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Deliverable abstract

This is the first progress report on the participation of AFMPS (the Belgian National Competent Authority for Marketing Authorisation of Medicinal Products) in UNICIOM.

During the first year of UNICOM an analysis was made on the “AS IS” situation in AFMPS as to the internal IT Systems regarding Medicinal Products, the current status of alignment to SPOR, and capability to provide an IDMP compliant data feed.

Risks and mitigations are discussed for the legal requirement for IDMP (and the alignment with the business processes of the agency), the need to comply with additional terminologies, the way to cope with the complexity of IDMP, and how to adjust to competing priorities.

Finally, the next steps are presented.

Keywords: AFMPS, IDMP, Implementation, SPOR, Mesea, MPM, DTS, HIRS, EMA, Belgium, ISO, SAM

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List of abbreviations

Abbreviation	Complete form
AFMPS	Belgian National Competent Authority regarding the authorisation of medicines. (FAGG)
BCFI	Belgian Centre for Pharmacological Information
DTS	Application: Dossiers Tracking System (will replace part of the functionalities of MESEA
E + R	Extra Plus Revised: internal database with data regarding Belgian authorised medicines
HIRS	Health Intelligence Reporting System (complex research on MPM and DTS data)
INAMI	the Belgian National Health Insurance Organisation (RIZIV)
MESEA	Workflow system used to process marketing authorisation of Medicines (Initials & Variations). Technically based on IBM Filenet
MESEA Vision 2020	Internal project to transform the Mesea in a java base double application MPM and DTS
MPM	Application: “Medicinal Product Management” (replacing E+R)
ORG-ID	In SPOR more particularly OMS (Organisation Management System) all “organisation” receive an unique Identification.
PhPID	In ISO IDMP the Pharmaceutical Product Identifier
RMS	Referential Management Services
SAM	Source Authentique des Médicament is the national database used in Belgium for e-prescription. This database is also the source for medicine substitution. This Database is “owned” and made compulsory by INAMI in Belgium.
SMS	Substance Management Services
SPOR	EMA service delivering quality data management services for substances, products, organisations and referential (SPOR) to power EU regulatory activities. The four SPOR data management services are: SMS, PMS. OMS, RMS
VET-UPD	Union Product Database as per new European regulation regarding Veterinary medicines
VET-MAH’s	Marketing Authorisation Holders for veterinary products

1 Executive summary

This is the first progress report of of AFMPS participation (the Belgian National Competent Authority for Marketing Authorisation of Medicinal Products) in UNICIOM.

During the first year of UNICOM an analysis was made on the “AS IS” situation in AFMPS as to the internal IT Systems regarding Medicinal Products, the current status of alignment to SPOR, and the special situation in Belgium, where the Agency is one of the partners in a consortium that produces a publically available Authentic Source of Medicines (SAM), to be used in all processes of the eHEALTH system (including the ePrescription system).

As foreseen in the Description of Action of the UNICOM project, an implementation plan is presented for :

- The refactoring of the internal databases, currently in transition from a previous legacy system to a new MEDEA 2020 system. After the completion of this transition, the conversion to an IDMP compliant system will be initiated.
- The completion of the alignement with SPOR
- The provision of an IDMP compliant data feed from SAM

Risks and mitigations are discussed for the legal requirement for IDMP (and the alignment with the business processes of the agency, the need to comply with additional terminologies, the way to cope with the complexity of IDMP and how to adjust to competing priorities.

Finally, the next steps are presented.

- AFMPS will subcontract its partner CBIP (Belgian Center for Pharmacotherapeutic Information) to perform a gap analyse of the national database SAM (used for e-prescription in Belgium) towards ISO-IDMP. Availability q3 2021
- This gap analyse will be used by internal analyst (AFMPS IT department) as a basis for further work. That second analyse will have to identify the gap between data owned by AFMPS and ISO-IDMP. Availability Q1 2022.
- A plan to cover this gap (for data owned by AFMPS) will be produced by Q3 2022.

Due to the COVID-19 crisis, which forced the agency to realign its projects portfolio with the new priorities, less then planned time was spent in 2021 on the participation in the UNICOM project.

2 Progress Report N°1 - Belgium

2.1 Role of AFMPS

The Agency is the competent authority to safeguard and assure the quality, safety and efficacy of medicinal products (including homeopathic and phyto-therapeutic products, magistral and officinal preparations and blood products). In addition, the Agency is responsible for health products (medical devices, basic substances, human corporal material) both for human use and veterinary use, in the market, and in clinical development.

2.2 Description of the situation "AS IS" for AFMPS in the Belgian Health Care Setting

2.2.1 Internal IT Systems regarding Medicinal Products

The legacy system Mesea

AFMPS has an internal workflow system managing marketing authorisation of new medicines and their variations as submitted to the Belgian NCA by existing or future marketing Authorisation Holders (MAH's).

This system called Mesea is based on IBM Filenet software, which supports enterprises to digitize content, manage the content lifecycle as well as business processes. The pertinent information regarding medicines is stored in an internal Database called E+R. The latter is used as a source to inform internal and external stakeholders about "regulatory" information regarding medicines both human and veterinary.

The ongoing refactoring of the legacy system: Mesea Vision 2020

In 2017 AFMPS started a project called "Mesea vision 2020". It had planned that from 2020, the **E + R** and **MeSeA applications** (human, veterinary, phyto and homeo) would be gradually replaced by new applications. This had a significant impact given that around 150 employees of AFMPS use these applications daily and that these systems collect a lot of data.

MeSeA will be replaced by three completely new applications.

- **MPM** (medicinal product management) collects all data relating to the life cycle of medicinal products for human or veterinary use.
- **DTS** (dossier tracking system) collects all the data relating to the follow-up of dossiers for granting a marketing authorization (MA), vigilance dossiers and dossiers of unmet medical needs (unmet medical need).
- **HIRS** (Health Intelligence Reporting System) for more complex research on MPM and DTS data.

These applications were being developed as part of **the Vision 2020 project** which started in the summer of 2016 and whose first realization, namely MPM, was scheduled for 2020.

This project was started well before the UNICOM project.

Business did not put forward, at the time of conception, the necessity to be fully compliant with "ISO-IDMP".

In Figure 1, a description is given of the logical datamodel of the AFMPS Drug database MPM, illustrating the rich granularity of the data, albeit not (yet) compliant with IDMP.

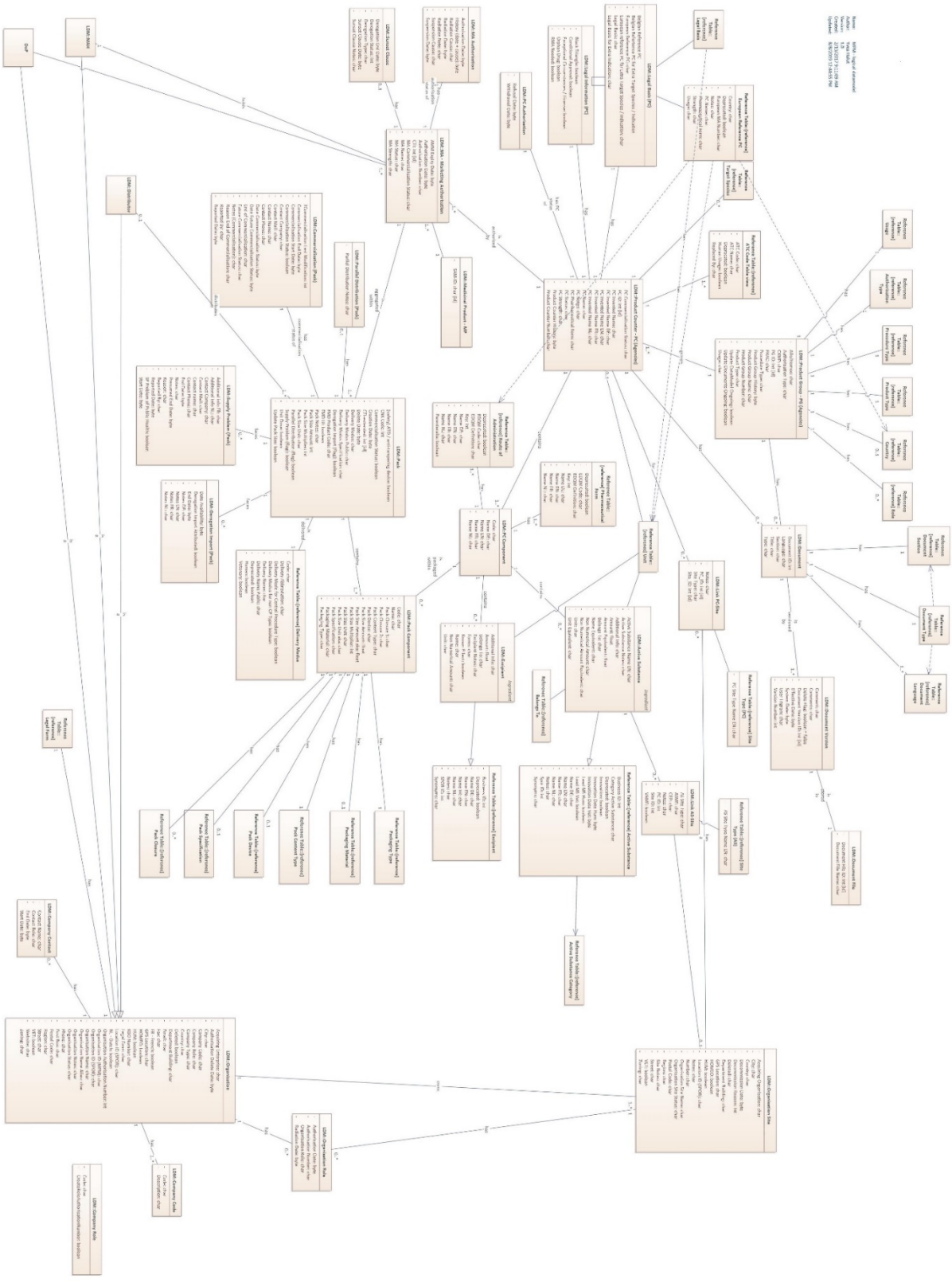

Figure 1: The current MPM logical Data Model

2.2.2 Current status of alignment to SPOR in AFMPS

Belgium is not part of the SPOR task force, so participation to EU level technical specifications was limited to reviews of documents shared for review to all NCA's.

=> review of chapters 1 and 3 of the SPOR EU implementation guide v2, quick overview of chapter 2

=> first look at the draft version of the FHIR data structure for medicinal products available on the HL7 website

A separate replication of SPOR-RMS and SPOR-OMS data has already been implemented in 2019 (without any links to our existing national medicinal product database).

2.2.3 Providing IDMP compliant Data Feed from the authentic Source of Medicines (SAM)

Context of provision of drug information in Belgium

Belgium maintains a central database with relevant information on all medicinal products marketed in the country. This database is called SAM (Source Authentique des Médicaments)

The Database is technically maintained by non-profit IT organisation (Smals) under the financing of the Belgian National Health Insurance Organisation (Inami) which receive its base data from different sources. AFMPS is one of these data suppliers for the “regulatory” part of the description of a medicine.

Belgian healthcare professionals and vendor systems of electronic health care records have to use that database from 2020 onwards when issuing an (e)Prescription.

Other data suppliers are Ministry of Economy for Price, Inami (Belgian National Health Insurance Organisation) for reimbursement rules, BCFI (Belgian Center for Pharmacological Information) for data regarding evidence-based medicine, substitution rules.

The database provides a code used within electronic prescription to facilitate medicine substitution during delivery: the VMP code (Virtual Medicinal Product). This VMP fulfils the role of PhPID in Belgium. But VMP is not 100% aligned with the PhPID. Note that this code is not produced by AFMPS but by a third body financed by it (BCFI). The expertise in creating this code or any other alike code (as PhPID) is therefore not available within AFMPS. This is one of the reasons why AFMPS plans to add this Non-Governmental Organisation to provide an analysis of what is the gap between the actual medicine national database and the ISO IDMP Standard. AFMPS will use that intermediary report as a base for its own analysis.

The Description of the SAM Database

The description of the conceptual, logical, and technical model of the SAM Authentic Source of Medicines can be found at the dedicated portal (http://www.samportal.be/fr/sam)

The authentic source of medicines (abbreviation: "SAM") is the reference database of medicines, made available in "open source" by the competent authorities in the field of medicines.

SAM data is managed by

- FAMHP (registration data)
- CBIP (pharmacotherapeutic groups, e.g. DCI clusters and other data, e.g. prescription name of packaging)
- INAMI (reimbursement terms)

- the FPS Economy (price)
- PDB (raw materials / formulas for magistral preparations - other products / non-drugs)

The scope of SAM is limited to public information on authorized drugs (including radiopharmaceuticals and raw materials for compounding preparations). A minimum data set on non-drugs that can also be prescribed is also part of SAM.

This authentic source is made available via the e-Health platform.

Initially, the SAM was set up as a reference database for “Chapter IV” drugs (“SAM 1.0”) as part of the electronic reimbursement authorization request procedure. At present, SAM (2.0) is the reference database for all drugs (e.g. for electronic prescribing).

Update

Updating the data in SAM depends on the frequency with which the changes are sent by the competent authority:

- FAMHP - data is updated in real time;
- CBIP - data is updated at least 3 times per month;
- INAMI - data is updated at least 2 times per month (i.e. monthly update with possible correction);
- SPF Economy - the data is updated daily;
- APB - data is updated daily.

The partners

	The **INAMI** is a key player in the social security. It fulfils a double mission. - The INAMI ensures that each insured person, whatever their situation, has effective access to the quality health care that is necessary (accessibility) and obtains reimbursement. This health care must be effective and provided at the agreed rates (tariff security). - The INAMI ensures that insured persons, salaried and self-employed workers, receive an adequate replacement income in the event of incapacity for work or maternity / paternity. It guarantees that they are offered real reintegration opportunities at the end of their incapacity for work. More information can be found on the INAMI website .
	In Belgium, the **FAMHP** is the competent authority responsible for ensuring the quality, safety and efficacy of medicinal products and health products (medical devices and accessories, raw materials, blood and blood compounds of human origin and human body), both for human and veterinary use, in clinical development and on the market. More information can be found on the FAMHP website .
	Since July 1974, **CBIP has** systematically provided independent information on drugs. This information is disseminated, under the direction of three editors, by an editorial board which is the executive body of CBIP and which is responsible for the selection and distribution of information. The CBIP is particularly careful that this information fits into the concept of "evidence based medicine". More information can be found on the CBIP website .

	In a rapidly changing Belgian and international economic context, the mission of the **FPS Economy**, SMEs, Middle Classes and Energy is to create the conditions for a competitive, sustainable and balanced operation of the goods and services market in Belgium. In this perspective, the FPS Economy, SMEs, Middle Classes and Energy intends to know and supervise the goods and services market to better stimulate it. More information can be found on the website of the FPS Economy .
	Smals is the common ICT organization of Belgian public institutions in social security. You will find more information on the Smals website .
	As a public institution, the **eHealth** platform's mission is ► promote and support well-organized electronic mutual service delivery and information exchange between all actors in health care ► with the necessary guarantees with regard to information security, protection of the privacy of the patient and of the healthcare provider and respect for medical confidentiality and this way ► optimize the quality and continuity of health care services ► optimize patient safety ► to simplify administrative formalities for all players in health care More information can be found on the eHealth-platform website .
	The mission of the **APB:** ► Stimulate, develop and promote the added value of the dispensing pharmacist for the benefit of the health and interests of the patient so as to contribute to better public health. ► Ensure the sustainability and development of the liberal practice of community pharmacy.

Comments on the SAM DATA MODEL “Product Definition”

The approach for information architecture of the SAM database was originally inspired by the logical model of the UK Dictionary of Medicines and Devices (Dm+d), which was itself inspired by the early versions of the IDMP datamodel. Hence, numerous elements within the logical model of SAM and IDMP have common roots.

The information about drugs is modelled in two parts: a virtual part and an actual part.

The Medicinal Product Virtual Part

The virtual part describes drugs used to treat patients that are commercialized on the Belgian market in a generic, brand independent and clinically oriented way - to be used by - health professionals.

Different levels of abstraction are defined, linking with clinically relevant concepts.

This part plays a key role in the generic prescription of drugs and has the BCPI as authentic source.

The virtual part is inspired on the NHS DM+D (Dictionary of Medicines and Devices) English model. However, the concepts are extended to a deeper level of details. (see fig 2)

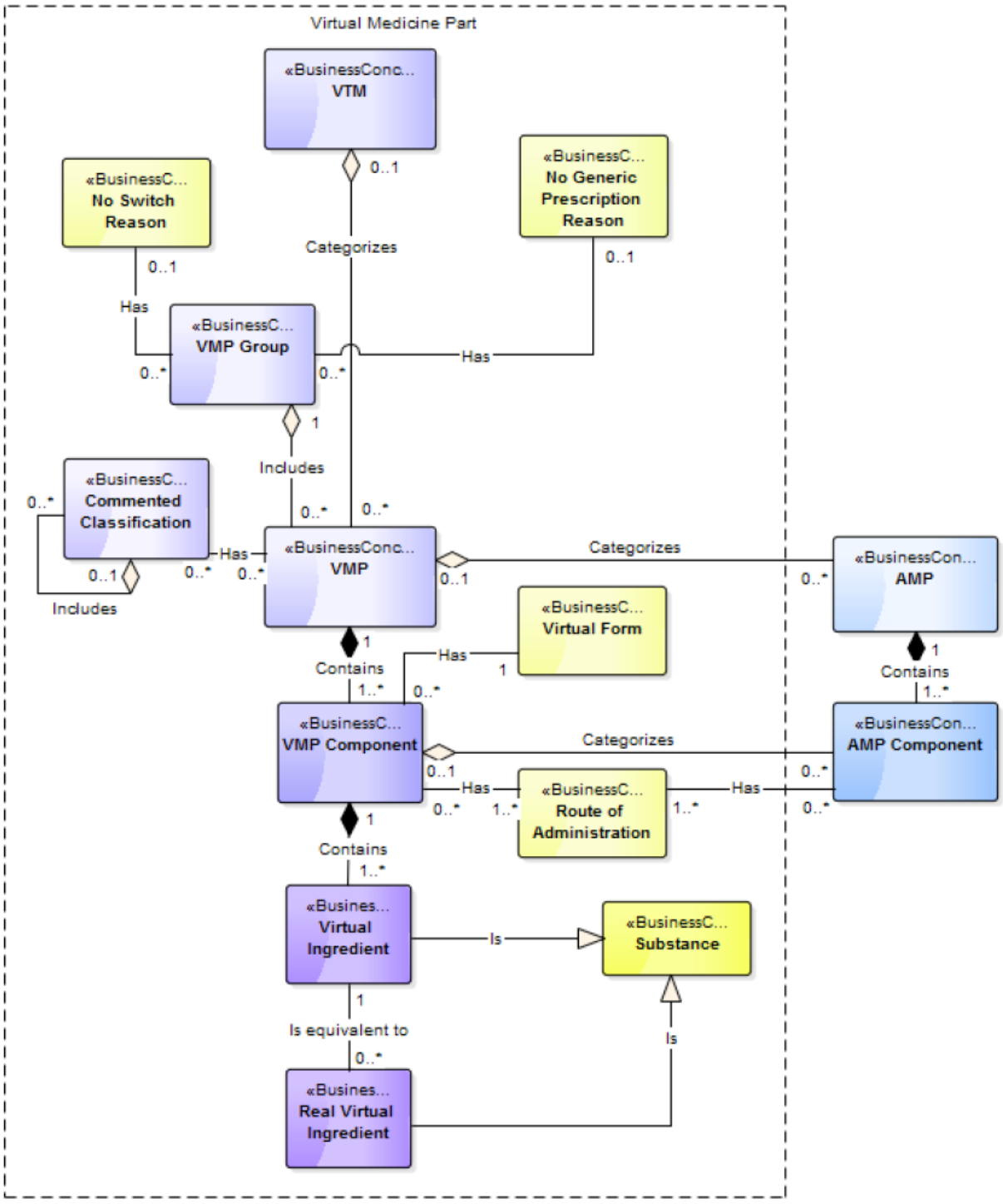

Figure 2: Medicinal Product Virtual Part Model

Medicinal Product Actual Part

The actual part describes branded drugs authorized for the Belgian market.
Includes brand names, MAH,..

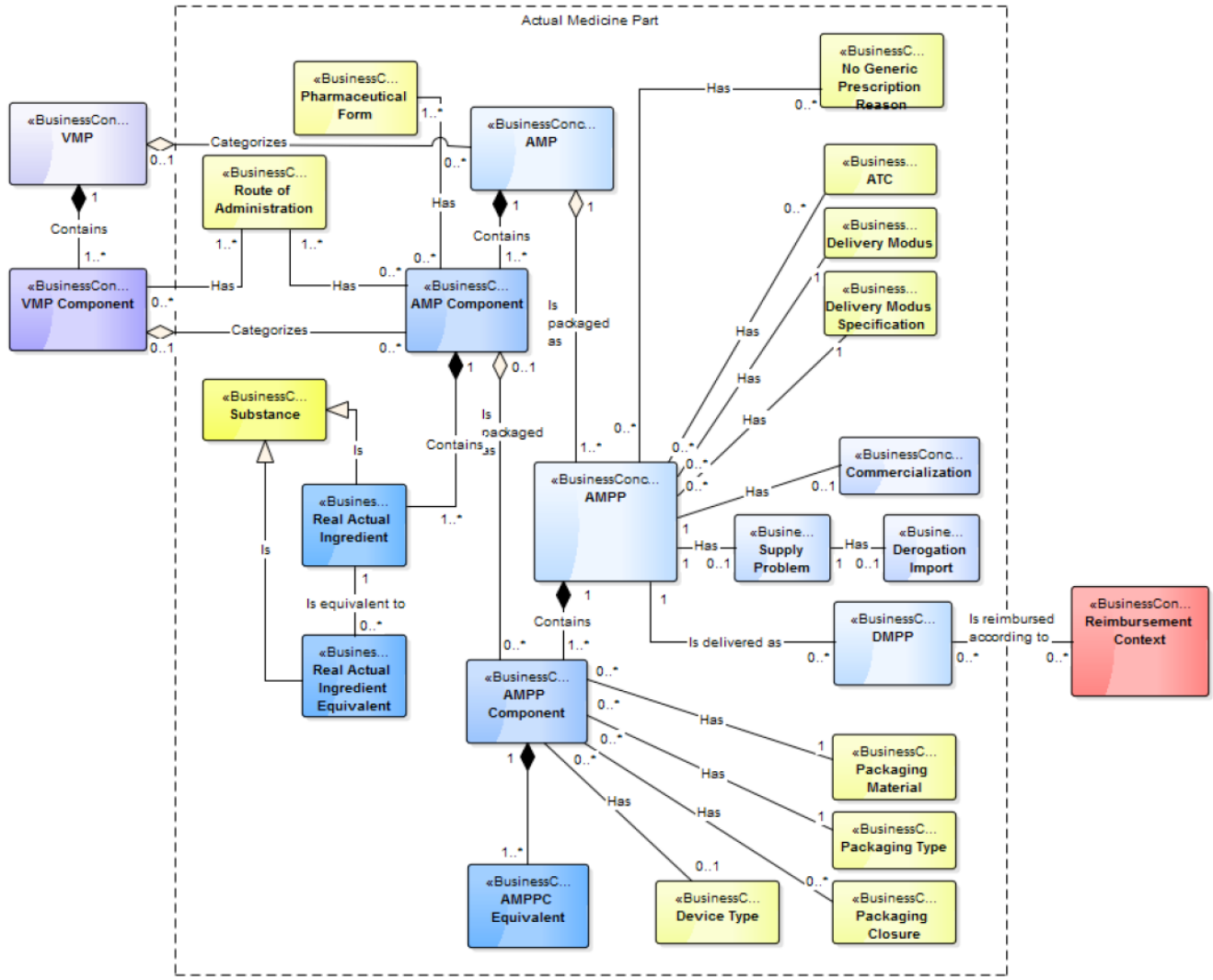

Figure 3: Medicinal Product Actual Part Model

2.3 Implementation plan for IDMP: Situation "TO BE"

2.3.1 Refactoring of internal databases

The IT systems of AMPS are currently in a long-planned transition to a new MESEA system. The objectives of this transition did not include conversion to IDMP.

Conversion to SPOR is however in the scope, and hence, the RMS referentials (substance, dose form) are already considered.

EMA and a number of national Competent Authorities are currently working on aligning the marketing authorisation process of new medicinal products to IDMP (Work Package 3 of UNICOM). In Work Package 4 of UNICOM, 11 agencies collaborate to establish the procedures to align with SPOR terminologies and convert to the IDMP logical models, to be ready to convert the data on already authorized data. The EMA implementation Guide is under construction, and currently in version 2, with more new versions expected in the coming two years.

The preparation of the conversion of the MESEA 2020 system to an IDMP compliant system needs to be carefully planned. Currently, priority is given to the implementation of the New Veterinary Regulation and the alignment to SPOR. An evolution towards a wider ISO IDMP "compliance" will be for after these two above mentioned priorities.

It was decided to start the consultation process for this transition, after completion of an analysis of the IDMP compliant data feed from SAM database, in which the AFMPS participates as a partner.

It is expected that by that time (early 2022), the guidance from EMA will have matured, and that FHIR resources will be available to test and validate pilot data on medicinal products.

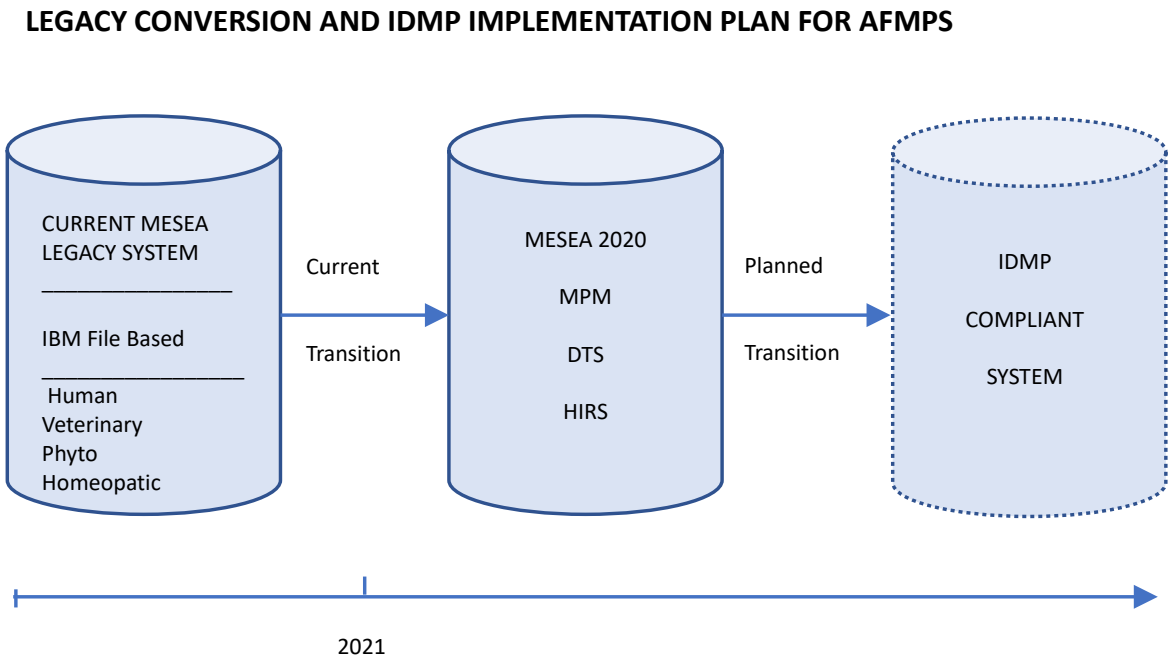

Fig 4. Legacy conversion of internal IT systems and IDMP implementation plan for AFMPS

2.3.2 Alignment with SPOR

Initiation of mapping with ID fields for organisations and referential data in our national medicinal products database.

A high-level review of the current data model for medicinal products in our national system is undertaken, in order to develop a consistent approach to future integration with SPOR: extending our existing model with necessary additional SPOR elements.

For organisations and locations: local data should be replaced by SPOR-OMS data in long term, but as a first intermediate step in the short term, we foresee to keep both datasets by adding the SPOR-ORG ID and LOC ID as additional data-element in our existing national database (containing the result of the ORG data mapping exercise).

For some specific RMS reference lists, the mapped SPOR IDs are registered into our database.

For SPOR-OMS, there is some doubt whether all organisations can be correctly mapped completely by ourselves, for the VET-UPD, we intend to contact all VET MAH's to have explicit confirmation on their correct ORG-ID. If this proves to be manageable, the same approach will also be applied for the HUM MAH's.

- Questions still needing further detailed analysis in 2021:
  - Further detailed analysis to extend our national data model and make it completely compatible with SPOR
  - How to deal with updates from SPOR-OMS (detect potential impacts on regulatory variation procedures, or triggering reviews by our business departments? => depends also on the results of the ROG workgroup)
  - How to automatically download updates from SPOR-PMS into our national system
  - How to automatically upload updates in our national system to SPOR-PMS => to be integrated in our existing event driven architecture
  - Downstream impact on the national authentic source for medicinal products used by our national eHealth Platform.
- Main potential problem identified relating to difference between national data model and SPOR data model:
  - National concept of virtual medicinal product (meant to group equivalent medicinal products for prescription/delivery purposes) vs. IDMP concept of Pharmaceutical Product (identified by PHPID), not yet available in the SPOR database.

There are some similarities, but they are certainly not identical. It is probable we will continue to use the VMP concept in the future, as this concept is being actively used within the national eHealth platform.

2.3.3 Provide IDMP compliant Data Feed from SAM

In Belgium, it has been decided that the platform to provide structured and authentic information on medicinal products through the SAM database. Hence, an IDMP compliant data feed to external partners in the eHEALTH system will be provided through SAM.

A thorough analysis of the similarities and differences of the logical model of SAM and IDMP is ordered, to identify the following concepts:

- Concepts already available in SAM
- Concepts available in SAM but in need of standardization
- Concepts not available in SAM but needed for IDMP.

The governance group of the SAM database (including all the partners, and also AFMPS) has ordered an information architect to make the initial analysis of the congruence of the two logical model to identify the issues to be solved, and to estimate the impact on the logical model of SAM.

Based on this analysis (expected by mid-2021), an estimation can be made of the IT-Implications and the editorial burden to standardize and add information items.

2.4 Risks and mitigations

2.4.1 The legal requirement

A legal reference for the use of ISO-IDMP can be found in COMMISSION IMPLEMENTING REGULATION (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council In article 25 & 26.

Article 25 concerns the use of internationally agreed terminology and article 26 concerns the use of internationally agreed formats and standards.

The “legal framework” seems to apply to pharmacovigilance activities but no other activities. We therefore identify this as a potential risk for the project.

The absence of a "legal" requirement making the use of ISO IDMP outside the "pharmacovigilance framework" is definitively a risk for the project. It is also a major risk for maintaining in production the system that could be developed with UNICOM.

(During our partnership with UNICOM it has been identify that only the TERMINOLOGY of one standard (**EN ISO 11615:2012**) is compulsory. The formats and standard of the other ISO IDMP components MAY be used (usage is not compulsory as per regulation).

Mitigation:

Identify with the NCA partners an agreed description of what is precisely the legal aspect of the implementation of ISO-IDMP.

2.4.2 The need to comply with additional terminologies

For regulatory purposes, also compliance with MedDRA and EDQM is mandated.

Mitigation:

In Belgium, SNOMED terminology is initiated in clinical care, and in the UNICOM project, bi-directional maps between SNOMED and MedDRA have been developed.

Compliance with EDQM will be achieved by implementing the alignment to SPOR RMS.

2.4.3 The complexity of IDMP

IDMP is a collection of 5 standards (and their technical specifications) :

- EN ISO 11615:2012 regulated medicinal product information
- EN ISO 11616:2012 regulated pharmaceutical product information
- EN ISO 11238:2012 regulated information on substances
- EN ISO 11239:2012 regulated information on pharmaceutical dose forms, units of presentation and routes of administration
- EN ISO 11240:2012 units of measurement

Hence, the ISO IDMP is a very large standard (more than 400 fields). Introducing a full compliancy will require more resources than wat is currently available.

Mitigation:

The current Unicom project should enable us to identify a scope reduction of the standard implementation: what would be necessary to use ISO-IDMP in the Belgian NCA to fulfil our legal mission.

2.4.4 Competing priorities

The Corona Crisis has brought a big strain on the resources of all NCAs.

This project requests a lot of technical IT resources and a reshaping of the business objectives of the agency. These resources are scarce and need to be aligned with the legal requirements and business objectives of the agency.

Mitigation:

Due to Corona, the project has requested an extension for 6 months.

The legal aspect of ISO-IDMP compliancy needs to be reflected into the business processes of the agency.

The AFMPS will identify a third party that could provide the “scientific” expertise that may be necessary to align database content with ISO – IDMP.

2.5 Next steps

- AFMPS will subcontract its partner CBIP (Belgian Center for Pharmacotherapeutic Information) to perform a gap analyse of the national database SAM (used for e-prescription in Belgium) towards ISO-IDMP. Availability q3 2021

- This gap analyse will be used by internal analyst (AFMPS IT department) as a basis for further work. That second analyse will have to identify the gap between data owned by AFMPS and ISO-IDMP. Availability Q1 2022.

- A plan to cover this gap (for data owned by AFMPS) will be produced by Q3 2022.