

Supporting the establishment of the Rwandan pharmaceutical and biotechnological sector

The challenge

70 to 90 per cent of pharmaceuticals consumed on the African continent are imported and less than one per cent of the vaccines administered are locally produced. Rwanda largely depends on international supply chains, as its pharmaceutical and biotechnological sector is still nascent. The pharmaceutical market on the African continent is rapidly growing and has the potential to generate significant economic value. Against this background the government of Rwanda prioritised the establishment of the pharmaceutical and biotechnological sector in the country.

Commissioned by the German Federal Ministry for Economic Cooperation and Development (BMZ) and co-financed by the European Union (EU), the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH supports Rwanda's ambition to become a regional hub for pharmaceutical production, including vaccines.

The production of pharmaceuticals and biotechnology is a complex process and requires a strong ecosystem throughout the entire value chain, including a capable regulatory body and framework. For this, the responsible Rwanda Food and Drug Authority (RFDA) does not only need the institutional maturity to regulate the sector but also requires adequate laboratory capacity to perform the necessary quality assurance and market release tasks for locally produced pharmaceuticals and vaccines.

Various other resources and processes are needed to enable the manufacturing of high-quality medical products – above all, skilled personnel. However, specialized programmes in technical and vocational education and training (TVET), addressing the needs of the pharmaceutical and biotechnological industry are missing in Rwanda.

Rwanda promotes the development of home-grown solutions. **This requires an infrastructure and support environment specifically geared towards the needs of local entrepreneurs and young start-ups in this field.**

Strengthening the regulatory framework

In Rwanda, the Rwanda Food and Drug Authority (RFDA) is, among other things, responsible for regulating the production and market release of medicines. Realised together with the RFDA, **organisational development** therefore helps to strengthen the regulatory framework in Rwanda. This encompassed various aspects geared towards supporting the implementation of recommendations made in the institutional development plan issued by the World Health Organization (WHO). These recommendations aim at the RFDA reaching the maturity level 3 – a pre-condition to regulate locally produced pharmaceuticals.

Activities covering a period of 18 months eventually led to the RFDA attaining this level. Building on this milestone, future measures will support the RFDA in reaching ISO certifications, implementing training programs for monitoring and evaluation and developing a human resource retention strategy, thereby strengthening it to become a key enabler for the regulation of Rwanda's pharmaceutical and biotechnological sector.

Project name	Support to the establishment of the pharmaceutical and biotechnological sector in Rwanda
Commissioned by	German Federal Ministry for Economic Cooperation and Development (BMZ)
Co-financed by	European Union (EU)
Project region	Rwanda
Lead executing agency	Ministry of Industry and Trade (MINICOM)
Duration	10/2022 – 12/2027

The construction of a National Quality Control Laboratory for the RFDA will allow the regulator to perform quality control tasks and the lot release of pharmaceuticals that will be produced in Rwanda. The laboratory is supposed to be part of the fast



Contact Person:

Ralf Elben

Ralf.elben@giz.de

L. to r.: students in the training laboratory at the Rwanda Bioeconomy Hub; GIZ team at National Quality Control Laboratory construction site

growing, so-called “Masaka Health City” – an area designated for institutions and organisations active in the field of health science. An expert advisory committee is already in place to accompany the construction – comprised of sector specific professionals with a wide array of relevant expertise ranging from laboratory workflow, Rwandan housing requirements, regulatory processes and construction with technical specifications among others.

A study tour to Germany allowed RFDA staff to participate in the inspection of the modular BioNTainers by the German company BioNTech. This marked a significant step towards the **capacity of RFDA staff to perform inspection procedures in Rwanda** in the near future.

Capacity development for the TVET sector

The project aims to strategically **strengthen the capacity of relevant government and TVET authorities in Rwanda**, including Rwanda Polytechnic (RP), the Rwanda TVET Board (RTB) and the Rwanda and the Rwanda TVET Trainer Institute. Together with the partner institutions, quality competency-based TVET training modules will be developed, focusing on cross-cutting quality management skills and ensuring their relevance to the pharmaceutical and biotechnological industry.

Moreover, **partnerships between TVET institutions in Rwanda and Europe**, particularly Germany will facilitate both, the translation of relevant learning content to the Rwandan context, and knowledge-transfer between teaching staff at German and Rwandan TVET schools.

Nurturing entrepreneurship

Together with the Rwandan Ministry of Education (MINEDUC), the University of Rwanda, UVU Bio, and financed via BMZ’s Special Initiative “Decent Work for a Just Transition”, GIZ launched the **Rwanda Bioeconomy Hub** located at the University of Kigali. The hub offers a skills development laboratory and training centre, a shared space for biotech business acceleration and a

dedicated acceleration programme designed to provide entrepreneurs and early-stage companies with the resources and support they need to develop and commercialise new biotech products and services. Continued and broadened support for the hub will help to include an additional range of technologies relevant to developing capacities in biotechnology, specifically in the field of agro-processing and agricultural technology, thus allowing more start-ups to receive support.

Additionally, a funding mechanism and investment trust will provide **financial support to selected start-ups and young entrepreneurs** in the field of biotechnology and pharmaceuticals, thereby helping start-ups bridge the transition from the acceleration support to investment driven operations.

Strengthening networks

A strengthened network of Rwanda’s key institutions and other regulatory authorities in Africa **enhances the experiences of experts within the regulatory environment and supports regional regulatory harmonisation initiatives**. The East Africa Pharma and Biotech Conference, supported by BMZ’s Special Initiative “Decent Work for a Just Transition”, provided a platform for regulatory authorities across the region to exchange on regulatory hurdles and enhance their collaboration.

There are several continental efforts to support the harmonization of regulatory structures and procedures in which the RFDA plays a key part. The establishment of the Africa Medicines Agency and other initiatives are examples of this. Facilitated by GIZ, the RFDA participates in multiple events and relevant study tours to grow their network and increase the visibility of the institution both, locally and globally.

Published by	Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH Registered offices Bonn and Eschborn, Germany	Photo credits	Uvu Bio, GIZ, page 1
		Text	Phama and Biotech Project
	GIZ Office Kigali, Rwanda Phone +250 788 187 800 Fax +49 (0)00 123 456 789 giz-ruanda@giz.de www.giz.de/rwanda	GIZ is responsible for the content of this publication.	
		On behalf of	Federal Ministry for Economic Cooperation and Development (BMZ)
			This programme is co-financed by the European Union (EU)
As at	February 2025		