

ISO/TS 16791:2014-04 (E)

Health informatics - Requirements for international machine-readable coding of medicinal product package identifiers

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
3.1	Terms	1
3.2	Abbreviations	5
4	Procedural background	6
4.1	General	6
4.2	Identification	6
4.3	International machine readable coding	6
4.4	Medicinal product	7
4.5	Labelling	7
4.6	Package identifier	8
4.7	Serialization	8
5	Usage requirements	9
5.1	General	9
5.2	Traceability	9
5.3	Measures to combat falsification of medicines	10
5.4	Improving patient safety at point of care	12
5.5	Support of healthcare systems	12
5.6	Procurement and stock management	14
5.7	Overview of the normative options	15
6	Economic aspects	15
6.1	General	15
6.2	Manufacturer perspective	16
6.3	Healthcare provider perspective	16
Annex A (informative)	Relationship between PhPID and MPID (Referencing ISO 11615 and ISO 11616)	17
Annex B (informative)	Packaging hierarchy	18
Annex C (informative)	Relationship between MPID, PCID and GTIN	19
Annex D (informative)	Examples for Package Identifier	20
Bibliography		22