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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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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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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ISO/TR 25257 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

## 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 section 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).

The Drug Code identifies a name, either a trade name or a generic preferred name.

The Drug Code is aggregated from Drug Record Number (DRECNO), Sequence number 1 and Sequence number 2. The code differs from the Medicinal Product ID in that the Drug Code has meaning. The Code is not only a unique identifier of a name: the Drug Code also gives information about the active ingredient(s) and salt/ester form of the substance.

### Pharmaceutical product identification

Pharmaceutical products are identified by their ingredients, pharmaceutical form, and strength. In the WHO-DD, the different levels of identification of pharmaceutical products are reflected in the hierarchical code system. The different levels are described below.

#### Level 1 – Identification of ingredients

The Drug Record Number (DRECNO) is the highest level of identification of a pharmaceutical product. The DRECNO identifies a generic ingredient identification level. In most cases the generic identification level is the one active ingredient, but the DRECNO can also identify a unique combination of active ingredients.

**Table 5 — Drug Record Number – Identification of Ingredients**

DRECNO	Ingredient
123456	Amoxicillin
234567	Paracetamol
345678	Paracetamol/codeine

#### Level 2 – Identification of the active moiety

The second level in the hierarchical code system for pharmaceutical products is the Sequence number 1 (SEQ1) which identifies the salt or ester of the active ingredient in single ingredient pharmaceutical products. The code value '01' identifies the base substance, without any salt or ester, and values above '01' will identify salts and esters. Pharmaceutical products with more than one active ingredient will have only one SEQ1 with the value '01'.

**Table 6 — Drug Record Number – Identification of the active moiety**

DRECNO	SEQ1	Ingredient
123456	01	Amoxicillin
123456	02	Amoxicillin sodium
123456	03	Amoxicillin trihydrate

### Proprietary name identification

Each medicinal product proprietary (brand) name has a unique code which is linked to the pharmaceutical product identification code system (SEQ2 in the table below).



**Table 7 — Drug Record Number – Proprietary name identification**

DRECNO	SEQ1	SEQ2	Product Name
123456	01	001	Amoxicillin
123456	01	002	Brand A
123456	01	003	Brand B
123456	02	001	Amoxicillin Sodium
123456	02	002	Brand C
123456	02	003	Brand D

All products in the table contain amoxicillin (DRECNO 123456). The entries with SEQ1 '01' contain amoxicillin in base form but the entries SEQ1 '02' contain amoxicillin sodium.

Level 3 – Identification of pharmaceutical form

The recorded forms of a pharmaceutical product are identified by a code (FORM in an annex).

**Table 8 — Drug Record Number – Identification of pharmaceutical form**

DRECNO	SEQ1	Ingredient	SEQ3	Form
123456	01	Amoxicillin	001	Unspecified
123456	02	Amoxicillin sodium	100	TAB
123456	03	Amoxicillin trihydrate	100	TAB
123456	03	Amoxicillin trihydrate	258	Liquids, Suspensions

Sequence Number 3 (Seq3) shows the pharmaceutical form of each product. The pharmaceutical forms are based on the NFC (New Form Code) from EphMRA.

EXAMPLE      Tablet, syrup, suspension, cream.

The pharmaceutical form of WHO-DD is different from the dosage form in which a medicinal product is intended to be administered to the patient, even if pharmaceutical form and dosage form often are the same. The pharmaceutical form is 'what' is in the package and dosage form is 'how' the medicinal product is to be administered to the patient.

EXAMPLE      A product is sold as a powder with sterile water which are to be mixed to form an emulsion that is taken orally.

The powder and the sterile water are pharmaceutical forms in the WHO Drug Dictionaries; however, only the powder will be listed since water is not an active ingredient though the emulsion is the dosage form.

The same code is always used for a specific pharmaceutical form.

Level 4 – Identification of strength

The recorded strengths of a pharmaceutical product that are the combined codes of amount of active ingredient/s and a unit of measurement) are identified by a unique code (STRENGTH in an annex).

**Table 9 — Drug Record Number – Identification of strength**

DRECNO	SEQ1	Ingredient	Form(Seq3)	SEQ4	Strength
123456	01	Amoxicillin			
123456	02	Amoxicillin sodium	Tablet		
123456	03	Amoxicillin trihydrate	Tablet		375 mg
123456	03	Amoxicillin trihydrate	Tablet	000062	500 mg
123456	03	Amoxicillin trihydrate	Suspension		50M g/ml

**Sequence number 4 (Seq4)** shows the strength-amount of active ingredient.

The same code is always used for specific strength information.

The pharmaceutical code as an example of Amoxicillin trihydrate 500MG Tablet is

123456-03001-100-00062

EXAMPLE

DRECNO	SEQ1	SEQ2	SEQ3	SEQ4	Name	Name Specifier	MaHolder	Country
000200	01	012	100	000062	Benuron	Tabletten	Milupa SA	Switzerland
000200	01	012	260	000014	Benuron	Sirup	Milupa SA	Switzerland
000200	01	012	350	000062	Benuron	500mg supp.	Milupa SA	Switzerland
000200	01	012	350	000068	Benuron	250mg supp.	Milupa SA	Switzerland

#### **Business requirements assessment:**

The coding system in WHO-DD is a hierarchical structure that allows data-retrieval and analysis at different levels of precision. But there is no concatenated code of drug formulation (clinical level). Although, the pharmaceutical code in WHO Drug Dictionary meets many of the international business requirements, there is no identifier for the concatenated code of route of administration at this moment. (According to WHO Drug Dictionary Sample Technical Description 2006, the addition of a clinical product level code is planned).

There is no product concept level that concatenates active ingredient, route of administration, dose form and strength, which can be used for same level of clinical information, development of list of candidates for substitution of dispensing environment, formulary, billing, price analysis as described in business requirements.

Since the coding structure is established by hierarchical method, some record numbers (DRECNO, SEQ1, SEQ3 and SEQ4) could be grouped to attain a similar type of drug formulation concept.

Without a concatenated identifier for drug class and route of administration, the WHO-DD does not satisfy the business requirements for an international coding structure for medicinal drug products.

## 5.5 Country status of coding of healthcare products (01/05/2003)

Country	Status
Argentina	Ninety percent (90 % ) of non-prescription drugs are coded and symbol marked with EAN.
Austria	<p>All pharmaceutical producers are members of EAN. The producers represent 95 % of the total revenue of pharmaceutical products in Austria. Eighty-five percent (85 %) of all ethical pharmaceuticals products are EAN-numbered and bar coded according to the structure below:</p> <p>90 8888X XXXX P</p> <p>90 = EAN-Prefix for Austria</p> <p>8888 = Prefix for Pharma-Code</p> <p>X XXXXX = Pharma-Code (Pharmazentralnummer)</p> <p>P = EAN check digit</p> <p>All drugs that are sold over the counter are coded with EAN 13. Austrian wholesalers of pharmaceutical products are connected with ECODEX for order and invoice - interchange with some 50 of their suppliers based on EANCOM. Numerous pharmacies scan the EAN bar codes.</p>
Australia	The Australian healthcare sector mandates EAN 13 for all prescription and OTC drugs.
Belgium	Drugs sold on prescription have a national registration number marked with an APB code (Association des Pharmacies de la Belgique). This 6-digit number marked by an MSI barcode. Most over the counter drugs are marked with APB and bar-coded with MSI. Hospital pharmacies UCC numbering and symbol-marking rules.□however, adhere to the EAN.
Bolivia	EAN numbering and symbology is used.
Bosnia and Herzegovina	All pharmaceutical products are numbered with EAN-13.
Brazil	<p>Medicines are required by Ministry of Health to have EAN-13 on packages. Currently almost all the Brazilian medicines are bar coded with EAN-13 and the Brazilian government is using the GTIN as the key number to control medicine registration.</p> <p>There is a working group coordinated by EAN BRASIL developing the Brazilian Medicines and Medical Devices Codification Guideline that recommends the use of UCC/EAN-128 standard to encode secondary data (lot number and expiration date) on those products in order to guarantee traceability. The working group is recommending RSS and Composite Symbologies for healthcare products with restricted or limited space. Currently, the working group is developing a pilot project to implement symbologies with the participation of one hospital and three manufacturers.</p> <p>There appears to be an increased use of EANCOM messages in the pharmaceutical sector.</p>
Chile	<p>Drugstores (Pharmacies 100 % of pharmaceutical products are bar coded with an EAN-13 or EAN-8 number issued by EAN Chile or by the corresponding country of origin. For cases, 100 % are required to be marked with GTIN-14 (ITF).</p> <p>Hospitals: ninety percent (90 % ): of pharmaceutical products are bar coded with an EAN-13 or EAN-8 number issued by EAN Chile or by the corresponding country of origin.</p> <p>Cases, when sold to Drugstores only must have a GTIN 14.</p> <p>Other Non-Pharmaceuticals: most do not conform to any coding system.</p>

Country	Status
China	All medical products use the EAN system and bear the EAN-13 bar codes.
Colombia	Due to the relationship between laboratories and Retailer, most of the pharmaceutical laboratories are members of IAC COLOMBIA, approximately eighty-five percent (85 %). Furthermore, 100 % of the products sold in the retail sector are identified with EAN/UCC standard. The unit dose is poorly identified, less than two percent (2 %), however ampoules are identified with EAN 8 on the glass. In the time of this TR, Columbia is implementing RSS and CS Pilots in two hospitals with the purpose to have some statistics about pharmaceutical improvements. The packages are mostly identified with ITF 14 (10 % ). The marking percentage with UCC/EAN 128 is lower (10 %) and presents several quality problems.
Costa Rica	Forty percent (40 %) of industrial pharmaceutical products in Costa Rica use EAN/UPC symbology. There is a formal agreement with the Social Security organization to ensure implementation of EAN/UCC standards.
Cyprus	The large pharmaceutical companies in Croatia barcode products using EAN-13.
The Czech Republic	All pharmaceutical products are numbered with EAN-13.
Denmark	Observe characteristics of Norway.
Dominican Republic	The first medicinal product target was the use of EAN.UCC -13 in all pharmaceutical and ethnic products. Ninety-five percent (95 % ) of the Dominican pharmaceutical producers are members of EAN and are bar-coded with EAN-13.
Ecuador	EAN coding is used on a small percentage of over-the-counter non-prescription products sold in retail outlets.
Egypt	<p>Most pharmaceuticals manufactures are members of EAN. EAN Egypt has allocated EAN 13 Company prefix numbers for more than 64 companies (Local and multinational producers). Most of drugs that are sold over the counter are coded with EAN 13. EAN-13 rules apply: 622 MMMM IIII C</p> <p>Where: 622 is the prefix of EAN Egypt organisation</p> <p>MMMMM is the number allocated to a manufacturer</p> <p>IIII is the number allocated to a product by the manufacturer</p> <p>C is the EAN check digit.</p> <p>Egypt has started to introduce consultation service for local pharmaceuticals companies to implement bar code based integrated solutions. The services are extending to Bar code applications in Hospitals.</p> <p>There are no official regulations for bar coding pharmaceutical products. However, ninety percent (90 %) of pharmaceutical companies are members of EAN Egypt using standard EAN-13 structure for pharmaceutical products. 10 % of pharmacies implementing barcode scanning. Five percent (5 % ) of the logistic units are identified by EAN 128.</p>
El Salvador	About sixty percent (60 %) of the national industry pharmaceutical products are coded using EAN 13, UPC or EAN 8 standards. EAN/UCC 14 and EAN 128 standards are not used by the El Salvadorian pharmaceutical industry. The country is currently working with the Social Security Institute on an agreement for the implementation of EAN standards.
Estonia	Pharmaceutical products are numbered with EAN-13 or EAN-8.
Finland	Observe characteristics of Norway.

Country	Status
France	<p>CIP, the pharmaceutical product association migrated from a proprietary codification scheme (7 digits and Code 39) to EAN 13 at the beginning of 2003.</p> <p>CIP uses the prefix 3400 and 3401 to envelop the 7 digit code, (AMM, authorisation number for medical product).</p> <p>In 2002, CIP and Gencod EAN France signed an agreement to attribute a global location member to all the healthcare centers in France.</p> <p>Healthcare centers and logistic providers ask the medical device suppliers to print an EAN 128 on their products and trade units with GTIN + lot number + expiry date.</p> <p>01/05/2003</p>
Germany	<p>All pharmaceutical products are numbered by IFA – Pharmazentralnummer" (Central Pharmaceutical Number, PZN) – a 7 digit identification system which can be bar coded in Code 39. However, German regulations state that the EAN-13 number is sufficient for identification in machine-readable format as long as the PZN number appears in human readable form on the product. The second alternative was introduced for pharmaceutical products sold at retail point of sale and pharmacies. In either case one of the two numbers must appear in machine-readable format.</p> <p>For the identification of medical/surgical products and devices the national associations representing suppliers and hospitals recommend to use the EAN number. The EAN number can either be bar coded in an EAN-13 symbol which is more common or in an EAN 128 symbol together with other important data such as expiry date and lot number.</p>
Greece	<p>Bar code systems are not yet used for pharmaceutical products, pharmacies are not using scanners. However, 10 % of pharmaceutical companies are members of EAN Hellas using standard EAN-13 structure mainly for OTC and parapharmaceutical products.</p>
Hungary	<p>All pharmaceuticals products are EAN numbered and bar coded. Medical aids sold on prescription use UCC/EAN 128 system for traceability for state insurance.</p> <p>All animal health care products are EAN numbered and bar coded.</p>
Iceland	See Norway.
Iran	<p>All pharmaceutical products must be bar coded with EAN-13. At the current time, there are 51 pharmaceutical manufacturers using EAN-13 on products.</p>
Ireland	<p>Sixty percent (60 %) of pharmaceutical products are bar coded with an EAN-13 or EAN-8 number. There are two solutions to identify the products:</p> <ul style="list-style-type: none"> <li>— EAN barcode issued by the Irish EAN organisation to a manufacturer</li> <li>— EAN code issued by the Irish EAN organisation to the IPU (Irish Pharmaceutical Union)</li> </ul> <p>The IPU (Irish Pharmaceutical Union) requested from ANAI (Irish EAN Organisation) that an EAN code be allocated to all products sold in pharmacies, until such time as manufacturers source mark their products. The IPU administers the EAN code, allocates the EAN to all new products and distributes the code to pharmacists who have computers. In case that the products are bar coded at source, the manufacturer communicates the information to IPU together with the price and other product information.</p>
Italy	<p>All pharmaceutical products must carry a bar code known as "PARAF" in accordance to specifications issued by the Italian Ministry of Health in 1983. The code is preceded by the letter 'A' that is not represented in the symbol. The letter differentiates pharmaceutical products from other types. The symbol uses code 39 and consists of 9 digits.</p>

Country	Status
Japan	<p>Japan has a standard code master of drugs that does not include Over-The-Counter (OTC) medicinal products. The key code Master is the HOT Code. The HOT code matches the JAN Code (Japanese Article Number) that is distributing number. The HOT Code fits the notification for drugs. Approximately 50,000 drugs are registered and maintained in database.</p> <p>Moreover, the Ministry of Health, Labour and Welfare published the notification of the display of the GS1 code (GS1 – 128 and RSS, etc.) on drugs in August 2006. The bar code display to the injection is executed from the shipment in September 2008.</p> <p>The Ministry of Health, Labour and Welfare publishes the notification of the display of the GS1 code (GS1 – 128 and RSS, etc.) on medical devices in March 2008. The notifications work for patient safety and the traceability.</p> <p>A database of approximately 550,000 medical devices are registered, and maintained, with JAN Codes.</p>
Jordan	Most pharmaceutical products produced are bar coded with EAN-13.
Korea	<p>Most pharmaceutical companies have an EAN manufacturer number. EAN numbers are used in the health sector. The number 6 following the EAN prefix 880 is reserved for Pharmaceutical industry.</p> <p>In the healthcare sector, EAN Korea has taken part in the implementation of EHCR in cooperation with Ministry of Health and Welfare. As a first step, the Government officially adopted GTINs for the identification of all pharmaceuticals distributed in Korea. Pharmaceuticals have been bar coded with EAN/UPC symbologies since July 2000. EANCOM is expected to be used for the transactions in this sector soon.</p> <p>As of October 31, 2001, the membership of pharmaceutical companies is 365 and expected to grow in the years to come.</p> <p>The data structure for the identification of pharmaceutical products is as follows:</p> <p>880 6MMMM XXXX C</p> <p>880 6MMMM: Company Prefix assigned by EAN Korea</p> <p>XXXX: Reference Number</p> <p>C: Check Digit</p> <p>In addition, a law specifying the use of GTINs for the identification of cosmetics distributed in Korea passed the Congress and took effect January 2002.</p>
Lebanon	The Association of Lebanese Drug Manufacturers has adopted EAN-13 for all products.
Macau	Almost all pharmaceutical products are imported and carry the bar code symbology used by suppliers with a majority of suppliers using EAN coding.
Malaysia	The pharmaceutical manufacturers who are members of EAN Malaysia have put the EAN bar codes on the locally manufactured products. Most of the products are OTC items. Many of the imported pharmaceutical products carry the EAN bar code of the country of manufacture. EAN Malaysia is working with the companies and healthcare service sector to encourage all pharmaceutical products to have EAN bar codes.
Mexico	Eighty percent (80 % ) of pharmaceutical products (prescription and non-prescription) use EAN. Ninety-five percent (95 %) of the symbology used is EAN-13 and 5 % EAN-8. AMECOP (EAN Mexico) has a formal agreement with the Social Security Hospitals and the Mexican Pharmaceutical Chamber to ensure the implementation of UCC standards including ITF 14 and UCC/EAN-128. EAN
Morocco	Most pharmaceutical products produced are bar coded with EAN-13.

Country	Status
Netherlands	<p>In the Netherlands there are two options for marking pharmaceutical products, EAN and EHIBCC. All organisations of pharmaceutical suppliers as well as the pharmacists are implementing the EAN-code system on pharmaceuticals. For medical devices, approximately fifty percent (50 % ) use EAN-barcodes (mostly UCC/EAN 128). The use of the UCC/EAN 128 system and EANCOM messages in the healthcare and pharmaceuticals sector is still expanding.</p> <p>The Dutch Healthcare sector is extremely interested in the EAN Data Alignment Service (SINFOS) and exploring use possibilities in healthcare.</p> <p>EAN Netherlands has developed user profiles for messages in healthcare. All participants in the EDI projects use the EAN Location Numbering system.</p>
New Zealand	<p>Pharmacode is a 6-digit number including check digit. The Pharmacy Guild of New Zealand allocates a number to every type of pharmaceutical. This is not in a barcode form. The numbers are used by all pharmacies, which are online to a central registry. Pharmacies who are scanning are converting the numbers into an EAN format. Eventually all Pharmacode numbers will be converted to EAN.</p> <p>In 1996, the healthcare industry agreed to adopt the EAN Standards for hospitals, pharmaceutical products and pharmacies.</p>
Norway	<p>All prescription drugs are coded according to the Nordic Pharmaceutical Numbering System (in EAN-13 format), developed by the "Norsk Medical Depot" in Oslo. The numbering structure for EAN-13 is as follows:</p> <p>70 4626 AAAAAA C</p> <p>70: EAN prefix</p> <p>4626: Norsk Medical Depot</p> <p>AAAAAA: Common Nordic Article Number</p> <p>C: Check digit</p> <p>Non-prescription drugs and other items within healthcare follow the regular EAN standards.</p>
Panama	<p>Forty percent (40 % ) of pharmaceutical products are coded with EAN-13 and UPC standards. The Social Security communicates plans to insure implementation of EAN/UCC standards.</p>
Peru	<p>In Peru, less than 1 % of pharmaceutical products are coded with EAN. The products include primarily OTC products sold in supermarkets and other retail outlets. Because of the low number of scanners in drugstores, most pharmaceutical products and prescription drugs are not coded.</p>
Philippines	<p>All Pharmaceutical products are identified and bar coded using the EAN-13 system.</p>

Country	Status
Poland	<p>EAN Poland assigned the Ministry of Health several 4-digit company prefixes, allowing the Ministry to allocate 5-digit number for each registered drug. The structure of the number is as following:</p> <p>590 9990 RRRRP C</p> <p>590 9991 RRRRP C</p> <p>590 9998 RRRRP C</p> <p>where</p> <p>590 - EAN prefix for Poland,</p> <p>9990-9998 - Prefixes allocated to the Ministry of Health,</p> <p>RRRR - Registration number of the registered drug,</p> <p>P - Packaging identifier, including content of the drug,</p> <p>C - EAN check digit.</p> <p>The EAN number is also the register number and obligatory on all packages. This procedure is obligatory also for foreign companies exporting drugs to Poland.</p>
Portugal	<p>There are national legal regulations developed by the Ministry of Health and the National Pharmacies Association. The number has 7 digits including 1 check digit and is represented in Code 39.</p>
Former Yugoslav Republic of Macedonia	<p>Pursuant to the Article 48 of the Law on medicines, auxiliary medicinal remedies and medical accessories</p> <p>("Official Gazette of the Republic of Macedonia", No. 21 May 8th, 1998), all the pharmaceutical and medical products in the Republic of Macedonia must have the bar code EAN 13. All the pharmaceutical producers are members of EAN Macedonia with obligatory use of the EAN-13 bar code.</p>
Romania	<p>Most pharmaceutical producers are members of EAN Romania.</p> <p>All of the pharmaceutical producers use EAN-13, EAN-8 and ITF-14 symbols representing seventy-five percent (75 % ) of Romanian pharmaceutical products sold in Romania.</p> <p>The structure of EAN-13 is as below:</p> <p>594 47MM PPPPP C where:</p> <p>594 - is the prefix of the Romanian</p> <p>EAN organization</p> <p>47MM - is the number allocated to manufacturers by</p> <p>EAN Romania</p> <p>PPPPP - is the number allocated to a product by</p> <p>EAN Romania</p> <p>C - is the EAN check digit</p>



Country	Status
Russia	<p>UNISCAN/EAN Russia and the Russian Health Ministry have a cooperation agreement on joint implementation of mandatory bar coding of pharmaceuticals with EAN/UCC GTINs.</p> <p>The Russian Health Ministry uses a unified numbering system for pharmaceuticals and medical products. All medical products and pharmaceuticals imported or sold in Russia, independently of their origin, must have an EAN-13 bar code. EAN-8 and UPC codes may also be used. Importers must present a document from their respective EAN Member Organisation confirming the allocation of an EAN/UPC code. 100 % of pharmaceutical products are coded with the EAN/UCC system. The EAN/UPC article numbers are used as unique identifiers in the Health Ministry's database of medical products. The Russian Health Ministry uses the Russian page of the GEPIR information system to access company data (GLN) and the EDI-UNISCAN information system to access product data (GTIN). Devices are numbered with EAN/UCC-13 and EAN/UCC-8 GTINs only.</p>
Singapore	<p>The standard EAN-13 bar coding rules apply: 888 MMMM IIII C. Ninety percent (90 % ) of OTC drugs use EAN codes. Currently SANC is working with the Singapore government to introduce the use of the EAN system in hospitals. In addition, the government has agreed to allow the Drug Registration number to be harmonised into EAN-13 system. The numbering structure has been adapted in such a way that will incorporate the size of the medicine for EDI purposes.</p>
Slovakia	<p>Pharmaceutical products are numbered according to the EAN structure with prefix 858. Law requires EAN bar codes. Approximately 10 % pharmacies use EAN.</p>
Slovenia	<p>All pharmaceutical and medical products are marked using EAN-13. Market authorisation and product identification are the same EAN-13 numbers given by the drug registration authorities in bar code format.</p> <p>The structure of the EAN-13 number is:</p> <p>383700 X RRRRR C</p> <p>383: EAN Prefix for Slovenia</p> <p>700X: Prefix allocated to the National Authority which registers healthcare products for use in Slovenia</p> <p>RRRRR: Registration number of medicine or medical device</p> <p>C: EAN check digit</p>
South Africa	<p>The Department of Health in South Africa introduced a firm policy many years ago that only pharmaceutical products bar coded in terms of the EAN.UCC system would be eligible for tendering purposes. A new association has been formed in the private sector called the Pharmaceutical Electronic Standards Authority (PESA) for the purpose of creating one unique price and product file. The initiative makes use of the EAN.UCC number as well as a local proprietary code (NAPPI) to identify pharmaceuticals sold through retail pharmacies.</p>

Country	Status
Spain	<p>Spain mandates a symbol mark with EAN-13 on all pharmaceutical products sold in pharmacies (prescription and non-prescription). Although there are no official regulations for coding medical supplies, UCC/EAN 128 is commonly printed on products.</p> <p>The EAN-13 number is structured as follows.</p> <p>8 4 7 0 0 0 X1 X2 X3 X4 X5 C1 C2</p> <p>7000 = reserved by AECOC for pharmaceutical industry</p> <p>X1...X5 = national code for pharmaceutical products assigned by the health authorities.</p> <p>C1 = check digit for national code (X1..X5).</p> <p>C2 = EAN check digit.</p> <p>The code 847000... is used on:</p> <ul style="list-style-type: none"> <li>— Products financed by the Social Security System (mainly medicines).</li> <li>— Non-financed products whose companies by their own initiative want to represent on a bar code the national code.</li> </ul>
Sweden	<p>In Sweden, there are two official statements affecting bar coding of medical devices.</p> <ul style="list-style-type: none"> <li>* The public sector electronic trade project is committed to EAN standards;</li> <li>* SLF, the medical devices suppliers association, has together with HSS, the Health Care Standardisation body, made an official recommendation to use EAN numbers and barcodes on all newly introduced products.</li> </ul>
Switzerland	<p>Pharmaceutical products are numbered with the EAN system; GTIN are allocated by the foundation RefData, which has delegated the process to e-mediat Ltd.:</p> <p>1: 76 80 XXXXX PPP C</p> <p>76: EAN Prefix for Switzerland</p> <p>80: Prefix for Refdata (Swissmedic products)</p> <p>XXXXX: Swissmedic-number (allocated by the health authorities)</p> <p>PPP: Packaging Code (allocated by the health authorities/ RefData)</p> <p>C: EAN check digit</p> <p>2: 76 819 XXXXX PP C</p> <p>76: EAN Prefix for Switzerland</p> <p>819: Prefix for RefData (products which were formerly registered by a separate body, the BAG; since 2001 these have been merged)</p> <p>XXXXX: BAG number (allocated by the health authorities)</p> <p>PP: Packaging Code (allocated by the manufacturers)</p> <p>C: EAN check digit</p> <p>The following bodies are involved in the pharmaceutical sector in Switzerland:</p> <ul style="list-style-type: none"> <li>* BAG – Federal Health Authorities</li> <li>* Swissmedic – federal organisation for drug control –<a href="http://www.swissmedic.ch">www.swissmedic.ch</a></li> <li>* RefData – foundation which insures that the Swiss HC can take advantages of the EAN System.</li> </ul>

Country	Status
Syria	Since 1999, all pharmaceutical products must be UCC system identified with the EAN.
Taiwan	<p>The Taiwan healthcare sector adopted the EAN.UCC system. The implementation can be divided into three parts.</p> <ol style="list-style-type: none"> <li>1. As a criterion in the forms of packaging: EAN-13/ EAN-14</li> <li>2. Selecting bar-code symbols according to operations demands: EAN-13/EAN-14/EAN-128</li> <li>3. Constructing a common database of electronic catalogue: E-healthcare industry promotion committee was formed by EAN TAIWAN on June 2000. The aim of launching medicine e-catalogue was to improve the efficiency in supply chain. The common format and exchange data rules of the "Basic info of medicine of e catalogue" were defined by the committee.</li> <li>4. Over 13000 Medicines with EAN/UCC 13 GTINs have been registered in the e-Catalogue of EAN Taiwan.</li> </ol>
Thailand	Pharmaceutical products are mandated to be identified and bar coded with the EAN-13 system.
Tunisia	Most pharmaceutical products produced are bar coded with EAN-13.
Turkey	<p>"All medicinal products are bar coded with EAN-13, the coverage is 100 %.</p> <p>The Ministry of Health maintains the Health Coding Reference Server (HCRS) which serves all the local and international coding systems that are used within the Health Level Seven (HL7) Clinical Document Architecture (CDA) based Electronic Healthcare Records (EHR) of Turkey. One of the coding systems in HCRS is the medicinal products; they are uniquely identified via their EAN-13 bar codes. In the prescription data set of the EHR instances, the bar code, route of administration, dose quantity, the usage instructions and the package quantity of the medicinal product is provided.</p> <p>Another aspect of the National Health Information System (NHIS) of Turkey is the Decision Support System (DSS). The EHR instances are collected in centralized servers. The HCRS serves the Anatomical Therapeutic Chemical Classification System (ATC) of WHO, which is used for the classification of drugs, and the mapping between all medicinal products in Turkey and ATC. While presenting statistical data analysis and presentation, the DSS automatically maps the medicines to their active ingredients provided by ATC mappings.</p> <p>The Social Security Institute (SSI) has a similar system as well. All the pharmacies are integrated with the SSI for years and here, the medicines are identified according to their bar codes. The SSI system has many intelligent controls such as preventing different medicines with the same active ingredient to be on the same prescription. If there is such prescription, the social security pays only one of the drugs with the same active ingredients.</p> <p>Finally, there is an ongoing project entitled Medicine Tracing System (MTS) for tracing the individual instances of all medicinal products in Turkey for preventing fake, outdated, or smuggled products. As a part of this system, the packaging of medicinal products regulation dated February 2<sup>nd</sup>, 2008 mandated the usage of Data Matrices in medicinal product packages starting by January 1<sup>st</sup>, 2009. A Data Matrix code is a two-dimensional matrix bar code consisting of black and white square spots. Similar to RFID technology, it allows instance based identification and tracing of products.</p>
Ukraine	As of 1 January 1998, all pharmaceutical and medical products must be bar coded with EAN-13.

Country	Status
United Kingdom	<p>The Medicines Control Agency licenses all drugs. The allocated number is printed on the packaging, but the almost universal acceptance of the EAN UCC system in the UK retail supply chain has ensured that the brand owners' EAN numbers and bar codes dominate for over the counter medicinal products.</p> <p>EAN-13 rules apply: 50 MMMMM IIII C</p> <p>Where: 50 is the prefix of the United Kingdom EAN organisation</p> <p>MMMMM is the number allocated to a manufacturer</p> <p>IIII is the number allocated to a product by the manufacturer</p> <p>C is the EAN check digit.</p> <p>In addition, the UK uses PIP codes in community Pharmacy.</p>
USA	<p>Prescription drugs in the USA are required by law to have a National Drug Code (NDC). The NDC follows 3 configurations (4-4-2, 5-3-2, 5-4-1) are:</p> <p>MMMDDDDDPP, MMMMMDDDDPP, MMMMMDDDDP</p> <p>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.</p> <p>The NDC is in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1.</p> <p>MMMMM = Manufacturer's assigned number (by FDA)</p> <p>DDDD = Drug Identification</p> <p>PP = Package Size</p>
Uruguay	10 % of pharmaceutical products are coded using EAN 13.
Venezuela	<p>Approximately seventy percent (70 % ) of pharmaceutical products are coded with EAN/UCC standards.</p> <p>From the seventy percent (70 % ), ninety-seven percent (97 % ) are coded with EAN-13; 2 % are coded with UCC-12 and 1 % are coded with EAN-8</p> <p>In October 2001, an agreement was reached which established the requirement beginning March 31, 2002, that 100 % of pharmaceutical products must be bar-coded with EAN/UCC standards. Venezuela is beginning the codification of Dispatch Units with code UCC/EAN-128.</p>
Vietnam	<p>Most large pharmaceutical producers are members of EAN Vietnam. Almost all of the local drugs sold in Vietnam are coded with EAN 13. Many of the pharmaceutical imported products are coded with EAN 13. Some pharmaceutical producers apply DUN and ITF on despatch units. EAN 13 symbology has been applied on local medical devices. A large proportion of imported medical devices on the market are coded with EAN 13.</p>
Yugoslavia	By Federal Law (1993), each medicine must have an EAN code (either EAN-13 or EAN-8) on packaging.

## 6 Analysis of existing coding systems with international business requirements

The GS1 System is an appropriate standard for logistical and administrative processes. However, GS1 is not connected with drug formulation product level (clinical product level) such as active ingredients, dosage, route of administration and strength. So, GS1 has limited use for the purpose of sharing clinical information.

Example: Korea made use of the GS1 code system compulsorily however system utilization is low in *healthcare* institutions with a low implementation rate in electronic data exchange.

Therefore, the Technical Report analysis is that the GS1 system would not suffice as an international coding system with the ability to fulfill the international business requirement described above in Clause 4.

The NDC product and pack codes are assigned by individual companies or firms with many duplications of product and pack codes. The product database set in the NDC directory are absent a combined ingredient, route of administration, dose form and strength code. Therefore, the NDC would not suffice as an international coding system with the ability to fulfill the business requirement described above in Clause 4.

The WHO-DD coding system is a hierarchical structure with flexible data-retrieval and analysis at various levels of information precision. However, there is an absent of concatenated code of drug formulation at the product level (clinical product level).

The pharmaceutical code in WHO Drug Dictionary (WHO-DD) has concepts compatible with the Technical Report business requirements. There is absent of an identifier for the concatenated code of route of administration at this moment.

There is no product concept level of clinical drug level that aggregate ingredient, route of administration, dose form and strength, which can be used for same level of clinical information, development of a list of candidates for substitution of dispensing environment, formulary building, price analysis as described in business requirements.

Since the coding structure is established by hierarchical method, some record numbers (DRECNO, SEQ1, SEQ3 and SEQ4) could be grouped to attain a similar type of drug formulation concept.

Without a concatenated identifier for drug class and route of administration, the WHO-DD does not satisfy the business requirements for an international coding structure for medicinal drug products described above in Clause 4.

## 7 Discovery of international business concepts for an international coding system

This Technical Report finds that the international business requirements for an international coding system for medicinal products could be established by the virtual product name concept as described in Clause 2.

A drug formulation code could identify a unique combination of the following data:

- active ingredient;
- product name;
- route of administration;
- dose form;
- strength and strength unit of measure;
- country code;
- company code;
- package size code.

Also the international business requirements may require a dummy code "00" for the representative of each product for the purpose of elevating the concept of an interoperable electronic health record related to medication because all healthcare domains and users do not require pack size information; perhaps only for the prescription and the clinical customer.

The coding system could establish the ingredients list identifier which would be a permanent numeric identifier and identifies a unique concatenation of active ingredients, irrespective of the manufacturer, package size, dosage form, route of administration, or strength. The ingredients identifier represents the active ingredient, will always be the same, allowing an expedited method of tracking active ingredients.

This Technical Report found the WHO-DD pharmaceutical product identifiers (DRECNO) are well established and available to identify ingredients (virtual product name). Therefore, this Technical Report recommends any work in this area be in collaboration with the WHO-DD.

The virtual active ingredient — product — route of administration name concept requires an identifier for ingredient name, product and with a route of administration (example below)

Virtual active ingredient – product – <b>route of administration</b> name (Active Ingredient + Product + Route of Administration)
ACETAMINOPHEN, TYLENOL, ORAL
ACETAMINOPHEN, TYLENOL, RECTAL

The virtual active ingredient — product — route of administration — dose form name concept requires an identifier for active ingredient, product, route of administration with dose form (example below).

Virtual active ingredient – product – route of administration – dose form name (Active Ingredient + Product + Route of Administration + Dose Form)
ACETAMINOPHEN, TYLENOL, ORAL CAPSULE
ACETAMINOPHEN ORAL, TYLENOL, ELIXIR
ACETAMINOPHEN, TYLENOL, ORAL SYRUP
ACETAMINOPHEN, TYLENOL, ORAL TABLET
ACETAMINOPHEN, TYLENOL, RECTAL SUPPOSITORY, RECTAL

Another level of virtual product name concept is displayed in the table below:

Virtual active ingredient - product – route of administration – dose form-strength name ( <i>Clinical Drug Level</i> )
ACETAMINOPHEN, TYLENOL, ORAL CAPSULE 325 mg
ACETAMINOPHEN, TYLENOL, ORAL CAPSULE 500 mg
ACETAMINOPHEN, TYLENOL, ORAL ELIXIR 120 mg/5 ml
ACETAMINOPHEN, TYLENOL, ORAL ELIXIR 240 mg/5 ml
ACETAMINOPHEN, TYLENOL, ORAL ELIXIR 80 mg/5 ml
ACETAMINOPHEN, TYLENOL, ORAL TABLET 500 mg
ACETAMINOPHEN, TYLENOL, ORAL TABLET 650 mg
ACETAMINOPHEN, TYLENOL, ORAL TABLET 80 mg
ACETAMINOPHEN, TYLENOL, RECTAL SUPPOSITORY, RECTAL 325 mg

Finally, the country code, company code and package size code could be concatenated to identify the individual medicinal product in a specific country and specific market holder.

## 8 Benefits of an international coding system for medicinal products

### 8.1 Knowledge sources for decision support (clinical parameters and guidelines)

The available clinical information varies depending on the virtual product name concept level (see 2.12) used to access the information. With the flow of information concerning medicinal products locally, nationally and internationally depending on unambiguous drug codes, the more specificity with which a drug concept is entered into a computer for processing, the more specific the clinical information will be received in return.

At the virtual active ingredient name level, certain information may be returned that does not necessarily apply to the identical drug.

At the virtual active ingredient product route of administration name level, it can be used for navigational purpose or to profile patient medications when dose form or strengths are unknown or not required.

At the virtual active ingredient product route of administration dose form name level, the code can be used for the navigational purpose or to profile patient medications when strength is unknown or for ordering prescriptions when the strength is not required.

**EXAMPLE** When prescribing, "Oral Prednisone Tablet 20 mg every morning" in an inpatient setting, the prescriber is not concerned about whether the tablet is administered as one 20 mg tablet or two 10 mg tablets or four 5 mg tablets.

Outpatient (ambulatory) prescribing must be specific as to dose form and strength. Using the Oral Prednisone, the dose required could be achieved using different strengths. The prescription could be written using Oral Prednisone 5 mg, 10 mg, 20 mg Tablets.

The most clinically useful level of product name concept identified through the business requirements is a concatenation of active ingredient, product, route of administration, dose form and strength name.

An international drug formulation code would be useful for clinician to identify drug products who share the same active ingredients, route of administration, dose form and strength that are marketed by multiple manufacturers since the product information is identical for the various packages of the product. A concatenated drug formulation code allows the free flow of information concerning medicinal products locally, nationally and internationally based on an efficient and unambiguous drug code that supports the linkage of data internationally.

International drug formulation codes could also be used to establish drug candidates for substitution in dispensing or price analysis.

If an international coding system contains a standardized drug formulation code structure and virtual product name concept level, the manpower for the medicinal product code mappings between unrelated parties or independent countries to be significantly less effort to share drug information with an identical product concept level.

Therefore, the increasing demands for interoperability and integration across distinct domains within health platforms supports an international coding system for medicinal drug products to permit clinical system interoperability between diverse clinical system (or drug regimens) by ensuring the safe and reliable exchange of e-pharmacy information.

### 8.2 Prescribing, dispensing and ordering (e-prescription and e-pharmacy)

An international business requirement is for clinicians to have consistent identification codes. If a drug formulation code can be associated with a medicinal in an international coding system, the drug formulation code could enhance the sharing of drug information and collaboration among healthcare professionals internationally such as with the identification of candidates for therapeutic substitution in the e-prescription and e-pharmacy environment.

Business requirements, when using a prescription support system, allow prescribers to select a product from a list. Foreign patients will be able to request prescriptions to replace a medicinal product from their home country. The prescriber will be able to identify the medicinal product from the patient's package and prescribe the equivalent product.

Also, foreign patients will be able to a refill prescription from outside their home country. The pharmacist will be able to identify the prescribed medicinal product and dispense the local national equivalent.

Lastly, a patient may need a medicinal product that is not available globally or has not yet been registered. The pharmacist may wish to order a medicinal product from a neighbouring country. The pharmacist will be able to select the desired product from the international codes of medicinal products or order the product by the products identifying characteristics.

### 8.3 EHR (electronic health record) system

The benefits of international coding system could elevate the concept of an interoperable EHR to an international level related to medication especially for meeting the business requirement to access and navigate active ingredient, or the individual product concept level for patient safety and continuity of health care for international travel.

The total number of pharmacy retail and mail order prescriptions dispensed within a single country (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 (Ukens, C. (2004). *How mail order pharmacy gained in market share in 2003*. Drug Topics Mar 22, 148.) While the majority of medicinal products (prescription and non-prescription) are used by ambulatory patients, the majority of research on medication-related errors has been conducted in hospital, health-system, and long-term care environments. The inpatient research focus may stem primarily from better access to inpatient records that include drug utilization data; however, given the volume of national prescriptions around the globe, the impact of the safe administration of medicines is significant.

- An aging population (through 2010, the fastest-growing age cohort will be those aged 45 to 64; after 2010, those aged 65 and up will be the fastest-growing cohort).
- An increase in expenditures on pharmaceutical direct-to-consumer advertising.
- Rapidly-expanding self-care market, particularly for "alternative" medicines such as dietary supplements which when taken in combination with prescription medicines, non-prescription medicines and supplements can increase the chance for dangerous drug-drug interactions and other adverse drug events.
- Broader range of outlets providing medications, such as: on-line global pharmacies, mail-order, and community retail pharmacies.
- Advent of managed care, resulting in more frequent switching among health care plans, providers, and pharmacies. Such switching may negatively impact a patient's continuity of care, thus impairing optimal medicine communication between all of the patient's health care providers and caregivers.

Types of errors occurring in ambulatory or home health care settings may include errors in provider drug prescribing (e.g. wrong dose, wrong medication, wrong route, prescribing a medication despite a known allergy, etc.), pharmacy dispensing, and parental administration. Outpatient drug complications related to medication errors are not well documented in adults or children.

Home health care settings also pose additional challenges. Not only are there opportunities for errors in the intravenous administration of medications (e.g. prepackaged medications, preparing and disposing of syringes) but also in the management of children on ventilators and other forms of medical equipment. This setting is critical to future research efforts given the interest in containing healthcare costs through early discharge to the home.

Namely, a pharmacist fills the prescription of a foreign patient. The pharmacist checks the medication history and other current use of drugs in the patient's electronic health record, provided by the internet.



## 8.4 Global comparison of market statistics

The statistical analysis of drug marketing activities globally would be expedited using drug formulation level and virtual product name concept level as described in 2.12.

The international coding system can be used for the price comparison on same dispensable clinical product level or sales volume, etc.

## 8.5 Inventory control and purchasing

Package codes and company codes may be useful in inventory control and purchasing in hospitals or community pharmacies. Also, packing package codes and company code may be useful in identifying price per package size with the same drug formulation.

## 8.6 Supply chain

The existing GS1 system is well established for supply chain. Therefore, this Technical Report will not solicit nor address business requirements for the e-pharmacy supply chain. But international coding system for the supply chain can make use of drug databases of all trading partners, cross referenced by the identifying characteristics of the medicinal products.

## 8.7 Pharmacovigilance tracking: Adverse Drug Reactions (ADR) recall

The World Health Organization Policy Perspectives on Medicine, October 2004, defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. The international coding system will become a pharmacovigilance tool to aid in the tracking, prevention, detection of adverse effects.

## 8.8 Coding transparency

The business requirements describe the clinical shortfalls with pharmaceutical terminologies and the need for coding transparency. For this Technical Report, the power of an international coding system for medicinal products comes from a clinical observance of the need for “atomic” level data. A clear definition of atomic level data makes the logical and physical design of pharmaceutical terminologies possible. There are many pharmaceutical terminologies creating redundancy among medicinal drug products. An international coding system would clarify multiple drug nomenclatures and create drug product transparency.

# 9 Issues in achieving an international coding system to fulfill business requirements

A Drug Formulation Code could be created and marketed internationally.

Each country presently may use different definition or different terminology of route of administration, dose form and strength.

For example: Zovirax (acyclovir) ophthalmic oint 3 % in USA; Zovirax topical oint 3 % in Korea highlighting that the vocabulary of the route of administration is distinct: ophthalmic is used in USA; topical in Korea.

The identification of the extent and terms for route of administration, dose form and strength, and strength unit measures are needed prior to the development of a medicinal product code.

This Technical Report is intended to facilitate the creation of a marketed active ingredients list, medicinal products list, company list, dose form list and strength of pharmaceutical product which should be made readily available.

## 10 Recommendations for next steps

This Technical Report finds no medicinal coding system with concatenated ingredient name, product name, route of administration, dose form, strength and strength unit, country code, company code and package size which can be used for clinical information. However, the Technical Report finds the World Health Organization- Drug Dictionary (WHO-DD) could meet the business requirements of an international coding system. Although the WHO-DD products codes do not have intrinsic meaning, the WHO-DD has the potential to achieve the necessary product specificity to support the clinical benefits. The existing WHO-DD codes could be modified to incorporate route of administration using a concatenation methodology over the existing schema. The Technical Report finds the international business requirements require a comprehensive international coding system for medicinal products. Therefore, a concatenated coding system is a priority for advancing the clinical use of international medicinal drug products.

The international coding system for medicinal products should meet the variable levels of specificity, depending on the amount of information available at the time. A drug formulation code is a current omission of the coding structures in the significant international coding systems in current use: GS1, NDC, WHO-DD.

A unified international medicinal code structure with a concatenative drug formulation code could provide a mechanism to uniquely identify a medicinal product, regardless of where the product is authorized and marketed.

## Annex A (informative)

### WHO Drug Dictionary

**Table A.1 — WHO-DD dose form codes and descriptions**

001	Unspecified
100	TABLETS
101	TABLETS, TONGUE SOLUBLE
102	TABLETS, BUCCAL
103	TABLETS, SUBLINGUAL
104	TABLETS, CHEWABLE
105	TABLETS, EFFERVESCENT
106	TABLETS, LAYERED
107	TABLETS, SOLUBLE
108	TABLETS, ENEMA
109	TABLETS, OTHER
110	TABLETS, COMBINATION PACK
125	COATED TABLETS
126	COATED TABLETS, GELATIN
127	COATED TABLETS, FILM
128	COATED TABLETS, ENTERIC
129	COATED TABLETS, SUBLINGUAL
130	COATED TABLETS, CHEWABLE
131	COATED TABLETS, MEMBRANE
132	COATED TABLETS, OTHER
133	COATED TABLETS, COMBINATION PACK
150	CAPSULES
151	CAPSULES, ENTERIC-COATED
152	CAPSULES, BUCCAL
153	CAPSULES, BITING
154	CAPSULES, CHEWABLE
155	CAPSULES, MEMBRANE
156	CAPSULES, CACHETS
157	CAPSULES, INHALER
158	CAPSULES, FOR TOPICAL APPLICATION
159	CAPSULES, OTHER

Table A.1 (continued)

160	CAPSULES, COMBINATION PACK
175	SPECIAL SOLID FORMS, PELLETS
176	SPECIAL SOLID FORMS, LOZENGES
177	SPECIAL SOLID FORMS, CHEWING GUM
178	SPECIAL SOLID FORMS, SWEETS/CANDY/BONBONS
179	SPECIAL SOLID FORMS, OCULAR THERAPEUTIC SYSTEMS
180	SPECIAL SOLID FORMS, CUBES
181	SPECIAL SOLID FORMS, CAKES/CHOCOLATE/BARS/BISCUITS
182	SPECIAL SOLID FORMS, GLOBULI AND HOMEOPATHIC GLOBULI
183	SPECIAL SOLID FORMS, OTHER
184	SPECIAL SOLID FORMS, COMBINATION PACK
200	POWDERS
201	POWDERS, GRANULES
202	POWDERS, DUSTING
203	POWDERS, MEDICINAL/PHARMACEUTICAL SOLID SUBSTANCES
204	POWDERS, SUBLINGUAL POWDERS/GRANULES
205	POWDERS, EFFERVESCENT POWDERS/GRANULES
206	POWDERS, SOLUBLE
207	POWDERS, UNIT DOSE POWDER INHALER NON-REFILLABLE
208	POWDERS, UNIT DOSE POWDER INHALER REFILLABLE
209	POWDERS, UNIT DOSE
210	POWDERS, ENEMA
211	POWDERS, OTHER POWDERS/GRANULES
212	POWDERS, COMBINATION PACK POWDERS/GRANULES
225	GASES, FOR INHALATION
250	LIQUIDS
251	LIQUIDS, DROPS
252	LIQUIDS, SPRAYS WITHOUT GAS
253	LIQUIDS, COLLODION/LACQUERS
254	LIQUIDS, INHALATIONS
255	LIQUIDS, SUBLINGUAL
256	LIQUIDS, OILS
257	LIQUIDS, DRY SUSPENSIONS/SYRUPS/DROPS
258	LIQUIDS, SUSPENSIONS
259	LIQUIDS, EMULSIONS
260	LIQUIDS, SYRUPS
261	LIQUIDS, UNIT DOSE

**Table A.1** (continued)

262	LIQUIDS, METERED-DOSE
263	LIQUIDS, SPIRITS/WINES
264	LIQUIDS, LOTIONS
265	LIQUIDS, SHAKING MIXTURES FOR DERMATOLOGICAL USE
266	LIQUIDS, SOAPS/WASHES
267	LIQUIDS, ENEMA
268	LIQUIDS, OTHER
269	LIQUIDS, COMBINATION PACK
275	PRESSURISED AEROSOLS
276	PRESSURISED AEROSOLS, POWDERS
277	PRESSURISED AEROSOLS, BREATH-ACTUATED METERED-DOSE INHALER
278	PRESSURISED AEROSOLS, BREATH-ACTUATED CFC-FREE M-DOSE INH.
279	PRESSURISED AEROSOLS, METERED DOSE
280	PRESSURISED AEROSOLS, CFC-FREE METERED-DOSE INHALERS
281	PRESSURISED AEROSOLS, OINTMENTS
282	PRESSURISED AEROSOLS, FOAMS
283	PRESSURISED AEROSOLS, SOAPS/WASHES
284	PRESSURISED AEROSOLS, OTHER
285	PRESSURISED AEROSOLS, COMBINATION PACK
300	BATHS
301	BATHS, SOLID SUBSTANCES
302	BATHS, OILS
303	BATHS, EMULSIONS
304	BATHS, PARTIAL
305	BATHS, FOOT
306	BATHS, FOAM
307	BATHS, TABLETS
308	BATHS, OTHER
309	BATHS, COMBINATION PACK
325	TEAS
326	TEAS, EXTRACT LIQUIDS
327	TEAS, INSTANT
328	TEAS, BAGS
329	TEAS, TABLETS
330	TEAS, OTHER
331	TEAS, COMBINATION PACK
350	SUPPOSITORIES

Table A.1 (continued)

351	SUPPOSITORIES, ADULT
352	SUPPOSITORIES, PAEDIATRIC
353	SUPPOSITORIES, VAGINAL
354	SUPPOSITORIES, MICRO ENEMAS
355	SUPPOSITORIES, OTHER
356	SUPPOSITORIES, COMBINATION PACK
375	AMPOULES
376	AMPOULES, DRY
377	AMPOULES, INTRAVENOUS
378	AMPOULES, INTRAMUSCULAR
379	AMPOULES, SUBCUTANEOUS
380	AMPOULES, INSTILLATION
381	AMPOULES, OTHER
382	AMPOULES, COMBINATION PACK
400	PRE FILLED SYRINGES
401	PRE FILLED SYRINGES, DRY
402	PRE FILLED SYRINGES, INTRAVENOUS
403	PRE FILLED SYRINGES, INTRAMUSCULAR
404	PRE FILLED SYRINGES, SUBCUTANEOUS
405	PRE FILLED SYRINGES, PENS
406	PRE FILLED SYRINGES, DRY PENS
407	PRE FILLED SYRINGES, INSTILLATION
408	PRE FILLED SYRINGES, OTHER
409	PRE FILLED SYRINGES, COMBINATION PACK
425	VIALS
426	VIALS, DRY
427	VIALS, INTRAVENOUS
428	VIALS, INTRAMUSCULAR
429	VIALS, SUBCUTANEOUS
430	VIALS, CARTRIDGES
431	VIALS, DRY CARTRIDGES
432	VIALS, UNIT DOSE CARTRIDGES
433	VIALS, INSTILLATION
434	VIALS, OTHER
435	VIALS, COMBINATION PACK
450	INFUSION AMPOULES
451	INFUSION AMPOULES, DRY

**Table A.1** (continued)

452	INFUSION AMPOULES, VIALS/BOTTLES
453	INFUSION AMPOULES, DRY VIALS/BOTTLES
454	INFUSION AMPOULES, BAGS
455	INFUSION AMPOULES, CARTRIDGES
456	INFUSION AMPOULES, DIALYSIS IRRIGATION AND PERFUSION SOLU.
457	INFUSION AMPOULES, OTHER
475	OINTMENTS
476	OINTMENTS, PASTES
477	OINTMENTS, EMULSION
478	OINTMENTS, UNIT DOSE OINTMENTS AND PASTES
479	OINTMENTS, SOAP PASTES
480	OINTMENTS, OTHER
481	OINTMENTS, COMBINATION PACK
500	CREAMS
501	CREAMS, EMULSION
502	CREAMS, UNIT DOSE
503	CREAMS, SOAPS /WASHES
504	CREAMS, OTHER
505	CREAMS, COMBINATION PACK
525	GELS AND SOLS
526	GELS AND SOLS, GEL DROPS
527	GELS AND SOLS, EMULSION GELS
528	GELS AND SOLS, UNIT DOSE GELS/SOLS
529	GELS AND SOLS, WASH/SHOWER GELS
530	GELS AND SOLS, OTHER
531	GELS AND SOLS, COMBINATION PACK
550	MEDICATED DRESSINGS, PLASTERS WITH SUBSTANCE
551	MEDICATED DRESSINGS, COTTON WITH SUBSTANCE
552	MEDICATED DRESSINGS, GAUZE OR FLEECE WITH SUBSTANCE
553	MEDICATED DRESSINGS, PADS WITH SUBSTANCE
554	MEDICATED DRESSINGS, TAMPONS WITH SUBSTANCE
555	MEDICATED DRESSINGS, BANDAGES WITH SUBSTANCE
556	MEDICATED DRESSINGS, SPONGES WITH SUBSTANCE
557	MEDICATED DRESSINGS, TRANSDERMAL PATCHES
558	MEDICATED DRESSINGS, POULTICES
559	MEDICATED DRESSINGS, OTHER
560	MEDICATED DRESSINGS, COMBINATION PACK

Table A.1 (continued)

575	OTHER SPECIAL FORMS - FOOD READY TO EAT
576	OTHER SPECIAL FORMS - FOOD NOT READY TO EAT
577	OTHER SPECIAL FORMS – CIGARETTES
578	OTHER SPECIAL FORMS - STYLI AND WOUND CONES NON-RECTAL
579	OTHER SPECIAL FORMS - STICKS AND ROLL ONS
580	OTHER SPECIAL FORMS - BONE CEMENTS WITH SUBSTANCE
581	OTHER SPECIAL FORMS - MECHANICAL PESSARIES WITH SUBSTANCE
582	OTHER SPECIAL FORMS - INTRA UTERINE DEVICES
583	OTHER SPECIAL FORMS - FUMIGATION CANDLES
584	OTHER SPECIAL FORMS – FOAMS
585	OTHER SPECIAL FORMS - IMPLANTS
586	OTHER SPECIAL FORMS - SOLID SOAPS/BARS
587	OTHER SPECIAL FORMS - PROMOTIONAL PACKS
588	OTHER SPECIAL FORMS – OTHER
589	OTHER SPECIAL FORMS - COMBINATION PACK
600	MEDICAL AIDS - PLASTERS WITHOUT SUBSTANCE
601	MEDICAL AIDS - COTTON WITHOUT SUBSTANCE
602	MEDICAL AIDS - GAUZE OR FLEECE WITHOUT SUBSTANCE
603	MEDICAL AIDS - PADS WITHOUT SUBSTANCE
604	MEDICAL AIDS - TAMPONS WITHOUT SUBSTANCE
605	MEDICAL AIDS - BANDAGES WITHOUT SUBSTANCE
606	MEDICAL AIDS - SPONGES WITHOUT SUBSTANCE
607	MEDICAL AIDS - TISSUE ABSORBABLE MEDICAL AIDS
608	MEDICAL AIDS - GEL AND COLLOID DRESSINGS
609	MEDICAL AIDS - BONE CEMENTS WITHOUT SUBSTANCE
610	MEDICAL AIDS - MECHANICAL PESSARIES WITHOUT SUBSTANCE
611	MEDICAL AIDS - DIAGNOSTIC STICKS
612	MEDICAL AIDS - DIAGNOSTIC TESTS EXCLUDING STICKS
613	MEDICAL AIDS – OTHER
614	MEDICAL AIDS - COMBINATION PACK
900	Combination



**Table A.2 — WHO-DD strength and strength units**

000013	100 mg
000014	200 mg
000023	25 mg
000039	75 mg
000053	80 mg
000062	500 mg
000068	250 mg
000083	1 g
000157	125 mg
000202	1 000 mg
001057	665 mg

## Annex B (informative)

### GS1

**Table B.1 — GS1 status chart (2008)**

Country (grouped by continent)	Type of ruling	Product boundary	What is happening in reality
	Law Regulation Guidance Proposal		Symbology (NGTIN = National code incorporated in GTIN)
Austria		Pharmaceutical	
Belgium		Animal health	
Belgium	Law (Royal Decree)	Pharmaceutical	
Denmark		Pharmaceutical	GTIN-13, GS1-128, Databar, DataMatrix; NGTIN (inc. VNR)
Finland		Pharmaceutical	<u>See Denmark</u>
France		Medical devices	GS1-128, DataMatrix
France	Law	Medical devices (surgical instr.)	GS1-128, DataMatrix, EPC
France	Regulation	Pharmaceuticals	NGTIN (inc. AMM)
Germany		Pharmaceutical	GTIN-13, PZN in Code 39
Greece	Law	Pharmaceutical	GTIN-13; NGTIN
Ireland		Pharmaceutical	NGTIN-13, NGTIN-8
Italy	Law	Pharmaceutical	Code39 (Inc. Bollino); Interleaved 2/5 (Serial No.)
Latvia		Pharmaceutical	GTIN-13
Netherlands		Pharmaceutical	GS1-128
Portugal		Pharmaceutical	Code 39 ; GTIN-13
Spain	Law	Medical devices	NGTIN
Spain	Law (Andalucia)	Medical devices	GS1-128; GTIN-13
Spain	Law	Pharmaceuticals	GS1-128; GTIN-13
Spain	Proposal	Pharmaceutical	GS1-128
Sweden		Medical devices	GTIN-13; GS1-128
Sweden		Pharmaceuticals	NGTIN-13; GS1-128
Sweden		Pharmaceuticals	<u>See Denmark</u>
UK	Guidance	All (products and people)	
UK	Guidance	Medical devices	
Iceland		Pharmaceutical	<u>See Denmark</u>

Table B.1 (continued)

Country (grouped by continent)	Type of ruling	Product boundary	What is happening in reality
	Law Regulation Guidance Proposal		Symbology (NGTIN = National code incorporated in GTIN)
Norway		Pharmaceutical	See Denmark
Switzerland		Animal Health	
Switzerland		Medical devices	
Switzerland	Law	Pharmaceuticals	GTIN-13
Turkey	Law	Medical devices	GTIN-13
Turkey	Law	Pharmaceuticals	
Czech Republic		Pharmaceuticals	GTIN-13; GTIN-8
Estonia		Pharmaceuticals	GTIN-13; GTIN-8
Hungary		Medical devices; Pharmaceuticals; (including animal health)	GS1-128
Poland	Law	Pharmaceuticals	NGTIN-13
Romania		Pharmaceuticals	NGTIN-13; NGTIN-8
Slovakia	Law	Pharmaceuticals	NGTIN
Slovakia	Law	Animal Health	
Slovenia	Regulation	Pharmaceuticals	NGTIN
Slovenia		Medical devices	NGTIN
Yugoslavia (seven countries: Bosnia and Herzegovina, Croatia, Kosovo, Macedonia, Montenegro, Serbia, Slovenia)	Law	Pharmaceuticals	GTIN-13; GTIN-8
Albania		Pharmaceuticals	QKKB sticker
Armenia		Pharmaceuticals	GTIN-13
Belarus		Pharmaceuticals	GTIN-13; GTIN-8
Bosnia and Herzegovina		Pharmaceuticals	GTIN-13
Croatia		Pharmaceuticals	GTIN-13
Former Yugoslav Republic of Macedonia	Law	Pharmaceuticals; Medical devices	GTIN-13
Kazakhstan	Regulation	Pharmaceuticals	GTIN-13; GTIN-8
Russia		Pharmaceuticals; Medical devices	GTIN-13; GTIN-8
Serbia	Regulation	Pharmaceuticals; Medical devices	GTIN-13; GTIN-8
Ukraine	Law	Pharmaceuticals	GTIN-13
Cyprus		Pharmaceuticals (for export)	GTIN-13; GTIN-8

Table B.1 (continued)

Country (grouped by continent)	Type of ruling	Product boundary	What is happening in reality
	Law Regulation Guidance Proposal		Symbology (NGTIN = National code incorporated in GTIN)
Egypt		Pharmaceuticals	NGTIN-13
Israel	MoH working on Regulation	Pharmaceuticals	GTIN-13
Jordan		Pharmaceuticals	GTIN-13
Lebanon		Pharmaceuticals	
Morocco		Pharmaceuticals	GTIN-13
South Africa		Pharmaceuticals	GTIN-13; GTIN-14
Syria		Pharmaceuticals	NGTIN-13; GS1-128
Tunisia		Pharmaceuticals	GTIN-13
Argentina		Pharmaceuticals	GS1 (not specified)
Bolivia			GS1 (not specified)
Brazil	Regulation	Pharmaceuticals	GTIN-13; GS1-128
Canada	Guidance	Pharmaceuticals; Medical devices	GTIN(95% for drugs); UPN/HIBCC
Chile	Regulation	Pharmaceuticals	GTIN-13; GTIN-8; GTIN-14
Colombia	Regulation [handling unit dose (resolution 1403, Chapter III Art 13-15)]	Pharmaceuticals	GTIN-13; GTIN-8; GS1-128
Costa Rica		Pharmaceuticals	GTIN
Cuba		Pharmaceuticals	GTIN
Dominican Republic		Pharmaceuticals	GTIN-13
Ecuador		Pharmaceuticals	GS1 (not specified)
El Salvador		Pharmaceuticals	GTIN-13; GTIN-8
Guatemala			
Mexico	Regulation	Pharmaceuticals Medical devices	GTIN-13; GTIN-8; GTIN-12
Panama		Pharmaceuticals	GTIN-13; GTIN-12
Paraguay		Pharmaceuticals	GTIN-13; GTIN-8
Peru		Pharmaceuticals	
Uruguay		Pharmaceuticals	GTIN-13; GTIN-8
USA	FDA Mandate + various state laws (e.g. California)	Pharmaceuticals	NGTIN (Inc. NDC)
USA	Law	Medical Devices	
Venezuela	Regulation	Pharmaceuticals	GTIN-13; GTIN-8

## Annex C (informative)

### RxNORM

RxNorm is the National Library of Medicine (NLM) standardized nomenclature for clinical drugs available through the Unified Medical Language System, UMLS®. <http://www.nlm.nih.gov/research/umls/rxnorm/>

**Table C.1 — RxNORM term type, type name and description (2008)**

Term type	Type name	Description	Examples
IN	Ingredient	A compound or moiety that gives the drug its distinctive clinical properties. The preferred name is usually the USAN name.	Fluoxetine, insulin, isophane, human gentamicin sulfate (USP)
PIN	Precise ingredient	A specified form of the ingredient that may or may not be clinically active. Most precise ingredients are salt or isomer forms.	<i>Fluoxetine hydrochloride</i>
DF	Dose form	See appendix 2 found in the overview for a list of dose forms available in RxNorm.	<i>Oral solution</i>
SCDC	Semantic clinical drug component	Ingredient plus strength see section on rules and conventions, below, for units of measurement and for rules pertaining to the calculation of strengths.	Fluoxetine 4 mg/ml
SCDF	Semantic clinical drug form	Ingredient plus dose form.	Fluoxetine oral solution
SCD	Semantic clinical drug	Ingredient plus strength and dose form.	Fluoxetine 4 mg/ml oral solution
BN	Brand name	A proprietary name for a family of products containing a specific active ingredient.	Prozac
SBDC	Semantic branded drug component	Branded ingredient plus strength.	Fluoxetine 4 mg/ml [Prozac]
SBDF	Semantic branded drug form	Branded ingredient plus dose form.	Fluoxetine oral solution [Prozac]
SBD	Semantic branded drug	Ingredient, strength, and dose form plus brand name.	Fluoxetine 4 mg/ml oral Solution [Prozac]
SY	Synonym	Synonym of another TTY, given for clarity	Prozac 4 mg/ml oral solution

## Annex D (informative)

### UNIQUE Identifier (UNII)

FDA/USP Substance Registration System (SRS) assigns a UNIQUE Identifier (UNII) to each unique substance. The UNII is used in FDA's Structured Product Labeling (SPL), RxNORM, UMLS®, & NDF-RT™. <http://www.fda.gov/oc/datacouncil/SRS.htm>

**Table D.1 — UNIQUE Identifier (UNII) for substances table (2008)**

Substance	UNII
.DELTA.8-TETRAHYDROCANNABINOL	B49D0HH807
1,1,1-TRICHLOROETHANE	113C650IR1
2-(DIETHYLAMINO)ETHANOL	S6DL4M053U
2',4',5',7'-TETRABROMOFLUORESCEIN DISODIUM SALT	TDQ283MPCW
3,6-DIAMINO-10-METHYLACRIDINIUM CHLORIDE	1TW3Q60E36
3-TYROSINE DL-	45KGG1D4BI
4-((5-((CYCLOPROPYLAMINO)CARBONYL)-2-METHYLPHENYL)AMINO)-5-METHYL-N-PROPYLPYRROLO(2,1-F)(1,2,4)TRIAZINE-6-CARBOXAMIDE HYDROCHLORIDE	3Z6GAP3R9Q
ABACAVIR	WR2TIP26VS
ALANINE, DL-	1FU7983T0U
ALANOSINE	2CNI71214Y
BEEF	4PIB2155QP
BEEF LIVER	W8N8R55022
BEFUNOLOL	418546MT3A
BELL PEPPER	JLH5RT8O28
BELLADONNA	WQZ3G9PF0H
BELLADONNA LEAF	6GZW20TIOI
BELLADONNA RADIX	6MW97Q6E8M
CAFFEINE	3G6A5W338E
CALAMUS OIL	5F9K5X640P
CARBENICILLIN INDANYL	5V278481KE

## Annex E (informative)

### National Drug File — Reference Terminology (NDF-RT)

The National Drug File Reference Terminology (NDF-RT™) is a Veterans Health Administration (VHA) reference standard for medications supporting clinical, administrative and analytical use. NDF-RT™ is the terminology used by FDA and other US Federal agency collaborations to code these essential pharmacologic properties of medications. It is composed of three tables:

- mechanism of action (see Table E.1);
- physiologic effect (see Table E.2);
- structural class (see Table E.3).

**Table E.1 — NDF-RT codes and names (2008)**

NDF-RT™ code	NDF-RT™ name
N0000020025	14-alpha demethylase inhibitors
N0000000126	5-alpha Reductase inhibitors
N0000010218	Absorbs ultraviolet A radiation

**Table E.2 — NDF-RT physiological effect**

NDF-RT™ code	NDF-RT™ name
N0000008290	Acetylcholine activity alteration
N0000008291	Adrenal cortical activity alteration
N0000008292	Adrenal medullary activity alteration
N0000008293	Alveolar surface tension alteration
N0000008294	Alveolar surface tension reduction
N0000175439	Analgesia
N0000175538	Anesthesia
N0000008295	Antacid

**Table E.3 — NDF-RT structural class**

NDF-RT™ code	NDF-RT™ name
N0000166498	(4-(m-Chlorophenylcarbamoyloxy)-2-butynyl)trimethylammonium Chloride
N0000166926	(R)-2,3,4,5-Tetrahydro-8-chloro-3-methyl-5-phenyl-1H-3-benzazepin-7-ol
N0000166560	1,2-Dimethylhydrazine
N0000007747	1,2-Dipalmitoylphosphatidylcholine

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- [3] <http://www.fda.gov/cder/ndc/database/Default.htm>
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