The role of drug database providers in the implementation of the IDMP Standard

access needs and business challenges of drug database providers
Belgian Centre for Pharmacotherapeutic Information (BCPI)

• The BCPI is a:
  • not for profit,
  • non-governmental organization
  • providing independent information on drugs and promoting Rational Prescribing,
  • intended for health professionals
Belgian Centre for Pharmacotherapeutic Information

• The BCPI is one of the partners of SAM (*Source Authentique des Médicaments* - Authentic Source of Medicines in Belgium)

• FAMHP: Federal Agency for Medicines and Health Products
• NIHDI: National Institute for Health and Disability Insurance
• BCPI: Belgian Centre for Pharmacotherapeutic Information
SAM data model

• Scope:
  • authorised medicines in Belgium
  • some of the information only present for commercialised medicines

• data suppliers
  • famhp (for official package information)
  • NIHDI (for legal and reimbursement information)
  • BCPI (for clinical information, groups for generic prescription in Belgium and implementation of international standards such as SNOMED CT)
  • ... other data suppliers can be added in future
SAM data model

- Medicinal product definition part is based on the dm+d model of UK
  - **Virtual part**: describes commercialised drugs in a generic, brand-independent and clinically oriented way, playing a key role in the generic prescription process
  - **Actual part**: describes authorised branded drugs

- Reimbursement law definition part
  - Models the law texts concerning reimbursement of branded drugs

- Reimbursement part
  - The link between a drug and reimbursement law texts
SAM data model

**Virtual part**

- **VTM** (Virtual Therapeutic Moiety):
  \( VTM\ id\ (BCPI) \)
  - amlodipine

- **VMP group** (Virtual Medicinal Product Group):
  \( VMP-group\ id\ (BCPI) \)
  - amlodipine oral 5 mg
  - amlodipine oral 10 mg
  - ...

- **VMP** (Virtual Medicinal Product)
  \( VMP\ id\ (BCPI) \)
  - amlodipine 5 mg capsule (or.)
  - amlodipine 5 mg tablet (or.)
  - ...

**Actual part**

- **AMP** (Actual Medicinal Products)
  \( AMP\ id\ (FAMHP) \)
  - Amlodipine Apotex tabl. 5 mg
  - Amlodipine EG tabl. 5 mg
  - ...

- **AMPP** (Actual Medicinal Product Packages)
  \( CTI\-extended\ (FAMHP) \)
  - Amlodipine Apotex tabl. 28 x 5 mg
  - Amlodipine Apotex tabl. 56 x 5 mg
  - Amlodipine Apotex tabl. 98 x 5 mg
VMP-group
paracetamol oral 500 mg
VMP-group id = 24901

VMP
Paracetamol
VTM id = 974

VTM
paracetamol 500 mg tablet
(or.)
VMP id = 26799

AMP
Paracetamol Sandoz tabl. 500 mg
AMP id = SAM436843-00

AMPP
Paracetamol Sandoz tabl. 240 x 500 mg
CTI-extended = 436843-10
The Medicinal product definition part will contain, among others:

**Administrative information**
- Company
- Route(s) of administration
- Pharmaceutical form
- Substances and their strengths
- Divisibility
- Commercialisation status
- Supply problems (if applicable)
- Price (public and reimbursement)

**Clinical information**
- Indication
- Contra-indications
- Cautions
- Side-effects
- Pregnancy and Breast feeding
- Interactions
- Dosing instructions
- Direct link to the SPC and patient leaflet
VMP: virtual but granular enough

**Use case**

- “international prescription”
- Basic concept for medical record system prescriber
- Fully clinical interchangeability AMP’s of the same VMP (except excipients)
- Granular enough for all clinical relevant links:
  - Intolerance (except excipients)
  - Medication list and history in Medical Record
  - Medical Record analysis

**VMP**
paracetamol 500 mg tablet (or.)
VMP id = 26799


VMP: virtual but granular enough

- VMP = basic concept of SAM for international interoperability
- VMP ≈ Generic drug preparation (GDPrep) of SNOMED CT default drug model
- VMP ≈ Pharmaceutical Product (PhPID)
VMP: virtual but granular enough

- **Active ingredient(s)** = from list of coded substances with specifications if it refers to the base, the salt or an ester

- **The strength(s)** ➔ UCUM (Unified Code for Units of Measure) is used for units

- **The pharmaceutical form(s)** ➔ EDQM

- **The route(s) of administration** ➔ EDQM

- Possible clinically relevant **additional information** is specified (e.g. for ASA cardiovascular >> pain and fever
  - acetyl salicylic acid oral 100 mg
  - acetyl salicylic acid oral 100 mg (cardiovascular use)
Decision support and clinical knowledge

• Implementation of the VMP concept well-suited for decision support
• Decision support should be linked to both the pharmaceutical product (actual and virtual) and to substances
  • because strength matters
  • because route of administration matters
  • because additional clinical information matters
• Several types of (often overlapping) groups of medicines are needed
  • anatomical groups
  • therapeutical groups
  • pharmacological groups
  • generic prescription groups
  • chemical groups
  • molecules