

DIN EN ISO 11615:2022-12 (E)

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO 11615:2017 + Amd 1:2022) (includes Amendment :2022)

| Contents | | Page |
|--|--|-------------|
| European foreword | | 5 |
| [A1] European foreword to Amendment [A1] | | 6 |
| Foreword | | 7 |
| [A1] Foreword to Amendment [A1] | | 8 |
| Introduction | | 9 |
| 1 | Scope | 11 |
| 2 | Normative references | 11 |
| 3 | Terms, definitions and abbreviated terms | 12 |
| 4 | Message exchange format | 23 |
| 5 | Conformance terminology and context as it relates to the ISO IDMP standards and corresponding IDMP technical specifications | 24 |
| 6 | Concepts required for the unique identification of Medicinal Products | 24 |
| 6.1 | General considerations | 24 |
| 6.2 | Authorised Medicinal Products | 24 |
| 6.3 | Investigational Medicinal Products | 25 |
| 6.4 | Concepts required for the unique identification of a Medicinal Product and the association with PhPID(s) | 25 |
| 6.5 | Concepts required for the unique identification of Medicinal Products and the association with the marketing authorisation number | 25 |
| 6.6 | Concepts required for the unique identification of Medicinal Products and the association with data carrier identifiers | 26 |
| 7 | Description of the information modelling principles and practices | 27 |
| 7.1 | General considerations | 27 |
| 7.2 | Conceptual overview diagrams | 27 |
| 7.3 | High-level diagrams | 28 |
| 7.4 | Detailed description diagrams | 28 |
| 7.4.1 | General | 28 |
| 7.4.2 | Relationships between classes | 29 |
| 7.4.3 | Attributes of classes | 30 |
| 7.4.4 | Generalised classes and patterns | 30 |
| 7.4.5 | Translation and language | 30 |
| 8 | Identifying characteristics for authorised Medicinal Products | 30 |
| 8.1 | Primary identifiers — General considerations | 30 |
| 8.2 | Medicinal Product Identifier (MPID) | 31 |
| 8.2.1 | General considerations | 31 |
| 8.2.2 | MPID code segments | 31 |
| 8.3 | Packaged Medicinal Product Identifier (PCID) | 32 |
| 8.3.1 | General considerations | 32 |
| 8.3.2 | Package description (PCID) code segment | 33 |
| 8.4 | Medicinal Product Batch Identifier (BAID1) | 33 |
| 8.5 | Medicinal Product Batch Identifier (BAID2) | 33 |
| 9 | Information for an authorised Medicinal Product | 34 |
| 9.1 | Authorised Medicinal Product — Information overview | 34 |

| | | |
|-----------|--|-----------|
| 9.1.1 | General..... | 34 |
| 9.1.2 | Medicinal Product..... | 34 |
| 9.1.3 | Medicinal Product name..... | 34 |
| 9.1.4 | Header..... | 35 |
| 9.1.5 | Manufacturer/Establishment (organisation)..... | 35 |
| 9.1.6 | Marketing authorisation..... | 35 |
| 9.1.7 | Packaged Medicinal Product..... | 35 |
| 9.1.8 | Pharmaceutical product..... | 35 |
| 9.1.9 | Ingredient..... | 35 |
| 9.1.10 | Clinical particulars..... | 35 |
| 9.2 | Medicinal Product..... | 35 |
| 9.2.1 | General..... | 35 |
| 9.2.2 | Detailed description of Medicinal Product information..... | 36 |
| 9.3 | Marketing authorisation..... | 42 |
| 9.3.1 | General..... | 42 |
| 9.3.2 | Detailed description of marketing authorisation information..... | 43 |
| 9.4 | Organisation..... | 48 |
| 9.4.1 | General..... | 48 |
| 9.4.2 | Detailed description of organisation information..... | 49 |
| 9.5 | Manufacturer/Establishment (organisation)..... | 51 |
| 9.5.1 | General..... | 51 |
| 9.5.2 | Detailed description of manufacturer/establishment (organisation) information..... | 51 |
| 9.6 | Packaged Medicinal Product, including manufactured item and device..... | 52 |
| 9.6.1 | General..... | 52 |
| 9.6.2 | Detailed description of Packaged Medicinal Product information..... | 53 |
| 9.7 | Ingredient, substance and strength..... | 62 |
| 9.7.1 | General..... | 62 |
| 9.7.2 | Detailed description of ingredients, substance and strength information..... | 62 |
| 9.8 | Pharmaceutical product and device..... | 65 |
| 9.8.1 | General..... | 65 |
| 9.8.2 | Detailed description of pharmaceutical product and device information..... | 65 |
| 9.9 | Clinical particulars..... | 67 |
| 9.9.1 | General..... | 67 |
| 9.9.2 | Detailed description for clinical particulars information..... | 68 |
| 10 | Identifying characteristics for Investigational Medicinal Products..... | 72 |
| 10.1 | General..... | 72 |
| 10.2 | Primary identifiers..... | 72 |
| 10.2.1 | General considerations..... | 72 |
| 10.3 | Investigational Medicinal Product Identifier (IMPID)..... | 73 |
| 10.3.1 | General considerations..... | 73 |
| 10.3.2 | IMPID code segments..... | 73 |
| 10.4 | Investigational Medicinal Product Package Identifier (IPCID)..... | 74 |
| 10.4.1 | General provisions..... | 74 |
| 10.4.2 | Package description code segment..... | 74 |
| 10.5 | Investigational Medicinal Product Batch Identifier (BAID1)..... | 75 |
| 10.6 | Investigational Medicinal Product Batch Identifier (BAID2)..... | 75 |
| 11 | Information for an Investigational Medicinal Product..... | 75 |
| 11.1 | General..... | 75 |
| 11.2 | Conceptual overview of the information for an Investigational Medicinal Product..... | 75 |
| 11.2.1 | General..... | 75 |
| 11.2.2 | Investigational Medicinal Product..... | 76 |
| 11.2.3 | Investigational Medicinal Product name..... | 76 |
| 11.2.4 | Header..... | 76 |
| 11.2.5 | Manufacturer/Establishment (organisation)..... | 76 |
| 11.2.6 | Clinical trial authorisation..... | 77 |
| 11.2.7 | Investigational Packaged Medicinal Product..... | 77 |
| 11.2.8 | Pharmaceutical product..... | 77 |
| 11.2.9 | Ingredient..... | 77 |
| 11.2.10 | Clinical particulars..... | 77 |
| 11.3 | Investigational Medicinal Product..... | 77 |
| 11.3.1 | General..... | 77 |
| 11.3.2 | Detailed description of Investigational Medicinal Product information..... | 77 |

| | | |
|---|---|-----------|
| 11.4 | Clinical trial authorisation | 80 |
| 11.4.1 | General..... | 80 |
| 11.4.2 | Detailed description of clinical trial authorisation information..... | 80 |
| 11.5 | Manufacturer/Establishment (organisation)..... | 82 |
| 11.6 | Investigational Packaged Medicinal Product..... | 82 |
| 11.7 | Pharmaceutical product..... | 82 |
| 11.7.1 | General..... | 82 |
| 11.7.2 | Pharmaceutical product..... | 83 |
| 11.7.3 | Dosing and route of administration | 83 |
| 11.8 | Ingredient..... | 83 |
| 11.9 | Clinical particulars..... | 84 |
| 11.10 | PhPID sets | 84 |
| 11.11 | Device nomenclature..... | 84 |
| 11.12 | Device batch identifier | 84 |
| 11.13 | Physical characteristics | 84 |
| 11.14 | Other characteristics..... | 84 |
| Annex A (normative) Full model — Authorised Medicinal Products detailed diagram..... | | 85 |
| Annex B (normative) Full model — Investigational Medicinal Products detailed diagram | | 86 |
| [A₁] Annex C (informative) Class name and attribute translations and synonyms for the identification of medicinal products (IDMP) [A₁] | | 87 |
| Bibliography | | 88 |