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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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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]

2) 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.

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

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.

International machine readable coding is not just limited to packaging identifiers; it also encompasses attributes such as batch/lot number, expiry date, and serial numbers. Depending on medicinal product's characteristics, all of these attributes require semantics in such a way as to allow encoding and then capturing regardless of the origin of the medicinal products. Application identifiers provide the semantics of the data carried in an international machine readable code, and shall therefore be used uniformly across the global market.

4.4 Medicinal product

Medicinal products are traded in various packaging configurations, between which there is an established relationship. For example, the pharmaceutical product "Painkiller" has a market authorization for 100 mg tablets (Medicinal Product). These tablets can be packed in 10. Packages of 10 tablets can be bundled by 5; bundles can be grouped into cartons of 12 and cartons can be grouped in shipping cases of 20.

Annex B illustrates these relationships referred to as "packaging hierarchy". There are numerous complex situations which are not illustrated in this document but for which the same principles shall apply.

In the packaging hierarchy, each packaging level shall be uniquely identified.

Medicinal products can be authorized with two or more strengths, each being identified using a different and unique Pharmaceutical Product Identifier (PhPID). "Painkiller" can be marketed in 100 mg and in 200 mg tablets. Each of these strengths corresponds to a different medicinal product. There will be different packaging hierarchies, one for each strength. Again for medicinal product, all levels of packaging require unique identification.

4.5 Labelling

The term AIDC is used to describe the process of automatically capturing (without manual key entry) the identifier assigned to a product for a given level of packaging using machine readable coding. AIDC shall be delivered using a range of technologies including optical symbols, e.g. bar codes, radio frequency identification (RFID) technologies, and biometrics.

For more than 40 years, standardized optical carriers such as linear bar codes and two dimensional symbols have been used by trading partners for AIDC. RFID was once considered as a technology that could be used for hands-free mass identification and still remains among the possibilities for the future AIDC widespread adoption. Likewise, trading partners have not adopted other AIDC solutions, such as OCR and biometrics, because of lack of efficiencies, ease of encoding, decoding, and the use of proprietary algorithms. However, the use of AIDC based on standardized optical carriers does offer the possibility for users attain more efficient and effective logistics and material management. For medicinal products, the possibility of implementing AIDC at the point of care given is enabled.

The number of possible optical symbols available needs to be contained and standardized. Effective AIDC uses globally standardized symbols with standardized globally-agreed data encoded in the symbols. This ensures overall efficiency, i.e. the same type data structures encoded in a set of pre-defined symbols shall be used by any geography or economy, regardless of the type products (e.g. food, medicinal products, office devices, etc.). As a result, manufacturers shall standardize their production processes by using consistent AIDC symbols and eliminating variability.

There are many devices and software solutions available for encoding and decoding the data in the AIDC symbol. All are capable of delivering a wide variety of solutions because of the use of global standards. Software and devices ensure that they are focused on delivery standard solutions that are interoperable.

Mass production requires high quality label printing. In addition to manufacturers selecting the right optical symbol (data carrier) and correct data for the symbol, suitable software shall ensure that the print quality of the AIDC symbol is satisfactory for reading purposes. Testing symbol readability is an essential process. ISO standards have been developed for testing and measuring the readability of bar codes. Manufacturers (labellers) shall further pay particular attention to packaging/label design so that

the placement of labels on package ensures that the AIDC process is not compromised. Data encoded in the symbol should be printed in human readable format to ensure process continuity where readers may not be available, or by equipment failure.

4.6 Package identifier

There are a number of identification relationships that should be understood for effective AIDC of Medicinal Products. This includes the relationship between the Pharmaceutical Product Identifier (PhPID), Medicinal Product Identifier (MPID), Packaging Identifier (PCID), Marketing Authorization number, and Global Trade Item Number (GTIN). The relationship between the Marketing Authorization number and the GTIN varies depending on regulatory framework. There are two main scenarios:

— The Marketing Authorization number and the GTIN can be the same (i.e. the same sequence of characters). Examples of this situation can be observed in the US or in France (see Annex D).

— A single Marketing Authorization number is delivered by a central Regulator for different markets. Different GTINs shall be used to distinguish the different packages of the same medicine as the actual packaging differs from one market to another. An example of this situation is seen in Europe (i.e. there is central marketing authorization, but there is country specific packaging in the European Member States). The Marketing Authorization number issued is related to the GTIN in a database, not via AIDC.

Annex D illustrates the current scenario in some countries.

The GTIN-14 standard is defined as the unique 14-digit identifier for items; it includes, in sequence, the following:

a) Indicator digit: The indicator digit is a one-digit logistical code, which value can be a zero (0);

b) Country code: The country code is the country code corresponding to the GS1 member organization of which the brand/license owner is a member;

c) Brand/license owner code - Company prefix: The brand/license owner code is a code allocated to the brand owner by the GS1 member organization of which the brand/license owner is a member;

d) Product code: Product codes are unique numbers. The value for product code is arbitrary and is at the discretion of the brand/license owner;

e) Check digit: A final digit calculated from the other digits of some GS1 Identification Keys. This digit is used to check that the data has been correctly composed.

4.7 Serialization

The serial number is an attribute of the product identifier (Global Trade Item Number, GTIN). This means that the combination GTIN + Serial Number provides the uniqueness required to develop tracking and/or verification to the ‘instance’ level of the item for a given level of packaging.

Serial numbers can be either alpha or numeric characters. Alpha characters, as well changing a character set (see ISO/IEC 8859-1:1998 and ISO/IEC 10646:2012 in the Bibliography), requires more space in the data carrier, but increases the numbering capacity with fewer characters. The user community has limited the size of the serial number to a maximum of 20 characters.

Serial numbers are allocated to secondary or tertiary level packaging, and shall not be found on the primary package (unit of use, i.e. blistered solid forms) packaging. A medicinal product marketed in its primary package [i.e. hospital packaging package (bottle) containing hundreds of solid form] shall have a GTIN and should be serialized.

When medicinal product packaging is assigned a GTIN and is serialized by the manufacturer at the time of production, the combination GTIN + Serial Number shall be stored in a database so that events about each item shall be recorded by supply chain partners.

5 Usage requirements

5.1 General

Machine readable coding systems (AIDC systems) are both widespread and international. The initial requirements arose from the need of businesses to implement automated re-ordering from suppliers (often, wholesalers) and when combined with AIDC at the point of sale, allowed businesses to adopt a non-specific AIDC schema regardless of product type.

Over the years, AIDC or international machine readable coding has grown in importance. AIDC is now used for stock management, traceability, patient safety, and in the combat against product falsification. Clause 5 provides a review of the business processes and normative requirements.

5.2 Traceability

5.2.1 Principles

For the purpose of this Technical Specification, traceability is considered from the point of manufacture to the finished and packaged medicinal product, ready for supply according to the market authorization. Traceability ends when the medicinal product has been dispensed, applied, or administered.

Traceability requires identification and other related information about the medicinal product being captured or exchanged throughout the supply chain.

Traceability can be required at different levels of granularity. Depending on regulatory requirements, trading partner needs, and business requirements, traceability shall be enabled by product identification (level one), by production batch and expiry date (level two), and by serial number, (level three). See 5.3 for more information.

NOTE When identification is required at the level of a unique serial number, the term "*unique identifier*" is commonly used.

EXAMPLE 1 European Union, Directive 2011/62/EU of the European Parliament and of the Council (…) on the Community Code relating to medicinal products for human use (…), "unique identifier" in Article 54a, § 2 (a).

As medicinal products are assembled in a packaging hierarchy, identification data shall be labelled in a machine readable form ready for AIDC on each level of the hierarchy.

Each level of packaging requiring traceability needs a unique identifier (GTIN). The unique identifier shall never be re-used (this applies to all packaging hierarchies). Batch number and expiry date shall be consistent/identical on the different levels of the hierarchy.

In some special cases (for example, kits where two or more different items are grouped in a single secondary packaging), the batch number and expiry date applied to the secondary packaging and higher levels of packaging refers to the grouping as a whole.

EXAMPLE 2 Sweetdream i.V. in a kit (BAID_1) including a vial with powder (BAID_2) and a second vial with water for injection (a second BAID_2 level).

5.2.1.1 Repackaging

If for any reason the medicinal product is repackaged along the supply chain channel, this process is considered a manufacturing step and traceability shall be secured from the original pack to the resulting 'repackaged' pack. Subsequently, the re-packager or the local distributor as a contracting party or local product 'sponsor' is legally responsible for the repackaged medicinal product. This change should lead to a new GTIN (e.g. for changes such as a new leaflet in another language being included in the packaging), however the assigned lot/batch number and expiry date should remain unchanged.

5.2.1.2 Compounded preparation

Compounded preparations are medicinal products generally consisting of active substances that can be combined with excipients, formulated into a dosage form suitable for the intended use (with a patient), where necessary after reconstitution, presented in a suitable and appropriately labelled container. New identification shall be issued to these products to secure traceability to the final use.

5.2.1.3 Reconstitution

Reconstitution is the manipulation to enable the use or application of a medicinal product with a marketing authorization (e.g. solving a powder to a solution) in accordance with the instructions given in the summary of product characteristics or the patient information leaflet. The identification of the separate products that are used to make the final product shall be available and linked to the new product for traceability of the process.

5.2.2 Normative options

To enable efficient and effective traceability, supply chain partners shall use the same identification schema or data structure, which includes product identification, and if required, batch identification, and expiry date or serial number. Medicinal product identifiers across all packaging hierarchies shall never be re-used. Standardized data carriers shall also be used, not only to ensure reading devices can be programmed to capture and process data, but also to provide a robust machine readable code for AIDC that can be processed automatically regardless of product type, its supplier, or its origin.

Several jurisdictions have adopted international machine readable coding for AIDC as a regulatory requirement.

EXAMPLE 1 France: Notice to human-use medicinal product marketing authorization holders and head pharmacists of the pharmaceutical establishments cited in article R. 51242 of the French Public Health Code (CSP) 21 February 2007, § 2: “In liaison with the representatives of the pharmaceutical industry, the French Agency for the Safety of Health Products (AFSSAPS) has selected the principle of switching CIP code, from 7 characters to 13 characters, and from barcode 39 to EAN 128 (combined with ECC.200 Data Matrix marking) as per the EAN.UCC system” (see www.ansm.sante.fr).

In other jurisdictions, stakeholders have added such a clause in their request for tenders.

EXAMPLE 2 Spain: “Technical Commission for Health Services Purchasing and Logistics (CTCL)”, Product identification through shared standards would lead to the unification of the bar code and symbol system so that products could be identified automatically by product suppliers through the use of GS1 codes (…)” (see see www.ctcl.es/).

There are also healthcare institutions that recommend the use of international machine readable coding for AIDC for their healthcare product suppliers.

5.3 Measures to combat falsification of medicines

5.3.1 Principles

A falsified medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Falsification equally applies to both branded and generic products.

Preventing falsification can involve various techniques on the secondary packaging. Together with the serialization of each medicinal product pack (i.e. use of a “unique identifier”), these techniques can be - overt, covert, and/or forensic solutions.

In addition, the user community has recognized that serial numbers shall not be issued sequentially (as sequential numbers can be predicted by non-authorized persons) but in a pseudo-randomized manner. Falsifiers face greater difficulty with randomly generated serial numbers. Pseudo-randomized means that each serial number remains unique but over the range of numbers that is not predictable. Serialized numbers shall never be reissued.

5.3.1.1 Using serialization

Using the product identifier GTIN and a serial number to create "unique identifier", there are two main approaches to fight against medication falsification:

— product authentication;

— supply chain integrity (example with ePedigree).

5.3.1.2 Product authentication

The product shall be authenticated at the end of the supply chain by validating, in a database, the unique identifier on the medicinal product packaging, besides checking further characteristics (overt, covert, and/or forensic solutions). In this case, the unique identifier shall have been issued by the manufacturer, and shall not have already been verified by another supply chain partner. It is assumed that the first authentication of GTIN and Serial Number corresponds to the authentic item.

Authentication fails if the same unique identifier is verified repeatedly (i.e. more than one instance of the serialized product exists), or if the unique identifier is not referenced in the database (i.e. the given instance of the product was never created by the manufacturer).

In the first situation, when several supply chain partners issue a database query for the same unique identifier, all of the medicinal product packages under review shall be considered suspicious. In the second scenario, when one or more supply chain partners issue a database query for an unknown unique identifier, all of the medicinal product packages under review shall be considered suspicious.

5.3.1.3 Supply chain integrity

Supply chain integrity consists of collecting and sharing information of the medicinal product along the supply chain at each point in the journey, i.e. from the manufacturer to dispensing or administration of the medicinal product to the patient. At each step in the journey, each event shall be recorded and linked to the previous and subsequent event. The integrity of the supply chain shall be verified at each step in detail. Incoming medicinal products, without the integrity of previously recorded steps, shall be detected and considered as suspicious.

5.3.2 Normative options

Manufacturer representative associations recognize that product serialization and the associated data processing provide additional security against falsification. This shall be achieved when product identification (GTIN) is associated with serial numbers which are generated using pseudo-randomized algorithms (this provides unique product identification). Each manufacturer shall implement secure randomization algorithms which ensure that serial numbers cannot be duplicated or predicted, and at the same time ensure that each serial number remains unique.

For the supply chain partner at the end of the supply chain, capturing product identification and serial number on the secondary pack level shall be the basis for implementing an authentication or integrity checking process.

For supply chain partners, such as logistics service providers, it may not be possible to access individual serial numbers on the secondary packaging because they were enclosed in tertiary units, e.g. logistic packaging. In this situation, machine readable codes on the tertiary level packaging should be used for tracking and tracing (see Annex B). If supply chain integrity is required, then manufacturers shall aggregate and share the product identification and serial numbers of all items in a tertiary or higher package level.

Printing pseudo-randomized serial numbers is an in-line process which takes place during packaging. When selecting printing solutions, particular attention should be given to:

— printing speed (i.e. line speed and ink drying time);

— verification speed (i.e. in-line reading device to capture the printed symbol and verify data content and then eliminate non-readable or damaged packages, etc.);

— printing quality (readability of symbols, according ISO/IEC 15415).

Repackaging or re-labelling of products can be accidentally or deliberately used to change the product expiry date and therefore undermine patient safety. A database should be set up by the manufacturer to allow the supply chain partners and, possibly, the patient access to the initial assigned expiry date. A query, with a scanner or mobile device, using the unique identifier on the package should allow the patient to look up and access the information and compare it with the date on the label. If the dates are different, the product can be unsafe to use.

5.4 Improving patient safety at point of care

5.4.1 Principles

Following the release of the 1999 Institue of Medicines (IOM) report[29] "To err is human", several discussions took place about how medication errors, which are a significant part of the healthcare system dysfunction, could be reduced and eliminated. At this time, the US-FDA proposed a rule for the identification of medicines down to the unit-of-use level (i.e. pre-filled syringe, blistered sold forms, etc.). Concurrently, a number of hospitals in The Netherlands and Belgium started to work on "bedside scanning". Since the IOM report, research, reported in academic publications, has demonstrated the effectiveness of "bedside scanning", i.e. AIDC at the point of care. This has resulted in implementations in numerous countries. International machine readable coding enables the infrastructure for AIDC at point-of-care. It allows healthcare providers to implement better patient safety using scanning at the point of care. This is independent of the supplier or/and the geographic origins of the product.

Identification of the product shall be captured by AIDC at the point of dispensing and prior to medication administration to improve patient safety at the point of care. Cross-matching shall be processed with patient's electronic prescription. When using AIDC, other benefits such as last minute prescription changes can be highlighted, "right" administration time can be verified, and patient records shall be captured without errors and delays that arise when manual recording is used.

5.4.2 Normative options

Product identification shall be the priority at the point of care. This ensures the correct medication and strength has been selected. The identification can be simply the GTIN or, depending on the type of product, the GTIN together with the batch number and the expiry date. Additional attributes may be required for special categories of medicines, e.g. biological products, blood derivatives, oncology products, or parenteral nutrition items.

The GTIN as an identifier shall remain active, even after the product has been deleted. For medicinal products GTIN shall never be reallocated.

Regardless of the supplier, the type of product, or its origin, healthcare providers require consistency in the identification data structures and the data carriers (bar codes) in order to implement AIDC at point of care. Likewise, software and hardware vendors require the same consistency of data and machine readable code to ensure that their products meet the requirements of the healthcare providers' and are affordable to implement.

Annex B illustrates that the same machine readable coding system shall be used along the product hierarchy. Implementation for manufacturers as well as for business users shall be facilitated with consistency of identifier and symbol. It further reduces the risk of interpretation and de-coding errors.

5.5 Support of healthcare systems

NOTE A Healthcare system is the organization of people, institutions, and resources to deliver healthcare services to meet the health needs of target populations.

5.5.1 Principles

AIDC, using international machine readable codes, provides the necessary infrastructure for automatically capturing and recording data in healthcare systems. The data capture and recording process usually involves a number of IT systems, such as those for stock management, reimbursement or cost calculation, and patient electronic health records, e.g. public health initiatives such as vaccination programmes, should use international machine readable coding for data capture in electronic health records, as would code scanning at point of dispensing or administration.

Research organizations that collect market data for commercial or academic analysis, profit from capturing the unique identification of products at various nodes and stages in the supply chain. Some jurisdictions have implemented regulatory processes by leveraging international machine readable identification: narcotic control, track and trace for radioactive medicinal products, etc.

Examples of other applications where international machine readable codes provide benefits in healthcare IT systems are as follows:

a) Pharmacovigilance: When patient treatment data are recorded across the community for epidemiology purposes, post-market surveillance, and Periodic Safety Reports (PSUR), AIDC shall ensure that speedy, accurate, and consistent data are captured for accurate and detailed analysis. GTIN and attributes such as batch number, expiry date, and serial number are important to be quoted into pharmacovigilance messages.

b) Product recall: If AIDC has been used throughout the supply chain to capture medicinal product identification, this would facilitate efficient realization of where the recalled products are located. In addition, AIDC is used to facilitate accurate retrieval of the recalled products from the storage locations and help prevent dispensing a recalled product.

c) Costing: In healthcare, costs are calculated processes such as Diagnose Related Groups DRGs, “cost based” reimbursement (also called case-based or procedure-based costing), and consumption reporting. Accurate data capture, for each patient, is a pre-requisite for accurate costing. AIDC is used to capture product usage ensuring the granularity necessary for accurate costing.

d) Statistics: Statistics, respecting privacy of both patients and healthcare providers, are regularly produced by various agencies. Statistics are often generated based on raw data collected using AIDC technologies. Accurate and relevant statistics impact decisions made by companies, healthcare providers, and public health bodies.

e) Regulatory control: Some medications such as narcotics and radiopharmaceuticals have particularly strict reporting requirement by users to Regulatory Bodies. AIDC is used throughout the supply chain, dispensing and administration processes facilitate accurate data capture for reporting purposes.

f) Health programmes: Within healthcare programmes such as homecare treatment of chronic illnesses (e.g. haemophilia, diabetes, peritoneal dialysis), AIDC supports supply chain delivery to the patient.

g) Mobile technology: AIDC enables mobile technology devices and applications to protect the patient from harm, i.e. prevent incorrect product being used, highlight batch numbers that should not be used because of a recall, etc., and populate an electronic patient record by transmitting information to the health record storage location. Particular attention has to be given to the source of information to which mobile applications link. Trusted source of information should be certified with solutions such as HON code (see Health on the Net Foundation, http://www.hon.ch).

5.5.2 Normative options

Fundamentally, healthcare systems (e.g. patient record systems, medication management systems, pharmacy dispensing systems, procurement systems, finance systems, etc.) shall hold the unique identifier (and associated traceability information such as batch number, expiry date, etc.) for the product at the required level of packaging, and link this to the product master data (e.g. description,

pack size, regulatory information, etc.). Given these, different healthcare systems deal in different levels of product packaging (e.g. the pharmacy procurement system can require identification of the tertiary level packaging, but the medications management system will require identification of the primary and secondary packaging), hierarchical linkages between these levels of packaging and their identifiers shall be established and maintained within these systems.

Public health messages (e.g. pharmacovigilance) and files (e.g. vaccination) shall include precise documentation with medicinal product's identification. This is achieved with a GTIN, batch number, expiry date and, when available, serial number.

5.6 Procurement and stock management

5.6.1 Principles

Warehouse and distribution operations are similar in all industry sectors that have a combined product movement-storage-pick operation or facility of any size, whether this facility handles single items, cartons, pallet loads or bulk materials. In recent years, warehouse, distribution operators, and inventory control managers have made significant progress in improving inventory control and stock management in the healthcare sector. The use of international machine readable codes (bar codes) and scanning devices enabling AIDC has improved procurement and stock management processes, leading to improved supply chain efficiency and performance through more accurate, readily available information.

It is clear that organizations benefit through efficiency gains and financially when supply chain, warehouse and logistics operations are based on and use internationally standardized and interoperable coding systems (i.e. identification systems and identifiers). Standardization, as outlined, offers enhanced supply chain visibility that assist all stakeholders both in realizing business efficiencies but also in improving patient safety outcomes.

The benefits of international machine readable coding can be realized in many areas including the following:

a) Inventory management: Inventory management or stock management are processes that ensure that the right product is in the right place or is transferred to the right place in the correct quantity. The processes move stock to locations that satisfy the production requirements at the lowest handling (storage-pick) cost. The benefits include stock optimization across the packaging hierarchies for procurement and order fulfilment requirements, minimising product spoilage and waste, enhancing warehouse utilization and improving stock visibility, providing more efficient stock audit, and detecting and managing shrinkage. AIDC, based on international standards, are used throughout the supply chain to capture data accurately for the inventory/stock management systems.

   Studies in the Australian pharmaceutical sector (see Bibliography) have indicated that use of AIDC (coupled with electronic messaging) can lead to:

   1) decreased claims: greater than 80 % reduction;

   2) decreased hospital receiving time: 15 % reduction;

   3) decreased incorrect deliveries: 46 % reduction.

   These statistics illustrate that when AIDC is used to capture and record medicinal product identifiers, it is more efficient, accurate, and effective than manual processes. The benefits of the inventory/stock management is maximised when AIDC is used.

b) Product safety alerts - product recall: Product safety alerts signal the need to isolate and remove defective goods from the supply chain. The safety concern can arise due to a manufacturing defect which can harm the user. While the safety alert or product recall procedures can vary between jurisdictions, the use of standardized product identifiers in international machine readable codes,

and where relevant, additional information such as batch, lot, serial number embedded within code, and AIDC enhances the efficacy of the alert/recall process.

c) Supply chain interoperability: The characteristics and complexity of global commerce has elevated the importance of interoperability to enhance productivity, efficiency, and competitiveness in many industry sectors. Data interoperability based on international identification standards is integral to efficient and agile product life-cycle management systems. A globally standardized product coding system across all packaging hierarchies is viewed as essential for creating seamless integration between applications and supply chain partners. Cooperation and information sharing across organizations helps everyone achieve product quality more cost-effectively while providing benefits that enhanced supply chain visibility provides.

5.6.2 Normative options

Software vendors shall develop solutions for Warehouse Management, Robotic Dispensing, etc. using international machine readable coding and AIDC. Using this type of software optimizes/maximizes the benefits and at same time reduces the cost of ownership. The software shall enable the use of product hierarchies, production identification, batch/lot/serial number tracking, expiry date management, as well as managing the space constrained warehouse. In addition, software shall include the use of electronic data interchange, by using international standards, so that collaborative processes can be operated with supply chain partners.

5.7 Overview of the normative options

Table 1 shows an overview of the normative options.

Table 1 — Overview of normative options

Usage requirements	Medicinal product package identifiers	Lot/batch number	Expiry date	Serial number
Traceability (5.2)	X	X	X	(X)
Measures to combat falsification of medicines (5.3)	X	(X)		X
Improving patient safety at point of care (5.4)	X	X	X	
Support of Healthcare Systems (5.5)	X	X	X	X
Procurement and Stock Management (5.6)	X	X	X	

6 Economic aspects

6.1 General

Based on Clause 5, implementing machine readable coding for medicinal products represents a reasonable investment. The level of investment required is impacted by the local, proprietary, or international aspects of the chosen solution and by the market and/or the regulatory influences.

This Technical Specification is focused on international machine readable coding and reflects the experiences reported by a considerable number of users, both manufacturers and healthcare providers. In some industries, and on a voluntary basis, international machine readable coding has been adopted and is part of the daily business activities. As healthcare is strongly regulated, this industry has not been

able to adopt machine readable coding on a voluntary basis. However, where there are opportunities, adoption of the most widely used international machine readable coding architecture, namely GS1, has come to reality.

Recent developments in the healthcare industry are strengthening the need to adopt globally harmonized machine readable coding. As regulation requires more granular traceability, adoption of proprietary solutions will increase manufacturing costs and user implementation costs.

6.2 Manufacturer perspective

Manufacturers in both addressing their home markets and other target markets recognize the need to implement harmonized machine readable coding system. International manufacturers are likewise seeking common approaches so that they can equip their production lines at different production sites and in different countries with the same methodologies and tools.

Producing medicinal products for specific target markets implies that the packaging has to be localized for language purposes and for other specific requirements imposed by the regulator. When these requirements include machine readable coding, the manufacturer shall establish a country specific solution which is, not only potentially costly, but also requires additional technical controls (particularly for product serialization).

Manufacturers reengineer production lines to address new regulatory requirements, i.e. serialization, a trend that is anticipated to gain more global momentum over the medium term.

6.3 Healthcare provider perspective

Healthcare providers are at the cross-road for receiving supplies from a wide variety of sources, such as office supplies, food, capital equipment, medical devices, and medicinal products. In many ways, hospitals are hubs.

Implementing stock management and internal logistics disciplines and procedures by using common global coding standards and IT network architecture, regardless of vendor, has recognized positive impacts on operational efficiency and consequently, constrained operating budgets. When considering quality and safety of patient care, this is when the product and supply chain identification keys and attributes enter the clinical IT infrastructure. Implicitly, primary packaging level identification availability, managed and maintained by the manufacturers, becomes essential. Disposing at the point of care of international machine readable coding facilitates implementation of verification tasks by the individual providers. To avoid any workaround, the data capture process shall be quick and transparent, which harmonized coding and architecture make possible.

Annex A
(informative)

Relationship between PhPID and MPID (Referencing ISO 11615 and ISO 11616)

A.1 Introduction

The relationship between PhPID and MPID is explained in ISO 11616, Clause 6. The example and graphic are reproduced below in Figure A.1.

A.2 Example

If a medicinal product contains the same elements as defined for a particular PhPID level, they will share an identical PhPID. For example, a medicinal product A with a drug substance X, will share a common PhPID1 level with medicinal product B containing the same drug substance X. Furthermore, if medicinal product A and B both contain substance X with an administrable dose form Y, but a different strength, PhPID1 and PhPID3 would be identical, but PhPID2 and PhPID4 levels would have a different PhPID assigned due to the differences in strength.

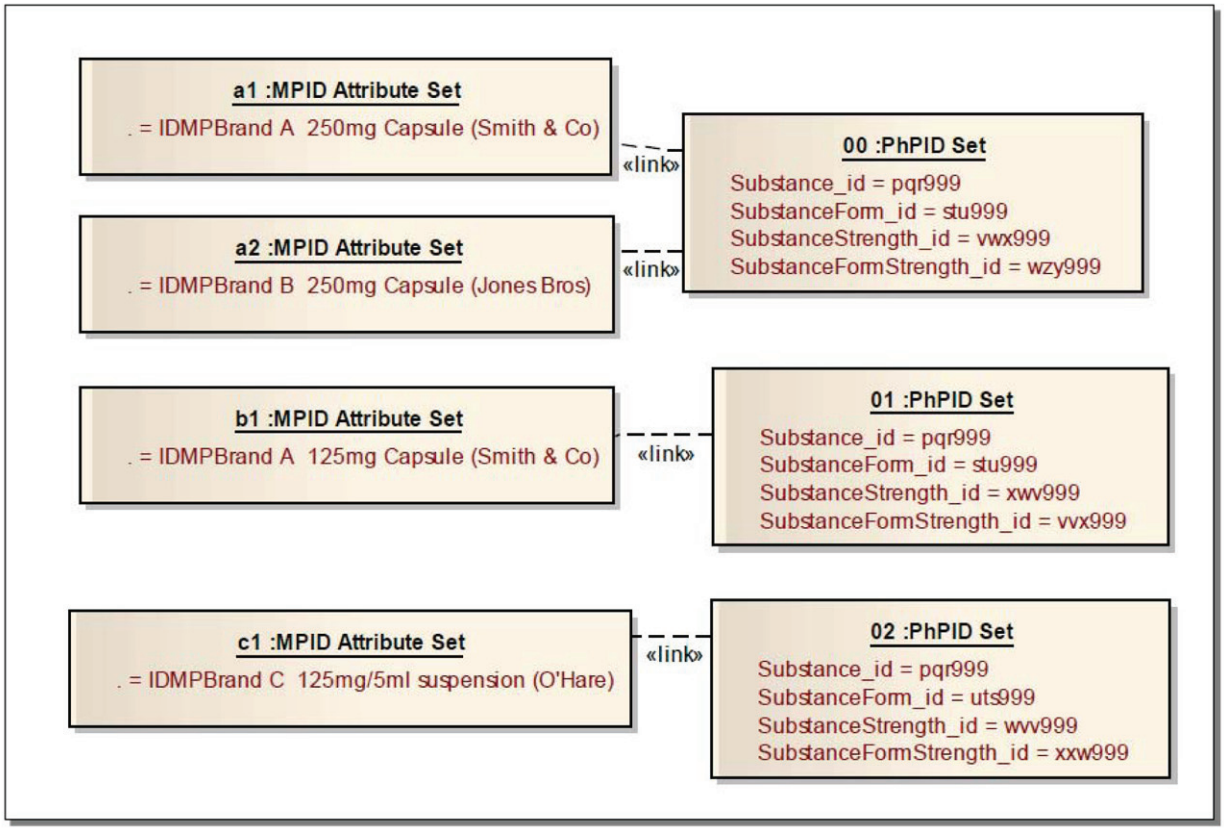

Figure A.1 — Illustration of the relationship between MPID and PhID

NOTE SOURCE: ISO 16616, 6.1, Figure 3.

Annex B
(informative)

Packaging hierarchy

Figure B.1 outlines the use of unique product identifiers for each level of packaging (i.e. 'The Packaging Hierarchy'); the relationship between the packaging hierarchies and the use of additional product attribute information, including batch/lot and expiry information. Depending on the product's characteristics, labelling (identification) requirements can vary.

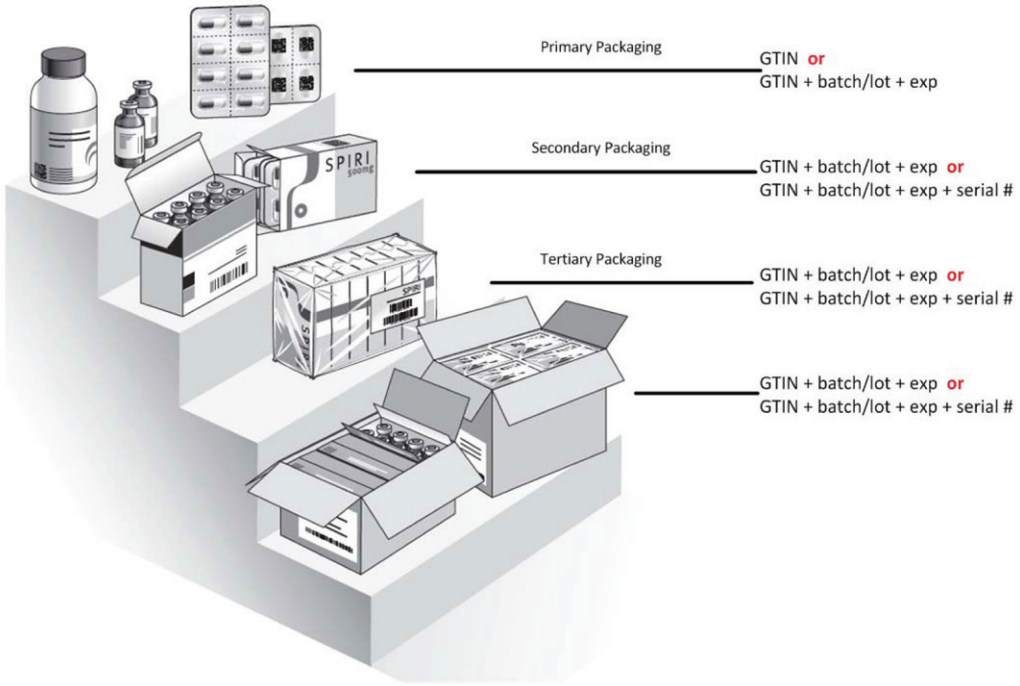

Figure B.1 — Packaging Hierarchy

Products packaged in primary packages can be used in different secondary packages. For example, Dourêve 20 mg caplets in blisters of 12 (primary packaging), can be packed in "24" or "96" secondary packs. The same blisters can be packaged for geographical markets (e.g. Switzerland, Belgium). The manufacturer uses the same GTIN to identify Dourêve 20 mg caplets in the primary package; however, the secondary packs will have different GTINs. When medicines are labelled with an international machine readable code at primary packaging level, as illustrated, the product identification at the primary packaging level has to be different to that of the secondary packaging.

When applying international machine readable codes to primary packaging, manufacturers must print the data carrier on a small surface at high speed. It has been demonstrated that DataMatrix (ISO/IEC 16022) is the best symbol for this type of implementation.

Annex C
(informative)

Relationship between MPID, PCID and GTIN

Figure C.1 shows the relationship between MPID, PCID and GTIN, when the same primary package is marketed in different pack sizes (secondary packs with two, respectively, one blister).

The PCID is the concatenation of MPID and a Package Description Code segment, which refers to an identifier for each package (see ISO 11615, 6.3.1).

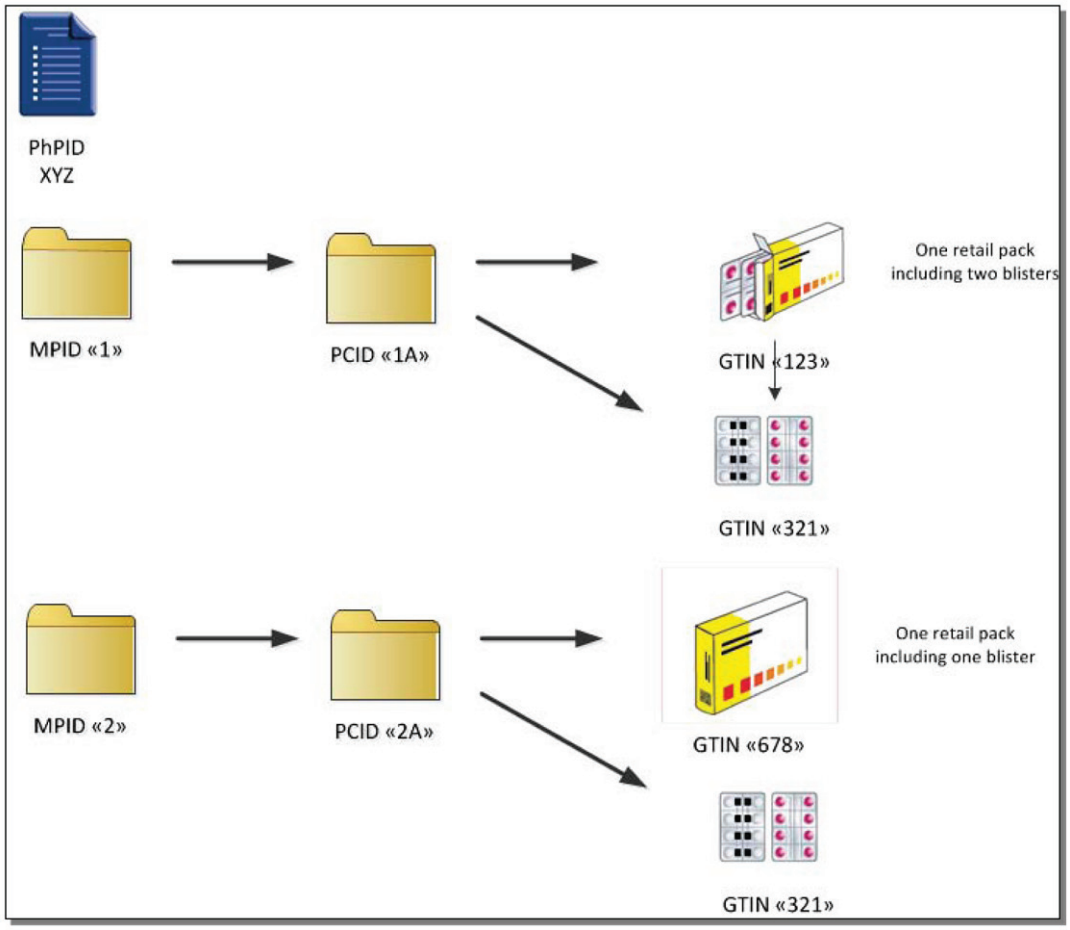

Figure C.1 — Relationship between MPID, PCID and GTIN

Annex D
(informative)

Examples for Package Identifier

The following is an example of a case for a package identifier. The situation is hypothetical and the names are fictional but can be used as an example of how package identifiers are set up in different jurisdictions.

Safedrug Ltd has developed a new medicinal product, which is submitted first to the US FDA, then to Regulators from European countries. The pharmaceutical product will be named “Sweetopam” [INN].

Sweetopam will be given “adb123” by the Maintenance Agency on behalf of US FDA as level 1 PhPID. This identification will be used by all regulators.

Table D.1 shows examples for package identifiers in different markets.

Table D.1 — Examples for package identifiers in different markets

Example 1 US Market		Sweetopam will be marketed in the US in oral solid forms (20 mg), packed in blisters of 10 caplets and called "**Sweetdream**":	
	One PhPID L4	sweetopam caplet 20 mg	sweetopam caplet 20 mg
	Two presentations	Sweetdream 20 mg caplets in a pack of 30	Sweetdream 20 mg caplets in a pack of 100
	One authorisation	delivered by US FDA for Sweetdream 20 mg caplets	
	One MPID	MPID (FD-12345-123) for Sweetdream 20 mg caplets	
	Two PCID's	delivered by US FDA: –01 (Sweetdream 20 mg caplets in a pack of 30)	delivered by US FDA: –02 (Sweetdream 20 mg caplets in a pack of 100)
	NDC	MPID + PCID constitute the NDC: 1234512301	MPID + PCID constitute the NDC: 1234512302
	GTIN (=embedded NDC)	GTIN 312345123017	GTIN 312345123024
	GTIN blister	31xxxxxxxxx	31xxxxxxxxxxx
Example 2 Dutch Market		Sweetopam will be marketed in The Netherlands in oral solid forms (20 mg) packed in blisters of 10 tablets and a vial of 250 tablets	
	One PhPID L4	sweetopam tablet 20 mg	sweetopam tablet 20 mg
	Two presentations	Slaapzacht 20 mg tablets in a pack of 3 blisters of 10 tablets	Slaapzacht 20 mg tablets in a vial of 250 tablets
	One authorisation	delivered by the Dutch Medicines Evaluation Board (MEB): RVG number 012345	
	One MPID (Z-Index)	HPK 1123456	
	Two PCID's		
	Zl-nr (Z-Index)	15123456	15789012
	GTIN blister (MoH)	8712345600044	-
	GTIN pack (MoH)	8712345600051	8712345600068
Example 3 Dutch Market		Sweetopam will be marketed in The Netherlands in oral solid forms (20 mg) packed in blisters of 14 tablets	
	One PhPID L4	sweetopam tablet 20 mg	sweetopam tablet 20 mg
	Two presentations	Slaapdiep 20 mg tablets in a pack of 2 blisters of 14 tablets	Slaapdiep 20 mg tablets in a pack of 7 blisters of 14 tablets
	Two authorisations (EU)	delivered by the European Medicines Agency (EMA)	
	EU-number	EU/1/00/999/004	EU/1/00/999/006
	One MPID (Z-Index)	HPK 1423456	
	Two PCID's		
	Zl-nr (Z-Index)	15345678	15901234
	GTIN blister (MoH)	8712345600075	8712345600075
	GTIN pack (MoH)	8712345600099	8712345600015

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