PHARMACEUTICAL SCARCITY AND ITS HUMAN COST: THE EFFECT ON HIV PATIENTS IN INDIA

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ABSTRACT

The uninterrupted availability of antiretroviral therapy (ART) is essential for safeguarding the lives, dignity, and well-being of People Living with HIV (PLHIV). India, despite operating one of the world's largest HIV treatment programmes through the National AIDS Control Organisation (NACO), has experienced recurring shortages of critical antiretroviral (ARV) medicines between 2020 and 2025. These shortages, intensified by the COVID-19 pandemic, procurement delays, and supply-chain inefficiencies, affected essential drugs such as Dolutegravir, Tenofovir, Lamivudine, and pediatric formulations. This paper examines the impact of pharmaceutical scarcity on the physical and mental health of PLHIV in India and evaluates the extent to which India's domestic policies and international obligations ensure uninterrupted access to HIV treatment.

The study adopts a doctrinal and analytical research methodology by examining government reports, parliamentary debates, judicial decisions, international instruments, policy documents, and civil-society reports. It argues that interruptions in ART not only accelerate disease progression and increase the risk of drug resistance but also create severe psychological consequences, including anxiety, depression, stress, social isolation, and loss of trust in public healthcare systems. The research further analyses the constitutional dimensions of ART access under Article 21 of the Constitution of India and India's obligations under international human-rights frameworks such as the International Covenant on Economic, Social and Cultural Rights (ICESCR) and the Doha Declaration on TRIPS and Public Health.

The paper highlights the gaps between policy commitments and ground-level implementation, particularly in procurement transparency, stock monitoring, and distribution mechanisms. It also emphasizes the need to integrate mental-health support into HIV care systems. The study concludes that ensuring uninterrupted access to essential HIV medicines is both a legal obligation and a public-health necessity. Strengthening supply-chain resilience, adopting real-time monitoring systems, expanding multi-month dispensing, and institutionalizing psychosocial support are crucial steps toward

protecting the rights, health, and dignity of PLHIV in India.

Keywords: HIV/AIDS; Antiretroviral Therapy (ART); Pharmaceutical Scarcity; Mental Health; People Living with HIV (PLHIV); Right to Health; Article 21; NACO; Access to Medicines; ICESCR; Public Health; Human Rights Law.

INTRODUCTION

Human Immunodeficiency Virus (HIV) affects approximately 40.8 million people worldwide, with an estimated range of 37.0 to 45.6 million according to WHO. As of 2025, Eswatini has the highest adult HIV prevalence rate globally, with approximately 25.1% of adults aged 15–49 living with HIV. In contrast, South Africa leads in the absolute number of people living with HIV, with an estimated 8 million individuals affected. Asia has an estimated prevalence in the region of 6.7 million, with 2.4 million being in India.

Combination therapies of Antiretroviral (ARV) drugs are the treatment of choice in HIV, and non-adherence is a main, if not the most important factor in treatment failure, and the development of resistance. To make sure that HIV treatment works effectively it is important that the drugs are taken on time, every time i.e. 100% medication adherence. Concerns about incomplete medication adherence among patients living in poverty have been an important consideration in expanding the access to anti-retroviral therapy (ART). Antiretroviral therapy (ART) is critical for People Living with HIV (PLHIV), as it not only sustains life but also ensures social and mental well-being.

India, home to one of the largest HIV treatment programs in the world, provides free ART to over 1.4 million PLHIV through government-run centres under the National AIDS Control Programme (NACO, 2021). Despite these efforts, persistent shortages of essential HIV medicines have been documented in India highlighting intermittent unavailability of critical ARVs such as Dolutegravir, Lopinavir/Ritonavir, and Abacavir across multiple states. Importantly, ART disruptions have profound consequences not only on physical health—including accelerated disease progression, increased viral loads, and heightened risk of drug resistance—but also on mental health, leading to anxiety, depression, stress, and social isolation among patients. Children and marginalized groups are particularly vulnerable, with pediatric formulations often in short supply, resulting in caregivers being forced to modify dosages or split adult tablets.

The mental-health dimension of ART shortages is particularly significant. Uncertainty around treatment continuity exacerbates psychological distress, contributes to stigma, and undermines patients' ability to adhere to life-saving therapies. From a public-health perspective, interruptions in ART threaten the effectiveness of national HIV-control programs by increasing the risk of transmission and burdening healthcare infrastructure. At the same time, ART shortages raise important legal and policy questions. Domestically, such interruptions challenge the constitutional guarantee of the right to life under Article 21 and the statutory protections of the HIV & AIDS (Prevention and Control) Act, 2017

This research seeks to analyze the impact of lack of essential HIV pharmaceuticals on the physical, mental, and social well-being of PLHIV in India, assess the effectiveness of domestic policies and international obligations in ensuring uninterrupted access, and explore strategies to mitigate the mental-health consequences of ART shortages.

OBJECTIVES

The primary objective of this research is to analyze the impact of lack of essential HIV pharmaceuticals on the physical, mental, and social well-being of People Living with HIV (PLHIV) in India, and to examine India's legal and policy obligations under domestic law and international human-rights frameworks to ensure uninterrupted access to these medicines. The study also aims to assess the link between ART shortages and mental-health outcomes, including anxiety, depression, and stress.

SCOPE

The study focuses on the period 2020–2025, when several reports and protests indicated disruptions in ART availability and civil society documented patient impacts. The research primarily examines India, with limited comparative references to other countries (e.g., South Africa, Brazil) to contextualize state obligations and policy responses. It focuses on HIV/AIDS patients receiving ART and examines their mental health challenges resulting from ART shortages.

RESEARCH QUESTIONS

1. What are the documented shortages of ARV medicines in India between 2020–2025, and which specific drugs were most affected?

2. How have ART shortages affected the mental health of PLHIV in India?

3. How have Indian government policies and supply chain mechanisms addressed ART availability and fulfilled its International Obligations as well?

4. What strategies can be implemented to mitigate mental health impacts during periods of pharmaceutical scarcity?

LITERATURE REVIEW

Access to essential medicines is recognized as a cornerstone of the right to health under both domestic and international legal frameworks. In the context of HIV, uninterrupted access to antiretroviral therapy (ART) is not only life-saving but also essential for mental and social well-being. Disruptions in the supply of ART have profound implications, especially for People Living with HIV (PLHIV), who face heightened stigma, anxiety, and depression.

India has one of the world's largest HIV treatment programs, with over 1.4 million PLHIV receiving free ART through government-run centres (NACO, 2021). However, shortages of essential HIV medicines have been documented repeatedly. Civil society organizations have been at the forefront of documenting ART shortages and their impact on PLHIV. The International Treatment Preparedness Coalition (ITPC) and other PLHIV networks reported in 2022 that essential ARVs, including Dolutegravir, Lopinavir/Ritonavir, and Abacavir, were intermittently unavailable in multiple states across India (ITPC, 2022a; ITPC, 2022b). These reports detailed delays in procurement, tendering issues, and logistical bottlenecks that disrupted access at government ART centres. Importantly, these shortages were linked to increased psychological distress among patients. Anxiety, depression, and stress increase when patients face the uncertainty of treatment continuity. Studies document that fear of disease progression and stigma associated with HIV intensifies psychological distress, sometimes leading to suicidal ideation or severe depressive episodes (PMC, 2020; AIDSmap, 2024). Social isolation, internalized stigma, and fear of discrimination exacerbate the mental-health burden, especially among women and marginalized groups.

Evidence suggests that interruptions in ART significantly accelerate disease progression among PLHIV. Shortages increase viral loads, reduce CD4 counts, and contribute to the development of drug-resistant HIV strains (Down to Earth, 2022). The 2022 stockouts in Delhi

and other urban centres left thousands of patients without access to essential medicines, compelling some to reuse expired or discarded medications (The Guardian, 2022). Pediatric patients were particularly vulnerable, as disruptions in specialized formulations adversely affected growth and development (amfAR, 2022). Such interruptions are not merely clinical inconveniences but pose life-threatening risks, which directly contravene both the domestic right to health and India's international obligations under treaties such as the ICESCR. Also Press reports reveal that in 2022, children living with HIV faced severe shortages of syrup formulations, forcing caregivers to split adult tablets (The Wire, 2022). Investigations by *Scroll.in* highlighted multiple episodes of ART stockouts across several states during COVID-19 lockdowns, leaving patients untreated for weeks. The BBC reported that PLHIV in India faced significant challenges due to the unavailability of essential medications, leading to increased anxiety and stress among patients. Also, patients worried they may lose employment due to illness, creating financial strain on families and increasing vulnerability to poverty (India Today, 2022). Public health is also affected, as uncontrolled viral loads heighten the risk of HIV transmission, undermining national HIV-control programmes.

Parliamentary debates corroborate these findings, with multiple MPs raising questions in the Lok Sabha about disruptions in ART supply (Lok Sabha, 2021). Civil society organizations, including the Lawyers Collective and SAATHII, have submitted letters to the Ministry of Health documenting patient distress during shortages. These reports consistently highlight that supply chain inefficiencies, procurement delays, and lack of planning were key contributors to ART disruptions.

Though some official government documents including Lok Sabha Q&As and press releases, claim that first- and second-line ART drugs are largely sufficient and supply chains cover most PLHIV in India (Lok Sabha, 2022a; 2022b; The Hindu, 2022). While these documents show procedural compliance, they reveal a gap between reported availability and patients' experiences, raising concerns about transparency and timely access to medicines.

From a rights-based perspective, shortages in HIV medicines constitute a violation of India's constitutional guarantees (Article 21) and statutory duties under the HIV & AIDS (Prevention and Control) Act, 2017. Supreme Court petitions filed by PLHIV networks in 2022–2025 sought intervention to ensure uninterrupted supply of essential medicines (Deccan Herald, 2025; Business Standard, 2025). The petitions emphasized the right to life and health under

Article 21 of the Constitution, as well as the mental health repercussions of treatment disruptions. Media reporting on the hearings indicates that the Court considered both state responses and civil society evidence.

India's struggles mirror global patterns. UNAIDS reports (2021, 2022) show that nearly 25% of low- and middle-income countries experienced ART supply chain interruptions during the COVID-19 pandemic. In South Africa, Human Rights Watch (2021) documented treatment lapses that led to heightened patient anxiety and increased risk of resistance to HIV drugs. Médecins Sans Frontières (MSF) similarly reported widespread stockouts in Nigeria, Kenya, and Mozambique, which threatened years of progress in HIV treatment.

At the international level, India is bound by the International Covenant on Economic, Social and Cultural Rights (ICESCR), Article 12 of which guarantees "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." CESCR General Comment No. 14 (2000) articulates the AAAQ framework (Availability, Accessibility, Acceptability, and Quality) for health services, including essential medicines, including ART, without discrimination (OHCHR, 2000). UNAIDS reports highlight the critical intersection of intellectual property, drug pricing, and access to life-saving medications (UNAIDS, 2016). WHO and other scholarly sources reinforce that uninterrupted access to ART is not only a domestic responsibility but also a component of fulfilling India's obligations under the ICESCR (The Guardian, 2022; Down to Earth, 2022).

The Doha Declaration on TRIPS and Public Health (2001) empowers states to use intellectual property flexibilities to secure access to affordable medicines. India, as a major producer of generic ARVs, plays a dual role as both a supplier to the Global South and a state responsible for domestic distribution. Comparative jurisprudence, such as South Africa's *Treatment Action Campaign v. Minister of Health* (2002), highlights how constitutional courts have compelled governments to expand access to HIV medicines as part of their human rights obligations.

HYPOTHESIS

By ensuring uninterrupted access to essential HIV medicines in India will not only safeguard the physical health of People Living with HIV (PLHIV) but also significantly improve their mental well-being by reducing anxiety, depression, and social stigma. Strengthening procurement mechanisms, enhancing accountability in supply chains, and aligning national

policies with international human-rights obligations can transform ART access into a sustainable and equitable system. In doing so, India can set a global example of how a rights-based approach to healthcare can mitigate the mental health burden associated with chronic diseases and reaffirm its commitment to the dignity and well-being of PLHIV.

CHAPTER 1: RUNNING OUT OF LIFELINES – INDIA'S ARV SHORTAGE STORY

Antiretroviral (ARV) medicines form the backbone of HIV treatment in India and are critical to ensuring the health and survival of people living with HIV (PLHIV). India has one of the world's largest HIV treatment programs, with over 1.8 million individuals receiving free ARV drugs through the National AIDS Control Organisation (NACO). Being a major producer of generic ARVs for global supply, India also plays a vital role in ensuring medicine accessibility across low- and middle-income countries. However, the period between 2020 and 2025 witnessed several documented challenges in the consistent supply and distribution of ARV medicines within India. These shortages were influenced by multiple factors, including the COVID-19 pandemic, procurement delays, distribution inefficiencies, and market vulnerabilities. The most prominently affected drugs during this period were the fixed-dose combination Tenofovir + Lamivudine + Dolutegravir (TLD), pediatric formulations such as Zidovudine (ZDV) syrup, and certain second- and third-line ARVs that depended on single suppliers.

Impact of the COVID-19 Pandemic (2020–2021)

The onset of the COVID-19 pandemic in 2020 severely disrupted global and domestic pharmaceutical supply chains. According to the World Health Organization's situational assessments, India's lockdowns, restrictions on factory operations, and interruptions in the transportation of raw materials led to widespread delays in the production and distribution of essential medicines, including ARVs. Manufacturing plants faced reduced workforce availability, and the import of active pharmaceutical ingredients (APIs) from countries like China was temporarily constrained. Although the Government of India and NACO took measures to mitigate these disruptions, reports indicated that certain ART (Antiretroviral Therapy) centers faced localized shortages, particularly of pediatric formulations and liquid syrups. These challenges did not amount to a nationwide stockout but created a risk environment that exposed the vulnerabilities of India's centralized ARV supply system.

Procurement and Distribution Challenges (2022)

A major episode of ARV shortages was documented in late 2021 and early 2022. The International Network of People who Use Drugs (INPUD) addressed a formal communication to India's National AIDS Control Organisation (NACO) in August 2022, highlighting an ongoing stock-out of ARV medicines. According to this report, nearly 72,500 people living with HIV (PLHIV) were affected across different states, with the shortage beginning as early as December 2021. The shortages included several critical medicines used in first-line and second-line HIV therapy. The report underscored that the supply disruptions were widespread and had the potential to increase viral resistance among patients due to interruptions in continuous treatment (INPUD, 2022).

Subsequent evidence of ARV unavailability was further reinforced in July 2022 when an investigative report detailing protests by PLHIV outside the NACO headquarters in New Delhi. The protestors alleged that Dolutegravir (DTG) 50 mg tablets, Tenofovir and Lamivudine — key drugs in India's first-line HIV regimen — were in short supply across various ART centers. The shortage was not limited to DTG alone; pediatric formulations and second-line and third-line ARV regimens were also reported as unavailable. These medicines are crucial for individuals whose bodies no longer respond to the standard first-line treatments, making their absence particularly alarming (India Today, 2022). Investigative reports and civil-society letters (July–Aug 2022) also documented DTG being out of stock or in short supply in several states (Assam, Bihar, Haryana, Jharkhand, Himachal Pradesh) and mention shortages of pediatric DTG formulations (The Guardian,2022).

Further substantiation of these shortages was reported in July 2022 that HIV patients across India were protesting "months-long drug shortages." The report quoted PLHIV networks and health activists who stated that ART (Antiretroviral Therapy) drug supplies had been inconsistent since November 2021, leading to treatment gaps and severe distress among dependent patients. The article attributed the shortages to procurement delays and administrative inefficiencies in the National AIDS Control Organisation's centralized drug distribution system (Down To Earth, 2022). Also, there was reports that community groups estimated up to 500,000 people were unable to get free ARVs from government centres over several months at the 2022 peak of the crisis (The Guardian,2022).

While independent organizations and civil society groups highlighted the severity of the

situation, the Government of India presented a slightly different perspective. In July 2022, government sources stated that there was "adequate stock of antiretroviral drugs for around 95% of people living with HIV in India," suggesting that shortages were localized or temporary (New Indian Express, 2022). Later, in August 2023, the Minister of State for Health informed the Rajya Sabha that "there is no reported nationwide shortage of dolutegravir," asserting that measures had been taken to ensure uninterrupted supply (New Indian Express, 2023). Despite these assurances, field evidence and reports from patient networks indicated ongoing logistical difficulties, particularly for children and patients on non-standard regimens.

Post-2023 Trends and Ongoing Vulnerabilities

From 2023 onwards, while large-scale national shortages of ARVs subsided, intermittent and localized disruptions continued to be reported. International agencies such as UNAIDS and the Clinton Health Access Initiative (CHAI) highlighted that India's ARV supply chain remained vulnerable to market fluctuations, donor funding uncertainty, and supplier concentration. The *UNAIDS HIV Commodity Snapshot* (May 2025) noted that pediatric formulations, particularly Zidovudine (ZDV) syrup, continued to experience shipment delays and limited stock availability in certain states. This was largely due to the low commercial profitability of pediatric ARVs, leading to fewer suppliers in the market.

Additionally, CHAI's 2025 market memo identified that low-volume and second-line drugs (used for patients with drug resistance) were at higher risk of supply disruption because they relied heavily on single manufacturers. Such vulnerabilities indicate that while India's ARV manufacturing capacity is vast, maintaining consistent availability across all formulations requires better diversification of suppliers, improved forecasting, and enhanced funding mechanisms.

From the synthesis of these sources, it becomes evident that ARV shortages in India between 2020 and 2025 were not continuous but episodic. The most affected drugs included Dolutegravir (DTG) 50 mg, Tenofovir and Lamivudine — a cornerstone of India's first-line HIV regimen — along with various pediatric ARV formulations, and second-line and third-line therapy combinations like Lopinavir/Ritonavir and Atazanavir. The shortages largely occurred due to procurement delays, supply chain mismanagement, and distribution lapses within NACO's system, particularly following disruptions caused by the COVID-19 pandemic.

CHAPTER 2: WHEN THE PILLS STOP, THE PANIC BEGINS – MENTAL HEALTH TOLL OF ART SHORTAGES

The interruption of antiretroviral therapy (ART) supply is not merely a logistical or clinical problem but it is a psychological assault on the people whose lives depend on continuous medication. In India, episodic ART shortages documented in 2021–2023 produced credible and wide-ranging harms to the mental health of people living with HIV (PLHIV). These harms took the form of acute anxiety and fear, worsening depressive symptoms, erosion of trust in health systems, social isolation, and increased caregiver distress — effects that in turn feed back into clinical outcomes (non-adherence, treatment failure and heightened risk of resistance). Evidence for these pathways comes from civil-society monitoring and reporting of the 2022 stock-out episode, international public-health guidance on ART interruptions, community-led monitoring studies, and recent judicial attention in India to procurement and stock-out problems. (amfAR, The Foundation for AIDS Research)

First, the immediate psychological reaction to a stock-out is acute anxiety. PLHIV who depend on daily ARVs experience overpowering fear that a missed dose or regimen change will allow viral rebound or create drug resistance ,outcomes with real clinical consequences. Community testimony during the 2022 protests outside the National AIDS Control Organisation (NACO) office made this explicit: placards reading "ARV is our lifeline" and prolonged sit-ins signalled that many patients felt their survival and future health were suddenly uncertain. Journalistic investigations and amfAR's contemporaneous reporting documented the distress of patients forced to ration pills, change clinics, or delay refills — all immediate triggers of anxiety. (amfAR, The Foundation for AIDS Research). A study in Pune during the COVID-19 lockdown found that among 167 PLHIV, 25 % had generalized anxiety (GAD-7 $\geq$ 10). Importantly, those with fewer remaining ART doses had higher anxiety scores ($p = 0.05$) — indicating a direct link between perceived ART supply risk and anxiety. (BioMed Central)

ART interruptions amplify depressive symptoms and hopelessness. India-specific mental-health literature already records high baseline rates of depression and anxiety among PLHIV, and multiple studies link depressive morbidity to poorer adherence and engagement in care. When shortages make medication access precarious, patients report feelings of helplessness and emotional exhaustion — familiar precursors to clinical depression. International guidance and syntheses on ART interruptions note that such programmatic failures increase psychosocial

stressors for affected individuals and families, reinforcing the plausible causal chain from stock-outs to worsening mental-health outcomes. (UNAIDS)

Stock-outs erode trust in health systems and lead to disengagement which is a social-psychological pathway with mental-health consequences. Repeated procurement lapses or opaque tendering processes send a signal of neglect to communities. Loss of confidence in the ability of public programmes to deliver care breeds demoralisation and perceived abandonment, which are associated with social withdrawal, reduced help-seeking and increased depressive symptomatology. Community-led monitoring in India has documented both the material stock-outs and the subsequent loss of faith among PLHIV, which often manifested as missed appointments or reluctance to disclose problems to providers out of fear that nothing would change. (PMC)

Children, adolescents and caregivers have borne a disproportionate psychosocial burden. Numerous reports from 2022 emphasised shortages in paediatric formulations (paediatric DTG, LPV/r), producing acute caregiver anxiety over growth, development and proper dosing. Caregivers frequently reported sleeplessness, constant worry, and panic when paediatric supplies were unavailable — stressors that are both immediate mental-health harms and drivers of long-term caregiver burnout. (aidsmap.com)

Finally, the prospect and reality of drug resistance and treatment failure create long-term psychological harm. WHO and UNAIDS guidance underline that interruptions heighten the risk of virological failure and resistance; for patients, the knowledge (or fear) that resistance could close off future treatment options carries chronic anxiety, trauma and despair. Thus mental-health harms extend beyond the interruption period into ongoing worry about disease trajectory and mortality. (World Health Organization)

India's legal and constitutional framework provides a rights-based lens on these harms. The Supreme Court's right-to-health jurisprudence — exemplified by decisions such as Paschim Banga Khet Mazdoor Samity v. State of West Bengal (1996) and Consumer Education & Research Centre v. Union of India (1995) — recognises that access to essential medical care is integral to Article 21's guarantee of the right to life and dignity; these precedents underpin arguments that persistent ART shortages may amount to a violation of constitutional health obligations when they endanger life and well-being. Pt. Parmanand Katara v. Union of India (1989) further emphasises duties on the system to provide urgent medical care; together, these

cases furnish a doctrinal foundation for demanding systemic measures to prevent stock-outs and to address the ancillary mental-health harms they cause. (Indian Kanoon)

Judicial attention to ART procurement and stock-outs is recent but rising: in 2025 the Supreme Court directed States to file affidavits addressing periodic stock-outs, procurement transparency and drug quality for ART drugs — a direct recognition that supply-chain failures demand systemic redress rather than ad hoc fixes. This judicial scrutiny opens avenues to remedy both the clinical and psychosocial harms of shortages by compelling accountability and improved supply governance. (Live Law)

Limitations in the empirical record should be noted. Quantitative, India-specific longitudinal studies measuring mental-health scores before and after documented stock-outs are scarce; much of the evidence combines qualitative community testimony, programme monitoring and global guidance. Nevertheless, the convergence of community reports (scale and lived experience), programmatic monitoring, international evidence of harms from ART interruptions, and emerging judicial attention creates a robust, multi-source picture: ART shortages in India between 2020 and 2025 meaningfully worsened mental-health outcomes for many PLHIV, especially among children and those on second/third-line regimens. (amfAR, The Foundation for AIDS Research)

In India, the documented stock-outs of 2021–2023 inflicted acute anxiety, worsened depressive symptoms, eroded trust in health services, increased caregiver burden, and heightened the long-term psychological burden of potential drug resistance. Remedies therefore must be twofold: (1) structural : fix procurement, tendering and distribution so ART is reliably available (a demand now reflected in judicial orders), and (2) clinical-programmatic: integrate mental-health screening and psychosocial support into HIV services so the psychological fallout of any future disruption is promptly identified and treated. Together, these steps protect both the bodies and the minds of PLHIV — which, under India's constitutional jurisprudence, is the State's duty. (World Health Organization)

CHAPTER 3: POLICIES, PROMISES, AND PITFALLS – INDIA'S RESPONSE TO THE ART SUPPLY CRISIS

The Indian government's response to HIV/AIDS has evolved through successive policy frameworks designed to ensure free and universal access to antiretroviral therapy (ART). These

measures, grounded in domestic constitutional commitments under Article 21 of the Constitution of India—the right to life and health—also align with India's obligations under international law, particularly under the World Health Organization (WHO), UNAIDS, and the Sustainable Development Goals (SDGs). Despite these commitments, episodic shortages of ART between 2020 and 2025 have tested the resilience of India's supply chain and its adherence to international norms on access to medicines.

Policy Framework for ART Provision

The National AIDS Control Organisation (NACO), functioning under the Ministry of Health and Family Welfare, is the primary agency responsible for formulating and implementing India's ART policies. Through the National AIDS and STD Control Programme (NACP)—currently in its Phase-V (2021–2026)—NACO has expanded ART coverage nationwide with an emphasis on the *"Test and Treat"* strategy and the transition to the tenofovir/lamivudine/dolutegravir (TLD) fixed-dose combination as the first-line regimen. (National AIDS Control Organization | MoHFW | GoI)

Under NACO's Procurement and Supply Management (PSM) system, the government maintains a centralised procurement mechanism with buffer stock requirements, annual forecasting, and vendor selection through open tendering (National AIDS Control Organization | MoHFW | GoI). The system aims to reduce price volatility and ensure continuity of supply through pooled procurement, yet delays in tender finalisation or distribution logistics at the state level have occasionally disrupted ART availability.

Supply Chain Mechanisms

NACO's *Standard Operating Procedures (SOPs)* for Supply Chain Management (SCM) outline the processes for forecasting, procurement, storage, quality assurance, and distribution of ART drugs across more than 600 ART Centres nationwide (NACO, *Standard Operating Procedures for Supply Chain Management* (2021)). To safeguard continuity, multi-month dispensing (MMD) was introduced during the COVID-19 pandemic, allowing patients to receive 3–6 months of ART supply at once. (World Health Organization, *Guidance on Handling Interruptions in Antiretroviral Treatment Due to Drug Shortages* (Geneva, WHO 2025). WHO and UNAIDS have both commended India's adoption of MMD as an essential measure to maintain adherence during health emergencies.

Despite such structural frameworks, reports between 2021 and 2022 documented localised ART shortages—especially of paediatric formulations and second-line regimens—across states such as Delhi, Maharashtra, and Manipur. These shortages were attributed to delays in procurement cycles and inadequate last-mile distribution rather than national-level scarcity. NACO later confirmed that central stocks were adequate for 95% of patients, yet the discrepancies between central and peripheral levels highlighted systemic weaknesses in logistics coordination.

Judicial Oversight and Domestic Legal Obligations

India's courts have consistently recognised the right to health as an integral facet of the right to life under Article 21. In Paschim Banga Khet Mazdoor Samity v State of West Bengal, the Supreme Court held that the government's failure to provide essential medical facilities constitutes a violation of the right to life. Likewise, in Consumer Education and Research Centre v Union of India, the Court emphasised the State's obligation to ensure health care for all workers as part of social justice.

More recently, the Supreme Court in 2025 directed all States and Union Territories to submit affidavits detailing ART stock positions in response to a Public Interest Litigation alleging nationwide shortages and substandard drug quality. This judicial intervention reinforced the constitutional imperative of maintaining uninterrupted ART supply as a State obligation under Article 21.

International Commitments and TRIPS Flexibilities

India's ART policy is also guided by its international obligations under the WHO Global Health Sector Strategy on HIV (2022–2030) and UNAIDS 95–95–95 targets—to diagnose 95% of all PLHIV, provide ART to 95% of those diagnosed, and achieve viral suppression in 95% of those treated. Additionally, under SDG 3.3, India is committed to ending the AIDS epidemic by 2030.

At the international trade-law level, India's Patents Act, 1970, as amended, incorporates TRIPS flexibilities to promote access to essential medicines. The Supreme Court's decision in Novartis AG v Union of India upheld Section 3(d), restricting the evergreening of pharmaceutical patents and thereby protecting access to affordable generics. Moreover, India's

use of compulsory licensing in *Natco Pharma Ltd v Bayer Corporation* (2013) demonstrated its willingness to prioritise public health over patent exclusivity. These actions align with India's obligations under the Doha Declaration on TRIPS and Public Health (2001), which affirms member states' rights to safeguard access to medicines.

Challenges and Recommendations

While India's policy framework and legal posture align with international expectations, operational deficiencies persist. The lack of real-time stock monitoring at ART centres, delays in state-level tenders, and limited public transparency in procurement data continue to undermine policy implementation. Regular publication of stock data, digitisation of inventory systems, and decentralised procurement authority could enhance resilience.

Additionally, integrating mental health services within ART centres—especially during supply disruptions—would ensure holistic care for PLHIV, consistent with WHO's recommendation of psychosocial support as a component of ART adherence.

CHAPTER 4: HEALING BEYOND MEDICINE – STRATEGIES TO PROTECT MENTAL HEALTH IN TIMES OF SCARCITY

Pharmaceutical shortages, especially in essential medicines like antiretroviral therapy (ART), create severe public health crises that extend beyond physical health outcomes. For people living with HIV (PLHIV), these shortages can lead to heightened anxiety, depression, and feelings of helplessness stemming from uncertainty about treatment continuity. According to the World Health Organization (WHO, 2025), interruptions in ART services, whether due to supply-chain disruptions or stockouts, are directly linked to declines in mental health, reduced adherence, and increased clinical complications. Consequently, effective mitigation must focus on both preventing shortages and protecting psychological well-being when they occur.

Strengthening Supply-Chain and Program Resilience

a. Multi-Month Dispensing (MMD): Providing three to six months of ART to stable patients reduces the frequency of clinic visits and shields individuals from short-term disruptions. UNAIDS (2022) reports that MMD significantly decreases anxiety related to medication availability, particularly in low- and middle-income countries during the COVID-19 pandemic.

b. Decentralized and Community ART Delivery: Establishing community-based distribution points and home delivery systems reduces dependence on centralized facilities. Such decentralization has proven to enhance treatment adherence and minimize mental distress during periods of scarcity (WHO, 2025).

c. Buffer Stocks and Pooled Procurement: National and state-level buffer stocks, combined with pooled procurement mechanisms, ensure continuity of ART even when global supply is unstable. The WHO (2025) emphasizes that such policies not only secure physical access but also stabilize mental health outcomes by reducing patient uncertainty.

d. Real-Time Monitoring and Early Warning Systems: Digital stock tracking allows rapid detection of impending shortages, enabling proactive redistribution. Transparent communication of supply data helps counter rumors and anxiety among patients (WHO, 2025).

Integrating Mental Health Support into ART Programs

a. Routine Mental Health Screening: Regular psychological screening during ART visits allows early detection of distress. UNAIDS (2022) recommends incorporating depression and anxiety assessments—such as PHQ-9 or GAD-7—to provide timely interventions.

b. Task-Shifting and Lay Counseling (mhGAP Implementation): The WHO's Mental Health Gap Action Programme (mhGAP) provides frameworks for training non-specialist health workers to deliver basic counseling. This approach effectively bridges the shortage of mental-health professionals in resource-limited settings (World Health Organization, 2016).

c. Tele-Mental Health Services: During ART stockouts, tele-counseling platforms and helplines can provide immediate emotional support and information. Studies show that such interventions reduce panic and help patients maintain treatment adherence (UNAIDS, 2022).

d. Support for Children and Caregivers: Shortages in pediatric ART formulations disproportionately affect caregivers' mental health. Tailored counseling and priority access policies can help reduce emotional strain for families (WHO, 2025).

Community-Based and Peer Support Interventions

a. Peer Navigator and PLHIV Network Engagement: Community-led organizations and peer

networks play a vital role in providing emotional support and accurate information. They also assist in coordinating community distribution systems during shortages (amfAR, 2022).

b. Transparent Communication by Health Authorities: Consistent public communication on ART availability and safe alternative regimens prevents misinformation and panic. WHO (2025) identifies effective communication as a key factor in maintaining public trust and mental stability.

Policy and Legal Mechanisms to Support Mental Health During Shortages

a. TRIPS Flexibilities and Emergency Licensing: India and similar nations can use the Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities to issue compulsory or voluntary licenses during ART shortages. This ensures continuous drug supply and mitigates mental distress among PLHIV (WHO, 2025).

b. Dedicated Funding for Mental Health Response: Emergency funding for psychosocial services—such as hotlines, counseling, and rapid training—ensures immediate support during crises. UNAIDS (2022) recommends integrating such funding into national HIV strategies.

c. Data Collection on Mental Health Outcomes: Monitoring psychological outcomes during ART shortages provides evidence for future policy design. Routine data on adherence, depression, and anxiety can guide national responses and resource allocation (WHO, 2025).

Implementation Roadmap

1. Institutionalize multi-month dispensing (MMD) across all ART centers.
2. Develop national digital dashboards for stock-level transparency.
3. Train peer counselors under the WHO's mhGAP framework.
4. Maintain tele-counseling hotlines as part of HIV services.
5. Activate emergency procurement and TRIPS flexibilities as needed.
6. Publish quarterly reports linking ART stock data with mental health metrics.

CHAPTER 5: CONCLUSION- RESTORING HOPE BEYOND SHORTAGES

The study establishes that the lack of consistent pharmaceutical availability, particularly of antiretroviral therapy (ART), has a direct and detrimental impact on the mental health of people living with HIV (PLHIV) in India. Such shortages not only undermine medical outcomes but also constitute a violation of the constitutional right to life and health enshrined under **Article 21** of the Constitution of India. Furthermore, these lapses challenge India's compliance with its international obligations under the *International Covenant on Economic, Social and Cultural Rights (ICESCR)*, which mandates the progressive realization of the highest attainable standard of health.

The findings reveal that ART shortages exacerbate psychological distress, leading to increased depression, anxiety, and non-adherence to treatment — issues that should be viewed through the lens of state accountability and public health governance**.** It is, therefore, imperative that India's legal and administrative framework for pharmaceutical distribution ensures transparency, equity, and uninterrupted access to essential drugs.

In addition, integrating mental health care into the legal and policy framework for HIV management is essential. Establishing statutory obligations for psychological support, regular mental health assessments, and community-based interventions will not only align with the principles of social justice and human dignity but also fulfill India's constitutional and international commitments.

In conclusion, the absence of reliable ART access is not merely a logistical or administrative lapse — it represents a failure of the state's legal duty to safeguard the health and mental well-being of its citizens. Upholding this right is vital to ensuring that every person living with HIV in India receives treatment, protection, and dignity under the law.

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