How to pave the road to African equity; insightful material supply chain market research

Situation assessment and overview

Report developed by TheMindCo for CEPI

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Executive Summary

Context and objectives

This project is being pursued in the context of the joint effort of scaling-up vaccine manufacturing in Africa

- The objectives of this project were:
    1) Understand and diagnose the key pain-points and constraints for supplying vaccine manufacturing input materials for African manufacturers from both the manufacturers perspective and the suppliers' perspective – Provide evidence that input materials supply chain should be a key and prioritized point in the agenda and that is critical for the development of a vaccine manufacturing platform in the continent
    2) Understand in-depth the pain-points and potential next steps
    3) Gather recommendations from global suppliers to vaccine manufacturers
    4) Perform an initial and preliminary assessment of "out-of-the box" solutions that came out during the project
    5) Identify a list of critical raw materials to be prioritized for further action

Methodology

The analyses in this document are based on:

- Reports and thorough secondary research
- Interviews with Global South vaccine manufacturers
- +25 interviews with key global input materials suppliers of whom most of them have experience in doing business in Africa

Input materials categorization

We categorized input materials into 12 categories to be able to identify the key pain points

- We then sampled 87 input materials within these categories and assessed the interchangeability potential of each material
- Around 10% of the materials sampled require a full clinical trial process; 35% have very limited interchangeability and 20% limited (require months or years of regulatory approval); ~40% have a least limited interchangeability potential
- Global suppliers play in almost all the categories of materials; nevertheless, when the materials are least sophisticated there are more potential suppliers
- Provided that most of the industrial capacity of African manufacturers will be fill and finish, we develop a materials demand back-of-the-envelope estimation to understand how many of sample categories will be required by 2030, for instance
    - Vials, stopers, seals and VVMs will be required in approximately 138 million units
    - Filtration systems will be required in around ~9,000 annually
    - Connectors will be required in around ~20,000 annually while 3,000 buffer bags

Pain-points assessment

We have structured the pain-points that we collected in terms of their impact in input materials price and lead times, which are the two critical factors that vaccine manufacturers expressed during the interviews

- In this sense, we have classified each pain-point into 3 variables: how much impact it may have on lead times, how much impact it may have on price and what is the current level of concern that issue is presenting today
- We were able to prioritize the following as key issues:
  - Credit terms, production capacity constraints, tariffs and duties, volume demand uncertainty and Forex that impact both price and lead times
  - Production costs and minimum order quantities that impact prices
  - Storage, distance and compliance requirements that impact lead times
- While many of these constraints are structural issues, most of the suppliers stressed-out the need for a joint coordination among the manufacturers and jointly with the suppliers – they mentioned that this could reduce lead-times and prices

Initial assessment of solutions

Finally, we jointly assessed with suppliers the feasibility and impact of potential solutions. When doing this we were able to develop a roadmap phasing structural solutions and identifying enablers

1) **Demand pooling / procurement support:** A coordinated demand pool or third-party coordinated procurement office may be the first step in terms of coordinating and facilitating procurement for vaccine manufacturers; this may impact lead times and costs
2) **Distribution centers:** Once a demand pool is in place, it is a natural step which may have impact on lead times
3) **Localized input materials manufacturing:** This alternative seems unfeasible in the short-term, but it is a clear next step once distribution centers are in place and once there is a functioning ecosystem and demand volume in the region. In this sense, we have identified the following enablers to set-up a demand pool and kick-start the roadmap
   - **Financial hedging:** Financial engineering and tools may help the mitigation of market volatility, but may increase costs in the short-term
   - **Increase capacity utilization:** If manufacturers were to diversify their production by including other pharmaceuticals (e.g. insulins)
   - **Regulatory standardization:** Governments to develop initial agreements and understandings to standardize regulatory processes and approvals
   - **Coordination / Standardization among manufacturers:** Coordination of platforms to standardize input materials demand

Based on our conversations with experts and suppliers, there are some solutions that may be addressed early on by vaccine manufacturers and that are also enablers for a demand pool

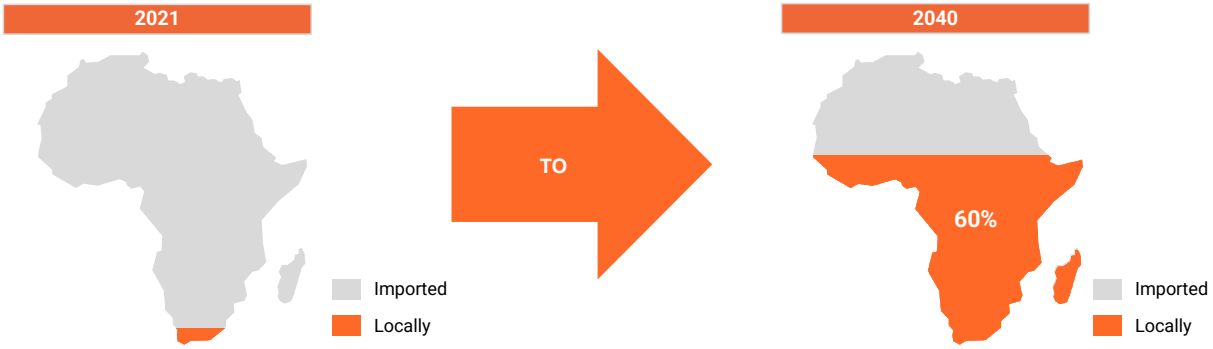
- **Forecast planning and strategy:** adequate forecast planning is the key to reduce costs and lead times of goods
- **Open and early communication with suppliers:** most of the interviewees mentioned that they do have the capabilities to support and advice manufacturers early in the process; all the interviewed suppliers mentioned that have strong bonds with manufacturers – suppliers' engagement is a key success factor

- **Estimation of total cost of ownership:** when building plants and choosing equipment, work out the total cost of ownership (some suppliers offered to help in this)
- **Continuous benchmarking:** Market benchmarking as a tool to evaluate market positioning, supplier capabilities and industry standards
  Furthermore, we achieved to generate awareness and engagement with suppliers for future support in the supply chain development

1. Introduction

In 2024, The African CDC established the Platform for Harmonized African Health Products Manufacturing (PHAHM) as a continuation of the Partnerships for African Vaccine Manufacturing (PAVM), established in 2024.

The PHAHM is supported by a variety of global, regional and local stakeholders and created the Framework for Action to increase the quantity of vaccines used in Africa to be manufactured in the continent, increasing the quantity from less than 1% in 2021 to 60% in 2040 1[1].

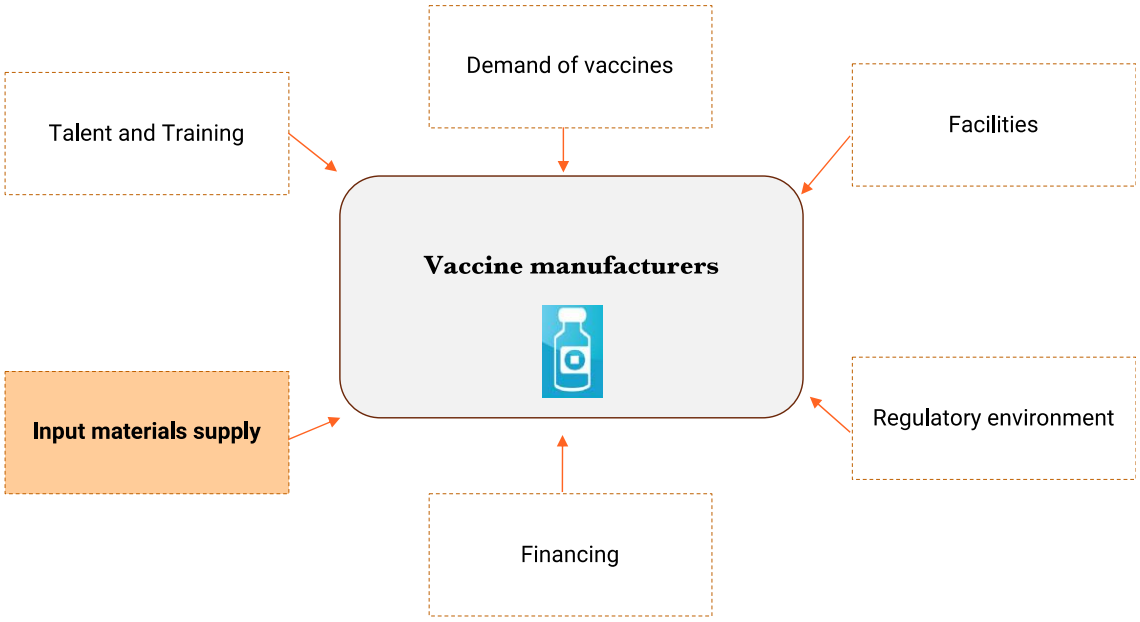


According to recent studies published by CHAI and Path[2], by 2030, there will be a 1.4 Bn vaccine manufacturing capacity in Africa – which could surge to 2 Bn in situation of pandemic outbreak/response

While there is marginal drug substance production on going or planned, most of the production (>90%) will be fill and finish. These will be potentially manufactured by the front runner manufacturers[3].

In this sense, the challenge is to develop an ecosystem for vaccine manufacturing in Africa:

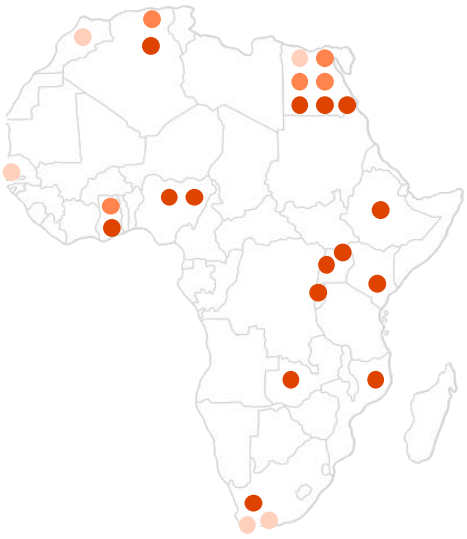
[1] https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/
[2] https://africacdc.org/download/african-vaccine-manufacturing-mapping-supply-and-demand-landscape/
[3] https://www.path.org/our-impact/articles/how-has-the-african-vaccine-manufacturing-landscape-changed-in-the-last-year/



Typically, these ecosystems take 10 to 20 years to develop when supported by organizations, governments and private companies. Without one part of the ecosystem, the whole endeavor will fail.

Today, there are 25 manufacturers and potential manufacturers working towards the development of the ecosystem in Africa.

Facilities with Tech Transfers underway	• Marbio • Vacsera • IP de Dakar • Aspen Pharmacare • Biovac
Facilities awaiting Tech Transfers	• Eva Pharma • Minapharm • Biogeneric • Saidal • Atlantic Biotech
Facilities in development	• VBC • Polygon • Gennecs • IP de Algerie • DEK • Innovative Biotech • BVNL • DEI Biopharma • VAI Uganda • Biovax • Shieldvax • BioNtech • Yash Life Pharma • Mozambique Holdings • Afrigen



To address this challenge, CEPI has undertaken a comprehensive study aimed at establishing a sustainable supply chain for vaccine manufacturing input materials in Africa. This initiative aligns with the broader goal of empowering African nations to produce their own vaccines, ensuring greater self-sufficiency and resilience during public health crises.

2. Methodology

The study employed a multifaceted approach to gather information and insights from various stakeholders involved in the vaccine manufacturing ecosystem. This involved two main streams of information gathering: secondary research and primary research through interviews.

Secondary research involved a thorough review of existing literature, reports, and data to provide a comprehensive understanding of the current landscape of vaccine manufacturing in Africa. This included academic papers, manufacturers' websites and portfolios, and demographic data, among other sources.[4]

Primary research was conducted through in-depth interviews with a range of experts, including vaccine experts, 8 vaccine manufacturers in Africa, 4 vaccine manufacturers in the Global South, and more than 30 executives of critical input materials suppliers. These interviews provided valuable firsthand insights into the challenges and potential solutions related to vaccine manufacturing in Africa.

3. Input Material Categorization

A key aspect of the study involved categorizing the various input materials required for vaccine manufacturing. These materials were broadly classified into two primary clusters: manufacturing and lab materials.

Manufacturing materials encompass those used directly in the vaccine production process and Lab materials, on the other hand those used in quality control and testing laboratories.

3.1 Defining Input Material Categories

To provide a clear understanding of the various input material categories, the study defined each category based on its function and role in the vaccine manufacturing process.

Manufacturing Cluster

- **Adjuvants** are substances added to vaccines to enhance their effectiveness by increasing antibody production, creating longer-lasting immunity, and reducing the required dosage.
- **Biological raw materials** are components derived from living or once-living organisms, essential for vaccine manufacturing.

[4] Source references used in this study can be found on Section 7

- **Chromatography and filtration materials** are used for separating mixtures into their individual components.
- **PPE & Disposable materials** are sterile, single-use components employed throughout the production process to enhance safety, efficiency, and flexibility.
- **Enzymes for manufacturing** are biological catalysts that accelerate specific chemical reactions crucial for producing and purifying vaccine components.
- **Lipids and surfactants** serve as delivery vehicles and immune boosters, while surfactants ensure vaccine stability, solubility, and aid in purification processes.
- **Raw materials** are non-biological raw materials used in vaccine manufacturing.
- **Primary Packaging** is the first layer of containment that directly contacts the vaccine, ensuring its sterility, stability, and safe delivery to the patient.
- **Starting materials** are foundational ingredients, either derived from biological sources or synthesized chemically, that initiate the production process for a specific vaccine.
- **Disinfectants** are critical chemical agents used to eliminate or inactivate potential contaminants like bacteria, viruses, and fungi on surfaces and equipment, ensuring a sterile environment.

Lab Cluster

- **Lab material for Quality Control** encompasses the wide array of tools, equipment, and consumables necessary for quality control testing.
- **Lab reagents for Quality Control** are specialized chemicals and biological substances used in laboratory analyses, testing, and processing.

3.2 Detailed Categorization and Sample Materials

3.2.1 Manufacturing Cluster

Within the manufacturing cluster we were able to sample 62 input materials

Category	Sample sub-categories /materials
Adjuvants	Aluminum-based Adjuvants, CpG, QS-21, Squalene, MPL, Liposomal.
Biological Raw Material	Incubated chicken eggs, Albumin, Fetal calves serum, Trypsin.
Chromatography and Filtration	Chromatography resins/gels, Depth filtration membranes, Disposable filters, Sterile filtration systems, Tangential flow filtration membranes, Ultra-/Diafiltration units, Chromatography columns.
Enzyme for Manufacturing	Enzymes for mRNA purification, Enzymes for mRNA transcription, mRNA cap analogs, Nucleoside triphosphates, Restriction endonuclease, DNA degradation enzymes (benzonase).
Disinfectants	Decon-quat, Decon clean, Isopropanol.
PPE & Disposable Material	Connectors, Optical adhesive foil, Bags for process and storage[5], Tubes/ hoses, Erlenmeyer flasks, Roller bottles, Cell factories, Tissue culture

[5] Is also a sub-category which includes a variety of different bags

	flasks, Pipette tips, Pipettes, Filter, Disposable Kits, Surgical masks, Gloves, Safety glasses, Lab coat.
Lipids and surfactants	Cationic lipids, Non-specific cholesterols, Non-specific phospholipids, PEG-ylated lipids, Polysorbate 20, Polysorbate 80.
Raw Material Categories[6]	Cell culture media, Buffer components for manufacturing, Preservatives, Sugars, Inactivation reagents.
Primary Packaging	Ampoules, Glass vials, Seals/caps, Stoppers.
Starting Material	Plasmids, Cell lines, Cell banks, Virus seeds.

3.2.2 Lab Cluster

The Lab cluster was divided into two subcategories: lab material for quality control and lab reagents for quality control. Each subcategory was then populated with sample materials commonly used in laboratory settings for vaccine testing and analysis.

Category	Sample input materials
Lab Material for Quality Control	(q)PCR plates, ELISA plates, Filter, Pipette tips, Electrophoresis gels, ELISA-assay substrates, HPLC-columns, Pipettes, Petri dishes/well plates (RNase-free), cell culture plates, Connectors, Bags for process and storage, Tubes/ hoses.
Lab reagents for Quality Control	(q)PCR-kits, Relevant antibodies, Buffer for the pH, Buffer for the lab, Enzymes for the lab, Relevant primers, Relevant reagents for endo-toxin (LAL), Reagents for bioburden, Relevant reagents for sterility determination, RNA-binding fluorescent dye (Ribogreen), Cell culture media, Chromatography reagents.

3.3 Input Material Interchangeability

The study also assessed the interchangeability of input materials, considering the regulatory constraints and the complexity of replacing certain materials during the manufacturing process.

3.3.1 Materials Requiring a New Full Clinical Trial Process

Around 10% of the sampled materials, such as certain adjuvants, raw materials, and starting materials, are critical to the vaccine formulation and would likely require a new full clinical trial process if replaced. For instance, the following materials

- **Adjuvants:** Aluminum-based; CpG; Liposomal; MPL; QS-21, Squalene
- **Raw material:** cell-culture media
- **Starting material:** cell banks, cell lines, virus seeds

3.3.2 Materials Requiring Complex Regulatory Approvals (Years)

Around 35% of the sampled materials, including specific biological raw materials, chromatography and filtration components, disposable materials, enzymes for

[6] We listed key raw material sub-categories, however there are hundreds of raw materials

manufacturing, lab reagents, lipids and surfactants, and primary packaging, may require complex regulatory approvals that can take years to obtain if replaced.

- **Biological raw material:** albumin, fetal calve serum, incubated chicken eggs, Trypsin
- **Chromatography and filtration:** resins/gels; depth filtration membranes
- **Disposable material:** Bags for process and storage, optical adhesive foil; single-use bio bags
- **Enzyme for manufacturing:** mRNA purification, mRNA transcription, mRNA cap analogs, Nucleoside triphosphates, restriction endonuclease
- **Lab reagent:** Relevant antibodies
- **Lipids and surfactants:** cationic lipids, non-specific cholesterols, non-specific phospholipids, PEG-ylated lipids
- **Primary packaging:** ampoules, vials, stoppers

3.3.3 Materials Requiring Regulatory Approvals (Months)

Around 20% of the sampled materials, such as specific chromatography and filtration components, disposable materials, enzymes for manufacturing, lab materials, and raw materials, may require regulatory approvals that can take months to obtain if replaced.

- **Chromatography and filtration:** columns, sterile filtration systems, tangential flow filtration membranes, ultra diafiltration units
- **Disposable material:** cell factories, connectors
- **Enzyme for manufacturing:** DNA degradation enzymes (benzonase)
- **Lab material:** disposable material (q)PCR plates, ELISA plates, ELISA-assay substrates
- **Raw material:** inactivation reagents, preservatives, sugars

3.3.4 Materials with No or Minor Regulatory Approvals

Finally, around 40% of the sampled materials, including specific chromatography and filtration components, disinfectants, disposable materials, lab materials, lab reagents, lipids and surfactants, primary packaging, raw materials, and starting materials, may not require any regulatory approvals or may only require minor approvals if replaced.

- **Chromatography and filtration:** disposable filters
- **Disinfectants:** Decon-quat; Decon clean; Isopropanol
- **Disposable material:** tubes**,** Erlenmeyer flasks, roller bottles and tissue culture flasks

- **Lab material:** Filter, Pipette tips, electrophoresis gels, HPLC-columns and pipettes
- **Lab reagent**: (q) PCR kits, cell culture plates, buffers, enzymes, reagents for bioburden, primers, and relevant reagents for endo-toxin (LAL), relevant reagents for sterility determination and RNA-binding fluorescent dye (Ribogreen)
- **Lipides and surfactants**: Polysorbate 20 and Polysorbate 80
- **Primary packaging**: seals / caps
- **Raw material**: buffer for manufacturing, buffer for the pH, buffer for the lab and enzymes for the lab
- **Starting material**: plasmids

3.4 Initial Input Material Demand Estimation

The study estimates the initial demand for key input materials, focusing on fill and finish operations, as most vaccines produced in Africa are expected to be fill and finish in the short to mid-term.

3.4.1 Breakdown of Initial Input Materials Demand Estimations for 2030

The study provides a detailed breakdown of the estimated demand for various input materials by 2030, considering factors such as the number of vaccine doses expected to be produced, and the types of materials required for different stages of the manufacturing process.

Type of Material	Demand characteristics
Primary Packaging	Vials, stoppers, and seals are expected to be required in approximately 138 million units, as each vial will contain between 3 and 8 doses.
Filtration	Filtration systems are expected to be required in quantities of thousands annually (~ 9,000 filters for product and buffer, (~3,000 filters for other purposes and (~9,000 sterile filtration kits for product and buffers).
Disposable Material	As these materials need to be replaced frequently, we anticipate that thousands of units will be demanded for most inputs, including ~18,000 connectors, ~3,000 product and buffer bags and ~15,000 sample bags).
Lab Material	To uphold high-quality standards, substantial lab materials are needed for Quality Assurance, with quantities ranging from thousands to millions due to the wide variety of materials involved. For instance, ~20,000 filters, ~50,000 pipettes, ~1,000,000 pipette tips, ~5,000 (q)PCR plates).
Temperature Monitoring Device	This category entails only one material, which will probably match the number of vials demanded at ~ 138Mn units.

4. Pain Points and Challenges

4.1 Identification Process

The study employed an iterative process of interviews with vaccine manufacturers and suppliers to identify and analyze key pain points related to the supply of input materials.

The interview process consisted of three iterative activities:

1. **Capture challenges and pain-points from the manufacturers**

- Gather initial insights on the challenges manufacturers face in sourcing and receiving materials.
- Analyze the most common pain points and understand which materials were most affected by the issues collected.

2. **Capture challenges and pain-points from the suppliers**
    - Gather structural and business as usual pain-points from the suppliers' standpoint
    - Discuss with suppliers the pain-points gathered from the manufacturers
3. **Analysis and synthesis**
    - Analyze both points of view and process in a structured manner the pain-points gathered
    - Discussion of pain-points and analysis with supply chain experts

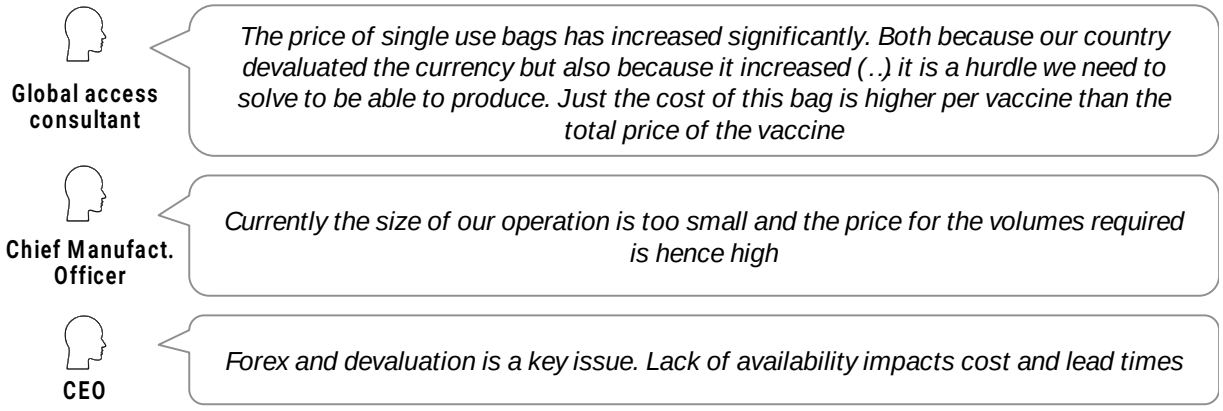
4.2 Value Chain Pain Points

The interviews revealed several key pain points in the value chain for vaccine manufacturing in Africa, categorized into economic/financial and order-to-delivery/operations challenges.

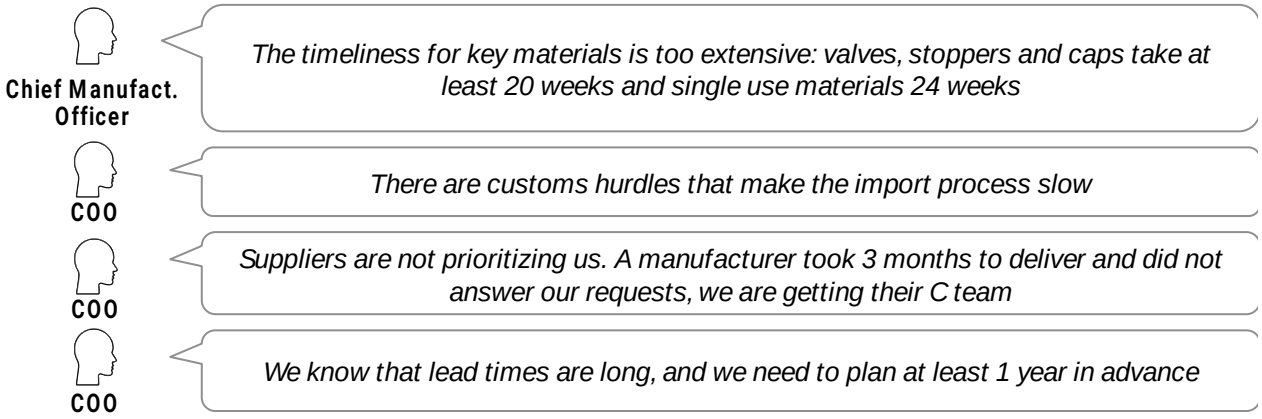
4.2.1 Pain Points Raised by Manufacturers

When talking to manufacturers, immediately most of the pain-points these raised had to do with input materials Price (costs) and lead times. They mainly raised general issues they are experiencing without deep diving into structural explanations.

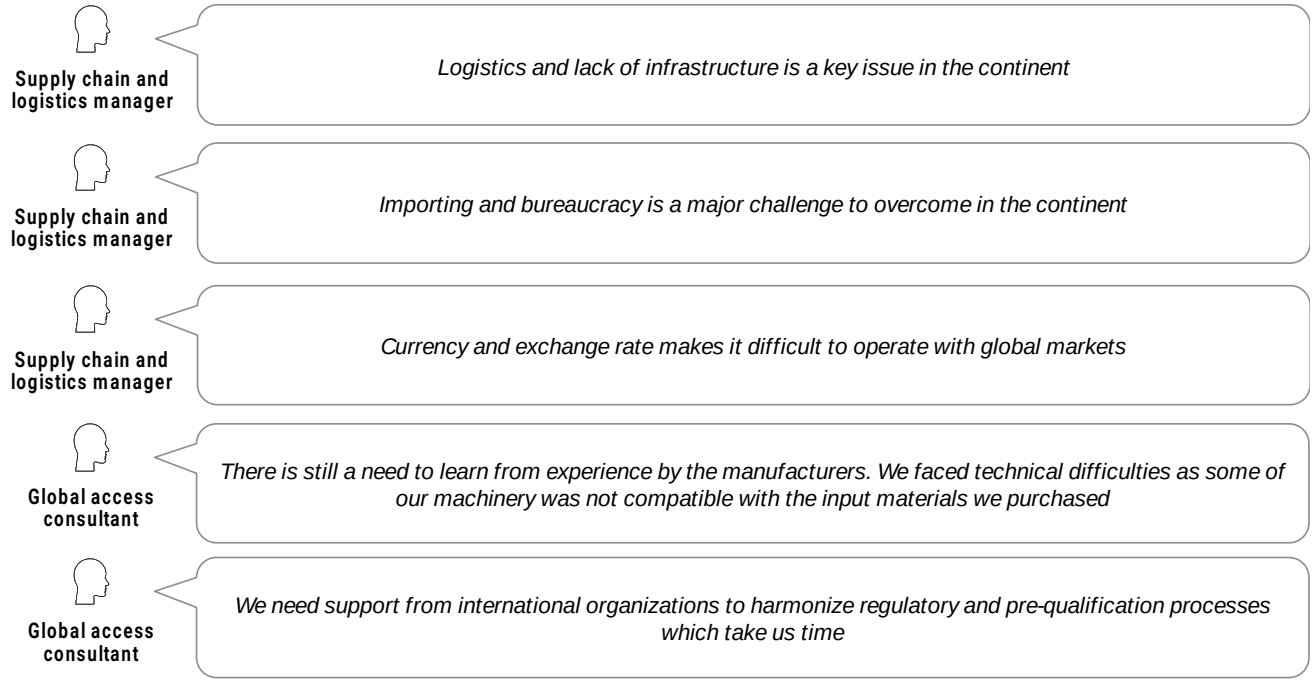
Selected quotes from manufacturers interviews on "Price"



Selected quotes from manufacturers interviews on "Lead times"



Selected quotes from manufacturers interviews on other topics

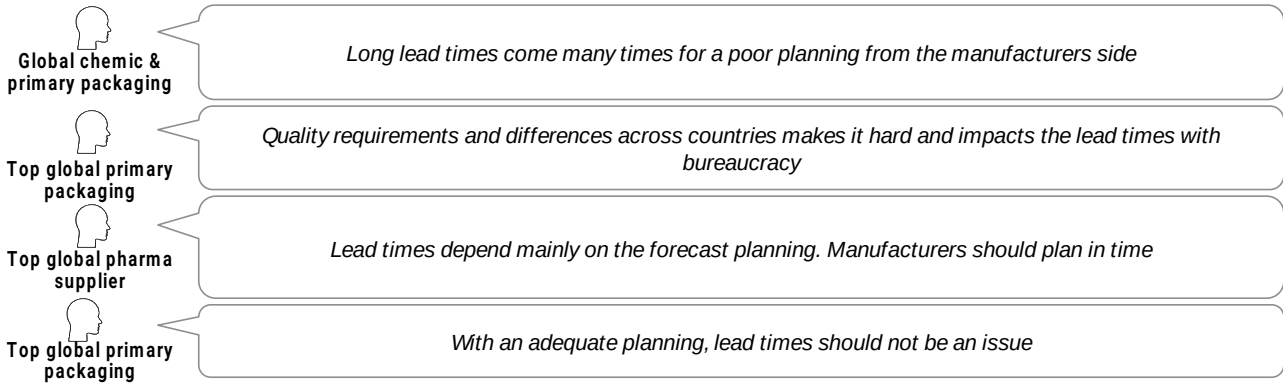


4.2.2 Pain Points Raised by Suppliers

Likewise, when talking with suppliers, these were able to shed some light on the issues raised by the suppliers and explain some of the root causes of the pain-points

Selected quotes from manufacturers interviews on "Price"

Selected quotes from manufacturers interviews on "Lead times"



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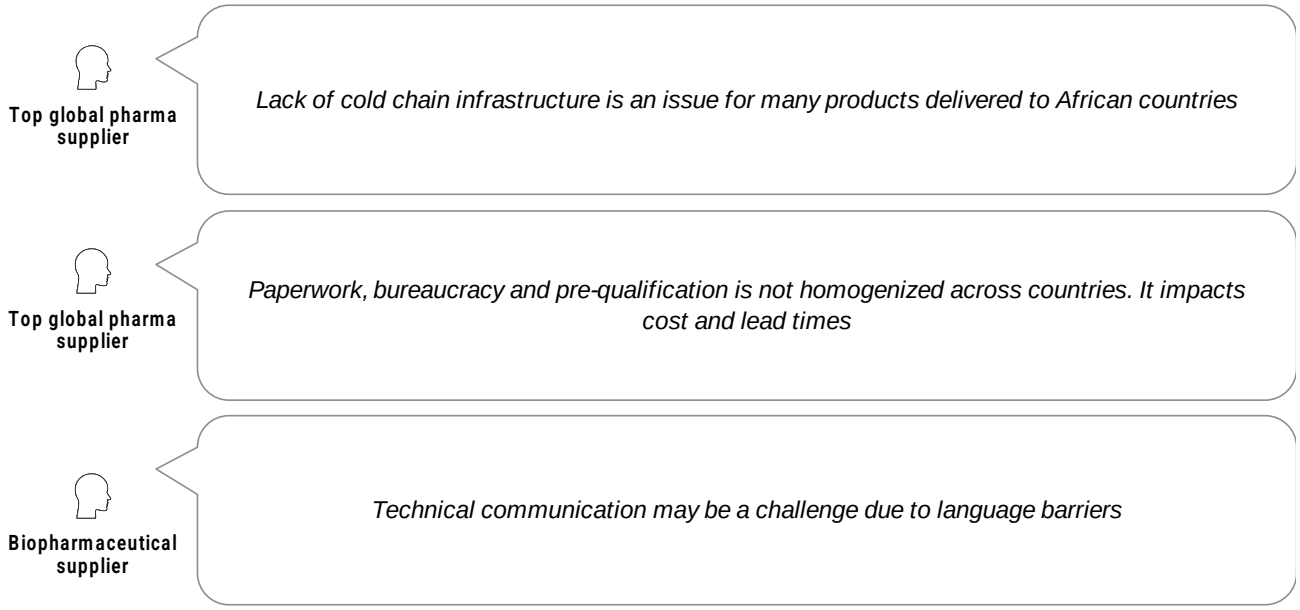


4.2.3 Categorization of Pain Points

Once we collected and process all the issues and pain points, we then analyzed them and divided specific pain-points into the following categories:

Category	Specific pain-points
Economic / Financial	• Tariffs and Duties • Insurance • Interest in Late Payments • Forex • Credit Terms • Payment Methods • Production costs
Order-to-delivery / Operations	• Distances • Volume uncertainty • Storage • Bureaucracy • Production Capacity Constraints (from the supplier's side) • Customs
Demand Guarantee	• Minimum Order Quantities (MOQs)
Communication	• Documentation and Communication
Quality requirements	• Compliance • Testing and Certification • Quality Control Failures

During this study we collected and classified the specific pain-points. Each of them has different level of relevance and impact on the current supply chain, which is analyzed in the following section.

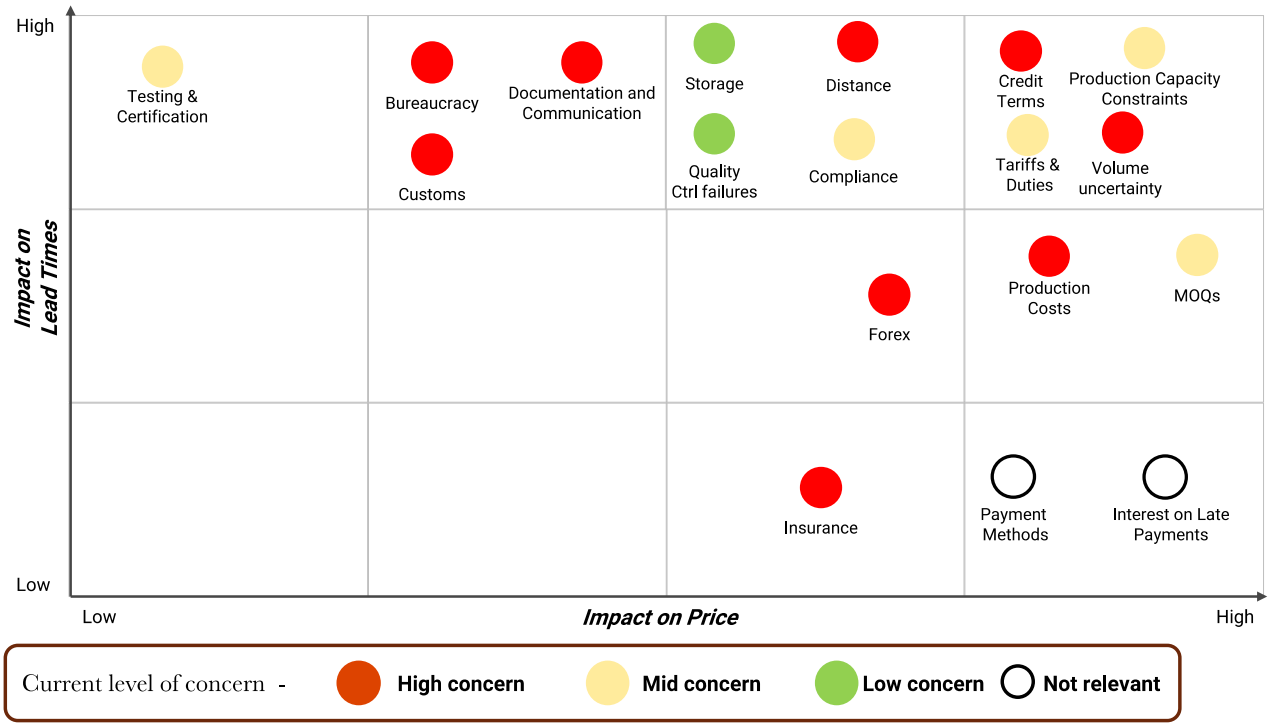
4.3 Impact of Pain Points

All the prior specific pain-points we collected may be plotted in a three-dimensional matrix:

- **Level of impact on Lead Times:** How much may this pain-point impact the supply chain lead times?
- **Level of impact on Price:** How much may this pain-point impact the price of the input materials?
- **Current level of concern:** What is the level of concern today for both suppliers and manufacturers? In other words, is this an issue today or may this impact in the short-term?

In this way, we plotted the following matrix based on the conversations held with the manufacturers, with the suppliers, experts and our own experience.

Pain-points plotted in terms of lead times, price and level of concern



The matrix can be read in the following way: the nearer the pain-points are to the upper side of the matrix, the larger the impact **they may have** on the lead times. On the other hand, the near they are to the right of the matrix, the larger the impact **they may have** on Price. The colors express **the current level of impact** / concern: Red means that it is currently a high concern; yellow means that it has some level of concern; green means that there is little concern and white that it is currently not relevant.

In this sense, for instance, “Credit terms” is currently a high concern since it impacts on price as manufacturers have restricted credit or are asked to pay upfront, impacting as well lead times due to contract terms negotiation, hence delaying delivery.

Furthermore, “Volume Uncertainty” is also currently a high concern as it impacts on price because the lack of visibility and predictability of demand impacts on the supplier’s industrial capability use and also highly on lead times as suppliers usually have their manufacturing already planned several months ahead.

“Product capacity constraints” (from the suppliers’ standpoint) seems to be a concern in the event of outbreak or pandemic. Currently, most suppliers mentioned they have spare capacity. Nevertheless, and although some measures have been taken, there is no certainty that African manufacturers will be prioritized in the event of an outbreak. If this is the case, it will seemingly impact both the price and lead times of the input materials.

“Tariffs and duties” are a concern for some specific geographies however not across the whole of Africa. On one hand, the tariffs itself and the bureaucracy involved ultimately, does impact on price; on another hand, duties delay may also impact lead times and shelf life.

“Foreign exchange (Forex)” is an issue that currently affects manufacturers in a variety of geographic locations. Ultimately it does impact the price for the manufacturers as they will have to hedge themselves and, also impacts lead times by delaying potential purchasing deals.

“Distance”, “Bureaucracy”, “Customs”, “Documentation” and “Communication” are factors that are currently highly impacting on lead times:

- Distance: provided the lack of a developed pharmaceutical market, the frequency of input materials delivery to many of the Global South countries is lower than to other markets; hence, the transportation of these materials may take longer than it takes to other regions.
- Bureaucracy: as the pharmaceutical industry is still in development in many African geographies and does not have a high level of standardization across countries, for some materials, obtaining regulatory approvals may impact on the lead times.
- Customs: For some geographies, the customs approval may delay the final delivery.
- Documentation and Communication: several suppliers mentioned that they still need to develop fluent communication channels with the manufacturers. In this sense, the lack of visibility and constant communication usually impacts their own internal planning and hence the lead times.

Finally, “Production costs” is a high concern as some of the input materials are highly sophisticated and hence more expensive than the potential market value of a vaccine.

5. Initial Assessment of Potential Solutions

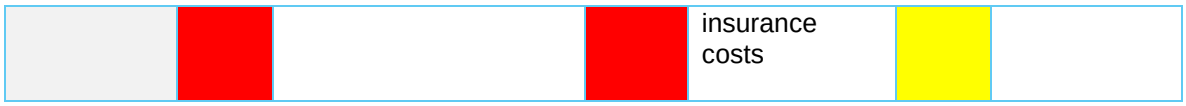
5.1 Stakeholder Roles in Mitigating Pain Points

After plotting the pain-points and assessing their current impact, it is relevant to make a preliminary analysis of the impact that diverse stakeholders (i.e. Vaccine manufacturers, Governments and NGOs and organizations) may have to address them:

What may diverse stakeholders do to mitigate the issues?						
Issue	Vaccine Manufacturers		NGOs and organizations		Governments	
	Level	Rationale	Level	Rationale	Level	Rationale
Production capacity constraints	**LOW**	While they have limited impact on this issue, they may provide demand forecasting according to suppliers’ recommendations	**LOW**	There is limited actionability for NGOs and organizations. They may be a communication channel to support networks	**LOW**	Limited control over supplier capacity

		Nevertheless, requirements from tech transfer and customers are unknown		between suppliers and manufacturers.		
Volume uncertainty	**MID**	Should develop adequate demand planning / forecasting However, the impact they may have is likely limited	**HIGH**	May support vax manufacturers in demand planning training	N/A	
Tariffs and duties	**MID**	May disclose and discuss with the governments the importance of supporting the vaccine manufacturing process.	**LOW**	While there is limited actionability, may perform a study on the impact, if it were necessary	**HIGH**	Governments should limit duties for input materials Furthermore, provide priority access and incentives to products requiring cold-chain or with short shelf life
Credit terms	**LOW**	May develop financial engineering (e.g., internationalized entities), nevertheless the impact may be marginal.	**MID /HIGH**	May potentially develop a project to guarantee credit terms for vaccine manufacturers.	**HIGH**	May support vaccine manufactures with collaterals.
Minimum order quantity	**HIGH**	May work together with the supplier and provide visibility of the plans and potential future orders.	**HIGH**	May support manufacturers by engaging with suppliers and providing visibility on the manufacturing plans. May also support in pooling demand.	N/A	

Production costs	**LOW**	Have limited impact on the input materials production costs.	**LOW**	Have limited impact on the input materials production costs.	N/A	
Storage	**MID**	May invest in storage facilities; nevertheless, these are CAPEX and OPEX intensive	**MID**	May facilitate the development of shared storage / distribution centers strategically located	**MID**	May subsidize the development of storage facilities
Distance	**MID**	May pool with other manufacturers to reduce logistic costs	**MID**	May facilitate demand pooling in order to reduce logistic costs	**MID**	There may be a cost review and understand if there are costs (e.g., port fees) that could be optimized
Quality control failures	**HIGH**	Should provide training and should engage actively with suppliers to have technical and quality support	**HIGH**	May support manufacturers in quality issues	N/A	
Forex	**LOW**	May develop financial engineering (e.g., internationalized entities), nevertheless the impact may be marginal	N/A		N/A	
Insurance	**LOW**	Being a structural issue, Vax manufacturers have limited impact on the insurance international costs	**LOW**	NGOs may support in developing a project with insurers to understand the underlying factors of	**MID**	May collaborate in tackling the underlying factors of high insurance cost



5.2 Structuring solutions and roadmap development

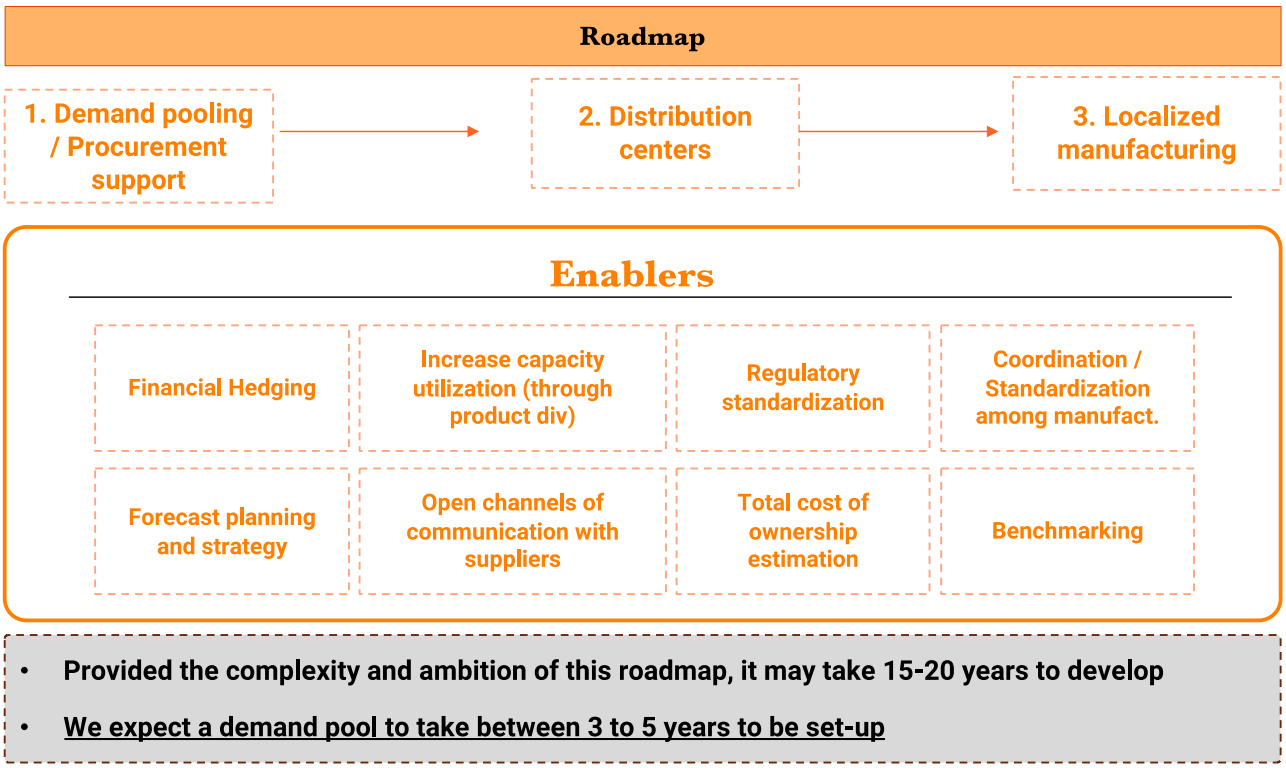
Once the pain-points were identified and analyzed, this study assesses the potential solutions that arose in the conversations with vaccine manufacturers, input material suppliers and market experts. Overall, there have been seven structural solutions identified:

Proposed solution	Expected Impact on lead times	Expected Impact on costs	Implementation complexity
Demand pooling / Procurement support	+++	++	MID TO HIGH
Distribution centers	+	+	HIGH
Localized manufacturing	+++	-	VERY HIGH
Financial Hedging	++	+	MID TO HIGH
Increase capacity utilization (through product div)	+	++	HIGH
Regulatory standardization	++	+	HIGH
Coordination / Standardization among manufact.	++	+++	VERY HIGH

We have also collected and assessed solutions that could be addressed by vaccine manufacturers in the short and mid-term:

- Forecast planning and strategy
- Open channels of communication with suppliers
- Total cost of ownership estimation
- Benchmarking

All these prior solutions and actions will be analyzed in the following sections. One initial conclusion is that most of them are highly connected, and it is possible to develop a roadmap based on them:



- **Provided the complexity and ambition of this roadmap, it may take 15-20 years to develop**
- **We expect a demand pool to take between 3 to 5 years to be set-up**

5.3 Demand pooling / Procurement Support

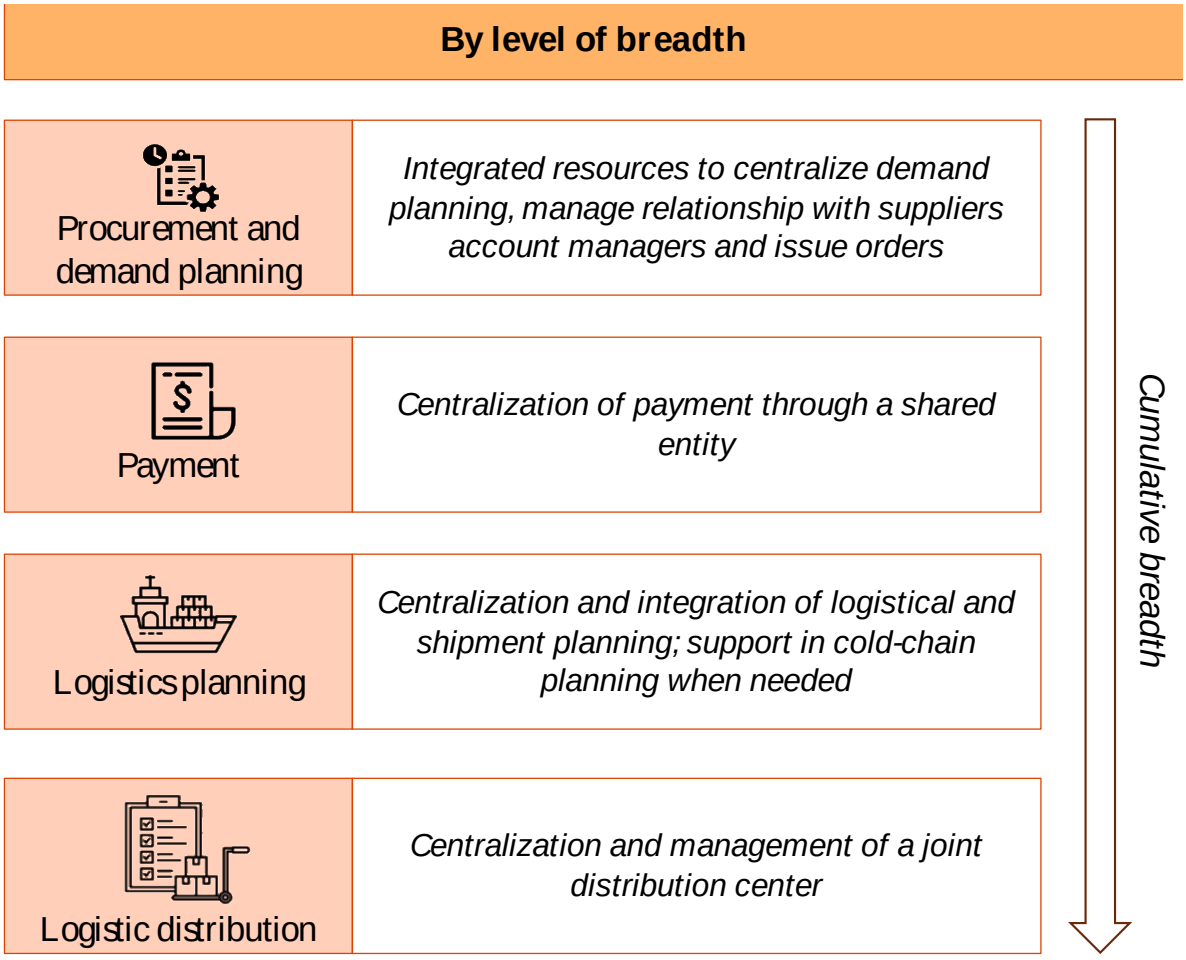
This solution refers to the development of an organization that may support vaccine manufacturers in pooling demand of input materials and/or support their procurement operations by managing with the global suppliers.

Among other responsibilities, this organization may support vaccine manufacturers in:

- Managing the relationship with the suppliers and having a fluent communication.
- Supporting the vaccine manufacturers in developing their forecast planning.
- Collecting orders from diverse manufacturers to achieve large order volumes.
- Supporting manufacturers in standardizing input materials based on the aggregated demand, without providing confident.
- Supporting the logistics and payments.

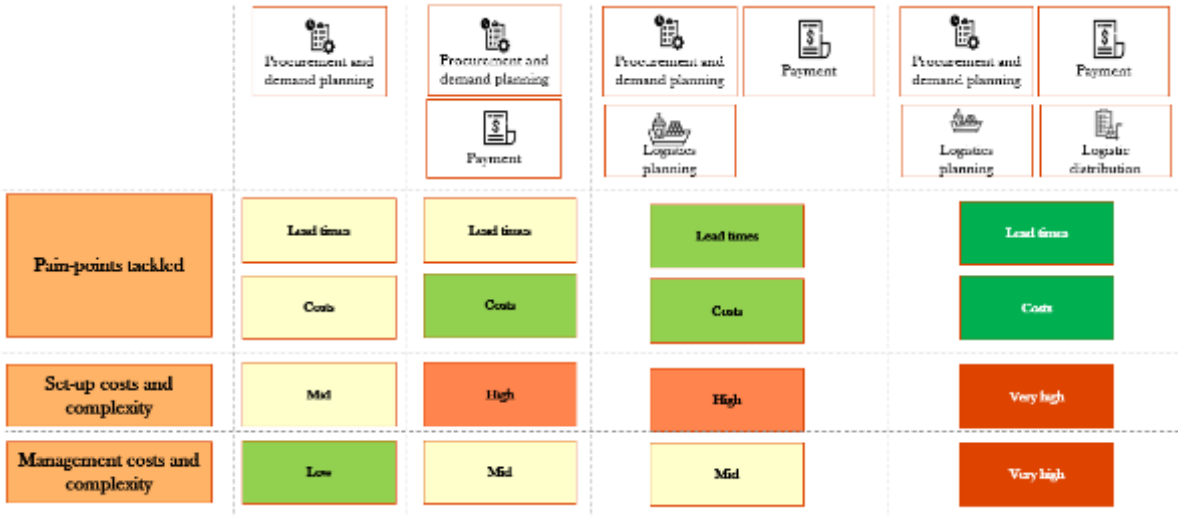
A procurement support organization that may be also able of pooling demand may be established by a private agreement between manufacturers or facilitated by a non-private third party such as a global organization or NGO. Provided the potential asymmetry of power between manufacturers and the potential conflicts of interest, a facilitated by a third-party organization would seem to be the most adequate form.

A procurement support organization or demand pool may have different responsibilities based on its potential size and role. This study classifies four potential archetypes this organization may take:



In its most simple form, such organization can help manufacturers manage supplier relations and issue combined orders. In the most complex form, it may include a logistics structure.

In this sense, an assessment of the potential impact of the different forms for a demand-pool / procurement organization may be performed:



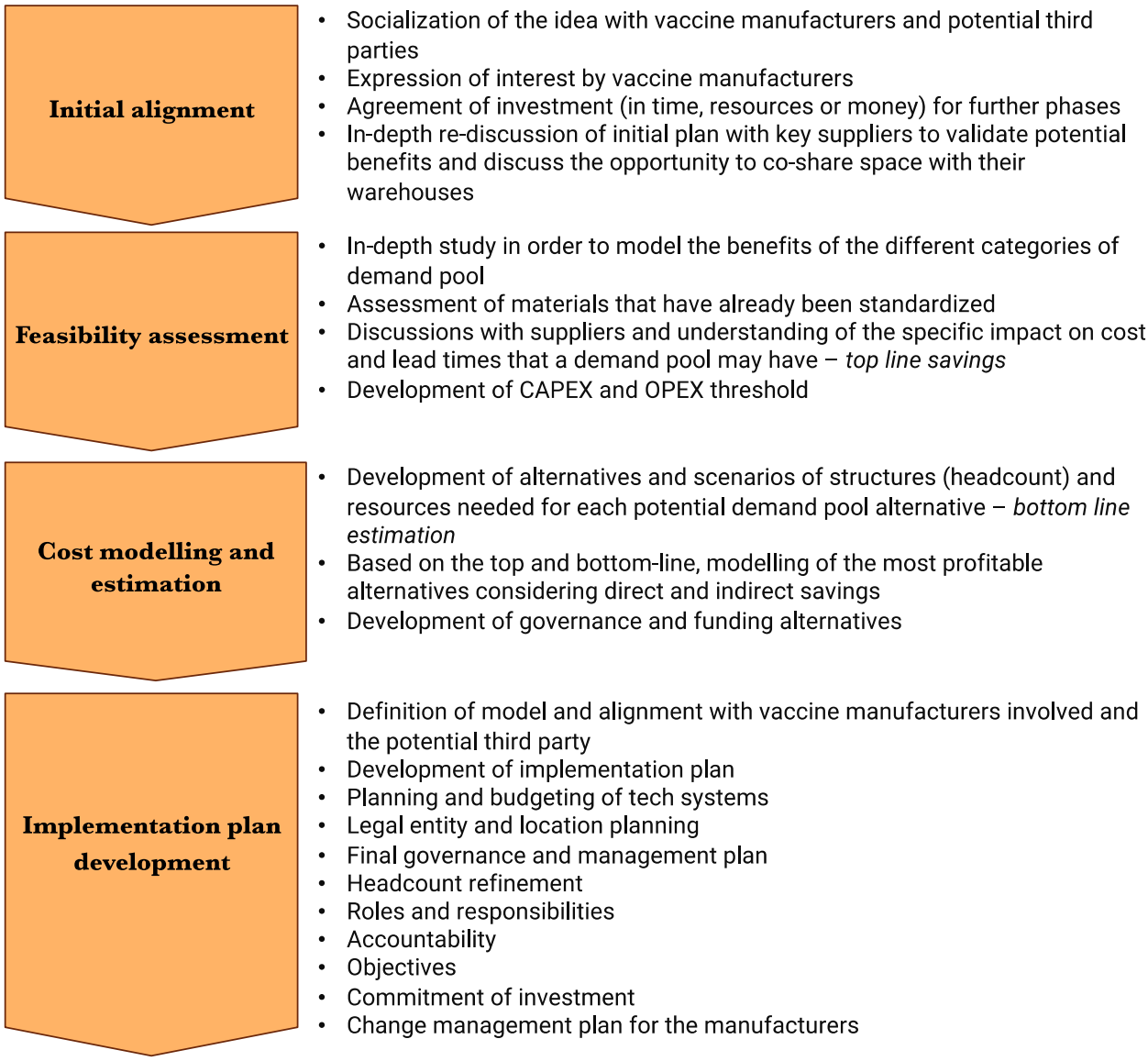
A demand pool can significantly impact both lead times and costs for vaccine manufacturers. Support in procurement and demand planning can influence costs by generating volume and facilitating clear communication with suppliers, leading to better visibility for their manufacturing planning. Additionally, lead times may be impacted if the demand forecast for vaccine input materials becomes more transparent and visible to key suppliers.

However, a more comprehensive organization might increase costs and complexity due to setup and management.

In this sense, the simplest form of a demand pool organization is likely to entail relatively high set-up costs, those associated with setting-up an organization and developing its scope, plus some initial funding for management and complexity.

It is relevant to note that a demand pool or procurement support is likely to largely help vaccine manufacturers, generating value and accelerating the supply chain development. The following section proposes next steps for a deeper assessment.

5.3.1 Next Steps for Demand Pooling



5.4 Distribution Centers

During this study, the feasibility of developing regional input material distribution centers was analyzed based on the opinions of diverse experts. This initiative means setting-up strategically located shared distribution centers, ideally managed by a third party to receive deliveries of key input materials from suppliers and then distribute them among vaccine manufacturers in the continent.

Initially, it seems that setting-up distribution centers may highly impact Lead Times, as there would be safety stocks and proximity to manufacturers. The existence of these safety stocks may also provide indirect benefits in a case of an outbreak or a pandemic.

However, establishing these distribution centers presents a significant challenge. For instance, the size of the continent complicates the process of determining suitable locations

for development. Additionally, many materials have limited shelf life, further complicating logistics. That is why this could be a second step after a demand pool is in place. In this sense, we were able to structure and assess some of these challenges:

High investment	• Setting-up and running a distribution center for vaccine input materials requires sophistication and hence high CAPEX and OPEX
Location	• Distribution centers must be strategically located to benefit most vaccine manufacturers and not some over others
Efficiency	• To be efficient, they would require a close and nimble relationship with the vaccine manufacturer (e.g. in terms of demand planning)
Operational excellence	• Setting up a high-quality operation with high standards, complying with QA requirements will be critical; Just in time may not be possible by suppliers
Increase of costs	• There may be increased costs due to the redundancy of inventories

In this sense, it seems that, at least in the short-term, the viability and cost-benefit of distribution centers may be limited.

5.5 Localized Manufacturing

This solution focuses on establishing regional production capabilities for critical vaccine input materials to reduce reliance on international suppliers and improve supply chain resilience. By producing input materials and consumables locally, manufacturers can shorten lead times, lower dependency on volatile global markets, and enhance the overall stability of vaccine production in Africa.

Localizing could be likely implemented once a demand pool is in place and has proven efficient and there is an ecosystem of distribution centers, as this kind of project faces significant challenges, including high initial capital requirements, the need for skilled labor, and compliance with stringent regulatory standards. In the following sections, we present an in-depth analysis of the necessary conditions for feasibility, as well as its potential benefits and challenges, drawing on insights from interviews conducted throughout the study and the research undertaken.

5.5.1 Conditions for Localized Manufacturing

For localized manufacturing to be viable, several critical conditions must be met. These factors ensure not only the feasibility of production but also its long-term sustainability and competitiveness. However, it is important to recognize that while each of these conditions adds meaningful value for manufacturers considering installing capacities in Africa, there are necessary but not sufficient on their own. The decision to establish local production will also depend on a range of unpredictable factors that may arise.

Some of these conditions are:

- **Sufficient and Sustained Demand -** A stable and predictable demand for input materials is essential to justify investment in local production. While many manufacturers consider it challenging to provide precise volume estimates, this seems more feasible for primary packaging producers.
  As one manufacturer noted, *"We would expect enough demand to justify between 20 to 50 vial production lines."*

- **Long-Term and Dynamic Demand –** Beyond ensuring an adequate initial market, demand must be sustained over the long term - typically for at least 10 to 20 years, according to most suppliers.
  Additionally, demand fluctuations must be accounted for, as certain input materials have limited shelf life and require a flexible supply chain to avoid wastage.

- **Availability of Skilled Local Talent –** The presence of a qualified workforce is a crucial factor in successfully implementing localized manufacturing. One supplier currently looking at a localization strategy emphasized the importance of having skilled professionals available to operate and manage production facilities effectively. Without sufficient technical expertise, local manufacturing efforts may struggle to maintain quality standards and operational efficiency.

5.5.2 Benefits of Localized Manufacturing

Establishing localized manufacturing for vaccine input materials presents several key benefits, enhancing both efficiency and long-term sustainability for manufacturers.

- **Reduced Lead Times –** Proximity to local vaccine manufacturers is expected to significantly shorten lead times by streamlining logistics and improving coordination. Closer geographic access facilitates faster deliveries, while a more direct account management relationship ensures better responsiveness and supply chain agility

- **Potential cost reduction –** Although cost reductions might not be immediate, localized production can potentially lower expenses in the long term. Savings can be achieved through reduced transportation costs and more favorable payment terms.

- **Indirect benefits –** Beyond direct operational benefits, local manufacturing fosters stronger relationships between suppliers and manufacturers. Increased proximity can lead to technical support, more frequent knowledge-sharing, and greater adaptability to evolving production needs. This closer collaboration may ultimately drive innovation and improve overall manufacturing efficiency.

5.5.3 Challenges in Localized Manufacturing

While localized manufacturing offers significant benefits, its successful implementation faces several challenges that must be carefully addressed to ensure feasibility and long-term sustainability.

- **Localization challenges –** Africa's size and diverse economies pose logistical and strategic difficulties for localization. Suppliers highlighted that selecting a single

manufacturing hub may benefit certain regions while being less attractive for others, potentially limiting the reach and impact of localized production

- **Country risks and high investment –** Investing in localized manufacturing requires substantial capital, and the inherent economic and political risks in some regions may lead to an internal rate of return (IRR) too high to justify the investment. *Stability*, *regulatory predictability*, and *financial incentives* will be critical in attracting and sustaining long-term commitments

- **Potential insufficiency of vaccine demand –** Several stakeholders expressed concerns that projected vaccine production volumes alone may not generate enough demand to sustain local manufacturing. As one interviewee noted, *"Manufacturers should consider producing other low-cost drugs that require similar input materials, such as diabetes medication, which also relies on vials or syringes."* Expanding the scope beyond vaccines may be necessary to achieve economies of scale

- **Challenges in identifying the right product and stage –** One of the most significant challenges is determining which specific products and value chain stages are most suitable for localization. For example, a supplier suggested that while establishing a glass-forming facility for vials could be feasible, a full-scale glass manufacturing plant may not be viable. Strategic decision-making and in-depth consideration of every singular case will be crucial in ensuring that investments align with market needs and production capabilities.

5.6 Financial Hedging

The study noted transaction and payment issues from vaccine manufacturers and suppliers, particularly due to Forex restrictions existing in specific countries, financial instability, and insecurity.

These issues impact mainly lead times as it is complex to put orders (sometimes even impossible) and, furthermore costs. In this sense, Financial Hedging may be a resource for manufacturers in order to streamline their operation.

In this study, Financial Hedging means developing a structured strategy, engineering and tools to overcome the prior mentioned constraints in a nimble manner. These kinds of structures may be developed privately by the manufacturers (by working with financial advisors) or supported by multi-national organizations such as The World Bank. Nevertheless, considering these structures are complex and should be customized, it is not the aim of this study to provide financial advice.

In this sense, Financial Hedging may have the following positive impact on the vaccine manufacturers:

Potential impact	Rationale
Improve supplier collaboration	• By managing exposure to currency or commodity risks, it could help to offer clarity and predictability in the interactions with suppliers. This approach could help to minimize price disputes, strengthens partnerships, and promote collaborative planning
Improve operations & explore opportunities	• With reduced financial volatility, the focus on the exploration of growth opportunities and improvement operational efficiency between suppliers and manufacturers could increase
Increased costs	• Financial hedging may increase costs to the manufacturers upfront; nevertheless, it may have a positive economic impact in the long-run

5.7 Increase Capacity Utilization

Another potential alternative to explore is increasing capacity utilization of the manufacturing facilities by including other pharmaceutical products, especially large volume ones such as heparins or insulins. This strategic solution was suggested by diverse stakeholders, and it is worth exploring as there are similar success cases in other regions, such as Latin America.

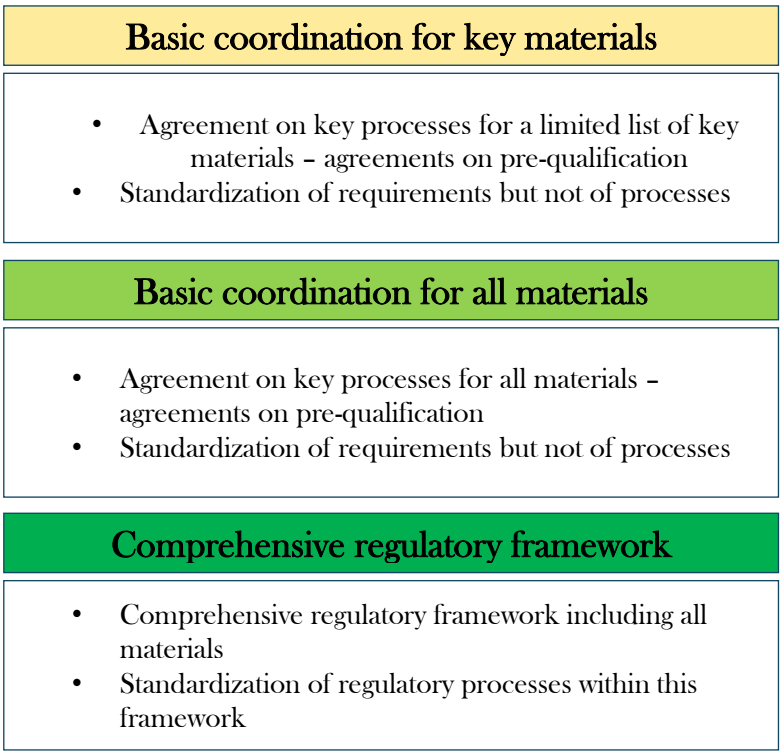
This approach could help optimize capacity utilization and provide additional incentives for localization, though this proposal comes with its own set of challenges:

Challenge	Rationale
High investment	• Diversifying entails a high level of investment, which is now being used for vaccines
Focus	• Developing a vaccine platform is challenging, requires effort and focus and that should not be deprioritized
Competitiveness	• It will take many years, subsidies and grants to develop a competitive pharmaceutical industry

5.8 Regulatory Standardization

Throughout this study, a variety of stakeholders suggested that working towards regulatory standardization across geographies may impact both the input materials supply chain as well as the distribution of vaccines.

In this sense, and focusing on vaccine input materials, there are a variety of levels that regulatory standardization may have:



This is an opportunity that may be explored by governments in countries where key manufacturers are developing capability.

5.9 Technical Coordination / Standardization among Manufacturers

Interviews with suppliers and market experts revealed opportunities for supply chain optimization, focusing on technical standardization and coordination among vaccine manufacturers.

On one hand this could be an enabler for a demand-pool. On another hand, standardization may simplify the manufacturing process and planning for suppliers, hence reducing costs and lead times.

5.9.1 Potential Impact of Technical Coordination

- **Increased bargaining power and better terms:** Coordinated technologies and platforms can consolidate demand, enhancing manufacturers' bargaining power with suppliers for better terms and pricing.

- **Mitigated supply risk and cost efficiencies:** Standardization can mitigate supply risks and lead to cost efficiencies in the long run.

5.9.2 Limitations in Switching Input Materials and Suppliers

Vaccine manufacturers face significant challenges in diversifying their suppliers due to both regulatory constraints and market limitations.

Once the production process is approved, vaccine manufacturers have minimal ability to switch suppliers or input materials. **Around 50% of sampled materials have strict regulatory limitations**, preventing changes during manufacturing.

Some of the key implications of this situation are the following:

- **Limited supplier options:** The global market for a great proportion of key input materials is small, meaning manufacturers must rely on a handful of suppliers except for more commoditized materials.

- **Need for long-term supplier relationships:** Since switching suppliers is difficult, manufacturers must invest in long-term partnerships to ensure a reliable supply chain, which are difficult to obtain.

Importance of coordination and standardization: To navigate these challenges, manufacturers must work together to establish technical coordination and industry-wide standardization.

6. Solutions Addressable by Vaccine Manufacturers

The prior section focused on structural solutions that require the involvement and alignment of a variety of stakeholders in different levels. In this section, we will review some courses of actions that the manufacturers may take to optimize supply chain. These levers were developed based on interviewees held with materials suppliers and with experts in the field.

6.1 Forecast Planning

Most of the suppliers interviewed throughout this research mentioned that the key for reducing costs and lead times is to perform constant forecast planning exercises and to socialize the potential demand of materials with the suppliers in advance.

They mentioned that in various regions, besides Africa, the manufacturers that devote time and resources to Forecast Planning are those that at the end of the day obtain better conditions. This is due to a variety of reasons, but mainly because with time the suppliers may plan their manufacturing, logistics and delivery in advance as well.

Forecast planning seemingly brings a variety of benefits. Among others we were able to map the following:

Category	Pain-point	Impact	Rationale
Order-to-delivery / Operations	Volume uncertainty	Very high	• Allows suppliers to include the manufacturers in their planning and reduce the expected lead times
	Production capacity	Mid	
	Bureaucracy	Very high	• Allows to develop a logistical plan in advance and reduce delivery times and bureaucracy
	Customs	Mid	
Economic / Financial	Production costs	Mid	• Suppliers mentioned that it optimizes their industrial capacity and manufacturing and hence reduce prices
	Credit Terms & Payment Methods	Low	• Forecast planning and strategy could lead to better terms regarding payment methods

While there are challenges for demand forecasting such as lack of historical data or unexpected volatility, especially for a developing industry such as in Africa, it is a best practice as well as the discussion of the forecast with key suppliers.

6.2 Open Communication Channels with Suppliers

On the same line as Forecast Planning, developing an open communication with suppliers, at least with the critical ones, is another best practice to implement. Vaccine input materials is a complex industry and many of the products are sophisticated and, in some ways, customized. In this sense, it is a common practice for this industry worldwide for account managers to have frequent and fluent communication with their clients.

This is a recommendation that the suppliers interviewed, strongly suggested for a developing industry in the African continent: nurture communication with their suppliers of choice who have vast experience in the industry and may provide advise based on their experience.

Beside other, having open channels of communication may have the following benefits:

Category	Pain-point	Impact	Rationale
Communication	Documentation and communication	Very high	• Allows the development of requirements from both parts and ensure the clarity and accuracy of documentation required through the process (e.g., contracts, invoices, product specifications)
Quality requirements	Compliance Testing and Certification		• Conversations with technical teams could diminish the risk of having compliance issues, and align the required quality processes
Order-to-delivery / Operations	Bureaucracy	High	• Open channels of communication could help to fasten some processes and evaluate ways to optimize costs
Economic / Financial	All pain points	High	• Fluent communication could lead to the optimization of costs through the discussion of options that could benefit both the suppliers and vaccine manufacturers
Demand guarantee	MOQ	Mid	• Conversations could lead to quickly validate which are the MOQs from both parties

6.3 Total Cost of Ownership Estimation

Total Cost of Ownership estimation is a powerful tool that allows manufacturers understand the total cost of acquiring, operating and maintaining an asset during its life span.

There is a variety of factors that may impact the TCO, including: breakage during transport, need of sterilization, need to adapt machinery, training required to the team, etc.

Among others, applying a TCO model may impact the following Pain-Points:

Category	Pain-point	Impact	Rationale
Economic / Financial		High	• TCO would help to identify hidden costs, such as maintenance, repairs, and energy use, enabling cost-effective investments that reduce long-term expenses and improve overall profitability
Order-to-delivery / Operations		Low	

6.4 Benchmarking

Market benchmarking serves as a strategic tool to evaluate market positioning, supplier capabilities, and industry standards, ultimately enabling informed decision-making across multiple dimensions. This is a best practice that all industrial manufacturers should have incorporated, even in their Procurement departments.

Adequate benchmarking may impact the following pain-points:

Category	Pain-point	Impact	Rationale
Economic / Financial		Mid	• Comparing pricing structures, cost drivers, and supplier offerings, could help to identify opportunities to optimize spending. This could facilitate the negotiation of better terms and reduce costs
Communication	Documentation and communication		• Helps to continuously understand industry best practices in stakeholder communication, ensuring alignment between internal teams. • Benchmarking could help to identify the quality standards upheld by market suppliers, setting expectations, and encouraging collaborative solutions
Quality requirements			

7. Appendix

7.1 Input materials – interchangeability assessment

Interchangeability has proven to be crucial when planning how to tackle future vaccine demands. Multiple interviews with top notch experts in vaccine manufacturing and industry leaders have highlighted this point and allowed us to develop the following assessment, categorizing our key input list into four groups according to their level of replaceability.

Category	Why?
Almost completely limited (7 of the sampled materials)	Critical materials that likely require a new full clinical trial process

- **Adjuvants**: Aluminum-based; CpG; Liposomal; MPL; QS-21, Squalene
- **Raw material**: cell-culture media
- **Starting material**: cell banks, cell lines, virus seeds

Category	Why?
Very limited (26 of the sampled materials)	Requires complex regulatory approvals that may take years

- **Biological raw material:** albumin, fetal calve serum, incubated chicken eggs, Trypsin
- **Chromatography and filtration:** resins/gels; depth filtration membranes
- Disposable material: Bags for process and storage, optical adhesive foil; single-use bio bags
- **Enzyme for manufacturing:** mRNA purification, mRNA transcription, mRNA cap analogs, Nucleoside triphosphates, restriction endonuclease
- **Lab reagent:** Relevant antibodies
- **Lipids and surfactants:** cationic lipids, non-specific cholesterols, non-specific phospholipids, PEG-ylated lipids
- **Primary packaging:** ampoules, vials, stoppers

Category	Why?
Limited (13 of the sampled materials)	Requires regulatory approvals that may take months

- **Chromatography and filtration:** columns, sterile filtration systems, tangential flow filtration membranes, ultra diafiltration units
- **Disposable material:** cell factories, connectors
- **Enzyme for manufacturing:** DNA degradation enzymes (benzonase)
- **Lab material:** disposable material (q)PCR plates, ELISA plates, ELISA-assay substrates
- **Raw material:** inactivation reagents, preservatives, sugars

Category	Why?
Least limited (29 of the sampled materials)	Most of them do not require any regulatory approval

- **Chromatography and filtration:** disposable filters
- **Disinfectants:** Decon-quat; Decon clean; Isopropanol
- **Disposable material:** tubes, Erlenmeyer flasks, roller bottles and tissue culture flasks
- **Lab material:** Filter, Pipette tips, electrophoresis gels, HPLC-columns and pipettes
- **Lab reagent:** (q) PCR kits, cell culture plates, buffers, enzymes, reagents for bioburden, primers, and relevant reagents for endo-toxin (LAL), relevant reagents for sterility determination and RNA-binding fluorescent dye (Ribogreen)
- Lipides and surfactants: Polysorbate 20 and Polysorbate 80
- **Primary packaging:** seals / caps
- **Raw material:** buffer for manufacturing, buffer for the pH, buffer for the lab and enzymes for the lab
- **Starting material:** plasmids

7.2 Input Materials - Demand Estimation

Estimated Vaccine Manufacturing Capacity and Demand in Africa by 2030

- Expected vaccine manufacturing capacity: 1.4 billion doses (could surge to 2 billion in emergency situations).
- Number of doses assuming 10% wastage rate: 1.5 billion.
- Projection for vaccine manufacturing demand: 687 million doses.

Demand Characteristics for Different Input Material Categories

- **Primary Packaging:** Vials, stoppers, and seals are expected to be required in approximately 300 million units, as each vial will contain between 3 and 8 doses. Syringes will be needed in quantities matching the number of doses, around 1.5 billion.

- **Filtration:** Filtration systems are expected to be required in quantities of thousands annually.
- **Disposable Material:** Thousands of units will be demanded for most disposable materials, as they need to be replaced frequently.
- **Lab Material:** Substantial lab materials are needed for Quality Assurance, with quantities ranging from thousands to millions due to the wide variety of materials involved.
- **Temperature Monitoring Device:** This category entails only one material (VVM), which will probably match the number of vials demanded at approximately 138 million units.

7.3 Pain Points Further Material

Additional Pain Points Raised by Manufacturers

- **Logistics and Infrastructure:** Lack of adequate infrastructure in Africa poses challenges for transportation and distribution.
- **Import and Bureaucracy:** Complex import processes and bureaucratic hurdles can delay the procurement of input materials.
- **Forex and Exchange Rates:** Currency fluctuations and exchange rate risks can impact the affordability of imported materials.
- **Technical Capabilities:** Some manufacturers may face technical difficulties due to incompatibility between machinery and input materials.
- **Regulatory Constraints:** Harmonization of regulatory processes and pre-qualification requirements is needed to facilitate efficient procurement.

7.4 Solutions Further Material

Demand Pooling Puzzle and Alternatives

The study explored different models for setting up and managing demand pooling initiatives, considering factors like funding, governance, and audit processes.

Distribution Centers

Different models for managing these distribution hubs present unique challenges and feasibility concerns. These are some of the option that have been analyzed:

- **Run by Suppliers**: Suppliers emphasized the need for sustained demand and a positive return on investment, similar to manufacturing facilities.

- **Run by Manufacturers**: Considered unfeasible due to the high operational costs manufacturers would need to absorb.

- **Multi-Product Run by a Third Party**: Some suppliers suggested that a government or organization could establish distribution centers to serve multiple input materials, making it a potentially viable solution.

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