

PREPARING SOCIETY AGAINST FUTURE PANDEMICS

Policy Perspectives from the Innovative
Biopharmaceutical Industry

IN BRIEF



IFPMA

In January 2020, as the global threat from COVID-19 first began to emerge, the research-based biopharmaceutical industry went straight into action to develop diagnostics, vaccines and therapies for the novel coronavirus. This Policy Perspective aims to show how lessons learned from the rapid and unprecedented response to the pandemic can help the world prepare better for the next. It recommends a number of policy and practical measures to further enhance effective pandemic preparedness and response, highlighting the role of the industry and the importance of coordination, collaboration and trust between all key stakeholders.

The biopharmaceutical industry is committed to improving pandemic preparedness for the future. Our vision for pandemic preparedness is based on two ambitious objectives:

- 1** Aim to develop effective and safe pandemic products within 100 days of a new pandemic declaration.
- 2** Collaborate with governments, multilateral organizations, regulators, and other companies and sectors to ensure equitable access to those products for people worldwide.



While the world is still grappling with COVID-19, the global community also needs to look ahead to how we can be better prepared for the next pandemic. Effective pandemic preparedness will require sustained political leadership, political will, global coordination, regulatory alignment, public-private partnerships, solidarity, and commensurate up-front and continuing financing.

Aiming for effective and safe pandemic products within 100 days

Pre-emptive R&D

Industry role: We are committed to investing in research and development (R&D) on target pathogens with epidemic and pandemic potential to build a portfolio of promising candidate vaccines, treatments and technologies.

Asks to stakeholders: Specify evidence-based target pathogens and technologies. Foster a life sciences R&D ecosystem with continued robust intellectual property (IP) protection, sustainable 'push and pull' incentives and effective industrial policies. Proactively explore novel risk-sharing models, including advance purchase commitments, because normal market forces do not apply when preparing for pandemics.

Immediate sharing of pathogens with epidemic and pandemic potential, and associated information

Industry role: We are committed to ensuring the highest safety protocols for our laboratories and only to use shared samples and genetic sequence data for research purposes and for the production of vaccines, medicines and diagnostics.

Asks to stakeholders: Establish a comprehensive multilateral commitment to ensure the rapid sharing of pathogens and associated information and avoid unnecessary delays. We request that all countries applying the Nagoya Protocol or other national requirements to human pathogens and associated information reconsider their position and exempt them from the scope of relevant legislation to facilitate their rapid sharing.

Regulatory convergence and reliance

Industry role: We are committed to prioritizing patient safety and product quality at all times, including during public health emergencies, by adhering to the strictest scientific and ethical standards in product development and manufacturing. We will work in partnership and collaboration with National Regulatory Authorities (NRAs) to define the best science-based regulatory strategies.

Asks to stakeholders: Define in advance the regulatory agilities to be used by NRAs in a pandemic setting so manufacturers can plan development, regulatory and manufacturing strategies to better ensure an adequate supply of quality medicines and vaccines. Establish broader and transparent collaboration between NRAs in relation to mutual recognition of approvals, reliance on approvals work by other NRAs, work sharing, and timely flow of safety data to reduce complexity, accelerate decision making and enhance efficiency of global supply chains.

Global clinical trial infrastructure

Industry role: We are committed to producing high-quality evidence on the efficacy and safety of our products, both prior to and during pandemic conditions, and maintaining the highest levels of quality and ethical standards, transparency and accountability.

Asks to stakeholders: Establish networks of clinical sites and trained clinicians capable of rapidly conducting high-quality studies around the world, which take into account the evolving standard of care during future pandemics. Explore how clinical trials can be better coordinated in the future to improve efficiency, prevent duplication and provide globally relevant results while avoiding bureaucracy and delays.

Equitable access to pandemic products for people worldwide

Effective pandemic procurement

Industry role: We will continue to work closely with regulatory authorities, governments, funders/payers and relevant global initiatives to make as many doses available as fast and as safely as possible, and to facilitate the timely approval and availability of affordable pandemic-related products, using tailored approaches.

Asks to stakeholders: When a pandemic is declared, make immediately available sufficient, dedicated and sustainable financing and technical assistance to countries with limited or no capacity to finance their own pandemic purchases and deployment activities. Ensure contract provisions make clear the mandate and responsibilities of the stakeholders involved as well as forecast volume requirements, procurement timelines and processes, and indemnity and liability clauses. No-fault compensation systems and anti-corruption measures would accelerate procurement in future pandemics.

Strengthening health systems planning and delivery

Industry role: We are committed to providing our on-the-ground experience and expertise to support the actions of governments and other stakeholders to improve health systems and pandemic preparedness.

Asks to stakeholders: Implement policies and plans to achieve the United Nations 2030 targets for Universal Health Coverage (UHC) and related Sustainable Development Goals, and address other health threats including antimicrobial resistance. Incorporate in pandemic plans the means to enable the rapid delivery of population-wide vaccination programs, including a cold-chain supply, and provisions for post-licensure safety monitoring and information sharing.

Sustaining manufacturing capacity

Industry role: As the industry's response to the COVID-19 pandemic has already demonstrated, individual companies are committed to working with governments and other stakeholders on new initiatives to ensure the necessary global manufacturing knowhow and capacity to vaccinate the world's population in the fastest possible timeframe during a pandemic.

Asks to stakeholders: With relevant stakeholders from the private and public sectors, develop a holistic strategy for flexible, sustainable global manufacturing capacity, using 2022 as a baseline for building the extensive upstream and downstream supply chains required for pandemic vaccines. Aim for a healthy market dynamic with appropriate incentives to balance global access and innovation, including in inter-pandemic periods. Ensure coordinated and coherent open trade policies, including in times of a pandemic, to allow the expeditious movement of pandemic-related technologies and avoid arbitrary export bans.

Improving global surveillance capabilities

Industry role: We are committed to the rapid sharing of relevant information that may provide insights into emerging diseases and their control, arising from our monitoring, clinical trials and other activities.

Asks to stakeholders: Conduct comprehensive viral mapping projects to increase understanding of potential pandemic threats. Develop core capacities for early-warning disease surveillance systems that ensure timely and clear information sharing and the systematic collection, analysis, interpretation and dissemination of health data.



International Federation of Pharmaceutical Manufacturers & Associations

IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 2 million employees discover, develop, and deliver medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.



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