



GHANA GEARS UP FOR LOCAL VACCINE PRODUCTION

UNITED STATES SUPPORTS GHANA'S VACCINE PRODUCTION

At the height of the COVID-19 pandemic, the United States Agency for International Development (USAID) partnered with the Ghana Food and Drugs Authority (FDA Ghana) to lay the groundwork for local vaccine production in Ghana. The government of Ghana is committed to developing Ghana as a vaccine manufacturing center in West Africa. USAID, through its Promoting the Quality of Medicines Plus program (PQM+), supported the regulatory and manufacturing capacity of six African countries, including Ghana, as part of the U.S. Government's Initiative for Global Vaccine Access (Global VAX). Support included strengthening the Ghana FDA's regulatory capacity, developing lab testing capacity, and strengthening Ghana's regulatory information management systems.

FOOD AND DRUGS AUTHORITY GHANA

FDA Ghana's mandate is to regulate and ensure the quality, safety, and efficacy of medical products, including vaccines. FDA Ghana has achieved significant results over the years. In March 2020, Ghana became the second Sub-Saharan African country, after Tanzania, to reach the World Health Organization's (WHO) "Maturity Level 3"¹ for regulation of medicines and imported vaccines, one level short of the highest ranking given to national medicines regulatory systems. On November 9, 2022, Ghana became the first country in West Africa to have its national medicines quality control laboratory achieve WHO prequalification, a distinction that signifies that the laboratory has been

¹ Ghana is WHO Maturity Level 3 as a non-vaccine producing country.

assessed, inspected and found to comply with the rigorous international standards recommended by WHO.

STRENGTHENING FDA GHANA'S CAPACITIES

USAID supported FDA Ghana to improve its regulatory and quality control capabilities, including independent lot release testing. Lot release testing involves evaluating individual vaccine lots before approving their release for use. USAID specifically supported FDA Ghana to:

- Establish the legal provisions, regulations, and guidelines for independent lot release, leading to the validation of 20 regulatory documents to align with international best practices and WHO requirements.
- Train and provide supportive supervision to 27 FDA Ghana staff to improve their ability to successfully conduct independent lot release. Staff conducted mock release of several vaccine lots, including for two COVID-19 vaccines.



FDA Ghana is working to attain WHO Maturity Level 3 for its lot release regulatory function by the end of 2024, a requirement for vaccine producing countries.

Laboratory testing is one of the nine functions required of national regulatory systems. USAID supported FDA Ghana to develop its laboratory testing capacity by:

- Procuring equipment needed to analyze vaccine purity and potency and training lab analysts on how to use the equipment. Lab personnel can now analyze key vaccine quality attributes to ensure they are correctly conducting lot release testing.
- Sponsoring two FDA Ghana lab analysts' study tour visits to the South African National Control Laboratory for Biological Products, a center of excellence, to improve their skills in vaccine testing.
- Training 14 FDA Ghana quality control staff on performing specific tests for vaccines.

A strong national regulatory system relies on a robust information management system to standardize regulatory processes. USAID supported FDA Ghana to procure and install an integrated regulatory information management system (IRIMS) which was installed and deployed on FDA Ghana's servers in November 2023. This electronic system:

- Standardizes regulatory processes, increasing the consistency, transparency, and efficiency of FDA Ghana's regulatory process and operations.
- Improves FDA Ghana's quality management system and will enable the FDA to detect and respond faster to medical products quality issues, including for vaccines.

TAKEAWAYS

- USAID support to FDA Ghana effectively contributed to these impressive achievements due to the government of Ghana's strong commitment and FDA Ghana's effective leadership.
- Support provided under Global VAX has prepared FDA Ghana to provide regulatory oversight and quality control testing of medical products for COVID-19 vaccines, as well as for childhood vaccines and lifesaving maternal and newborn health medicines.