

# DIN CEN ISO/TS 19256:2017-06 (E)

Health informatics - Requirements for medicinal product dictionary systems for health care (ISO/TS 19256:201 6); English version CEN ISO/TS 19256:2017

---

<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>2</b>
<b>3</b>	<b>Terms and definitions</b> .....	<b>2</b>
<b>4</b>	<b>Abbreviated terms</b> .....	<b>9</b>
<b>5</b>	<b>Boundary between MPD-systems and IDMP, ancillary information to build an MPD-system and local implementation</b> .....	<b>9</b>
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
<b>6</b>	<b>Positioning of Medicinal Product Dictionary Systems for Healthcare</b> .....	<b>11</b>
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

<b>7</b>	<b>The Functional Requirements for MPD-systems</b>	<b>18</b>
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
	<b>Annex A (informative) IDMP series in context, serving this Technical Specification</b>	<b>33</b>
	<b>Bibliography</b>	<b>35</b>