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Posted Date: 11 March 2026

doi: 10.20944/preprints202603.0839.v1

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Article

Building COVID-19 Vaccine Manufacturing Capacity in Nigeria: A Qualitative Needs Assessment of Barriers and Resource Requirements

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Abstract

Background: During the COVID-19 pandemic, Nigeria relied largely on imported vaccines, underscoring vulnerabilities in supply chains and the absence of domestic vaccine manufacturing. Understanding supply-related barriers and the resources required for local vaccine production is critical for future pandemic preparedness and population health outcome. The objective of the study was to identify stakeholder-perceived barriers to COVID-19 vaccine manufacturing in Nigeria and to describe the resources and enabling conditions required for local production. **Methods:** We conducted a qualitative needs assessment using semi-structured interviews with senior personnel from Nigerian pharmaceutical manufacturing firms and regulatory agencies. Participants were recruited purposively and consecutively. Interviews (30-60 minutes) were conducted via Zoom, audio-recorded with consent, transcribed, and analyzed using inductive thematic analysis following established six-phase procedures. Reporting adheres to the Consolidated Criteria for Reporting Qualitative Research (COREQ). **Results:** Six participants (two regulators and four pharmaceutical executives) identified three interrelated barrier to domestic COVID-19 vaccine production: (1) technical and knowledge gaps (loss of hands-on expertise, absence of operational vaccine manufacturing facilities, limited technology transfer), (2) financial and infrastructure barriers (high cost of capital, serial taxation, unreliable electricity and logistics constraints), and (3) systemic and institutional barriers (inconsistent political commitment, policy discontinuity, regulatory capacity gaps, and concerns about public confidence). To enable local production, participants emphasized coordinated investment in workforce development, technology-transfer partnerships, modern utilities and cold chain systems, access to specialized equipment and high-quality inputs, and predictable policy, financing, and regulatory environments. **Conclusions:** Participants perceived Nigeria's current capacity as insufficient for COVID-19 vaccine manufacturing but identified actionable levers, particularly human capital development, infrastructure strengthening, and regulatory and financing reforms, to enable sustainable local production. These findings provide a practical roadmap for policymakers, regulators, and industry leaders seeking to strengthen Nigeria's biomanufacturing and long-term pandemic preparedness.

Keywords: COVID-19; vaccine manufacturing; Nigeria; technology transfer; qualitative; needs assessment; regulatory systems; cold chain; financing

1. Introduction

The COVID-19 pandemic renewed global attention to inequities in vaccine access and highlighted the vulnerability of countries without domestic manufacturing capacity. Despite unprecedented vaccine development speed, early production and supply remained concentrated in a small number of manufacturers and regions, leaving many low- and middle-income countries dependent on external supply chains and donation mechanisms. This supply concentration created delays and uncertainty that undermined equitable access and preparedness for future outbreaks [1,2].

Across Africa, end-to-end vaccine manufacturing capacity has historically been limited, with many facilities focused on fill-finish, labeling, or distribution rather than antigen production and integrated quality systems. Recent analyses emphasize that building sustainable vaccine manufacturing on the continent requires systems-level investments spanning workforce, infrastructure, technology transfer, regulation, and market-shaping mechanisms [3,4]. Continental initiatives, including the African Union and Africa Centres for Disease Control and Prevention's Partnership for African Vaccine Manufacturing (PAVM), have called for coordinated action to strengthen regulatory convergence, de-risk investment, and expand production ecosystems [5,6].

Nigeria, Africa's most populous country [7], has a sizable pharmaceutical manufacturing sector yet relied largely on imported and donated COVID-19 vaccines during the pandemic. Import dependence created both supply interruptions and operational risks. For example, COVAX announced delivery delays in March 2021 due to constrained availability of Serum Institute of India-produced AstraZeneca doses, illustrating the vulnerability of countries dependent on a small number of external suppliers [8]. In Nigeria, vaccine administration was halted on July 9, 2021 when supplies ran out and resumed only after new shipments arrived [9]. Import dependence also interacted with short shelf life and cold-chain constraints; in December 2021, Nigeria destroyed more than one million expired AstraZeneca doses received with limited time remaining, a high-profile episode that underscored the challenges of last-minute shipments and threatened to erode public confidence [10]. In parallel, global efforts to expand technology transfer, such as the World Health Organization (WHO) mRNA vaccine technology-transfer hub and related end-to-end initiatives, illustrate practical pathways for accelerating local capability when paired with workforce training and regulatory strengthening [11,12].

To translate national and continental aspirations into feasible industrial plans, stakeholders must understand both the supply-side constraints that have prevented Nigeria from developing operational vaccine manufacturing and the concrete resource requirements needed to establish an enterprise capable of producing vaccines under internationally acceptable quality standards. While prior work has described manufacturing bottlenecks across Africa and policy options for strengthening Nigeria's pharmaceutical sector, empiric stakeholder data focused on Nigeria-specific operational barriers and resource needs remain limited [13,14].

This study therefore aimed to: (1) identify perceived limitations of Nigeria's pharmaceutical industry for producing COVID-19 vaccines and (2) describe the resources and enabling conditions stakeholders believe are required to establish a viable vaccine manufacturing enterprise.

2. Materials and Methods

Study Design

We conducted a qualitative needs assessment to identify barriers and resource requirements for COVID-19 vaccine manufacturing in Nigeria. Needs assessment is a formal process for identifying

gaps that must be closed to improve performance and achieve desired outcomes, and it has long been used to guide health planning and prioritize interventions [15,16].

Setting and Participants

Participants were recruited from key stakeholder organizations, including Nigerian pharmaceutical manufacturing firms and relevant national regulatory agencies. Eligibility criteria included senior leadership roles with strategic planning, oversight of manufacturing operations, quality systems, or regulatory compliance.

Sampling and Recruitment

Participants were selected purposively and consecutively. Potential participants were approached via telephone and email. If an invitee declined, another eligible senior personnel from the same or a comparable organization was approached. Recruitment continued until the study team determined that thematic saturation had been achieved, with later interviews yielding redundant themes.

Data Collection

Semi-structured interviews were conducted via Zoom and lasted approximately 30-60 minutes. Participants provided informed consent prior to participation. Interviews were conducted once per participant at times and locations convenient for participants, including at home or workplace, and were audio-recorded with consent. Zoom's automated transcription was used to generate transcripts; transcripts were then reviewed against audio recordings and corrected to ensure accuracy. Transcripts were not returned to participants for comment or correction.

Interview Guide

The semi-structured interview guide (Appendix A) was developed by the principal investigator based on the study objectives and expert input of the research team. Draft questions were circulated for feedback, and the guide was informally piloted with professional colleagues and refined to improve clarity and contextual relevance to the Nigerian context. The guide included questions about participants' professional roles, perceived barriers to vaccine production, and resource necessary for establishing vaccine manufacturing capacity in Nigeria

Data Analysis

Data was thematically analyzed using an inductive approach following the six-phase framework described by Braun and Clarke and colleagues [17,18]. The analytic process included repeated familiarization with transcripts, inductive coding, grouping codes into categories, developing and refining themes and subthemes, and producing a coherent narrative supported by illustrative participant quotes. A codebook and audit trail were maintained throughout to enhance transparency and consistency.

Rigor and Reporting

Reporting followed the Consolidated Criteria for Reporting Qualitative Research (COREQ) where applicable [19,20]. Strategies supporting trustworthiness included reflexive journaling to bracket assumptions, maintenance of an audit trail and evolving codebook, iterative theme refinement, and periodic peer debriefing with colleagues experienced in qualitative methods. These measures aimed at strengthening credibility, dependability, confirmation, and transparency.

Ethical Considerations

The University of Minnesota Institutional Review Board determined the research aims to be non-human research (IRB ID: STUDY00021458). All participants provided verbal consent prior to participation. Transcripts were de-identified prior to analysis to protect confidentiality.

3. Results

3.1. Participants

Six individuals participated: two regulators and four pharmaceutical-sector executives. For analytic purposes, pharmaceutical participants were grouped by years of experience to capture both historical and contemporary perspectives: participants with more than 25 years of industry experience were classified as “Old Pharma,” and those with more than five but fewer than 25 years of experience as “New Pharma.” Participant characteristics are summarized in Table 1.

Table 1. Characterization of interview participants.

Participant label	Role / title	Affiliation	Classification
Participant 1	State Coordinator	National Agency for Food and Drug Administration and Control (NAFDAC)	Regulatory
Participant 2	State Officer	Pharmacist Council of Nigeria (PCN)	Regulatory
Participant 3	Senior Executive	Nigerian pharmaceutical company	Old Pharma
Participant 4	Director	Nigerian pharmaceutical company	Old Pharma
Participant 5	Executive	Nigerian pharmaceutical company	New Pharma
Participant 6	Executive	Nigerian pharmaceutical company	New Pharma

3.2. Overview of Themes

Findings are organized around the two study aims. For Aim 1 (limitations to vaccine manufacturing), three interrelated barrier domains emerged (Table B1). For Aim 2 (resources required), participants described a complementary set of priorities across human capital, policy and financing supports, and physical/technological infrastructure (Table B2).

Aim 1: Perceived limitations of Nigeria’s pharmaceutical industry for producing COVID-19 vaccines

Theme 1: Technical and knowledge gaps

Stakeholders emphasized that Nigeria lacks both the specialized tacit knowledge and the physical production context needed for vaccine manufacturing. Participants described loss of hands-on expertise over time, the absence of operational vaccine facilities to train and validate processes, and limited access to structured technology transfer.

“So far, we don’t have any existing vaccine facility in Nigeria. So there’s nobody with practical experience.” (Participant 6)

“Vaccine production is even more advanced than infusions... We lack training in that area.” (Participant 3)

“At the moment a single vaccine production facility does not exist in Nigeria.” (Participant 1)

“The technical know-how is also part of the problem... What you are not doing, you lose with time. That is knowledge. The knowledge you do not put into practice, you lose it with time.” (Participant 1)

Theme 2: Financial and infrastructure barriers

Participants described financial constraints as tightly linked with infrastructure constraints. They highlighted the high cost of capital and fiscal burdens as major deterrents to long-horizon manufacturing investments. Infrastructure concerns centered on unreliable electricity, transport limitations, and the difficulty of sustaining well-controlled production environments and cold-chain logistics.

"To access fund in Nigeria is a big challenge... the rate as of today is about 36 percent, which is on the high side." (Participant 6)

"You pay taxes to the state, federal, and local governments... This serial tax burden weighs heavily on companies." (Participant 5)

"Our power supply in Nigeria is epileptic... Imagine producing a high-quality vaccine, and then the power needed to store it is not there." (Participant 1)

"The erratic power supply and frequent grid failures make it almost impossible to run a reliable production facility." (Participant 4)

Theme 3: Systemic and institutional barriers

Beyond technical and financial constraints, participants argued that governance and institutional factors shape investor confidence and feasibility. They noted inconsistent political commitment and policy discontinuity, regulatory capacity and process gaps, and concerns about the downstream market and public confidence in locally produced vaccines.

"The political will is seriously lacking... We have a lot of bureaucratic bottlenecks in government... it's not going to be easy." (Participant 1)

"Lack of policy continuity discourages investors." (Participant 3)

"We are struggling here in Abuja... we have not yet reached the regulatory authority for stringent regulatory authority status." (Participant 1)

"We have a serious problem of vaccine hesitancy... You can produce a product that will not be marketable." (Participant 1)

Aim 2: Resources required to establish COVID-19 vaccine manufacturing capacity in Nigeria

Theme 1: Human capital and technical expertise

Participants consistently framed workforce capability as foundational. They emphasized specialized training in sterile and biologics manufacturing, practical exposure to modern equipment and controlled processes, and structured mentorship or technical assistance from experienced vaccine manufacturers. Several noted that regulatory workforce capacity must expand in parallel to effectively oversee production.

"We need technical assistance and training. The technical aspects of vaccine production must be imparted to our people... that's another level." (Participant 3)

"You need people with experience. You need technically skilled personnel. The machines used are very different from what we use for tablets or syrups." (Participant 6)

"We also need expertise. Vaccine production is a gray area in Nigeria... We need those with real experience to put us through." (Participant 5)

"Regulatory staff themselves need training so they can effectively support and monitor vaccine production efforts." (Participant 5)

Theme 2: Government support and policy reform

Stakeholders described public-sector leadership as essential for lowering barriers to entry and sustaining investment. Suggested measures included fiscal and tax relief for equipment, supportive industrial policy (e.g., industrial parks or shared infrastructure), predictable regulation, and coordinated collaboration between government, manufacturers, and donors.

"Government must support the industry by removing taxes on imported machinery." (Participant 5)

“There should be funding mechanisms... The government should consider creating a pharmaceutical hub... where 2, 3, or more companies can collaborate and share basic infrastructure.” (Participant 3)

“We need donor support, both local and international.” (Participant 3)

Theme 3: Physical and technological infrastructure

Participants identified reliable utilities and cold-chain capability as prerequisites for vaccine production and distribution. They also highlighted challenges in access to specialized equipment and high-quality inputs, including dependence on imported active pharmaceutical ingredients (APIs) and the need for predictable supply chains.

“A vaccine is a specialized product that requires specialized storage, and you cannot break the cold chain from point A to point B.” (Participant 1)

“Stable electricity, clean water, properly equipped labs, and reliable logistics systems must be in place.” (Participant 4)

“We import about 90 percent of APIs. Removing VAT and other taxes on pharmaceutical products could reduce prices.” (Participant 2)

“Raw materials and packaging materials should be sourced from reliable, high-standard sources. These should not be left to chance.” (Participant 3)

4. Discussion

This qualitative needs assessment found that participants viewed Nigeria’s current readiness for COVID-19 vaccine manufacturing as constrained by interdependent technical, financial, infrastructure, and institutional barriers. The complementary resource priorities articulated by participants suggest that progress requires coordinated action across human capital development, structured technology transfer, reliable utilities and cold-chain systems, access to specialized equipment and high-quality inputs, and predictable policy and regulatory environments.

These findings align with broader evidence that sustainable vaccine manufacturing in Africa depends on ecosystem investments rather than isolated facility upgrades [3,4]. Participants’ emphasis on technology transfer and mentorship resonates with global initiatives supporting structured transfer of know-how, including WHO-supported mRNA technology-transfer efforts and end-to-end transfer programs [11,12]. The prominence of political commitment, regulatory predictability, and coordinated industrial policy also echoes continental calls under PAVM for aligned standards, pooled resources, and market-shaping approaches that reduce risk for investors and manufacturers [5,6].

Policy and Practice Implications

Stakeholder accounts suggest a pragmatic sequence of interventions. First, human capital development, including training in Good Manufacturing Practice (GMP), aseptic processing, quality assurance/quality control, and biologics regulation for both manufacturers and regulators, should be treated as a parallel track to infrastructure investment. Second, structured technology transfer partnerships (with clear quality and process benchmarks, on-site mentorship, and stepwise validation) can accelerate capability-building and reduce learning curves; the WHO mRNA technology-transfer hub model illustrates how coordinated transfer of know-how and quality systems can build capacity among recipient manufacturers [11]. Third, utilities and end-to-end cold chain systems must be strengthened to support controlled manufacturing and distribution; this is consistent with evidence that cold-chain gaps can compromise vaccine integrity and contribute to wastage [21]. Fourth, access to specialized equipment and high-quality inputs require targeted trade facilitation and procurement strategies; for example, duty and VAT exemptions for critical equipment and consumables, expedited customs clearance for temperature-sensitive inputs, pooled procurement or framework agreements for scarce materials, and government-backed offtake

commitments. These measures are salient in Nigeria, where pharmaceutical production depends heavily on imported ingredients and inputs [22].

Financing and De-Risking Strategies

Participants described high borrowing costs as a major deterrent to capital-intensive investment. Two categories of financing approaches may help de-risk vaccine-manufacturing investments: 1) blended finance packages that combine concessional capital with private investment, supported by partial credit guarantees or other risk-sharing facilities; and 2) demand-certainty mechanisms, such as advance purchase agreements (APAs) or longer-term government offtake contracts, that improve revenue predictability and make long-horizon projects more bankable [23–25].

Public Confidence as a Supply-Related Constraint

Notably, stakeholders framed public confidence and hesitancy as part of the manufacturing feasibility problem: a viable industry requires a market that trusts product quality. Confidence-building strategies should therefore be integrated into manufacturing plans, including transparent regulatory decision-making, and visible GMP inspection and lot release processes, robust pharmacovigilance and post-market surveillance, and proactive engagement with community and faith leaders. Strengths and limitations

This study has several Strengths and some limitations. Strengths include perspectives from both regulatory officials and industry leaders, enabling triangulation across key governance and operational domains. The use of an explicit needs-assessment approach with systematic thematic analysis and COREQ-informed reporting enhances methodological transparency and rigor [19]. Limitations include the small sample size and the absence of perspectives from some potentially relevant actors (e.g., additional manufacturers, financing institutions, or government ministries). However, the recurrence of themes across participant groups suggests that the major constraints and priorities identified are salient within the sector. As with all qualitative studies, findings are intended for analytical generalization informing theory, policy design, and strategic planning rather than statistical representativeness.

5. Conclusions

Interviews with senior regulators and industry leaders suggest that Nigeria's current readiness for COVID-19 vaccine manufacturing is constrained by three linked domains: 1) limited hands-on expertise and technology transfer; 2) high-cost financing alongside unreliable utilities, logistics, and cold-chain systems; and 3) policy and regulatory uncertainty that undermines investment and public confidence. Participants articulated a feasible and actionable path forward. Priority actions include investing in specialized workforce training for manufacturers and regulators; securing structured technology-transfer partnerships; strengthening electricity, water, waste management, and cold-chain infrastructure; improving access to critical equipment and quality inputs; and implementing predictable financing and regulatory reforms. Coordinated action across these areas could make local vaccine production viable and strengthen national and regional preparedness for future infectious disease outbreaks.

Author Contributions: Conceptualization, T.O.A.; methodology, T.O.A.; software, T.O.A.; validation, T.O.A., O.N.O., C.G., S.B.B., D.M.T., and J.C.S.; formal analysis, T.O.A.; investigation, T.O.A.; resources, T.O.A.; data curation, T.O.A.; writing—original draft preparation, T.O.A.; writing—review and editing, T.O.A., O.N.O., C.G., S.B.B., D.M.T., and J.C.S.; visualization, T.O.A.; supervision, T.O.A.; project administration, T.O.A.; funding acquisition, T.O.A. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: The data presented in this study are available on request from the corresponding author. The data is not publicly available due to privacy reasons.

Acknowledgments: The authors thank Dr. Chijioke Okoro, DrPH (World Bank), for his expert advice and timely recommendations, which significantly enriched this study. The authors also thank Dr. Adedotun Ajelabi, MD, for coordinating the research assistants involved in data collection, and the five research assistants whose contributions were essential to the successful conduct of the fieldwork and related logistics.

Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

APA / APAs	Advance Purchase Agreement(s)
API / APIs	Active Pharmaceutical Ingredient(s)
COREQ	Consolidated Criteria for Reporting Qualitative Research
COVID-19	Coronavirus Disease 2019
COVAX	COVID-19 Vaccines Global Access
GMP	Good Manufacturing Practice
mRNA	Messenger Ribonucleic Acid
NAFDAC	National Agency for Food and Drug Administration and Control
PAVM	Partnership(s) for African Vaccine Manufacturing
PCN	Pharmacist Council of Nigeria
VAT	Value-added Tax
WHO	World Health Organization

Appendix A

Semi-Structured Interview Guide

1. Thank you & Welcome!
2. Project Information
3. Consent to participate in this interview and record (audio & video).
 - a. We will report our findings without identifying who you are.
4. Introduction:
 - b. First name
 - c. Job title
 - d. Length of service
5. What are some of the limitations of the existing Nigerian pharmaceutical industry to produce the COVID-19 vaccine.
6. What are some of the resources required to establish successful pharmaceutical entities that can produce the COVID-19 vaccine in Nigeria.

Appendix B

Table B1. Barriers to local COVID-19 vaccine manufacturing.

Theme	Subtheme	Illustrative quote
Technical and knowledge gaps	Loss of expertise and training	<i>So far, we don't have any existing vaccine facility in Nigeria. So there's nobody with practical experience. (Participant 6) Vaccine production is even more advanced than infusions. It involves cold chain logistics, temperature control during transport, and</i>

		<i>specialized infrastructure. This is a high-tech operation, and we lack training in that area. (Participant 3)</i>
	Absence of manufacturing facilities	<i>At the moment a single vaccine production facility does not exist in Nigeria. (Participant 1)</i> <i>So far, we don't have any existing vaccine facility in Nigeria. So there's nobody with practical experience. (Participant 6)</i>
	Lack of technology transfer	<i>The technical know-how is also part of the problem. For a country that has stayed long without engaging in such production, even those who knew how to produce it must have lost whatever technology they had. What you are not doing, you lose with time. That is knowledge. The knowledge you do not put into practice, you lose it with time. (Participant 1)</i>
Financial and infrastructure barriers	Capital and fiscal limitations	<i>To access fund in Nigeria is a big challenge. The commercial banks, their standing rates as of today is about 36%, which is on the high side. (Participant 6)</i> <i>You pay taxes to the state, federal, and local governments... This serial tax burden weighs heavily on companies. (Participant 5)</i>
	Infrastructure and logistics challenges	<i>Our power supply in Nigeria is epileptic... Imagine producing a high-quality vaccine, and then the power needed to store it is not there. (Participant 1)</i> <i>Add power supply challenges, bad roads, high operational costs, these all discourage investment. (Participant 2)</i> <i>The erratic power supply and frequent grid failures make it almost impossible to run a reliable production facility. (Participant 4)</i>
Systemic and institutional barriers	Lack of political will	<i>The political will is seriously lacking, in my opinion, with our government.... We have a lot of bureaucratic bottlenecks in government... it's not going to be easy for anyone willing to come and establish a vaccine production facility here to succeed so easily. (Participant 1)</i> <i>There's also a lack of strong political will... Right now, the environment discourages people due to the high cost of drugs, instability, and import dependence, especially for APIs [Active Pharmaceutical Ingredients]. We import about 90% of APIs. (Participant 2)</i>
	Regulatory capacity gaps	<i>Lack of policy continuity discourages investors. (Participant 3)</i> <i>At the moment, we are struggling here in Abuja as a regulator of food and drugs to see how our processes align with international standards. Yes, we have just attained World Listing Authority Level 3, so we have</i>

not yet reached the regulatory authority for stringent regulatory authority status. (Participant 1)

Low public confidence and hesitancy

We have a serious problem of vaccine hesitancy... You can produce a product that will not be marketable. (Participant 1)

Table B2. Barriers to local COVID-19 vaccine manufacturing.

Theme	Subtheme	Illustrative quote
Human capital and technical expertise	Specialized training and capacity building	<i>We need technical assistance and training. The technical aspects of vaccine production must be imparted to our people. Right now, I can't name a single manufacturing company in Nigeria producing vaccines. Technological transfer is very important. Yes, pharmacists have basic knowledge, but when it comes to the practical and highly controlled processes involved in vaccine production, that's another level. (Participant 3)</i> <i>You need people with experience. You need technically skilled personnel. The machines used are very different from what we use for tablets or syrups. (Participant 6)</i>
	Access to expertise and knowledge transfer	<i>We also need expertise. Vaccine production is a gray area in Nigeria, and we have very few, if any, experts in this field. We will need help from companies that are already into vaccine production. Even if we have people with experience in related areas, we still need training and technical guidance. We need those with real experience to put us through. (Participant 5)</i> <i>Regulatory staff themselves need training so they can effectively support and monitor vaccine production efforts. (Participant 5)</i>
Government support and policy reform	Favorable regulatory and policy environment	<i>Government must support the industry by removing taxes on imported machinery. (Participant 5)</i> <i>Government support is key. Local manufacturing needs encouragement and supportive policies. (Participant 2)</i>
	Political will and multisectoral collaboration	<i>There should be funding mechanisms. The government should consider creating a pharmaceutical hub, an industrial park, where 2, 3, or more companies can collaborate and share basic infrastructure. (Participant 3)</i>
Physical and technological infrastructure	Utility and cold chain	<i>A vaccine is a specialized product that requires specialized storage, and you cannot break the cold chain from point A to point B. (Participant 1)</i> <i>Stable electricity, clean water, properly equipped labs, and reliable logistics systems must be in place. Vaccine production demands a stable electricity supply. (Participant 4)</i>

Cooling systems need electricity consistently. With consistent electricity, operations would be easier. (Participant 6)

Equipment and raw material access *We import about 90% of APIs. Removing VAT and other taxes on pharmaceutical products could reduce prices. (Participant 2)*

Raw materials and packaging materials should be sourced from reliable, high-standard sources. These should not be left to chance. (Participant 3)

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