

Regional self-reliance for innovation and manufacturing of pandemic tools

Now more urgent than ever

May 2025

If outbreaks are to be stopped before they become pandemics, regions must work now towards self-reliance in order to innovate and produce their own medical countermeasures. The challenge is that ownership of technology, knowledge, and intellectual property remains in the hands of entities within a few countries, and a largely market-based approach has not historically fostered public health-oriented outcomes to manage health emergencies.

The COVID-19 emergency highlighted that while effective medical countermeasures (MCMs) can be developed and produced in a matter of months, the bigger challenge is to deliver them equitably within a highly unequal world. It requires at minimum more balanced distribution of manufacturing capabilities throughout the regions, alongside a shift in governance over critical technologies.

Current geopolitical shifts, massive and erratic cuts to development assistance, and a breakdown of solidarity in domestic and global policies underscore that a core strategy for pandemic prevention, preparedness and response must be regional and subregional self-reliance for MCM innovation and manufacturing. This self-reliance must be complemented by regional and national political leadership and based on the principle of subsidiarity.

The pandemic agreement text confirms the importance of regional self-reliance. It includes numerous provisions that can help move the needle, including commitments to share a 20% target percentage of real-time production and to promote equity, technology sharing, access to pathogens and benefit sharing, regional diversification of technological capacity, and access conditionalities for publicly funded research.¹

The Independent Panel is clear that implementation cannot wait for the agreement to come into force. Global, regional, and national leadership and investment are needed now to build an end-to-end pandemic MCM ecosystem where regions and subregions are equipped and empowered for research and development, manufacturing, and delivery.

The Panel has recommended and is glad to see several global and regional efforts underway to rebalance a system that has centred power in high-income countries. These efforts, however, are uneven and fragmented. They also have been under-resourced and tend towards market-based solutions that have not solved the issues of equity and access in the past. Globally, the World Health Organization's Research and Development (R&D) Blueprint for Epidemics provides a valuable scientific framework even as coordination gaps remain.² From 2020–2023, just US\$1.45 billion was spent for priority pathogen MCM R&D, with 78% of that provided by the United States.³ Global R&D funding has been far from sufficient and is now at greater risk due to US budget cuts.

The Coalition for Epidemic Preparedness Innovations (CEPI), a global partnership, effectively leads vaccine development efforts but funds innovation primarily in high-income countries and invests comparatively little in research capabilities in low- and middle-income countries (LMICs) beyond manufacturing partnerships.⁴ After recent challenges, the future role of FIND (the Foundation for Innovative Diagnostics) whose mission is to ensure equitable access to diagnostics, remains to be established for PPPR. As of yet, there is no coordinated, resourced action to develop pandemic therapeutics.

A promising development in regional self-reliance is the WHO/MPP mRNA technology transfer programme, which is equipping manufacturing partners in 15 middle-income countries for mRNA vaccine and therapeutics development and for manufacturing.⁵ The important progress of this initiative must be sustained particularly through regional and subregional investment and governance. The programme should also be given freedom to operate from intellectual property barriers to encourage the creation of new products.

If a new pandemic threat emerged today, our deeper-dive analysis shows there are regions, large countries like India and China, and small countries like Cuba that can at once care for their own needs and add to the global availability of pandemic MCMs, while other regions and subregions require much more support including from finance mechanisms, technology and knowledge transfer, together with industrial health policy that fosters R&D for public health priorities and outcomes.

> For a deeper dive into regional self-reliance for innovation and manufacturing of pandemic tools see the next section

Given regional epidemiology, lack of finance and that current efforts focus primarily on manufacturing, there is a risk that the Global South will need to continue to depend on high-income countries for R&D and innovation into the future. At the same time, many high-income countries are pulling support away from LMICs, compounding the risk that in the next major outbreak or pandemic, people in these countries will once again be the last to receive vaccines and other tools. That is why a strong commitment to establish technological sovereignty for MCMs is critical.

Actions towards regional self-reliance:

Begin work now to implement MCM provisions of the pandemic agreement, including investment in scientists and developers in LMICs. Pathogens will not wait. Regional and national leaders must take charge now, assess current initiatives, strengthen regional plans, and identify the gaps and needs to be filled through public and private investment, technology and knowledge transfer, and freedom to operate to expand innovation. CEPI and other Global North actors should go further beyond their current approach to include significant R&D investment and equal partnerships in LMICs.

Sustain progress of the WHO/MPP mRNA technology transfer programme, and use lessons to build further regional initiatives. The mRNA technology transfer programme has achieved much progress, and its efforts must not to go waste. Its partners deserve continued investment to realise the transformative potential for building regional innovation and manufacturing capacity to address regional and local health priorities. Regional initiatives such as Brazil's G20 Global Coalition for Regional and Local Production, Innovation, and Equitable Access, the Pan American Health Organization's Regional Innovation and Manufacturing Platform, the BRICS Vaccine R&D Centre, and the Association of Southeast Asian Nations' coordination efforts should incorporate lessons from the hub experience in order to ensure LMIC-led governance.

Top 10 vaccine manufacturers by volume or financial value, portfolio size and technology types used

In this chart, vaccine manufacturers depicted below the horizontal line are mainly headquartered in India and China, and account for approximately 70% of the total volume of vaccine doses produced. The five manufacturers above the line are affiliated with the International Federation of Pharmaceutical Manufacturers and Associations, and amount to approximately 30% of global volumes but capture almost 80% of total financial value.



Adapted from the WHO Global Vaccine Market Report, 2024.6

Middle-income countries and existing funds must play a financing role. Middleincome countries could collectively finance regional R&D and manufacturing projects addressing shared health needs, especially given uncertainties in US funding. The BRICS countries could play a leading role. The Pandemic Fund and Africa Epidemics Fund should integrate access to outbreak and pandemic MCMs as fundamental components of preparedness financing.

Closing message—regional self-reliance for health security

If a new deadly outbreak spread rapidly today, many countries would still be scrambling to have timely access to tools like vaccines, tests and treatments. People's lives would be at risk, and the world would be at risk of another pandemic. Despite some progress in support for regionalised manufacturing, ownership of technology and knowledge to create pandemic countermeasures remains with a handful of countries. Pandemic preparedness requires a shift to regional self-reliance in research and development as well as manufacturing.

This will take time to build and regions should solidify their plans now, invest in them, and be clear on the gaps. In turn, countries that currently hold the power must implement the provisions in the pandemic agreement starting today, and ensure their industries partner to share the technology and knowledge required for all regions to be equipped to stop outbreaks before they become pandemics.

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A deeper dive into regional self-reliance for innovation and manufacturing of pandemic tools

May 2025

Here we provide a deeper dive on current global, regional, and country initiatives and capacities. There is at once a picture of hopeful progress, but structural barriers to regional self-reliance remain, particularly in vulnerable regions. There are no shortcuts, and investment in a sustainable end-to-end ecosystem must begin now.

Background

COVID-19 demonstrated that collaborative research and development (R&D) involving public, private, and nonprofit actors can produce pandemic medical countermeasures in record time. It also revealed, however, that dynamics around ownership, control of information, technologies, and financing led to inequitable access, benefitting the wealthiest countries first and resulting in preventable deaths in low- and middle-income counties (LMIC). Leaders vowed to never let that happen again.

In 2021, The Independent Panel recommended that in order to stop outbreaks where and when they occur, medical countermeasures (MCMs) for health emergencies had to be considered global health commons.¹ This would require a shift from purely market-driven innovation to a more inclusive approach in which all regions have agency over not only manufacturing, but also research and development of products tailored to local epidemiology and conditions. The panel also recommended that a pre-negotiated end-to-end R&D to access ecosystem be established, with regional research and manufacturing hubs, provisions for timely and effective technology transfer and sharing, the freedom to operate to adopt these technologies towards local priorities, and adequate financing to achieve public health objectives.²

Lessons from COVID-19 have prompted initiatives aimed at increasing and decentralising pharmaceutical production capacity, in particular in Africa. To date, most of the focus has been on infrastructure and technical capacity rather than addressing structural and political barriers to equitable access such as the governance over technologies and financing.^{3,4}

Progress to date: a patchwork of global and regional initiatives

The latest report of the 100 Days Mission by the Independent Pandemic Preparedness Secretariat (IPPS) shows some progress in relation to MCMs for individual health threats. At the same time, however, it highlights few systemic changes in the broader R&D ecosystem to sustain and accelerate clinical development, regulatory approval, and equitable access for MCM targeting priority pathogens.⁵ The response to several outbreaks since COVID-19, including two public health emergencies of international concern (PHEIC), suggests some progress but points to a long road ahead (see box).

Stress-testing the system with mixed results

Mpox (2022–2025): The contrasting responses to two mpox emergencies demonstrate persistent inequities. In the 2022–2023 mpox PHEIC initially affecting Europe and North America, stockpiled health security vaccines were deployed swiftly, as was a treatment initially developed for smallpox. Through relatively rapid access to MCMs and effective community mobilisation, the PHEIC, ultimately affecting 110 countries, was over within nine months. Yet despite continued lowlevel mpox transmission, none of the MCMs was registered, made available, or used in West and Central African countries where mpox is endemic.

In August 2024, transmission of the clade 1a virus accelerated particularly amongst children in the Democratic Republic of Congo (DRC) and a new clade 1b was identified. A new PHEIC and African continental emergency was declared, but vaccines arrived months later and in limited quantities. Barriers included diagnostic limitations, hoarding of preferred vaccines in wealthy countries' stockpiles, complex administrative hurdles, high prices, and reluctance to transfer technology to African producers (though it will be transferred to India). By 22 April 2025, 662,740 vaccine doses had been administered of only 1,045,180 million doses delivered to the African continent, with the WHO advising providers to use spare dose strategies given limited vaccine supply.⁶ In addition to supply challenges, mpox vaccination is subject to vaccine hesitancy, heightened insecurity in the most affected eastern provinces of DRC, and most recently the fallout of the US funding freeze. As of 9 May 2025, the mpox outbreak remained a PHEIC.

Marburg in Rwanda (2024): Rwanda's response to its first Marburg outbreak proved highly effective. Building on strong government leadership and public health infrastructure, and with international support including from the United States and the WHO, the outbreak was efficiently contained with nonpharmaceutical infection control measures, as vaccine and treatment trials were also being initiated. The outbreak was declared over in December 2024 with 66 confirmed cases and 15 deaths.

Sudan Ebola in Uganda (2025): When Sudan ebolavirus reappeared in Uganda in January 2025, researchers and WHO partners including IAVI, the International AIDS Vaccine Initiative, initiated a vaccine trial within four days thanks to prepositioned vaccines and preapproved clinical trial protocols.

In each of these outbreaks, vaccines, including trial candidates, had been developed through publicly funded research (mainly by the US government), were manufactured in high-income countries, and all had to be shipped to the African region.

H5N1 bird flu: The ongoing H5N1 outbreak in US dairy cattle highlights how political considerations can hamper effective outbreak response even in wealthy countries when agricultural industry interests are prioritised over public health. A key mRNA vaccine development contract is now under review, potentially reversing prevention and preparedness efforts. The experience also underscores why one country should not be the prime investor in R&D.

The WHO R&D blueprint provides a scientific framework for preparedness, but gaps remain in coordinating global research priorities. Newer WHO initiatives such as the Collaborative Open Research Consortium⁷ and i-MCM-Net⁸ are important, but add to a complex landscape of overlapping networks with uncertain integration including with the future Global Pandemic Supply Chain and Logistics Network agreed in the text of the pandemic agreement.⁹

Funding for R&D investments in MCM is completely insufficient, and the future is uncertain: IPPS reports US\$1.45 billion mainly for vaccines, some therapeutics, and diagnostics R&D for priority pathogens (excluding COVID-19) during 2020– 2023.⁵ US government departments provided 78% of this funding, and this already thin pipeline is now at greater risk due to abrupt US cuts in 2025.

The Coalition for Epidemic Preparedness Innovations CEPI has remained at the centre of many efforts to support PPPR vaccine development and manufacturing and is expanding into biological drugs. So far, the majority of CEPI's R&D investments have been granted to entities in high-income countries (HICs),¹ with LMIC partners solicited primarily for manufacturing. CEPI's funding may also be vulnerable to US funding cuts. The future of the Foundation for Innovative Diagnostics (FIND), important in guiding diagnostic development and rollout during COVID-19, is uncertain. There is as of yet no effective coordination or funding to establish a global PPPR therapeutics development coalition.

Several global initiatives focus on increasing Global South resilience. The WHO/ Medicines Patent Pool (MPP)-coordinated mRNA technology transfer programme, supported by Canada and European donors including France, represents a potentially transformative initiative supporting regional R&D capacities.¹⁰ The South African technology hub has developed and is sharing an mRNA platform with manufacturers in 15 middle-income countries. Brazil has also developed its own mRNA technology. However, the endeavour is challenged to develop new products with freedom to operate and without intellectual property barriers which is critical to become economically sustainable.

With a greater focus on manufacturing and hosted by CEPI, the Regionalized Vaccine Manufacturing Collaborative (RVMC) aims to foster sustainable regional manufacturing networks that can produce vaccines for routine use and ramp up in times of crisis, ¹¹ while the International Vaccine Institute (IVI) has increased its footprint with projects including the Advancing Vaccine End-to-End Capabilities initiative in Africa. ¹² Under Brazil's leadership, BRICS countries are discussing a BRICS vaccine R&D centre.

How resilient are regions and what are the barriers?

Several regions are harnessing political leadership towards greater self-resilience and resilience, but finance, governance, regulatory simplification, and other issues need continued attention and resolution.

Latin America

Latin America has diverse pharmaceutical manufacturing capabilities, particularly in Argentina, Brazil, Chile, Colombia, Cuba, and Mexico. Publicly funded vaccine producers form cornerstones of health systems in Brazil and Cuba, and Cuba was the only Latin American country to develop its own COVID-19 vaccines, for which it transferred technology within and beyond the region.¹³ During the pandemic, several countries received technology transfers, primarily for fill-and-finish operations, from AstraZeneca, CanSino, Gamaleya, and Sinovac.¹⁴ Brazil's public manufacturers (Butantan and Bio-Manguinhos) were key recipients, with only Bio-Manguinhos receiving both fill-and-finish and drug substance transfers from AstraZeneca, enabling fully sovereign production.¹⁵ While mAbxience in Argentina received drug substance technology, fill-and-finish was transferred in Mexico, creating bottlenecks to supply and access.¹⁴

The region is actively strengthening innovation capabilities, and Brazil and Argentina are participants in the WHO/MPP mRNA technology transfer programme. Argentina, Brazil, and Cuba have substantial and growing diagnostics R&D and manufacturing across multiple platforms.¹⁶ Generic drug manufacturing including some biological drugs is significant, though home-grown therapeutic innovation remains limited.

Recent regional resilience initiatives include PAHO's Innovation and Regional Production Platform¹⁷ and Brazil's G20-launched Global Coalition for Local and Regional Production, Innovation, and Equitable Access.¹⁸ These build upon PAHO's successful pooled procurement mechanisms, so far used primarily to buy at low cost in the international market. With political will and the right policy framework, it could be harnessed as an incentive for regional developers. Sinergium Biotech in Argentina will be the first Latin American company to supply a regionally produced vaccine (a technology transfer from Pfizer) to PAHO's Revolving Fund.¹⁹ Bio-Manguinhos' mRNA development project, designed to navigate the complex intellectual property (IP) landscape and establish freedom to operate, exemplifies local innovation efforts.

Key challenges in Latin America persist, including limited access to new technologies and continued reliance on international companies for new product R&D, restrictive licensing agreements that constrain freedom to operate beyond initial products, and financing difficulties as countries face historic debt burdens and high interest rates for international capital.

Africa

Despite numerous new initiatives strengthening pandemic preparedness in Africa, pharmaceutical self-sufficiency remains primarily framed around building a competitive marketplace, with unclear implications for equitable access.

The African Union (AU) and Africa Centres for Disease Control and Prevention (Africa CDC) have taken steps to strengthen regional pharmaceutical manufacturing capacity, and more modestly R&D capacity, with a goal to locally manufacture 60% of Africa's immunisation needs by 2040.^{4,20} This builds upon AU pooled vaccine procurement for COVID-19 and includes the Platform for Harmonized African Health Products Manufacturing with investments in infrastructure, local manufacturing, and regulatory oversight. These efforts receive support from international partners including the World Bank, European Investment Bank, US International Development Finance Corporation, Team Europe, and development agencies and foundations including Gavi, the Vaccine Alliance; CEPI, IVI, the Gates Foundation, Wellcome Trust, and the Mastercard Foundation. Africa CDC leads on PPPR and coordinates this complex, multiyear effort. As of mid-2024, 25 vaccine manufacturers operate on the continent in varying stages of maturity and technology transfer, backed by different investors. While three manufacturers are expected to produce eight WHO-prequalified vaccines by 2030, ²⁵ affordable supply is already available through mainly India-based high-volume, low-cost suppliers and procured by UNICEF. Incentivising sustainable local production will require novel approaches including a clear health-industrial policy as is common practice in HICs that finance industry to benefit society. ²¹ For local manufacturing for health equity, this could include Africa CDC efforts to prioritise regional health needs such as Ebola, Marburg, and mpox, and focusing on collaboration for equitable access rather than the marketplace competition approach currently envisaged, including through Gavi's African Vaccine Manufacturing Accelerator.²²

Specialised workforce capacity is another challenge. Africa CDC's Regional Capability and Capacity Networks address skills gaps in biomanufacturing and research, with five African institutions leading the efforts. Sustainable investments must include prepositioned clinical trial capacities and robust R&D pipelines.²³ Africa CDC has also launched a continental blueprint to combat endemic and neglected tropical diseases.²⁴

The WHO/MPP-coordinated mRNA technology transfer programme centres on an R&D hub at Afrigen in South Africa, includes six African manufacturers, and has expanded research to include TB, HIV, RSV (respiratory syncytial virus), and Rift Valley Fever. However, it struggles to secure long-term financial and political support and economic sustainability. Each manufacturer is expected to compete in the market, including with each other and with other donor-supported mRNA initiatives as in Rwanda and Egypt. It also remains to be seen which of these initiatives will have the freedom to operate from IP constraints to adapt the mRNA platform to address regional health needs, and not merely produce under license of HIC innovators.

China and its role as supplier to LMICs

Since the 2003 SARS outbreak, China has invested substantially in MCM R&D, yielding a diversified pipeline to support rapid response to disease outbreaks.²⁶ The nation's emphasis on self-sufficiency in pharmaceutical development has resulted in end-to-end capacities across vaccine, therapeutic, and diagnostic value chains. Chinese researchers actively engage in pandemic readiness research through international collaborations such as the Pandemic Research Alliance.²⁷ China recently developed its own R&D blueprint for emerging infectious diseases and adapted WHO methodology to domestic risks of endemic and imported disease.²⁸

During the COVID-19 pandemic, China emerged as the world's largest supplier of vaccines by volume (40% of global total)²⁹ and produced approximately 4 billion doses for domestic use and 2 billion for export. Primary manufacturers Sinovac Biotech (21%) and Sinopharm-BBIBP (19%) both produced inactivated virus-based vaccines that received WHO Emergency Use Listing in mid-2021. Chinese entities subsequently developed and manufactured vaccines using diverse technology platforms, including adenoviral vector, recombinant protein, and mRNA technologies.³⁰

China's comprehensive capabilities mean it could rapidly adapt various technology platforms to emerging health threats and scale production to supply its population with vaccines, while also supporting international needs through donations, commercial sales, or technology transfer as it did during the COVID-19 emergency. Of note, China has large-scale and low-cost capabilities across the full supply chain, from raw materials to a range of finished products, as well as equipment, laboratory consumables, vials, and other products needed to supply pharmaceutical manufacturers globally, which can help lower the cost of R&D and MCM manufacturing.

India

India has long functioned as the "pharmacy of the developing world," with extensive capacity for low-cost generic drugs and vaccines. The Serum Institute of India (SII) is the world's largest vaccine producer. It supplied 22% of global doses in 2024, while Bharat Biotech, another Indian company, contributed an additional 9%.³¹ India also leads in essential medicines production, including antiinfectives that were in short supply during the COVID-19 emergency. At that time, multiple Indian companies played crucial roles: SII, following technology transfer, produced over 2 billion doses of Oxford/AstraZeneca's adenoviral vector vaccine (Covishield), with 500 million exported across Africa, Asia, and Latin America; Dr. Reddy's Laboratories manufactured the Russian adenoviral vector vaccine Sputnik V, mainly for the Indian private market; and Bharat Biotech developed Covaxin, India's first domestically developed COVID-19 vaccine.

The country has demonstrated wide technological versatility, with Biological E producing Corbevax (a recombinant protein vaccine based on technology from Texas Children's Hospital), Zydus Cadila creating ZyCoV-D (the world's first DNA vaccine), and Gennova Biopharmaceuticals developed a self-amplifying mRNA vaccine (Gemcovac). Biological E has also joined the WHO/MPP mRNA technology transfer programme, positioning India to expand its mRNA capabilities. Several Indian manufacturers also signed licensing agreements with the Medicines Patent Pool to produce antivirals including molnupiravir and nirmatrelvir.

Despite these impressive capabilities across multiple technology platforms, Indian producers have primarily contributed to large-scale manufacturing of externally developed technologies rather than innovating their own. The question for the future is whether they will remain the high-cost, low-volume supplier for LMICs, or whether India's skilled scientists will also be incentivised to develop novel MCMs during future disease outbreaks and include commitments to affordable equitable access.

Rest of Asia

Many Asian countries, having experienced both SARS and COVID-19 and recognising risks exacerbated by climate change, continue to prioritise outbreak preparedness. Public-private initiatives including those catalysed by the Asian Development Bank, ASEAN (the Association of Southeast Asian Nations), and APEC (Asia-Pacific Economic Cooperation) advance regional collaboration across the R&D to manufacturing value chain including on active pharmaceutical ingredient production. The region's heterogeneity in technological capabilities, wealth, and health system structures provides opportunities for complementary approaches. An ASEAN workshop concluded that vaccine R&D and manufacturing represent regional public goods that promote equity and system resilience.³²

In Southeast Asia, emerging regional networks share commitments to public health R&D to fuel growing manufacturing capabilities and build regional resilience. For instance, the WHO/MPP SEA Vaccine R&D Consortium is researching mRNA vaccine candidates that target regional priorities such as dengue, hand-foot-mouth disease, and malaria. Another key initiative is the UK–SEA Vax Hub, aimed at synchronising R&D and manufacturing efforts across the region. The National Vaccine Institute in Thailand has established a strategic funding mechanism to support Good Manufacturing Practice clinical batch manufacturing and early clinical development efforts by academic researchers.

Europe

The **European Union** (EU) has strengthened its pandemic preparedness through the European Health Union³³ to improve coordination amongst member states, with key roles for the European Medicines Agency, European Centre for Disease Prevention and Control, and the Health Emergency Preparedness and Response Authority (HERA). The EU is home to a strong base of large and smaller pharmaceutical companies considered strategic partners for PPPR. The companies also wield significant influence with policymakers at the national and EU levels. HERA pioneered EU-wide pooled procurement during COVID-19 and oversees a network of four prepositioned vaccine manufacturing sites across three technology platforms (EU FAB) to be activated during emergencies.³⁴

The EU is discussing an EU-wide compulsory licensing framework for emergency use, ³⁵ despite opposing the TRIPS compulsory licensing waiver during COVID-19 and in pandemic agreement negotiations. While reasonably prepared for rapid MCM development and production, the EU's complex administrative structure, including the fragmentation of competencies between the EU governance and its members, proved a barrier during the 2022–2023 mpox outbreak. Similarly, PPPR funding is fragmented with countries both collaborating and competing. Recent geopolitical shifts are increasing investment in defence and the likely deprioritisation of other issues that could include health, environment, development cooperation, and PPPR, all of which are relevant to epidemic preparedness. Individual EU countries may retain a vested interest in PPPR, like Germany through its support of BioNTech both domestically and in Rwanda.

The United Kingdom has significant infectious disease research capacity and vaccinology expertise, with substantial government support for academic institutions and biopharmaceutical companies. For COVID-19, Oxford University rapidly developed a vaccine that was commercialised by AstraZeneca, then transferred to over 20 manufacturing sites globally and distributed to more than 170 countries. Unlike mRNA vaccines targeting wealthy markets, Oxford's vaccine was designed for global use with relative heat-stability, affordability, and nonexclusive licensing arrangements. The UK has recently established dedicated research infrastructure including Oxford's Pandemic Sciences Institute and Liverpool's Pandemic Institute, though government budget constraints for research and development aid, together with companies' concerns about a deteriorating investment climate, may affect future potential.

Russia has maintained pharmaceutical self-sufficiency, developing and producing the Sputnik V COVID-19 vaccine without significant international collaboration.³⁶

For the **rest of Europe**, two of the WHO/MPP mRNA technology transfer partners are in Ukraine and Serbia.

United States

The US government's longstanding investments in health research and MCM development through the National Institutes of Health (NIH) and the Biomedical Advanced Research Development Authority (BARDA) provided the backbone of global pandemic response capacity. The US government was the largest research funder during COVID-19, providing an estimated US\$2.2 billion for vaccine R&D alone, and by mid-2023 had donated some 685 million doses overseas.³⁷

In addition to COVID-19 vaccines and treatments, the US health security ecosystem includes a range of pharmaceutical companies that have successfully delivered treatments and vaccines for Ebola, mpox, Marburg, and other outbreaks and is well equipped to mobilise its scientific and technological capacity against novel health threats. During 2020–2023, the United States was the biggest funder (78%) of the US\$1.45 billion in investments in vaccines, therapeutic, and diagnostics R&D across PPPR priority pathogens globally (excluding COVID-19).⁵

US policy frameworks primarily derisk private sector innovation without conditions on access or pricing, which enabled Moderna and Pfizer to generate nearly US\$100 billion in revenue during 2021–2022 while maintaining commercial monopolies that impeded equitable access. Recent steps to address this include NIH's policy requiring companies to develop access plans for publicly funded research.³⁸

Recent major funding cuts and staff departures at NIH, CDC, and the Food and Drug Administration, however, signal a deprioritisation of science and research for health security, and big questions remain as to the role of the United States in R&D, manufacturing, and distribution of pandemic MCMs going forward.

An uneven system needs governance, investment, and orientation to equity

There are hopeful signs of progress and models upon which to draw, but the global and regional picture is fragmented and uneven. There are regions, large countries like India and China, and small countries like Cuba that can both care for their own needs and add to the global availability of PPPR MCMs. Others require much more financial support including from regional finance mechanisms, technology and knowledge transfer, and industrial health policy that favours R&D for public health outcomes. Given regional epidemiology, a focus on manufacturing without also investing into R&D capacity in an end-to-end ecosystem will maintain Global South dependency on HICs.

How to improve the ecosystem

Work to implement MCM provisions of the pandemic agreement must start now. The pandemic agreement contains provisions on R&D, technology and knowledge transfer, and manufacturing, which, if implemented in the spirit of equity, solidarity, and also subsidiarity, can lead to a system of collaborative research and regional resilience where outbreaks can be contained through rapid access to medical countermeasures.

Regional and national leaders must continue to build now towards the capacities agreed in the pandemic agreement, and they should treat outbreak and pandemic MCMs as public goods. They must take full stock of vulnerabilities to outbreaks and pandemic threats in their own country and region, and they must act to fill the gaps in health industrial policies, investment in R&D, arrangements for technology transfer, and manufacturing capacities to ensure sustained regional resilience.

Priority should be given to foster pilot R&D and manufacturing projects, for instance by adopting and adapting mRNA technologies or developing and producing therapeutic monoclonal antibodies. This will require equitable technology transfer and knowledge sharing to regional R&D hubs, with freedom to operate without undue IP barriers. This is a difficult hurdle, but overcoming it is essential to future pandemic preparedness and response.

CEPI and other predominantly Global North actors within the PPPR MCM ecosystem should expand their modus operandi to include significant R&D investments and equal partnerships in LMICs. They also should support technology and knowledge transfer for local/regional innovation, not just manufacturing.

Sustain the WHO/MPP hub, and use lessons to build further regional initiatives

The mRNA technology transfer programme holds promise but continued investments are not guaranteed, putting this potentially transformative project at risk. Future efforts must be designed with LMIC-led governance, address the needs of local developers and manufacturers, and financed to achieve regional resilience and equitable access.

Regional initiatives such as the G20 Global Coalition for Local and Regional Production, Innovation and Equitable Access, PAHO's Innovation and Regional Production Platform, and ASEAN's coordination efforts are promising and can also learn from the hub experience.

Middle-income countries must play a role in sustainable finance for MCMs

Financing for an MCM ecosystem must become a regional and also global priority, given the scale of funds required and now in major question due to US cuts. Middle-income countries could come together and collectively finance some regional pilot R&D and manufacturing projects that address critical shared health needs, for instance in Asia or under the umbrella of PAHO's Innovation and Regional Production Platform. The BRICS could also play a leading role, including through the BRICS R&D Vaccine Centre.

Eventual pandemic agreement financing must ensure investment in regional selfreliance, and in the interim, existing mechanisms including the Pandemic Fund and the Africa Epidemics Fund should consider access to outbreak and pandemic MCMs as integral to pandemic preparedness.

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