

IDMP Project Scope Statements

Per ISO CD documents, dated 1 May 2009

ISO [CD-11615](#), dated 2009-05-01

Health informatics – Identification of Medicinal Products - Data elements and structures to uniquely identify medicinal products (MPIDs) for the exchange of regulated medicinal product information

1 Scope

1.1 Domain

The project will develop a single format for the exchange of information that uniquely and certainly identifies a medicinal product, wherever authorised. Furthermore, the project will adapt, adopt, or if necessary, develop a set of rules, and a format for the generation of unique identifiers for medicinal products that can be used for their worldwide unambiguous identification.

1.1.1 Immediate scope

The immediate scope addresses the needs of healthcare professionals, patients, investigators and sponsors of clinical trials, marketing authorisation holders and regulators in the human pharmaceutical domain. The scope of the initial standard is addressing the following areas:

- Health care business and prescribing of medicines to patients
- Medicinal product registration (with initial focus on information required to support the monitoring of the safety of medicinal products)
- Pharmacovigilance i.e. the supervision of the safety of medicinal products for human use including the area of clinical trials
- Facilitation of communication between the regulatory and healthcare domains
- Limited information on the medicinal product manufacturer(s), packaging and medical device¹ details
- Recording in Electronic Health Records (EHR), referring to an individual patient's [medical record](#) in digital format

Medicinal products for human use are included in the immediate scope:

- Chemical Medicinal Products
- Radio-Pharmaceuticals and Precursors
- Antisense Oligonucleotides
- Vaccines
- Allergens
- Immunoglobulins and Immunoserum
- Gene therapy medicinal product
- Somatic cell therapy medicinal product

¹ This relates to advanced therapies (including a description of the physical characteristics and performance of the advanced therapy medicinal product containing medical devices, bio-materials, scaffolds or matrices).

- Other Biologicals that include:
 - Toxins (general)
 - Albumins and other Plasma derived products for human use
 - Plasma derived and recombinant coagulation factors
 - Agents acting on Haematopoietic System
 - Hormones
 - Immunomodulators and Immunostimulants
 - Enzymes
 - Traditional herbal medicinal products and herbal, animal and mineral preparations

Medicinal products for human use include the following:

-- Medicinal products, which have been subject to a regulatory authorisation process i.e. a medicinal product may only be placed on the market following approval by a regulator (e.g. in the European Economic Area (EEA) when a marketing authorisation has been issued by the competent authority of a Member State (or EEA country) for its own territory (national authorisation) or when an authorisation has been granted via the centralised procedure; in Japan the regulatory authority is the PMDA; in the US the Food and Drug Administration (FDA)).

EXAMPLE: TAMIFLU® Capsule 75, <Oseltamivir phosphate formulation> Standard Commodity Classification No. of Japan 87625, Approval No. 21200AMY00238

-- Medicinal products, which are actually marketed following authorisation e.g. after a marketing authorisation is granted, the holder of the authorisation shall inform the regulator of the date of actual marketing of the medicinal product, taking into account the various product presentations authorised.

-- Medicinal products, which are authorised but not marketed i.e. the holder maintains the medicinal product authorisation but the medicinal product is only marketed when applicable e.g. pandemic influenza vaccines.

-- Medicinal products, where the authorisation has been subject to a regulatory suspension, revocation or withdrawal. For drug regulatory and pharmacovigilance purposes it is important to maintain information in case the medicinal product authorisation was withdrawn. Suspensions are not reflected in the model, as the authorisation is still valid but is subject to further evaluations.

-- Medicinal products, where the marketing authorisation has not been renewed i.e. the marketing authorisation is no longer valid. For drug regulatory and pharmacovigilance purposes it is important to maintain the medicinal product information.

-- Medicinal products, which do not require a marketing authorisation i.e. depending on regional laws and regulations a formal marketing authorization might not be required for certain categories of medicinal products (e.g. certain OTC drugs, 'grandfather' drugs in the US).

-- Medicinal products, which are subject to an investigation in a clinical trial.

-- Medicinal products, which are combination medicinal products and where the basis for deciding which regulatory regime is applicable to combinations of medicinal products and medical devices is the principal mode of action of the combination product.

EXAMPLE: Taking into account the complexity of combined advanced therapy medicinal products containing viable cells or tissues, in the EU these products are classified as medicinal products. This is independent of the role of the medical device and the pharmacological, immunological or metabolic action of the cells or tissues should be considered to be the principal mode of action of the combination product.

[ISO CD-11616](#), dated 2009-05-01

[Health informatics – Identification of Medicinal Products - Data elements and structures to uniquely identify and exchange pharmaceutical products \(PhPIDs\)](#)

2 Scope

2.1 Domain

The project will adapt, adopt, or if necessary, develop a set of rules, and a format for the generation of unique identifiers for pharmaceutical medicinal products that can be used for their worldwide unambiguous identification. The project will also develop a system for the linking of the Pharmaceutical Product Identifiers (PHPIDs) with the relevant Medicinal Product Identifiers (MPIDs).

2.1.1 Immediate scope

The immediate scope addresses the needs of healthcare professionals, patients, investigators and sponsors of clinical trials, marketing authorisation holders and regulators in the human pharmaceutical domain. The scope of the initial standard is addressing the following areas:

- Clinical and healthcare domain: the clinical use cases are divided into four areas reflecting the core areas in which the description of medicinal products is most fundamental: the Prescribing (drug selection from a range), Dispensing, and Administration of medicines for patients and Decision Support functionality to support these processes.
- Medicinal product registration (with main focus on pharmacovigilance) and the identification of pharmaceutical products
- Pharmacovigilance i.e. the supervision of the safety of human medicinal products
- Facilitation of communication between the clinical, healthcare and regulatory domains

Medicinal products for human use are included in the immediate scope:

Note: same products as identified in CD-11615

Medicinal products for human use include the following:

Note: same products as identified in CD-11615

[ISO CD-11238](#), dated 2009-05-01

Health Informatics – Identification of Medicinal Products – Data elements and structures to uniquely identify and describe substances and specified substances

3 Scope

3.1 Scope from the ISO new work item ballot – Form 4

The document will adapt, adopt, or if necessary, develop a set of elements necessary for definition and a format for the generation of unique identifiers for ingredients and substances that can be used worldwide to unambiguously identify substances and ingredients present in medicinal products. The urgency of the need for a global system for the identification of substances and ingredients favors the adapting or adopting an existing system to generate identifiers. The initial scope of the document will be ingredients and substances in drugs, therapeutic biologics, allergens, botanicals (herbals) and vaccines approved for human or veterinary use by authorized regulatory authorities. Many pharmaceutical substances display pleiotropic activity influencing several biological pathways and can be used to treat diverse medical conditions. To avoid ambiguity or misinformation substances should be defined based on the elements necessary for complete definition and not by functional or therapeutic class. Each substance that can be defined at the molecular level will be defined by a two dimensional structural representation or the primary amino-acid sequence. When a substance cannot be defined at the molecular level because of insufficient structural information or complexity (e.g., polymers and botanicals) it will be defined using a fielded controlled vocabulary. A set of criteria will be developed for both structure entry and the use of terms that is deemed by experts to be sufficient to distinguish related and unrelated substances from one another. Substances will be classified by the elements necessary for definition. Chemical substances will be defined primarily by a two dimensional molecular structure, recombinant and purified proteins by the primary amino-acid sequence, botanicals by the plant and plant part of origin. Substances include, but are not necessarily limited to, chemicals, biologics (including vaccines, allergenic extracts, proteins, blood-derived products, cells, tissues, gene therapy) botanicals and select foods known to interact with drugs. This standard will initially address active, inactive substances, and impurities known to be present in pharmaceutical products.

3.2 Purpose and Justification of the ISO new work item ballot – Form 4

In the context of the regulation of substances, and particularly for the purpose of uniquely identifying medicinal products, it is necessary to establish accepted controlled vocabularies that are used for specific concepts. Maintenance and use of these controlled vocabulary terms, particularly as facilitated through the use of a reliable standard, will result in unambiguous vocabulary terms and their unique identifiers that can be used consistently by all stakeholders. Examples of specific uses of these terms and identifiers include the exchange of adverse event/adverse drug reaction reports, use in electronic prescribing and exchange of product information that can be used to create drug dictionaries and the tracking of substances and ingredients. Use of such controlled vocabularies and identifiers will contribute to the improved protection of public health and the exchange of information throughout the world, as well as minimize medication errors.

The relationship between this New Work Item Proposal and other New Work Items proposed in the group of items dealing with the identification of medicinal products is critical. The generation of unique and unambiguous identifiers for substances is essential for defining pharmaceutical products. The determination of the elements necessary to define substances will guide the extent of information that

needs to be captured under other New Work Items. This standard should result in a mechanism for generating unique identifiers for all classes of substances. The globalization of the pharmaceutical industry makes common substance definitions and identifiers essential for pharmacovigilance, regulatory actions and a variety of other purposes. An ingredient will contain a limited subset of additional elements that may be necessary to further describe a given material.

3.3 Scope statement

The document will develop structures, controlled vocabularies and identifiers for substances and ingredients that are used worldwide for both human and veterinary medicinal products, homeopathic products, food and feed additives and cosmetics. This includes both the vocabulary structure(s) and the controlled terms themselves. These must be translatable into any other required languages. Initially, languages include English, German, French, Spanish and Japanese.

- For the purposes of determining scope, an initial set of substances was identified. Substances will include chemicals, vaccines, allergenic extracts, recombinant coagulation factors, plasma derivatives including immune globulins, recombinant allergens, biologicals, botanicals, animal preparations, radiochemicals (or radiopharmaceuticals), hormones, enzymes, toxins, select food substances that are known to interact with drugs or cause adverse reactions, and substances used in gene and cell therapy. This is not meant to represent an inclusive list.
- Substances within both marketed and investigational products are included. Substances in investigational products may be included with restricted access.
- Substances include both the active substances and the inactive substances, e.g., excipients, contaminants and adjuvants.
- Substances have a spectrum of complexity from a pure single synthetic chemicals to herbals, vaccines, or sera that may contain thousands of different chemicals.
- Classification of substances, will be based on the minimal set of elements needed for definition and distinction. A proposed list of classes or categories of substances has been developed. The need for additional classes needs to be explored.
- Substances will be defined by a set of elements and will be divided into classes based on the set of elements necessary for definition. Potential elements include two-dimensional molecular structure, genus, species, and plant or animal part of origin, essential process steps, stereochemistry descriptors, and protein primary structure.
- If new elements are necessary to define or distinguish within a class of substances, the elements will either be added to an existing class of substances or a new class of substances will be created.
- Ingredients can include additional elements to further define a given material. These elements could describe the physical form, grade, source and manufacturer of a given material.
- An ingredient will only map to a single substance or a single set of substances. A substance can map to many ingredients.
- In addition to the elements necessary for definition, all substances and ingredients will be linked to strong non-semantic identifier, and a limited number of names or synonyms. Names and synonyms will be taken from official sources such as INN and USAN when available.

NOTE The scope of this standard is acknowledged to be broader than the scopes defined for regulated Product Information for Drug Dictionaries (prEN ISO 11615 MPID) and Pharmaceutical Product Identifiers (prEN ISO 11616 PhPID), which have a relationship to this standard.

[ISO CD-11239](#), dated 2009-05-01

[Health informatics - Identification of Medicinal Products - Data elements and structures to uniquely identify pharmaceutical dose forms, units of presentation and routes of administration](#)

4 Scope

A phased approach to the development of this work item has been adopted as the overall scope is too broad to be addressed effectively within the timelines specified for international standards by ISO. This scope section is therefore structured to address the immediate scope, and the eventual scope.

4.1 Purpose and justification of the new work item

In the context of the regulation of products used for human and veterinary treatment, it is necessary to establish accepted controlled vocabularies that are used for specific concepts. Maintenance and use of these controlled vocabulary terms, particularly as facilitated through the use of a reliable standard, will result in unambiguous vocabulary terms and their unique identifiers that can be used consistently by all stakeholders. The primary use of these terms and identifiers is in the exchange of adverse event/adverse drug reaction reports for the purposes of pharmacovigilance, but they will also have applications in other fields such as communications between manufacturers and regulatory authorities. Use of such controlled vocabularies will contribute to the improved protection of public health.

4.2 Scope statement

This standard will adapt, adopt or, if necessary, develop a set of rules and a system that can be used worldwide to unambiguously identify dose forms, units of presentation and routes of administration of products used for human and veterinary treatment. It will define both the vocabulary structures, which have to be common among the different controlled vocabularies, and the controlled terms themselves. These must be translatable into any other language requested (initial languages being English, French and Japanese), and will be made available in a specified form and maintained by a specified organization according to defined requirements.

The identification of a maintenance mechanism of vocabularies for dose forms, units of presentation and routes of administration is required and within scope. Assessment criteria shall be established and may include but are not limited to the organization providing the maintenance, how often maintenance is performed, and the criteria of the maintenance.

Each controlled term, once defined, will be associated with a unique identifier that can be used to link the dose form, unit of presentation or route of administration to synonyms used by regulatory authorities. The unique identifier should be non-semantic, random, of fixed length and have internal consistency or structure (i.e. check digit/character). The identifier can be a combination of alpha/numeric characters with a sufficient range to cover a large number of substances. The use of these unique identifiers shall be unencumbered (i.e. royalty-free, regardless of use). The ability to obtain a unique identifier should also not be restricted. A mechanism should also be present to generate identifiers for dose forms, units of presentation and routes of administration whose description or definition must be kept confidential. The scope of this standard is acknowledged to be broader than the scopes defined for prEN ISO 11238 and prEN ISO 11616, which have a relationship to this standard.

4.2.1 Immediate scope

The immediate scope comprises dose forms, units of presentation and routes of administration of medicinal products that are used worldwide for both human and veterinary treatment. Both marketed and investigational products are included (the latter with restricted access).

[ISO CD-11240](#), dated 2009-05-01

Health informatics - Identification of Medicinal Products - Data elements and structures to uniquely identify Units of Measurement

5 Scope

This draft international standard specifies information structures, a set of terms and term identifiers that can be used to communicate Units of Measurement in the human medicines domain to express:

- The quantitative composition of medicinal products;
- Any Units of Measurement required for adverse drug reaction reporting in the frame of Individual Case Safety Reports (ICSRs);
- The amount of a medicinal product taken in a certain time interval by a patient.

Aspects concerning the dosage syntax are not within the scope of this draft international standard. This draft international standard is applicable for the pharmacovigilance reporting of Individual Case Safety Reports, but may also be applicable to other use cases within the regulatory and clinical areas. The scope includes:

- The vocabulary structure(s) and the content i.e. controlled terms themselves;
- Message specifications to populate local dictionaries and repositories with terms and term identifiers;
- Plan for terminology maintenance.