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Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information

Informatique de santé — Identification des médicaments — Lignes directrices pour l'implémentation des éléments de données et structures ISO 11615 pour l'identification unique et l'échange d'informations réglementées sur les médicaments

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Contents

Page

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

This document is a guide for implementing ISO 11615, one of the five ISO IDMP standards. The five ISO standards and four ISO Technical Specifications, when used together, provide the basis for exchanging data elements that will support the unique and unambiguous identification of Medicinal Products. The primary purpose for this document is to provide technical guidance to software implementers. Short descriptions of business rationale are also included, where relevant, to provide context. Thus, this document focuses on business and technical considerations for implementation that will construct and parse well-formed, transmittable IDMP messages. Following transmission of required data elements, unique identifiers are to be produced in conformance with the standards to support applications where it is necessary to reliably identify and trace regulated biopharmaceutical products. However, this document does not include extensive information on creation or maintenance of identifier repositories. Reference is made to regional guidance/implementation guides to support practical implementation within a given region/jurisdiction. The development of an ISO technical report for identifying core principles for the maintenance of identifiers and terms for ISO IDMP is to be developed and referenced for applicable ISO IDMP standards and corresponding technical specifications.

Purpose

To meet the primary objectives of the regulation of medicines (pharmacovigilance) it is necessary to reliably exchange Medicinal Product information in a robust and consistent manner. The data elements and message specifications described in this document support, at a minimum, the following interactions within the following scope:

— regulator to regulator;

— biopharmaceutical company to regulator;

— sponsor of clinical trials to regulator;

— regulator to other stakeholders;

— regulator to worldwide-maintained data sources.

Unique identifiers produced in conformance with this document are aimed at supporting applications where it is necessary to reliably identify and trace the use of Medicinal Products.

In the context of exchange of regulatory information, the purpose of this document is twofold:

— to specify data elements, structures and relationships between the data elements which are required to uniquely identify Medicinal Products for human use;

— to specify definitions of terms for all data elements required to uniquely identify Medicinal Products for human use.

Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information

1 Scope

This document defines concepts and describes data elements and their structural relationships, which are required for the unique identification and the detailed description of Medicinal Products.

Taken together, all ISO IDMP standards (ISO 11615, ISO 11616, ISO 11238, ISO 11239 and ISO 11240) define, characterise, and uniquely identify regulated Medicinal Products for human use from approval, to post-marketing and renewal or withdrawal from the market, where applicable.

Furthermore, to support successful information exchange in relation to the unique identification and characterisation of Medicinal Products, the normative use of HL7 common product model (CPM) and structured product labeling (SPL) messaging is described. References to the use of other relevant standards for Medicinal Product information are included in this document to support successful information exchange.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

ISO/IEC 5218, *Information technology — Codes for the representation of human sexes*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 11238, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated information on substances*

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*

ISO 11240, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of units of measurement*

ISO 11615, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated Medicinal Product information*

ISO 11616, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

ISO/TS 20440, *Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11239 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*

HL7 Reference Information Model (RIM).

HL7 Version 3 Standard, Common Clinical Product Model

HL7 Version 3 Standard, Common Product Model CMETs

HL7 Version 3 Standard, Regulated Product Submission

HL7 Version 3 Standard, Structured Product Labeling

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Message exchange

4.1 General

HL7 messaging standards are widely implemented globally. The HL7 V3 messaging standard deals with a static model of healthcare information as viewed within the scope of HL7 standards development activities. ISO recognises HL7 as an accredited partner organisation for mutually issuing standards. The first mutually published standard was ISO/HL7 21731:2006.

HL7 V3 was developed to address the complex requirements of health information technology. The HL7 Reference Information Model (RIM) is the cornerstone of V3 and the essential model from which all HL7 messages are derived. The RIM defines data content needed in a specific context and provides an explicit representation of the semantic and lexical connections that exist between the information carried in the elements of a message. V3 seeks to develop specifications that facilitate interoperability between systems. The HL7 model-driven methodology is used to develop consensus-based standards for healthcare system interoperability and information exchange. HL7 V3 messages are based on an XML encoding syntax.

The ISO IDMP standards were designed to specify the necessary data elements and associated standards to be used for unique identifiers. These were developed as an integral part of the IDMP consensus requirements and are consistent with the HL7 Common Product Model (CPM). The IDMP data elements represent a subset of those in the CPM. The normative use of HL7 standards will facilitate the integration of IDMP into the broader healthcare community.

4.2 Message exchange format

In the context of this document, the normative message exchange format to be utilised as reference in transactions is HL7 Structured Product Labeling (SPL). SPL is a standard message exchange format based on Clinical Document Architecture (CDA) and the HL7 Reference Information Model (RIM). Various solutions for creating SPL files exist and range from basic software tools to comprehensive information management systems. SPL instances (code snippets) are provided throughout to illustrate the representation of an IDMP concept within the HL7 SPL message exchange format. Technical conformance criteria for SPL messages will not be addressed in this document and shall be left to regional guidance/implementation per their respective requirements. A reference to the most up to date HL7 CPM and SPL reference as a resource for IDMP implementation is accessible on the HL7 website[1)].

4.3 Controlled vocabularies

There are many terms in use to describe basic concepts in the regulatory, pharmaceutical and healthcare standards development domain for different purposes and in different contexts. The terms and definitions described in this document apply to the concepts, which are required to uniquely identify, characterise, and exchange regulated Medicinal Products and associated information. A long-term goal for IDMP is to promote the development of controlled vocabularies for worldwide application, with transitional measures envisioned to accommodate regional requirements. Regional guidance/implementation guides shall be developed to support practical implementation within a given region/jurisdiction. The development of a technical report for identifying core principles for the maintenance of identifiers and terms for ISO IDMP shall be developed and referenced for applicable ISO IDMP standards and corresponding technical specifications upon completion.

NOTE Harmonisation by regions to adopt identical controlled vocabularies for IDMP implementation is out of the scope of this document, but is being facilitated by external activities outside of ISO. It is anticipated that this will be revisited as an in scope activity within ISO IDMP as the standard is adopted worldwide over time.

5 Conformance terminology and context as it relates to the ISO IDMP standards and corresponding technical specifications

— *Mandatory*: Defining elements ***necessary*** for the unique identification of Medicinal Products per the ISO IDMP standards/technical specifications.

— *Conditional*: Conditional applies to the "*within category*" data elements, as applicable, when there are alternative data sources for a given data element(s) to identify a medicinal/pharmaceutical product. Regional implementation of the ISO IDMP standards/technical specifications may elevate the conditional conformance categories to "***mandatory***" per regional requirements.

— *Optional*: When listed at the category level (e.g. specified substance), optional corresponds to ISO categories or data elements that are not absolutely necessary for the ***unique*** identification of medicinal/pharmaceutical products according to the ISO IDMP standards/technical specifications. Regional implementation of the ISO IDMP standards/technical specifications may elevate the optional conformance categories to "***mandatory***" or "***conditional***" per regional requirements.

6 Maintenance of IDMP data elements and IDMP identifiers

6.1 General

Creation, maintenance, and publication of the actual IDMP identifiers are envisioned as a distributed process where each participating regulatory authority would establish and maintain the identifiers utilised in their respective regions. Over the longer term, a list of certain identifiers for global use may be developed and agreed via a federated approach, and associated with the regulatory process in each respective region. It is anticipated that IDMP maintenance requirements will mature and evolve over time and IDMP scope and use cases expand.

6.2 Translation and language

With the specific exception of Medicinal Product name information (see A.2.13), there is no description of the translation of information described in ISO 11615. It was acknowledged that, for global implementation, translation of the information will be required and will occur according to regional implementation guidelines as applicable.

The requirement for translation is determined by a region. An international body may or may not require documents translated in some or all languages of its member nationalities. In addition, a country with multiple sizable sub-populations using multiple languages may or may not require translations into more than one of these languages. The IDMP standards do not set such requirements. The multilingual make-up of many regions are supported by HL7 CPM and SPL for multilingual contexts

and international exchange of IDMP data. Annex J specifies how SPL is to be utilised in support of multilingual requirements.

7 Why standardisation of identification of Medicinal Products is needed

Medicines regulatory authorities and pharmaceutical industry engage in an intensive information exchange during drug development, drug evaluation and approval phase and the post-authorisation phase. The standardisation of Medicinal Product information is regarded as one of the key elements of this information flow.

However, regulators in the various regions have established their own procedures and applications with standards that differ in data format, content, language, and applied terminology (e.g. different terminology is used for describing substances, routes of administration, pharmaceutical dose forms, pharmaceutical products, and Medicinal Products).

Due to the lack of a common and harmonised approach, both regulators and pharmaceutical industry are confronted with the following issues:

— no possibility to exchange Medicinal Product information between medicines regulatory authorities and pharmaceutical industry in a structured and efficient way;

— difficulties in ensuring data consistency and in evaluating and comparing Medicinal Product-related information across the regions due to the lack of harmonised definitions of terminologies and data sets, which impairs pharmacovigilance and electronic prescription/dispensing activities, especially across borders;

— for the pharmaceutical industry, major administrative burdens and duplication of efforts requiring substantial human and financial resources to comply with and handle different regional requirements;

— lack of consistency in the use of terminology in the healthcare community.

The objectives of the IDMP are to address the issues outlined above by developing harmonised standards that build on the regulatory, scientific, and technical processes already established and to support the population and maintenance of existing systems/applications with fully reliable regulatory Medicinal Product information.

Harmonised standards will support external stakeholders in developing “off-the-shelf” interoperable tools in conformance with international standards. International standards will also help maximise forward compatibility of data and minimise the complexities of backward compatibility.

8 General considerations

8.1 Overview

This document is intended to accompany, but not replace, ISO 11615 or HL7 CPM/SPL standards.

To satisfy the requirements as described in this document, the following identifiers shall be specified as described in this document for the unique identification of Medicinal Products:

— Medicinal Product Identifier (MPID),

— Medicinal Product Package Identifier (PCID);

— Medicinal Product Batch Identifier (BAID 1), allocated to a specific batch of a Medicinal Product, which appears on the outer packaging of the Medicinal Product;

— Medicinal Product Batch Identifier (BAID 2), allocated to a specific batch of a Medicinal Product, which appears on the immediate packaging, where this is not the outer packaging;

— expiration date;

— serialisation-package level identification of a packaged Medicinal Product (including the particular package configuration). Serial numbers should be numeric (numbers) or alphanumeric (include letters and/or numbers) and should have no more than 20 characters (letters and/or numbers).

NOTE 1 Serialisation requirements are given in regional guidance.

NOTE 2 In addition, there is an association with Pharmaceutical Product Identifiers (PhPIDs) as defined in ISO 11616 and ISO/TS 20451.

NOTE 3 Reference made to ISO 11615 for description/context of BAID 1 and BAID 2.

8.2 General considerations related to the description of the information modelling principles and practices

8.2.1 Overview

The information modelling in this document uses the Unified Modelling Language (UML), which is maintained by the Object Management Group (OMG).

UML may say the same thing in several different ways, and there are different styles and patterns that may be followed. The use of UML in this document utilises classes, attributes and basic association relationships only. Some constructs (such as stereotypes and complex relationships) have been explicitly avoided for the reason cited above. In addition, colour has been used in the diagrams to help visualise groups of associated entities together with one another (see Figure 1).

Figure 1 explains the represented approach for this document.

Figure 1 — Legends for colour coding of model classes

8.2.2 Conceptual overview diagrams

The conceptual overview diagram provides a framework with which to view the more detailed descriptions of information (see Figure 2).

The Medicinal Product and investigational Medicinal Product overarching models (see Figure 5 and Figure 7) show a single representative class from each particular information section, related to the core concept (either the Medicinal Product or the Investigational Medicinal Product).

Basic cardinalities between the Medicinal Product or the Investigational Medicinal Product and these core classes are shown, but none of the detailed entities, relationships or attributes is described.

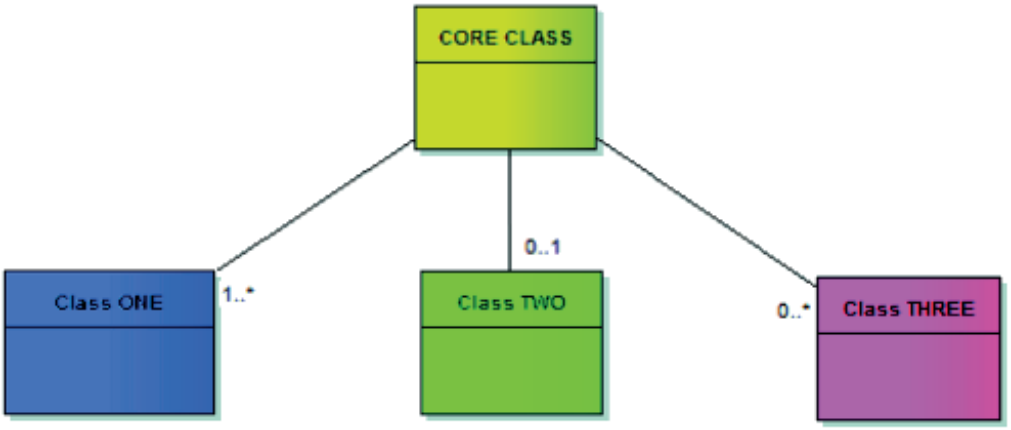

Figure 2 — Example conceptual overview diagram

8.2.3 Section high-level diagrams

The high-level diagrams provided at the start of each section of information show all the classes required to describe the information for that section and the conceptual relationships between those classes, with the starting point always as the (Investigational) Medicinal Product.

No attributes and no detailed cardinalities are shown in these conceptual diagrams, as again their primary purpose is to provide a framework with which to view the more detailed descriptions of information that follow in the detailed description diagrams.

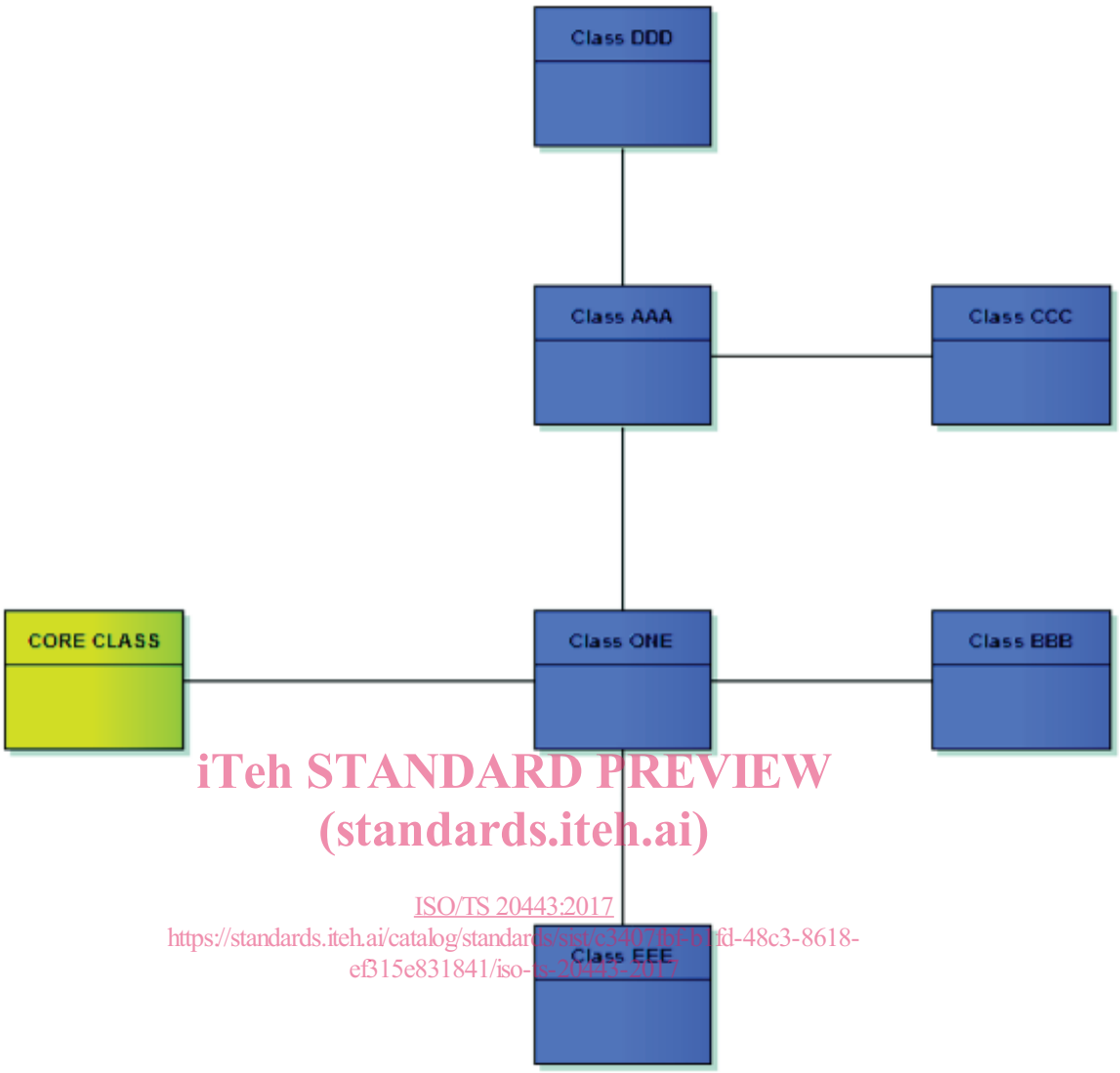

Figure 3 — Example section high-level diagram

8.2.4 Detailed description diagrams

The detailed description diagrams for each section show all the classes and all the attributes required to describe the information for that section, and the detail of the conceptual relationships between those classes.

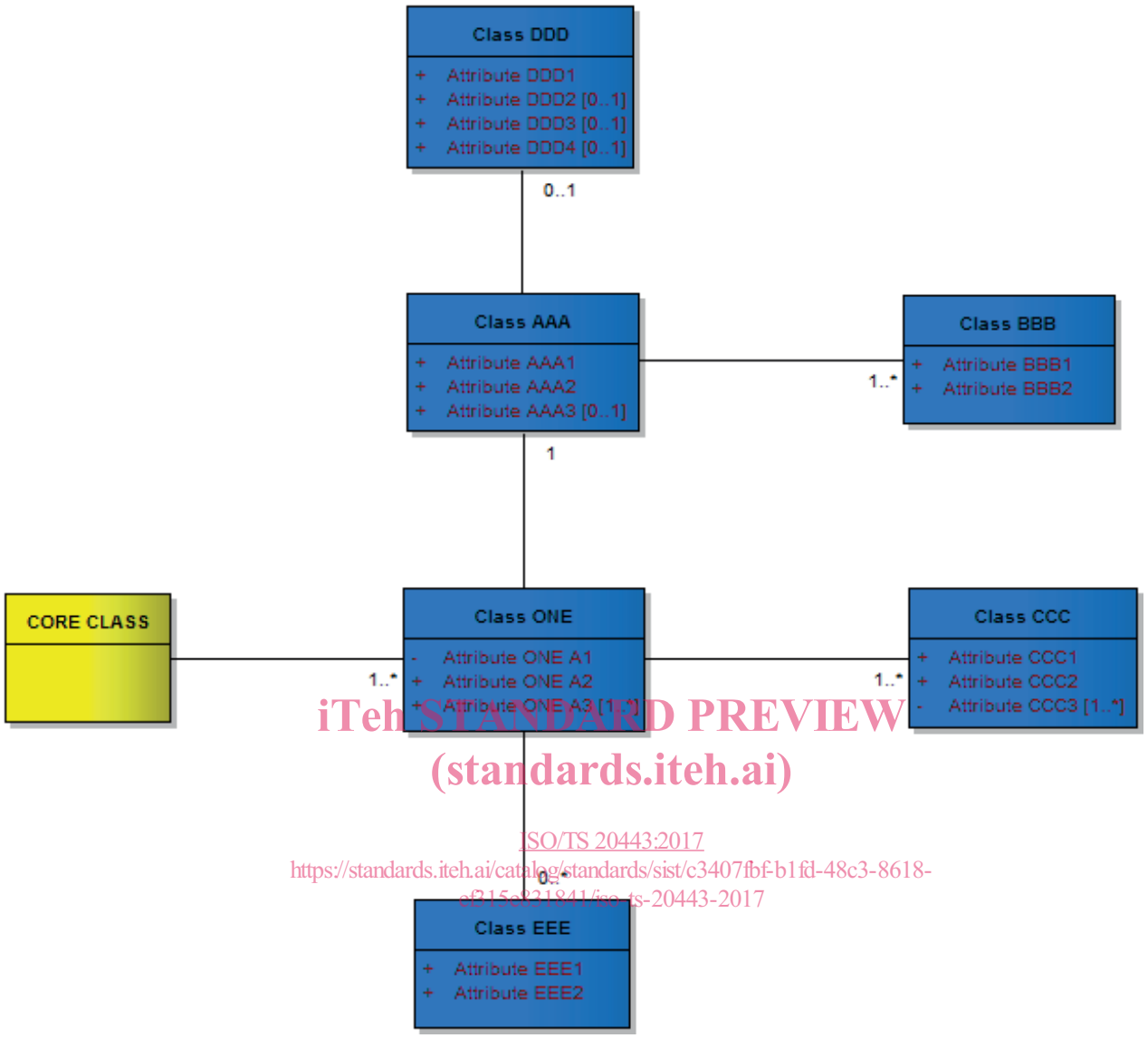

Figure 4 — Example detailed description diagram

8.2.5 Relationships between classes

Relationships between classes are described in the context of the (Investigational) Medicinal Product, and are described simply as associations, with no further qualification as to the role or type of the association, in order to keep the model simple.

Cardinalities on relationships are given in a single direction only: the direction with the (Investigational) Medicinal Product always as the direct or indirect source entity. The rationale for this is that the scope of this document is to describe the (Investigational) Medicinal Product and its associated information; therefore, having the (Investigational) Medicinal Product always as the source entity brings clarification and avoids describing complex many-to-many cardinalities that might occur in a reverse direction from an entity towards the (Investigational) Medicinal Product.

A cardinality of "1" is synonymous with a cardinality of "1..1".

A cardinality of "1" between entities is reflected in the text as the information for that entity shall be specified, and that only one set of the entity information shall be given.

A cardinality of “1..*” between entities is reflected in the text as the information for that entity shall be specified, and that one or more sets of the entity information shall be given.

A cardinality of “0..1” between entities is reflected in the text as the information for that entity can be specified, and that one set of the entity information can be given.

A cardinality of “0..*” between entities is reflected in the text as the information for that entity can be specified, and that one or more sets of the entity information can be given.

Some optional attributes can be elevated to mandatory if some conditions are met. Please see Clause 5.

See ISO 21090 for more information on composition of attributes. A datatype for the data in each attribute is not specified directly in the model. However, the text description for each attribute indicates the form in which data should be specified.

8.2.6 Attributes of classes

Attributes of a class are described using an attribute name in the model. The definition, description and example values for the attribute are given in the text following the model diagram.

An attribute showing no explicit cardinality means that the attribute shall be valued with one value (this is the equivalent to [1]).

An attribute showing a cardinality of [1..*] means that the attribute shall be valued with one or more values.

An attribute showing a cardinality of [0..1] means that the attribute can be valued with one value.

An attribute showing a cardinality of [0..*] means that the attribute can be valued with one or more values.

8.2.7 Generalised classes and patterns

There is one use of a generalised class in the diagrams whereby the pattern for a set of information is described once, but applied for use for several classes. For simplicity, this has not been described by using the formal UML generalisation/specialisation relationships, but by using a specialised class name.

The detailed representation of an “Organisation”, its “Contact Persons” and its “Other Locations” is described in Annex G. Wherever information of type “Organisation” with its “Contact Person(s)” and/or “Other Locations” is required, as for example in the class “Manufacturer/Establishment (Organisation)” or the “Medicines Regulatory Agency (Organisation)” class, the “(Organisation)” in the class name indicates that the information shall be described as per the generalised “Organisation” class.

There is also one generalised pattern used several times in the diagrams whereby generic classes provide the ability to describe something using (unspecified) classification, nomenclature or identification systems. To do this at the conceptual level, the model shows a class with two attributes: the first to identify the system itself (a classification, nomenclature or identification system), and the second to describe the applicable term or value from that system.

9 Information for an authorised Medicinal Product

9.1 General

The main concepts modelled in Figure 3 and described below should apply in order to identify and characterise an authorised Medicinal Product which itself is identified by the MPID/PCID.

