

COOKBOOK

Business project: the medication scheme

Annotated by RSW / RSB in the context of the action point 3 of the eHealth roadmap



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DOCUMENT MANAGEMENT

1.1

History of the document

Version	Date	Description of the amendments / comments
0.2	30/01/2012	Initial (draft) version of the cookbook, based on the template.
0.3	02/02/2012	Update based on input from VAZG (Wim van Slambrouck, Thomas van Langendock). Integration 2 (small) modifications to the data model based on feedback on the technical data model (including modification of XML examples).
0.4	20/04/2012	Update of the cookbook.
1.0	10/05/2012	Update of the cookbook.
1.1	01/06/2012	Update cookbook following release 1.0.0 of the Vitalink Connector: <ul style="list-style-type: none">– Addition of use of Vitalink Connector, addition to chapter 6 and 7;– Modification of validation rules Kmehr message (paragraph 4.2.2);– Modification to paragraph 4.4.4.2 (option 2).
1.2	04/07/2012	Update cookbook following release 1.1.0 of the Vitalink Connector: <ul style="list-style-type: none">– Modification of validation rules Kmehr message (paragraph);– Clarification following work meeting (13/06/2012) and questions from software developers (paragraph 4.3.3);– Modification of XML examples (paragraph 4.5).
1.3	08/08/2012	Update cookbook: <ul style="list-style-type: none">– Addition of versions of Kmehr defined lists (paragraph 4.3.5);– Modification of XML examples (paragraph 4.5).
1.4	10/09/2012	Update cookbook: <ul style="list-style-type: none">– Modification of versions of document references.
1.5	30/10/2012	Update cookbook: <ul style="list-style-type: none">– Modification of optional fields in author block (paragraph 4.4.1);– Clarification in paragraph §4.4.2: Option 2.
1.6	27/11/2012	Update cookbook: <ul style="list-style-type: none">– Addition of extra validation rules following technical

		forum (21/11/2012)(paragraph 4.2.2);
		<ul style="list-style-type: none"> – Clarification with regard to the definition of the provided medication (paragraph 4.4.2); – Clarification with regard to the use of the <posology> tag (paragraph 4.4.3.2).
1.7	17/12/2012	Update cookbook: <ul style="list-style-type: none"> – Update of reference to kmehr website (paragraph 4.2.1); – Clarification of the used kmehr lists (paragraph 4.3.5).
2.0	01/07/2013	Update cookbook: <ul style="list-style-type: none"> – Further clarification of several use cases (Chapter 3).

2.1	01/08/2013	<p>Update cookbook for the purpose of adding guidelines regarding input and display of a summary document.</p> <ul style="list-style-type: none"> – Addition of guidelines with regard to the display of a summary document (paragraph 5.1); – Addition of guidelines with regard to input (paragraph 5.2); – Modification of the summary of Kmehr defined lists with the addition of unauthorized codes (paragraph 4.3.5); – Modification of validation rules in accordance with new/revised guidelines (paragraph 4.2.2); – Expansion of the data of which the name should be included for a pharmaceutical compound (paragraph 4.4.2, option 4 “In the case of a pharmaceutical compound”);
2.2	30/10/2013	<p>Update cookbook:</p> <ul style="list-style-type: none"> – Explanation with the new version of the used Kmehr list CD-ADMINISTRATIONUNIT; – Modification of the guideline with regard to the absence of frequency/periodicity.
3.0	10/01/2014	<p>Update cookbook:</p> <ul style="list-style-type: none"> – Chapter 5 and 6 (Example of how to use the Vitalink Connector (Java/.NET) subsumed in a separate cookbook.
4.0	28/03/2014	<p>Update cookbook:</p> <ul style="list-style-type: none"> – Addition of user groups; – Expansion of the metadata.
4.1	29/09/2014	<p>Update cookbook:</p> <ul style="list-style-type: none"> – Addition of user groups: dentist and midwife.
5.3	20/07/2017	<p>Update Cookbook:</p> <ul style="list-style-type: none"> -Addition of the Vitalink Gateway -addition of NIS-code -changes regarding RFC's
5.4	08/08/2017	<p>Annotation by RSW/RSB in the context of the action point 3 of the eHealth roadmap.</p> <ul style="list-style-type: none"> - Highlighting of regional “safe” specificities
5.5	08/12/2017	<p>Additional business validations:</p> <ul style="list-style-type: none"> - ‘beginmoment’ does not contain ‘time’ - ‘regimen’ cannot be combined with hourly ‘periodicity’ - ‘posology’ or ‘regimen’ is mandatory - All ‘unit’ have the same value within the transaction

Purpose of the document

As part of the set of documents that will be made available to software developers, this document provides a general overview of the business project pertaining to the medication scheme.

This document contains the following information:

- It contains functional and technical information with regard to the medication scheme as a Vitalink business project;
- It describes the data to be exchanged and their specific structure;
- It translates the functional use cases to the use of Vitalink services;
- Recommendations are given regarding the integration into end-user software applications;

The information contained in this document, together with all other technical information that is offered should enable a software developer or the IT department of an organisation to achieve integration with the Vita-Link solution.

This document is not a comprehensive manual for the development or modification of a software application but provides all the information to analyse and perform such activities.

Explanation with regard to the current status of this document

The information contained in this cookbook was correct at the time of publication, the reader is advised to consult or contact the location where this information is published, or contact VAZG (Flemish Agency for Care and Health) for any new versions of this document.

RSW/RSB annotation

In the context of the AP3 eHealth roadmap, the regional safes in Wallonia, RSW, and in Brussels, RSB-BGN, reuse the business data structure defined by Vitalink for the medication scheme. Consequently, we just annotate the document elaborated by VAZG just to point out some “specificities”. Those “specificities” are however more related to architecture and to the approach with respect to some sectors (points slightly addressed in this document) than to the business data structure itself.

2

INTRODUCTION TO THE MEDICATION SCHEME

2.1 Context

Various modules will run on the Vitalink platform. The ICT working group, a working group of the Primary Health Care Collaboration Platform, decided in April 2011 to start with the medication scheme. This project is intended to provide a patient's medication scheme to all authorized care providers.

A medication scheme firstly provides an overview of all the medication that a patient takes at a particular time. Secondly it indicates for each individual medicine, during which period which dose should be taken/administered at which time (duration, frequency and dosage).

2.2 Users and players

2.2.1 Users

The users of the medication scheme are:

Healthcare users (patients/clients)

Individual care providers

- Physicians
- Pharmacists
- Nurses (self-employed or in a group practice)
- Dentists
- Midwives

Care providers in a facility from

- Home care/home nursing, teams for home nursing (312)
- Home care and additional home care, day care centres, local service centres, babysitting facilities, day centres for palliative care, logistical assistance, host families (207)
- Residential elderly care, assisted living centres, service flats and housing complexes, rest and nursing homes, short stay centres (220)
- Hospitals
- Hubs

2.2.2 Needs and requirements of the users

It is not easy for a care provider to know which medication a patient uses. There are different medication information sources and each party has the information that is important to gain an insight into which medication a patient uses. This project will be a tool to optimize these information flows.

Healthcare providers authorized to prescribe medicines (physicians) and pharmacists have the possibility to create a medication and to consult on the Vitalink platform. Nurses have the possibility to change a medication scheme and to request a validation from the prescriber and they can also consult the medication scheme.

Care providers working in facilities have the possibility to create and consult a medication scheme. With the exception of the care and social workers in services from the home care and additional home care, day care centres, local service centres, babysitting facilities, day centres for palliative care, logistical assistance, host families only a few have the possibility to consult the medication scheme.

The healthcare user (patient/client) has the possibility to consult his own medication scheme.

2.2.3 **General practitioner**

A general practitioner knows which medication he has prescribed. Several doctors can prescribe medication for a patient. This information is not always shared.

A general practitioner requires the fullest possible information about current and recent medication use to be able to prescribe an appropriate medication, to specify the proper dosage and to monitor the usage pattern in relation to the patient's health, the overall medication use and the necessary treatment.

2.2.4 **Pharmacist**

A pharmacist knows which medication was dispensed. To a certain extent this is consistent with the prescribed medication. However, not every medicine is provided exactly according to the prescription (e.g. replacement of the prescribed medicine by an equivalent) and besides the prescribed medication a patient may also use OTC medicines (medication without a prescription). A pharmacist not only has more or less information available, he also has additional information. When a prescription indicates the name of a substance, the pharmacist must dispense a corresponding medicine.

A pharmacist needs to have information about the current medication use. This will allow the pharmacist to dispense an adapted medication, indicate the correct dosage and monitor the usage pattern in relation to the patient's health, the overall medication use and the necessary treatment.

2.2.5 **Midwives**

Midwives have the right to prescribe medication and they administer medication that is prescribed by a doctor. Therefore it is important for midwives to be able to consult and change medication schemes.

2.2.6 **Dentists**

Dentists need access to the medication scheme because:

- they are health care providers performing medical acts like surgery. A medication scheme can provide important indications about the health situation of a given patient;

- dentists treat, on a daily basis, patients with a complex health situation like very old people. These treatments require a good knowledge about the general condition of the patient.

- dentists prescribe medication. Consultation of a medication scheme can prevent interactions with other medication.

2.2.7 **Nurses**

Nurses (self-employed or in a group practice) have an insight into the medication that the healthcare users actually use. It is possible that not every medicine dispensed by a pharmacy is actually taken/administered. On the other hand the healthcare user may still have medication and starts using this again. Furthermore, nurses can help the healthcare user in administering/taking the medication as well as monitoring the actual medication use.

2.2.8

Care providers in facilities

Care providers in facilities have an insight into the medication that the healthcare users actually use. It is possible that not every medicine dispensed by a pharmacy is actually taken/administered. On the other hand the healthcare user may still have medication and starts using this again. Furthermore, these care providers can help the healthcare user in administering/taking the medication as well as monitoring the actual medication use.

Facilities operating in the following domains can use the Vitalink medication scheme:

- Home care/home nursing, teams for home nursing
- Home care and additional home care, day care centres, local service centres, babysitting facilities, day centres for palliative care, logistical assistance, host families
- Residential elderly care, assisted living centre, service flats and housing complexes, rest and nursing homes, short stay centres

For this group of organisations, the collective use of Vitalink by multiple users is possible after signing an agreement between the organisation and the Flemish Agency of Care and Health. The facility has the responsibility to determine to what extent and in which way the data in individual records are accessible to people who are involved as part of their activities in the healthcare or welfare. The facility takes into account the function of the persons in question, the nature of the data and the potential risks associated with the data. Specifically for Vitalink it was determined by the Sectorial Health Committee that the registration and evidence of a care relationship between the healthcare user and the care provider or care provider of a facility is organised by the facility. More information is available on the website of Vitalink under the subject of "Circles of trust (COT)".

RSW/RSB annotation

The principles underlying the connexion of organisations is not the same within RSW/RSB. For more information about this please contact the information lines of RSW/RSB (info@rsw.be/info@abrumet.be).

2.2.9

Healthcare user (patient/client)

A healthcare user should be able to consult his own medication scheme. This can be provided through an application of a health insurance company or an application of a software producer.

RSW/RSB annotation

For RSW/RSB, this service is provided throughout the RSW/RSB portals.

USE OF VITALINK FOR STORING AND CONSULTING THE MEDICATION SCHEME

The medication scheme in Vitalink allows end users to share information about the actual medication use of a patient with other care providers. This chapter explains the general principles concerning the storage and consultation of such data.

Some important points of attention:

- The unit of processing a medication scheme is the global (current) scheme. The details therefore need to be displayed, validated and checked in their entirety.
- With the 'current scheme' all the medication is intended that is taken at that time by the patient in question. Medication that has already been stopped or has not been taken within the Vitalink medication scheme, does therefore not fall under 'current scheme'.
- The author of the last adaptation to one or more medication scheme elements is the author of the global scheme.

The typical CRUD operations (Create, Read, Update, Delete) are offered by Vitalink:

- Save medication scheme (refer to 'create' and 'update');
- Consultation on medication scheme, retrieval of indication of 'last change' and consulting details to be validated (refer to 'read');
- Deleting medication (refer to 'delete').

Comment: For the removal of a medication from the active medication scheme, an update needs to be made for the complete medication scheme from which that obsolete medication is actually removed.

These different operations are placed in different use cases that describe the functionality of the parts of the medication scheme. Each use case can be implemented by one (or several) operations within the 'Vitalink Gateway'. This chapter clarifies this "mapping" of use cases to the service of the 'Vitalink Gateway' to be used.

Apart from calling up the operation of the 'Vitalink Gateway' prior steps also often have to be carried out by the end users software application. After execution Vitalink will also give feedback on whether or not the operation has been successful.

The table below gives an overview of the various use cases and their corresponding service and refers to a following paragraph where additional explanations can be found with regard to the actions that need to be executed beforehand (and possibly afterwards) by the end users software application.

Use case number	Use case title	Corresponding service Vitalink Gateway	Additional explanation (reference to following paragraphs)
1.1	Authentication	Session Management – createSession	3.1 Authentication (no more Session Management)
1.4	Addition of new medication details to the medication scheme	Vitalink Service - PutTransactionSet	3.2.1 Addition of new medication details to the medication scheme (refer to create)
1.4	Modification of existing medication details	Vitalink Service - PutTransactionSet	3.2.2 Modification of existing medication details (refer to update)
1.3	Retrieval of current medication scheme	VitalinkService – GetTransactionSet	3.3.1 Retrieval of current medication scheme
1.3	Retrieval of information of medication details to be validated	VitalinkService – GetTransactionSet	3.3.2 Retrieval of information of medication details to be validated
1.5	Retrieval of indication of last change	VitalinkService - GetLatestUpdate	3.4 Retrieval of indication of “last change”
1.7	Delete medication on the basis of a unique reference by author	VitalinkService - PutTransactionSet	3.5.1 Delete medication on the basis of a unique reference by author

The following paragraphs give an explanation regarding the expected functionality that needs to be built into the end users software application to develop the use cases explained above. As part of the reference implementation this will also be used as basis for the unitary code examples.

3.1 Authentication

The basic principles surrounding authentication of the ‘Vitalink Gateway’ are explained briefly below. Detailed information is available in other Vitalink documentation and on the eHealth platform (<https://www.ehealth.fgov.be/nl/support/sts-secure-token-service>)

To gain access to the functionality within Vitalink, the end user must be able to authenticate himself. This occurs on the basis of the ‘security token’ that is delivered by the ‘Secured Token Service’ (STS) of the eHealth platform. This token will be implemented within the ‘Vitalink Gateway’.

It is the task of the end user (and his/her software) to ensure that the ‘security token’ is valid. If this is not the case, access to Vitalink will be rejected and a new token must be requested.

To create a ‘security token’ via STS the end user must make use of his/her electronic identity card and/or an eHealth platform certificate.

3.2 Save medication scheme

Every medication that forms part of the medication scheme is saved separately within Vitalink. Saving ‘the medication scheme’ therefore technically involves the addition or modification of medication details. We expect that the End User software, each time, sends the complete actual

scheme. We don't expect the user anymore to manipulate the VitalinkURI for the Medication Scheme¹. Around the Vitalink gateway the following interpretations will be done:

- A new element will be added to the Central Platform. No URI will be given for this element.
- A missing element will be deleted from the Central Platform.
- A modified element will be updated, the <Date> and <Time> of the transaction are more recent than those of the transaction saved in Vitalink.
- An un-modified element will be ignored. The <Date> and <Time> of the transaction match those saved in Vitalink.

We distinguish two use cases when saving the medication scheme. On the one hand there is the situation where a new medication must be added to the scheme, on the other hand there is medication that is already in the scheme and for which the information needs to be modified.

It is important to know that it is not necessary as such to create a medication scheme. The addition of a first medication element will automatically imply its creation.

Since the medication scheme always needs to be interpreted as a whole, Vitalink, when saving new medication details, will check whether this has been based on the last version of this scheme. This check will be carried out on the basis of the version number of the medication scheme; (version number at Vitalink node level) that needs to be provided with each request.

A list of URI's will be submitted with the response message. In this list you'll find the active medication of the complete medication scheme. So these are the unchanged, added and modified medications.

RSW/RSB annotation

In the RSW and RSB implementations, only the ID of the medication scheme as a whole will be returned.

3.2.1

Addition of new medication details to the medication scheme (refer to create)

If a new medication needs to be added to the medication scheme, then use must be made of this use case. Account needs to be taken with a few points:

- Firstly, as stated above, a valid eHealth platform session must be initiated. Additionally the patient for whom the action will be carried out must be uniquely identified based on his/her NISS. These are basic requirements of Vitalink. These conditions apply to all following use cases and will not be repeated again.
- The 'business data' of the medication element must be drawn up in accordance with the kmehr standard (see chapter 0) A valid kmehr message (as XML) must be provided.
- The medication details are also accompanied within Vitalink with a list of metadata (see 4.1). This list will be partly completed by Vitalink itself. However, another part of this needs to be provided by the end users software application. This must be made available by the software application in the SOAP-message
- The system recognizes a new medication by the lack of a LOCAL id, named VitalinkURI, for the transaction

¹ The Vitalink Connector requested the user to build this URI in different ways, depending on the desired action (eg Addition of "/new")

RSW/RSB annotation

In the RSW, this local_id is named “RSWID” and in RSB “RSBID”

- When adding a new medication Vitalink will automatically generate a unique code as identification of the medication element as well as assigning the version number 1. This information, after being successfully saved in Vitalink, is returned to the end users software application by means of the URI of the data element. This URI contains both the unique code and the version number.
- It is recommended to implement this URI in the end users software application. This URI will indeed be used to save newer versions of this element.
- Finally Vitalink will also provide feedback, more specifically whether saving the medication details was successful and if not, the reason(s) why.

RSW/RSB annotation

When adding a new medication, RSW and RSB will not give back the ID of the new medication elements and do not recommend end users software application to save them. The reason is that the local version of the medication scheme (in that application) could be rapidly out of date with multidisciplinary usage. So the local versions of the individual medication lines could not be used anymore: a read of the new version of the whole medication scheme should be required (with the GetTransactionSet method) before further update.

The term “URI” is not used in these platforms where “LOCAL id” is preferred to reference the unique identifier of a document at the server level.

3.2.2

Adaptation of existing medication details (cfr. update)

If an already existing medication element needs to be modified, then use must be made of this use case. Account needs to be taken with a few points. These are explained below.

The “modification” of a medication covers the changing of some information within the data element (metadata or business data).

- Examples of the modification of metadata²:
 - the “validation” of the data by a doctor: this is possible by the modification of the relevant metadata element: transaction/isvalidated [true, false];
- Examples of the modification of business data:
 - Modifications to the content of the kmehr message: change of medication, posology, etc.

The steps and procedure as described in paragraph 3.2.1 are also applicable here, with these differences:

- Since it concerns a modification, there is already a set of data available. To implement a modification the transaction *LOCAL id* of this data element must be available.
- Since Vitalink wants to avoid that information is lost, no information will be overwritten. Every modification of a medication element will therefore ensure that a new version of that medication element is created within Vitalink. Another danger is that the modifications are not based on the last version of the medication scheme in Vitalink. This could also lead to the loss of information.

² Since the introduction of the Vitalink Gateway all metadata is located in the SOAP-message, therefore the difference between metadata and business data fades away for the user

To avoid this Vitalink requires that the modifications are based on the most recent version of the medication scheme that is stored at that time within Vitalink. With the request to save, the end user (software) will therefore have to indicate on which version the modifications are based (this by means of specifying a URI³, as well as the version number of the whole medication scheme).

A good habit for the end users software application is therefore to check with Vitalink, before changing data of a medication element, whether the system is still up-to-date with the last version of the whole medication scheme.

RSW/RSB annotation

The transaction *LOCAL id*, which identifies uniquely the transaction within the storage system, is platform-dependant. It has the following forms, resp. for Vitalink, RSW and RSB:

```
<transaction> <!-- for Vitalink platform -->
    <id S="LOCAL" SL="vitalinkuri" SV="1.0">...</id>
    ...
</transaction>

<transaction> <!-- for RSW platform -->
    <id S="LOCAL" SL="RSWID" SV="1.0">...</id>
    ...
</transaction>

<transaction> <!-- for RSB platform -->
    <id S="LOCAL" SL="RSBID" SV="1.0">...</id>
    ...
</transaction>
```

Moreover, no assertion can be made on the internal structure or the value of that ID (also referred as URI in the Vitalink context).

Common to all platforms, the version of the transaction is indicated by the *version* element.

```
<transaction> <!-- for both platforms -->
    ...
    <version>1</version>
</transaction>
```

3.3 Consultation of medication scheme (cfr. read)

3.3.1 Retrieval of current medication scheme

The medication scheme must always be considered as one functional whole for the end user. It is therefore the intention that all medication elements are always displayed together as one consolidated whole. The use case “retrieval of current medication scheme” satisfies the requirement to provide the current medication scheme to the end user.

The ‘Vitalink Gateway’ operation that can satisfy this requirement, is ‘GetTransactionSet’. Using this action will retrieve the complete medication scheme, not just one medication line.

The following steps need to be provided before and after calling the ‘Vitalink Gateway’ service:

³ An explanation with regard to the use of URIs within Vitalink is available in the document: “Vitalink Cookbook: General introduction to Vitalink and the use of the Vitalink Gateway”.

- The search criteria for this operation need to be defined as input parameters of the web service method (request/select): the patient identification (NISS), and the type of transaction (<cd S="CD-TRANSACTION" SV="1.6">medicationscheme</cd>)
- The data elements that are delivered via the 'Vitalink Gateway' include both the metadata and the business data.
- The end users software application must be able to interpret the kmehr xml structure that is returned as business data. All these medication elements then need to be displayed to the end user as one functional whole.
- It is recommended that the information with regard to the individual medication elements (such as the URIs, version numbers and time stamps that can be retrieved from the metadata) is maintained as a function of future communication with Vitalink. URIs and version numbers are necessary to add new versions of medication elements and time stamps are used to indicate whether an up-to-date version of the medication scheme is still being used.

3.3.2 **Retrieval of information of medication details to be validated**

Apart from the current medication scheme doctors can also be interested in information that is not yet validated. Pharmacists and nurses can indeed always add and modify data in a medication scheme. However it is sometimes necessary that this information is validated by an authorized doctor. The user who applies and saves the modification in Vitalink will then activate the relevant metadata flag.

When retrieving the complete current medication scheme (see 3.3.1) the individual data elements can be gone through and the metadata element 'isvalidated'⁴ can be examined. In this way the data still to be validated can be displayed in a specific manner.

3.4 **Retrieval of indication of 'last change' (GetLatestUpdate)**

This use case enables the end users software application to check whether the local data in the system is still up-to-date with the data in Vitalink. In this (fast) way the software can check whether or not new medication elements need to be retrieved. This operation can be carried out in the background without impact for the end user.

The following steps need to be taken account of when calling up this service:

- The end users software application needs to know what the time stamp / 'revision number' is of the local data. As described in paragraph 3.3.1 it is recommended to implement this data during the retrieval or writing of data.
- There must be a list of patients available (from NISS) for which this indication is required. It is recommended to only carry this out for those patients for which this is useful or for which the end user has specifically indicated this.
- After receiving these indications it can be appropriate to request any new medication details for the patients where the local time stamp / 'revision number' is no longer the same as that in Vitalink.

3.5 **Delete medication (cfr. delete)**

The deletion of a medication happens while saving a new version (via PutTransactionSet) by omitting this medication. This way the medication scheme from the latest PutTransactionSet matches each time with the central saved medication scheme.

Remark: we do not use the method RevokeTransaction.

⁴ The element <isvalidated> of the transaction matches the metadata 'validation status'

4

DATA STRUCTURES OF THE MEDICATION SCHEME DATA ELEMENT

4.1

Metadata

Metadata is information about the business data. Such metadata describe the actual business data and is used by the 'Vitalink Central Platform' for various purposes.

A distinction is made between on the one hand metadata that is added by the end user (his software application) and that which is assigned automatically by the 'Vitalink Central Platform'.

Remark: when using the Vitalink Gateway the metadata becomes available as a part of the specific Kmehr transaction.

The metadata will be included in the different transactions as separate data. The updated cookbooks will point out where they are. The metadata will be available on different levels, as is today. On medication-line level and on scheme level.

Depending on the medication scheme the result of the GetTransactionSet operation (to retrieve the medication scheme) will contain only the active medication lines (as is today). The ID of a medication line remains the URI for Vitalink (which will only be present once)

The metadata is validated before a data element is uploaded in Vitalink. Each business project defines which metadata elements are necessary for each data element type.

The following metadata is applicable for medication scheme data elements:

ID	Metadata element	Description	Source (added by)
Metadata that needs to be added by the end user (or his software application)			
1	languageCode KMEHR: Patient/usuallanguage	The language in which the document is drawn up. Possible values: - nl-BE - fr-BE - de-BE	End user software application
2	formatCode KMEHR: Header/Standard/cd S="CD-STANDARD"	The format of the document in which the business data is drawn up. This also contains the version of this format. – Expected value for the medication scheme: 'KMEHR_20161201' or higher.	End user software application
3	validationStatus ⁵	Indicates the validation status of the medication scheme data element. Possible values: - true: the modifications of the data element are validated. - False: the modifications of the data element need to be	End user software application

⁵ The validation process does not necessarily have to occur via the 'Vitalink' solution. Changes can also be validated verbally, in writing or any other channel before they are added to Vitalink.

		validated.	
4	Address	Contains: -CD-ADDRESS = careaddress -NIS-code ⁶	End user software application
Added by the 'Vitalink Central Platform' or 'Vitalink Gateway'			
5	availabilityStatus	The availability status of the data element. Meaning that the medication still is actively being taken, or that the treatment had been suspended. Possible values: - active - ended	Vitalink (this value will be derived from the availability of the data element in the PutTransactionSet-request)
6	Author KMEHR: author	Information concerning the author of the data element	Vitalink (based on the 'eHealth STS token')
7	Person	Contains: - FamilyName - FirstName - SSIN - NIHII (optional RIZIV number) - Role	Vitalink (based on the 'eHealth STS token')
8	Organisation	Contains: - Name - Role - CBE (KBO number) or - NIHII (RIZIV number) or - EHP (EHP number)	Vitalink (based on the 'eHealth STS token')
9	authorRole	Role of the author (e.g.: doctor).	Vitalink (based on the 'eHealth STS token')
10	creationTime KMEHR: date time	Time of creation (within the 'Vitalink Central Platform'). Format: yyyy-MM-dd HH:mm:ss	Vitalink
11	patientID KMEHR: Patient/Id	NISS of the patient	Vitalink (on the basis of 'input parameters request')
12	DataEntryURI KMEHR: Transaction/id SL="vitalinkuri"	URI that uniquely identifies the data element. The URI is not in the list of metadata but is included as an attribute of the data element itself.	Vitalink

⁶ http://statbel.fgov.be/nl/modules/publications/statistiques/enquetes_et_methodologie/downloads/codes_nis.jsp

RSW/RSB annotation

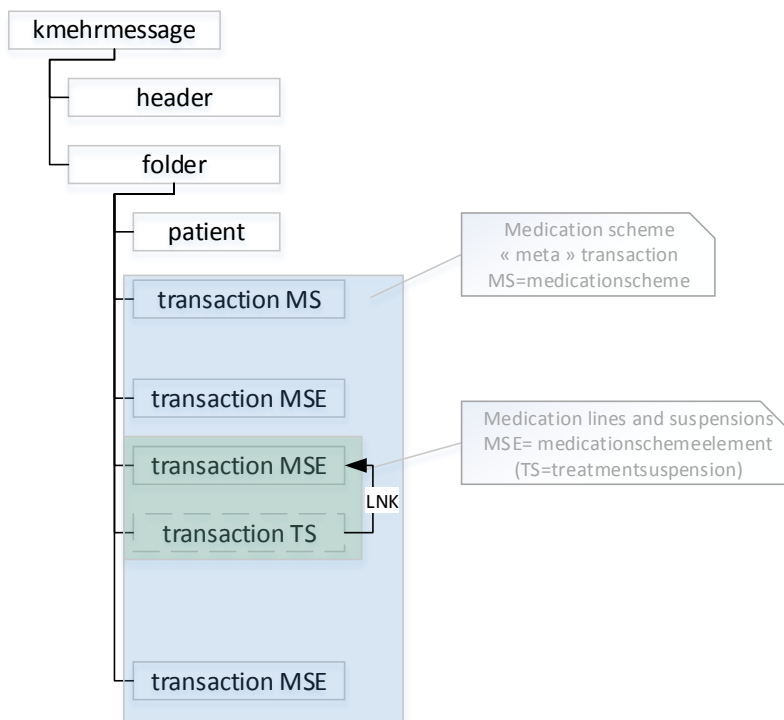
4. The *address* element of the end user software application is not required in the RSW / RSB platforms.
12. As stated previously, the identification of data element (transaction) is platform-dependant; the “SL” attribute of the *LOCAL id* is “vitalinkuri” for Vitalink, “RSWID” for RSW and “RSBID” for RSB.

4.2

Business data

The business data is the actual “useful” information about the patient that the end user wants to share. It is defined for each business project the manner (the standard and version to be used) in which this data needs to be delivered.

For a medication scheme data element the business data needs to be delivered to the ‘Vitalink Gateway’ as a XML KMEHR message (Kind Message for Electronic Healthcare Record) of the type: ‘medicationscheme’ (and additional ‘medicationschemeelement’ and ‘treatmentsuspension’). This structure is also explained in more detail on the kmehr website of the eHealth platform.



As already stated earlier in this document 1 kmehr message contains a complete medication scheme.

It is the task of the end users software application to be able to compose such a kmehr message and to also be able to open, interpret and (graphically) present it to the end user.

Validation of this business data is also necessary. The validation will occur in two steps:

- XSD validation
- Additional validation

The validation will be carried out automatically within the 'Vitalink Gateway' but should also be implemented by the end users software application to be sure that data will be accepted by the platform. To avoid errors and delays it is recommended that the software application composes this kmehr message in the correct manner.

4.2.1 **KMEHR validation**

The XML scheme definition of the kmehr-standard (.XSD file) can be found at the eHealth website with URL: <https://www.ehealth.fgov.be/standards/kmehr/content/page/home>.

At this time the medication scheme data element must satisfy version "20161201-kmehr" of the XSD definition (these XSD definitions can be downloaded via the URL: <https://www.ehealth.fgov.be/standards/kmehr/content/page/93/xschema>).

Along with the XSD scheme validation the kmehr message will also be subjected to a general structure validation. This structure validation will on the one hand produce errors and on the other hand warnings. In the event that errors occur during the validation, the action will be suspended and the error reported. In the event that there are only warnings, the request will be dealt with. The final response will however be enhanced with the warnings, to construct a correct request.

4.2.2 **Additional validation**

The kmehr standard defines all kinds of different types of messages with regard to the healthcare sector. Within the medication scheme project only kmehr messages of the type "medicationscheme" (and additionally "medicationschemeelement" and "treatmentsuspension") are accepted. Additional validation is therefore also necessary before data can be sent to Vitalink.

The table below describes the various checks that will be carried out.

Description
'cd' in 'standard' must be '20161201'
'id' in 'header' must be entered ⁷
'cd' in 'hcparty' (sender, recipient and author) must be entered ⁷
'name' in 'recipient' must be 'Vitalink'
'cd' in 'recipient' must be 'application'
Contains exactly 1 'folder'
'firstname', 'familyname' and 'id' in 'patient' must be entered ⁷
When using a 'date', this 'date' must have a full date format (day, month and year) Example: 'beginmoment' or 'endmoment'
Each transaction contains exact 1 'URI': 'id' with S="LOCAL" and SL="vitalinkuri" For each transaction, being an addition or an update, the author must match with the one from the SAML token
Contains exactly 1 'medicationscheme' transaction for which:
Contains exact 1 'version'
Contains transaction(s) 'medicationschemeelement' for which:
Contains exactly 1 healthcare element for which 'CD-ITEM-MS' = 'adaptationflag'
Contains exactly 1 item 'medication' for which:
Contains exactly 1 'beginmoment'
'beginmoment' cannot contain a 'time', this should be specified in the 'regimen'
Contains exactly 1 of: 'medicinalproduct', 'substanceproduct', 'compoundprescription' or 'CD-EAN' list
If 'compoundprescription' or 'CD-EAN' list is included: contains exactly 1 associated 'text' field
If 'medicinalproduct' or 'substanceproduct' is included: 'intendedcd' and 'intendedname' must be entered ⁷
If 'CD-EAN' is included: 'cd' and 'text' field must be entered ⁷
If 'compoundprescription' is included: 'compoundprescription' and 'text' field must be entered ⁷
If 'tempoerality' is included: 'CD-TEMPORALITY' allows only following values: "acute", "chronic" and "oneshot".
If 'frequency' is included:
'frequency' makes use of 'periodicity'
For 'periodicity' the values 'Per 5h (UQ)', 'Per 7h (US)', 'Per 9h (UN)', 'Per 10h (UX)' and 'Per 11h (UE)' are not permitted
If the values 'Per hour (U)', 'Per 8h (UA)', 'Per 3h (UD)', 'Per half hour (UH)', 'Per 2h (UT)', 'Per 4h (UV)', 'Per 12h (UW)' or 'Per 6h (UZ)' are used, then the use of 'regimen' is not allowed.
Contains exactly 1 'posology' or 'regimen' (they do not occur together)
If 'posology' is included: 'posology' makes use of a completed 'text' field
If 'text' filled: no control on unit in 'text' field
If 'regimen' is included:
For 'dayperiod' the values 'aftermeal', 'betweenmeals', 'afternoon:', 'evening', 'night' are not permitted
'dayperiod' is only allowed once per day per 'regimen'

⁷ When it is possible within the kmehr standard to add the tag several times, it is checked whether there is at least or exactly one entered tag present.

<p>If 'quantity' is included: Contains exact 1 element 'unit' All 'unit' elements have the same value within the transaction</p>
<p>For all 'healthcarelement':</p>
<p>Contains exactly 1 'cd' with list 'CD-ITEM-MS' (permitted values: 'origin', 'adaptationflag', 'medicationuse', 'medicationtype', 'begincondition' or 'endcondition')</p>
<p>If 'adaptationflag' is included: contains at least 1 'cd' with list 'CD-MS-ADAPTATION' (permitted values: 'nochanges', 'medications', 'posology' or 'treatmentsuspension')</p>
<p>If 'origin' is included: contains exactly 1 'cd' with list 'CD-MS-ORIGIN' (permitted values: 'regularprocess' or 'recorded')</p>
<p>If 'medicationtype' is included: contains exactly 1 'cd' with list 'CD-MS-MEDICATIONTYPE' (permitted values: 'onprescription', 'otc' or 'other')</p>
<p>If 'medicationuse' is included: contains exactly 1 completed 'text' field⁷</p>
<p>Included as 'begincondition': contains exactly 1 completed 'text' field⁷</p>
<p>If 'endcondition' is included: contains exactly 1 completed 'text' field⁷</p>
<p>The Kmehr-element 'Instructionforoverdosing' is not being used, therefor will not be mentioned in the medication scheme</p>
<p>For all 'treatmentsuspension' transactions:</p>
<p>Contains exactly 1 item 'medication' for which:</p>
<p>Contains exactly 1 of: 'medicinalproduct', 'substanceproduct', 'compoundprescription' or 'CD-EAN' list (identical to the definition in the transaction 'medicationschemeelement')</p>
<p>Contains exactly 1 'start moment'</p>
<p>Contains exactly 1 'lifecycle' with list 'CD-LIFECYCLE' (permitted values: 'suspended' or 'stopped')</p>
<p>If 'stopped' only an end date may be inputted, no begin date</p>
<p>Contains exact 1 'lnk' (the validation on 'exact 1 lnk' applies to the type 'treatmentsuspension'. Since a folder now contains multiple medications, there must be a link with a treatmentsuspension to the correct medication. See also 4.4.5 Treatment suspension) for which:</p>
<p>Attribute URL:XPath to the concerning 'medicationschemeelement'</p>
<p>Attribute Type: isplannedfor</p>

4.3 Code lists

The medication scheme data element makes use of several lists that are defined within the kmehr standard. In the most recent kmehr version there are four new project specific lists added that are discussed briefly below.

4.3.1 CD-ITEM-MS

To include certain project specific information within the medication scheme data element, use must be made of separate 'healthcarelement' items. In order to further define these items the list CD-ITEM-MS is available with as permitted values:

- origin
- adaptationflag
- medicationuse
- medicationtype
- begincondition
- endcondition

Hereby two examples in which it is explained how these 'healthcarelement' items need to be set up:

Option 1: additional project specific list

```
<item>
  <id SV="1.0" S="ID-KMEHR">2</id>
  <cd SV="1.3" S="CD-ITEM">healthcareelement</cd>
  <content>
    <cd SV="1.0" S="CD-ITEM-MS">adaptationflag</cd>
    <cd SV="1.0" S="CD-MS-ADAPTATION">medication</cd>
    <cd SV="1.0" S="CD-MS-ADAPTATION">posology</cd>
  </content>
</item>
```

In the case of the healthcare elements 'origin', 'adaptationflag' or 'medicationtype' there are additional lists defined (see 0, 4.3.3 and 4.3.4).

Option 2: text field

```
<item>
  <id SV="1.0" S="ID-KMEHR">2</id>
  <cd SV="1.3" S="CD-ITEM">healthcareelement</cd>
  <content>
    <cd SV="1.0" S="CD-ITEM-MS">medicationuse</cd>
  </content>
  <content>
    <text L="nl">For stomachache</text>
  </content>
</item>
```

In the case of the healthcare elements 'medicationuse', 'begincondition' and 'endcondition' a text field should be used to add the required information.

4.3.2 CD-MS-ORIGIN

With the help of the list CD-MS-ORIGIN it can be indicated via which path the medication is included in the medication scheme. Has this occurred by means of the 'normal' path by which the medicine is prescribed by the doctor and is delivered by the pharmacist (or in the case of OTC medication, is only delivered by the pharmacist)? This path will be indicated with the code 'regularprocess'.

The other manner is that the patient or a care player indicates that he ingests certain medication. This medication can already be present at the patient's home; they have been obtained via friends or family or possibly purchased via the Internet or abroad. This medication can then still be included in the medication scheme and be indicated with the code 'recorded'.

Permitted values for this list are:

- regularprocess
- recorded

4.3.3 CD-MS-ADAPTATION

By means of the list CD-MS-ADAPTATION it can be indicated in a simple manner where in the kmehr message modifications have been made by the end user.

Permitted values for this list are:

- nochanges
- medication

- posology
- treatmentsuspension

If changes have taken place to several parts of the kmehr message, it is possible to enter several codes. However if the value 'nochanges' is used, only this value is permitted and no other codes may be added.

4.3.4 **CD-MS-MEDICATIONTYPE**

The type of the medication can be indicated via CD-MS-MEDICATIONTYPE.

Permitted values for this list are:

- onprescription
- otc
- other

4.3.5

Kmehr defined lists

Apart from the project specific lists use is also made within the medication scheme of several lists that are defined on the kmehr website. Below is the list of the used lists with the used and non-permitted values.

List	Used values ⁸	Non-permitted values
CD-ADMINISTRATIONUNIT ⁹		
CD-DAYPERIOD		- aftermeal - betweenmeals - afternoon - evening - night
CD-DRUG-CNK		
CD-DRUG-ROUTE		
CD-EAN		
CD-HCPARTY		
CD-INNCLUSTER		
CD-ITEM	- healthcarelement - medication - transactionreason	
CD-ITEM-MS		
CD-LIFECYCLE	- stopped - suspended	
CD-MS-ADAPTATION		
CD-MS-MEDICATIONTYPE		
CD-MS-ORIGIN		
CD-PERIODICITY		- per 5h (UQ) - per 7h (US) - per 9h (UN) - per 10h (UX) - per 11h (UE)
CD-SEX		
CD-STANDARD	20161201	
CD-TEMPORALITY	- Acute	- reactivation

⁸ If there are no values stated next to 'used values' then all values (with the exception of those stated under 'non-permitted values') are permitted.

⁹ Version 1.1 of the list CD-ADMINISTRATIONUNIT was published on 1/10/2013. This contains modifications that are of importance for the medication scheme project. It is therefore also recommended to support the most recent version of this list.

	- Chronic	- remission
	- Oneshot	- subacute
CD-TRANSACTION	- medicationscheme	
	- medicationschemeelement	
	- treatmentsuspension	
CD-WEEKDAY		

4.4 Description of structure of kmehr message

For the exchange of the business details for the medication scheme the choice is made for the use of kmehr as the standard. A choice has also been made for maximum adjustment and agreement with regard to the existing data structures such as already in use with other projects (refer to Recip-e). Where necessary modifications have been made (and elements added) to obtain the complete desired functionality.

The tables below give an overview of the various information elements that can be included within a medication scheme data element. However the kmehr standard also allows other information to be included. The information below is therefore indicative and only the information fields that are enforced at the level of the kmehr xsd or the additional Vitalink validation are guaranteed.

4.4.1 General information

Concept	Purpose and fields
General information about the medication scheme data element	<p>A list of general information about the medication scheme data element.</p> <p>Fields :</p> <ul style="list-style-type: none"> - ID [1-1] : ID-KMEHR - Origin [0-1] : CD-MS-ORIGIN¹⁰ - Creation time [1-1] - Adaptation flag [1-1] : CD-MS-ADAPTATION³
Author (hcparty)	<p>A medication scheme data element has one author. This author must be identified as an individual, but can furthermore also be part of an organisation.</p> <p>Fields (as individual) [1-1]:</p> <ul style="list-style-type: none"> - INAMI/NIHII [0-1] - SSIN [0-1] - Type of individual [1-1]: CD-HCPARTY - Name [0-1] - First name [0-1] <p>Fields (as organisation) [0-1]:</p> <ul style="list-style-type: none"> - INAMI/NIHII [0-1] : ID-HCPARTY - Type of organisation [1-1]: CD-HCPARTY

¹⁰ All fields enclosed in a frame, have to be displayed within kmehr in an individual <item> (healthcareelement) (see XML examples under **Error! Reference source not found.**).

	- Name [0-1]: name of the organisation
Patient	A medication scheme data element is linked to one patient. This patient is identified by his/her NISS number. Fields : - SSIN [1-1] - Name [1-1] - First name [1-1] - Gender [1-1]: CD-SEX

4.4.2 Medicationscheme information

Information with regard to the complete scheme will be included in a transaction of the 'medicationscheme' type.

Concept	Purpose and fields
Scheme information	Information with regard to the medication scheme. Fields : – The version number of the scheme will be included using the tag <version>[1-1]

4.4.3 Medication information

Information with regard to the medication can be included in four different ways. The method that is used depends on whether:

- the medication is prescribed on product name;
- the medication is prescribed on substance name ('Prescription On Substance (POS)');
- the medication needs to be identified via an EAN code;
- the medication is a pharmaceutical compound¹¹.

Option1: In the case of product name

Concept	Purpose and fields
Medication information	Information with regard to the medication. Fields : – Description [0-1]: (medication use) with regard to the purpose of the medication ³ – Medication type [0-1] : CD-MS-MEDICATIONTYPE ³ – Start date of treatment [1-1] – End date of treatment [0-1] or Duration of the treatment [0-1] – The medication is defined with the help of the tag <medicinalproduct>

¹¹ In the current kmehr release it is only possible to enter a pharmaceutical compound in textual form. However steps have been taken to do this in a more structured manner in a future version. When these modifications are included in kmehr Vitalink will align itself with this.

[1-1] :

- Name [1-1] : <intendedname>
- Medication code [1-1]: <intendedcd>: CD-DRUG-CNK + code

It is possible along with the prescribed medication to also specify the delivered medication:

- Name [0-1] : <deliveredname>
- Medication code [0-1]: <deliveredcd>: CD-DRUG-CNK + code

Option 2: In the case of POS

Concept	Purpose and fields
Medication information	<p>Information with regard to the medication.</p> <p>Fields :</p> <ul style="list-style-type: none">- Description [0-1]: (medication use) with regard to the purpose of the medication³- Medication type [0-1]: CD-MS-MEDICATIONTYPE³- Start date of treatment [1-1]- End date of treatment [0-1] or Duration of the treatment [0-1]- The medication is defined with the help of the tag <substanceproduct> [1-1] :<ul style="list-style-type: none">- Name of POS [1-1]: <intendedname>- Medication code POS [1-1]: <intendedcd> : CD-INNCLUSTER + code- Name of delivered medication [0-1]: <deliveredname>- Medication code of delivered medication [0-1]: <deliveredcd>: CD-DRUG-CNK + code

Option 3: In the case of EAN code

Concept	Purpose and fields
Medication information	<p>Information with regard to the medication.</p> <p>Fields :</p> <ul style="list-style-type: none">- Description [0-1] : (medication use) with regard to the purpose of the medication³- Medication type [0-1] : CD-MS-MEDICATIONTYPE³- Name EAN [1-1] : <text>- Medication code EAN [1-1] : CD-EAN- Start date of treatment [1-1]- End date of treatment [0-1] or Duration of the treatment [0-1]

Option 4: In the case of a pharmaceutical compound

Concept	Purpose and fields
Medication information	<p>Information with regard to the medication.</p> <p>Fields :</p> <ul style="list-style-type: none">– Description [0-1] : (medication use) with regard to the purpose of the medication³– Medication type [0-1] : CD-MS-MEDICATIONTYPE³– Description [1-1] : A textual description of the pharmaceutical compound : <compoundprescription>– Name [1-1] : A descriptive name of the pharmaceutical compound : <text>. The following information should be included as name of the compound: the compound number + active components + dose per unit or content.– Start date of treatment [1-1]– End date of treatment [0-1] or Duration of the treatment [0-1]

4.4.4

Posology

The information below about the posology information of a medication gives a description of the various ways, within the kmehr standard, in which this information can be included.

There are a number of guidelines drawn up to ensure that the posology information can be included in an unambiguous manner within the 'medicationschemelement'.

The documents with guidelines and examples can be found on the [website](#) of Vitalink:

Vitalink Medication scheme: guidelines and examples:

Vitalink_Richtlijnen_en_Voorbeelden_v0.9.pdf

Vitalink Medication scheme: XML examples:

Vitalink_innamepatroon_XML_voorbeelden_v0.9.zip

4.4.4.1

General posology information

General information about the posology of the medication:

Concept	Purpose and fields
General posology information	<p>Fields :</p> <ul style="list-style-type: none">– Posology type [0-1] : CD-TEMPORALITY– Means of administration [0-1] : CD-DRUG-ROUTE– Instruction for overdosing [0-1] : <instructionforoverdosing>

- Comments for patient [0-1] : <instructionforpatient>
- Start condition [0-1]³
- End condition [0-1]³

4.4.4.2

Specific posology information

Other information about the posology can be included in two ways:

- With the help of <posology>: written text.
- Via <regimen>: structured.

Option 1: In the case of <posology>

Concept	Purpose and fields
Posology information	<p>Information with regard to the posology of the medication. When use is made of the <posology> tag, then this is still to write the ingestion pattern in textual form. For a structured ingestion pattern use is made of the tag <regimen>.</p> <p>Fields :</p> <ul style="list-style-type: none"> - Text [1-1]

Option 2: In the case of <regimen>

Concept	Purpose and fields
Posology information	<p>Information with regard to the posology of the medication. When using <regimen> one (or a set of) specific ingestion time(s) are defined. It is then also possible within one <regimen> tag, to use the series of elements several times.</p> <p>Fields [1-*] :</p> <ul style="list-style-type: none"> - Unit [0-1] : CD-ADMINISTRATIONUNIT - Quantity [1-1] - Time of the day [1-1] : <time> OR <dayperiod> - Day of ingestion [0-1] : this can be included in various ways : <p><u>Option 1 : date</u></p> <ul style="list-style-type: none"> - Date [1-1] <p><u>Option 2 : weekday</u></p> <ul style="list-style-type: none"> - Weekday [1-1] : CD-WEEKDAY <p><u>Option 3 : day number</u></p> <ul style="list-style-type: none"> - Day number [1-1] <p>When the ingestion pattern displays a cyclic behaviour, then it can be</p>

indicated what the period is with the help of a 'frequency':

- Frequency [0-1] : <frequency>¹²

4.4.5 Treatmentsuspension

With the help of the 'treatmentsuspension' it is possible to indicate that a medication is temporarily or definitely stopped. This 'treatmentsuspension' must be included within the kmehr standard in a separate transaction ('treatmentsuspension'). If necessary, several suspensions can be included within the same medication scheme data element. These are then placed in separate transactions.

Concept	Purpose and fields
Treatment suspension	<p>Information about the treatment suspension of the medication.</p> <p>Fields [0-*] :</p> <ul style="list-style-type: none"> - Decision date [0-1] : <date> - Decision taker [1-1] : <author> - Medication [1-1]: the identification of the medication (as already made earlier, must be named again in this transaction) - Date of suspension [1-1] : <start time> - Re-start date [0-1] : <end time> - Temporary/definite [1-1] : <lifecycle> - Reason [0-1] : <item> (transactionreason) - Link [1-1][:<link> (using a XPath a link to the transaction of the medicine will be defined) <p>ex: <lnk URL="//transaction[id[@S='ID-KMEHR']='5']" TYPE="isplannedfor"/> Where 5 is the ID-KMEHR of the medicine to be suspended.</p>

4.5 XML examples kmehr message

To illustrate, there are several examples worked out that clarify this kmehr structure. The .zip-file (*MS_XML_examples_v1.4.zip*) contains 7 xml examples:

	Definition of medication	Posology	Additional description
Ex 1	Product name	Instruction via " <code><instructionforpatient></code> "	Extensive version with optional fields + medications
Ex 2	Pharmaceutical compound (textual description)	With the help of the 'regimen' tag	2 medication stops
Ex 3	EAN code	With the help of the 'regimen' tag	
Ex 4	Substance name	With the help of the 'regimen' tag	Limited version, without optional fields
Ex 5	Substance name	With the help of the 'regimen' tag	

¹² The <frequency> tag may only occur once within the <item> tag.

Ex 6	Substance name	With the help of the 'regimen' tag
Ex 7	Product name	Posology in text form

5 GUIDELINES FOR INTEGRATION IN END-USER SOFTWARE APPLICATIONS

5.1 Guidelines for displaying the Vitalink Medication scheme as an overview scheme

5.1.1 Objective

This chapter aims at making explicit the requirements which are imposed on end use software within the scope of on-line data sharing between care providers in the first line via Vitalink with regard to displaying medication schemes for printing and in patients' viewers. The guidelines were drawn up on the basis of the experiences acquired by care providers and patients during the pilot project. It was decided during the ICT Work Group of 26/06/2013 to update these guidelines and offer them to the software houses as additional guidelines. The Vitalink user group is authorized for the amendment of these guidelines. Amendments always have to be approved by the ICT Work Group.

RSW/RSB annotation

There are no strict visualisation guidelines for RSW and RSB. However, this can be viewed as recommendations.

5.1.2 Display

The medication scheme must be offered to **the patient** in a well-organised and uniform manner in printed form or with the help of a viewer. Substantively the medication scheme should contain the same information for all software systems.

The **readability** of such a scheme is improved by ensuring that the horizontal rows are only displayed if they contain content. The columns with specific hours are printed dynamically depending on whether there is medication present at specific hours in the medication scheme. If more ingestion times are present than can be displayed in the standard lay-out, the information is displayed in a text field instead of in columns. Several **remarks**:

- Unambiguous identification of the patient (name, first name and NISS number) in the header;
- Time of last change and print in the header;
- Care provider that has last adapted the medication scheme in the header;
- Care provider that has printed the medication scheme in the header;
- Version number of the medication scheme;
- Information text to display in a footnote: "This is a medication scheme that is managed by your care team and is shared via Vitalink. More information can be found at www.vitalink.be/toelichtingms/."

It is desirable to offer the medication scheme in an **accessible textual version** for low educated patients. Clear user instructions grouped by ingestion time with minimum interpretation by the patient can prevent mistakes with the ingestion of medication. There are no guidelines available for this. A master's thesis at the UGent is studying the readability of medication schemes. The results of this research are being awaited.

The provision of **administration schemes** on a daily or weekly basis is desirable for nurses and, if necessary, for patients' viewers. There are no guidelines available for this. These guidelines concern **overview schemes**, that in the first place are suitable for communication between care providers and with the patient.

An example of an overview scheme based on the standard lay-out can be found on the following page.

Patiënt : Naam Voornaam		Laatst gewijzigd door:												Afdruk door :										
INSZ:		Tijdstip:												Tijdstip opvraging:										
Chronische medicatie		Frequentie	Begin	Eind	Inname /Eenheid	s'morgens	Ontbijt			Middagmaal			Avondmaal			Slaap	20u00	Opmerkingen						
FASTUM GEL 2,5% 60GR		dagelijks	14/06/2012		Op de huid	1										1					Indicatie : Spierpijn Gebruiksaanwijzing : Gel aanbrengen aan de nek			
MOXONIDINE 0,4 MG COMP PEL 1'00 X 0,4 M		dagelijks	10/06/2012		Innemen Tablet	1															Indicatie : bloeddruk Gebruiksaanwijzing : Inslikken en doorspoelen met een glas water			
SIMVASTATINE EG 20mg 84co		dagelijks	10/06/2012	19/06/2012				1													Indicatie : Hoge cholesterol			
			20/06/2012	26/06/2012		! STOP ! Wegens interactie met Sporanox																		Gebruiksaanwijzing : Inslikken en doorspoelen met een glas water
		dagelijks	27/06/2012				1																	
SOTALOL MYLAN 160 MG TABL 56X160MG		dagelijks	10/06/2012		Innemen Tablet		1										1				Indicatie : Hartritmestoornis Gebruiksaanwijzing : Inslikken en doorspoelen met een glas water			
UNITRANXENE CAPS 30X15MG		dagelijks	10/06/2012		Innemen Tablet												1				Indicatie : Angst of stress Gebruiksaanwijzing : Inslikken en doorspoelen met een glas water			
TRANXENE CAPS 100X10MG		dagelijks	01/07/2012		Innemen Tablet												1				Indicatie : Angst of stress Gebruiksaanwijzing : Inslikken en doorspoelen met een glas water			
			stop UNITRANXENE																					
LANOXIN 125 COMP 60X0,125MG		in de 2 dagen : da	15/06/2012					1/2													Indicatie : Hartfalen Gebruiksaanwijzing : Inslikken en doorspoelen met een glas water			
		in de 2 dagen : da	15/06/2012					1																
LAXIDO NATUUR ZAKJES 50X13,7G		in de 2 dagen : da	16/06/2012		Zakje		1														Indicatie : Verstopping Gebruiksaanwijzing : Oplossen in een glas water en opdrinken			
MEDROL tab 30x 4mg		dag 1	10/06/2012					1			1					1					Indicatie : Onsteking Gebruiksaanwijzing : Inslikken en doorspoelen met een glas water			
		dag 2	10/06/2012					1			1					1								
		dag 3	10/06/2012					1			1					1								
		dag 4	10/06/2012					1			1					1								
		dag 5	10/06/2012					1								1								
		dag 6	10/06/2012					1								1								
		dag 7	10/06/2012					1								1								
		dag 8	10/06/2012					1								1								
MEDROL tab 30x 4mg		dagelijks	18/06/2012				1														Indicatie : Onsteking Gebruiksaanwijzing : Inslikken en doorspoelen met een glas water			

Tijdelijke Medicatie	Frequentie	Begin	Eind	Inname /Eenheid	Ontbijt			Middagmaal			Avondmaal			Slaap	20u00				Opmerkingen
					Voorgemogen	Tijdens	Na	Voorgemogen	Tijdens	Na	Voorgemogen	Tijdens	Na						
FURADANTINE MC CAPS 50X100MG	dagelijks	15/06/2012	24/06/2012			1						1							Indicatie : Urineweginfectie (blaasontsteking) Gebruiksaanwijzing : Inslikken en doorspoelen met een glas water
SPORANOX 100mg 28 co	dagelijks	20/06/2012	26/06/2012			2						2							Indicatie : Schimmelinfectie Gebruiksaanwijzing : Inslikken en doorspoelen met een glas water
LASIX COMP 12 X 40 MG	Wekelijks : maanda	15/06/2012				1													Indicatie : Vochttopstapeling Gebruiksaanwijzing : Inslikken en doorspoelen met een glas water
LASIX COMP 12 X 40 MG	Wekelijks : woensda	15/06/2012				1													
LASIX COMP 12 X 40 MG	Wekelijks : vrijdag	15/06/2012				1													

Indien Nodig	Frequentie (Max)	Begin	Eind	Inname /Eenheid	Ontbijt			Middagmaal			Avondmaal			Slaap				Opmerkingen	
					Voorgemogen	Tijdens	Na	Voorgemogen	Tijdens	Na	Voorgemogen	Tijdens	Na						
MUCO-RHINATHIOL 5% SIR AD 200ML	dagelijks	10/06/2012																	Indicatie : Vastzittende hoest Gebruiksaanwijzing : Inslikken en doorspoelen met een glas water / 15ml = 1 eetlepel

Dit is een medicatieschema dat beheerd werd door uw zorgteam en gedeeld via Vitalink. Meer informatie vindt u op www.vitalink.be/XXXX

No.	Description	Comment
1	Uniform content	
1.1	<i>Header</i>	
1.1.1	Unambiguous identification of the patient	Name, first name & NISS number
1.1.2	Date and hour of last change + identification of the care provider who changes the medication scheme	Date format = dd/mm/yyyy Hour format = XX:XX
1.1.3	Date and hour of print + identification of the care provider who prints the medication scheme (details of the pharmacy + owner)	Date format = dd/mm/yyyy Hour format = XX:XX
1.2	<i>Sorting of medication lines in columns, Stopped medication (End date = expired) is not displayed.</i>	<i>Chronic medication (CD-TEMPORALITY = chronic) Temporary medication (CD-TEMPORALITY = acute) "If required" (CD-TEMPORALITY = one shot¹³)</i>
1.2.1	Within the column the medication lines are sorted according to periodicity.	Daily <ul style="list-style-type: none"> - daily - per x hour¹⁴ Non-daily <ul style="list-style-type: none"> - No frequency - 2-daily, ... - weekly, ... - monthly, ...
1.2.2	Columns (see 1.2) and periodic subdivisions (see 1.2.1) that are not entered in the medication scheme are not printed.	
1.3	<i>Display of columns</i>	
1.3.1.	Fixed pattern of 16 columns	Column / description of the product: – Frequency – Start – End – Ingestion / unit – Morning – Breakfast (before, during and after) – Lunch (before, during and after) – Dinner (before, during and after) – Sleep. Refer to example on previous page.
1.3.2	Dynamic display of columns for specific times: ingestion times at specific hours are only displayed if they are filled in.	If more than 5 specific hours are used in a medication scheme, the 6 th and following are printed as text in a line without columns. E.g. "Once a day at 16:00". Specific times are displayed to the minute: format XX:XX.

¹³ Proposal to eHealth KMEHR working group to change the code "one shot" to "ad hoc"

¹⁴ X = divisor of 24, refer to restriction within Vitalink.

1.3.3	Ingestion times (Code table CD DAYPERIOD) that cannot be assigned to a column, are displayed as text in a line without columns	Between breakfast and lunch (“betweenbreakfastandlunch”) - Between dinner and sleep (“betweendinnerandsleep”) - Between lunch and dinner (“betweenlunchanddinner”)
1.4	<i>The complete description of the product: (content / medicinalproduct / intendedname or deliveredname¹⁵) displayed in the “medication” column including dose and galenic form.</i>	The dose is not provided as separate attribute in KMEHR. Information about brand name, galenic form, dose and packaging size is available via the CNK (National Code Number) ¹⁶ , but not all care providers have a databank of CNKs available.
1.5	<i>Unit uniformly displayed We take the first CD-ADMINISTRATIONUNIT element from regimen as the unit. There is 1 column ingestion /unit entered for the ingestion pattern. We provide the same patient oriented translation for form/unit in all software packages. See document Translation tables.</i>	<i>The unit cannot be entered at the medication line level. CD-ADMINISTRATIONUNIT is provided with item/regimen/quantity.</i>
1.6	<i>Ingestion uniformly displayed from table CD-Drug-Route. There is 1 column Ingestion /unit entered for the ingestion pattern. We provide the same patient oriented translation for ingestion between all software suppliers. See document Translation tables.</i>	
1.7	<i>Indication and instructions for use are displayed in the “remark” column.</i>	<i>Indication = health care element medication use Instructions for use = instruction for patient</i>
1.8	<i>Medication lines with the validation status “to be validated” are always printed. There is <u>no</u> mention of this status in the print for the patient.</i>	
1.9	<i>Information message in footnote text</i>	<i>“This medication scheme is managed by your care team and shared via Vitalink. More information can be found at www.vitalink.be/toelichtingms/.”</i>

¹⁵ “intendedname”, the name of the medicament that the doctor prescribes, can in the case of prescription on substance name or occurring substitution differ from the “<deliveredname>” the name of the medication that the pharmacist delivers. If the “<deliveredname>” is available and differs from the “<intendedname>” the “<deliveredname>” must be displayed.

¹⁶ CNK = National Code Number. The CNK is a unique code that is assigned to each medicine. For more information see APB information brochure (last update 21/12/2006):
<http://health.belgium.be/internet2Prd/groups/public/@public/@dg1/@acutecare/documents/ie2divers/10806463.pdf>

2	Uniform format	
2.1	<i>Sorting of medication lines in a uniform manner</i>	Feature Periodic subdivision Day in period (with weekly, monthly, once-only or no frequency) Alphabetic Start date
2.1.1	Sort daily medication in a uniform manner "Frequency" column = daily	Periodicity DT = daily
2.1.2	Sort non-daily medication in a uniform manner "Frequency" column = every 2 days + day number 1 & 2	Periodicity DT = 2-daily Ditto for 3-daily, etc.
2.1.3	Sort weekly medication (non-daily) in a uniform manner. With medication on several fixed days per week days are displayed on different lines. "Frequency" column = periodicity + "day" + day number. Interpretation for day scheme = Start date + daynumber – 1 + (x*periodicity)	Frequency Daynumber: day of the week Alphabetic Start date
2.1.4	Sort monthly medication (non-daily) in a uniform manner. Use day of the month from regimen / date. With medication on several fixed days per month days are displayed on different lines. "Frequency" column = "monthly" + day of the month of regimen / date + "e". ¹⁷	Frequency Day of the month Alphabetic Start date
2.2	<i>Empty horizontal bar between different columns and periodic subdivisions</i>	
2.3	<i>Start date or condition / End date or condition displayed</i>	<i>At the front in the table Date format = dd/mm/yyyy</i>
2.4	<i>Subsequent medication: indicate with the help of start & end condition in start/end column</i>	<i>GM 1: end condition "OP = STOP" GM 2: begin condition "With stop GM 1"</i>
2.5	<i>Treatment suspension</i>	<i>The KMEHR format provides the possibility to interrupt a treatment</i>
2.5.1	Permanent suspension: medication line is only displayed for the patient if the suspension lies in the future.	
2.5.2	Temporary suspension: the Treatment suspension is only displayed if the suspension lies in the future.	

¹⁷ In an administration scheme (per day or per week) the 29th, 30th & 31st is placed on the last day of the month, if that date does not occur in the current month.

2.5.3	A treatment suspension is displayed as a line under the medication line to which it is applicable, with red background and provided with the text “!STOP! Due to: ...”	
2.6	<i>Specific times are added as column on the right of the scheme, separated from the fixed pattern by a bold printed horizontal line. (Refer to example p. 4).</i> ¹⁸	
2.7	Convert decimal numbers in “quantity” to fractions. 0.25 = ¼ / 0.50 = ½ 0.75 = ¾ 1.25 = 1 + ¼ 1.50 = 1 + ½ 1.75 = 1 + ¾ Numbers and fractions > 1 also have to be provided.	¼, ½ and ¾ cannot be entered as quantity in KMEHR
2.8	Posology is displayed as a non-structured text field in a line without columns instead of the ingestion times.	In KMEHR posology can be used as text field instead of “regimen”.
2.9	Medication lines for which the frequency is not entered, are considered as non-recurring.	
2.10	Standard format	A uniform format of the overview scheme with regards to font and style is aimed at. There is no logo displayed, except the Vitalink logo.

¹⁸ The provider makes the best choice between the use of times or meals. That can be proposed as a guideline for the input of data by the care provider or enforced by the end user software by obliging the care provider beforehand to make a choice and only offer the associated ingestion times.

5.2 Guidelines for input

5.2.1 Objective

These guidelines are based on the experiences that were acquired during the Vitalink pilot project in 2012 and 2013.

These guidelines need to be interpreted as functional restrictions or suggestions that need to be observed by the end users software application.

5.2.2 Description of guidelines

5.2.2.1 No use of default values

The use of default values for input fields (both free text fields as selection lists) is very strongly advised against.

The end users software application may not fill in any value automatically that is not entered by an end user. It must be possible to modify or delete all of the data. If deleted the relevant field is not included in the kmehr message.

Means of administration (CD-DRUG-ROUTE)

The general guideline is that the use of default values (a pre-filled default value) is very strongly advised against. This is also the case for the means of administration field (via CD-DRUG-ROUTE) . No standard value may be selected.

Alternatives to increase the ease of use with a selection list:

- The addition of a priority list that is displayed at the top of the alphabetically sorted selection list.
- The suggestion of a value by the software solution (to the end user or automatically completed if it can be unambiguously assigned) with, for example, the possible means of administration for the selected medication.

Administration unit (CD-ADMINISTRATION-UNIT)

The general guideline is that the use of default values (a pre-filled default value) is very strongly advised against. This is also the case for the administration unit field (via CD-ADMINISTRATION-UNIT). No standard value may be selected.

Alternatives to increase the ease of use with a selection list:

- The addition of a priority list that is displayed at the top of the alphabetically sorted selection list.
- The suggestion of a value by the software solution (to the end user or automatically completed if it can be unambiguously assigned) with, for example, the possible administration unit for the selected medication.

5.2.2.2 Ingestion quantity per ingestion as fraction

To improve the readability a display as fraction instead of a decimal number needs to be provided. The kmehr message should include the decimal value.

If a selection list for the ingestion quantity is provided this should also contain the values 1.5 (1½) and 2. Furthermore, if required, it must be possible to enter every other quantity.

5.2.2.3 Use of (patient-friendly) translations for codes

There is a translation available for the patient for several kmehr text fields (see separate document). The “translation for the patient” may only be used in the print of the “overview scheme”.

- During input the extensive possibilities for choice must be retained (possibly supplemented with a readable form).
- With a display for a provider the specific code must also be displayed along with the readable form.

Specifically with the use of the **“CD-DRUG-ROUTE” code table** it is compulsory to display the codes during input so that a specific selection can be made by the provider.

5.2.2.4 User friendly procedure to add a method of preparation or ingestion explanation to a medication line

A method of preparation, instructions for use or an ingestion explanation need to be included as comment/explanation for the patient via “<instructionforpatient>”.

The end users software application must allow these explanations to be added in a user friendly manner. This can be done by providing a selection list with frequently used explanations. However, it must be possible for the end user to add to and/or modify this.

An example list that can serve as a basis:

Instructions for use / comment	Priority ¹⁹
Ingest and swallow with half a glass of water	1
Swallow without chewing	1
Suck	1
Under the tongue	2
Dissolve in water and drink	1
Dissolve in fruit juice and drink	2
Shake before use	1
Store in a cool place	1
Oral hygiene after use	2
Use spacer devices with inhalator	2
After administering remain lying down for 15 minutes	2
Do not lie down after ingestion	2

¹⁹ The priority is assigned with a number:

1 = high priority, frequently used and placed at the top in a drop-down list (preferably chronological)

2 = high priority, infrequently used and placed at the bottom in a drop-down list (preferably chronological)

After ingestion do not eat for 1 hour	2
Do not break/split/crush	1
Only split with a splitting device	2
Inhale quickly, deeply and forcefully	1
Simultaneously inhale and activate	1
Massage	1
Apply in a thin layer	1
Apply in a thick layer	2
Not on damaged or irritated skin	2
Do not wash the skin beforehand with soap	2
Remove protective layer of plaster	2
Save the plaster bag and after removing the plaster, place it folded up in the bag and bring to the pharmacy	2
Do not cut through	2
Strict regulation necessary. Watch for bruising	2

5.2.2.5

Use of metadata for indicating the validation status of a medication line

Paragraph 4.1 **Error! Reference source not found.** describes the metadata concept as used by Vitalink and specifically the metadata details linked to a medication scheme line.

The end user software application should make it possible for the end user to modify the validation status. For a doctor as end user this standard can be set to “validated” (isvalidated=true), but it must be possible to easily modify it. This must be modifiable for other types of users.

A medication line for which the status is “toBeValidated” (isvalidated=false) must be clearly distinguished from the others. The application is requested to make this as recognizable as possible.