Towards Regionalised Vaccine Manufacturing

First Status Report

RVMC
Regionalized Vaccine Manufacturing Collaborative

CONTENTS

FOREWORD

This is a pivotal moment for global health: a generational opportunity for regions that were left behind during Covid-19 for self-determination and to build the capabilities to address their healthcare needs and priorities.

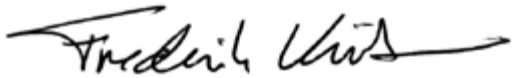
The circumstances are challenging. Donor governments are shifting their focus away from the development agenda and towards national security and defence, leading to significant reductions in donor financing for health. Economic headwinds have also left many countries heavily indebted.

Against this backdrop, the regionalisation agenda is drawing more interest than ever. New forms of resilient interdependence – within and between regions – are taking shape. 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, enables vaccine equity, and grows economies.

Developing RVM is a long-term effort, and we cannot expect it to happen overnight. But over time, and with appropriate support, it can contribute to a stronger, more balanced, and more resilient vaccine ecosystem worldwide. RVM aims to do this by responding to local needs on a routine basis and during outbreaks, and by providing additional geographically distributed manufacturing capacity across diverse platforms and technologies.

For our partners across the collaborative and beyond to contribute to achieving RVM, we need to know where we stand and where more progress is needed – at the technical level, but especially at the political and financial levels, which determine whether and how RVM is incentivised. This first RVM Status Report is an important step in understanding where we are. Our data show that while recent years have seen considerable levels of interest and commitment to RVM, these need to be translated into concrete action.

We hope this report can serve as a useful guide for aligning and coordinating efforts across the collaborative – leading to measurable progress on RVM when we repeat the assessment in 2027.



Dr Frederik Kristensen
Managing Director, RVMC

GLOSSARY

Business archetypes

The classification of vaccine manufacturers based on the portion of the production process involved for each individual vaccine:

- Drug substance-only manufacturer (focusing only on bulk antigen and drug substance manufacturing);
- Drug product-only manufacturer (focusing on formulation, fill & finish/packaging, and commercialisation/lot release);
- Fully integrated manufacturer (bulk antigen manufacturing/ drug substance production, drug product formulation, fill & finish/packaging, and performing all production and commercialisation steps).

Disease of specific regional relevance

A vaccine-preventable disease (VPD) with a burden primarily concentrated in the region as defined by the relevant WHO Regional Offices. Both WHO-SEARO and WHO-WPRO priorities have been considered for the Association of Southeast Asian Nations (ASEAN) Member States.

Fully functional (manufacturer)

A manufacturer that has commercialised vaccines of the appropriate quality (stratified based on the maturity level of the National Regulatory Authority (NRA) under whose jurisdiction the manufacturer operates).

Marketing authorisation (also Registration, Licensure)

The official approval granted by an NRA that allows a vaccine to be marketed, distributed, and used within a specific jurisdiction. This authorisation confirms that the vaccine has met rigorous quality, safety, and efficacy standards, based on comprehensive data from preclinical studies and clinical trials. It ensures that the benefits of the vaccine outweigh any potential risks when used as intended.

Originator

A manufacturer that owns intellectual property (IP) and global commercialisation rights as well as know-how and seed materials for a vaccine, which it can bestow upon technology transfer (TT) partners.

Production process steps

(1) Drug substance (DS) production – Antigen bulk manufacturing, including the upstream part (cell culture/ fermentation, virus propagation where applicable, harvesting) and the downstream part (filtration, inactivation if required, purification)

(2) Drug product (DP) production – formulation, filling & finishing (i.e., visual inspection, packaging, and product release).

Packaging-only operations are not considered drug product production. Distribution is not part of the production process.

Regional manufacturer

A manufacturer whose ownership is based in the region in scope and whose manufacturing plants are primarily based in the region in scope.

Regions in scope

- Africa (geographical definition);
- Latin America and the Caribbean (geographical definition);
- Southeast Asia (ASEAN member states).

Regulatory reliance

The act, governed by a legal agreement, whereby a regulatory authority in one jurisdiction takes into account the scientific assessments and regulatory decisions by another regulatory authority in reaching its own decision. The relying authority remains independent and responsible for its own regulatory decisions.

Technology transfer

The structured process by which the knowledge, methods, protocols, materials, equipment specifications, and quality standards required to produce a vaccine are transferred from one organisation (the originator or developer) to another (the recipient or manufacturer). This process enables the recipient to replicate and scale up vaccine production in compliance with regulatory, safety, and quality standards. The transfer can involve different steps of the production process.

Vaccine demand

The willingness and capacity of a country to procure the vaccine doses required to immunise its target populations against specific vaccine-preventable diseases. It is typically measured as programmatic dose requirements: the average estimated number of doses a country must procure to meet its immunisation programme needs, including allowances for wastage and buffer stocks. This concept is distinct from population demand for immunisation, which refers to the expressed willingness of individuals to receive vaccination.

Vaccine platform

A standardised and adaptable technological framework, process, or system used to develop and produce multiple vaccines. These platforms provide a common foundation for producing different vaccines by utilising the same core components, processes, or production infrastructure.

1. Whole pathogen platforms (inactivated, live-attenuated);
2. Subunit platforms (inactivate/toxoid, polysaccharide, conjugate, protein-based, nanoparticle-based)
3. Genetic platforms (nucleic acid RNA-based, nucleic acid DNA-based, viral vectored).

A longer glossary table accompanies a detailed Methodology document, which is available at www.rvmc.net.

EXECUTIVE SUMMARY

After COVID-19, more RVM is widely recognised as critical. The RVM model prioritises local production, strengthens regional health security, enables vaccine equity, and grows economies.

This RVM Status Report presents a baseline assessment of regionalised vaccine manufacturing (RVM) in Africa, Southeast Asia (the ASEAN member states), and Latin America and the Caribbean (LAC), across the 8 pillars of the RVMC Framework – Business Archetypes, Healthy Markets, Financial Models, R&D & Manufacturing Innovation, Technology Transfer & Workforce Development, Supply Chain & Infrastructure, Product Regulation, and Policy & Governance.

The 8 pillars are grouped into 3 thematic areas: Finance & Demand, Regulatory & Governance, and Technology & Supply. This report aims to help stakeholders know where we stand and where further action is required to achieve sustainable RVM.

Publicly available data are presented in our dashboard. Indicators included in this first dashboard were selected following a 6-month, iterative and consultative process with key stakeholders. Not all indicator data are equally complete: RVMC will continue to work with stakeholders to fill data gaps and strengthen datasets for future updates.

The data show that while recent years have seen considerable interest and commitment to RVM, these need to be translated into concrete action. The results also remind us that each region is at a different stage in its journey towards RVM, though all regions show promise.

KEY FINDINGS

FINANCE AND DEMAND

RVM remains constrained by limited scale, fragmented demand, and uneven distribution of capacity.

- Only 3 manufacturers across the regions (1 in ASEAN and 2 in LAC) produce 5 or more vaccines and have scaled their operations. Africa lacks comparable capacity.
- The proportion of vaccine doses demanded by regions that regional manufacturers meet is low – manufacturers in ASEAN supply 29% of vaccine doses demanded, while the number is 25% for manufacturers in LAC, and African manufacturers contribute only 1% of demanded vaccines across Africa.
- Ability to supply vaccines for each region's priority diseases is uneven, with manufacturers in LAC and ASEAN producing the majority of their region's priority vaccines, but African producers making just 1 out of their 16 regional priority vaccines.
- Government spending over the past 3 years on immunisation now accounts for over 20% of total routine immunisation expenditure in Africa and more than 85% in LAC – evidence of stronger domestic financing – but predictable demand for regionally produced products remains elusive.
- Pooled procurement mechanisms like PAHO's Revolving Fund have proven effective in reducing prices, yet similar systems have not yet been developed in Africa and ASEAN. UNICEF Supply Division remains a successful global procurement mechanism that countries can also use to purchase vaccines at low prices.

REGULATORY AND GOVERNANCE

Strong, harmonized, and effective regulatory systems are essential for sustainable RVM.

- While 19 out of 97 countries have achieved at least WHO Maturity Level 3 (ML3) or PAHO Reference Authority status, regulatory harmonisation remains limited.
- Publicly available data on average approval times for marketing authorisation (BLA) show that: in 2 of the 5 LAC countries hosting DP-producing or fully integrated vaccine manufacturers, the estimated timelines ranged from 9-15 months; in 1 of the 4 relevant African countries approvals took from 16-19 months; and in 4 of the 6 relevant ASEAN countries approval timelines ranged from 11-36 months.
- The majority of vaccines produced in the regions obtained their marketing authorisation from a National Regulatory Authority (NRA) with ML3, making them eligible for export, but only 20% of vaccines have WHO prequalification (PQ), restricting their eligibility for UNICEF procurement. The ability to supply beyond domestic markets is critical for regional vaccine manufacturers.
- The African Medicines Agency (AMA) shows promise for regulatory alignment, but slow ratification and limited operational capacity hinder progress. Without harmonised frameworks, manufacturers face delays and uncertainty in cross-border approvals.
- A lack of organised tracking of countries' implementation laws and policies that enable RVM makes it challenging to assess whether political commitments to RVM are being translated into concrete action.

KEY FINDINGS

TECHNOLOGY AND SUPPLY

Technology access and platform diversity are critical for RVM.

- LAC leads in platform coverage, followed by ASEAN, with Africa further behind. Crucially, newer and more flexible platforms remain underrepresented across all 3 regions, thereby limiting their role in addressing unmet local needs and rapid response applications.
- LAC and ASEAN have a strong clinical trial foundation that can be used for accelerating innovation. Sponsorship by regional organisations with active participation from local companies is crucial to this goal. In Africa, by contrast, there is a greater reliance on organisations or academic institutions outside the region.
- The number of publicly announced technology transfer agreements across the 3 regions remains broadly stable but has grown in Africa. However, success rates for those transfers vary.
- Workforce and supply chain reliability data remain sparse, limiting visibility into the resilience of regional ecosystems to support technology transfers.

ASSESSMENT AND WAY FORWARD

Our findings, along with the regions' own perspectives, underscore that RVM is still in its formative phase. National efforts have laid meaningful groundwork, but regional coordination and decisive political action are essential to achieve scale and sustainability. Key priorities for action include:

- **Predictable demand:** Translate demand for vaccines into predictable regional markets through clear policy and budgetary commitments – supported by mechanisms such as pooled procurement – that drive uptake of regionally produced vaccines.
- **Regulatory strengthening and harmonisation:** Stronger and better-aligned systems that reduce duplication, accelerate approvals, and uphold quality standards.
- **Technology and supply diversification:** Targeted investment in appropriate production platforms aligned with regional health priorities, supported by clinical development capacity and well-functioning supply chains.

Addressing these priorities is essential to attracting investment, including from the private sector. The foundation for RVM has been established, but this report demonstrates that there is a long way to go. Sustaining development will, in part, depend on a stronger evidence base to guide action. RVMC will conduct a follow-up assessment in 18 months to assess measurable progress against this baseline, hopefully demonstrating that concrete actions are underway, investments are yielding results, and regional manufacturing capacity continues to develop sustainably.

RVMC will also work towards assessing data on our secondary indicators including, for example, manufacturing input materials and risks to the sustainability of global and regional systems.

REGIONAL PERSPECTIVES

A core principle of RVMC's work is that RVM is regionally led. Accordingly, Africa CDC, PAHO, and the Thailand National Vaccine Institute – the ASEAN Vaccine Security and Self-Reliance (AVSSR) focal point – as representatives of their regions, were invited to share their perspectives on the data. All affirmed that these priorities are essential to their respective pathways towards RVM and welcomed the role this report can play in building a shared evidence base to track progress, identify opportunities, and foster inter-regional dialogue.

We hope this report supports regional progress towards resilient vaccine manufacturing ecosystems.


COVID-19
Vaccine

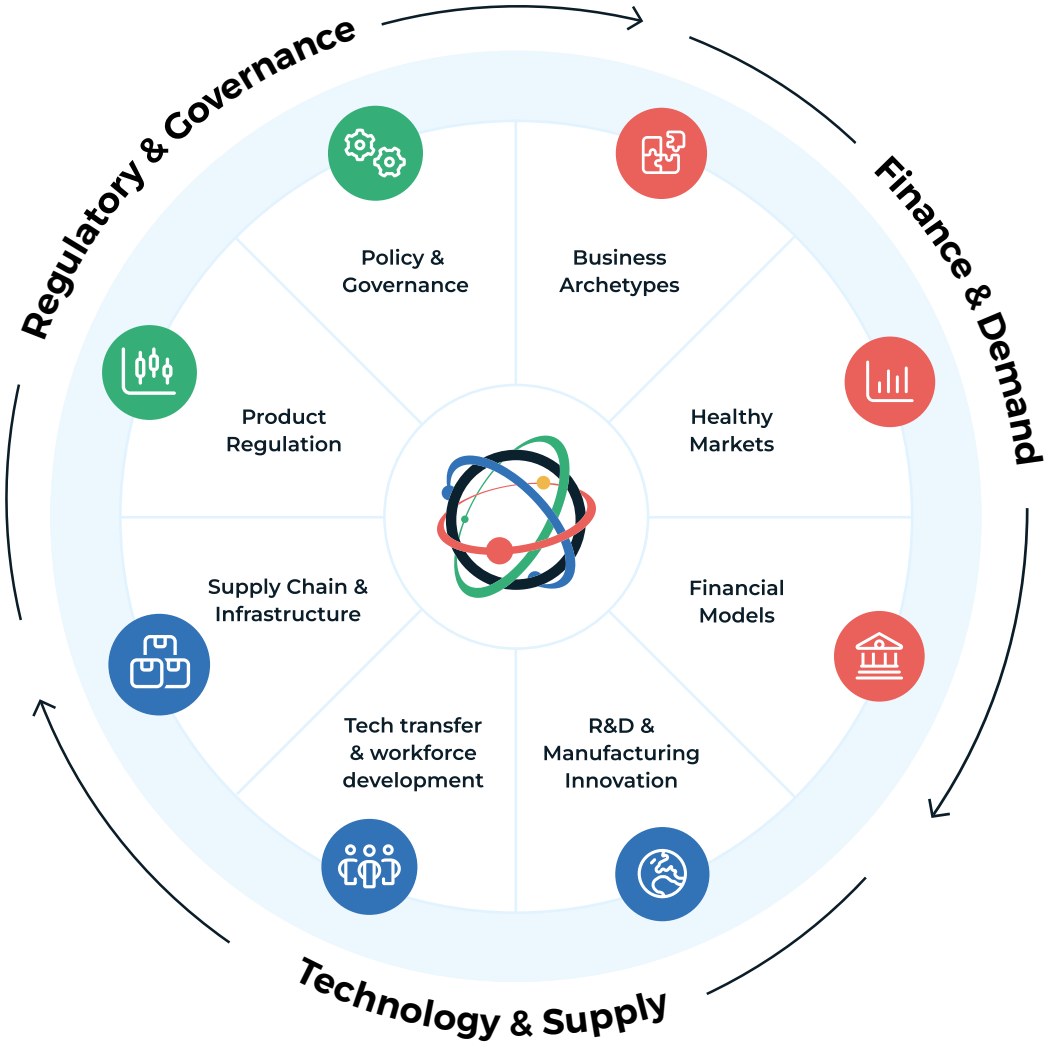
INTRODUCTION

Making vaccines is difficult and requires time, and the ecosystem needed to establish and sustain such manufacturing is complex.

After COVID-19, more regionalised vaccine manufacturing (RVM) is widely recognised as critical for epidemic and pandemic preparedness, to better address regional health needs, and for industrial development. This report seeks to assess how regions are progressing towards that goal.

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

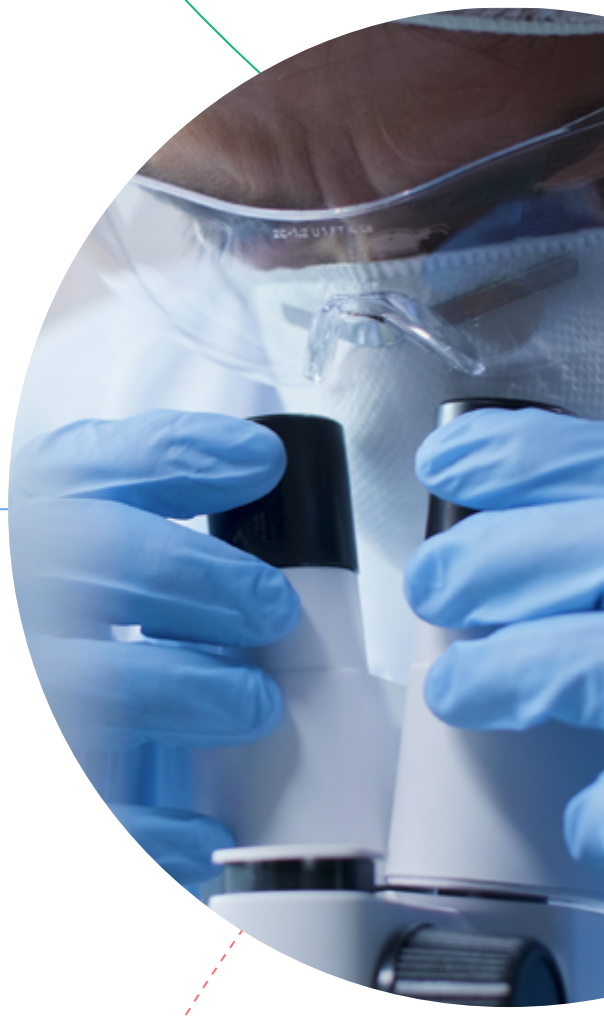
RVM requires a balanced ecosystem across technologies and supply, finance and demand, and regulatory and governance. The RVMC Framework sets out 8 pillars across these 3 thematic areas.



Knowing where we stand across the 8 pillars is important for:

- Establishing a baseline that helps to calibrate our expectations of what is possible in the next few years;
- Identifying gaps for regional partners to address;
- Highlighting progress over time, across regions;
- Providing a single source of reliable data for investors;
- Catalysing better data collection;
- Facilitating the development of a common language that enables all stakeholders to comprehend the dynamics of the RVM ecosystem.

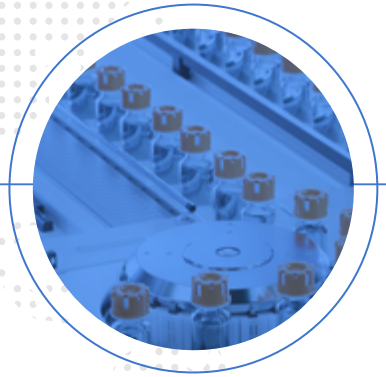
In this first Status Report, we set out to establish a starting point, a baseline, but also to highlight progress and persistent barriers where possible, across Africa, ASEAN, and LAC. Over time, repeated assessments will allow us to track trends, identify successful interventions, and provide governments, industry leaders, and international partners with a guide to areas where further action is needed. To do so in an effective way, transparency and access to data will prove critical.



METHODS

Over the past 6 months, RVMC has developed a dashboard to assess the current status of RVM across the Africa, ASEAN, and LAC regions through an iterative, consultative process involving key regional and global stakeholders convened in a stakeholder working group (SWG) and subject matter experts.

The dashboard presents publicly available data across the 8 pillars of our Framework, which shape sustainable RVM and supply chain networks. Together, these data provide insight into the core enablers of RVM – predictable demand, strengthened and harmonised regulatory systems, and diversified technology and supply.



The design process began by identifying 44 strategic indicators that reflect key enablers of RVM, grouped under the 8 pillars of the Framework. Additionally, 16 mission and vision indicators were defined to represent the long-term goals of RVM. For each indicator, the rationale, alignment with RVMC's mission, calculation method, and potential data sources were outlined. Standardised definitions were created to ensure clarity and consistency. The initial list was reviewed by the SWG to refine and improve the indicators.

Next, a structured triage process was used to evaluate the indicators using 6 criteria: accuracy, accessibility, timeliness, comprehensiveness, validity, and traceability. Indicators were also assessed for their ability to reflect short-term changes, recognising that many vaccine manufacturing impacts emerge over longer periods. Based on this review, 21 core indicators were selected for the dashboard. The rest were retained as secondary indicators to supplement findings and/or be reported on in future reports. Vision indicators were excluded from this first version due to their long-term nature.

The dashboard was then populated using publicly available data. Because of differences in reporting cycles and data availability, the scope and reference periods vary across indicators. Each underwent systematic and transparent quality assurance and control (QA/QC) to ensure consistency and transparency. Subject-matter experts reviewed preliminary findings, and brief narratives were added to explain the results. Data gaps were clearly marked to guide future updates.
A second round of consultations with the SWG helped validate the final set of indicators.

The findings offer a directional view of the current status of RVM based on the best public information. As data systems mature and transparency improves, both the dataset and the indicators will be updated. RVMC and partners will review the dashboard regularly to ensure it remains fit for purpose, reliable, and policy-relevant in guiding efforts to strengthen RVM capacity.

A detailed methodology document, including data sources, indicator definitions, analytical approach, and supporting data tables for each of the 21 selected indicators, as well as the complete list of indicators initially considered, is available at **www.rvmc.net.**

RVM *DASHBOARD*

REGIONS

Population data

	Africa	ASEAN	LAC	3 Regions
Number of countries: Number of WHO member states (2024)	54	10	33	97
Population size: Estimated total number of individuals (persons) in a given population (in millions) (2024)	1,496	691	655	2,842
Surviving infants: Estimated total number of live-born infant who survives to age one year (in millions) (2024)	44.9	10.0	9.1	64

FINANCE AND DEMAND

	Indicator	*Africa*	*ASEAN*	*LAC*	*3 Regions*	*Data Quality*
Business archetypes	**1.1 Manufacturing Breadth:** Number of fully functional regional manufacturers (2025)	5	10	8	23	★★★
	2.1 Manufacturing Depth: Number of fully functional regional manufacturers, with a portfolio of 5 or more vaccines which produced >70 million doses/year (2022-23)	0	1	2	3	★★☆
Healthy markets	**3.1a Regional Scale (volume):** Percentage of regional demand served by fully functional manufacturers from the region / excluded packaging only (2023)	1	29	25	10	★★★
	3.1b Regional Scale (portfolio): Number of priority diseases for which at least one vaccine is produced by a fully functional regional manufacturer (2025)	1 of 16	14 of 18	9 of 13		★★★
	4.1 Distributed manufacturing ecosystem: for regional priority diseases, average proportion of the global doses produced supplied by fully functional regional manufacturers	No data	No data	No data	No data	☆☆☆
	5.1 Premium vs. Lowest Available Prices: Median price difference between regionally produced vaccines and UNICEF Supply Division price for Gavi (2024)	Too few data	Too few data	Too few data	41% higher	★★☆
	6.1a Sustainable demand: Median government vaccine expenditure per surviving infant (2021-2023)	$14	$33	$195		★★☆
	6.1b Sustainable demand: Median annual vaccine expenditure from national budget resources as % of total routine immunization expenditure for the country (2022-2024)	21	Insufficient sample	85		★★☆
Financial models	**7.1a Announced investment in manufacturing:** Average annual announced investments (in million) in regional vaccine manufacturing initiatives (2022-2024)	$530	$153	$494	$1,177	★☆☆
	7.1b Announced investment in manufacturing: Percentage from public & multilateral donors, domestic government resources and from private sector (2022-2024)	86, 5, 9	14, 36, 50	44, 36, 20	59, 22, 19	★☆☆

REGULATORY AND GOVERNANCE

	Indicator	Africa	ASEAN	LAC	3 Regions	Data Quality
Product regulation	**8.1a Regulatory strength:** Number of vaccines that have achieved WHO PQ (2025)	1	11	4	16	★★★
Product regulation	**8.1b Regulatory strength:** Number of vaccines with marketing authorization from a Maturity Level 3 or WHO-listed NRA or PAHO reference NRA (2025)	5	33	36	74	★★★
Product regulation	**9.1 Speed of regulatory processes:** Number of months between Biologics License Application (BLA) and Marketing Authorisation (various years in the period 2017-24)*	16-19	11-36	9-15		★☆☆
Govern-ance	**10.1 Political action:** Proportion of countries that implemented legislation enabling RVM (e.g., procurement, regulatory harmonization, etc.) aligned with a Regional Policy Framework	No data	No data	No data	No data	☆☆☆

TECHNOLOGY AND SUPPLY

	Indicator	Africa	ASEAN	LAC	3 Regions	Data Quality
R&D & manufacturing innovation	**11.1a New vaccine pipeline to manufacturers:** Number of phase III-IV vaccine clinical trials started with at least one regional sponsor, excluding COVID-19 (2022-2024)	14	6	10	30	★★★
R&D & manufacturing innovation	**11.1b New vaccine pipeline to manufacturers:** Percentage of phase III-IV clinical trials started with main sponsor from region (2022-2024)	20	93	76	63	★★★
R&D & manufacturing innovation	**12.1 Localised manufacturing platforms:** Number of operational localised manufacturing platforms (2025)	2/10	5/10	7/10		★★★
Tech transfer & workforce development	**13.1 Technology transfers:** Number of signed tech transfers by fully functional regional manufacturers (2022-2024)	9	5	4	18	★★☆
Tech transfer & workforce development	**14.1 Regional workforce development:** Proportion of highly qualified workforce originating from region	No data	No data	No data	No data	☆☆☆
Supply chain & infrastructure	**15.1 Supply interruptions:** Number of stockouts classified as supply side (shortages, quality, and procurement delays)	Incomplete data	Incomplete data	Incomplete data	Incomplete data	★☆☆
Supply chain & infrastructure	**16.1 Regionally focused procurement:** Number of doses (in millions) procured via regional pooled procurement mechanisms (2024)	0	0	224	224	★★★

** Based on individual studies, may not include all steps*

KEY FINDINGS

The dashboard is structured around the 3 thematic areas and the 8 pillars of the RVMC Framework. Collectively, these components provide a comprehensive overview of each region's current position in developing RVM and establishing the enabling environment required for its sustainability. The following section provides for each thematic area: a detailed analysis of the indicators, integrating insights from secondary indicators, and summarising the key findings; RVMC's assessment on the way forward; and a relevant case study from a region.

FINANCE AND DEMAND

Achieving scalable and sustainable RVM depends fundamentally on the number and type of manufacturers, predictable demand, coordinated investments in manufacturing scale-up, and credible, stable budgetary allocations for vaccine procurement. Without these, the long-term viability of RVM cannot be ensured.

The vaccine manufacturing landscape across Africa, ASEAN and LAC is diverse. Each region comprises a mix of smaller domestic producers established with the goal of fulfilling individual country demand. These producers often operate on legacy, less flexible manufacturing platforms.

There are a limited number of larger manufacturers with broader vaccine portfolios and, for selected vaccines, fully integrated production capabilities. As of 2025, public information shows 23 fully functional manufacturers in the 3 regions (Indicator 1.1). Among these, only 3 – PT Bio Farma in Indonesia, Bio-Manguinhos, and Instituto Butantan in Brazil – produce 5 or more vaccines and have annual outputs exceeding 70-80 million doses (Indicator 2.1). While PT Bio Farma and Bio-Manguinhos export part of their production, their primary focus remains domestic.
By contrast, Africa currently has no manufacturer operating at a comparable scale, reflecting its earlier stage of ecosystem development.

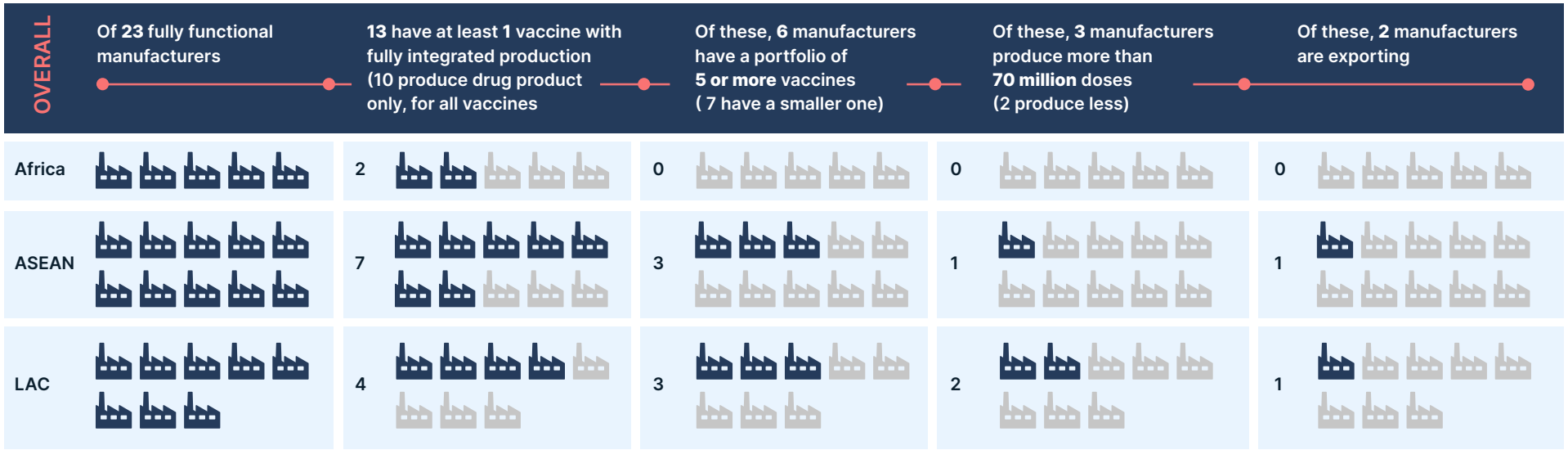


Figure 1: The Supply Landscape Across Africa, LAC and ASEAN

The ability to meet regional demand remains constrained by the relatively limited scale and diversification of current manufacturing capacity in these regions. Data generated using the WHO Global Vaccine Market Dataset (supplementing the country-reported data from the MI4A Public Vaccine Purchase Dataset) shows that in 2023, regional manufacturers accounted for only 10% of the total number of vaccine doses commercialised across the 3 regions – 29% in ASEAN, 25% in LAC, and just 1% in Africa (Indicator 3.1a). This constraint also affects the ability of each region to supply vaccines for its priority diseases, with the degree of self-sufficiency varying. Manufacturers in LAC and ASEAN produce at least some of their region's priority vaccines (9 out of 13 and 14 out of 18, respectively). In contrast, African producers currently manufacture only 1 out of the 16 regional priority vaccines (Indicator 3.1b).

Further information is needed to assess the extent to which these manufacturers can supply markets beyond their countries of origin, given potential regulatory and capacity constraints. Thus, the overall outlook remains limited, even in LAC and ASEAN, where the situation appears more favourable than in Africa. Similarly, more detailed market data are required to evaluate how regional producers contribute to establishing a distributed manufacturing ecosystem capable of addressing regional priority diseases (Indicator 4.1). In general, granular data quantifying the market dynamics across regions, vaccines, and manufacturers are critical, particularly for assessing progress in demand, financing, and supply. Understanding trends in market shares, prices, and volumes can provide valuable insights into what has worked and where improvement is needed.

Predictable and stable demand is one key requirement for sustainably expanding the footprint of regional vaccine manufacturers. Without this, manufacturers face significant financial risks, discouraging long-term investment. Sustained demand depends primarily on reliable health budgets that cover an increasing share of vaccine procurement needs. Considerable differences exist across regions, reflecting varying levels of government investment in immunisation, the differing roles of external financing sources (such as Gavi), and the number of vaccines included in national immunisation programmes. According to WHO financing data, median government vaccine expenditure per surviving infant between 2021 and 2023 was estimated at USD 13.5 in Africa, USD 33.4 in ASEAN, and USD 195.1 in LAC (Indicator 6.1a). Compared to the 2018–2020 period, government spending increased in all 3 regions – by 11% in Africa, 20% in ASEAN, and 40% in LAC.

Although these figures were influenced by COVID-19 vaccine procurement, they indicate a growing willingness and capacity of governments to invest in immunisation. However, divergent trends emerge when examining the proportion of government contributions within total immunisation spending. Between 2020–2021 and 2022–2024, the median government share declined from 35% to 21% in Africa, whereas it remained consistently above 85% in LAC. Data for ASEAN were not included in this comparison due to limited country reporting during the reference period (Indicator 6.1b). These results should also be interpreted in light of the substantial impact of COVID-19 vaccine donations and donor co-financing during the reference period.

Pooled procurement mechanisms (PPMs) can improve vaccine access by increasing the market size, thus allowing for economies of scale that lead to lower prices compared to bilateral procurement. Among the 3 regions examined, only PAHO currently operates a functioning regional pooled procurement mechanism, which procured approximately 224 million doses of vaccines in 2024 (Indicator 16.1). UNICEF Supply Division – supported by Gavi, the Vaccine Alliance's financing mechanisms – has created a more diversified manufacturing base and continues to play a pivotal role in enabling countries to purchase vaccines. By providing manufacturers with predictable demand, these mechanisms have reduced market uncertainty and incentivised long-term investment in vaccine production, although historically with less emphasis on enabling RVM. However, in recent years, efforts have aimed to add more suppliers from low- and middle-income countries and/or increase the procurement volume of regionally produced immunisation products.

Differences in procurement mechanisms generally translate into significant price variations for the same vaccine. In 2024, median bilateral procurement prices from regional manufacturers, as reported by WHO (in MI4A vaccine purchase data), were 29% higher than median prices through the PAHO Revolving Fund and 41% higher than those obtained via UNICEF procurement channels (Indicator 5.1). However, this comparison is based on a limited sample – specifically, 40 vaccines that were both self-procured and purchased through at least one pooled procurement mechanism. The findings nonetheless suggest that larger pooled procurement mechanisms can achieve substantial price discounts. While pooled procurement alone is not a universal solution for enabling RVM, it remains a critical instrument within regions' broader toolkit for strengthening vaccine supply security.

Expanding manufacturing capacity and broadening the base of regional vaccine manufacturers require substantial investment. Unfortunately, comprehensive datasets on investment flows in this sector are not yet available.

However, a recent draft analysis conducted by the Clinton Health Access Initiative (CHAI) on regional vaccine manufacturing technology transfers and financing (based on publicly announced investments in vaccine manufacturing infrastructure), indicates that between 2021 and 2024, an average of USD 1.1 billion in investments was announced annually across the 3 regions, with the majority directed towards Africa (Indicator 7.1a). Other financing mechanisms exist to incentivise RVM, such as Gavi's African Vaccine Manufacturing Accelerator (AVMA), and help manufacturers to mature.

The sources of announced funding vary considerably by region. In Africa, investment has been driven primarily by multilateral donors; in LAC, governments have complemented multilateral contributions with domestic public resources; while in ASEAN, private sector investors have played a relatively stronger role (Indicator 7.1b). Due to the limited availability of data on actual disbursements, it remains unclear to what extent these announced commitments have been translated into financial flows that effectively supported capacity expansion and strengthened RVM.

RVMC'S ASSESSMENT AND WAY FORWARD

Vaccine manufacturing capacity is uneven across regions, and strengthening this base will require sustained investment, which can only be measured through greater transparency on disbursements towards RVM. Even where production capacity exists, regional demand remains fragmented and unpredictable for Africa and ASEAN.

While governments have increased immunisation spending, limited mechanisms direct funding towards regional producers, leading to market uncertainty and weak incentives for growth.

The PAHO Revolving Fund is a notable exception – 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 African Vaccine Manufacturing Accelerator (AVMA) – Gavi's innovative financing instrument designed to help catalyse the sustainable growth of vaccine manufacturing in Africa – is also a welcome effort to incentivise RVM. In order for funds to be dispersed, there is more work to be done by manufacturers in Africa to bring products to WHO PQ and commercialise doses.

Sustainable RVM will depend on complementing these rising expenditures with predictable demand through clear budgetary commitments and coordinated procurement frameworks. Given the limited fiscal space of many governments, increased co-payments for Gavi-supported vaccines, and upcoming graduations from Gavi support for specific countries, funding for vaccine procurement will need to be prioritised. PPMs have effectively aggregated demand and achieved lower prices than bilateral purchasing. However, to enable RVM, PPMs can also be leveraged to encourage the active uptake and demand for regionally produced vaccines through provisions that facilitate their purchase. This would help align supply with demand, strengthen market predictability, and support the long-term viability of local production.

Finally, efficient vaccine production depends on achieving adequate scale and continuous process improvement, which can only be realised over time. Except for the 3 previously mentioned manufacturers, none of the producers in the 3 regions currently operate at large-scale volumes. Furthermore, none are comparable in size to the major global manufacturers that have achieved the lowest production cost levels.

As countries increasingly turn to regional producers as sources of vaccine supply, they will need to anticipate, at least initially, higher prices for equivalent vaccines until economies of scale and process efficiencies are progressively established. They will also need to follow an approach that balances affordability and sustainability, ensuring that success is not measured by cost alone.

CASE STUDY

PUBLIC-PRIVATE MODELS FOR ADVANCING RVM

Sinergium Biotech, established in 2009, offers a compelling example of how a smaller manufacturer can progress from a nationally focused enterprise towards establishing itself as a regionally oriented player through government commitment, long-term planning, and strategic partnerships. The company was founded through a partnership between Grupo Insud, Elea Phoenix, and Biogénesis Bagó, with strong initial backing from the Argentine government. Through an international public tender requiring local production, this support was instrumental in securing long-term purchase guarantees for locally produced vaccines under national immunisation programmes, creating the financial stability needed to invest in state-of-the-art manufacturing infrastructure.

The company's evolution has been characterised by strategic technology transfer partnerships with major global vaccine producers. A first major milestone was the collaboration with Novartis for the local fill-and-finish of the seasonal and pandemic influenza vaccines, marking the beginning of large-scale vaccine manufacturing in Argentina under international good manufacturing practice (GMP) standards. This was followed by partnerships with Merck Sharp & Dohme (MSD) for human papillomavirus (HPV4) and with Pfizer for the 13-valent pneumococcal conjugate vaccine (PCV13). These agreements enabled Sinergium to progressively expand its technical capabilities – from local packaging to formulation, filling, quality control, and release.

In 2021, Sinergium also began supplying seasonal flu vaccines in response to PAHO Revolving Fund tenders. However, the recent collaboration with PAHO and Pfizer on the 20-valent pneumococcal conjugate vaccine (PCV20) marked a significant step towards expansion outside the domestic market, as it implies supplying all PCV20 for the PAHO member states from Argentina. The involvement of PAHO's Revolving Fund was essential to securing regional production of the vaccine, towards a multi-year supply agreement that secures a minimum volume.

These public procurement guarantees, together with international certifications and sustained technology partnerships, positioned Sinergium as a strong benchmark for the expansion of domestic vaccine manufacturing. Over time, the company invested in upstream process development, formulation, and analytical capacity, moving closer to becoming a fully integrated manufacturer. The company's proven fill-and-finish and formulation infrastructure, regulatory compliance with PAHO standards, and experience in managing complex technology transfers provide a foundation for an expanding role in the LAC vaccine ecosystem. Sinergium is also part of the mRNA Technology Transfer programme established by WHO and MPP and has already finished the technology transfer at 100 mL scale. Moreover, Sinergium is currently completing the construction of a 1,000 square metre dedicated mRNA facility and is developing a pandemic flu H5N1 candidate. These new capacities are fundamental not only to have pandemic preparedness capabilities in the region, but also to co-develop and build future candidates with Global South partners from other regions.

REGULATORY AND GOVERNANCE

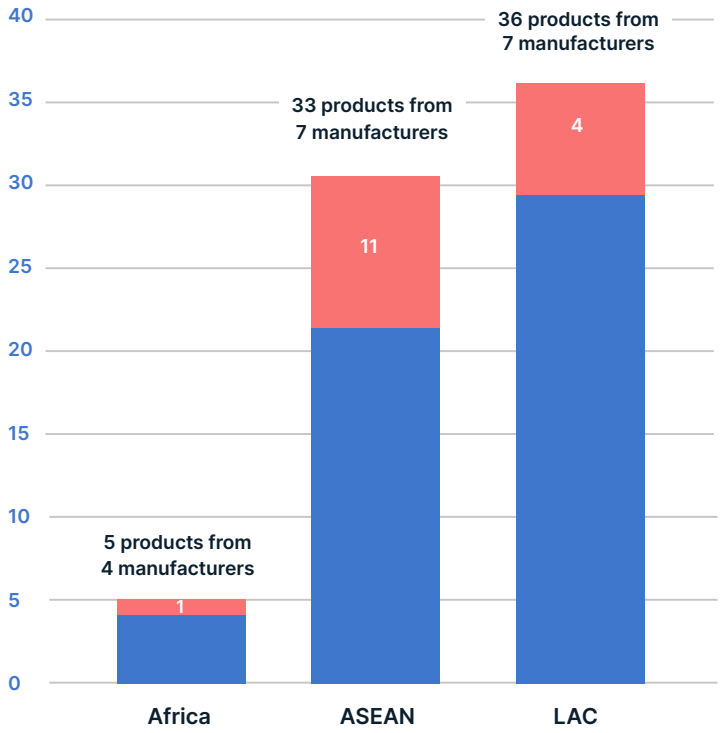
Establishing a sustainable and effective RVM ecosystem depends on a strong, timely, coherent, and enabling regulatory and governance infrastructure at national and regional levels. Political action, including implementing legislation to enable RVM and/or regional procurement, aligned with regional policy frameworks, will also be critical.

Unfortunately, publicly available data on approval timelines remain limited and unsystematic across all 3 regions. Based on a compilation of studies covering vaccines and other biological products (excluding COVID-19 vaccines), estimated timelines from biologics license application (BLA) submission to marketing authorisation range from approximately 11-36 months in 4 of the 6 ASEAN countries hosting drug-product-producing or fully integrated vaccine manufacturers; 9-15 months in 2 of the 5 relevant LAC countries; and 16-19 months in 1 of the 4 relevant countries in the African region. (Indicator 9.1) These figures, which span studies conducted between 2013 and 2024, are derived from heterogeneous methodologies and definitions and should therefore be interpreted with caution. Strengthening the systematic monitoring, tracking, and public reporting of these timelines is highly relevant to RVM and should be prioritized to enhance transparency and performance benchmarking.

As of September 2025, the NRAs of 9 of the 54 countries in the African region and 4 of the 10 ASEAN member states have attained at least Maturity Level 3 under the WHO Global Benchmarking Tool (GBT). Similarly, 6 of the 33 countries in the LAC region have been designated as PAHO National Regulatory Authorities of Reference. This status is broadly comparable to GBT Maturity Level 3 (ML3) as the region continues its progressive alignment with WHO standards. Those achievements confirm a growing country ability to provide effective oversight of vaccine use within their territories and, where applicable, of vaccine manufacturing activities conducted under their jurisdiction.

Obtaining marketing authorisation from an NRA with ML3 is also an important step for any manufacturer seeking to export vaccines. Currently, the majority of vaccines in the regions meet those requirements. Both ASEAN and LAC have over 30 vaccines approved by NRAs with ML3 or PAHO Reference Authority status, representing over 90% of the vaccines currently commercialised by regional producers. 5 of 7 vaccines in Africa fall within this category (Indicator 8.1b). Importantly, only vaccines authorised by an ML3 regulatory authority are eligible for WHO PQ – a requirement to supply the UNICEF Supply Division global procurement mechanism. As of 2025, only 20% of the vaccines produced by the 5 fully functional regional manufacturers across Africa, LAC and ASEAN have achieved WHO PQ. Of these, 11 are produced by 1 single manufacturer in ASEAN, 4 by 3 manufacturers in the LAC region, and 1 by a single African manufacturer. This reflects the mainly domestic focus of regional vaccine manufacturers. (Indicator 8.1a).

Figure 2: Number of products with marketing authorisation from NRA with WHO ML3 or above or with PAHO reference authority status, and with PQ



Portion of products with marketing authorisation that also received pre-qualification

RVMC'S ASSESSMENT AND WAY FORWARD

Strong and functional NRAs are a cornerstone of an effective vaccine ecosystem, ensuring the quality, safety, and reliability of vaccines available to populations.

Achieving higher maturity levels is therefore an important goal for all countries. However, when considering the ability of manufacturers to export – and thereby advance towards becoming regional suppliers – the situation is more nuanced. A higher maturity level is not the only pathway to enable exports. Regulatory harmonisation, through regional reliance frameworks or mutual recognition agreements, can also facilitate cross-border vaccine supply and strengthen regional integration. This approach can prove faster and more efficient since it does not require manufacturers to undergo multiple parallel, time-consuming, and costly processes.

As of the time of this report, none of the 3 regions have achieved full regulatory harmonisation at the regional level. This situation places continued pressure on the WHO PQ mechanism, which remains the most effective pathway for vaccine exports – particularly for access to the UNICEF Supply Division's pooled procurement. As regulatory harmonisation advances, ensuring that the WHO PQ programme is adequately resourced, both financially and in terms of staffing, will be critical to support a smooth and efficient progression towards RVM.

Establishing and operationalising regulatory reliance frameworks or mutual recognition agreements in all 3 regions will require sustained intra-regional collaboration and national legislative reforms, which take time to enact. Currently, there is no systematic tracking of countries that have adopted these enabling laws, making it challenging to assess how political commitments to RVM are being translated into concrete legal and institutional measures. Capturing legislative developments – such as treaty ratifications, amendments to procurement laws, and the introduction of policy incentives – will provide valuable insights into whether regions are establishing an enabling policy environment for RVM. (Indicator 10.1). Such data are presently unavailable.

CASE STUDY

ADVANCING REGULATORY HARMONIZATION TO ENABLE RVM

The establishment of the African Medicines Agency (AMA) is a landmark initiative towards harmonising regulatory systems across Africa. Historically, the 55 countries of the African Union have followed separate approval pathways, making it complex, costly, and time-consuming for vaccine manufacturers to bring products to market.

The African Union proposed AMA to improve access to quality, safe, and efficacious medical products in Africa. The AMA has the potential to streamline vaccine approvals, promote regulatory reliance, and support a more integrated RVM ecosystem.

Complementary initiatives such as the African Medicines Regulatory Harmonisation (AMRH) programme are already laying the groundwork for AMA's operationalisation. AMRH works with member states to align regulatory standards, including GMP and quality assurance protocols. It also provides technical guidance and capacity-building support to strengthen NRAs and help them meet international benchmarks. Furthermore, in June 2025, a memorandum of understanding was signed by 8 African NRAs with ML3 status, signalling intent to establish a regulatory reliance framework for accelerating the approval of medicines, vaccines, and medical devices.

However, establishing AMA has not been without challenges. Ratification of the AMA treaty by African Union member states has lagged, constraining the agency's scope and authority. To date, 39 countries have signed the treaty with 25 having ratified and deposited, allowing for operationalisation to begin. AMA's governance and financing structures remain under development, meaning it is not yet positioned to serve as a fully functional regulatory pathway for manufacturers.

In the meantime, WHO PQ remains the primary route for vaccine access in Africa. While not the only pathway, WHO PQ is critical for accessing UNICEF procurement, unlocking donor funding - particularly through mechanisms such as Gavi's African Vaccine Manufacturing Accelerator (AVMA) – and maintaining confidence in the safety, quality, and effectiveness of regionally produced vaccines. Nonetheless, comparable regulatory harmonisation frameworks have historically taken considerable time to establish, and in this context, AMA's progress to date deserves recognition.

Despite ongoing challenges, AMA's progress highlights the potential of regional regulatory hubs to strengthen health systems, foster collaboration, and enable regional production. Accelerating AMA's operationalisation, formalising reliance mechanisms, and investing in national regulatory capacity will be essential to transform political commitment into an enabling regulatory environment, unlocking Africa's regional vaccine market and ensuring the long-term sustainability of vaccine manufacturing on the continent.

Learnings from the emergence of the European Medicines Agency remain relevant and will help inform next steps, but Africa must continue to forge a path that best suits its own environment.

TECHNOLOGY AND SUPPLY

The availability of an adequate supply of effective vaccines that aligns with regional public health priorities depends on several interrelated factors – the development and manufacture of appropriate vaccines, access to relevant technologies, a skilled and well-trained workforce, and efficient supply chains.

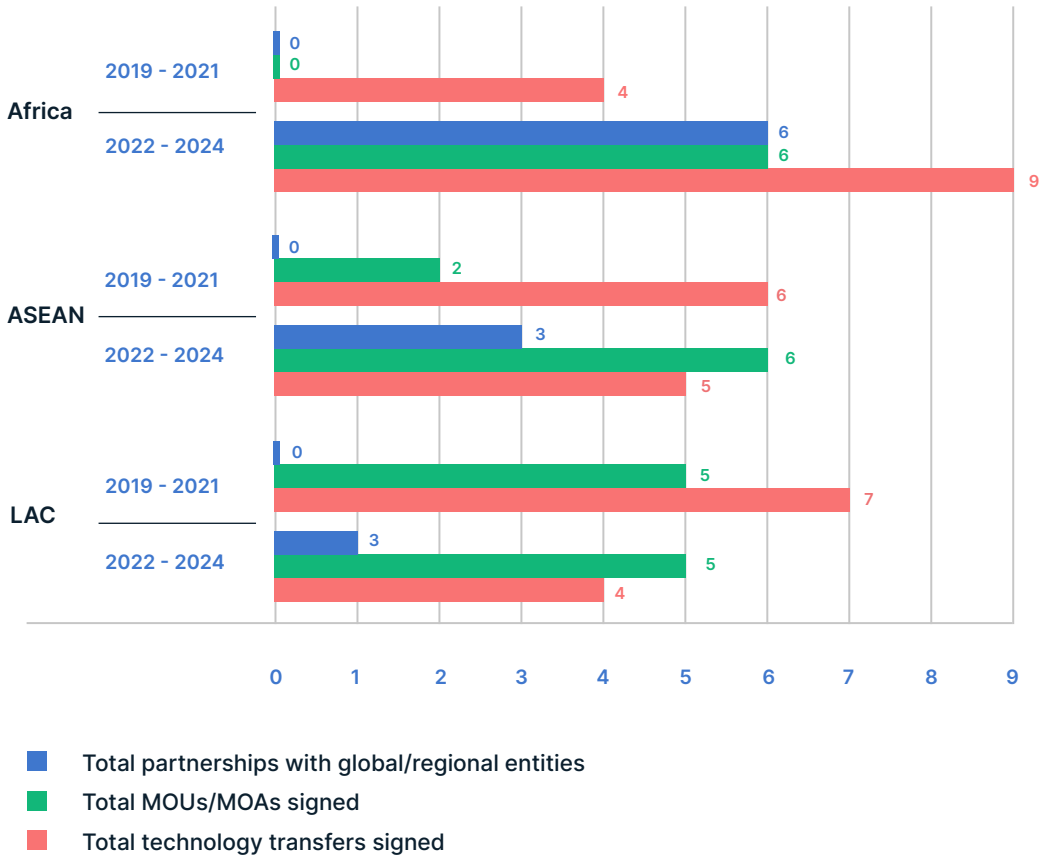
To meet both routine immunisation and outbreak response needs, regions must have access to the technologies required to produce vaccines for their priority diseases. As of 2025, manufacturers in LAC are using 7 out of 10 major technology platforms to manufacture at least 1 vaccine (with both DS and DP). In ASEAN, 5 of the 10 platforms are in use, while in Africa, only 2 are used (Indicator 12.1). The newer and more flexible platforms remain underrepresented across all 3 regions. However, these are essential, including for developing and producing vaccines for vaccine-preventable diseases that have not yet been addressed and for rapid-response applications.

A clinical development effort that aligns with regional health priorities is an important component of the RVM value proposition. Such alignment may contribute to vaccine equity by improving access to existing and needed vaccines, and to health security, by helping to ensure the availability of vaccines relevant to regional needs that may not attract global commercial interest. Achieving this alignment requires clinical trials led by local organisations and involving local producers capable of bringing those vaccines to market.

Between 2019-2021 and 2022-2024, the number of Phase III and IV trials (excluding COVID-19) across the 3 regions remained stable (Indicator 11.1a), although regional patterns differed. In LAC and in ASEAN, most trials (76% and 93% respectively) were sponsored by regional organisations with active participation from local companies, creating a foundation that can be leveraged to accelerate and promote local and regional innovation. In Africa, by contrast, there was a greater reliance on organisations or academic institutions outside the region as primary sponsors, with limited involvement from local manufacturers (20%) (Indicator 11.1b).

Establishing fully integrated vaccine manufacturing operations at a scale and quality suitable for regional or global supply is a multi-decade undertaking. Accessing existing technologies through technology transfer agreements can significantly shorten this timeline and lay the groundwork for home-grown innovation. Analyses by CHAI, PATH, and Africa CDC, complemented by desk research (see Figure 3) indicate that the number of publicly announced technology transfer agreements across the 3 regions remained broadly stable between 2019-2021 and 2022-2024 (17 and 18, respectively). Importantly, the number of technology transfers shifted towards Africa where there are now 9 compared to 4 in the prior period (Indicator 13.1), establishing a potential platform for future progress.

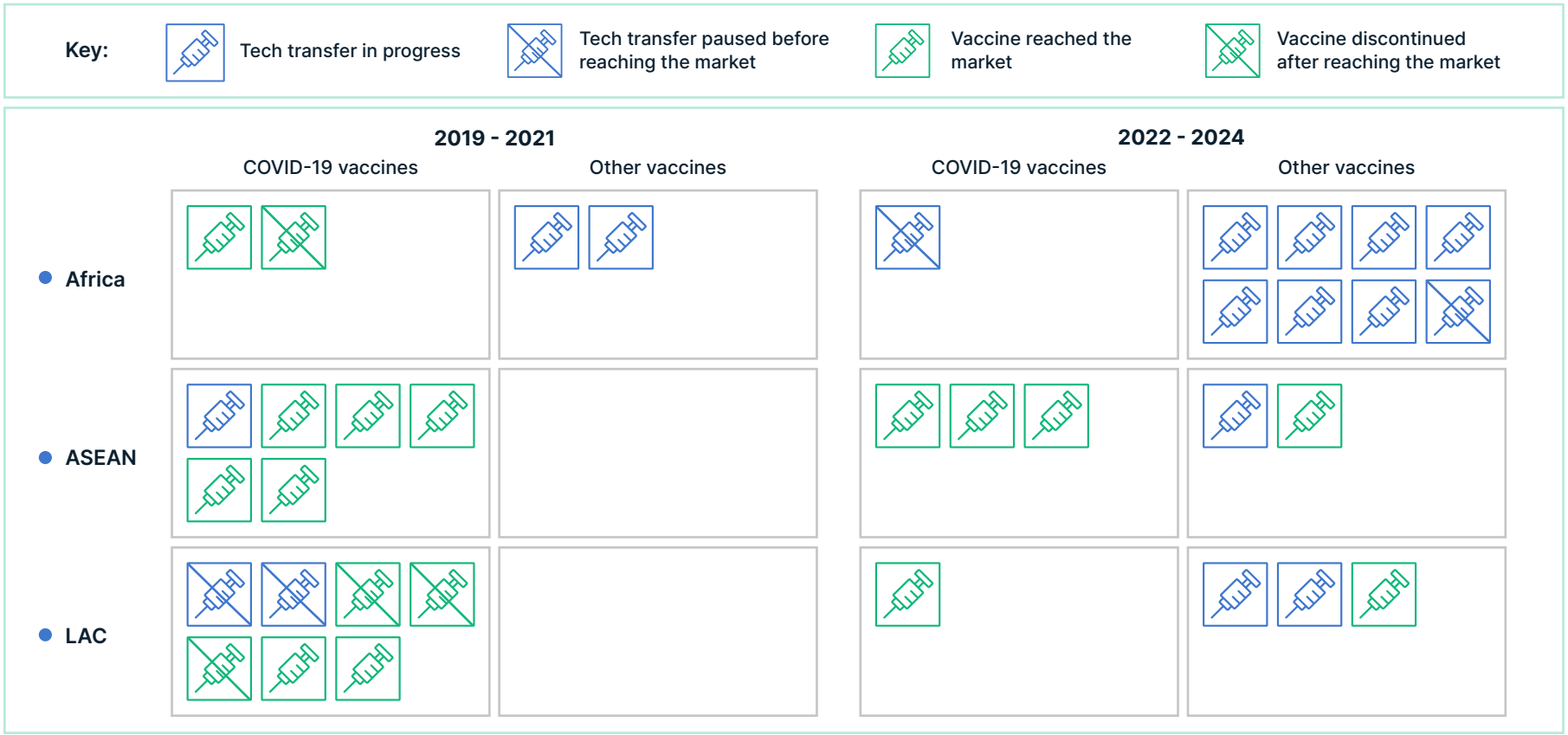
Figure 3: Total partnerships, MOUs, and technology transfers signed by regions in 2019-2021 versus 2022-2024



At the same time, a notable shift in focus occurred during this period. Attention moved away from COVID-19 vaccines (declining from 15 to 5 tech transfers) toward other disease areas. Of those 20 COVID-19 tech transfers signed in the period 2020-2024, 16 resulted in marketed products of which 4 were subsequently officially withdrawn and 3 were discontinued before completion. Those dynamics reflect the rapid contraction of market demand and commercial interest. When assessing success - defined as the completion of technology transfer and subsequent market introduction - a greater proportion of earlier agreements have resulted in marketed products, largely due to the longer period available for outcomes to materialize. Since 2020, 35 Memoranda of Agreement or Understanding have been signed, 9 of which pertain to COVID-19 vaccines. 9 also involve global or regional organizations, including 6 focused on establishing mRNA technology hubs. This trend reflects a possible accelerating momentum toward strengthening RVM capacity.

Partnerships are defined here as a collaborative arrangement between one or more vaccine manufacturers and one or more non-manufacturing organizations aimed at strengthening know-how, technical capacity, or infrastructure in support of vaccine production. Such partnerships focus on building general capabilities rather than developing or producing a particular vaccine.

Figure 4: Outcomes of technology transfers, 2019-2021 versus 2022-2024



Success in these areas depends fundamentally on the availability of a specialised regional workforce and on the reliability of well-functioning supply chains, both upstream, for access to critical raw materials and components, and downstream, for efficient vaccine storage, distribution, and delivery. Both enablers are widely recognised as regional priorities and essential pillars of sustainable vaccine manufacturing.

While workforce development initiatives are underway (at Institut de Pasteur Dakar in Senegal and Biovac in South Africa, for example), the limited availability of consistent data in each region makes it difficult to assess progress and to identify specific capacity gaps that must be addressed to strengthen the resilience of the RVM ecosystem (Indicators 14.1 and 15.1).

RVMC'S ASSESSMENT AND WAY FORWARD

Technology transfer is a vital entry point for regional vaccine manufacturers, where domestic research and development ecosystems are still emerging. In partnership with CHAI, RVMC is developing a technology transfer tracker to monitor progress and identify challenges along the pathway to commercial success. The tracker will provide partners with consolidated visibility into the expected product pipeline while also highlighting potential barriers to commercialisation, enabling partners to deliver targeted support where it is most needed.

However, achieving greater self-reliance in RVM depends on building local and regional innovation capacity that allows manufacturers to design, test, and produce vaccines aligned with regional health priorities. This will require targeted investment in R&D infrastructure, clinical development, and the skilled workforce needed to translate technologies into new products.

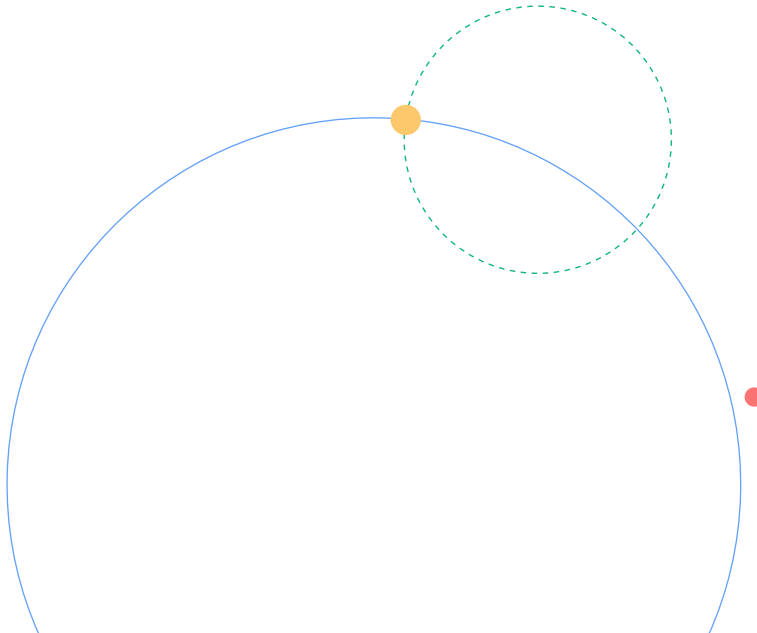
Platform diversification is also critical across the regions. The right mix of established technologies and newer, more flexible platforms – such as nucleic acid, subunit protein-based, and viral vector-based platforms – is key to ensuring the fulfilment of regional routine immunisation goals and outbreak preparedness. To balance these needs, regional partners must identify and invest in priority technologies that balance preparedness with predictable demand. Achieving this balance will require established, sustained collaboration among funders, governments, and industry.

Ultimately, the goal is to establish a balanced ecosystem with an optimal number of manufacturers, recognising that too few may limit access, while too many may compromise long-term sustainability. Such an ecosystem should provide the technological platforms to meet regional health priorities and ensure timely and equitable access to the newest, most effective, quality-assured vaccines.

CASE STUDY

STRENGTHENING RVM THROUGH STRATEGIC PARTNERSHIPS AND TECHNOLOGY DEVELOPMENT

PT Bio Farma (Persero) is Indonesia's state-owned vaccine and biologicals manufacturer and one of the oldest and largest vaccine producers in the ASEAN region.
Founded in 1890 and headquartered in Bandung, West Java, the company operates as a strategic public enterprise under the Ministry of State-Owned Enterprises, with a mandate to ensure national vaccine security and public health resilience.



As the primary producer for the national Expanded Programme on Immunisation (EPI), PT Bio Farma supplies nearly all routine vaccines required by the Ministry of Health, benefitting from a large and predictable domestic market that has supported reinvestment in production facilities, workforce development, and research. Consistent government backing through fiscal incentives, R&D funding, and policies promoting domestic manufacture have further strengthened its technological and supply base.

Over the past decades, PT Bio Farma has developed extensive drug-substance (DS) and drug-product (DP) capabilities. This has been made possible by technology transfers from partners such as the International Vaccine Institute (IVI), the Baylor College of Medicine, BioNet and collaborations with the Gates Foundation, CEPI and WHO that supported diversification into new technologies, including participation in the WHO mRNA Technology Transfer Programme.

These partnerships were possible due to PT Bio Farma's proven record as a reliable, high-quality manufacturer. Looking ahead, PT Bio Farma is starting to expand its export footprint and engaging in technology-transfer and South-South partnerships such as the collaborations with Atlantic Lifesciences (Ghana) and Biovax (Kenya).

PT Bio Farma's experience highlights both progress and remaining gaps in ASEAN's vaccine ecosystem. Despite its strong technical capacity, regional expansion has been constrained by differing regulatory frameworks, limited procurement coordination, and fragmented demand. Greater regional cooperation could help create the scale and consistency needed to maximise the contribution of manufacturers like PT Bio Farma to regional vaccine security.

AN EMERGING VIEW OF THE STATUS OF REGIONALISED VACCINE MANUFACTURING

The data presented in this baseline report indicate that RVM remains in its formative stages of development. The foundations for sustainability are emerging, but the conditions required to secure long-term success are not yet fully in place. This reflects the different starting points and developmental trajectories across regions.

While national initiatives have been instrumental in establishing the foundations of vaccine manufacturing, progress towards integrated regional systems remains limited. As a result, most activity continues to occur within national borders, with few connections linking production, regulation, and demand across countries.

Not all manufacturers must operate at a regional scale or develop fully integrated capabilities. Instead, a clearer understanding of how diverse business models can collectively contribute to shared regional objectives for RVM is needed. Therefore, strengthening collaboration and knowledge exchange within and across regions will be essential to building on existing national investments, achieving greater complementarity among vaccine portfolios, and creating more resilient and self-sustaining systems.

As the case studies illustrate, meaningful progress will depend on translating political commitment into practical mechanisms that align procurement, financing, technology transfer, and regulation over time.

RVMC views this baseline not as a final assessment, but as a foundation for continued collaboration and learning. Regular, comprehensive data collection, transparent reporting, and the exchange of experience within and between regions will be vital to monitoring progress and identifying effective practices. The following section presents each region's perspective on the data, their assessment of the current RVM baseline, and the actions underway to advance collective progress.

REGIONAL PERSPECTIVES: AFRICA

Authored by The Africa Centres for Disease Control and Prevention (Africa CDC)

We welcome this inaugural RVM Status Report as an important step in establishing a shared evidence base to assess progress and guide collective efforts to advance RVM in Africa and other regions. The COVID-19 pandemic, mpox, Marburg, Cholera and other recent health emergencies have reaffirmed Africa's determination to achieve health sovereignty. Building regional manufacturing is no longer aspirational, it is essential to ensure timely access, resilience, and equity for African populations.

The report rightly underscores the urgent need to expand, consolidate, and diversify Africa's vaccine manufacturing base and ecosystem, a priority that sits at the heart of the Africa CDC Framework for Action. The findings align with the focus areas identified through this strategic initiative: strengthening vaccine manufacturing capacity, creating a predictable market, regulatory systems strengthening and harmonisation, and mobilising sustainable financing. These priorities were reaffirmed during the 2nd Vaccines and Other Health Products Manufacturing Forum for African Union Member States, co-convened by Africa CDC, Gavi, and RVMC, and hosted by Egypt's Unified Procurement Authority in February 2025. This effort forms part of the broader Platform for Harmonized African Health Products Manufacturing (PHAHM), which extends beyond vaccines to include diagnostics, therapeutics, and other essential health products, reflecting Africa CDC's integrated vision for health product security.

Africa CDC welcomes RVMC's emphasis on building stable and predictable demand for regionally produced vaccines. A reliable market is essential to give African manufacturers the certainty to invest and scale. The African Pooled Procurement Mechanism, being developed under Africa CDC's leadership, aims to aggregate demand and enable the purchase of African-made health products, including vaccines. We appreciate RVMC's convening role in facilitating collaboration with the PAHO Revolving Fund, whose experience offers valuable lessons for designing a mechanism suited to the African context.

Regulatory strengthening and harmonisation remain central to unlocking Africa's regional market.

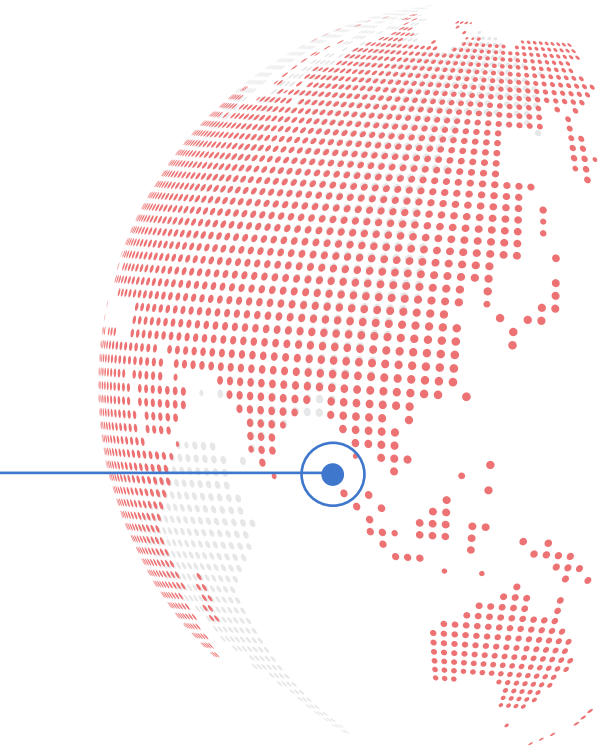
We welcome RVMC's recognition of progress made by African NRAs in achieving WHO Maturity Level 3, a key step towards export readiness. The recent Memorandum of Understanding among these NRAs to advance regulatory reliance mechanisms marks an important milestone that complements the ongoing establishment of the African Medicines Agency (AMA), which will be crucial for enabling faster, more coordinated vaccine approvals across the continent.

Africa CDC also agrees with the findings about the growth in technology transfer agreements in the region – a critical foundation for establishing viable product pipelines. In the long term, these must be complemented by sustained investment in regional R&D and innovation ecosystems to design, test, and produce vaccines in Africa, for Africa. This includes developing flexible platforms, building a skilled workforce, and strengthening supply chains to support both routine immunisation and outbreak response.

Financing remains a fundamental challenge. As the report highlights, Africa's vaccine manufacturing initiatives are disproportionately funded by donors, an approach that is neither sustainable nor conducive to long-term resilience. To address this, Africa CDC has launched a 3-pillar strategy focusing on domestic resource mobilisation, innovative financing, and blended finance models. We look forward to seeing progress reflected in future assessments as countries and partners begin implementing these approaches.

Data and transparency are essential to tracking progress, evaluating interventions, and informing evidence-based decision-making. In October 2025, Africa CDC launched the African Manufacturing Market Intelligence and Network Analysis (AMMINA) platform to provide comprehensive, accessible data on manufacturers, production capacities, and market trends. We look forward to working closely with RVMC to leverage this data in the next report cycle, ensuring that Africa's continued progress towards RVM is accurately captured and effectively supported.

Finally, Africa CDC remains committed to ensuring that future assessments measure not only commitments and capacities but also concrete outcomes. Partnerships that are based on co-development, mutual benefit, and accountability will be key to sustaining this progress and achieving a more balanced global health architecture.



REGIONAL PERSPECTIVES: ASEAN

Authored by the National Vaccine Institute, Thailand, as the focal point for AVSSR

Strengthening information sharing is one of the key priorities under the ASEAN Vaccine Security and Self-Reliance (AVSSR) Strategic Plan. Accordingly, we welcome this first Status Report, which contributes to building a shared evidence base to track progress, identify opportunities and inform joint efforts to enhance the region's vaccine production capabilities.

In particular, we are encouraged that the report highlights the diversity and depth of Southeast Asia's vaccine manufacturing landscape. With proven strength as a recipient of technology transfers and steady progress in translating agreements into production, the region hosts several recognised vaccine manufacturers such as BioFarma (Indonesia) and Siam Bioscience (Thailand). The region also comprises a diverse mix of public and private manufacturers that operate primarily at the national level but are increasingly contributing to regional and global supply chains. In parallel, Southeast Asia is strengthening its role as a hub for clinical research and development, with an increasing number of regionally sponsored clinical trials.

This innovative environment provides a strong foundation for diversifying platform technologies, including those that enable rapid response, which is essential for regional health security. It also generates opportunities for South-South collaboration, enabling Southeast Asian manufacturers to work more closely with partners beyond the region on products and platforms of shared interest. Nonetheless, sustaining and expanding this ecosystem will require continued investment. While the region has demonstrated dynamism and a track record of private sector financing, governments are also beginning to play a more active role in supporting vaccine manufacturing and development. This growing public sector engagement, alongside deeper industry collaboration, holds potential for advancing regional capacity in the years ahead.

Translating the region's capacity into sustainable supply will depend on developing mechanisms that connect production with demand. With a population exceeding 600 million, ASEAN Member States represent a significant and expanding vaccine market.

With the support of RVMC as an inter-regional convening platform, we have commissioned research to explore strategies for leveraging this market to support regional production, including through pooling demand. Findings from this initiative are expected to guide discussions in 2026 on the second phase of the AVSSR strategic plan, which is currently under development and will undergo further consultation. Regardless of which model emerges as most suitable for the region, such dialogue on regional demand may provide a basis to explore practical examples of potential intra- and inter-regional collaboration.

Finally, regulatory harmonisation is central to unlocking the full potential of the regional market. The ASEAN Pharmaceutical Regulatory Framework, adopted in 2023, represents a step towards addressing regulatory challenges and strengthening cooperation among national authorities. However, regulatory alignment for regionalised vaccine manufacturing is only one part of a broader effort. A holistic approach to regulatory harmonisation – encompassing research and development, manufacturing, outbreak response, and linkages across different product types – will be essential to achieving sustainable, regional self-reliance.

As ASEAN Member States expand collaboration on immunisation-related data sharing through initiatives such as the ASEAN Vaccine Capacity Survey and the ASEAN Vaccine Dashboard, a digital platform currently under development, we look forward to ongoing engagement with RVMC on future editions of this report. We also remain committed to working with RVMC and other partners to strengthen data collection and quality, generate deeper insights into regional progress and capacities, and enhance our shared understanding of Southeast Asia's evolving vaccine manufacturing ecosystem.

REGIONAL PERSPECTIVES: LATIN AMERICA AND THE CARIBBEAN

Authored by the Pan American Health Organisation

We welcome this first report of RVMC in tracking progress towards a sustainable regionalised vaccine manufacturing ecosystem around the globe.

We are pleased that the findings highlight the significant diversity of our region's vaccine manufacturing landscape, encompassing a wide range of business models, product portfolios, platforms, technologies, and technical capacities. Continued investment in technologies, manufacturing capabilities, and supply systems will be essential to keep pace with scientific advances and the evolution of vaccine development. This was reaffirmed in June 2025 during our regional workshop "Strengthening Value Chains for Production in Latin America and the Caribbean" organised in collaboration with RVMC, the Government of Canada, and Colombia's Ministry of Health and Social Protection. Such investment supports not only the long-term sustainability of manufacturers but also the capacity to keep up with technological developments and meet the changing health needs of the region's populations.

PAHO welcomes RVMC's emphasis on building an enabling regional market, recognising that reliable demand consolidation and regulatory strengthening are central to this goal. We continue to support the region's NRAs in their transition and designation as WHO-listed authorities. Achieving this status will advance regulatory reliance, enhance confidence in regional oversight, and ensure that products authorised by these authorities are eligible for both regional and global procurement.

The recent amendments to the Revolving Fund further demonstrate the potential of pooled procurement to advance regionalised manufacturing. In 2020, regional manufacturers represented less than 1% of its total vaccine procurement value. Following the 2024 resolution adopted by PAHO Member States to utilise the Revolving Fund to incentivise regional production and innovation, the Revolving Fund focused its efforts to increase investments and partnerships with regional suppliers. In 2 years, these figures have increased substantially.

The Revolving Fund has agreements to supply almost one quarter of procured volume, and around 30% of procurement value from regional manufacturers. These outcomes demonstrate important progress in aligning regional pooled procurement strategies with regionalised manufacturing capabilities and priorities.

While the PAHO's Revolving Fund cannot be considered a suitable model for all contexts, it continues to serve as a valuable example for other regions considering establishing similar mechanisms. PAHO has signed MoUs with Africa CDC and WHO-EMRO to share practices, experiences, and lessons learned with the Revolving Fund. With RVMC's support, PAHO is pleased to collaborate further with partners, including Thai NVI, to share lessons learned on the design and implementation of pooled procurement systems. Our experience highlights the importance of end-to-end technical support to Member States, transparency, and institutional inclusiveness in building trust and ensuring effective and sustainable operations.

Above all, Member States' ownership and solidarity are critical principles for its successes. It also requires sustained investment from member states in immunisation. Furthermore, although considerable progress has been made, the region has many opportunities to leverage the Revolving Fund further to incentivise vaccine manufacturing. PAHO remains committed to working with global and regional partners to explore additional ways to strengthen healthy vaccine markets and support the sustainable growth of regionalised production.

Looking ahead, PAHO welcomes RVMC's next report in 18 months, through which we hope to see continued progress across key indicators reflecting the shared priority of this agenda for PAHO and its Member States. During this period, PAHO will continue working closely with RVMC to refine data collection and analysis, ensuring that progress is accurately tracked and targeted support is provided where needed and appropriate to share lessons as well as learn from other regions.

CALL TO ACTION

A more comprehensive evidence base is essential to identify where interventions are effective and where further effort is required. Current data limitations are most notable for workforce availability and development and country-level progress on policies and legislation that enable RVM. Closing these gaps through collaboration and improved access to market and supply data will enhance the relevance of future assessments. This will require data-holding institutions to strengthen information systems and ensure greater quality and consistency.

RVMC is committed to supporting these efforts while assessing progress against secondary indicators – such as manufacturing input materials – to deepen a collective understanding of progress and to remain alert to potential emerging risks on existing supply and demand dynamics as RVM evolves. It is also important that regions themselves account for progress on RVM, using the common language introduced in this report, in order to keep global and regional stakeholders informed.

Achieving meaningful progress in RVM depends on translating commitments into tangible, coordinated action and establishing more effective partnerships between the public and private sectors. While the building blocks are well understood, the challenge now lies in charting a path that is politically, financially, and technically feasible. Consistent with our Vision and RVMC's assessment of the data, 3 priorities remain central to achieving sustainable RVM:

- **Predictable demand:** Translate demand for vaccines into predictable regional markets through clear policy and budgetary commitments, supported by mechanisms such as pooled procurement, that drive uptake of regionally produced vaccines.
- **Regulatory strengthening and harmonisation:** Stronger and better-aligned systems that reduce duplication, accelerate approvals, and uphold quality standards.
- **Technology and supply diversification:** Investment in flexible production platforms, clinical development, and well-functioning supply chains to strengthen resilience.

Delivering on these priorities will require sustained investment in infrastructure, R&D, technology, workforce development, and vaccine procurement to build lasting regional capacity. Progress depends on strong alignment among regional partners. In particular, governments need to transform high-level commitments into fully funded implementation programmes that are aligned with regional plans and guided by clear timelines and accountability mechanisms. The private sector and philanthropies should actively support these efforts through coordinated technical and financial assistance. Public investment (both donor and domestic), in turn, must be structured to leverage access terms that encourage innovation and address unmet regional health needs, ensuring each step forward strengthens both sustainability and equity.

Experience across regions demonstrates that manufacturing ecosystems can mature rapidly when political commitment aligns with strategic investment and coordination and we are seeing that regions can learn from each other's experiences. Ultimately, sustained collaboration – anchored in predictable demand, strengthened and harmonized regulation, and diversified technology and supply – is integral to a resilient, regionally led vaccine manufacturing system that prioritises local production, strengthens regional health security, enables vaccine equity, and grows economies.

ANNEX A: MAIN DATA SOURCES

A detailed list of all data sources can be retrieved in the detailed methodological annex available on the RVMC website at www.rvmc.net.

1. WHO Full Vaccine Product List [Internet]. [cited August 2025]. Available from https://www.who.int/publications/m/item/full-vaccine-product-list
2. How has the African vaccine manufacturing landscape changed in the last year? [Internet]. [cited 18 October 2024]. Available from https://www.clintonhealthaccess.org/report/how-has-the-african-vaccine-manufacturing-landscape-changed-in-the-last-year
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