ISO/TS 20443:2017-10 (E)

Health informatics - Identification of me dicinal products - Implementation guidelines for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 Message exchange 2
4.1 General 2
4.2 Message exchange format 2
4.3 Controlled vocabularies 3

5 Conformance terminology and context as it relates to the ISO IDMP standards and corresponding technical specifications 3

6 Maintenance of IDMP data elements and IDMP identifiers 3
6.1 General 3
6.2 Translation and language 3

7 Why standardisation of identification of Medicinal Products is needed 4

8 General considerations 4
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

9 Information for an authorised Medicinal Product 9
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

10 Investigational Medicinal Product Identifier (IMPID) 13

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