

# ISO 11616:2012-11 (E)

## Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

---

<b>Contents</b>	<b>Page</b>
Foreword .....	iv
Introduction .....	v
<b>1 Scope .....</b>	<b>1</b>
<b>2 Normative references .....</b>	<b>1</b>
<b>3 Terms, definitions and abbreviations .....</b>	<b>2</b>
<b>3.1 Terms and definitions .....</b>	<b>2</b>
<b>3.2 Abbreviations .....</b>	<b>7</b>
<b>4 Requirements .....</b>	<b>8</b>
<b>4.1 Elements required for the unique identification of pharmaceutical products .....</b>	<b>8</b>
<b>4.2 Exchange of pharmaceutical product information .....</b>	<b>9</b>
<b>5 Identifying characteristics for the identification of pharmaceutical products .....</b>	<b>9</b>
<b>5.1 Pharmaceutical product identification strata and levels .....</b>	<b>9</b>
<b>5.2 Cardinality .....</b>	<b>11</b>
<b>5.3 Representation of strength concentration .....</b>	<b>12</b>
<b>5.4 Pharmaceutical product identifier (PhPID) .....</b>	<b>12</b>
<b>5.5 Pharmaceutical product substance stratum elements (PhPID_SUB_Lx) .....</b>	<b>13</b>
<b>5.6 Pharmaceutical Product Specified Substance Stratum Elements (PhPID_SpSUB_Lx) .....</b>	<b>15</b>
<b>5.7 Identifying characteristics to express strength .....</b>	<b>17</b>
<b>6 Relationship between MPID and PhPID .....</b>	<b>19</b>
<b>6.1 Concepts required for the unique identification of a medicinal product and the association with PhPIDs .....</b>	<b>19</b>
<b>6.2 Pharmaceutical product identification criteria .....</b>	<b>21</b>
<b>7 Relationship between IMPID and PhPID .....</b>	<b>23</b>
<b>8 Conceptual model .....</b>	<b>25</b>
<b>Annex A (informative) Examples .....</b>	<b>27</b>
<b>Annex B (informative) Tabled examples .....</b>	<b>35</b>
<b>Bibliography .....</b>	<b>38</b>