



S A M 2

CONCEPTUAL DATA DOSSIER V2.1

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List of abbreviations

ATC	Anatomical Therapeutic Chemical
BCPI	Belgian Centre for Pharmacotherapeutic Information
BCFI	Belgisch Centrum voor Farmacotherapeutische Informatie
CBIP	Centre Belge d'Information Pharmacothérapeutique
DDD	Daily Defined Dose
INAMI	Institut National d'Assurance Maladie et Invalidité
INN	International Nonproprietary Name
NIHDI	National Institute for Health and Disability Insurance
RIZIV	Rijksinstituut voor Ziekte- en InvaliditeitsVerzekering
FAGG	Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
AFMPS	Agence Federal pour Médicaments et Produits de santé
FAMHP	Federal Agency for Medicines and Health Products
Dm+d	Dictionary of Medicines and Devices
EHR	Electronic Health Record

Introduction

Conceptual Analysis

This conceptual analysis is the first step towards the development of a useful and flexible structure of the authentic source of medicines for use by healthcare professionals in Belgium. This model will describe a national therapeutic arsenal with 6 basic concepts (3 universal and 3 with country and brand specification).

The conceptual analysis gives a listing of the essential concepts, a thorough delineation of the concepts and a graphical representation of the logic relations between the different concepts.

1. Context

This conceptual analysis is part of the Authentic Source on Medicines (SAM) project (second phase). The objective of this project is to merge all information concerning medicinal products in Belgium (pharmaceutical and therapeutical information, registration and reimbursement information, ...) into a well-structured and user-friendly database, available to all healthcare partners in Belgium.

At present, the information about medicinal products in Belgium is dispersed over several partners. The Federal Agency for Medicines and Health Products (FAMHP/FAGG/AFMPS) registering and licensing medicinal and health products, has a database with the pharmaceutical and registration information of licensed medicines. The National Institute for Health and Disability Insurance (NIHDI/RIZV/INAMI) owns and maintains a database with the price information of reimbursed medicines and reimbursement conditions. The Belgian Centre for Pharmacotherapeutic Information (BCPI/BCFI/CBIP) is an independent organisation of clinical pharmacology, producing its own reference database with evidence-based information to guide the drug choice process and to support decision systems embedded in the medical record systems and which is published each year in a booklet 'Gecommentarieerd Geneesmiddelenrepertorium/ Répertoire Commenté des Médicaments' which can also be consulted online on their website, and is available as a reference database.

A flux of data from the NIHDI to BCPI is operational since many years. However, the granularity of the medicinal product information stored in the different databases differs considerably, making it more cumbersome and complex to merge the information.

Between BCPI and the FAMPH, an intense cooperation and exchange of data exists, now formalised also in a monthly flux of data between the two organisations.

During the first phase, called SAM1, interviews were held with the different partners (FAMHP, BCPI, NIHDI), each containing a part of the information that will feed the future database with information, in order to analyse the content and structure of their information and to position this information on a general conceptual model. This general conceptual model is based on the model developed in the UK at the National Health Service as the Dictionary of Medicines and Devices (Dm+d).

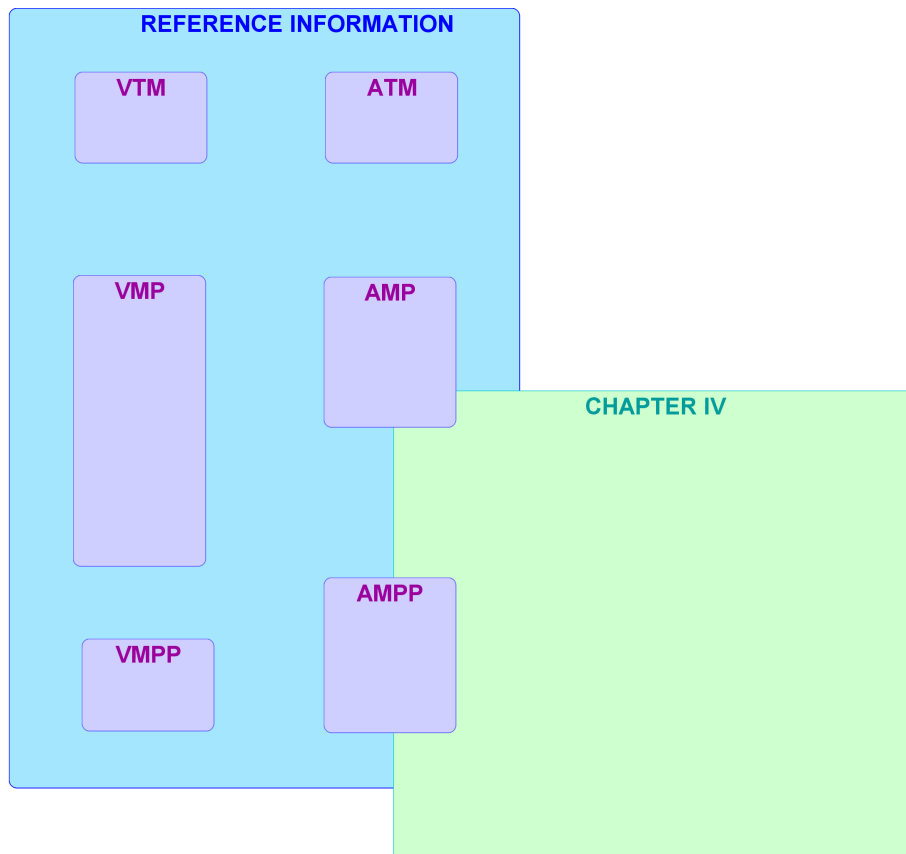
In the second (current) phase of the project SAM, henceforth called SAM2, this model will be further elaborated in order to develop a full conceptual model for the information on medicines and health products in Belgium.

The emphasis in the second phase will be on:

- the integration with the databases of the NIHDI;
- the integration in the conceptual model of the notion of INN-prescription ("voorschrijven op stofnaam/ Prèscription à DCI "). For this purpose, the BCPI has coordinated an expert task force for the elaboration of guiding principles, and the application to a model list of Virtual Medicinal Product Groups (VOS-groups);
- the structured reimbursement conditions for medicines with reimbursement subjected to prior authorisation, as mentioned in chapter IV of the legislation on reimbursable pharmaceuticals (royal decree of 21 December 2001);
- the reimbursement data of hospital medicines.

2. Conceptual Data Diagram

Global view



The information content within SAM can be divided into two large blocks of data:

- Part 1: The information concerning medicinal products, organised into 6 core concepts (in violet on the figure) based on the NHS model (in blue).
- Part 2: The information regarding Chapter IV dealing with the structured reimbursement conditions medicines for which the prescribing physician must request a prior authorisation (in green).

These two information blocks collide when the reimbursement conditions of medicinal products are determined for a diagnosed pathology listed in Chapter IV.

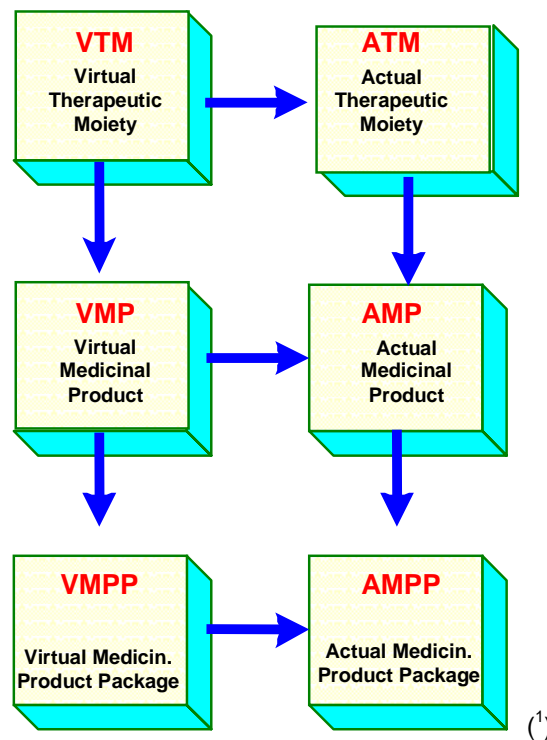
Part 1 : Medicinal Products

The core of the data model is made up of 6 fundamental concepts that are essential for the comprehension of the model at a more detailed level. This analysis is based on the model developed in the United Kingdom, at the National Health Service (dm + d, dictionary of medicines and devices). This method facilitates the correct storage of specific properties of medicines at the correct level.

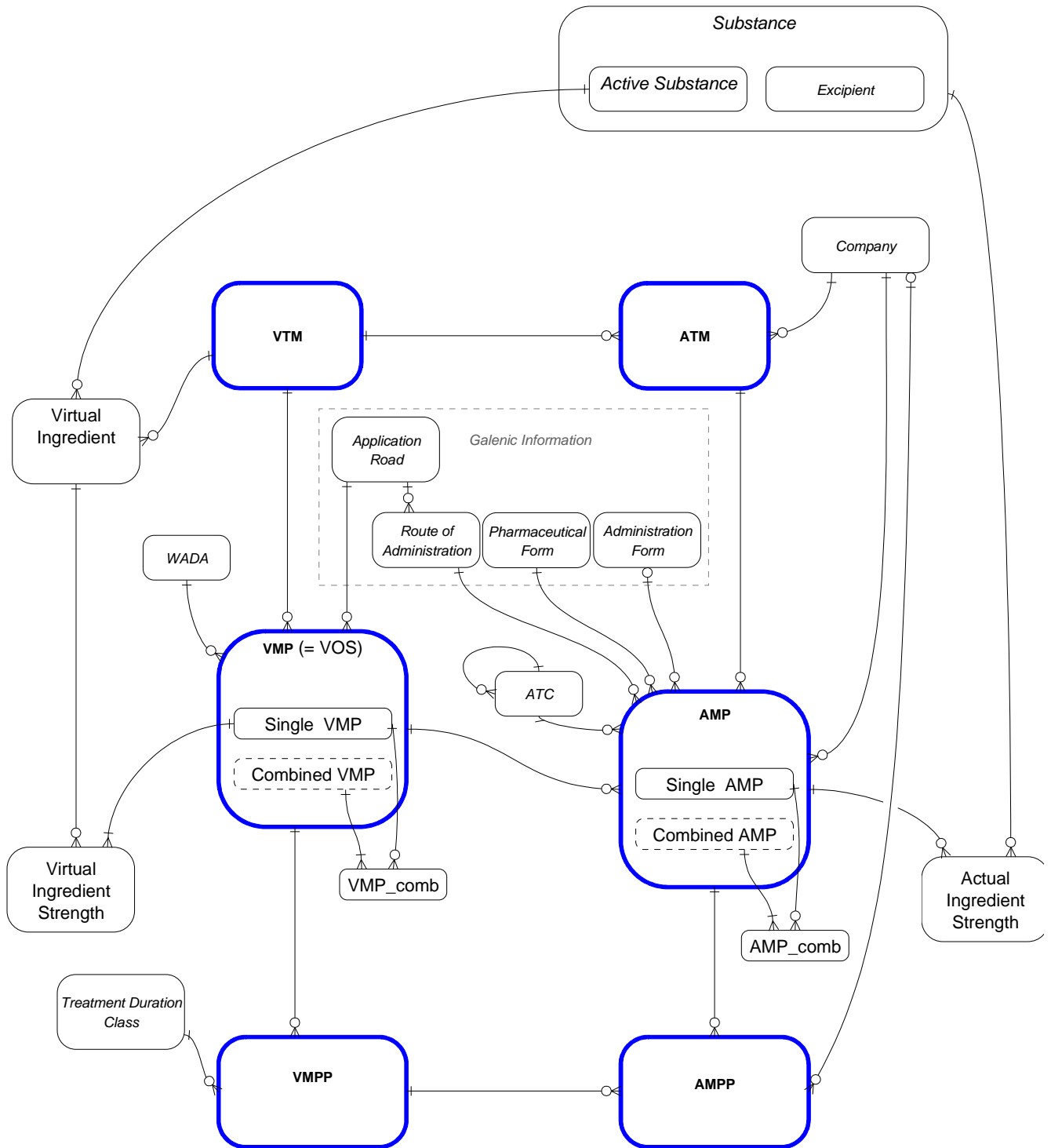
The 3 concepts on the left side of the diagram are 'virtual' concepts in the sense that they refer to pure pharmacological information, independent of country and company, and can be seen on a European level or even a global level.

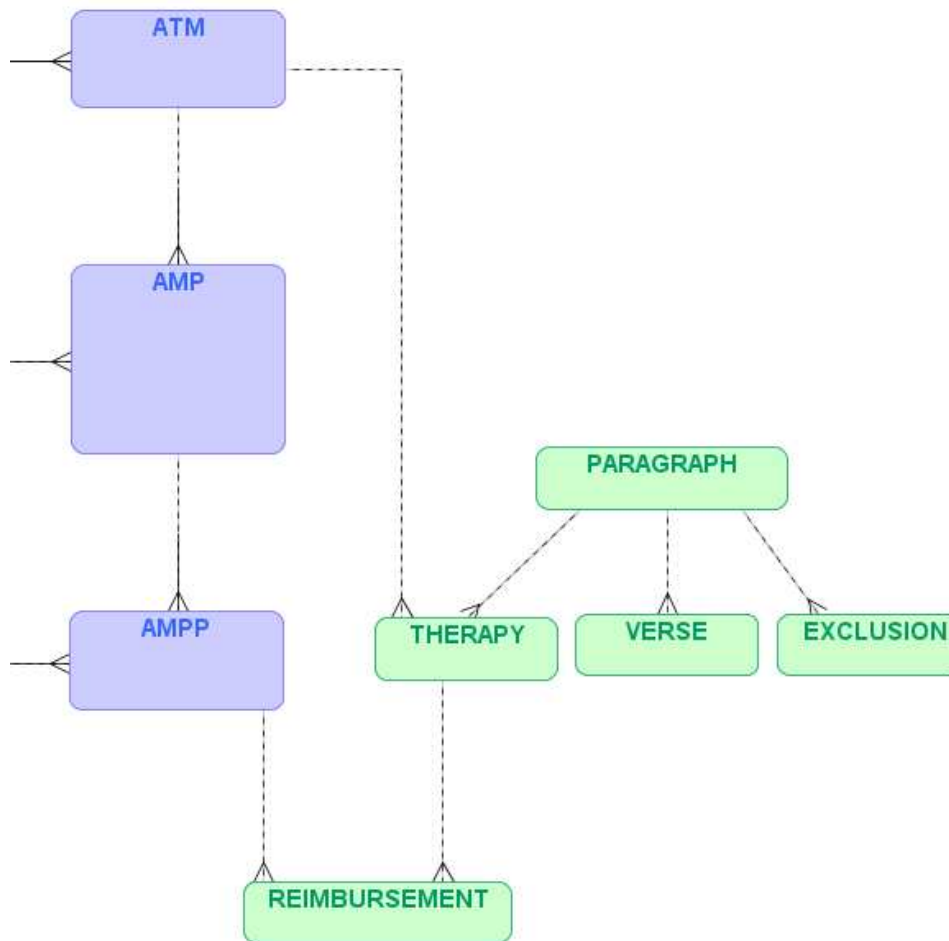
The 3 concepts on the right side of the diagram are the 'actual' concepts and contain information that is specific to medicines on a national market (in this case the Belgian market). These concepts refer to pharmacological information in connection with commercial brands and packages available on the market.

The first horizontal axis represents information about the therapeutic moiety with the generic name on the left side and the commercial name on the right. The second horizontal axis represents the medicinal products with a specific strength and an abstract categorisation of the route of administration. The third horizontal axis contains information about the medicinal product packages as they are available on the market (including pack size and inner package).



These 6 core concepts originally presented in the NHS model, also form the kernel of our conceptual model. Their definition has been slightly changed in order to be adapted to the Belgian market. The model is completed with auxiliary concepts and reference data organised around these core concepts, each at the appropriate level. The diagram below shows the conceptual model for the medicines part, each of the concepts will be explained in the data dictionary in next chapter.



Part 2 : Chapter IV


In many countries, a system of prior approval of medicines has been established. In Belgium this system is managed by the NIHDI. Medicines for which prior approval is needed are called 'Medicines pertaining to Chapter IV'.

The information in Chapter IV contains the structured data extracted from the legislation dealing with the reimbursement conditions of a specific medicinal product for a specific diagnose and therapy.

The concepts "paragraph", "verse", "exclusion", "therapy" and "reimbursement" will be explained in more detail below.

This information builds on the former medicinal product data through the concepts:

- Actual Therapeutic Moiety (ATM), equivalent to the concept Specialiteit/Specialité/Speciality used in the law text.
- Actual Medicinal Product Package (AMPP), equivalent to the concept Drug Package used in the law text.

Thanks to this link between the paragraphs in Chapter IV and medicinal product specialities, reimbursement conditions can make use of all the available information on medicines.

3. Data Dictionary

Part 1 : Medicinal Products

The data dictionary starts with the elaboration of the 6 core concepts that form the kernel of the future database structure.

Subsequently, all other association concepts are discussed that are necessary to complete the model.

The data dictionary is completed with the description of the reference concepts.

CORE CONCEPTS	
	VTM
	ATM
	VMP
	AMP
	VMPP
	AMPP
ASSOCIATION CONCEPTS	
	VIRTUAL INGREDIENT
	VIRTUAL INGREDIENT STRENGTH
	ACTUAL INGREDIENT STRENGTH
REFERENCE CONCEPTS	
	SUBSTANCE
	ACTIVE SUBSTANCE
	EXCIPIENT
	COMPANY
	APPLICATION ROAD
	ROUTE OF ADMINISTRATION
	PHARMACEUTICAL FORM
	ADMINISTRATION FORM
	ATC
	TREATMENT DURATION CLASS
	WADA

Core Concepts

VTM – VIRTUAL THERAPEUTIC MOIETY

Explanation of the concept:

The Virtual Therapeutic Moiety (VTM) provides a high level description of pharmaceutical agents or combinations of agents, regardless of the indication, their strength, pharmaceutical or route form. It is the abstract representation of the substance(s) as a therapeutic moiety, intended by an authorising health professional for use in the treatment of the patient.

One VTM occurrence represents the collection of pharmaceutical specialities with the same active substance (or combination of active substances) regardless of their strength, pharmaceutical form, route of administration, pack size or authorisation holder.

A VTM can be composed of only one active ingredient or can be a multi-ingredient VTM; this means a combination of 2 or more active substances. These active substances are usually expressed as the active base of the molecule, but can exceptionally also be a salt or ester form of the molecule. In case of a multi-ingredient VTM with more than two substances, all substance names appear in the VTM name, e.g. atenolol + chloortalidon, up to a combination of maximum 3 substances. For VTMs with more than 3 substances, the notification [3+] will be added to the VTM name.

There can be a fixed order in the combination of substances (most important first) or the order in which the components appear in the VTM name can be of minor importance.

A VTM can also be a therapeutic moiety only available as an magistral preparation (not available as a commercialized brand product, but practically available through artisan preparation by the pharmacist).

A European list of Virtual Therapeutic Moieties is under construction, linked to the Swedish Sfinx database, the Period Safety Update Report (PSUR) list, the list of therapeutic moieties in Dutch publication Farmacologisch Kompas, the World Health Organisation (WHO)-Essential list of medicines, and the Dutch/Flemish List of Medicines for Bachelor and Master Medical training.

Note: The VTM concept is not related in a one to one basis to the ATC5-code (5th level of the Anatomical Therapeutic Chemical Classification system). An active substance (and also a VTM) therefore can have more than one ATC-code. For example, acetylsalicylic acid (aspirin) has 3 different ATC-codes, each for another anatomical main group.

Authentic source:

The VTM database is currently constructed by the BCPI, from international lists from the European Heads of Agencies, from the WHO list of Essential Medicines, and from various knowledge databases (SFINX, Farmacotherapeutisch Kompas). In the future, this function could be fulfilled by a more international consortium of Drug Information Centres or Health Authorities (e.g. EMEA).

Lifecycle:

A new VTM arises when a patent is granted (or when two patented drugs are for the first time combined in a fixed combination). Another important milestone can be the appearance of the substance on the radar of Health Technology institutes, or the first registration as a drug in another continent than the European. After the European registration, the substance is registered in Belgium and introduced on the Belgian market in a concrete medical product package. At this stage, the VTM is effectively introduced in the database. A VTM ceases to be active in the database when the therapeutic moiety, in whatever form, can no longer be purchased in Belgium, in Europe, or in the world.

Alias – twin concepts:

NL : Virtueel Therapeutisch Middel

FR : Moyen Thérapeutique Virtuel

Possible data flows from and towards other applications:

This is the basis for international exchange of information on international regulatory issues, as well as exchange of information from clinical pharmacology knowledge databases.⁹

Dependencies between concepts in the diagram:

The VTM (mono- or multi-ingredient) represents the highest level in the hierarchy of concepts. The other kernel concepts are all directly (ATM and VMP) or indirectly dependant on this concept.

Examples :

- a) [VTM] *atenolol*
- b) [VTM] *atenolol + chloortalidon*
- c) [VTM] *calcium carbonate + kaoliin + magnesiumhydroxide*
- d) [VTM] *adenosinefosfaat + ascorbinezuur+ biotine [3+]*
- e) [VTM] *ethinylestradiol + norethisteron*

ATM – ACTUAL THERAPEUTIC MOIETY**Explanation of the concept:**

= [VTM] + brand name or principle marketing company (the marketing authorisation holder or national licence holder)

An ATM represents a collection of medicinal products with the same therapeutic moiety(ies) and the same trade name.

An ATM is the trade level version of a VTM. It has a recognizable brand name or, in case of a generic product, a generic drug name and the name of its registration holder, without indication of strength or pack size.

The brand name is the commercial name for the original product. This name can vary from one country to another.

Authentic source:

This will be the national registration authority, i.c for Belgium, the FAMHP..

Life cycle:

A new ATM arises when a company requests a marketing authorisation for a therapeutical moiety in Belgium and when the product is effectively introduced on the Belgian market. It disappears when the company recalls the last form of the product from the market, or when the marketing authorisation for all medicinal products within this concept is withdrawn.

Alias – twin concepts - subtype - supertype:

Alias: Brand name, “Specialiteit/Spécialité” in the NIHDI database

Possible data flows from and towards other applications:

This concept is identical to the concept "specialiteit" in the NIHDI database of reimbursable medicines and hence a possible link to the reimbursement information. These 2 concepts can be completely synchronised.

Dependencies between concepts in the diagram:

An ATM is always linked to one and only one VTM. A VTM may have several ATM's.

The concept AMP (directly) and AMPP (indirectly) are dependent on this concept. An AMP is always linked to one and only one ATM. An ATM may have one or more AMPs.

Examples:**a) [VTM] *atenolol***

[ATM] Tenormin ASTRA ZENECA
[ATM] Tenormin IMPEXO
[ATM] Tenormin PHARMA PARTNER
[ATM] Tenormin PI-Partner
[ATM] Atenolol TEVA
[ATM] Atenolol MYLAN
[ATM] Atenolol EG
[ATM] Atenolol SANDOZ
[ATM] Atenolol KELA
[ATM] Atenolol RATIOPHARM
[ATM] DOCATENO
[ATM] ATENOTOP
[ATM] MERCK-ATENOLOL

b) [VTM] *atenolol + chloortalidon*

[ATM] Tenoretic ASTRAZENECA
[ATM] Tenoretic PHARMA PARTNER
[ATM] Atenolol / Chlortalidone TEVA
[ATM] Atenolol / Chlortalidone EG
[ATM] Atenolol / Chlortalidone MYLAN
[ATM] Atenolol / Chlortalidone SANDOZ
[ATM] Atenolol / Chlortalidone EG

c) [VTM] *calcium carbonate + kaoliin + magnesiumhydroxide*

[ATM] Restofit

d) [VTM] *adenosinefosfaat + ascorbinezuur+ biotine [3+]*

[ATM] Ol-amine

e) [VTM] *ethinylestradiol + norethisteron*

[ATM] Trinovum

VMP - VIRTUAL MEDICINAL PRODUCT**Explanation of the concept:**

= [VTM] + strength + application road

This concept represents the collection of medicinal products with the same therapeutic moiety and with the same strength and application road. The strength is expressed per administration unity (e.g. tablet, ampoule) or as a concentration (e.g. mg/ml). The VMP is an abstract collection of actual medicinal products (and indirectly medicinal product packages), without supplier or trade name information.

This level also supports aspects of decision support and INN prescribing scenarios ('VOS, voorschrijven op stofnaam', 'prescription DCI'). It represents the group (or cluster) of medicinal product packages a pharmacist can choose from when dispensing a drug from an INN prescription, and can therefore also be called 'VMP group' ('VOS-groep'/'Groupe DCI'). A separate codification system (with a public system of unique identifiers) will be implemented for this level.

In most cases, the combination of VTM name and strength will be sufficient to unambiguously define a VMP. However, in some cases therapeutic use will depend on the application road. Therefore, as a third criterion in the definition of a VMP group, an 'application road' has to be specified.

The application road is a limited (+- 20 possibilities) but standardised classification of routes of administration, for use in the determination of VMP groups. (see definition further below).

A VMP may also be a combination product. This means that it contains two or more products delivered together in one package, each product with its own composition of active substances, strength and/or application road. E.g. the 3-phase combined oral contraceptive pill contains 3 types of tablets in one package, all containing the same combination of 2 active substances but differing in strength. This combined product is represented as a VMP entry (of subtype Combined VMP), composed of 3 Single_VMPs, one for each type of tablet. This relation is expressed by the association concept VMP_comb (see definition further below). As a result, it may not be possible to prescribe a single VMP on itself, only as part of a combination VMP. Another example of a combined VMP is Prepacol, which is a combination of 4 tablets + a solution in one package.

In case the administration of a combined VMP must be given in a certain sequence, e.g. the 3-phase combined oral contraceptive pill, where the different types of tablets should be taken in a certain sequence, the notification [SEQ] will be added to the VMP name.

VMP groups excluded from the INN legislation (e.g. biologicals) will yet be available in the database, defined as the combination of therapeutic moiety, strength, and application road.

Note: The definition of the concept VMP in this system must be viewed at a somewhat higher level of abstraction than the original definition of the VMP concept as elaborated by the NHS, where details of both route of administration and pharmaceutical form are specified in more detail at the VMP level.

Authentic source:

For this concept, as defined in Belgium, governance has been attributed to FAMHP, together with the registration authority (the Commission of Medicines). These bodies will decide on the rules for the definition of VMP groups, and their further specifications. The BCPI will assume a coordination role and elaborate a model list of VMP groups by classifying the currently available medicinal products by the rules mentioned above.¹⁰

The association of community pharmacists (APB) will be in charge of the codification of the VMP groups, which will be implemented by the BCPI.

Life cycle:

A new VMP is created when the FAMHP registers a product with a new therapeutic moiety or a product with an existing therapeutic moiety but a new strength or application road. A VMP

disappears when the last product with a certain therapeutic moiety and certain strength is no longer available on the market.

Alias – twin concepts - subtype - supertype:

Alias: VOS-groep (NL), INN group (EN), groupe DCI (FR)

Subtypes:

- Single VMP : A VMP composed of one single product, with a certain strength and application road.
- Combined VMP: A combination of two or more products distributed together in one package, each product having its own combination of active ingredients, strength and application road, e.g. 3-phase combined oral contraceptive pill (3 types of tablets distributed in one package), Prepacol (combination of tablets and solution in one package).

Possible data flows from and towards other applications:

It is on this level that the daily dose and the duration of treatment can be determined, important in the determination of the pack size to be delivered.

Dependencies between concepts in the diagram:

A VMP is always linked to one and only one VTM.

A VMP represents a group of commercialised medicinal products and may therefore be linked to one or more AMPs (commercialised medicinal products).

A VMP is available in various pack sizes and may therefore be linked to one or more VMPPs.

A Single VMP must always have exactly one application road and each Single VMP must be connected to at least one Virtual Ingredient Strength.

A Combined VMP is always composed of two or more Single VMPs and is therefore always linked to at least one VMP_comb. A Single VMP may be linked to one or more VMP_comb.

Examples:

a) [VTM] *atenolol*

[VMP] atenolol 50 mg (oraal)

[VMP] atenolol 100 mg (oraal)

b) [VTM] *atenolol + chloortalidon*

[VMP] atenolol 50 mg + chloortalidon 12,5 mg (oraal)

[VMP] atenolol 100 mg + chloortalidon 25 mg (oraal)

c) [VTM] *calcium carbonate + kaoliin + magnesiumhydroxide*

[VMP] calciumcarbonaat 388 mg + kaolien 466 mg + magnesiumhydroxide 543 mg / 10 g (oraal)

d) [VTM] *adenosinefosfaat + ascorbinezuur+ biotine [3+]*

[VMP] adenosinefosfaat 2 mg + ascorbinezuur 100 mg + biotine 0,25 mg [3+] (oraal)

e) [VTM] *ethinylestradiol + norethisteron*

[VMP] ethinylestradiol 0,035 mg + norethisteron 0,5 mg + ethinylestradiol 0,035 mg [SEQ] (oraal)

AMP – ACTUAL MEDICINAL PRODUCT**Explanation of the concept:**

= [VMP] + brand name or principle marketing company + pharmaceutical and administration form + route of administration.

= [ATM] + strength + route of administration + pharmaceutical and administration form

An AMP is the branded form of the VMP-group, without the pack size. An AMP shall provide sufficient information to uniquely identify the product but not the size of the pack that the supplier makes available for dispensing. This also includes more detailed information regarding the pharmaceutical form, the route of administration, the administration form, excipients and a more specific determination of the active substances (which salt or ester). This is the central object in the registration of medicines. On this level the marketing authorisation should be granted.

All AMP's corresponding to a certain VMP contain the same therapeutic moiety, but may vary in the actual ingredients used: the excipients and the form (e.g. salt or ester) of the active product ingredient used. The actual product ingredient used in the AMP may be the salt or ester form of the active substance, with possibly a slightly different expression of strength.

Therefore, all AMP's linked to a certain VMP should not contain exactly the same form of the active ingredient substance. Also subtle differences in acknowledged indications may exist between different AMP's of a certain VMP.

Just like a VMP, an AMP may also be a combination product. A Combined AMP can contain two or more Single AMPs delivered together in one package, each product with its own composition of actual product ingredients, route of administration, pharmaceutical and administration form.

Authentic source:

Clearly the national registration authority is the mandated provider of the validated data supporting this concept. In Belgium this is the FAMHP.

Life cycle:

An AMP is created when a company decides to register packages with a specified therapeutic moiety and a specific strength and pharmaceutical form and route (but possibly with different pack sizes and different intermediate packages) on the Belgian market. It disappears when the last package with that strength, form and route is no longer available on the market.

Alias – twin concepts - subtype - supertype:

Alias: Aktueel Medicinaal Product (NL), Produit Medicinal Actuel (FR)

Possible data flows from and towards other applications:

This concept plays an important role in the representation of listing of medicines in repertoria. The concept is also employed for principal decisions about the reimbursement in the system of reference prices of medicinal products.

Dependencies between concepts in the diagram:

Each AMP can be classified into exactly one VMP group.

Each AMP is linked to exactly one ATM.

A medicinal product or AMP can be available in various pack sizes and is therefore linked to one or more AMPPs.

An AMP can be composed of one or more actual product ingredients (excipient or specific form (e.g. ester or salt) of the active substance, as far as these differ from the form used in the VMP definition).

Examples:
a) [VTM] atenolol

[VMP] atenolol 50 mg (oraal)

[AMP] Atenolol Kela (Kela) 50 mg	compr.
[AMP] Atenolol EG (Eurogenerics) 50 mg	compr. (deelb.)
[AMP] Atenolol-Ratiopharm (Ratiopharm) 50 mg	compr. (deelb.)
[AMP] Atenolol Teva (Teva) 50 mg	compr. (deelb.)
[AMP] Atenolol Mylan (Mylan) 50 mg	compr.
[AMP] Atenolol EG (Eurogenerics) 50 mg	compr. (deelb.)
[AMP] Atenolol Sandoz (Sandoz) 50 mg	compr. (deelb.)
[AMP] Atenolol EG (Eurogenerics) 50 mg	compr. (deelb.)
[AMP] Atenolol Kela (Kela) 50 mg	compr.
[AMP] Atenolol Sandoz (Sandoz) 50 mg	compr. (deelb.)
[AMP] Atenolol Teva (Teva) 50 mg	compr. (deelb.)
[AMP] Atenolol Teva (Teva) 50 mg	compr. (deelb.)
[AMP] Docateno (Docpharma) 50 mg	compr. (deelb.)
[AMP] Tenormin (AstraZeneca) 50 mg	compr. Mitis

b) [VTM] atenolol + chloortalidon

[VMP] atenolol 50 mg + chloortalidon 25 mg (oraal)

[AMP] Atenolol / Chlortalidone EG (Eurogenerics)	compr. (deelb.)
[AMP] Atenolol / Chlortalidone Mylan (Mylan)	compr.
[AMP] Atenolol / Chlortalidone Teva (Teva)	compr.
[AMP] Atenolol / Chlortalidone EG (Eurogenerics)	compr. (deelb.)
[AMP] Atenolol / Chlortalidone Teva (Teva)	compr.
[AMP] Atenolol / Chlortalidone Sandoz (Sandoz)	compr.
[AMP] Tenoretic (AstraZeneca)	compr. Mitis

[VMP] atenolol 100 mg + chloortalidon 25 mg (oraal)

[AMP] Atenolol / Chlortalidone EG (Eurogenerics)	compr. (deelb.)
[AMP] Atenolol / Chlortalidone Teva (Teva)	compr.
[AMP] Atenolol / Chlortalidone Mylan (Mylan)	compr.
[AMP] Atenolol / Chlortalidone Teva (Teva)	compr.
[AMP] Atenolol / Chlortalidone EG (Eurogenerics)	compr. (deelb.)
[AMP] Atenolol / Chlortalidone EG (Eurogenerics)	compr. (deelb.)
[AMP] Atenolol Chlortalidone Sandoz (Sandoz)	compr.
[AMP] Tenoretic (Pharmapartner)	compr.
[AMP] Tenoretic (AstraZeneca)	compr.

c) [VTM] calcium carbonate + kaoliin + magnesiumhydroxide

[VMP] calciumcarbonaat 388 mg + kaolien 466 mg + magnesiumhydroxide 543 mg / 10 g
(oraal)

[AMP] Restofit (Sterop) poeder (zakjes)

d) [VTM] adenosinefosfaat + ascorbinezuur+ biotine [3+]

[VMP] adenosinefosfaat 2 mg + ascorbinezuur 100 mg + biotine 0,25 mg [3+] (oraal)

[AMP] Olamine (Therabel) compr

e) [VTM] ethinylestradiol + norethisteron

[VMP] ethinylestradiol 0,035 mg + norethisteron 0,5 mg + ethinylestradiol 0,035 mg [SEQ]
(oraal)

[AMP] Trinovum (Janssen-Cilag) compr.

VMPP – VIRTUAL MEDICINAL PRODUCT PACKAGE**Explanation of the concept:**

= [VMP] + treatment duration class

A Virtual Medicinal Product Package (VMPP) is an abstract concept representing the properties of one or more quantitatively equivalent AMPPs. This is the delivery unit for a Virtual Medicinal Product.

On this level not only the therapeutic moiety, the strength, the application road, but also the pack size is taken into account, albeit in an abstract manner.

Pack sizes are aggregated and expressed in terms of duration treatment (single shot treatment, one day treatment, 2 till 4 days, 5 to 7 days, weeks (multiple of 7 days + up to 6 days – further to be aggregated in fortnight, month, trimester, half year, year). This concept arranges commercialized packages in groups of equal days of treatment, according to a default dosage instruction for each medicinal product (the usual posology for the main indication of a product).

This concept also includes the uni-dose distribution in the hospital (where distribution is recorded by the administration unit). Pack sizes of larger hospital packages should also be included.

The name of an VMPP consists off the referenced VMP name+ treatment duration class.

Authentic source:

The governance of this concept, including determination of the usual posology per VMP group and the calculation of pack size into length of predefined periods of treatment is until now taken up by the BCPI..

Life cycle:

A VMPP arises/disappears when a certain range of pack sizes for a particular VMP becomes available/is no longer available.

Alias – twin concepts - subtype - supertype:

Alias: Virtueel Medicinaal Product Pack (NL), Packet de Produits Medicinal Virtuel (FR)

Possible data flows from and towards other applications:

This concept is important in order to be able to compare prices between different packages. Information about available pack sizes and variety in pack sizes often determines the choice between different AMPs. In hospital environments both very small distribution sizes (unit dose) and very large distribution sizes (hospital and bulk packages) are available.

Dependencies between concepts in the diagram:

Each VMPP is always associated with one instance of a VMP.

Each VMPP will have one to many AMPPs linked to it.

Examples:

atenolol, 100 mg (oraal), 28 tab.

paracetamol oploss. (oraal) Pediatrie, 90 ml 150 mg/5ml

a) [VTM] atenolol

[VMP] atenolol 50 mg (oraal) (Usual posology = one tablet per day)

[VMPP] atenolol 50 mg (oraal), 3 months of treatment

[VMPP] atenolol 50 mg (oraal), 2 months of treatment

[VMPP] atenolol 50 mg (oraal), 1 month of treatment

b) [VTM] atenolol + chloortalidon

[VMP] atenolol 50 mg + chloortalidon 25 mg (oraal) (Usual posology = One tablet per day)

[VMPP] atenolol 50 mg + chloortalidon 25 mg (oraal), 3 months of treatment

[VMPP] atenolol 50 mg + chloortalidon 25 mg (oraal), 2 months of treatment

[VMP] atenolol 100 mg + chloortalidon 25 mg (oraal) (Usual posology = one tablet per day)

[VMPP] atenolol 100 mg + chloortalidon 25 mg (oraal), 3 months of treatment

[VMPP] atenolol 100 mg + chloortalidon 25 mg (oraal), 2 months of treatment

[VMPP] atenolol 100 mg + chloortalidon 25 mg (oraal), 1 month of treatment

c) [VTM] calcium carbonate + kaoliin + magnesiumhydroxide

[VMP] calciumcarbonaat 388 mg + kaolien 466 mg + magnesiumhydroxide 543 mg / 10 g (oraal) (Usual posology = one tablet per day, daily treatment not recommended)

[VMPP] calciumcarbonaat 388 mg + kaolien 466 mg + magnesiumhydroxide 543 mg / 10 g (oraal), 10 days of treatment

[VMPP] calciumcarbonaat 388 mg + kaolien 466 mg + magnesiumhydroxide 543 mg / 10 g (oraal), 1 month of treatment

d) [VTM] adenosinefosfaat + ascorbinezuur+ biotine [3+]

[VMP] adenosinefosfaat 2 mg + ascorbinezuur 100 mg + biotine 0,25 mg [3+] (oraal)

(Usual posology = once daily one tablet)

[VMPP] adenosinefosfaat 2 mg + ascorbinezuur 100 mg + biotine 0,25 mg [3+] (oraal), 2 months of treatment

e) [VTM] ethinylestradiol + norethisteron

[VMP] ethinylestradiol 0,035 mg + norethisteron 0,5 mg + ethinylestradiol 0,035 mg [SEQ] (oraal) (Usual posology = Once daily for 21 days, then 7 pill free days)

[VMPP] ethinylestradiol 0,035 mg + norethisteron 0,5 mg + ethinylestradiol 0,035 mg [SEQ] (oraal), 3 monthly cycles of treatment

AMPP – ACTUAL MEDICINAL PRODUCT PACKAGE
--

Explanation of the concept:

= [AMP] + pack size

The AMPP is the commercialized packaged product, within the unit-of-use distribution system, available on the Belgian market, and supplied for direct patient use. It is identified in Belgium by a unique identifier (CNK-number). Only commercially available product packages are contained within this concept, some of these being reimbursable, some of them on (controlled) prescription, others not.

The concept AMPP contains information concerning the pack size (e.g. the number of tablets in the package, the volume of a solution), the inner package (package form and material) and also price, reimbursement information and other administrative info is linked to this concept.

The name of an AMPP consists of the referenced AMP name+ pack size.

Authentic source:

The source for this concept is currently BCFI. The unique CNK-number is assigned by the APB.

Life cycle:

Medicinal Product Packages have to have a marketing authorisation number and have to be available on the market.

Alias – twin concepts - subtype - supertype:

This concept is called “medicinal product package” in the EN 12610, and is currently called ‘MPP’ in the current BCFI reference database.

Possible data flows from and towards other applications:

This is the level where the medicinal product is distributed from the company to wholesaler, to pharmacy, and finally to the patient. Also on this level refund conditions are determined, which may vary according to the company, the pack size and strength. Also on this level pack size is expressed in Defined Daily Dose terms as in the international ATC/DDD system.

Dependencies between concepts in the diagram:

Each AMPP is always associated with exactly one instance of a VMPP.

Each AMPP is always associated with exactly one instance of a AMP.

Examples:
a) [VTM] atenolol

[VMP] atenolol 50 mg (oraal) (one tablet per day)

[VMPP] atenolol 50 mg (oraal), 3 months of treatment

[AMPP] Atenolol EG (Eurogenerics)	compr. (deelb.)	98 x
[AMPP] Atenolol-Ratiopharm (Ratiopharm)	compr. (deelb.)	100 x
[AMPP] Atenolol Teva (Teva)	compr. (deelb.)	90 x
[AMPP] Atenolol Sandoz (Sandoz)	compr. (deelb.)	98 x

[VMPP] atenolol 50 mg (oraal), 2 months of treatment

[AMPP] Atenolol Kela (Kela)	compr.	60 x
[AMPP] Atenolol Mylan (Mylan)	compr.	56 x
[AMPP] Atenolol EG (Eurogenerics)	compr. (deelb.)	56 x

[AMPP] Atenolol Sandoz (Sandoz)	compr. (deelb.)	56 x
[AMPP] Atenolol Teva (Teva)	compr. (deelb.)	60 x
[AMPP] Docateno (Docpharma)	compr. (deelb.)	56 x
[AMPP] Tenormin (AstraZeneca)	compr. Mitis	56 x
<i>[VMPP] atenolol 50 mg (oraal), 1 month of treatment</i>		
[AMPP] Atenolol EG (Eurogenerics)	compr. (deelb.)	28 x
[AMPP] Atenolol Kela (Kela)	compr.	30 x
[AMPP] Atenolol Teva (Teva)	compr. (deelb.)	30 x

b) [VTM] atenolol + chloortalidon

[VMP] atenolol 50 mg + chloortalidon 25 mg (oraal) (One tablet per day)

[VMPP] atenolol 50 mg + chloortalidon 25 mg (oraal), 3 months of treatment

[AMPP] Atenolol / Chlortalidone EG (Eurogenerics)	compr. (deelb.)	98 x
[AMPP] Atenolol / Chlortalidone Teva (Teva)	compr.	90 x
[AMPP] Atenolol / Chlortalidone Mylan (Mylan)	compr.	56 x

[VMPP] atenolol 50 mg + chloortalidon 25 mg (oraal), 2 months of treatment

[AMPP] Atenolol / Chlortalidone EG (Eurogenerics)	compr. (deelb.)	56 x
[AMPP] Atenolol / Chlortalidone Teva (Teva)	compr.	60 x
[AMPP] Atenolol Chlortalidone Sandoz (Sandoz)	compr.	56 x
[AMPP] Tenoretic (AstraZeneca)	compr. Mitis	56 x

[VMP] atenolol 100 mg + chloortalidon 25 mg (oraal) (one tablet per day)

[VMPP] atenolol 100 mg + chloortalidon 25 mg (oraal), 3 months of treatment

[AMPP] Atenolol / Chlortalidone EG (Eurogenerics)	compr. (deelb.)	98 x
[AMPP] Atenolol / Chlortalidone Teva (Teva)	compr.	90 x

[VMPP] atenolol 100 mg + chloortalidon 25 mg (oraal), 2 months of treatment

[AMPP] Atenolol / Chlortalidone Mylan (Mylan)	compr.	56 x
[AMPP] Atenolol / Chlortalidone Teva (Teva)	compr.	60 x
[AMPP] Atenolol / Chlortalidone EG (Eurogenerics)	compr. (deelb.)	56 x
[AMPP] Atenolol Chlortalidone Sandoz (Sandoz)	compr.	56 x
[AMPP] Tenoretic (Pharmapartner)	compr.	56 x
[AMPP] Tenoretic (AstraZeneca)	compr.	56 x

[VMPP] atenolol 100 mg + chloortalidon 25 mg (oraal), 1 month of treatment

[AMPP] Atenolol / Chlortalidone EG (Eurogenerics)	compr. (deelb.)	28
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c) [VTM] calcium carbonate + kaoliin + magnesiumhydroxide

[VMP] calciumcarbonaat 388 mg + kaolien 466 mg + magnesiumhydroxide 543 mg / 10 g (oraal) (one tablet per day, daily treatment not recommended)

[VMPP] calciumcarbonaat 388 mg + kaolien 466 mg + magnesiumhydroxide 543 mg / 10 g (oraal), 10 days of treatment

[AMPP] Restofit (Sterop)	poeder (zakjes)	10x10 g
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[VMPP] calciumcarbonaat 388 mg + kaolien 466 mg + magnesiumhydroxide 543 mg / 10 g (oraal), 1 month of treatment

[AMPP] Restofit (Sterop) poeder (zakjes) 30x10

d) [VTM] adenosinefosfaat + ascorbinezuur+ biotine [3+]

[VMP] adenosinefosfaat 2 mg + ascorbinezuur 100 mg + biotine 0,25 mg [3+] (oraal) (once daily one tablet)

[VMPP] adenosinefosfaat 2 mg + ascorbinezuur 100 mg + biotine 0,25 mg [3+] (oraal), 2 months of treatment

[AMPP] Olamine (Therabel) compr 60 x

e) [VTM] ethinylestradiol + norethisteron

[VMP] ethinylestradiol 0,035 mg + norethisteron 0,5 mg + ethinylestradiol 0,035 mg [SEQ] (oraal) (Once daily for 21 days, then 7 pill free days)

[VMPP] ethinylestradiol 0,035 mg + norethisteron 0,5 mg + ethinylestradiol 0,035 mg [SEQ] (oraal), 3 monthly cycles of treatment

[AMPP] Trinovum (Janssen-Cilag) compr. 3 x21

Association concepts

VIRTUAL INGREDIENT

Explanation of the concept:

This concept describes the active substances contained within a VTM. A VTM may be composed of one or more virtual ingredients. In most cases, these are represented by the base part of the active substance. However, if the majority of the corresponding VMPs uses a salt or ester form of the active substance, it can also be this derived form of the molecule that is associated to a VTM.

The strength is not expressed at this level, only the composition of the virtual ingredients.

Authentic source:

For the time being, this will be the Belgian national drug information centre (BCPI/BCFI/CBIP).

Life cycle:

A new instance of Virtual Ingredient arises when a new instance of VTM is introduced in the database and its composition of active substances has to be expressed. An instance of Virtual Ingredient disappears when the corresponding VTM is deleted from the database.

Alias – twin concepts - subtype - supertype:

Therapeutic Moiety Ingredient.

Possible data flows from and towards other applications:

Dependencies between concepts in the diagram:

A Virtual Ingredient is an active substance that is an ingredient of a VTM. It is therefore always associated to exactly one Substance and exactly one VTM.

The Virtual Ingredient represents an active substance that, always in a certain strength, is part of a VMP. It is therefore linked to one or more strengths (Virtual Ingredient Strength).

Examples:

a) [VTM] atenolol

[Virtual Ingredient] *atenolol* - 29122-68-7 (atenolol)

b) [VTM] amlodipine

[Virtual Ingredient] *amlodipine* - 111470-99-6 (amlodipine besylate)*

* in the case the majority of VMP's uses the besylate salt form of amlodipine

VIRTUAL INGREDIENT STRENGTH

Explanation of the concept:

The Virtual Ingredient Strength describes for each active ingredient in a VMP, in what strength it is available.

For medicinal products available in discrete unit dose units (e.g. 1 tablet, 1 unit dose powder, 1 ampoule) the strength is expressed per weight quantity (e.g. 500mg). For medicinal products only available in continuous dose units (e.g. sirup, cream), the strength refers to a concentration (e.g. 500mg/ml solution, 125 mg/g powder or cream)

Authentic source:

BCPI

Life cycle:**Alias – twin concepts - subtype - supertype:**

Alias: strength, virtual product ingredient (NHS)

Possible data flows from and towards other applications:**Dependencies between concepts in the diagram:**

The Virtual Ingredient Strength is expressed as the strength of a Virtual Ingredient within a certain VMP, and is therefore always linked with exactly one Virtual Ingredient and exactly one (single) VMP.

Examples:

[VMP] atenolol 50 mg (oraal)

[Virtual Ingredient Strength] *atenolol* - 29122-68-7 (atenolol) - 50 mg

[VMP] domperidon 5 mg/5ml

[Virtual Ingredient Strength] *domperidon* - 57808-66-9 (domperidon) - 5 mg/5ml

[VMP] amlodipine 5 mg (oraal)

[Virtual Ingredient Strength] *amlodipine* - 111470-99-6 (amlodipine besylate) - 5 mg

ACTUAL INGREDIENT STRENGTH**Explanation of the concept:**

The Actual Ingredient Strength describes the excipients and the actual active ingredients (together with its strength) used in the AMP, as communicated on the product package leaflet and as far as another form of the active ingredient (e.g. the salt or ester) is used than defined for the corresponding VMP group.

The strength is expressed the same way as for the Virtual Ingredient Strength.

The list of excipients for an AMP is optional and should not be complete. Nor does the absence of excipients imply the absence of all or any excipients. Absence of actual ingredients at this level implies that the same form of active ingredient is used as expressed on the corresponding VMP level.

Authentic source:

The FAMHP will have the governance of this table, with the BCPI as coordinator.

Life cycle:**Alias – twin concepts - subtype - supertype:****Possible data flows from and towards other applications:****Dependencies between concepts in the diagram:**

The Actual Product Ingredient represents the strength of exactly one Ingredient Substance (Active Substance or Excipient) within exactly one AMP.

Examples:

[VMP] amlodipine 5 mg (oraal)

[Virtual Ingredient Strength] *amlodipine* - 111470-99-6 amlodipine besylate 5 mg

[AMP] Amlodipine Mylan 5 mg tabl.

[Actual Ingredient Strength] *Amlodipine Mylan* - 88150-47-4 amlodipine maleate 5,24 mg

Reference Concepts

SUBSTANCE

Explanation of the concept:

This concept lists the chemical substances which may act as ingredients of medicinal products. These may be

- an actual ingredient within a medicinal product (this may be the active base or a salt, ester or other form of the molecule), e.g. paroxetine, paroxetine hydrochloride.
- an excipient.

An Substance will be identified by its CAS-number and will only contain relevant chemical information about the substance, e.g. molecular weight.

International non-proprietary names (INN) should be used for the name of a Substance, if available.

Authentic source:

The governance of this concept will be up hold by the FAMHP, in collaboration with the BCPI.

Life cycle:

An new instance of a substance arises when an AMP with this ingredient becomes available.

Possible data flows from and towards other applications:

This is a universal concept, and clearly needs to be connected to international systems and European databases.

Dependencies between concepts in the diagram:

A Substance can, as a Virtual Ingredient, be part of one or more VTMs.

A Substance can, as an Actual Ingredient, or excipient, be part of one or more AMPs.

Alias – twin concepts:

Chemical substance

Subtypes:

ACTIVE SUBSTANCE

Explanation of the concept:

A substance that alone or in combination with one or more other ingredient substances is considered to fulfil the intended activity of a medicinal product.

Dependencies between concepts in the diagram:

An Active Substance can be associated to one or more Virtual Ingredients.

An Active Substance can be linked to one or more Actual Ingredient Strengths. In this case, it is a salt, ester or other derived form of the virtual ingredient substance specified at VMP level, and that is specifically used in this commercialised product.

Alias:

Active substance, active pharmaceutical ingredient (API)

Examples:

CAS-nr 88150-42-9 amlodipine (base)

CAS-nr 111470-99-6 amlodipine besylate

CAS-nr 88150-47-4 amlodipine mesylate

EXCIPIENT**Explanation of the concept:**

An excipient is an inactive substance used as a carrier for the active ingredients of a medicinal product.

Dependencies between concepts in the diagram:

The concept Actual Ingredient Strength will contain the excipients used in the commercialised product, as far as they are mentioned on the SPC.

Examples:

CAS-nr 63-42-3 lactose

CAS-nr 546-93-0 magnesium carbonate

COMPANY**Explanation of the concept:**

This concept holds relevant information concerning the pharmaceutical company that is the holder of the national licence or marketing authorisation (at ATM level), or that is the distributor of the product (either specified at AMP or AMPP level).

In case of a foreign company, the Belgian distributor or representative is given. If the company has no point of contact in Belgium, the foreign company is mentioned.

Authentic source:

FAGG

Life cycle:**Alias – twin concepts - subtype - supertype:**

MAH (marketing authorisation holder)

Alias (BCFI): IR (Information Responsible)

Possible data flows from and towards other applications:**Dependencies between concepts in the diagram:**

Each ATM is linked to a company that is the owner of the tradename, or the national licence holder or marketing authorisation holder. Therefore each ATM is linked to exactly one Company.

A medicinal product (AMP) is always linked to company that is the distributor or producer of the product. Occasionally, a distributor has to be specified for an individual product package (AMPP). Therefore an AMPP may also be linked to a Company.

Examples:

MSD, Novartis, Pfizer, Teva, Eurogenerics

APPLICATION ROAD

Explanation of the concept:

The application road is a limited (+- 25 possibilities), high-level, abstracted classification of routes of administration. It is the highest level of granularity for expressing the dosage form and represents the third pillar in the VMP concept.

All injectable routes of administration are gathered together in one application route "inj.", e.g. : "inj." = "i.m." and/or "i.v." and/or "s.c." and/or "i.art." and/or "i.artic.", ...

Perfusion is clearly distinguished from Injection ("perf." <> "inj.")

Combinations e.g. "inj./inf." also exist and are regarded as separate application roads ("inj./inf." <> "inj." <> "inf.").

Authentic source:

BCFI

Alias – twin concepts - subtype - supertype: none

Possible data flows from and towards other applications:

To be aligned with EDQM

Dependencies between concepts in the diagram:

Each VMP is linked to one and only one Application Road

Examples:

Inj, inf,

I, orofar, orofar/derm,

ROUTE OF ADMINISTRATION

Explanation of the concept:

The concept Route of Administration indicates the part of the body on which, through which or into which the product is to be introduced, and is a level more detailed than the application road defined earlier.

Authentic source:

EDQM

Alias – twin concepts - subtype - supertype:

NL: Toedieningsweg

Possible data flows from and towards other applications:

Information concerning the Route of Administration is currently available at the BCFI in the table GAL.

Dependencies between concepts in the diagram:

The Application Road concept represents an abstract and high-level classification of routes of administration, so that every Route of Administration is linked to exactly one Application Road.

Each AMP is associated with exactly one Route of Administration.

Examples:

auricular, endocervical, endosinusal, i.m., i.v., s.c., Inf.

PHARMACEUTICAL FORM

Explanation of the concept:

The concept Pharmaceutical Form represents the form in which a pharmaceutical product is presented by the manufacturer (form of presentation). (This definition does not exactly match the one given in the EN 12610, which will not be followed for the concept Pharmaceutical Form)

It is often, but not always, identical to the administration form.

Authentic source:

EDQM

Possible data flows from and towards other applications:

Information concerning the Pharmaceutical Form is currently available at the BCFI in the table GAL.

Dependencies between concepts in the diagram:

Each AMP is associated with exactly one Pharmaceutical Form.

Examples:

tablet, powder for sirup preparation

ADMINISTRATION FORM

Explanation of the concept:

The form in which a medicinal product is administered, including the physical form. This form may differ from the pharmaceutical form for products that require preparation by the pharmacist before being delivered to the patient.

Authentic source: BCFI

Possible data flows from and towards other applications:

Information concerning the Administration Form is currently available at the BCFI in the table GAL.

Dependencies between concepts in the diagram:

An AMP may be associated with one Administration Form.

Examples:

Sirup

ATC

Explanation of the concept:

Anatomical Therapeutical Chemical Classification. A classification system of medicines where the active substances are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.

Authentic source:

WHO Collaborating Centre on Drugs Statistics Methodology in Oslo, Norway.

Twin concepts:

Read codes (UK), SNOMED (US)

Possible data flows from and towards other applications:

This provides the basis for Drug Utilisation Research and continuous monitoring (e.g. Pharmanet in Belgium)

Dependencies between concepts in the diagram:

Each AMP is linked to one and only one ATC code.

Examples:

C01CE02 milrinone

TREATMENT DURATION CLASS**Explanation of the concept:**

This concept represent a classification of durations of treatment into days, weeks, months, ...

This concept is used to arrange commercialised packages into groups of equal days of treatment

Authentic source:

BCFI

Possible data flows from and towards other applications:**Dependencies between concepts in the diagram:**

Each VMPP is categorised into exactly one Treatment Duration Class is linked to one and only one ATC code.

Examples:

One-shot, one day, 2 till 4 days, 5 to 7 days, weeks (multiple of 7 days + up to 6 days), month, trimester, half year, year.

WADA**Explanation of the concept:**

One of the most significant achievements in the fight against doping in sport to date has been the drafting, acceptance and implementation of a harmonized set of anti-doping rules, the World Anti-Doping Codes List.

This list is the core document that provides the framework for harmonized anti-doping policies, rules and regulations within sport organizations and among public authorities.

This harmonization works to address the problems that previously arose from disjointed and uncoordinated anti-doping efforts, such as, among others, a scarcity and splintering of resources necessary to conduct research and testing, a lack of knowledge about specific substances and procedures being used and to what degree, and an uneven approach to penalties for athletes found guilty of doping.

Authentic source:

The World Anti-Doping Agency's (WADA) mission is to lead a collaborative worldwide campaign for doping-free sport.

WADA was established in 1999 as an international independent agency composed and funded equally by the sport movement and governments of the world. Its key activities include scientific research, education, development of anti-doping capacities, and monitoring of the World Anti-Doping Code (Code) – the document harmonizing anti-doping policies in all sports and all countries. WADA is a Swiss private law Foundation. Its seat is in Lausanne, Switzerland, and its headquarters are in Montreal, Canada.

Possible data flows from and towards other applications:**Twin concepts:**

The WADA works in conjunction with five International Standards aimed at bringing harmonization among anti-doping organizations in various areas: testing, laboratories, Therapeutic Use Exemptions (TUEs), the List of Prohibited Substances and Methods, and for the protection of privacy and personal information.

Dependencies between concepts in the diagram:

A VMP may be linked to one and only one WADA code.

Examples:

The WADA code has possible values: A, B, 2, 2C, B2, C, c, D, DB, d, Hman, H, M, N, O, AO, p, S, S, ...

Part 2 : Chapter IV

The information is based on the arrangement of the section of the law entitled:

Chapitre IV - Conditions de remboursement Des spécialités admises sur avis du médecin-conseil.

Chapitre IV - Vergoedingsvoorwaarden voor de Aangenomen specialiteiten op advies Van de adviserend geneesheer.

This article is in turn subdivided into paragraphs grouping pathologies that react favourably to – unfortunately enough – expensive medicines.

Each paragraph may therefore consist of different indents that provide a definition of:

- Diagnoses ;
- Pathologies ;
- Reimbursement conditions ;
- Conditions that exclude reimbursement ;
- Criteria for patient distribution ...

But also one or more tables with reimbursement amounts for medicines with mention of :

- the speciality ;
- the place of delivery ;
- the number or volume ;
- the regime ...

Paragraaf 240200

De specialiteit is vergoedbaar als ze werd voorgeschreven voor de behandeling van diabetespatiënten met nefropathieën die gepaard gaan met proteïnurie of albuminurie.

In dit geval is de toelating van de adviserend geneesheer afhankelijk van de ontvangst van een geschreven verslag waarin de anamnese van het geval is opgenomen.

Op basis daarvan reikt de adviserend geneesheer aan de rechthebbende de machtiging uit waarvan het model is vastgesteld onder "d" van bijlage III van dit besluit en waarvan de geldigheidsduur tot maximum 12 maanden is beperkt.

De terugbetaling van de voortzetting der behandeling kan worden gemachtigd voor nieuwe periodes van maximum 60 maanden, op basis van het model "d" behoorlijk ingevuld door de behandelende arts en terugbezorgd aan de adviserend geneesheer van de' verzekeringsinstelling.

Als het gaat om patiënten met een hartdecompensatie die in het bezit zijn van een toestemming voor vergoeding voor een orale dopaminerge agonist die is aangenomen volgens de vergoedingsgroep B-207, mag de gelijktijdige toestemming voor vergoeding slechts worden toegestaan als uit bovengenoemd verslag blijkt dat het gebruik van dat geneesmiddel noodzakelijk was.

Paragraphe 240200

La spécialité est remboursable si elle a été prescrite pour le traitement de patients diabétiques avec néphropathies albuminuriques ou protéinuriques.

Dans ce cas, l'autorisation du médecin-conseil est subordonnée à la réception d'un rapport écrit, comportant l'anamnèse du cas.

Sur base de ces éléments, le médecin-conseil délivre au bénéficiaire l'autorisation dont le modèle est fixé sous "d" de l'annexe III du présent arrêté et dont la durée de validité est limitée à 12 mois maximum.

Le remboursement de la poursuite du traitement peut être accordé pour de nouvelles périodes de 60 mois maximum sur base du modèle "d" dûment complété par le médecin traitant et renvoyé au médecin-conseil de l'organisme assureur.

S'il s'agit de patients souffrant de décompensation cardiaque qui sont en possession d'une autorisation de remboursement pour un agoniste dopaminergique oral admis en vertu du groupe de remboursement B-207, l'autorisation simultanée de remboursement ne peut être accordée que si le rapport susvisé a établi la nécessité d'avoir recours à ce médicament.

Benaming / Dénomination (Aanvrager / Demandeur)								
Cat.	Code	Verpakkingen	Conditionnements	Opm Obs	Prijs Prix	Basis v tegemeetk Base de remb.	I	II
CAPOTEN (PI-Pharma)		PI-PHARMA		ATC: C09AA01				
B-21	1589-142	30 tabletten, 100 mg	30 comprimés, 100 mg	R	34,64	26,87	11,80	14,49
B-21 *	0771-394	1 tablet, 100 mg	1 comprimé, 100 mg	R	0,9920	0,6767	+0,3153	+0,3153
B-21 **	0771-394	1 tablet, 100 mg	1 comprimé, 100 mg	R	0,8147	0,5557		

PARAGRAPH**Explanation of the concept:**

The PARAGRAPH corresponds with the arrangement of the legislation text into numbered paragraphs. These numbers can comprise up to 7 figures. The paragraph thus groups a series of descriptions of diagnoses or pathologies to which it connects pharmaceutical specialities for which it gives the conditions for possible reimbursements. In addition to the reimbursable medicines, it also defines other medicines for which reimbursement is excluded if such reimbursement was available before. A series of key words is also connected to the paragraph to help the prescribing physician to look them up.

Authentic source:

The legislation text has been published in the “Belgisch Staatsblad/Moniteur Belge”; the original source thereof is in fact the NIHDI (INAMI/RIZIV).

Lifecycle:

The paragraph concept is connected to the number of the paragraph in the legislation text. All new numbers that appear in the legislation must be inserted in the database. Then only information relating to concepts connected to the heading or the paragraph as a whole may require processing, e.g.: the list of key words (provided it is one indivisible data item).

Paragraphs may evolve over time, i.e. can be split into 2 or more paragraphs if the conditions need to be differentiated or they can be and given a new paragraph name. The split of the paragraph name is done by adding a value to the 4 trailing numbers, for instance §7500000 might split in §7500100 and §7500200.

Alias – twin concepts - subtype - supertype:

-

Possible data flows from and towards other applications:

The legislation texts on reimbursement are published by the NIHDI and sent on to the “Belgisch Staatsblad/Moniteur Belge.” SAM would have to be fed information directly by the NIHDI via the BCPI.

Dependencies between concepts in the diagram:

The paragraph coordinates the information on the reimbursement of the accepted specialities on the advice of the consulting physician, and thus serves as the point of contact for all information relating to reimbursement and related conditions.

The paragraph consists of different VERSES which are specific for one PARAGRAPH.

In the THERAPY concept(s), the paragraph provides the AMP specialities that correspond to the pathologies cited in the VERSES.

The reimbursement conditions contained in the VERSES include also exclusions. There will be no reimbursement if the condition is ascertained. These EXCLUSIONS pertain to one PARAGRAPH only.

The paragraph references its preceding paragraph name in case of split or merge.

Examples:

Paragraphe 470102

réduction de masse tumorale en vue de prostatovésiculectomie totale curative

reductie van de tumorgrootte met het oog op curatieve totale prostavesiculectomie

VERSE

Explanation of the concept:

Each paragraph in Chapter IV contains different verses. Each verse in turn contains a collection of coherent information that can be detached from the rest of the paragraph because it introduces a new alternative or a new subject that is separate from the previous one. For this reason, a verse will group information relating to a diagnosis, a reimbursement criterion or prescription clauses. As these information groups at times require choices, some of these will have to be chosen or rejected by the prescribing physicians. At the end of the prescription procedure, the options not descriptive for the patient's situation will be removed from the legislation text.

The information managed by the concept will make it possible to re-insert the fragment at the right place in the legislation text, and to code information at this level in order to automate the prescription authorisation.

The VERSES thus constitute an arrangement of the legislation text published in the Belgisch Staatsblad/Moniteur Belge. This arrangement does not put all verses on the same level. A hierarchical architecture is provided so as to be able to process the semantic logic of the legislation text regarding the choice of the prescribing physician. This makes it possible to ensure the coherence of the prescribing physician's choices regarding the content of the text and thus to minimise the number of choices that s/he has to make.

Authentic source:

Chapter IV.

Lifecycle:

As with the PARAGRAPH, the concept of VERSE is connected to the publication in the Belgisch Staatsblad/Moniteur Belge. The creation or amendment of a part of the legislation has a repercussion on the VERSES.

Alias – twin concepts - subtype - supertype:

-

Possible data flows from and towards other applications:

As parts of the PARAGRAPHS, the verses follow the same flow.

Dependencies between concepts in the diagram:

The PARAGRAPHS are subdivided manually into verses. The structuring in verses can be understood only through the semantic content. This process can therefore be carried out only by human intervention.

Examples:

Le remboursement de la spécialité est autorisé pour traiter l'acromégalie.

Le remboursement de la spécialité PARLODEL est également autorisé si elle est prescrite pour traiter des cas démontrés d'hypogonadisme prolactinodépendant chez l'homme.

La spécialité ne fait l'objet d'un remboursement que si elle a été prescrite pour le traitement de l'endométriose dont le diagnostic a été confirmé par un interniste ou un gynécologue sur base d'un rapport clinique mentionnant les résultats d'examens par laparoscopie et biopsie. En cas de contre-indication à la biopsie, une imagerie démonstrative par voie laparoscopique est jointe à la demande.

EXCLUSION**Explanation of the concept:**

The reimbursement of medicines provides also clauses for non-reimbursement. This can be attributed to a combination with other medicines or for another reason. The non-combination can be defined at different levels. Either at the level of the restructuring of medicines: substance, speciality or DCI level; or by reference to another part of the legislation, e.g. the non-combination of different medicines within the same paragraph.

Authentic source:

Chapter IV.

Lifecycle:

As the EXCLUSION content is a coding of the content of the VERSE concept, their life cycles are connected. The EXCLUSION content may however vary when formalised. As it is possible to limit the reference to a verse as being an EXCLUSION clause, without further structuring the content of the text, it can be considered to carry out this coding of information on non-combination regarding a structural element of medicines in a second phase.

Alias – twin concepts - subtype - supertype:

-

Possible data flows from and towards other applications:

As a coded reproduction of the information on the non-combination of the verses, exclusions follow the same flow.

Dependencies between concepts in the diagram:

The exclusions are expressed at paragraph level, but as they may differ, the relationship to the PARAGRAPH is of the parent-children type.

Examples:

Le remboursement simultané de cette spécialité et des antagonistes des récepteurs H2 (B-45, C-30), des inhibiteurs de la pompe à proton (B-48, B-273, C-31), de CYTOTEC (B-47), d'ARTHROTEC (B-242) ou avec des préparations magistrales dans lesquelles un ou plusieurs principes actifs de ces spécialités sont incorporés, n'est jamais autorisé.

THERAPY

Explanation of the concept:

The leading point of convergence between the paragraphs of the section of the law and the information on medicines is the use of pharmaceutical specialities as an answer to the diagnoses made by the prescribing physicians. It therefore comes down to summarising the different reimbursable pharmaceutical answers that doctors have for their prescriptions.

This level pertains only to the reimbursable pharmaceutical answers, not to the reimbursement itself. Products for which there is no reimbursement for the pathologies discussed in the paragraphs are not included here.

Authentic source:

Chapter IV, Reimbursement section.

Lifecycle:

As the THERAPY content is a coding of the PARAGRAPH section pertaining to medicines, their life cycles are connected.

Alias – twin concepts - subtype - supertype:

-

Possible data flows from and towards other applications:

The coded reproduction of the connecting information between PARAGRAPH and Medical Product (AMP): THERAPY, is fully connected with the paragraph and follows the same channel.

Dependencies between concepts in the diagram:

The pathologies in the paragraph can have different pharmaceutical answers and the pharmaceutical product can be under different paragraphs. There can be several connections for both parents, therefore.

Examples:

CH IV

380200	METOCLOPRAMIDE EG
380200	DOCMETOCLO
380200	LITICAN
380200	PRIMPERAN

510201	ACICLOVIR APOTEX
510201	ZOVIRAX
510201	DOCACICLO
510201	ACICLOVIR EG

REIMBURSEMENT

Explanation of the concept:

The reimbursement of medicines contained in Chapter IV is described on the level of the medicinal product package. This information contains the CNK number and part of the packaging characteristics and is therefore placed in between the information of the medicinal product package and the therapies suggested in the verses.

REIMBURSEMENT is therefore the more detailed level of THERAPY, which is no longer based on the pharmaceutical product but on the medicinal product package.

This concept therefore structures all information relating to the reimbursable amounts contained in the paragraph of the section of the law.

Authentic source:

Chapter IV, one line of the reimbursement section.

Lifecycle:

As the REIMBURSEMENT content is a coding of the content of the VERSE concept, their life cycles are connected.

Alias – twin concepts - subtype - supertype: -
Possible data flows from and towards other applications:

The coded reproduction of the connecting information between THERAPY and Medical Product Package (AMPP): REIMBURSEMENT, is fully connected with the paragraph and follows the same channel.

Dependencies between concepts in the diagram:

The reimbursement amounts are expressed on the same level as the medicinal product package, we will therefore not repeat the information regarding the product package but rather establish a direct relation with the concept AMPP. This would be an equivalency relation if the legislation made no distinction between the copayment amounts according to the pathology in question. REIMBURSEMENT can thus be repeated with different amounts depending on the therapy for which it provides an answer. On the contrary, the price and the reimbursement amount are attributed on AMPP level depending on the delivery type (public, hospital, ambulant), they are independent on the reimbursement category.

Examples:

Benaming / Dénomination (Aanvrager / Demandeur)									
Cat.	Code	Verpakkingen	Conditionnements	Opm Obs	Prijs Prix	Basis v tegemoetk Base de remb.	I	II	
ALBUMINE 20 %		C.A.F.-D.C.F. CVBA-SCRL				ATC: B05AA01			
B-190 *	0725-697	1 injectieflacon 100 ml oplossing voor intraveneuze infusie, 200 mg/ml	1 flacon injectable 100 ml solution pour perfusion (intraveineuse), 200 mg/ml		63,0600	63,0600			
B-190 **	0725-697	1 injectieflacon 100 ml oplossing voor intraveneuze infusie, 200 mg/ml	1 flacon injectable 100 ml solution pour perfusion (intraveineuse), 200 mg/ml		63,0600	63,0600			
ALBUMINE 20%		C.A.F.-D.C.F. CVBA-SCRL				ATC: B05AA01			
B-190 *	0764-043	1 injectieflacon 10 ml oplossing voor intraveneuze infusie, 200 mg/ml	1 flacon injectable 10 ml solution pour perfusion (intraveineuse), 200 mg/ml		10,5100	10,5100			
B-190 **	0764-043	1 injectieflacon 10 ml oplossing voor intraveneuze infusie, 200 mg/ml	1 flacon injectable 10 ml solution pour perfusion (intraveineuse), 200 mg/ml		10,5100	10,5100			

4. Major differences with the NHS model

As stated in the previous chapter, this conceptual model for part 1 concerning medicinal product information is based on the dm+d (dictionary of medicines and devices) model developed at the National Health Service (NHS) in the UK. The dm+d model was developed as part of the UK Standard Clinical Products Reference Source project (UKCPRS) in order to deliver a common/standardised vocabulary and identifiers for clinical products (medicines, appliances, medical devices).²

The 6 core concepts originally presented in the NHS model (ATM, ATM, VMP, AMP, VMPP and AMPP) are also incorporated in our conceptual model, but their definition has been slightly changed in order to be adapted to the Belgian context.

Our definition of the concept VMP is intended to support INN prescription as it is defined in Belgium. Therefore, the definition of the concept VMP has been modified in order to meet the (Belgian) INN prescription guidelines. In these guidelines a INN are based on 3 principal elements : the virtual ingredient (INN name), the strength, and an 'application road' ('toedieningsvorm'). This latter element represents an abstract classification of the route of administration, into +-25 possibilities. For this reason, the definition of the concept VMP in the Belgian context is placed at a somewhat higher level of granularity than the VMP concept in the NHS model, where the detailed route of administration and pharmaceutical form are defined for a VMP.

In the Belgian context, at AMPP level only commercially available packages are present which have a national identification (CNK) number. Therefore, where for the combined products (e.g. tablets and a solution in one package) there exist separate VMPs and AMPs for the single components as well as for the combined product, at AMPP level only the final combined product will be present.

The VMPP level represents a classification of commercially available product packages in terms of treatment duration. Instead of the exact pack size (e.g. 28 tablets), it will suffice to specify a treatment duration category (e.g. 1 month treatment).

The NHS model does not implement the ATM level. In the Belgian context, this is the place where marketing authorisation holders are linked to a brand name.

5. References

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5. "Gecommentarieerd geneesmiddelenrepertorium, 2009", BCFI.
6. "Eindverslag – Project VOS/DCI Cluster", 05/2007, <https://portal.health.fgov.be>
7. "Voorschrijven op stofnaam – Voorstellen voor de praktische toepassing in de medische praktijk en in het elektronisch medisch dossier", FAGG, 03/2010, http://www.bcfi.be/download/Nota_INN_2010_march_3_NL.doc
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9. Birgit Eiermann, Pia Bastholm Rahmner, Seher Korkmaz, Carina Landberg, Birgitta Lilja, Tero Shemeikka, Aniko Veg, Björn Wettermark and Lars L Gustafsson (2010). Knowledge Bases for Clinical Decision Support in Drug Prescribing – Development, Quality Assurance, Management, Integration, Implementation and Evaluation of Clinical Value, Decision Support Systems, Chiang S. Jao (Ed.), ISBN: 978-953-7619-64-0, INTECH, Available from: <http://scijo.com/articles/show/title/knowledge-bases-for-clinical-decision-support-in-drug-prescribing-development-quality-assurance-mana>

6. Document rectifications / modifications / updates

Rectification on 27/07/2012 :

- p. 28 : Concept ATC and its dependencies. "Each AMP is linked tot one and only one ATC code. ATC no longer relates to the virtual medicinal product but to the actual instance.
- p. 31 : Concept PARAGRAPH lifecycle and dependencies : references to parents in case of split or merge.

Rectification on 24/08/2012 :

- p. 7 : Conceptual Diagram for Medicinal Product : ATC is linked to AMP (not VMP) and WADA is added and linked to VMP.
- p. 28 : Concept WADA and its dependencies. "Each A VMP may be linked to one and only one WADA code." WADA no longer relates to the actual medicinal product but to the virtual instance.