

**Project: Identification of Medical Products**  
**Content with adds from meeting**  
**November 24, 2009**

1. Identification of Medical Products (Set of 5 draft documents)
2. Project proposed
  - a. ISO, HL7, CEN, CDISC
  - b. Ian Shepherd - Current overall project lead
3. Project Intent  
Normative - International Standard
4. Project Purpose
  - a. The justification for this project is that Electronic Prescribing and Medication Management require precise standards to define and format all of the required components for prescribing a medication. The components of prescribing include drug naming, drug form, route of administration, and units of measurement.
  - b. This project should be JIC because all of the SDO members of JIC have an interest in and wish to contribute to this standard.
  - c. The market is global and includes ICH with members EMEA, FDA and other countries.

5. Project Scope

This project includes five specific different but related sub projects. Each subproject will be defined separately with scope, participation and leadership defined for each. Each title begins with: [Health informatics - Identification of Medicinal Products -](#)

[11615 - Data elements and structures to uniquely identify medicinal products \(MPIDs\) for the exchange of regulated medicinal product information](#)

Scope: 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.

[16116 Data elements and structures to uniquely identify and exchange pharmaceutical products \(PhPIDs\)](#)

Scope: 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).

[11238 Data elements and structures to uniquely identify and describe substances and specified substances](#)

Scope: 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.

#### [11239 Data elements and structures to uniquely identify pharmaceutical dose forms, units of presentation and routes of administration](#)

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.

#### [11240 Data elements and structures to uniquely identify Units of Measurement](#)

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.

**SDO's Participation, lead and other details:**

- a. 11238: Data elements and structures to uniquely identify and describe substances and specified substances for medical products

- i. Participating SDOs

1. ISO Host

- a. 11238-- Name and ID of project
      - b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
      - c. SDO is already working on this specific project? Yes
      - d. Lead: Ian Shepherd
      - e. Approximate number of persons from SDO working on project are---35

2. HL7

- a. 11238-- Name and ID of project
      - b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
      - c. SDO is already working on this specific project? Yes
      - d. Lead: Garry Cruickshank and Julie James
      - e. Approximate number of persons from SDO working on project---35

3. CDISC

- a. 11238-- Name and ID of project
      - b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
      - c. SDO is already working on this specific project? Yes
      - d. Lead: Bron Kisler and Chris Tolk
      - e. Approximate number of persons from SDO working on project---2

4. CEN

- a. 11238-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Ian Shepherd
- e. Approximate number of persons from SDO working on project---2

#### 5. IHTSDO

- a. 11238-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Jim Shalaby , Bojan Pijetlovic/Cathy Trench
- e. Approximate number of persons from SDO working on project--2

#### b. 16116 2: Data elements and structures to uniquely identify and exchange pharmaceutical products (PhPIDs)

##### i. Participating SDOs

##### 1. ISO Host

- a. 16116-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Ian Shepherd
- e. Approximate number of persons from SDO working on project--35

##### 2. HL7

- a. 16116-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Garry Cruickshank and Julie James
- e. Approximate number of persons from SDO working on project--35

##### 3. CDISC

- a. 16116-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Bron Kisler and Chris Tolk
- e. Approximate number of persons from SDO working on project--2

## 4. CEN

- a. 16116-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Ian Shepherd
- e. Approximate number of persons from SDO working on project--2

## 5. IHTSDO

- a. 16116-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Leonora Grandia and Esme Parr
- e. Approximate number of persons from SDO working on project--2

## ii. 11239 3: Data elements and structures to uniquely identify pharmaceutical dose forms, units of presentation, and routes of administration.

## Participating SDOs

## 1. ISO Host

- a. 11239-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Ian Shepherd
- e. Approximate number of persons from SDO working on project--35

## 2. HL7

- a. 11239-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Garry Cruickshank and Julie James
- e. Approximate number of persons from SDO working on project--35

## 3. CDISC

- a. 11239-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes

- d. Lead: Bron Kislner and Chris Tolk
- e. Approximate number of persons from SDO working on project--2

4. CEN

- a. 11239-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Ian Shepherd
- e. Approximate number of persons from SDO working on project--2

5. IHTSDO

- a. 11239-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Julie James and Alison Merchant
- e. Approximate number of persons from SDO working on project--2

iii. 11240 4: Data elements and structures to uniquely identify units of measurements.

Participating SDOs

1. ISO Host

- a. 11240-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Ian Shepherd
- e. Approximate number of persons from SDO working on project--35

2. HL7

- a. 11240-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Garry Cruickshank and Julie James
- e. Approximate number of persons from SDO working on project--35

3. CDISC

- a. 11240-- Name and ID of project

- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Bron Kislner and Chris Tolk
- e. Approximate number of persons from SDO working on project--2

#### 4. CEN

- a. 11240-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Ian Shepherd
- e. Approximate number of persons from SDO working on project--2

#### 5. IHTSDO

- a. 11240-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: John Barned and Bryan Kang
- e. Approximate number of persons from SDO working on project--2

- iv. 11615 5: Data elements and structures to uniquely identify medicinal products (MPIDs) for the exchange of regulated medicinal product information.

#### Participating SDOs

##### 1. ISO Host

- a. 11615-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Ian Shepherd
- e. Approximate number of persons from SDO working on project--35

##### 2. HL7

- a. 11615-- Name and ID of project
- b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
- c. SDO is already working on this specific project? Yes
- d. Lead: Garry Cruickshank and Julie James
- e. Approximate number of persons from SDO working on project--35

3. CDISC
  - a. 11615-- Name and ID of project
  - b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
  - c. SDO is already working on this specific project? Yes
  - d. Lead: Bron Kisler and Chris Tolk
  - e. Approximate number of persons from SDO working on project--2
4. CEN
  - a. 11615-- Name and ID of project
  - b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
  - c. SDO is already working on this specific project? Yes
  - d. Lead: Ian Shepherd
  - e. Approximate number of persons from SDO working on project--2
5. IHTSDO
  - a. 11615-- Name and ID of project
  - b. 24 November 2009 --Date project approved for harmonization effort by the sponsoring SDO
  - c. SDO is already working on this specific project? Yes
  - d. Lead: Emma Melhuish and Pan Teng
  - e. Approximate number of persons from SDO working on project--2
6. Host SDO: ISO for all 5 documents
7. Project Objectives and deliverables (commitment levels)
  - a. Time line to be developed by the project teams
8. Where work will be done (primarily) in HOST SDO or combined SDO WG. Work needs to be scheduled at a time and place for maximum participation of all groups.
9. Project dependencies
  - a. Complementary work in HL7: Common Product Model which will be submitted to ISO as part of ISO/HL7 Pilot Project.
  - b. EMEA, ICH, FDA
  - c. Volunteer
10. Comments: Considerable cooperation and coordination will be required to properly identify all of the requirements of the multiple groups participating.
11. Date of JIC approval 24 November 2009