RVMC
Regionalized Vaccine Manufacturing Collaborative

CLINTON HEALTH ACCESS INITIATIVE

Market-shaping strategy for a sustainable vaccine manufacturing footprint in ASEAN

May 2026

Key takeaways

- The COVID-19 pandemic exposed critical vulnerabilities in ASEAN's regional vaccine ecosystem. Heavy reliance on external suppliers and the limited ability of regional manufacturers to repurpose capacity left member states exposed when global demand surged. Since then, approximately US$1 billion in investments have been committed to advance regionalized vaccine manufacturing (RVM) across ASEAN, generating significant momentum behind the ecosystem.
- Strengthening RVM in ASEAN is ultimately about solving two interdependent problems: building the strategic supply chain resilience needed for an effective pandemic response and ensuring that regional manufacturers are commercially sustainable to maintain that readiness. The analysis presented in this paper is framed around these twin imperatives.
- The current manufacturing landscape indicates three major structural risks to achieving a resilient and commercially viable RVM ecosystem:
    - Manufacturing capacity is currently concentrated among a limited number of regional manufacturers. PT Bio Farma in Indonesia is estimated to account for around 60–90% of total installed regional capacity. While this represents an important regional asset, such concentration may create supply security risks in the event of manufacturing disruptions or demand surges, underscoring the need to strengthen complementary capacity across the region.
    - Fragmented and unharmonized regulatory frameworks across ASEAN significantly increase the time, cost, and complexity of cross-border market access, limiting the ability of manufacturers to serve the regional market.
    - The absence of viable routine demand, driven by the modest size of the ASEAN vaccine market and fragmented procurement across ten[1] member states, undermines manufacturers' ability to maintain the ever-warm, pandemic-relevant capacity that effective emergency response requires.
- To address these risks and achieve a sustainable and pandemic-responsive RVM footprint, three interconnected intervention areas have been identified:
    - Complementary manufacturing capacity should be deliberately strengthened by supporting select manufacturers in developing drug substance capabilities at epidemic-relevant scale.
    - The regulatory environment must be strengthened to support regional market access, with regulatory reliance mechanisms offering a practical near-term pathway to reduce time to market ahead of full harmonization.
    - Regional demand should be consolidated to create the viable peacetime market conditions needed by manufacturers to sustain ever-warm capacity, orient them towards supplying the regional ASEAN market, and reduce their dependence on external markets to achieve commercial viability.

[1] This analysis predates Timor-Leste's admission to ASEAN and therefore covers ten member states only

Background and Context

Despite established **Drug Substance** (DS) and **Drug Product** (DP) manufacturing capabilities across the Association of Southeast Asian Nations (ASEAN), the COVID-19 pandemic exposed critical vulnerabilities in the regional vaccine ecosystem. Heavy reliance on external suppliers left ASEAN member states exposed when global demand surged[2]. Access to vaccines across the region varied, with better-resourced countries able to negotiate early access while others faced prolonged delays[3]. Compounding this, the limited ability of regional manufacturers to repurpose existing infrastructure or rapidly scale-up production in response to the novel pathogen constrained the overall regional response capacity[2]. Together, these gaps underscored the urgent need to strengthen the regionalized vaccine manufacturing (RVM) ecosystem and build a more resilient foundation for pandemic preparedness and response.

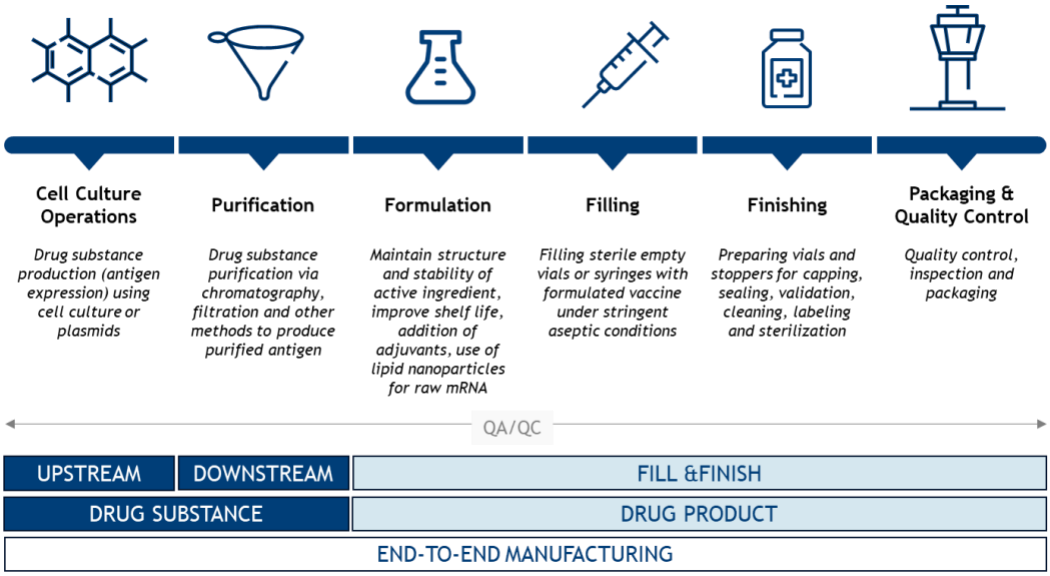

Figure 1[4,5]*: Overview of vaccine manufacturing stages: Drug Substance (DS) and Drug Product (DP), and end-to-end manufacturing*

Since the onset of the pandemic, an estimated US$1 billion in investments have been committed to advance RVM across ASEAN[6]. Average annual announced investments reached approximately US$153 million between 2022 and 2024[7]. Notably, private sector investors played the dominant financing role, accounting for ~50% of announced funding, while domestic government resources contributed ~36% and public and multilateral donors the remaining ~14%[7].

The current manufacturing landscape reflects both this investment momentum and its limitations. As depicted in Figure 2, there are presently 24 active vaccine manufacturers across the region, but they vary significantly in maturity[6]. Of these, 15 fall in Segment 1, meaning they have commercial scale facilities with active commercial production or an ongoing Vaccine Technology Transfer[6]. PT Bio Farma

[2] "ASEAN Regional Vaccine Manufacturing and Development: Regional Synthesis Report," World Bank Group, 2023
[3] "Southeast Asia and COVID-19 Vaccines Explained," Asia Society Policy Institute, 2021
[4] "Towards Vaccinating the World: Landscape of Current COVID-19 Supply Chain and Manufacturing Capacity, Potential Challenges, Initial Responses, and Possible "Solution Space" - a Discussion Document," Prepared by CEPI for IFPMA summit, 2021
[5] "Expanding global vaccine manufacturing capacity: Strategic prioritization in small countries," PLOS Global Public Health, 2023
[6] CHAI Analysis based on publicly announced financing commitments and manufacturer interviews
[7] "Towards Regionalized Vaccine Manufacturing: First Status Report," RVMC Secretariat, 2025

in Indonesia stands out due to its vast scale, producing ~2.5 billion[8] doses (2024) across a multi-vaccine portfolio, and maintaining a meaningful export footprint. The majority of the remaining manufacturers operate primarily at the national level, serving domestic markets without the scale or product diversity needed to develop a resilient regional supply base. This concentration of capacity in a single manufacturer, while a significant asset, highlights a structural fragility and a need to strengthen complementary capacity across the region.

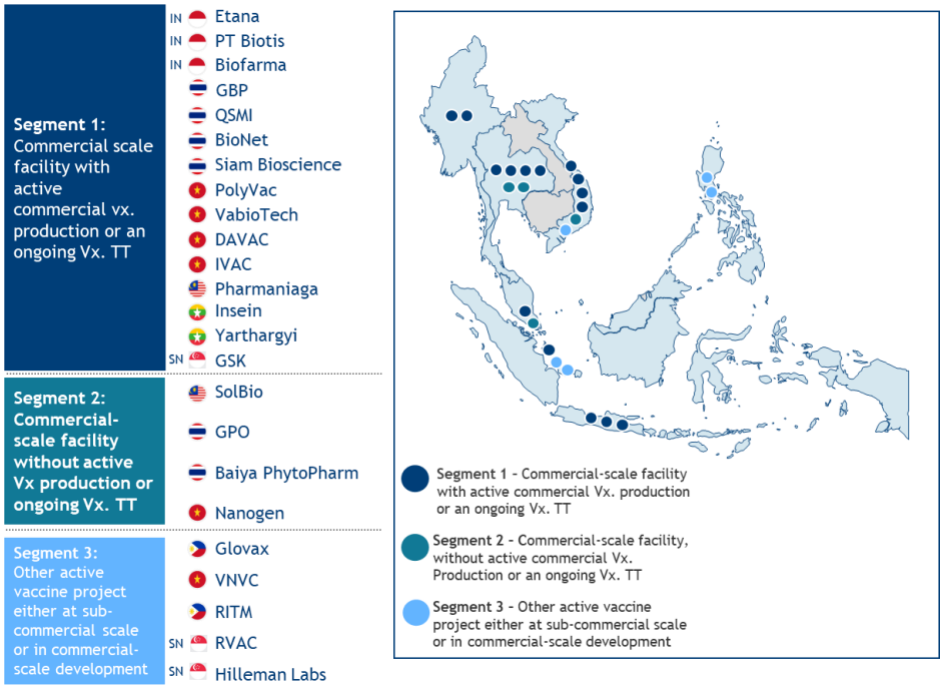

***Figure 2**: 24 active vaccine manufacturers in ASEAN segmented by commercial scale and Vx technology status*

From a demand perspective, ASEAN is a diverse bloc of ten[9] member states spanning low-, middle-, and high-income classifications[10], a heterogeneity that shapes the procurement and financing structures across the region. Seven member states self-finance their national immunization programs, while the remaining three procure through UNICEF with Gavi support, although all three are in transition and expected to graduate from Gavi eligibility in the coming years[11]. With a projected birth cohort of just ~10 million in 2035, ASEAN's estimated routine immunization demand is expected to reach ~220 million doses annually by 2035[12]. This represents a much smaller volume in comparison to LAC (~400 million doses, ~8 million birth cohort) and Africa (~1.1 billion doses, ~44 million birth cohort).[12] China (~240 million doses, birth cohort ~8 million) represents a market of similar scale to ASEAN, whereas India (~560 million doses, birth cohort ~22 million) is significantly larger, though both benefit from integrated demand structures unlike ASEAN, where demand is distributed across ten member states[9,12]. Indonesia, the Philippines, and Vietnam alone account for ~80% of total regional volume, leaving the remainder fragmented across seven smaller markets[9,12].

[8] Biofarma 2024 Annual Report
[9] This analysis predates Timor-Leste's admission to ASEAN and therefore covers ten member states only
[10] World Bank Group Income classification
[11] Countries' GAVI eligibility Status, July 2025
[12] Linksbridge demand forecasts

Against this backdrop, this study, commissioned by the Regionalized Vaccine Manufacturing Collaborative (RVMC) Secretariat, and jointly developed with Clinton Health Access Initiative (CHAI), aims to map the current state of RVM in ASEAN, identify risks and gaps that must be addressed to achieve a manufacturing footprint capable of sustaining routine immunization and responding effectively to future health emergencies, and outlines the targeted interventions required to get there. This work builds on RVMC's Framework, which sets out 8 pillars essential for regionalized vaccine manufacturing[13], as well as RVMC's Vision for Regionalized Vaccine Manufacturing[14], which identifies the foundational priorities for achieving sustainable RVM ecosystems globally. This whitepaper is an extension of that vision, tailored to the ASEAN context, examining how the key pillars of a regional manufacturing ecosystem interact and what it will take to make them work together toward durable, regionally owned outcomes.

To inform this assessment, CHAI and the RVMC Secretariat conducted a structured review of the RVM landscape in 2025, drawing on eight manufacturer interviews, five site visits, consultations with financiers and other ecosystem stakeholders, and secondary analysis of procurement, regulatory, and financing dynamics across the region (Details in Appendices 1 and 2). The assessment examined key dimensions of the vaccine manufacturing ecosystem, including manufacturing capabilities, technology access, financing, demand and procurement, and the regulatory environment, to identify the most significant gaps and risks, and to propose targeted market-shaping recommendations. In this whitepaper, we prioritize the areas demanding the most attention and propose market-shaping recommendations accordingly.

The findings are intended to inform global and regional partners, financiers, and governments on the concrete actions needed to sustain a resilient vaccine manufacturing ecosystem in peacetime, capable of responding effectively to a future health emergency.

The case for Regionalized Vaccine Manufacturing in ASEAN

Crafting a strategy for RVM requires first establishing why the endeavor is worth pursuing.

As outlined in the previous section, the modest size of the ASEAN public market makes it an insufficient commercial opportunity for regional manufacturers on its own. The modest size of the public market, compounded by demand fragmentation across member states that are largely self-procuring with disjoint regulatory requirements, makes achieving the economies of scale necessary for commercial viability structurally difficult. As such, most regional manufacturers do not view the ASEAN public market as their primary market.

Yet the experience of some manufacturers in the region points to a viable strategic alternative. By developing differentiated product portfolios that address underserved needs in global markets, such as the novel oral polio vaccine (nOPV), some manufacturers have built businesses partly cross-subsidized by global market revenues. This indicates that commercial sustainability for manufacturers in the region is more likely to be achieved through global and/or private market participation than through dependence on ASEAN public procurement alone. Product portfolio decisions and market positioning must therefore extend well beyond the region.

An even stronger rationale for investing in the RVM ecosystem, however, is to build strategic supply chain resilience required for an effective pandemic response. While external suppliers may offer more

[13] "A Framework for Enhancing Vaccine Access Through Regionalized Manufacturing Ecosystems," RVMC, 2024
[14] RVMC Vision, 2025

cost-competitive alternatives for routine immunization under normal circumstances, the COVID-19 pandemic exposed the fragility of a health security architecture built on imports. A fit-for-purpose regional manufacturing base, developed and sustained during 'peacetime', represents an essential hedge against future supply shocks. Regional manufacturers with established pandemic-relevant platforms, qualified facilities, and resilient supply chains are materially better positioned to surge capacity and respond when a public health emergency demands it.

Market risks to achieving pandemic preparedness and routine sustainability

While the preceding section has outlined the rationale for a stronger RVM ecosystem, several structural risks in the current landscape may obstruct achieving this goal. The most significant of these include a concentrated manufacturing footprint, a fragmented regulatory environment that limits regional market access, and an absence of viable regional routine demand to sustain manufacturers during peacetime.

A. Concentrated manufacturing footprint

ASEAN's installed vaccine manufacturing capacity[15] is, in total, sufficient to meet projected routine immunization demand through 2035[16]. However, an estimated ~60-90% of that capacity is concentrated at PT Bio Farma in Indonesia[9]. While Bio Farma represents a strong regional asset, a high concentration of large-scale capacity may create supply security risks during manufacturing disruptions, regulatory bottlenecks, or sudden demand surges like a pandemic scenario.

Beyond Bio Farma, the capacity residing with remaining manufacturers in the region is largely fragmented and underutilized. The majority of these manufacturers are focused on DP manufacturing for domestic markets due to capability constraints and the limited interest in DS technology transfers from originators, as indicated by some in our consultations with them. Finishing and packaging of vaccines from biological ingredients produced elsewhere, leaves manufacturers commercially constrained and dependent on external suppliers for key inputs. In a pandemic, when global supply chains come under the most pressure, this dependency would be acutely felt. In the longer term, end-to-end manufacturing capacity is likely to be key for manufacturers to support pandemic preparedness goals and achieve commercial viability.

Additionally, while manufacturers across ASEAN are collectively using five of ten major vaccine technology platforms[17], existing assessments have not examined platform-specific capacity and flexibility in sufficient granularity to conclusively evaluate pandemic readiness. Until this question is appropriately investigated and addressed, the region's apparent manufacturing breadth may not translate into meaningful, platform-relevant capacity for pandemic preparedness and response.

B. Complex regulatory pathways

A basic requirement for market access is a functioning regulatory architecture. Here, ASEAN faces a structural challenge. Varying NRA maturity across member states (Figure 3), combined with country-specific regulatory requirements that differ markedly in scope and standard, significantly increase the

[15] Self-reported capacity collected through manufacturer engagements
[16] Linksbridge demand forecasts for ASEAN
[17] "Towards Regionalized Vaccine Manufacturing: First Status Report," RVMC, 2025

time, cost, and complexity for regional manufacturers seeking to bring their products to market across borders. A further barrier to export is that many local manufacturers lack WHO prequalification, the internationally recognized standard for vaccine quality, safety, and efficacy required to access procurement channels such as UNICEF. Compounding this, the absence of bilateral regulatory agreements between countries means the pathway for products approved in one market to be licensed or exported to another is complex. While emergency use pathways and regulatory flexibility can accelerate approvals during a pandemic, as seen with COVID-19 vaccines, it remains uncertain if these mechanisms are sustainable[18]. In the absence of meaningful regulatory harmonization, cross-border trade will remain limited regardless of manufacturers' production capabilities, and the vision of a regionally integrated vaccine manufacturing ecosystem may be difficult to realize.

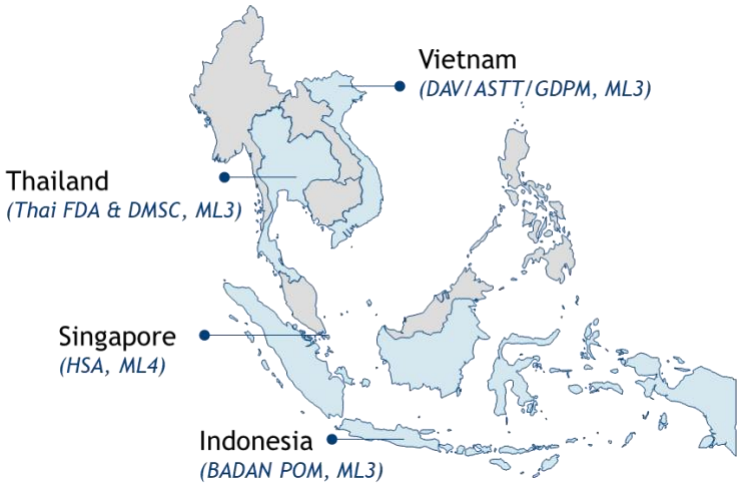

***Figure 3**: Four NRAs in ASEAN are recognized by WHO as having achieved ML3/ML4*

C. Absence of viable routine demand

In addition to these technical risks, an additional but significant risk lies in the potential absence of geographically diversified "**ever-warm**" DS manufacturing capacity within the region due to a lack of viable routine demand in ASEAN. Without viable 'peacetime' markets, manufacturers cannot maintain the infrastructure, workforce, and platform readiness, that effective pandemic response requires.

"Ever-warm" capacity refers to manufacturing infrastructure, workforce, and biological platform capabilities that are kept continuously active and operationally ready, so that production can be scaled up rapidly when needed. In contrast, capacity that exists only on paper would require significant time and investment to reactivate. Maintaining ever-warm drug substance capacity requires a viable commercial rationale in peacetime, which is why sustainable routine demand is considered foundational to pandemic preparedness.

[18] "Enhancing Vaccine Regulation for Pandemic Preparedness," Duke-NUS and ADB, 2025

As established earlier in this paper, the most commercially realistic path for regional manufacturers is one anchored in global and/or private market participation, with ASEAN public procurement playing a supporting rather than a primary role. This model has proven viable for Bio Farma, and elements of it are evident among other manufacturers in the region. BioNet, a Franco-Thai vaccine biotech group, offers another example of market diversification. Its standalone recombinant acellular pertussis (aP) vaccine received marketing authorization from the European Commission in January 2026[19]. Having already been licensed in Thailand and other parts of Asia[20], and submitted for approval in Australia[19], BioNet reflects a deliberate strategy of geographic expansion beyond the ASEAN public market.

The risk with this approach, however, is that a purely global-market-oriented strategy leaves the RVM ecosystem exposed to competitive pressures and demand volatility that ASEAN cannot govern. Manufacturers optimizing for global market competitiveness may find themselves with little structural incentive to maintain the platform diversity, geographic distribution, or surge readiness that the region's pandemic preparedness objectives require.

Regional demand consolidation is therefore required not entirely from a commercial perspective, but as a mechanism through which ASEAN can exercise meaningful, coordinated influence over its own supply security. By exploring appropriate forms of demand aggregation across member states, ASEAN may be able to strengthen regional demand signals, and contribute to the sustainability of regional manufacturers, without extensive reliance on export markets. Such an approach will help orient manufacturers toward regional needs, sustain "ever-warm" capacity during ‘peacetime,’ and reduce the region's exposure to the supply nationalism and allocation inequities that characterized the COVID-19 pandemic response globally[21].

ASEAN's strategic options exist on a spectrum ranging from direct subsidies from the public sector to regional manufacturers at one end, to market-driven sustainability through demand consolidation and regulatory harmonization at the other.

As the following section will explore, these three risks are interconnected and mutually reinforcing. Addressing them requires coordinated, strategically sequenced interventions across the supply, regulatory, and demand dimensions of the ecosystem.

Proposed market-shaping strategies to address market risks

To develop a pandemic-responsive and commercially sustainable RVM footprint, stakeholders across the public, private, and social sectors must address the market risks outlined in the preceding section. CHAI and the RVMC Secretariat propose below a three-part market-shaping strategy, identifying where targeted action is most urgently needed. The interventions described below aim to ensure that ASEAN's manufacturing ecosystem is oriented toward regional needs, complementing, rather than replacing,

[19] BioNet Asia website
[20] BioNet Asia website
[21] “Export restrictions do not help fight COVID-19,” UNCTAD, 2021

manufacturers' global market strategies with a regional demand signal and regulatory architecture needed to sustain ever-warm, pandemic-relevant capacity.

A. Strengthen complementary manufacturing capacity

The risks associated with a highly concentrated large-scale manufacturing footprint and limited regulatory diversification should be addressed through deliberate efforts to strengthen complementary capacity across the region, aligned with both regional pandemic preparedness needs and manufacturers' commercial sustainability objectives.

Concretely, this means supporting select manufacturers in developing the ability to produce drug substance at epidemic-relevant scale, whether through in-house R&D or targeted technology transfer partnerships with originators. It also requires ensuring that these manufacturers can meet the regulatory requirements necessary to supply across borders in a timely manner, a prerequisite for their relevance to any regional pandemic response. Identifying which manufacturers are best placed will require assessing a range of factors, including, their technical capabilities, geographic location relative to existing large-scale manufacturers, willingness as well as ability to export, the vaccine platforms they operate, and alignment with the region's priority antigens.

B. Strengthen the regulatory environment to support regional market access

In the absence of alignment in regulatory standards across ASEAN, regional vaccine manufacturers risk remaining domestically focused and unable to meaningfully contribute to regional pandemic preparedness goals, regardless of their production capabilities. Governments and partners must therefore work toward strengthening the regulatory environment in a way that enables regional market access to manufacturers that meet appropriate quality standards.

Full regulatory harmonization across ASEAN is a long-term endeavor. A more immediately actionable step is the implementation of regional regulatory reliance mechanisms across a subset of vaccine producing and vaccine purchasing member states, arrangements through which national NRAs accept or give significant weight to assessments conducted by a trusted reference authority, reducing duplicative review and accelerating time to market. The inclusion of vaccine-producing countries with strong regulators, such as Singapore and Indonesia, as reference authorities within such mechanisms would be essential to ensuring their relevance. For countries with less mature NRAs, reliance mechanisms offer a practical pathway to accessing vaccines that would otherwise be unavailable or delayed, for both routine immunization and emergency response.

Several initiatives are already advancing regulatory strengthening and harmonization in the region. The ASEAN Pharmaceutical Regulatory Policy (APRP)[22] established the foundational policy basis for regional regulatory cooperation, upon which the ASEAN Pharmaceutical Regulatory Framework (APRF)[23] was developed, which provides a legally binding basis for NRAs to facilitate the development of harmonized strategies that enhance national regulatory systems and expedite market integration initiatives. This is complemented by the ASEAN Joint Assessment Procedure[24], which allows for the simultaneous review of pharmaceutical dossiers by multiple national regulators to expedite market entry.

[22] The ASEAN Pharmaceutical Regulatory Policy (APRP)
[23] ASEAN Pharmaceutical Regulatory Framework (APRF)
[24] ASEAN Joint Assessment Procedure for Pharmaceutical Products Information for applicants

However, so far, these initiatives have largely advanced independently of one another, with limited coordination. Any future work should build on these foundations, coordinating existing efforts where feasible, with a targeted focus on closing the gaps that remain.

C. Consolidate regional demand to sustain ever-warm manufacturing capacity

Regional demand consolidation, even at modest volumes, is necessary to create the viable 'peacetime' market opportunities that allow manufacturers to maintain ever-warm, pandemic-relevant capacity. Without a credible regional demand signal, manufacturers will continue to focus on a combination of domestic and/or global market opportunities, a commercially rational response that nonetheless risks leaving ASEAN without the supply security and surge readiness it needs. The alternative, direct public subsidization of regional manufacturers, risks creating dependency without resolving the structural conditions that make the regional market unviable in the first place.

A concrete and immediately actionable step in this direction is for ASEAN member states to adopt, where appropriate and consistent with national procurement regulations, the locality of manufacturing and capability for manufacturing for the region as a criterion in vaccine product selection, alongside quality, safety, efficacy, affordability, supply reliability, and programmatic suitability. This would create a meaningful market signal within existing procurement channels without requiring new institutional infrastructure. Over the longer term, more formalized coordinated buying mechanisms, through existing ASEAN platforms, offer a pathway to more structured demand consolidation.

Other initiatives in the region are also worth noting. The Thai National Vaccine Institute (Thai NVI), in collaboration with the National University of Singapore (NUS) and other partners, has been supporting technical discussions to explore strategic, policy, financing, regulatory, and operational considerations related to regional pooled procurement.[25]. This work builds on NUS and partners' earlier policy proposal for an ASEAN Vaccine Revolving Fund, modelled on the PAHO Revolving Fund, designed to coordinate pooled vaccine procurement across ASEAN, strengthen country-level delivery, and build national capacity for public procurement of goods and services more broadly[26]. Future efforts should build on these foundations, with an emphasis on implementing solutions that are evidence-based and tailored to the unique context of ASEAN.

D. Priorities for further investigation

This study has identified a few areas where the evidence base requires further development:

First, platform-level capacity and capabilities have not been assessed in adequate detail in this or prior studies. A natural and high-priority next step is a platform-specific assessment, evaluating the capacity, capabilities, and constraints of individual manufacturing platforms across the region to generate the insights needed to design targeted support for pandemic preparedness and surge readiness.

Second, while the availability of a skilled workforce and access to inputs and consumables were identified as critical success factors for regional manufacturers, resource and scope constraints precluded a detailed examination of these dimensions in the current exercise. A structured assessment of these topics would meaningfully strengthen the evidence base and inform the design of targeted interventions in these areas.

[25] RVMC 2.0 Secretariat Mid Term Review, March 2026
[26] Southeast Asia needs a revolving fund for vaccines," The Lancet, November 2022

Third, universities, research institutions, and vaccine development platforms are important not only to manufacturing but also to building longer-term regional capacity for product and platform development. While this may be a longer-term priority, the role of R&D and regional innovation capacity warrants deeper exploration.

Finally, strengthening RVM in ASEAN is not solely a health sector challenge but also one of industrial policy, trade, and cross-sector coordination. Ministries of industry, trade, and finance, alongside health authorities, have a direct bearing on the conditions in which regional manufacturers operate. Future work should therefore examine the broader governance architecture required to align incentives across sectors and identify where cross-ministerial coordination mechanisms are most needed.

Conclusions

Strengthening the manufacturing footprint, advancing regulatory harmonization, and consolidating demand are mutually reinforcing imperatives. Progress on any one dimension without corresponding advances on the others will limit the impact on strengthening RVM in ASEAN. This interdependence makes alignment among stakeholders essential.

Realizing this vision of a fit-for-purpose manufacturing footprint in ASEAN will require ecosystem stakeholders to collectively advance the following priorities:

- **Governments** can strengthen regional supply resilience by exploring coordinated procurement approaches for selected vaccines, where appropriate and consistent with national regulations, through existing ASEAN mechanisms. In the near term, this could include considering regional manufacturing as one factor in product selection and advancing regulatory reliance mechanisms as a practical step toward broader harmonization. Over the medium-to-long term, efforts must be focused on consolidating demand to ensure viable market opportunities for regional manufacturers. Pooled procurement is one outcome of procurement coordination that ongoing regional work is actively evaluating. A durable solution will require explicit risk- and benefit-sharing arrangements, whether through bilateral or multilateral agreements, or reciprocal commitments that align incentives across member states. While RVMs will likely continue to rely on global and private markets to underwrite much of their commercial viability, predictable regional demand, even at modest volumes, plays an important role in sustaining the "ever-warm" infrastructure and platform readiness that pandemic response requires.
- **Regional and global partners** can, in the near-to-medium term, direct targeted support toward select manufacturers that complement Bio Farma's leadership and align with the region's routine and pandemic preparedness needs. A critical first step is determining which manufacturers should be prioritized to advance specific strategic objectives. Coordination among partners will be critical to avoid duplication, maximize ecosystem impact, and ensure that available resources are directed where they can do the most to strengthen the regional manufacturing base.
- **Manufacturers**, with support from governments and regional and global partners, should, in the near-term, take deliberate steps to engage with the specific needs of the ASEAN market. This includes understanding product preferences, adapting their offerings where commercially viable, and contributing to the development of resilient regional supply chains. Over the medium to longer term, inter-regional collaboration through coordinated "capacity-shaping" will be essential to enabling specialization and preventing duplication and overcrowding in viable but limited markets.

Strong data infrastructure underpins effective market-shaping. Credible demand forecasting, procurement visibility, shared market intelligence, and transparent information on supply and platform

capacity are foundational inputs to every intervention proposed in this paper. Without them, regional strategies risk being built on incomplete information, and manufacturers, financiers, and policymakers alike lack the visibility needed to act with confidence.

We believe that this whitepaper will serve as a valuable tool within the RVM ecosystem to support ASEAN vaccine manufacturing in a way that not only promotes regional health security and pandemic preparedness, but also ensures the commercial viability of manufacturers. The recommendations outlined in this paper may be adopted to guide priority activities under the next AVSSR strategy, ensuring alignment with regional needs and opportunities across the ASEAN RVM ecosystem. The choices made in the coming years will be critical to ensuring that the investments already committed to RVM in ASEAN translate into a durable, fit-for-purpose ecosystem, and the risks of misalignment, overcapacity, and unresolved demand constraints are mitigated.

About Us

About RVMC

The Regionalized Vaccine Manufacturing Collaborative (RVMC) is a global initiative advancing vaccine equity and health security by enabling sustainable regionalized vaccine manufacturing ecosystems. Founded in 2022 by the Coalition for Epidemic Preparedness Innovations, the National Academy of Medicine, and the World Economic Forum, RVMC focuses on strengthening manufacturing and supply chain networks across three priority regions - Africa, Latin America and the Caribbean, and Southeast Asia.

Hosted and funded by CEPI, the RVMC Secretariat operates through a collaborative, partner-led model, working across sectors to advocate for change, align stakeholders to accelerate progress, advise on sustainable approaches, and account for progress. Through this approach, RVMC strengthens regional manufacturing ecosystems and helps enable more equitable and resilient access to vaccines worldwide.

For more information, please visit: www.rvmc.net

About CHAI

The Clinton Health Access Initiative, Inc. (CHAI), is a global health organization committed to saving lives and reducing the burden of disease in low-and middle-income countries. CHAI works to strengthen the capabilities of both governments and the private sector in those countries to create and sustain high-quality health systems that can succeed without ongoing assistance.

CHAI's approach is unique. Our aim is not just to impact a problem, but to fundamentally change the way in which the problem is addressed to solve the issue. We use a business-minded methodology to shape healthcare markets to reduce the costs of lifesaving medications and other critical health care products. We work in partnership with governments to reform their health systems, targeting areas where current methods are failing.

For more information, please visit: www.clintonhealthaccess.org

Acknowledgments

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Appendices

Appendix 1: Scope of the study

- This assessment, commissioned by RVMC and jointly conducted with CHAI, in its entirety, is structured around five critical success factors for RVMs:
  - **Manufacturing footprint:** Does the region have sufficient manufacturing infrastructure and installed capacity to produce vaccines at a scale meaningful for both routine immunization and pandemic response?
  - **Access to Products:** Do RVMs have access to the necessary technologies, and product portfolios to meet market demand across ASEAN?
  - **Regulatory environment:** Are regulatory pathways sufficiently robust, harmonized, and efficient to enable timely market access for RVMs across ASEAN countries?
  - **Demand & Procurement landscape:** Is demand sufficiently predictable and are procurement mechanisms structured in a way that creates viable, scaled market opportunities for RVMs?
  - **Access to Financing:** Do RVMs have adequate access to the financing instruments needed to sustain investment in capacity expansion, R&D, and long-term operations?
- While all five dimensions were assessed, the analysis revealed the most significant gaps and market risks concentrated in three areas, namely, Regulatory Environment, Demand & Procurement, and Manufacturing Capacity. Accordingly, this paper directs its market shaping recommendations toward these three factors, which also closely align with RVMC's strategic vision and priorities for 2030.
- For those interested in a deeper exploration of the remaining dimensions, i.e., Access to Products and Access to Financing, please reach out directly to RVMC or CHAI.

Appendix 2: Data Sources

To ensure the analysis is grounded in both data and practical realities, the study draws on a combination of primary and secondary research:

- **Secondary sources** include reliable databases such as the Linksbridge GVMM demand forecast, the WHO MI4A database, Global Burden of Disease studies, as well as existing literature on RVM in ASEAN, including surveys conducted by the ASEAN Secretariat and reports published by partners such as the World Bank.
- **Direct engagements were conducted with eight manufacturers** across Thailand, Vietnam, Malaysia, and Indonesia to capture the supply landscape, including installed capacity, R&D initiatives, and technology transfer partnerships, as well as manufacturer perspectives on demand-side challenges and enabling factors such as regulation and financing.
- **Findings were further validated through consultations** with regional and global financiers to assess their appetite for investment in ASEAN vaccine manufacturing, and with partners including Thai NVI and CEPI, both of whom are actively advancing important work in this space.

Appendix 3: Glossary

The following abbreviations and key terms are used throughout this whitepaper.

Abbreviations and acronyms:

Abbreviation	Expansion
aP	Acellular pertussis
APRF	ASEAN Pharmaceutical Regulatory Framework
APRP	ASEAN Pharmaceutical Regulatory Policy
ASEAN	Association of Southeast Asian Nations
AVSSR	ASEAN Vaccine Security and Self-Reliance
CEPI	Coalition for Epidemic Preparedness Innovations
CHAI	Clinton Health Access Initiative
COVID-19	Coronavirus Disease 2019
DP	Drug Product
DS	Drug Substance
GVMM	Global Vaccine Market Model (Linksbridge)
LAC	Latin America and the Caribbean
MI4A	Market Information for Access to Vaccines (WHO database)
ML3 / ML4	Maturity Level 3 / Maturity Level 4 (WHO classification of National Regulatory Authority maturity)
nOPV	Novel Oral Polio Vaccine
NRA	National Regulatory Authority
NUS	National University of Singapore
PAHO	Pan American Health Organization
R&D	Research and Development
RVM	Regionalized Vaccine Manufacturing
RVMC	Regionalized Vaccine Manufacturing Collaborative
Thai NVI	Thai National Vaccine Institute
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Key terms:

Term	Definition
Birth cohort	The number of children born in a given year, used as the basis for projecting routine immunization demand.
Drug Substance (DS)	The production of the active ingredient used in a vaccine. For example, growing a virus in cell cultures or synthesizing an mRNA sequence
Drug Product (DP)	Commonly known as fill-and-finish, involves formulating that ingredient into the final vaccine and packaging it into vials or syringes.
End-to-end manufacturing	Refers to performing both Drug Substance (DS) and Drug Product (DP) steps.
Ever-warm capacity	Manufacturing infrastructure, workforce, and biological platform capabilities kept continuously active and operationally ready, so that production can be scaled up rapidly when needed.
Pooled procurement	A mechanism through which two or more buyers (countries) aggregate vaccine demand and purchase jointly to achieve better prices, predictability, and supply security.
Regulatory harmonization	The alignment of regulatory standards, requirements, and procedures across multiple countries to facilitate cross-border market access for medical products.
Regulatory reliance	An arrangement through which a National Regulatory Authority accepts or gives significant weight to the assessments and decisions of a trusted reference authority, reducing duplicative review and accelerating time to market.
Routine immunization	The regularly scheduled program of vaccinations delivered to children and other priority populations as part of national immunization schedules.
Technology transfer	The process by which an originator transfers vaccine production technology, know-how, and processes to another manufacturer to enable local or regional production.
Vaccine platform	The underlying technology used to develop and produce vaccines (e.g., mRNA, viral vector, protein subunit, inactivated, live-attenuated).
WHO Prequalification	WHO's program for assessing the quality, safety, and efficacy of vaccines; a prerequisite for procurement through UN agencies such as UNICEF.