ISO 11616:2017-10 (E)

Health informatics - Identification of medicinal products - Data elements and structures for unique identification and exchange of regulated pharmaceutical product information

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Terms, definitions and abbreviated terms 2

4 Conformance terminology and context as it relates to the ISO IDMP standards and corresponding IDMP technical specifications 9

5 Requirements 9
5.1 Elements required for the unique identification of pharmaceutical products 9
5.2 Exchange of pharmaceutical product information 10

6 Description of the information modelling principles and practices 10
6.1 General considerations 10
6.2 Conceptual overview diagrams 11
6.3 High-level diagrams 11
6.4 Detailed description diagrams 12
6.4.1 General 12
6.4.2 Relationships between classes 13
6.4.3 Attributes of classes 14
6.4.4 Generalised classes and patterns 14
6.4.5 Translation and language 14

7 Identifying characteristics for the identification of pharmaceutical products 14
7.1 Pharmaceutical product identification strata and levels 14
7.1.1 General 14
7.1.2 PhPID specified substance 15
7.1.3 Pharmaceutical product specified substance identification (PhPID SpSub) 16
7.2 Cardinality 17
7.3 Representation of strength concentration 17
7.4 Pharmaceutical product identifier (PhPID) 18
7.5 Pharmaceutical product substance stratum elements (PhPID_SUB_Lx) 18
7.5.1 Construct of the pharmaceutical product substance stratum 18
7.5.2 Substance set 18
7.5.3 Administrable dose form 19
7.5.4 Unit of presentation 19
7.5.5 Medical device 19
7.6 Pharmaceutical product specified substance stratum elements (PhPID_SpSUB_Lx) 19
7.6.1 Construct of the pharmaceutical product specified substance stratum 19
7.6.2 Specified substance set 20
7.6.3 Administrable dose form 20
7.6.4 Unit of presentation 20
7.6.5 Medical device 20
7.7 Identifying characteristics to express strength 20

7.7.1 Expressing strength 20
7.7.2 Attributes for representation of strength in PhPID stratum elements 21
7.7.3 Representation of strength for a patch 23

8 Relationship between MPID/PCID and PhPID 23
8.1 Concepts required for the unique identification of a Medicinal Product and the association with PhPIDs 23
8.2 Pharmaceutical product identification criteria 25
8.2.1 General considerations 25
8.2.2 Multiple products packaged as a kit and administered as separate Medicinal Products 25

8.2.3 Multiple products packaged as a kit for reconstitution and administered as one Medicinal Product 26
8.2.4 Components of kits which are not packaged together (e.g. radiopharmaceutical kits) 26
8.2.5 Different representations of strength in two or more regions for identical products 26
8.2.6 Representation of PhPID for a patch 27

9 Relationship between IMPID/IPCID and PhPID 27

10 Conceptual model 29

Bibliography 30