Product Management Services & Substance Management Services (P&SMS) Projects

Implementation of ISO IDMP standards through SPOR master data
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1. Background
• **ISO IDMP standards** (five standards) define the rules that uniquely identify medicinal product and the relevant elements to identify them

• **Commission Implementing Regulation (EU) No 520/2012** (articles 25 and 26) obliges European Union (EU) Member States, marketing authorisation holders and EMA to make use of the ISO IDMP standards.

• The **SPOR projects** implements the ISO IDMP standards as well as the processes to manage four domains of data (**master data**) in pharmaceutical / regulatory industry:
  - **Substance Management Services (SMS)** – ISO 11238
  - **Product Management Services (PMS)** – ISO 11615, 11616
  - **Organisation Management Services (OMS)**
  - **Referentials Management Services (RMS)** – ISO 11239, 11240

• **Delivery of SPOR is phased**
  - RMS and OMS services were delivered in June 2017
  - Delivery of PMS and SMS will follow
    - **P&SMS Iteration 1 covers authorised human & veterinary medicinal products**
    - P&SMS Iteration 2 covers Investigational medicinal products.
    - P&SMS Iteration 3 covers Clinical Particulars.

• **SPOR applies to both domains Human & Veterinary**
What will SPOR deliver?

SPOR data is accessible via a web **User Interface** (UI) and **SPOR APIs** (Application Programming Interface)

A specialised team of **EMA data stewards** will manage SPOR data and provide support to stakeholders

**New process** for industry and NCAs to **pre-register**/update SPOR data before submitting regulatory applications. Data is **entered once and reused** in different processes.

**List of organisations (OMS dictionary), Referentials Lists/Terms and Substances** for stakeholders to use in EU regulatory activities

**New data management** approaches for industry, NCAs and the EMA:
- Data synchronisation on an ongoing basis
- Possible need for data transformation/enrichment
2. Implementation of IDMP through SPOR data management services
A. Past
Feb 2015: Selection of the technology to support SPOR implementation.

Mar 2015: SPOR Roadmap agreed.

Mar 2015: SPOR TF set up.

May 2015: RMS project started.

July 2015: Green light form HMA for RMS & OMS Target Operating Model (TOM).

Jul 2015: Technology purchase.

Jul 2015: OMS project started.

Mar 2016: Change Liaison Network set up.

Jun 2016: Veterinary Stakeholders join the SPOR Task Force (TF).

Jun 2017: RMS went live and replaced EUTCT as preferred source of regulatory referential data.


Q2 2017: P&SMS project started.


Q1- Q2 2017: P&SMS project started.

Q1 2015: SPOR strategy and approach agreed with Industry, Regulators and EC.

Q2 2015: First two SPOR projects ongoing.

2015-2016: Engaging with Industry and regulators through SPOR TF and cascading communications through Change Liaison network.

Jun 2017: RMS implements ISO11239 and ISO11240 standards; makes EMA regulatory compliant.

2017: Users start using SPOR Target Operating Model for pre-registration of master data to improve regulatory submissions.
SPOR data management services

Delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities.

The four SPOR data management services are:

- Substance Management Services (SMS)
- Product Management Services (PMS)
- Organisation Management Services (OMS)
- Referentials Management Services (RMS)

OMS and RMS are the first services to go live and they provide the data foundations for PMS and SMS.

SMS and PMS are not currently activated. More information on the implementation of SPOR data management services is available on the EMA corporate website.

The SPOR portal provides users with the following data management services:

- view, search, export SPOR data;
- request new and updated SPOR data;
- translate SPOR data;
- browse relevant SPOR documentation.

Data management and data quality processes drive the SPOR data management services to ensure that the highest quality of data is available to support EU regulatory processes.

SPOR portal is compatible with web browsers Internet Explorer (version 10 and above) and Chrome (version 58 and above)
B. The next steps
The next steps (2017-2018) – SPOR Plans

Q1 - Q2 2017: P&SMS project started.

Q4 2017: MAH content is available.
Q4 2017: Integrate OMS with ECD.
Q4 2017: Integrate OMS with eAF; RMS already integrated with eAF.
Q4 2017: TOM (draft) agreed.
Q4 2017: MAPI content is available.

2017-2018: Organisation data is incrementally available.

Q1 2018: Sponsor content is available.
Q3 2018: CAP & NAP Manufacturers are available.
Q4 2018: Integrate RMS & OMS with CT Portal.
Q4 2018: Integrate RMS & OMS with Art 57/xEVMPD.
Q4 2018: (draft) API specs & User Onboarding strategy.

Q2 2017: Remaining SPOR projects ongoing.

2017: Users start using SPOR Target Operating Model for pre-registration of R & O data to improve regulatory submissions.

Q3 2018: Messaging Format agreed.

2018: RMS & OMS master data is integrated with business processes i.e it is entered once and reused across different business processes.

Q4 2018: P&SMS It 1 Phase 1 delivers Art 57 Migration.

2018: Guidance is available to support Industry and regulators implementing SPOR.
P&SMS projects

• P&SMS project was initiated early 2017

• Considering:
  – Project vision and scope
  – Available capabilities and skill set
  – Brexit and other constraints

• The approach the EU network is taking:
  – PMS implementation is led and undertaken by EMA
  – SMS implementation is shared as follows:
    • SMS - IDMP light – implemented by EMA
    • EU SRS - ISO IDMP compliant – implemented by MEB (NL)
PMS Iteration 1 will be the first iteration of ISO IDMP 11615 and 11616 compatible data management solution for authorised human & veterinary products. It will support generation and maintenance of MPIID, PhPID & PCID.

To fully address the implementation of IDMP 11238 further projects will be required.

PMS Iteration 1 has been divided into multiple phases. Phase 1, before relocation, is an EMA internal delivery comprising:

- A new ISO IDMP compliant Master Data Management (MDM) hub (also covering Veterinary and other needs)
- Two way synchronisation of medicinal product information (including S, R and O) between Art.57 database and the new MDM solution
- Data Quality (DQ) assurance/data entry of human medicinal Product information by EMA and possibly by some NCAs
### EU SMS projects

**SMS implementation is shared as follows:**

<table>
<thead>
<tr>
<th>SMS “IDMP light”</th>
<th>EU SRS ISO IDMP compliant</th>
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<tbody>
<tr>
<td><strong>Who:</strong> Implemented by EMA</td>
<td><strong>Who:</strong> Implemented by MEB (NL)</td>
</tr>
<tr>
<td><strong>Data:</strong> SMS data is the “simplified” PUBLIC substance data, that supports selection in regulatory processes and therefore enables you to distinguish two or more similar substances</td>
<td><strong>Data:</strong> EU SRS contains ISO IDMP substance data that supports scientific identification of substances. It includes PUBLIC and CONFIDENTIAL information subject to controlled access</td>
</tr>
<tr>
<td><strong>Technology:</strong> SMS solution covers:</td>
<td><strong>Technology:</strong> EU SRS solution covers only Substance data management</td>
</tr>
<tr>
<td>- Search, browse and export of PUBLIC substance data</td>
<td>- Software development/implementation led by NL in the short term in collaboration with EMA, under EU Telematics governance</td>
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<tr>
<td>- Management of substance change requests</td>
<td>- Software maintenance to be transferred to EMA</td>
</tr>
<tr>
<td>- Translation management</td>
<td></td>
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<tr>
<td><strong>Process/People:</strong> EMA provides a broker service by managing substance requests, supporting translations and assuring data quality.</td>
<td><strong>Process/People:</strong> This project is responsible to set up the EU Substance Validation Group (SVG) who will:</td>
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<td>- Prepare the EU substance list</td>
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<td></td>
<td>- Maintain the EU list by approving substance requests and managing substance data</td>
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</table>
• **SMS Iteration 1** will be the first iteration towards ISO IDMP 11238 compatible data management solution for substances

• To fully address the implementation of IDMP 11238 further projects will be required

• SMS Iteration 1 has been divided into two phases. Phase 1, before relocation, is an EMA internal delivery comprising:

  • New MDM hub for the substance management service
  
  • Migration of substance data from multiple EMA sources (EV H, EUTCT H, EUTCT V, EV V) to MDM hub, which support future consolidation and synchronisation

    • *This data is not yet mapped to other external sources such as G-SRS*

  • Management of substance data as per current process/DQ standards
In parallel to SMS Phase 1, EU SRS project led by MEB (NL) will:

- Set up SVG
- Set up initial EU list by consolidation of FDA + NCA + EMA lists in English and with some translations
- Prepare EU SRS implementation
C. EU Guidance
EU Guidance Process

**Draft EU IG**
- **2018:** Several sections of EU IG available:
  - **(Draft) API specs**
  - **(Draft) Data fields & business rules**
  - User on-boarding strategy
  - User registration process
  - Data Migration strategy
  - Data Validation/DQ assurance strategy
  - **(Draft) TOM**

**Develop/Test /UAT API**
- **Not before 2019:**
  - PMS API UAT:
    - Minor changes/improvements are expected as result of API development and testing

**Finalise EU IG**
- **Not before 2019:**
  - (Final) EU IG is available:
    - **API specs**
    - **Data fields & business rules**
    - User onboarding strategy
    - User registration process
    - Data Migration strategy
    - Data Validation/DQ assurance strategy
    - **TOM**
    - **Submission/Registration process**

**Start Transition**
- **Not before 2020:**
  - Industry can start to submit product information using new IDMP compatible format to comply with Art 57
    - EU IG + 12 months

**Enforcement**
- **Not before 2021:**
  - Enforcement: Industry can only submit product information using new IDMP compatible format to comply with Art 57
    - Transition + 12 months
EU Guidance and Relevant milestones for Human Industry

2017:
- High-level principles agreed:
  - Data scope;
  - Migration & Validation strategy;
  - Business processes (Ph1)
- (Draft) TOM

2017:
- (Draft) TOM

2018:
- Messaging Format agreed
- Several sections of EU IG available:
  - (Draft) API specs
  - (Draft) Data fields & business rules;
  - User onboarding strategy;
  - User registration process;
  - Data Migration strategy;
  - Data Validation/DQ assurance strategy

2018:
- (Final) EU IG is available

2018-2019:
- Revised plans published

2018-2019:
- (Draft) API specs
- (Draft) Data fields & business rules;
- User onboarding strategy;
- User registration process;
- Data Migration strategy;
- Data Validation/DQ assurance strategy

Not before 2019:
- (Final) EU IG is available

Not before 2019:
- PMS API UAT
- Not before 2019:
- Not before 2020:
- Not before 2021:
- Enforcement:
  - Industry can only submit product information using new IDMP compatible format to comply with Art 57

Not before 2019:
- Start Transition: Industry can start to submit product information using new IDMP compatible format to comply with Art 57

Not before 2019:
- Enforcement:
  - Industry can only submit product information using new IDMP compatible format to comply with Art 57

Not before 2020:
- P&SMS It 1 Phase 4 delivers the Human Products Target Operating Model:
  - PMS collects (new/updated) product data submitted by Industry via eAF/CESSP to support all regulatory processes including Art. 57

12 months available for preparatory work since (final) EU IG is published to start of Transition

Transition period extended to 12 months

(Draft) Sections of EU IG enable to plan in 2018 and start some preparatory work 2019

Agency Relocation

© EMA 2016
EU Guidance and Relevant milestones for Vet Industry

2017:
High-level principles agreed:
• Data scope;
• Validation strategy;
• Business processes (Ph1)

2017:
(Draft) TOM

2018:
Several sections of EU IG available:
• (Draft) API specs
• (Draft) Data fields & business rules;
• User onboarding strategy;
• User registration process;
• Data Validation/DQ assurance strategy

2018:
Messaging Format agreed

2018-2019:
Revised plans published

Not before 2019:
Several sections of EU IG available:
• TOM
• Submission/Registration process

Not before 2019:
PMS API UAT

Not before 2019:
 Several sections of EU IG available:
• (Draft) API specs
• (Draft) Data fields & business rules;
• User onboarding strategy;
• User registration process;
• Data Validation/DQ assurance strategy

Not before 2020:
Legacy data will be transmitted by NCAs to Eudrapharm/PMS (NVR Art 51)

Not before 2020:
P&SMS It 1 Phase 4 delivers the Vet Products Target Operating Model:
• PMS collects (new/updated) product data submitted by Industry via eAF/CESSP (not more data than eAF!)
• Assessment/validation of that product data is solely the responsibility of NCAs
• EMA acts as custodian

Agency Relocation

Documentation produced enables vet Industry to be aware of developments and prepare for future process

The current plan does not require Industry to backfill details on already approved products (the provisions of pharmacovigilance Art.57 do not apply to veterinary medicines)
EU Guidance and Relevant milestones for NCAs

2017:
- High-level principles agreed:
  - Data scope;
  - Validation strategy;
  - Business processes (Ph1)
- (Draft) TOM

2018:
- OMS content is expanded:
  - MAH > CAP Manufacturers > NAP Manufacturers
- Messaging Format agreed
- Several sections of EU IG available:
  - (Draft) API specs
  - (Draft) Data fields & business rules;
  - Data Validation/DQ assurance strategy – Validation of legacydata
- Revised plans published

2018-2019:
- Several sections of EU IG available:
  - TOM
  - Submission/Registration process
- EU Substance list is available
- PMS API UAT

Not before 2019:
- Revised plans published
- Several sections of EU IG available:
  - TOM
  - Submission/Registration process
- EU Substance list is available
- PMS API UAT

2016-2018: NCAs to map the referentials in their systems against RMS

2018-2019: NCAs to map the Organisations in their systems against OMS

2019-2020: NCAs to map the Substances in their systems against SMS

P&SMS TOM ensures data is validated by NCAs so only trusted substance and product data is available for use in regulatory processes

Not before 2020:
- Human NCAs check product data in their systems against PMS
- Vet NCAs send a core set of product data to EudraPharm/PMS

2020: Human NCAs check product data in their systems against PMS
- Vet NCAs send a core set of product data to EudraPharm/PMS
D. Future
The journey ahead (2019 +) – SPOR Roadmap

P&SMS Iteration 1 covers authorised human & veterinary medicinal products.

P&SMS implements ISO 11238; makes EMA regulatory compliant.

PMS implements ISO 11615 and ISO 11616 standards; makes EMA regulatory compliant.

P&SMS TOM ensures data is validated by NCAs so only trusted substance and product data is available for use in regulatory processes.

SPOR master data is integrated with business processes i.e. it is entered once and reused across different business processes.

Agency Relocation

EU Implementation Guides are available

P&SMS Iteration 2 opportunity to expand scope, eg Investigational Medicinal Products

Integrate P&SMS with CT processes

Integrate P&SMS with PhVig processes

P&SMS Iteration 3 further opportunity to expand scope e.g. Clinical Particulars

Integrate P&SMS with Regulatory processes

P&SMS It 1 Phase 2 delivers PMS API & SMS ISO 11238 Compliant data

P&SMS It 1 Phase 3 delivers Migration of Vet products

P&SMS It 1 Phase 4 delivers the Human Products Target Operating Model

P&SMS It 1 Phase 5 delivers PMS User Interface

P&SMS It 1 Phase 6 delivers the Veterinary Products Target Operating Model

P&SMS It 1 Phase 7 delivers reporting & document management

Start Transition: Industry can start to submit product information using new IDMP compatible format

Enforcement: Industry can only submit product information using new IDMP compatible format

SMS implements ISO 11238; makes EMA regulatory compliant.
PMS Iteration 1 has been divided into multiple phases. After relocation PMS will deliver:

- Authorised human & veterinary medicinal products accessible via a web User Interface (UI) and SPOR Application Programming Interface (APIs)
- New ISO IDMP compliant message
- **Products Target Operating Model**
  - No changes to regulatory processes (including timelines as well as roles and responsibilities)
  - Simultaneous submission of product information to NCAs as part of regulatory procedures and registration in PMS to support multiple use cases
  - New ways to assess information electronically
(Draft) PMS Target Operating Model

EU Phase

- NCA (RMS) Common EU details
- MAH National details

NCA Phase

- NCA (RMS/CMS) Details assigned by NCA
- MAH Closing sequence

Post-MA Phase

- MAH Details added by EMA

Similar regulatory procedures

Only minor changes to regulatory procedures (same timelines as well as roles and responsibilities)

New digital ways of working

Align evaluation of dataset as part of regulatory process

Different parts of the data (data groups) are processed in different steps of the regulatory process

EU data groups
- Added by MAH
- Validated by RMS
- Examples:
  - Name
  - Active substance
  - Dosage Form Strength

National data groups
- Added by MAH
- Validated by RMS/CMS
- Examples:
  - Legal basis for the supply

NCA data groups
- Added by RMS/CMS
- Examples:
  - Date of approval
  - MA number

MAH data groups
- Added by MAH
- After approval
- No regulator validation
- Examples:
  - Sales start
  - Risk of shortage
  - Agreed new fields for Art 57 (Human only)

Additional data group
- Added by EMA
- Examples:
  - EURD Identifier

PMS TOM ensures:
- Clearer governance and ownership of data
- Data is validated by NCAs so only trusted product data is available for use in regulatory processes

All required product/procedure data submitted in the same way to:
- NCAs as per current submission to support regulatory procedures (MAA & var/ren) and other such as withdrawals, corrections, etc
- EMA/PMS (closing sequence) to be reused in regulatory procedures and support multiple use cases

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• SMS Iteration 1 has been divided into two phases. After relocation SMS will deliver:

• Substances accessible via a web User Interface (UI) and SPOR Application Programming Interface (APIs)

• Synchronisation with EU SRS

• **Substances Target Operating Model**
  - New process for industry and NCAs to pre-register/update Substance data before submitting regulatory applications
  - EU-US alignment
  - Substance data is assessed in parallel with MA review
  - Substance data is approved before conclusion of regulatory processes
(Draft) SMS Target Operating Model

**Industry/requestor**
- Substance request

**EMA**
- Substance request validation
- Substance assessment
- Substance alignment
- Substance approval
- Substance request outcome

**SVG**
- Substance request validation
- Substance assessment
- Substance alignment
- Substance approval

**FDA**
- Substance request validation
- Substance assessment
- Substance alignment
- Substance approval

**PROVISIONAL**
- Substance ID (SMS-ID)
- Substance ID (EU IDMP ID)
- UNII
- Global IDMP code
- Global IDMP code + EU IDMP ID + SMS ID

**EU-US alignment**
- Update Substance with Global IDMP code + EU IDMP ID + SMS ID
- Update substance status
- Inform EMA of outcome

**EU SRS-SMS sync**
- Close Substance request
- Inform Industry/requestor

**Regulatory submission (e.g. MAA) review**
- Substance can be used in regulatory submissions

**SMS TOM ensures:**
- Regulatory processes can start as soon as substance is Provisionally registered
- EU-US alignment
- Data is approved by SVG before conclusion of regulatory processes i.e. **only trusted data is used in regulatory processes**
E. Data Migration Strategy
Migration Strategy

**EMA migration**
- **2018:**
  - EMA Migration:
    - EMA migrates xEVMPD data into PMS
    - PMS has same data content as xEVMPD
    - PMS data is transformed into a new ISO compatible format (as possible)

**PMS API**
- **Not before 2019:**
  - PMS API:
    - Industry solutions (RIM) can import/pull Product data from PMS API (ISO message)

**Industry enrichment**
- **Not before 2019:**
  - Industry is expected to validate the data migrated/transformed from Art 57 and enrich/transform the data as per specifications in the EU IG:
    - Industry can perform validation/enrichment via own RIM solution

**TOM (Start Transition)**
- **Not before 2020:**
  - Industry can start to submit product information using new IDMP compatible format:
    - comply with Art 57 and/or
    - support any regulatory procedure (TOM)
  - Industry can also use the PMS UI to:
    - Export product data – ISO message, xls
    - Perform their own validation/enrichment
  - Data submitted by Industry overwrites previous versions in PMS
  - Data submitted by Industry is DQ assured by NCAs (also creates a new version)

**Enforcement**
- **Not before 2021:**
  - Enforcement:
    - (Using RIM or PMS capabilities)
    - Industry can only submit product information using new IDMP compatible format:
      - comply with Art 57 and/or
      - support any regulatory procedure (TOM)
    - Industry can also use the PMS UI to:
      - Export product data – ISO message, xls
      - Perform their own validation/enrichment

3. SPOR in the Regulatory context
R & O (& S) in the Regulatory context

**Start**

Prepare Application Form

Does correct Referential data exist?

**N**

Access SPOR to check Master data

SPOR

Master data exists

**N**

Submit request to include new Master data

Submit change request to update Master data

**Y**

Confirmation of registration or update

Completion of application

Receive App Form

Complete and submit App Form

SPOR = Single source of master data

Refreshed data automatically pulled into IT systems

NCAs do not need to review SPOR master data, only confirm it has been approved

Conclude application

Finish

• Industry needs to go to SPOR and pre-register new/updated data.
• NCAs do not need to review master data, only confirm it has been approved.
SPOR integration with eAF
Handling variations Type 1, where there is administrative change (12% of total variations)

<table>
<thead>
<tr>
<th>As Is today</th>
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</thead>
<tbody>
<tr>
<td><strong>Manufacturer name change</strong></td>
</tr>
<tr>
<td>Manufacturer</td>
</tr>
<tr>
<td>Manufacturer</td>
</tr>
<tr>
<td>Manufacturer</td>
</tr>
<tr>
<td>Manufacturer</td>
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</tbody>
</table>

(*) - several products belonging to the same MAH can be impacted
Handling variations Type 1, where there is administrative change (12% of total variations)

How SPOR can improve the process and how it could work with ROG

Pre-requisite: there is a regulatory change (process, communication)

Manufacturer name change -> Data entered by MAH or Manufacturer -> NCA & MAH are automatically informed -> All products automatically updated or flagged for updating
Thank you for your attention

Further information

Please send any queries regarding the IDMP/SPOR to:
SPOR-Change-Liaisons@ema.europa.eu

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### Glossary

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<th><strong>Backward compatibility</strong></th>
<th>Capability of a new solution to successfully interface/work with previous versions of software/hardware.</th>
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<tr>
<td><strong>CESSP</strong></td>
<td>The Common European Single Submission Portal (CESSP) is an ongoing Telematics programme that aims to integrate the electronic Application Form (eAF) data sets in to CESP. CESP is the current submission channel for all procedures (not technically integrated with eAF).</td>
</tr>
<tr>
<td><strong>Controlled vocabularies</strong></td>
<td>(aka Referentials) are lists of terms that refer to attributes of medicinal and pharmaceutical products e.g. dosage form, route of administration, unit of measurement.</td>
</tr>
<tr>
<td><strong>CT Portal</strong></td>
<td>(aka EU Portal and Database) will be the upgraded version of Eudra CT enabling a single entry point for submission and assessment of clinical trial applications at an EU level.</td>
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<tr>
<td><strong>eAF</strong></td>
<td>The eAF is a collection of Application Forms that facilitate electronic submission of data relating to Renewals, Variations, Marketing Authorisation Applications (Human &amp; Vet).</td>
</tr>
<tr>
<td><strong>Eudra CT</strong></td>
<td>The existing platform for submitting and viewing information relating to regulatory activities relating to Clinical Trials.</td>
</tr>
<tr>
<td><strong>EUTCT</strong></td>
<td>A repository and provider of controlled terms (or controlled vocabularies) in multiple languages. It is the predecessor of RMS. RMS will replace EUTCT with regards to management of controlled vocabularies. EUTCT can only be fully replaced after SMS implementation as it also contains substances.</td>
</tr>
<tr>
<td><strong>Unique identifiers</strong></td>
<td>The ISO IDMP standards outline a set of attributes/data elements that make up a <strong>unique identifier</strong>. This enables the creation of a unique record for each medicinal product, packaged product, pharmaceutical product, substance and referential.</td>
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