European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

EUDRAVIGILANCE (EV) ACCESS SIMPLE DATABASE VERSION 2.0

ACCESS TABLES DOCUMENTATION

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1 Introduction

The EudraVigilance Medicinal Product Dictionary version 1.0 (EVMPD) and the respective EudraVigilance Product Database (EVPDB) have been developed by the EMEA in collaboration with the EudraVigilance Joint Implementation Group. The main objective of the EVMPD is to assist the pharmacovigilance activities in the European Economic Area (EEA). As such, the EVMPD has been designed to support the collection, reporting, coding and evaluation of medicinal product data in a standardised and structured way.

The EudraVigilance Medicinal Product Dictionary (EVMPD) version 2.0 has been extended to include the requirements for the collection, reporting, coding and evaluation of Investigational Medicinal Product (IMP) data as defined in Directive 2001/20/EC and the implementing texts, in particular the "Detailed Guidance on the European Clinical Trials Database (EUDRACT Database)"[1].

A detailed description of the EVMPD version 2.0 including the applicable standard terminologies and definitions is provided in the document 'EudraVigilance Medicinal Product Dictionary Version 2.0 Technical Specifications' (Doc. Ref. EMEA/140327/2004). The EudraVigilance Medicinal Product Dictionary (EVMPD) Message and Acknowledgement Specifications are published in Doc. Ref. EMEA/140327/2004.

This document describes the EudraVigilance Access Simple Database data structure and the corresponding Access tables, which corresponds to the EVMPD version 2.0. It is intended for Organisations (Sponsors of Clinical Trials in the EEA, Marketing Authorisation Holders in the EEA (MAHs)) that have a local computer system established that contains structured medicinal product information and that wish to transfer the data automatically in the EV Simple DB Access Database tables.

The Organisations that wish to enter the medicinal product information manually (e.g. Organisations with a small product portfolio) should use as reference the document *EudraVigilance Simple Database - Forms Documentation.*

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[1] http://pharmacos.eudra.org/F2/home.html

2 EV Simple Database

The EV Access Simple DB has been developed to assist Sponsors and MAHs to populate the EVMPD version 2.0 by providing the following features:

1. **Medicinal Products Tables**

   Two different sets of tables store *Authorised* and *Development Medicinal Products* data.

   The concept of a Pharmaceutical Product has been introduced and included in the new data structures.

2. **Lookup tables**

   To collect information in a coded way, some lookup tables in the EVMPD have been exported in the EV Access Simple DB. Some of these lookup tables can be updated by the user (Updateable Lookup Tables), whereas some other lookup tables cannot be modified. The Updateable Lookup Tables are as follows:

   i. Organisation

   ii. Source

   iii. Approved Substance

   iv. Development Substance

   v. ATC Code

   vi. Pharmaceutical Forms

   vii. Route of Administration

   viii. MedDRA version

   If a user tries to update a lookup table that is 'Non-Updatable', the XML file created from the EV Access Simple DB will not include that information. In this way the EVMPD will not be affected by those changes.

   Every time there is a need to update a Non-Updateable Lookup Table (e.g. publication of a new European Standard Term List), the EMEA will publish a new version of the EV Access Simple DB on the EudraVigilance website.

3. **Application forms**

Together with the Access tables some application forms are provided to support the user to insert the necessary product information and to update the updatable lookup tables. The description of the EV Access Simple DB application forms is outside the scope of this document. It is provided in the document *EudraVigilance Simple Database - Forms Documentation.*

4. **Printouts**

To check the inserted information in the EV Access Simple DB, printouts are now available. The user can print the following information:

   i. Authorised Medicinal Products

   ii. Development Medicinal Products

   iii. Approved Substances

   iv. Development Substances

   v. Organisations

5. **Creation of an XML file (EVPRM)**

To send the information collected in the EV Access Simple DB, the user can create an XML file and send it to the EMEA. The XML file contains all the information entered in the EV Access Simple DB. The format of the XML file is completely compatible with the EudraVigilance Product Report Message (EVPRM) XML Schema (Doc. Ref. EMEA/140327/2004).

The information contained in the EV Access Simple DB together with this document should provide an exhaustive description of the data structure and the tables present in the EV Access Simple DB.

3 The Data Structure

The EV Access Simple DB data structure consists of four main sections (Figure 1):

1. Authorised Products Section
2. Development Products Section
3. Updateable Lookup Tables Section
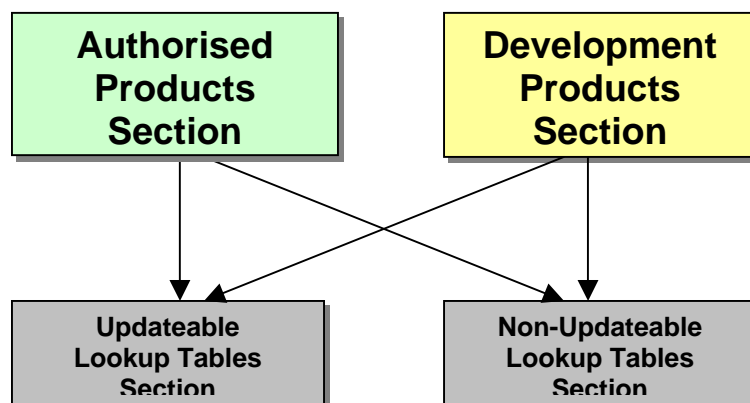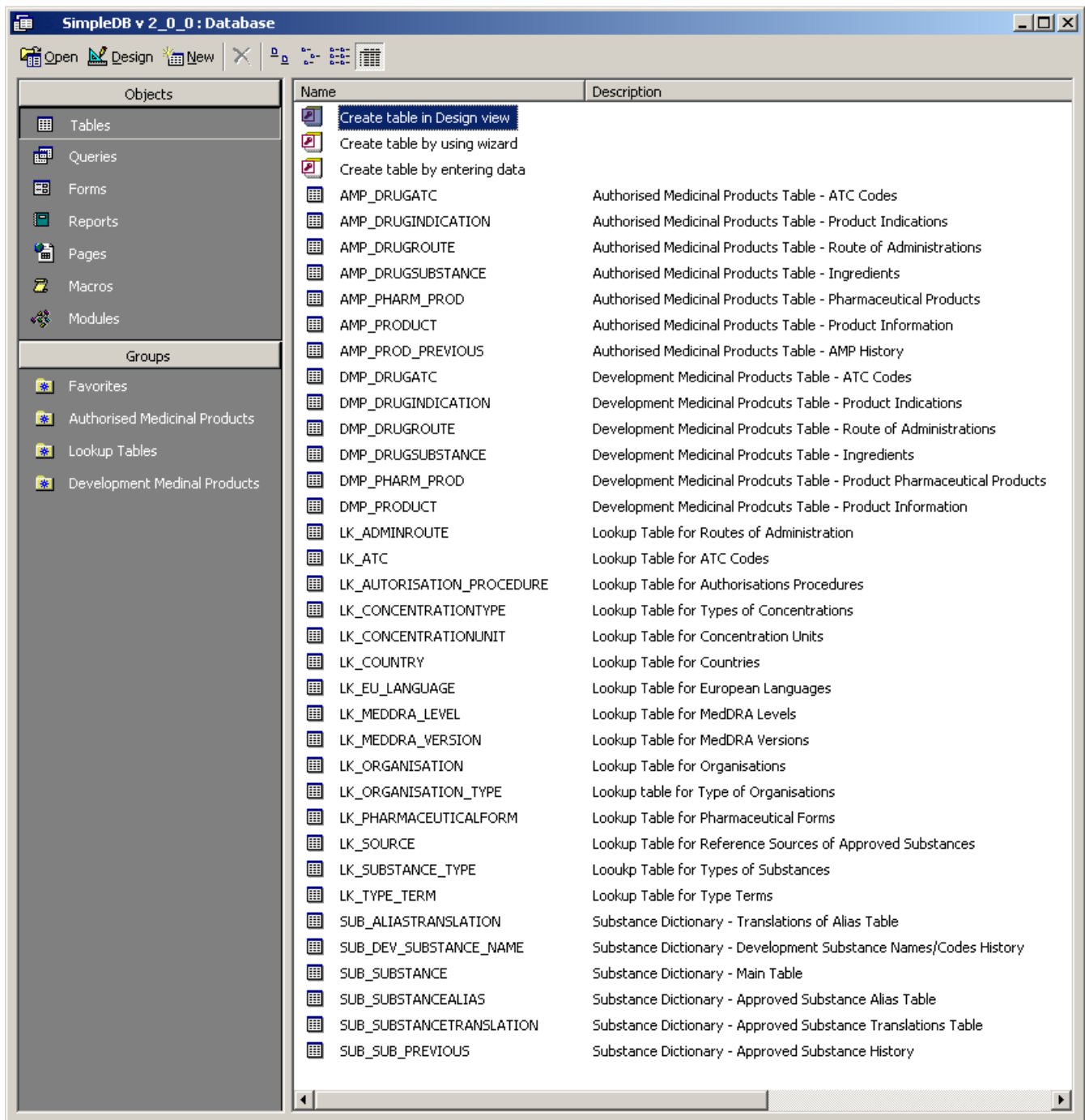4. Non-Updateable Lookup Tables Section

Figure 1 - Access Simple DB Sections

The Authorised Products section contains tables of *Authorised Medicinal Product*, the Development Product section contains tables of *Development Medicinal Products*, the Updateable Lookup Tables and Non-Updateable Lookup Tables sections contain all the lookup tables included in the EV Access Simple DB. The Updatable Lookup Tables can be updated by the user, whereas the Non-Updatable Lookup Tables cannot be modified.

Figure 2 shows the list of all the tables available within the EV Access Simple DB.
The tables starting with the prefix 'AMP_' refer to the Authorised Products Section. The tables starting with the prefix 'DMP_' refer to the Development Products Section. The tables starting with the prefix 'LK_' are lookup tables.
Because the Substance lookup table is physically mapped in more than one table, all the tables that refer to the Substance Sections have the prefix 'SUB_'.

Name	Description
Create table in Design view	
Create table by using wizard	
Create table by entering data	
AMP_DRUGATC	Authorised Medicinal Products Table - ATC Codes
AMP_DRUGINDICATION	Authorised Medicinal Products Table - Product Indications
AMP_DRUGROUTE	Authorised Medicinal Products Table - Route of Administrations
AMP_DRUGSUBSTANCE	Authorised Medicinal Products Table - Ingredients
AMP_PHARM_PROD	Authorised Medicinal Products Table - Pharmaceutical Products
AMP_PRODUCT	Authorised Medicinal Products Table - Product Information
AMP_PROD_PREVIOUS	Authorised Medicinal Products Table - AMP History
DMP_DRUGATC	Development Medicinal Products Table - ATC Codes
DMP_DRUGINDICATION	Development Medicinal Prodcuts Table - Product Indications
DMP_DRUGROUTE	Development Medicinal Prodcuts Table - Route of Administrations
DMP_DRUGSUBSTANCE	Development Medicinal Prodcuts Table - Ingredients
DMP_PHARM_PROD	Development Medicinal Prodcuts Table - Product Pharmaceutical Products
DMP_PRODUCT	Development Medicinal Prodcuts Table - Product Information
LK_ADMINROUTE	Lookup Table for Routes of Administration
LK_ATC	Lookup Table for ATC Codes
LK_AUTORISATION_PROCEDURE	Lookup Table for Authorisations Procedures
LK_CONCENTRATIONTYPE	Lookup Table for Types of Concentrations
LK_CONCENTRATIONUNIT	Lookup Table for Concentration Units
LK_COUNTRY	Lookup Table for Countries
LK_EU_LANGUAGE	Lookup Table for European Languages
LK_MEDDRA_LEVEL	Lookup Table for MedDRA Levels
LK_MEDDRA_VERSION	Lookup Table for MedDRA Versions
LK_ORGANISATION	Lookup Table for Organisations
LK_ORGANISATION_TYPE	Lookup table for Type of Organisations
LK_PHARMACEUTICALFORM	Lookup Table for Pharmaceutical Forms
LK_SOURCE	Lookup Table for Reference Sources of Approved Substances
LK_SUBSTANCE_TYPE	Looukp Table for Types of Substances
LK_TYPE_TERM	Lookup Table for Type Terms
SUB_ALIASTRANSLATION	Substance Dictionary - Translations of Alias Table
SUB_DEV_SUBSTANCE_NAME	Substance Dictionary - Development Substance Names/Codes History
SUB_SUBSTANCE	Substance Dictionary - Main Table
SUB_SUBSTANCEALIAS	Substance Dictionary - Approved Substance Alias Table
SUB_SUBSTANCETRANSLATION	Substance Dictionary - Approved Substance Translations Table
SUB_SUB_PREVIOUS	Substance Dictionary - Approved Substance History

Figure 2 - EV Simple DB Tables

In chapter 4 the Authorised Products Section, in chapter 5 the Development Products Section and in chapter 6 the Updatable and Non-Updatable Lookup Tables Sections are described. The Annex contains the description of all the tables in the EV Access Simple DB.

4 Authorised Product Section

The logical structure of the Authorised Products Section is as follows:
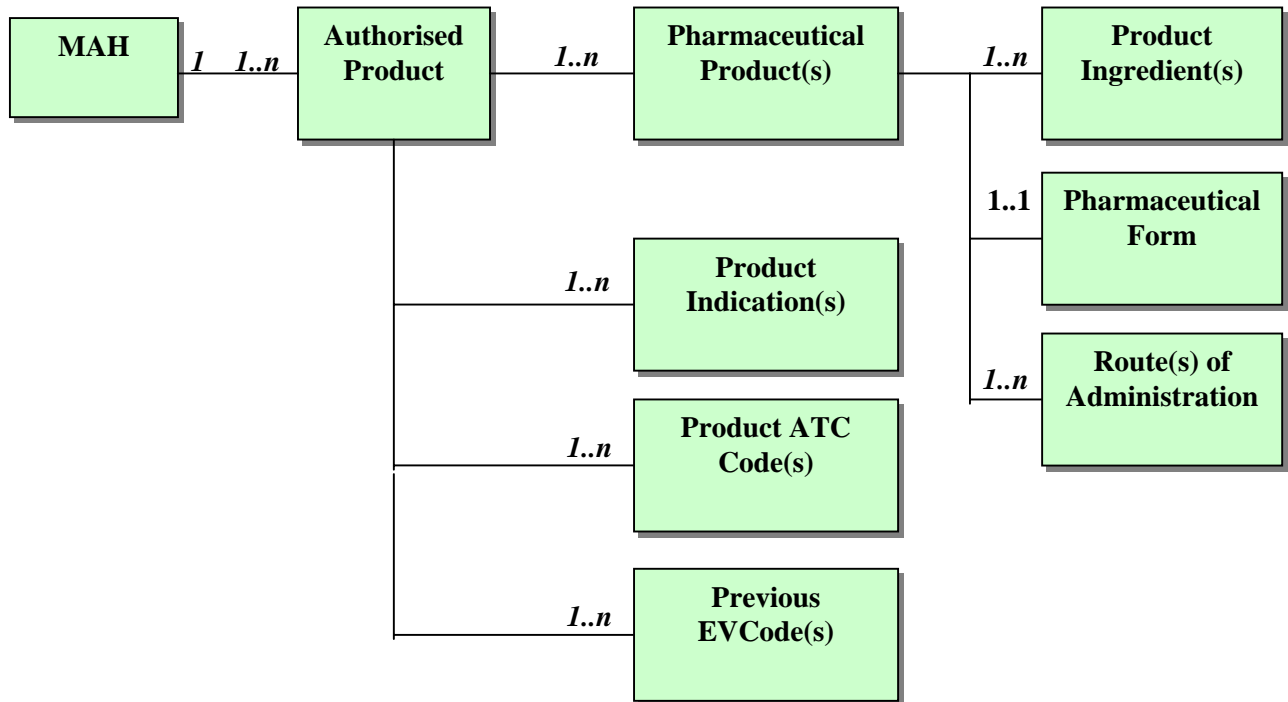

Figure 3 - Authorised Products Section – Logical Data Structure

The relations are as follows:

- One MAH can have <u>more than one</u> Authorised Medicinal Product
- One Authorised Medicinal Product <u>has one and only one</u> MAH
- One Authorised Medicinal Product can have <u>more than one</u> Pharmaceutical Product
- One Authorised Medicinal Product can have <u>more than one</u> Product Indication
- One Authorised Medicinal Product can have <u>more than one</u> Product ATC Code
- One Authorised Medicinal Product can have <u>more than one</u> Previous EVCode
- One Pharmaceutical Product can have <u>more than one</u> Ingredient
- One Pharmaceutical Product can have <u>one and only one</u> Pharmaceutical Form
- One Pharmaceutical Product can have <u>more than one</u> Route of Administration

The implementation of the Authorised Product Section in the EV Accesss Simple DB strucutre is described in Figure 4.

Figure 4 - Authorised Product s Section
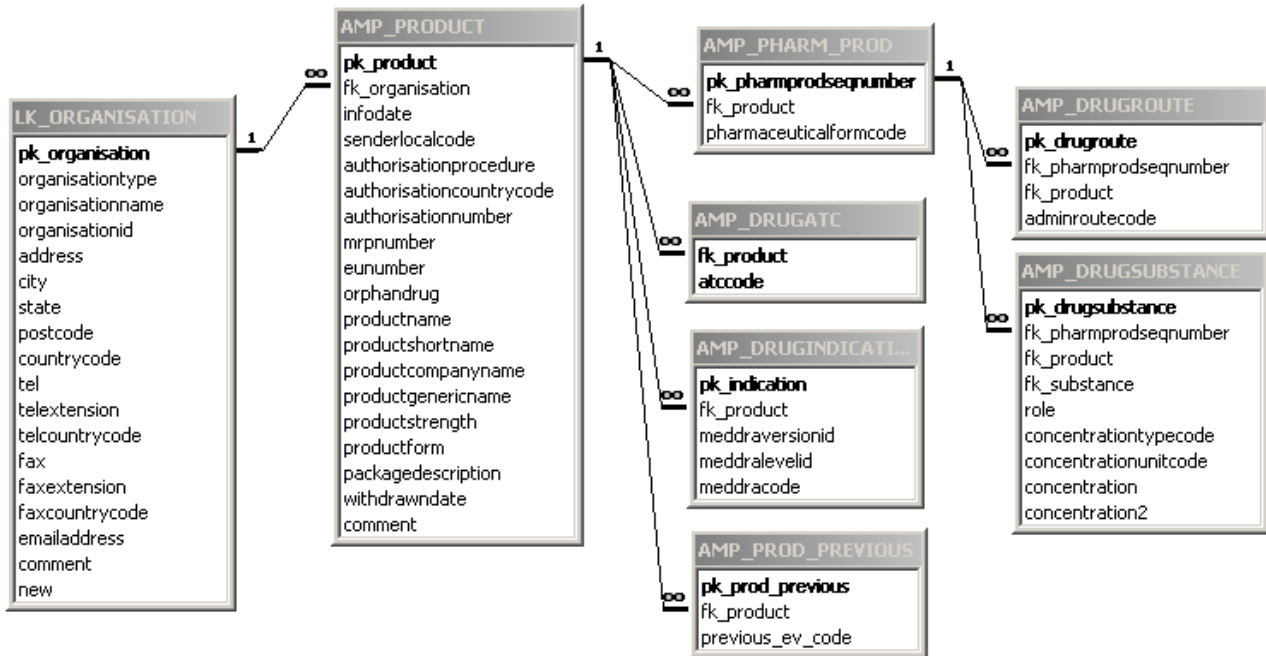
The DD_ORGANISATION table reflects the of MAH Table in the Authorised Products Section and the Sponsor Table in the Development Products Section. In this case the DD_ORGANISATION table contains information about MAHs. The entries that refer to a MAH have the value of the field *type_org* set to 1. For a complete description of the DD_ORGANISATION table refer to the annex.

5 Development Product Section

The logical structure of the Development Products Section is as follows:
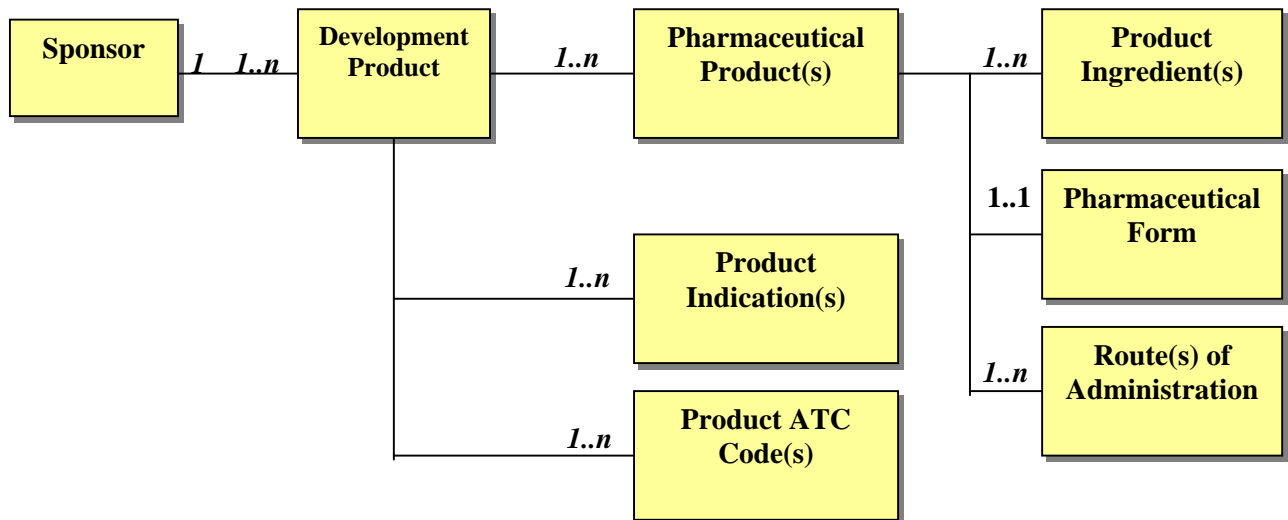
Figure 5 – Development Products Section – Logical Data Structure

The relations are as follows:

- One Sponsor can have <u>more than </u>one Authorised Medicinal Product
- One Development Medicinal Product <u>has one and only one </u>Sponsor
- One Development Medicinal Product can have <u>more than one </u>Pharmaceutical Product
- One Development Medicinal Product can have <u>more than one </u>Product Indication
- One Development Medicinal Product can have <u>more than one </u>Product ATC Code
- One Pharmaceutical Product can have <u>more than one </u>Ingredient
- One Pharmaceutical Product <u>one and only one </u>Pharmaceutical Form
- One Pharmaceutical Product can have <u>more than one </u>Route of Administration

The implementation of the Development Products Section in the EV Accesss Simple DB strucutre is described in Figure 6.
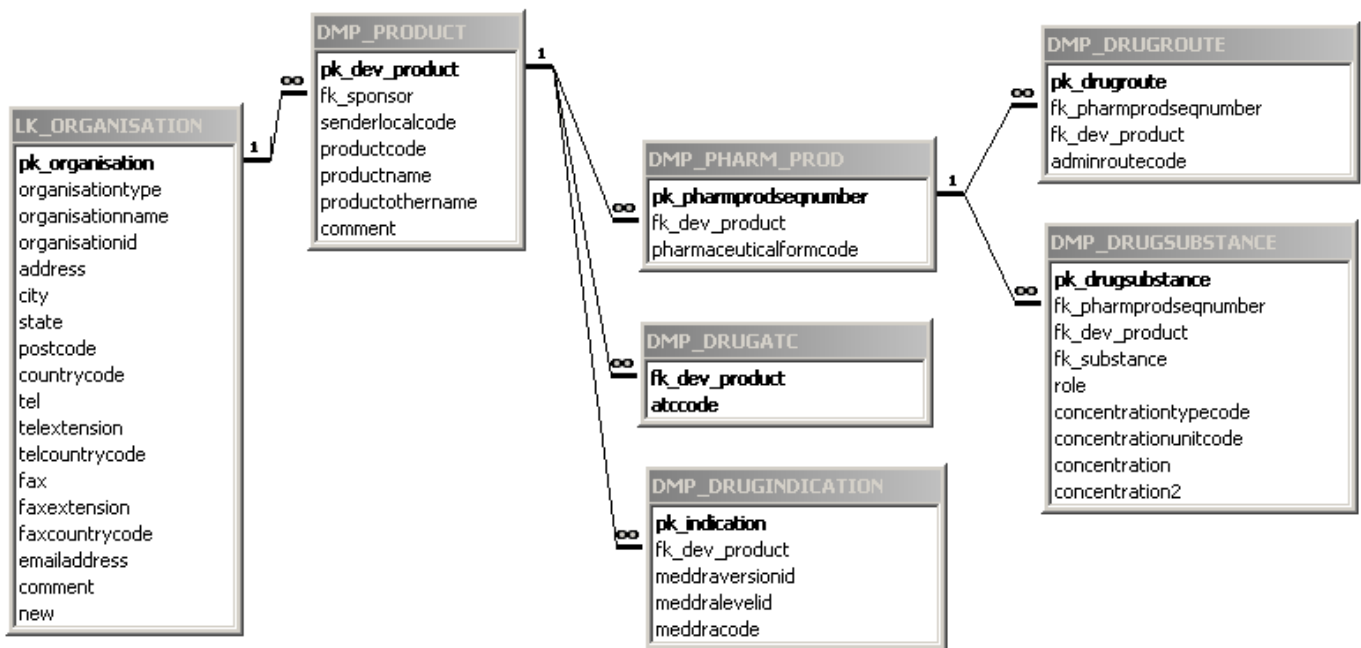
Figure 6 - Development Products Section - Logical Data Structure

The DD_ORGANISATION table refers to the MAH Table in the Authorised Products Section and to the Sponsor Table in the Development Products Section. In this case the DD_ORGANISATION table contains information about Sponsors. The entries that refer to a Sponsor have the value of the field *type_org* set to 2. For a complete description of the DD_ORGANISATION table refer to the annex.

6 Lookup Tables

The Substance lookup table has been structured in a sub-sections within the database to collect information about

- Development Substances
- Approved Substances
- All substance names and codes, all synonyms, translations and alias
- Chemical Biological Description
- CAS Registry Number and the empiric molecular formula

The following paragraph contains the description of the Substance section. The last paragraph lists all other lookup tables in the EV Access Simple DB.

Please refer to the annex for the complete description of each lookup table.
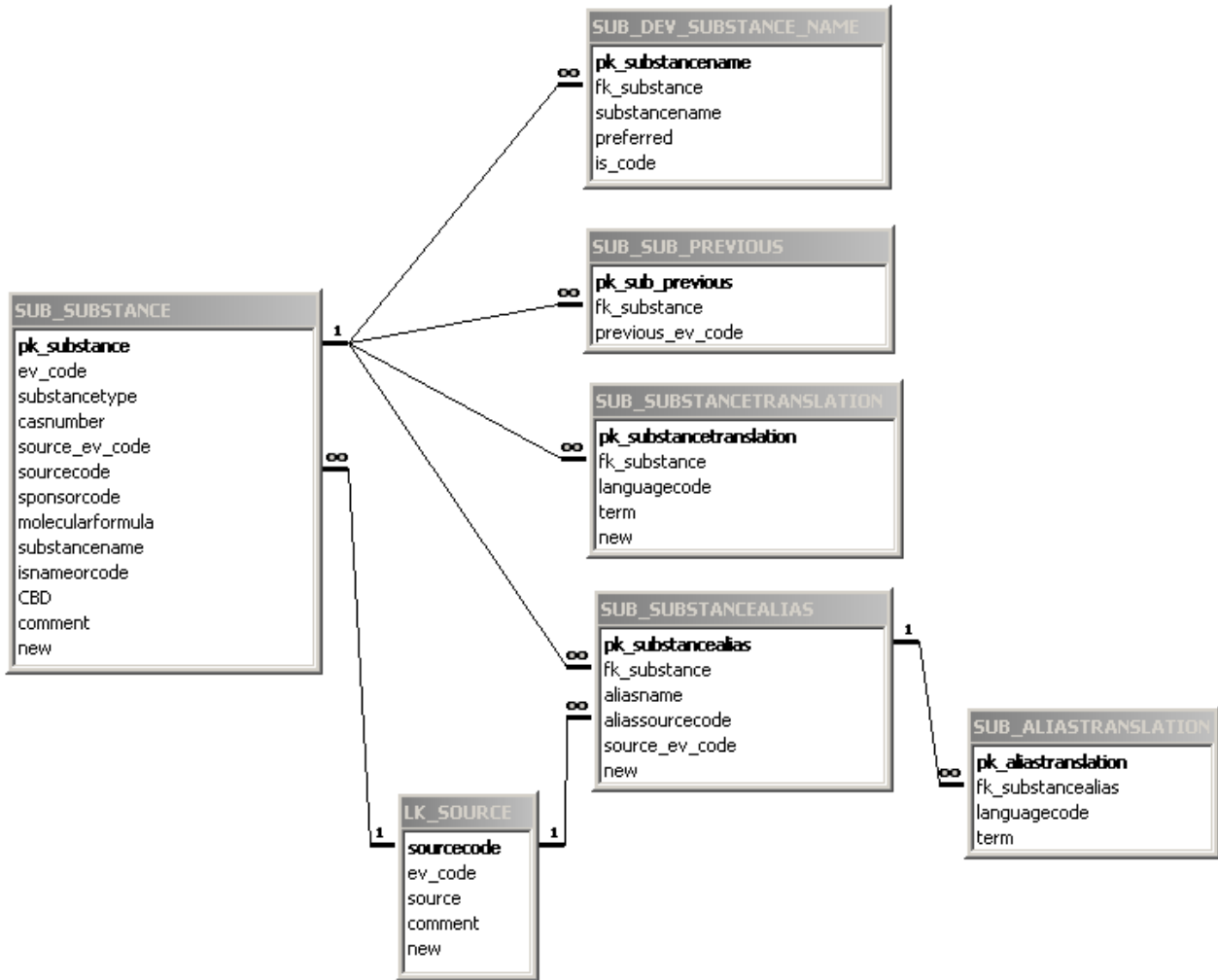
6.1 Substance Section

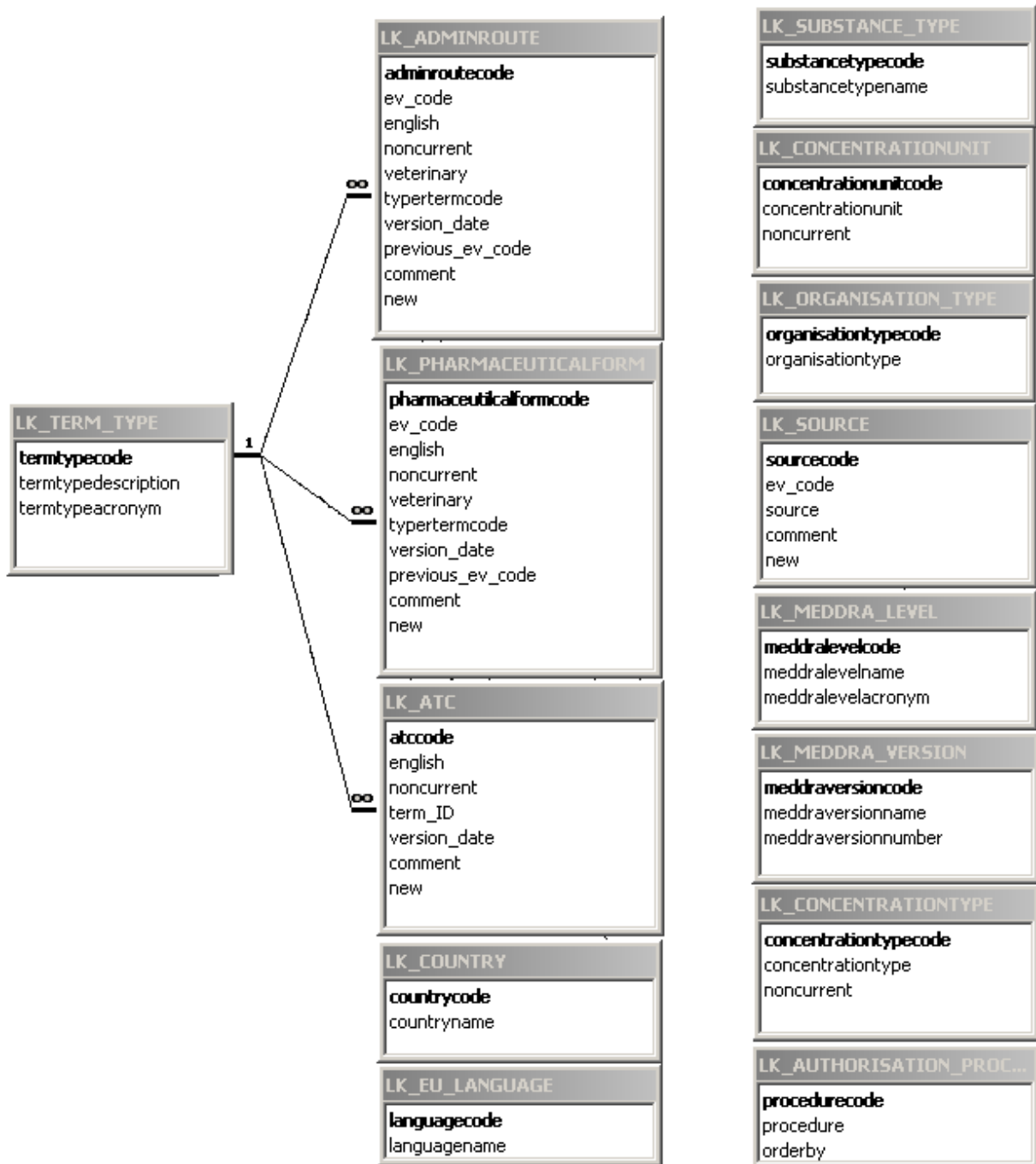

Figure 7 - Substance Dictionary

6.2 Other Lookup Tables

LK_ADMINROUTE
- **adminroutecode**
- ev_code
- english
- noncurrent
- veterinary
- typertermcode
- version_date
- previous_ev_code
- comment
- new

LK_PHARMACEUTICALFORM
- **pharmaceuticalformcode**
- ev_code
- english
- noncurrent
- veterinary
- typertermcode
- version_date
- previous_ev_code
- comment
- new

LK_ATC
- **atccode**
- english
- noncurrent
- term_ID
- version_date
- comment
- new

LK_COUNTRY
- **countrycode**
- countryname

LK_EU_LANGUAGE
- **languagecode**
- languagename

LK_TERM_TYPE
- **termtypecode**
- termtypedescription
- termtypeacronym

LK_SUBSTANCE_TYPE
- **substancetypecode**
- substancetypename

LK_CONCENTRATIONUNIT
- **concentrationunitcode**
- concentrationunit
- noncurrent

LK_ORGANISATION_TYPE
- **organisationtypecode**
- organisationtype

LK_SOURCE
- **sourcecode**
- ev_code
- source
- comment
- new

LK_MEDDRA_LEVEL
- **meddralevelcode**
- meddralevelname
- meddralevelacronym

LK_MEDDRA_VERSION
- **meddraversioncode**
- meddraversionname
- meddraversionnumber

LK_CONCENTRATIONTYPE
- **concentrationtypecode**
- concentrationtype
- noncurrent

LK_AUTHORISATION_PROC...
- **procedurecode**
- procedure
- orderby

Figure 8 - Lookup Tables

ANNEX - TABLES DESCRIPTION

AMP_DRUGATC

fieldname	fieldtype	fieldsize	description
atccode	adVarWChar	7	The ATC Code of the Authorised Medicinal Product (LK_ATC). An Authorised Medicinal Product can refer to an ATC code that is either a 'Standard' or 'Proposed' term.
fk_product	adInteger		The foreign key of the Authorised Medicinal Product that the ATC Code is referrring to.

AMP_DRUGINDICATION

fieldname	fieldtype	fieldsize	description
fk_product	adInteger		The foreign key of the Authorised Medicinal Product that the Indication(s) is/are referring to
meddracode	adInteger		The MedDRA Code for the Authorised Medicinal Product Indication(s). Users with a MedDRA license can create a lookup table for this field by importing the MedDRA terminology in the lookup table and, then, by linking this field to the lookup table.
meddralevelid	adInteger		The level of of MedDRA specified in the meddracode field (LK_MEDDRA_VERSION)
meddraversionid	adInteger		The version of MedDRA used (LK_MEDDRA_VERSION)
pk_indication	adInteger		The key automatically assigned by the EV Access Simple DB to each Indication of the Authorised Medicinal Product

AMP_DRUGROUTE

fieldname	fieldtype	fieldsize	description
adminroutecode	adInteger		The route of administration (LK_ADMINROUTE). An Authorised Medicinal Product can refer to a Route of Administration that is either a 'Standard' or 'Proposed' term
fk_pharmprodseqnumber	adInteger		The foreign key of the Pharmaceutical Product this Route of Administration is referring to
fk_product	adInteger		The foreign key of the Authorised Medicinal Product the Route of Administration is referring to
pk_drugroute	adInteger		The key automatically assigned by the EV Access Simple DB to each Route of Administration specified

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AMP_DRUGSUBSTANCE

fieldname	fieldtype	fieldsize	description
concentration	adDouble		The concentration of the Ingredient
concentration2	adDouble		The upper value of the concentration of the Ingredient (only applicable if the user has to specify a concentration range)
concentrationtypecode	adSmallInt		The concentration type of the Ingredient (LK_CONCENTRATIONTYPE)
concentrationunitcode	adSmallInt		The concentration unit of the Ingredient (LK_CONCENTRATIONUNIT)
fk_pharmprodseqnumber	adInteger		The foreign key of the Pharmaceutical Product the Ingredient is referring to
fk_product	adInteger		The foreign key of the Authorised Medicinal Product the Ingredient is referring to
fk_substance	adInteger		The substance as the Ingredient (SUB_SUBSTANCE)
pk_drugsubstance	adInteger		The key automatically assigned by the EV Access Simple DB to each Ingredient specified in this table
role	adSmallInt		The role of the substance as Ingredient being either an Active Ingredient (1) or Excipient (2)

AMP_PHARM_PROD

fieldname	fieldtype	fieldsize	description
fk_product	adInteger		The foreign key of the Authorised Medicinal Product the Pharmaceutical Product is referring to
pharmaceuticalformcode	adInteger		The Pharmaceutical Form of the Pharmaceutical Product (LK_PHARMACEUTICALFORM). An Authorised Medicinal Product can refer to a Pharmaceutical Form that is either a 'Standard' or 'Proposed' term
pk_pharmprodseqnumber	adInteger		The key automatically assigned by the EV Access Simple DB to each Pharmaceutical Product

AMP_PROD_PREVIOUS

fieldname	fieldtype	fieldsize	description
fk_product	adInteger		The foreign key of the Authorised Medicinal Product the Previous EV Code is referring to
pk_prod_previous	adInteger		The key automatically assigned by the EV Access Simple DB to each Previous EV Code specified in this table
previous_ev_code	adVarWChar	60	The EV Code of the Development Medicinal Product the Authorised Medicinal Product is referring to

AMP_PRODUCT

fieldname	fieldtype	fieldsize	description
authorisationcountrycode	adVarWChar	2	The country in which the product has been authorised (LK_COUNTRY)
authorisationnumber	adVarWChar	100	The Marketing Authorisation Number
authorisationprocedure	adInteger		The procedure the product has followed to be authorised (LK_PROCEDURE)
comment	adVarWChar	250	Comment
eunumber	adVarWChar	50	If the authorisation procedure is "EU centralised procedures" this field must be filled with the "EU Number of the product"
fk_organisation	adInteger		The MAH of the Authorised Medicianal Product (LK_ORGANISATION with organisationtype = (1) "MAH"
infodate	adDate		The date of the last update of the SPC
mrpnumber	adVarWChar	50	If the authorisation procedure is "EU mutual recognition procedure" this field must be filled with the "Mutual Recognition Procedure Number of the product"
orphandrug	adBoolean	2	Flag if authorised medicinal product is an EU orphan drug or not
packagedescription	adVarWChar	250	A package description as free text
pk_product	adInteger		The key automatically assigned by the EV Access Simple DB to the Authorised Medicianal Product
productcompanyname	adVarWChar	250	The name of the company as reported in the presentation name (if present)
productform	adVarWChar	250	The pharmaceutical form as reported in the Product Presentation Full Name (if present)
productgenericname	adVarWChar	250	The generic name as reported in the Presentation Full Name (if present)
productname	adVarWChar	250	The product presentation full name as it has been authorised
productshortname	adVarWChar	250	The short name of the product as reported in the Product Presentation Full Name
productstrength	adVarWChar	250	The strength and strength unit reported in the product presentation full name (if present)
senderlocalcode	adVarWChar	50	The code assigned to the Authorised Medicinal Product in the Medicinal Product Database of the Sender Organisation (if available)
withdrawndate	adDate		The date of the withdrawal from the market of the medicinal product (if applicable)

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DMP_DRUGATC

fieldname	fieldtype	fieldsize	description
atccode	adVarWChar	7	The ATC Code of the medicinal product (LK_ATC). A Development Medicinal Product can refer to an ATC code that is either a 'Standard', 'Proposed' or 'Development' term
fk_dev_product	adInteger		The foreign key of the Development Medicinal Product the ATC Code is referring to

DMP_DRUGINDICATION

fieldname	fieldtype	fieldsize	description
fk_dev_product	adInteger		The foreign key of the Development Medicinal Product the Indication(s) is/are referring to
meddracode	adInteger		The MedDRA Code for the Development Medicinal Product Indication(s). Users with a MedDRA license can create a lookup table for this field by importing the MedDRA terminology in the lookup table and, then, by linking this field to the lookup table.
meddralevelid	adInteger		The Level of MedDRA specified in the meddracode field (LK_MEDDRA_VERSION)
meddraversionid	adInteger		The Version of MedDRA used (LK_MEDDRA_VERSION)
pk_indication	adInteger		The key automatically assigned by the EV Access Simple DB to each /indication of a Development Medicinal Product

DMP_DRUGROUTE

fieldname	fieldtype	fieldsize	description
adminroutecode	adInteger		The Route of Administration (LK_ADMINROUTE). A Development Medicinal Product can refer to a Route of Administration that is either a 'Standard', 'Proposed' or 'Development' term
fk_dev_product	adInteger		The foreign key of the Development Medicinal Product the Route of Administration is referring to
fk_pharmprodseqnumber	adInteger		The foreign key of the Pharmaceutical Product the Route of Administration is referring to
pk_drugroute	adInteger		The key automatically assigned by the EV Access Simple DB to each Route of Administration specified

DMP_DRUGSUBSTANCE

fieldname	fieldtype	fieldsize	description
concentration	adDouble		The concentration of the Ingredient
concentration2	adDouble		The upper value of the concentration of the Ingredient (only applicable if the user has specified a concentration range)
concentrationtypecode	adSmallInt		The concentration type of the Ingredient (LK_CONCENTRATIONTYPE)
concentrationunitcode	adSmallInt		The concentration unit of the Ingredient (LK_CONCENTRATIONUNIT)
fk_dev_product	adInteger		The foreign key of the Development Medicinal Product the Ingredient is referring to
fk_pharmprodseqnumber	adInteger		The foreign key of the Pharmaceutical Product the Ingredient is referring to
fk_substance	adInteger		The substance as the Ingredient (SUB_SUBSTANCE)
pk_drugsubstance	adInteger		The key automatically assigned by the EV Access Simple DB to each Ingredient specified in this table
role	adSmallInt		The role of the substance as Ingredient being either an Active Ingredient (1) or an Excipient (2)

DMP_PHARM_PROD

fieldname	fieldtype	fieldsize	description
fk_dev_product	adInteger		The foreign key of the Development Medicinal Product the Pharmaceutical Product is referring to
pharmaceuticalformco de	adInteger		The Pharmaceutical Form of the Pharmaceutical Product (LK_PHARMACEUTICALFORM). A Development Medicinal Product can refer to a Pharmaceutical Form that is either a 'Standard',' Proposed' or 'Development' term
pk_pharmprodseqnu mber	adInteger		The key automatically assigned by the EV Access Simple DB to each Pharmaceutical Product

DMP_PRODUCT

fieldname	fieldtype	fieldsize	description
comment	adVarWChar	250	Comment
fk_sponsor	adInteger		The Sponsor of the Development Medicinal Product (LK_ORGANISATION with organisationtype = (2) "Sponsor").
pk_dev_product	adInteger		The key automatically assigned by the EV Access Simple DB to the Development Medicinal Product
productcode	adVarWChar	60	The code of the Development Medicinal Product as assigned by the Sponsor during the clinical trial (if applicable).
productname	adVarWChar	250	The code of the Development Medicinal Product as assigned by the Sponsor during the clinical trial (if applicable).
productothername	adVarWChar	250	Other name of the Development Medicinal Product assigned by the Sponsor during the clinical trial (if applicable).
senderlocalcode	adVarWChar	100	The code assigned to the Development Medicinal Product in the Medicinal Product Database of the Sender Organisation (if applicable)

LK_ADMINROUTE

fieldname	fieldtype	fieldsize	description
adminroutecode	adInteger		The key automatically assigned by the EV Access Simple DB to the Route of Administration
comment	adVarWChar	250	Comment
english	adVarWChar	255	The description of the Route of Administration
ev_code	adVarWChar	60	The EVCODE assigned by the EVMPD to the Route of Administration
new	adBoolean	2	Flag if a Route of Administration has been entered by the user. The user can enter only a Route of Administration that is a 'Proposed' or 'Development' term
noncurrent	adBoolean	2	Flag f the Route of Administration is current or non current
previous_ev_code	adVarWChar	50	The EV Code of previous Route of Administration this Route of Administration is referring to
typetermcode	adInteger		Flag if the Route of Administration is a 'Standard', 'Proposed' or 'Development' term
version_date	adDate		The version date of the publication (mandatory for 'Standard ' Route of Administrations)
veterinary	adBoolean	2	Flags if the Route of Administration refers to a veterinary entry

LK_ATC

fieldname	fieldtype	fieldsize	description
atccode	adVarWChar	7	The ATC Code
comment	adLongVarWChar		Comment
english	adVarWChar	255	The description of the ATC Code
new	adBoolean	2	Flag if the ATC Code has been entered by the user. The user can enter only ATC Codes that are a 'Proposed' or 'Development' Code
noncurrent	adBoolean	2	Flag if the ATC Code is current or non current
typetermcode	adInteger		Flag if the ATC Code is a 'Standard', 'Proposed' or 'Development' term
version_date	adDate		The version date of the publication (mandatory for 'Standard ' 'ATC Codes)

LK_AUTHORISATION_PROCEDURE

fieldname	fieldtype	fieldsize	description
orderby	adInteger		The order used when showing the Authorisation Procedures lookup table
procedure	adVarWChar	150	The Authorisation Procedure
procedurecode	adInteger		The key automatically generated by the EV Access Simple DB

LK_CONCENTRATIONTYPE

fieldname	fieldtype	fieldsize	description
concentrationtype	adVarWChar	50	The Concentration Type
concentrationtypecode	adSmallInt		The key automatically generated by the EV Access Simple DB
noncurrent	adBoolean	2	Flag if the Concentration Type is current or non current

LK_CONCENTRATIONUNIT

fieldname	fieldtype	fieldsize	description
concentrationunit	adVarWChar	50	The Concentration Unit
concentrationunitcode	adSmallInt		The key automatically generated by the EV Access Simple DB
noncurrent	adBoolean	2	Flag if the Concentration Unit is current or non current

LK_COUNTRY

fieldname	fieldtype	fieldsize	description
countrycode	adVarWChar	2	The two letters ISO 3166 Country Code
countryname	adVarWChar	255	The Country Name

LK_EU_LANGUAGE

fieldname	fieldtype	fieldsize	description
languagecode	adVarWChar	2	The two letters language code
languagename	adVarWChar	255	The Language

LK_MEDDRA_LEVEL

fieldname	fieldtype	fieldsize	description
meddralevelacronym	adVarWChar	50	The MedDRA level acronym
meddralevelcode	adInteger		The key automatically generated by the EV Access Simple DB
meddralevelname	adVarWChar	250	The MedDRA level name

LK_MEDDRA_VERSION

fieldname	fieldtype	fieldsize	description
meddraversioncode	adInteger		The key automatically generated by the EV Access Simple DB
meddraversionname	adVarWChar	250	The MedDRA Version as text
meddraversionnumber	adDouble		The MedDRA Version as number (double)

LK_ORGANISATION

fieldname	fieldtype	fieldsize	description
address	adVarWChar	100	The address
city	adVarWChar	50	The city
comment	adLongVarWChar		Comment
countrycode	adVarWChar	2	The country
emailaddress	adVarWChar	100	The email address
fax	adVarWChar	50	The fax number
faxcountrycode	adVarWChar	50	The country code extension of the fax number e.g. +44
faxextension	adVarWChar	50	The extension of the fax number
new	adBoolean	2	Flag if the Organisation has been entered by the user or not
organisationid	adVarWChar	60	The Organisation Sender ID received after the registration with the EudraVigilance system (if available)
organisationname	adVarWChar	100	The name of the Organisation
organisationtype	adInteger		The type of the organisation
pk_organisation	adInteger		The key automatically assigned by the EV Access Simple DB to the Organisation
postcode	adVarWChar	50	The postcode
state	adVarWChar	50	The state
tel	adVarWChar	50	The telephone number
telcountrycode	adVarWChar	50	The country code extension of the telephone number e.g. +44
telextension	adVarWChar	50	The extension of the telephone number

LK_ORGANISATION_TYPE

fieldname	fieldtype	fieldsize	description
organisationtype	adVarWChar	50	The Organisation Type
organisationtypecode	adInteger		The key automatically generated by the EV Access Simple BD

LK_PHARMACEUTICALFORM

fieldname	fieldtype	fieldsize	description
comment	adLongVarWChar		Comment
english	adVarWChar	255	The description of the Pharmaceutical Form
ev_code	adVarWChar	60	The EVCODE assigned by the EVMPD to the Pharmaceutical Form
new	adBoolean	2	Flag if a new Pharmaceutical Form has been entered by the user. The user can enter only a Pharmaceutical Form that is a 'Proposed' or 'Development' term
noncurrent	adBoolean	2	Flag if the Pharmaceutical Form is current or non-current
pharmaceutilcalformcode	adInteger		The key automatically assigned by the EV Access Simple DB to the Pharmaceutical Form
previous_ev_code	adVarWChar	60	The EV Code of previous Pharmaceutical Form this Pharmaceutical Form is referring to
typetermcode	adInteger		Whether the Pharmaceutical Form is a 'Standard', 'Proposed' or 'Development' Term
version_date	adDate		The version date of the publication (mandatory for 'Standard ' Pharmaceutical Forms)
veterinary	adBoolean	2	Flag if the Pharmaceutical Form refers to a veterinary entry

LK_SOURCE

fieldname	fieldtype	fieldsize	description
comment	adLongVarWChar		Comment
ev_code	adVarWChar	60	The EVCODE assigned by the EVMPD to the Source
new	adBoolean	2	Flag if the source has been entered by the user or not
source	adVarWChar	70	The Source name
sourcecode	adInteger		The key automatically assigned by the EV Access Simple DB to the Source

LK_SUBSTANCE_TYPE

fieldname	fieldtype	fieldsize	description
substancetypecode	adInteger		The key automatically generated by the EV Access Simple DB
substancetypename	adVarWChar	100	The Substance Type

LK_TERM_TYPE

fieldname	fieldtype	fieldsize	description
termtypeacronym	adVarWChar	2	The Term Type acronyms
termtypecode	adInteger		The key automatically assigned by the EV Access Simple DB
termtypedescription	adVarWChar	50	The Term Type name

SUB_ALIASTRANSLATION

fieldname	fieldtype	fieldsize	description
fk_substancealias	adInteger		The foreign key of the Substance Alias
languagecode	adVarWChar	2	The language code for the translation
pk_aliastranslation	adInteger		The key automatically assigned by the EV Access Simple DB to each Substance Alias Translation
term	adVarWChar	150	The translation of the Substance Alias

SUB_DEV_SUBSTANCE_NAME

fieldname	fieldtype	fieldsize	description
fk_substance	adInteger		The foreign key of the Substance the Name/Code is referring to
is_code	adInteger		Flag if the name/code of the Development Substance has been added by the user or not
pk_substancename	adInteger		The key automatically assigned by the EV Access Simple DB to each Development Substance Name/Code
preferred	adInteger		Flag if the Name/Code of the Development Substance is the preferred name
substancename	adVarWChar	250	The Name/Code of the Development Substance

SUB_SUB_PREVIOUS

fieldname	fieldtype	fieldsize	description
fk_substance	adInteger		The foreign key of the Approved Substance the Previous EV Code is referring to
pk_sub_previous	adInteger		The key automatically assigned by the EV Access Simple DB to each Previous EV Code specified in this table
previous_ev_code	adVarWChar	60	The EV Code of the Development Substance the Approved Substance is referring to

SUB_SUBSTANCE

fieldname	fieldtype	fieldsize	description
casnumber	adVarWChar	10	The CAS Registry Number of the substance (if applicable)
CBD	adVarWChar	250	Chemical Biological Description of the substance (if applicable)
comment	adLongVarWChar		Comment
ev_code	adVarWChar	60	The EV CODE assigned by the EVMPD to the Substance
isnameorcode	adVarWChar	1	Whether the name specified is a Code or a Name (only applicable to Development Substances)
molecularformula	adVarWChar	255	The empiric molecular formula of the Substance (if applicable)
new	adBoolean	2	Flag if the substance has been added by the user or not
pk_substance	adInteger		The key automatically assigned by the EV Access Simple DB to the Substance
source_ev_code	adVarWChar	60	
sourcecode	adInteger		The reference source of the substance (mandatory for Approved Substances) (LK_SOURCE)
sponsorcode	adInteger		The Sponsor of the 'Development' Substance (LK_ORGANISATION with organisationtype = (2) "SPONSOR") (Mandatory for Development Substances)
substancename	adVarWChar	100	The name of the Substance
substancetype	adSmallInt		Flag if the substance is a "Development" or "Approved' Substance (LK_SUBSTANCE_TYPE)

SUB_SUBSTANCEALIAS

fieldname	fieldtype	fieldsize	description
aliasname	adVarWChar	100	The Alias Name
aliassourcecode	adInteger		The source of the Alias Name
fk_substance	adInteger		The foreign key of the Substance the Substance Alias is referring to
new	adBoolean	2	Flag if the alias has been added by the user or not
pk_substancealias	adInteger		The key automatically assigned by the EV Access Simple DB to each Substance Alias
source_ev_code	adVarWChar	60	The EVCode assigned by the EVMPD to the aliassourcecode specified (if available)

SUB_SUBSTANCETRANSLATION

fieldname	fieldtype	fieldsize	description
fk_substance	adInteger		The foreign key of the Substance the Translation is referring to
languagecode	adVarWChar	2	The language in which the Translation is specified (LK_EU_LANGUAGE)
new	adBoolean	2	Flag if the Translation has been added by the user or not
pk_substancetranslation	adInteger		The key automatically assigned by the EV Access Simple DB to each Substance Translation
term	adVarWChar	100	The Translation of the Substance