

ISO/TS 19256:2016-06 (E)

Health informatics - Requirements for medicinal product dictionary systems for health care

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	2
3	Terms and definitions	2
4	Abbreviated terms	9
5	Boundary between MPD-systems and IDMP, ancillary information to build an MPD-system and local implementation	9
5.1	Boundary between MPD-systems and IDMP	9
5.2	Boundary between MPD-systems and ancillary information to build an MPD-system	9
5.3	Boundary between MPD-systems and local implementation	9
5.4	Content of the MPD-systems in terms of product coverage	10
5.5	Definition of Medicinal Product Dictionary MPD-systems	10
5.6	Benefits of the Technical Specification	10
5.7	Target users for the Technical Specification	10
6	Positioning of Medicinal Product Dictionary Systems for Healthcare	11
6.1	Base materials for MPD-systems	11
6.1.1	Relation with ISO IDMP standards	12
6.1.2	Relation with health/clinical/pharmacy information systems, decision support, EHR and dose instructions	13
6.1.3	Relation with EHR-S FM	14
6.2	Use cases for requirements for an MPD-system	14
6.2.1	Prescribing use case	15
6.2.2	Dispensing use case	15
6.2.3	Administration use case	15
6.2.4	Recording medication history use case	15
6.2.5	Reconciling medication list use case	15
6.2.6	Ordering and supply chain (logistics) use case	16
6.2.7	Analysis, statistics, and pharmacoepidemiology use case	16
6.2.8	Electronic data exchange of medicinal product information between healthcare systems and/or related systems, i.e. reporting use case	16
6.2.9	Reimbursement use case	16
6.2.10	Clinical research use case	16
6.2.11	Tracking and tracing for patient and public safety use case	17
6.2.12	Pharmacovigilance use case	17
6.2.13	Patient safety through linking personal data with the decision support system on medicinal products use case	18
6.2.14	Migration use case	18
7	The Functional Requirements for MPD-systems	18
7.1	Introduction	18
7.2	Goal of an MPD system	19
7.3	Normative content	19
7.3.1	Content of regulated medicinal products	19

7.3.2	Prescription	23
7.3.3	Dispensing	23
7.3.4	Administration	24
7.3.5	Recording and reconciliation	24
7.3.6	Order and supply chain and logistics	25
7.3.7	Analysis, statistics, pharmacoepidemiology, and clinical research	25
7.3.8	Ensuring patient safety through linking personal data with the decision support system on medicinal products	27
7.3.9	Interaction with reimbursement systems	27
7.3.10	Interaction of MPD-systems with pharmacovigilance systems	27
7.3.11	Data exchange and technical functions	28
7.4	Governance	29
7.5	Maintenance	30
7.5.1	Regular maintenance processes of the MPD-system	30
7.5.2	Interaction with regulatory information	31
7.6	Localization	32
Annex A (informative) IDMP series in context, serving this Technical Specification		33
Bibliography		35