LOCAL ARV PRODUCTION IN SOUTH AFRICA

FINAL REPORT

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How Can South Africa Strengthen Its Local Antiretroviral Production Amidst Changing Donor Country Attitudes?

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Credits

This thesis is submitted in partial fulfilment of the requirements for the degree of Master of Public Administration at University College London Department of Science, Technology, Engineering and Public Policy (STEaPP).

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The views and interpretations expressed herein are solely those of the author and do not necessarily reflect those of UCL STEaPP or Kiara Health.

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Authors' Background

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Celeste holds a B.S.E. in Biomedical Engineering from the University of Michigan, with a minor in Materials Science. She brings over four years of experience in tissue engineering and research laboratory management. Her industry tenure focused on the design of orthopaedic implants. Celeste is dedicated to revolutionising healthcare through interdisciplinary approaches.

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Glossary of Abbreviations

Abbreviation	Meaning
AIDS	Acquired Immunodeficiency Syndrome
API	Active Pharmaceutical Ingredient
ARV	Antiretroviral
B2B	Business to Business
DFI	Development Finance Institutions
DHET	Department of Higher Education and Training
DoH	Department of Health
DSTI	Department of Science, Technology and Innovation
DTIC	Department of Trade, Industry and Competition
EMA	European Medicines Agency
eSPPS	electronic SADC Pooled Procurement Platform
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice
HIV	Human Immunodeficiency Virus
IDC	Industrial Development Corporation
NRA	National Regulatory Authority
NSP	National Strategic Plan
MPP	Medicines Patent Pool
MRF	Medicines Regulatory Forum
PEPFAR	President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV
SA	South Africa
SADC	Southern African Development Community
SAHPRA	South African Health Products Regulatory Authority

Abbreviation	Meaning
SANAC	South African National AIDS Council
SIPS	Support to Industrialisation and Productive Sectors
SPPS	SADC Pooled Procurement Services
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
VAT	Value Added Tax
WHO PQ	WHO Pre-qualification
ZAR	South African Rand

Executive Summary

South Africa (SA) has made extraordinary progress in expanding access to Antiretroviral (ARV) therapy, transforming Human Immunodeficiency Virus (HIV) from a fatal illness into a manageable condition for millions of people. Yet this achievement is now under pressure. Immediate challenges stem not from medicine shortages but from disruptions in service delivery caused by donor funding volatility, particularly the uncertainty surrounding the United States President's Emergency Plan for AIDS Relief (PEPFAR). Clinics have struggled to retain staff, laboratory systems have been weakened, and treatment delivery to people living with HIV (PLHIV) has been compromised.

Our research found that the direct impact of recent funding shocks on local production has so far been limited. SA continues to import nearly all Active Pharmaceutical Ingredients (APIs) and most finished ARVs, yet national stock shortages have been few. The reliance on imports presents long-term supply security risks, but a more pressing concern lies downstream, where patients face growing obstacles accessing medicines already procured. This mismatch highlights a central insight from our study: while localisation of ARV production is often presented as a safeguard for future resilience, diverting scarce public funds into industrial initiatives today risks neglecting the urgent task of stabilising service delivery.

Recommendations from this study point therefore have two directions. In the short term, government and partners should prioritise immediate measures to protect treatment continuity by allocating funds to replace donor cuts, retaining HIV workforce capacity, keeping clinics open, and ensuring that laboratory testing and monitoring remain functional. These steps should be reinforced by implementing the accelerated National Strategic Plan (NSP) and strengthening transparency and monitoring of the fast-track pathway by the South African Health Products Regulatory Authority (SAHRA). Without these interventions, gains in medicine procurement or manufacturing capacity will do little to prevent avoidable illness and death.

In the mid- and long-term, however, there remains a strong case for reforming the system to make local ARV formulation viable. Given the technical and economic complexity of API synthesis, our findings suggest that efforts should first strengthen ARV formulation capacity, where SA firms already have a foundation. In the medium term, this requires targeted policy support to level the playing field, including multisectoral collaboration, preferential procurement, and technology transfer and education that encourage uptake of domestically formulated ARVs. Over the longer term, sustained reform will be needed to address deeper regulatory and market barriers: SAHPRA's reliance pathways must evolve from informational to binding, regional initiatives such as ZAZIBONA must gain legal force, and procurement rules must balance price with supply security. Only by tackling these obstacles can local formulation contribute meaningfully to SA's treatment resilience.

In summary, the evidence shows that the current crisis is not one of medicine supply, but of service delivery. Stabilising downstream systems must come first. Yet building a resilient and self-reliant HIV response over the longer term will also require aligning regulatory, financial, and procurement policies to support sustainable local production. SA thus faces a dual challenge: safeguarding patient access today while laying the groundwork for long-term supply resilience.

1. Introduction

1.1 The Global and National HIV Context

Human Immunodeficiency Virus (HIV) remains one of the most significant global health challenges, with an estimated 39.9 million People Living with HIV (PLHIV) worldwide in 2023 and more than 42 million lives lost since the epidemic began in the 1980s (WHO, 2024). Sub-Saharan Africa carries the highest burden, and South Africa (SA) alone accounts for nearly 20% of global cases equating to ~7.7 million PLHIV in 2023 (UNAIDS, 2024). This makes SA the country with the largest HIV-positive population globally, positioning its domestic policy choices as critical not only for national outcomes but also for regional and global HIV trajectories. This burden made it pertinent to select SA as a case study country.

While Acquired Immunodeficiency Syndrome (AIDS), the final stage of HIV infection, was once considered an inevitable and fatal consequence, advances in Antiretroviral (ARV) therapy have transformed the epidemic. ARVs suppress viral replication, enabling PLHIV to live long and productive lives. With consistent adherence to ARVs, a 35-year-old person living with HIV can now have a life expectancy approaching that of the general population (Burger et al., 2022). In SA, the scale-up of ARV therapy has been one of the most successful public health interventions of the post-apartheid era. AIDS-related deaths decreased from a peak of 231,000 in 2006 to approximately 50,000 in 2023 (UNAIDS, 2024), underscoring the profound impact of universal treatment access. Importantly, HIV is also a major driver of tuberculosis, the leading cause of death among PLHIV in SA, highlighting that effective HIV treatment contributes to reducing TB incidence as well (WHO, 2024).

This transformation, however, comes with enduring demands. Because HIV treatment is lifelong, ARV provision is not a time-bound intervention but a continuous obligation. Any significant cessation of therapy rapidly increases viral load, heightening the risk of HIV transmission and progression to AIDS. In 2023, 5.9 million South Africans were receiving ARVs, representing 77% of PLHIV in the country (UNAIDS, 2024). Yet gaps remain: only 71% of PLHIV had achieved viral suppression, and coverage for children lagged at 63% compared to 78% among adults. Key populations — sex workers, men who have sex with men, transgender people, and people who inject drugs — also face disproportionate burdens, with HIV prevalence ranging from 29% to 62% in these groups. Sustaining and expanding ARV coverage, particularly for vulnerable groups, remains a national priority if SA is to meet the 95-95-95 targets of the Joint United Nations Programme on HIV/AIDS (UNAIDS), which aim to ensure 95% of PLHIV know their status, 95% of those diagnosed receive treatment, and 95% of those treated achieve viral suppression (DoH, 2023).

1.2 Financing the HIV Response: Achievements and Vulnerabilities

The SA government has been at the forefront of financing and implementing its HIV response. Since the rollout of free ARV therapy in public facilities in 2004, domestic funding has progressively grown, now covering roughly 75% of HIV-related expenditures (UNAIDS, 2023). The Comprehensive HIV and AIDS Conditional Grant more than doubled in nominal terms in less than a decade, reaching about South African Rand (ZAR) 24 billion in 2020/21 (~$1.44 billion), and plays a crucial role in sustaining treatment (Health Economics and Epidemiology Research Office, 2021).

Despite this commitment, SA remains dependent on external partners for critical aspects of its HIV programme. The United States President's Emergency Plan for AIDS Relief (PEPFAR) has been the largest external contributor, supporting up to 17% of the national response. Importantly, PEPFAR resources are disproportionately allocated to high-burden districts and key populations, amplifying their impact beyond their budgetary share. Other donors, including the Global Fund, provide essential support to research, clinical trials, and service delivery (UNAIDS, 2023).

The HIV response, therefore, rests on a hybrid financing model: domestically funded ARV procurement and donor-funded human resources, research, and service delivery. While effective, this leaves the system vulnerable to donor volatility.

1.3 Disruption in Donor Support: PEPFAR Uncertainty

Recent political developments in the U.S., including uncertainty over PEPFAR's reauthorisation, have underscored the fragility of this hybrid arrangement. Even temporary funding suspensions reverberate quickly across the health system, jeopardising service continuity, research partnerships, and the stability of the HIV workforce. If funding is not replaced, SA could face an additional 565,000 new HIV infections and 601,000 more deaths by 2032 (AIDSMap, 2025a)

The current crisis has revealed how donor dependence shapes the system's functioning: while SA covers the bulk of ARV procurement, foreign actors remain essential for the infrastructure that connects manufacturers to patients. This exposes the systemic interdependence between upstream pharmaceutical production and downstream service delivery.

1.4 Local Production as a Strategic Response

The funding shock has reinvigorated debates on local ARV production in developing countries. SA currently imports around 85% of ARVs and nearly 100% of Active Pharmaceutical Ingredient (API), primarily from India and China (T.Ntsele, 2022). This dependence exposes the supply chain to foreign price fluctuations, exchange rate volatility, and global shocks, as evidenced during the COVID-19 pandemic (GIZ, 2024). The vulnerabilities of such a supply chain have been further exposed by the funding cuts, renewing recognition of the need to strengthen resilience through domestic production.

The localisation of ARV production can also be understood through the lens of mission-oriented innovation policy. As Mazzucato (2018&2021) argues, mission-oriented approaches mobilise public and private actors around bold, societally relevant challenges, combining industrial policy with health and social objectives. Rather than narrowly correcting market failures, mission-oriented policies set clear public purpose goals — such as eradicating HIV or building resilient health systems — and align investment, regulation, and innovation around them. Applying this perspective highlights that local ARV production is not simply a matter of cost competitiveness but part of a broader societal mission to secure treatment access, reduce dependence on imports, and build regional health sovereignty.

Local production in Africa has increasingly been framed as both a health security and industrial development priority. Strengthening pharmaceutical manufacturing can expand access to essential

medicines while also building the technological, workforce, and institutional capacities needed for resilient health systems across the continent (Mugwagwa et al., 2017). This broader perspective situates SA's localisation agenda within a wider African policy discourse that links supply chain resilience with long-term socio-economic development.

In summary, local production can strengthen supply security, lower long-term import costs, generate skilled jobs through industrialisation, and position South Africa as a regional supplier within the 16-country SADC market of 340 million people.

However, localisation is not without challenges. ARV production requires advanced infrastructure, a highly skilled workforce, and stringent regulatory oversight (dos Santos Pinheiro, 2014). API synthesis demands substantial investment, advanced chemical engineering, and stable markets to achieve economies of scale. In SA, the failure of Ketlaphela, a government-led initiative to establish local API capacity, illustrates the risks of politically ambitious but commercially unfeasible ventures (Tomlinson, 2020).

The SADC Support to Industrialisation and Productive Sectors (SIPS) programme (2019-2024) has laid the groundwork for addressing some of these barriers. It supported pilot API production (CPT Pharma's dolutegravir initiative), strengthened regional regulatory harmonisation, and SADC Pooled Procurement Services (SPPS). These efforts demonstrate both the opportunities and obstacles in aligning industrial policy with public health imperatives (GIZ, 2024).

1.5 The Research Gap

While the effects of funding cuts on service delivery are well documented, the upstream consequences for ARV production remain understudied. Most analyses treat political, financial, and technical dimensions in isolation, overlooking their interconnectedness.

This research addresses that gap, guided by the overarching research question: How Can South Africa Strengthen Its Local Antiretroviral Production Amidst Changing Donor Country Attitudes? This question invites a multi-method approach by combining an extensive literature review with semi-structured interviews across government, industry, academia, and civil society, to investigate:

- The impacts of donor funding cuts on SA's ARV supply chain, particularly upstream production.
- The systemic barriers (financial, regulatory, technical, and institutional) that constrain local production.
- Practical strategies for strengthening local ARV production and building resilience against external shocks.

1.6 Report Structure

The remainder of this report is structured as follows:

- *Section 2* reviews existing literature on the impact of donor funding cuts, the local ARV supply chain, and gaps in current knowledge.

- *Section 3* outlines the research methodologies, including the conceptual framework (the WHO Health Systems Building Blocks), interviews, coding and analysis, ethical considerations and external collaboration.
- *Section 4* presents the results of our empirical investigation, mapping issues and challenges based on the framework.
- *Section 5* discusses three critical themes emerging from the findings: interactions between service delivery and production, pathways for localisation, and regulatory fragmentation versus market access.
- *Section 6* puts forward short-, medium-, and long-term recommendations for policymakers, industry, and regional bodies.
- *Section 7* concludes with reflections on achievements, limitations, and future directions.

2. Literature Review

This section systematically reviews the existing literature. It first examines the broad social impacts of the U.S. January 2025 funding cuts and the SA government's responses, noting that the upstream supply chain has not been fully emphasised. It then provides a detailed overview of SA's supply chain, critically highlighting deficiencies in the literature related to local ARV production. These gaps inform the scope of the research questions.

2.1 Funding Cut Impacts and Government Response

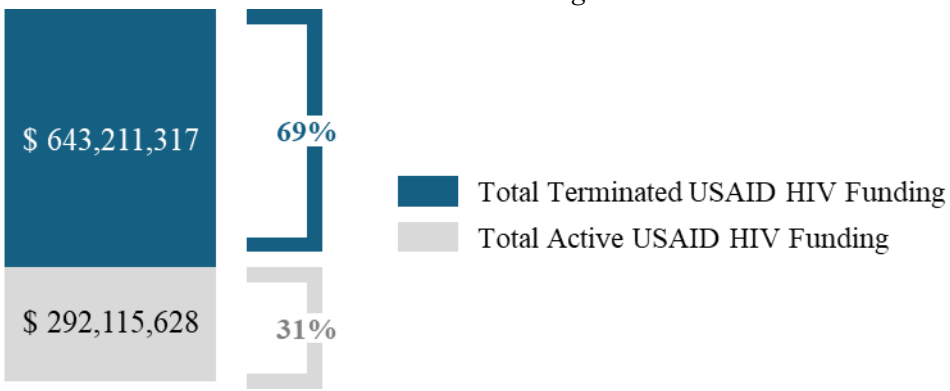
This section investigates updated research on the emerging financial disruptions of January 2025. *Section 2.1.1* illustrates the impacts resulting from funding cuts, *Section 2.1.2* evaluates the government's response, and the last section identifies gaps in the literature.

2.1.1 Funding Cut Impacts

Before U.S. funding cuts, SA was a primary beneficiary of PEPFAR (UNAIDS, 2023). In addition to PEPFAR cuts, the U.S. cancelled 83% of its foreign aid contracts and dismantled the United States Agency for International Development (USAID). PEPFAR's original strategy envisioned a gradual, five-year phase-out of funding, intended to transfer greater financial responsibility and ownership to recipient countries. However, in the conclusion of the 90-day freeze and subsequent review of PEPFAR, 14 awards worth a total of $643,211,317 were terminated immediately (six awards totalling $292,115,628 were retained) across SA, as shown in Figure 1 (Oberth et al., 2025).

Figure 1

Total Active and Terminated USAID HIV Funding in SA



Note. Adapted from research article by G. Oberth, 2025, VeriXiv. Copyright: © 2025 by Oberth G et al.

Since then, PEPFAR's latest reauthorisation expired on March 25th, 2025, leaving the already decimated programme in a state of instability. Without reauthorisation, PEPFAR officials cannot secure new co-financing arrangements, make long-term strategic investments, or plan sustainability partnerships with governments and local actors. This instability complicates securing long-term ARV procurement contracts. Building on that, these studies provide a multifaceted assessment of how funding reductions impact the HIV response, examining several key dimensions.

Temporary and Permanent Closures of Medical Facilities and Termination of Workers

PEPFAR primarily funded staffing, while SA locally funds approximately 90% of its ARVs (Oberth et al., 2025). Due to the cancellation of 40 USAID-funded health projects across the country, 8,493 PEPFAR-funded staff involved in the HIV response were furloughed (UNAIDS, 2025a). This led to the permanent and temporary closure of clinics across the country. Twelve specialised HIV clinics funded by USAID were permanently closed (Associated Press, 2025). The Western Cape, Northwest, and Gauteng province health systems were particularly devastated. Some districts, including Tshwane and Ehlanzeni, had clinics that were temporarily closed and forced to stop providing services for 15 days (Harm Reduction International, 2025).

The closure of specialised HIV clinics has forced individuals to transfer their care to public clinics. Over 60,000 patients were being served by these clinics and now must be transferred to public institutions (Associated Press, 2025). This rapid, large-scale transition from specialised service points to public clinics has been detrimental to the population's access to ARV medication. Due to the influx of new patients, waiting times at clinics have increased exponentially and reported quality of service has decreased (Oberth et al., 2025). Some patients report that they must arrive at hospitals at 4 or 5 am and may still spend the entire day waiting to receive medication.

Additionally, patients have been turned away from treatment due to stigma and public clinics being "reluctant to treat them" (Oberth et al., 2025). In 2022, 55% of all new HIV infections were within key populations (UNAIDS, 2025b), who are often subjected to increased stigma within the region and subsequently less open to pursuing treatment for fear of having their identity exposed (The Guardian, 2025a).

Changes like the lack of staff sending SMS notification reminders and performing house calls can have a large downstream impact on patient health. Patients rely on SMS notifications to know when to receive and collect their medication; Trained staff perform house calls to ensure HIV-positive mothers take their medication on time and that their babies attend monthly check-ups to prevent disease transmission (Oberth et al., 2025).

Effect on Research and Clinical Trials

U.S. funding cuts affect decades of investment into research infrastructure, threaten multiple research sites and the care of people in clinical trials. With the growing number of programme cancellations, there are concerns over the future of NIH funding, which has been integral to research and clinical trials across SA (The Guardian, 2025b). The Treatment Action Group reported that 39 HIV clinical research sites and 24 HIV trials were at risk from potential further funding cuts (TAG, 2025).

When research sites are prohibited from patient enrolment, follow-up, data collection, or analysis, their capacity to produce meaningful results diminishes dramatically, rendering the trials Sisyphean. This makes previous investments into the trials inefficient and ineffective. Trials can even fail, leading to financial losses, portfolio revaluation, and innovation stagnation (BioSpectrum Asia, 2024). This potentially leads to fewer investments within the region and creates a cycle of even less funding into the local pharmaceutical sector.

Additionally, ethical considerations come into play during the cancellation of clinical trials. Participants within these studies may depend on these trials as a means of receiving treatment. Some patients rely on novel trial treatments because they cannot be treated with currently distributed medications (The Guardian, 2025a).

Information, Testing, and Disease Monitoring Changes

USAID and PEPFAR supported many HIV testing initiatives, which are integral to identifying the disease and preventing its progression (WHO, 2023). Effective disease surveillance enables early detection of outbreaks, evaluation of prevention and treatment interventions, and monitoring of transmission trends (Ndwandwe et al., 2022).

Viral load testing, which measures the amount of HIV in the blood, has decreased by 21% in SA. These tests ensure a patient is adequately suppressing their viral load and understands their HIV status to prevent transmission to others (Associated Press, 2025).

Additionally, within the past year, HIV diagnoses have decreased by 31% and treatment initiation by 30%. The rapid pace of this decline suggests an issue in identifying HIV cases due to the loss of healthcare workers, rather than a true decrease in HIV rates (AIDSMap, 2025b). This could indicate that more patients are going undiagnosed, increasing the risks of the disease spreading throughout the community. The absence of this information makes it harder for the government to identify highly affected areas and address regions of concern.

2.1.2 Government Response

The SA government has acutely recognised the significant funding cut impacts of PEPFAR and other donors. Although over 75% of SA's HIV response is currently funded domestically, Health Minister Dr. Aaron Motsoaledi has questioned the country's reliance on donors, underscoring concerns about sovereignty (AIDSMap, 2025c; Jones, 2025).

In response to funding cuts, the Ministry of Finance allocated over ZAR 750 million (~$42 million) to supplement domestic HIV financing (Citizen Reporter, 2025). Concurrently, philanthropic entities, namely the Bill & Melinda Gates Foundation and the Wellcome Trust, committed targeted funds to sustain critical research activities. Minister Motsoaledi further pledged an acceleration in the provision of novel prevention modalities, including the antiretroviral lenacapavir, emphasising vulnerable groups such as adolescent girls (AIDSMap, 2025a).

Additionally, the SA government reaffirmed its commitment to long-term frameworks, including the National Strategic Plan (NSP), which targets eliminating HIV as a public health threat by 2030 (SANAC, 2023a). The NSP adopts a person-centred, community-driven approach to advance the UNAIDS 95-95-95 targets (SANAC, 2023a).

However, the NSP has a limited focus on the upstream ARV supply chain. Scholars criticise this omission (Oliver et al., 2023), noting that allocating funds solely to HIV service delivery while neglecting local production fails to address systemic fragility. This deficiency has raised concerns about the validity of the

NSP (Venter, 2025), especially following the unexpected funding cut that could not be accounted for (SANAC, 2023b).

2.1.3 Gaps in Literature on Funding Cuts Impacts and Government Response

Although many studies detail the impacts of funding cuts using macro-level data, they focus on downstream effects in the ARV supply chain, with limited insight into upstream segments. Current research, as well as the SA government, insufficiently addresses how pharmaceutical manufacturers respond to funding cuts, creating a critical knowledge gap regarding upstream supply chain resilience.

While distribution and service delivery disruptions are the most visible and cause immediate short-term impacts, upstream ARV production remains crucial. As argued by Azcona et al. (2025), domestic production capacity decisively stabilises the supply chain's foundation. The COVID-19 pandemic's shocks, detailed in the SIPS report (GIZ, 2024) and recent PEPFAR funding cuts, highlight that sole reliance on external procurement renders the system vulnerable. Expanding local production not only strengthens supply security but also enables more agile responses to unforeseen crises.

However, advancing this research agenda requires precise identification of how and where funding cuts alter the ARV supply ecosystem and the broader landscape. Without this, policies may overlook upstream bottlenecks critical to long-term supply chain durability and fail to foster a truly robust pharmaceutical industry in SA.

2.2 Local ARV Production

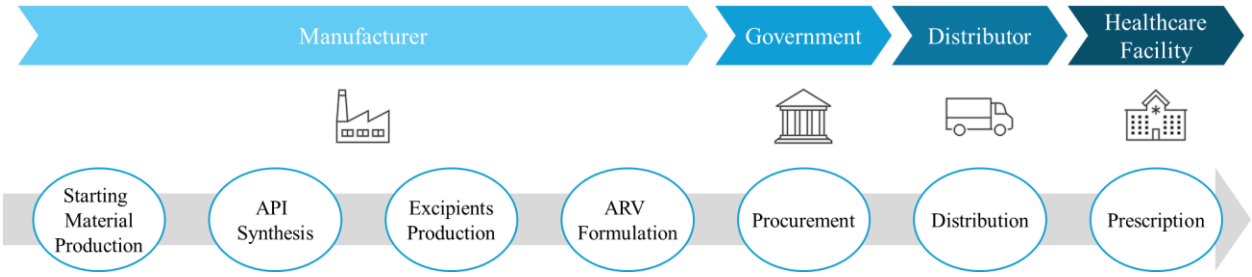
This section firstly provides an overview of the local ARV supply chain and identifies its pathways in SA. It then explores existing literature and highlights knowledge gaps in local ARV Production.

2.2.1 ARV Supply Chain Overview in SA

A brief overview of the general ARV supply chain is provided in Figure 2 to aid understanding in subsequent sections. The chain begins with the production of starting materials from raw inputs, followed by API synthesis from them. Excipients are then produced to stabilise the APIs, and ARVs are formulated by combining APIs with excipients. The packaged ARVs are then procured by the government, distributed to healthcare facilities, and prescribed to patients (GIZ, 2022).

Figure 2

Overview of ARV Supply Chain



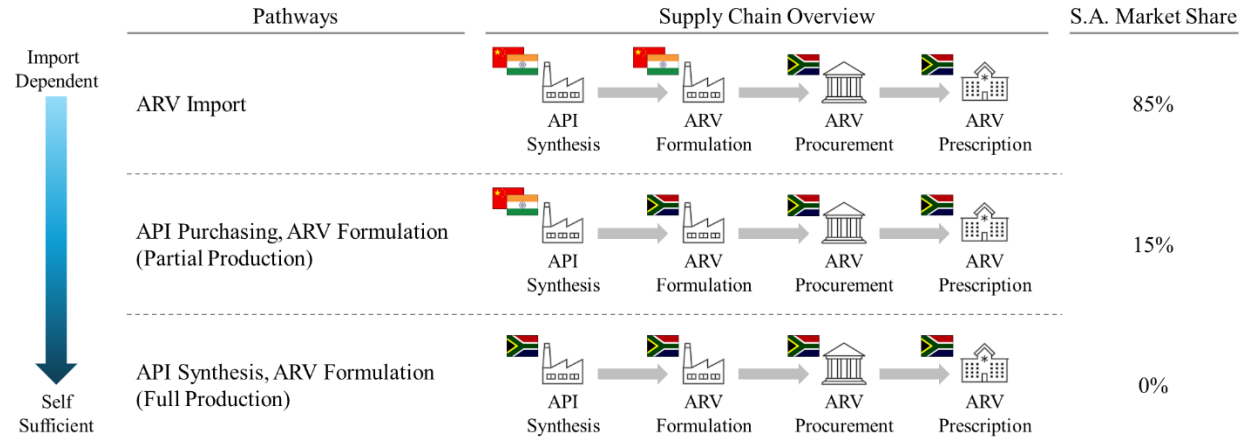
Note. Adapted from the *SIPS report* by GIZ, 2022, VeriXiv. Copyright: © 2022 by GIZ.

In SA, however, the ARV supply chain is not streamlined, marked by a multiple structure with competing models operating in parallel. As illustrated in Figure 3, there are three main pathways through which ARVs reach patients:

- ARV Import: The SA government procures finished ARVs manufactured primarily in China and India.
- ARV Formulation: Local companies import APIs synthesised abroad to formulate into ARVs.
- API Synthesis and ARV Formulation (full production): Both API synthesis and ARV formulation are undertaken domestically.

Figure 3

ARV Supply Chain Pathways in SA



Note. Data depicted is original to the report.

Currently, approximately 85% of ARVs in SA are imported (Sikhakhane, 2024). Although procurement is largely financed with domestic public funds, thereby insulating the supply from direct funding cut impacts, the COVID-19 pandemic underscored supply chain vulnerabilities, which reinforced the case for domestic production (T.Ntsele, 2022).

Among the two models of local manufacturing, most domestic companies engage only in ARV formulation (GIZ, 2022). Aspen, a prominent example, pioneered generic ARV production in Africa (Aspen, 2023) but struggles to match the lower prices of Chinese and Indian suppliers (GIZ, 2022).

In contrast, only CPT Pharma possesses API synthesis capability, and even in this remains at the pilot stage, without commercial-scale output (GIZ, 2024). As a result, SA imports 100% of APIs (Z.Ntsele, 2022).

2.2.2 Gaps in Literature on Local ARV Production

Although existing studies provide an overview of the ARV supply chain in SA, they offer limited insights into the current barriers hindering domestic production. This literature gap stems from constraints, including the lack of SA-specific analysis, the prevalence of siloed approaches, and the added complexities from funding cuts.

Lack of SA-Specific Analysis

Research exhibits a major gap in holistic, context-specific analyses of ARV production in SA. Historical studies on ARV scale-up focus on international clinical breakthroughs and broad policy interventions (Mukherjee&Tan, 2020). Several comparative reviews sought locally applicable recommendations by examining globalisation and local manufacturing in countries like India and Brazil, where production was supported by flexible intellectual property regulations and significant government investment (Kaplan et al., 2012; Chaves et al., 2018).

However, these studies often overlook challenges particular to South Africa, such as the interplay of industrial structure, market dynamics, local regulatory pathways, and public health infrastructure, which uniquely shape its production capacity and complicate the ARV supply chain from API synthesis to patient delivery (Ncube et al., 2023). Without such contextually nuanced studies, localisation efforts risk being misaligned with the tangible needs and challenges.

Siloed Approach

Another deficiency lies in the predominantly siloed approach to examining barriers and making decisions on local ARV production. Political, financial, technical, and sociocultural dimensions are often treated separately: for instance, political-economy analyses underscore government commitment (Mhazo et al., 2022), whereas financial studies emphasise cash-flow optimisation within manufacturing firms (Zimmermann et al., 2018).

Yet, as Netsele (2022) argues, local production constitutes a complex adaptive network of stakeholders where policy, finance, technology, and community engagement co-evolve. Borghi et al. (2022a) also support this viewpoint, emphasising that these factors interact in a complex network-like manner. Without interdisciplinary perspectives from various stakeholders that integrate these domains, policy prescriptions are likely to ignore the complex current landscape, thus risking being incomplete or impractical.

Additional Complexity due to Funding Cuts

Recent funding cuts have added another layer of complexity. Points in *Section 2.1.1* on the funding cut impacts notes that these shocks are likely to reshape SA's local ARV production capacities. Although the SIPS report explored aspects of pharmaceutical industrialisation in SA (GIZ 2024), it is important to note that its scope primarily focused on the disruptions and responses related to COVID-19. This nuance hints at a critical limitation within the SIPS report's approach: focusing primarily on supply chain vulnerabilities from a pandemic perspective overlooks the compounded risks from post-pandemic austerity measures.

Beyond the SIPS report, the validity and feasibility of other recommendations should be reconsidered in light of funding cuts. Prevailing research disproportionately advocates rapid, full-scale ARV production "all at once" (Barker et al., 2007; Mate et al., 2013), overlooking pragmatic, stepwise strategies such as immediate procurement and partial production that could secure incremental progress and ensure uninterrupted patient access during transition. As several scholars emphasise, government interventions should strategically balance immediate mitigation efforts with long-term capacity building to preserve continuity of care and sustain the supply chain (Appiedu-Addo et al., 2025).

In summary, although the imperative to boost local production is widely recognised, ARV manufacturing in SA demands targeted inquiry into context-specific barriers, interdisciplinary dimensions, and phased implementation under fiscal constraints. Addressing these gaps will be essential to building a resilient, locally anchored ARV supply chain.

2.3 Identifying Research Questions

To address the knowledge gap identified in the literature review and in collaboration with our partner Kiara Health, our primary research question is: How Can South Africa Strengthen Its Local Antiretroviral Production Amidst Changing Donor Country Attitudes?

To explore this question comprehensively, we have designed three main sub-questions:

1. What are the impacts of funding cuts on SA's existing ARV supply chain?
2. What barriers does SA face in realising a localised ARV production pathway?
3. What strategies should SA adopt to develop a robust and resilient domestic ARV supply chain?

In response to *Section 2.1 and 2.2*, the first sub-question maps the evolving supply chain landscape and addresses the research gap on the upstream consequences of funding reductions. Regarding *Section 2.2*, the second question centres on SA-specific barriers from multiple stakeholder perspectives, increasing the relevance and applicability of policy recommendations. The third question integrates findings from the first two, emphasising the feasibility of strategies to enhance supply chain resilience and sustainability.

This approach allows nuanced analysis that acknowledges the complex, interconnected challenges facing SA's ARV production, ensuring that recommendations are evidence-based and aligned with local realities and global funding dynamics.

3. Research Methodologies

Research for this report in partnership with Kiara Health was done through conceptual frameworks, interviews, and analytical methods. The selected conceptual framework runs as a continuing theme throughout the results and discussion sections. Interviews and analysis followed were performed under a rigorous ethical protocol detailed in S*ection 3.4*.

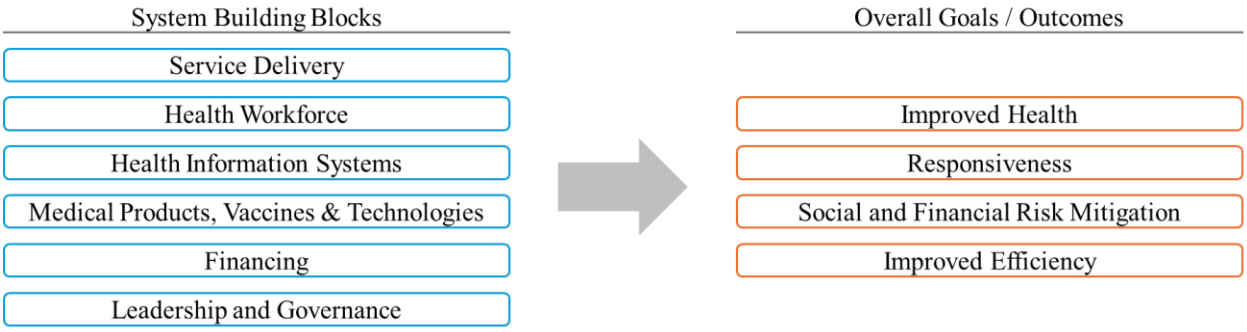
3.1 The WHO Blocks as a Conceptual Framework

The WHO Health System Building Blocks were adopted as a conceptual framework for this report. This standardised framework offers a systematic approach to evaluating health system components globally and facilitates the analysis of system dynamics, including the interactions and interdependencies among health system functions.

3.1.1 Introduction of the WHO Blocks

As illustrated in Figure 4, the WHO Blocks consist of six core components that describe and guide the functioning and strengthening of health systems.

Figure 4
The WHO Health System Building Blocks



Note. Adapted from *National Health Planning Tools* by WHO 2010. Licensed under CC BY-NC-SA 3.0 IGO

Table 1 further provides details on each block based on the definition of WHO (2010). These components work interactively to achieve key goals, including better health outcomes, health equity, responsiveness to population needs, social and financial risk protection, and efficient use of resources. Their integration supports the resilience and sustainability of the ARV supply chain, thus improving population health.

Table 1
Explanation of the WHO Block

WHO Block	Explanation
1. Service Delivery	The provision of effective, safe, quality health services that are accessible to those who need them.
2. Health Workforce	The availability, competency, motivation, and management of health personnel.
3. Health Information Systems	The collection, analysis, dissemination, and use of timely and reliable health data.
4. Medical Products, Vaccines & Technologies	The timely and equitable access to necessary medical products and technologies that are safe, effective, and affordable.
5. Financing	Adequate funds for health, ensuring financial protection against catastrophic health expenditures, and allocating resources in a way that encourages quality, equity, and efficiency.
6. Leadership and Governance	Strategic policy frameworks, effective oversight, regulation, accountability mechanisms, and coalition-building necessary to steer the health system and ensure its sustainability and responsiveness.

Note. Adapted from *National Health Planning Tools* by WHO 2010. Licensed under CC BY-NC-SA 3.0 IGO

3.1.2 Rationale for Adopting the WHO Blocks

Many conceptual frameworks to evaluate health systems have specific focuses. For instance, the economic evaluation frameworks assess the costs and benefits of health interventions, strictly adhering to economic efficiency and overall value (Barber et al., 2021), while Health Technology Assessment particularly considers clinical effectiveness, safety, and economic implications to provide solid evidence for adopting health technologies (Thee, 2023).

However, compared to these frameworks, the WHO blocks have two outstanding advantages: unveiling interplaying dynamics in the local production landscape and connectivity with other frameworks.

Unveiling Dynamics in Local Production Landscape
The WHO Blocks comprise six interrelated components that collectively provide a full lens of a dynamic and integrated system — a character aligning with the complex reality of localised pharmaceutical production. As described by Borghi et al. (2022b), the landscape of SA local pharmaceutical manufacturing is multifaceted, with the components interconnected in a network-like manner rather than isolated silos.

Specifically, the Health Workforce delivers services through skills and management, underpinned by adequate financing and governance; Service Delivery relies on a competent workforce, medicine availability, and sustainable financing; Health Information Systems generate data critical for decision-making across all domains (WHO 2010).

Connective to Multi-Fields and Frameworks
This framework is notably connective, another key reason for its adoption in this study. Rather than focusing solely on health policy, it links with multiple policy domains during the analysis of each block. For instance,

discussions around financing for local manufacturing cannot be isolated from economic policy, which encompasses government strategies to influence economic activity and growth (Stiglitz, 1989). Similarly, feasibility discussions for local enterprise manufacturing must incorporate industry policy, defined as targeted government measures to promote and regulate industrial sectors (Lall, 2004). Such a cross-sectoral lens is indispensable, especially when addressing complex policy interventions involving diverse stakeholders, as highlighted by the multifaceted landscape of local pharmaceutical production.

Furthermore, the WHO Blocks do not conflict with other theoretical frameworks; rather, they complement and integrate well with them. For example, mission-oriented approaches (Mazzucato 2021) illustrated in *Section 1.4* fit well with the WHO blocks. To exemplify that, regarding health information systems, this approach fosters enhancement of data collection and analytical frameworks centred on an integrated system, providing an evidence base to inform health policy formulation. By setting explicit public missions, mission-oriented approaches advance a more resilient and sustainable health system within blocks.

3.2 Interviews

Primary data was obtained through interviews with localised manufacturers, academic experts, policymakers and other relevant actors, providing firsthand insights into the challenges affecting SA. Participants were purposively selected based on their sector-specific expertise and the strategic relevance of their perspectives to the objectives of this report, as detailed in *Section 3.2.1.*

3.2.1 Interview Aims

Stakeholder interviews constitute the cornerstone empirical data collection method in this research. As defined by Nielsen Norman Group (2023), this method involves a one-on-one conversation with a person vested in a project to explore key areas. In this case, recognising ARV production systems as complex adaptive ecosystems, the research team conducted semi-structured stakeholder interviews, balancing a consistent framework of key questions with flexibility to explore unexpected insights (Lyssna, 2025), to achieve the following aims.

Aims for Stakeholder Interviews:

- Map the current landscape: Provide a holistic understanding of the ecosystem of SA's local pharmaceutical industry amidst changing donor funds
- Recognise obstacles for local production: Extract crucial areas that hinder the local ARV supply chain, categorising by the WHO Blocks
- Identify intervention points: Establish evidence base for strategies on enhancing SA's local ARV supply chain

3.2.2 Sampling Strategy

The research team primarily employed purposive sampling supplemented by snowball sampling to identify and select stakeholders for this study on enhancing local ARV production in SA. Purposive sampling was used deliberately to ensure that participants were chosen based on their relevance to the project scope

outlined in *Section 2.3*, yielding focused and insightful perspectives (Palinkas et al., 2007; Flick, 2017). Snowball sampling served as a practical means to expand the participant base through referrals, especially useful in this context where frontline practitioners and knowledge experts within SA's local ARV supply chain are interconnected (Flick, 2017).

Specifically, the team began by mapping the stakeholder ecosystem into clearly defined categories to encompass the full spectrum of expertise: government (regulatory bodies, policymakers), global health initiatives (international organisations), local manufacturers (API & ARV intended producers), academics (researchers and technical experts), and civil society (NGOs, community advocates).

Within this framework, the team collaborated with Kiara Health to compile an initial list of interviewees for each stakeholder category. The pool was expanded by five referrals via participant recommendations, of whom 12 accepted, resulting in a 60% participation rate. The remaining eight either declined or did not respond within the study's timeframe.

Although interviews were successfully conducted across all categories, the majority of respondents came from local manufacturers and academics. The representation of government stakeholders was relatively lower, which is not unexpected given the time required to engage policymakers and their limited responsiveness to studies of this kind. This gap was mitigated by triangulating interviewees' perspectives with relevant literature on past initiatives and forthcoming policy plans, thereby ensuring diversity of information sources.

3.3 Analytical Methods

This section outlines the structured analysis to examine stakeholders' perspectives on the barriers to ARV production in SA. The process involved three phases: thematic coding, issue mapping and prioritisation, and solution mapping. This multi-stage approach ensured rigour, contextual relevance, and the generation of actionable, evidence-informed insights.

3.3.1 Individual Coding and Integrated Coding

This study employs thematic analysis, a qualitative method widely used to identify and report themes (Braun&Clarke, 2006), to examine 12 interview transcripts compiled in Excel. In this research, thematic analysis uncovers contextual insights and effectively accommodates the diverse stakeholder perspectives on donor funding cuts and identifies barriers and potential intervention points for SA's ARV production.

The research team, after familiarising with transcripts, systematically extracted core barriers to local production and categorised them into the six WHO Blocks. An additional, separate block was added to capture the funding cut effects, as these were observed to be cross-cutting phenomena across the blocks. Each data point was timestamped for traceability, and any personally identifying information was anonymised to preserve confidentiality. Within each domain, a two-tier grouping process was implemented: comments addressing similar themes were clustered into corresponding sub-groups for nuanced categorisation.

To ensure accuracy and consistency, the research team first conducted individual coding of transcripts, followed by a collaborative review verifying that the identified themes accurately represented the coded data and the entire dataset. This review also validated groupings to uphold rigour and reliability.

3.3.2 Issue Mapping and Prioritisation

After standardising and compiling the interview content, the team conducted issue mapping to systematically remove out-of-scope perspectives, clarify inter-issue connections, and identify root causes to facilitate subsequent prioritisation (Kiekens et al., 2022). This step used Miro, a visual tool for qualitative data organisation and analysis.

Specifically, the team established distinct zones within Miro labelled "Funding Cut Impacts," "Issues," and "Solutions," each subdivided by the WHO Blocks. Then, irrelevant content was filtered out from the list developed in *Section 3.3.1*. Subsequently, coded data related to "Funding Cut Impacts" and "Issues" were plotted within the corresponding sub-zones.

Following data entry and initial organisation, the team utilised Miro's connector tool to visualise causal and logical relationships among issues. This visualisation helped synthesise diverse stakeholder viewpoints and unpack interdependencies underpinning local production challenges.

Ultimately, this comprehensive mapping provided a structured foundation for identifying priority barriers and enabled framing of discussions around conflicting viewpoints and conditionalities to address multifaceted challenges of the local production.

3.3.3 Solution Mapping

The team's mapping of the solution followed the prioritisation of issues, based on the rationale that developing solutions for areas with the greatest impact or urgency significantly enhances the effectiveness of implementation (Fibery, 2024). Solution brainstorming began with a literature review expanding the "Solutions" area in Miro, which was designed to correspond directly with the previously mapped "Issues" section.

This "Solutions" area primarily compiled stakeholders' perspectives on local production in SA, providing an evidentiary base for structured, actionable interventions. After establishing a shared understanding, the team categorised solutions into short-, medium-, and long-term initiatives. These were further refined into detailed, implementable actions based on multiple criteria, including urgency, resource efficiency, and scalability.

This methodical approach ensured that interventions were contextually grounded and strategically aligned with prioritised problems, optimising resource allocation and enhancing the potential for sustainable, scalable outcomes.

3.4 Ethics Protocol

This study (Project ID: 1924) has gained ethical approval and strictly adheres to ethical norms to ensure research integrity, the protection of participants' rights, and responsible data handling, guided by UCL Research Ethics.

First, the research team prioritised informed consent, ensuring voluntary, uncoerced participation. All interviewees signed consent forms detailing the study's purpose, voluntary nature, data use, and their right to withdraw without penalty, protecting autonomy.

Second, to safeguard confidentiality, pseudonymisation was employed. Additionally, all data and audio files were securely stored in encrypted systems accessible only to the research team.

Third, power imbalances were addressed through neutral facilitation and purposive sampling to ensure diverse stakeholder representation. During interviews, the team encouraged open dialogue and equal opportunity for all stakeholders to express their views and sought feedback from participants on whether they felt heard and represented.

These measures upheld ethical rigour while producing actionable insights to improve ARV access in SA.

3.5 Kiara Health Collaboration

Engagement with Kiara Health and alignment with their priorities were essential across all project stages to ensure outputs met defined requirements and objectives. The research team maintained consistent, close and transparent communication with the Kiara Health, specifically as follows:

- During the scoping phase, multiple online consultations were held to comprehensively understand the partner's interest in the current landscape and future of localised ARV production.
- In the data collection phase, guided by Kiara Health's insights, the research team developed and executed a detailed data collection strategy focusing on key facets of local ARV production identified from collaborative scoping and utilised Kiara Health's network to amplify snowball sampling.
- Throughout the data analysis and reporting phase, co-creation was emphasised by submitting draft reports for review and seeking feedback from Kiara Health.

Beyond external reviews, regular communication with supervisors and project team members was maintained to ensure professional rigour and smooth progress. Specifically, a cadence of weekly update meetings was established to keep supervisors informed of project milestones and facilitate ongoing optimisation of the research.

Through consistent engagement and transparency regarding partner input, the project paid significant attention to achieving outcomes that ensure a mutually beneficial collaboration, advancing local ARV production goals.

4. Results

Table 2 summarises the barriers to local ARV production identified through interviews, organised by the WHO Blocks. A seventh block was added to assess the funding cut impact. As explained in *Section 3.3.1*, these challenges and impacts were grouped into two thematic categories.

Table 2

List of Issues Categorised by the WHO Blocks

WHO Block	Issue Group	Issue Detail
1. Service Delivery	Patient Affordability	High cost of ARVs
	Patient Accessibility	High pill burden of ARVs
		ARV side effects and resistance
		Stigma associated with HIV
2. Health Workforce	University Training	Lectures not aligned with industry needs
		Lack of lab-based training
	Job Opportunities	Limited jobs domestically
	Expertise for Local Production	Shortage of specific expertise in companies
	Regulatory Capability	Unfamiliarity with the regulatory process in companies
	Workforce Training	Lack of training in companies
3. Health Information Systems	Link between Information Systems	Fragmentation on the continent
		Fragmentation in SA
4. Medical Products, Vaccines & Technologies	Infrastructure and Facility	Unstable infrastructure and facility
	Technology	Burdens on tech transfer and licensing
	Product	No age-appropriate ARVs
		Complex manufacturing process of APIs
		Complex WHO prequalification
5. Financing	Cost	High capital investment cost
		Expensive R&D
		Tax for imported raw materials
		Cost fluctuation due to currency exchange
		No deposit for government procurement
		High labour cost
		High inspection cost
		High investment for scale-up
	Market	Lack of international competitiveness
		Small domestic market size
		Limited access to international market
		Unpreferable tender mechanism
	Funding	Lack of private sector funding
		Lack of government funding

WHO Block	Issue Group	Issue Detail
6. Leadership and Governance	Regulation	Complex imports regulation
		Lack of regulator efficiency
		Lack of expertise on regulations
		Deficient expertise acquirement model
		Lack of binational reliance-based assessment
		Lack of regional labelling harmonisation
		Lack of regional medicine registration harmonisation
		Lack of continental trade harmonisation
	Political Will	Lack of global funding commitment
		Lack of domestic funding commitment for health agenda
		Lack of domestic funding commitment for local production
		Lack of strategic policy planning
		Lack of internal company incentives
	Collaboration	Lack of trust between business and government
		Lack of intra-governmental collaboration
	Perception	Negative perception for API local production
7. Funding Cut Impact	Local Production	No PEPFAR fund used for production
	R&D	Funds cut to supplement gaps in delivery
	Technology Transfer	Impact on TB-API programmes
	Quality Management	Delay in the development of quality management mechanism
	Delivery	Impact on treatment and community support

Note. Data depicted is original to the report.

Among the barriers to local production, the most frequently cited by interviewees and those with trade-offs or divergent views were Block 5 (Financing) and Block 6 (Leadership and Governance).

Given the definitions of the WHO Blocks, this finding is reasonable, as these two blocks underpin the others. Financing secures the investments and resource allocations that sustain workforce capacity, service provision, medicine availability, and the functioning of information systems. Meanwhile, Leadership and Governance establish the policies and regulations driving local pharmaceutical manufacturing (Borghi et al., 2022a; Manyazewal, 2017; WHO, 2010). Accordingly, the following sections focus on these two blocks, while also illustrating their interlinkages with the remaining four.

Regarding the funding cut impacts, interviewees' perspectives aligned with previous studies. The direct impact on local production was limited, while the consequences were more pronounced in the downstream supply chain, particularly in service delivery, which requires immediate actions. Subsequent sections will therefore discuss the relationship between service delivery and local production, as well as the priority of related interventions.

5. Discussion

This discussion draws together insights from the literature review and stakeholder interviews to build the central insights underpinning the report's recommendations. For this report, three key themes have been identified: 1) Ecosystem of Service Delivery, Local Production, and Funding Cut Interactions, 2) Priority Approach for Local Production, and 3) Regulatory Fragmentation vs. Market Access.

5.1 Ecosystem of Service Delivery, Local Production, and Funding Cut Interactions

The interactions between service delivery, local production, and funding cuts form a complex ecosystem of trade-offs and reliance. Both service delivery and local production are vital yet were unequally impacted by funding cuts. This discussion explains why service delivery must be secured before promoting local production, and how a damaged service delivery system affects local production.

5.1.1 Trade-off between Service Delivery and Local Production Focus

Funding cuts have primarily affected the last downstream point of the ARV supply chain: service delivery. Literature and interviewees have reinforced this idea, pointing to the effect of funding cuts on access to medication as an area of immediate concern. The SA government provides 90% of ARVs, yet this large-scale purchasing of ARVs is not reaching patients, indicating medication shortages at the facility-level rather than nationally (Parliament of South Africa, 2025). Some interviewees noted that focusing on local production does little to address the imminent morbidity should service delivery issues remain unresolved. As one interviewee explained, *"You can have the medicines procured, but if the clinics are closed or people can't get there, patients still won't be treated."*

A key goal of local production is to ensure stable access to ARVs through reduced reliance on imported products and mitigating risks of global supply chain disruptions (Mugwagwa et al., 2017). Yet the supply chain issues in question are inherently domestic due to the disconnect between facility-level and national supplies. As a result, expanding local production at this stage will not directly resolve the current domestic supply chain issues due to furloughs and clinic closures (Gumede, 2025).

Without a stable service delivery system, local producers also face difficulties. One academic interviewed noted that manufacturers require an accessible market to sell their products. As funding cuts strain service delivery and limit patient access, the domestic market weakens. Local producers then face diminished market viability and reduced demand when service delivery constraints remain unaddressed.

5.1.2 Funding Cut Indirect Impacts on Local ARV Production

Interviewees reinforced findings from the literature that recent funding cuts primarily affected the service delivery of HIV treatment; as such, there was little direct effect on local production of ARVs. However, funding cuts have created a large financial burden for the SA government. According to one estimate from the Annals of Internal Medicine, the extra healthcare required to treat the potential new infections between 2025-2034 could cost $1.7 billion (Gandhi et al., 2025). This substantial fiscal burden may limit the government's capacity to invest in local production initiatives.

As discussed in *Section 2.1.1*, reductions in donor funding have led to a sharp decline in testing and diagnostic services, with viral load testing down 21%, HIV diagnoses by 31%, and treatment initiation by 30% (Associated Press, 2025; AIDSMap, 2025a). These disruptions the likelihood of undiagnosed or untreated cases, hampering the government's ability to monitor disease transmission and target interventions. For local manufacturers, this lack of reliable epidemiological data complicates demand forecasting, increasing the risk of stock imbalances such as shortages or expiries. As one industry expert noted, *"If you don't have reliable surveillance data, you cannot predict demand — and that's how you end up with stock-outs or wasted stock."* The resulting uncertainty undermines the rationale for scaling up production and may erode investor confidence.

5.2 Priority Approach for Local Production

This section examines the approaches for domestic ARV production in SA. *Section 5.2.1* identifies reasons for reliance on imports, and *Section 5.2.2* compares specific approaches to local production.

5.2.1 Trade-off between Imports and Local Production

All interviewees agreed that heavy reliance on ARV imports is undesirable and, in the medium to long term, local production is essential for safeguarding health sovereignty and enabling sustainable growth through industrial development.

Several interviewees cited a lack of political will as a key reason for the limited scale of local production despite this consensus. This stems partly from divergent priorities among government ministries. The Department of Health (DoH) prioritises maximising patient coverage at the lowest possible cost, favouring imports. In contrast, the Department of Science, Technology and Innovation (DSTI) and the Department of Trade, Industry and Competition (DTIC) emphasise the economic benefits of domestic ARV production.

The absence of policy alignment has prevented a coherent strategy, as is reflected in the NSP. While the plan emphasises a robust public health supply chain, its focus lies on downstream delivery to patients, without clear guidance on domestic production (DoH, 2023).

Limited political commitment also leads to insufficient budget allocation for local production initiatives. One manufacturer observed that the lack of political will reduces public funding, which in turn discourages the private sector from assuming investment risks, creating a vicious cycle. A scholar further noted that this dynamic has made health a less attractive investment domain for the SA private sector.

Interviews identified insufficient collaboration as a primary cause of the lack of political will. One academic emphasised the absence of a coordinating body to mediate competing agendas and concrete measures across government agencies. Industry stakeholders similarly noted that mistrust between the public and private sectors hampers information sharing and technical cooperation, hindering decision-making aligned with actual needs and capabilities. The fact that the NSP omits a domestic production plan, while companies such as Aspen and CPT Pharma are actively pursuing local manufacturing, suggests inadequate coordination between the two sectors. This absence of political leadership and the failure to coordinate

public and private actors to mobilise resources illustrate the lack of a mission-oriented approach (Mazzucato, 2018)

The literature also connects this mistrust to previous policy failures. In 2012, the SA government established Ketlaphela, a joint venture with the Industrial Development Corporation (IDC) and a local company, to promote domestic API production (South African Government, 2013). However, the partnership with Swiss firm Lonza was dissolved due to cost and risk concerns, leading to the project's collapse (Tomlinson, 2020).

Following this failure, government-led domestic production was excluded from the NSP. Nevertheless, local manufacturing remains indispensable for achieving NSP's goal of strengthening the supply chain. Interviewees across academia, research, industry, and regulators emphasised its importance, underscoring the need to frame local production as an integrated industrial, health, and social mission and to mobilise resources from both the public and private sectors accordingly.

5.2.2 Trade-off between ARV Formulation and Full Production

Even among proponents of domestic production, opinions diverged on the most appropriate strategy for SA. Academics and ARV manufacturers claimed that, given the technical complexity of API synthesis and SA's decades-long lag behind India and China, efforts should first focus on the already-established capability of ARV formulation. Meanwhile, API manufacturers argued that the challenges of API synthesis are overstated and that full production is both feasible and desirable. Notably, this divergence was also evident within the business sector.

When selecting from ARV formulation and full production, it is instructive to analyse the two major risk factors highlighted by Ketlaphela's failure: the scale of investment and the degree of risk.

From an investment perspective, interviewees admitted that both API synthesis and ARV formulation face the lack of education tailored to local production at all stages, university training, laboratory practice, and continuous workplace development. However, they highlighted that API synthesis entails a much wider skills gap against international competitors and therefore demands substantially higher investment.

As one interviewee emphasised, *"For a very long time, Africa was not in the business of API manufacturing, and it meant that there was no need for skills in that space… We don't have the chemistry skills that are needed, we don't have the technology and the know-how in terms of how to do production, how to scale up. This is the gap we are trying to close."*

They attributed this gap to the technical complexity of API synthesis involving multiple reaction steps. Taking lamivudine (3TC) as an example, its synthesis involves a seven-step chemical sequence with six bond-breaking and reforming reactions to build the desired molecular structure (Fortunak, 2014).

This complexity also demands dedicated manufacturing facilities. Particularly, purification processes require tight control and high precision with advanced equipment to remove unwanted by-products and impurities (Stevens et al., 2015). Consequently, ARV formulation holds a relative advantage in terms of investment size.

From a risk perspective, the most frequently cited concern was the pace of technological change. For instance, lenacapavir for HIV prevention and treatment has introduced a paradigm shift, from daily oral tablets to twice-yearly injections (WHO, 2025a). Such innovations could necessitate rapid overhauls of existing infrastructure, and given its higher dependency on specialised facilities, it leaves full production more vulnerable to obsolescence.

This risk also extends to human capital development. As one manufacturer explained, *"You have to start at the point of deciding that you make specific APIs, and then from there you put up the funds that are required… Otherwise there's no point in training the technical people when there's no end product, those skills will remain with unemployed people."*

This vulnerability is particularly significant given SA's predominant role as a producer of generic medicines. One manufacturer noted that domestic firms often rely on technology transfer from overseas license holders, making it difficult to maintain competitiveness when adapting to new products. The WHO (2011) similarly observed that technology transfer and confidentiality arrangements for patented products are subject to commercial negotiations, often disadvantaging firms in developing countries when pursuing domestic production. Taken together, these dynamics suggest that the catch-up risks are especially pronounced in API synthesis, where technical complexities and skills gaps are greater than in ARV formulation.

Another risk concerns maintaining price competitiveness in existing products. In theory, combining API synthesis with ARV formulation can lower the final product price. Indeed, companies in India and China leverage this advantage to offer ARVs 15-20% cheaper than those produced in SA through formulation alone (GIZ, 2022). However, the Ketlaphela case illustrates that domestic API synthesis does not guarantee immediate cost advantages (Tomlinson, 2020).

Interviewees attributed this limitation to the small domestic market and limited access to international markets and advocated the expansion of exports, particularly to neighbouring countries. This, however, constitutes a longer-term challenge to be addressed, as discussed in the next section.

5.3 Regulatory Fragmentation and Market Access

Interviewees consistently described how national policy choices and regional fragmentation shape market access. The interaction between domestic approval signals, regional harmonisation realities, and global eligibility requirements creates sequential, duplicative steps that raise time-to-market and depress export potential.

5.3.1 Domestic: Approvals, Capacity, and Pre-Submission Frictions

Interviewees converged on a domestic bottleneck that compounds as firms move from SA to SADC and then to global markets. The registration backlog of the South African Health Products Regulatory Authority (SAHPRA) remained the headline constraint, with several participants describing approval timelines for generics and ARVs in the 18-36-month range. This aligns with SAHPRA's performance plans, acknowledging a multiyear registration backlog (SAHPRA, 2025). At the same time, interviewees flagged SAHPRA's newer fast-track pathway for locally manufactured products as 'a step in the right direction',

signalling intent to improve predictability and throughput. SAHPRA's recently adopted policy position on enabling local manufacturing formalises priority review for qualifying locally manufactured products and signals reduced fees and shorter evaluation times (SAHPRA, 2025).

Capacity concerns at the regulator were raised primarily in relation to future API manufacturing. Stakeholders noted that inspection and evaluation depth specific to APIs would become salient if domestic API projects scale; currently, 100% of APIs used in local ARV formulation are imported, so this gap is forward-looking rather than the dominant driver of today's delays. Balancing these critiques, a SAHPRA interviewee noted a demand-side challenge: some local manufacturers are unfamiliar with procedural requirements and submit incomplete documentation, which elongates review cycles and contributes to queue growth.

Upstream of filing, firms pointed to customs and import controls on R&D reagents and pilot-scale equipment as adding lead time and cost. These frictions slow formulation, bioequivalence studies, and other pre-submission work, pushing back the point at which dossiers are ready to enter the queue. Taken together, the domestic picture is less a single chokepoint than a sequence of frictions, backlog, dossier quality, and border delays that cumulatively stretch time-to-decision.

5.3.2 Regional: Non-Binding Work-Sharing and Technical-Compliance Barriers

Interviewees linked export potential directly to the credibility of reliance and harmonisation of medicine registration and labelling/packaging standards. ZAZIBONA — a collaborative medicines registration initiative established in 2013 under the SADC Medicines Regulatory Forum (MRF) to accelerate access through joint dossier reviews — was repeatedly cited as the relevant regional initiative; however, stakeholders stressed that joint assessments are non-binding. After a positive recommendation, companies still submit nationally, fund separate Good Manufacturing Practice (GMP) inspections, and obtain each country's authorisation (ZAZIBONA, n.d.; BoMRA, n.d.; Dube-Mwedzi et al., 2025). An industry stakeholder remarked, *"ZAZIBONA gives us a recommendation, but it's not binding - we still have to go through each national authority separately, with extra inspections and extra costs."* This design choice strips out much of the efficiency that work-sharing is meant to deliver and imposes duplication costs that are especially punishing for smaller local manufacturers. Because ZAZIBONA does not create a single marketing authorisation, firms must secure multiple national approvals before any cross-border contracting can proceed.

Beyond the assessment step, divergent SADC labelling and packaging rules were described as an operational brake: consignments can be held at ports or embargoed when packs fail to meet all country-specific requirements embedded in principal legislation, with changes often requiring legislative amendment rather than guidance updates. A comparative analysis found that 11 of 16 SADC countries would require national legislative reform to implement a harmonised outer-pack labelling standard, explaining recurrent port holds when packs fail country-specific statutory requirements (Narsai et al., 2024). These statutory differences mean a single pack cannot circulate region-wide without the country variants, complicating tender specifications and cross-border distribution.

Interviewees also referenced pooled procurement as a prospective demand signal for market expansion; yet policy heterogeneity across SADC and uneven buyer readiness mean practical use of pooled tenders

remains limited even as regional bodies continue to develop the SPPS (SADC, 2025a; GIZ, 2024). In short, the combination of non-binding joint reviews and statutory labelling divergence raises clearance risk and delays, weakening export incentives.

5.3.3 Global: Domestic Eligibility vs. Global Credibility

Globally, the discussion turned on which quality signal the system rewards. SA public tenders require SAHPRA registration (Medicines Registration Certificate and SAHPRA-approved professional information), not WHO Prequalification (WHO PQ) (DoH, 2023). Interviewees argued this removes the immediate incentive for local firms to pursue PQ, even though absence of PQ can exclude them from large multilateral procurement channels that emphasise PQ-aligned technical standards (WHO, 2013). The result is a structural divergence: domestic eligibility (SAHPRA-only) versus global credibility (WHO PQ).

Timing magnifies the problem. Interviewees characterised the end-to-end path as sequential: approximately two years for national registration; then 18-24 months for WHO PQ; then additional national registrations across African markets, cumulatively approaching five years. While the WHO Collaborative Registration Procedure aims to compress post-PQ national decisions to approximately 90 working days, participation is voluntary and sovereignty rests with each National Regulatory Authority (NRA); decisions therefore remain country by country (WHO, 2025a). In practice, interviewees argued, SA firms face a higher bar to become globally tender-eligible on the same calendar as competitors, especially manufacturers in India who typically combine stringent regulatory approvals with WHO PQ and can enter tenders sooner and at scale.

5.3.4 Cross-Cutting: Reliance Without Reciprocity

Across these levels runs a common theme of reliance without reciprocity. Interviewees acknowledged that SAHPRA now operates formal reliance routes (abridged, verified, recognition) that draw on trusted regulators' reports to streamline parts of the review. Yet without mutual recognition, reliance is informational rather than binding: SAHPRA can use trusted regulators' reports to shorten its own review, but firms still face each country's separate inspections and approvals, including post-ZAZIBONA national decisions. As one interviewee explained, *"These reliance mechanisms help, but they don't compel anybody. Every regulator still wants to do their own inspection, their own sign-off, so you lose the time you thought you were saving."*

Continental guidance reinforces this reading: reliance is promoted as a pragmatic means to accelerate access while preserving sovereignty, not as a binding instrument obliging peers to adopt each other's outcomes (AUDA-NEPAD/AMRH, 2025). Comparative Europe-Africa work underscores that durable time savings typically followed binding regional law in Europe, whereas most African initiatives remain recommendatory, keeping reliance largely voluntary and sequential (Mantel-Teeuwisse et al., 2025).

This has two implications. First, timelines stack rather than compress: even narrow frictions (e.g., customs delays on R&D inputs or statutory labelling misalignments) lengthen the *start* of the sequence, and those lost weeks are not recovered downstream.

Second, the burden of coordination falls on applicants who must maintain dossier sameness, manage multiple review clocks, and finance repeated inspections where sharing is not accepted. Put differently,

three legitimate objectives collide: sovereignty and safety at the national level (SAHPRA and peer NRAs), efficiency and security of supply at the regional level (ZAZIBONA, SADC labelling), and globally recognised quality signals at the international level (WHO PQ for pooled procurement).

When these signals are misaligned, SAHPRA sufficiency at home, non-binding work-sharing and statutory pack divergence in the region, and PQ as the global entry ticket, the result is a sequential, duplicative pathway that disadvantages SA firms against competitors who clear those signals earlier. From a mission-oriented perspective, this fragmentation reflects a lack of regulatory alignment around a shared societal goal such as sustained HIV treatment access. If regulations were explicitly mobilised as part of a mission-driven innovation strategy (Mazzucato, 2021), reliance pathways could evolve from voluntary, duplicative processes into coordinated instruments that actively enable local production and regional health security.

6. Recommendations

Recommendations target actions that the SA government, including DoH, SAHPRA, and DTIC, can undertake. Each recommendation is linked to a specific issue as outlined in either *Section 2* or *Section 5* (displayed within tables below). An overview of actions has been outlined in *Section 6.1*. Steps have been categorised into short-term, mid-term, and long-term solutions, all designed to be implemented concurrently. Detailed implementation plans for each step are outlined in their respective subsequent sections.

6.1 Overview of Recommendations

In the short term, SA should prioritise addressing service delivery gaps, which have been the primary casualty of recent funding cuts. Due to the disconnect between national and facility-level ARV supplies, upstream production issues are less urgent in the immediate horizon. Expanding domestic manufacturing alone will not resolve downstream challenges; unless delivery bottlenecks are addressed first, increased local production will not necessarily translate into improved access to medicines.

In the medium term, the priority is to strengthen ARV formulation capacity to stabilise the supply chain and reduce import dependence. Funding cuts have highlighted the need for a system that can withstand external shocks, and advancing domestic production is central to addressing these structural vulnerabilities. Cost and risk considerations must guide this process: ARV formulation requires smaller capital outlays than API synthesis and offers greater flexibility to adapt to technological change, making it the logical entry point for expanded local manufacturing.

Full production should be approached cautiously; every new treatment regimen represents a new ARV, which requires additional investment in new APIs. Therefore, the shift to API synthesis should occur only after large-scale ARV formulation is achieved with minimal resources, and only when APIs for globally used ARVs are technically and economically reachable.

In the long term, competitiveness will depend on securing sufficient market demand through regional and continental integration. Since the domestic market alone cannot sustain large-scale production, exports to SADC and broader African markets will be essential. Achieving this requires regulatory and procurement harmonisation across countries, an ambition that is both technically demanding and politically complex, and therefore best pursued as a long-term strategy.

6.2 Short-Term Initiatives

This section sets out near-term, actionable recommendations to mitigate the effects of current funding reductions. Short-term initiatives were developed to provide immediate mitigation of the direct effects of funding cuts on the accessibility of ARVs for patients. Given the substantial financial gap left by the potential withdrawal of PEPFAR support, which exceeds the current fiscal capacity of the SA government, these interventions are designed to stabilise the supply chain within existing resources constraints. Steps are to 1) Mitigate Immediate Issues in HIV Service Delivery, 2) Implement Accelerated NSP to Address New Landscape, and 3) Strengthen SAHPRA's Local Fast-Track Pathway Regulations.

6.2.1 Overview of Short-Term Implementation Plan

An overview of the short-term initiatives is shown below in Table 3. The measures span financial, planning, and regulatory pathways, enabling a coordinated, multi-pronged response.

Table 3

Implementation Plan for Short-Term Initiatives

Problem from §2.1	Recommendation	Lead Actor(s)	Implementation Measures	Actionability
Lack of funding for staff, clinics, and research	Allocate government funding to replace funding cuts	Minister of Health	1) Target urgent downstream needs: staff, clinic closures, viral load testing, information systems 2) Support current clinics	Requires extensive funding not readily available in the SA government
Lack of strategic government plan in response to funding cuts	Implement accelerated NSP	DoH, SANAC	1) Develop and implement sustainability and transition plans 2) Designate emergency task teams for community responses	Requires revisitation of national goals
Domestic backlog and throughput constraints; limited ability to track outcomes of local fast-track policy	Strengthen transparency and performance monitoring of SAHPRA's local fast-track pathway	SAHPRA	1) Introduce tiered urgency categories for ARV registration 2) Implement full reliance systems on trusted regulatory authorities 3) Improve transparency in regulatory processes	Requires SAHPRA involvement

Note. Data depicted is original to the report.

6.2.2 Step 1: Mitigate Immediate Issues in HIV Service Delivery

A sustained response to the closure of medical facilities and the termination of HIV response workers requires a financing package that protects staffing, clinics, and research. Securing funding is a necessity to address the direct impacts of funding cuts.

The SA government has already attempted to secure funding through a tax increase. The tax increase would raise the Value Added Tax (VAT) by half a percentage point, with another half a percentage point rise introduced the following year (Gumede, 2025). However, this plan was met with public outcry and failed to pass the national budget. Without this revenue, the Finance Minister Enoch Godongwana states that the country does not have the finances to fill the gap left by funding cuts.

In order to address the funding gap, the private sector must be called on. Currently, the private sector contributes 2% towards the HIV response. The UNAIDS Regional Director for Eastern and Southern Africa, Anne Githuku-Shongwe, states that if the sector were to add 10% more funding, a huge difference could be made (UNAIDS, 2025a).

This funding should prioritise restoring and retaining the 8,493 PEPFAR-funded staff whose services ceased when about 40 USAID projects were terminated. Retention of these staff can stabilise HIV testing, linkage, and continuity of care (UNAIDS, 2025b).

Information systems, communication, and monitoring also require immediate protection. Funding should ensure continued HIV testing, patient communication, and data retention.

Since 12 specialised HIV clinics have closed, 63,322 patient files were transferred to public facilities (Singh, 2025). In order to address the extreme influx of patients, funds need to be provided to expand clinic hours, add triage and queue-management staff, and strengthen community medication distribution. This allows for the absorption of patients into new health systems and transferring the caseload without degrading the quality of care.

6.2.3 Step 2: Implement Accelerated NSP to Address New Landscape

In addition to securing funding, a strategic government response plan must be implemented to ensure goals are met and money is efficiently appropriated. The South African National AIDS Council (SANAC) currently engages with government, civil society, and the private sector in policy advice and the creation of NSP (SANAC, n.d.). NSP's financing logic presumes steady contributions from partners alongside growth in public allocations and new private flows. However, the external environment has shifted materially, with partner funding volatility and service disruptions altering.

In order to meet NSP requirements under changed conditions, sustainability and transition plans must be created for every province. Each plan should list services formerly funded by partners, specify whether they will be absorbed into provincial payrolls, contracted through non-profit organisations, and set deadlines for each pathway. Human-resources actions should include fast-track rehiring, retention allowances for critical cadres, and portability of benefits for staff moving from donor-funded entities to public employment. Subsequently, a financial roadmap should be issued by DoH and the Ministry of Finance. The plan should define essential functions previously supported by partners, quantify the monthly cash need for staffing, laboratories, information systems, and key-population services, and identify immediate financing levers. These levers should include in-year virements within current grants, temporary ceilings on nonessential items, expedited procurement for high-impact inputs, and time-bound matching of private contributions.

Additionally, a designated Emergency Task Team for community responses should be constituted. This task team can operate under SANAC, with representation from DoH, provincial health departments, civil society, key-population networks, laboratory services, and private logistics and telecommunications partners. The team's mandate should include incident management for the clinic closures, rapid re-establishment of outreach, restoration of appointments and medication reminders, and deployment of mobile units to service gaps. Subsequently, the Emergency Task Team should operate a national coordination cell that tracks daily facility status, stock availability, turnaround times for viral-load testing, and patient transfer volumes. Clear activation triggers should be defined, such as any district experiencing a sustained drop in testing or treatment initiation beyond a predetermined threshold. Once triggered, predefined actions should include weekend clinic hours, transport vouchers for displaced patients, and temporary staff redeployment from lower-burden sites.

6.2.4 Step 3: Strengthen SAHPRA's Local Fast-Track Pathway Regulations

New regulations from SAHPRA have the potential to increase the rate of new, safe, and cheaper medications to the population. To address domestic backlog and throughput constraints, SAHPRA can introduce tiered urgency categories for ARV registration, implement full reliance systems on trusted regulatory authorities, and increase transparency in its processes.

Through the implementation of a tiered medicine registration approach by stratifying applications into urgency categories, ARV imports can be fast-tracked to reach individuals.

To further improve approval times and decrease required private funding, SAHPRA can implement a full reliance pathway for trusted regulatory authorities. With this pathway, a product that has WHO PQ, European Medicines Agency approval, or Food and Drug Administration approval can quickly be implemented into the SA market. This would also help aid companies in completing their dossiers to SAHPRA, and speed regulatory processes by avoiding re-review, reserving local effort for context-specific benefit-risk, vigilance, and labelling.

Finally, to enhance transparency, SAHPRA could consolidate existing performance data, such as registration outcomes, and publish new quarterly metrics (e.g. median review times by application stream).

6.3 Mid-Term Initiatives

This section sets forth recommendations for strengthening SA's domestic capacity for ARV formulation. It begins with a summary of proposals derived from the challenges identified in *Section 5.2* and organises them into three sequential steps: 1) Increase Political Will and Coordination, 2) Strengthen Local Production Finance Mechanisms, and 3) Expand Tech Transfer and Training. The discussion then elaborates on specific implementation measures, responsible actors, and potential risks for each step.

6.3.1 Overview of Mid-Term Implementation Plan

An overview of the mid-term initiatives is shown below in Table 4. The measures span addressing political will, finance and tech transfer, detailed in the following steps.

Table 4

Implementation Plan for Mid-Term Initiatives

Problem from §5.2	Recommendation	Lead Actor(s)	Implementation Measures	Actionability
1) Increase Political Will and Coordination				
Lack of political will for local production	Declare a clear commitment and vision for local production	SA Cabinet	1) Strong statement of intent from the highest level of government 2) Call for cooperation among stakeholders	Requires appealing evidence to allow decision makers to prioritise local production over other agendas

Problem from §5.2	Recommendation	Lead Actor(s)	Implementation Measures	Actionability
Lack of strategic and long-term planning	Coordination between government agencies and between the public and private sectors	SANAC	1) Promote engagement of government bodies responsible for finance, education, and industry 2) Promote greater private sector involvement 3) Develop a feasible and long-term implementation plan	Requires political will, even though an existing organisation can take this role
2) Strengthen Local Production Finance Mechanisms				
Limited public budgets and subsequent investor risk aversion	Assure public funding and diversify funding sources	DoH, Ministry of Finance	1) Translate SANAC recommendations into concrete policies and allocate public resources accordingly 2) Provide incentives to offset increased costs (e.g., tariff exemptions on APIs, and preferable procurement) 3) Attract private investment by demonstrating commitment to local production and potential returns on investment	Requires strong leadership and political will to secure funding
3) Expand Tech Transfer and Training				
Dependence on overseas tech transfer leading to reduced technological competitiveness	Diversify sources of technology transfer	DoH	1) Disseminate information on voluntary license mechanisms such as MPP 2) Establish consortia for technology sharing between technically advanced firms such as Aspen and other companies 3) Foster university-industry collaboration to facilitate licensing arrangements	Requires a strategic approach from DoH
Shortage of human resources specialised in local production	Improve curriculum content and lab-based practical training	DHET, DSTI, DoH	1) Upgrade university curricula at the national level 2) Design lab-based internship programmes and offer related tax incentives	Requires the benefits of collaboration for the industry to improve lab-based programmes

Note. Data depicted is original to the report.

6.3.2 Step 1: Increase Political Will and Coordination

Reviving local production after previous setbacks requires a clear expression of intent and vision from the highest levels of government, such as the Cabinet. Strong leadership at the outset is essential to prevent policy derailment arising from divergent opinions.

Subsequently, a feasible and long-term implementation plan must be developed. This requires a coordination mechanism across relevant ministries, including DoH, DSTI, DTIC, the Ministry of Finance, and the Department of Higher Education and Training (DHET). Given the current misalignment between private-sector initiatives and government policy, engagement between ministries and private actors, such as pharmaceutical companies and civil society organisations, will also be critical.

One academic suggested that a coordinating body should combine independence from ministries with proximity to political authority. SANAC, chaired by the Deputy President (DoH, 2023) and mandated to engage stakeholders from different sectors in policy advice and NSP formulation, appears well-suited to this role (SANAC, n.d.).

However, SANAC has been criticised for over-representing civil society organisations and under-representing the industry (Mahlangu et.al, 2017). Likewise, government agencies dealing with finance, education, and industry are insufficiently represented (SANAC, 2023a), factors that may contribute to weak political will on local production.

To address these gaps, SANAC should broaden participation to include a wider range of governmental and private-sector stakeholders and actively recommend policies on domestic manufacturing. This would strengthen local ARV formulation as a structural solution to supply chain vulnerabilities. This expands the SANAC initiative described in *Section 6.2* on modifying the existing NSP to respond to funding cuts immediately.

6.3.3 Step 2: Strengthen Local Production Finance Mechanisms

Once political commitment and policy measures are in place, the next critical element is funding. On the public finance side, DoH should translate SANAC's recommendations into concrete policy and work with the Ministry of Finance to ensure sufficient budget allocation.

Since APIs account for 70-80% of the final product cost, importing APIs for domestic formulation substantially increases production costs (GIZ, 2022). Thus, public funding should incentivise pharmaceutical companies to absorb this cost, for example, through tariff exemptions. According to one scholar, ARVs procured from abroad to SA are exempt from tariffs, whereas imported APIs are not. Therefore, API tariff exemptions should be considered. Another incentive mentioned by interviewees is preferable procurement. Currently, price-competitive imported ARVs dominate the SA government's tenders, creating the need for a mechanism that prioritises ARVs formulated domestically. Given the industrial benefits of localisation, DoH and DTIC should pursue these incentives.

In light of PEPFAR cuts and declining global support, it is imperative to offset downstream impacts while advancing domestic manufacturing in parallel. Considering the risk of escalating funding requirements,

diversifying financing sources is crucial. Private-sector investment from other industries and financial institutions offers one solution. Recognising that such investment depends on clear policy signals, DoH must demonstrate long-term government commitment to local production through concrete plans and clearly outline expected returns to investors.

6.3.4 Step 3: Expand Technology Transfer and Training

Expanding ARV formulation capacity requires sustained access to relevant technologies, making technology transfer central (WHO, 2011). Lessons from Ketlaphela, where technology transfer relied mainly on partnerships with international pharmaceutical companies (Tomlinson, 2020), highlight the need to diversify sources of technological input.

One viable approach is voluntary licensing, exemplified by the UN-supported Medicines Patent Pool (MPP) (Gaayeb et al., 2023). This initiative facilitates licensing and technology transfer to developing countries to access ARVs at affordable prices (MPP, n.d.). DoH should position such mechanisms as strategic tools for technology acquisition and actively promote awareness of them.

However, one academic noted a drawback: voluntary licensing may strain relationships with license-holding firms, which often produce medicines beyond ARVs. Bypassing licenses to obtain technology can damage these broader relationships. Therefore, voluntary licensing should be complemented by other modalities.

Domestic technology transfer is one such complementary approach. Companies like Aspen, which already lead in ARV formulation, could form consortia with other firms to share technology, infrastructure, and skilled labour, enabling large-scale production. DrugPatentWatch (2025) also emphasise the role of universities in patents and licensing. Strengthening academia-industry links could facilitate the transfer of university-generated innovations into commercial applications.

Such collaboration is also vital for workforce development. SA faces a shortage of personnel with the skills required for local production. Based on industry needs for ARV formulation, DHET, working with DSTI and DoH, should revise university curricula nationwide. To promote laboratory-based training, internship programmes and tax incentives, as implemented in other countries, should be introduced (Fasteau, 2024).

While workforce development may impose short-term costs on pharmaceutical firms, a well-designed system can offer reciprocal benefits, including a stable talent pipeline from universities and enhanced technology transfer from academia to industry.

6.4 Long-Term Initiatives

This section sets forth recommendations for creating the enabling conditions for SA's ARV manufacturing sector to integrate competitively into regional and global markets. It begins with a summary of proposals derived from the challenges identified in *Section 5.3* and organises them into three sequential steps: 1) Enable Parallel Submissions for Regulatory Approvals, 2) Scale Pooled Procurement, and 3) Build Export-

Readiness Capacity. The discussion then elaborates on specific implementation measures, responsible actors, and considerations for maximising benefits while mitigating risks for each step.

The SIPS, funded by the EU and the German Government, laid important groundwork for these recommendations. The SIPS supported regional regulatory harmonisation through the MRF, built industry GMP compliance capacity, launched the SADC Industrial Pharmacy Fellowship Programme, and designed both the technical platform and governance framework for the SPPS and electronic SADC Pooled Procurement Platform (eSPPS) (GIZ, 2024). The long-term initiatives proposed here build on these achievements, moving from preparatory work to operationalisation, while ensuring that SA manufacturers can take advantage of expanded market access opportunities.

6.4.1 Overview of Long-Term Implementation Plan

An overview of long-term initiatives is detailed below in Table 5. These measures form a multi-pronged approach to strengthen the SA regulatory system, including implementing parallel reviews, scaling up SPPS, and expanding export systems.

Table 5

Implementation Plan for Long-Term Initiatives

Problem from §5.3	Recommendation	Lead Actor(s)	Implementation Measures	Actionability
Sequential regulatory reviews causing long time-to-market	Enable parallel submissions to SAHPRA, ZAZIBONA, and WHO PQ	SAHPRA, SADC MRF, industry associations	1) Develop procedural alignment between SAHPRA, ZAZIBONA, and WHO PQ to allow simultaneous dossier submission 2) Produce an industry guidance note clarifying requirements and timelines for parallel submissions 3) Pilot the approach on a small set of ARV products to assess impact and refine processes	Requires political and policy coordination; can be piloted for selected ARV products
Fragmented national procurement limits regional market scale	Scale up SPPS through phased procurement pilots and governance finalisation	SADC Secretariat, SPPS Steering Committee, DoH, Member States	1) Secure SADC-level agreement on SPPS Charter and establish a Steering Committee of national procurement leads 2) Launch pilot procurements for selected ARV lines via eSPPS, using joint demand forecasts 3) Engage SA as an anchor buyer, committing a share of ARV tenders to pooled procurement 4) Coordinate procurement calendars with ZAZIBONA approvals to facilitate cross-border supply	Requires sustained political commitment at the SADC level

Problem from §5.3	Recommendation	Lead Actor(s)	Implementation Measures	Actionability
Limited readiness of firms to compete in export tenders	Expand export-readiness programme for ARV manufacturers	DTIC, DoH, SADC Secretariat, WHO, DFIs	1) Extend the SADC Industrial Pharmacy Fellowship Programme to cover regulatory affairs, quality management, and export logistics 2) Organise mock WHO PQ audits and gap analyses for targeted firms 3) Facilitate access to DFI-backed financing for facility upgrades and quality system improvements 4) Coordinate regional B2B events to connect manufacturers with procurement agencies	Requires coordination between national and SADC-level capacity-building initiatives

Note. Data depicted is original to the report.

6.4.2 Step 1: Enable Parallel Submissions for Regulatory Approvals

One of the persistent challenges for SA ARV manufacturers is the sequential nature of product registration, which can extend time-to-market to as long as five years when moving from domestic approval to regional and global eligibility. In interviews conducted for this study, industry representatives specifically proposed enabling parallel submissions to SAHPRA, the ZAZIBONA joint review process, and the WHO PQ programme as a more realistic short- to medium-term solution than legally binding mutual recognition. Unlike the short-term measure in *Section 6.2*, which focuses on monitoring SAHPRA's national fast-track, this recommendation targets cross-jurisdictional efficiency by enabling simultaneous engagement with SAHPRA, ZAZIBONA, and WHO PQ, addressing broader coordination challenges between domestic, regional, and global review systems.

The first implementation measure is to develop procedural alignment between SAHPRA, ZAZIBONA, and WHO PQ so that companies can file dossiers simultaneously with all relevant authorities (WHO, 2025b). The second is to produce an industry guidance note clarifying the requirements, timelines, and dossier format adaptations necessary for parallel submissions. Finally, the third is to pilot the approach on a small set of ARV products to assess its impact and refine processes before wider adoption.

Allowing parallel submissions could, according to stakeholder estimates (see *Section 5.3.4*), compress regulatory timelines to around two to three years for products that already meet shared technical requirements, improving competitiveness against suppliers from India or China who operate under more synchronised approval systems. The WHO Collaborative Registration Procedures framework demonstrates how reliance mechanisms can shorten national approval timelines to as little as 90 working days after prequalification (WHO, 2025b). While this reform does not eliminate the need for multiple reviews, it mitigates delays without requiring legislative change. A foreseeable risk is that parallel processing could strain the limited human resources of regulators, particularly if dossier volumes increase sharply. This can be mitigated by starting with a pilot phase supported by targeted technical assistance to review teams through SADC channels.

6.4.3 Step 2: Scale Pooled Procurement and Operationalising SPPS

As outlined in *Section 5.3.2*, limited uptake of pooled procurement to date has been driven by misaligned tender cycles, sovereignty concerns, and weak demand forecasting. Building on the initial design and technical assistance provided through the SIPS project, the SADC Secretariat has now endorsed a hybrid pooled procurement model, set out in the SPPS business plan, that combines centralised contracting, shared market information, and national-level procurement, supported by eSPPS, developed with technical input from Tanzania's Medical Stores Department (SADC, 2025b). Much of the technical infrastructure is already in place, and governance discussions are progressing at the regional level. There is also a conceptual link between SPPS and ZAZIBONA: pooled procurement can serve as a demand-side incentive for regulatory convergence, while regulatory harmonisation ensures that products procured jointly can move smoothly across borders (GIZ, 2024).

The first implementation measure is to secure SADC-level agreement on the SPPS Charter and establish a Steering Committee of national procurement leads to guide phased implementation. The second is to launch pilot procurements for selected ARV lines via eSPPS, using joint demand forecasts to coordinate tender calendars. The third is for SA to act as an anchor buyer, committing a share of its ARV tenders to pooled procurement, thereby sending a strong market signal and encouraging other member states to participate. Finally, the fourth is to coordinate procurement calendars with ZAZIBONA approvals to facilitate cross-border supply without delays.

The benefits of this approach include potential price reductions through economies of scale, improved supply security, and stronger market-shaping effects that favour compliant regional manufacturers (SADC, 2025b). However, it will require careful management of risks such as fiscal misalignment between national budget cycles and reluctance from some governments to share procurement sovereignty. These can be mitigated by starting with voluntary, small-scale tenders and by offering technical assistance to align procurement planning and financing mechanisms. Donor catalytic funding could also be leveraged to underwrite initial pooled orders, thereby reducing risk for both buyers and suppliers.

6.4.4 Step 3: Build Export-Readiness Capacity

While regulatory efficiency and pooled procurement can open doors to larger markets, SA manufacturers will only be able to seize these opportunities if they have the technical capabilities, quality systems, and market linkages required to compete effectively. The SIPS programme began addressing this through the SADC Industrial Pharmacy Fellowship Programme, GMP training, and technical support for regulatory compliance (GIZ, 2024). To achieve sustained competitiveness, these efforts should be expanded into a comprehensive export-readiness programme.

The first implementation measure is to extend the fellowship programme to cover regulatory affairs, quality management systems, and export logistics. The second is to organise mock WHO PQ audits and gap analyses for targeted firms, providing them with concrete compliance roadmaps. The third is to facilitate access to Development Finance Institutions (DFI) backed financing for facility upgrades and quality system improvements. The fourth is to coordinate regional Business to Business (B2B) events to connect manufacturers with procurement agencies and large buyers.

Ownership of activities should be clearly defined. At the national level, DTIC, in collaboration with DoH, should coordinate domestic firm participation, provide co-financing for facility upgrades, and facilitate access to financing. DoH should also work with WHO and other partners to organise mock audits and dossier-preparation support. At the SADC level, the Secretariat could coordinate training modules, enable cross-border industry exchanges, and link manufacturers to procurement opportunities emerging from SPPS pilots. The primary benefit of this step is to ensure that SA firms can not only access but also sustain their presence in export markets, meeting the technical and quality standards required by large-scale buyers. Risks include the possibility of trained staff leaving for better opportunities abroad and over-reliance on donor funding. These can be mitigated by embedding retention incentives such as certification recognition and career progression pathways, and by securing cost-sharing commitments from the private sector to embed sustainability.

7. Conclusion

SA's HIV response has been one of the most ambitious and successful public health programmes on the African continent. The expansion of ARV therapy since the early 2000s has transformed AIDS from a fatal illness into a chronic, manageable condition. Yet this success is now at risk. The abrupt reduction of donor support, particularly from PEPFAR, has exposed systemic vulnerabilities in both service delivery and upstream pharmaceutical supply chains. At the same time, SA's dependence on imported APIs and finished ARVs underscores the fragility of its treatment security.

This report has sought to examine how SA can strengthen local ARV production in the face of these challenges. By combining a literature review with twelve semi-structured interviews across manufacturers, academics, regulators, and civil society stakeholders, we mapped systemic barriers, identified intervention points, and developed a set of phased recommendations. The analysis was structured using the WHO Blocks, which provided a holistic framework for examining the interconnections between financing, regulation, service delivery, governance, and workforce development.

7.1 Final Reflections

SA stands at a crossroads in its HIV response. On one hand, it has demonstrated remarkable achievements in expanding ARV therapy coverage, reducing mortality, and mobilising domestic resources. On the other hand, sudden donor funding contractions and persistent reliance on imports expose structural vulnerabilities. Strengthening local ARV production is not a silver bullet, but it represents a critical lever for building a resilient, sovereign, and equitable health system.

The challenge is not merely technical or financial, but systemic: aligning public health priorities with industrial policy, reconciling domestic sovereignty with regional harmonisation, and balancing short-term service delivery needs with long-term supply chain resilience. These are inherently complex trade-offs, but they are navigable with evidence, policy coordination, and sustained political will.

By drawing attention to both the opportunities and barriers in local ARV production, this report contributes to an urgent policy debate that will shape the future of HIV care in SA and the broader region. Future research and sustained stakeholder engagement will be essential to translate these insights into durable reforms. Ultimately, the resilience of SA's HIV response will depend not only on securing medicines today, but also on building the capacity to produce, regulate, and deliver them for generations to come.

7.2 Key Findings

Three broad conclusions emerge from this study:

First, donor funding cuts most acutely affect the downstream delivery system but create ripple effects upstream. The sudden furloughing of nearly 8,500 donor-funded staff, closure of 12 specialised HIV clinics, and disruption of viral load testing and information systems have significantly stressed service delivery. While ARV supply remains relatively stable due to domestic procurement financing, strain on delivery diminishes the domestic market for local manufacturers, undermines demand forecasting, and increases

investor uncertainty. This confirms the interdependence between downstream service delivery and upstream production capacity.

Second, local ARV production is widely recognised as essential for long-term resilience but faces formidable barriers. While SA has the industrial base and market size to pursue localisation, high capital investment requirements, the lack of stakeholder coordination, and limited expertise slow progress. Industry actors, including Aspen and CPT Pharma, have demonstrated capacity in formulation and pilot-stage API synthesis, but they remain disadvantaged in competing with lower-cost Indian and Chinese producers. The legacy of the failed Ketlaphela initiative also continues to cast a shadow over government-led efforts, reinforcing the need for careful, phased approaches to strengthen ARV formulation capabilities rather than politically symbolic ventures.

Third, regulatory fragmentation and misaligned policy incentives create structural disadvantages for SA firms. At the domestic level, SAHPRA's backlog and procedural inefficiencies extend approval timelines. Regionally, the non-binding nature of ZAZIBONA joint reviews and divergent statutory labelling rules within SADC undermine the potential benefits of harmonisation. Globally, the divergence between SAHPRA eligibility (required for national tenders) and WHO Prequalification (required for multilateral procurement) forces SA firms into duplicative, sequential pathways, often delaying their entry into global tenders by years. Collectively, these factors create a calendar and incentive structure that is structurally unfavourable to local producers.

On this basis, our recommendations call for a phased approach: short-term measures to restore service delivery and stabilise the fast-track regulatory pathway; medium-term efforts to build political will, secure financing, and strengthen technology transfer; and long-term strategies to enable parallel regulatory submissions, scale pooled procurement, and build export readiness.

7.3 Limitations of this Research

While this study has generated important insights, it is necessary to acknowledge its limitations.

Scope and Focus
The project concentrated primarily on SA, even though regional integration and global market forces are critical to the dynamics of ARV production. While we drew on the SIPS programme and SADC policy frameworks to situate the analysis regionally, our interview sample and data collection were primarily South Africa-focused. This may limit the generalisability of findings to neighbouring countries.

Stakeholder Representation
Our sample of twelve interviews was diverse but not comprehensive. Government actors, particularly from DoH and DTIC, were underrepresented relative to manufacturers and academics. While this limitation was mitigated by triangulating with existing literature, the absence of stronger government perspectives may have constrained our ability to capture policy intent and political dynamics.

Temporal Uncertainty
The donor funding landscape remains highly fluid. PEPFAR's reauthorisation status, future U.S. policy directions, and the scale of philanthropic or multilateral responses were unresolved at the time of writing.

This means that some of the recommendations in this report may need adjustment depending on subsequent developments.

By flagging these limitations, we underscore that this report represents a timely and exploratory contribution, not a definitive or exhaustive analysis.

7.4 Next Steps for Future Research

Building on these findings, several avenues for future research are recommended:

Comparative Regional Studies
Extending research beyond SA to include other African countries pursuing pharmaceutical localisation (e.g., Nigeria, Kenya, Ethiopia) would generate comparative insights into what strategies are most feasible, scalable, and sustainable in different contexts.

Patient and Civil Society Perspectives
Future research should systematically include patients and key populations to understand how localisation affects access, trust, and equity in HIV care, complementing the predominantly institutional and industry focus of this study.

Quantitative Modelling of Costs and Market Dynamics
More rigorous economic modelling is needed to compare the costs of imports, local formulation, and API synthesis under different demand and funding scenarios. Such modelling could inform procurement strategies, subsidy design, and investment choices.

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