TECHNICAL SPECIFICATION

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Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers

Informatique de santé — Exigences pour une identification internationale, lisible par capture automatique, des produits médicinaux

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

Introduction

Globally, healthcare regulators, medicinal product suppliers, and healthcare providers, among others, are facing increased pressure to ensure a more secure and safer supply chain for medicinal products. The primary objective is to ensure optimal patient safety outcomes. International organizations such as the World Health Organization (WHO) and the Council of Europe, along with many other healthcare organizations are also seeking robust systems that will deliver outcomes to enhance overall supply chain integrity, to prevent product falsification and to improve patient safety, especially at the point of care.

Machine readable coding is a technology capable of achieving these stated outcomes. Therefore, the core purpose of this Technical Specification is to provide guidance for machine-readable coding based on globally harmonized and interoperable standards for wide scale international implementation.

This Technical Specification outlines the requirements to implement international machine-readable coding on medicinal product packages in the healthcare supply chain. It assists all stakeholders implement, use, and optimize Automatic Identification and Data Capture Identification (AIDC) technologies in their respective enterprises with a particular attention to Health Informatics. In that respect, it complements ISO 11615.

As AIDC offers a wide spectrum of potential solutions, particularly for data carriers such as barcodes, it has highlighted the importance of properly defining data structures to prevent ambiguity when information is encoded and captured.

Furthermore, the semantics of data carried can be defined by a number of organizations (also called "issuing agencies"), some with commercial activities, some with a national emphasis, and others with a standard development organizations' objective. This particular specification focuses on the GS1 System of Standards[1)].

The majority of supplies (such as processed food, office supplies, apparels, medical devices and equipment, medicinal products, etc.) in healthcare around the world use the GS1 System of Standards for AIDC as it is multi-sectorial and a globally implemented system of standards. Interoperability along the supply chain is easier to achieve once a single system of standards is used in any market, including healthcare.

This Technical Specification is intended to guide healthcare packaging designers, regulatory affairs specialists, logistics operators, and others to implement AIDC solutions for healthcare.

1) GS1 is a registered trademark. Any trademark used in this document is information given for the convenience of users and does not constitute an endorsement.

Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers

1 Scope

This Technical Specification provides guidance on identification and labelling of medicinal products from the point of manufacture of packaged medicinal product to the point of dispensing the product.

This Technical Specification outlines best practice for AIDC barcoding solutions for applications. Users can, however, consider the coding interoperability requirements for other AIDC technologies e.g. Radio Frequency Identification (RFID).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO/IEC 15415, *Information technology — Automatic identification and data capture techniques — Bar code symbol print quality test specification — Two-dimensional symbols*

ISO/IEC 15416, *Information technology — Automatic identification and data capture techniques — Bar code print quality test specification — Linear symbols*

ISO 28219, *Packaging — Labelling and direct product marking with linear bar code and two-dimensional symbols*

ISO 22742, *Packaging — Linear bar code and two-dimensional symbols for product packaging*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 Terms

3.1.1
application identifier
AI
GS1[2)] prefix that defines the meaning and purpose of the data element that follows, as defined in ISO/IEC 15418 and GS1 General Specifications

[SOURCE: ISO 19762-1:2008, 01.01.94]

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3.1.2
AIDC
automatic identification and data capture
methods or technologies for automatically identifying objects, collecting data about them, and entering that data directly into computer systems, eliminating manual entry

Note 1 to entry: The methods or technologies typically considered as part of AIDC include bar codes which can be linear or 2-dimensional symbols and Radio Frequency Identification (RFID) tags/chips.

3.1.3
authentication
comparing the attributes of the object itself to what is known about objects of that origin

Note 1 to entry: Attributes include unique identifier besides overt, covert, and/or forensic solutions.

3.1.4
BAID_1
unique identifier allocated to a specific batch of a medicinal product which appears on the outer packaging of the medicinal product

3.1.5
BAID_2
unique identifier allocated to a specific batch of a medicinal product which appears on the immediate packaging (not the outer packaging)

3.1.6
batch
lot
specific manufacturing release of a medicinal product or item by the manufacturer

[SOURCE: ISO 11615:2012, 3.1.7 — modified, "lot" was added as a preferred term.]

3.1.7
batch number
lot number
identifier assigned to a specific batch of a medicinal product or item resulting from a manufacturing process at a specific point of time

Note 1 to entry: Batch number permits its manufacturing history to be traced.

Note 2 to entry: Batch number is made of series of ASCII characters.

[SOURCE: ISO 11615:2012, 3.1.8 — modified, "lot number" was added as a preferred term; notes were added.]

3.1.8
bar code
optical machine-readable representation of data, showing data about the object to which it attaches

Note 1 to entry: Originally bar codes represented data by varying the widths and spacings of parallel lines, and can be referred to as linear or one-dimensional (1D). Later they evolved into rectangles, dots, hexagons, and other geometric patterns in two dimensions (2D). Although 2D systems use a variety of symbols, they are generally referred to as bar codes as well.

3.1.9
dispense medication
prepare and give out a medicinal product in accordance with a prescription

Note 1 to entry: This includes asessing the pharmaceutical appropriateness including decision support.

3.1.10
falsified medicines
fake medicines that pass themselves off as real, authorized medicines

[SOURCE: European Medicines Agency]

Note 1 to entry: It can be contaminated or contain the wrong or no active ingredient. They could have the right active ingredient but at the wrong dose.

Note 2 to entry: WHO is using the concept of "Spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines".

3.1.11
GTIN[3)]
global trade item number
number that is used for the unique identification of trade items worldwide

EXAMPLE 1 GS1 Identification Key which comprises a GS1 Company Prefix, an Item Reference and Check Digit.

EXAMPLE 2 Used to identify trade items such as pharmaceuticals and medical devices.

Note 1 to entry: See Annex C for the relationship between MPID, PCID, and GTIN.

[SOURCE: ISO/IEC 15420:2009, 3.7 — modified, examples added; note 1 to entry added; digit length removed.]

3.1.12
healthcare system
organization of people, institutions, and resources to deliver healthcare services to meet the health needs of target populations

3.1.13
identification
way information about an object such as a trade item can be found in IT systems such as databases

Note 1 to entry: It refers to a sequence of characters (numerals and/or alpha characters). The identifier is intended to be a unique sequence structured according to a globally agreed architecture or syntax, and can or can not contain inbuilt significance.

3.1.14
identification schema
namespace
container for a set of identifiers that allows the disambiguation of homonym identifiers residing in different identification schema

3.1.15
identifier
ID
description that is sufficient to represent an object in a given environment identification schema

3.1.16
machine readable code
code, readable by a machine, that contains information used to establish a relationship between a physical object such as a medicinal product package and data sources such as medical, production, logistical and/or reimbursement coding systems

3.1.17
manufacturing/manufacture
process of production from the acquisition of all materials through all processing stages, including final packaging

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3) GTIN is a registered trademark. Any trademark used in this document is information given for the convenience of users and does not constitute an endorsement.

3.1.18
marketing authorization
authorization issued from a Medicines Reulatory Agency that a Medicinal Product may be placed on the market

[SOURCE: ISO 11615:2012, 3.1.40]

3.1.19
marketing authorization holder
organization that holds the authorization for marketing a medicinal product in a jurisdiction

[SOURCE: ISO 11615:2012, 3.1.38, — modified, "for marketing a medicinal product in a jurisdiction" added]

3.1.20
medicinal product
any substance or combination of substances that can be administered to human beings for treating or preventing disease, with the view of making a medical diagnosis or to restore, correct, or modify physiological functions

Note 1 to entry: The same definition applies for animal health.

[SOURCE: ISO 11615:2012, 3.1.49, — modified, "(or animals" removed; notes 1-2 removed and a new note 1 to entry added.]

3.1.21
MPID
medicinal product identifier
identifier allocated to a medicinal product supplementary to any existing authorization number as ascribed by a medicines regulatory authority in a jurisdiction

[SOURCE: ISO 11615:2012, 3.1.50, — modified, "unique" removed; note removed.]

3.1.22
PCID
medicinal product package identifier
identifier allocated to a packaged medicinal product supplementary to any existing authorization number as ascribed by a medicines regulatory agency in a jurisdiction

[SOURCE: ISO 11615:2012, 3.1.53, — modified, "unique" removed; note removed.]

Note 1 to entry: See Annex C for relationship between MPID, PCID, and GTIN.

3.1.23
OID
object identifier
globally unique value associated with an object to unambiguously identify it

3.1.24
outer packaging
external container in which a medicinal product is supplied

Note 1 to entry: Corresponds frequently to "secondary packaging" (see Annex B).

[SOURCE: ISO 11615:2012, 3.1.55 — modified, examples and notes removed; new note added.]

3.1.25
packaging hierarchy
relationship between a medicinal product package and its grouping in larger/smaller quantities

Note 1 to entry: See Annex B for illustration of "primary packaging", "secondary packaging", etc.

3.1.26
packaged medicinal product
medicinal product in a container being part of a package, representing the entirety that has been packaged for sale or supply

Note 1 to entry: Corresponds frequently to "primary packaging" (see Annex B).

[SOURCE: ISO 11615:2012, 3.1.57 — modified, note 1 to entry added.]

3.1.27
pharmacovigilance
science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem

[SOURCE: WHO]

3.1.28
PhPID
pharmaceutical product identifier
identifier for a pharmaceutical product

Note 1 to entry: Pharmaceutical product: qualitative and quantitative composition of the pharmaceutical product as administered to the patient in line with the regulated product information.

[SOURCE: ISO 11615:2012, 3.1.60 — modified, "unique" removed; note 1 to entry added.]

3.1.29
RFID
radio frequency identification
wireless non-contact system that uses radio-frequency electromagnetic fields to transfer data from a tag attached to an object, for the purposes of automatic identification and tracking

3.1.30
serialization
assigning a unique identifier (e.g. a number) to an item (e.g. pack, case or pallet)

Note 1 to entry: This identifier is stored on a database along with other information about the item (e.g. manufacturer, batch info, etc). Serialization typically includes randomly selected, encrypted, numerical or alpha-numeric serial number.

3.1.31
traceability
ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application, or location of that which is under consideration

[SOURCE: Global Traceability Standard for Healthcare, GS1, 2009]

3.1.32
verification
reading unique identifier numbers and checking these in a database

3.2 Abbreviations

AIDC	Automatic Identification Data Capture
PCID	Medicinal Product Package Identifier
GTIN	Global Trade Item Number (from GS1)
INN	International Non-proprietary Name

NDC	National Drug Code (from US FDA)
OID	Object Identifier
PhPID	identifier for a pharmaceutical product
RFID	Radio Frequency Identification

4 Procedural background

4.1 General

Clause 4 specifies the distinctions between identification and data carriers (machine readable coding and its international characters). It then focuses on medicinal product and the characteristics of their physical packaging in the marketplace.

Supply chain, traceability, and patient safety require appropriate labelling and the use of packaging identifiers (as described in ISO 11615). Since new processes are in development in many countries to fight against falsification, reimbursement fraud, etc., 4.7 addresses serialization, namely the unit (or instance) identification.

4.2 Identification

In this Technical Specification, "identification" means the way information about an object such as a trade item can be found in IT systems such as databases. It refers to a sequence of characters (numerals and/or alpha characters). This identifier shall be a unique sequence structured according to a globally agreed architecture or syntax, and may or may not contain inbuilt significance.

EXAMPLE 1 The identifier for one pre-filled syringe of XYZ medication is: 7665431234887. The identifier for one telephone-service subscription is: 022 592 74 25.

Uniqueness of the identifier is the key to ensuring unambiguous identification. It is important to note that the same sequence of characters can identify different items or objects belonging to different domains (or contexts), but each unique object within a single domain (or context) shall also have an unambiguous identifier. Uniqueness is also governed by the selected identification schema (or namespace) and the domains (contexts) in which the schema applies. The identification schema rules are therefore paramount.

EXAMPLE 2 7665431234887 uniquely identifies the class pre-filled syringe of XYZ medication in the domain "GS1". 022 592 74 25 uniquely identifies a web conference access point in the domain "telephone-service subscription numbers, Switzerland".

Identification is used in data processing and is usually qualified with an Object Identifier (OID), which corresponds to the data processing domain. Identification is also used in the Automatic Identification and Data Capture (AIDC) process.

EXAMPLE 3 OID < 2.51.1.1 > delimits the domain "GS1 GTIN" in which product identifier 7665431234887 is unique. OID < 0.0.17.825.0.6.8 > delimits the domain "callingPartyNumber" in which web conference access point 022 592 74 25 is unique.

4.3 International machine readable coding

Machine readable coding is the process to transcribe and capture unique identification from a data carrier such as a bar code or two dimensional symbols.

Unique coding, as described in 4.2, is required when medicinal products are intended to be used in the international market, if they physically circulate, or if information about them is used across the jurisdictions. That means that the domain (or context) is not national or regional, but global.

