SAM Export

Version	Status	Date	Author(s)	Modifications
0.1	Draft	22/03/2016	Smals	First Draft Version
0.2	Update	23/08/2016	Smals	Update
0.21	Update	29/08/2016	Smals	Update delta export of references
3.2.0	Update	14/04/2017	Smals	Update to most recent XSD Match document version with XSD version
3.3.0	Draft	06/05/2017	Smals	Include NIHDI RFC – still needs descriptions
3.3.0	Update	28/06/2017	Smals	Included descriptions
3.4.0	Update	28/06/2018	Smals	Several minor updates, eg AMPP Status field

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1. Introduction to SAM data

1.1. Quick overview of SAM

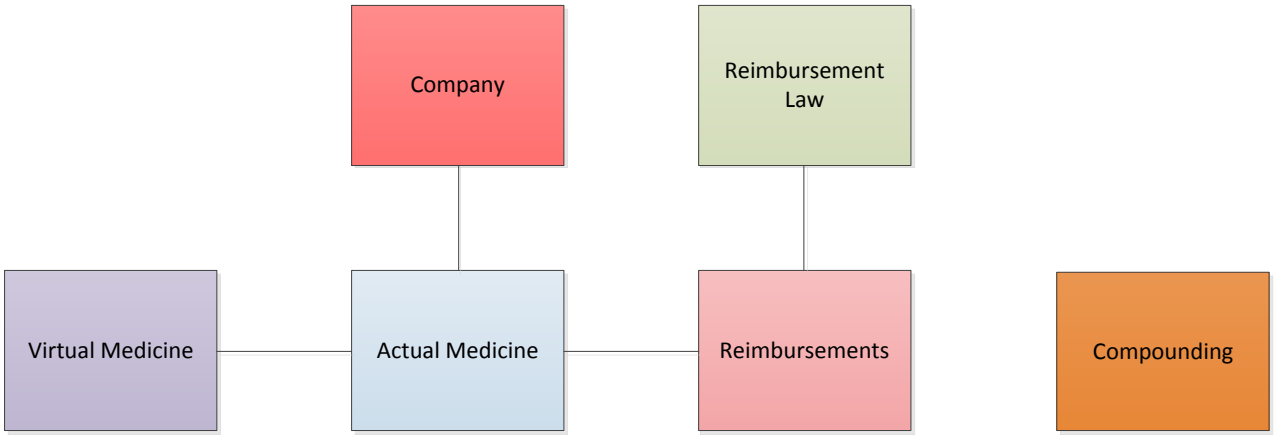
This document describes the regular exports of the SAM database. SAM stands for “Source Authentique des Medicaments” (Authentic Source of Medicinal Products in French – the abbreviation SAM is just easier to pronounce than ASMP or ABG).

The goal of the project is to combine all public data on medicinal products available in Belgium from different data providers. The information is currently managed by these public institutions: BCPI[1], FAMHP[2] and NIHDI[3].

The published data is then made available for consultation by the general public.

A first use case of the project is to allow the prescribers and insurance institutions to electronically communicate information and decisions in order to accelerate the reimbursement process for the patient.

The database is divided in six domains:



1. **Company**: information about the pharmaceutical company that is responsible for delivered drug packages. The FAMHP is responsible for monitoring this information;
2. **Actual Medicine**: information about actual drug products and the related packages authorized on the Belgian market. The FAMHP is responsible for monitoring this information. BCPI and NIHDI can register additional information on a drug product when it has been created by the FAMHP.
3. **Reimbursement**: information about the reimbursement of a delivered drug package managed by the NIHDI.
4. **Reimbursement Law**: information about the legislation that describes the conditions and terms of the reimbursement of a drug package, i.e. Chapter IV describing the conditions for reimbursement of specialties which are refundable through a medical advisor’s agreement. This part is managed by the NIHDI.

[1] Belgian Center for Pharmaceutical Information: http://www.cbip.be/.

[2] Federal Agency for Medicinal and Health Products: http://www.fagg-afmps.be/en/famhp/.

[3] National Institution for Health and Disability Insurance: http://www.inami.fgov.be/fr/Pages/default.aspx.

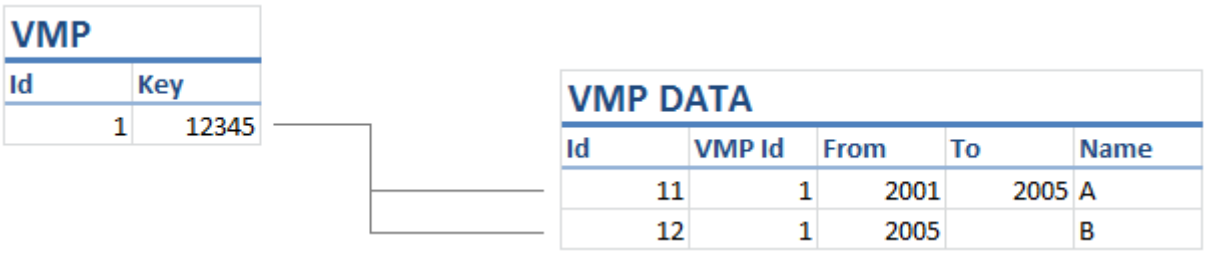
5. **Virtual Medicine**: extra information about the drug products for prescription managed by the BPCI.
6. **Compounding**: Ingredients and Formulas for the preparation of pharmaceutical compounds (préparations magistrales / meesterlijke bereidingen). Currently only a link between the CNK code and a list of possible names and synonyms.

For a full description of the different domains and their objects, please refer to the Conceptual and Platform Independent Data Models.

1.2. Objects with temporal data

One of the main goals of SAM v2 was to allow objects to evolve over time. This means that an object (for example a Virtual Medicinal Product) may exist from 2001-01-01 up till now, but in 2005, the name has changed from A to B.

In SAM v2, we have implemented this requirement by separating (fixed) identity attributes (e.g. the VMP Code) and variable attributes (e.g. the name) into different tables. Identity tables never change; data tables contain a 'from' and 'to' date to indicate validity. An object exists on a given date if the given date is covered by one of the associated validity periods.



VMP

Id	Key
1	12345

VMP DATA

Id	VMP Id	From	To	Name
11	1	2001	2005	A
12	1	2005		B

The example above gives one entry in the identity table (key = the VMP code), and two entries in the data table (from 2001 to 2005 name A, from 2005 to indefinite name B).

For more information about SAM v2 temporality, see the PIM document.

1.3. Root objects and referenced objects

Although in our database each sub-object has its own validity periods, we will offer an export based on a collection of root objects, similar to the consultation services.

A root object is an object which is published as a whole. An object which is published as one object, will be exported as one object. For example, VMP Component and Virtual Ingredient are published as part of a Virtual Medicinal Product. The exported root object will be a VMP.

In the consultation service, References are expanded in the result. The export will follow this example: all references are displayed including their content. The same goes for the smaller but temporal business objects like VMP Group and Commented Classification.

All references (and reference-like temporal objects) will also be exported separately, in order to allow a full reconstruction of reference tables (even if some references are never used – yet).

Following root objects will be exported:

- Virtual Medicinal Product (also includes the expanded temporal references VTM, VMP Group and Commented Classification)
- Actual Medicinal Product (contains Product Packages as child elements)

- Company
- Reimbursement Context
- Legal Basis

In addition, following temporal references will be exported alongside VMP:

- Virtual Therapeutic Moiety
- VMP Group
- Commented Classification

References will be exported separately (without temporal information).

2. Export: General principles

2.1. Full vs Incremental

Two types of export will be offered.

1. A full export, which allows building a local copy of the SAM by itself.
2. An incremental export (delta), which will update a local copy with all changes since the last incremental export.

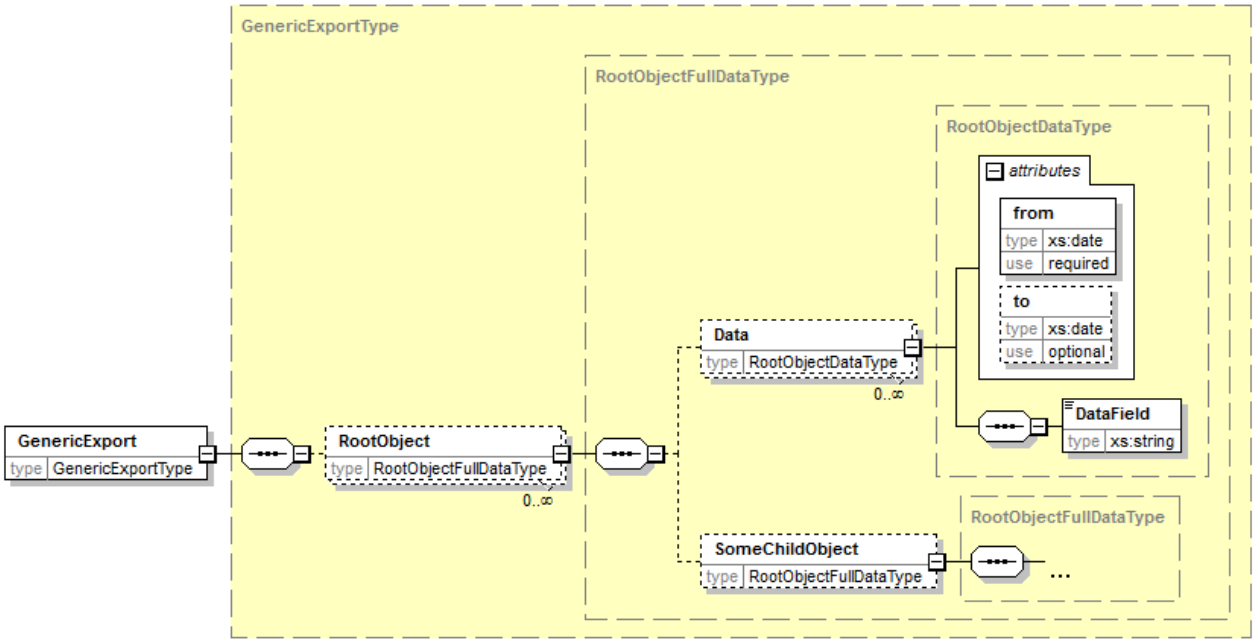
These exports will follow the business representation as specified in the publication and consultation XSD as closely as possible, staying independent from any physical database implementation.

Both exports will follow the same XSD.

2.2. Common interface

All temporal exports follow the same structure. Temporal objects have the type "*FullDataType". These complex types consist of:

- The unique identifiers of the object as attributes.
- A Data element (optional, unbounded) with from and to attributes indicating validity periods. This data element contains all information linked to a given validity period of an object. The elements in the Data object can be simple fields, expanded reference objects or full temporal objects.
- Objects which are linked through the Identity tables. These objects are usually temporal and follow the same structure as the root object.



The schema above represents the general structure using non-specific object names. Real examples below for each exported object type.

2.3. Full Export

Our main design goal is to export business objects, not a database dump.

The Identity table for the root object will define the elements in the export. These identity elements will contain one or more Data elements with the temporal data and a validity period.

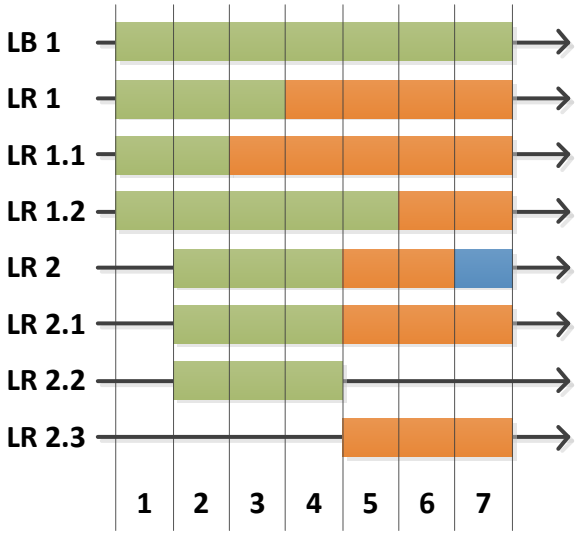
For example, we have an existing Actual Medicinal Product, starting in 2001. In 2002, we add an AMPP. In 2003, the AMPP gets commercialized. In 2006, we had a supply problem for this AMPP lasting one year.

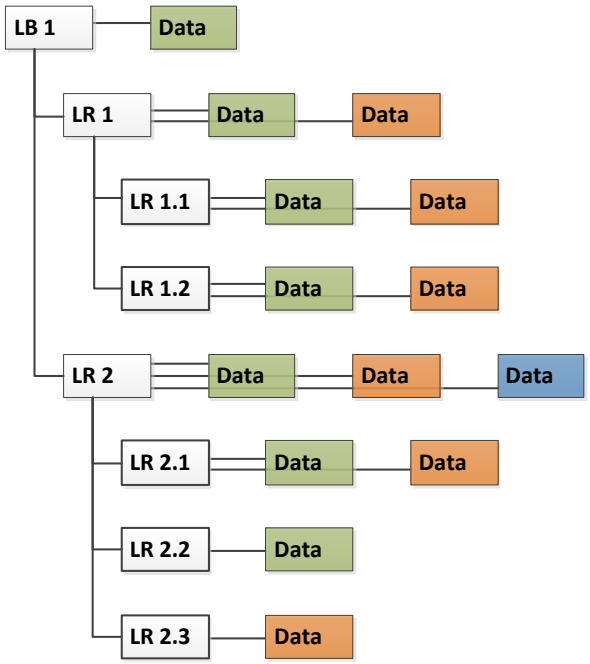
The AMP export would look like this:

- AMP
  - Data (from 2001)
  - AMPP
    - Data (from 2002)
    - Commercialization
      - Data (from 2003)
    - Supply Problem
      - Data (from 2006 to 2007)

Below, we will include a graphical example of a legal basis with two levels of legal references, for a total of 7 objects exported as one root object. Please note that in reality, a single legal basis tree will be much larger, containing legal texts as well as formal interpretations for hundreds of paragraphs.

In the example, colors indicate different versions of an object. The from and to dates of each version are present in the Data object.





2.4. Incremental Export

The incremental export will have the same structure as the full export. Only those objects which have changed since the last incremental update will be included, but these objects will be exported fully, as in a Full Export.

An incremental update of an object replaces the object completely.

A deleted object will be present without Data sub element.

To determine which objects have changed, we look at both the functional and technical history. For each table belonging to an exported object we compare the creation date to the date of the last export. If after, the full situation of the object is exported.

Since reference tables do not have history information, they will be exported fully and included in the incremental export.

2.4.1. Example

Consider a VMP with name 'VMP 1' valid from 2001, and a VMP with name 'VMP 2' valid from 2005.

Between the previous and current incremental export, the first VMP name changed to 'Virtual Medicinal Product 1'. The second VMP did not change.

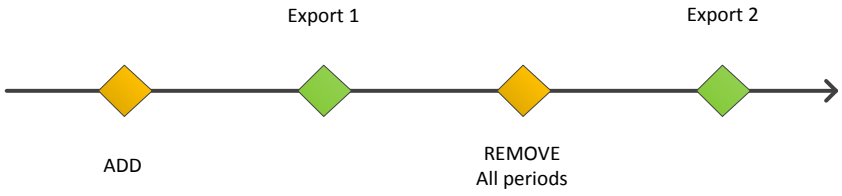
The incremental export will contain all data for the first VMP, but nothing for VMP 2.

- VMP 1
  - Data
    - From: 2001
    - To: 2016
    - Name: VMP 1
  - Data
    - From: 2016
    - Name: Virtual Medicinal Product 1

Full XML examples will be provided.

2.4.2. Fully removed object

A fully removed object (no validity periods exist) will not be present in the Full Export. In the incremental export, a removal must be indicated. We do this by exporting an object without Data elements.



Export 1

```
<ExportCompanies xmlns="urn:be:fgov:ehealth:samws:v2:export"
       xmlns:company="urn:be:fgov:ehealth:samws:v2:company:submit">
       <Company actorNr="12345">
              <Data from="2016-01-01">
```

```
                    <company:Denomination>Some Company</company:Denomination>
                    <company:Language>NL</company:Language>
                </Data>
        </Company>
</ExportCompanies>
```

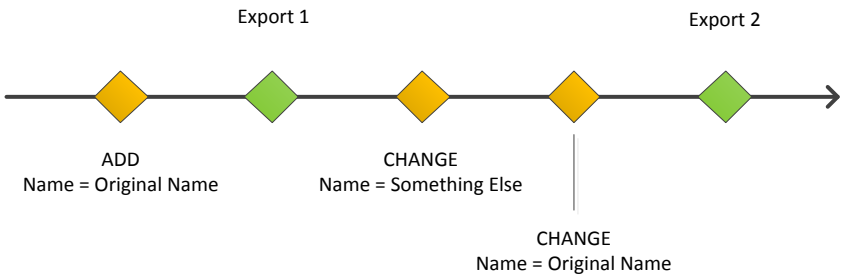
Export 2

```
<ExportCompanies xmlns="urn:be:fgov:ehealth:samws:v2:export"
        xmlns:company="urn:be:fgov:ehealth:samws:v2:company:submit">
        <Company actorNr="12345"/>
</ExportCompanies>
```

2.4.3. Changed object but returned to original state before second delta

Between two incremental exports, an object can be modified but returned to the original state before the second incremental export was created.

The object will be exported again in the second export, but will be identical in both exports. The user consulting the delta will know something has happened to the object, but will not know what.



2.5. Where to get the export

The export is available on the SAM Civics Download page.

https://www.vas.ehealth.fgov.be/websamcivics/samcivics

Direct links to the latest files are constructed as follows:

1. Full
    a. Get latest full version number:
    https://www.vas.ehealth.fgov.be/websamcivics/samcivics/download/samv2-full-getLastVersion
    b. If this version is different from your version, get the file:
    https://www.vas.ehealth.fgov.be/websamcivics/samcivics/download/samv2-download?type=full&version=999
2. Incremental (Delta)
    a. Get latest delta version number:
    https://www.vas.ehealth.fgov.be/websamcivics/samcivics/download/samv2-delta-getLastVersion

b. Get file: https://www.vas.ehealth.fgov.be/websamcivics/samcivics/download/samv2-download?type=delta&version=999

SAM exists in three environments, Integration, Acceptance and Production. The only environment with the official and complete SAM data is Production. The addresses of the other environments are:

- Integration: https://wwwint.vas.ehealth.fgov.be/websamcivics/samcivics
- Acceptance: https://wwwacc.vas.ehealth.fgov.be/websamcivics/samcivics

3. Exported objects

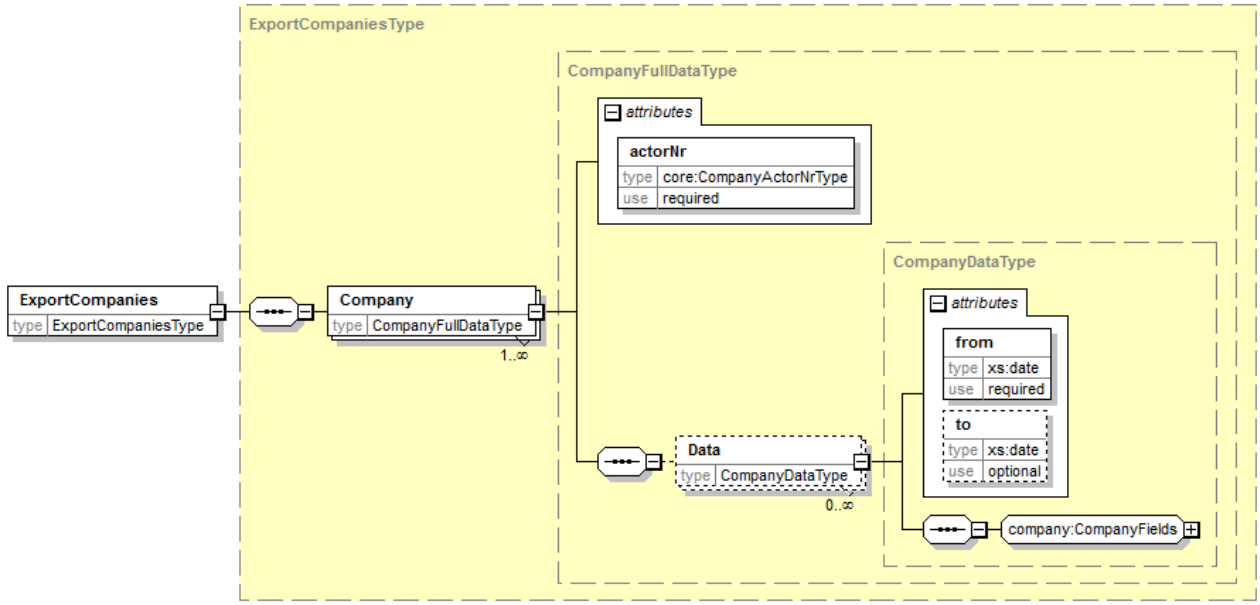
This chapter describes the export XSD in graphical and textual form. All root elements are described in the file /export/SamExport.xsd.

The export zip contains following files, containing the corresponding element:

File name	Element
AMP-%d.xml	{urn:be:fgov:ehealth:samws:v2:export}ExportActualMedicines
CPN-%d.xml	{urn:be:fgov:ehealth:samws:v2:export}ExportCompanies
REF-%d.xml	{urn:be:fgov:ehealth:samws:v2:export}ExportReferences
RML-%d.xml	{urn:be:fgov:ehealth:samws:v2:export}ExportReimbursementLaws
RMB-%d.xml	{urn:be:fgov:ehealth:samws:v2:export}ExportReimbursements
VMP-%d.xml	{urn:be:fgov:ehealth:samws:v2:export}ExportVirtualMedicines
CMP-%d.xml	{urn:be:fgov:ehealth:samws:v2:export}ExportCompounding

With %d being the timestamp of the generation of the file in milliseconds.

3.1. Export Companies

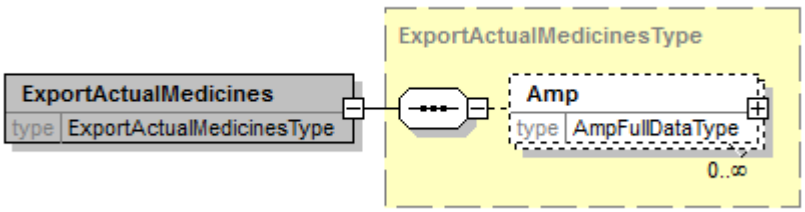


3.1.1. Company Data fields

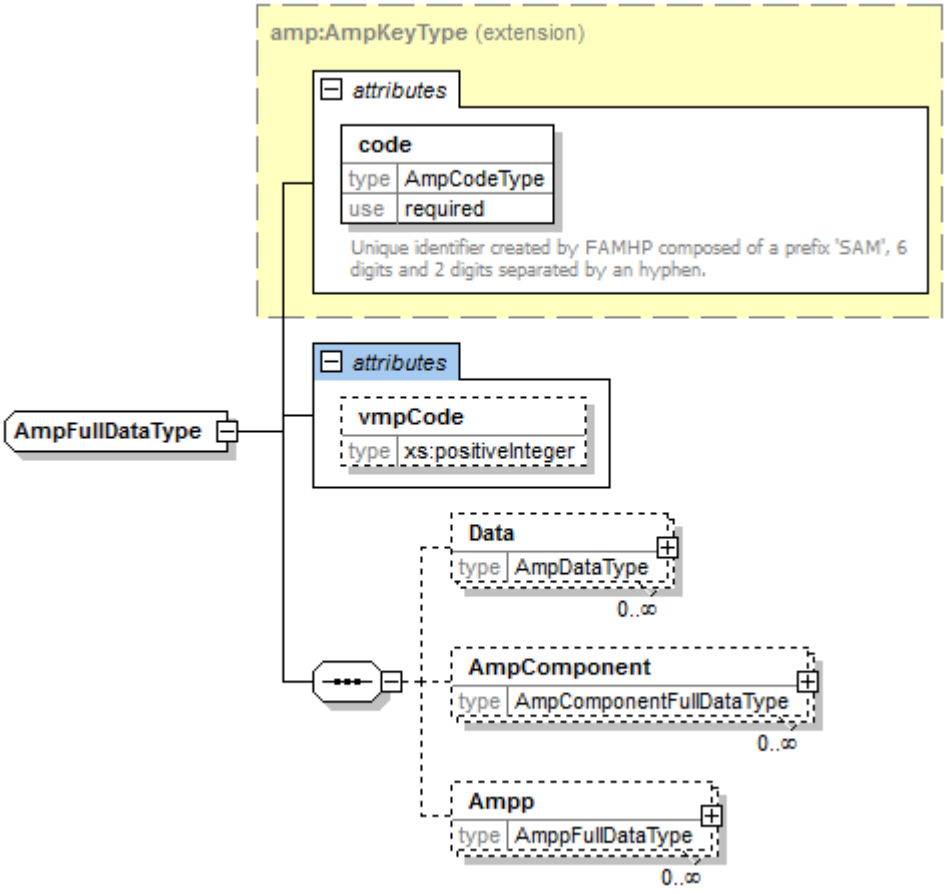
Group *CompanyFields*		
Field name	**Required**	**Description**

AuthorisationNr	**No**	Authorisation number of the company.
VatNr	**No**	VAT Number. No validation is performed on this field.
attribute: CountryCode of VatNr	**Depends**	Country code associated to the VAT number is only required if the VatNr field is used.
EuropeanNr	**No**	European number.
Denomination	**Yes**	Name of the company in the company's official language.
LegalForm	**No**	Legal form of the company.
Building	**No**	Information related to the building used as head office by the company.
StreetName	**No**	Name of the street in the address of the company's head office.
StreetNum	**No**	Street number in the address of the company's head office.
Postbox	**No**	Post box in the address of the company's head office.
Postcode	**No**	Post code in the address of the company's head office.
City	**No**	Name of the city in the address of the company's head office.
CountryCode	**No**	Country code in the address of the company's head office
Phone	**No**	Contact phone number.
Language	**Yes**	Official language of the company. Possible values : 'FR', 'NL', 'EN', 'DE', 'FR/NL'.
Website	**No**	Website of the company.

3.2. Export Actual Medicines



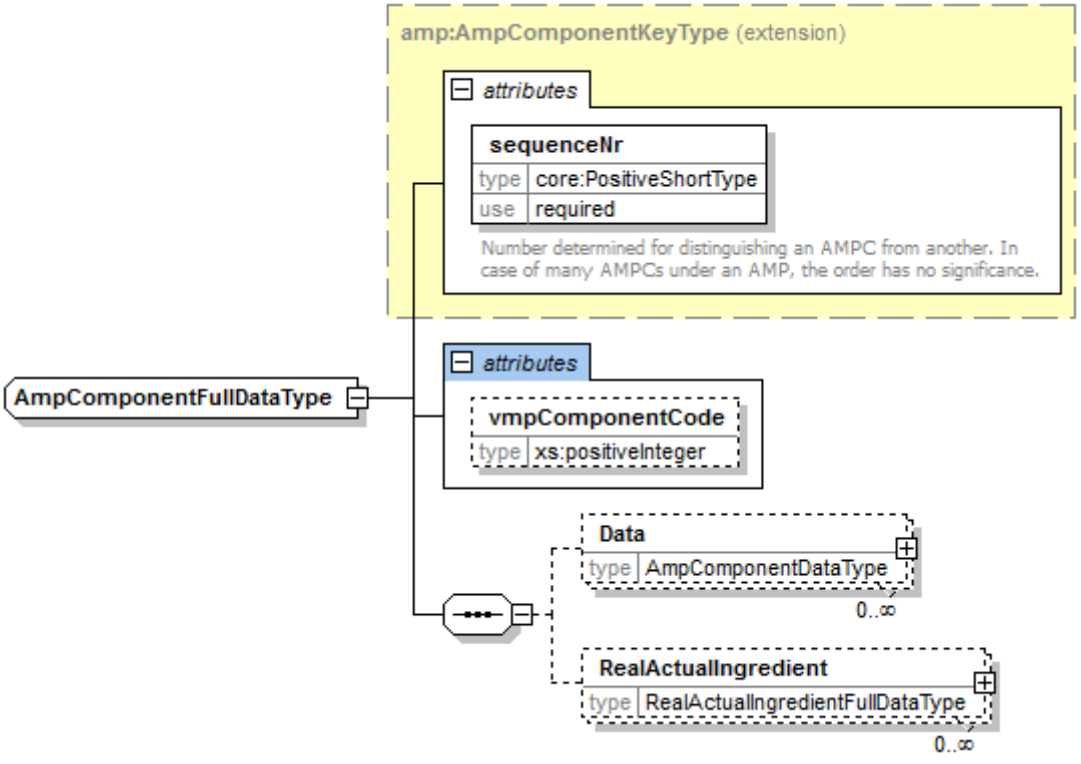
3.2.1. Amp



Field name	Required	Description
OfficialName	**Yes**	The AMP's official name in the language mentioned on the marketing authorisation. The name contains the strength of the medicinal product.
Status	**No**	The status is calculated based on the AMPP status: - ACTIVE: the medicinal product has an authorization number for marketing in Belgium and can be commercialized; - SUSPENDED: the medicinal product can't temporarily be commercialized due to i.a. health problem; - REVOKED: the medicinal product is finally removed from the Belgian market and can't be commercialized anymore. If all AMPPs are REVOKED, then the AMP status is REVOKED. If at least one AMPP is ACTIVE, the AMP status is ACTIVE. If at least one AMPP is SUSPENDED, but none are ACTIVE, the AMP status is SUSPENDED.
Name	**Yes**	The translations of the AMP's official name of the AMP in French, Dutch, German and English.
BlackTriangle	**Yes**	Marks an AMP with a black triangle indicating that it is subject to additional monitoring. This mark draws the attention to the fact that experience with such a product is limited or that safety questions have

		been raised.
MedicineType	**Yes**	Used to indicate whether a medicinal product is a conventional medicine or a homeopathic product. Values: 'ALLOPATHIC' or 'HOMEOPATHIC'
Company	**Yes**	The company responsible for marketing the medicinal product. This company can change over time and as such is part of the references in the Data element.
AbbreviatedName	**No**	Abbreviation of the medicinal product name. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional.
ProprietarySuffix	**No**	Suffix given to a medicinal product by its distributor. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional. Example: 'Antizuur-Antireflux Unidose'.
PrescriptionName	**No**	Standard name identifying a medicinal product for prescriptions, structured uniformly by BCPI. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional.

3.2.2. AmpComponent

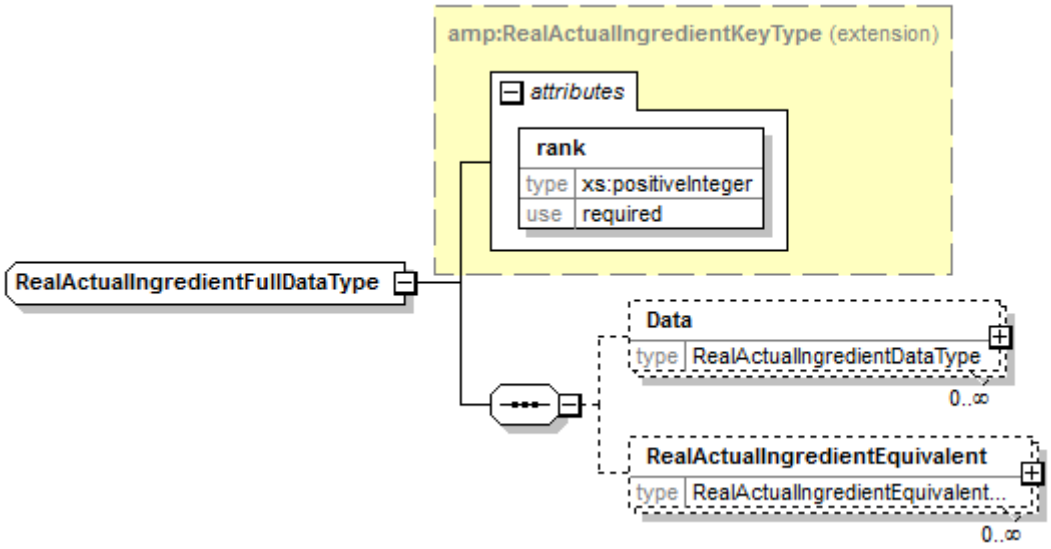


AmpComponentDataType		
Field name	**Required**	**Description**
PharmaceuticalForm	**Yes**	An AmpComponent can have one or more pharmaceutical forms.
RouteOfAdministration	**Yes**	An AmpComponent can have one or more routes of administration.

Dividable	**No**	Indicates whether it concerns a dividable pharmaceutical form: 2 – at least dividable in 2 equal parts 3 – at least dividable in 3 equal parts 4 – at least dividable in 4 equals part N – not dividable in equal parts X – not applicable (not a tablet) null – missing data
Scored	**No**	Indicates whether it concerns a scored tablet or not: 2 – scored as to allow division in at least 2 parts 3 – scored as to allow division in at least 3 parts 4 – scored as to allow division in at least 4 parts N – not scored X – not applicable (not a tablet) null – missing data
Crushable	**No**	Indicates whether it concerns a crushable tablet: Y – crushable N – not crushable X – not applicable (not a tablet) null – missing data
ContainsAlcohol	**No**	Indicates whether the product contains alcohol. Y – contains alcohol N – doesn't contain alcohol X – not applicable Default is null (missing data).
SugarFree	**No**	The product does not contain glucose, sucrose or fructose for products whose AMP have an oral liquid form. Default is null (missing data).
ModifiedReleaseType	**No**	Type of release modification: 0 – release not modified 1 – prolonged release 2 – delayed release 3 – multiphasic release 4 – depot – transdermal null – missing data Other values can be added later.
SpecificDrugDevice	**No**	Indicates whether a specific device is needed: 0 – a device is neither required nor optional 1 – a specific device is required and is included 2 – a specific device is required but not included 3 – an optional device is included 4 – an optional device is not included 50 – this AMP is a pen device 99 – not applicable null – missing data Other values can be added later.
Dimensions	**No**	Text field with the dimensions of the product in the case of e.g. adhesives.
Name	**No**	Uniformly structured name given by the BCPI to identify the specific component from the medicinal product. This field is translated in French, Dutch, German and English.

		French and Dutch versions are mandatory and others are optional.
Note	**No**	Useful textual information related to the component. This field is translated in French, Dutch, German and English. When it is specified, French and Dutch versions are mandatory and others are optional.

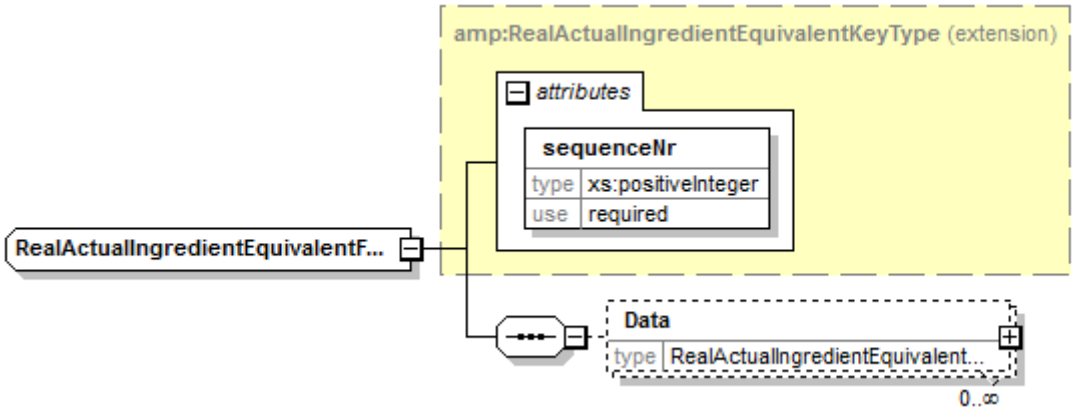
3.2.3. RealActualIngredient



RealActualIngredientDataType		
Field name	**Required**	**Description**
Type	**Yes**	Type of use for the specified substance (given by the link to the reference entity Substance). Possible values : - ACTIVE_SUBSTANCE: the substance participates in the medicinal product effect ; - EXCIPIENT: not active substance.
KnownEffect	**No**	This ingredient (always excipient) has known effect(s). Default is null, meaning this excipient is considered as an excipient without a known effect.
Strength	**No**	Strength of the ingredient when it is an Active Substance.
StrengthDescription	**No**	Alternative description of the strength that not fits in the fields Strength Quantity / Strength Unit. This field is empty when these fields can be filled in. In the case where the ingredient really contained in the medicinal product has an unknown strength, the following value is mentioned: "Quantum satis". Examples: - '50 U DL50' for ingredient 'Clostridium Botulinum Toxin, Type A' - 'MT' for ingredient 'Calendula Officinalis' - 'D1' for ingredient 'Aconitum Napellus' - 'Quantum satis' for ingredient 'Clopidogrel Hydrogen Sulphate'

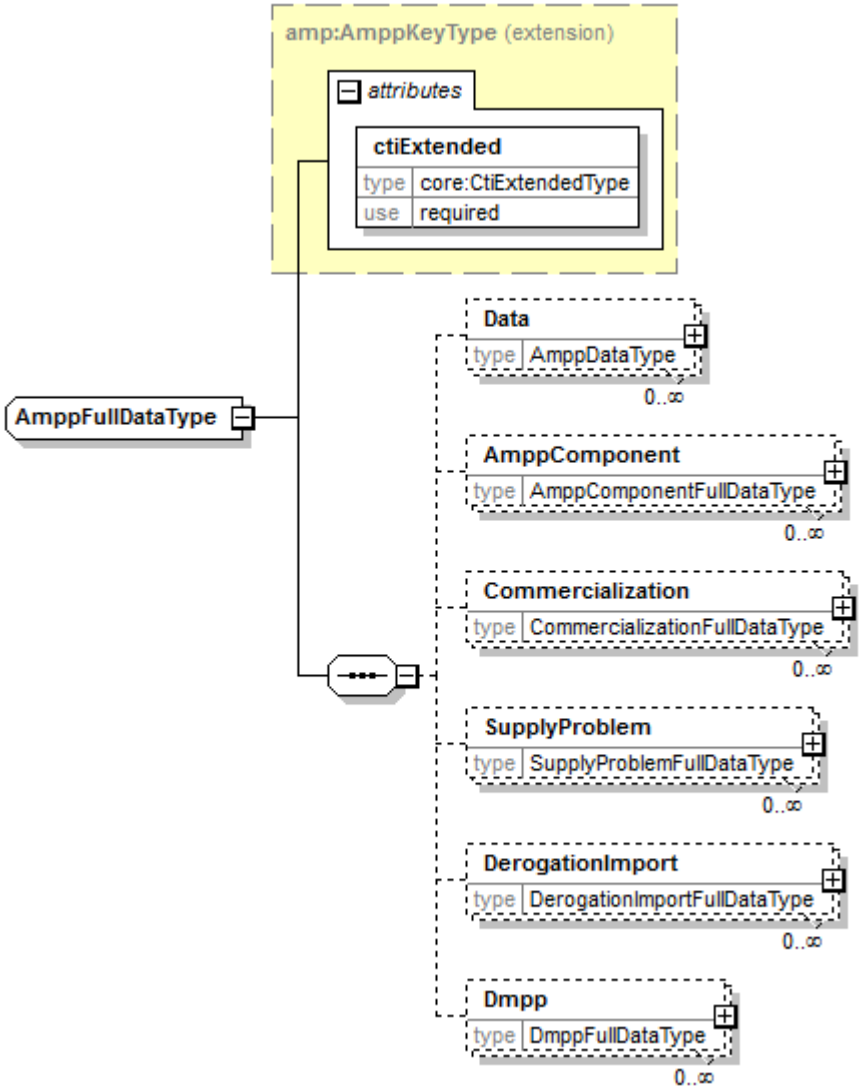
AdditionalInformation	**No**	Additional (textual) information about the active ingredient.
Substance	**Yes**	The substance reference for this ingredient.

3.2.4. RealActualIngredientEquivalent



RealActualIngredientEquivalentDataType		
Field name	**Required**	**Description**
Type	**Yes**	Type of use for the specified substance (given by the link to the reference entity Substance). Possible values : - ACTIVE_SUBSTANCE: the substance participates in the medicinal product effect ; - EXCIPIENT: not active substance.
KnownEffect	**No**	This ingredient (always excipient) has known effect(s). Default is null, meaning this excipient is considered as an excipient without a known effect.
Strength	**No**	Strength of the ingredient when it is an Active Substance.
StrengthDescription	**No**	Alternative description of the strength that not fits in the fields Strength Quantity / Strength Unit. This field is empty when these fields can be filled in. In the case where the ingredient really contained in the medicinal product has an unknown strength, the following value is mentioned: "Quantum satis". Examples: - '50 U DL50' for ingredient 'Clostridium Botulinum Toxin, Type A' - 'MT' for ingredient 'Calendula Officinalis' - 'D1' for ingredient 'Aconitum Napellus' - 'Quantum satis' for ingredient 'Clopidogrel Hydrogen Sulphate'
Substance	**Yes**	The substance reference for this ingredient.

3.2.5. Ampp



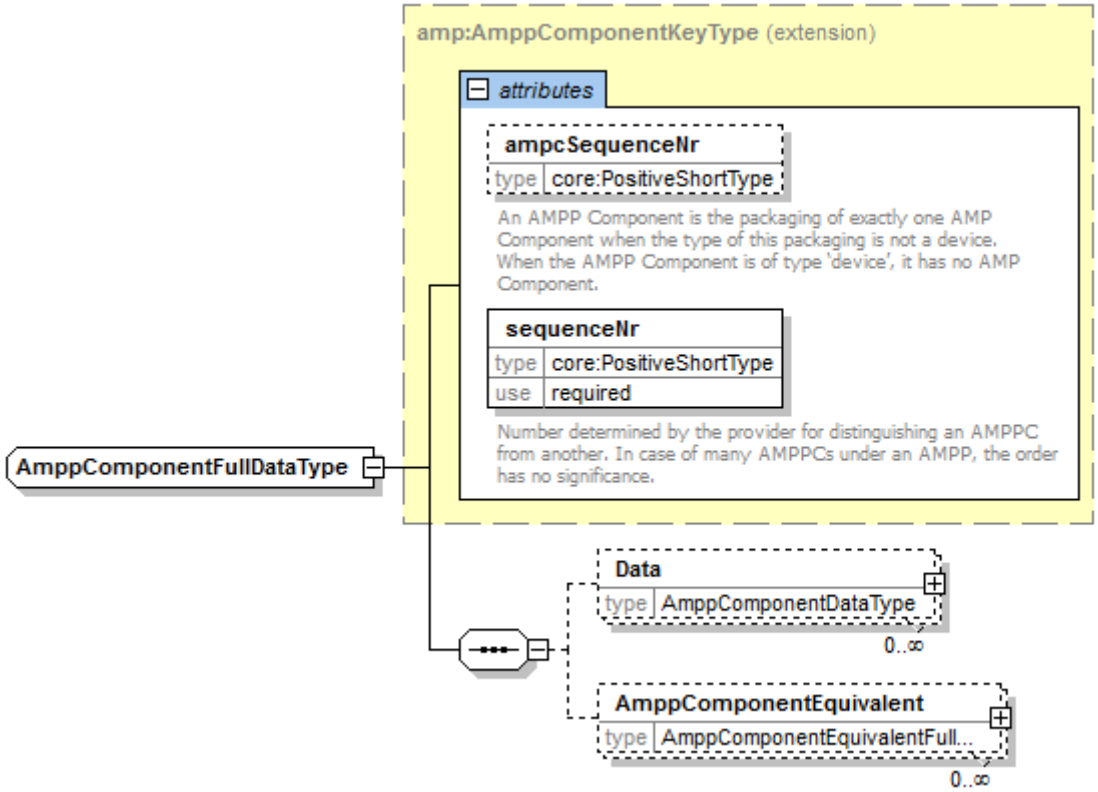
AmppDataType		
Field name	**Required**	**Description**
AuthorisationNr	**Yes**	Authorisation number given by FAMPH or European Commission when authorised to be commercialised on the Belgian market.
Orphan	**Yes**	This AMPP is an orphan drug.
LeafletLink	**No**	Link to the leaflet for this AMPP, specified according to the language French, Dutch, German and English. When it is specified, French and Dutch versions are mandatory and others are optional.
SpcLink	**No**	Link to SPC specified according to the language French, Dutch, German and English. When it is specified, French and Dutch versions are

		mandatory and others are optional.
RmaPatientLink	**No**	Link to the RMA (Risk Minimization Activities) material (patients) for this AMPP, specified according to the language: French, Dutch and German.
RmaProfessionalLink	**No**	Link to the RMA material (health care professionals) for this AMPP, specified according to the language: French and Dutch.
ParallelCircuit	**No**	Possible values: 0 – No parallel circuit 1 – Parallel import 2 – Parallel distribution
ParallelDistributor	**No**	Value can only be set when field Parallel Circuit = '2'. If that field is set to another value, this value is to be set to null. This field indicates the denomination of the company responsible for the parallel distribution of a medicinal product.
PackMultiplier	**No**	Multiplier of total Amount of the Pack Size. Only filled in case of Packs with different components which need further specification on total pack level. Example: Three-phase medicinal product '3' in 3 x 28 (12 + 10 + 6)
PackAmount	**No**	Total Amount of the Pack Size. Only filled in case of Packs with different components which need further specification on total pack level. Example: Three-phase medicinal product '28' in 3 x 28 (12 + 10 + 6) Has an optional reference to a unit type for amounts in a specific unit (e.g. ml for a pack containing a mixture of 150 ml total fluid)
PackDisplayValue	**No**	Calculated field based on information in the fields Pack Multiplier (AMPP), Pack Amount (AMPP), Content Multiplier (AMPPC), Content Amount (AMPPCES), Content Unit (AMPPCES), Pack Specification (AMPPC). Examples: '2 x 10 doses (25 ml)' '3 x 500 mg + 3 x 10 ml + 3 x Needle' '3 x 50 ml Easyflex N' '3 x 28 (12 + 10 + 6)'
Status	**Yes**	The status can be one of the following: - ACTIVE: the medicinal product has an authorization number for marketing in Belgium and can be commercialized; - SUSPENDED: the medicinal product can't temporarily be commercialized due to i.a. health problem; - REVOKED: the medicinal product is finally removed from the Belgian market and can't be commercialized anymore.
GTIN	**No**	The Global Trade Item Number is a globally unique 14-digit number used to identify trade items, products, or services.

Atc	**No**	ATC Classification of this package
DeliveryModus	**Yes**	Delivery modus of this package: on which condition can this package be delivered
DeliveryModusSpecification	**No**	Delivery modus specification of this package: more specific conditions than those specified above.
SingleUse	**No**	Is this medicinal product to be used a single time?
SpeciallyRegulated	**No**	The AMPP is specially regulated. Possible values: 0 – No special regulation 1 – Yes, no narcotic 2 – Yes, narcotic Other values can be added later.
AbbreviatedName	**No**	Abbreviated name of the medicinal product package. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional.
PrescriptionName	**No**	Structured and uniformly attributed name of the AMPP given by the BCPI as it is intended for consultation by the medicine prescriber. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional.
Note	**No**	Any useful textual information related to the medicinal product package. This field is translated in French, Dutch, German and English. When it is specified, French and Dutch versions are mandatory and others are optional.
PosologyNote	**No**	Note about the posology for the AMPP. This field is translated in French, Dutch, German and English. When it is specified, French and Dutch versions are mandatory and others are optional.
CrmLink	**No**	URL Link to the online commented directory of medicines page for this AMPP. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional.
NoGenericPrescriptionReason	**No**	If this medicine cannot be delivered based on a generic prescription, the reason is specified in this element.
ExFactoryPrice	**No**	Ex-factory price in Euro. This information is available only for reimbursable medicinal product packages.
ReimbursementCode	**No**	Possible status of the reimbursement: 0 – Original 1 – Copy 2 – Generic 3 – Reference 4 – Reference (exception) 5 – Reference (combi) 6 – Reference (exception combi) Other values can be added later.

DefinedDailyDose	**No**	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) in six days, he can have said to have consumed four DDDs of this drug.
OfficialExFactoryPrice	**No**	Ex-factory price in Euro, as defined in the agreement with FPS Economy.
RealExFactoryPrice	**No**	Ex-factory price in Euro, as accounted in practice.
PricingInformationDecisionDate	**No**	Date of the agreement with FPS Economy

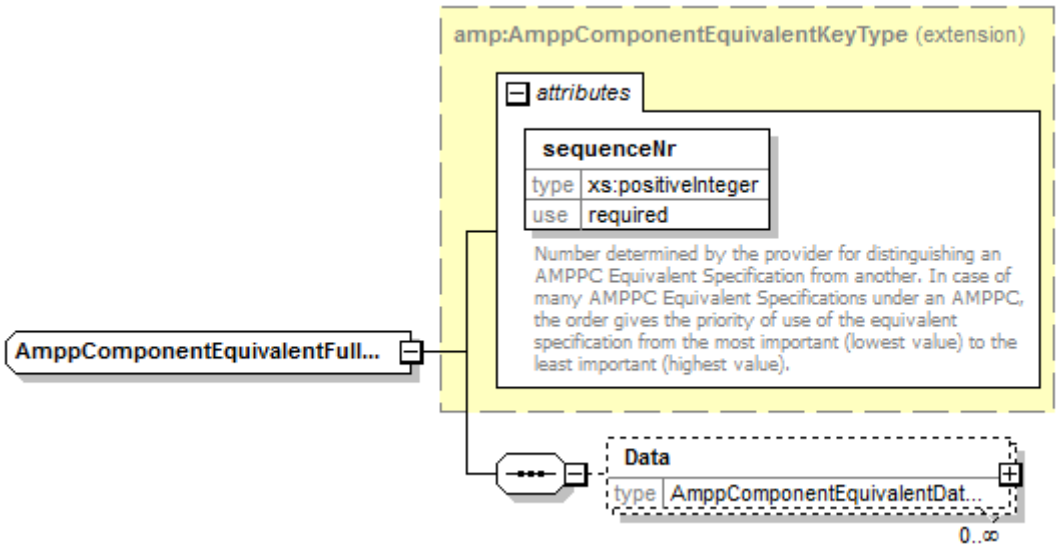
3.2.1. AmppComponent



AmppComponentDataType		
Field name	**Required**	**Description**

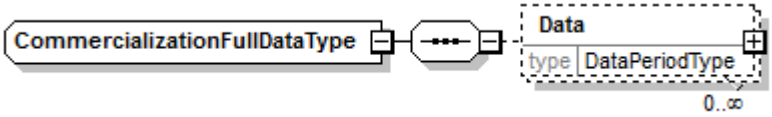
ContentType	**Yes**	Code value for the type of the component: - ACTIVE_ COMPONENT: part of the packaging information on the active substance(s) described as AMP component(s); - SOLVENT: part of the packaging information describing what solvent is contained in the AMPP; - DEVICE: medical device added to the packaging.
ContentMultiplier	**No**	Multiplier of the concerned component. Example: '3' in '3 x 500 mg'.
PackSpecification	**No**	Specification of the concerned component. Example: 'FreeFlex', 'EasyFlex N'
DeviceType	**No**	Type of device
PackagingClosure	**No**	Packaging closure of this component
PackagingMaterial	**No**	Packaging material of this component
PackagingType	**No**	Packaging type of this component

3.2.2. AmppComponentEquivalent



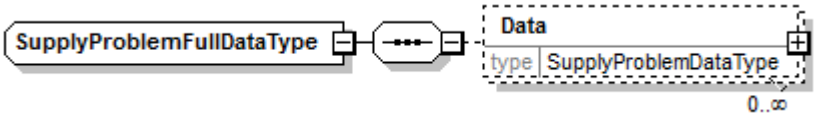
AmppComponentEquivalentDataType		
Field name	**Required**	**Description**
Content	**Yes**	This extra detail level in the AMPPC has been created because the packaging described in an AMPP can have one or many equivalent specification(s) which have to be specified for the medicinal product prescription. For example, a substance is described on the package with a quantity of "10 doses". It is important to also specify that these doses are equivalent to "10x 20ml" of that substance.

3.2.3. Commercialization



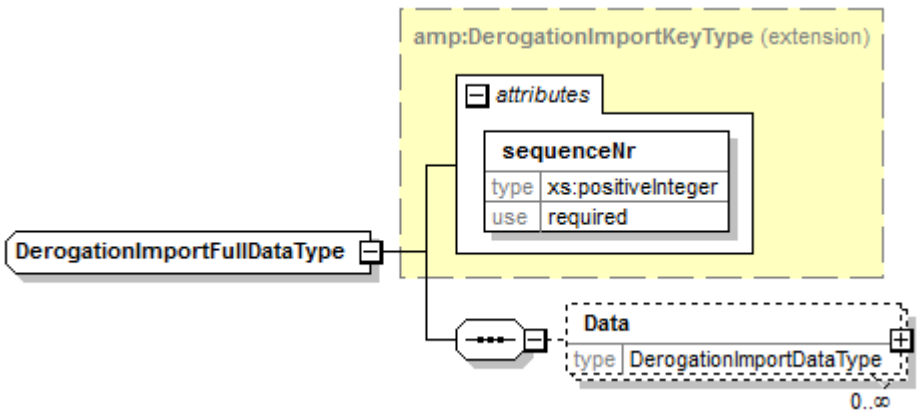
The commercialization type has neither attributes nor any data. It just indicates the period(s) in which the package was/is commercialized.

3.2.4. SupplyProblem



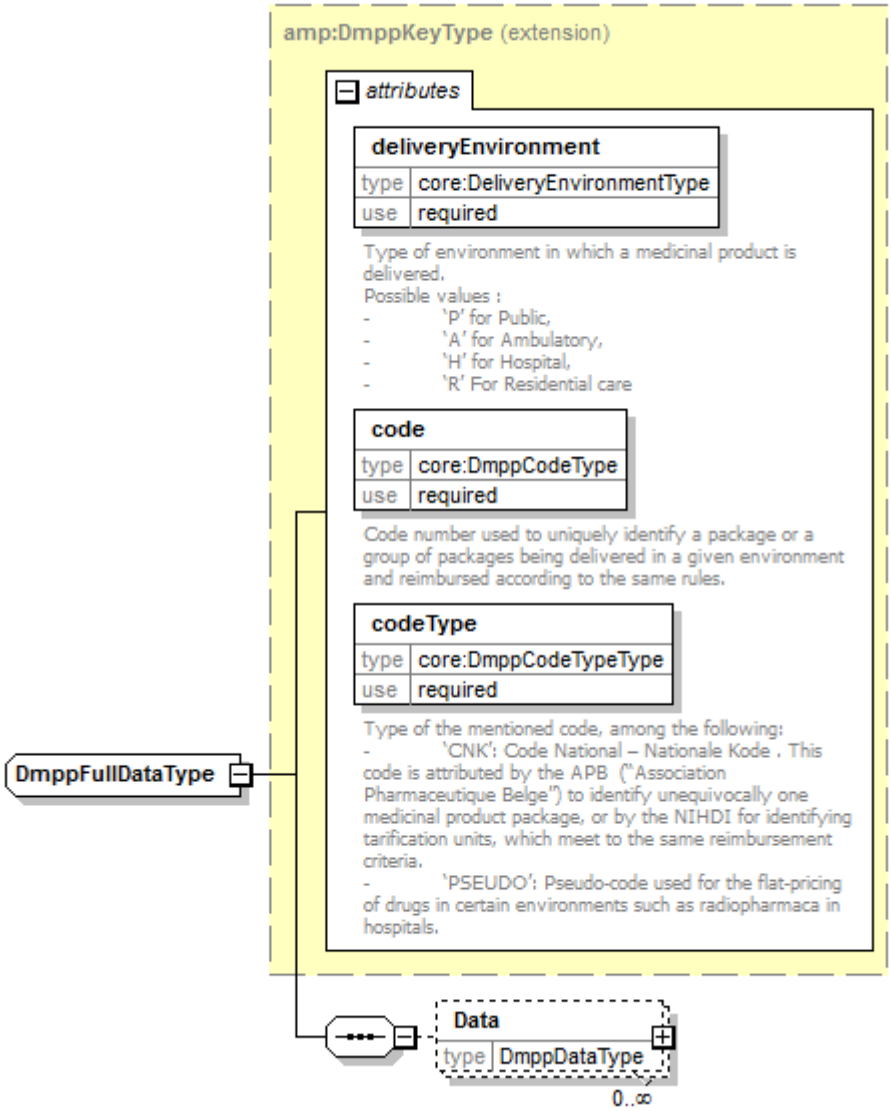
SupplyProblemDataType		
Field name	**Required**	**Description**
ExpectedEndOn	**No**	Expected end date of the supply problem.
ReportedBy	**No**	Name of the reporter of the supply problem: company ,doctor, patient, pharmacist, other.
ReportedOn	**No**	Date of the notification of the supply problem.
ContactName	**No**	Contact name for the supply problem.
ContactMail	**No**	Contact's mail address.
ContactCompany	**No**	Contact's company.
Phone	**No**	Contact's phone number.
Reason	**No**	If there is a supply problem, here's why. This field is translated in French, Dutch, German and English. When it is specified, French and Dutch versions are mandatory and others are optional.

3.2.5. DerogationImport



DerogationImportDataType		
Field name	**Required**	**Description**
Note	**Yes**	Available information (identification or description) of the imported drug. When it is specified, French and Dutch versions are mandatory and others are optional.

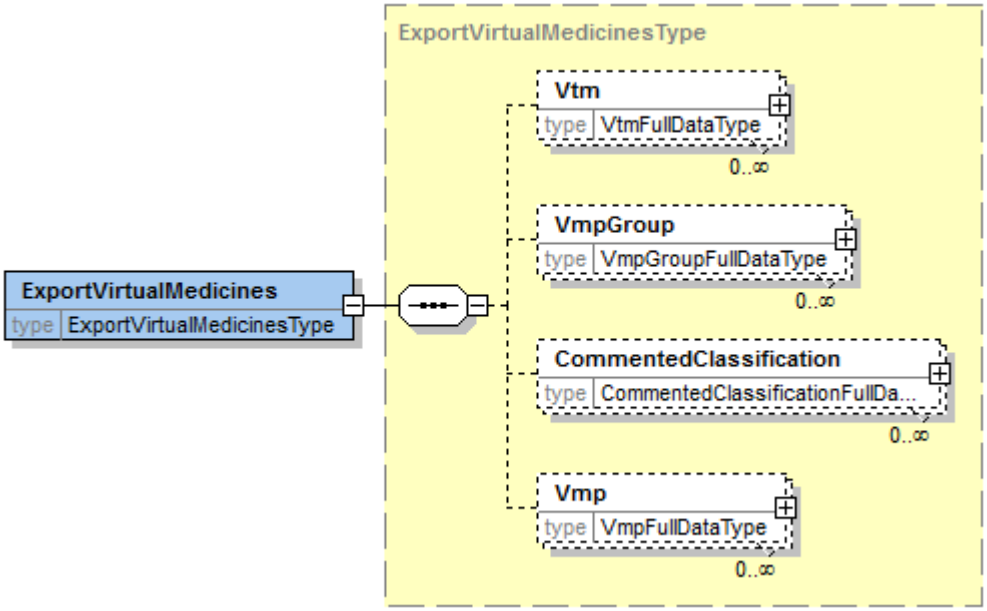
3.2.6. Dmpp



DmppDataType		
Field name	**Required**	**Description**
Price	**No**	Price in Euro of the AMPP in this environment.
Cheap	**No**	This product is considered by NIHDI as cheap.

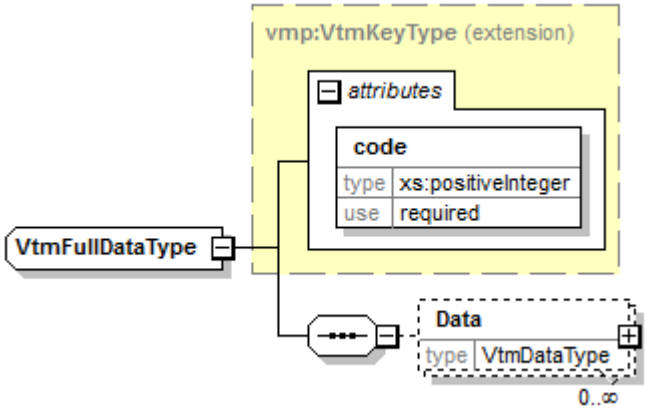
Cheapest	**No**	This product is considered by NIHDI as the cheapest on the market.
Reimbursable	**Yes**	By default, a DMPP is not reimbursed, even if an existing reimbursement context references the same CNK. The NIHDI must set this flag explicitly to True if the DMPP is Reimbursable.

3.3. Export Virtual Medicines



The Export Virtual Medicines is a bit different compared to the other exports of temporal data, in the sense that not only the root object (VMP) is exported, but also the temporal objects Vtm, VmpGroup and CommentedClassification from the Virtual Medicines domain. These objects are referenced from the Vmp tree, and will be expanded like normal references in the Vmp export. However, these objects can exist independently, and might be published without associated Vmps.

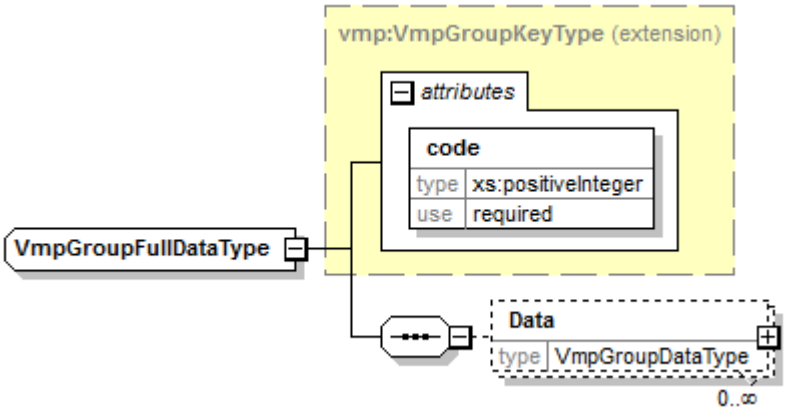
3.3.1. Vtm



VtmDataType

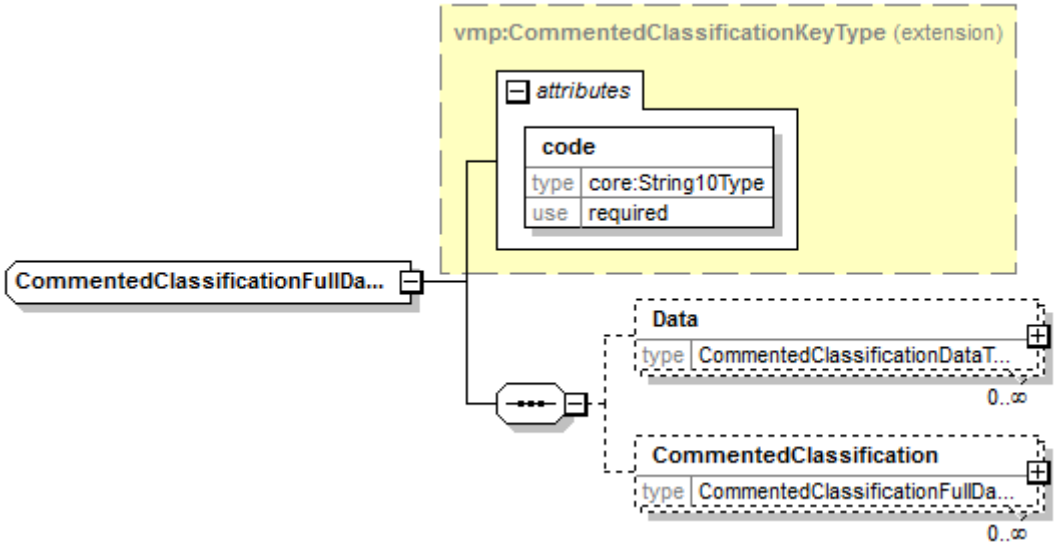
Field name	Required	Description
Name	**Yes**	The name of the VTM. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional. Example: 'actetylsalicylzuur + metoclopramide'.

3.3.2. VmpGroup



VmpGroupDataType		
Field name	**Required**	**Description**
Name	**Yes**	Name of this group. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional. Example: 'amoxicilline 1g oraal'.
NoGenericPrescriptionReason	**No**	Indicates the reason why this VMP Group can't be generically prescribed.
NoSwitchReason	**No**	The generic prescription for VMP's in this group cannot change. The code indicates the reason.

3.3.3. CommentedClassification

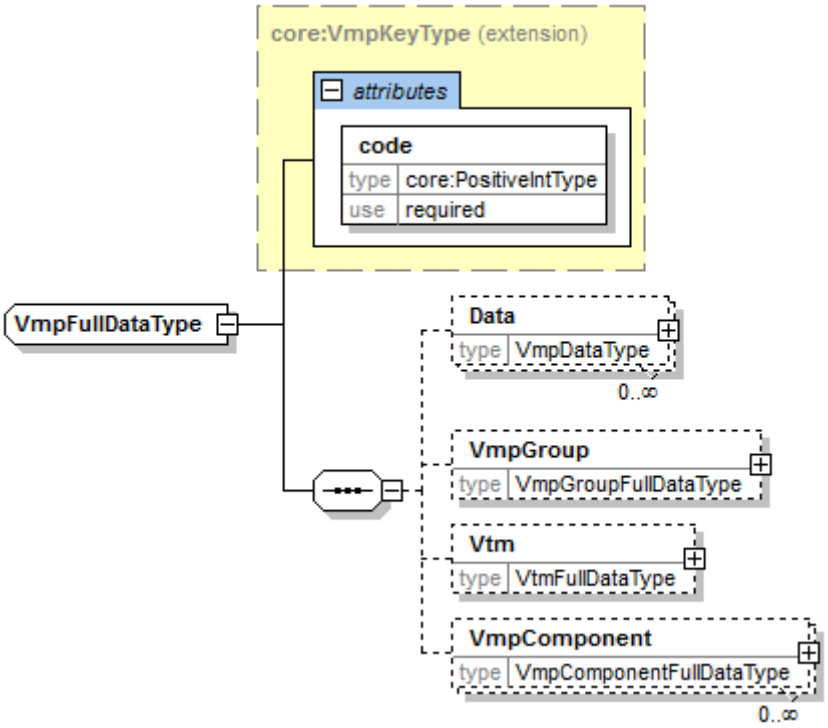


Commented Classification is a recursive data type. The exported Commented Classification is always the root Commented Classification, and children are exported as a tree structure.

The same goes for the incremental export: even if just a leaf node has changed, the entire tree starting from the root commented classification is exported again (following the same logic as the incremental export for the other root objects).

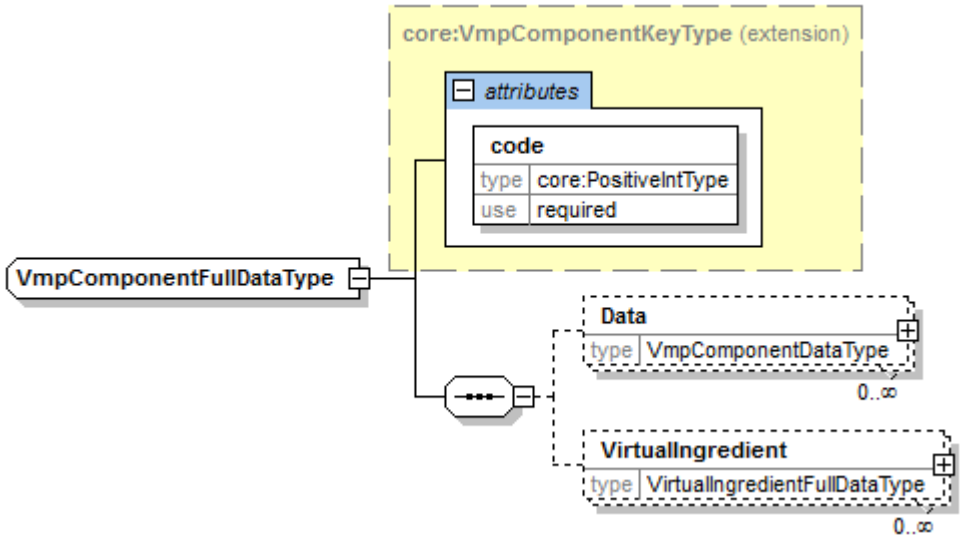
CommentedClassificationDataType		
Field name	**Required**	**Description**
Title	**No**	Title of the referenced classification level. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional.
Content	**No**	Content of the referenced classification level. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional.
PosologyNote	**Yes**	Any note about the posology for the referenced classification level. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional.
URL	**No**	URL to relevant information from BCPI about the referenced classification level. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional.

3.3.4. Vmp



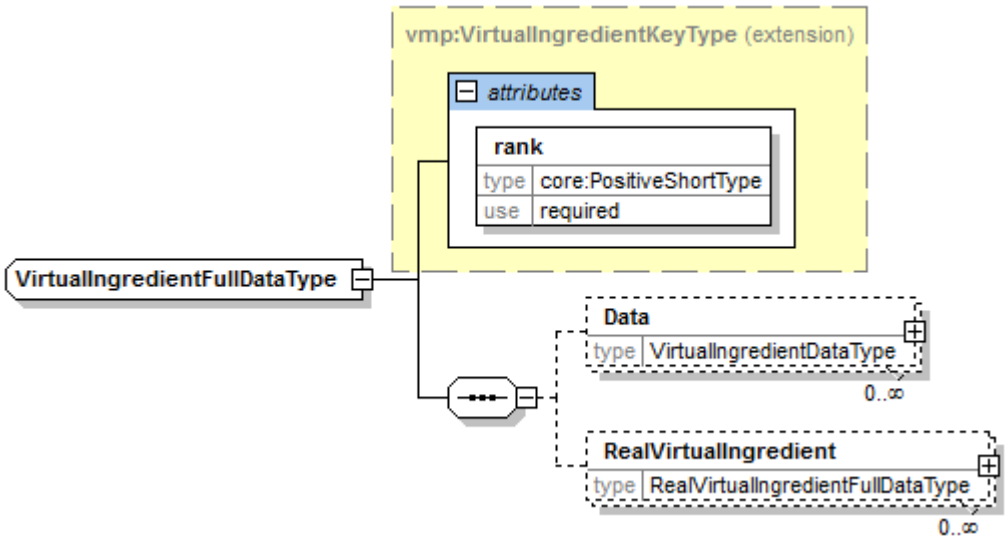
VmpDataType		
Field name	**Required**	**Description**
Name	**Yes**	Name of the VMP. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional. Ex.: “pérampanel 8mg (oral)”
Abbreviation	**Yes**	Abbreviated name of the VMP. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional.
Wada	**No**	A VMP can be attributed zero, one or many WADA code(s).
CommentedClassification	**No**	A VMP can be attributed zero, one or many Commented Classifications.

3.3.5. VmpComponent



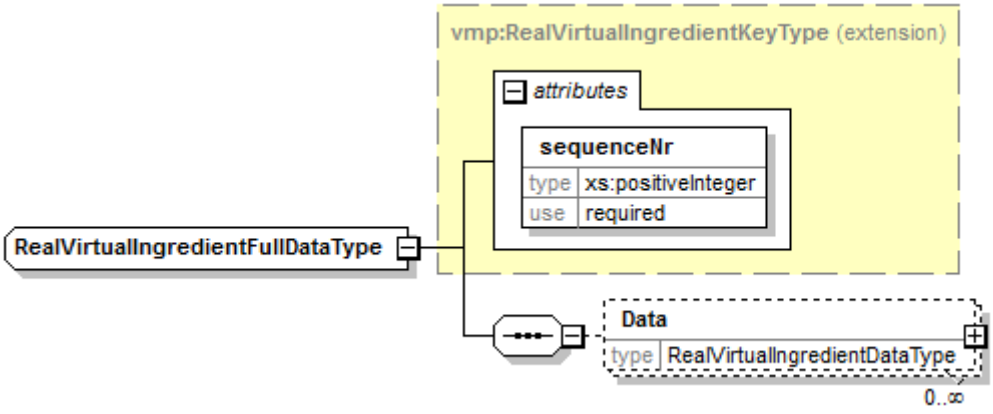
VmpComponentDataType		
Field name	**Required**	**Description**
PhaseNumber	**No**	For multi-phased VMP's only, the number of the phase this component applies to. This phase number is used for displaying the components in the correct order on the internet site and in the booklet. In case of a sequential product, this also represents the order of intake of the different components.
Name	**Yes**	Name of the VMP Component. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional.
VirtualForm	**Yes**	A VMP Component has exactly one virtual form.
RouteOfAdministration	**Yes**	A VMP Component has one or many route(s) of administration.

3.3.6. VirtualIngredient



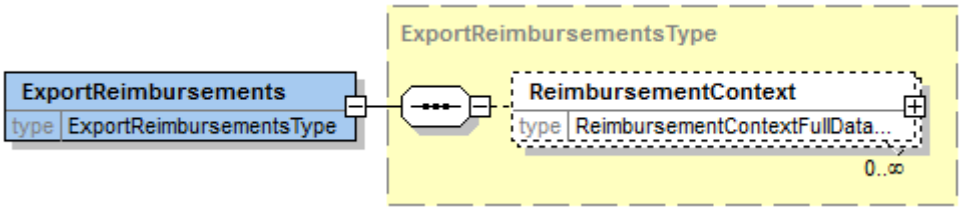
VirtualIngredientDataType		
Field name	**Required**	**Description**
Type	**Yes**	Type of use for the specified substance (given by the link to the reference entity Substance). Possible values : - ACTIVE_SUBSTANCE: the substance participates in the medicinal product effect ; - EXCIPIENT: not active substance used to make the medicinal product more attractive.
Strength	**No**	Strength of the specified substance. Some substance quantities cannot be specified exactly, so a range is provided. If an exact quantity is known, minimum and maximum will have the same value.
Substance	**Yes**	The substance reference for this ingredient.

3.3.7. RealVirtualIngredient

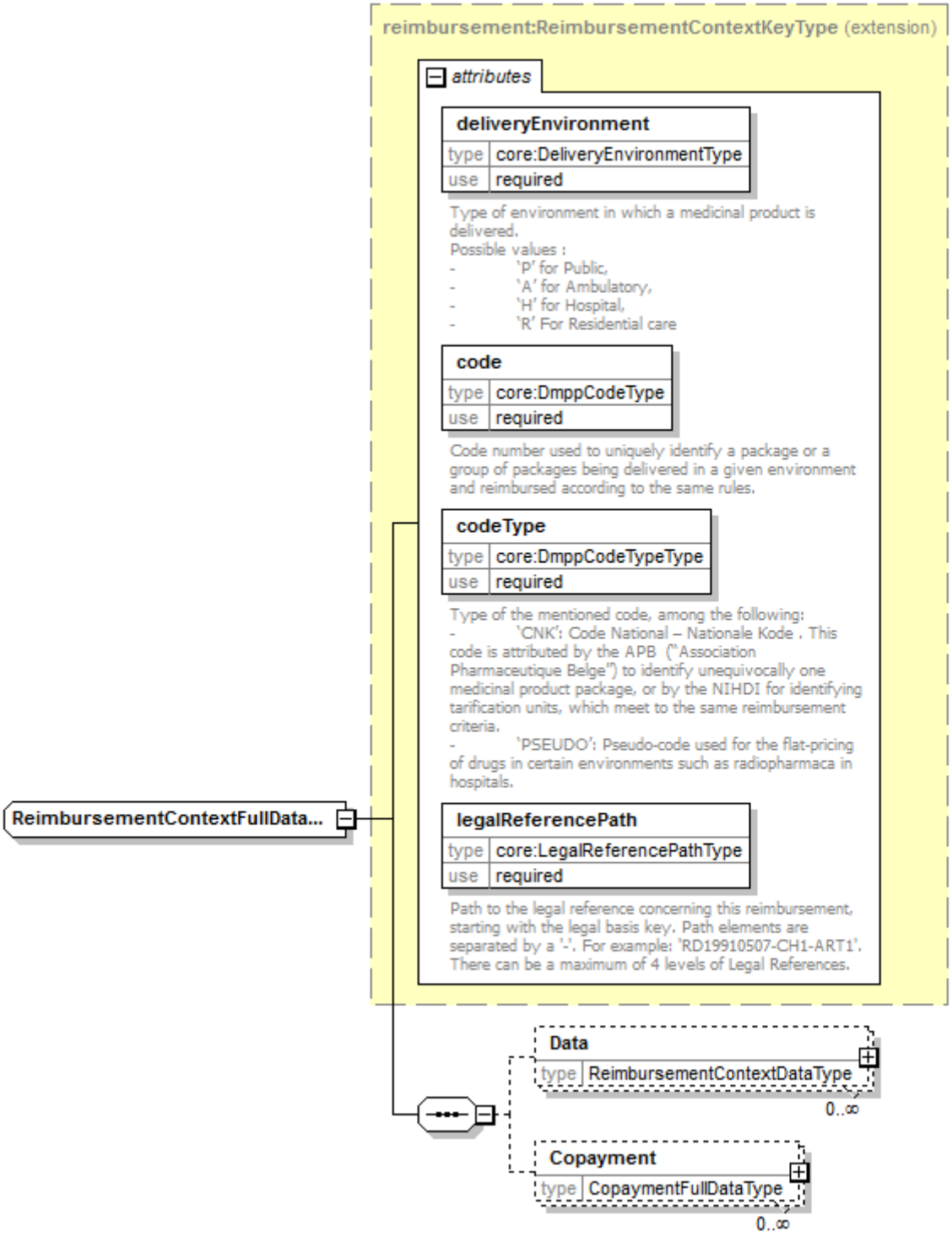


RealVirtualIngredientDataType		
Field name	**Required**	**Description**
Type	**Yes**	Type of use for the specified substance (given by the link to the reference entity Substance). Possible values : - ACTIVE_SUBSTANCE: the substance participates in the medicinal product effect ; - EXCIPIENT: not active substance used to make the medicinal product more attractive.
Strength	**No**	Strength of the specified substance. Some substance quantities cannot be specified exactly, so a range is provided. If an exact quantity is known, minimum and maximum will have the same value.
Substance	**Yes**	The substance reference for this ingredient.

3.4. Export Reimbursements



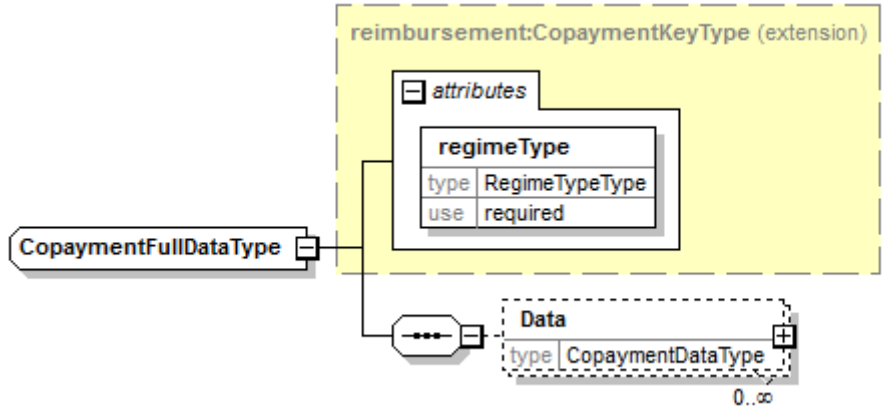
3.4.1. ReimbursementContext



ReimbursementContextDataType		
Field name	**Required**	**Description**
Multiple	**No**	Does the reimbursement context allow to mention several

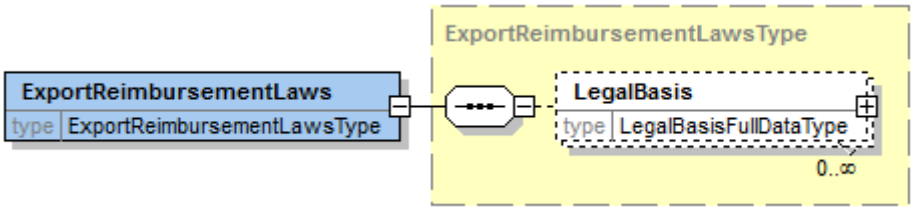
		packages of the same AMPP on the same prescription? Certain particularities of the agreement are expressed here according to codes. Possible values: - 'Null' = no possibility of prescription and reimbursed delivery of several packages, - 'M' = possibility of prescription and reimbursed delivery of several packages, - 'V' = possibility of reimbursed delivery of several packages in case of a prescription expressed as a posology and treatment duration, Default is 'Null'.
Temporary	**Yes**	Does it concern a temporarily reimbursable pharmaceutical (on the basis of an agreement between the NIHDI and the pharmaceutical company)? Yes or no.
Reference	**Yes**	Does the reference reimbursement system apply? Yes or no.
FlatRateSystem	**Yes**	Does a flat-rate system applies to this reimbursement? Yes or no.
ReimbursementBasePrice	**Yes**	Does a flat-rate system applies to this reimbursement? Yes or no.
ReferenceBasePrice	**Yes**	Amount in Euro of the reimbursement level for the related delivery environment – no reference reimbursement system.
CopaymentSupplement	**No**	Amount in Euro to be paid by the patient if – in case the reference reimbursement system applies – the price applied by the manufacturer is higher than the reimbursement level.
PricingUnit	**Yes**	Amount and unit (in French and Dutch) of the pricing (tarification) unit.
PricingSlice	**No**	Amount and unit (in French and Dutch) of the pricing (tarification) slice.
ReimbursementCriterion	**Yes**	See the definition in the Reimbursement Criterion entity.

3.4.2. Copayment

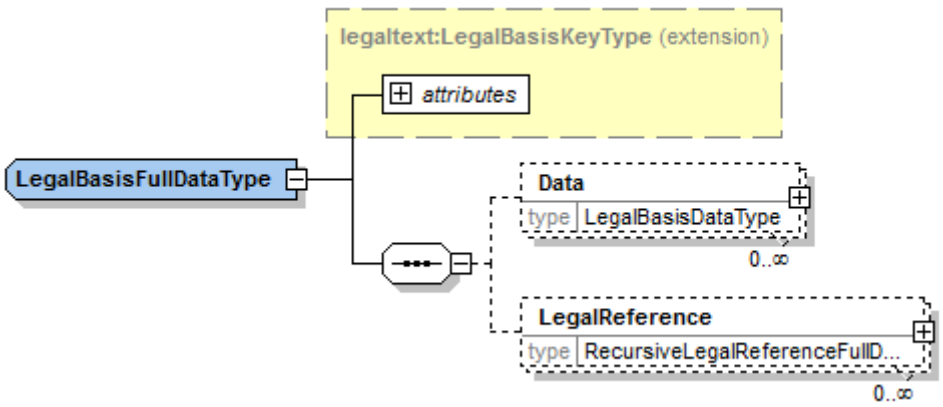


CopaymentDataType		
Field name	**Required**	**Description**
FeeAmount	**Yes**	Amount paid according to this regime

3.5. Export Reimbursement Laws

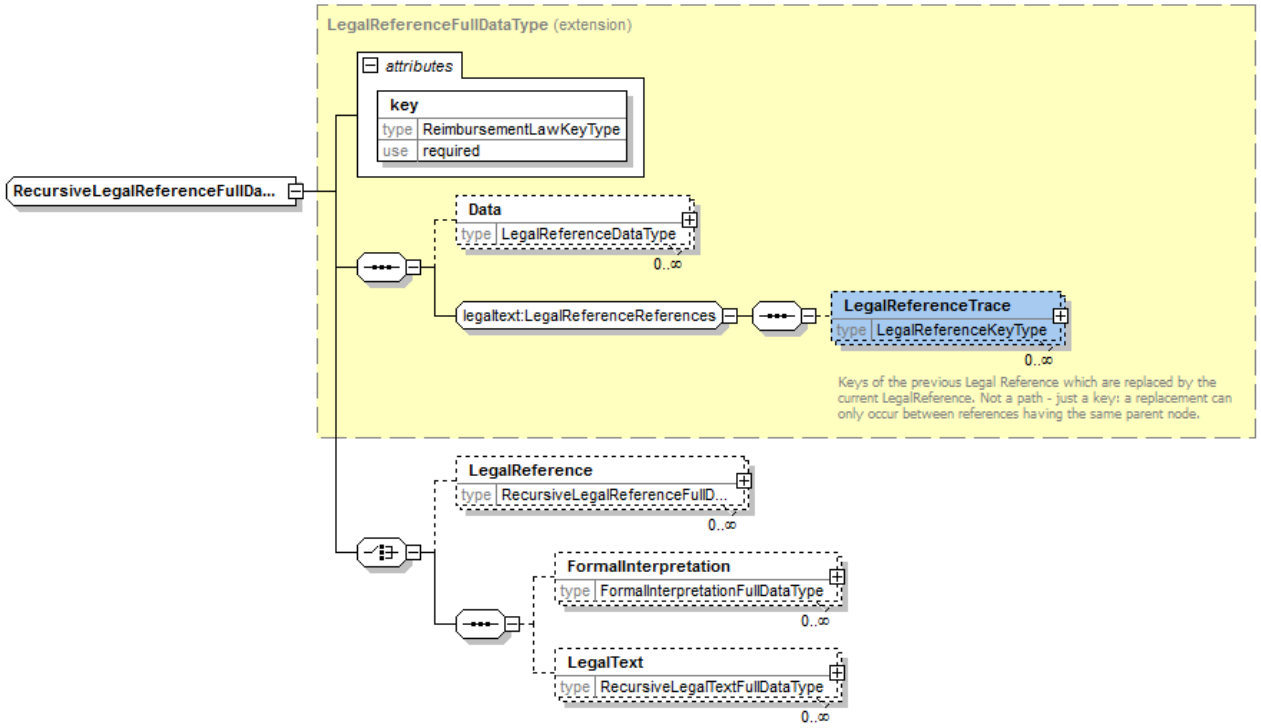


3.5.1. LegalBasis



LegalBasisDataType		
Field name	**Required**	**Description**
Title	**Yes**	Official title of the legal basis (retrieved from the referenced legislation text). This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional.
Type	**Yes**	The type of the legal basis.Possible values: - ROYAL_DECREE - COORDINATED_LAW Other values can be added later.
EffectiveOn	**No**	Legal basis effective on this date.

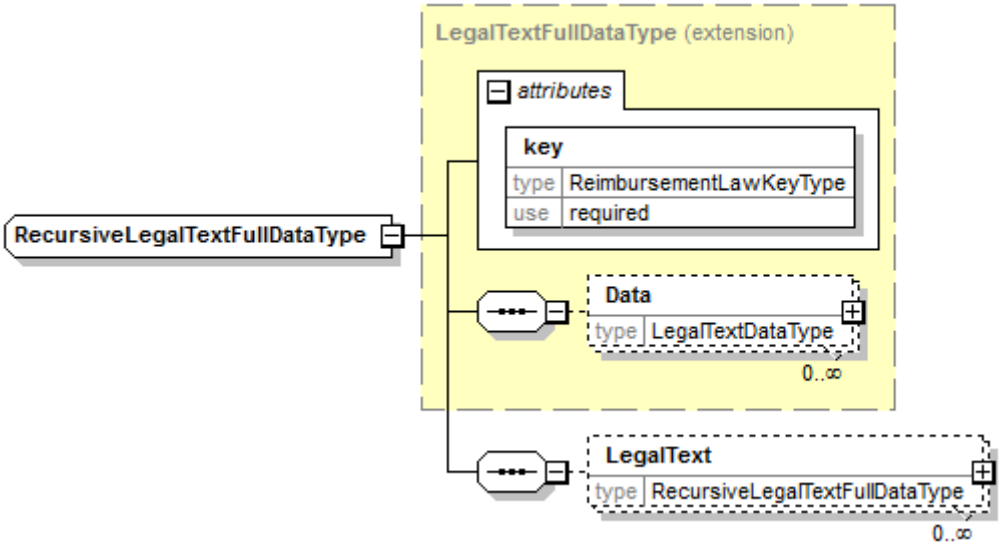
3.5.2. LegalReference



LegalReferenceDataType		
Field name	**Required**	**Description**
Title	**Yes**	Title of this legal reference. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are

		optional.
Type	**Yes**	Possible values: - ARTICLE - PARAGRAPH - CHAPTER - SECTION Other values can be added later.
FirstPublishedOn	**No**	Date of the first publication in the Belgian Monitor.
LastModifiedOn	**No**	Date of the last modification.
LegalReferenceTrace	**No**	Keys of the previous Legal Reference which are replaced by the current LegalReference. Not a path - just a key: a replacement can only occur between references having the same parent node.

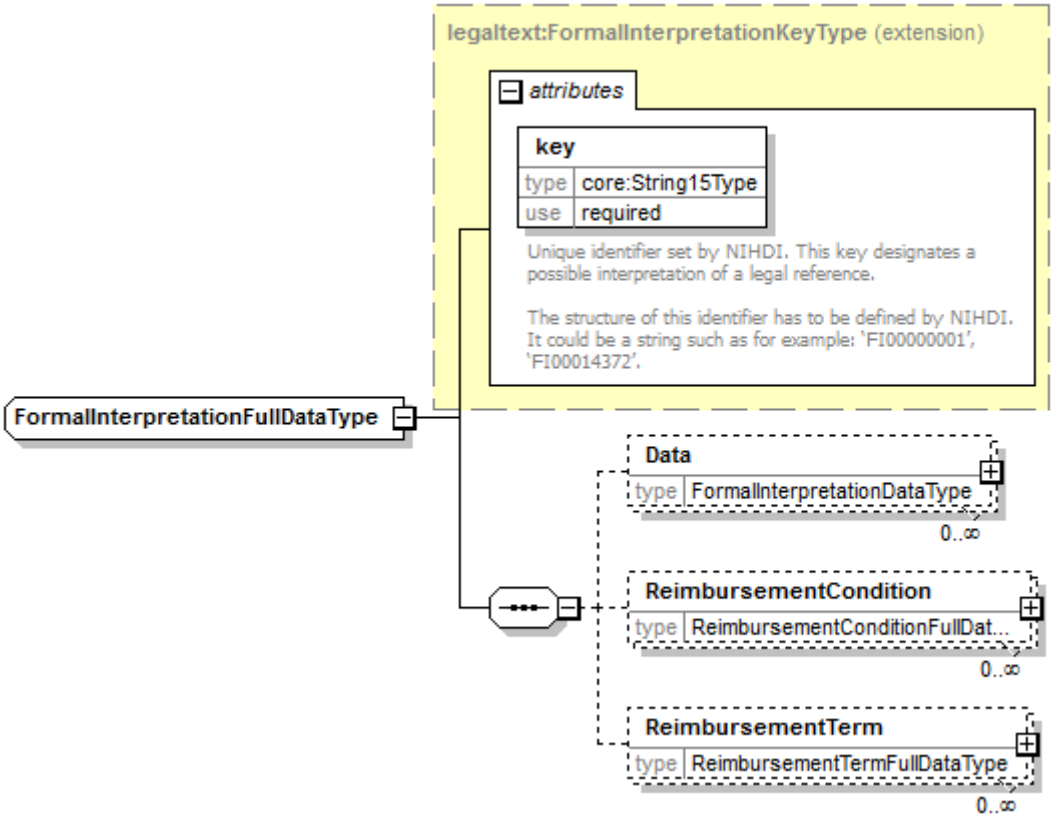
3.5.3. LegalText



LegalTextDataType		
Field name	**Required**	**Description**
Content	**Yes**	Content of the legal text. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional
Type	**Yes**	Type of the text defined by NIHDI. Possible values : - ALINEA - POINT Other values can be added later.

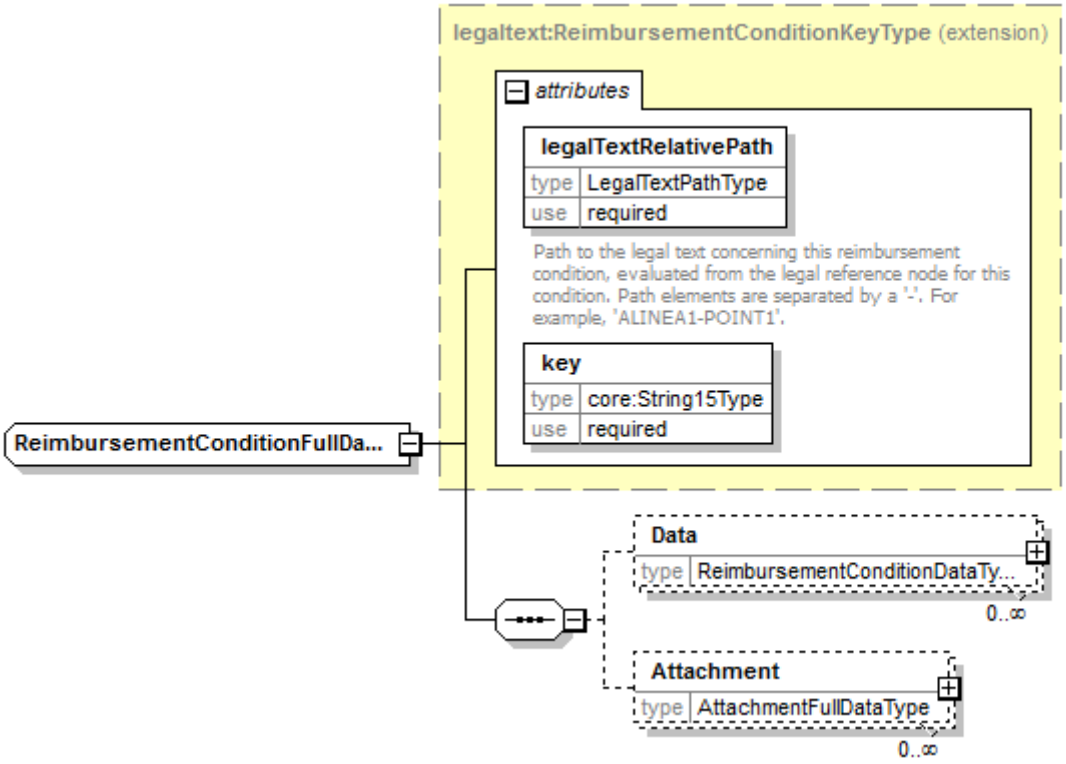
SequenceNr	**Yes**	Sequence number used for sorting different legal text elements at the same level. No business checks are done on this number. The provider is responsible for publishing a sequence number only once for a given parent and validity period.
LastModifiedOn	**No**	Date of the last modification.

3.5.4. FormalInterpretation



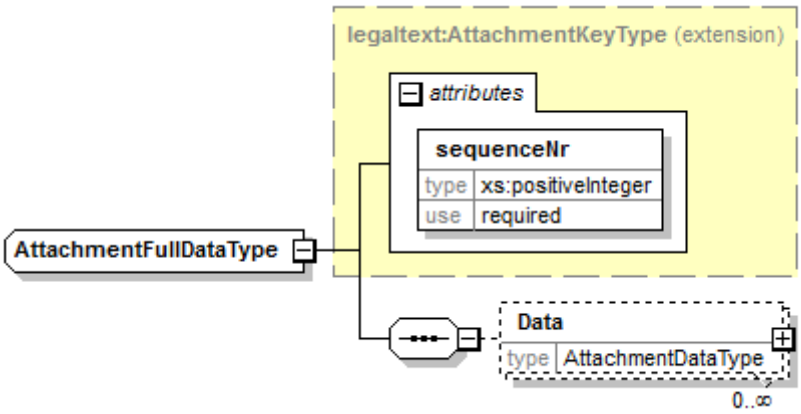
FormalInterpretationDataType		
Field name	**Required**	**Description**
Rule	**Yes**	A logical expression involving conditions. An interpreter is needed to evaluate the expression. Example: “[cond1] and [cond2]” where [cond1] and [cond2] refer to “Reimbursement Condition”.

3.5.5. ReimbursementCondition



ReimbursementConditionDataType		
Field name	**Required**	**Description**
Expression	**Yes**	A logical expression involving Variables.

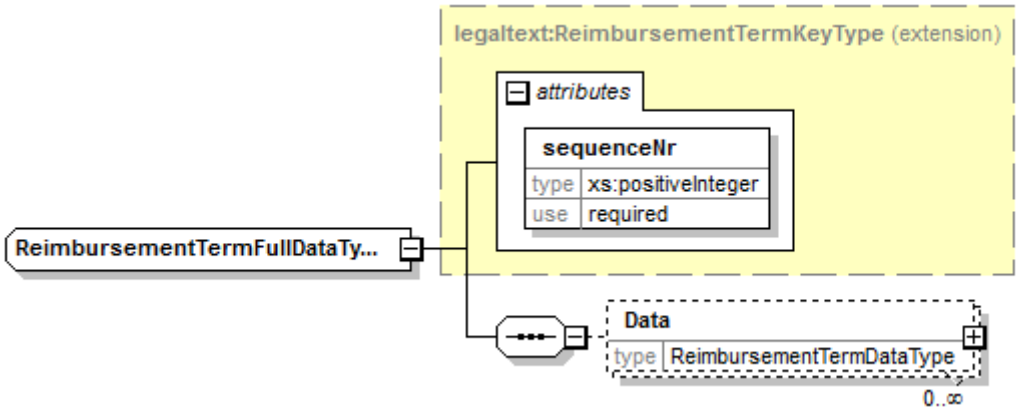
3.5.6. Attachment



AttachmentDataType		
Field name	**Required**	**Description**

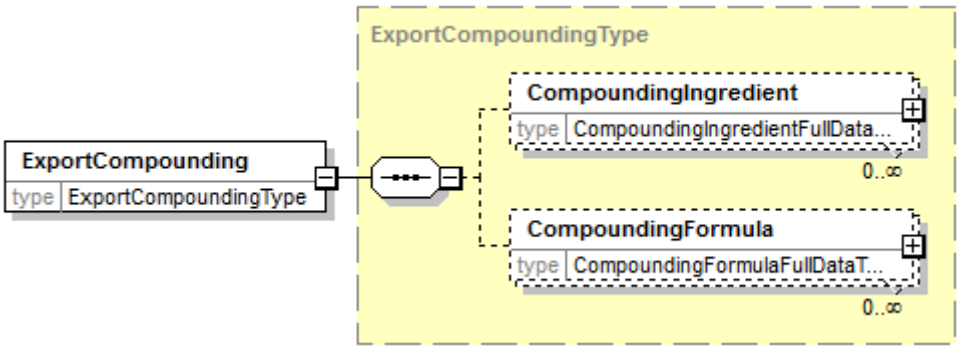
Name	**Yes**	Name of the added document in attachment of the reimbursement condition. This field is translated in French, Dutch, German and English. French and Dutch versions are mandatory and others are optional.
TemplateUrl	**Yes**	Location where to retrieve the document.
Mandatory	**Yes**	Indicates whether this attachment has to be attached to an electronic request. If False, the attachment must not be sent electronically but must be held by the requesting party at the disposal of the insurance organisation.
Appendix	**Yes**	Unique code set by NIHDI for each possible appendix.
FormCategory	**Yes**	See the description in the entity Form Category.

3.5.7. ReimbursementTerm

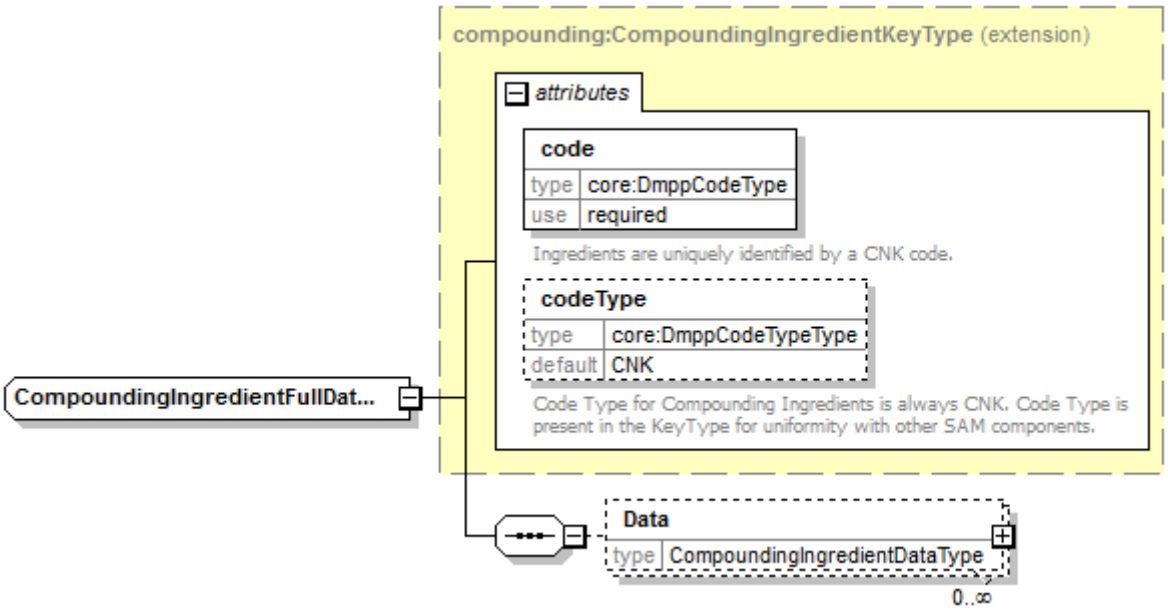


ReimbursementTermDataType		
Field name	**Required**	**Description**
ValueUnit	**Yes**	Unit for the referenced quantity
Parameter	**Yes**	Unique name given to the parameter.

3.6. Export Compounding

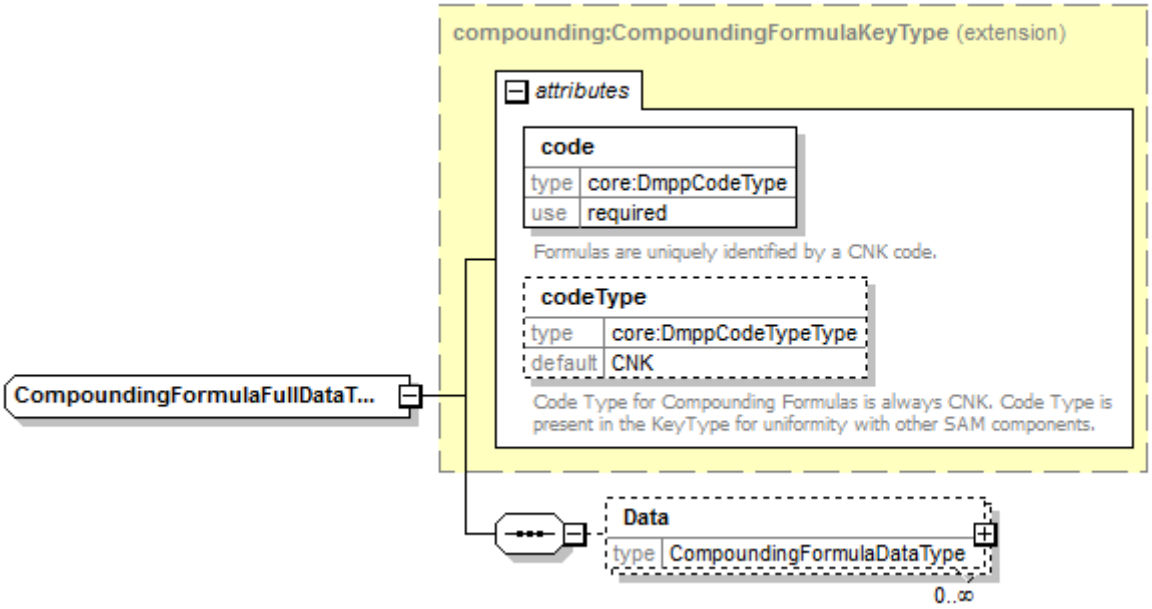


3.6.1. Compounding Ingredient



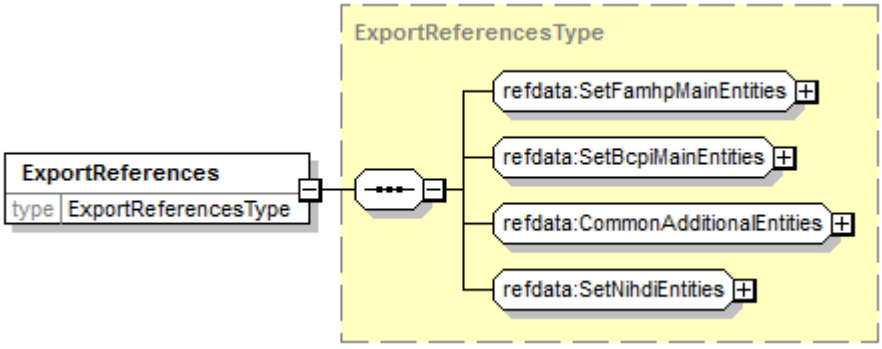
Compounding Ingredient Data Type		
Field name	**Required**	**Description**
Synonym	**No, Unbounded**	List of (Language, Rank, Value) tuples. The same ingredient can be known under several names. All synonyms are added with their language code and rank (1 being the most important or most frequently used).

3.6.2. Compounding Formula



Compounding Formula Data Type		
Field name	**Required**	**Description**
Synonym	**No, Unbounded**	List of (Language, Rank, Value) tuples. The same formula can be known under several names. All synonyms are added with their language code and rank (1 being the most important or most frequently used).

3.7. Export References



References are always exported completely the Full Export. In the Incremental export, there is a complete export of reference entities that had a change.

3.7.1. FAMHP Main Entities

Data per reference type:

- AtcClassification

    - Code
    - Description
- DeliveryModus
    - Code
    - Description
- DeliveryModusSpecification
    - Code
    - Description
- DeviceType
    - Code
    - Name
    - EDQM Code
    - EDQM Definition
- PackagingClosure
    - Code
    - Name
    - EDQM Code
    - EDQM Definition
- PackagingMaterial
    - Code
    - Name
- PackagingType
    - Code
    - Name
    - EDQM Code
    - EDQM Definition
- PharmaceuticalForm
    - Code
    - Name
- RouteOfAdministration
    - Code
    - Name
- Substance
    - Code
    - Chemical Form
    - Name
    - Note

3.7.2. BCPI Main Entities

Data per reference type:

- NoSwitchReason

    - Code
    - Description
- VirtualForm
    - Code
    - Abbreviation
    - Name
    - Description
- Wada
    - Code
    - Name
    - Description
- NoGenericPrescriptionReason
    - Code
    - Description

3.7.3. Common Additional Entities

Data per reference type:

- StandardForm
    - Standard
    - Code
    - Name
    - Definition
    - Url
    - PharmaceuticalFormCode
    - VirtualFormCode
- StandardRoute
    - Standard
    - Code
    - Name
    - Definition
    - URL
    - RouteOfAdministrationCode
- StandardSubstance
    - Standard
    - Code
    - Name
    - Definition
    - URL
    - SubstanceCode
- StandardUnit

- Name

3.7.4. NIHDI Entities

Data per reference type:

- Appendix
  - Code
  - Description
- FormCategory
  - Code
  - Description
- Parameter
  - Unit Type
  - Domain
- ReimbursementCriterion
  - Category
  - Code
  - Description