



United States-Sub-Saharan Africa Trade and Economic Cooperation Forum (AGOA Forum)

"Beyond 2025: Reimagining AGOA for an Inclusive, Sustainable and Prosperous Tomorrow"

July 24-26, 2024, Washington, D.C.

HEALTH BREAKOUT SESSION

Accelerating the Ratification of the African Medicines Agency: U.S.-Africa Cooperation to Enhance Public Health and Economic Growth

DATE: July 25, 2025

TIME: 4:30PM – 5:45PM | **LOCATION:** U.S. Department of State

Opening Remarks for U.S. Co-Chair, Mark Abdo

- Good afternoon distinguished ladies and gentlemen. It is my pleasure to be chairing this important session highlighting the significance of accelerating the ratification of the African Medicines Agency treaty, and to be doing so alongside the Honorable Minister of Trade and Industry, Dr. Jean-Chrysostome Ngabitsinze from the Government of Rwanda.
- I'd like to begin by recognizing the longstanding health cooperation between the U.S. and Africa.
- The United States Government is proud to advance shared public health goals in partnership with governments and institutions in Africa, such as the African Union Commission, the Africa Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD), the Africa Centres for Disease Control and Prevention, and global non-profit organizations. For example, working with bilateral and multilateral partners across the region, we are committed to strengthening health systems and institutions; advancing global health security; and accelerating efforts to achieve the 2030 Agenda for Sustainable Development.
- U.S. investments on health in Africa have saved millions of lives and have made the world better prepared for health security threats.
- Under the Biden-Harris Administration, the United States has invested and committed to provide nearly \$20 billion in health programs in the Africa region.
 - This includes nearly \$11.5 billion to address HIV/AIDS; more than \$2 billion to combat malaria; more than \$2 billion in support of family planning and reproductive health as well as maternal and child health; and more than \$2 billion to address the health, humanitarian, and economic impacts of COVID-19.

- One notable success is the U.S. President’s Emergency Plan for AIDS Relief (or PEPFAR). In the last twenty years, PEPFAR has saved more than 25 million lives, prevented millions of HIV infections, and helped countries build a strong foundation to prevent and respond to other health threats.
- PEPFAR has also created unique health systems and infrastructure that continue to be leveraged in key areas such as pandemic preparedness and regional manufacturing.
- The United States is committed to working with our partners to accelerate regional manufacturing. To this end, major U.S. partnership programs like those under the Bureau of Global Health Security and Diplomacy, continue to accelerate regional manufacturing capacity and build more resilient supply chains.
- These are notable successes, but challenges and opportunities remain.
- Today we address a pivotal issue that lies at the intersection of public health and economic prosperity, a matter that calls for your leadership.
- Africa bears a disproportionate share of the global burden of both communicable and non-communicable diseases:
 - 70% of all people living with HIV are in Africa.
 - 94% of global malaria cases and deaths occur on the continent.
 - Africa bears 25% of global tuberculosis burden.
 - Non-communicable diseases such as diabetes, hypertension, and cancer are on the rise, compounding the continent’s demand for health commodities.
- As our colleagues from AUDA-NEPAD have importantly noted, African countries are significantly relying on the importation of diagnostics, medications, vaccines, personal protective equipment, and other medical supplies to manage these diseases. For example, Africa is importing almost 99% of vaccines for diseases, and over 95% of medications, while consuming approximately 25% of the world's vaccine production.
- This substantial demand for a wide range of health commodities illustrates the urgent need for local manufacturing.
- Local manufacturing is not just a health imperative, but an economic opportunity. Local manufacturing can reduce the cost of medical products, ensure a more reliable supply, and foster economic growth.
- Several countries across sub-Saharan Africa have made significant strides in local manufacturing, regulatory strengthening, and building capacity. Each should be applauded.
- A unified, effective regulatory framework under the African Medicines Agency (or AMA) would have significantly enhanced access of medical products in Africa during the COVID-19 pandemic.
- Your support as Finance and Trade Ministries is critical to ratifying the AMA treaty in your country and to AMA’s successful implementation.

- Supportive engagement from Ministries could include:
 - Providing the financial support, tax incentives, and subsidies to spur local pharmaceutical manufacturing.
 - Creating conducive trade policies that facilitate the import of raw materials and the export of finished products.
 - Fostering collaboration and coordination between finance, trade, and health to create a coherent strategy that supports the AMA's objectives.
- The economic opportunities for local manufacturing of health commodities in Africa are vast. African countries can meet their own healthcare needs and even become significant players in the global market, all leading to job creation, a skilled workforce, and overall economic growth.
- Putting on my FDA hat, regulatory systems strengthening is critical to realizing these opportunities. It enables access to locally manufactured product by ensuring product quality, safety, and efficacy and, thereby, the confidence of consumers. It strengthens confidence in these products when marketed for distribution in Africa and beyond.
- Regulatory convergence and harmonization are key enablers of cross-border trade by reducing industry burden for marketing in multiple countries. Regulatory collaboration leverages collective resources.
- The U.S. government supports regulatory harmonization efforts of regional economic communities under the African Medicines Regulatory Harmonization (AMRH) and provides technical assistance to strengthen national regulatory authorities.
- On behalf of FDA, I recently met with a number of African regulators, industry, WHO representatives, and others in Kenya and through meetings convened by the Bill and Melinda Gates Foundation in Rwanda. These discussions offered important opportunity to discuss regulatory capacity needs and to further regulatory convergence. FDA looks forward to opening an office at our U.S. Embassy in Kigali to provide direct support to AMA. We, like so many of you, would like to see regional manufacturing succeed.
- An AMA that advances regulatory harmonization and good regulatory practices will importantly enable access to quality, safe, and effective medical products and manufacturing on the continent.
- As recognized in U.S. trade agreements, good regulatory practices and regulatory convergence can facilitate international trade, investment, and economic growth, while contributing to achieving public health objectives.
- Currently, of the 55 African Union Member States, 37 have signed and/or ratified the AMA treaty. We encourage finance and trade ministers to champion this cause, urging swift ratification to unlock the full potential of the AMA.
- Supporting AMA's success contributes to enhancing public health, promotes economic growth, and strengthens regional integration.

- Your leadership is essential to realizing this vision. The United States government stands ready to support your efforts to create a resilient and prosperous future for Africa where health and economic development go hand in hand.
- I look forward to our discussion and now I would like to turn to my co-chair, the Honorable Minister of Trade and Industry, Dr. Jean-Chrysostome Ngabitsinze representing the Government of Rwanda and the host country of the African Medicines Agency.

Closing Remarks for U.S. Co-Chair, Mark Abdo

- As we come to the end of the session, I would like to thank my distinguished co-chair, Minister Ngabitsinze, our moderator Dr. Nicolaou, and all the panelists for their engaging and informative contributions to this important conversation.
- I look forward to working with FDA's counterparts and the many other interested parties committed to the success of the African Medicines Agency. Your attendance today and your thoughtful discussion already demonstrate your essential support for the goals of a successful African Medicines Agency and of strengthening health systems and institutions in Africa.
- Thank you for your participation and engagement.