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HANDBOOK Lifescience

Procedure for the release of vaccine batches according to Algerian regulations and its governance

Executive Summary

• The National Pharmaceutical Products Agency (ANPP) holds exclusive authority to release or refuse any batch of vaccines intended for the Algerian market, whether produced locally or imported.

• Customs clearance is possible, but distribution cannot proceed without the release certificate issued by the ANPP.

• The process includes: document verification, potential analytical controls, examination of the cold chain for temperature-sensitive products, followed by a formal decision (release or refusal).

• Any proven non-compliance results in the refusal of the batch and potential administrative or regulatory measures.

Key Legal Framework

• Order No. 18 of September 25: establishes the mandatory procedure for the release of vaccine lots.

• ANPP Note No. 13/MIP/ANPP/DG/NOTE/2026 (January 26, 2026): reinforced requirements for temperature-sensitive products (proof of cold chain, specifications for recorders, transit limits).

Scope

• All vaccines for human use (registered, authorized on a temporary basis, local or imported).

• Specifically includes temperature-sensitive vaccines subject to controlled storage conditions.

Actors and Roles

• ANPP: regulatory authority, issues the final decision, and can impose sanctions.

• Marketing Authorization Holder / Importer: prepares and submits the release application file, provides samples.

• Manufacturer: conducts internal tests, transmits analysis certificates, CAPA data, annual report.

• Pasteur Institute of Algeria: scientific support (occasional production, biological analyses, epidemiological monitoring), without regulatory release authority.

Release Process – Typical Workflow

Step 1: Submission of the "Batch Release Request File":

- Complete identification of the vaccine/batch.

- Manufacturer's analysis certificates (bulk + finished product).

- Quality results, stability data, compliance with specifications.

- Traceability of storage & transport (temperature, duration, equipment).

- Cold chain data for temperature-sensitive products (see Note 13/2026).

Step 2: Document Control (ANPP):

- Completeness of the file.

- Consistency of batch/dates/signatures.

- Verification of discrepancies, CAPA, recall reports.

Step 3: Analytical Controls (if required):

- Sampling of representative samples provided by the establishment.

- Confirmation tests: sterility, potency, impurities, pH, etc.

- Analysis of temperature recorders for temperature-sensitive products.

Step 4: ANPP Decision

-Release: issuance of a certificate; authorizes customs clearance + distribution.

-Refusal: written notification, detailed reason, corrective measures or destruction.

Step 5: Archiving & Post-Release Monitoring

-Vaccination campaign reports and coverage audits feed into the evaluation of future batches.

Specific requirements for temperature-sensitive products

- Continuous proof of compliance with 2-8 °C (or specified range) from manufacturing to receipt.
- Approved temperature recorders; tamper-proof and time-stamped data.
- Drift analysis: sensors out of tolerance → automatic non-compliance.

Non-compliances & sanctions

- Documentation shortcomings (incomplete file, inconsistencies).
- Analytical results outside specifications.
- Break in the cold chain, unjustified deviation.

Consequences: rejection of the batch, suspension of import, withdrawal of marketing authorization, financial or administrative penalties in accordance with the legislation.

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Points of Attention & Best Practices

• Anticipate thermosensitive requirements from the logistics planning stage (choice of packaging, transport validation).

• Update the deviation/CAPA register in real-time and attach it to the ANPP file.

• Conduct an internal pre-check, such as a "mock release," before each shipment to minimize rejections.

• Maintain a direct channel between ANPP and the holder for quick responses to requests for additional data.

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- Batch Release Compliance Audit:** alignment with Algerian requirements, MA/authorizations, GMP/GDP, official lot control/OCABR where applicable, cold chain evidence.

- Governance & SOP Build-Out:clear QA/RA/Logistics roles, decision matrix Release / Hold / Reject**, documentation controls (ALCOA+).

- Critic Incident Management: deviations, OOS/OOT, temperature excursions, lot holds, authority-facing responses and remediation plans.

- Contracts & Liability: Quality Agreements, recall/indemnity clauses, penalties, allocation of responsibilities across MAH–CMO–importer–distributor.

- inspections, Enforcement & Disputes inspection readiness, response to findings, defense in case of release refusal, suspension, or recall.

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