

Dispatch

IGAS – General Health Inspection Office

ARFAME – Regulatory Authority for Pharmacy, Laboratory and Medicines

Issued jointly by IGAS and ARFAME under authority of the Dispatch N° 31/GMSP/2025 of September 19th 2025.

Subject: Implementation of the National Pharmaceutical Traceability System for Guinea-Bissau

Introduction

Pursuant to the Dispatch N° 31/GMSP/2025 of September 19th 2025 on the Introduction of the Transparency Track and Trace Platform for the Supply Chain of Medicine within Guinea-Bissau ("AVG Pharmaceutical Traceability Hub").

The *General Health Inspection Office (IGAS)* and the *Regulatory Authority for Pharmacy, Laboratory and Medicines (ARFAME)* act jointly under this Dispatch, with IGAS responsible for inspection and enforcement and ARFAME responsible for regulatory guidance and product approvals.

IGAS and ARFAME hereby issue the following Dispatch to provide clarification on sign-up, required information, and implementation timelines.

All questions and inquiries must be addressed exclusively to: gov-support@antaresvision.com.

Sign-up Portal, information, training resources, and a dedicated Q&A section are available at <https://guinea-bissau.avgroupHub.com> from Dispatch N° 31/GMSP/2025 of September 19th 2025.

Definitions

Pharmaceutical Manufacturer: Any person or company engaged in the manufacture of pharmaceutical products intended for use in Guinea-Bissau.

Wholesaler: Any company authorized to distribute pharmaceutical products in bulk to pharmacies, hospitals, or clinics. This includes wholesalers based abroad that export medicines into Guinea-Bissau, who are equally mandated to register and comply with the National Traceability System.

For all other definitions not listed herein, reference shall be made to the Dispatch N° 31/GMSP/2025 of September 19th 2025.

Implementation Timeline

Card

Antares

- Manufacturers / Marketing Authorization Holders (MAHs)

By 15 November 2025

Complete sign-up in the National Traceability System, submit product and location master data.

By 19 March 2026

Mandatory serialization of primary packages (SGTIN). Identification with GTIN, lot number, and expiration date. Submission of serialization data via GS1 EPCIS (Commission, Ship), in accordance with GS1 EPCIS event standards.

By 19 September 2026

Mandatory serialization of secondary and higher packaging, and logistic units (SSCC). Submission of serialization and aggregation data via GS1 EPCIS (Commission, Aggregate, Ship).



- Distributors and Dispensers (Importers, Wholesalers, Pharmacies, Hospitals, Clinics)

By 30 November 2025

Complete sign-up in the National Traceability System, submit location master data.

By 18 December 2025

Establish connectivity with the National Traceability System. Connectivity may be achieved either through automated system integration (API or interface) or through manual system use via the provided application. Participants are not required to implement automated connectivity if manual operation is sufficient for their activities.

By 19 September 2026

Compliance with primary package serialization requirements. Data submission via GS1 EPCIS (Receive, Ship, Dispense).

By 19 September 2027

Compliance with secondary and higher packaging, and logistic unit serialization requirements. Data submission via GS1 EPCIS (Receive, Ship, Dispense, Aggregate, Disaggregate).

Sign-Up Information Required

During sign-up, entities must provide:

- Company name and full address
- Company Global Location Number (GLN) and GS1 Company Prefix (mandatory for manufacturers, optional for wholesalers, distributors and dispensers)
- Company representative details (names, roles, emails, phone numbers)



For Manufacturers & Wholesalers:

- list of medicines imported into Guinea-Bissau, including:
 - Name of the original MAH (if not manufactured by registered entity)
 - Medicine name and brand name
 - Global Trade Item Number (GTIN) per GS1 standards
 - Importer(s) of record
 - Attributes (dosage form and count, strength, unit of measure)
 - Primary package artwork

Sign-up Procedure

The sign-up portal will be available for all registrants from 27 October 2025.

Entities shall complete the following mandatory steps:

1. Visit the National Traceability System sign-up portal (<https://guinea-bissau.avgroupub.com>), navigate to Resources → Trainings, and complete the initial sign-up training.
2. Proceed to the Sign-up section and submit required details following the training instructions.
3. Verify the account by following the confirmation link sent to your email.
4. The system shall issue a confirmation email within 72 hours of submission.

Compliance Reminder

All pharmaceutical supply chain actors, including manufacturers, importers, distributors, wholesalers (including those based abroad exporting to Guinea-Bissau), pharmacies, hospitals, and clinics, are required to comply fully with these provisions. Sanctions shall be imposed in accordance with Articles 13 and 14 of the Dispatch.

This Dispatch shall enter into effect on the date of its publication.

Issued jointly by:

IGAS – General Health Inspection Office

ARFAME – Regulatory Authority for Pharmacy, Laboratory and Medicines

Bissau, 14 October 2025

O Presidente de ARFAME, LP



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O Inspetor Geral (IGAS)



Dr. Abdalaha Umaro Cande