

ISO 11615:2017-10 (E)

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

Contents		Page
Foreword		vi
Introduction		vii
1	Scope	1
2	Normative references	1
3	Terms, definitions and abbreviated terms	2
4	Message exchange format	13
5	Conformance terminology and context as it relates to the ISO IDMP standards and corresponding IDMP technical specifications	14
6	Concepts required for the unique identification of Medicinal Products	14
6.1	General considerations	14
6.2	Authorised Medicinal Products	14
6.3	Investigational Medicinal Products	15
6.4	Concepts required for the unique identification of a Medicinal Product and the association with PhPID(s)	15
6.5	Concepts required for the unique identification of Medicinal Products and the association with the marketing authorisation number	15
6.6	Concepts required for the unique identification of Medicinal Products and the association with data carrier identifiers	16
7	Description of the information modelling principles and practices	17
7.1	General considerations	17
7.2	Conceptual overview diagrams	17
7.3	High-level diagrams	18
7.4	Detailed description diagrams	18
7.4.1	General	18
7.4.2	Relationships between classes	19
7.4.3	Attributes of classes	20
7.4.4	Generalised classes and patterns	20
7.4.5	Translation and language	20
8	Identifying characteristics for authorised Medicinal Products	20
8.1	Primary identifiers -- General considerations	20
8.2	Medicinal Product Identifier (MPID)	21
8.2.1	General considerations	21
8.2.2	MPID code segments	21
8.3	Packaged Medicinal Product Identifier (PCID)	22
8.3.1	General considerations	22
8.3.2	Package description (PCID) code segment	23
8.4	Medicinal Product Batch Identifier (BAID1)	23
8.5	Medicinal Product Batch Identifier (BAID2)	23
9	Information for an authorised Medicinal Product	24

9.1	Authorised Medicinal Product -- Information overview	24
9.1.1	General	24
9.1.2	Medicinal Product	24
9.1.3	Medicinal Product name	24
9.1.4	Header	25
9.1.5	Manufacturer/Establishment (organisation)	25
9.1.6	Marketing authorisation	25
9.1.7	Packaged Medicinal Product	25
9.1.8	Pharmaceutical product	25
9.1.9	Ingredient	25
9.1.10	Clinical particulars	25
9.2	Medicinal Product	25
9.2.1	General	25
9.2.2	Detailed description of Medicinal Product information	26
9.3	Marketing authorisation	32
9.3.1	General	32
9.3.2	Detailed description of marketing authorisation information	33
9.4	Organisation	38
9.4.1	General	38
9.4.2	Detailed description of organisation information	38
9.5	Manufacturer/Establishment (organisation)	41
9.5.1	General	41
9.5.2	Detailed description of manufacturer/establishment (organisation) information	41
9.6	Packaged Medicinal Product, including manufactured item and device	42
9.6.1	General	42
9.6.2	Detailed description of Packaged Medicinal Product information	43
9.7	Ingredient, substance and strength	52
9.7.1	General	52
9.7.2	Detailed description of ingredients, substance and strength information	52
9.8	Pharmaceutical product and device	55
9.8.1	General	55
9.8.2	Detailed description of pharmaceutical product and device information	55
9.9	Clinical particulars	57
9.9.1	General	57
9.9.2	Detailed description for clinical particulars information	58
10	Identifying characteristics for Investigational Medicinal Products	62
10.1	General	62
10.2	Primary identifiers	62
10.2.1	General considerations	62
10.3	Investigational Medicinal Product Identifier (IMPID)	63
10.3.1	General considerations	63
10.3.2	IMPID code segments	63
10.4	Investigational Medicinal Product Package Identifier (IPCID)	64
10.4.1	General provisions	64
10.4.2	Package description code segment	64
10.5	Investigational Medicinal Product Batch Identifier (BAID1)	65
10.6	Investigational Medicinal Product Batch Identifier (BAID2)	65
11	Information for an Investigational Medicinal Product	65
11.1	General	65
11.2	Conceptual overview of the information for an Investigational Medicinal Product	65
11.2.1	General	65
11.2.2	Investigational Medicinal Product	66
11.2.3	Investigational Medicinal Product name	66
11.2.4	Header	66
11.2.5	Manufacturer/Establishment (organisation)	66
11.2.6	Clinical trial authorisation	67
11.2.7	Investigational Packaged Medicinal Product	67
11.2.8	Pharmaceutical product	67
11.2.9	Ingredient	67

11.2.10	Clinical particulars	67
11.3	Investigational Medicinal Product	67
11.3.1	General	67
11.3.2	Detailed description of Investigational Medicinal Product information	67
11.4	Clinical trial authorisation	70
11.4.1	General	70
11.4.2	Detailed description of clinical trial authorisation information	70
11.5	Manufacturer/Establishment (organisation)	72
11.6	Investigational Packaged Medicinal Product	72
11.7	Pharmaceutical product	72
11.7.1	General	72
11.7.2	Pharmaceutical product	73
11.7.3	Dosing and route of administration	73
11.8	Ingredient	73
11.9	Clinical particulars	74
11.10	PhPID sets	74
11.11	Device nomenclature	74
11.12	Device batch identifier	74
11.13	Physical characteristics	74
11.14	Other characteristics	74
Annex A (normative) Full model -- Authorised Medicinal Products detailed diagram		75
Annex B (normative) Full model -- Investigational Medicinal Products detailed diagram		76
Bibliography		77