WP 1: Identifiers - Medicinal Product, Marketing Authorization, Pharmaceutical Product and Package Medicinal Product

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### Acronyms

- **DB**: Database  
- **DCID**: Data Carrier Identifier  
- **EMVO**: European Medicines Verification Organisation  
- **EMVS**: European Medicines Verification System  
- **FMD**: Falsified Medicine Directive  
- **GTIN**: Global Trade Identifier Number  
- **IDMP**: Identification of Medicinal Product  
- **MAH**: Marketing Authorisation Holder  
- **MMP**: Multi-Market Pack  
- **MP**: Medicinal Product  
- **MPID**: Medicinal Product Identifier  
- **NCA**: National Competent Authority  
- **NMVS**: National Medicines Verification System  
- **NTIN**: National Trade Identifier Number  
- **OBP**: On-boarding Partner  
- **PCID**: Package Identifier  
- **PhPID**: Pharmaceutical Product Identifier  
- **PIC**: Package Item Container  
- **PMP**: Package Medicinal Product  
- **RIMS**: Regulatory Information Management System  
- **SC**: Supply Chain  
- **SKU**: Stock Keeping Unit  
- **SMP**: Single-Market Pack  
- **SPOR**: Substance, Product, Organisation and Referential
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Reconciliate data domains with independant lifecycle:
• regulatory
• manufacturing (down to SKU/SKU identification in the supply chain and Manufactured Item)
• formulation and substance/CMC
IDMP is:

- Providing a standardize backbone (ladder)
- Enabling an End-2-End connectivity
- Allowing each function to manage its own life-cycle.

Condition:
Each system/process which is involved share a dedicated amount of master data with the backbone.
**Medicinal Product & Pharmaceutical Product Example**

<table>
<thead>
<tr>
<th>Medicinal Product</th>
<th>MPID 123</th>
<th>MPID 234</th>
<th>MPID 345</th>
<th>MPID 456</th>
<th>MPID 567</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicinal Product</td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
<td><img src="image4.png" alt="Image" /></td>
<td><img src="image5.png" alt="Image" /></td>
</tr>
<tr>
<td>Administreable dose form:</td>
<td>Tablet</td>
<td>Tablet</td>
<td>Tablet</td>
<td>Tablet</td>
<td>Capsule, soft</td>
</tr>
<tr>
<td>Unit of Presentation:</td>
<td>Paracetamol</td>
<td>Paracetamol</td>
<td>Paracetamol/</td>
<td>Paracetamol</td>
<td>Paracetamol</td>
</tr>
<tr>
<td>Active Ingredient:</td>
<td>1 g</td>
<td>500 mg</td>
<td>500 mg</td>
<td>1 g</td>
<td>500 mg</td>
</tr>
<tr>
<td>Strength:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PhPID Sub:**
- L1: Active Substance(s)
- L2: Active Substance(s) + Strengths
- L3: Active Substance(s) + Administreable Dose Form
- L4: Active Substance(s) + Strengths + Administreable Dose Form

<table>
<thead>
<tr>
<th>PhPID Sub</th>
<th>MPID 123</th>
<th>MPID 234</th>
<th>MPID 345</th>
<th>MPID 456</th>
<th>MPID 567</th>
</tr>
</thead>
<tbody>
<tr>
<td>L1: Active Substance(s)</td>
<td>1</td>
<td>1</td>
<td>12</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>L2: Active Substance(s) + Strengths</td>
<td>1-1000</td>
<td>1-500</td>
<td>12-500</td>
<td>1-1000</td>
<td>1-500</td>
</tr>
<tr>
<td>L3: Active Substance(s) + Administreable Dose Form</td>
<td>1-A</td>
<td>1-A</td>
<td>12-A</td>
<td>1-B</td>
<td>1-C</td>
</tr>
</tbody>
</table>

**Why?** Determination of equivalence in prescription, trans-border prescription, pharmacovigilance

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The images are only used to illustrate the example and remain the property of their respective registered brand holders.

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What are the relations between:
• MPID
• PhPID
• MA
• PCID (and then, DCID)?

What’s the hierarchy between these IDs?
**Pharmaceutical Product**

PhPID Set

1..*

**Medicinal Product**

MPID

Pharmaceutical product or combination of pharmaceutical products that may be administered to human beings (or animals) for treating or preventing disease, with the aim/purpose of making a medical diagnosis or to restore, correct or modify physiological functions.

**Marketing Authorisation**

MA number

Authorization provided by a Medicines Regulatory Agency to manufacture Medicinal Products within a region

**Packaged Medicinal Product**

PCID

Medicinal Product in a container being part of a package, representing the entirety that has been packaged for sale or supply

**Package Item**

(Container)

DCID

<container> individual, distinct item(s) contained in a Packaged Medicinal Product which act as containers for manufactured item(s)

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Centralized Procedure: 1 authorization – N PCID – X×N GTIN

Derived from ISO/DTS 16791 Annex D EMA Centralized

Subs Lamiv 150mg
PhPID: expected from Reg Authority

Lamiv 150mg_tablets (20)_EU
Mark. Auth.: EU/1/09/596/001
Proc. Type: Centralised Procedure

Lamiv 150mg_tablets (80)_EU
Mark. Auth.: EU/1/09/596/015
Proc. Type: Centralised Procedure

Lamiv 300mg_tablets (80)_EU
Mark. Auth.: EU/1/09/596/016
Proc. Type: Centralised Procedure

Subs Lamiv 300mg
PhPID: expected from Reg Authority

Packaged Med. Product

Lamiv 150mg_tablets (20)_EU
PCID: expected from Reg Authority

Pack. Item Container

(20)_CY+GR
Type: MMP
SKU: Manufacturer ref

(20)_DK+NO
Type: SMP
SKU: Manufacturer ref

(20)_DE
Type: SMP
SKU: Manufacturer ref

Data Carrier ID

GTIN 5292343001744

GTIN 5054626151214

NTIN 908883920098

NTIN 415094611227
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National Procedure, with National-Packs: 1 authorization – X PCIDs – X GTINs
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Thank you for your attention
PhPID set (ISO 11615 and 11616)

PhPID set consists of 8 different IDs based on the following information:

PhPID active substance stratum
- PhPID_SUB_L1 → Substance(s)
- PhPID_SUB_L2 → Substance(s) + strength + reference strength
- PhPID_SUB_L3 → Substance(s) + administrable dose form
- PhPID_SUB_L4 → Substance(s) + strength + reference strength + administrable dose form

PhPID specified substance stratum
- PhPID_SpSUB_L1 → Specified substance(s)
- PhPID_SpSUB_L2 → Specified substance(s) + strength + reference strength
- PhPID_SpSUB_L3 → Specified substance(s) + administrable dose form
- PhPID_SpSUB_L4 → Specified substance(s) + strength + reference strength + administrable dose form
MPID (ISO 11615 and 11616)

► Country code segment
► Marketing Authorization Holder (Organisation Identifier) code segment
► Medicinal Product code segment (Unique MP Identifier)
  ▶ Marketing authorization indicated in a region
  ▶ Legal status of supply as a value/attribute
  ▶ Medicinal Product name;
  ▶ Pharmaceutical dose form;
  ▶ Active ingredient(s)/active moieties and their corresponding strength;
  ▶ Device(s) where a Medicinal Product is combined with a medical device and where the pharmacological, immunological or metabolic action should be considered as the principal mode of action; the medical device is presented as part of the Medicinal Product;
  ▶ Therapeutic indication(s) as authorised for the Medicinal Product
PCID (ISO 11615 and 11616)

► MPID

► Package description code segment
  ▶ Packaged item (container)(s) — the type, quantity (items per package), material(s) and alternate material(s);
  ▶ Package component(s) — type, material(s) and alternate material(s);
  ▶ Manufactured item(s) — manufactured dose form, unit of presentation, quantity (items per package).

► In this case, needles are considered as device, then not entering in the package description code segment.