



DELIVERING THE AFRICAN MEDICINES AGENCY (AMA): WHY SOUTH AFRICA MUST RATIFY THE AMA TREATY NOW



AN ADVOCACY BRIEF FOR THE MINISTRY OF HEALTH
SEPTEMBER 2026

I. SOUTH AFRICA'S HEALTH RESEARCH AND DEVELOPMENT LANDSCAPE

Despite its leadership in health research and regulation, South Africa had not signed, ratified or acceded to the AMA Treaty in the African Union status list dated 22 May 2026. The domestic process has nevertheless advanced: Parliament's Portfolio Committee on Health previously recommended approval of the Treaty, and civil-society and research stakeholders, including SAHTAC, have continued to call for completion of the process^{1,2,3}.

South Africa has one of the continent's strongest health research ecosystems and a highly developed national regulator, the South African Health Products Regulatory Authority (SAHPRA). The National Department of Health Strategic Plan 2025–2030 places implementation of National Health Insurance (NHI) at the centre of efforts toward universal health coverage. The National Health Insurance Act 20 of 2023 was signed into law in May 2024 and establishes the framework for phased implementation of the NHI Fund⁴.

The resilience of this ecosystem was tested in 2025 when the suspension of United States research funding disrupted clinical research programmes across the country^{5,6}. Although emergency funding and the subsequent lifting of funding restrictions helped stabilise the sector^{7,8}, the episode underscored the importance of strengthening African health research and regulatory systems through greater continental coordination.

South Africa brings significant regulatory capacity to this agenda. SAHPRA has achieved WHO Maturity Level 3 for vaccine regulation and participates in regional reliance and work-sharing mechanisms, including ZaZiBoNa. This experience could make South Africa an important technical contributor to continental regulatory cooperation through AMA.

The case for completing ratification is reinforced by the outcomes of the 76th Session of the WHO Regional Committee for Africa in August 2026. Member States adopted the Regional Strategy on Regulation of Medical Products in the African Region 2026–2035, which prioritises stronger national regulatory systems, regulatory convergence, local manufacturing, sustainable financing and closer cooperation with AMA^{9,10}.

1 Parliamentary Monitoring Group. Portfolio Committee on Health: report on the Treaty for the Establishment of the African Medicines Agency. <https://pmg.org.za/tailed-committee-report/5384/>

2 African Union. (2026). List of Countries Which Have Signed, Ratified/Acceded to the Treaty for the Establishment of the African Medicines Agency (status as of 22 May 2026). https://au.int/sites/default/files/treaties/36892-sl-TREATY_FOR_THE_ESTABLISHMENT_OF_THE_AFRICAN_MEDICINES_AGENCY_5.pdf

3 SAHTAC (2023). Call to the Government of South Africa to fully ratify the AMA Treaty. <https://sahtac.org.za/2023/11/15/call-to-the-government-of-south-africa-to-fully-ratify-the-african-medicines-agency-treaty/>

4 National Department of Health, South Africa. (2025). Strategic Plan 2025–2030. <https://www.health.gov.za/>

5 Spotlight (2025, May 9). US pulls funding for South African medical research. <https://www.spotlightnsp.co.za/2025/05/09/us-pulls-funding-for-south-african-medical-research/>

6 PMC (2025). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11984525/>

7 Spotlight (2026, April 15). SAMRC rolls out rescue grants. <https://www.spotlightnsp.co.za/2026/04/15/samrc-rolls-out-rescue-grants-what-next-for-research-projects-hit-by-us-funding-cuts/>

8 GroundUp (2026). World's largest research funder lifts ban on South Africa. <https://groundup.org.za/article/worlds-largest-research-funder-lifts-ban-on-south-africa/>

9 WHO Regional Office for Africa. (2026). Regional Strategy on Regulation of Medical Products in the African Region, 2026–2035. <https://www.afro.who.int/>

10 Keyter, A. et al. (2025). Pharmaceutical Medicine. <https://doi.org/10.1007/s43441-025-00879-8>



II. WHAT SOUTH AFRICA CAN DO NOW

South Africa's research, regulatory and manufacturing capabilities position it to play a leading role in AMA's operationalisation. In 2026, the African Union was finalising AMA's 2026–2029 multi-year strategic plan and financial contribution framework. South Africa can support these continental objectives while advancing national health, manufacturing and innovation priorities in the following ways.

Recommendation	Responsible actor	Immediate next step
Complete ratification of the AMA Treaty	Minister of Health, Cabinet and Parliament	Complete the remaining domestic procedures and deposit South Africa's instrument of ratification or accession with the African Union.
Prepare for participation in AMA regulatory mechanisms	SAHPRA	Develop a plan for engagement in AMA joint reviews, reliance arrangements and coordinated GMP inspection activities.
Commit sustainable financial and technical support to AMA	National Department of Health and National Treasury	Allocate the State Party contribution following ratification and identify South African experts for AMA technical committees and working groups.
Leverage AMA to strengthen research, manufacturing and innovation	National Department of Health, Department of Science, Technology and Innovation (DSTI) and SAHPRA	Identify priority programmes, including the mRNA Technology Transfer Hub and major research initiatives, that could benefit from AMA-supported regulatory cooperation and regional market access.
Shape emerging continental regulatory frameworks	National Department of Health and SAHPRA	Nominate South African experts to participate in AMA governance and technical structures to ensure South African experience informs continental regulatory standards.

III. HOW SOUTH AFRICA'S PRIORITIES ALIGN WITH AMA'S MANDATE

In August 2026, the African Voices of Science Health R&D Champions issued a policy brief at the 76th Session of the WHO Regional Committee for Africa (RC76), urging African governments to ratify the AMA Treaty and establish sustainable, member-state financing for the Agency.

The brief argues that a fully operational AMA is important for accelerating regulatory cooperation for clinical research, improving regulatory pathways for locally manufactured medical products and strengthening science-based regulation across Africa.



AMA complements national and regional regulatory authorities; broader health-data governance remains led through national frameworks and Africa CDC-led continental initiatives.

South Africa's established research base, manufacturing capacity, and regulatory maturity mean it has more to offer a continental agency, and following the 2025 funding crisis, more to gain from the diversified partnerships and continental integration AMA would enable.



Clinical trials: strengthening African research leadership

Africa remains underrepresented in global clinical research relative to its disease burden. A fully operational AMA could support more efficient multicountry research through harmonised approaches, regulatory reliance and joint assessments. For South Africa, deeper participation could help expand continental research partnerships and make greater use of the country's established clinical-trial infrastructure.



Local manufacturing and health sovereignty

The continent produces only about 3% of global medicines, imports over 70% of what it consumes, and depends on foreign suppliers for more than 95% of its active pharmaceutical ingredients. Expanding regional markets is therefore critical to strengthening local pharmaceutical manufacturing.

South Africa hosts the WHO-supported mRNA Technology Transfer Programme hub in Cape Town, centred on Afrigen, the South African Medical Research Council and Biovac. While national regulatory authorities retain responsibility for market-authorisation decisions, AMA-supported reliance, work-sharing and coordinated inspection mechanisms could reduce duplication and improve regulatory convergence across African markets. For South Africa, this could support more predictable regional pathways for locally developed and manufactured products¹¹.

Ratification would also complement South Africa's efforts to strengthen regulatory oversight and combat substandard and falsified medical products, while allowing the country to help shape emerging continental regulatory frameworks.

¹¹ World Health Organization. (2022, October 5). South Africa's vaccine regulator reaches a new WHO maturity level. <https://www.who.int/news/item/05-10-2022-south-africa-s-vaccine-regulator-reaches-new-who-level-to-ensure-safety-quality-effectiveness>



Health data and genomics: strengthening African governance

Health and genomic data in South Africa are governed nationally, including through the Protection of Personal Information Act (POPIA), while Africa CDC is leading continental work on health-data governance. AMA's role is more specific and complementary: it can support regulatory cooperation relevant to clinical research, innovative medical products and related standards. South Africa's participation would help ensure that its regulatory and scientific expertise informs these evolving continental mechanisms¹².

IV. KEY MESSAGES FOR THE MINISTRY OF HEALTH

01

Strengthening evidence-informed regulatory decision-making: AMA ensures regulatory decisions are grounded in African-generated evidence. For South Africa, this means SAHPRA can enhance efficiency by drawing on shared continental regulatory intelligence, reducing the burden of evaluating every product in isolation.

02

Advancing regulatory harmonization and reliance across Africa: A harmonized continental framework eliminates costly duplication. For South Africa, this builds on SAHPRA's existing participation in ZaZiBoNa, the ML3 reliance framework, and the Egypt work-sharing arrangement - extending proven mechanisms to continental scale.

03

Supporting local manufacturing through stronger research and innovation ecosystems: A harmonised regulatory environment gives manufacturers predictable standards and continental market access. For South Africa, this means products from the mRNA hub can reach SADC and continental markets through one pathway — realising the 33:1 regional return.

04

Advancing scientific leadership and health data and genomics: Continental governance of health and genomic data under African-led standards ensures the continent leads global health science. For South Africa, this means the 110,000 Human Genome Programme operates within a continental framework South Africa helped design.

05

Strengthening regulatory institutions and governance: Engaging with AMA gives SAHPRA access to continental scientific networks and shared inspection capacity while retaining final authority over South Africa's own market. South Africa's regulatory maturity contributes to strengthening the continental system.

¹² PMC (2020). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7118803/>



V. WHY SHOULD SOUTH AFRICA RATIFY AMA NOW?

- ▮ **Ratification is within reach:** South Africa's ratification process is already well advanced, including a favourable recommendation from the Portfolio Committee on Health, creating an opportunity for timely completion of the remaining domestic steps.
- ▮ **South Africa has the regulatory capacity to shape AMA's future:** SAHPRA's regulatory maturity including WHO maturity level 3 status for vaccines, and participation in regional reliance mechanisms (ZaZiBona) position South Africa to play a leading role in continental regulatory cooperation.
- ▮ **South Africa's pharmaceutical manufacturing stands to gain from a more integrated regulatory environment:** The country's pharmaceutical manufacturing, vaccine-development and clinical research capabilities, including the Cape Town mRNA technology transfer hub, could benefit from increased regulatory cooperation, reliance and the resultant market integration across Africa.
- ▮ **Recent research funding disruptions highlight need for stronger continental collaborations:** the 2025 US funding withdrawal demonstrated the risks of relying heavily on a narrow set of external partners, reinforcing the case for broader African collaboration in research, regulation, and innovation.

The costs of non-ratification are increasingly strategic. Ratification is required for South Africa to participate fully as a State Party in AMA's governance, including the Conference of States Parties and the rights and obligations established by the Treaty. Remaining outside the Treaty would limit South Africa's formal influence as AMA's regulatory cooperation mechanisms and institutional framework continue to develop^{13,14}.

VI. REFERENCES

1. African Union. (2023). Signature and ratification table: Treaty for the Establishment of the African Medicines Agency. https://au.int/sites/default/files/treaties/36892-sl-TREATY_FOR_THE_ESTABLISHMENT_OF_THE_AFRICAN_MEDICINES_AGENCY.pdf
2. National Department of Health, South Africa. (2025). Strategic plan 2025–2030. <https://khub.africacdc.org/records/resource/south-africa-strategic-plan-2025-2030>
3. Spotlight. (2025, May 9). US pulls funding for South African medical research. Spotlight. <https://www.spotlightnsp.co.za/2025/05/09/us-pulls-funding-for-south-african-medical-research/>
4. Early impact of US funding withdrawal on TB services and research in South Africa]. PMC. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11984525/>
5. Spotlight. (2026, April 15). SAMRC rolls out rescue grants: What next for research projects hit by US funding cuts? Spotlight. <https://www.spotlightnsp.co.za/2026/04/15/samrc-rolls-out-rescue-grants-what-next-for-research-projects-hit-by-us-funding-cuts/>
6. GroundUp. (2026). World's largest research funder lifts ban on South Africa. GroundUp.

¹³ African Union. *Treaty for the Establishment of the African Medicines Agency, Article 26 (Financial Resources)*. https://au.int/sites/default/files/treaties/36892-treaty-0069_-_ama_treaty_e.pdf

¹⁴ African Union. (2026). *Assembly decision on the operationalisation of the African Medicines Agency, including development of the AMA Multi-Year Strategic Plan (2026–2029) and financial contribution framework*. <https://au.int/>



<https://groundup.org.za/article/worlds-largest-research-funder-lifts-ban-on-south-africa/>

7. World Health Organization. (2026, August 24). Mozambique strengthens regulation of medicines and imported vaccines, boosting health protection [includes SAHPRA ML3 retention recommendation]. WHO. <https://www.who.int/news/item/24-08-2026-mozambique-strengthens-regulation-of-medicines-and-imported-vaccines--boosting-health-protection>
8. Keyter, A., et al. (2025). [Title to be confirmed: SAHPRA regulatory reliance and medicines maturity assessment]. Pharmaceutical Medicine. <https://doi.org/10.1007/s43441-025-00879-8>
9. Parliamentary Monitoring Group. (2023). Portfolio Committee on Health: Tabled committee report — Recommendation on AMA Treaty. <https://pmg.org.za/tabled-committee-report/5384/>
10. South African Health Technologies Advocacy Coalition. (2023, November 15). Call to the Government of South Africa to fully ratify the African Medicines Agency Treaty. SAHTAC. <https://sahtac.org.za/2023/11/15/call-to-the-government-of-south-africa-to-fully-ratify-the-african-medicines-agency-treaty/>
11. World Health Organization. (2022, October 5). South Africa's vaccine regulator reaches new WHO level to ensure safety, quality, effectiveness. WHO. <https://www.who.int/news/item/05-10-2022-south-africa-s-vaccine-regulator-reaches-new-who-level-to-ensure-safety-quality-effectiveness>
12. World Health Organization. (2025, October 26). South Africa launches national action plan to protect millions from substandard and falsified medical products. WHO. <https://www.who.int/news/item/26-10-2025-south-africa-launches-national-action-plan-to-protect-millions-from-substandard-and-falsified-medical-products>
13. Frontline Genomics. (n.d.). World of genomics: South Africa. Frontline Genomics. <https://frontlinegenomics.com/world-of-genomics-south-africa/>
14. World Bank. (2025, April 7). Strengthening genomic surveillance in Africa: Capacity building beyond COVID-19. World Bank. <https://www.worldbank.org/en/news/feature/2025/04/07/strengthening-genomic-surveillance-in-afe-africa-capacity-building-beyond-covid-19>
15. Staunton, C., Adams, R., Botes, M.,»»»; de»»»; Vries, J. (2020). [Title to be confirmed: Consent and cross-border sharing of health and genomic data in South Africa under POPIA]. PMC. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7118803/>

Controlled source document:

African Voices of Science. (2026). How delivering the African Medicines Agency unlocks Africa's health research and innovation economy [Policy brief]. Speak Up Africa.

