AFRICAN-LED HIV CONTROL WORKING GROUP

AHCWG 2026 Webinar Series

WEBINAR 3 OF 3

Regulatory Environments and Resilience Partnership Models

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SESSION PARTICIPANTS

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EXECUTIVE SUMMARY

The third and concluding webinar of the African-led HIV Control Working Group 2026 Financing and Resilience Series convened on 24 June 2026 under the title Regulatory Environments and Resilience Partnership Models, with a deliberate focus on what the series described as the operational layer of health sovereignty: the systems through which protected budgets and enabling legislation are either translated into actual access, or undermined by structural dependencies built into the architecture of production, procurement, regulation, and partnership.

Where Webinar 1 established the fiscal architecture of domestic resource mobilisation and Webinar 2 examined the legislative and policy frameworks through which financing decisions acquire durability, Webinar 3 completed the analytical sequence by examining whether the supply-side systems that move commodities from manufacturer to patient are designed to serve African health systems on African terms, or whether they replicate at the operational level the same donor-dependency that domestic financing was intended to address at the fiscal level.

The session produced four interconnected analytical findings. First, Africa's pharmaceutical manufacturing landscape, while demonstrating proof of concept through recent milestones in African-manufactured HIV treatment reaching multilateral procurement channels, remains geographically concentrated and structurally dependent on imported active pharmaceutical ingredients, with more than 85 percent of continental manufacturing capacity concentrated in North Africa and the continent producing less than two percent of the medicines it consumes. Second, the African Medicines Agency, formally launched in November 2025 with Rwanda as host, represents a structural transformation in the continental regulatory architecture, providing for the first time a harmonised pathway through which manufacturers can obtain a single scientific opinion applicable across multiple member states, but the pace of regulatory harmonisation is outstripping the industrial investment and political commitment required to create the market conditions on which manufacturing scale depends. Third, pharmacovigilance and safety surveillance are not technical adjuncts to procurement systems but foundational governance infrastructure without which no procurement framework can protect the quality, safety, and continuity of HIV commodity supply chains, particularly under transition conditions. Fourth, equitable partnership is not defined by the volume of funding or the quality of technical support a partner provides, but by whether the terms of that partnership preserve or limit the ability of the recipient country to control its health agenda, build its own systems, and negotiate on equal terms.

Mr. Robert Agyarko of the African Union Commission closed the session by synthesising the lessons of the full three-part series and centering them on a structural conclusion: that Africa has built a life-saving HIV response on a structurally fragile foundation, and that the task before the continent is not incremental reform but architectural reconstruction, requiring deliberate action at the level of HIV budget protection, AMA-anchored regulatory harmonisation, collective procurement, and the political will to route health investment through African systems and African manufacturers.

SERIES ARCHITECTURE AND CONTINUITY

The three-webinar AHCWG 2026 Financing and Resilience Series was conceived as a progressive analytical architecture. Each session built on the preceding one, with each adding a layer to the argument that sustainable HIV responses require not only money,

but the legal, institutional, and operational systems capable of directing that money toward durable health outcomes on African terms.

Webinar 1, convened on 22 April 2026 under the title Protecting Core Services with Domestic Investments, established the financing baseline: the structural gap between what African governments are spending on HIV and what is required to sustain programme continuity, the mechanisms through which protected financing architecture can be built, and the criteria against which PEPFAR transition memoranda of understanding should be assessed. Its central finding was that domestic financing sustainability requires deliberate architectural decisions encompassing protected budget lines, earmarked levies, and treasury-health system alignment, and that financing architectures that fail to name and resource the populations most affected will not hold the response through periods of external financing contraction.

Webinar 2, convened on 27 May 2026 under the title Policy Frameworks for Sustainable HIV and Healthcare Financing, examined the legislative and policy layer: the national strategic plans, continental frameworks, and enabling laws that determine whether financing gains can survive changes in political administration, fiscal pressure, or the withdrawal of external partners. Its central finding was that legislative protection is the only mechanism through which HIV financing commitments have demonstrated durable survival across changes in government, as evidenced by the Zimbabwe AIDS Levy and the South African Act of Parliament, and that the distance between continental commitment and domestic legal implementation is the governance gap most urgently requiring deliberate closure.

Webinar 3 completed the sequence by examining the operational layer of sovereignty, which is the supply-side architecture through which legislation and financing are either converted into access or diverted by structural dependencies in production, procurement, and partnership. Its central argument was that a financing architecture protected by law and aligned to national strategic plans still fails if the commodities it is meant to procure cannot be manufactured on the continent, cannot move through accountable procurement channels, and cannot be delivered through partnerships that preserve rather than undermine national ownership.

SESSION DISCUSSIONS

Welcome and Strategic Framing

Prof. Mohamed Chakroun | Moderator

Prof. Mohamed Chakroun, Infectious Diseases Specialist and member of the African-led HIV Control Working Group, opened the session by situating Webinar 3 within the progressive architecture of the series, noting that the first session had addressed the money, the second had addressed the law and the frameworks, and the third was turning to the delivery: the systems and governance arrangements through which financing and policy are translated into real-world access to medicines and services.

His framing was grounded in a structural observation: that when PEPFAR funding was suspended in January 2025, the fractures that emerged were not only financial but operational, visible in supply chains disrupted, regulatory processes stalled, data systems dismantled, and community partnerships defunded overnight. The response to those fractures, including African manufacturers scaling production and the African Medicines Agency moving toward operationalisation, demonstrated both the urgency and the practical achievability of supply chain sovereignty. His core question for the session was whether Africa's health supply systems are built on African terms or whether structural

dependency continues to determine how medicines are produced, regulated, procured, and delivered.

He introduced the four interconnected areas the session would examine: local manufacturing and diagnostics production, regulatory harmonisation and the role of the African Medicines Agency, procurement systems and supply chain resilience, and the design principles of equitable partnership models for access to medicines. The session opened with a Mentimeter poll inviting participants to name in one or two words the biggest barrier to health sovereignty in their country. The dominant responses were funding dependency and political will, patterns that reappeared in different configurations throughout the panel discussion.

Manufacturing Capacity, Regulatory Architecture, and the African Medicines Agency

Mr. Alex Juma Ismail | Technical Lead, Products Evaluation and Scientific Opinions, African Medicines Agency

Mr. Alex Juma Ismail opened his presentation with the structural baseline: Africa has over 600 pharmaceutical manufacturers across the continent, a number that appears significant in isolation but is negligibly small relative to the continent's population of 1.5 billion people, its disease burden, and the scale of medicines consumption it requires. The distribution is structurally skewed, with more than 85 percent of manufacturing concentrated in five North African countries, principally Egypt, Morocco, Algeria, and Tunisia, alongside Nigeria in West Africa, Kenya in East Africa, and South Africa in the southern region. The entire central African region has no pharmaceutical manufacturing capacity. The continent produces less than two percent of the medicines it consumes.

Beyond finished pharmaceutical products, dependence extends to the inputs on which manufacturing depends. Approximately 99.9 percent of active pharmaceutical ingredients consumed on the continent are imported, and more than 80 percent of packaging and other raw materials are sourced externally. For HIV and tuberculosis commodities specifically, import dependence approaches or reaches 100 percent in most high-burden countries. The continent is not simply a consumer of finished medicines; it is structurally excluded from the full value chain of medicines production.

Mr. Ismail situated the African Medicines Agency within this structural reality as the institutional mechanism most likely to change the market conditions that have historically made Africa commercially unattractive to pharmaceutical investment. His argument was specific: the reason Africa has not attracted the manufacturing investment its population and disease burden should warrant is not a technical failure but a market design failure. A manufacturer seeking access to the African market currently faces up to 55 separate national registration processes, each with different requirements, timelines, fees, and standards, which means that the notional market of 1.5 billion people does not function as a single market in practice. AMA's value proposition is to remove that fragmentation by providing a single scientific assessment process whose outcome is recognised across multiple member states.

He described the trajectory from aspiration to operation with precision. The African Medicines Regulatory Harmonisation initiative had spent fifteen years building the technical committees and regional harmonisation structures that AMA inherited when the Agency was formally launched in November 2025 with Rwanda as host. Between 2023 and October 2025, AMA ran a simulated centralised procedure involving 64 submitted products, of which 24 met the criteria for full assessment, and 21 were

evaluated, with 12 receiving positive opinions. The pilot demonstrated not only the technical viability of continental harmonised assessment but the variability in how national regulatory authorities subsequently acted on those continental opinions, which Mr. Ismail described as the implementation gap that AMA must now systematically close.

On diagnostics specifically, he identified the continental gap in HIV testing, viral load monitoring, and point-of-care diagnostics as a distinct and underaddressed challenge. The medical devices and diagnostics manufacturing landscape is even less developed than the pharmaceutical landscape, and the regulatory infrastructure for devices and diagnostics has historically lagged behind medicines regulation. He noted that the African Medical Devices Forum, under the chairmanship of Paulyne Wairimu, was advancing harmonisation work in this area, but that the gap between regulatory capacity and manufacturing reality in diagnostics remains significant.

> *"The challenge that we have on the African continent is that most manufacturers usually interact with regulators across the continent who are waiting for manufacturers to come to them. If we need to ask what is missing, the answer from most of our studies and landscaping is that we are not attractive enough, we do not provide the incentive that is needed. America is one third of the African continent's population but it is the biggest pharmaceutical market in the world because it functions as a single market. We do not have that advantage yet. The African Medicines Agency is how we build it." | Mr. Alex Juma Ismail*

Procurement Reform, Pharmacovigilance Infrastructure, and Regulatory Sovereignty

Ms. Priscilla Nyambayo | Head, Pharmacovigilance and Clinical Trials Division, Medicines Control Authority of Zimbabwe

Ms. Priscilla Nyambayo opened by grounding her contribution in the structural reality of Africa's regulatory and procurement environment, noting that African countries import between 70 and 100 percent of finished pharmaceutical products, between 90 and 100 percent of active pharmaceutical ingredients, and approximately 99 percent of vaccines, with HIV and tuberculosis products remaining highly import-dependent across the continent. She situated her analysis within Zimbabwe's institutional experience as a member of the SADC regulatory harmonisation framework and as a country that has invested in pharmacovigilance infrastructure through the Medicines Control Authority of Zimbabwe.

Her central analytical argument was that pharmacovigilance and post-marketing surveillance are not technical functions situated downstream of procurement decisions, but core governance infrastructure that must be embedded within procurement systems if those systems are to deliver quality, safety, and continuity of supply. She illustrated this with concrete examples: products recalled from markets because of safety concerns, anaesthetic products with documented quality failures, oxytocin formulations with potency issues identified through post-marketing analysis. Her argument was that a procurement system that does not have embedded pharmacovigilance intelligence cannot make defensible product selection decisions, cannot protect populations from substandard or falsified medicines, and cannot provide

the evidentiary foundation for holding suppliers accountable through contract enforcement.

She addressed the fragmented regulatory landscape as the primary structural obstacle to regional procurement reform. Within the SADC region alone, 16 countries operate under different regulatory requirements, which means that the same manufacturer must navigate 16 separate approval processes to supply the regional market. The Zambia-South Africa Regulatory Initiative (ZAZIBONA) had sought to address this through a joint review mechanism, and she described the lessons from that initiative as directly informing the design of AMA's centralised assessment process, but she was candid about the pace of national uptake: even where regional harmonisation processes had produced positive opinions, individual countries were still making independent procurement decisions that bypassed or ignored those regional assessments.

On transition governance, she identified the risks embedded in poorly designed memoranda of understanding with procurement conditionalities that impose externally designated supply chains on national systems. Her argument was structural: where MOU terms require that commodities be procured through externally contracted suppliers rather than through the Medicines Control Authority of Zimbabwe, the National Pharmaceutical Company of Zimbabwe, or equivalent national systems, they actively limit the market available to African manufacturers while simultaneously preventing the institutional learning that strong national procurement systems require to develop.

She described the Afrivigilance platform, a safety database for African safety data established under Africa CDC, as a critical institutional investment that links pharmacovigilance data across national systems and connects to the global safety monitoring infrastructure hosted by WHO. She argued that embedding Afrivigilance intelligence into procurement decisions, alongside enforcement of Good Manufacturing Practice inspections and systematic post-marketing surveillance, is the technical foundation on which sustainable procurement reform depends.

> *"Pharmacovigilance and market authorisation, post-marketing surveillance, monitoring of substandard and falsified products, that whole package is what ensures that procurement decisions are defensible and that populations are protected. It is not enough to procure; you have to track what you procured. I am happy that the Afrivigilance platform now has tools for monitoring both safety and quality, because that is the information governments need to make sovereign procurement decisions." | Ms. Priscilla Nyambayo*

The Political Economy of Equitable Partnerships, Intellectual Property, and Access to Medicines

Dr. Mohga Kamal-Yanni | Global Health and Access to Medicines Consultant; Policy Lead, People's Medicine Alliance

Dr. Mohga Kamal-Yanni approached the question of equitable partnership by deconstructing the term analytically, arguing that there is no agreed operational definition of equitable partnership in global health, and that the absence of such a definition is not an oversight but a structural feature of a system designed to serve the interests of those with funding and technology. Her analytical entry point was that equitable relationships require equal power, not extractive power, common goals that

are genuinely agreed upon rather than unilaterally defined, a shared methodology for measuring progress against those goals, and clear accountabilities that run in both directions.

She organised her substantive contribution around two extended case studies that illustrated the gap between partnership rhetoric and partnership reality. The first concerned the TRIPS Agreement, the trade-related intellectual property rules that emerged from the negotiations establishing the World Trade Organisation and that govern technology transfer in ways that create structural barriers to local pharmaceutical manufacturing in low- and middle-income countries. She described the theoretical flexibilities available under TRIPS, including compulsory licensing and parallel imports, but was direct about their practical limitations: the political and commercial pressure brought to bear on countries that invoke these flexibilities is substantial, and most African countries lack the domestic legal infrastructure, the technical capacity, and the negotiating protection to use them without paying significant diplomatic and commercial costs.

She illustrated the practical consequences of voluntary licensing, the mechanism through which most access to patented HIV medicines is currently achieved, through the example of lenacapavir, Gilead's long-acting injectable HIV prevention medicine. Following significant advocacy pressure, Gilead issued voluntary licences for lenacapavir production to six companies: four in India, one in Pakistan, and one in Egypt. South Africa, with the largest HIV-positive population in the world, received no voluntary licence. She presented this not as an anomaly but as a structural illustration of who controls access decisions: it is the originator company, not African health authorities, that determines whether a voluntary licence is issued, to whom it is granted, under what conditionalities, what markets it covers, and what ingredients can be sourced from where.

Her second case study addressed the WHO pandemic treaty negotiations, focusing specifically on the Africa Group's position on pathogen sharing and technology transfer. She described the principle that technology and financial benefits derived from pathogen samples shared by countries in the context of a public health emergency should flow back to those countries through equitable benefit-sharing arrangements. She contrasted this multilateral negotiating position with bilateral MOU frameworks through which some governments had been asked to commit to pathogen sharing without receiving corresponding technology transfer or benefit-sharing guarantees, and described the decisions by Zimbabwe, Zambia, Ghana, and other countries to decline those MOU terms as evidence that African governments are capable of exercising principled negotiating sovereignty when they choose to do so.

She concluded by drawing a clear analytical distinction between partnerships funded from an asymmetric power relationship and partnerships that produce sustainable equity. The former may deliver services in the short term but systematically prevents the recipient country from developing the capacity to deliver those services independently. She described the Medicines Patent Pool, established in 2010 to negotiate voluntary licences on behalf of public health rather than on behalf of individual companies or donor governments, as one institutional model for how power asymmetries in access negotiations can be partially counterbalanced.

> *"Equitable partnership is not defined by how much money one partner brings. It is defined by whether the terms of that partnership allow the recipient country to build its own systems, define its own agenda, and exit the partnership stronger than when it entered. Funding that comes with conditionalities designed to perpetuate dependency is not partnership. It*

> *is a different form of the same structural problem that domestic financing is supposed to solve." | Dr. Mohga Kamal-Yanni*

Continental Commitments, Series Synthesis, and the Architecture of Health Sovereignty

Mr. Robert Agyarko | Senior Strategic Advisor for Health, Office of the Commissioner for Health, Humanitarian Affairs and Social Development, African Union Commission

Mr. Robert Agyarko opened his closing contribution with a personal historical reference that he described as a formative lesson in institutional fragility: nearly 25 years earlier, he had led a study on the impact of HIV and AIDS on older people in Africa using Zimbabwe as a case study, and among 685 orphaned children, 73 percent were being raised by people over the age of 60 at a time when antiretroviral treatment was unavailable and resources were negligible. The older people of those communities became the last line of a response that formal institutions could not sustain. That lesson, he argued, has not been fully absorbed, because the continent has again built a life-saving programme on a structurally fragile foundation.

He synthesised the evidence of the series directly: when PEPFAR funding was suspended in January 2025, care for over 20.6 million people was placed at risk, including approximately 550,000 children. Domestic government financing currently covers roughly 20 percent of the African HIV response. The continent carries 65 percent of the global HIV and AIDS burden while relying on external benevolence to finance 80 percent of the response. These are not peripheral vulnerabilities to be managed at the margins; they are structural facts that define the architecture the continent must reconstruct.

On the lessons of the three-webinar series, he offered a synthesis across the three layers the series had examined. The first webinar had established that the money can be found domestically but requires deliberate architectural decisions, including dedicated HIV budget lines, levy mechanisms modelled on Zimbabwe's AIDS levy, and parliamentary accountability frameworks that bind successive administrations to financing commitments. The second had established that legislative protection is the only mechanism with a proven track record of surviving political transition. The third was adding the supply-side dimension: that protected financing and enabling legislation are necessary but insufficient conditions for sovereignty if the medicines financed cannot be manufactured on the continent, regulated through continental authorities, and delivered through procurement systems that support African manufacturers.

He identified three priority levers from a continental policy perspective. The first is the African Medicines Agency, which he described as a game changer and, critically, as no longer aspirational: it is operational, and the question is whether African governments will route regulatory decisions and procurement actions through it rather than continuing to maintain parallel national processes that fragment the continental market. The second is collective procurement, and he drew explicitly on the African Vaccine Acquisition Trust as proof of concept for the power of aggregate demand negotiation, arguing that extending the AVAT model to ARVs, diagnostics, and laboratory commodities would shift price dynamics and reduce per-country dependency on single procurement channels in ways that no single-country procurement system can achieve. The third is political will, which he identified as the decisive variable in both the regulatory harmonisation and collective procurement

agendas: the technical capacity exists, the institutional architecture is being built, and the missing ingredient is the political commitment by health and finance ministries to route procurement through African systems and to resist the supplier pressure and transition costs that such decisions inevitably encounter.

He addressed the partnership dimension by arguing that no single African country can negotiate from a position of equivalent power with the global actors whose decisions shape the continent's medicine supply, but that African countries acting together through the AU and continental institutions can. He called specifically for HIV financing to be protected at the legislative level and connected structurally to the procurement and laboratory systems that give it operational meaning, and for continental institutions, including the African Union, Africa CDC, and AMA, to prioritise the creation of scale and coherence in the regulatory and procurement architecture.

> *"We have built a life-saving programme on a structurally fragile foundation. It is when we go together as a continent that we can negotiate, that we can set terms, that we can tell our partners what kind of partnership we want. No single African country can do this on its own. That is what the African Union, the African Medicines Agency, and our regional institutions are for. The political will to use them is the missing ingredient." | Mr. Robert Agyarko*

PANEL DISCUSSION

Following the four presentations, Prof. Chakroun convened a structured panel discussion that brought together all four speakers and was joined by Mr. Robert Agyarko for questions directed at the continental governance perspective. The panel was organised around four moderated questions designed to connect the manufacturing, regulatory, procurement, and partnership dimensions of the session into a coherent analysis of health sovereignty as a systems challenge.

- What Are the Most Binding Regulatory Constraints Limiting Manufacturing Scale-Up?

Prof. Chakroun directed this question first to Mr. Alex Juma Ismail, framing it around the gap between the formal progress of regulatory harmonisation and the pace of manufacturing investment. Ismail's answer centred on market unpredictability and regulatory systems that are reactive rather than proactive. He argued that the fundamental constraint is not the absence of manufacturers who want to produce for African markets, but the absence of a market structure that makes such investment predictable and commercially rational. African regulators have historically waited for manufacturers to approach them rather than actively facilitating market entry, and the result is that Africa remains commercially unattractive to pharmaceutical investment despite its scale and disease burden. He argued that AMA's harmonisation architecture addresses this by creating a single predictable regulatory pathway, but emphasised that the pathway alone is insufficient without the accompanying market intelligence, investment facilitation, and workforce development that would give manufacturers the confidence to commit capital to African manufacturing at the scale required.

- Why Should Pharmacovigilance Be Understood as Core Regulatory and Procurement Infrastructure?

Prof. Chakroun posed this question to Ms. Priscilla Nyambayo, framing it around the tendency to treat pharmacovigilance as a post-market technical function rather than as foundational governance infrastructure. Nyambayo's response was direct:

pharmacovigilance is not downstream of procurement; it is the evidentiary system that makes accountable procurement possible. She cited documented examples of products recalled from markets because of safety or quality concerns, including anaesthetic products, oxytocin formulations, and other essential medicines, noting that without active pharmacovigilance systems, procurement authorities cannot identify which manufacturers are producing products that meet quality standards consistently across batches and over time. She argued that the Afrivigilance platform, by consolidating safety data across national systems and linking to the global WHO monitoring infrastructure, provides the continental safety intelligence that procurement authorities need to make defensible product selection decisions, and that embedding this intelligence routinely into procurement frameworks is the governance reform that most directly addresses the quality and continuity gaps that arise in transition contexts.

- What Clearly Distinguishes Equitable Partnership from Dependency-Reproducing Partnership?

Prof. Chakroun posed this question to Dr. Mohga Kamal-Yanni, framing it around the observation that well-funded and technically sophisticated partnerships can still reproduce dependency even when their stated objectives are aligned with country ownership. Kamal-Yanni's response was analytically direct. She described a recent bilateral MOU framework through which the United States had offered funding for HIV programmes, maternal and child health services, and other priority areas to several African countries, with conditions requiring recipient countries to commit to sharing pathogen samples, aligning data systems with external platforms, and routing procurement through externally designated supply chains. Several countries, including Zimbabwe and Zambia, had declined these terms, and she described their position as the exercise of genuine negotiating sovereignty: a recognition that the country has assets of strategic value, whether pathogens, minerals, or policy alignment, and that it will not trade those assets without equivalent return. She argued that the distinguishing characteristic of an equitable partnership is not the presence of good intentions on the part of the funder but the structural design of the relationship: whether exit from the partnership leaves the recipient country stronger or more dependent than when it entered, whether accountability runs in both directions, and whether the terms of the agreement preserve the recipient country's ability to make sovereign decisions about its own health agenda.

- What Are the Most Important Continental Levers for Reducing Dependency and Strengthening Collective Bargaining Power?

This question was directed to Mr. Robert Agyarko, and his response structured the panel's convergence around three institutional levers. He identified the African Medicines Agency as the first and most transformative, arguing that it is no longer an aspiration but an operational institution whose value will be realised only when African governments choose to route regulatory decisions and procurement actions through it rather than maintaining the fragmented national processes that prevent the continental market from functioning as a single investment destination. He identified collective procurement as the second lever, arguing that the AVAT experience demonstrated the magnitude of price and market access gains achievable through continental aggregation, and that failing to extend that model to ARVs, diagnostics, and laboratory commodities is not a technical limitation but a political choice. He identified political will as the decisive third lever, noting that the continent's challenge is no longer primarily one of technical capacity, because the regulatory institutions, the procurement mechanisms, and the manufacturing proof of concept all exist, and the variable that determines whether those assets are mobilised is whether political leadership at the ministerial and head-of-state level chooses to use them.

AUDIENCE ENGAGEMENT: PARTICIPANT QUESTIONS AND MENTIMETER RESULTS

Questions from Participants

Participant contributions during the question and answer segment addressed three interconnected themes that amplified and extended the panel discussion.

On diagnostic manufacturers and access: A participant asked whether there is a database of African pharmaceutical and diagnostics manufacturers that civil society and procurement authorities can access. Mr. Ismail confirmed that such a database exists, hosted through the Africa CDC manufacturing platform, currently listing between 18 and 20 manufacturers across member states, and provided the access link via the session chat. He acknowledged that the database represents a small fraction of the estimated 600 manufacturers on the continent and identified the gap between listed manufacturers and the full manufacturing landscape as an information infrastructure challenge that AMA is systematically addressing through its prequalification and manufacturer engagement programmes.

On substandard and falsified medicines: A participant raised the challenge of substandard and falsified medical products as a specific quality and safety risk affecting African procurement decisions. Mr. Ismail confirmed that AMA is developing a continental strategy for combating substandard and falsified medicines, involving a multisectoral network encompassing regulatory authorities, judiciary systems, police, immigration, and border management agencies, alongside the establishment of a network of African Reliance Laboratories to support product testing. He described a planned Continental Safety Monitoring System linked to the Afrivigilance platform and to the global WHO safety monitoring infrastructure, as well as a manufacturer watch list to identify and systematically monitor producers with documented quality or safety concerns.

On integration and the human resources challenge: A participant from rural Tanzania noted that her facility serves 3,200 HIV-positive clients and that integrating HIV services into primary health care under existing staffing conditions would be extremely difficult, illustrating the human resource constraint that underpins most procurement and supply chain reform discussions. This intervention was complemented by a broader participant observation that while integration creates opportunities for efficiency and sustainability, it also creates specific risks to quality, equity, and the community-led service models that have historically been most effective in reaching key and marginalised populations.

Mentimeter Poll Results

Four Mentimeter polls were conducted across the session. The results provided a live participant evidence base that reinforced the analytical positions developed in the presentations and panel discussion.

Poll 1: In one or two words, what is the biggest barrier to health sovereignty in your country?

Response Option	Participant Ranking
Funding dependency and lack of domestic financing	**Highest**
Political will and leadership commitment	Second
Regulatory fragmentation and weak systems	Third

External procurement conditionalities	Fourth

Poll 2: Which area requires the most urgent long-term reform to secure access to HIV medicines and diagnostics in your country**?**

Response Option	**Participant Ranking**
Local manufacturing capacity and industrial policy	**Highest**
Procurement and supply chain systems	Second
Regional market cooperation and pooled procurement	Third

Poll 3: As countries move toward greater ownership of HIV programmes, what principle should guide future partnerships?

Response Option	**Participant Ranking**
Technical, financial, and strategic support aligned to national needs	**Highest**
National leadership with partner support in a defined role	Second
Sovereignty and protection of human rights as non-negotiable terms	Third
Sustainable country ownership with mutual accountability	Fourth

Poll 4: Based on today's discussion, which reform will most strengthen health sovereignty in your context?

Response Option	Participant Ranking
Operationalising the African Medicines Agency at full scale	**Highest**
Establishing continental pooled procurement for HIV commodities	Second
Embedding pharmacovigilance into procurement governance frameworks	Third
Renegotiating partnership terms to reflect country ownership principles	Fourth

POLICY OUTPUTS AND ADVOCACY POSITIONS

The session generated five consolidated analytical positions that extend beyond individual speaker contributions and reflect the convergence reached across the panel discussion and participant engagement.

1. Manufacturing Sovereignty Requires Market Architecture, Not Only Production Capacity

The session established that Africa's pharmaceutical manufacturing deficit is not primarily a function of the absence of manufacturers willing to produce for African markets. It is a function of market design: the fragmentation of 55 regulatory systems into separate approval processes makes Africa structurally unattractive as a

manufacturing investment destination despite having 1.5 billion potential consumers. The African Medicines Agency's core institutional value is that it converts this fragmented landscape into a single market from the regulatory and investment perspective. Realising that value requires deliberate industrial policy decisions, including preferential procurement for AMA-approved manufacturers, investment facilitation through Afreximbank and national development banks, and active government engagement with the manufacturing investment agenda rather than passive waiting for investment to arrive.

2. Pharmacovigilance Is Procurement Governance Infrastructure

The session produced a clear convergence between the manufacturing and procurement presentations on the functional relationship between pharmacovigilance and procurement integrity. Post-marketing surveillance, product quality monitoring, and safety intelligence are not technical activities that follow procurement decisions; they are the evidentiary infrastructure on which accountable procurement depends. Countries that do not embed safety surveillance into their procurement governance frameworks cannot protect populations from substandard or falsified medicines, cannot build the institutional trust in national procurement systems that collective bargaining requires, and cannot make defensible arguments for national system strengthening to external partners and donors. Integrating the Afrivigilance platform into national procurement information systems is therefore not a technical enhancement but a foundational governance investment.

3. Voluntary Licensing Is Not Sovereignty

Dr. Kamal-Yanni's analysis of voluntary licensing established a structural distinction that the series had circled around but had not previously stated this directly. Access to patented HIV medicines in Africa currently depends on voluntary licences whose terms are set not by African health authorities but by originator pharmaceutical companies, whose geographical coverage excludes the African countries with the highest HIV burdens, and whose continuity is contingent on the commercial and political calculations of private actors. The Medicines Patent Pool represents a partial counterbalance, but its capacity is limited and its leverage depends on the willingness of originator companies to engage. Structural reform at the TRIPS level, including the operationalisation of compulsory licensing and the full use of TRIPS flexibilities in national patent legislation, is the architectural change that voluntary licensing cannot provide and that the African Group's position in the WHO pandemic treaty negotiations has identified as the appropriate multilateral venue for the continent to advance these demands collectively.

4. Equitable Partnership Terms Must Be Operationalised, Not Declared

The Lusaka Agenda, the AU Roadmap to 2030, and the continental consensus on country ownership provide the normative architecture within which partnership negotiations should be conducted. The session's panel discussion made clear that the gap between this normative consensus and operational partnership reality is where the work of sovereignty is won or lost. MOU terms that require commodity procurement through externally contracted suppliers, data sharing through external platforms as a condition of funding, and programme design aligned to external rather than national strategic priorities each represent operational departures from the normative position that the continental frameworks endorse. The criteria for equitable partnership need to be operationalised into specific negotiating terms that African governments can apply consistently across bilateral, multilateral, and global health initiative partnership

agreements, and those terms need to be enforced through parliamentary oversight and civil society accountability mechanisms rather than left to ad hoc institutional discretion.

5. The Three-Webinar Series Has Generated a Coherent Continental Advocacy Framework

Taken together, the three sessions have generated a coherent advocacy architecture. Webinar 1 established the fiscal layer: deliberate domestic resource mobilisation, protected budget lines, earmarked levies, and PEPFAR MOU criteria. Webinar 2 established the legislative layer: enabling laws that anchor financing commitments to parliamentary accountability, national strategic plans that translate continental commitments into costed implementation frameworks, and human rights protections that extend to the populations most affected by the legal environments that determine their access to services. Webinar 3 has added the supply-side layer: AMA operationalisation, collective procurement, pharmacovigilance governance, and equitable partnership terms as the operational translation of the fiscal and legislative architecture into actual access. The three layers, taken together, constitute what the series described as the architecture this series has been building toward, a sovereign HIV response in which medicines are manufactured on the continent, procured through continental systems, regulated by continental authorities, and delivered through partnerships in which African governments and communities define the terms.

CONCLUSION

The third session of the AHCWG 2026 Financing and Resilience Series closed with a synthesis that Prof. Chakroun articulated as the central architectural lesson of the series: health sovereignty is not achieved through a single intervention or a single institutional mechanism. It depends on how multiple systems work together in practice: manufacturing capacity, regulatory harmonisation, pharmacovigilance governance, procurement architecture, and the design of global health partnerships. The integrity of that systemic connection is the variable that determines whether protected budgets and enabling legislation translate into actual access or dissipate into structural dependencies operating below the level at which policy commitments are made.

Mr. Agyarko's closing synthesis for the African Union Commission added the political economy dimension that makes this systemic connection either possible or impossible: the continent's challenge is no longer primarily one of technical knowledge, institutional design, or even financial resources. The African Medicines Agency is operational. Collective procurement mechanisms exist. Manufacturing proof of concept has been established. The missing ingredient is the political will of African governments to route their health systems decisions, their regulatory processes, their procurement authorities, and their partnership negotiations through the continental architecture that their own institutions have built. That political decision, more than any specific technical reform, is what the series identified as the binding constraint and the most consequential lever available.

The AHCWG 2026 webinar series closes with a consolidated resource library spanning financing instruments, policy and legislative frameworks, and regulatory and partnership models. These outputs are available for adaptation by any African government, civil society actor, or regional institution engaged in the work of building domestic HIV response ownership. The series has demonstrated both the urgency and the practical achievability of the architecture it has described. The work of translating that architecture from webinar outputs into legislative decisions, procurement reforms, and partnership renegotiations is the task that the AHCWG carries forward.

EVENT DETAILS

Webinar Title	Regulatory Environments and Resilience Partnership Models
Series Title	AHCWG 2026 Financing and Resilience Series | Webinar 3 of 3
Date	24 June 2026
Format	Virtual Webinar with AI-Powered Multilingual Interpretation
Duration	90 Minutes
Convener	African-led HIV Control Working Group (AHCWG)
Supported By	Policy Strategy Group (PSG)
Preceding Sessions	Webinar 1: Protecting Core Services with Domestic Investments (22 April 2026); Webinar 2: Policy Frameworks for Sustainable HIV and Healthcare Financing (27 May 2026)
Moderator	Prof. Mohamed Chakroun, Infectious Diseases Specialist, Faculty of Medicine of Monastir
Speakers	Mr. Alex Juma Ismail (AMA); Ms. Priscilla Nyambayo (MCAZ Zimbabwe); Dr. Mohga Kamal-Yanni (People's Medicine Alliance); Mr. Robert Agyarko (African Union Commission)