

Strengthening global regulatory capacity for equitable access to vaccines in public health emergencies

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Three high-impact steps could be taken by global health leaders to reshape the global regulatory framework and help address the pressing

need for equitable access to diagnostics, therapeutics, and vaccines during public health emergencies, according to a Georgetown global health law expert and a medical student.

In their "Perspective" published today in the *New England Journal of Medicine*, Georgetown School of Health professor Sam Halabi, JD, and George O'Hara, a Georgetown [medical student](#) and David E. Rogers Student Fellow, say these reforms aim to enhance the capacity of national regulatory bodies, particularly in low- and middle-income countries to ensure timely and safe access to essential medical products.

The U.S. Food and Drug Administration (FDA) and a select group of national regulatory authorities currently dominate the approval process for medical products. However, this concentration of regulatory capacity in high-income countries has led to bottlenecks and delays in the distribution of critical medical supplies during emergencies, as seen during the COVID-19 pandemic.

A recent analysis highlights that few national regulatory bodies, primarily in high-income countries, meet the World Health Organization's (WHO) stringent criteria for being "highly performing." Approximately three-quarters of WHO member states lack the regulatory maturity to assure their populations of the quality of medical products, including vaccines.

To address these weaknesses, Halabi, who directs the Center for Transformational Health Law at the O'Neill Institute for National and Global Health Law, and O'Hara propose three key measures for the WHO and global health leaders:

1. **Expand Regulatory Coordination and Planning:** The WHO should actively engage in focused planning with national regulatory authorities that have achieved advanced maturity

levels. This includes integrating regulators from countries like Korea, Saudi Arabia, and Singapore into a regional coordination initiative for dossier review and approval during emergencies.

2. **Leverage Regional and Multilateral Development Banks:** Development banks should agree to extend loans for procuring medical products approved by WHO-listed authorities with a given certification. This would alleviate the bottlenecks and access issues exacerbated by the dependence on WHO's Emergency Use Listing designation during the COVID-19 pandemic.
3. **Promote Regulatory Flexibility in Pandemic Agreements:** As negotiators finalize a global pandemic agreement, provisions should focus on a coordinated and multilateral approach to leveraging emerging regulatory capacity. By decentralizing regulatory review and expanding the approval process to include authorities from countries with stronger regulatory systems, LMICs can secure vaccine doses earlier in future pandemic responses.

"Together, these steps can drive more cohesive responses to future [public health emergencies](#)," write Halabi and O'Hara.

The WHO has already initiated steps to reduce reliance on the European Medicines Agency and the FDA by creating a new framework of WHO-listed authorities to replace the stringent regulatory authority designation. However, the authors stress the need for additional efforts to ensure greater national control over vaccine supply and reduce dependence on global entities like COVAX.

"Expansion of regulatory pathways would prioritize public health by enabling diagnostics, therapeutics, and vaccines to reach populations sooner," they write. "By taking incremental but high-impact steps based on the WHO's classifications of regulatory systems, global health leaders

can mount a more equitable and rapid response."

More information: Preparing for the Next Pandemic — Expanding and Coordinating Global Regulatory Capacity, *New England Journal of Medicine* (2024).

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