux; Boehringer Ingelheim; Bristol Myers Squibb; Eisai; Eli Lilly; Gilead; GSK; Johnson & Johnson; Merck & Co. (known as MSD outside the U.S. and Canada); Merck KGaA, Darmstadt, Germany; Novartis; Pfizer; Roche; and Sanofi together with the Bill & Melinda Gates Foundation each pledged ourselves to the fight against COVID-19

Collectively, we have launched the most expansive and ambitious pandemic R&D response effort in history, with the promise of a range of interventions that can help end the pandemic. Creating these innovations is not enough, however. Through partnerships with other stakeholders we are committed to ensuring global access to diagnostics, therapeutics, and vaccines that will help to accelerate the end of the pandemic. To accomplish this critical goal, we will:

- Develop innovations for patients worldwide. We will continue advancing the research and development of COVID-19 diagnostics, therapeutics, and vaccines that
 are suitable to meet the needs of populations around the world. To do so, we will work to expand clinical trials to account for diverse representation including
 lower-income settings and endeavor to address the specific product characteristics needed for use in lower-income settings even after new innovations are
 brought forward.
- Strive for timely availability. By scaling up manufacturing at unprecedented speed and much earlier than usual, we will bring large quantities of safe and effective innovations to countries around the world for broad distribution as early as possible, no matter their income level. Mechanisms for rapidly escalating supply must be aligned with the specific context of a rapid pandemic response and tailored to each product, with options including early voluntary licensing and appropriate approaches to peer-to-peer innovator company manufacturing agreements.
- Enable affordability for lower income countries. We will pursue a range of approaches to make products we are developing or supporting affordable in lower-income countries. These approaches will be independently determined by each supplier in response to the pandemic to address the significant affordability challenges, including approaches such as donations, not-for-profit supply, or equity-based tiered pricing based on countries' needs and capabilities.
- Support effective and equitable distribution of these innovations globally. We will strive towards equitable allocation of our products and support global mechanisms like COVAX, recognizing the most effective approach to equitable access will vary across vaccines, therapeutics, and diagnostics. We also will use our collective voice alongside other global health stakeholders to advocate for the strengthening of health systems and distribution networks so crucial innovations reach everyone who needs them. In doing so, we support evidence-based prioritization so that health care workers, high-risk individuals, and other priority groups identified by WHO and other health authorities are protected for the duration of the pandemic, regardless of the country they live in. We will advocate for equitable distribution, recognizing that sovereign nations have final decision-making authority.
- Maintain public confidence in our innovations. We will continue making the safety of individuals who receive products we are developing or supporting the highest
 priority. Adherence to the strictest scientific and ethical standards in product development and in manufacturing processes will remain the top priority over speed or
 politics.

Access to interventions to fight COVID-19 on a global scale requires financial resources, assets, infrastructure, and jurisdictional support and collaboration beyond the capacity or role of the signatories to this commitment. We therefore call on governments, multilateral institutions, companies, NGOs, and others to build on our commitments and efforts already underway to:

- Provide sufficient, dedicated, sustainable, and timely funding for the procurement and delivery of the tools necessary to end the COVID-19 pandemic.
- Diversify representation in critical decision-making and coordination bodies with special emphasis on voices representing low-income and lower-middle-income countries.
- Continue quickly developing and communicating clear guidance on product needs in lower-resource settings as early as possible as our understanding of COVID-19 and the tools to combat it evolve.
- Advance fit-for-purpose regulatory and liability processes for all stakeholders involved, which prioritize safety while not slowing down access to critical new tools.
- Build and maintain public confidence in the approval mechanisms for diagnostics, therapeutics, and vaccines by ensuring robust safety and efficacy reviews and removing unwarranted political considerations from these discussions and the approval process.
- Enhance country readiness and in-country delivery systems by ensuring adequate expertise and resources are in place for effective country planning, distribution, and follow-up for new diagnostics, therapeutics, and vaccines.

The world's extraordinary situation requires unprecedented collaboration across every part of society. To date, we as life science and philanthropic organizations have risen to this challenge and recognize the need to push further. The commitments above will save lives only if partners across the entire development-to-deployment pathway work together to guarantee products reach the people who need them. The ACT-Accelerator offers a forum for collaboration and action, and the global community must collectively mobilize the resources partners have identified as critical to ending this pandemic for communities everywhere. By aligning those resources with the commitments above, we believe we will not only enable a faster path out of the current COVID-19 crisis but will also lay the foundation for a strong pandemic preparedness ecosystem the next time a pandemic arises.

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This pandemic will go down as one of the defining moments of our time, and no one - regardless of their country, their income, or anything else - should have to worry about whether they will have access to the care and innovation that could help them and their loved ones combat COVID-19. This is also a defining moment for the life sciences industry - a moment for a new kind of leadership - and with this agreement, we've committed to collectively pursuing a healthier, more equitable future for the good of mankind.

Vas Narasimhan, CEO of Novartis

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