National Guideline for Issuing Product and Location Identifiers

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Contents

1. Purpose & Scope

This guideline defines the **mandatory national requirements** for issuing **Product Identifiers (Trade Item Number)** and **Location Identifiers (Location Number)** within a **national Track & Trace ecosystem** aligned with **international identification and traceability standards**. The guidelines apply to:

- Authorized identifier issuing entities
- Coding and serialization service providers
- Technology and solution vendors
- National registries and validation services
- Systems integrated with the national traceability platform

This document establishes **global equivalency**, ensuring interoperability with international supply-chain, regulatory, and traceability systems.

2. Global Identification Principles

All identifiers issued under this guideline shall comply with the following **international principles**:

- Identifiers are **keys**, not data containers
- No business, regulatory, or geographic meaning shall be embedded in the identifier
- Identifiers shall be **numeric-only** and machine-readable
- Identifiers shall be **globally unique**
- Identifiers shall be **permanent** and **non-reusable**
- Identifier lifecycle shall be centrally governed
- Trust shall be established through authoritative validation

Technical readability does not imply regulatory trust.

3. Trust & Governance Model

- **The National Regulatory Authority acts as the:**
    a. Issuing Authority
    b. Validation Authority
    c. Trust Anchor
- **Recognition of issued identifiers is:**
    a. Conditional Subject to continuous compliance
    b. Revocable in case of violations

Issuance rights are granted only to entities authorized and supervised by the authority.

4. National Central Registry Requirements

A **National Central Registry** shall serve as the **single source of truth** for all issued identifiers and must:

- Store all issued product and location identifiers
- Enforce uniqueness and non-reusability
- Maintain full lifecycle status **(Active / Inactive / Withdrawn)**
- Preserve historical records without overwrite
- Maintain complete audit trails
- Support secure lookup and validation services
- Provide official validation APIs

Any identifier not registered in the Central Registry is considered **invalid by design**.

5. Product Identifier (Trade Item Number) Issuance Guidelines

5.1 Identifier Structure

- Fixed-length numeric identifier
- Preferred length: **14 digits**
- Check digit calculated using an international Mod-10 algorithm
- No embedded intelligence or classification logic

5.2 Allocation Rules

- One identifier per unique product and packaging level
- Identifier shall never change during the product lifecycle
- Identifier shall never be reassigned or reused
- Packaging hierarchy relationships are mandatory

5.3 Serialization

- Product identifiers shall support serialization
- Serialized identifiers consist of:
  Product identifier and unique serial number
- Serial numbers shall be:
  1) Unique
  2) non-repeating
  3) Fixed- length

  Note: Serial reuse is strictly prohibited

6. Location Identifier (Location Number) Issuance Guidelines

6.1 Identifier Structure

- Fixed-length numeric identifier
- Length: **13 digits**
- Check digit calculated using an international Mod-10 algorithm

6.2 Permanency Rule

The location identifier **shall not change** due to:

- Name changes
- Address changes
- Ownership changes

The identifier is deactivated only if the location permanently ceases to exist. Deactivated identifiers shall **never be reused**.

6.3 Location Scope

Location identifiers may represent:

- Legal entities
- Physical locations
- Functional locations

7. Mandatory Master Data & Attributes

7.1 Mandatory Data for Location Identifier Issuance

Legal Entity Attributes

- Registered legal name
- Commercial registration number
- Tax identifier
- Regulatory license number
- License validity dates
- Legal status

Location Attributes

- Location name
- Location type
- Full postal address
- Administrative region and country
- Geographic coordinates (recommended)
- Operational status
- Activation and deactivation dates

No location identifier shall be issued without validated legal and licensing data.

7.2 Mandatory Product Attributes for Product Identifier Issuance

A. Regulatory Attributes

Attribute	Description
Product Trade Name	Official registered name
Marketing Authorization Holder	Legal entity
Authorization Number	Issued by authority
Authorization Status	Active / Suspended / Withdrawn
Authorization Validity	Issue & expiry dates
Product Category	Prescription / OTC / Controlled

B. Pharmaceutical Attributes

Attribute	Description
Dosage Form	Tablet, Capsule, Injection, Syrup, etc.
Strength	e.g. 500 mg, 10 mg/ml
Route of Administration	Oral, IV, IM, Topical
Shelf Life	In months
Storage Conditions	Ambient / Cold Chain / Controlled

C. Packaging Attributes

Attribute	Description
Packaging Level	Each / Inner / Case / Pallet
Pack Size	Units per pack
Parent Identifier	Mandatory for hierarchy
Repack Indicator	Yes/No

D. Serialization Attributes

Attribute	Description
Serialization Indicator	Serialized / Non-serialized
Serial Number Length	Fixed
Serial Number Format	Numeric / Alphanumeric
Randomization Method	Sequential / Random
Serial Reuse	Prohibited

E. Governance Attributes

Attribute	Description
Identifier Issue Date	Creation date
Identifier Status	Active / Inactive / Withdrawn
Effective Dates	Start / End
Issuing Authority	National Registry
Audit Trail	full history

No product identifier shall be issued unless all mandatory product attributes are validated and approved.

8. Barcode, Scanner & Encoding Rules

1) Encoding shall comply with internationally recognized **2D barcode** standards

2) Identifiers shall be encoded using structured application identifiers
3) Proprietary barcode formats are prohibited
4) Barcode-level encryption is prohibited
5) Vendor-specific encoding schemes are not permitted

Any compliant scanner shall successfully read identifiers issued under this guideline without customization.

9. Validation & Lookup API Requirements: A National Validation API is mandatory and shall support:

Product Identifier Validation

- Structural validation
- Issuing authority verification
- Product status
- Packaging level

- Effective dates

Location Identifier Validation

- Structural validation
- Location status
- Entity reference
- License reference
- Effective dates

APIs shall be:
- REST-based
- JSON formatted
- Versioned
- Highly available

10. Traceability & System Interoperability

Issued identifiers shall be usable **without transformation** in:

- Traceability event models
- Aggregation and disaggregation workflows
- Shipment and receiving events
- Enterprise resource planning systems
- Regulatory reporting systems

  Custom extensions to compensate for non-standard identifiers are not permitted.

11. Compliance, Audit & Enforcement

- Continuous compliance is mandatory
- Periodic audits may be conducted
- Issuance privileges may be suspended or revoked
- Non-compliant identifiers may be blocked
- Violations may trigger regulatory escalation

12. Non-Compliance Consequences

Non-compliance may result in:

- Identifier rejection
- Event processing failure
- Market onboarding suspension

- Regulatory penalties

13. References to International Standards

- International product identification standards
- Global location identification frameworks
- International barcode and symbology standards
- Global traceability and event exchange models
- Pharmaceutical supply-chain traceability guidelines