ISO 16791:2026-03 (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, definitions and abbreviated terms 1
3.1 Terms and definitions 1
3.2 Abbreviated terms 7

4 Procedural background 7
4.1 General 7
4.2 Identification 7
4.3 International machine-readable coding 8
4.4 Medicinal product 8
4.5 Labelling 8
4.6 Package identifier 9
4.7 Serialization 10

5 Usage requirements 10
5.1 General 10
5.2 Traceability 10
5.2.1 Principles 10
5.2.2 Requirements 12
5.3 Measures to combat falsification of medicines 12
5.3.1 Principles 12
5.3.2 Requirements for both approaches 13
5.3.3 Product authentication 14
5.3.4 Supply chain integrity 14
5.4 Improving patient safety at point of care 15
5.4.1 Principles 15
5.4.2 Requirements 15
5.5 Support of healthcare systems 15
5.5.1 Principles 15
5.5.2 Requirements 16
5.6 Procurement and stock management 17
5.6.1 Principles 17
5.6.2 Requirements 17
5.7 Overview of requirements 18

6 Economic aspects 18
6.1 General 18
6.2 Manufacturer perspective 18
6.3 Healthcare provider perspective 19

Annex A (informative) Relationship between PhPID and MPID 20

Annex B (informative) Packaging hierarchy, relationship between MPID, PCID and GTIN® 22

Annex C (informative) Identification of trade items and logistic units 24

Annex D (informative) Examples for package identifier 25

Annex E (informative) Personalized medicine 34

Annex F (informative) Accessing electronic product information (ePI) by scanning the supply chain unique identifier 35

Bibliography 37