Up-scaling the global univocal identification of medicines

IDMP in Europe and in Belgium

Paul De Troch – Goedele Louwagie

Federal Agency of Medicines and Health Products (Belgium)

13/04/2023

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Contents

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

What is IDMP?

Identification of Medicinal Products

famhp
federal agency for medicines and health products

UNICOM

ISO standards

ISO IDMP standards cover the following aspects to **describe a human medicinal product**:

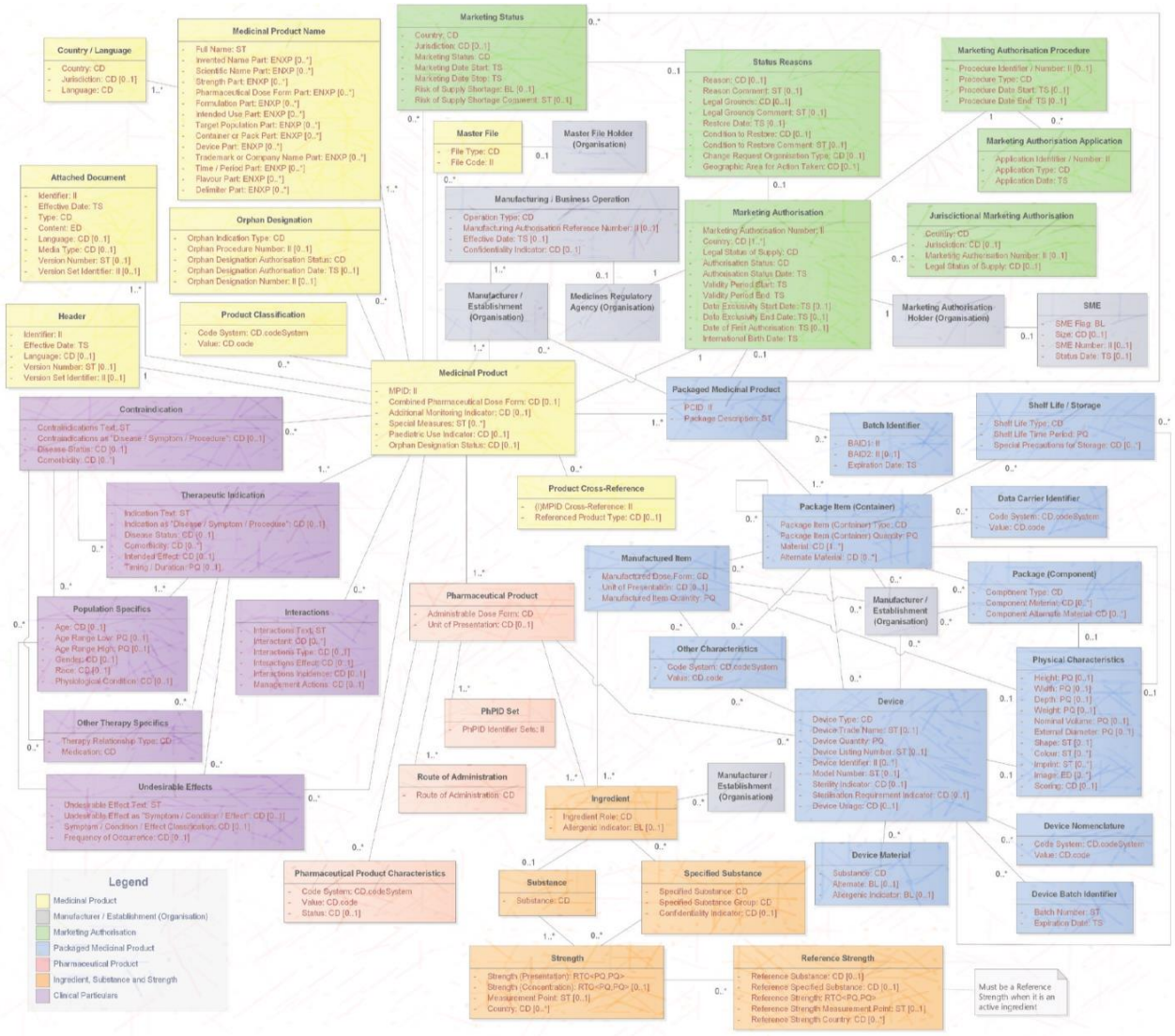
- Medicinal product name
- Ingredient substance
- Pharmaceutical product (route of administration, strength, active substance)
- Marketing authorization
- Clinical particulars
- Packaging
- Manufacturing

5 Standards

- ISO 11615 – Data elements for regulated medicinal product information
- ISO 11616 – Data elements for regulated pharmaceutical product information
- ISO 11238 – Data elements for regulated information on substances
- ISO 11239 – Data elements for pharmaceutical dose forms, units of presentation, routes of administration and packaging
- ISO 11240 – Data elements for units of measurement

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

IDMP Datamodel



Source: ISO

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Investigational versus Authorised

Investigational Medicinal Product	Authorised Medicinal Product
An Investigational Medicinal Product is described by • A Clinical Trial Status (Standardised Term) • Either a Regulator Product Code or a Sponsor Product Code • An IMPID	An Authorised Medicinal Product is described by • - • - • An MPID
An Investigational Medicinal Product Name is described by either • A Full Name • A Code	An Authorised Medicinal Product is described by only • A Full Name

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Investigational versus Authorised

Investigational Medicinal Product	Authorised Medicinal Product
An Investigational Medicinal Product can have one or more Clinical Trial Authorisations	An Authorised Medicinal Product can have only one Marketing Authorisation
A Clinical Trial Autorisation is described by	A Marketing Autorisation is described by
• A Registration Number	• A Marketing Authorisation Number
• An Investigation Code	• -
• One or more Countries (standardised term)	• One or more Countries (standardised term)
• A Protocol Number	• -
• An Autorisation Date	• A Date of First Authorisation
• An Anticipated End Date	• -
• -	• An International Birth Date
• -	• A Legal Status of Supply (Standardised term)
• -	• An Autorisation Status (Standardised term)
• -	• An Autorisation Status Date
• -	• A Validity Period Start
• -	• A Valididy Period End
• -	• Zero or one Date Exclusivity Start Date
• -	• Zero or one Date Exclusivity End Date

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Investigational versus Authorised

Investigational Medicinal Product	Authorised Medicinal Product
A Clinical Trial Authorisation can have zero or more Local Clinical Trial Authorisations A Local Clinical Trial Authorisation is described by • - • A Local Clinical Trial Registration Number • An Local Investigation Code • One or more Juridictions (standardised term) • A Local Autorisation Date • A Local Anticipated End Date • -	A Marketing Autorisation can have zero or more Jurisdictional Marketing Authorisations A Jurisdictional Marketing Authorisation is described by • A Country (standardised term) • Zero or one Marketing Autorisation Number • - • Zero or more Jurisdictions (standardised term) • - • - • A Legal Status of Supply (standardised term)

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Investigational versus Authorised

Investigational Medicinal Product	Authorised Medicinal Product
A Clinical Trial Authorisation is issued by one Medicines Regulatory Agency (Organisation)	A Marketing Authorisation is issued by one Medicines Regulatory Agency (Organisation)
A Clinical Trial Authorisation is requested by one Sponsor (Organisation)	A Marketing Authorisation is requested by one Marketing Authorisation Holder (Organisation)
A Sponsor can be or not an SME	A Marketing Authorisation Holder can be or not an SME
-	A Marketing Authorisation can have zero or one Status Reason
-	An Authorised Medicinal Product can have zero or more Marketing Statuses
-	A Marketing Authorisation is initiated by one Marketing Authorisation Procedure
-	A Marketing Authorisation Procedure is driven by zero or more Marketing Authorisation Applications
Packaged Investigation Medicinal Product	Packaged Medicinal Product

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Contents

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

IDMP at EMA

European Medicines Agency

famhp
federal agency for medicines and health products

UNICOM

SPOR

- SPOR is the EMA implementation of IDMP.
- EMA has created defined lists of **s**ubstances, **o**rganisations and all other elements in IDMP which need defined terminology (**r**eferentials). Some of these lists with defined terminology are maintained by third parties (WHO, EDQM)
- PMS (products) follows the guidelines set in ISO 11615, but with extensions by EMA

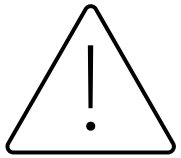
  Extension is e.g.
  Domain: Veterinary or Human
  Textual description of packaging and its language

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Data elements

Three categories:

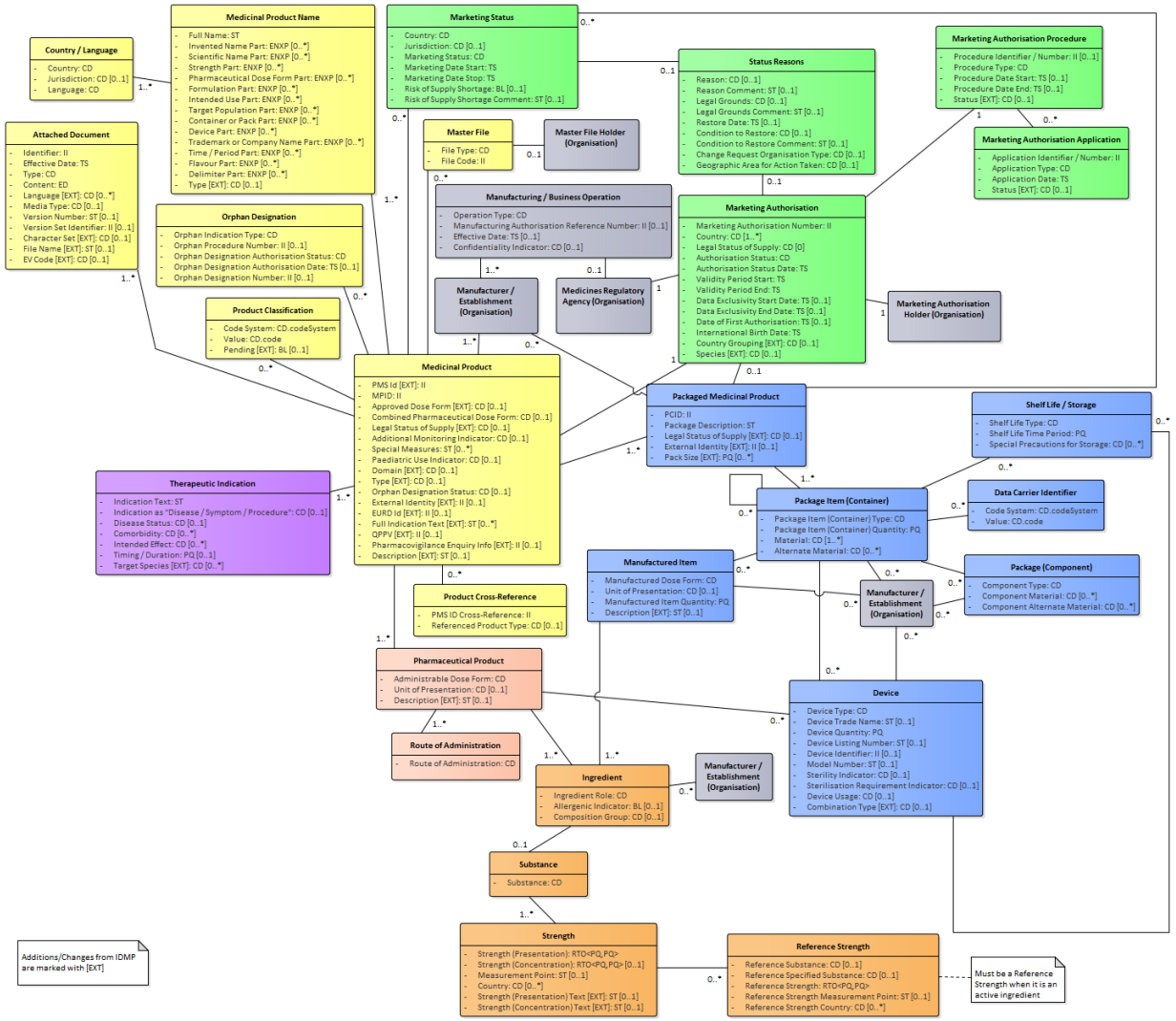
- IDMP and EMA are using the same path for the data elements
- EMA is only using some IDMP data elements in the first iteration
- EMA deviates from IDMP (differences and extensions)



The items in these categories might shift to other categories with time.

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Contents



Source: EMA

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Contents

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

IDMP in Belgium

Federal Agency for Medicines and Health Products

famhp
federal agency for medicines and health products

UNICOM

Medicinal Products Management

- New application which went into production in 07/2022.

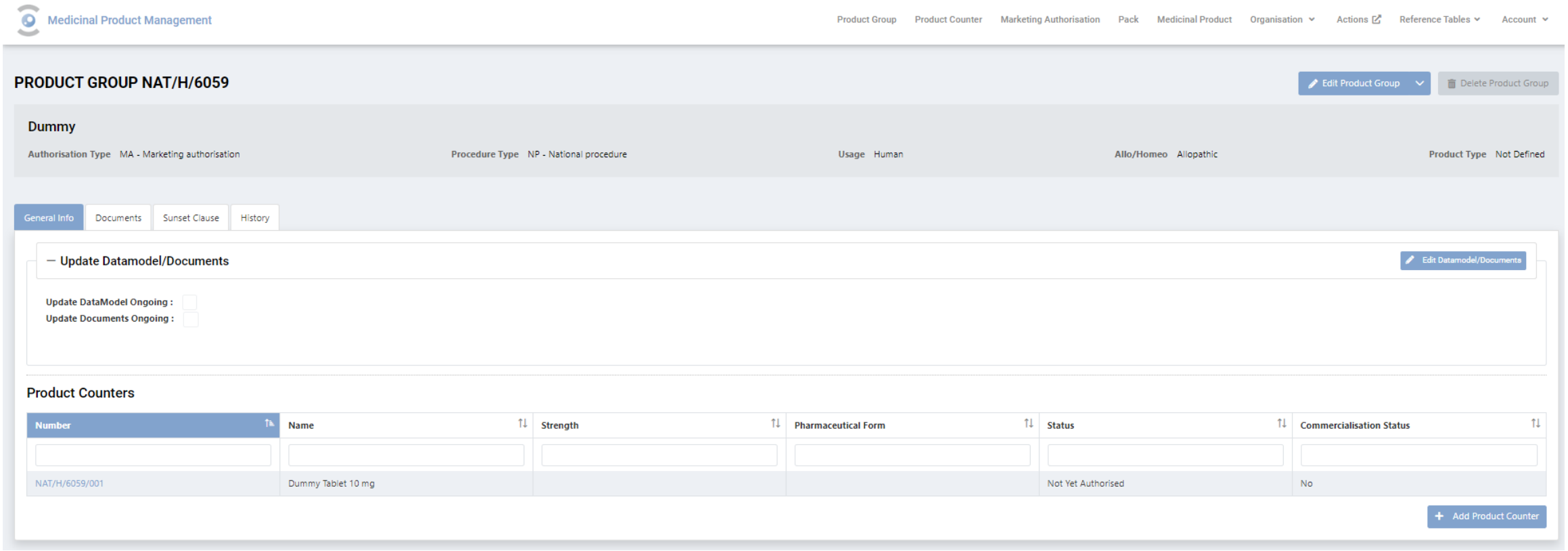
  This new application partially takes into account the data model of IDMP.
  As a result, 45% of data fields map, and basic national terminology has been mapped with SPOR, like country, language, pharmaceutical form.

- The remaining of the data model is part of the gap analysis presented.

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Medicinal Products Management

- The system used in Belgium to manage authorised medicinal medicines.

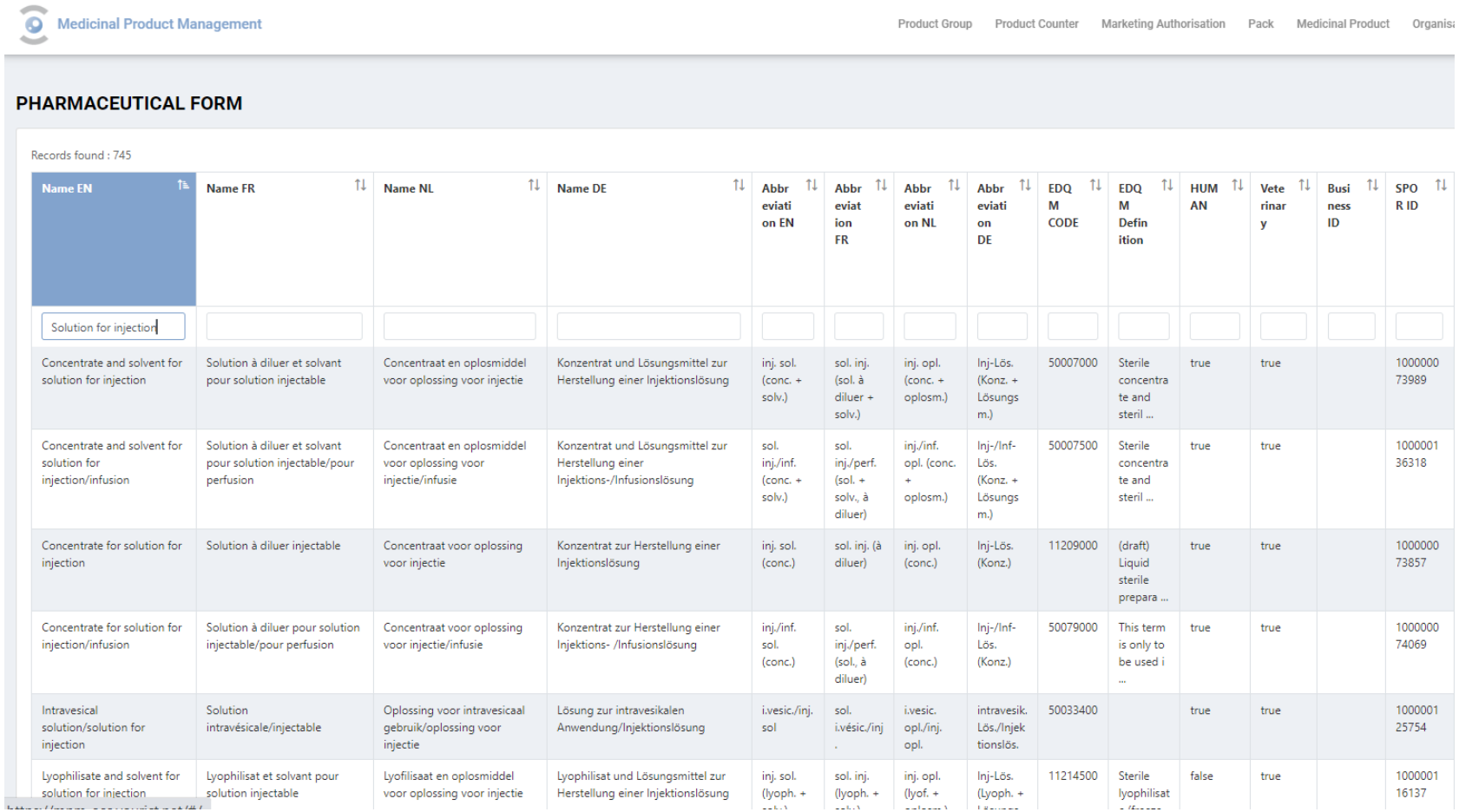


This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Medicinal Products Management

UNICOM

- Reference table link to SPOR



Name EN	Name FR	Name NL	Name DE	Abbreviation EN	Abbreviation FR	Abbreviation NL	Abbreviation DE	EDQM CODE	EDQM Definition	HUMAN	Veterinary	Business ID	SPOR ID
Solution for injection													
Concentrate and solvent for solution for injection	Solution à diluer et solvant pour solution injectable	Concentraat en oplosmiddel voor oplossing voor injectie	Konzentrat und Lösungsmittel zur Herstellung einer Injektionslösung	inj. sol. (conc. + solv.)	sol. inj. (sol. à diluer + solv.)	inj. opl. (conc. + oplosm.)	Inj-Lös. (Konz. + Lösungsm.)	50007000	Sterile concentrate and steril ...	true	true		100000073989
Concentrate and solvent for solution for injection/infusion	Solution à diluer et solvant pour solution injectable/pour perfusion	Concentraat en oplosmiddel voor oplossing voor injectie/infusie	Konzentrat und Lösungsmittel zur Herstellung einer Injektions-/Infusionslösung	sol. inj./inf. (conc. + solv.)	sol. inj./perf. (sol. + solv., à diluer)	inj./inf. opl. (conc. + oplosm.)	Inj-/Inf-Lös. (Konz. + Lösungsm.)	50007500	Sterile concentrate and steril ...	true	true		100000136318
Concentrate for solution for injection	Solution à diluer injectable	Concentraat voor oplossing voor injectie	Konzentrat zur Herstellung einer Injektionslösung	inj. sol. (conc.)	sol. inj. (à diluer)	inj. opl. (conc.)	Inj-Lös. (Konz.)	11209000	(draft) Liquid sterile prepara ...	true	true		100000073857
Concentrate for solution for injection/infusion	Solution à diluer pour solution injectable/pour perfusion	Concentraat voor oplossing voor injectie/infusie	Konzentrat zur Herstellung einer Injektions- /Infusionslösung	inj./inf. sol. (conc.)	sol. inj./perf. (sol, à diluer)	inj./inf. opl. (conc.)	Inj-/Inf-Lös. (Konz.)	50079000	This term is only to be used i ...	true	true		100000074069
Intravesical solution/solution for injection	Solution intravésicale/injectable	Oplossing voor intravesicaal gebruik/oplossing voor injectie	Lösung zur intravesikalen Anwendung/Injektionslösung	i.vesic./inj. sol	sol. i.vésic./inj.	i.vesic. opl./inj. opl.	intravesik. Lös./Injektionslös.	50033400		true	true		100000125754
Lyophilisate and solvent for solution for injection	Lyophilisat et solvant pour solution injectable	Lyofilisaat en oplosmiddel voor oplossing voor injectie	Lyophilisat und Lösungsmittel zur Herstellung einer Injektionslösung	inj. sol. (lyoph. +	sol. inj. (lyoph. +	inj. opl. (lyof. +	Inj-Lös. (Lyoph. +	11214500	Sterile lyophilisat	false	true		100000116137

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

famhp federal agency for medicines and health products

Gap analysis @ start

Result and type of remediation:

Start of phase 2:

- On ± 160 fields in EMA IDMP, 45% are fully mapped
  - Missing fields in MPM → Addition of field in MPM datamodel, some information not available yet in EMA
  - Other field structure in MPM → Data condensation/cleanup
  - Information present in MPM, but not in the required format → Data transformation
- Missing Referentials in MPM → Addition of SPOR-IDs or SPOR-List

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Example missing field

- Therapeutic (product) indication Co-morbidity

  Link with other projects of EMA, like ePI?

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Example missing referential

- SPOR LIST 200000018799 Reason for Marketing Unavailability

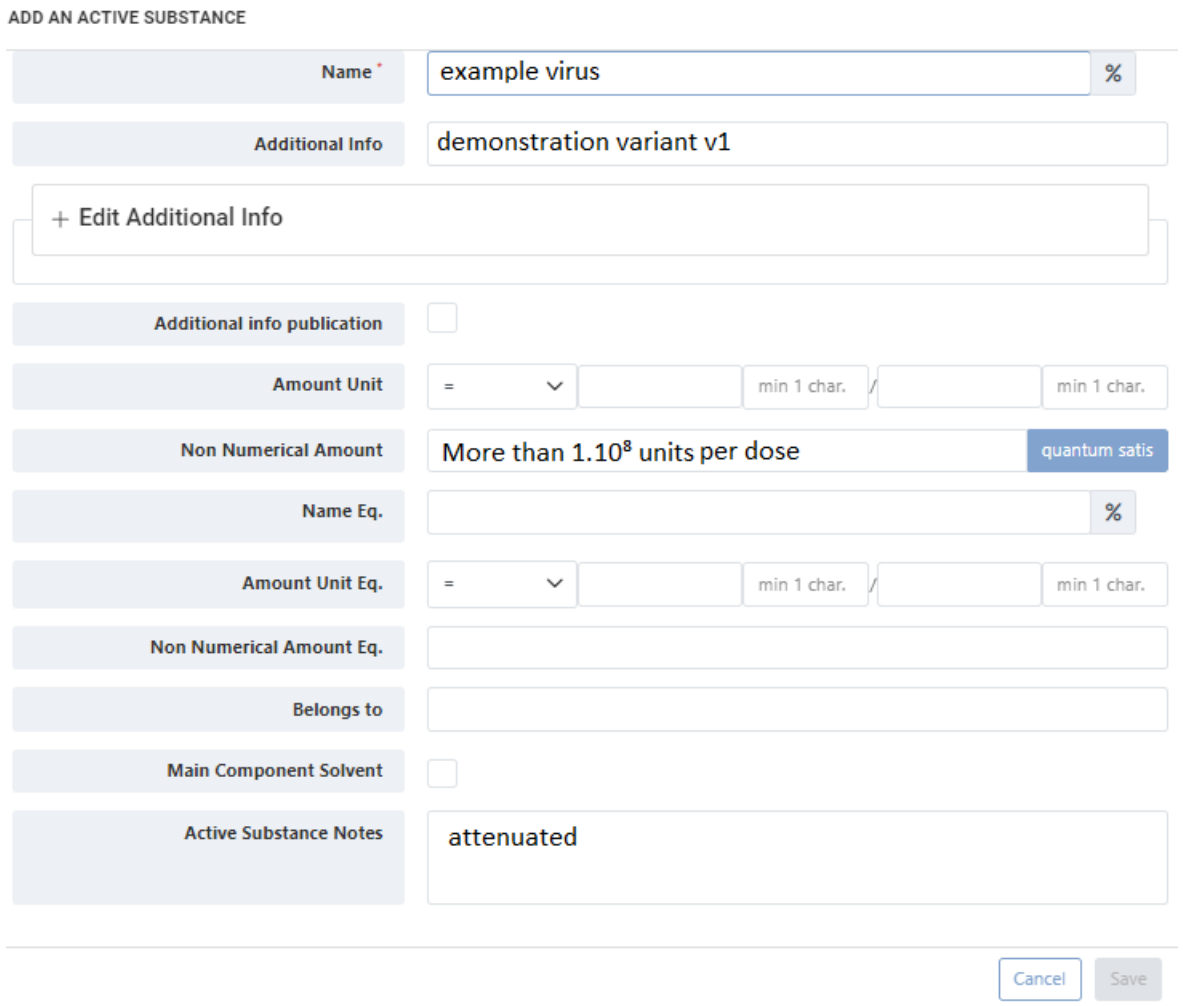
Identifier ▲	Term Name
200000018808	Safety - Medicine is harmful (Art. 116, 117(1a) of Directive No 2001/83/EC)
200000018809	Efficacy – Lack of efficacy (Art. 116, 117(1b) of Directive No 2001/83/EC)
200000018810	Risk/benefit - Not favourable (Art. 116, 117(1c) of Directive No 2001/83/EC)
200000018811	Quality - Composition not as declared (Art. 116, 117(1d) of Directive No 2001/83/EC)
200000018812	Quality - Controls have not been carried out or MA obligations not fulfilled (Art. 117(1e) of Directive No 2001/83/EC)
200000018813	Particulars of Art. 8-11 incorrect/not amended as Art. 23 (obligation to keep dossier updated) (Art. 116 of Directive No 2001/83/EC)
200000018814	Any conditions as per Art. 21, 22 not fulfilled (e.g. PAES, PASS) (Art. 116 of Directive No 2001/83/EC)
200000018815	Commercial reasons (excl. Art. 116, 117 of Directive No 2001/83/EC)

In Belgium a different coding is used for market unavailability
Link with ESMP (European Shortages Medicines Platform)?

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Example other field structure

- Ingredients have several fields in MPM to describe the composition of the ingredient



This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Example data transformation

- Full name of product = concatenation of invented name + Strength + pharmaceutical form

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Example constant value

- Regulator: LOC-ID of FAMHP LOC-100050707

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Contents

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

e-Prescription

Authentic source of authorized drugs (SAM)

famhp
federal agency for medicines and health products

UNICOM

SAM Introduction

- SAM = the authentic source of drugs authorized for the Belgian market.
  - The SAM data model consists of three parts:
    - A “Medicinal Product Definition part”. This part focuses on the medicinal information such as substances and properties of products. It is subdivided into two parts:
      - *the “virtual part” provides data about medicinal products on a generic and a fortiori brand independent level and*
      - *the “actual part” provides concrete, branded medicinal products authorized for the Belgian market including availability.*
    - A “Reimbursement Law Definition part” that consists in first the legislation text content (legal basis, references and texts) and second the legislation text modelling (formal interpretations, reimbursement conditions and terms).
    - A “Reimbursement part” part that includes all the information that relates to the delivery environments, prices, copayment amounts, etc.

Core business of FAMHP

=> mandatory use of SAMv2 as source of information for electronic prescriptions as from 1/1/2020 (included in the homologation conditions of the software applications)

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Focus on medicinal product definition part (1/2)

- Actual part: describes drugs
  that are brand name drugs
  that are auhorised (only complete when on the market)
  e.g. Flemoxin oplosb. tabl. (deelb.) Solutab 500 mg

- Virtual part: describes drugs
  in a generic, brand-independent, way
  in a clinically oriented way
  that are on the market (= subset of authorised drugs)
  e.g. amoxicilline 500 mg capsule (or.)

- Availability status (see next slide)

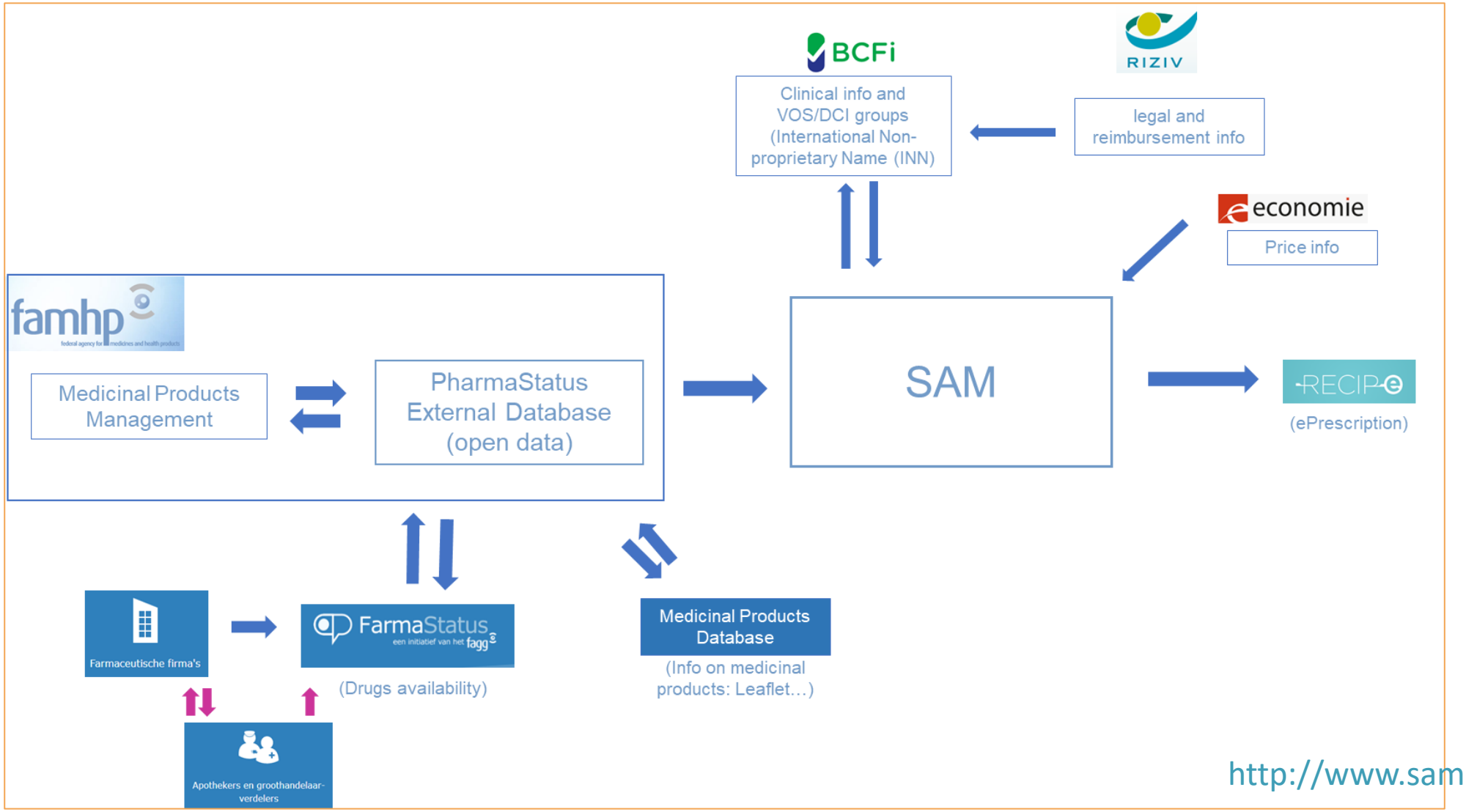
This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Focus on medicinal product definition part (2/2)

- Availability status
  - Temporary Supply Problem => symbol indicating there is an actual temporary supply problem of the concerned pack size of the medicinal product. Additional information (e.g. via hovering) contains the following data:
    - start date supply problem,
    - presumed end date supply problem,
    - reason supply problem,
    - impact supply problem,
    - additional information concerning alternative medicinal products or treatments.
  - End of commercialisation => symbol indicating the end of commercialisation of the concerned pack size of the medicinal product. Additional information (e.g. via hovering) contains the following data:
    - reason end of commercialisation,
    - impact end of commercialisation,
    - additional information concerning alternative medicinal products or treatments.

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

PharmaStatus & SAM Architecture



http://www.samportal.be

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Acknowledgements

- The information presented is derived from the UNICOM Innovation Action, which receives funding from the European Commission Directorate General for Communications Networks, Content and Technology, in the context of the European Horizon 2020 research and innovation programme under grant agreement No 875299 - support which is gratefully acknowledged.
- Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the information presented. The views expressed are solely those of the author(s) and do not necessarily reflect those of the European Commission or any other organisation.
- We are most grateful to colleagues at the participating organisations as well as external experts who contribute and critically review project work.

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Thank you!

famhp
federal agency for medicines and health products

UNICOM

Further Information on UNICOM

unicom-project.eu
Twitter: @ unicom_idmp
linkedin.com/company/unicom-idmp