INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH E2B(R3) EXPERT WORKING GROUP / IMPLEMENTATION WORKING GROUP

INFORMATION PAPER REGARDING THE USE OF ISO IDMP STANDARDS IN E2B(R3) MESSAGES

Final version

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Document History

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Introduction

This information paper explains the current situation about the International Organization for Standardization (ISO) standards related to the identification of medicinal products (IDMP) that are used in E2B(R3) messages (as of 16 February 2021).

Background

In collaboration with ICH, ISO developed a set of standards to enhance exchange of information for medicinal products[1-5]. The Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) E2B(R3) Data Elements and Message Specification (E2B(R3) IG) in its Section 3.4 describes the data elements that use ISO IDMP vocabularies and identifiers (IDs) when they are available. The E2B(R3) Expert Working Group (EWG)/Implementation Working Group (IWG) anticipates that global controlled vocabularies and IDs conforming to ISO IDMP standards should be used in E2B(R3) messages when the global controlled vocabularies and the global IDs for the ISO IDMP are identified.

Until the controlled vocabularies for the ISO IDMP are available, temporary rules are applied to the data elements. Terms and identifiers/codes may be provided by each region until the ISO IDMP controlled vocabularies are implemented. See web sites of regional regulators for additional regional considerations, as appropriate.

Medicinal Product Identifier (MPID)

MPIDs are assigned and maintained regionally. See regional guidance for MPID use in E2B(R3) messages.

Pharmaceutical Product Identifier (PhPID)

PhPID is generated by an algorithm using Substance or Specified Substance TermID(s), a Pharmaceutical Dose Form TermID and a specific strength. However, at the time of writing this paper there is no global PhPID. Instruction of PhPID use in E2B(R3) messages will be provided by the E2B(R3) EWG/IWG when global PhPIDs and their maintenance organization are identified.

Substance/Specified Substance TermID

There are Substance/Specified Substance TermIDs maintained regionally. For example, U.S. FDA uses the unique ingredient identifier or UNII for substance identification. However, global Substance/Specified Substance TermIDs have not been available yet. Instruction of Substance/Specified Substance TermID use in E2B(R3) messages will be provided by E2B(R3) EWG/IWG when global Substance/Specified Substance TermIDs and their maintenance organization are identified.

Pharmaceutical Dose Form and Route of Administration TermID

Regarding Pharmaceutical Dose Form and Route of Administration TermID, E2B(R3) EWG/IWG agreed to use the Standard Terms for Dose Form and Route of Administration published by the European Directorate for the Quality of Medicines and Healthcare (EDQM) in E2B(R3) messages and has published the User Guide: Use of EDQM Terminologies for Dose Forms and Routes of Administration for Individual Case Safety Reports in E2B(R3)

message. See the ICH E2B User Guide for detailed instruction.

Unified Code for Units of Measure (UCUM)

The E2B(R3) IG explains how to use UCUM in E2B(R3) messages and UCUM is conformed to the ISO 11240. See the E2B(R3) IG and UCUM web site for further information.

Reference

1. ISO 11238 Health informatics − Identification of medicinal products − *Data elements and structures for the unique identification and exchange of regulated information on substances*

2. ISO 11239 Health Informatics − Identification of medicinal products − *Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

3. ISO 11240 Health informatics − Identification of medicinal products − *Data elements and structures for the unique identification and exchange of units of measurement*

4. ISO 11615 Health Informatics − Identification of medicinal products − *Data elements and structures for the unique identification and exchange of regulated medicinal product information*

5. ISO 11616 Health informatics − Identification of medicinal products − *Data elements and structures for the unique identification and exchange of regulated pharmaceutical product*