

# ISO/TS 16791:2014-04 (E)

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

---

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