Towards Regionalised Vaccine Manufacturing

OUR VISION

RVMC
Regionalized Vaccine
Manufacturing Collaborative

Acknowledgements

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FOREWORD

We are living in a time of profound transformation in global health. After 25 years of growth in donor funding for health – and in the wake of a pandemic that exposed deep vulnerabilities in our national, regional and global health systems – the future seems less certain, especially in access to vaccines. We have made tremendous gains for globally endemic diseases through routine immunisation (RI), but addressing epidemics, pandemics, and region-specific diseases remains a challenge.

The COVID-19 crisis revealed how over-reliance on a few major manufacturing hubs left many regions unable to procure life-saving vaccines against Covid when they needed them most. While global initiatives like COVAX helped mitigate some of these challenges, regional leaders have underscored the urgent need for a more regionally integrated model that prioritises self-sufficiency and cooperation—ensuring all countries, regardless of their economic or geopolitical standing, can access the vaccines they need to protect their populations through routine immunisation and in outbreak response.[1,2]

Today, as geopolitical and economic shifts reshape international development priorities, relying solely on existing global vaccine supply models will not be sufficient to address unmet needs. Regions have begun taking decisive action to develop their own sustainable vaccine ecosystems that interact with, are complementary to external supply chains, and can help provide vaccines to other regions through global systems. This shift is not only critical for regional health security and tackling regionally endemic diseases but also for a globally resilient and diversified vaccine production system.

The **Regionalized Vaccine Manufacturing Collaborative (RVMC)** was founded to support the establishment of sustainable Regionalised Vaccine Manufacturing (RVM) – a model that prioritises local production, strengthens regional health security, and grows economies.

Achieving RVM is complex and requires long-term commitment, but it needs immediate and sustained action including investment and partnership in regionally based research and development (R&D). We believe this is a defining moment to advance RVM and align incentives, building on existing RVM capacity. Encouraging progress is being made across regions, with governments, manufacturers, and partners stepping up to address historic inequities. However, more remains to be done to turn ambition into reality.

In this vision document we outline the critical changes needed for RVM to succeed, along with priority actions for the next 5 years.

RVMC's Framework Report provides guidance on all the areas that will eventually be required to sustain RVM ecosystems. In this vision document, we focus on three key areas – political action, predictable demand, and regulatory strengthening and harmonisation – which will act as drivers for local manufacturing and together form the foundation of effective regional vaccine systems. Further analyses and more detailed policy documents will be produced in each of these areas.

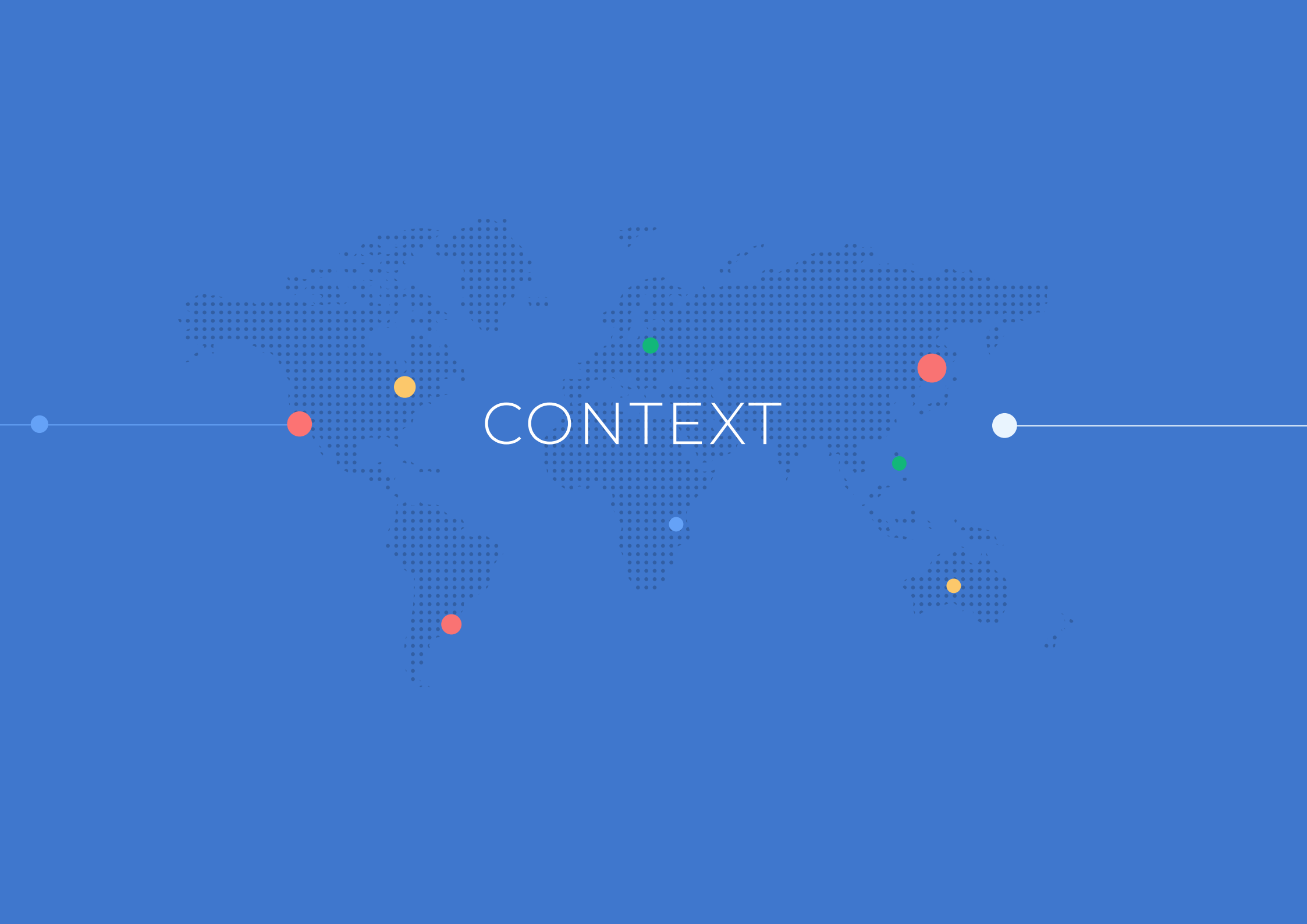
Importantly, we acknowledge the critical role of the existing global system in delivering routine immunisation, particularly for lower-income countries (LICs), who have benefitted from lower prices and greater access to vaccines, particularly over the past 25 years. For RVM to be sustainable, regional manufacturers will need to contribute to global and regional routine immunisation to achieve sufficient economies of scale. RVM will complement and interact with the existing global system, creating a more balanced, resilient, and responsive approach to vaccine access.

In this rapidly changing environment for global funding, we recognise the importance of ensuring that financing for RVM is sustainable and complementary to existing initiatives. It will be critical for all partners to carefully coordinate funding approaches as regions move away from development assistance towards greater self-sufficiency.

We hope this vision stimulates debate and, more importantly, leads to decisive action from leaders. We invite you to join us in working towards a future in which regional vaccine ecosystems are locally responsive, regionally led, and globally connected.

Dr Frederik Kristensen

Managing Director, RVMC


CONTEXT

Vaccines: A Cornerstone of Public Health

Vaccines have saved millions of lives and driven dramatic reductions in the burden of infectious diseases worldwide. From inoculation through variolation in the 16th century to Edward Jenner's groundbreaking discovery of the smallpox vaccine in the late 18th century, immunisation has become one of the most cost-effective and impactful public health interventions.

The global success of vaccines is undeniable:

- **Smallpox eradication is a historic achievement that showcased vaccines' power to eliminate diseases**[3]
- **Diseases like polio, measles, and diphtheria have been controlled or nearly eliminated through mass immunisation campaigns**[3,4]
- **Measles vaccination alone has saved over 23 million lives between 2000 and 2018, contributing to a 73% reduction in global mortality from measles**[3]

Global initiatives, such as WHO's Expanded Programme on Immunization (EPI), have played a crucial role in improving vaccine access. Indeed, under-5 mortality has dropped by about 70% since 1974. Vaccination alone is responsible for 40% of that decline - or over 150 million lives saved.[5,6]

Organisations like Gavi and UNICEF continue to ensure that millions of children annually, particularly in low- and middle-income countries (LMICs), receive life-saving vaccines every year.[7] The success of these programmes demonstrates that global collaboration and financing mechanisms have significantly improved vaccine access and lowered prices over the past two decades. They will continue to play a vital role into the future.

Beyond health impacts, vaccines also generate substantial economic returns by reducing healthcare costs, enabling healthier societies that improve workforce productivity. For example, the widespread use of pneumococcal conjugate vaccines (PCVs) has led to significant declines in childhood pneumonia deathsin LMICs, alleviatingstrain on healthcare systems and contributing to economic stability.[8–10]

Routine immunisation systems have been greatly strengthened over the past decades. Since its inception in 2000, Gavi has helped immunise over 1 billion children and prevented more than 18.8 million future deaths.[11]

Vaccines alone are responsible for over 50% of the reduction in child mortality across Africa. Manufacturing concentrated in a few global hubs has achieved significant economies of scale, lowered production costs, and incentivised innovation, leading to efficiencies in production and supply chain management.

An Inequitable System

Despite these successes, the current vaccine manufacturing and distribution system is not set up to meet all needs. In particular, ensuring timely access to new vaccines, pandemic response capacity, and addressing region-specific disease burdens are issues. Several structural challenges continue to prevent many countries from accessing vaccines when they need them most, with profound human and economic consequences.

Key weaknesses include:

- **A geographical overconcentration of manufacturing** – The vast majority of global vaccine production is distributed in a handful of countries, leaving much of the world dependent on external suppliers, particularly during crises[12,13]
- **A global impact model not set up to address region-specific disease burdens** – While the current global model has improved global vaccine access, significantly reduced infant mortality, and introduced regular reviews to incorporate global and regional needs, some gaps in region-specific priorities will understandably remain[14]
- **Supply chain fragility** – Export restrictions, geopolitical tensions, and raw material shortages can leave LMICs unable to access critical vaccines in a timely manner, leading to delays, vaccine wastage, and inequitable distribution[15-17]
- **Market structures that perpetuate disparities** – Supply-demand mismatches, affordability constraints, and varied country bargaining power mean that vaccines are not always accessible
- **Limited access to novel technologies –** While initiatives like the Health Technology Access Pool aim to increase technology transfer, actual access to cutting-edge vaccine technologies remains limited, and country approaches to IP and innovation are underdeveloped[18]

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The consequences of these systemic weaknesses are stark. During COVID-19, delayed vaccine access in Africa, Latin America and the Caribbean (LAC), and parts of Asia resulted in avoidable deaths and prolonged economic stagnation.[19-21] COVAX, the global initiative aimed at ensuring equitable access to COVID-19 vaccines, played a significant role in reducing mortality during the pandemic by delivering over 2 billion vaccine doses to 146 economies, with approximately 90% of these doses going to lower-income countries saving around 2.7 million lives.[22] However, there were clear delays in the first year of the pandemic, in particular, as high-income countries crowded out access to doses and countries implemented export restrictions.

The World Bank estimates that global economic losses due to the pandemic exceeded $12.5 trillion, with LMICs experiencing the heaviest burden.[23, 24] However, COVID-19 was not an isolated example. The global response to Mpox in 2022 underscored some of the same inequities—while high-income countries secured vaccine supplies, LMICs initially struggled to access doses due to prohibitive costs and limited manufacturing capacity (although programmatic readiness in-country was a further barrier to vaccine distribution). Once WHO pre-qualification of the MVA-BN vaccine was granted, Gavi was able to secure 500,000 doses for LICs, but bottlenecks around delivery and uptake remain.

This experience and the likelihood of future health emergencies is a key driver in the desire of regions for RVM.

In a world where new pathogens emerge unpredictably and regional needs are increasingly diverging from global priorities, manufacturing systems need to evolve.[2] The current system has delivered significant gains for routine immunisation. As regional manufacturing systems catalyse, their sustainability will depend on their ability to contribute both to routine immunisation and outbreak response. This requires a close and ongoing dialogue between global and regional systems.

The Opportunity: A New Model

REGIONALISED VACCINE MANUFACTURING

The development, production, procurement, and distribution of quality vaccines made within a region, tailored to address regional health priorities. Integrated with existing regional and global systems for routine immunisation and responsive to regional health crises.

RVM is a necessary response to the unmet needs regions face – it presents a transformative opportunity to:

- **Strengthen regional and global health security** through coordinated efforts between countries within a region, and collaboration between regions
- **Build sustainable economic ecosystems** by aligning local innovation, financing, production, and workforce development with regional health priorities
- **Ensure equitable access to vaccines in health emergencies** by reducing dependency on external suppliers and enabling faster, more localised responses
- **Address region-specific diseases** by providing a targeted response to unmet needs
- **Enhance adaptability to emerging threats,** by developing manufacturing capacity that can quickly pivot to respond to local outbreaks and scale up during global health emergencies

Our current system for vaccine manufacturing is unable to meet all needs. It must evolve, and RVM is a key part of this evolution – helping to better meet regionally specific health priorities and contribute to a stronger system for vaccines around the world. RVM can support the global system by providing additional manufacturing capacity that is more geographically dispersed, helping to ensure a more balanced, resilient, and responsive whole.

Why Now? A Unique Moment

The urgency for Regionalised Vaccine Manufacturing has never been greater.

While the COVID-19 pandemic exposed the vulnerabilities of concentrated vaccine production, a unique convergence of health, technological, economic, and political factors makes this the right moment to act:

01. The world is increasingly multi-polar

This next decade is likely to be defined by new political, military and economic alliances that realign patterns of trade and consumption. Such changes make it important for regions to take positive action to ensure their own security – in health and beyond. Developing industrial capabilities such as vaccine manufacturing will become more critical.

02. The era of growth in Overseas Development Assistance (ODA) is ending - countries and regions must invest in their own resilience.

For decades, global health financing has been heavily reliant on a few donor governments, with institutions like Gavi, the Global Fund, and multilateral aid programmes playing a critical role in the disbursement of these funds in relevant regions. However, the global funding landscape is shifting. Major donors - including the United States, the UK, and Germany - are scaling back their commitments to global health, citing domestic fiscal pressures, geopolitical priorities, and new strategic focuses, such as regional security.[25,26] This development places greater emphasis on domestic financing, requiring regions to develop sustainable models that prioritise long-term resilience over donor reliance (e.g. in some cases, a trade-off between short-term price premiums and longer-term health security within health budgets). To ensure an effective transition from donor reliance to self-sufficiency, there needs to be better coordination between donor funding and other sources of financing, including domestic funds. These efforts should build on existing transition policies of the global system.

03. Regional realities demand localised solutions.

Many regions are facing endemic infectious diseases like chikungunya, dengue, and Mpox.[27] These same regions are experiencing rising rates of non-communicable (NCDs), with certain LMICs disproportionately affected by cervical cancer (caused by human papillomavirus) and liver cancer (caused by hepatitis B virus). RVM provides an opportunity to address those regional-specific needs while also contributing to global efforts to address access gaps, pandemic preparedness, and strengthen supply chains for under-prioritised vaccines.

04. Globalisation, urbanisation, and climate change are increasing the frequency and severity of outbreaks.

As human activity accelerates the spread of infectious diseases, the risks of vaccine inequity are becoming more pronounced. COVID-19 revealed how supply chain disruptions and export bans left vulnerable populations behind.[28,29] Future pandemics, as well as climate-driven disease shifts, will only exacerbate these challenges. A distributed, flexible, capacitated, and regionally resilient vaccine system is the best way to ensure preparedness.

05. Technological advances could make RVM more viable than ever.

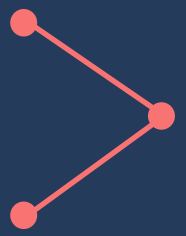
Innovations in vaccine platforms - such as mRNA[30], viral vectors, and modular manufacturing systems[31] - are revolutionising production and production economics. These technologies offer LMICs a chance to leapfrog traditional barriers and develop flexible, adaptive manufacturing capabilities. If harnessed effectively, RVM can position regions at the forefront of the next generation of vaccine innovation.[32]

The evolution from the present system to a future where RVM is strong and sustainable will be a multi-decade journey. Across three priority areas (political action, predictable demand, and regulatory strengthening and harmonisation), we set out what could be achieved by 2040, where we are today, what needs to change, and the most urgent priorities that political leaders must focus on in the next five years.

To ensure accountability and track progress towards achieving this vision, we plan to publish a scorecard later in 2025, complemented by regionally- and issue-focused guidance and briefs.

PRIORITY 1

POLITICAL ACTION



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What is our vision?

In 2040, Regionalised Vaccine Manufacturing is a fully operational and self-sustaining reality for nearly all regions in the world.

Ongoing political and financial commitment ensures robust regionalised manufacturing ecosystems that provide timely and equitable access to vaccines, reducing dependency on a handful of global suppliers. These regionalised ecosystems effectively meet regional immunisation needs and health priorities, and respond rapidly to health emergencies, strengthening overall health security. RVM is also a driver of scientific and economic progress, fostering local research and development and ensuring vaccine innovation aligns with the health priorities of the regions it serves. Enlarged capacities for R&D and innovation, supported by intellectual property (IP), allow further progress in regions towards the production of drug substances and drug products, and agreements are in place within and between regions to safeguard access to critical input components and raw materials.

Momentum for RVM comes from a coalition of interested countries, private companies, and partners in each region, working together to identify the most promising opportunities for a regionalised approach, and coordinating what each of them can bring to the effort along the value-chain – leading to increased co-dependence and collaboration. In time, RVM is embedded within national and regional strategies as a cornerstone of economic resilience and sovereignty.

Governments have stable policies and financial mechanisms that provide predictability, sustaining manufacturing capacity across political and economic cycles. Intraregional political interests are aligned, with motivated countries working together to define and agree on manufacturing responsibilities, supply of vaccine components, procurement mechanisms, and financing structures, with support from regional bodies. These agreements ensure that RVM operates efficiently, equitably, and with long-term sustainability. The scope of discussions reaches from R&D all the way through to distribution and logistics and is part of wider efforts across all medical countermeasures.

RVM is an integral part of an evolved global health ecosystem, providing a more diversified manufacturing base and enhancing global resilience by ensuring that no region is left vulnerable during crises while contributing to vaccine equity globally. Governments, regional bodies, and global institutions collaborate to reinforce these efforts, aligning regulatory frameworks, investment priorities, and procurement strategies.

The political momentum behind RVM has translated into processes and principles being embedded within existing institutions, governance structures, and financing models that secure its sustainability. Leaders at all levels - national, regional, and global - uphold vaccine manufacturing as a shared responsibility, safeguarding public health and economic stability.

PRIORITY 1

POLITICAL ACTION

Where are we now?

Political will for RVM has grown since the COVID-19 pandemic, with political leaders having acknowledged the importance of RVM in speeches and set goals in declarations and frameworks. [33-36]

However, this momentum has not yet translated into a comprehensive, coordinated and actionable approach. For instance, the absence of regionally coordinated financing strategies has left many RVM initiatives without clear funding pathways.

Political will within regions is inconsistent and varies between regions, with few countries having invested in RVM initiatives. Some governments have demonstrated commitment to expanding domestic manufacturing and investing in production capacity and infrastructure,[37,38] but much of the investment in manufacturing infrastructure has come from Development Finance Institutions and private investments from companies themselves. Varied levels of interest within and commitment from countries have made it more difficult for regions to develop and implement a unified strategy.

Regional roadmaps towards RVM exist, but they are incomplete. For example, the Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action highlights the need for $30 billion of support over the next 20 years but doesn't set out where that money will come from. And the ASEAN Vaccine Security and Self-Reliance (AVSSR) initiative calls for the establishment of a vaccine strategic procurement and regional stockpiling mechanism, but it is not clear how this will work. A lack of political action is at the heart of this, meaning that manufacturers, investors, and funders remain uncertain about the long-term viability of RVM efforts.

While political leaders have made broad commitments to RVM, these commitments have not been backed by comprehensive implementation plans that address the most pressing challenges. Some elements crucial for developing RVM already exist in regions, with The Pan American Health Organization (PAHO) operating a highly effective pooled procurement mechanism and Africa CDC advancing towards its own pooled procurement, regulatory harmonisation mechanisms, and developing vaccine manufacturing infrastructure. But much remains to be done. Key barriers to progress include the lack of focused discussions and actionable plans in some regions and the absence of joint decision-making mechanisms at regional levels. Existing regional political discourse lacks clarity on key enablers of RVM, such as financing mechanisms, procurement frameworks, regulatory coordination, and innovation ecosystems (including IP frameworks).

In some regions, political fragmentation has made it challenging to establish collective action on RVM, with regional bodies driven by member states with competing national interests. Although these challenges have slowed momentum, they also highlight where action is needed to move from political will to action.

Political leadership must now focus on creating the mechanisms necessary to drive meaningful, sustained action, ensuring that regional vaccine manufacturing is not just a political aspiration but a tangible reality.

What needs to change?

Moving from fragmented political will to sustained political action.

The change we want to see is the translation of political will for Regionalised Vaccine Manufacturing (RVM) into political action. While political leaders have acknowledged the importance of RVM in speeches, and set goals in declarations and frameworks, what is needed now is sustained, concrete implementation that delivers measurable results.

In practice, we need:

01. Leaders to decide their regional approach to RVM

For RVM to succeed, each region must establish clear objectives and strategies. Political leaders need to determine their approach to key issues, ensuring that partners understand the investment opportunities and operational frameworks. Simply signalling intent, such as pooling demand, is insufficient – regional plans must set out comprehensive actions and actionable timelines. This is particularly critical in the area of financing, where the donor funding landscape is rapidly changing, requiring political leaders to prepare for greater self-sufficiency.

Where consensus cannot be reached across a whole region, coalitions of countries with existing vaccine manufacturing capabilities should lead in defining models for collaboration and investment, helping to build momentum in regions.

Key political decisions must address:

- **Financing** – ensuring investment in infrastructure, R&D, technology, workforce development, and vaccine procurement
- **Aggregated demand and procurement** – defining models that deliver against regional health priorities
- **Infrastructure** – aligning manufacturing infrastructure within regions
- **Regulatory harmonisation** – reducing duplication and costs by coordinating regional efforts
- **Accountability and joint decision making** – establishing mechanisms to ensure commitments are met
- **Regional innovation** – developing an innovation ecosystem, including IP, required to support local and regional innovation for medical research and manufacturing

02. Political decisions translated into actionable regional policies

To sustain RVM beyond political cycles, governments must institutionalise commitments at the national level. Codifying political decisions through national legislation and embedding RVM in government policies and budgets will provide the institutional framework necessary for its long-term viability.

Manufacturers, investors, and funders must have clarity on how regional plans are resourced and integrated into national health strategies.Cross-government coordination is essential, ensuring that health, industrial, and trade policies align with RVM objectives and create an enabling environment for the broader vaccine ecosystem. This is especially important during this time when government priorities are being shaped by global geopolitical developments.

PRIORITY 1

POLITICAL ACTION

03. Coordination and alignment between regional and global plans

To ensure RVM makes a positive contribution in each region and at the global level requires: effective coordination between countries within regions so that they are making the most efficient use of available capacity and capability to address unmet regional needs; and ongoing alignment of that regional capacity and capability, where appropriate, to areas of global need that require more diverse sources of manufacturing.

The change we want to see is a closer alignment of the activities of global health partners to regional health priorities – with tailored funding and technical assistance to regional priorities, supporting infrastructure, technology transfer, and capacity-building without undermining local sovereignty. This requires strong, clear and consistent regional political leadership that sets out what it needs from global institutions like WHO, Gavi, and the World Bank.

By aligning global efforts with regional political will, RVM becomes a globally integrated yet regionally driven solution, balancing health equity, resilience, and economic opportunity.

Priorities to 2030

01. Each region must create a roadmap for RVM, setting out the key features of their approach, a timeline for implementation, and clear pathways for partners to engage in delivering the plan.

Essential decisions to reach include: an understanding of regional demand; the required manufacturing capacity in each region to deliver RVM; which countries are best-placed to act as the manufacturing hubs; what the appropriate mix and distribution of technology platforms is; commitment from countries to sourcing vaccines locally and agreement on which vaccines to source; what local and regional institutions are needed to support RVM ecosystem development and how these will be financed; how mutual support between countries is sustained during and between outbreaks; and the role of diagnostics and therapeutics alongside a healthy RVM ecosystem.

How?

- Key issues should be placed on regional (or sub-regional) political and economic forums, for leaders to discuss and agree, leading to resolutions and agreements that commit countries and regions to action with a defined timeline
- Regions should appoint RVM Champions at the Head of State level, with defined roles in advancing the regionalisation agenda at regional and global political fora
- Missing elements of existing regional plans should be prioritised, such as whether regions will undertake their own procurement and how such mechanisms will be funded

02. Countries must introduce legislation, policies and budget commitments that enable the regional plan to be implemented.

How?

- Country taskforces should be established, with membership across trade, treasury, health, science, technology, and innovation departments, civil society, and industry to undertake the work of embedding RVM within their strategies, and reflect it in national health plans, industrial policies and budget frameworks – such taskforces must be driven from the office of the country leader to ensure sufficient weight and urgency to the effort
- Regional bodies, such as the African Union (AU), Association of Southeast Asian Nations (ASEAN), and PAHO, should drive alignment and coordination across member states, ensuring RVM remains a shared, long-term priority
- Civil society should mobilise to hold policymakers accountable for existing commitments to RVM, and highlight where further action and clarity is needed from political leaders

03. Political leaders must build coalitions that champion RVM within the region and at the global level, ensuring that commitments are not limited to words, and RVM is on the agenda at regional and global levels.

How?

- RVM does not require full regional buy-in but can build from a few willing countries within regions
- Country leaders with the most advanced manufacturing capabilities undertake sustained advocacy with their fellow leaders within the region
- Regional bodies create robust governance structures to monitor regional plans, ensuring accountability and tracking progress
- Regional political leadership works with donors to align their support with regional plans, ensuring that international funding complements local efforts

PRIORITY 1

CASE STUDY

The Platform for Harmonized African Health Products Manufacturing (PHAHM)

The African Union Platform for Harmonized African Health Products Manufacturing (PHAHM) represents a ground-breaking effort to transform political will into coordinated action for regional manufacturing.

African countries faced severe delays and inequities in accessing life-saving vaccines during the COVID-19 pandemic.

While vaccine nationalism and hoarding contributed to this situation, Africa's heavy dependency on external vaccine manufacturers also played a part. In 2021, the African Union mandated the Africa Centres for Disease Control and Prevention (Africa CDC) to establish the Partnerships for African Vaccine Manufacturing (PAVM) in response to this problem. The PAVM Framework for Action followed.

The Framework set an ambitious target for Africa to produce 60% of its vaccine needs locally by 2040.[39] Only 1% of Africa's vaccines were being produced locally at the time.[40]

African leaders demonstrated an understanding that local manufacturing not only ensures equitable access during crises but also strengthens economic resilience, reduces dependency, and creates opportunities for regional innovation. In 2024, the AU directed Africa CDC to include the local manufacturing of all medical countermeasures towards building a self-sufficient healthcare manufacturing sector within Africa.

The PHAHM initiative demonstrates the power of political leadership in driving regional solutions. African heads of state have embraced the framework, providing a clear political mandate for action. Africa CDC acts as the convening body, aligning countries, regional organisations, and donors toward a common goal.

Early successes have included: an AU Communique in May 2022 from Heads of State requesting Gavi to ensure that at least 30% of the vaccines it procures for Africa be produced in Africa; and fostering partnerships with global manufacturers for technology transfer. Countries like South Africa, Senegal, Egypt, Morocco, and Rwanda have also emerged as early champions, with investments directed toward expanding manufacturing capacity. However, slow progress towards predictable demand and regulatory harmonisation remains a substantial barrier to meeting the local manufacturing target.

PRIORITY 02

PREDICTABLE DEMAND

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What is our vision?

In 2040, regionalised vaccine manufacturing delivers vaccines that align with regions' long-term health priorities. Predictable demand for regionally produced vaccines underpins a thriving RVM ecosystem, providing manufacturers in the region with the confidence and stability needed to sustain production, invest in innovation, and scale operations to meet public health needs.

Coordinated regional demand mechanisms aggregate purchasing, ensuring that vaccine manufacturers have consistent signals to incentivise production. Governments, procurement agencies, and manufacturers operate a seamless system that balances maintaining security of supply for routine immunisation with the ability to rapidly scale up production in response to outbreaks and emerging health threats.

Manufacturers, funders, and investors have market confidence due to multi-year commitments and pooled procurement, leading to greater investment in RVM and increased production capacity, as well as a move from drug product to drug substance production.

Predictable demand mechanisms interact with existing global procurement structures, such as UNICEF; enable more production to take place in regions; and serve as a potential transition pathway for countries moving away from donor-supported models.

Regions maintain strong links with the global vaccine ecosystem, ensuring that locally manufactured vaccines contribute to a broader supply chain rather than operating in isolation. RVM is both sustainable and complementary to global supply strategies, strengthening the overall resilience of the vaccine ecosystem.

PRIORITY 02

PREDICTABLE DEMAND

Predictable Demand System:

A reliable system in which vaccines desired within a specific region are consistently procured from regional manufacturers at mutually agreed-upon volumes, prices, and schedules.

This system must align the interests of both countries that generate the demand and regional manufacturers, ensuring that demand commitments support the financial sustainability of manufacturers and that manufacturers' vaccine portfolios meet the current and future immunisation needs of countries and the region.

It seeks to align country immunisation programs around a common set of vaccines in a region and secure long-term commitments, providing manufacturers with the stability needed to invest in production capacity while achieving the economies of scale necessary for long-term viability. Such systems interact closely between regional and global levels to ensure complementary efforts on routine immunisation, unmet regional health needs, and outbreak response through a combination of regional and global manufacturers.

Where are we now?

Presently, vaccine demand systems vary greatly between regions - so too do the types of vaccine for which predictable demand exists. In each region, the balance between vaccines needed for routine immunisation and those for outbreak response will look different.

In most regions, national governments operate independently when procuring vaccines, with no regional mechanisms to aggregate demand or negotiate pricing. In some, regional mechanisms exist but do not always provide long-term contracts. This has led to inefficiencies, with manufacturers hesitant to invest in production capacity due to the lack of long-term contracts and originators less likely to pursue technology transfer.[41,42] In other regions, there is a heavy reliance on external donors.

Donor-driven mechanisms, such as those operated by UNICEF, have played a crucial role in ensuring vaccine access for low-income countries. For countries transitioning out of donor eligibility, the pathway to ongoing affordable vaccine procurement can be complex, increasing the risk of supply insecurity.[43] While UNICEF continues to provide an option for graduating countries to procure vaccines, without RVM, we lack regionally-led and locally-responsive pathways to sustainability.

The absence of regional pooled procurement mechanisms (PPMs) in Africa and Asia has made it difficult for middle-income countries without vaccine manufacturers to secure vaccines at competitive prices.[3,43] Moreover, donor-driven PPMs have been reluctant to establish policies that give preference to manufacturers from a region for a region.

Predictable regional, pooled demand mechanisms are rare. In Latin America and the Caribbean, whilst the PAHO Revolving Fund was not set up to support RVM, it has demonstrated the potential of regional demand aggregation, allowing countries to secure vaccines more efficiently,[44] but it could improve its long-term commitments that would further incentivise more vaccine production within the region. Where demand coordination initiatives have been attempted, they often lack political backing, institutional structures, and financial mechanisms to ensure long-term viability.

Domestic demand forecasting and data systems remain weak outside of Gavi-relevant vaccines and PAHO, making it difficult to anticipate future vaccine needs accurately. Many countries lack the technical capacity to conduct detailed demand forecasting, leading to frequent mismatches between supply and need.[45] Without robust data, manufacturers may struggle to make informed production decisions, further contributing to market instability.

The absence of predictable demand for regionally produced vaccines is one of the most significant barriers to scaling RVM. Without clear commitments from governments and procurement agencies, manufacturers and investors face considerable risk, limiting their willingness to engage in technology transfer and long-term production efforts. If RVM is to succeed, the current piecemeal approach to demand must be replaced with structured, coordinated systems that provide stability, transparency, and long-term assurance.

PRIORITY 02

PREDICTABLE DEMAND

What needs to change?

Moving from demand uncertainty to structured regional demand systems

The change we want to see is the establishment of regional demand systems that reduce uncertainty, build market confidence, unlock complementary investments in R&D and innovation, and create a more resilient and healthy regionalised vaccine production ecosystem.

To deliver this change we need:

01. Countries with a shared interest in working together to define regional approaches to predictable demand

For manufacturers, investors, and donors to confidently support RVM, regions must clarify their demand structures.

While demand systems will vary based on regional characteristics, a common set of urgent questions must be answered for these systems to succeed:

- How can country, regional, and donor budgets for vaccine procurement be sustained and grown, and what is the appropriate mix?
- How will countries commit to purchasing locally manufactured vaccines?
- How will countries work interdependently across the production process, ensuring that countries can contribute to the final product?
- How will diagnostics and therapeutics be integrated alongside vaccines?
- Will regions pool demand and manage coordinated/unified procurement?
- What length of demand commitment can be reached?
- What is the acceptable time-limited price premium for locally manufactured vaccines?
- How will country needs be reflected in regional health priorities, and what role can regional R&D play in addressing these priorities?

Without resolving these key questions, the uncertainty surrounding vaccine demand will continue to hinder investment in RVM.

02. Health financing solutions that provide robust push and pull incentives for regional manufacturing

For RVM to be viable in the long term, demand forecasting must be accurate and fully funded. Governments must commit to sustained health expenditure (recognising differing fiscal capacities) and prioritise regionally manufactured vaccines, reducing dependency on donor funding.

Potential financing solutions could include, but are not limited to:

- **Advance Purchase Agreements** – guaranteeing markets for vaccines and providing financial stability for producers, particularly during emergencies
- **Demand Guarantees for Region-Specific Vaccines backed by development finance institutions (DFIs) and other funders** – ensuring production for vaccines targeting diseases like dengue and chikungunya, which traditionally lack strong commercial markets
- **Incentive mechanisms for locally produced vaccines** – that address the price premium associated in the short term with such vaccines
- **Creation and Financing of Regional Vaccine Stockpiles** – that ensure a minimum availability of vaccines needed for countries to rapidly respond to outbreaks or risks of outbreaks. This is particularly important for vaccines not included in routine EPI programmes
- **Blended Push Funding Financing Models** – leveraging DFIs, donor contributions, private sector funding, and public-private partnerships to create pooled financing mechanisms that support vaccine R&D and manufacturing as well as provide upfront capital for vaccine procurement

One such example is the African Vaccine Manufacturing Accelerator (AVMA), a financing mechanism introduced in 2024 as the result of a close collaboration between Gavi, the African Union, and Africa CDC to accelerate the expansion of commercially viable vaccine manufacturing in Africa. This will provide downstream incentives to manufacturers to help offset initial costs of development and production.[46]

03. Demand systems designed to complement the global vaccine ecosystem

To ensure that RVM is sustained, emerging regional demand systems must interact closely with the future global vaccine ecosystem. By design, regional approaches should aim to generate manufacturing that fills regional gaps that the global system is unable to address, has the potential to feed into global procurement systems, and acts as an effective follow-on mechanism for countries graduating from Gavi.

Well-designed regional demand systems will:

- Collaborate with global procurement networks, enabling more regional manufacturers to supply vaccines for routine immunisation at scale and be prepared for pandemic surge capacity
- Support countries transitioning from Gavi support by providing a structured follow-on mechanism for them to access vaccines that reflect regional health priorities
- Acknowledge the importance of financing mechanisms that help cover any short-term price premium associated with regionally produced vaccines
- Strengthen global vaccine supply chains, reducing reliance on sourcing the majority of vaccines from singular geographies

By embedding regional demand mechanisms within both national policies and global procurement frameworks, we can ensure that RVM becomes a sustainable, integrated component of the global vaccine landscape, delivering long-term health security and equitable vaccine access.

PRIORITY 02

PREDICTABLE DEMAND

Priorities to 2030

01. Modify national, regional, and global procurement laws and practices, so that regional demand aggregation and regional procurement can be operationalised.

How?

- Cross-departmental taskforces anchored at the heads of state level should be established across each region and within relevant countries to draft and embed the policy changes needed to create a regional demand and procurement system. Such taskforces may be integrated with National and Regional Immunization Technical Advisory Groups
- Where they do not already exist, countries should institutionalise procurement systems within their regional health policies, with national buy-in and coordination, allowing, for example, multi-year procurement, which is essential for signalling long-term intent to manufacturers and investors

02. Introduce financing mechanisms that enable predictable demand and incentivise manufacturers to invest in regional production capacity.

How?

- Countries – with support and coordination from relevant regional bodies – must agree and finance an acceptable time-limited price premium for regionally manufactured vaccines, if needed, to ensure financial viability while economies of scale are built
- With a defined list of priority health products, political leaders in the region should commit to providing the necessary funding to enable ongoing procurement
- Other funding bodies, including DFIs and multilateral agencies, should explore their role in partnering with domestic financing to introduce mechanisms such as advance market commitments (AMCs) and volume guarantees where they are needed, ensuring manufacturers have long-term confidence in demand

03. Operationalising regional demand systems in close coordination with the global system to ensure donor-funded initiatives align with regional demand systems, and that regional demand systems act as an effective option for countries transitioning from donor support.

How?

- New regional bodies should develop their regional procurement platforms with support from PAHO, UNICEF, and WHO to learn and integrate best practice
- New regional demand systems should prioritise unmet regional needs and products where regional production is most feasible, and where opportunities may exist to supply to the global system
- The global and regional systems should continue to identify where it would most benefit from a more diverse set of manufacturers and how donor-funded programmes can evolve to better reflect regional health priorities
- Governments and regional financing institutions should implement more effective transition financing strategies to help countries gradually shift from donor-funded procurement, ensuring sustainable domestic co-financing, and consider innovative financing mechanisms to provide financing for MICs
- For an effective transition from donor dependency to domestic financing, donors, development finance institutions and countries should establish co-financing models that blend external contributions with domestic funding, helping to maintain demand stability for an initial period
- Governments and regional development organisations should strengthen the intellectual property, science, technology, and innovation ecosystem to support local vaccine manufacturing and self-sufficiency
- Regional economic communities and national regulators should harmonise regulatory and procurement policies to ensure regionally produced vaccines meet global quality and pricing standards
- Global and regional procurement agencies and global health partners should strengthen data-sharing agreements to improve demand forecasting and enhance supply chain efficiency

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PRIORITY 02

CASE STUDY

PAHO's Revolving Fund for Access to Vaccines

PAHO's Revolving Fund for Access to Vaccines

The PAHO Revolving Fund for Access to Vaccines demonstrates how pooled demand and procurement is a powerful way to improve vaccine affordability, accessibility, and sustainability across a region.

Countries in Latin America and the Caribbean once faced significant challenges in vaccine procurement. Following the global resolution of WHO on the establishment of the Expanded Programme on Immunization in 1974, countries needed to have regular and sustained access to vaccine products. Yet vaccine markets were fragmented, leading to higher prices, inconsistent supplies, and limited access for smaller or less-resourced nations. Recognising the need for a coordinated approach, PAHO Member States established the RF in 1977 with two primary objectives:

- To pool the demand for vaccines across the region, creating economies of scale and negotiating power with manufacturers
- To provide a financial mechanism (as a revolving fund giving bridge financing support) that ensured a predictable and sustainable vaccine supply for participating countries

To achieve these goals, PAHO works with member countries by providing technical cooperation to support decision-making on vaccines, developing forecasts of vaccine needs, and integrating data on target groups, immunisation coverage, and disease burden. These forecasts provide manufacturers with a clear picture of future demand, reducing risks and encouraging investment in production capacity.

By aggregating demand across multiple countries, the Revolving Fund achieves considerable economies of scale. This pooled demand gives the region stronger bargaining power and can enable the PAHO RF to negotiate lower prices with manufacturers while ensuring quality standards. Smaller countries benefit significantly from the pooled system, as their vaccine needs are combined with those of larger nations. This approach ensures equitable access to vaccines, regardless of a country's economic classification.

The RF's model on bridge financing ensures timely payment to manufacturers, creating a reliable market. Bridge financing support provided by the Revolving Fund credit line reduces financial uncertainty for manufacturers and ensures uninterrupted vaccine supply during procurement cycles. The PAHO RF combines several advantages to the Member States: reliable access, assured quality, sustainable financing support (e.g. the Revolving Fund credit line), operational excellence, and regional solidarity.

It should also be noted that the PAHO RF has a sustainable operating model that helps to sustain its overall operations and the credit line. From the procurement orders, a 1.75% charge is taken for sustaining the operations, and a 2.5% charge is taken towards capitalisation of the Revolving Fund.

Key milestones for the RF include the procurement of life-saving vaccines such as the pneumococcal conjugate (PCV), rotavirus, and HPV vaccines to address pneumonia, diarrhoea, and cervical cancer in the region. During the COVID-19 pandemic, the RF also played a critical role in supporting COVAX to secure vaccine doses for participating countries, demonstrating its ability to address both routine immunisation needs and emergency demands.[47]

In 2024, member states agreed on a resolution to grant greater flexibility to PAHO to accelerate access to health technologies by incentivising local production and innovation projects.

The PAHO Revolving Fund for Access to Vaccines shows how predictable demand needs to be directly tied to regional financing solutions. Ensuring financial sustainability for all participants, maintaining supply chain resilience, and integrating new vaccine technologies are ongoing priorities But for other regions looking to develop Regionalised Vaccine Manufacturing, the PAHO Revolving Fund offers a proven model for success, underscoring the importance of predictable demand in creating sustainable and resilient vaccine supplies.

PRIORITY 3

REGULATORY STRENGTHENING & HARMONISATION

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What is our vision?

In 2040, each region is closer to a "one submission, one review, and one (collective) approval" approach for vaccines during emergencies and routinely. Harmonised and well-resourced regulatory systems enable the timely, robust assessment, consistent manufacturing, and seamless inter-regional distribution of vaccines across regions. Manufacturers operate within a transparent, predictable, accountable, scientifically robust, and efficient regulatory environment that helps accelerate the availability of safe, high-quality, and effective vaccines. These environments mean manufacturers gain quicker access to larger markets, allowing for economies of scale.

Regional regulatory bodies or networks of national regulatory authorities (NRAs) function as collaborative platforms, pooling technical expertise and capabilities (e.g. laboratory lot testing), aligning standards, and operating under regional reliance mechanisms.

This regulatory ecosystem facilitates:

- **Seamless market access** for vaccines, both within and across regions, reducing time-to-market delays
- **Rapid responses to health emergencies**, ensuring vaccines are swiftly assessed, approved, and deployed
- **A stable investment environment**, where manufacturers and investors have clear regulatory pathways to market
- **Consistent quality and safety of product,** with harmonised quality control, quality assessments, product safety and pharmacovigilance and market surveillance approaches that promote international quality standards and mitigate substandard and falsified versions of products on markets

Vaccine assessments are streamlined across entire regions, allowing one submission, harmonised joint review and, if the data supports, collective approval or efficient national authorisation based on the joint review – thereby eliminating unnecessary duplication and reducing delays. This can be done using regional reliance mechanisms, which use their existing regional Maturity Level (ML) 3 or 4 NRA capabilities to reduce the time to market for regionally manufactured products.

In a larger continent, this may require establishing inter-regional regulatory reliance mechanisms. Governments recognise regulatory harmonisation and production of international quality products as critical enablers of vaccine manufacturing, ensuring that locally produced vaccines are used both within and beyond their regions.

NRAs serve as the backbone of this system, supported by regional regulatory bodies that coordinate policies, provide technical assistance, and align processes with Good Regulatory Practice (GRP). Regional regulatory frameworks ensure that vaccines manufactured under Regionalised Vaccine Manufacturing ecosystems are eligible for global procurement mechanisms either directly or through global prequalification (PQ).

Harmonised policies, mutual recognition agreements, and strengthened regulatory institutions provide a robust foundation for sustainable vaccine manufacturing, innovation, and global health security.

PRIORITY 3

REGULATORY STRENGTHENING & HARMONISATION

Where are we now?

The WHO PQ programme exists to assess individual manufacturers' versions of products to ensure they meet international quality, safety, and efficacy standards, and to inspect manufacturing sites and organise quality control testing. This mechanism has helped to improve access to priority medical products globally, and many donor programmes require WHO PQ or WHO-Listed Authority (WLA)/ Stringent Regulatory Authority (SRA) authorisation to assure the quality of the versions of the products they are purchasing. However, WHO PQ has faced issues such as long wait times and staff shortages, which are being addressed.

Despite growing recognition of the need for strong and harmonised regulatory systems as well as the observed constructive developments resulting from the COVID-19 pandemic, the current landscape remains highly fragmented, with significant disparities in regulatory capabilities and capacity across countries and regions. NRAs vary in their capacity to review and approve vaccines, address post-approval changes, and monitor vaccine production. RVM may happen in a country where a local NRA is not capable of providing regulatory oversight for vaccines. In the absence of supportive regional regulatory mechanisms, these NRAs will have to depend on NRAs like the US Food and Drug Administration, European Medicines Agency, or WHO PQ. This lack of local support delays the time to market, and time to regional access for regionally manufactured products.[48]

Many regions have no unified regulatory approach, leaving manufacturers to navigate different approval processes for each country, leading to costly delays and inefficiencies.[48]

The absence of mutual recognition or mutual reliance agreements between national regulators further complicates this process, as vaccines approved in one country often require separate, time-consuming reviews in neighbouring nations. In LMICs, this lack of coordination has contributed to prolonged vaccine shortages, slower responses to health emergencies, and an unpredictable regulatory environment that discourages investment in local manufacturing.

The African region has taken a significant step forward, establishing the African Medicines Regulatory Harmonization (AMRH) programme to facilitate regulatory harmonisation on the continent. Moreover, Africa has recently established the African Medicines Agency (AMA), designed to create a coherent regulatory framework across the continent. However, the AMA is still in its early stages, with 24 of the 54 African countries yet to ratify the AMA treaty and fully integrate their national regulatory processes under its umbrella.[49] Other regions, such as Latin America and the Caribbean and Asia, lack an equivalent regional regulatory authority, leaving manufacturers to navigate a complex web of national requirements that limit the efficiency and scalability of regional vaccine production.

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The lack of national implementation of harmonised regulatory standards in many national agencies also poses a challenge for vaccine exports. Without stronger alignment with global regulatory systems, including WHO PQ, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and international pharmacopoeia standards, regional manufacturing efforts may struggle to create a sustainable business model and reach their full potential.

At the same time, regulatory bottlenecks can be a major barrier to scaling up local vaccine production and developing new products, particularly during public health emergencies; however, as we observed in the COVID-19 pandemic, this does not have to be the case. The absence of expedited approval pathways, reliance mechanisms, digital regulatory tools, and pre-positioned regulatory approval of platforms can lead to long and unpredictable assessment timelines, preventing quality vaccines from reaching populations quickly when they are needed most.

While progress has been made in recognising the importance of regulatory strengthening, harmonisation, and reliance-based regulatory pathways, meaningful action is needed to ensure that commitments translate into practical reforms. The next step must be a concerted effort to ensure that regulatory systems not only meet global benchmarks but are also designed to support a timely, reliable, predictable, accountable, and scalable vaccine manufacturing ecosystem that serves both regional and global needs.

PRIORITY 03

REGULATORY STRENGTHENING & HARMONISATION

What needs to change?

Moving from fragmented regulatory systems to harmonised, efficient, and resilient frameworks.

While regulatory strengthening is widely recognised as essential for RVM, the current landscape remains fragmented. Inconsistent regulatory processes, duplicative reviews, and limited recognition and reliance-based regulatory pathways slow vaccine access. To support regional manufacturing, every region must establish predictable, transparent, accountable, and globally complementary regulatory pathways.

01. Embedding regulatory harmonisation into legal and institutional frameworks

Many countries lack the legal structures to support regulatory reliance, meaning that even where political commitments exist, implementation is slow. Governments must introduce legislation that facilitates regional reliance mechanisms or regional regulatory decision-making. Positive opinions, inter-regional learnings and digital transformation will help some of these processes achieve their full potential. Regional bodies such as the AU, ASEAN, and PAHO can exchange learnings, coordinate policy alignment between regions to ensure regulatory harmonisation is a core political priority, not just a technical ambition. This could reduce the time to market for critical lifesaving products such as vaccines.

02. From national-level regulation to regional and inter-regional harmonisation through reliance and mutual recognition

Regulatory systems remain largely fragmented, with most countries operating independent assessment and approval processes. This results in inefficiencies, delays, and unnecessary duplication. Countries must transition towards a harmonised regional framework, where regulatory reliance and recognition agreements facilitate pathways, which enable vaccines assessed in one country to be rapidly assessed across multiple markets. Stronger NRAs should lead in providing leadership positions in mutual review for countries with more limited capabilities and capacity, ensuring efficient regulatory processes without each country needing to build identical systems from scratch. While recognising that perspectives on clinical benefit/harm profiles can vary between countries and health care systems, when it comes to the assessment of the manufacturing quality of a product (i.e., the

quality portion of the dossier and the Good Manufacturing Practice (GMP) inspection of the manufacturing site), the quality dossier assessment and GMP inspection of a recognised, accredited WHO-Listed Authority or WHO PQ should be more easily relied upon.

03. Aligning regional regulatory frameworks with global standards

Regional regulatory frameworks must be designed to ensure that vaccines manufactured in RVM ecosystems meet WHO PQ standards, the ICH, or equivalent. Without this alignment, regionally manufactured vaccines risk being excluded from international procurement mechanisms. Clear pathways for global accreditation, such as the current WLA assessment process, must be built into regional regulatory systems, ensuring that vaccines produced within harmonised regional frameworks contribute to the broader global vaccine ecosystem.

PRIORITY 03

REGULATORY STRENGTHENING & HARMONISATION

Priorities to 2030

01. Strengthen regional and national regulatory bodies and governance mechanisms

By 2030, regional regulatory bodies must be fully operational, coordinating efforts across member states. Where full regional authorities are not yet feasible, sub-regional regulatory hubs must be established to facilitate cooperation, capability and capacity-sharing, and streamlined assessment processes and approvals based on positive assessment outcomes.

Governance mechanisms must ensure that commitments to regulatory harmonisation and reliance-based regulatory pathways are upheld. NRAs in countries where vaccine production exists must prioritise getting to ML3 (vaccine producing) so that they can provide regulatory oversight for vaccines produced and increase the potential for these products to be considered by the global demand system.

How?

- Work towards establishing regional regulatory bodies to oversee vaccine assessments or, where they already exist, ensure they have the requisite authority, resources, and expertise to do so
- Develop sub-regional regulatory cooperation mechanisms where full regional harmonisation is not yet possible
- Implement clear governance structures to track progress on regulatory harmonisation, including reliance-based regulatory pathways, and hold stakeholders accountable
- Embed regulatory strengthening within broader regional health security strategies to ensure sustained political support with publicly declared goals regarding the short - and long-term WHO regulatory maturity level goals for national and regional authorities

02. Establish reliance mechanisms to accelerate vaccine assessments

By 2030, NRAs must have reliance-based regulatory pathways fully implemented, enabling vaccines assessed in one country to be rapidly assessed in others without redundant reviews, especially with respect to the assessment of the quality portion of the dossier and GMP inspections. This will reduce costs for regulatory agencies and industry, potentially accelerate market entry, and help ensure that vaccines reach populations faster while maintaining quality and safety standards.

How?

- Develop legally binding recognition and reliance agreements that allow regulatory decisions or work products (scientific assessments and inspection reports) to be recognised across multiple countries
- Establish joint regulatory review platforms to streamline timelines and accelerate vaccine assessment
- Expand reliance-based regulatory pathways, allowing NRAs to use decisions from trusted regional or international regulatory agencies (e.g. WHO PQ and WLAs) to inform their own regulatory decisions without having to repeat the work (e.g. scientific assessment or inspection)
- Ensure alignment with global best practices by integrating recognition and reliance-based regulatory pathways into public health agreements
- Reduce time to market for regionally manufactured products by ensuring an assessment process with guaranteed time frames and adequate staffing and financial resources

03. Align regional regulatory frameworks with global standards to enable access to international markets

By 2030, regional regulatory systems must be fully aligned and accredited by WHO as aligned with WHO prequalification and other global standards (e.g. WLA), ensuring that regionally manufactured vaccines can be procured internationally. Without this alignment, vaccines produced under RVM risk being confined to domestic markets, limiting their financial viability.

How?

- Support regions in developing alternative mechanisms or pathways to accelerate time to market for regionally manufactured vaccines
- Ensure all NRAs in all countries where vaccine manufacturing occurs adopt internationally recognised risk-based regulatory approaches such as WHO's Good Reliance Practices (GRPs) and attain, at a minimum, WHO ML3 (vaccine producing), so that their vaccines are eligible for PQ assessment(50)
- Integrate WHO Collaborative Registration Procedures (CRP) into regional frameworks to streamline market entry
- Align regional regulatory systems with WHO PQ and GMP to ensure compliance with international quality standards.

By 2030, regulatory strengthening and harmonisation must be an operational reality, as evidenced by the attainment of appropriate WHO maturity levels and, ultimately, WHO Listed Authorities. These achievements will provide a predictable and efficient system that supports RVM, facilitates global market access, and ensures timely vaccine availability for all.

PRIORITY 03

CASE STUDY

The ASEAN Pharmaceutical Regulatory Framework

The ASEAN Pharmaceutical Regulatory Framework

The Association of Southeast Asian Nations (ASEAN) member countries are Indonesia, Malaysia, Philippines, Singapore, Thailand, Brunei Darussalam, Vietnam, Laos, Myanmar and Cambodia. A key goal for ASEAN is to create common regulations for pharmaceuticals in the region, reduce barriers to trade, and ensure timely access to high-quality, safe and effective pharmaceutical products for the ASEAN people.

A major milestone towards this vision came in 2022 when ASEAN Economic Ministers and ASEAN Health Ministers adopted the ASEAN Pharmaceutical Regulatory Policy (APRP).[51]

The Policy aims to harmonise regulatory requirements, increase collaboration between ASEAN's national regulators, and create a supportive environment for innovation, investment, and trade in the pharmaceutical sector. To turn ARRP into practice, in 2023, ASEAN Economic Ministers and Health Ministers adopted the ASEAN Pharmaceutical Regulatory Framework (APRF).[52]

The Framework is a legally binding agreement to establish a comprehensive and coherent overall approach towards an integrated market for pharmaceuticals in ASEAN. APRF provides a basis for Member States to develop harmonised strategies that enhance national regulatory systems and support market integration initiatives.

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The Framework encourages strengthened collaboration between National Regulatory Authorities so they can jointly agree on regulatory and technical standards, practices, and guidelines. APRF facilitates arrangements for information sharing, work-sharing, and coordination and cooperation on regulatory decisions on pharmaceutical products and pharmaceutical operators. It also strengthens cooperation among NRAs to act in cases of non-compliance with relevant legislation and regulatory requirements.

Under APRF, Member States have agreed to integrate supply chains of pharmaceuticals across ASEAN through the alignment of regulatory pathways. Member States will also work to enhance regional collaboration and undertake institutional strengthening through the adoption and implementation of regulatory standards aligned with international and WHO standards.

The APRF will build on existing commitments and initiatives to provide a structure and the legal and organisational instruments to realise regulatory harmonisation. Member State representatives to the ASEAN Pharmaceutical Product Working Group, ASEAN Health Cluster 3, and other relevant stakeholders are coordinating a consultation on an implementation plan and mechanism.

APRF shows how countries in a region can work together towards regulatory harmonisation through a legally binding regional agreement and close cooperation and collaboration between NRAs and governments. Full implementation of this framework will make a strong contribution towards regulatory strengthening and harmonisation.

HOW WILL WE MEASURE PROGRESS?

As we advance this vision for Regionalised Vaccine Manufacturing, RVMC is committed to working with partners to support tangible outcomes that strengthen health security, equity, and resilience across regions.
This document sets the foundation for a more sustainable and collaborative vaccine manufacturing ecosystem, but the success of RVM will ultimately be measured by the real-world impact of our efforts—ensuring timely, affordable, and regionally produced vaccines reach the communities that need them most.

Recognising the importance of accountability, we will develop a comprehensive scorecard, to be released later in 2025, that will define key metrics against which we will measure RVM progress. This scorecard will serve as a tool to track achievements, identify gaps, and guide necessary course corrections across the pillars of the RVMC Framework.[53] By regularly assessing our collective progress, we aim to enable RVM to continue evolving and remain relevant and responsive to changes in regional and global health systems.

We will also develop regional perspectives and policy briefs during 2025, to provide further detail on how this vision for RVM can be achieved.

References

1. Dzau VJ, Balatbat CA, Offodile AC. Closing the global vaccine equity gap: equitably distributed manufacturing. Lancet. 2022 May 21;399(10339):1924–6.

2. Dzau V, Hatchett R, Bishen S, Kaseya J, Barbosa J, Fezoua F, et al. The time for regionalised vaccine manufacturing has arrived. Lancet. 2025 Jan 25;405(10475):280–2.

3. Immunization Agenda 2030 Partners. Immunization agenda 2030: A global strategy to leave no one behind. Vaccine. 2024 Apr 8;42 Suppl 1:S5–14.

4. MacDonald N, Mohsni E, Al-Mazrou Y, Kim Andrus J, Arora N, Elden S, et al. Global vaccine action plan lessons learned I: Recommendations for the next decade. Vaccine. 2020 Jul 14;38(33):5364–71.

5. Shattock AJ, Johnson HC, Sim SY, Carter A, Lambach P, Hutubessy RCW, et al. Contribution of vaccination to improved survival and health: modelling 50 years of the Expanded Programme on Immunization. Lancet. 2024 May 25;403(10441):2307–16.

6. Global immunization efforts have saved at least 154 million lives over the past 50 years [Internet]. [cited 2025 Mar 28]. Available from: https://www.who.int/news/item/24-04-2024-global-immunization-efforts-have-saved-at-least-154-million-lives-over-the-past-50-years

7. Bura VK, Srivastava R, Chawla AK, Njambe TOE, Khanal S, Sangal L, et al. Essential programme on immunization in WHO South-East Asia: A five-decade journey of saving millions of lives & ending diseases. Indian J Med Res. 2024;160(3 & 4):267–78.

8. Prunas O, Shioda K, Toscano CM, Bastias M, Valenzuela-Bravo MT, Tito JD, et al. Estimated Population-Level Impact of Pneumococcal Conjugate Vaccines Against All-Cause Pneumonia Mortality Among Unvaccinated in 5 Latin American Countries. J Infect Dis. 2024 Oct 16;230(4):e768–76.

9. de Oliveira LH, Shioda K, Valenzuela MT, Janusz CB, Rearte A, Sbarra AN, et al. Declines in pneumonia mortality following the introduction of pneumococcal conjugate vaccines in latin american and caribbean countries. Clin Infect Dis. 2021 Jul 15;73(2):306–13.

10. The fight against pneumonia in five charts [Internet]. [cited 2025 Feb 26]. Available from: https://www.gavi.org/vaccineswork/fight-against-pneumonia-5-charts

11. Gavi, the Vaccine Alliance. Protecting Our Future: Investment Opportunity 2026-2030 [Internet]. Gavi, the Vaccine Alliance; 2025 [cited 2025 Mar 28]. Available from: https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/Gavi-Investment-Opportunity-2026-2030.pdf

12. Khan MI, Ikram A, Hamza HB. Vaccine manufacturing capacity in low- and middle-income countries. Bull World Health Organ. 2021 Jul 1;99(7):479-479A.

13. Boro E, Stoll B. Barriers to COVID-19 Health Products in Low-and Middle-Income Countries During the COVID-19 Pandemic: A Rapid Systematic Review and Evidence Synthesis. Front Public Health. 2022 Jul 22;10:928065.

14. Moradpour J, Chit A, Besada-Lombana S, Grootendorst P. Overview of the global vaccine ecosystem. Expert Rev Vaccines. 2023;22(1):749–63.

15. CEPI. Manufacturing and supply chain | CEPI [Internet]. [cited 2025 Feb 26]. Available from: https://cepi.net/manufacturing-and-supply-chain

16. Feddema JJ, Fernald KDS, Schikan HGCP, van de Burgwal LHM. Upscaling vaccine manufacturing capacity - key bottlenecks and lessons learned. Vaccine. 2023 Jul 5;41(30):4359–68.

17. Trump BD, Golan MS, Keisler JM, Cegan JC, Linkov I. Vaccine supply chain: Resilience-by-design and resilience-by-intervention. Vaccine. 2022 Mar 15;40(12):1695–8.

18. Access to Medicine Foundation. End-to-end technology transfer initiatives for vaccines to improve availability [Internet]. 2024 [cited 2025 Mar 28]. Available from: https://accesstomedicinefoundation.org/resource/end-to-end-technology-transfer-initiatives-for-vaccines-to-improve-availability

19. Duroseau B, Kipshidze N, Limaye RJ. The impact of delayed access to COVID-19 vaccines in low- and lower-middle-income countries. Front Public Health. 2022;10:1087138.

20. WHO. Global excess deaths associated with COVID-19, January 2020 - December 2021 [Internet]. 2022 [cited 2025 Mar 28]. Available from: https://www.who.int/data/stories/global-excess-deaths-associated-with-covid-19-january-2020-december-2021

21. World Bank. Global Economic Prospects. World Bank; 2025 Jan.

22. Gavi, the Vaccine Alliance. A preliminary assessment of COVAX's impact in lower-income countries. Gavi, the Vaccine Alliance; 2023 May.

23. Poverty and Shared Prosperity 2020 [Internet]. [cited 2025 Feb 26]. Available from: https://www.worldbank.org/en/publication/poverty-and-shared-prosperity-2020

24. COVID-19 and Economic Inequality : Short-Term Impacts with Long-Term Consequences [Internet]. [cited 2025 Feb 26]. Available from: https://documents.worldbank.org/en/publication/documents-reports/documentdetail/219141642091810115/covid-19-and-economic-inequality-short-term-impacts-with-long-term-consequences

25. Center For Global Development. Rethinking Development Cooperation: Aid 2.0 [Internet]. 2024 [cited 2025 Feb 26]. Available from: https://www.cgdev.org/blog/rethinking-development-cooperation-aid-20

26. UN DESA. Financing for Sustainable Development Report 2024. UN DESA; 2024 Apr.

27. GBD 2021 Forecasting Collaborators. Burden of disease scenarios for 204 countries and territories, 2022-2050: a forecasting analysis for the Global Burden of Disease Study 2021. Lancet. 2024 May 18;403(10440):2204–56.

28. World Disasters Report 2022 | IFRC [Internet]. [cited 2025 Feb 26]. Available from: https://www.ifrc.org/document/world-disasters-report-2022

29. OECD. Ready for the Next Crisis? Investing in Health System Resilience. OECD; 2023 Feb.

30. Al Fayez N, Nassar MS, Alshehri AA, Alnefaie MK, Almughem FA, Alshehri BY, et al. Recent Advancement in mRNA Vaccine Development and Applications. Pharmaceutics. 2023 Jul 18;15(7).

31. Vicardo T. The Revolutionary Role of Modular Production in Vaccine Development. Pharm Regul Aff. 2024 Jan 29;13(01).

32. Barnsley G, Olivera Mesa D, Hogan AB, Winskill P, Torkelson AA, Walker DG, et al. Impact of the 100 days mission for vaccines on COVID-19: a mathematical modelling study. Lancet Glob Health. 2024 Nov;12(11):e1764–74.

33. Africa CDC. Africa CDC Spearheads Bold Move to Secure Africa's Health Future by Creating a 50 billion Dollar Medical Market [Internet]. 2024 [cited 2025 Mar 28]. Available from: https://africacdc.org/news-item/africa-cdc-spearheads-bold-move-to-secure-africas-health-future-by-creating-a-50-billion-dollar-medical-market/

34. G20 Brazil. Rio de Janeiro Declaration of the G20 Health Ministers [Internet]. 2024 [cited 2025 Mar 28]. Available from: https://www.g20.utoronto.ca/2024/241031-HWG_Ministerial_Declaration_-_Rio_de_Janeiro_ENG.pdf

35. PAHO. Countries of the Americas agree on measures to encourage innovation and regional production of health technologies [Internet]. 2024 [cited 2025 Mar 28]. Available from: https://www.paho.org/en/news/3-10-2024-countries-americas-agree-measures-encourage-innovation-and-regional-production

36. Association of Southeast Asian Nations. Regional Strategic and Action Plan for ASEAN Vaccine Security and Self Reliance (AVSSR) 2021–2025 [Internet]. 2021 [cited 2025 Mar 28]. Available from: https://asean.org/wp-content/uploads/2021/10/AHMM-ADOPTED_AVSSR-Strategic-and-Action-Plans-2021-2025-cleaned-version_FINAL.pdf

37. CEPI. BioNTech and CEPI expand partnership to strengthen Africa's mRNA vaccine ecosystem [Internet]. 2024 [cited 2025 Mar 28]. Available from: https://cepi.net/biontech-and-cepi-expand-partnership-strengthen-africas-mrna-vaccine-ecosystem

38. Health Policy Watch. Landmark Vaccine Deals Signal Africa's Shift Toward Local Manufacturing [Internet]. 2025 [cited 2025 Mar 28]. Available from: https://healthpolicy-watch.news/landmark-vaccine-deals-signal-africas-shift-toward-local-manufacturing/

39. Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action – Africa CDC [Internet]. [cited 2025 Feb 26]. Available from: https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/

40. Why Africa needs to manufacture its own vaccines [Internet]. [cited 2025 Feb 26]. Available from: https://www.gavi.org/vaccineswork/why-africa-needs-manufacture-its-own-vaccines

41. Peacocke EF, Heupink LF, Frønsdal K, Dahl EH, Chola L. Global access to COVID-19 vaccines: a scoping review of factors that may influence equitable access for low and middle-income countries. BMJ Open. 2021 Sep 30;11(9):e049505.

42. Md Khairi LNH, Fahrni ML, Lazzarino AI. The Race for Global Equitable Access to COVID-19 Vaccines. Vaccines (Basel). 2022 Aug 12;10(8).

43. World Bank. ASEAN Regional Vaccine Manufacturing and Development: Regional Synthesis Report. World Bank; 2023 Apr.

44. PAHO. Over $800 million in vaccines, medicines and health technology procured by PAHO's Regional Revolving Funds in 2024 [Internet]. 2025 [cited 2025 Mar 28]. Available from: https://www.paho.org/en/news/24-2-2025-over-800-million-vaccines-medicines-and-health-technology-procured-pahos-regional

45. Mueller LE, Haidari LA, Wateska AR, Phillips RJ, Schmitz MM, Connor DL, et al. The impact of implementing a demand forecasting system into a low-income country's supply chain. Vaccine. 2016 Jul 12;34(32):3663–9.

46. Gavi, the Vaccine Alliance. African Vaccine Manufacturing Accelerator (AVMA) [Internet]. 2025 [cited 2025 Mar 28]. Available from: https://www.gavi.org/programmes-impact/types-support/regional-manufacturing-strategy/avma

47. PAHO. PAHO paving the way for COVID-19 vaccination in the Americas [Internet]. 2021 [cited 2025 Feb 26]. Available from: https://www.who.int/news-room/feature-stories/detail/paho-paving-the-way-for-covid-19-vaccination-in-the-americas

48. Khadem Broojerdi A, Alfonso C, Ostad Ali Dehaghi R, Refaat M, Sillo HB. Worldwide Assessment of Low- and Middle-Income Countries' Regulatory Preparedness to Approve Medical Products During Public Health Emergencies. Front Med (Lausanne). 2021 Aug 13;8:722872.

49. Wairagkar N, Djoudalbaye B, Moubarak I, Zakari M, Shaffer DN, Ismail AJ, et al. The African Medicines Agency - A potential gamechanger that requires strategic focus. PLOS Glob Public Health. 2025 Feb 14;5(2):e0004276.

50. WHO. TRS 1033 - Annex 10: Good reliance practices in the regulation of medical products: high level principles and considerations. WHO; 2021 Oct.

51. ASEAN Pharmaceutical Regulatory Policy - ASEAN Main Portal [Internet]. [cited 2025 Feb 26]. Available from: https://asean.org/book/asean-pharmaceutical-regulatory-policy/

52. ASEAN. ASEAN Pharmaceutical Regulatory Framework (APRF) . ASEAN; 2023 Apr.

53. RVMC. Regionalized Vaccine Manufacturing Collaborative Framework: A Framework for Enhancing Vaccine Access Through Regionalized Manufacturing Ecosystems [Internet]. 2024 [cited 2025 Mar 28]. Available from: https://www.weforum.org/publications/regionalized-vaccine-manufacturing-collaborative-rvmc-global-framework-a-guide-for-increasing-vaccine-access-through-regionalized-vaccine-eco-systems/

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