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S A M 2

LOGICAL DATA DOSSIER 3

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List of abbreviations

ATC	Anatomical Therapeutic Chemical
BCFI	Belgisch Centrum voor Farmacotherapeutische Informatie
BCPI	Belgian Centre for Pharmacotherapeutic Information
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
MHRA	Medicines and Healthcare products Regulatory Agency

1. Logical Data Diagram – Entities / Relations (ERD)

1.1. Composition of the document

The structuring of the database SAM is divided into two parts:

- The Medicinal Product part that explains in detail the areas dedicated to substances, specialities, galenic forms, packages, etc.
- The Reimbursement part that represents all information relative to the conditions, procedures, medical and social profiles, amounts, etc.

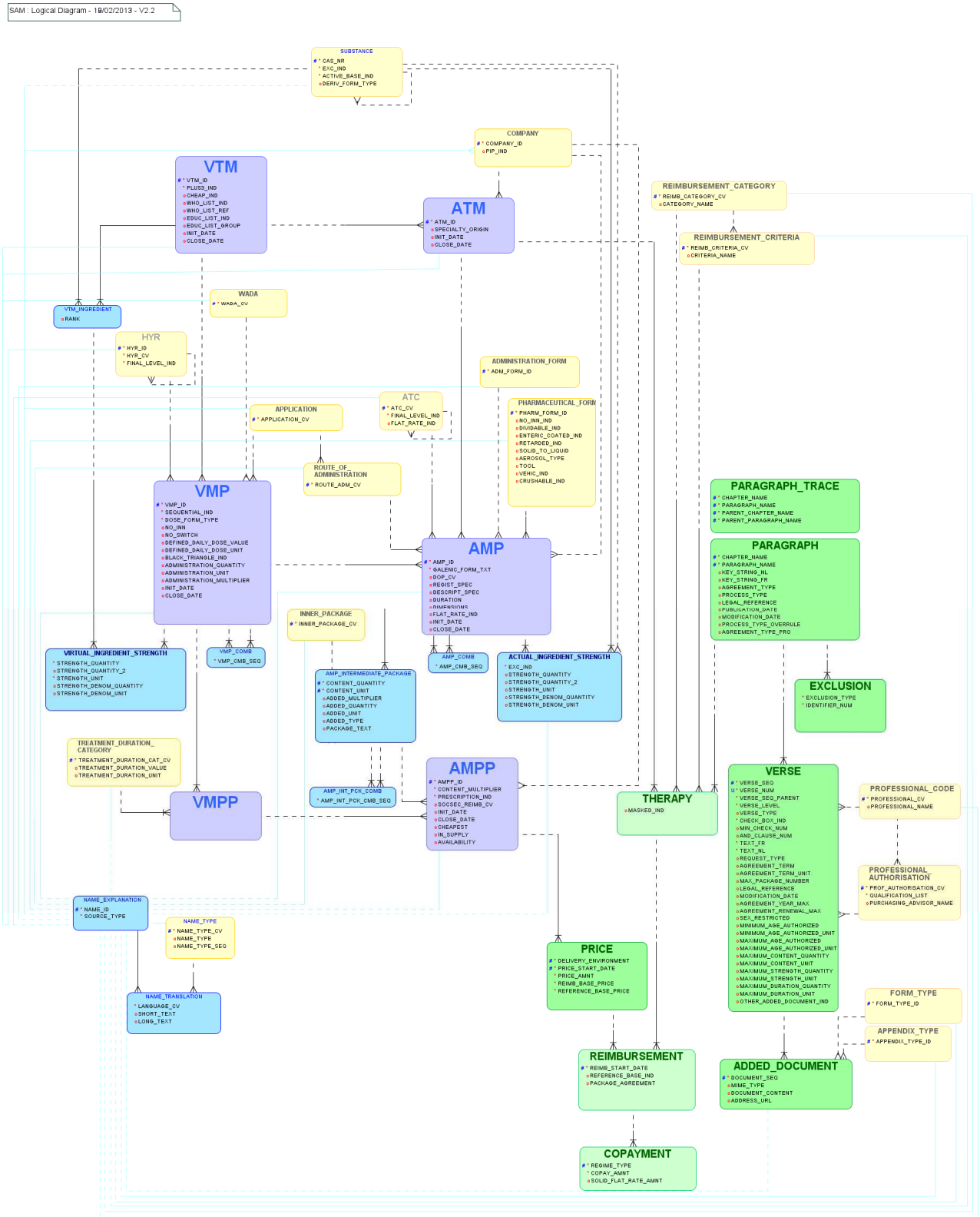
1.2. Diagram

There are several types of entities represented in the diagram:

- Reference entities are represented in yellow
- The 6 Core entities in the medicinal product sphere are indicated in violet
- The other Application entities in the medicinal product sphere are represented in blue
- The other Application entities in the reimbursement sphere are represented in green

Remind that the logical model does NOT take into account the technical fields necessary for the relations

An electronic version is available on demand.


SAM : Logical Diagram - 19/02/2013 - V2.2
SUBSTANCE
COMPANY
VTM
ATM
REIMBURSEMENT_CATEGORY
REIMBURSEMENT_CRITERIA
VTM_INGREDIENT
WADA
HYR
ADMINISTRATION_FORM
ATC
APPLICATION
PHARMACEUTICAL_FORM
ROUTE_OF_ADMINISTRATION
VMP
AMP
PARAGRAPH_TRACE
PARAGRAPH
INNER_PACKAGE
VIRTUAL_INGREDIENT_STRENGTH
VMP_COMB
AMP_COMB
ACTUAL_INGREDIENT_STRENGTH
EXCLUSION
AMP_INTERMEDIATE_PACKAGE
TREATMENT_DURATION_CATEGORY
AMPP
VERSE
PROFESSIONAL_CODE
VMPP
AMP_INT_PCK_COMB
THERAPY
PROFESSIONAL_AUTHORISATION
NAME_EXPLANATION
NAME_TYPE
PRICE
FORM_TYPE
APPENDIX_TYPE
NAME_TRANSLATION
REIMBURSEMENT
ADDED_DOCUMENT
COPAYMENT

2. Data Dictionary

2.1. Entities

Part 1 : Medicinal Products

2.1.1. VTM (VIRTUAL_THERAPEUTIC_MOIETY)

The virtual therapeutic moiety (VTM) provides a high level description of pharmaceutical agents or combinations of agents, regardless of the indication, their strength or route of administration. It is the abstract representation of the substance(s), intended by an authorising health professional for use in the treatment of the patient.
The VTM entity represents the collection of pharmaceutical specialties 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.
In case of a multi-ingredient VTM with two substances, both substance names appear in the VTM name, e.g. atenolol + chloortalidon, up to a combination of maximum 3 substances. This can be a fixed combination of substances, or a group of substances for which the difference between the components is of minor importance. A VTM can also be a therapeutic moiety only available as an officinal preparation.

Alias:
Semantic key: VTM_ID

[Attributes]

VTM_ID: Unique identifier for the Virtual Therapeutic Moiety
This can be:
- a Virtual Therapeutic Moiety containing one active substance (Single Ingredient VTM)
- a Virtual Therapeutic Moiety containing two or more active substances (Multi Ingredient VTM)

Type: Numeric(10) Mandatory
Domain :

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

PLUS3_IND: Indicates whether the substance has more than 3 active ingredients.

Alias : Plus3Stoffen (table VTM in DB BCFI)
Type : Boolean Mandatory
Domain : ‘Y’es / ‘N’o

CHEAP_IND: Indicates whether the substance is a cheap molecule or not. Not applicable in case of a multi-ingredient substance.

Type : Boolean Optional
Domain : ‘Y’es / ‘N’o ‘Null’ equals ‘N’

WHO_LIST_IND: Indicates whether the therapeutic moiety is present on the model list of the WHO or not.

Alias : WHO_Model_List (table VTM, DB BCFI)
Type : Boolean Optional
Domain : 'Y'es / 'N'o 'Null' equals 'N'

WHO_LIST_REF: Reference number in the WHO model list of therapeutic moieties.

Alias : WHO_Ref_Nr_Model_list (table VTM, DB BCFI)
Type : String(12) Optional
Domain :

EDUC_LIST_IND: Indicates whether the therapeutic moiety is on the educational list of therapeutic moieties.

Alias : Lijst_Basisonderwijs (table VTM, DB BCFI)
Type : Boolean Optional
Domain : 'Y'es / 'N'o 'Null' equals 'N'

EDUC_LIST_GROUP: Reference of the Group in the educational list of therapeutic moieties.

Alias : Groep_Lijst_Basisonderwijs (table VTM, DB BCFI)
Type : String(12) Optional
Domain :

INIT_DATE: Date of creation or first appearance of the VTM.

Type: Date Optional
Domain :

CLOSE_DATE: Date on which the VTM ceases to exist.

Type : Date Optional
Domain:

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.2. ATM (ACTUAL_THERAPEUTIC_MOIETY)

=[VTM] + brand name or marketing company (either the authorisation holder or national licence holder with an identifiable information responsible)
The entity ATM represents the collection of medicinal products with the same active substance(s) and marketed by the same company. 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.

Example of an ATM:
- Panadol (GlaxoSmithKline)
- Tenormin (AstraZeneca)
- Atenolol Teva (Teva)

Alias:
Semantic key: ATM_ID

[Attributes]

ATM_ID: Unique identifier for the Actual Therapeutic Moiety

Type : Numeric(10) Mandatory

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

VTM_ID: Foreign key (FK) inherited from VTM

Type : Numeric(10) Mandatory

COMPANY_ID: Foreign key (FK) inherited from FIRM.

Type : Numeric(5) Mandatory

SPECIALTY_ORIGIN: Origin of the drug specialty as specified in Chapter IV. For the present the notion with or without college procedure is not completed; only value 'O' is present referring to orphan medecines.

Type : Character Optional
Domain : C=Copy, G=Generic, R=Reference, O=Orphan (without college procedure), P=Orphan (with college procedure), I=Import Parallel.

INIT_DATE: Date of creation or first appearance of the VTM.

Type: Date Optional
Domain :

CLOSE_DATE: The date on which the ATM ceases to exist.

Type : Date Optional
Domain:

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.3. VMP (VIRTUAL_MEDICINAL_PRODUCT)

=VTM + strength + application road

This concept represents the collection of medicinal products with the same active substance (or combination of active substances) 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).
It represents the cluster of medicinal product packages a pharmacist can choose from when dispensing a drug from an INN (or VOS) prescription, and can therefore also be called 'VMP group' ('VOS-cluster').
In rare occasions, a VMP may 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 form. 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 other VMPs (of subtype Single VMP), one for each type of tablet. This relation is expressed by the association concept VMP_comb. It may not be possible to prescribe a single VMP on itself, only as part of a combination VMP. A VMP could also be a combination pack with a mixture of pharmaceutical forms (e.g. ampoule + tablets, cream + pessary).
The strength is always expressed for a Single VMP.

Aliases: VMP-group, VOS-groep, INN cluster

Examples:
- paracetamol 1g (inj.)
- atenolol 100mg (oraal)
- acetylsalicylzuur 400 mg + ascorbinezuur 240 mg (oraal)

Semantic key: VMP_ID

[Attributes]

VMP_ID: Unique identifier for the Virtual Medicinal Product. All VMP's for which there exists a commercialised medicinal product package are identified in Belgium by a CNK number starting with the number 8. A specific range of CNK numbers will be reserved for VMP's that are not commercialised on itself but only exist as a component of a combination VMP. The APB will be in charge of the codification of VMP's.
Alias : DCI_num, INNgroup_CNK

Type : Numeric(7) Mandatory
Domain : CNK-number with 7 positions starting with an '8'

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

VTM_ID: Foreign key (FK) inherited from VTM

Type : Numeric(10) Mandatory

APPLICATION_CV: Code value representing the application Road for the VMP. Foreign key inherited from APPLICATION

Type : string(2) Mandatory

SEQUENTIAL_IND: Indicates whether the VMP is a sequential product or not. Sequential products are all products for which the order of intake is important.

e.g. triphasic anticonception pill: 3 different types of pills that have to be taken in a certain order. Note: A medicine that contains e.g. 7 tablets of which 76 tablets containing active substances and 1 placebo is also considered as a sequential product!

Type : Boolean Mandatory
Domain : 'Y'es / 'N'o

DOSE_FORM_TYPE: Code that indicates whether the VMP has a discrete unit dose form (e.g. tablet, ampoule, capsule) or a continuous dose form (liquid, cream) or not applicable (e.g. adhesives)

Type : Character Mandatory
Domain : D: discrete, C: continuous, N: not applicable

ADMINISTRATION_QUANTITY: (ADMQ) Numerical value in the administration form expression.
Example: "5" in "3 x 5ml daily"

Type : Numeric(12,3) Optional
Domain : Quantity

ADMINISTRATION_UNIT: (ADMU) Numerical value in the administration form expression.
Example: "ml" in "3 x 5ml daily"

Type : String(5) Optional
Domain : list of predefined units

ADMINISTRATION_MULTIPLIER: (ADMM) Multiplier associated with the Administration Quantity.
Example: "3" in "3 x 5ml daily"

Type : Numeric(4) Optional
Domain :

HYR_ID: Unique identifier for the HYR-level. Each HYR_ID is always associated with an HYR_CODE (e.g. 'AABB') that represents a node in an hierarchical tree. The code corresponding with the identifier can change in time whereby the identifier continues to point to the same node in the hierarchy.
Not all VMP's have to be associated with a HYR-code, e.g. the single VMP's that are part of a combination product but do not exist by themselves, will not have a HYR-code.

Type : Foreign key inherited from HYR. Optional

NO_INN: Code value that gives the reason why the substance may not be the subject of INN prescription. Possible values:
1 biologische geneesmiddelen
2 preparaten met meer dan 3 actieve bestanddelen
3 multifasische anticonceptiepillen
4 actieve verbandmiddelen"

Alias : NoVos (table , DB BCFI)
Type : Numeric(1) Optional
Domain : 1, 2, 3 or 4

NO_SWITCH: Reason why INN (VOS) prescription may not change for this substance.
Possible values:
1 nauwe therapeutische marge
2 oncologische middelen
3 transdermale systemen
4 producten voor lokaal gebruik

5 orale anticonceptiva
6 inhalatiepreparaten
7 diagnostica en middelen gebruikt bij anesthesie
8 mesalazine en sulfasalazine
66 preparaten voor verneveling

Type : Numeric(2) Optional
Domain : 1..8, 66 for now

DEFINED_DAILY_DOSE_VALUE: Defined daily doses (DDDs) are a WHO statistical measure of drug consumption. DDDs are used to standardize the comparative usage of various drugs between themselves or between different health care environments. The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults. (maximum of 6 digits). DDD's are defined at the WHO.
For example, paracetamol has a DDD of 3g, which means that an average patient who takes paracetamol for pain relief (Paracetamol main indication) uses 3 gram per day. This is equivalent to six standard (500mg) tablets. If a patient consumes twenty four (500mg) tablets (i.e. 12g of paracetamol in total) over the space of six days, he can have said to have consumed four DDDs of this drug.

Alias : Dagdosis(NL)
Type : Numeric(12,3) Optional
Domain :

DEFINED_DAILY_DOSE_UNIT: Unit used to express the DDD, e.g. mg, ml, …

Authentic source : WHO
Type : String(5) Optional
Domain : List of predefined units used at the WHO.

BLACK_TRIANGLE_IND: Indicator that says whether the products in the VMP group have a Black Triangle label, this means that it concerns a new product or an existing product that is used for a new indication or by a new route of administration and therefore its use needs to be surveilled and prescription should be handled with care. It is the MHRA that sets the BT indicators for certain products.

Alias : bt (table BT, DB BCFI)
Type : Boolean Optional
Domain : 'Y'es / 'N'o 'Null' equals 'N'

INIT_DATE: Date of creation or first appearance of the VTM.

Type: Date Optional
Domain :

CLOSE_DATE: The date on which the VMP ceases to exist.

Type : Date Optional
Domain:

WADA_CV: WADA doping code. References the entity WADA.

Type : Foreign key to WADA Optional

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.4. AMP (ACTUAL_MEDICINAL_PRODUCT)

= [VMP] + brand name or marketing company + administration form + route of administration (and possibly pharmaceutical form)
= [ATM] + strength + route of administration + administration form

The entity AMP represents the branded forms of a 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 detailed information regarding the pharmaceutical form, the route of administration, the administration form, excipients and possible derivatives used as actual ingredients.

Examples:
Tenormin 100mg (oraal) AktualPharma
Perfusalgan 1 g (inf.) Bristol-Myers Squibb

Alias:
Semantic key: AMP_ID

[Attributes]

AMP_ID: Unique identifier for the AMP.

Type : Numeric(10) Mandatory
Domain :

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

VMP_ID: Identifier of the corresponding VMP. References the entity VMP.

Type : Foreign key to VMP Mandatory

ATM_ID: Identifier to the corresponding ATM. References the entity ATM.

Type : Foreign key to ATM Mandatory

ROUTE_ADM_CV: Code value of the route of administration. References the entity ROUTE_OF_ADMINISTRATION.

Type : Foreign key to ROUTE_OF_ADMINISTRATION Mandatory

PHARM_FORM_ID: Code value representing the pharmaceutical form. References the entity PHARMACEUTICAL_FORM.

Type : Foreign key to PHARMACEUTICAL_FORM Mandatory

GALENIC_FORM_TXT: Text field with a detailed description of the galenic form. This is a specific description for each medicinal product and therefore not taken from a reference table. This is the most detailed description of the galenic properties of a product.
Examples:
- compr. Chrono 500 (vertraagde vrijst., deelb.)
- Turbohaler (poeder voor nasaal gebruik)
- oplossing Rood Kinderen (oraal) zonder suiker
- poeder (zakjes) chocoladesmaak"

Authentic source : BCFI
Alias : nHTM (table GAL , DB BCFI)

Type : String(90) Mandatory
Domain : Free text

ADM_FORM_ID: Code value of the route of administration. References the entity ADMINISTRATION_FORM.

Type : Foreign key to ADMINISTRATION_FORM Optional

DIMENSIONS: Text field with the dimensions of the product in case of for example adhesives.
Example : "(7.5 x 7.5 cm)" in "Allevyn adhesive (7.5 x 7.5 cm)""

Type : String(30) Optional
Domain : Free text

DOP_CV: Type of Doping attention mark (D-d)

Authentic source : BCFI
Type : Character Optional
Domain : D, d

REGIST_SPEC: Text value that represents a registered specification by the company.
Example: Forte, Chrono 500

Alias : NProp, FProp (table GAL , DB BCFI)
Type : String(30) Optional
Domain : Free text

DESCRIPT_SPEC: Description specification between parentheses.

Alias : NAdj, FAdj (table GAL, DB BCFI)
Type : String(50) Optional
Domain : Free text

DURATION: Duration of activity (werkingsduur) for a medicinal product.
This is independent of the pack size, but may vary from one brand to another.
This attribute is mostly used for patches.

Alias : during (table MPP, DB BCFI)
Type : String(30) Optional
Domain : Free text

FLAT_RATE_IND: This indicator overrules the FLAT_RATE_IND in the ATC for this instance of AMP only.

Type : Boolean Optional
Domain : ‘Y’es / ‘N’o ‘Null’ equals ‘N’

DISTRIBUTOR_ID: The distributor of the medicinal product. References the entity COMPANY.

Type : Foreign key to COMPANY Optional

INIT_DATE: Date of creation or first appearance of the VTM.

Type: Date Optional
Domain :

CLOSE_DATE: The date on which the AMP ceases to exist.

Type : Date Optional
Domain:

ATC_CV: ATC-code for the VMP. Foreign key inherited from ATC

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.5. VMPP (VIRTUAL_MEDICINAL_PRODUCT_PACK)

= [VMP] + treatment duration
The entity Virtual Medicinal Product Package (VMPP) contains the properties of one or more quantitatively equivalent AMPPs. This entity contains all available pack size categories for one VMP, in terms of equal treatment duration. It is identified by the VMP_ID and the treatment duration category.

Alias:
Semantic key: VMP_ID + TREATMENT_DURATION_CAT_CV
[Attributes]

VMP_ID: = VMP_CNK_NR**:** Identifier of the corresponding VMP. References the entity VMP.

Type : Foreign key to VMP Mandatory

TREATMENT_DURATION_CAT_CV: Pack size in which a VMP is available, expressed in terms of a treatment duration category. The treatment duration category arranges commercialised packages in groups of equal days of treatment (single shot, one day, 2 till 4 days, 5 to 7 days, weeks, fortnight, months, trimester, half year, year).

Type : Foreign key to TREATMENT_DURATION_CATEGORY Mandatory

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.6. AMPP (ACTUAL_MEDICINAL_PRODUCT_PACK)

= VMPP + brandname or marketing company + pack size + package information
= AMP + pack size + package information

The AMPP is the commercialized packaged product, available on the Belgian market, and supplied for direct patient use. It is identified in Belgium by a unique CNK-number. An AMPP contains information concerning a medicinal product that has been made available by a manufacturer and/or supplier as a packaged entity. It contains information concerning the pack size, the inner package and also price, reimbursement information and other administrative info

Examples:
Panadol 500mg soluble tablets, 24 tablet pack
Tenormin 100mg 28 tablets

Alias: MPP (BCFI)
Semantic key: AMPP_ID (CNK_NR)
Authentic source : APB/BCFI

[Attributes]

AMPP_ID: = CNK_NR : Medicinal Product Package code value. Unique identifier of an MPP, in Belgium identical to the CNK code.

Alias : MPPCV (table MPP , DB BCFI)
Type : Numeric(7) Mandatory
Domain :

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

AMP_ID: Identifier of the corresponding AMP.

Type : Foreign key to AMP (through AMP_INTERMEDIATE_PACKAGE) Mandatory

VMP_ID: Identifier of the corresponding VMP.

Type : Foreign key to VMPP (through AMP_INTERMEDIATE_PACKAGE) Mandatory

CONTENT_QUANTITY: (CQ) Numerical value of the amount of AMP expressed by mass, volume or number of entities in the package as supplied..

Type : Foreign key to AMP_INTERMEDIATE_PACKAGE Mandatory

CONTENT_UNIT: (CU) Unit of measure of the amount of AMP expressed by mass, volume or number of entities in the package as supplied. (ml, mg, vials, tabs, dose, …)

Type : Foreign key to AMP_INTERMEDIATE_PACKAGE Mandatory

TREATMENT_DURATION_CAT_CV: Code value for the pack size in which a VMP is available, expressed in terms of a pack size category.

Type: Foreign key to TREATMENT_DURATION_CATEGORY Mandatory

CONTENT_MULTIPLIER: Multiplier associated with the Content Quantity in AMP_Intermediate_Package. It represents the number of intermediate containers or inner containers in a medicinal product package.This can be:
- the number of flacons in case of a continuous product
  e.g. "3" in "Alopexy oploss 3 x 60ml 20mg/ml"
  e.g. "25" in "Cathejell gel 25 x 12,5g 0,5/20"
- the number of blister units in a package
  e.g. "1" in "Cerazette tab 28 tab 0,075mg"
  e.g. "3" in "Cerazette tab 3x 28 tab 0,075mg"
  e.g. "3" in "Trigynon 3x 21(6+5+10) tab"

Type : Numeric(4) Mandatory
Domain :

PRESCRIPTION_IND: Indicates whether a prescription by a physician is necessary or not.

Alias : law (table MPP, DB BCFI)
Type : Boolean Mandatory
Domain : ‘Y’es / ‘N’o

PROD_SPEF: Medicinal Product Specifier used for some products and as specified on the package (e.g. "NITRODERM TTS 5:…")

Alias : spef (table nMPP , DB BCFI)
Type : String(30) Optional
Domain :

SOCSEC_REIMB_CV: Social security reimbursement code (NIHDI)

Alias : ssecr (table MPP, DB BCFI)
Type : String(9) Optional
Domain : a, a4, a4b, a4b2, …, c, c2, c4, …

DISTRIBUTOR_ID: The distributor of the medicinal product. References the entity COMPANY.

Type : Foreign key to COMPANY Optional

INIT_DATE: Date of creation or first appearance of the VTM.

Type: Date Optional
Domain : Valid date

CLOSE_DATE: The date on which the AMPP ceases to exist.

Type : Date Optional
Domain: Valid date

CHEAPEST: Indicates if the medicinal product is considered by the NIHDI the cheapest on the market for the validity period.

Type : Char Optional
Domain: 'Y' = yes, null = no.

IN_SUPPLY: Indicates from which date the medicinal product is in supply. A date in the future indicates that the product is out of stock.

Type : Date Optional
Domain: Valid date

AVAILABILITY: Availability date of the medicinal product given by the distributor.

Type : Date Optional
Domain: Valid date

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.7. VTM_INGREDIENT (VTMING)

This is an association entity that represents the active ingredients a Virtual Therapeutic Moiety is composed of. In most cases this will be the active base of a substance, but it can possibly also be a salt or ester form of the substance.

Alias: VTMING
Primary key: CAS_NR + VTM_ID
Authentic source : BCFI

[Attributes]

CAS_ID: Identification number of the active substance which is part of the therapeutic moiety. References the entity SUBSTANCE.

Type : Foreign key to SUBSTANCE Mandatory

VTM_ID: Identifier of the corresponding VTM. References the entity VTM.

Type : Foreign key to VTM Mandatory

RANK: Ranking of active ingredients in the therapeutic moiety. This is used to indicate which ingredients are the most important in the therapeutic moiety. Only relevant in case of a multi-ingredient VTM.

Alias : rank (table SAM, DB BCFI)
Type : Numeric(2) Mandatory
Domain : 1,2,3… (default 1)

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.8. VMP_COMB (VMPCMB)

This entity describes the components of a combination VMP. Certain VMPs may consist of two or more products in one package. These products can differ in the strength or the composition of the active ingredients, or they can differ in the application road.
E.g. two different tablets (differing in the strength or the composition of the active ingredients), or a sirup and a cream together in one package.

Alias: VMPCMB
Semantic key: VMP_ID + VMP_ID_CMB

[Attributes]

VMP_ID_CMB: Identifier of the combination VMP, that is composed of two or more single VMPs in this association.

Type : Foreign key to VMP Mandatory

VMP_ID: Identifier of the component VMP. This is the single VMP that is part of a combined VMP in this association.

Type : Foreign key to VMP Mandatory

VMP_CMB_SEQ: Pharmaceutical Product Sequence Number that identifies the different parts (single VMPs) of a combination VMP. This sequence number is used for displaying the components in the correct order on the internet site and in the booklet. In case of a sequential product, this also represents the order of intake of the different components.
Example :
Trinordiol 3 x (6 + 5 + 10)

I	ethinylestradiol 0.03 mg
	levonorgestrel 0.05 mg
II	ethinylestradiol 0.04 mg
	levonorgestrel 0.75 mg
III	ethinylestradiol 0.03 mg
	levonorgestrel 0.125 mg

Alias : PPID (table SAM, DB BCFI)
Type : String(4) Mandatory

Domain : I, II, III, IV, V, VI, VII, VIII, IX, X.

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.9. AMP_COMB (AMPCMB)

This entity describes the components of a combination AMP. Certain AMPs may consist of two or more products in one package. These products can differ in the composition of actual ingredients or excipients used, or they can differ in the pharmaceutical form or route of administration.

Alias: AMPCMB
Primary key: AMP_ID+ AMP_ID_CMB

[Attributes]

AMP_ID: Identifier of the component AMP. This is the single AMP that is part of a combined AMP in this association.

Type : Foreign key to AMP Mandatory

AMP_ID_CMB: Identifier of the combination AMP, that is composed of two or more single AMPs in this association.

Type : Foreign key to AMP Mandatory

AMP_CMB_SEQ: Sequence number that identifies the different parts (single AMPs) of a combination AMP. This sequence number is used for displaying the components in the correct order on the internet site and in the booklet. In case of a sequential product, this also represents the order of intake of the different components.
Example :
Trinordiol 3 x (6 + 5 + 10)

I	ethinylestradiol 0.03 mg
	levonorgestrel 0.05 mg
II	ethinylestradiol 0.04 mg
	levonorgestrel 0.75 mg
III	ethinylestradiol 0.03 mg
	levonorgestrel 0.125 mg

Alias : PPID (table SAM, DB BCFI)
Type : String(4) Mandatory
Domain : I, II, III, IV, V, VI, VII, VIII, IX, X.

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, E'volved

2.1.10. VIRTUAL_INGREDIENT_STRENGTH (VIRTSTR)

The VIRTUAL INGREDIENT STRENGTH describes the content (value + unit) of the active ingredient in the medicinal product (VMP) according to the pharmaceutical form in a single dose unit, e.g. 1 tablet, 1 unit dose powder, 1 ampoule, ...
For medicinal products only available in continuous dose units, the strength refers to a concentration (e.g. per 5 ml solution, per 1 gram powder or cream.)

Alias: VIRTSTR
Semantic key: CAS_NR + VTM_ID + VMP_ID

[Attributes]

CAS_ID: Identifier of the active substance for which the strength is expressed in this association. References SUBSTANCE through the entity VTM_INGREDIENT

Type : Foreign key inherited from SUBSTANCE Mandatory

VTM_ID: Identifier of the Therapeutic Moiety. References the entity VTM.

Type : Foreign key inherited from VTM Mandatory

VMP_ID: Identifier of the corresponding VMP

Type : Foreign key inherited from VMP Mandatory

STRENGTH_QUANTITY: (SQ) Quantity of strength. This is the numerical value in the numerator of the strength expression. .
Example: " 5 " in "amp. inf. 20 x 5mg/10ml"

Alias : SVN (NHS)
Q / INQ (table SAM, DB BCFI)
Type : Numeric(12,3) Mandatory
Domain : Quantity

STRENGTH_QUANTITY_2: (SQ2) End of the range in the Strength Quantity expression. Only meaningful in case the strength is expressed as a range.
Example: “10” in “5 à 10 mg”

Alias : SVN2 (NHS)
Q2 / INQ2 (table SAM, DB BCFI)
Type : Numeric(12,3) Optional
Domain : Quantity

STRENGTH_UNIT: (SU) Unit of strength. This is the unit of measure associated with the Strength_Quantity (in the numerator of the strength expression).
Example: “ mg " in "amp. inf. 20 x 5mg/10ml"

Alias : SVNU (NHS)
U / INU (table SAM, DB BCFI)
Type : String(15) Mandatory
Domain : see reference list for existing units.

STRENGTH_DENOM_QUANTITY: (SDQ) The numerical value in the denominator of the strength expression..This attribute is only used in case of a continuous product (e.g. liquid, cream, …)
Example: “10" in "amp. inf. 20 x 5mg/10ml"

Alias : SVD (NHS)
BASQ / INBASQ (table SAM, DB BCFI)
Type : Numeric(12,3) Optional
Domain : Quantity

STRENGTH_DENOM_UNIT: (SDU) The unit of measure in the denominator of the strength expression. This attribute is only used in case of a continuous product (e.g. liquid, cream, …)
Example: “ml" in "amp. inf. 20 x 5mg/10ml"

Alias : SVDU (NHS)

BASU / INBASU (table SAM, DB BCFI)
Type : String(15) Optional
Domain : see reference list for existing units.

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.11. ACTUAL_INGREDIENT_STRENGTH (ACTSTR)

Contains information about the excipients in an AMP and the actual form of the active ingredient used (e.g. salt, ester), as far as these differ from the one used in the definition of the VMP-group.
This attribute confirms the presence of an excipient. However, if there are no excipient substances listed for this AMP, then this merely infers that the excipient was not stated on the SPC, or the SPC data was not available.
This attribute confirms the presence and strength of an actual ingredient. If there are no actual ingredients listed for this AMP, then this merely infers that in the AMP the same form of the active substance (e.g. active base, salt, ester) is used as on VMP level.

Alias: ACTSTR
Semantic key: CAS_NR + AMP_ID

[Attributes]

CAS_ID: Identifier of the ingredient substance for which the strength is expressed in this association. This can be a salt or ester form of the active ingredient or an excipient. References SUBSTANCE .

Type : Foreign key to SUBSTANCE Mandatory

AMP_ID: Identifier of the corresponding AMP.

Type : Foreign key to AMP Mandatory

NAME_ID : Text field used in this entity to store a third possible strength expression that may be printed on the product package and that is different from the strength expression of the virtual ingredients and the strength expression of the actual ingredients.

Example: a medicinal product belongs to a VMP-group with as an virtual ingredient salt1 in strength1 (see Virtual_Ingredient_Strength), but actually contains salt2 in strength2 (see Actual_Ingredient_Strength). It may now happen that on the product package yet another strength expression is printed, that is the strength in terms of the active base. This strength does not have to be stored in structured form, it will suffice to store the expression in text form.
e.g. in entity VIRTUAL_INGREDIENT_STRENGTH → amlodipine-besilaat 5mg
in entity ACTUAL_INGREDIENT_STRENGTH → amlodipine-mesilaat 5,2mg
on product package → "amlodipine-4mg"

Type: Foreign key to entity NAME_EXPLANATION Optional

VIRTUAL_INGREDIENT_CAS_NR: CAS-nr of the virtual ingredient that is replaced by the actual ingredient. This CAS-nr should correspond to one of the CAS-nrs of the virtual ingredients determined for the corresponding VTM.

Type : Foreign key to SUBSTANCE Optional

EXC_IND: Indicates whether the ingredient substance is an excipient or not. For excipients,

the strength is never given.

Type : Boolean Mandatory
Domain : ‘Y’es / ‘N’o

STRENGTH_QUANTITY: (SQ) Quantity of strength. This is the numerical value in the numerator of the strength expression. The strength is never given for excipients.
Example: " 5 " in "amp. inf. 20 x 5mg/10ml"

Alias : SVN (NHS)
Q / INQ (table SAM, DB BCFI)
Type : Numeric(12,3) Optional
Domain : Quantity

STRENGTH_QUANTITY_2: (SQ2) End of the range in the Strength Quantity expression. Only meaningful in case the strength is expressed as a range.
Example: “10” in “5 à 10 mg”

Alias : SVN2 (NHS)
Q2 / INQ2 (table SAM, DB BCFI)
Type : Numeric(12,3) Optional
Domain : Quantity

STRENGTH_UNIT: (SU) Unit of strength. This is the unit of measure associated with the Strength_Quantity (in the numerator of the strength expression). The strength is never given for excipients.
Example: “ mg " in "amp. inf. 20 x 5mg/10ml"

Alias : SVNU (NHS)
U / INU (table SAM, DB BCFI)
Type : String(15) Optional
Domain : see reference list for existing units.

STRENGTH_DENOM_QUANTITY: (SDQ) The numerical value in the denominator of the strength expression..This attribute is only used in case of a continuous product (e.g. liquid, cream, …)
Example: “10" in "amp. inf. 20 x 5mg/10ml"

Alias : SVD (NHS)
BASQ / INBASQ (table SAM, DB BCFI)
Type : Numeric(12,3) Optional
Domain : Quantity

STRENGTH_DENOM_UNIT: (SDU) The unit of measure in the denominator of the strength expression. This attribute is only used in case of a continuous product (e.g. liquid, cream, …)
Example: “ml" in "amp. inf. 20 x 5mg/10ml"

Alias : SVDU (NHS)
BASU / INBASU (table SAM, DB BCFI)
Type : String(15) Optional
Domain : see reference list for existing units.

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: ‘C’orrected, ‘E’volved

2.1.12. AMP_INTERMEDIATE_PACKAGE (AMPINTPCK)

This entity describes the inner package and content quantity (a volume or quantity in case of a continuous substance or the number of units in case of a discrete product) of the AMPP. This entity is necessary to be able to store the inner package of a component of a combination product package. As the AMPP entity can only contain existing commercialised medicinal product packages (identified by a CNK number), the entity AMPP cannot hold the components of a combination pack that do not exist on themselves.
Example: a combination pack with a syrup (I) and tablets (II) in one pack. For this example, this entity holds an occurrence for the inner package for component I and an occurrence for the inner package for component II.

Alias: AMPINTPCK
Semantic key: AMP_ID + CONTENT_QUANTITY + CONTENT_ UNIT

[Attributes]

AMP_ID: Identifier of the corresponding AMP.

Type : Foreign key to AMP Mandatory

CONTENT_QUANTITY: (CQ) Numerical value of the amount of AMP expressed by mass, volume or number of entities in the package as supplied..
Example:
"100" in " Voltaren Emulgel gel 100g 10mg/g PI-Pharma"
“500” in “Lactulose Teva sir. 500ml 3.1g/5ml”
“28” in “Zestoretic 20/12,5 28 tab (oraal)””

Alias : CFQ (table MPP, DB BCFI)
Type : Numeric(12,3) Optional
Domain : Quantity

CONTENT_UNIT: (CU) Unit of measure of the amount of AMP expressed by mass, volume or number of entities in the package as supplied. (ml, mg, vials, tabs, dose, …)
Example:
"g" in " Voltaren Emulgel gel 100g 10mg/g PI-Pharma"
“ml” in “Lactulose Teva sir. 500ml 3.1g/5ml”
“tabs” in “Zestoretic 20/12,5 28 tab (oraal)””

Alias : CFU (table MPP, DB BCFI)
Type : String(5) Optional
Domain : list of predefined units

ADDED_MULTIPLIER: (AM) Multiplier for the solvent volume to be added
Example: "2" in "Flolan flac inf 1 x 1,5mg + 2 x 50 ml solv."

Alias : AQ (table MPP, DB BCFI)
Type : Numeric(4) Optional
Domain : range 0-9999

ADDED_QUANTITY: (AQ) Numerical value for the amount of solvent to be added.
Example: "50" in "Flolan flac inf 1 x 1,5mg + 2 x 50 ml solv."

Alias : AFQ (table MPP, DB BCFI)
Type : Numeric(12,3) Optional
Domain : Quantity

ADDED_UNIT: (AU) Unit of measure for the amount of solvent to be added.
Example: "ml" in "Flolan flac inf 1 x 1,5mg + 2 x 50 ml solv."

Alias : AFU (table MPP, DB BCFI)
Type : String(5) Optional
Domain :

ADDED_TYPE: Code value for the type of the solvent to be added.

Alias : ATYPE (table MPP, DB BCFI)
Type : Character Optional
Domain : s

INNER_PACKAGE_CV: Code value for the inner package

Type: Foreign key to INNER_PACKAGE Optional

PACKAGE_TXT: Free text enabling to store information concerning the package or pack size in free text form.

Type : String(255) Optional
Domain : free text field

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.13. AMP_INT_PCK_COMB (AMPINTCMB)

This entity describes the components of a combination AMP_INTERMEDIATE_PACKAGE. Certain AMPs may consist of two or more products in one package. Each component may have a different inner package and pack size inside the combination package. In this case there will exist an AMP_INTERMEDIATE_PACKAGE for each individual component and an AMP_INTERMEDIATE_PACKAGE for the combination product. This entity describes the different components a combination proudct is composed of.

Semantic key: AMP_ID + CONTENT_QUANTITY + CONTENT_UNIT + AMP_ID_CMB + CONTENT_QUANTITY_CMB + CONTENT_UNIT_CMB

[Attributes]

AMP_ID: Identifier of the single AMP.

Type : Foreign key to AMP Mandatory

CONTENT_QUANTITY: Content Quantity of a single AMP.

Type : Foreign Key to AMP_INTERMEDIATE_PACKAGE Mandatory

CONTENT_UNIT: Content Unit of a single AMP.

Type : Foreign Key to AMP_INTERMEDIATE_PACKAGE Mandatory

AMP_ID_CMB: Identifier of the combination AMP.

Type : Foreign key to AMP Mandatory

CONTENT_QUANTITY_CMB: Content Quantity of a combination AMP.

Type : Foreign Key to AMP_INTERMEDIATE_PACKAGE Mandatory

CONTENT_UNIT_CMB: Content Unit of a combination AMP.

Type : Foreign Key to AMP_INTERMEDIATE_PACKAGE Mandatory

AMP_INT_PCK_CMB_SEQ: Sequence number that identifies the different parts (single AMPs) of a combination AMP. This sequence number is used in order to assign a quantity for each component.
Example :
Trinordiol 3 x (6 + 5 + 10)
I 6 x
II 5x
III 10x

Alias : PPID (table SAM, DB BCFI)
Type : String(4) Mandatory
Domain : I, II, III, IV, V, VI, VII, VIII, IX, X.

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.14. NAME_EXPLANATION (NAMEXP)

For each occurrence of an entity (VTM, ATM, VMP, AMP, AMPP, ...) that has some part of text (name, alias, abbreviation, leaflet text, ...) to be stored, a new name identifier (NAME_ID) is created. This NAME_ID provides a link to all possible types of text and all possible translations of these text parts to be stored for this occurrence.

Semantic key: NAME_ID

[Attributes]

NAME_ID: Identifier that is used by all entities as a link to find all types of text (in different languages) associated to an occurrence of this entity.
The identifier can be linked to a name, posology, leaflet, ...in all possible languages.

Type : Numeric(10) Mandatory
Domain :

SOURCE_TABLE_ID: Number of the entity source name.

Type : String(30) Mandatory
Domain :

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.15. NAME_TYPE (NAMTYP)

Reference entity that covers all types of text in the SAM database (short name, long name, abbreviations, leaflet texts, posology and every other part of text that has to be available in different languages) that can be associated to an occurrence of an entity.

Semantic key: NAME_TYPE_CV

[Attributes]

NAME_TYPE_CV: Code value for the type of the instance name, e.g. 'short name', 'abbreviation', 'alias', 'posology', 'leaflet', ...

Type : string(6) Mandatory
Domain : list of predefined code values

NAME_ID: Link to the name text (in several languages) associated with this NAME_TYPE_CV.

Type : Foreign key to NAME_EXPLANATION Mandatory

NAME_TYPE: String that contains the name type. This is one of the text values (or several concatenated) that can be found through the reference NAME_ID.

Type : string(50) Optional
Domain :

NAME_TYPE_SEQ: Sequence number in order to publish the different text parts in the right order on the website or in the booklet.

Type : number(2) Optional
Domain : values 0 to 99

2.1.16. NAME_TRANSLATION (NAMTRS)

The purpose of the entity is the multilingual management of all sorts of text in the database.
Whenever a name or some piece of text in the database has to be stored in several languages or formats, it is managed by the table NAME_TRANSLATION.
The entity not only handles multilingual texts but also links different types of text content to the same name identifier.

The semantic key is composed of a combination of a name identifier present in the origin table (which can be VTM, ATM, VMP, …), a name type and a language code.
Semantic key: NAME_ID + LANGUAGE_CV + NAME_TYPE_CV

[Attributes]

NAME_ID: Foreign key to NAME_EXPLANATION Mandatory

NAME_TYPE_CV: Foreign key to NAME_TYPE Mandatory

LANGUAGE_CV: Language code value, ISO 639 (2-letter code)
e.g. NL → “Dutch”, FR → “French”, EN → “English”, DE → “German”,…

Type : string(2) Mandatory
Domain : 2-letter codes defined in ISO 639

SHORT_TEXT: Short text field for the names, alias names, … In most cases either SHORT_TEXT or LONG_TEXT will be present.

Type : string(300) Optional
Domain :

LONG_TEXT: Long text field for the posology, indications, leaflet text, …

Type : clob Optional

Domain : String - Memo

LONG_BINARY_TEXT : Binary Long object for PDF document about the posology, indications, leaflet text, …

Type : blob Optional
Domain : Binary

ADDRESS_URL: field to store an URL address

Type : string(255) Optional
Domain :

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.17. SUBSTANCE (SUBST)

This entity describes the chemical properties of substances.
These can be active substances (the active base as well as salt or ester forms will have an occurrence) or excipients. The information within this entity concerns the chemical properties of the substances, NOT their characteristics as a therapeutical moiety.
Substances should not necessarily exist as a therapeutic moiety. Every therapeutic moiety however, should be linked with at least one substance.

Alias: SUBST
Primary key: CAS_ID

[Attributes]
CAS_ID: technical identifier of a substance Mandatory

Type : Numeric(10)
Domain :

CAS_NR: CAS registry number (Chemical Abstract Service). Unique numerical identifiers for chemical elements, compounds, polymers, biological sequences, mixtures and alloys. There is however not a CAS_NR for every substance stored in the database.
Format: A CAS registry number is separated by hyphens into three parts, the first consisting of up to 7 digits, the second consisting of two digits, and the third consisting of a single digit serving as a check digit. The numbers are assigned in increasing order and do not have any inherent meaning.

Type : Numeric(10) Mandatory
Domain :

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

EXC_IND: Flag that indicates whether the substance is an excipient or not.

Type : Boolean Mandatory
Domain : 'Y'es / 'N'o

ACTIVE_BASE_IND: Flag that says whether the substance represents an active base or not. This means, an active substance in its base form.

Type : Boolean Mandatory
Domain : 'Y'es / 'N'o

BASE_FORM_CAS_NR: CAS_NR of the base form of the substance. References itself.

Type : Numeric(10) Optional
Domain :

DERIV_FORM_TYPE: Type of the substance: (code-value)
Example: salt, ester, amide, ...

Type : String(2) Optional
Domain : predefined list of derived forms (e.g. salt, ester, amide, ..)

2.1.18. ATC

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. The ATC classification is controlled by the WHO Collaborating Centre for Drug Statistics Methodology (WHOCC).

Semantic key: ATC_CV
Authentic source : WHO

[Attributes]

ATC_CV: ATC code in 5 levels representing the classification system for drugs.

Type : String(7) Mandatory
Domain :

ATC_CV_PARENT: ATC code of the parent in the hierarchical classification (one level higher)

Authentic source : WHO
Type : String(7) Optional
Domain :

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

FINAL_LEVEL_IND: Indicates whether this is a leaf in the hierarchy or not.

Type : Boolean Mandatory
Domain : 'Y'es / 'N'o

FLAT_RATE_IND: Is there any flat rate on this ATC Code ?

(Depuis le 1er juillet 2006, l'assurance obligatoire soins de santé rembourse à chaque hôpital aigu un montant forfaitaire par admission pour les médicaments remboursables. Le forfait, fixé sur base des consommations moyennes des médicaments par pathologie est défini pour chaque hôpital en fonction des pathologies qu'il traite. Les médicaments coûteux et peu fréquents n'ont pas été intégrés dans le forfait. Une série de produits spécifiques ont été exclus de la forfaitarisation, notamment les médicaments orphelins, les cytostatiques, les immunoglobulines, l'albumine, les anti-sida et les radio-isotopes.)

Type : Boolean Optional

Domain : 'Y' or 'N' = 'Null'

2.1.19. HYR

HYR Classification is an internal hierarchical classification used at the BCFI for the layout of the booklet (Gecommentarieerd Geneesmiddelenrepertorium) and the BCFI website.
This is not the same classification as the ATC classification system.

Semantic key: HYR_ID
Authentic source : BCFI

[Attributes]

HYR_ID : Unique identifier for the HYR-level. Each HYR_ID has an HYR_CODE (e.g. 'AABB') that represents a node in an hierarchical tree. This identifier will always point to the same node in the hierarchy, but the corresponding code can change in time whereby the old code value can be attributed to a new node. Therefore, the HYR code itself cannot serve as the primary key and an HYR identifier
is necessary.

Type : Numeric(10) Mandatory
Domain :

HYR_CV : HYR code as used in the internal hierarchical classification by the BCFI .

Type : String(10) Mandatory
Domain :

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

FINAL_LEVEL_IND: Indicates whether this is a leaf in the hierarchy or not.

Type : Boolean Mandatory
Domain : 'Y'es / 'N'o

HYR_ID_PARENT: Identifier for the HYR code of the parent level

Authentic source : BCFI Optional
Type : Foreign key to HYR

2.1.20. APPLICATION (APPL)

The application road is a limited (+- 20 possibilities) but standardised classification of route forms, an abstracted and high-level combination of pharmaceutical form and route of administration. It is the highest level of granularity for expressing the dosage form and represents the third pillar in the VOS-cluster concept. The application road is represented by a character code and a name and description in NL and FR.

Alias: APPL
Semantic key: APPLICATION_CV
Authentic source : BCFI

[Attributes]

APPLICATION_CV: Code value for the application road (unique).

Alias : NBASIS/FBASIS (table GAL, DB BCFI)
Type : String(15) Mandatory
Domain : inhal., inj., oral, inj./oral, …

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

2.1.21. ROUTE_OF_ADMINISTRATION (ROUTE)

The Route(s) of Administration is the representation of the path by which a drug is brought into contact with the body in order to achieve the desired therapeutic effect.

Alias: ROUTE
Semantic key: ROUTE_ADM_CV
Authentic source : EDQM

[Attributes]

ROUTE_ADM_CV: Code value of the route of administration.

Alias : NROAD/FROAD (table GAL, DB BCFI)
Type : String(15) Mandatory
Domain : List of roads to be defined. Examples: inj., inf., inj./inf., oral, dermal, …

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

APLLICATION_CV: Code value of the corresponding application road. Every route of administration can be classified into exactly one application road.

Type : Foreign key to APPLICATION_ROAD Mandatory

2.1.22. ADMINISTRATION_FORM (ADM)

The administration form is the form in which a medicinal product is administered, including the physical form.

Alias: ADM
Semantic key: ADM_FORM_ID
Authentic source : EDQM

[Attributes]

ADM_FORM_ID: Code value for the Administration Form (unique).

Authentic source : EDQM
Type : Number(5) Mandatory
Domain: List to be defined.

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

2.1.23. PHARMACEUTICAL_FORM (PHARMF)

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)

Alias: GAL
Semantic key: PHARM_FORM_CV
Authentic source : EDQM

[Attributes]

PHARM_FORM_CV: Code value for the Pharmaceutical Form (unique).

Type : Number(5) Mandatory
Domain: List to be defined.

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

NO_INN_IND: No-VOS label. INN prescription is not allowed for this pharmaceutical form.

Alias : NoVos (table GAL, DB BCFI)
Type : Boolean Optional
Domain : 'Y'es / 'N'o 'Null' equals 'N'

DIVIDABLE_IND: Flag that indicates whether it concerns a dividable pharmaceutical form or not.

Alias : DEELB (table GAL, DB BCFI)
Type : Boolean Optional
Domain : 'Y'es / 'N'o 'Null' equals 'N'

ENTERIC_COATED_IND: Enteric coated or not. (Maagsap resistent)

Alias : EC (table GAL, DB BCFI)
Type : Boolean Optional
Domain : 'Y'es / 'N'o 'Null' equals 'N'

RETARDED_IND : Retarded activity or not..

Alias : RET (table GAL, DB BCFI)
Type : Boolean Optional
Domain : 'Y'es / 'N'o 'Null' equals 'N'

SOLID_TO_LIQUID: Code that represents the solid to liquid transformation.

Alias : S2L (table GAL, DB BCFI)
Type : String(2) Optional
Domain : list of codes for solid to liquid transformations

AEROSOL_TYPE: Type of aerosol to be used.

Alias : AERO (table GAL, DB BCFI)
Type : String(2) Optional
Domain : list of predefined types

TOOL: Code for the tool to use for the application.

Alias : TOOL (table GAL, DB BCFI)
Type : String(2) Optional
Domain :

VEHIC_IND : Flag indicating whether the pharmaceutical form needs a vehiculum in order to be applied or not. e.g. creams.

Alias : VEHIC (table GAL, DB BCFI)
Type : Boolean Optional
Domain : 'Y'es / 'N'o 'Null' equals 'N'

CRUSHABLE_IND : Indicates whether the product may be crushed or not.

Alias : PLET (table GAL, DB BCFI)
Type : Boolean Optional
Domain : 'Y'es / 'N'o 'Null' equals 'N'

2.1.24. WADA (WADA)

This entity describes the WADA doping codes with their description and translation in NL, FR and EN.

Semantic key: WADA_CV
Authentic source : WADA

[Attributes]

WADA_CV: WADA code

Type : String(6) Mandatory
Domain: /, A, B, 2, 2C, B2, C, c, D, DB, d, Hman, H, M, N, O, AO, p, S, s, … new values are possible.

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

2.1.25. COMPANY (CPY)

This entity contains information regarding pharmaceutical companies. This company is generally the marketing authorisation holder (on Belgian market), but can also be the distributor of the product.

Alias: IR, FIRM
Semantic key: COMPANY_ID

[Attributes]

COMPANY_ID: Unique identification of the company.

Type : Number(5) Mandatory
Domain:

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

PIP_IND: Flag that indicates whether the information responsible is active or not.

Type : Boolean Optional
Domain: Y(es), N(o)

2.1.26. INNER_PACKAGE (PCKG)

The inner package is the material that is in direct contact with the medicinal product.
Example: ampoule glass, blister alu/alu, blister pvc/alu, flacon glass, ..

Alias: PCKG
Semantic key: PACKAGE_CV

[Attributes]

INNER_PACKAGE_CV: Code value for an inner package

Type : String(2) Mandatory
Domain:

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

2.1.27. TREATMENT_DURATION_CATEGORY (DURCAT)

Category of the pack size in terms of treatment duration. This can be one shot, one day, 2 till 4 days, 5 to 7 days, week, month, trimester, … The rule that is applied here is: 7 x + 6.

Semantic key: TREATMENT_DURATION_CAT_CV

[Attributes]

TREATMENT_DURATION_CAT_CV: Code value representing the category of treatment duration.

Type : String(2) Mandatory
Domain:

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

TREATMENT_DURATION_VALUE: Value for expressing the treatment duration.

Type : Number(4) Optional
Domain: 0 to 9999

TREATMENT_DURATION_UNIT: Unit for expressing the treatment duration.

Type : String(5) Optional
Domain: ‘day’, ‘week’, ‘month’, ‘trimester’, ..

Part 2 : Chapter IV

2.1.28. PARAGRAPH (PARA)

This entity corresponds with the arrangement of the section of the legislation into numbered paragraphs and subparagraphs (the numbers of the paragraphs end in 4 consecutive zeros, the subparagraphs have numbers at these positions)

Semantic Key : Chapter name + Paragraph name

CHAPTER_NAME : The name of the chapter involved in the reimbursement conditions of medicines as stated in the royal decree of 21 December 2001 and the royal decrees modifying this one. Attention has to be paid that this name should continue to be unique even if other legislations equally produce chapters on the reimbursement of medicines.

Type : String (10) Mandatory
Domain : Currently presumed : 'I', 'II', 'III', 'IV', 'IV-BIS', 'V', 'VI'.

PARAGRAPH_NAME : The name of the paragraph or the subparagraph, which for the presumed chapters (see below), is limited to an identification number. The last 4 numbers representing variations within the same subject. Although currently no letter has made an appearance, the option to restrict this name only to numbers is not imposed.

Type : String(10) Mandatory
Domain : Currently presumed : Numeric(8)

KEY_STRING_NL : String of characters covering the most representative key words (in NL) of the paragraph content. Words are not taken independently of one another in order to make an index, but rather to univocally express the primary destination of the paragraph, hereby avoiding ambiguities and removing possible redundancies with other paragraphs.

Type : String (500) Optional
Domain : Group of keywords

KEY_STRING_FR : Idem as KEY_STRING_NL but covering key words in FR.

Type : String (500) Optional
Domain : Group of keywords

AGREEMENT_TYPE : Value identifying the authorisation model and therefore also the documents delivered by the insurance organisation to the patient. If only one authorization model is defined for the paragraph, it is stored in this field. If there is a different model to be delivered in case of prolongation of an existing agreement, this field contains the authorizations model in case of a new or first request.

Type : Character Optional
Domain : 'B', 'C', 'D' et 'E'

PROCESS_TYPE : information reserved to insurance organisations

Type : Numeric(1) Optional
Domain : 0, 1, 2, 3 (= 1 + 2), 4 (= 2 + 1), 5, 6, 7. Value can't be null when CHAPTER_NAME = 'IV'.

LEGAL_REFERENCE : References to the legal text that created this paragraph for the first time.

Type : String (100) Mandatory
Domain : e.g. reference number of the Belgisch Staatsblad/Moniteur Belge

PUBLICATION_DATE : Date of the first publication of the paragraph in the reference specified by LEGAL_REFERENCE.

Type : Date Mandatory
Domain : Valid date

MODIFICATION_DATE : Date of the last update of the content of the paragraph. This can be an update of the text inside the verses or an update of the parameters saved within the entity PARAGRAPH, except for modifications concerning the amounts of the reimbursements. The entity REIMBURSEMENT will handle its history independently of the paragraph history.

Type : Date Mandatory
Domain : Valid date > PUBLICATION_DATE

PROCESS_TYPE_OVERRULE : information reserved to insurance organisations

Type : String (10) Optional
Domain :

AGREEMENT_TYPE_PRO : Value identifying the authorisation model in case of prolongation of an agreement. Null means that first and renewal authorisation are the same; see AGREEMENT_TYPE.

Type : Character Optional
Domain : 'B', 'C', 'D' et 'E'

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.29. PARAGRAPH_TRACE (PARTRA)

This entity corresponds with the history of splitting and merging of the paragraphs. Each paragraph may point to its obsolete parent. In case of paragraph splitting, the two new paragraphs reference the same old parent. In case of merge, the new paragraph references the originally separate parents.

Semantic Key : Chapter name + Paragraph name + Parent Chapter name + Parent Paragraph name.

CHAPTER_NAME : The name of the chapter containing the current paragraph. See the entity PARAGRAPH for more details.

PARAGRAPH_NAME : The name of the current paragraph or subparagraph, which for the presumed chapters, is limited to an identification number. See the entity PARAGRAPH for more details.

PARENT_CHAPTER_NAME : The name of the chapter containing the parent paragraph. See the entity PARAGRAPH for more details.

PARAGRAPH_NAME : The name of the parent paragraph or subparagraph, which for the presumed chapters, is limited to an identification number. See the entity PARAGRAPH for more details.

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: ‘C’orrected, ‘E’volved

2.1.30. VERSE (VERS)

The entity VERSE is the partition of the text of the paragraph according to specific topics or exclusive conditions. Every time the text expresses a choice to make by the prescriber, the paragraph is divided into VERSES. So the text representing the diagnostics linked with the paragraph will be the subject of a VERSE, or several VERSEs if the prescriber has to choose among several propositions of pathologies. The parts of the text containing information to be structured like the minimum and maximum age, limitations linked to the profession of the prescriber, … will be highlighted in a particular verse thus enabling to be marked as type ‘AGE or ‘PROF’. In case the paragraph does not present any alternatives, there is no reason to split the paragraph, and so certain paragraphs have only one VERSE.

Semantic key : Chapter name + Paragraph name + Sequence number of the verse.

CHAPTER_NAME : Foreign key (FK) inherited from PARAGRAPH

PARAGRAPH_NAME : Foreign key (FK) inherited from PARAGRAPH

VERSE_SEQ : Sequence number of the verse within the paragraph. This number enables among other things to rearrange the original legislation text.

Type : Numeric(2) Mandatory
Domain : Unique sequence within a paragraph

VERSE_NUM : Unique number assigned to a verse, among all the verses of the database. This number enables among others to handle the different versions modified.

Type : Numeric(6) Mandatory
Domain : Unique sequence among all the verses of the database.

VERSE_SEQ_PARENT : Pointer towards the parent verse of the actual verse. The notion of parent is essential in the hierarchical structuring of the paragraph in verses. In fact, the alternatives are always arranged side by side underneath a header verse. This header does not only group the alternatives of the same level, but also specifies the minimum number of choices to make within these alternatives one level lower.

Type : Numeric(2) Mandatory
(for the first verse VERSE_SEQ_PARENT = 0)
Domain : The largest sequence number below the current sequence number for which the level is the current level minus one.

VERSE_LEVEL : Position of the verse in the hierarchy of the paragraph, this number gives the level of the current verse compared to the other verses.

Type : Numeric(2) Mandatory
Domain : 1 to <= (previous level + 1).

VERSE_TYPE : Type of the verses, according to the content of the verse the type will be diagnostic, condition, exclusion, notification , title, warnings, …

Type : String(2) Optional
Domain : Actually only value “E” is used to indicate where the verse stipulates exclusion restrictions.

CHECK_BOX_IND : Does the current verse represent a choice among several alternatives of the same level ? If so a flag must be set in the interface, this field enables to indicate this characteristic.

Type : Boolean Mandatory
Domain : 'Y'es / 'N'o

MIN_CHECK_NUM : Minimum amount of choices to be made within the verses one level higher (level + 1) - uninterrupted by a lower level - in order for the choice to be validated according to the legislation. So every verse with a checkbox has to have a parent verse with a granted MIN_CHECK_NUM. And vice versa, every verse with a value > 0 for MIN_CHECK_NUM has to have minimum two children verses with CHECK_BOX_IND equal to 'Y'.

Type : Numeric(2) Optional
Domain : Number value lower or equal to the number of children verses having CHECK_BOX_IND = 'Y'.

AND_CLAUSE_NUM : Number of the group for which several branches are involved in order to realise a coherent choice. If the valid choice foresees to mark several verses in different non contiguous parts of the paragraph, and therefore in branches not depending on the same parent, grouping according to a random number is planned.

Type : Numeric(6) Optional
Domain : Random number, different for each group within the DB.

TEXT_FR: French version of the part of the legislation text within the verse.

Type : Long text Mandatory
Domain : Extract from the legislation text or form.

TEXT_NL: Dutch version of the part of the legislation text within the verse.

Type : Long text Mandatory
Domain : Extract from the legislation text or form.

REQUEST_TYPE : The reimbursement requests can be made for a first prescription of a medicine or for the prolongation of an already prescribed medicine for this patient. The legislation text may itself allude to one or the other of these options. The verse can thus itself be dedicated to a request of the type prescription prolongation or to a first request. Not all the verses are required for these two types of requests, this indicator enables to formalise the application field of the verse. 'Null', the default option, represents the common option, this means that the verse is valid for a first prescription as well as for a prolongation.

Type : Character Optional
Domain : N = New request, P = Renewal (prolongation), 'Null' = both (N & P)

AGREEMENT_TERM : In accordance with the field AGREEMENT_TERM_UNIT, the number of units of periods during which the authorisation of the reimbursement is valid.

Type : Numeric(3) Optional
Domain : The choice among days/months/years is made by minimising the multiplying factor.

AGREEMENT_TERM_UNIT : Unit in which the validity period of the reimbursement authorisation is expressed.

Type : Character Optional
Domain : 'D' days / 'M' months / 'W' weeks / 'Y' years

MAX_PACKAGE_NUMBER : The maximum number of packages reimbursed during the

period of reimbursement authorisation.

Type : Numeric(3) Optional
Domain : -

PURCHASING_ADVISOR_QUAL_LIST : The prescription of certain medicines is limited to certain recognised medical profiles. If the profession does not have a well-established code or if there are several authorised codes to prescribe or if there is a list with the names of authorised prescribers, an exhaustive list will be set up mentioning either the codes or the names and will be saved in an entity ad hoc. The term by which this list will be known, will be saved in this field.

Type : String(10) Optional
Domain : the list of medical professions recognised by the NIHDI.

LEGAL_REFERENCE : The references to the legal text for a verse are only justified if these are different from the ones of the paragraph. It will therefore always be a modification subsequent to the initial creation of the paragraph.

Type : String (100) Mandatory
Domain : <> LEGAL_REFERENCE of the paragraph

MODIFICATION_DATE : The date of the modification of the verse will be set only if this one is different from the PUBLICATION_DATE of the paragraph. This difference in date can occur if a modification is done for one particular verse or if a new verse is added to the paragraph. If any part of the paragraph text changes the MODIFICATION_DATE of the paragraph, the paragraph must find at least one echo among the MODIFICATION_DATEs of the verses. Only parameter changes on paragraph level can create a singularity, a change in PROCESS_TYPE or KEY_STRING.

Type : Date Optional
Domain : Valid date > PUBLICATION_DATE of the paragraph

AGREEMENT_YEAR_MAX : The maximum number of years during which the reimbursement authorisation is valid.

Type : Numeric(2) Optional
Domain : -

AGREEMENT_RENEWAL_MAX : The maximum number of renewals allowed for this agreement.

Type : Numeric(3) Optional
Domain : -

SEX_RESTRICTED : Does there exist an inadequacy between the medicine and one of the two sexes ?

Type : Character Optional
Domain : 'F' = Female restriction, 'M' = Male restriction

MINIMUM_AGE_AUTHORIZED : If there is a restriction in relation to the minimum age of the patient for this medicine, this field gives the lower bound of the number. The minimum age is 'inclusive', i.e. permitting higher values. E.g. value 2 means "2 or older" or "at least 2".

Type : Numeric(3,1) Optional
Domain :

MINIMUM_AGE_AUTHORIZED_UNIT : Unit for the minimum age of the patient for this medicine.

Type : String(5) Optional
Domain : D(ays), W(eeks), M(onths), Y(ears)

MAXIMUM_AGE_AUTHORIZED : If the medicine can only be reimbursed for a patient who has past a certain age, this field gives this upper bound.

Type : Numeric(3,1) Optional
Domain :

MAXIMUM_AGE_AUTHORIZED_UNIT : Unit for the maximum age of the patient for this medicine.

Type : String(5) Optional
Domain : D(ays), W(eeks), M(onths), Y(ears)

MAXIMUM_CONTENT_QUANTITY : Maximum number of medicinal product unities (tablets, ampoules, ...) or maximum volume of a solution that is reimbursed during a certain period.
Alias: MAX_CQ
E.g. paragraph 1880000, MAX_CQ=364 (13 x 28) in :
" De machtiging tot vergoeding op basis van de in 1) vermelde voorwaarden wordt verleend voor hernieuwbare periodes van 12 maanden en wordt beperkt tot maximum 13 verpakkingen van 28 x 75 mg per periode of tot maximum 1 verpakking van 28 x 75 mg en 4 verpakkingen van 84 x 75 mg per periode."

Type : Numeric(12,3) Optional
Domain : -

MAXIMUM_CONTENT_UNIT : Unit for the maximum number of medicinal product unities (tablets, ampoules, ...) or maximum volume of a solution that is reimbursed during a certain period.
Alias: MAX_CU
E.g. paragraph 1880000, MAX_CU=unit in :
" De machtiging tot vergoeding op basis van de in 1) vermelde voorwaarden wordt verleend voor hernieuwbare periodes van 12 maanden en wordt beperkt tot maximum 13 verpakkingen van 28 x 75 mg per periode of tot maximum 1 verpakking van 28 x 75 mg en 4 verpakkingen van 84 x 75 mg per periode."

Type : String(5) Optional
Domain :

MAXIMUM_STRENGTH_QUANTITY: Strength of the unities (tablets, ampoules, ..) or strength of the solution in the maximum daily posology during a certain period.
Alias: MAX_SQ
E.g. paragraph 1250000, MAX_SQ = 40 in :
"De patiënt bij wie endoscopie of, in geval van onmogelijkheid gestaafd door documenten, het radiografie-onderzoek een maagulcus aantoont, kan terugbetaling krijgen voor :
- een behandeling met een maximum posologie van 40 mg per dag gedurende 8 weken;"

Type : Numeric(12,3) Optional
Domain :

MAXIMUM_STRENGTH_UNIT : Unit of Strength of the unities (tablets, ampoules, ..) or strength of the solution in the maximum daily posology reimbursed during a certain period.
Alias: MAX_SU
E.g. paragraph 1250000, MAX_SU= mg in :
"De patiënt bij wie endoscopie of, in geval van onmogelijkheid gestaafd door documenten, het radiografie-onderzoek een maagulcus aantoont, kan terugbetaling krijgen voor :
- een behandeling met een maximum posologie van 40 mg per dag gedurende 8 weken;"

Type : String(15) Optional
Domain :

MAXIMUM_DURATION_QUANTITY : Numerical value in the expression of the duration of reimbursement for a maximum daily posology. In exceptional cases, the numerical value in the expression of the administration frequency may be stored in this field instead.
Alias: MAX_DURQ
E.g. paragraph 1250000, MAX_DURQ= 8 in :
"De patiënt bij wie endoscopie of, in geval van onmogelijkheid gestaafd door documenten, het radiografie-onderzoek een maagulcus aantoont, kan terugbetaling krijgen voor :
- een behandeling met een maximum posologie van 40 mg per dag gedurende 8 weken;"

Type : Numeric(12,3) Optional
Domain :

MAXIMUM_DURATION_UNIT : Unit to express the duration of reimbursement for a maximum daily posology. In exceptional cases, the unit in the expression of the administration frequency may be stored in this field instead.
Alias: MAX_DURU
E.g. paragraph 1250000, MAX_DURU= 'weeks' in :
"De patiënt bij wie endoscopie of, in geval van onmogelijkheid gestaafd door documenten, het radiografie-onderzoek een maagulcus aantoont, kan terugbetaling krijgen voor :
- een behandeling met een maximum posologie van 40 mg per dag gedurende 8 weken;"

Type : String (5) Optional
Domain : ‘days’, ‘weeks’, ‘months’, …

OTHER_ADDED_DOCUMENT_IND : Are there complementary documents that are indispensable to take a decision concerning the reimbursement authorisation ? Attention, this indicator is not a denormalisation of the electronic documents specified within ADDED_DOCUMENT, it references the medical documents that are part of the patient file and for which there does not exist an electronic version in this DB. In order to know if there are complementary documents to deliver, one should not only verify if there are no occurrences of document in the entity ADDED_DOCUMENT but also check this indicator.

Type : Boolean Optional
Domain : ‘Y’es / ‘N’o ‘Null’ equals ‘N’ : no complementary documents

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: ‘C’orrected, ‘E’volved

2.1.31. QUALIFICATION_LIST

Table enabling the storage of multiple qualification lists of professional codes and/or the names of the prescribers authorised to prescribe a certain panel of medicines. These lists will be associated to verses, the same list possibly being used for several verses, even in different paragraphs.

Semantic key : QUALIFICATION_LIST

QUALIFICATION_LIST : Listname of the list of professional qualification or codes as defined by the NIHDI

Type : String(10)
Domain : Unique free text within all the lists

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

EXCLUSIVE_IND : indicates whether qualifications in the list should all apply simultaneously or just one.

Type : String(1) Optional
Domain : 1 = OR; 2 = AND

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.32. PROFESSIONAL_CODE (PROFCD)

List of medical professions recognised by the NIHDI.

Semantic key : PROFESSIONAL_CV

PROFESSIONAL_CV : Professional classification code within the medical sphere.

Type : String(10) Mandatory
Domain : All codes in the list of medical professions of the NIHDI

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

PROFESSIONAL_NAME : The prescription for certain medicines is limited to certain recognised medical profiles. These restrictions are subject of a list linked to by the field PURCHASING_ADVISOR_QUAL_LIST.

Type : String(50) Optional
Domain : The default denomination of the medical profiles according to the code

2.1.33. PROFESSIONAL_AUTHORISATION (PROFAU)

This entity sets up the list of professional codes and/or the names of the prescribers authorised to prescribe a certain panel of medicines. These lists will be associated to verses, the same list possibly being used for several verses, even in different paragraphs.

Semantic key : PROFAU_ID

PROFAU_ID : unique technical identifier to PROFESSIONAL_AUTHORISATION

Type : Number(10)

QUALIFICATION_LIST : Identifier for the list enabling the grouping of its members. All the professional codes and the names of potential prescribers of the same list will have the same QUALIFICATION_LIST.

Type : Foreign key to entity QUALIFICATION_LIST Mandatory
Domain : Unique free text within all the lists

PROFESSIONAL_CV : Foreign key (FK) inherited from the entity PROFESSIONAL_CODE.

Type : String(10) Optional

PURCHASING_ADVISOR_NAME : Name of an authorised prescriber.

Type : String(50) Optional
Domain : Free text

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.34. FORM_TYPE

Classification of the form types related to an added document.

FORM_TYPE_ID: Identifier for the form type. The ID is managed by the NIHDI/INAMI/RIZIV and NOT in the database SAM!

Type : Numeric(3) Mandatory
Domain :

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

2.1.35. APPENDIX_TYPE

Type of the annex connected to an added document.

APPENDIX_TYPE_ID: Identifier for the appendix type.
The ID is managed by the NIHDI/INAMI/RIZIV and NOT in the database SAM!

Type : Numeric(2) Mandatory
Domain :

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

2.1.36. ADDED_DOCUMENT (ADDOC)

This entity holds the electronic version of the complementary documents requested as part of a reimbursement request for the medicines listed in the verses. (These documents are not in relation to the indicator ADDED_DOCUMENT_IND, see VERSE).

CHAPTER_NAME : Foreign key (FK) inherited from VERSE

PARAGRAPH_NAME : Foreign key (FK) inherited from VERSE

VERSE_SEQ : Foreign key (FK) inherited from VERSE

DOCUMENT_SEQ : Sequence number of the document within the verse.

Type : Numeric(4) Mandatory
Domain : Unique sequence within a verse

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

FORM_TYPE_ID : Unique Form Demand identifier internal at NIHDI.
This identifier is managed at the NIHDI.

Type: Foreign key to entity FORM_TYPE

APPENDIX_TYPE_ID : Identifier for the appendix type.

Type: Foreign key to entity APPENDIX_TYPE

MIME_TYPE : Electronic type of the document content.

Type : String(10) Optional
Domain : list of recognised extension codes for electronic files.

DOCUMENT_CONTENT : Electronic version of the complementary document to be provided.

Type : Long Binary Optional
Domain : Electronic format of the document described in the field MIME_TYPE.

ADDRESS_URL : Field to store an URL address

Type : String(255) Mandatory
Domain :

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.37. EXCLUSION (EXCL)

The authorisation of the reimbursement can also depend on a previous authorisation granted for another medicine. If this one appears within the exclusions linked to the accused paragraph, the authorisation will be rejected.

Semantic key : CHAPTER_NAME + PARAGRAPH_NAME + EXCLUSION_TYPE + IDENTIFIER_NUM

CHAPTER_NAME : Foreign key (FK) inherited from PARAGRAPH

PARAGRAPH_NAME : Foreign key (FK) inherited from PARAGRAPH

EXCLUSION_TYPE : What is the type of formulation used to express the exclusion of this medicine in the reimbursement possibilities for this patient. In other ways, in what form has the exclusion been formulated in the legislation text, according to a speciality, an active

substance, a group of medicines, an enumeration, … Type 'T' refers to the text itself when the exclusion could not be structured in any other type of formulation.

Type : Character Optional
Domain :
T : Text => VERSE_NUM of the verse containing the text of the exclusion
C : Criteria => reimbursement criterion fixed by the NIHDI
S : Speciality => ATM ID
A : ATC Code => ATC code
D : Cluster Code => VMP_ ID
J : Paragraph = PARAGRAPH NAME
I : Internal => all specialities attached to the PARAGRAPH (THERAPY) = list of ATM ID
K : Packaged product = AMPP => CNK Identifier
E : Exception => Certain medicines within a classification can nevertheless be the subject of a reimbursement authorisation.

IDENTIFIER_NUM : Identifier in another entity of the term excluding the reimbursement. The determination of the entity is made thanks to the field EXCLUSION_TYPE. (The implementation of these identifiers in one or several fields remains the domain of the physical structuring)

Type : String Mandatory
Domain : In function of the EXCLUSION_TYPE

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.38. THERAPY (THER)

Link between the diagnoses formulated in the paragraphs and the pharmacological answers equally mentioned in the paragraphs.

CHAPTER_NAME : Foreign key (FK) inherited from PARAGRAPH

PARAGRAPH_NAME : Foreign key (FK) inherited from PARAGRAPH

ATM_ID : Foreign key (FK) inherited from ATM

MASKED_IND : Certain specialities do not have to be presented to the user for reasons of manipulation effected only in hospital or ambulant environment. Hospitals are not required to request a prior agreement for specialties exclusively administered in a hospital or ambulant setting. But among these, certain specialities nevertheless have to be visible (classification 'Orphan' or 'Anti-tnf'). Other medicines are reimbursed within paragraphs dedicated to care programs or diabetes conventions, for which no prior agreement needs to be requested.The specialties assembled under these paragraphs are also given a different indicator. At last, another indicator point out the medecines to which the third payer regulation applies without prior agreement

Type : Numeric(1) Optional
Domain :
0 all public specialties (CNK_PUB)
1 all paragraphs refunding specialties exclusively administered in hospitals (CNK_AMB and/or CNK_HOSP) and which are NO Orphan medecines or Anti-tnf
2 all paragraphs refunding specialties exclusively administered in hospitals (CNK_AMB and/or CNK_HOSP) and which are Orphan medecines or Anti-tnf
3 all paragraphs refunding specialties prescribed in careprograms or diabetes

conventions
4 medecines to which the third payer regulation applies without prior agreement

REIMB_CATEGORY_CV : Reimbursement category of the speciality.

Type: Foreign key (FK) inherited from REIMBURSEMENT_CATEGORY. Mandatory

REIMB_CRITERIA_CV: Reimbursement criteria of the speciality.

Type: Foreign key (FK) inherited from REIMBURSEMENT_CRITERIA . Mandatory

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.39. PRICE (PRC)

Definition of the price section and calculation basis for the reimbursement in function of the environment in which the medicine is delivered.

Semantic key : AMPP_ID + DELIVERY_ENVIRONMENT

AMPP_ID: Foreign key (FK) inherited from AMPP

DELIVERY_ENVIRONMENT: Type of the environment in which the medicine is delivered : in the pharmacy, in the hospital or ambulant. The price 'Ex-Usine / buiten bedrijf' is also considered to be a particular price of the entity PRICE.

Type : Character Mandatory
Domain : 'P' = Public , 'H' = Hospital , 'A' = Ambulant , 'E' = Ex-Usine

PRICE_AMNT : Price of the medicine in Euro.

Type : Numeric(10,4) Mandatory
Domain : Amount in Euro

REIMB_BASE_PRICE : Base price in Euro for the calculation of the reimbursement.

Type : Numeric(10,4) Mandatory
Domain : Amount in Euro

REFERENCE_BASE_PRICE : Reference price for the calculation of the reimbursement.

Type : Numeric(10,4) Mandatory
Domain : Amount in Euro

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.40. REIMBURSEMENT_CATEGORY (RMCAT)

List of the different categories of reimbursements defined by the NIHDI.

REIMB_CATEGORY_CV : Reimbursement category.

Type : String(2) Mandatory
Domain : 'A' , 'B', 'C' , 'Cs' , 'Cx', 'Fa', 'Fb'

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

CATEGORY_NAME : Standard name for the reimbursement category.

Type : String(50) Optional
Domain : Free text

2.1.41. REIMBURSEMENT_CRITERIA (RMCRT)

Statement of all the reimbursement criteria defined by the NIHDI.

REIMB_CRITERIA_CV: Reimbursement criterion

Type : String(6) Mandatory
Domain : par exemple "B_215, Cs_004, …"

NAME_ID : Identifier that links an occurrence to all types of text associated to this occurrence, e.g. name, posology, leaflet, ...and this in different languages.

Type: Foreign key to entity NAME_EXPLANATION Mandatory

CRITERIA_NAME : Standard name for the reimbursement criterion.

Type : String(50) Optional
Domain : Free text

2.1.42. REIMBURSEMENT (REMB)

Point of convergence of the information coming from the Medicines sphere and the Social sphere. At this point the social component is taken into account in the price of the medicine and therefore in the reimbursement price.

CHAPTER_NAME : Foreign key (FK) inherited from THERAPY

PARAGRAPH_NAME : Foreign key (FK) inherited from THERAPY

ATM_ID : Foreign key (FK) inherited from THERAPY

AMPP_ID : Foreign key (FK) inherited from PRICE

DELIVERY_ENVIRONMENT : Foreign key (FK) inherited from PRICE

REFERENCE_BASE_IND : Is the reference price to be used for this reimbursement or not ?

Type : Boolean Optional
Domain : 'Y'es / 'N'o 'Null' equals 'N' : Normal base price

PACKAGE_AGREEMENT : Does the agreement on the reimbursement allow several packages for the same authorisation ? Certain particularities of the agreement are expressed here according to codes.

Type : Character Optional
Domain : 'Null' / 'M' = possibility of delivery of several packages, 'V'

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.1.43. COPAYMENT (COPAY)

This entity represents the patient contribution in function of the social or medical profile of the patient, evidently taking into account the environment in which the medicine is delivered.

CHAPTER_NAME : Foreign key (FK) inherited from REIMBURSEMENT

PARAGRAPH_NAME : Foreign key (FK) inherited from REIMBURSEMENT

ATM_ID : Foreign key (FK) inherited from REIMBURSEMENT

AMPP_ID : Foreign key (FK) inherited from REIMBURSEMENT

DELIVERY_ENVIRONMENT : Foreign key (FK) inherited from REIMBURSEMENT

REGIME_TYPE : Type of the regime applicable to the reimbursement, dependent on the social or medical profile of the patient.

Type : Numeric(2) Mandatory
Domain : 1 or 2 for now

COPAY_AMNT : Patient contribution in function of the patient regime.

Type : Numeric(10,4) Mandatory
Domain : Amount in Euro

SOLID_FLAT_RATE_AMNT: This is an amount ranging from 0€ to maximum 14€.

Type : Numeric(10,4) Optional
Domain : Amount in Euro, ranging from 0 to 14 €.

MODIFICATION_STATUS: Indicates the reason of eventual updating.

Type : Character Mandatory
Domain: 'C'orrected, 'E'volved

2.2. Relationships

2.3. Domains

2.4. Examples of quantities and strengths expressed at VMP and AMPP level

Example 1 :
[VMP] Lactulose 10 g (oraal)
SQ SU
[AMPP] Lactulose EG poederzakjes 30 x [10g]
CM
CQ = 1
CU = dose

Example 2 :
[VMP] Lactulose 10 g / 15 ml (oraal)
SQ SU SDQ SDU
[AMPP] Lactulose EG sir. zakjes 20 x [10g / 15ml]
CM
CQ = 1
CU = dose

Example 3 :
[VMP] Lactulose 3.1 g / 5 ml (oraal)
SQ SU SDQ SDU
[AMPP] Lactulose Teva sir. 500 ml [3.1g / 5ml]
CQ CU
CM = 1

Example 4 :
[VMP] Milrinon 10 mg (inf.)
SQ SU
[AMPP] Corotrope amp. Inf. 10 x [10 ml 1 mg / ml]
CM CQ CU

Example 5 :
[VMP] Epoprostenol 1.5 mg (inf.)
SQ SU

[AMPP] Flolan (1 x [1.5 mg] + 2 x 50 ml solv.)
CM AM AQ AU

Example 6 :
[VMP] ethinylestradiol 0,04 mg + desogestrel 0,025 mg + ethinylestradiol 0,03 mg + ...
SQ SU SQ SU SQ SU

[AMPP] Gracial 22 tab
CQ CU
[AMPP] Gracial 13 x 22 tab
CM CQ CU

Example 7 :
[VMP] estradiol 2 mg + estradiol 2 mg + medoxyprogesteron 10 mg
SQ SU SQ SU SQ SU

[AMPP] Diviplus 3 x 28 (9 I + 12 II + 7 I)
CM CQ CQ1 CQ2 CQ3
[AMPP] Diviva 3 x 21 (11 I + 10 II)
CM CQ CQ1 CQ2

3. Volumetry

This first estimation of the volumetry only serves to give an idea of the volumes to handle and is certainly to be refined. The volumes are expressed in terms of the number of occurrences without historical instance.

Entity	Expected
VIRTUAL_THERAPEUTIC_MOIETY (VTM)	500
ACTUAL_THERAPEUTIC_MOIETY (ATM)	1 500
VIRTUAL_MEDICINAL_PRODUCT (VMP)	700
ACTUAL_MEDICINAL_PRODUCT (AMP)	5 000
VIRTUAL_MEDICINAL_PRODUCT_PACK (VMPP)	10 000
ACTUAL_MEDICINAL_PRODUCT_PACK (AMPP)	20 000
VTM_INGREDIENT (VTMING)	1 000
VMP_COMB (VMPCMB)	200
AMP_COMB (AMPCMB)	500
VIRTUAL_INGREDIENT_STRENGTH (VIRTSTR)	1 500
ACTUAL_INGREDIENT_STRENGTH (ACTSTR)	4 500
VMPP_COMB (VMPPCMB)	500
AMP_INTERMEDIATE_PACKAGE (AMPINTPCK)	15 000
AMP_INT_PCK_COMB (AMPINTPCKCMB)	
NAME_EXPLANATION (NAMEXP)	*20 000*
NAME_TYPE (NAMTYP)	
NAME_TRANSLATION (NAMTRS)	
SUBSTANCE (INGR)	5 000
ATC	100
HYR	200
APPLICATION (APPL)	30
ROUTE_OF_ADMINISTRATION (ROUTE)	50
ADMINISTRATION_FORM (ADM)	30
PHARMACEUTICAL_FORM (PHARMF)	50
WADA	
INNER_PACKAGE (PCKG)	20
COMPANY (CPY)	
TREATMENT_DURATION_CATEGORY (DURCAT)	
PARAGRAPH (PARA)	300
PARAGRAPH_TRACE (PARTRA)	100
VERSE (VERS)	6 000
PROFESSIONAL_CODE (PROFCD)	50
PROFESSIONAL_AUTHORISATION (PROFAU)	100
ADDED_DOCUMENT (ADDOC)	1 000
EXCLUSION (EXCL)	300
THERAPY (THER)	1 000
PRICE (PRC)	50 000
REIMBURSEMENT_CATEGORY (RMCAT)	5
REIMBURSEMENT_CRITERIA (RMCRT)	100
REIMBURSEMENT (REMB)	100 000
COPAYMENT (COPAY)	200 000
FORM_TYPE	
APPENDIX_TYPE	

4. Document rectifications / modifications / updates

Rectification on 10/05/2010 :

- The attribute INIT_DATE in the 6 core entities is not mandatory. There will probably be occurrences for which the original version date is not known.
- Change of the business logic for handling names and translations. Each occurrence of an entity that is linked to some text e.g. a name, posology description, leaflet, … will have a reference to a NAME_ID, the identifier of the entity NAME_EXPLANATION that handles all names , translations and other parts of text (e.g. posology) to be stored for this occurrence.
- Entity PARAGRAPH, attribute KEY_STRING splitted into a Dutch (_NL) and a French (_FR) version
- Entity VERSE, attribute OTHER_ADDED_DOCUMENT_IND instead of PAPER_ADDED_DOCUMENT_ID to avoid confusion.

Rectification on 28/05/2010 :

- Added 2 new reference entities FORM_TYPE and APPENDIX_TYPE related to the entity ADDED_DOCUMENT
- Added entity NAME_TRANSLATIONS and NAME_TYPE.
- Replaced the attribute PHARM_PROD_SEQ in VMP with a (mandatory) sequence number in the entities VMP_CMB, AMP_CMB and AMP_INT_PCK_CMB. (sequence number that represents the order of the components in a combination product (VMP, AMP, AMP_INT_PCK).

Rectification + update on 31/05/2010 :

- New attribute SEQUENTIAL_IND in entity VMP. Indicates whether the product is sequential or not (the product contains different types of units and these have to be taken in a certain order, e.g. trifasic anticonception pills).

Rectification + update on 08/06/2010 :

- Attribute DIMENSIONS moved from entity VMP to entity AMP
- Attribute ADM_FORM_CV in entity AMP optional.
- Entity COPAYMENT : rename + change datatype attribute SOLID_FLAT_RATE_**AMNT** number (**8,4**)
- Entity VMP : DOSE_FORM_IND number(1) → DOSE_FORM_**TYPE character**(1)
- Entity VMP : NO_INN change datatype to number(2) to number (**1**)
- Entity HYR: new HYR_ID as primary key, datatype HYR_CV number (5) to number(**10**)
- Entity COMPANY: datatype COMPANY_ID string(2) to number(5)
- Entity APPLICATION_ROAD: datatype ROAD_CV string(2) to string(15)
- Entity ROUTE_OF_ADMINISTRATION_: datatype ROUTE_ADM_CV string(2) to string(15)
- Entity ADMINISTRATION_FORM: datatype ADM_FORM_CV string(2) to string(15)
- Entity PHARMACEUTICAL_FORM: datatype PHARM_FORM_CV string(2) to string(15)
- Entity VERSE : new attributes MAXIMUM_CONTENT_QUANTITY, MAXIMUM_CONTENT_UNIT, MAXIMUM_STRENGTH_QUANTITY, MAXIMUM_STRENGTH_UNIT, MAXIMUM_DURATION_QUANTITY, MAXIMUM_DURATION_UNIT.

Rectification + update on 18/06/2010 :

- Entity PARAGRAPH: Domain of PROCESS_TYPE_OVERRULE:

  Domain : **e.g. 'AQS' => Structuring is not yet completed on the fields represented by A, Q and S**.

  FIELDS

E	Exclusion rules
F	Information from forms to be integrated in paragraph text
T	AGREEMENT_TERM & AGREEMENT_TERM_UNIT
P	MAX_PACKAGE_NUMBER
Q	PURCHASING_ADVISOR_QUAL_LIST
Y	AGREEMENT_YEAR_MAX
R	AGREEMENT_RENEWAL_MAX
S	SEX_RESTRICTED
A	MIN_AGE_AUTHORIZED & MAX_AGE_AUTHORIZED & MIN_AGE_AUTHORIZED_UNIT & MAX_AGE_AUTHORIZED_UNIT

D OTHER_ADDED_DOC_IND
U MAXIMUM_CONTENT_QUANTITY & MAXIMUM_CONTENT_UNIT & MAXIMUM_STRENGTH_QUANTITY & MAXIMUM_STRENGTH_UNIT & MAXIMUM_DURATION_QUANTITY & MAXIMUM_DURATION_UNIT

- Entity VERSE: Domain VERSE_NUM: Unique sequence ~~within a paragraph~~ **among all the verses of the database**
- Entity VERSE: Domain VERSE_LEVEL: 1 to <= (previous level + 1).
- Entity VERSE: MIN_CHECK_NUM : Minimum amount of choices to be made within the verses one level higher (level + 1) **- uninterrupted by a lower level -** in order for the choice to be validated according to the legislation.
- Entity EXCLUSION: Domain EXCLUSION_TYPE: **J** : Paragraph = PARAGRAPH NAME

Rectification on 28/06/2010 :

- Change datatype length from number(9,3) to number(12,3) in following attributes :

Entity	Attribute
VIRTUAL_INGREDIENT_STRENGTH	STRENGTH_QUANTITY
	STRENGTH_QUANTITY_2
ACTUAL_INGREDIENT_STRENGTH	STRENGTH_QUANTITY
	STRENGTH_QUANTITY_2
AMP_INTERMEDIATE_PACKAGE	CONTENT_QUANTITY
	ADDED_QUANTITY
AMP_INT_PCK_COMB	AMP_INT_PCK_CQ
	AMP_INT_PCK_CQ_CMB
AMPP	CONTENT_QUANTITY
	TOTAL_PACK_SIZE_VALUE
VERSE	MAXIMUM_CONTENT_QUANTITY
	MAXIMUM_STRENGTH_QUANTITY

- REIMBURSEMENT_CRITERIA, REIMBURSEMENT_CATEGORY linked to THERAPY (instead of ATM) → via foreign keys REIMB_CRITERIA_CV and REIMB_CATEGORY_CV
- Updated explanation for attribute MINIMUM_AGE_AUTHORIZED in entity VERSE: can be a negative number (from -0,9 to 99,9)

Rectification on 09/07/2010 :

- Changed length DOCUMENT_SEQ from number(2) to number(4)
- Added attribute ADDRESS_URL in entity NAME_TRANSLATION and ADDED_DOCUMENT.

Rectification on 16/07/2010 :

- Modification attribute length STRENGTH_DENOM_QUANTITY in ACTUAL_INGREDIENT_STRENGTH and VIRTUAL_INGREDIENT_STRENGTH from 9,3 to 12,3

Rectification on 16/07/2010 :

- Changed entity name APPLICATION_ROAD into APPLICATION
- Changed attribute name ROAD_CV into APPLICATION_CV

Rectification on 20/09/2010 :

- Changed length SHORT_TEXT in NAME_TRANSLATION from varchar2(280) to varchar2(300)
- Changed length DEFINED_DAILY_DOSE_VALUE in VMP from number(6) to number(12,3)
- Changed length STRENGTH_UNIT in ACTUAL_INGREDIENT_STRENGTH from varchar2(5) to varchar2(15)
- Changed length STRENGTH_UNIT in VIRTUAL_INGREDIENT_STRENGTH from varchar2(5) to varchar2(15)
- Deleted VMP_TYPE in entity VMP
- Changed length PRICE_AMNT, REIMB_BASE_PRICE, REFERENCE_BASE_PRICE in PRICE from number(8,4) to number(10,4)
- Changed length PRICE_AMNT, REIMB_BASE_PRICE, REFERENCE_BASE_PRICE in PRICE from number(8,4) to number(10,4)

- Changed length PRICE_AMNT, REIMB_BASE_PRICE, REFERENCE_BASE_PRICE in PRICE from number(8,4) to number(10,4)
- Changed entity name APPLICATION_ROAD into APPLICATION
- Changed attribute name ROAD_CV into APPLICATION_CV
- In PHARMACEUTICAL_FORM changed attribute PHARM_FORM_CV varchar2(15) into PHARM_FORM_ID number(5)
- In ADMINISTRATION_FORM changed attribute ADM_FORM_CV varchar2(15) into PHARM_FORM_ID number(5)
- In entity AMPP deleted attribute PROD_SPEF

Rectification on 30/12/2010 :

- Added field LONG_BINARY_TEXT to entity NAME_TRANSLATIONS (already in the diagram)
- Changed length KEY_STRING_NL & KEY_STRING_FR in PARAGRAPH from varchar2(200) to from varchar2(500)
- Added field AGREEMENT_TYPE_PRO to table PARAGRAPH for renewal authorisation

Rectification on 04/04/2011 :

- Deleted attribute in entity VERSE: MINIMUM_AGE_AUTHORIZED_2
- Deleted attribute in table VERSE: MAXIMUM_AGE_AUTHORIZED_2
- New attribute to table VERSE : MINIMUM_AGE_AUTHORIZED_UNIT varchar2 (5)
- New attribute to table VERSE : MAXIMUM_AGE_AUTHORIZED_UNIT varchar2 (5)
- Deleted attribute in table VERSE: PURCHASING_ADVISOR_QUAL_CV
- New attribute to table QUALIFICATION_LIST : EXCLUSIVE_IND char(1)
- Add primary key PROFAU_ID to table PROFESSIONAL_AUTHORISATION number (10)
- CHAPTER_NAME + PARAGRAPH_NAME + EXCLUSION_TYPE + IDENTIFIER_NUM are promoted to primary key in table EXCLUSION
- Rendering VERSE_SEQ_PARENT in table VERSE mandatory
- Rendering NAME_ID in table ADDED_DOCUMENT mandatory
- In table LOGGING_TRANSFER, changed field length for SENDER_ORGANISM from varchar2 (50) to varchar2 (200)
- Changed description of field SPECIALTY_ORIGIN in table ATM
- Changed description of field MASKED_INDICATOR in table THERAPY
- Changed description of field AGREEMENT_TYPE in table PARAGRAPH
- Changed description of field AGREEMENT_TYPE_PRO in table PARAGRAPH
- Changed description of field VERSE_TYPE in table VERSE
- Changed description of field MAXIMUM_DURATION_QUANTITY in table VERSE
- Changed description of field MAXIMUM_DURATION_UNIT in table VERSE

- Add primary key CAS_ID to table SUBSTANCE number(10)
- Delete foreign keys CAS_NR from tables VTM_INGREDIENT, VIRTUAL_INGREDIENT_STRENGTH, ACTUAL_INGREDIENT_STRENGTH
- Propagation of CAS_ID as foreign keys to tables VTM_INGREDIENT, VIRTUAL_INGREDIENT_STRENGTH, ACTUAL_INGREDIENT_STRENGTH
- Foreign key BASE_FORM_CAS_NR in table SUBSTANCE is replaced by FK BASE_FORM_CAS_ID
- Foreign key VIRTUAL_INGREDIENT_NR in table ACTUAL_INGREDIENT_STRENGTH is replaced by FK VIRTUAL_INGREDIENT_ID
- CAS_NR in table SUBSTANCE is reduced to an optional attribute with no key value
- Added technical table ORGANISM
- Added technical table STATUS_TRANSFER

Rectification on 27/07/2012 :

- New attribute to every business table : MODIFICATION_STATUS char(1)
- New attribute to table AMP : WADA_CV varchar2 (7)
- New attribute to table VMP : ATC_CV varchar2 (6)
- Deleted attribute in table AMP : ATC_CV
- Deleted attribute in table VMP : WADA_CV
- Added table PARAGRAPH_TRACE

Rectification on 24/08/2012 :

- Logical Data Diagram : added PARAGRAPH_TRACE and updated links ATC-AMP and WADA-VMP
- Table AMP : updated SPECIALTY_ORIGIN domain
- Table AMPP : added fields CHEAPEST, IN_SUPPLY, AVAILABILITY
- Table AMPP : updated SOCSEC_REIMB_CV domain
- Table AMP_COMB : updated AMP_CMB_SEQ domain
- Table AMP_INTERMEDIATE_PACKAGE : updated ADDED_TYPE domain
- Table PHARMACEUTICAL_FORM : updated WADA_CV domain
- Table PARAGRAPH : changed field type of AGREEMENT_TYPE from 'Mandatory' to 'Optional'
- Table PARAGRAPH : updated CHAPTER_NAME & PROCESS_TYPE domains
- Table VERSE : updated AGREEMENT_TERM_UNIT domain
- Table PARAGRAPH_TRACE : updated semantic key
- Table PARAGRAPH_TRACE : updated field (PARENT_)CHAPTER_NAME domain
- Table SUBSTANCE : deleted field MODIFICATION_STATUS
- All business tables with field MODIFICATION_STATUS : deleted value 'U'nknown

Rectification on 06/09/2012 :

- Table REIMBURSEMENT_CATEGORY : Added values 'Fa' and 'Fb' to field REIMB_CATEGORY_CV domain

Rectification on 19/02/2013:

- Table VIRTUAL_INGREDIENT_STRENGTH : field STRENGTH_DENOM_UNIT format size updated from 5 to 15 bytes
- Table ACTUAL_INGREDIENT_STRENGTH : field STRENGTH_DENOM_UNIT format size updated from 5 to 15 bytes
- Table VERSE : field MAXIMUM_STRENGTH_UNIT format size updated from 5 to 15 bytes
- Table PARAGRAPH : added values 'IV-BIS', 'V' and 'VI' into CHAPTER_NAME domain
- Table PARAGRAPH : PROCESS_TYPE is optional but can not be null when CHAPTER_NAME = 'IV'
- Table PARAGRAPH_TRACE : CHAPTER_NAME and PARENT_CHAPTER_NAME description now refer to field CHAPTER_NAME from table PARAGRAPH
- Table PARAGRAPH_TRACE : PARAGRAPH_NAME and PARENT_PARAGRAPH_NAME description now refer to field PARAGRAPH_NAME from table PARAGRAPH
- Table VERSE : rendering field CHECK_BOX_IND mandatory
- Table REIMBURSEMENT_CATEGORY : rendering CATEGORY_NAME optional
- Table REIMBURSEMENT_CRITERIA : rendering CRITERIA_NAME optional
- Deleted attributes PRICE_START_DATE and REIMB_START_DATE from tables COPAYMENT, PRICE and REIMBURSEMENT

Rectification on 04/03/2013:

- Table ADDED_DOCUMENT : rendering DOCUMENT_CONTENT optional

Rectification on 15/04/2013:

- Table PARAGRAPH : updated PROCESS_TYPE domain with new value '7'