



IFPMA

Principles for a fit-for-purpose global health architecture

Biopharmaceutical industry's considerations on key elements for an effective multilateral Pandemic Prevention, Preparedness, and Response (PPR) instrument

OCTOBER 2022

Inclusive and transparent negotiation process

All critical contributors to the PPR value chain, including the innovative pharmaceutical industry, should be included in the formal process leading to the drafting of a future PPR instrument. As reinforced by the real-life experience of the COVID-19 pandemic, the instrument should acknowledge that a multistakeholder partnership that includes industry, public agencies, multilateral organizations, financial institutions, governments, civil society, and philanthropic organizations is the only viable solution to managing pandemic crises.

Efficiency first: the principle of subsidiarity

While global coordination is fundamental, tasks and decision-making processes that are more efficiently performed nationally or regionally should remain at these levels. A future PPR system should build on already-existing infrastructures and, in respect of the principle of subsidiarity, be the reference instrument to coordinate at global level only what cannot be more efficiently achieved regionally or nationally. We believe that while the World Health Organization would have a key role, it should not be within a command-and-control structure.

A predictable system with aligned expectations

A new PPR system should be predictable and align expectations by clearly defining the roles of different actors, so that when a pandemic strikes, less time is spent creating institutions or negotiating complex legal agreements. In our view, a new predictable system should:

- *Reduce red-tape.* Countries should implement legislation and/or harmonized regulations allowing for the use of reliance processes to expedite registration and facilitate trade. Legislation should also include a predefined scheme for no-fault compensation and liability limitation.
- *Enhance forecasting.* Any system should aggregate real-time epidemiological data, including prioritized target sub-populations, and facilitate rapid development of robust forecasting models. It should also promote clear, coordinated demand planning to inform governments and manufacturers decisions on clinical development, scale-up, and right-sizing of manufacturing assets for pandemic medical countermeasures.

- *Promote regulatory convergence.* A future system should define in advance the regulatory pathways, collaborative procedures, and agilities to be used by National Regulatory Authorities (NRAs) in a pandemic setting. This would allow development, regulatory, and manufacturing strategies to be better planned and aligned to support adequate supply needs.

Complementarity to existing instruments

As per common practice in international law, a future instrument should include clarifications on how it would relate to other international instruments, including discussing the compatibility and complementarity to the 2005 International Health Regulations (IHRs), the Convention on Biological Diversity (CBD), and the 2011 Pandemic Influenza Preparedness Framework. It is critical to avoid mission creep and fragmentation of health emergencies governance.

A facilitated, predictable access to pathogens

Our ability to prepare for and respond to pandemics swiftly rests on improved global pathogen surveillance, immediate samples and data sharing, and the scientific community's ability to collaborate efficiently. Any delay in this process directly impacts the delivery times for new vaccines, therapeutics, and diagnostics. Any system should correct the potentially negative impact on response timing from access and benefit-sharing (ABS) legislation.

- National implementations of the Nagoya Protocol and its associated bilateral ABS provisions under the CBD have already resulted in delays in the sharing of both genetic sequence data and physical samples for several pathogens including influenza, Zika, and Ebola. Proposals to bring digital sequence information into the scope of the Nagoya Protocol may significantly increase the risk of delays and hinder basic R&D for vaccines, therapeutics, and diagnostics.
- Mechanisms that require commercial negotiations before access is granted, such as those proposed for the new WHO Biohub, will cause unnecessary delays and provide a significant disincentive for innovative pharmaceutical companies.

Promote more equitable access

One of the lessons learned in this pandemic is that achieving equitable access is not a straightforward process. The PPR system should enhance international solidarity and clarify the expected behavior of various stakeholders, including government and industry, that would lead to enhanced equity in access to vaccines, therapeutics, and diagnostics. The system must give ample leeway for companies to tailor their access strategies and should not attempt to centralize global procurement, pricing, or production.

International funds must be available in advance so that efficient, established procurement mechanisms purchasing on behalf of countries with limited capacity to finance their own pandemic purchase are able to quickly draw on pre-approved financing to purchase doses on a par with high-income countries.

Keep borders open and trade flowing

A future PPR system should protect existing supply chains from export restrictions and other trade barriers. During the COVID-19 pandemic, we witnessed the impact of export bans and restrictions on distribution, leading to vaccine hoarding, shortages of raw materials, limitation of cross-borders movement of skilled workforce, and tariffs. It is therefore critical for future pandemics to adopt policies that expedite the cross-border supply of vaccines, medicines, and diagnostics, key raw inputs, essential manufacturing materials, along with the prioritized movement of skilled workforce needed for their production.

While guaranteeing trade flows, a new pandemic response system should not force companies to transfer technology or localize production. During the COVID-19 pandemic, industry has voluntarily entered into more than 360 manufacturing deals to meet the unprecedented demand, 75% of which involved technology transfer.

Protects IP and leverages private sector efficiencies

The system should build on the private sector's strengths for R&D, manufacturing, and distribution, which can only be achieved through a robust intellectual property system. The rapid response during early days of the COVID-19 pandemic reflected many years of investment and scientific discovery in academia and within biotechnology and biopharmaceutical companies. We support evidence-based prioritization of target pathogens to build a portfolio of candidate vaccines, treatments, and technologies, based on established as well as novel and promising technologies.

While the public sector may play a larger role in a pandemic setting, and there would be a role for structures like CEPI and BARDA, the system should not attempt to create a centralized, publicly funded R&D infrastructure for medical countermeasures. Continued robust IP protection, sustainable 'push and pull' incentives, and effective industrial policies are critical to fostering a life sciences ecosystem that delivers innovation for pandemics while continuing to pursue innovations for other unmet medical needs.