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Health informatics — Business requirements for an international coding system for medicinal products

*Informatique de santé — Exigences d'affaire pour un système
de codage international pour les produits médicaux*



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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Introduction

As pharmacy and medication business computerisation expands across all aspects of the health sector, there are increasing demands for interoperability and integration across distinct domains and among health platforms. Therefore, the computerisation of the health sector extends to drug administration and management including the prescribing, dispensing, administration and management of commercial supply chains. The satisfactory free flow of information concerning medicinal products locally, nationally and internationally will depend on the efficient and unambiguous use of international medicinal product drug codes. For the electronic sharing of pharmacy information (e-pharmacy) at an international level, an international coding system is a core product. The purpose of this Technical Report is to define the business requirements of an interoperable electronic health record at an international level as the exchange of information relates to medication and medicinal products.

Government agencies, healthcare providers and healthcare related companies all face obstacles in managing drug information due to the absence of a unified international medicinal code system as it relates to international sharing, not necessarily for domestic use. There is currently considerable duplication of effort in this area created by divergent coding systems. For example, in Korea, a national policy for implementing a Drug Utilisation Review (DUR) program is being enforced to improve medication safety and quality of prescribing and dispensing. Because there are no national identification drug codes for all products, each medical institute or system vendor is facing difficulties in mapping codes for sharing DUR information. The Korean government therefore commissioned a research project to develop a national coding system for medicinal products and to establish ancillary coded information by 2006. Whereas the EAN (European Article Number) system was evaluated and seen to have very efficient code structures, the EAN was deemed to have weaknesses in that there is no systemic ancillary code system. Other countries are experiencing similar problems and seeking similar solutions since code mapping requires a large expenditure of resources and imposes considerable expense.

If an international coding system for medicinal products could be created and maintained, this would be a major contribution to solving some of the problems currently being experienced.

The aim of this Technical Report is to:

- 1) identify the international business requirements an international coding system will need to satisfy;
- 2) determine the extent to which existing international coding systems meet the business requirements; i.e. why and to what extent an existing system could provide the basis of a unified international medicinal code structure;
- 3) discover the key international business concepts for a unified international coding system for medicinal products;
- 4) consider the issues involved in reconciling divergent systems into a satisfactory international system;
- 5) identify the next steps to bring forth or produce a unified international coding system.

Health informatics — Business requirements for an international coding system for medicinal products

1 Scope

The scope of this Technical Report covers:

- a) specifying the international business requirements for an international coding system for medicinal products;
- b) analysing the most significant international coding systems for medicinal products in current use and within the context of the objectives that each system was designed to serve;
- c) assessing the potential ability of each international coding system to fulfil the identified *international* business requirements of an international coding system for medicinal products;
- d) considering the issues involved in producing a unified international coding system which will meet all business requirements;
- e) recommending next steps for a unified international coding system for medicinal products.

2 Terms and definitions

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

2.1

medicinal product

manufactured product intended to be administered to human beings for treating or preventing disease, with the view to making health diagnosis or to restore, correct or modify physiological functions

2.2

medicinal product code

code assigned to each uniquely identified medicinal product. The code is used once within the lifetime of the database without duplication internationally for each medicinal product

2.3

country code

unique identifier code for a country in which the product is marketed

2.4

company code

A unique identifier for a company that manufactures and/or distributes the drug product

2.5

drug formulation code

potential coding structure/schema that supports ISO/TR 25257 business requirements

NOTE 1 This is a unique identifier code that is a concatenation representing the unique combination of active ingredient name, product name, route of administration, dose form, strength and strength unit of measure, country code, company code and package size.

NOTE 2 The drug formation code supports a hierarchy naming concept consisting of several levels each providing more specific information about the medicinal product.

2.6
route of administration
path by which a drug is administered in the body. In the case of injection, an intravenous route is injection in a vein

NOTE 1 In the case of parenteral/non-injection route, inhalation is medication to be taken by inhaling.

NOTE 2 Other examples are oral, translingual, buccal, injection, perfusion, topical and nasal.

2.7
pharmaceutical form
physical presentation of a drug, such as tablet, capsule, or liquid

NOTE The pharmaceutical form can incorporate the delivery and release mechanism of the drug.

[ENV 12610]

2.8
strength and strength unit of measure
potency of the drug, usually expressed in a metric quantity

EXAMPLE 500 mg

2.9
package size code
'number of billing units' in the labelled quantity which the pharmacist dispenses; identifier code for the package size of the products where a product may have more than a single type of package

EXAMPLE 100 tablets or 10 capsules or 10 vials. PLAVIX Film Coated Tablet 75 mg 100. Packaged as 100 tablets per container. For the lowest level of pack size to identify a unit of the product, the package size code can be assigned as dummy code "00".

2.10
virtual product name concept
permanent numeric identifier for the varying levels of medicinal product specificity virtual forming the framework of the proposed international coding system for medicinal products

See Table 1.

Table 1 — Type of virtual product name concept

Virtual Product Name Concept (class)	Description	Example (similar to)
Virtual Active Ingredient Name	Ingredient Name	Warfarin Sodium
Virtual Active Ingredient Name — Virtual Product Name	Ingredient Name + Product Name	Warfarin Sodium; Coumadin
Virtual Active Ingredient Name Virtual Product Name — Route of Administration	Ingredient + Product Name + Route of Administration	Warfarin Sodium, Coumadin, Oral
Virtual Active Ingredient Name — Virtual Product Name — Route of Administration — Dose Form	Ingredient + Product Name + Route of Administration + Dose Form	Warfarin Sodium, Coumadin, Oral, Tablet
Virtual Active Ingredient Name — Virtual Product Name — Route of Administration — Dose Form — Strength and Strength Unit	Ingredient + Product Name + Route of Administration + Dose Form + Strength + Strength Unit	Warfarin Sodium, Coumadin, Oral, Tablet, 10mg
Virtual Active Ingredient Name — Virtual Product Name — Route of Administration — Dose Form — Strength and Strength Unit — Country Code	Ingredient + Product Name + Route of Administration + Dose Form + Strength + Strength Unit + Country Code	Warfarin Sodium, Coumadin, Oral, Tablet, 10mg, US
Virtual Active Ingredient Name — Virtual Product Name — Route of Administration — Dose Form — Strength and Strength Unit — Country Code — Company Code	Ingredient + Product Name + Route of Administration + Dose Form + Strength + Strength Unit + Country Code + Company Code	Warfarin Sodium, Coumadin, Oral, Tablet, 10mg, US, Bristol Myers Squibb
Virtual Active Ingredient Name — Virtual Product Name — Route of Administration — Dose Form — Strength and Strength Unit — Country Code — Company Code — Package Size	Ingredient + Product Name + Route of Administration + Dose Form + Strength + Strength Unit + Country Code + Company Code + Package Size	Warfarin Sodium, Coumadin, Oral, Tablet, 10mg, US, Bristol Myers Squibb, 100

NOTE The examples above are intended only for illustrative purpose and to help the reader with understanding the document. The examples are not dictating the design of the international coding system for medicinal drug products.

2.11

virtual active ingredient name

name of active ingredients (substance included as a component in a product that has the intended pharmaceutical effect)

2.12

virtual product name

actual label name

label name given by the manufacturer

EXAMPLE Coumadin is the product name for the ingredient name Warfarin. If the active ingredient is available, the product name is Warfarin and the ingredient name is also Warfarin.

NOTE The virtual product name represents the most general concept.

2.13

virtual active ingredient – product name

name linked to the one or more routed products

EXAMPLE Warfarin Sodium, Coumadin.

2.14

virtual active ingredient – product – route of administration name

name linked to the one or more ingredient products which adds the route of administration for the product

EXAMPLE Warfarin Sodium, Coumadin, oral.

2.15

virtual active ingredient – product – route of administration – dose form name

name linked to one or more products which adds the dose form

EXAMPLE Warfarin Sodium, Coumadin, oral, tablet.

2.16

virtual active ingredient – product – route of administration – dose form-strength and strength unit name

name linked to one or more products which adds the strength and strength unit

EXAMPLE Warfarin Sodium, Coumadin, oral, tablet, 10 mg.

2.17

virtual active ingredient – product – route of administration – dose form-strength and strength unit – country code name

name linked to one or more products which adds the country code

EXAMPLE Warfarin Sodium, Coumadin, oral, tablet, 10 mg, US.

2.18

virtual active ingredient – product – route of administration – dose form-strength and strength unit – country code – company code name

name – country code linked to one or more products which adds the company code

EXAMPLE Warfarin Sodium, Coumadin, oral, tablet, 10 mg, US, Bristol Myers Squibb.

2.19

virtual active ingredient – product – route of administration – dose form-strength and strength unit name – country code – company code – package size

name – country code linked to one or more products which adds the package size

EXAMPLE Warfarin Sodium, Coumadin, oral, tablet, 10 mg, US, Bristol Myers Squibb, 100.

NOTE The reason why the proposed international coding system would be based on the above virtual product concept level is that each layer of product concept has a well-defined level of clinical drug information and allows diverse users to access specific types of information.

The virtual product name concepts may have separate drug identifiers at each level. The most specific level of product name concept (class) is the clinical drug level for clinicians and pharmacists; a combination of active ingredient, product name, route of administration, dose form and strength resembling Warfarin Sodium, Coumadin, oral tablet, 10 mg.

The name of medicinal products may vary from country to country. But the clinical drug level (drug formulation in 2.5) which aggregates ingredients, product name, route of administration, dose form and strength could be standardized internationally to achieve unified (same) clinical drug information.

If an international coding system would take into account the virtual ingredient – product name – route of administration – dose form-strength drug concept level, there would be standardized access to drug references between countries. Thus removing barriers, including product mappings, and allowing the exchange of electronic pharmacy information (e-pharmacy) at an international level.

3 Abbreviated terms

- EAN European Article Number
- EHR Electronic Health Record
- GS1 A global not-for-profit organization dedicated to the design and implementation of global standards to improve the efficiency and visibility of supply chains globally and across sectors

- MOHW Minister of Health and Welfare, Korea
- NDC National Drug Code, assigned to a drug product by the U.S. Food and Drug Administration (FDA) and the manufacturer
- UCC Uniform Code Council

NOTE The two expressions (EAN and UCC) are currently corresponding with GS1.

- UMC Uppsala Monitoring Centre
- WHO World Health Organization
- WHO DD World Health Organization Drug Dictionary, Switzerland

4 Business requirements for an international coding system to identify the medicinal product

This Technical Report presents the business requirements from the clinical community to demonstrate the importance of data presentation in improving the management, use and exchange of medicinal products using automated systems. All the benefits below could reduce the considerable duplication of effort in generating divergent international coding systems.

- 1) Ensures the safe and reliable exchange of knowledge and e-pharmacy information internationally according to each level of virtual product identifier. Each level of product concept will have consistent drug information.
- 2) Clinicians in geographically separated regions using international medicinal product identifiers and drug formulation codes could have specific types of information available at the clinical drug level.
- 3) The international coding system could enable the identification of candidates for drug substitution because the drug formulation code could no longer refer to more than one international code or more than one manufacturer. Thus, reducing the ability of incorrect international medicinal product selections/matches and avoiding international medication-related errors due to lack of familiarity with medicinal products produced and/or marketed in other countries.
- 4) Multi-country disease studies could collect drug information using the same level of drug formulation code or same level of product identifier.
- 5) Support the concept of an interoperable EHR to an international level related to medication, especially to drug data or for the continuity of care for international travel as well as reduce adverse drug reactions/events (ADR/ADE) for international travellers.
- 6) Improve the statistical analysis of drug marketing activities globally.
- 7) An international coding system for medicinal products could be used to navigate a drug list according to name of virtual product name concept. A prescriber could navigate a list of products by virtual active ingredient name or virtual product name (example: acetaminophen; Tylenol); virtual active ingredient – product – route name (example: acetaminophen, Tylenol, oral, injection, rectal, etc); virtual active ingredient – product – route – dose form name (example: acetaminophen, Tylenol, oral syrup, oral tablet, oral capsule); virtual active ingredient – product – route – dose form name – strength and strength unit of measure (example: acetaminophen, Tylenol, oral tablet, 325 mg, 500 mg, 1 000 mg); virtual active ingredient – product – route – dose form name – strength and strength unit of measure – country code (acetaminophen, Tylenol, oral tablet, 500 mg, US, KR); virtual active ingredient – product – route – dose form name – strength and strength unit of measure – country code – company code (acetaminophen, Tylenol, oral tablet, 500 mg, KR, McNeil).

- 8) A coding system would meet the international business requirement for formulary building and identifying the candidates for drug substitution when interviewing patients about medicinal product history recognizing that all that may be available could be product name, route of administration (e.g. oral), and dose form (e.g. tablet).
- 9) The international identification of a set of discrete (atomic) data fields for automated medicinal product systems.
- 10) Ability to retrieve and manage data at the level of each medicinal product component.
- 11) Ability to conduct automated searching of medicinal products.
- 12) Ability to build compound search terms to aid in the identification of clinical international medicinal products (e.g. route, dose, etc.).
- 13) Ability to facilitate compliance with current government regulatory requirements.
- 14) A transparent coding methodology for medicinal products.

5 Description and assessments of existing coding systems

5.1 Selection rationale

GS1 is the leading global organization dedicated to the design and management of a global system of supply chain standards. GS1 Healthcare is a voluntary, global user group bringing together all related healthcare stakeholders: pharmaceutical/medical device manufacturers, wholesalers and distributors, group purchasing organizations, hospitals, pharmacies, logistics providers, governmental and regulatory bodies, and associations. GS1 was formed in 2005 when the Uniform Code Council (UCC) and the Electronic Commerce Council of Canada (ECCC) joined EAN (European Article Numbering) International. The Uniform Code Council was the Numbering Organization to administer and manage the EAN.UCC System in the United States. The Uniform Code Council became GS1 US and the Electronic Commerce Council of Canada became GS1 Canada.

The United States is a large consumer of pharmaceutical and medical products. Currently, there are approximately 100,000 pharmaceutical sales representatives in the United States pursuing 830,000 pharmaceutical prescribers. The total number of pharmacy retail and mail order prescriptions dispensed within the United States in 2003 was 3.4 billion or an average of 11.7 prescriptions filled for each of the 290 million people in that country. Therefore, in the United States, the Drug Listing Act of 1972 requires registered drug firms to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution. Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC) which is a universal product identifier for human drugs. The NDC identifies the labeler/vendor, product, and trade package size.

The World Health Organization (WHO) Programme for International Drug Monitoring provides a forum for WHO member states to collaborate in the monitoring of drug safety. Since 1978, the Programme has been carried out by the Uppsala Monitoring Centre (UMC). The Uppsala Monitoring Centre is responsible for the collection of data about adverse drug reactions from around the world. The WHO Drug Dictionary (WHO-DD) is a unique international classification of drugs created by the WHO Programme and managed by the UMC. The WHO DD is used by pharmaceutical companies, clinical trial organizations and drug regulatory authorities for identifying drug names in spontaneous Adverse Drug Reaction reporting as well as identifying drug active ingredients, and therapeutic use, in the course of clinical research.

5.2 GS1 system

The GS1 System is a code system that permits the unique identification of products, services, shipping units, assets, locations and services relations. The GS1 System provides several types of codes. Each GS1 System code type has differing strengths and weaknesses. The international business requirement would guide the selection of the bar code type to fit the business need. There are several code systems such as European Article Number (EAN) International-Uniform Code Council (EAN-UCC)-13, EAN/UCC-14 and EAN/UCC-128. The GS1 codes (See Table 2 below) are used by nearly 1,000,000 member companies in 150 countries.

Table 2 — GS1 System code structure and features

Type	EAN/UCC-13	EAN/UCC-14	AI and EAN/UCC-128
Symbol name	EAN/UCC-13	ITF-14	EAN/UCC-128
Number of digit	Numeric 13	Numeric 14	Numeric, Character, Special character
Structure (sample)	Country code (880) Labeller code (61000-69999) Product code (0000-9999) Check digit (1)	Logistic code (1-8) Country code (880) Labler code (61000-69999) Product code (0000-9999) Check digit (1)	EAN 13 or EAN 14 plus Application Identifier Number (AI) (batch number, lot number, serial number, expire date, package, unit, location code etc) (01)18806104200405(10)ABC123(17)081231 AI(01) EAN (GTIN) AI(10) Lot No AI(17) Exp.date AI (..) More Max :48
Main users	Retail trade	Wholesalers (logistic Management)	Wholesalers (logistic management)
Function	Identifier of unit product	Identifier of Box product	With logistic information

Business requirements assessment:

Although the GS1 is a concatenated product system, the system does not support drug formulation identification such as active ingredient, route of administration, drug class since the system was specifically designed for the distribution sector. The GS1 system identifies medicinal products without providing clinical information which is a business requirement for the international coding structure.

EXAMPLE 1 Cozaar 50 mg 30 Tab (880-61116-1091-4).

EXAMPLE 2 Cozaar 50 mg 100 Tab (880-61116-1903-8).

5.3 NDC

NDC is a USA product identifier for human drugs. The NDC is assigned by the FDA. NDC identifies the labeler/vendor, product, and package size. The first segment indicates labeler code representing a manufacturer, distributor, or repackager. The second segment indicates the product code, identifies a specific strength, dosage form, and formulation for a particular firm. The third segment, the package code identifies package sizes. Both the product and packages codes are assigned by manufacturer or distributor. The third segment, the package code identifies package sizes. Both the product and packages codes are assigned by manufacturer or distributor.

The NDC is in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1.

The NDC directory includes the following relational drug information descriptions.

Table 3 — NDC drug information descriptions

Content	Number of digit	Description
NDC number	10 or 11	
Trade name	Max 100	Product name
Dosage form	3	10 character abbreviation
Route of administration	3	001: Oral, 002: Intravenous
Active ingredients		Listed alphabetically
Strength and unit	Abbr. code	% VV: percent vol/vol, AMP: ampoule
Package size and type	Abbr. code	AMP: ampoule
Drug class	4	0501: Cardiac glycoside 0514: ACE inhibitors

Business requirements assessment:

While product package codes have been assigned by the firm in the past, new regulation requires that these now be registered with the FDA to ensure uniqueness.

Although NDC is a concatenated system for labeler products and package size, the NDC aggregates the ingredient, dose form, and strength into a product code. Therefore, since each field is not discrete and identifiable NDC does not satisfy the business requirements for an international coding structure.

5.4 WHO DD

The WHO Drug Dictionary Enhanced is the world's most comprehensive dictionary of medicinal product information. The WHO-DD was developed and is maintained by the Uppsala Monitoring Centre (UMC; WHO Foundation Collaborating Centre for International Drug Monitoring).

The WHO-DD is used by pharmaceutical companies, clinical trial organizations and drug regulatory authorities for identifying drug names, drug active ingredients, and therapeutic use, in the course of clinical research.

September 1, 2005 the WHO-DD contained:

- 80,000 unique proprietary (trade) names;
- 266,000 non-identical medicinal products, form and strength included.

March 1, 2007 the Directory contained:

- 185 463 unique names;
- 1 095 695 non-identical medicinal products, trade names when including additional information for example, form and strength information;
- 9 814 different ingredients are mentioned in the WHO-DD information products.

Medicinal product identification

The medicinal product ID identifies a unique entry in the WHO Drug Dictionary Enhanced.

The ID is a 'numeric name' of the medicinal product and has no intrinsic meaning.

The Medicinal product ID identifies a unique combination of the following data:

- Medicinal product Name
- Name specifier (e.g. forte, pediatric)
- Drug Code (drug record number + sequence 1 + sequence 2)
- Market authorisation holder
- Country
- Dosage form (pharmaceutical form)
- Strength (amount and unit of active ingredients)

For each medicinal product, the discrete levels of specificity of the information are recorded as separate entries, each with a unique ID. This is done to allow WHO-DD users to select the entry which corresponds to the specificity of information available to them. For instance, many adverse reaction reports sent to a regulator or a pharmaceutical company will not contain complete information about the medicinal product. In most cases, the only information available is the brand name; not the form and strength of the product.

Table 4 — WHO-DD Format

MP ID	Drug code	Name	Name specifier	MAH	Country	Dosage form	Strength
000001	12345601002	DrugnameAA					
000002	12345601002	DrugnameA A	SR				
000003	12345601002	DrugnameAA		Company 1	FRANCE		
000004	12345601002	DrugnameAA	SR	Company 1	FRANCE		
000005	12345601002	DrugnameAA	SR	Company 1	FRANCE	Tablet	
000006	12345601002	DrugnameAA	SR	Company 1	USA	Tablet	
000007	12345601002	DrugnameAA	SR	Company 1	FRANCE	Tablet	500 mg

In the example (above), several entries are available for the drug called Drugname AA. The entry with medicinal product ID 000001 holds only information about the name and active ingredients through the Drug Code.

The entry with MPID 000002 has a name specifier – SR.

Entries 000003-0000007 hold additional information in the different fields, so each entry is given a unique Medicinal Product ID.

The Medicinal Product ID identifies a unique combination of the following data:

Medicinal product name + Name specifier + Drug Code (Drug Record number+Seq1+Seq2) + Market authorization holder + Country + Pharmaceutical form (Seq3) Strength (Seq4).