HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FMD Workshop 27 June 2016

Meeting outcome

Presented by **Paolo Alcini**
Head of Data Standardisation and Analytics Service

Point Discussed during the WS

- Review of draft agenda and Tour de table
- Points to foster alignment of concepts and understanding:
  - Key sections of the FMD delegated act
  - Status of the ISO IDMP standards
  - SPOR, vision, Target Operating Model (TOM)and current status of SPOR roadmap
  - EMVO to explain status of the development of the FMD database in detail including UI including timelines
  - Technical understanding of the Product IDs:
    - ISO PCID
    - FMD Unique product ID
    - GTIN
    - NTIN
- Listing of the possible options
- Technical analysis on the possible integration options with definition of pros/cons
- Agreement on the recommendation from the FMD subgroup with rationale to be presented at the EUNDB and ISO IDMP taskforce

Participants

Attendees list (Industry)

Name	
Neil Newman	John Kiser
Kelly Hnat	Christian Hay
Dave Wilson	Andreas Franken
Paul Mills	

Attendees list (EMA)

Name
Paolo Alcini
Ilaria Del Seppia
Rik Smithies
Ana Cochino

Additional Expert UK Department of Health

Name
Steve Graham

Key sections of the FMD delegated act

Article 4

Composition of the unique identifier

The manufacturer shall place on the packaging of a medicinal product a unique identifier which complies with the following technical specifications:

(a) The unique identifier shall be a sequence of numeric or alphanumeric characters that is unique to a given pack of a medicinal product.

(b) The unique identifier shall consist of the following data elements:

(i) a code allowing the identification of at least the name, the common name, the pharmaceutical form, the strength, the pack size and the pack type of the medicinal product bearing the unique identifier ('product code');

(ii) a numeric or alphanumeric sequence of maximum 20 characters, generated by a deterministic or a non-deterministic randomisation algorithm ('serial number');

(iii) a national reimbursement number or other national number identifying the medicinal product, if required by the Member State where the product is intended to be placed on the market;

Key sections of the FMD delegated act

Article 33

1.

[…]

The information shall be stored in all national or supranational repositories serving the territory of the Member State or Member States where the medicinal product bearing the unique identifier is intended to be placed on the market. The information referred to in paragraphs 2(a) to (d) of this Article, with the exception of the serial number, shall also be stored in the hub.

Info from P.Mills:
The Hub at the moment is foreseen to have all of the elements in the next sections with the exclusion of the serial number

Key sections of the FMD delegated act

Article 33

[…]

2.For a medicinal product bearing a unique identifier, at least the following information shall be uploaded to the repositories system:

(a) the data elements of the unique identifier in accordance with Article 4(b);
(b) the coding scheme of the product code;
(c) the name and the common name of the medicinal product, the pharmaceutical form, the strength, the pack type and the pack size of the medicinal product, in accordance with the terminology referred to in Article 25(1)(b) and (e) to (g) of the Commission Implementing Regulation (EU) No 520/2012 (1);
(d) the Member State or Member States where the medicinal product is intended to be placed on the market;
(e) where applicable, the code identifying the entry corresponding to the medicinal product bearing the unique identifier in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004 of the European Parliament and the Council (2);
(f) the name and address of the manufacturer placing the safety features;
(g) the name and address of the marketing authorisation holder;
(h) a list of wholesalers who are designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf.

Status of the ISO IDMP

- MPID/PCID/PHPID related standards and Technical specification:
  - decision for publication is expected in November 2016
- Substance standards and relevant TS:
  - Decision for publication is expected in April 2017

Technical understanding of the Product IDs:

Info on MPID and PCID

1. The MPID shall use a common segment pattern related to a Medicinal Product, which when each segment is valued shall define a specific MPID concept. The pattern is:
   - a) Country code segment (ISO 3166-1 alpha-2 code elements);
   - b) Marketing Authorization Holder (Organization Identifier) code segment;
   - c) Medicinal Product code segment (Unique Medicinal Product Identifier).
   - Any change of the values related to these three code segments shall result in the assignment of a new MPID.

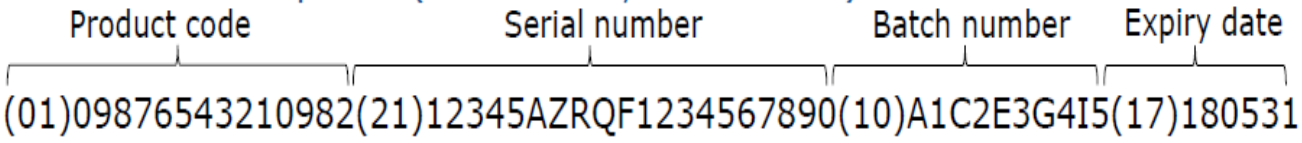
2. The PCID shall use a common segment pattern related to a package of a Medicinal Product, which when each segment is valued, shall define a specific PCID concept. The pattern is:
   - a) MPID for the Medicinal Product
   - b) package description code segment, which refers to a unique identifier for each package.

Technical understanding of the Product IDs:

Info on FMD UI:

The UI - Composition

- The UI will contain:
  - **Product code:** ISO-compliant (ISO 15459); < 50 characters; globally unique; issued by ISO-compliant coding agencies;
  - **Serial number** (max 20 characters; randomised)
  - A **national reimbursement or identification number** (optional)
  - **Batch number**
  - **Expiry date**
- UI also ISO-compliant (ISO 15418; ISO 15434).



Illustrative example – not binding

Comparison of PCID and GTIN:

GTIN-14:

The GTIN-14 standard is defined as the unique 14-digit identifier for items; it includes, in sequence, the following:

a) Indicator digit: The indicator digit is a one-digit logistical code, which value can be a zero (0);

b) Country code: The country code is the country code corresponding to the GS1 member organization of which the brand/license owner is a member;

c) Brand/license owner code - Company prefix: The brand/license owner code is a code allocated to the brand owner by the GS1 member organization of which the brand/license owner is a member;

d) Product code: Product codes are unique numbers. The value for product code is arbitrary and is at the discretion of the brand/license owner;

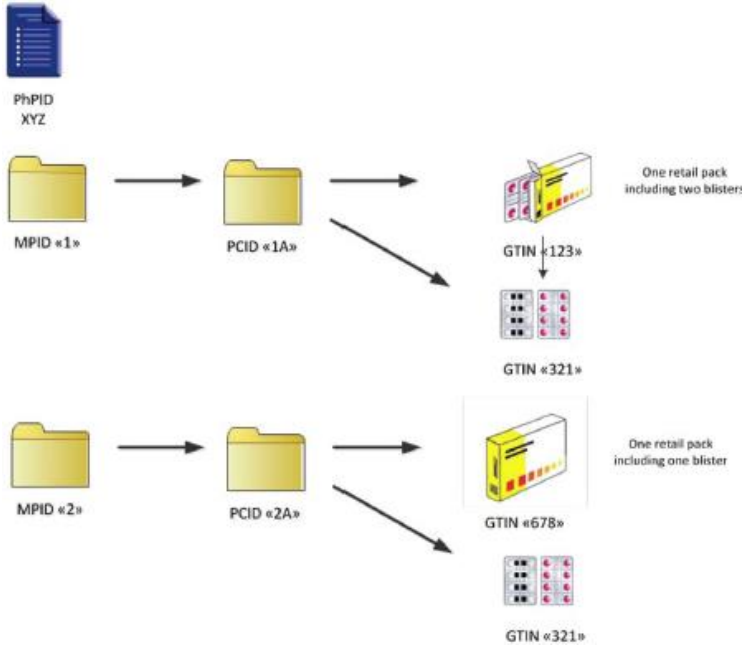
e) Check digit: A final digit calculated from the other digits of some GS1 Identification Keys. This digit is used to check that the data has been correctly composed.

Source: ISO TS 16791- Health informatics — Requirements for international machine readable coding of medicinal product package identifiers

Comparison of PCID and GTIN:

The diagram below shows the relationship between MPID, PCID and GTIN, when the same primary package is marketed in different pack sizes (secondary packs with two, respectively, one blister).
The PCID is the concatenation of MPID and a Package Description Code segment, which refers to an identifier for each package (see ISO 11615, 6.3.1).

It can also happen that the same GTIN for the secondary package corresponds to 2 different PCIDs



Source: ISO TS 16791- Health informatics — Requirements for international machine readable coding of medicinal product package identifiers

Possible options:

I. **Link SPOR and FMD via the Data Carrier Identifier in the ISO IDMP Model**

II. **Use the FMD Unique product ID as PCID**

III. **Use the PCID as the FMD Unique prod ID**

Recommended option:

I. link SPOR and FMD via the *Data Carrier Identifier in the ISO IDMP Model*

- Capture the Product Code in the FMD (e.g. GTIN) within the SPOR model at the level of the Packaged Item as *Data Carrier Identifier*
- Restrict the SPOR model via the EU Implementation Guide to allow GTIN only for the secondary package
- Leave *Data Carrier Identifier* as optional

Rationale for this option is because:

- **Option II** is not feasible due to the fact that 1 GTIN may correspond to multiple PCIDs
- **Option III** is not feasible because it will require substantial investments and process changes in the supply chain

Thank you

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