

# ISO/TS 20443:2017-10 (E)

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

---

<b>Contents</b>		<b>Page</b>
Foreword .....		v
Introduction .....		vi
<b>1</b>	<b>Scope .....</b>	<b>1</b>
<b>2</b>	<b>Normative references .....</b>	<b>1</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>2</b>
<b>4</b>	<b>Message exchange .....</b>	<b>2</b>
4.1	General .....	2
4.2	Message exchange format .....	2
4.3	Controlled vocabularies .....	3
<b>5</b>	<b>Conformance terminology and context as it relates to the ISO IDMP standards and corresponding technical specifications .....</b>	<b>3</b>
<b>6</b>	<b>Maintenance of IDMP data elements and IDMP identifiers .....</b>	<b>3</b>
6.1	General .....	3
6.2	Translation and language .....	3
<b>7</b>	<b>Why standardisation of identification of Medicinal Products is needed .....</b>	<b>4</b>
<b>8</b>	<b>General considerations .....</b>	<b>4</b>
8.1	Overview .....	4
8.2	General considerations related to the description of the information modelling principles and practices .....	5
8.2.1	Overview .....	5
8.2.2	Conceptual overview diagrams .....	5
8.2.3	Section high-level diagrams .....	6
8.2.4	Detailed description diagrams .....	7
8.2.5	Relationships between classes .....	8
8.2.6	Attributes of classes .....	9
8.2.7	Generalised classes and patterns .....	9
<b>9</b>	<b>Information for an authorised Medicinal Product .....</b>	<b>9</b>
9.1	General .....	9
9.2	Medicinal Product .....	11
9.3	Header .....	11
9.4	Medicinal Product name .....	11
9.5	Manufacturer/establishment (organisation) .....	11
9.6	Marketing authorisation .....	12
9.7	Packaged Medicinal Product .....	12
9.8	Pharmaceutical Product .....	12
9.9	Ingredient .....	13
9.10	Clinical particulars .....	13
<b>10</b>	<b>Investigational Medicinal Product Identifier (IMPID) .....</b>	<b>13</b>

10.1	Conceptual overview of the information for an Investigational Medicinal Product .....	13
10.2	Investigational Medicinal Product .....	15
10.3	Clinical trial authorisation .....	15
10.4	Investigational Medicinal Product name .....	15
10.5	Header .....	15
10.6	Manufacturer/establishment (organisation) .....	15
10.7	Pharmaceutical product .....	16
10.8	Investigational Packaged Medicinal Product .....	16
10.9	Ingredient .....	17
10.10	Clinical particulars .....	17
Annex A (normative) Medicinal Product .....		20
Annex B (normative) Marketing authorisation .....		47
Annex C (normative) Packaged Medicinal Product (including manufactured item and device) .....		71
Annex D (normative) Ingredient, substance and strength .....		110
Annex E (normative) Pharmaceutical product and device .....		125
Annex F (normative) Clinical particulars .....		133
Annex G (normative) Organisation .....		151
Annex H (normative) Manufacturer/establishment .....		156
Annex I (normative) Investigational Medicinal Product .....		164
Annex J (normative) SPL documents .....		180
Annex K (informative) Abbreviations .....		200
Bibliography .....		202