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Patent Pools and Local Manufacturing: Pathways to Equitable Access for Long-Acting Antiretrovirals in Tanzania

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Abstract

This brief report examines the potential of patent pools and local pharmaceutical manufacturing to overcome critical access barriers to long-acting antiretrovirals (LA-ARVs) in Tanzania. As transformative therapies like long-acting injectable cabotegravir and rilpivirine become the global standard, their prohibitive cost and complex intellectual property (IP) landscapes threaten to exacerbate health inequities across Africa. The analysis employs a desk-based review of policy documents, Medicines Patent Pool licensing agreements (2021–2024), and Tanzanian industrial policy to assess their alignment with public health objectives. Findings indicate that voluntary licensing through patent pools has facilitated generic entry forecasts for 2025–2026. However, local manufacturing capacity for these complex formulations remains nascent. The report contends that a dual strategy is imperative: leveraging pooled IP to secure affordable supply in the immediate term, while strategically investing in regional manufacturing capabilities under the African Medicines Agency framework for long-term health security. This integrated approach is vital for transforming Tanzania's and the wider region's HIV response, shifting from dependency towards a more self-reliant and equitable model. It concludes that without deliberate policy to synchronise IP management with industrial development, the promise of LA-ARVs will remain out of reach for most Africans, perpetuating a tiered system of global healthcare.

Keywords: *Patent pools, local pharmaceutical manufacturing, long-acting antiretrovirals, access to medicines, Sub-Saharan Africa, health equity, technology transfer*

REPORT

This report examines the role of patent pools and local manufacturing in improving access to long-acting antiretroviral therapies (LA-ARTs) in Africa, with a focus on Tanzania (Adachi, 2025; Banda et al., 2024). The integration of these mechanisms presents a viable pathway, yet its success hinges on navigating interconnected structural challenges (Duvenage, 2024). A foundational issue is the scope of technology transfer. For complex LA-ARTs, such as injectables or implants, transfer must extend beyond basic active pharmaceutical ingredient (API) synthesis to include advanced fill-finish processes and device assembly (Ekusai-Sebatta et al., 2025). A tiered approach is therefore essential, where initial local activities focus on secondary packaging and assembly, concurrently building technical and regulatory capacity for more complex stages (Paschal et al., 2025). Licences from pools like the Medicines Patent Pool must be explicitly designed to support this trajectory, including provisions for training Tanzanian personnel in relevant Good Manufacturing Practice (GMP) (Sorato et al., 2024).

Economic viability is equally critical and depends on predictable, large-scale procurement (Essien & Mgbere, 2025). The high capital cost for sterile injectable production necessitates multi-year purchase commitments from bodies like Tanzania's Medical Stores Department to justify investment and achieve economies of scale (Hegde, 2025). The evolving African Medicines Agency could enhance viability by harmonising regulations, thus expanding the potential regional market (Rusconi, 2025). However, such strategic procurement strains national budgets, requiring innovative financing mechanisms that blend public funding, development finance, and impact investment to de-risk the venture (Boampong, 2025; Parker & Liddle, 2025). The business case must also encompass full product lifecycle costs, including reverse logistics for safe device disposal (de Vos et al., 2025).

Concurrently, the regulatory pathway must be strengthened (Duvenage, 2024). Tanzania's regulatory authority (TMDA) requires enhanced capacity to assess the complex 'sameness' of long-acting formulations, where subtle differences can affect efficacy (Katende-Kyenda, 2025; Ibrahim et al., 2024). This demands sustained investment in specialist training and technology (Mosha & Ngulube, 2025). Collaborative models, such as regulatory reliance, can expedite approvals while building local expertise (Ndaro, 2024). Local manufacturing also offers a unique advantage for robust, context-specific pharmacovigilance, enabling direct monitoring of real-world safety and adherence within the Tanzanian population (Seo & Kim, 2024).

Underpinning all this is the need for skilled human capital (Kohnert, 2024). A sustainable industry requires a pipeline of professionals, from industrial pharmacists to regulatory affairs officers, countering the current brain drain (Krautwald, 2024). This necessitates aligning tertiary education with industry needs and creating attractive local career pathways to retain talent (Maige et al., 2025). The development must also be equitable, promoting fair labour practices and gender-inclusive participation throughout the sector (Mirugwe, 2025).

Finally, the political economy presents both opportunities and challenges (Ibrahim et al., 2024). While national industrial policies provide political will, negotiations with patent holders and foreign

partners must be strategically managed to ensure genuine technology transfer and avoid dependency (Osier, 2024). Diversifying international partnerships can provide more aligned support (Bolarinwa, 2025). Throughout, sustained advocacy from civil society is crucial to hold stakeholders accountable, ensuring local production ultimately delivers affordable, dignified access for people living with HIV, rather than serving symbolic interests alone (Sagandira, 2025).

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