

DIN EN ISO 11616:2018-04 (E)

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (ISO 11616:2017)

Contents		Page
European foreword.....		4
Foreword.....		5
Introduction.....		6
1	Scope	8
2	Normative references	8
3	Terms, definitions and abbreviated terms	9
4	Conformance terminology and context as it relates to the ISO IDMP standards and corresponding IDMP technical specifications	16
5	Requirements	16
5.1	Elements required for the unique identification of pharmaceutical products.....	16
5.2	Exchange of pharmaceutical product information.....	17
6	Description of the information modelling principles and practices	17
6.1	General considerations.....	17
6.2	Conceptual overview diagrams.....	18
6.3	High-level diagrams.....	18
6.4	Detailed description diagrams.....	19
6.4.1	General.....	19
6.4.2	Relationships between classes.....	20
6.4.3	Attributes of classes.....	21
6.4.4	Generalised classes and patterns.....	21
6.4.5	Translation and language.....	21
7	Identifying characteristics for the identification of pharmaceutical products	21
7.1	Pharmaceutical product identification strata and levels.....	21
7.1.1	General.....	21
7.1.2	PhPID specified substance.....	22
7.1.3	Pharmaceutical product specified substance identification (PhPID SpSub).....	23
7.2	Cardinality.....	24
7.3	Representation of strength concentration.....	24
7.4	Pharmaceutical product identifier (PhPID).....	25
7.5	Pharmaceutical product substance stratum elements (PhPID_SUB_Lx).....	25
7.5.1	Construct of the pharmaceutical product substance stratum.....	25
7.5.2	Substance set.....	25
7.5.3	Administrable dose form.....	26
7.5.4	Unit of presentation.....	26
7.5.5	Medical device.....	26
7.6	Pharmaceutical product specified substance stratum elements (PhPID_SpSUB_Lx).....	26
7.6.1	Construct of the pharmaceutical product specified substance stratum.....	26
7.6.2	Specified substance set.....	27
7.6.3	Administrable dose form.....	27
7.6.4	Unit of presentation.....	27
7.6.5	Medical device.....	27
7.7	Identifying characteristics to express strength.....	27
7.7.1	Expressing strength.....	27
7.7.2	Attributes for representation of strength in PhPID stratum elements.....	28
7.7.3	Representation of strength for a patch.....	30

8	Relationship between MPID/PCID and PhPID	30
8.1	Concepts required for the unique identification of a Medicinal Product and the association with PhPIDs	30
8.2	Pharmaceutical product identification criteria	32
8.2.1	General considerations	32
8.2.2	Multiple products packaged as a kit and administered as separate Medicinal Products	32
8.2.3	Multiple products packaged as a kit for reconstitution and administered as one Medicinal Product	33
8.2.4	Components of kits which are not packaged together (e.g. radiopharmaceutical kits)	33
8.2.5	Different representations of strength in two or more regions for identical products	33
8.2.6	Representation of PhPID for a patch	34
9	Relationship between IMPID/PCID and PhPID	34
10	Conceptual model	36
	Bibliography	37