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Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2), second subparagraph of Regulation (EC) No 726/2004

Chapter 3.I: XEVPRM Technical Specifications

Version 5.3

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Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

Executive Summary of Changes 5

3.I.a EudraVigilance Product Report Message (XEVPRM) Overview 7

3.I.a.1 Reference key management and resolution mode 7

3.I.a.2 XEVPRM XSD 8

3.I.a.3 XEVPRM structure 8

3.I.a.3.1 The XEVPRM structure overview 9

3.I.a.4 Use of enumerations within the schema structure 11

3.I.a.5 Data Operations and Ownership 12

3.I.a.6 Attributes to support product exports 14

3.I.b XEVPRM schema structure in detail 16

3.I.b.1 Introduction 16

3.I.b.2 EVPRM (M) 16

3.I.b.3 ICHICSR Message Header (M.H) 20

3.I.b.4 Organisation (O) 23

3.I.b.5 Source (S) 28

3.I.b.6 Attachment (ATT) 31

3.I.b.7 Master File Location (MF) 35

3.I.b.8 Development Substance (DS) 38

3.I.b.8.1 Repeatable elements within the Development Substance element 44

3.I.b.9 Approved Substance (AS) 51

3.I.b.9.1 Repeatable elements within the Approved Substance element 58

3.I.b.10 Standard Terms (M.ST) 68

3.I.b.10.1 ATCs (ST.ATCs) 68

ATC (ST.ATC) 69

3.I.b.10.2 Pharmaceutical Forms (ST.PFs) 72

Pharmaceutical Form (ST.PF) 73

3.I.b.10.3 Administration Routes (ST.ARs) 76

Administration Route (ST.AR) 78

3.I.b.11 Development Product (DP) 82

3.I.b.11.1 Repeatable elements within the Development Product element 86

3.I.b.11.2 Pharmaceutical Product (DP.PP) 92

3.I.b.12 Authorised Product (M.AP) 94

3.I.b.12.1 Authorised Product - Authorisation (AP.12) 102

3.I.b.12.2 Authorisation – Medicinal Product Types (AP.12.MPTs) 108

3.I.b.12.3 Authorised Product - Presentation Name (AP.13) 109

3.I.b.12.4 Authorised Product – authpharmforms (AP.APFs) 111

3.I.b.12.5 Authorised Product – Product ATCs (AP.ATCs) 113

3.I.b.12.6 Authorised Product - Product Indications (AP.INDs) 115

3.I.b.12.7 Authorised Product - Pharmaceutical Product (AP.PP) 116

3.I.b.12.8 Authorised Product - Previous EV Code (AP.PEV) 117

3.I.b.12.9 Authorised Product - Printed Product Information (AP.PPI) 119
3.I.b.13 Pharmaceutical Product (PP) 122
3.I.b.13.1 Pharmaceutical Product – Administration Route (PP.AR) 125
3.I.b.13.2 Pharmaceutical Product - Active Ingredient (PP.ACT) 127
3.I.b.13.3 Pharmaceutical Product – Excipient (PP.EXP) 134
3.I.b.13.4 Pharmaceutical Product – Adjuvant (PP.ADJ) 141
3.I.b.13.5 Pharmaceutical Product – Medical Device (PP.MD) 148
3.I.c Business Rules Overview 149
3.I.c.1 Explanation of the meaning of key words used in business rules 149
3.I.c.2 Conventions used within the business rules section of this document 150
3.I.d Business Rule Tables 150
3.I.d.1 EVPRM (M) 150
3.I.d.2 ICHICSR Message Header Type (M.H) 150
3.I.d.3 Organisations (M.Os) 151
3.I.d.3.1 Organisation Type (O) 151
3.I.d.4 Sources (M.Ss) 154
3.I.d.4.1 Source Type (S) 154
3.I.d.5 Standard Terminology (M.ST) 155
3.I.d.5.1 ATCs (ST.ATCs) 155
3.I.d.5.2 Pharmaceutical Forms (ST.PFs) 156
3.I.d.5.3 Administration Routes (M.ST.ARs) 158
3.I.d.6 Attachments (M.ATTs) 161
3.I.d.7 Master File Locations (M.MFs) 162
3.I.d.8 Development Substances (M.DSs) 164
3.I.d.8.1 Repeatable elements within the Development Substance element 165
3.I.d.9 Approved Substances (M.ASs) 172
3.I.d.9.1 Repeatable elements within the Approved Substance element 173
3.I.d.10 Repeatable elements within the Substance Alias element 175
3.I.d.11 Development Products (M.DPs) 182
3.I.d.12 Repeatable elements within the Development Product element 184
3.I.d.13 Authorised Products (M.APs) 188
3.I.d.13.1 Repeatable elements within the Authorised Product.Authorisation element 196
3.I.d.13.2 Repeatable elements within the Authorised Product element 197
3.I.d.14 Reused elements with the XEVPRM – Business Rules 203
3.I.d.14.1 Pharmaceutical Product (PP) 203
3.I.d.14.2 Repeatable elements within the Pharmaceutical Product element 204

Appendices 219
3.I.e Appendix 1 – List of enumerations in the XEVMPD schema 219
3.I.f Appendix 2 – Use of amount fields in the ingredient sections 223
3.I.g Appendix 3 – Change log 225
Appendix 4 – Message Process Order 240
3.I.h Appendix 5 – Element Acknowledgement Codes 241
3.I.i Appendix 6 – Elements with decoding attributes for product exports 242
3.I.j Appendix 7 – Previous version Summaries 245
Version 3.0 245
Version 3.1 246
Version 4.0 247
Version 4.1 248
Version 5.0 249
Version 5.1 250
Version 5.3 251
Appendix 8 – Version 5 xEVMPD schema 252
3.I.k Appendix 9 – Version 5.0 Corrections 253

Executive Summary of Changes

Version 3: Moved to appendix 7

Version 3.1: Moved to appendix 7

Version 4.0: Moved to appendix 7

Version 4.1: Moved to appendix 7

Version 5.0: Moved to appendix 7

Version 5.01: Moved to appendix 7

Version 5.2: Guidance updated to reflect that it is not possible to perform any operations on substances. Any XEVPRM messages containing operation type 'Insert (1)', 'Update (2)' or 'Nullification (4)' of an approved or development substance will be rejected and will generate a negative XEVPRM acknowledgement.

Version 5.3: changes (in red) were introduced in the below listed sections of this document:

- Table 3.
- Table 4.
- Figure 5.
- 3.I.b.8
- Table 7.
- 3.I.b.9
- Table 12.
- 3.I.b.10.1
- Table 21.
- Table 23.
- Table 25.
- Table 29.
- Table 37.
- Table 40.
- Table 51.
- Table 53.
- Table 55.
- Table 57.
- Table 59.
- Table 61.
- Table 63.
- Table 89.
- Table 95.
- Table 97.
- Table 99.
- Table 107.
- Table 108.
- Table 109.
- Table 111.
- *Table 123. Appendix 7 – Previous version Summaries*

NOTE:

For technical reasons, the Detailed Guidance also describes the format for the electronic submission of information on Investigational Medicinal Products (IMPs) as defined in Directive 2001/20/EC. The submission of information on IMPs is outside the scope of Article 57(2), second sub-paragraph of Regulation (EC) No 726/2004.

However, the electronic submission of information on IMPs as required in accordance with the Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use" ('CT-3') (OJ 2011/C 172/01) published by the Commission on 11 June 2011 should be followed.

3.I.a EudraVigilance Product Report Message (XEVPRM) Overview

Please note: Since both the external test and production systems are live systems in which XEVMPD entities are added to the system and EV-Codes assigned in chronological order of receipt it is not possible to prepare messages in the external test system and subsequently submit these message as valid data to the production system.

3.I.a.1 Reference key management and resolution mode

For a set of entities (e.g., organisation, pharmaceutical dose form) with exception of the Anatomical Therapeutic Chemical (ATC) Classification System code, the receiving system of the Agency automatically generates a unique key referred to as an EV Code (EudraVigilance Code). The EV Code is a global key that identifies an entity within the database and in the XEVPRM. The Sender Organisation can uniquely refer to an entity generated using the EV Code.

The ATC Code is the EV Code for an ATC Term.

The following keys are the global keys generated for each entity:

1. EV Code Organisation
2. EV Code Source
3. ATC Code
4. EV Code Pharmaceutical Dose Form
5. EV Code Administration Route
6. EV Code Substance
7. EV Code Product
8. EV Code Attachment
9. EV Code Master File Location

These global keys are used to join different entities within the database. For example, when a Sender Organisation has to specify a substance as an ingredient of a medicinal product, it uses the "EV Code Substance" to refer to the correct entity.

The EV Code is also used to support the operation types, which are used to maintaining the information on medicinal products submitted via the XEVPRM.

If a Sender Organisation has to maintain an entry using the operation type 'Update', 'Nullify' or 'Invalidate MA, it also has to specify the EV Code of the entity related to the operation type.

The XEVPRM contains a field in each section as applicable where the Sender Organisation can specify the appropriate EV Code.

When a Sender Organisation has to make reference to a specific entity, the following two scenarios are possible:

Referring to an entity, for which an EV Code is already available (**Global Key**).

Referring to a new entity reported in the XEVPRM where no EV Code is yet available. The XEVPRM contains a section (with operation type 'Insert') that permits for the new entity and its Local Number (**Local Key**) instead of the EV Code.

As a result, a Sender Organisation referring to an entity must specify whether the code used is a Global Key (EV_CODE) or a Local Key (Local Number). To do so each field that specifies a reference in the XEVPRM XML schema has an attribute called Resolution Mode.

Resolution Mode = 1 → 'LOCAL' (The code specified is a Local Number).

Resolution Mode = 2 → 'GLOBAL' (The code specified is an EV_CODE).

3.I.a.2 XEVPRM XSD

The technical specification of the XEVPRM is contained within the XML Schema Definition (XSD) file, which is located here:

http://eudravigilance.ema.europa.eu/schema/emaxevmpd.xsd

This schema includes a reference to the SSI schema which is located here:

http://eudravigilance.ema.europa.eu/schema/emaxevmpd_ssi.xsd

Taken together, these define the structure to be provided when submitting medicinal product information. Please note that the business rules will make some elements, which are indicated as optional within the schema, become mandatory.

In order to allow interested parties access to the proposed schemas that will be in place when version 5 of this document (as corrected) comes into force, the amended schema and the acknowledgement schema are available within:

http://eudravigilance.ema.europa.eu/schema/emaxempd_v50_schemas.zip

NOTE: No attempt should be made to submit product information to the XEVMPD using the schema within this zip file prior to the date of coming into force of Version 5 of this document.

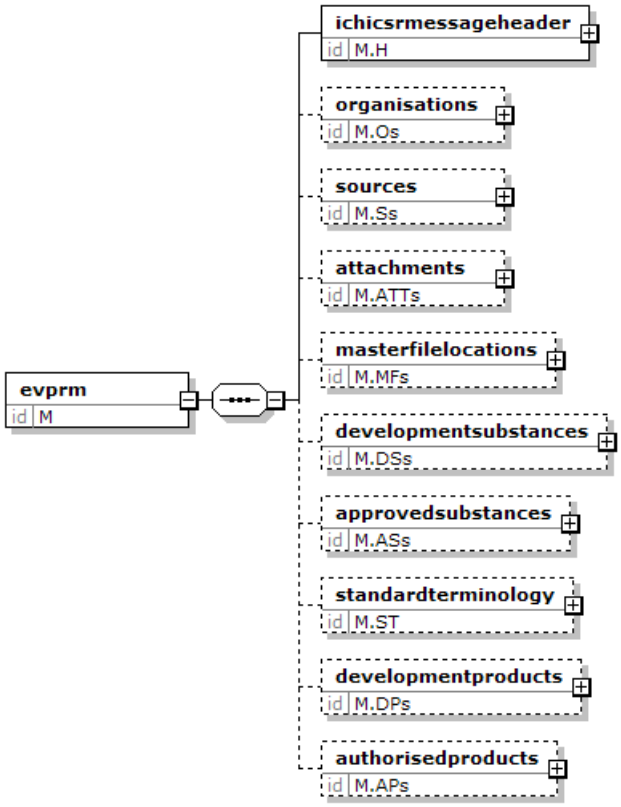
3.I.a.3 XEVPRM structure

The mandatory sections/data elements are presented as boxes with *solid lines* (e.g. as the message header) and the *non-mandatory sections/data elements* as boxes with *dotted lines* (e.g. as the Organisations, Sources, and Substances, Standard Terminology Substances and Products sections). As described in the business rules section of this document, under certain conditions some elements identified as optional will become mandatory. This concept should also be considered when reviewing the XSD.

3.I.a.3.1 The XEVPRM structure overview

The XEVPRM has 10 sections, as presented below.

Figure A XEVPRM – Overall Structure



The Message Header is constructed in the same manner as the *ICHICSR message header for* Individual Case Safety Reports.

The *Organisations* section contains information about two types of *organisations*: Marketing Authorisation Holders and Sponsors. For each *organisation*, the applicable operation type needs to be specified.

The *Sources* section contains information about reference *sources* with the possibility to specify the operation type, which is explained below.

The *Attachments section* contains references to the printed medicinal product and substance information. The printed product information attachment must be produced by providing in a single file the following regulatory documents, as applicable:

- A copy of Annex I - Summary of product Characteristics
- A copy of Annex IIA - Manufacturing Authorisation Holder responsible for Batch Release
- A copy of Annex IIB - Conditions of the Marketing Authorisation
- A copy of Annex IIIA – Labelling
- A copy of Annex IIIB - Package Leaflet

The attachment information for Investigational Medicinal Products must be produced by providing, in a single file, the following documents as applicable:

- Investigator's brochure
- Summary of Product Characteristics

The *Master File Location* section refers to the location of the Pharmacovigilance System Master File of a marketing authorisation holder. The pharmacovigilance system master file is a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised medicinal products.

The *Development Substances* and *Approved Substances* sections contain information about the *substance(s)* of a medicinal product. More than one *substance* can be specified in one XEVPRM. For each *substance* specified, the applicable operation type needs to be specified.

The Standard Terminology section allows for the creation of new entries or maintaining existing entries in relation to *Standard Terms* (*ATC Code*, *Pharmaceutical Form* and *Administration Route*).

- There are three Standard Terminology sub-sections: *ATC Code*, *Pharmaceutical Form* and *Administration Route*. Each sub-section contains information about a specific *standard term*. The user can specify more than one *standard term* in the same XEVPRM. For each *standard term* specified, the user must identify the applicable operation type.

The *Development Product* and *Authorised Product* sections contain information about a medicinal *product*. Information on one or more medicinal products can be submitted electronically in the same XEVPRM. For each *product* specified, the user must specify the applicable operation type.

3.I.a.4 Use of enumerations within the schema structure

In some instances the schema controls the values within fields by the use of restrictions built into the schema in the form of an enumeration. An enumeration defines a list of acceptable values e.g.

```
<xs:element name="filetype" id="ATT.3">
        <xs:annotation>
                <xs:documentation>The file type of the attachment.
                        Allowed values are as contained within the restriction allowedfiletypes
                </xs:documentation>
        </xs:annotation>
        <xs:simpleType>
                <xs:restriction base="xs:int" id="allowedfiletypes">
                        <xs:enumeration value="1" id="pdf"/>
                        <xs:enumeration value="2" id="doc"/>
                        <xs:enumeration value="3" id="docx"/>
                        <xs:enumeration value="4" id="xls"/>
                        <xs:enumeration value="5" id="xlsx"/>
                </xs:restriction>
        </xs:simpleType>
</xs:element>
```

In this example the value in the field filetype (ATT.3) is restricted to one of the values in the allowedfiletypes list (1 – 5 inclusive). Any other value in the filetype field will lead to the generation of a message which is invalid according to the schema and thus a 03 acknowledgement and the entire message will be rejected.

The EMA has implemented enumerations in a limited number of cases where the list of acceptable values is small and unlikely to change.

Appendix 1 contains a list of all of the enumerations that are used within the schema, the values accepted and their meaning.

3.I.a.5 Data Operations and Ownership

The medicinal product information provided via the XEVPRM is "owned" by the HQ of the Sender Organisation that submitted the information on medicines. The operation types that an owner organisation can perform by sending an XEVPRM are as follows:

Table A Operation Types (Version 5.0: Allowable operations changes highlighted in yellow)

	Insert	Update	Variation	*Nullify	Invalidate MA
Authorised Product	√	√	⊘	√	√
Development Product	√	√	⊘	√	⊘
Approved Substance	⊘	⊘	⊘	⊘	⊘
Development Substance	⊘	⊘	⊘	⊘	⊘
Attachment	√	⊘	⊘	⊘	⊘
**Master File Location	√	√	⊘	√	⊘
Source	√	√	⊘	√	⊘
MAH	√	√	⊘	√	⊘
Sponsor	√	√	⊘	√	⊘
Development Pharmaceutical Form	√	√	⊘	√	⊘
Proposed Pharmaceutical Form	√	⊘	⊘	⊘	⊘
Development Route of Administration	√	√	⊘	√	⊘
Proposed Route of Administration	√	⊘	⊘	⊘	⊘
Development ATC Code	√	√	⊘	√	⊘
Proposed ATC Code	√	√	⊘	√	⊘

*See nullification restrictions note in following bulleted list

**Master file locations added to figure as omitted pre version 5.0

The possible operation types are:

- **Insert:** This operation type allows the sender organisation to provide new medicinal product information via an XEVPRM.
- **Update:** This operation type allows the owner organisation to update the content of medicinal product information previously submitted via an XEVPRM.
- **Variation** operation type for authorised products is not supported. For information regarding how to notify the EMA about legal variations for authorised products refer to Chapter 3.II and the XEVMPD frequently asked questions document both of which are available from the 'Guidance documents related to data submission for authorised medicines' webpage.
- **Nullification:** This operation type allows the owner organisation to nullify medicinal product information previously submitted via an XEVPRM. Note that for all but products, if any entity (e.g., MAH/sponsor organisation, PSFML etc.) is used in any product with valid marketing authorisation statuses, then the nullification will be rejected with a 03 acknowledgement.
- **Invalidate MA:** This operation allows the owner organisation to inform, via an XEVPRM, about the marketing authorisation being no longer valid. The 'Invalidate MA' operation covers several scenarios including the transfer of an authorised medicinal product. For further guidance on the use of this operation type please refer to Chapter 3.II: XEVPRM User Guidance. This operation type applies only to authorised medicinal products.

Note that not all operations are available for all XEVMPD entity types. Please see the operation type enumeration table for a definitive list.

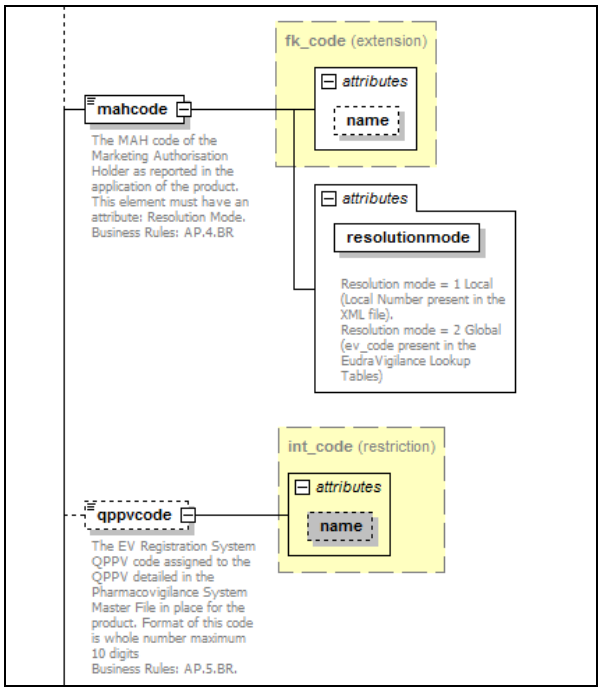
Ownership of products can be changed by the EMA upon request from the current owner.

3.I.a.6 Attributes to support product exports

Added V4.1

To support product data exports; many fields, where the content of the field represents a code, have had a decoding attribute added to them, this attribute is always called "name" and is a string which contains a human readable form of the data in the xEVMPD. A typical example of the presence of this attribute is shown below:

Figure B Typical decoding name attributes



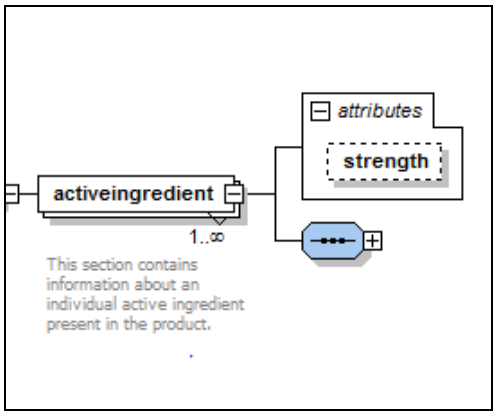
The attribute is always optional and always extends a sub type depending on the type of data in the related code field – i.e., where the code is an EV Code the attribute extends fk_code, where the code is an integer, the attribute is of int_code type.

Tests have been performed to confirm that the presence or absence of these attributes do not affect loading of xEVPRM messages, but if the attribute is present, it must contain a string value which has a meaning (not a series of spaces for instance). Note that the data in this field is ignored by message loading and has no bearing on the underlying data for the element referenced and is also not validated in any way other than the schema validation requirement that if the element is present, it must contain a value.

For a full list of the fields that have had the attribute added please refer to Appendix 6.

In addition to the name attribute a similar attribute called strength has been added to the activeingredient, excipient and adjuvant as shown below:

Figure C Example of the ingredient strength attribute



In the xml export file, the strength attribute contains a concise description of the concatenation of the various amount fields, example of the use of the decoding fields is shown in the extract of xml from an export of a fictitious product shown below:

Figure D Example of decoding in a product export xml

```
<activeingredients>
 <activeingredient strength="20 U G / milli (1x10^-3) Litre">
  <substancecode name="[Approved] METHOXSALEN" resolutionmode="2">SUB14541MIG</substancecode>
  <concentrationtypecode name="Equal">1</concentrationtypecode>
  <lowamountnumervalue>20</lowamountnumervalue>
  <lowamountnumerprefix name="micro (1x10^-6)">U</lowamountnumerprefix>
  <lowamountnumerunit name="Gram(s)">G</lowamountnumerunit>
  <lowamountdenomvalue>1</lowamountdenomvalue>
  <lowamountdenomprefix name="milli (1x10^-3)">M</lowamountdenomprefix>
  <lowamountdenomunit name="Litre">54</lowamountdenomunit>
 </activeingredient>
```

In this case the substance code SUB14541MIG has a name attribute value indicating that the substance is an approved substance with the preferred name METHOXSALEN and that the amount of the substance is 2µG/ML. As can be seen each amount field that references a code also has a decoding name attribute.

3.I.b XEVPRM schema structure in detail

3.I.b.1 Introduction

This document describes the technical implementation of the XEVPRM schema; it describes the schema, explains the type and cardinality of each element, and provides guidance of what is expected in each section or element. Each element is described by use of a diagram and table showing the data type and schema cardinality along with explanatory notes.

Where an element is a wrapper for other elements hyperlinks are provided to these child elements. Because there are already many entities within the XEVMPD and there remains a need for stakeholders to be able to manage these entities it is necessary to implement business rules that control the quality of new data submitted outside of the schema, these business rules are detailed in the business rules section of the document. Hyperlinks in the notes column of the tables describing each element can be followed to show the reader the business rules applying to the field in question. Return links are provided with the first business rule for each element.

3.I.b.2 EVPRM (M)

The XEVPRM is organised into wrapper elements each of which contains data on aspects of the information required to describe medicinal products. Each element has a unique ID that is used to identify both the element and the business rules that apply to it.

The structure of the message at the highest level (EVPRM) is as follows.

Figure 1. XEVPRM - EVPRM element structure

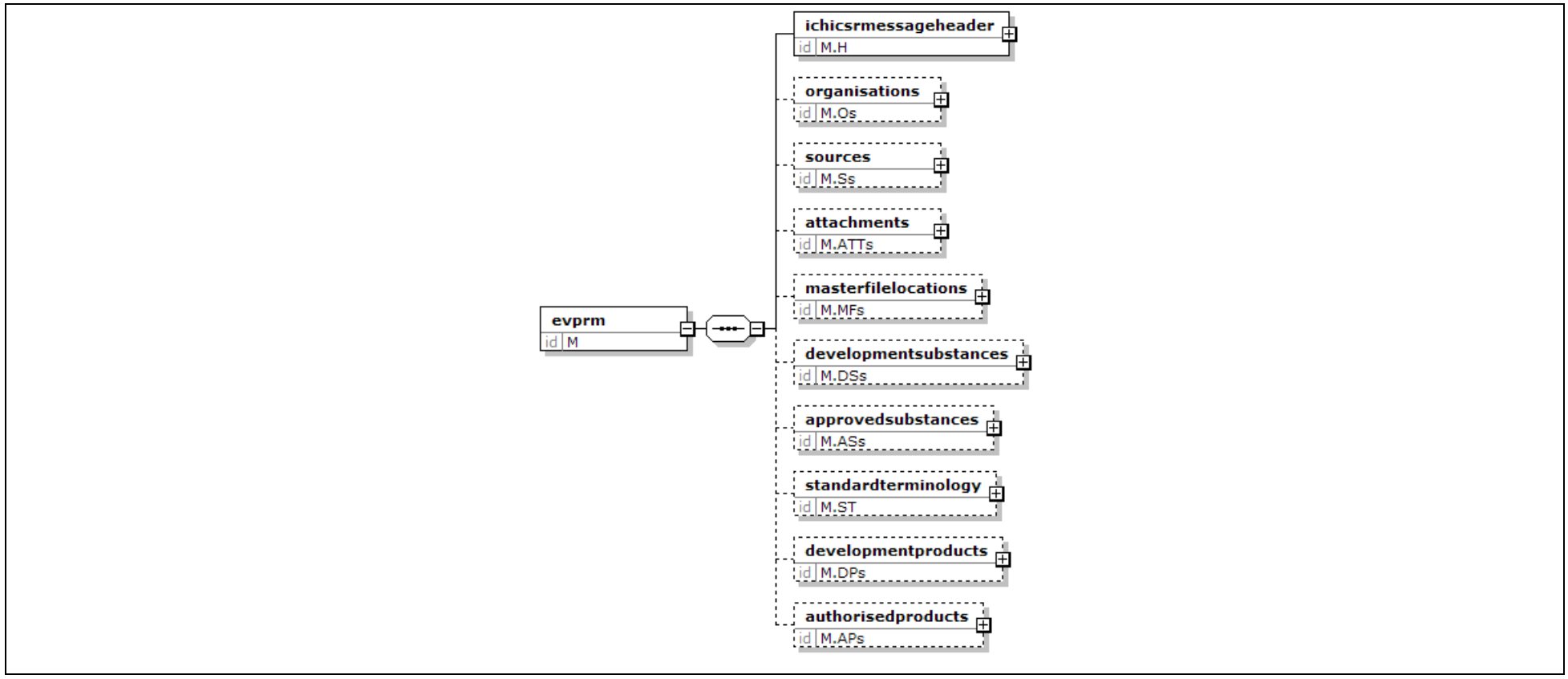


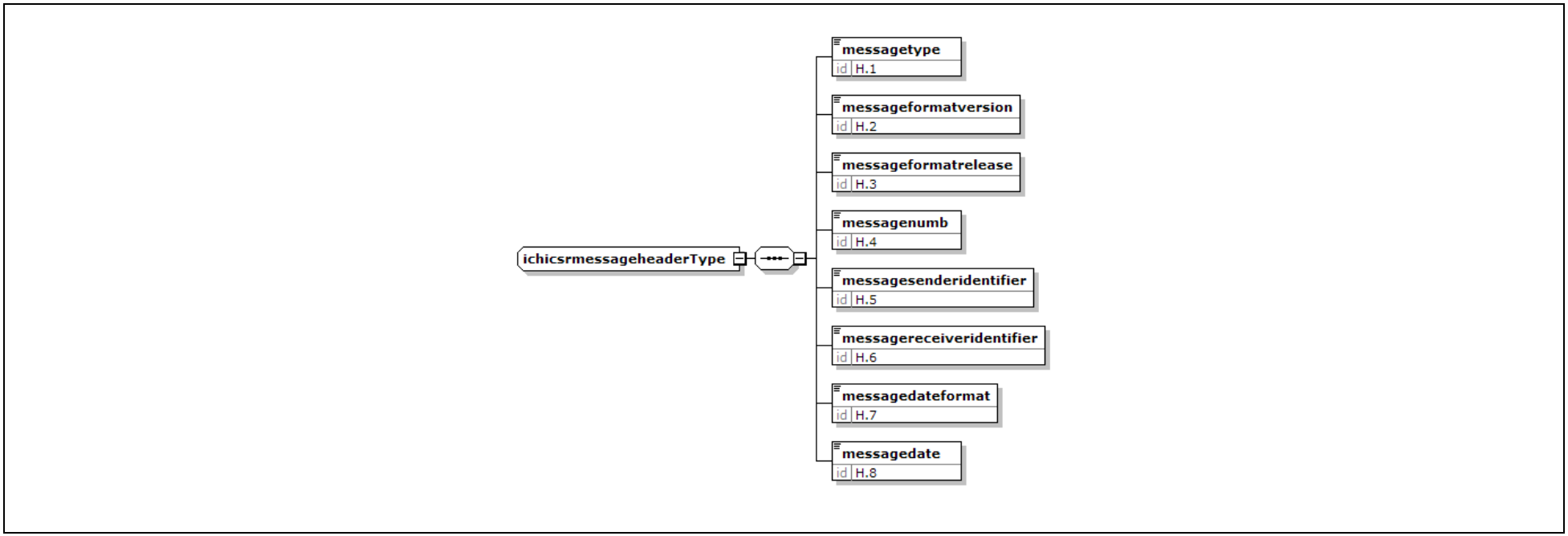
Table 1. EVPRM data elements

Reference Code	Reference Name	Data Type (length)	Cardinality	Notes
M	evprm	Sequence	1	Eudravigilance Medicinal Product Report Message The EudraVigilance Medicinal Product Report Message (EVPRM) This is the root element for the extended EudraVigilance Product Reports Message (XEVPRM). Must contain element M.H and at least one of the other child elements of M. Business Rules: M.BR.
M.H	ichicsrmessageheader	Sequence	1	Message Header The message header section must be completed. Contains information related to sender, receiver, the type of information being transmitted and the transmission date.
M.Os	organisations	Sequence	0 - 1	Organisations Contains the data for each new/updated organisation within the XEVPRM. Business Rules: M.Os.BR
M.Ss	sources	Sequence	0 - 1	Sources Contains the data for each new/updated source within the XEVPRM. Business Rules: M.Ss.BR.
M.ATTs	attachments	Sequence	0 - 1	Attachments Contains each new attachment required by the XEVPRM. Business Rules: M.ATTs.BR.
M.MFs	masterfilelocations	Sequence	0 - 1	Pharmacovigilance System Master File Location Contains the data for each new/updated pharmacovigilance system master file location within the XEVPRM. Business Rules: M.MFs.BR.

Reference Code	Reference Name	Data Type (length)	Cardinality	Notes
M.DSs	developmentsubstances	Sequence	0 - 1	Development Substance Contains the data for each new/updated development substance within the XEVPRM. Business Rules: M.DSs.BR.
M.Ass	approvedsubstances	Sequence	0 - 1	Approved Substance (authorised substance) Contains the data for each new/updated approved substance within the XEVPRM Business Rules: M.ASs.BR.
M.ST	standardterminology	Sequence	0 - 1	Standard Terminology Contains information about XEVPRM standard terms: ATC Codes, Pharmaceutical Forms and Administration Routes.
M.DPs	developmentproducts	Sequence	0 - 1	Development Product Contains the data for each new/updated development medicinal product studied in clinical trials. Business Rules: M.DPs.BR
M.APs	authorisedproducts	Sequence	0 - 1	Authorised Product (Authorised Medicinal Product) Contains the data for each authorised medicinal product. Business Rules: M.APs.BR.

3.I.b.3 ICHICSR Message Header (M.H)[1]

Figure 2. Message header element structure



Back to parent element

[1] The use of "ICHICSR" for this element is for gateway compatibility reasons and is confirmed correct.

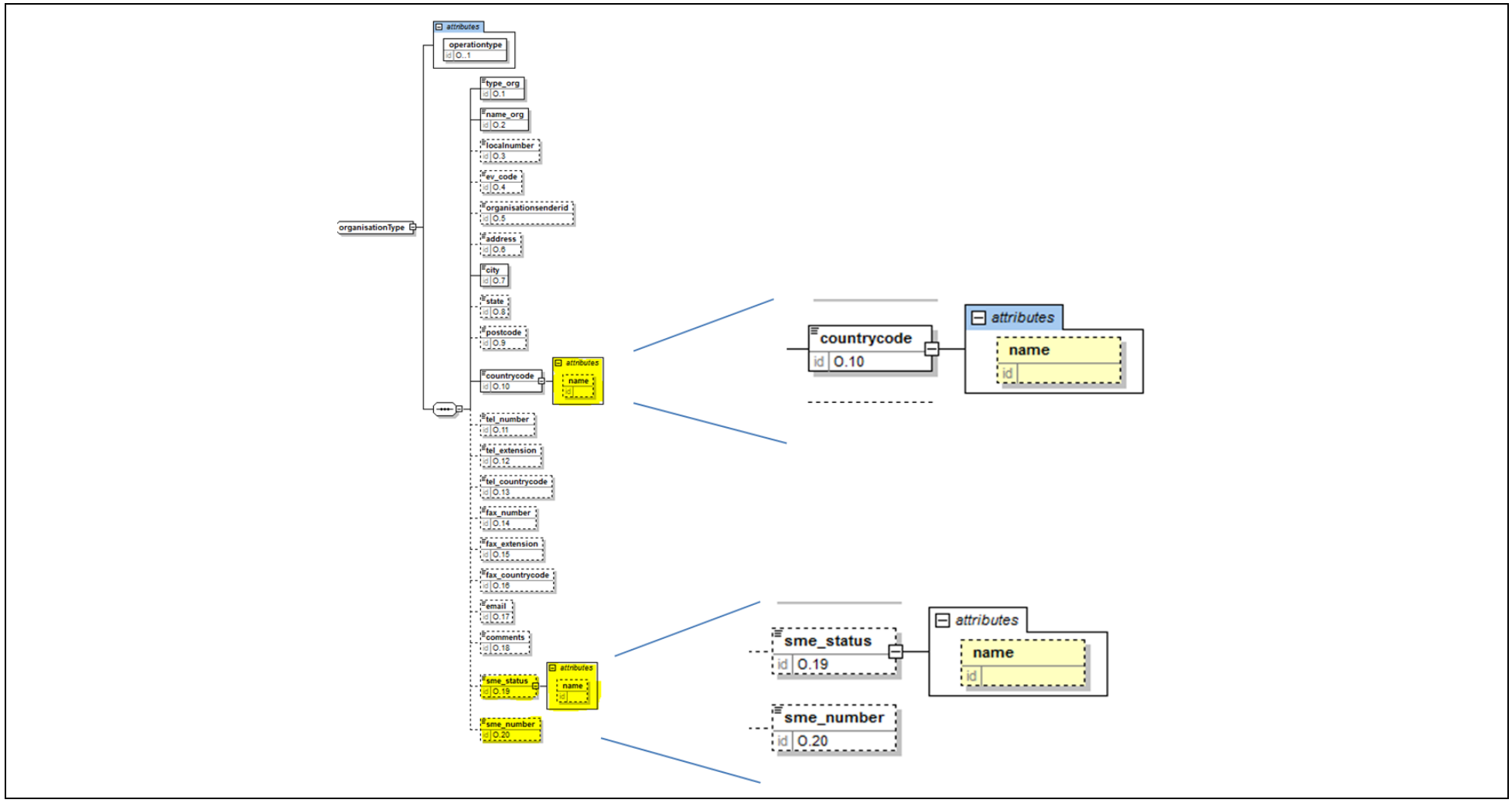
Table 2. Message header elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
M.H	ichicsrmessageheader	Sequence	1	ICH ICSR Message Header The message header section must be completed. The section contains information related to sender, receiver, the type of information being transmitted and the transmission date.
H.1	messagetype	string (Enum)	1	Message Type The message type must be specified. It contains information on the type of information being transmitted. When creating a message, the value of this field must be "XEVPRM".
H.2	messageformatversion	string (Enum)	1	Message Format Version The message format version must be specified. It refers to the release number of the message format version of the XSD SCHEMA. The only value accepted is "2" Change Log: V3.
H.3	messageformatrelease	string (Enum)	1	Message Format Release The message format release must be specified. The message format release contains the release number of the message format release number of the XSD SCHEMA.
H.4	messagenumb	string (0-100)	1	Message Number The message number must be specified. It refers to the unique tracking number assigned to a specific medicinal product report message file transmitted by the sender. The message number is unique to the sender.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
H.5	messagesenderidentifier	string (3-60)	1	Message Sender Identifier The message sender identifier must be specified. It refers to the unique identifier of the sender organisation as assigned during the EudraVigilance registration process. Business Rules: H.5.BR.
H.6	messagereceiveridentifier	string (Enum)	1	Message Receiver Identifier The message receiver identifier must be specified. This refers to the unique identifier of the receiving organisation i.e. the European Medicines Agency. Business Rules: H.6.BR.
H.7	messagedateformat	string (Enum)	1	Message Date Format The format of the message date must be specified. The only value accepted is "204".
H.8	messagedate	string (0-14)	1	Message Date The message date must be specified in accordance with the business rules. Business Rules: H.8.BR.

3.I.b.4 Organisation (O)

Figure 3. Organisation element structure (V5.0– updated by addition of highlighted fields)



The Organisation element may be repeated as many times as required. The element contains a number of fields and a single attribute as detailed below.

Back to parent element

Table 3. Organisation elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
O	organisation	Sequence	1 - ∞	Organisation The organisation section contains information about a marketing authorisation holder or a sponsor that will be stored directly in the XEVMPD. The sender should use this section to send data on a new organisation and/or send updates on an existing organisation already present in the XEVMPD look up list (e.g. add affiliate/edit telephone number or email address). Business Rules: O.BR.
@ O..1	(@) operationtype	int (Enum)	1	Operation Type The type of the operation for this entity must be specified. 1 = Insert 2 = Update 4 = Nullify Business Rules: O..1.BR.
O.1	type_org	int (Enum)	1	Organisation Type The type of organisation must be specified i.e. Marketing Authorisation Holder (MAH) = 1 Sponsor = 2
O.2	name_org	string (0-100)	1	Organisation Name The name of the MAH/Sponsor must be specified.

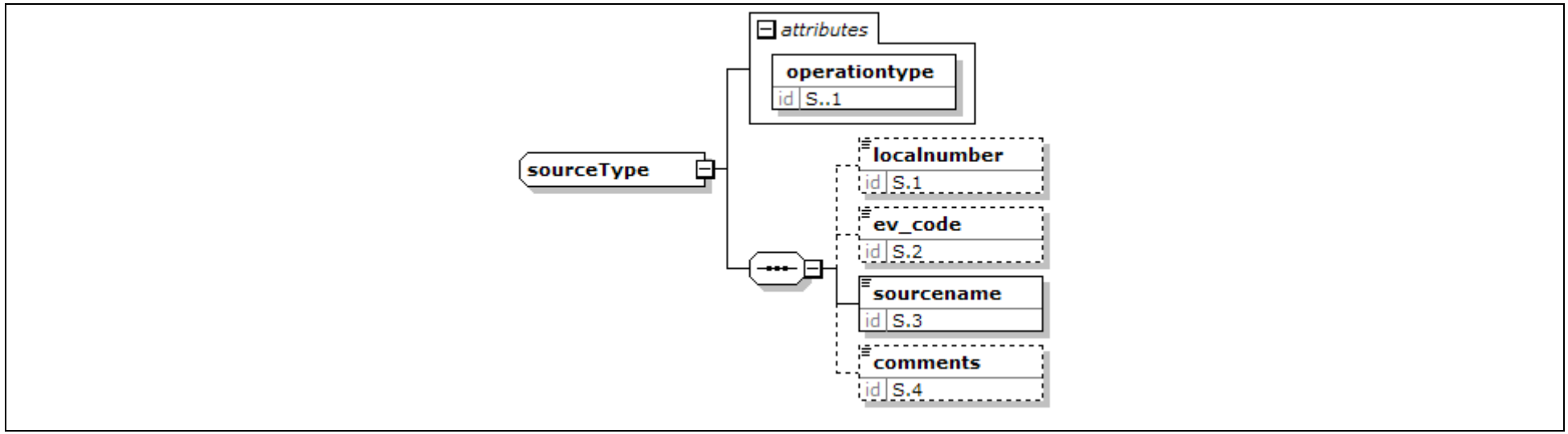
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
O.3	localnumber	string (0-60)	0 - 1	Local Number The unique reference for the entity in the message. It is mandatory for operation type Insert. Business Rules: O.3.BR.
O.4	ev_code	string (0-60)	0 - 1	EV Code An EV Code is assigned to every new organisation. It is mandatory for all operation types except Insert. Business Rules: O.4.BR.
O.5	organisationsenderid	string (0-60)	0 - 1	Organisation Sender Identifier The ID of the organisation that corresponds to the same organisation as assigned in the registration system should be provided.
O.6	address	string (0-100)	0 - 1	Address The address of the organisation. The address is mandatory unless the operation type is "nullification" Business Rules: O.6.BR Change Log: V3
O.7	city	string (0-50)	1	City The city of the organisation must be specified.
O.8	state	string (0-50)	0 - 1	State The state of the organisation should be specified, where applicable.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
O.9	postcode	string (0-50)	0 - 1	Postcode The postcode of the organisation. The postcode is mandatory unless the operation type is "nullification". In territories where post codes are not available the Value "N/A" should be specified. Business Rules: O.9.BR Change Log: V3
O.10	countrycode	string (0-2)	1	Country Code The country code of the location of the organisation must be specified. Business Rules: O.10.BR.
(@) NA	(@) name	string	0 -1	V4.1 Name attribute for exports (contains country name)– should not be submitted
O.11	tel_number	string (0-50)	0 - 1	Telephone Number The telephone number of the organisation should be specified.
O.12	tel_extension	string (0-50)	0 - 1	Telephone Extension The extension of the telephone number of the organisation should be specified, where applicable.
O.13	tel_countrycode	string (0-5)	0 - 1	Telephone Country Code The country code of the organisation's telephone number should be specified.
O.14	fax_number	string (0-50)	0 - 1	Fax Number The organisation's fax number should be specified, where applicable.
O.15	fax_extension	string (0-50)	0 - 1	Fax Extension Number The extension of the fax number of the organisation should be specified, where applicable.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
O.16	fax_countrycode	string (0-5)	0 - 1	Fax Number Country Code The country code of the organisation's fax number should be specified, where applicable.
O.17	email	string (0-100)	0 - 1	Email Address The email address of the organisation should be specified, where applicable.
O.18	comments	string (0-500)	0 - 1	Comments Further information on the organisation should be supplied in the comments field, if required. When the organisation operation type is "Nullification", the comment field is mandatory and the reason for nullification must be provided. When the organisation details are inserted in the XEVMPD as present in OMS, the LOC ID of the organisation entity in OMS must be referenced in this field. Business Rules: O.18.BR
O.19	sme_status	int (Enum)	0 – 1	Version 5.0: Added element The SME status is required for all updates and inserts of organisations that are Marketing Authorisation Holders Business Rules: O.19.BR
(@) NA	(@) name	string	0 - 1	Version 5.0: Name attribute for exports (contains sme status name) – should not be submitted
O.20	sme_number	string (0-50)	0 -1	Version 5.0 Added element This field contains the SME number of the organisation where applicable. Business Rules: 0.20.BR

3.I.b.5 Source (S)

Figure 4. Source element structure



Back to parent element

Table 4. Source elements

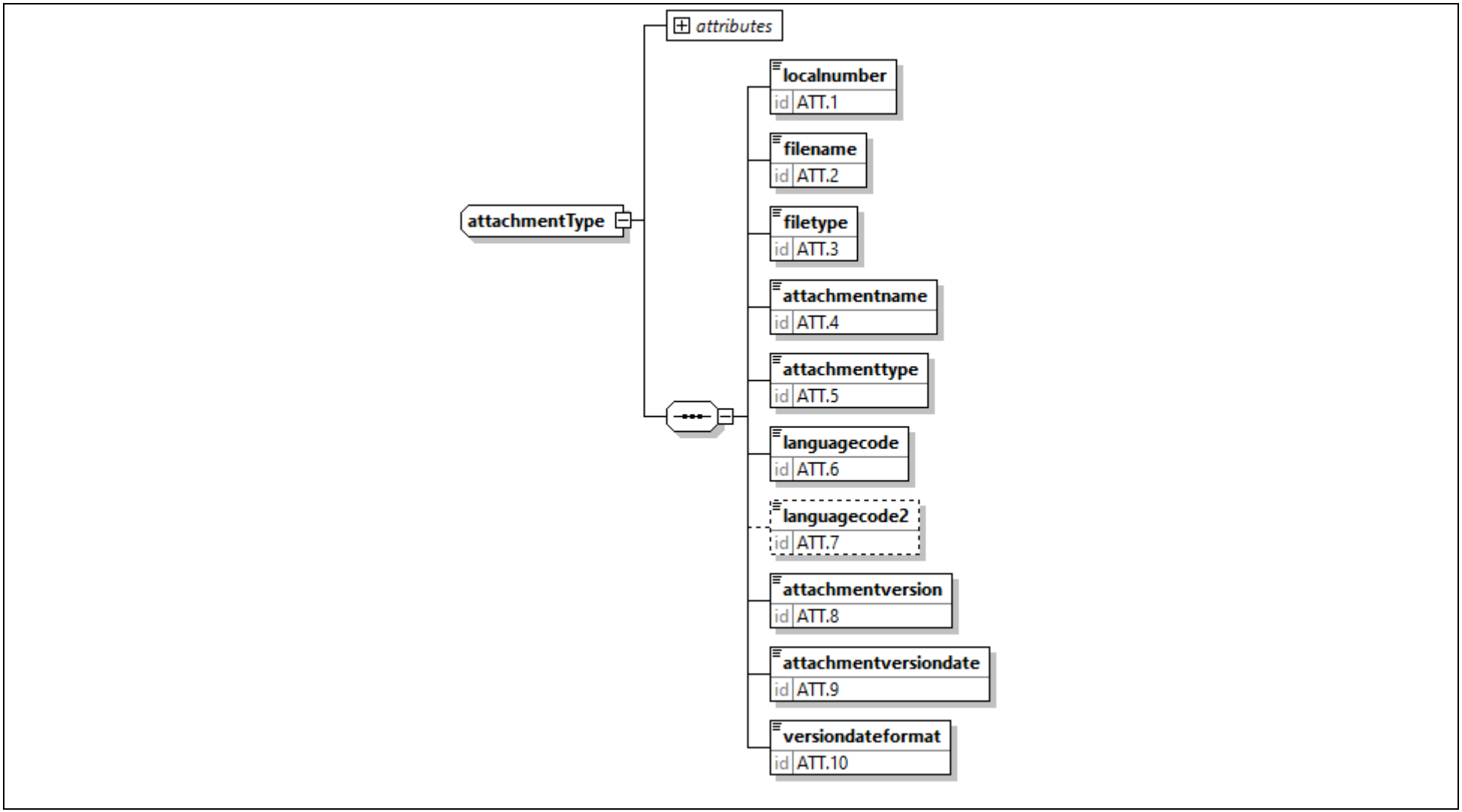
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
S	source	Sequence	1 - ∞	Source The source section contains information for each reference source that will be stored directly in the XEVMPD. The sender must use this section to send data on a new source and/or send updated information about a reference source already present in the XEVMPD. Business Rules: S.BR.
@ S..1	(@) operationtype	int (Enum)	1	Operation Type The type of the operation for this entity. Insert = 1 Update = 2 Nullify = 4 From 18 January 2024, sources may be inserted and maintained in the XEVMPD by the EMA only. Business Rules: S..1.BR.
S.1	localnumber	string (0-60)	0 - 1	Local Number The unique reference for the entity in the message. This field is mandatory for Operation Type Insert. Business Rules: S.1.BR.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
S.2	ev_code	string (0-60)	0 - 1	EudraVigilance (EV) Code An EV Code is assigned to every new valid reference source received in the XEVMPD. If the operation type (S..1) is NOT "Insert" then this field is mandatory and must contain a valid EV Code . Business Rules: S.2.BR.
S.3	sourcename	string (0-70)	1	Source Name The name of the reference source must be provided. Business Rules: S.3.BR.
S.4	comments	string (0-500)	0 - 1	Comments Further information may be supplied in the comment field. The comment field is mandatory when the operation type is "Nullification" (S..1 = 4). Business Rules: S.4.BR.

3.I.b.6 Attachment (ATT)

An attachment is any allowed file (defined in the business rules) that is sent in the zip file containing the XEVPRM message with the information on either medicinal products or substances. Content of attachments cannot be updated, and the updated attachment(s) must be resubmitted when necessary.

Figure 5. Attachment element structure



Back to parent element

Table 5. Attachment elements

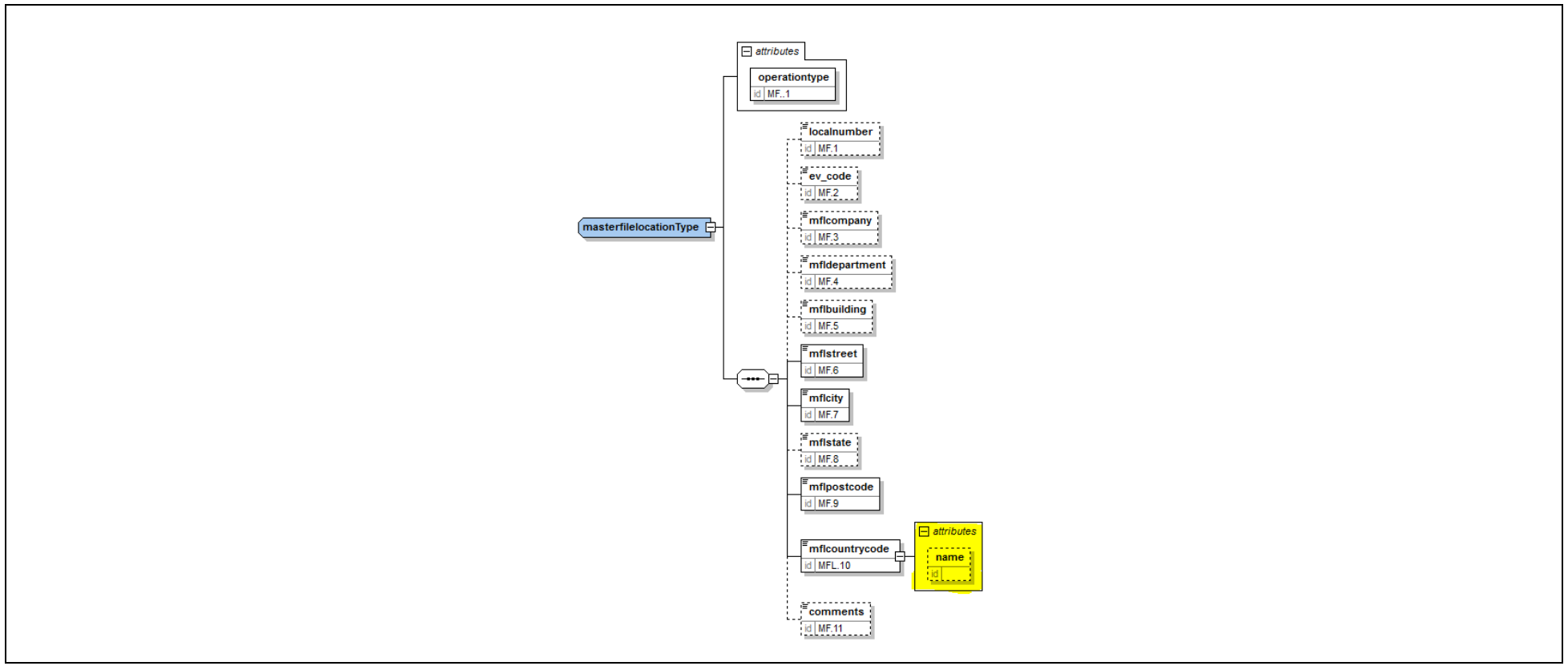
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
ATT	attachment	Sequence	**1 - ∞**	Attachment This section refers to each document submitted in support of the XEVPRM message being sent Business Rules: ATT.BR
@ ATT..1	(@) operationtype	int (Enum)	1	Operation Type The type of the operation for this entity must be specified. The only value accepted is Insert = 1 Business Rules: ATT..1.BR.
ATT.1	localnumber	string (0-60)	1	Local Number The unique reference for the entity in the message must be specified. Business Rules: ATT.1.BR.
ATT.2	filename	string (0-200)	1	File Name The file name of the attachment with file extension must be specified.
ATT.3	filetype	int (Enum)	1	File Type The file type of the attachment must be specified. Allowed values are defined within the restriction enumeration allowedfiletypes contained within the schema.
ATT.4	attachmentname	string (1-2000)	1	Attachment Name The name of the attachment given by the sender should be specified. Change Log: V3

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
ATT.5	attachmenttype	int (Enum)	1	Attachment Type The type of attachment must be specified. Allowed values are: Printed Product Information (PPI) = 1 Printed Substance Information (PSI) = 2
ATT.6	languagecode	string (0-2)	1	Language Code The code of the language must be specified using the "LANGUAGE" reference list. Business Rules: ATT.6.BR.
ATT.7	languagecode2	string (0-2)		2nd Language Code Optional field to add a 2nd language in the attachment. The code of the language must be specified using the "LANGUAGE" reference list. Business Rules: ATT.7.BR
~~ATT.7~~ ATT.8	attachmentversion	string (5)	1	Attachment Version The version of the PPI/PSI attachment must be specified. Change log: V3.1
~~ATT.8~~ ATT.9	attachmentversiondate	string (8)	1	Attachment Version Date The date of the last update of the PPI document must be specified. Business Rules: ATT.9.BR
~~ATT.9~~ ATT.10	versiondateformat	string (Enum)	1	Format of the Version Date. The value must be "102" for "CCYYMMDD".

3.I.b.7 Master File Location (MF)

The location of the Pharmacovigilance System Master File

Figure 6. Master File Location element structure (V4.1– updated by addition of highlighted export name attribute)



[Back to parent element]

Table 6. Master File Location elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
MF	masterfilelocation	Sequence	**1 - ∞**	Master File Location This section contains the details for each pharmacovigilance system master file (PSMF) location Business Rules: M.MF.BR
@ MF..1	(@) operationtype	Int (Enum)	1	Operation Type The type of the operation for this entity must be specified. The allowed values are: Insert = 1 Update = 2 Nullify = 4 Business Rules: MF..1.BR.
MF.1	localnumber	string (0-60)	0 - 1	Local Number The unique reference for the entity in the message. Mandatory for Operation Type "Insert". Business Rules: MF.1.BR.
MF.2	ev_code	string (0-60)	0 - 1	EudraVigilance (EV) Code The EV Code of the entity. Mandatory if the operation type is NOT "Insert". Business Rules: MF.2.BR.

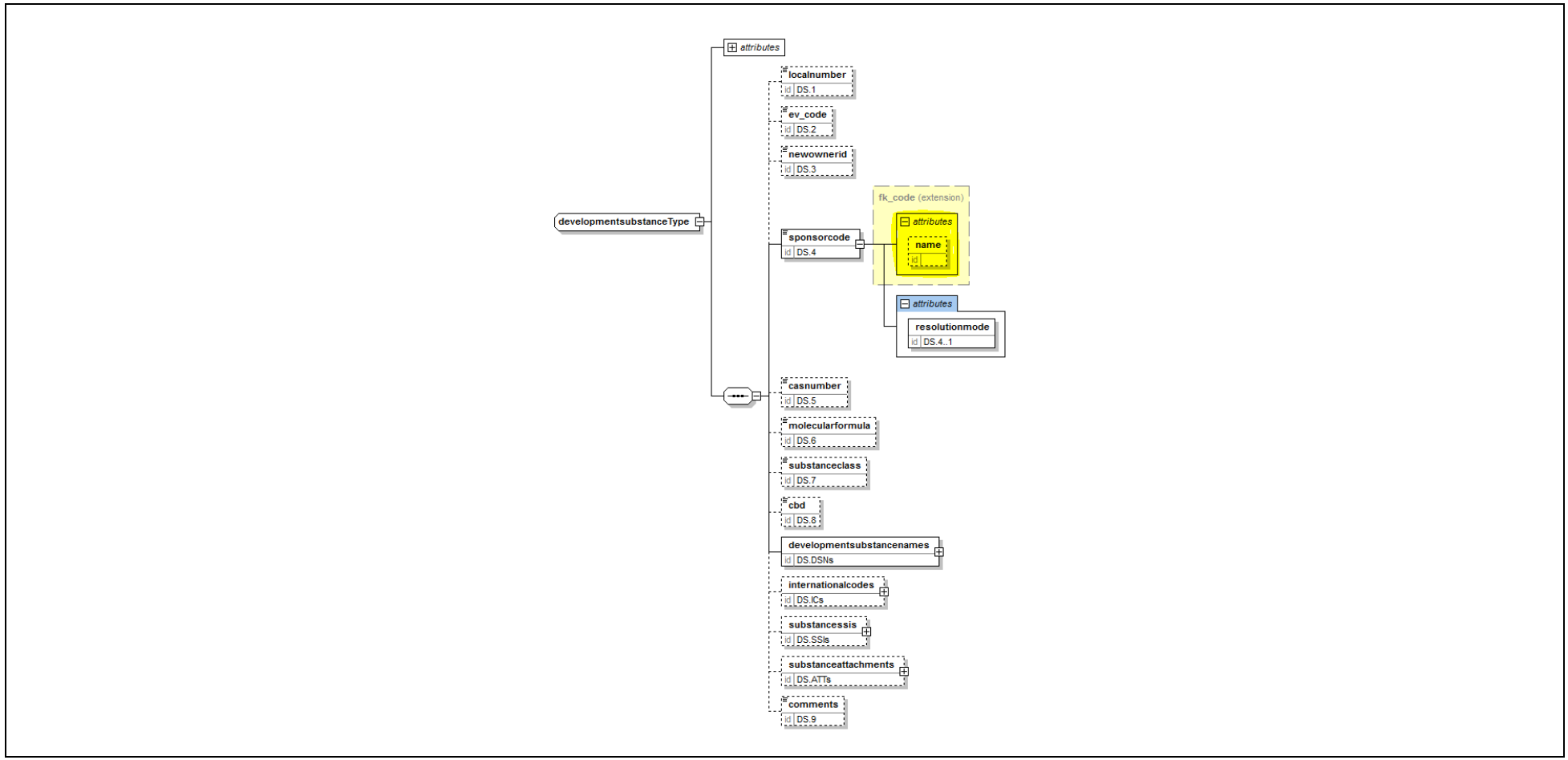
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
MF.3	mflcompany	string (0-100)	0 - 1	Pharmacovigilance System Master File (MF) Company The name of the company that holds the PSMF should be specified where applicable.
MF.4	mfldepartment	string (0-100)	0 - 1	Pharmacovigilance System Master File (MF) Department The name of the department that holds the PSMF should be specified where applicable.
MF.5	mflbuilding	string (0-100)	0 - 1	Pharmacovigilance System Master File (MF) Building The building name, if part of the address, should be specified where applicable.
MF.6	mflstreet	string (0-100)	1	Pharmacovigilance System Master File (MF) Street The street of the address of the MF location should be specified where applicable.
MF.7	mflcity	string (0-35)	1	Pharmacovigilance System Master File (MF) City The city of the address of the MF location must be specified.
MF.8	mflstate	string (0-40)	0 - 1	Pharmacovigilance System Master File (MF) State The state of the address of the MF location should be specified where applicable.
MF.9	mflpostcode	string (0-15)	1	Pharmacovigilance System Master File (MF) Postcode The postcode of the address of the location of the MF must be specified. In countries where no post or zip code exists as part of the address "NA" must be used.
MF.10	mflcountrycode	string (2)	1	Pharmacovigilance System Master File (MF) Country Code The country code of the address of the location of the MF must be specified. Business Rules: MF.10.BR

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
@NA	@name	string	0 - 1	Version 4.1: Name attribute for exports (contains country name) – should not be submitted
MF.11	comments	string (0-500)	0 - 1	Comments Further information may be supplied in the comment field. The comment field is mandatory when the operation type is "Nullification" (MF..1 = 4). Business Rules: MF.11.BR.

3.I.b.8 Development Substance (DS)

Since July 2019, only the EMA can insert and maintain substance information (approved and development) in the XEVMPD.

Figure 7. The development substance element structure (V4.1– updated by addition of highlighted export name attribute)



This repeatable section is applicable to a substance of an Investigational Medicinal Product (IMP) which is NOT yet authorised, and information is not available in the public domain. For development substances specific confidentiality rules apply. In addition to the description of the single data elements, the section contains several repeatable elements each of which are described within a separate table below.

Back to parent element

Table 7. Development Substance elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DS	Developmentsubstance	Sequence	1 - ∞	Development Substance This section should be used to provide data on a new development substance/or to update data on a development substance. Business Rules: DS.DSs.BR
@ DS..1	(@) operationtype	Int (Enum)	1	Operation Type The type of the operation for this entity must be specified. Insert = 1 Update = 2 Nullify = 4 Change Owner = 5 (Reserved for EMA). From July 2019, substances (approved and development) may be inserted and maintained in the XEVMPD by the EMA only. Business Rules: DS..1.BR.
@ DS..2	(@) virtual	int	0 - 1	Virtual Reserved for EMA Use only. Business Rules: DS..2.BR.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DS.1	Localnumber	string (0-60)	0 - 1	Local Number The unique reference for the entity in the message. Mandatory for Operation Type "Insert". Business Rules: DS.1.BR.
DS.2	ev_code	string (0-60)	0 - 1	EudraVigilance (EV) Code An EV Code is assigned to every valid new development substance received. If the operation type DS..1 ≠ 4 then the EV Code of the development substance must be specified. Business Rules: DS.2.BR.
DS.3	Newownerid	string (0-60)	0 - 1	New Owner Identifier This field identifies the Owner of the development substance for instances when the EMA may have inserted development substances on behalf of another organisation (pre-July 2019). Reserved for EMA use only. Business Rules: DS.3.BR. Change Log: V3
DS.4	Sponsorcode	string (0-60)	1	Sponsor Code The code of the sponsor must be specified. The sponsor code must have an attribute 'Resolution Mode'. Business Rules: DS.4.BR

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
@ DS.4..1	(@) resolutionmode	int (Enum)	1	Resolution Mode The resolution mode must be specified. Local Number = 1 EV Code = 2
(@)NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains sponsor name, country code, city) - should not be submitted
DS.5	Casnumber	string (0-15)	0 - 1	Chemical Abstracts Service (CAS) Number The Chemical Abstracts Service (CAS) number of the development substance may be specified.
DS.6	moleculerformula	string (0-255)	0 - 1	Molecular Formula The empirical molecular formula of the development substance may be specified. Change Log: V3
DS.7	substanceclass	int (3)	0 - 1	Substance Class The substance classification code referring to the substance classification look up list may be specified. Mandatory if the operation type is insert or update. Business Rules: DS.7.BR Change Log: V3
DS.8	cbd	string (0-20000)	0 - 1	Chemical Biological Description (CBD) The Chemical Biological Description (CBD) of the Development Substance may be specified.

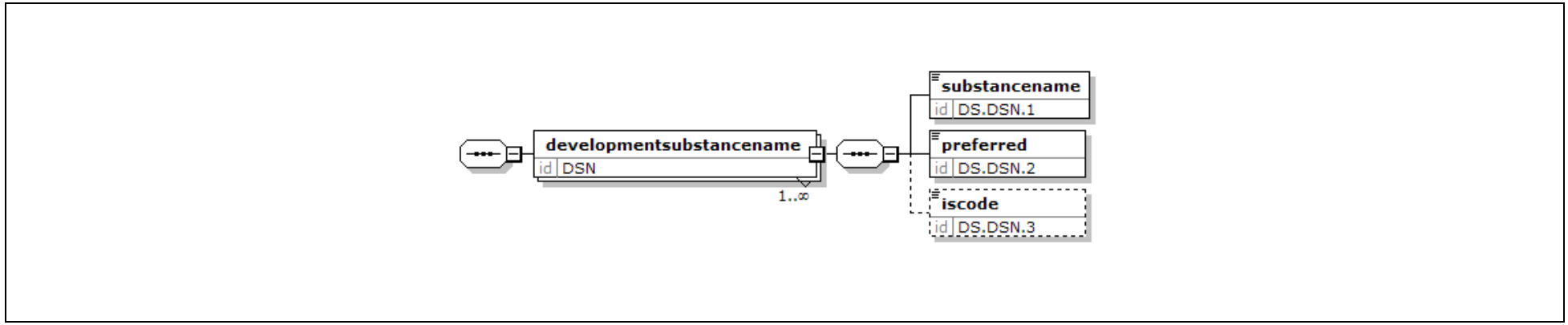
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DS.DSNs	developmentsubstancenames	Sequence	**1**	Development Substance Name Development substance names section that contains repeatable development substance name sections Business Rules: DS.DSNs.BR.
DS.ICs	internationalcodes	Sequence	**0 - 1**	International Code See development substance international code section.
DS.ATTs	substanceattachments	Sequence	**0 - 1**	(Development) Substance Attachment For development substances, attachments may be absent. See development substance attachments section. Business Rules: DS.ATTs.BR.
DS.SSIs	substancessis	Sequence	**0 - 1**	(Development) Structured Substance Information (SSI) Contains the development substance SSI section. This field is provided for the eventual of ISO compliant structured substance information and is **currently not required** by the EMA. If, however, the field is present, then the content must conform to the published schema. Business Rules: DS.SSIs.BR Change Log: V3

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DS.9	comments	string (0-500)	0 - 1	Comments Further information on the development substance may be supplied in the comment field. If the operation type is nullification, then the reason for nullification must be given in this field. Business Rules: DS.9.BR

3.I.b.8.1 Repeatable elements within the Development Substance element

i Development Substance Name (DSN)

Figure 8. Development substance name element structure



Back to parent element

Table 8. Development Substance - Substance Name elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DSN	developmentsubstancename	Sequence	**1 - ∞**	The development substance name section is used to specify the name and/or code of the development substance. Business Rules: DS.DSN.BR.
DS.DSN.1	substancename	string (0-2000)	1	(Development) Substance Name The name and/or code of the development substance must be specified in English. Business Rules: DS.DSN.1.BR.
DS.DSN.2	preferred	int (Enum)	1	Preferred Name Mandatory field that specifies if the name given in DS.DSN.1 is the preferred name for the development substance. The following values are allowed: Name is the preferred name = 1 Name is not the preferred name = 2 Business Rules: DS.DSNs.BR
DS.DSN.3	iscode	int (Enum)	0 - 1	Is code To be specified if the development substance name specified in DS.DSN.1 represents a code by which the development substance is known by the sending organisation. The value 1 specifies that DS.DSN.1 is a company code. A value of 2 specifies that DS.DSN.1 is NOT a code. Change Log: V3

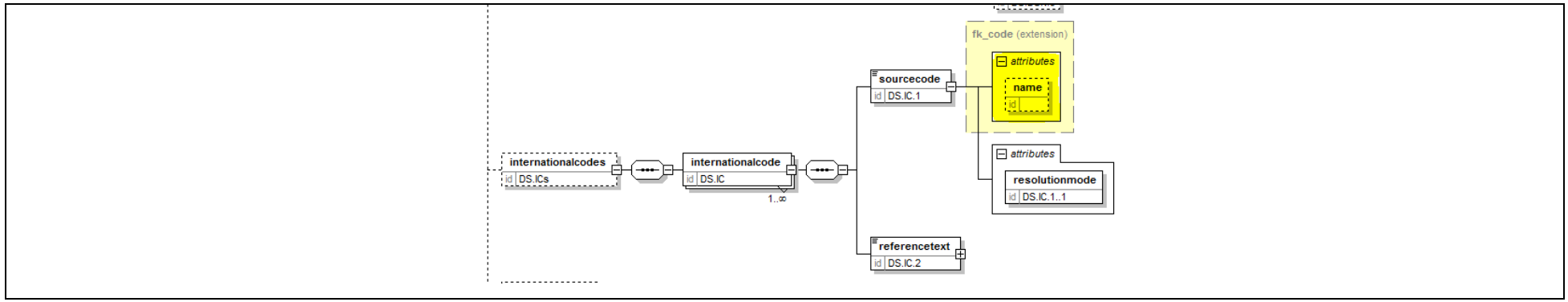
ii International Code (DS.IC)

This repeatable section is used to provide cross references between the XEVMPD and other systems by supplying codes by which the same substance is known in other systems such as the FDA Substance Registration System (SRS). In addition, for specified substances, the section is used for supplying a cross reference between the substance being submitted and "parent" substance(s).

The section is optional and may be omitted by removing the entire international codes section from the substance, if the international codes element is present then at least one valid international code element must be present.

Change Log: V3

Figure 9. International code element structure (V4.1– updated by addition of highlighted export name attribute)



Back to parent element

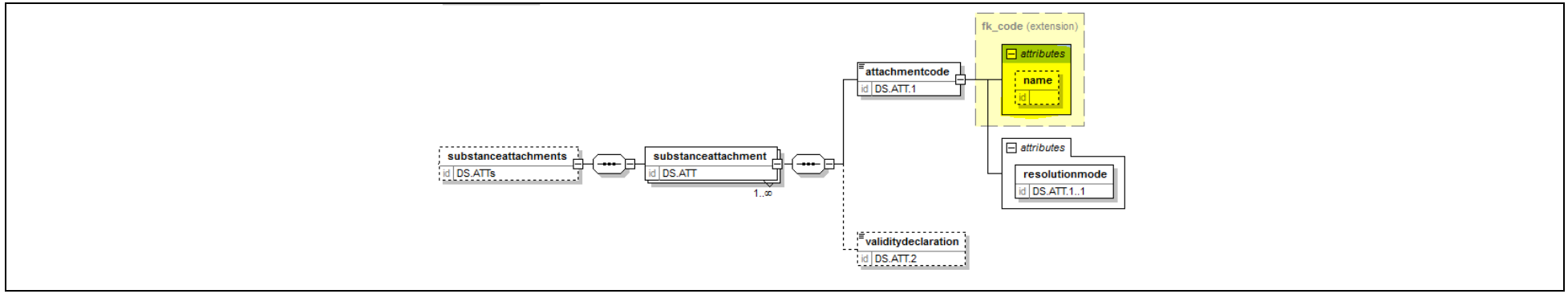
Table 9. Development Substance - International Code elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DS.IC	internationalcode	Sequence	1 - ∞	International Code Any internationally recognised code by which the substance can be identified may be specified as applicable. For specified substances the international code section is used to provide a cross reference the appropriate single substance in the XEVMPD or current message. Business Rules: DS.ICs.BR
DS.IC.1	sourcecode	string (0-60)	1	Source Code A valid reference source for the substance code must be specified. The Source code must have an attribute 'Resolution Mode'. Business Rules: DS.IC.1.BR
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports – should not be submitted
@ DS.IC.1..1	(@) resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 - Local (Local Number present in the XML file in the sources section.) Resolution mode = 2 - Global (EV Code present in the EudraVigilance Lookup Tables)

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DS.IC.2	referencetext	string (0-2000)	1	Reference Text The identifying name/code for the substance within the reference source system provided in DS.IC.1 must be specified. If the reference source is an EV Code referring to a substance or specified substance at a lower level of detail than the current substance then the resolution mode (DS.IC.2..1) must be specified. Business Rules: DS.IC.2.BR Change Log: V3
@ DS.IC.2..1	(@) resolutionmode	int (Enum)	0-1	Resolution Mode Resolution mode = 1 - Local (Local Number of substance present in the XML file in the development substances section.) Resolution mode = 2 - Global (Substance EV Code present in the EudraVigilance Lookup Tables) Business Rules: DS.IC.2..1.BR Change Log: V3

iii Substance Attachment (DS.ATT)

Figure 10. Development substance attachment element structure (V4.1– updated by addition of highlighted export name attribute)



Back to parent element

Table 10. Development Substance - Attachment elements

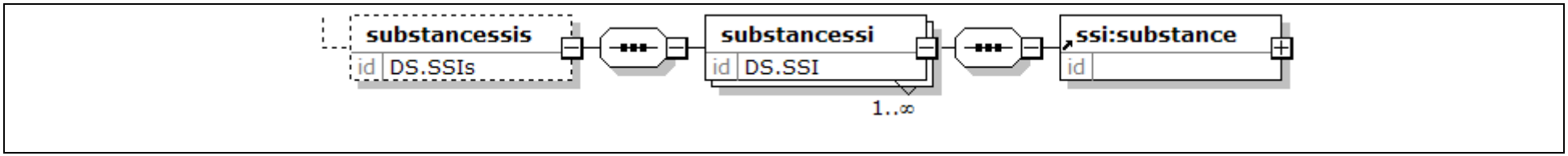
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DS.ATT	substanceattachment	Sequence	1 - ∞	The attachment section should be used to reference an attachment, if applicable. The referenced attachment may be included as a file in the message or may reference an attachment that is already stored in the XEVMPD. Business Rules: DS.ATTs.BR

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DS.ATT.1	attachmentcode	string (0-60)	1	Attachment Code The reference for the printed substance information attachment must be specified. This must refer to the local reference number if the attachment is included in the message, otherwise it must be the EV Code for the attachment. This element must have an attribute: Resolution Mode. The pattern of the EV Code is 'ATT followed by six digits'. Business Rules: DS.ATT.1.BR. Change Log: V3
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports – should not be submitted
@ DS.ATT.1..1	(@) resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 when the code is a Local Number. Resolution mode 2 when the code is an EV Code.
DS.ATT.2	validitydeclaration	int (Enum)	0 - 1	Validity Declaration When performing an update of an existing development substance where an attachment for a development substance was previously loaded and referenced, a confirmation must be provided that the referenced attachment is the latest version of the documentation. The value is 1 if the attachment is the latest version. Business Rules: DS.ATT.2.BR.

iv Structured Substance Information (DS.SSI)

The provision of an SSI for development substance is currently not required by the Agency and the entire section may be absent. If, however, the section is present then it must contain xml that is valid according to the published SSI schema.

Figure 11. Development substance - Structured Substance Information element



Back to parent element

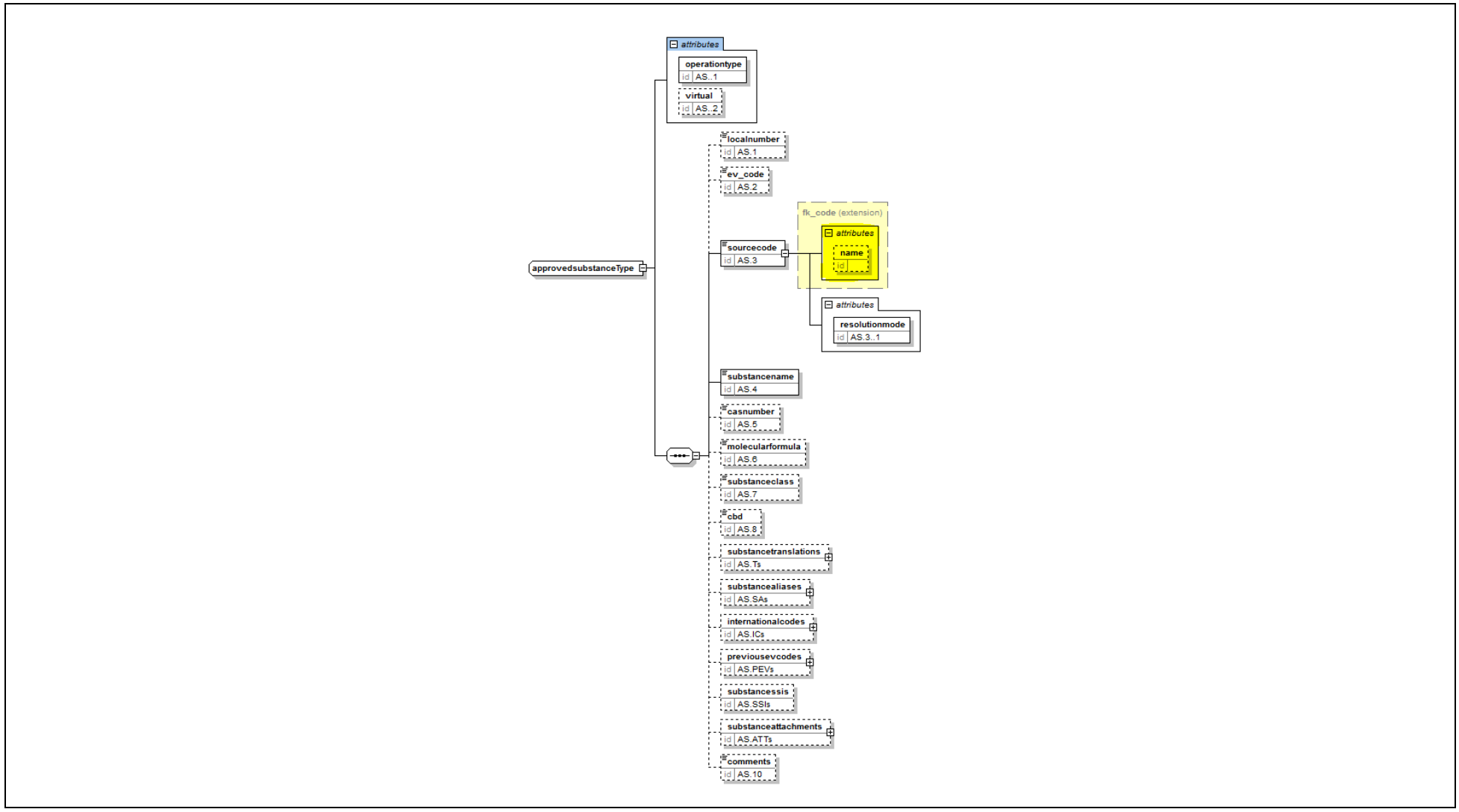
Table 11. Development Substance - Structured Substance Information element

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DS.SSII	Substancessii	Sequence	1 - ∞	(Development) Structured Substance Information (SSI) If present, it must be valid according to the SSI schema and business rules. Business Rules: DS.SSI.BR

3.I.b.9 Approved Substance (AS)

Since July 2019, only the EMA can insert and maintain substance information (approved and development) in the XEVMPD.

Figure 12. Approved substance element (V4.1– updated by addition of highlighted export name attribute)



This repeatable section is applicable to a substance of medicinal products that are authorised. In addition to single data elements, the section contains several repeatable elements each of which is described within a separate table below.

Back to parent element

Table 12. Approved Substance element

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AS	approvedsubstance	Sequence	1 - ∞	The approved substance section is used to specify the data for a substance contained in a medicinal product that is authorised. Business Rules: M.AS.BR
@ AS..1	(@) operationtype	int (Enum)	1	Operation Type The type of the operation for this entity must be specified. Insert = 1 Update = 2 Nullify = 4 From July 2019, substances (approved and development) may be inserted and maintained in the XEVMPD by the EMA only. Business Rules: AS..1.BR
@ AS..2	(@) virtual	int	0 - 1	Virtual Reserved for EMA Use only. Business Rules: AS..2.BR.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AS.1	localnumber	string (0-60)	0 - 1	Local Number The unique reference for the entity in the message. Mandatory if the operation type is "Insert" Business Rules: AS.1.BR Change Log: V3
AS.2	ev_code	string (0-60)	0 - 1	EudraVigilance (EV) Code The EV Code of the approved substance; Mandatory if the operation type is NOT "Insert". An EV Code is assigned to every new approved substance. Business Rules: AS.2.BR.
AS.3	sourcecode	string (0-60)	1	Source Code A valid reference source for the approved substance name must be specified. The source code must have an attribute 'Resolution Mode' (AS.3..1). Business Rules: AS.3.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains the source name) – should not be submitted
@ AS.3..1	(@) resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 when the code is a Local Number Resolution mode = 2 when the code is an EV Code as a source

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AS.4	substancename	string (0-2000)	1	(Approved) Substance Name The name of the approved substance in English must be provided Once submitted a substance name cannot be changed except by the EMA. Business Rules: AS.4.BR. Change Log: V3.1
AS.5	casnumber	string (0-15)	0 - 1	Chemical Abstracts Service (CAS) Number The Chemical Abstracts Service (CAS) number of the approved substance may be specified.
AS.6	moleculardformula	string (0-255)	0 - 1	Molecular Formula The empirical molecular formula of the approved substance may be specified. Change Log: V3
AS.7	substanceclass	int (3)	0 - 1	Substance Class The substance class code referring to the substance classification. A value must be specified from the published list if the operation type is "Insert" or "Update". Business Rules: AS.7.BR. Change Log: V3
AS.8	cbd	string (0-20000)	0 - 1	Chemical Biological Description (CBD) The Chemical Biological Description (CBD) of the Approved Substance may be specified.

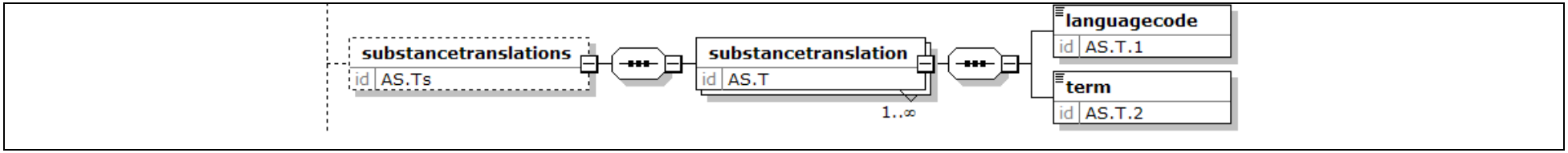
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AS.Ts	substancetranslations	Sequence	0 - 1	Substance Translation The substance translation section may be used to specify the substance names by which the substance is known in languages other than English. Business Rules: AS.Ts.BR
AS.SAs	substancealiases	Sequence	0 - 1	Substance Alias The optional substance aliases section should be used to supply synonyms of the approved substance name. Business Rules: AS.SAs.BR
AS.ICs	internationalcodes	Sequence	0 - 1	International Code This international codes section should contain as many international code sections as required. Business Rules: AS.ICs.BR
AS.PEVs	previousevcodes	Sequence	0 - 1	Previous EudraVigilance (EV) Codes The previous EV Codes section should contain as many previous EV Code sections as required. Business Rules: AS.PEVs.BR.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AS.SSIs	substancessis	Sequence	0 - 1	(Approved) Structured Substance Information (SSI) This field is provided for the eventual of ISO compliant structured substance information and is **currently not required** by the EMA. If, however, the field is present then the content must conform to the published schema. Business Rules: AS.SSIs.BR. Change Log: V3
AS.ATTs	substanceattachments	Sequence	0 - 1	Substance Attachment The substance attachments section should be used to reference a substance attachment as defined by the business rules. Business Rules: AS.ATTs.BR.
AS.10	comments	string (0-500)	0 - 1	Comments Further information may be supplied in the comment field. When the operation type is "Nullification", the comment field is mandatory, and the reason of nullification must be provided. Business Rules: AS.10.BR.

3.I.b.9.1 Repeatable elements within the Approved Substance element

i Substance Translation (AS.T)

Figure 13. Substance translation element structure



The repeatable substance translation section should be used to define names by which the substance is known in languages other than English, if the substance translations element is present then there must be at least one substance translation element.

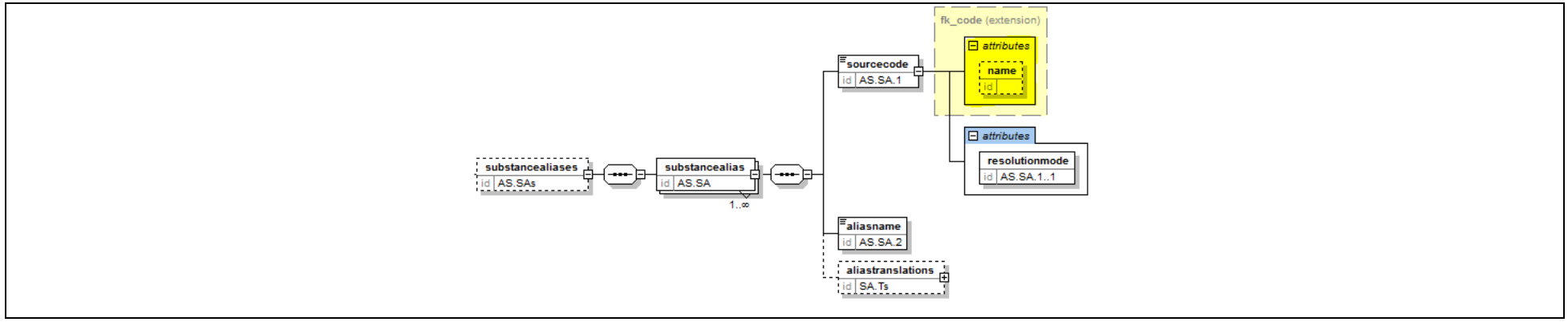
Back to parent element

Table 13. Approved Substance - Substance Translation element

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AS.T	substancetranslation	Sequence	1 - ∞	The section must be used to add or update a translation for the substance name if the substance translations element is present.
AS.T.1	languagecode	string (0-2)	1	Language Code The two letter code of the LANGUAGE list must be used. Business Rules: AS.T.1.BR
AS.T.2	term	string (0-2000)	1	Term The translation of the substance name must be specified. Business Rules: AS.T.2.BR.

ii Substance Alias (AS.SA)

Figure 14. Substance alias element structure (V4.1– updated by addition of highlighted export name attribute)



The repeatable substance alias section should be used to define, if required, other names by which the substance is known in English. The section contains an optional element for translations of each alias and this is described in the substance alias translation section below. If the substance aliases section is present then there must be at least one substance alias section present.

Back to parent element

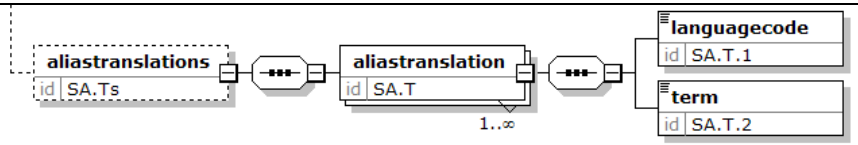
Table 14. Approved Substance - Substance Alias element

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AS.SA	substancealias	Sequence	1 - ∞	Where applicable, a synonym of the substance name should be provided or updated using this section.
AS.SA.1	sourcecode	string (0-60)	1	Source Code A valid reference source of the approved substance synonym must be specified. The Source code must have an attribute 'Resolution Mode' (AS.SA.1..1). Business Rules: AS.SA.1.BR.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains the source name)– should not be submitted
@ AS.SA.1..1	(@) resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 Local (Local Number present in the XML file) Resolution mode = 2 Global (EV Code present in the EudraVigilance Lookup Tables for Sources).
AS.SA.2	aliasname	string (0-2000)	1	Alias Name The synonym of the substance name must be provided and be specified in English. Business Rules: AS.SA.2.BR
SA.Ts	aliastranslations	Sequence	0 - 1	Alias Translation This section should be used to add or update translations of an alias of the substance name as required. Business Rules: SA.Ts.BR.

iii Substance Alias Translation (SA.T)

Figure 15. Substance alias translation element structure



This repeatable section should be used to provide translations of an alias (synonym) of the preferred substance name. Each translation should be in a language other than English. If the alias translations element is present then at least one alias translation must be present.

Back to parent element

Table 15. Approved Substance - Substance Alias Translation elements

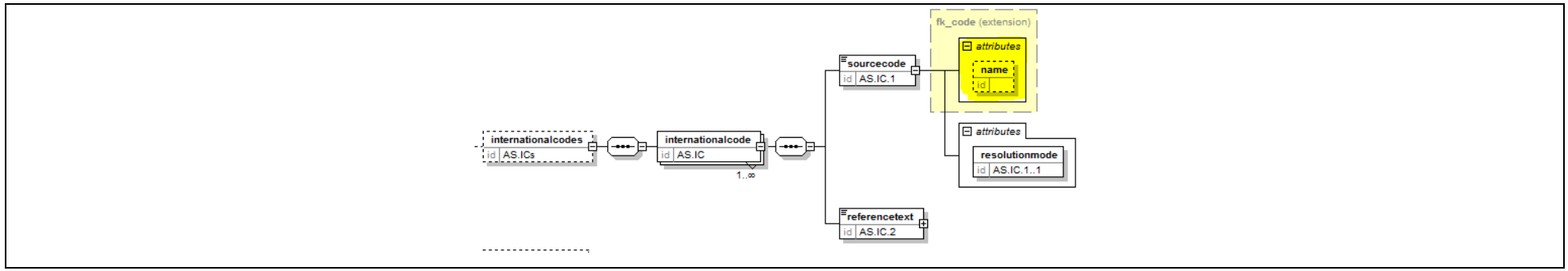
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
SA.T	aliastranslation	Sequence	1 - ∞	This section should be used to add or update a translation of an alias (repeatable if more than one translation is specified).
SA.T.1	languagecode	string (0-2)	1	Language Code The language code must be specified in accordance with the LANGUAGE list. Business Rules: SA.T.1.BR.
SA.T.2	term	string (0-2000)	1	Term The translation of the substance alias name must be specified. Business Rules: SA.T.2.BR.

iv International Code (AS.IC)

This repeatable section is used to provide cross references between the XEVMPD and other systems by supplying codes by which the same substance is known in other systems such as the FDA Substance Registration System (SRS). In addition, for specified substances, the section is used for supplying a cross reference between the substance being submitted and "parent" substance(s).

The section is optional and may be omitted by removing the entire international codes section from the substance, if the international codes element is present then at least one valid international code element must be present.

Figure 16. Approved substance international code element structure (V4.1– updated by addition of highlighted export name attribute)



Back to parent element

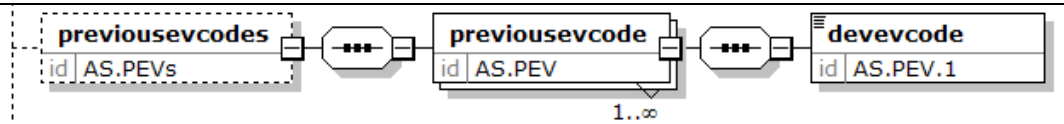
Table 16. Approved Substance – International Code elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AS.IC	Internationalcode	Sequence	1 - ∞	Any internationally recognised code by which the substance can be identified should be specified as applicable. Business Rules: AS.ICs.BR

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AS.IC.1	sourcecode	string (0-60)	1	Source Code A valid reference source of the approved substance name must be specified. The Source code must have an attribute 'Resolution Mode' AS.IC.1..1. Business Rules: AS.IC.1.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains the source name) – should not be submitted
@ AS.IC.1..1	(@) resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 Local (Local Number present in the XML file) Resolution mode = 2 Global (EV Code present in the EudraVigilance Lookup Tables)
AS.IC.2	referencetext	string (0-2000)	1	Reference Text The identifying name/code for the substance within the reference source system provided in AS.IC.1 must be specified. If the reference source is an EV Code referring to a substance or specified substance at a lower level of detail than the current substance then the resolution mode (AS.IC.2..1) must be specified. Change Log: V3 Business Rules: AS.IC.2.BR
@ AS.IC.2..1	(@) resolutionmode	int (Enum)	0 - 1	Resolution Mode Resolution mode = 1 - Local (Local Number of referenced substance present in the XML file in the approved substances section.) Resolution mode = 2 - Global (referenced Substance EV Code present in the EudraVigilance Lookup Tables) Change Log: V3 Business Rules: AS.IC.2..1.BR

v Previous EV Code (AS.PEV)

Figure 17. Approved substance international code element structure



Back to parent element

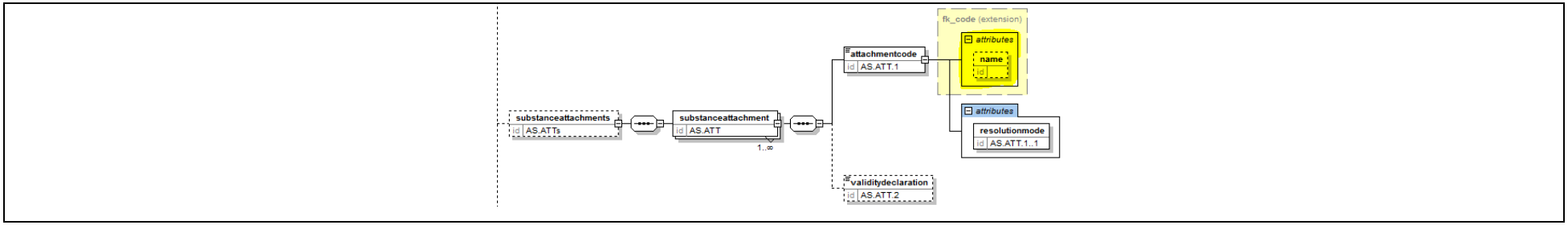
Table 17. Approved Substance – Previous EV Code elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AS.PEV	Previousevcode	Sequence	1 - ∞	This repeatable section may be used when an approved substance should be linked to the EV Codes of one or more development substance(s). Business Rules: AS.PEVs.BR
AS.PEV.1	Devevcode	string (0-60)	1	Development (DEV) EudraVigilance (EV) Code This field must contain an EV Code that corresponds to the same substance in development form in the XEVMPD i.e., this substance before it was considered approved. Business Rules: AS.PEV.1.BR

vi Approved Substance Attachment (AS.ATT)

This section may be used to provide a reference to documentation that supports the information for the approved substance.

Figure 18. Approved substance attachment structure (V4.1– updated by addition of highlighted export name attribute)



Back to parent element.

Table 18. Approved Substance - Substance Attachment elements

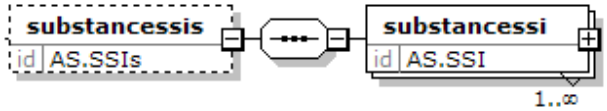
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AS.ATT	Substanceattachment	Sequence	1 - ∞	The attachment section should be used to reference an attachment where required. The referenced attachment may take the form of a file included in the message (via the attachments section) or a reference to an attachment that is already stored in the XEVMPD. Change Log: V3

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AS.ATT.1	Attachmentcode	string (0-60)	1	Attachment Code This field references the printed substance information attachment. This must be the local reference number if the attachment is included with the current message, otherwise it will be EV Code of the attachment. This element must have an attribute: Resolution Mode. The pattern of the EV Code is 'ATT' followed by six digits. Business Rules: AS.ATT.1.BR Change Log: V3
@NA	@name	string	0 - 1	Version 4.1: Name attribute for exports (contains attachment name) - should not be submitted
AS.ATT.1..1	(@) resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 Local (Local Number present in the XML file). Resolution mode = 2 Global (EV Code of the attachment present in the EudraVigilance Lookup Tables.
AS.ATT.2	Validitydeclaration	int (Enum)	0 - 1	Validity Declaration In performing an update or insert of an approved substance where an attachment was already previously loaded and referenced, a confirmation must be provided that the referenced attachment is the latest version of the documentation. The value is 1 if the attachment is the latest version. Business Rules: AS.ATT.2.BR. Change Log: V3

vii Structured Substance Information (AS.SSI)

Note: The provision of an SSI for development substance is currently not required by the Agency and the entire section may be absent. If, however, the section is present then it must contain xml that is valid according to the published SSI schema.

Figure 19. Approved substance - Structured Substance Information element structure



Back to parent element

Table 19. Approved Substance – Structured Substance Information element

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AS.SSII	substancessii	Sequence	1 - ∞	(Approved) Structured Substance Information (SSI) Must be valid according to the SSI schema and business rules. Business Rules: AS.SSI.BR

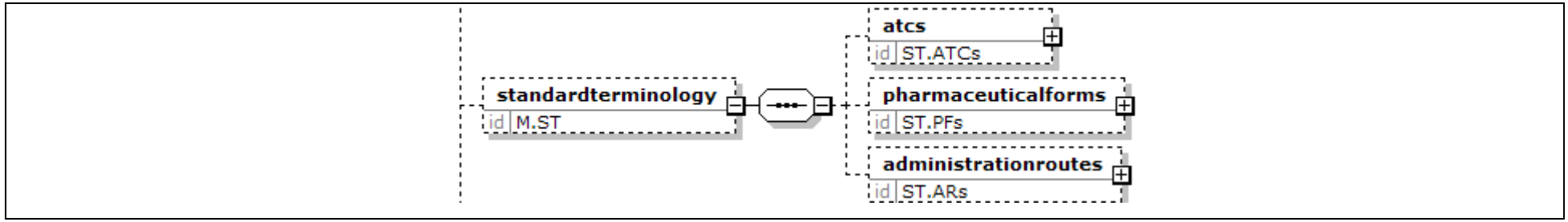
3.I.b.10 Standard Terms (M.ST)

The standard terms section contains elements that are used to support the standardisation of medicinal product or substance information whereby submitted terms become available in look up lists of values.

Only the EMA can insert and maintain standard terms in the XEVMPD.

3.I.b.10.1 ATCs (ST.ATCs)

Figure 20. Standard Term – Anatomical Therapeutic Chemical (ATC) classification system element structure



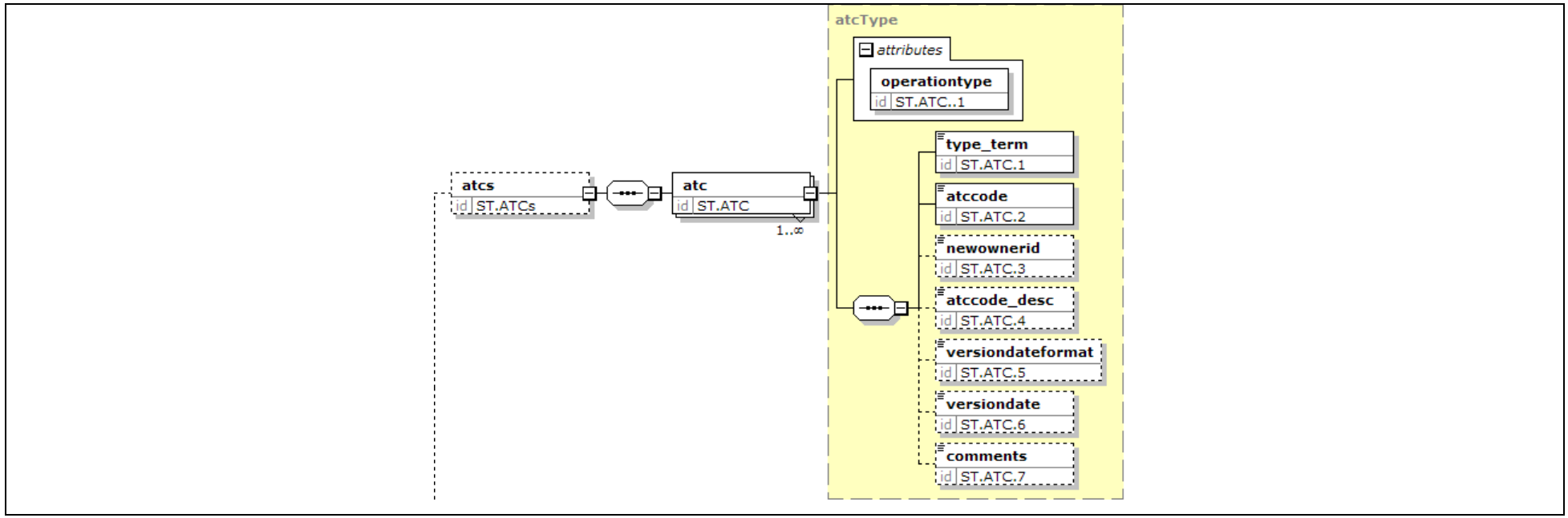
Back to parent element

Table 20. Standard Terms – ATCs elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
ST.ATCs	atcs	Complex	**0 - 1**	The ATCs section contains information about each ATC Code in relation to a medicinal product (investigational, authorised). Business Rules: ST.ATCs.BR

ATC (ST.ATC)

Figure 21. ATC element structure



Back to parent element

Table 21. Standard Terms – ATC elements

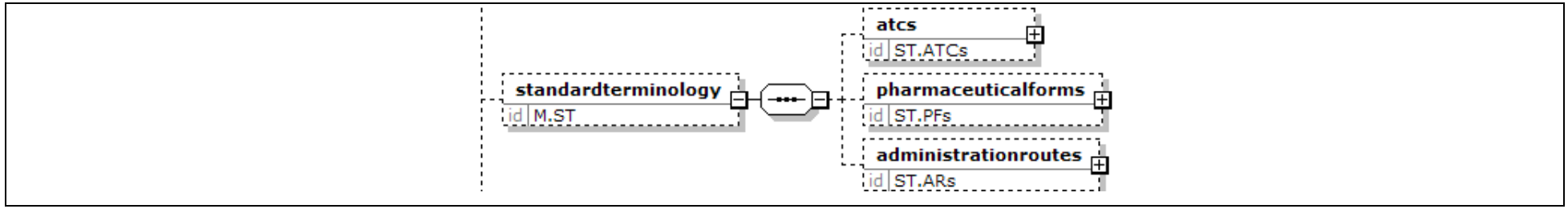
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
ST.ATC	atc	Sequence	**1 - ∞**	The ATC section contains information about each ATC Code in relation to a medicinal product (investigational, authorised). The ATC container may be used to: Add a new ATC Code to the XEVMPD Maintain an existing ATC code within the XEVMPD
@ ST.ATC..1	(@) operationtype	int (Enum)	1	Operation Type Insert = 1 Update = 2 Nullify = 4 Business Rules: ST.ATC..1.BR.
ST.ATC.1	type_term	int (Enum)	1	Type Term The type of term must be specified. Development Term = 1 Proposed Term = 2 (From 18 January 2024 EMA USE ONLY) Standard Term (EMA USE ONLY) = 3 Business Rules: ST.ATC.1.BR.
ST.ATC.2	Atccode	string (0-10)	1	ATC Code The ATC Code must be specified. Business Rules: ST.ATC.2.BR.
ST.ATC.3	Newownerid	string (0-60)	0 - 1	New Owner Identifier (ID) This field identifies the Owner of the Development ATC Term. Reserved for EMA use only. Business Rules: ST.ATC.3.BR.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
ST.ATC.4	atccode_desc	string (0-200)	0 - 1	ATC Code Description The ATC Classification System term should be specified in English. Mandatory for “Insert” and “Update” operations. Business Rules: ST.ATC.4.BR.
ST.ATC.5	Versiondateformat	string (Enum)	0 - 1	Version Date Format Format of the Version Date is “102” for "CCYYMMDD” may be specified. Business Rules: ST.ATC.5.BR
ST.ATC.6	Versiondate	string (0-14)	0 - 1	Version Date The date of the last update of the specified ATC code may be specified. Business Rules: ST.ATC.6.BR
ST.ATC.7	Comments	string (0-500)	0 - 1	Comments This element should be used to add comments. Mandatory when there is a request for “Nullification”. Business Rules: ST.ATC.7.BR.

3.I.b.10.2 Pharmaceutical Forms (ST.PFs)

Figure 22. Standard Term - Pharmaceutical Forms element structure



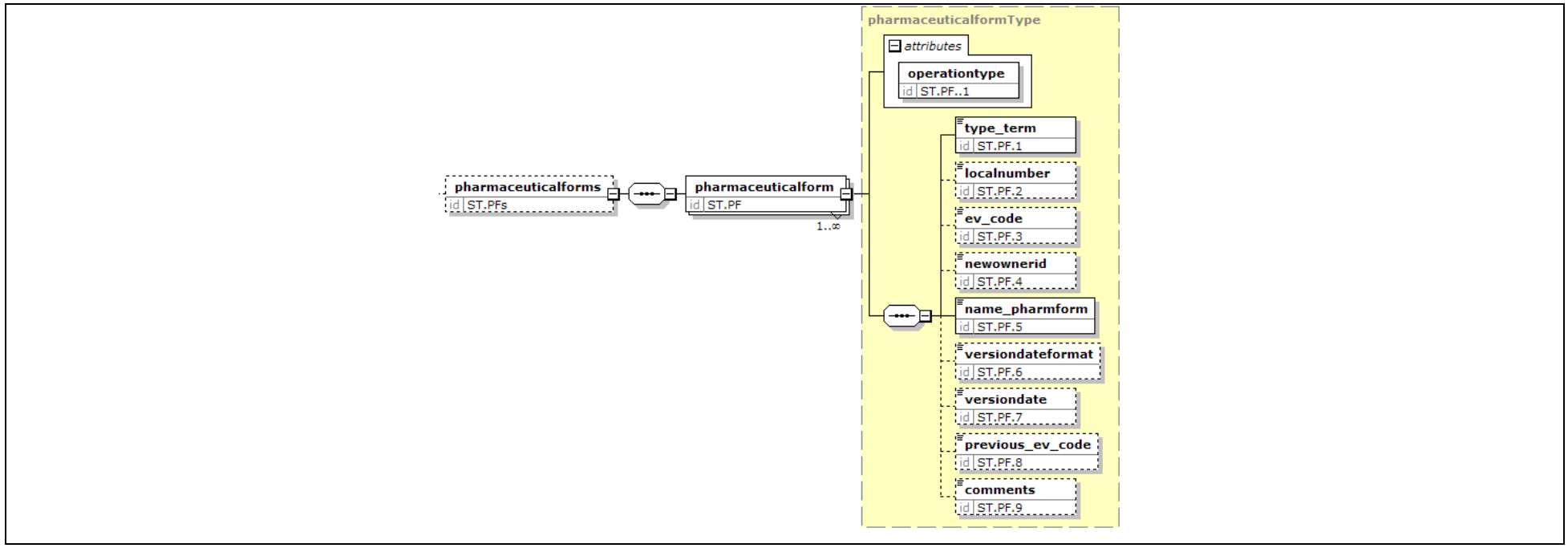
Back to parent element

Table 22. Standard Terms – Pharmaceutical Forms elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
ST.PFs	pharmaceuticalforms	Complex	**0 - 1**	The pharmaceutical forms section contains information about one or more pharmaceutical form used in relation to medicinal products (investigational, authorised). Business Rules: ST.PFs.BR

Pharmaceutical Form (ST.PF)

Figure 23. Pharmaceutical Form element structure



Back to parent element

Table 23. Standard Terms – Pharmaceutical Form elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes

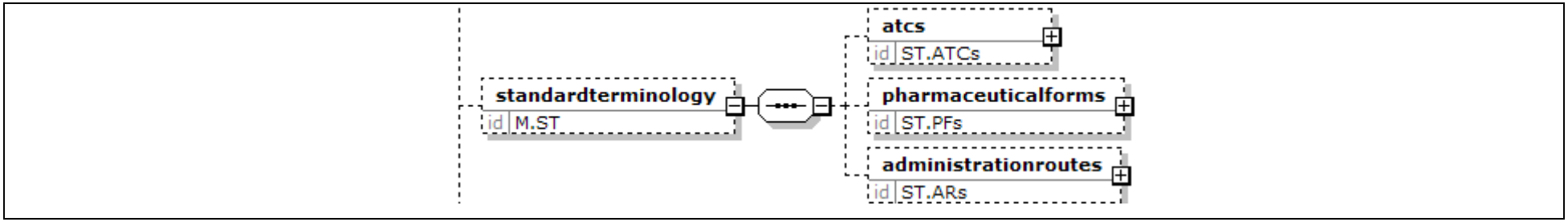
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
ST.PF	pharmaceuticalform	Sequence	**1 - ∞**	The Pharmaceutical Form section contains information about a pharmaceutical form of a medicinal product (investigational, authorised). The pharmaceutical form container should be used to: • Add a new Pharmaceutical Form to the XEVMPD • To maintain an existing Pharmaceutical Form within the XEVMPD
@ ST.PF..1	(@) operationtype	int (Enum)	1	Operation Type Insert = 1 Update =2 Nullify = 4 Business Rules: ST.PF..1
ST.PF.1	type_term	int (Enum)	1	Type Term The type of term must be specified. Development Term = 1 Proposed Term = 2 (From 18 January 2024 EMA USE ONLY) Standard Term = 3 (EMA USE ONLY) Business Rules: ST.PF.1.BR.
ST.PF.2	localnumber	string (0-60)	0 - 1	Local Number The unique reference for the entity in the message. Mandatory for Operation Type "Insert". Business Rules: ST.PF.2.BR.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
ST.PF.3	ev_code	string (0-60)	0 - 1	EudraVigilance (EV) Code The EV CODE of the pharmaceutical form may be specified. Mandatory if the operation type is NOT an “Insert”. Business Rules: ST.PF.3.BR.
ST.PF.4	newownerid	string (0-60)	0 - 1	New Owner Identifier This identifies the owner of the Development Term. Reserved for EMA Use only. Business Rules: ST.PF.4.BR.
ST.PF.5	name_pharmform	string (0-200)	1	Name Pharmaceutical Form The English Description of a Term must be specified. Business Rules: ST.PF.5.BR.
ST.PF.6	versiondateformat	string (Enum)	0 - 1	Version Date Format The format of the Version Date is “102” for "CCYYMMDD” Business Rules: ST.PF.6.BR
ST.PF.7	versiondate	string (0-14)	0 - 1	Business Rules: ST.PF.7.BR

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
ST.PF.8	previous_ev_code	string (0-60)	0 - 1	Previous EudraVigilance (EV) Code For a Development Term this field is not applicable. For a Proposed Term this field should refer to the EV Code of the previous Development Term. For a Standard Term this field should refer to the EV Code of the previous Proposed or Development Term. Business Rules: ST.PF.8.BR.
ST.PF.9	comments	string (0-500)	0 - 1	Comments This element should be used to add comments. The element must be specified when there is a request for "Nullification" (ST.PF..1 = 4). Business Rules: ST.PF.9.BR

3.I.b.10.3 Administration Routes (ST.ARs)

Figure 24. Standard Terms - Administration Routes element structure



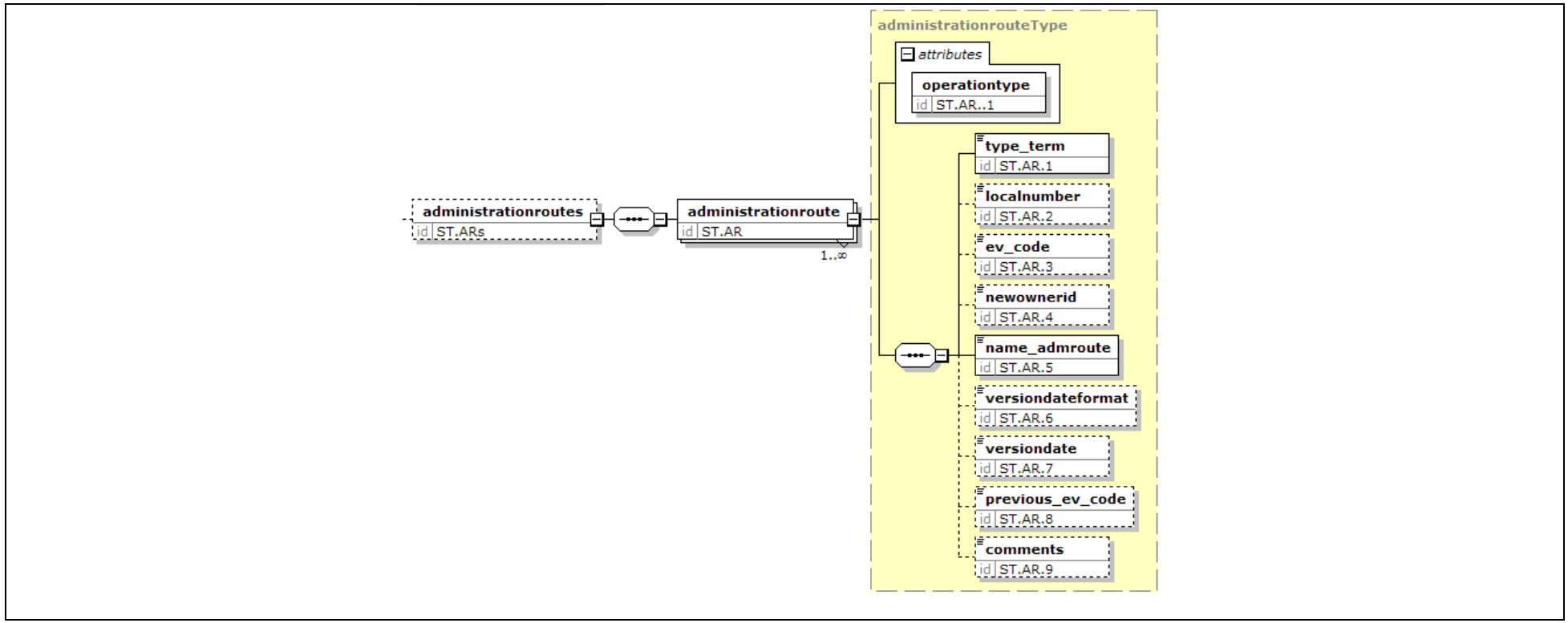
Back to parent element

Table 24. Standard Terms – Administration Routes elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
ST.ARs	Administrationroutes	Sequence	0 - 1	This section may be used to provide one or more administration route. Business Rules: ST.ARs.BR.

Administration Route (ST.AR)

Figure 25. Administration Route element structure



Back to parent element

Table 25. Standard Terms – Administration Route elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
ST.AR	administrationroute	Sequence	1 - ∞	The Administration Route section contains information about an administration route to be referenced by a medicinal product (investigational, authorised). The Administration Route container is used to add a new Administration Route to the XEVMPD or to maintain an existing Administration Route within the XEVMPD
@ ST.AR..1	(@) operationtype	int (Enum)	1	Operation Type Insert =1 Update = 2 Nullify = 4 Business Rules: ST.AR..1.BR.
ST.AR.1	type_term	int (Enum)	1	Type Term The type of the term must be specified. Development Term = 1 Proposed Term = 2 (From 18 January 2024 EMA USE ONLY) Standard Term = 3 (EMA USE ONLY) Business Rules: ST.AR.1.BR.
ST.AR.2	localnumber	string (0-60)	0 - 1	Local Number The unique reference for the entity in the message. Mandatory for the operation type "Insert". Business Rules: ST.AR.2.BR.

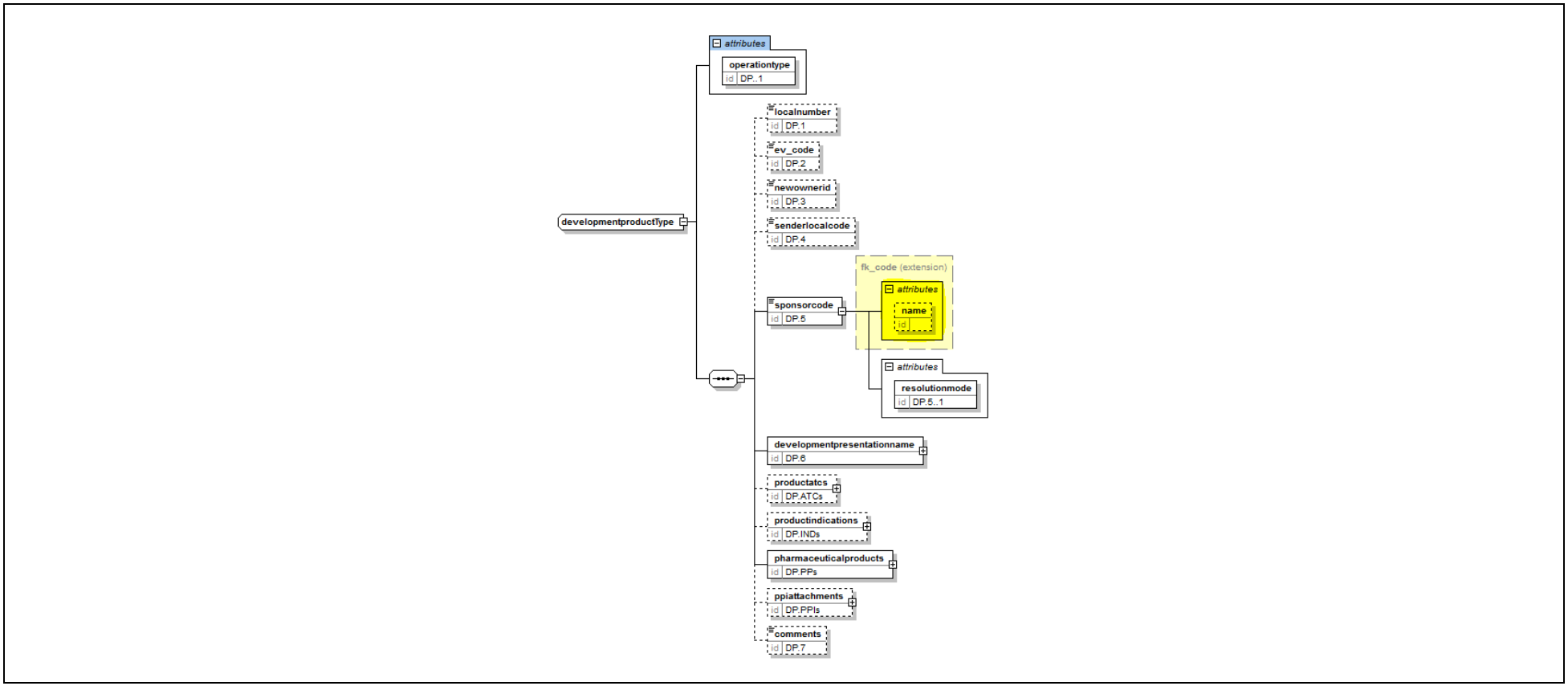
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
ST.AR.3	ev_code	string (0-60)	0 - 1	EudraVigilance (EV) Code The EV CODE of the administration route is mandatory if the operation type is NOT “Insert”. Business Rules: ST.AR.3.BR.
ST.AR.4	newownerid	string (0-60)	0 - 1	New Owner Identifier (ID) This field identifies the owner of a Development Term. Reserved for EMA use only. Business Rules: ST.AR.4.BR.
ST.AR.5	name_admroute	string (0-200)	1	Name Administration Route The English description of a term must be specified. Business Rules: ST.AR.5.BR.
ST.AR.6	versiondateformat	string (Enum)	0 - 1	Version Date Format Format of the Version Date is “102” for "CCYYMMDD”. Business Rules: ST.AR.6.BR
ST.AR.7	versiondate	string (0-14)	0 - 1	Version Date The date of the last update of the administration route should be specified. Business Rules: ST.AR.7.BR

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
ST.AR.8	previous_ev_code	string (0-60)	0 - 1	Previous EudraVigilance (EV) Code • For a Development Term, this field is not applicable. • For a Proposed Term, this field refers to the EV Code of the previous Development Term. • For a Standard Term, this field refers to the EV Code of the previous Proposed or Development Term. Business Rules: ST.AR.8.BR.
ST.AR.9	comments	string (0-500)	0 - 1	Comments This element may be used to add comments. If the operation type is nullification, then the reason for nullification must be given in this field. Business Rules: ST.AR.9.BR.

3.I.b.11 Development Product (DP)

This repeatable section is used to submit or update information on investigational i.e., development medicinal products. The element contains several sub elements some of which are repeatable. Where this is the case, each element is presented after the main development product table.

Figure 26. Development Product element structure (V4.1– updated by addition of highlighted export name attribute)



Back to parent element

Table 26. Development Product elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DP	developmentproduct	Sequence	1 - ∞	Development Product
@ DP..1	(@) operationtype	int (Enum)	1	Operation Type The type of the operation for this entity must be specified. The following operation types are applicable: Insert = 1 Update = 2 Nullify = 4 Change Ownership (EMA USE ONLY) = 5 Business Rules: DP..1.BR.
DP.1	localnumber	string (0-60)	0 - 1	Local Number The unique reference for the entity in the message may be specified. The local number is mandatory for the operation type "Insert". Business Rules: DP.1.BR
DP.2	ev_code	string (0-60)	0 - 1	EudraVigilance (EV) Code The EV Code for the development product may be specified. Mandatory if the operation type is NOT an "insert". Business Rules: DP.2.BR

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DP.3	newownerid	string (0-60)	0 - 1	New Owner Identifier (ID) This field identifies the Owner of the Development Term. Reserved for EMA use only. Business Rules: DP.3.BR
DP.4	senderlocalcode	string (0-100)	0 - 1	Sender Local Code
DP.5	sponsorcode	string (0-60)	1	The code of the sponsor must be specified. The sponsor code must have an attribute 'Resolution Mode': Resolution mode 1 = code is a Local Number (organisation is present in the current message) Resolution mode 2 = code is an EV Code where the organisation is already present in the XEVMPD. Business Rules: DP.5.BR
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains sponsor name, Country Code, city) – should not be submitted
@ DP.5..1	(@) resolutionmode	int (Enum)	1	Resolution Mode 1 = Local Number 2 = EV Code
DP.6	developmentpresentationname	Sequence	1	Development (Product) Presentation Name This section contains information on the product presentation name.
DP.6.1	productcode	string (0-60)	0 - 1	Product Code The code assigned to a development product may be specified, where applicable. Business Rules: DP.6.1.BR.

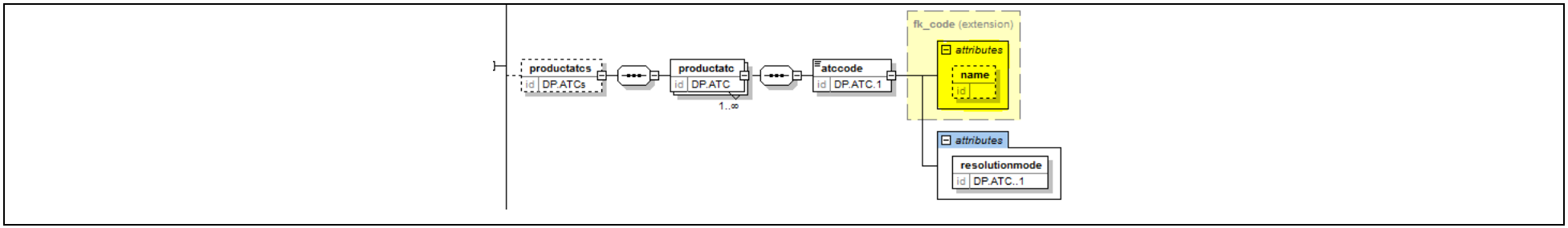
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DP.6.2	productname	string (0-2000)	0 - 1	Product Name The name of the development product may be specified, where applicable. Business Rules: DP.6.2.BR.
DP.6.3	productothername	string (0-500)	0 - 1	Product Other Name The other descriptive name of the development product may be specified where applicable. Business Rules: DP.6.3.BR.
DP.ATCs	productatcs	Sequence	0 - 1	Product ATCs This section contains information on the development product ATC code(s). Business Rules: DP.ATCs.BR
DP.Inds	productindications	Sequence	0 - 1	Product Indications This section contains information about the indication(s) of a development medicinal product. The section contains one or more development product indication section. Business Rules: DP.Inds.BR.
DP.PPs	pharmaceuticalproducts	Sequence	1	Pharmaceutical Products This section contains information about the pharmaceutical product(s) that constitutes the development product. Some development products can consist of more than one pharmaceutical product.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DP.PPIs	ppiattachments	Sequence	0 - 1	Printed Product Information (PPI) Attachments This element contains each printed product information attachment reference in support of the development product. Business Rules: DP.PPIs.BR
DP.7	comments	string (0-500)	0 - 1	Comments This element should be used to add comments. Mandatory when there is a request for "Nullification" of the development product. Business Rules: DP.7.BR

3.I.b.11.1 Repeatable elements within the Development Product element

i Development Product ATC (D.ATC)

Figure 27. Development product – ATC code element structure



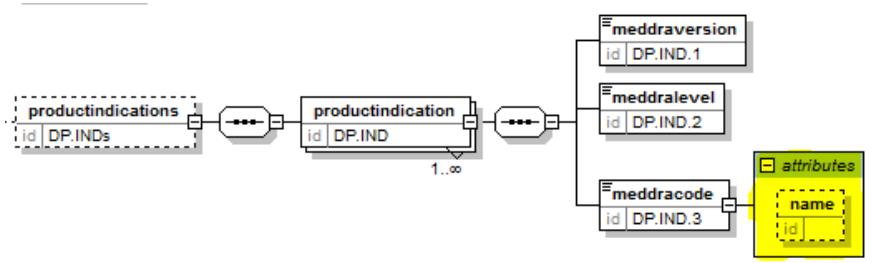
Back to parent element

Table 27. Development Product - ATC elements (V4.1– updated by addition of highlighted export name attribute)

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DP.ATC	productatc	Sequence	1 - ∞	This section contains information on the ATC code(s) for the development product. Business Rules: DP.ATCs.BR
DP.ATC.1	atccode	string (0-60)	1	ATC code The ATC code of the development product must be specified. The ATC code must have an attribute: Resolution Mode. Business Rules: DP.ATC.1.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains ATC Code text) – should not be submitted
@ DP.ATC..1	(@) resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 Local (local key of ATC code present in the XML file) Resolution mode = 2 Global (EV Code present in the Eudravigilance Lookup Tables) Change Log: V3

ii Development Product Indication (D.IND)

Figure 28. Development product – Indication element structure (V4.1– updated by addition of highlighted export name attribute)



Back to parent element

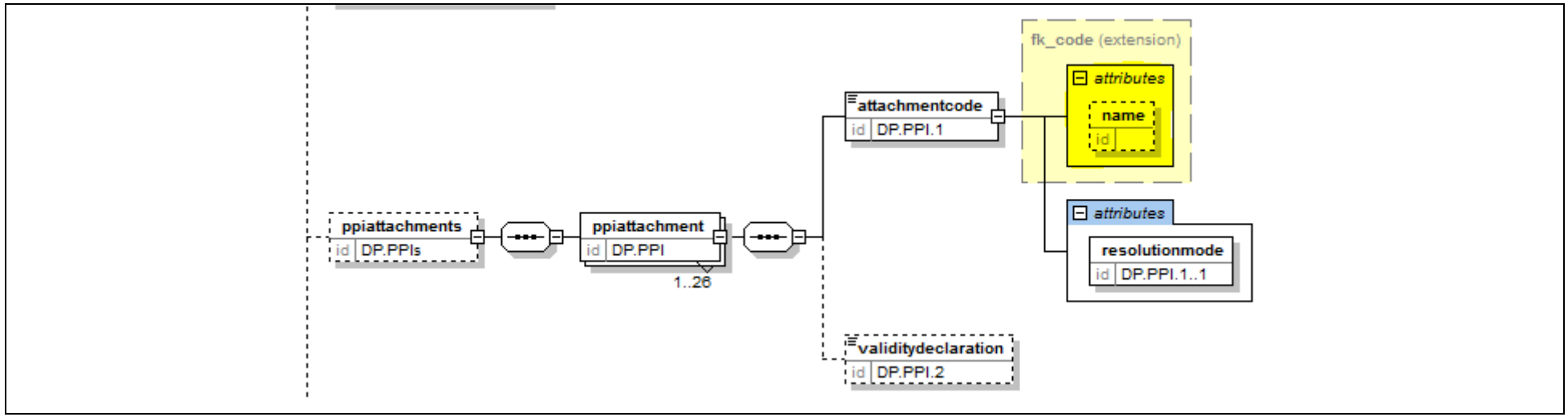
Table 28. Development Product - Indication elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DP.IND	productindication	Sequence	1 - ∞	This section contains information about each indication of a development product.
DP.IND.1	meddraversion	decimal (3(.1))	1	MedDRA Version The MedDRA version in relation to the coded MedDRA indication must be specified. Business Rules: DP.IND.1.BR.
DP.IND.2	meddralevel	string (Enum)	1	MedDRA Level This field indicates the level of Drug Indication in the MEDDRA's version.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DP.IND.3	meddracode	int (8)	1	MedDRA Code The MedDRA code for the development product must be specified. Business Rules: DP.IND.3.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains MedDRA code text) – should not be submitted

iii Printed Product Information (DP.PPI)

Figure 29. Development product – Printed product information element structure



The printed product information section may be used to provide a link between the development product and one or more attachment files that support the information submitted.

Back to parent element.

Table 29. Development Product – Printed Product Information elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DP.PPI	ppiattachment	Sequence	1 - 26	Each PPI section contains a reference to a Printed Product Information document in a specific language for the development product either submitted with the product message or referring to a document already present in the XEVMPD.

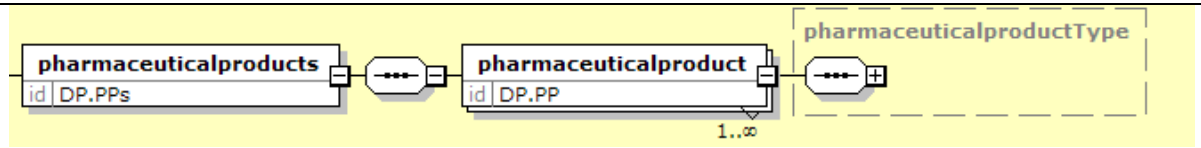
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DP.PPI.1	attachmentcode	string (0-60)	1	Attachment Code This field references the attachment for the development product. This must be the local reference number relevant to sender organisation if it is an "Insert" operation, otherwise the EV Code of the attachment must be specified. This element must have an attribute: Resolution Mode. The pattern of the EV Code is 'ATT' followed by six digits Business Rules: DP.PPI.1.BR Change Log: V3
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains attachment name) - should not be submitted
@ DP.PPI.1..1	(@) resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 Local (Key for a PPI present in the current XML file) Resolution mode = 2 Global (EV Code present in the EudraVigilance Lookup Tables) Change Log: V3

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DP.PPI.2	validitydeclaration	int (Enum)	0 - 1	Validity Declaration During an **insert** of a development product, where the referenced PPI attachment is loaded in the XEVMPD, a confirmation must be provided that the referenced attachment is the latest version of the documentation. The value 1 specifies that the attachment is the latest version. During an **update** of a development product, where the PPI attachment is referenced, the business rule is relaxed, and it is not required to specify the validity declaration. Business Rules: DP.PPI.2.BR Change Log: V3, V5.3

3.I.b.11.2 Pharmaceutical Product (DP.PP)

The pharmaceutical product section is shared by both development and authorised products, the structure of the element is the same in both cases, but different business rules apply. For detailed information about the structure, refer to the pharmaceutical product section presented after the Authorised Product section of this document.

Figure 30. The pharmaceutical products section of development products element structure



Back to parent element.

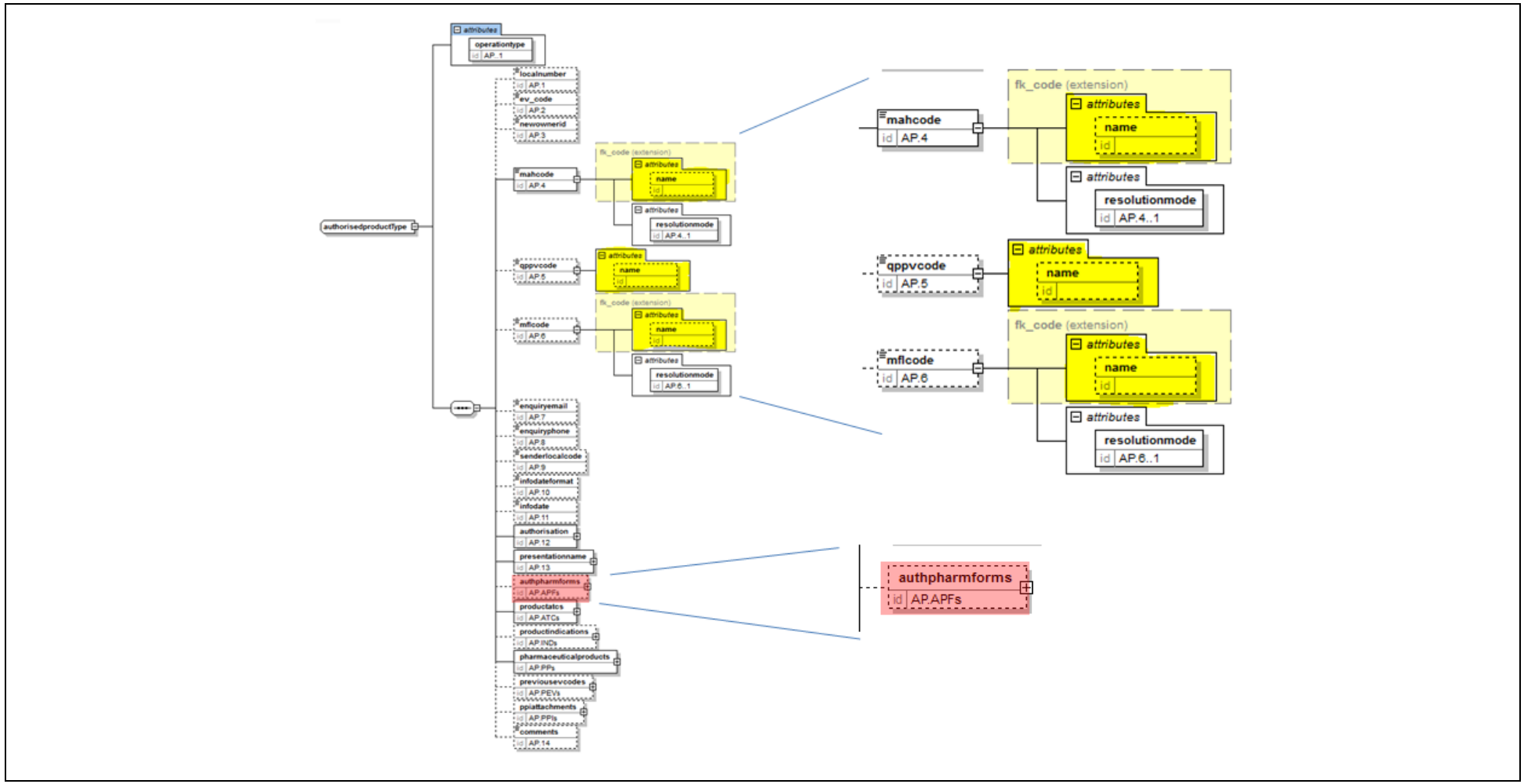
Table 30. Development Product – Pharmaceutical Product element.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
DP.PP	pharmaceuticalproduct	Sequence	1 - ∞	This section contains information about each pharmaceutical product contained in a development product.

3.I.b.12 Authorised Product (M.AP)

This repeatable section is used to submit or update information on authorised medicinal products. The element contains several sub elements some of which are repeatable.

Figure 31. Authorised product element structure (Updated V4.1 (yellow highlight) and 5.0 (red highlight- corrected)



Back to parent element

Table 31. Authorised Product elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
M.AP	Authorisedproduct	Sequence	1 - ∞	Each authorised product section contains information regarding an authorised medicinal product.
@ AP..1	(@) operationtype	int (Enum)	1	Operation Type The type of the operation for this entity must be specified. The operation types are: Insert = 1 Update = 2 Nullify = 4 Change Ownership (EMA USE ONLY) = 5 Invalidate MA = 6 Business Rules: AP..1.BR
AP.1	localnumber	string (0-60)	0 - 1	Local Number The unique reference for the entity in the message. Must be specified if the operation type is "Insert" (AP..1 = 1). Business Rules: AP.1.BR
AP.2	ev_code	string (0-60)	0 - 1	EudraVigilance (EV) Code The EV Code of the authorised medicinal product. Mandatory if the operation type is NOT an "insert" (AP..1 ≠ 1). Business Rules: AP.2.BR.

Reference Code	Reference Name		Data Type (Length)	Cardinality	Notes
AP.3	newownerid		string (0-60)	0 - 1	New Owner Identifier (ID) This field identifies the new Owner of the authorised product. The field is reserved for EMA use only. Business Rules: AP.3.BR.
AP.4	mahcode		string (0-60)	1	Marketing Authorisation Holder (MAH) Code The MAH code in relation to the marketing authorisation holder may be specified. If present, the element must have an attribute: Resolution Mode. Business Rules: AP.4.BR
	(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports, (contents; MAH name, country code, city) – should not be submitted
@ AP.4..1	(@) resolutionmode		int (Enum)	1	Resolution Mode Must be specified if the element AP.4 is present Resolution mode = 1 Local (Local Number present in the XML file). Resolution mode = 2 Global (EV Code present in the EudraVigilance Lookup Tables)

Reference Code	Reference Name		Data Type (Length)	Cardinality	Notes
AP.5	qppvcode		PositiveInteger (10 digits max)	0 - 1	Qualified Person Responsible for Pharmacovigilance (QPPV) The QPPV code, as assigned following the EudraVigilance registration of the QPPV, must be specified unless the operation type is "*nullification*" or "*Invalidate MA*". The format of this code is number (whole number up to 10 digits in length). This code can be retrieved in the EudraVigilance restricted area section under "QPPV list" (Gateway users) or in the look-up tables of the "QPPV" field (WebTrader Users). Business Rules: AP.5.BR. Change Log: V3 Change Log: V3.1
	(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports – should not be submitted
AP.6		mflcode	string (0-60)	0 - 1	Pharmacovigilance System Master File (MFL) Code The code for the MFL may be specified. If specified, then the resolution mode attribute must be specified. Business Rules: AP.6.BR. Change Log: V5.1 Change Log: V3
	(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains: (Country Code), City, Postcode, Street) – should not be submitted

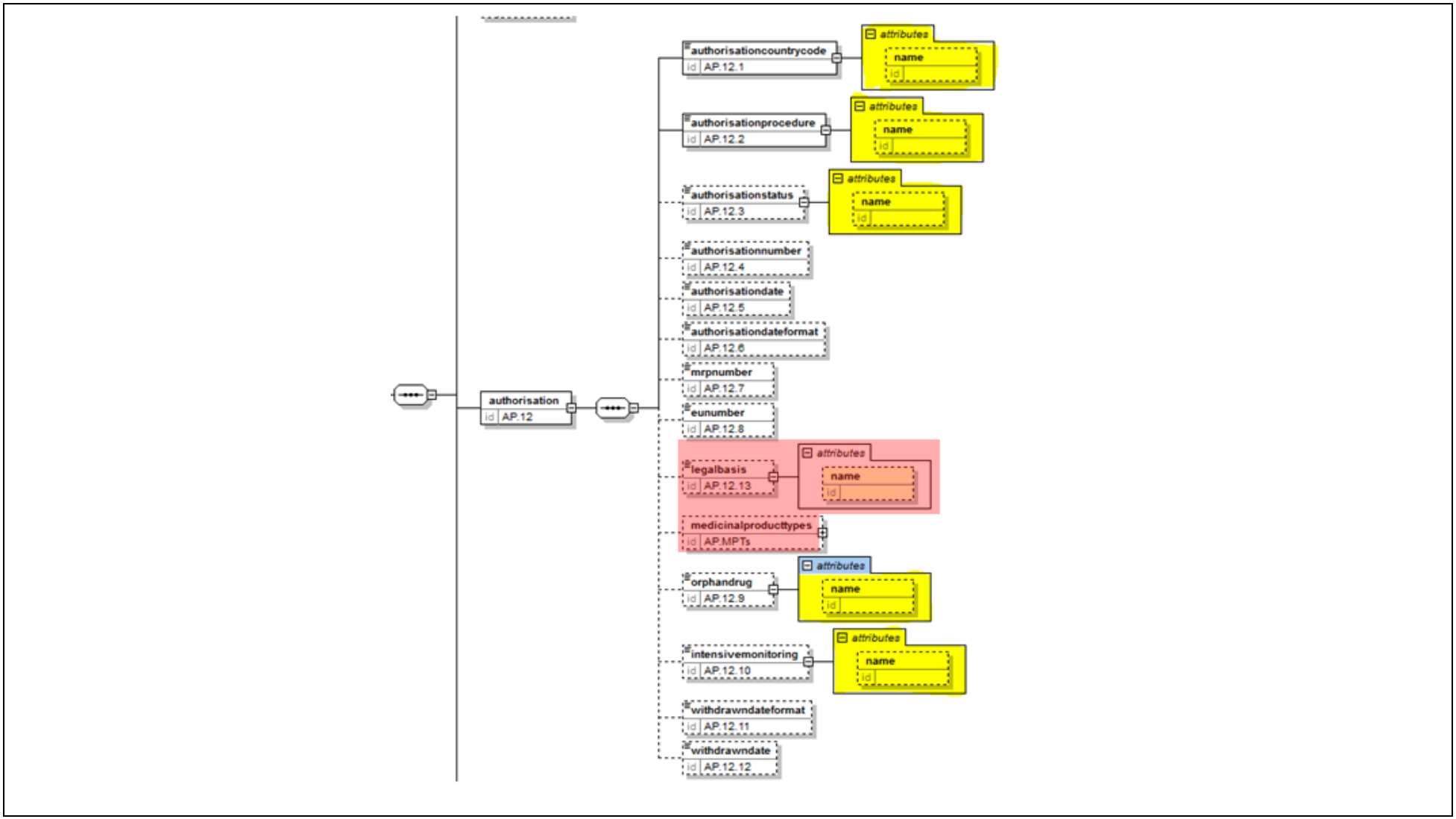
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
@ AP.6..1	(@) resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 Local (Local Number of master file location present in the current XML file). Resolution mode = 2 Global (EV Code present in the EudraVigilance Lookup Tables) The format of stored master file location codes is MFL123456.
AP.7	enquiryemail	string (0-100)	0 - 1	Enquiry Email The email address for pharmacovigilance enquiries may be specified. Business Rules: AP.7.BR
AP.8	enquiryphone	string (0-50)	0 - 1	Enquiry Phone Number The phone number for pharmacovigilance enquiries may be specified. Business Rules: AP.8.BR.
AP.9	senderlocalcode	string (0-100)	0 - 1	Sender Local Code The sender local code for the authorised medicinal product may be specified as applicable.
AP.10	infodateformat	string (Enum)	0 - 1	Information Date Format The date format of "infodate" (AP.11). The value permitted is "102" corresponding to "CCYYMMDD". Business Rules: AP.10.BR.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.11	infodate	string (0-14)	0 - 1	Information Date: Used in conjunction with "infodateformat" (AP10). Please, refer to "Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004: Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance" for additional guidance. Change Log: V3.1 Business Rules: AP.11.BR.
AP.12	authorisation	Sequence	1	This section contains all the information on the product authorisation/registration.
AP.13	presentationname	Sequence	1	This section contains all the information on the product presentation name.
AP.APFs	authpharmforms	Sequence	0 – 1	Version 5.0: Added This section contains information about the authorised pharmaceutical forms for an Authorised product. Business Rules: AP.APFs.BR
AP.ATCs	productatcs	Sequence	1	This section contains information on one or more ATC code for the authorised product. Business Rules: AP.ATCs.BR

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.INDs	productindications	Sequence	0 - 1	This section contains information on one or more indication for the authorised medicinal product. The section is mandatory if the product operation is "insert" or "update". Business Rules: AP.INDs.BR. Change Log: V3, V5.0(correction)
AP.PPs	pharmaceuticalproducts	Sequence	1	Pharmaceutical Product This section contains information on one or more pharmaceutical product in relation to an authorised medicinal product.
AP.PEVs	previousevcodes	Sequence	0 - 1	This section may be used to reference one or more EV Code of development products (if they exist in the XEVMPD) that are the same as the approved product. Business Rules: AP.PEVs.BR.
AP.PPIs	ppiattachments	Sequence	0 - 1	This section represents the container for the Printed Product Information attachment documents for the authorised product. Business Rules: AP.PPIs.BR.
AP.14	comments	string (0-500)	0 - 1	This element may be used to add comments. When the operation type is "Nullification", the comment field is mandatory and the reason for nullification must be provided. Business Rules: AP.14.BR.

3.I.b.12.1 Authorised Product - Authorisation (AP.12)

Figure 32. Authorised product - authorisation element structure (V4.1 Additions highlighted yellow, V5.0 additions highlighted red)


authorisation
id AP.12
authorisationcountrycode
id AP.12.1
attributes
name
id
authorisationprocedure
id AP.12.2
attributes
name
id
authorisationstatus
id AP.12.3
attributes
name
id
authorisationnumber
id AP.12.4
authorisationdate
id AP.12.5
authorisationdateformat
id AP.12.6
mrpnumber
id AP.12.7
eunumber
id AP.12.8
legalbasis
id AP.12.13
attributes
name
id
medicinalproducttypes
id AP.MPTs
orphandrug
id AP.12.9
attributes
name
id
intensivemonitoring
id AP.12.10
attributes
name
id
withdrawndateformat
id AP.12.11
withdrawndate
id AP.12.12

Back to parent element.

Table 32. Authorised Product – Authorisation element.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.12	authorisation	Sequence	**1**	This section contains all the information on the product authorisation.
AP.12.1	authorisationcountrycode	string (0-2)	1	Authorisation Country Code Country code of the country in which the product has been authorised must be specified. Business Rules: AP.12.1.BR
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains country name) – should not be submitted
AP.12.2	authorisationprocedure	integer (1)	1	Authorisation Procedure The authorisation procedure applied to a medicinal product must be specified, using the Authorisation Procedure Controlled Vocabulary. Business Rules: AP.12.2.BR
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains authorisation procedure name) – should not be submitted
AP.12.3	authorisationstatus	integer (2)	0 - 1	Authorisation Status The status of the authorisation of a medicinal product may be specified using the Authorisation Status Controlled Vocabulary. Business Rules: AP.12.3.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains authorisation status name) – should not be submitted

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.12.4	authorisationnumber	string (0-100)	0 - 1	Marketing Authorisation Number The marketing authorisation/registration number may be specified Business Rules: AP.12.4.BR.
AP.12.5	authorisationdate	string (0-14)	0 - 1	Marketing Authorisation (Status) Date The date of marketing authorisation/date of registration may be specified. Mandatory unless performing a nullification or Invalidate MA operation. Business Rules: AP.12.5.BR. Change Log: V3
AP.12.6	authorisationdateformat	string (Enum)	0 - 1	Marketing Authorisation Date Format If specified, the marketing authorisation/registration date format must be one of the following values as applicable: "102" corresponding to "CCYYMMDD" "610" corresponding to "CCYYMM" Business Rules: AP.12.6.BR.
AP.12.7	mrpnumber	string (0-50)	0 - 1	EMA/MRP/DCP/Registration Procedure Number Change Log: V3.1 Business Rules: AP.12.7.BR
AP.12.8	eunumber	string (0-50)	0 - 1	EU Authorisation Number Change Log: V3.1 Business Rules: AP.12.8.BR.

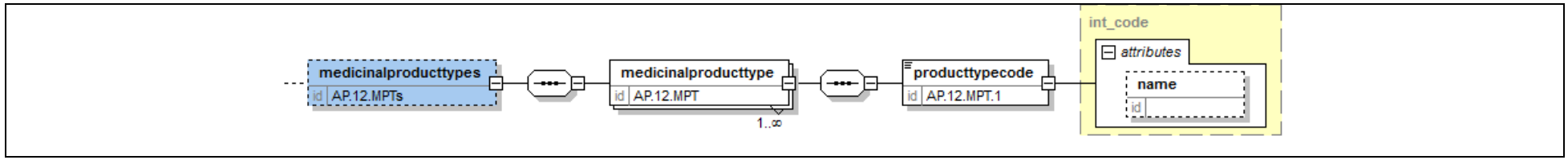
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.12.13	legalbasis	int (2)	0 - 1	V5.0: Added Section The legal basis for the authorisation of the product Business Rules: AP.12.13.BR
@NA	@name	string	0 - 1	Version 5.0: Name attribute for exports (contains legal basis name) – should not be submitted
AP.12.MPTs	medicinalproducttypes	sequence	0 – 1	V5.0: Added section For the authorised product each medicinal product type applicable shall be specified. Business Rules: AP.12.MPTs.BR
AP.12.9	orphandrug	int (Enum)	0 - 1	Orphan Drug This field is used to specify whether the medicinal product is an orphan drug or not. Must be specified, unless the operation type is "nullification" or "Invalidate MA". Business Rules: AP.12.9.BR Change Log: V3
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains yes/no)– should not be submitted
AP.12.10	intensivemonitoring	int (Enum)	0 - 1	Additional Monitoring If the medicinal product is subject to additional monitoring, then this field should be specified. 1 = medicinal product is subject to additional monitoring 2 = medicinal product is NOT subject to additional monitoring Business Rules: AP.12.10.BR

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains yes/no) – should not be submitted
AP.12.11	withdrawndateformat	string (Enum)	0 - 1	Invalidate MA Date Format V4.0: Updated Guidance If the MA has been invalidated, the date format for the value in AP.12.12 (withdrawndate) must be specified as value "102" corresponding to "CCYYMMDD". Note: Field name not changed to minimise technical impact. Business Rules: AP.12.11.BR
AP.12.12	withdrawndate	string (0-14)	0 - 1	Invalidate MA Date V4.0: Updated Guidance If the MA has been invalidated, the date when this occurred must be specified in this field. Note: Field name not changed to minimise technical impact. Business Rules: AP.12.12.BR

3.I.b.12.2 Authorisation – Medicinal Product Types (AP.12.MPTs)

This element is used to submit or update information on the medicinal product types for authorised medicinal products. The element is mandatory (controlled by business rules) for MAHs for all product operations except nullification.

Figure 33. Medicinal product type element structure (Added Version 5.0)



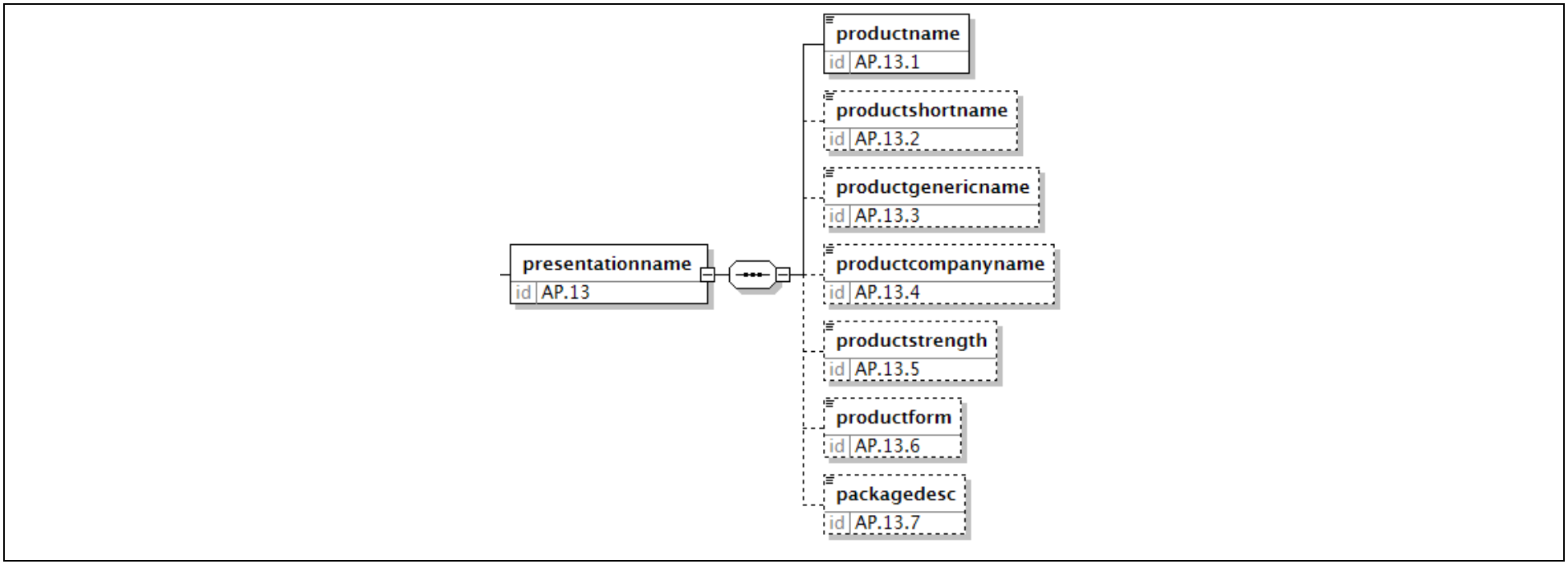
Back to parent element.

Table 33. Authorisation – Medicinal Product Type elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.12.MPT	medicinalproducttype	Sequence	1 - ∞	This section contains information for each pharmaceutical form as authorised of the authorised product. Change Log: V5.0
AP.12.MPT.1	producttypecode	int (2)	1	Product Type Code. If the parent element is present, then the code of a valid medicinal product type must be present. Change Log: V5.0 Business Rules: AP.12.MPT.1.BR
(@) NA	(@) name	string	0 – 1	Version 5.0: Name attribute for exports (contains medicinal product type description) – should not be submitted

3.I.b.12.3 Authorised Product - Presentation Name (AP.13)

Figure 34. Authorised product - Presentation name element structure



Back to parent element.

Table 34. Authorised Product – Presentation Name elements

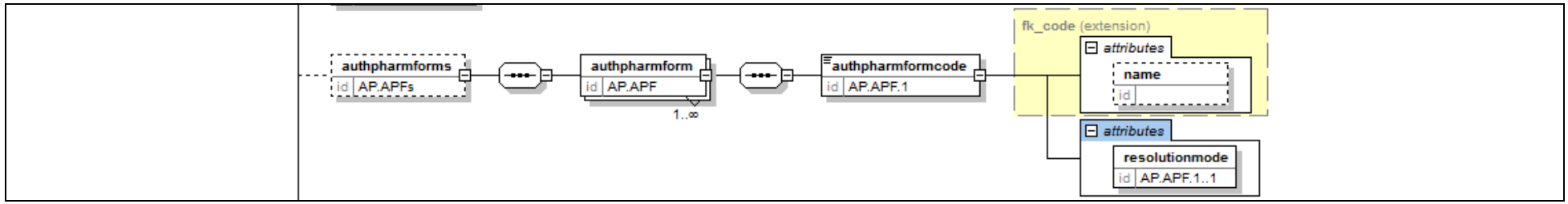
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.13	presentationname	Sequence	1	This section contains all the information on the authorised medicinal product name.
AP.13.1	productname	string (0-2000)	1	Full Presentation Name The "Full Presentation Name" of the medicinal product must be specified. Business Rules: AP.13.1.BR
AP.13.2	productshortname	string (0-250)	0-1	Product Short (Invented) Name The invented name part (if present) of the "Full Presentation Name." Either this or the product generic name (AP.13.3) must be specified. Business Rules: AP.13.2.BR. Change Log: V3
AP.13.3	productgenericname	string (0-1000)	0 - 1	Product Generic Name The generic name (if present) as part of the "Full Presentation Name." Either this or the product short name (AP.13.2) must be specified. Business Rules: AP.13.3.BR. Change Log: V3
AP.13.4	productcompanyname	string (0-250)	0 - 1	Product Trademark (Company) Name The name of company/trademark/manufacturer (if present) as part of the "Full Presentation Name" should be specified. Must be present if product short name is absent. Business Rules: AP.13.4.BR. Change Log: V3

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.13.5	productstrength	string (0-250)	0 - 1	Product Strength The strength and strength unit (if present) as part of the "Full Presentation Name" should be specified. Business Rules: AP.13.5.BR.
AP.13.6	productform	string (0-500)	0 - 1	Product (Pharmaceutical) Form The pharmaceutical form (if present) as part of the "Full Presentation Name" should be specified. Business Rules: AP.13.6.BR.
AP.13.7	packagedesc	string (0-2000)	0 - 1	Package Description The packaged presentation of the medicinal product may be specified.

3.I.b.12.4 Authorised Product – authpharmforms (AP.APFs)

This element is used to submit or update information on the pharmaceutical forms as authorised for authorised medicinal products. The element is mandatory (controlled by business rules) for MAHs for all product operations except nullification.

Figure 35. Authorised product - Authorised Pharmaceutical Forms element structure (Added V5.0)



Back to parent element.

Table 35. Authorised product - Authorised Pharmaceutical Form elements

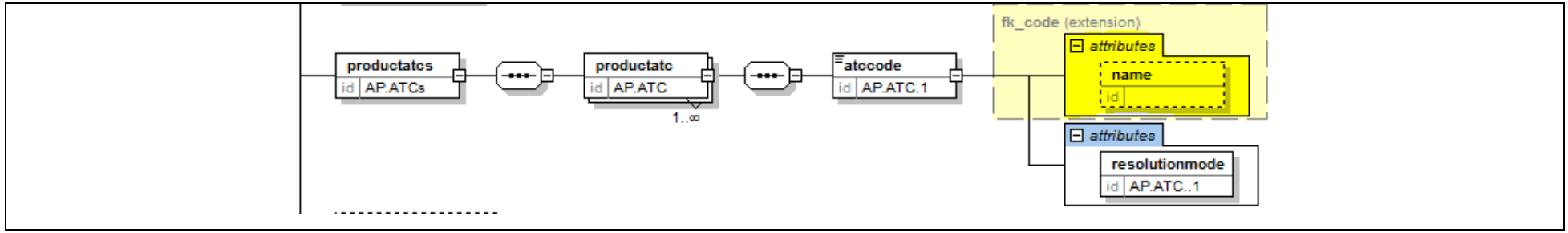
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.APF	authpharmform	Sequence	1 - ∞	This section contains information for each pharmaceutical form as authorised of the authorised product. Change Log: V5.0
AP.APF.1	authpharmformcode	string (0–60)	1	Authorised Pharmaceutical Form Code. If the parent element is present, then the code of a valid pharmaceutical form must be present Change Log: V5.0 Business Rules: AP.APF.1.BR

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
@ AP.APF..1	resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 Local (Local Number of master file location present in the current XML file). Resolution mode = 2 Global (EV Code present in the EudraVigilance Lookup Tables) The format of stored pharmaceutical form codes is PHF123456. Change Log: V5.0
(@) NA	(@) name	string	0 – 1	Version 5.0: Name attribute for exports (contains [form type[2]] + name of the pharmaceutical form as authorised) - should not be submitted

3.I.b.12.5 Authorised Product – Product ATCs (AP.ATCs)

This mandatory section is used to submit or update information on the ATC codes applicable to authorised medicinal products. The element must contain at least one ATC (AP.ATC) element which is repeatable if appropriate.

Figure 36. Authorised product - ATC element structure (Updated V4.1 highlighted in yellow)



[2] Either [Standard], [Proposed] or [Development]

Back to parent element.

Table 36. Authorised Product – ATC elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.ATC	Productatc	Sequence	1 - ∞	This section contains information for each ATC code of the authorised product. Change Log: V3
AP.ATC.1	Atccode	string (0-60)	1	ATC Code The ATC code of the authorised product must be specified. The ATC code must have an attribute: Resolution Mode. Business Rules: AP.ATC.1.BR. Change Log: V3
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains [ATC Type[3]] + ATC code description)– should not be submitted
@ AP.ATC..1	(@) resolutionmode	int (Enum)	1	Resolution Mode: Resolution mode = 1 Local (Local key of ATC Code present in the current XML file) Resolution mode = 2 Global (EV Code present in the Eudravigilance Lookup Tables) Change Log: V3

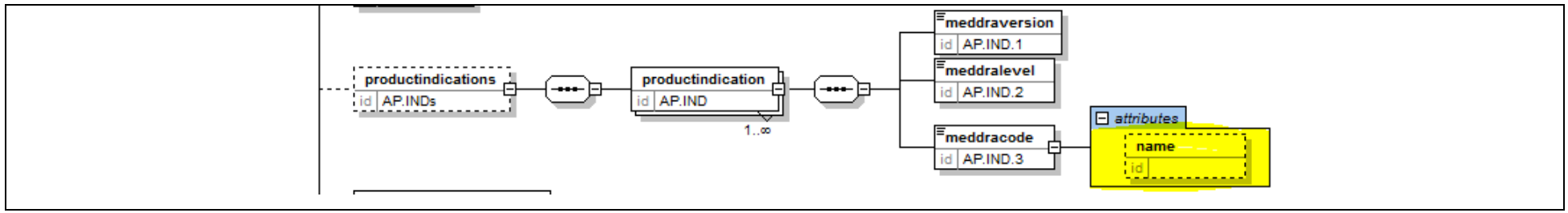
[3] Either [Standard], [Proposed] or [Development]

3.I.b.12.6 Authorised Product - Product Indications (AP.INDs)

This section is used to submit or update information on the indications for which the product is authorised. Indications are specified via MedDRA codes. Whilst the indications element is optional, business rules are in place to mandate that the section must be present if the product operation is "insert" or "update" (AP.INDs.BR). The element must contain at least one Indication (AP.IND) element which is repeatable if appropriate.

Change Log: V3, V5.0 correction

Figure 37. Authorised product - Indication element structure (Updated V4.1 [yellow highlight])



Back to parent element.

Table 37. Authorised Product –Product Indication elements

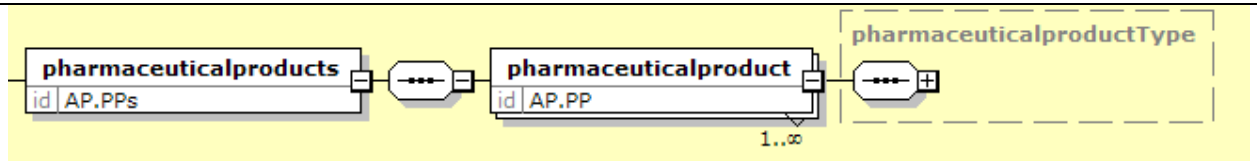
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.IND	productindication	Sequence	1 - ∞	This repeatable section describes each indication of a medicinal product.
AP.IND.1	meddraversion	decimal (3(.1))	1	MedDRA Version MedDRA version must be specified. In case of nullification or invalidation the business rule applied is relaxed and MedDRA version is not validated. Business Rules: AP.IND.1.BR. Modified in V5.3
AP.IND.2	meddralevel	string (Enum)	1	MedDRA Level The level of the MedDRA hierarchy applied to code the indication must be specified. The most granular level should be used.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.IND.3	meddracode	int (8)	1	MedDRA Code The MedDRA code for the indication term must be specified. The most granular term/level appropriate should be specified. Business Rules: AP.IND.3.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains the term name) - should not be submitted

3.I.b.12.7 Authorised Product - Pharmaceutical Product (AP.PP)

The pharmaceutical product section is shared by both authorised products and development products, the structure of the element is the same in both cases, but different business rules apply. For detailed information about the structure refer to the pharmaceutical product section presented below the Authorised Product section.

Figure 38. The pharmaceutical products section in authorised products



Back to parent element.

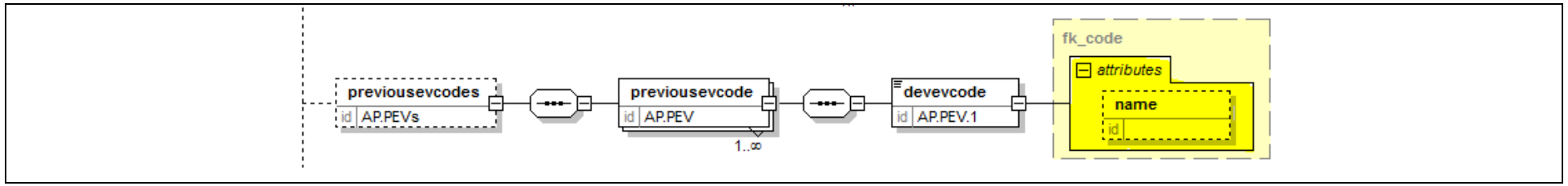
Table 38. The Authorised Product – Pharmaceutical Product container.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.PP	pharmaceuticalproduct	Sequence	1 - ∞	This section describes the pharmaceutical product, which refers to the medicinal product in terms of its qualitative and quantitative composition and in the pharmaceutical dose form authorised for administration in line with the summary of product characteristics. For certain medicines, a

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
				device can form an integral part of the medicinal product, for example to support the administration of the medicine. In these instances, the pharmaceutical product contains the device component information as an additional characteristic.

3.I.b.12.8 Authorised Product - Previous EV Code (AP.PEV)

Figure 39. Authorised product – previous EV Code element structure (Updated V4.1 [yellow highlight])



This optional element may be used to specify any EV Codes, if applicable, by which the development equivalent of the authorised product is known. If it is not required then the container element (previousevcodes) may be omitted.

Back to parent element.

Table 39. The Authorised Product – Previous EV Code elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.PEV	previousevcode	Sequence	1 - ∞	This repeatable section describes a previous EudraVigilance (EV) Code applicable to an authorised product.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.PEV.1	devevcode	string (0-60)	1	Development EV Code Update: V4.0 If the authorised product is in the xEVMPD as a development product or another product with an invalidated MA, then this field contains the EV Code of the previous product. Replaces: Business Rules: AP.PEV.1.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains [product type[4]] + either the full presentation name if referenced product is authorised or the product name if it is development) – should not be submitted

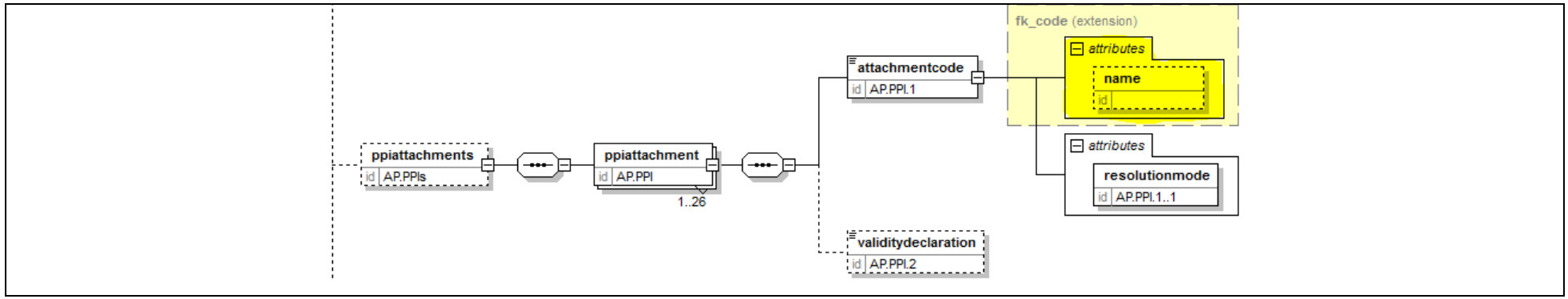
[4] Either[Authorised] or [Development]

3.I.b.12.9 Authorised Product - Printed Product Information (AP.PPI)

This section provides the means to associate a submitted printed product information (PPI) attachment with an authorised medicinal product.

The section may be used up to 26 times per product in order to associate the information in several languages where necessary.

Figure 40. The printed product information section in authorised products (Updated V4.1 [yellow highlight])



Back to parent element.

Table 40. The Authorised Product – Printed Product Information Attachment elements

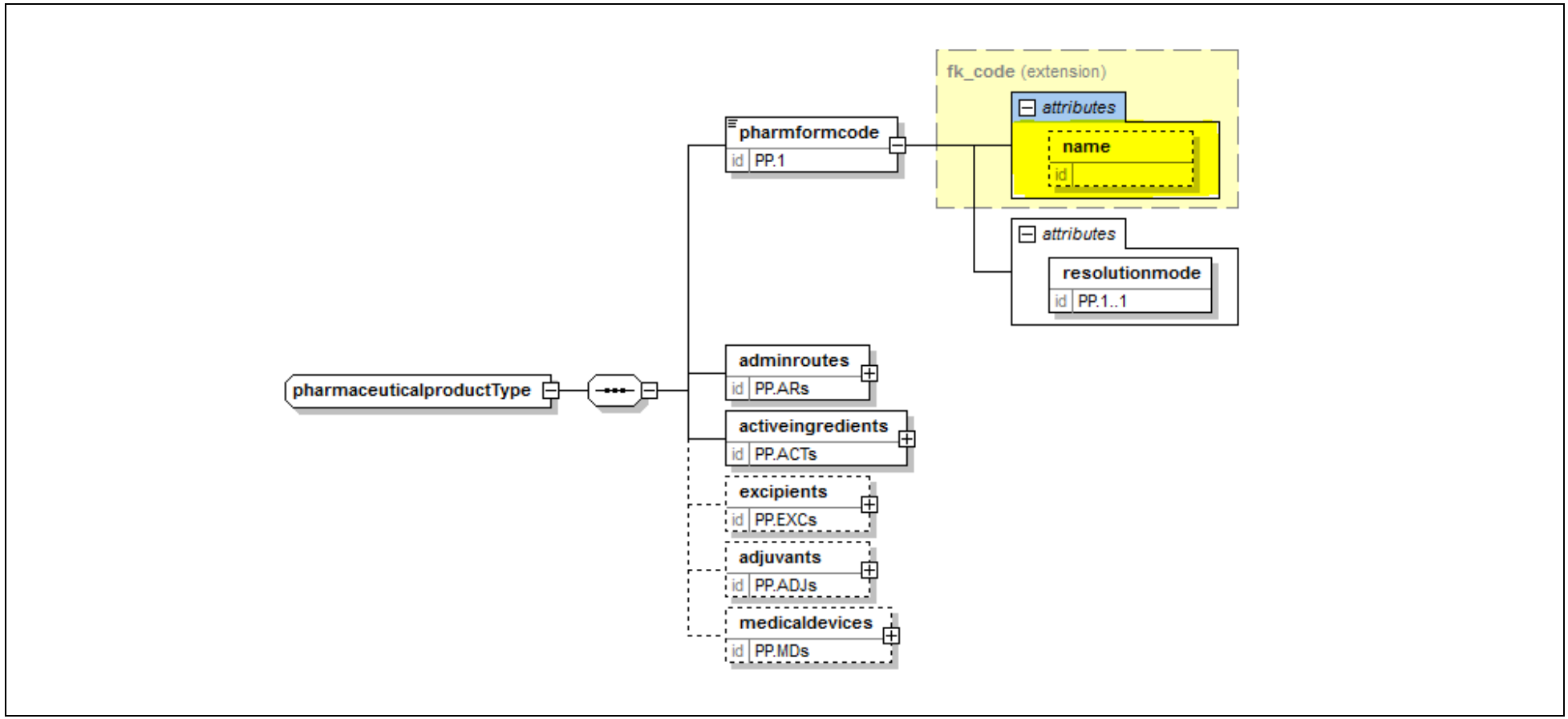
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.PPI	ppiattachment	Sequence	1 - 26	Contains details for each individual Printed Product Information (PPI) document (e.g., SmPC, PIL, Annexes) in a specific language for the authorised medicinal product.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.PPI.1	attachmentcode	string (0-60)	1	Attachment Code This field references the attachment for the authorised medicinal product. If the code is for an attachment already in the XEVMPD then the pattern of the EV Code is 'ATT' followed by six digits. This element must have an attribute: Resolution Mode. Business Rules: AP.PPI.1.BR Change Log: V3
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains the name given at the time of attachment submission) – should not be submitted
@ AP.PPI.1..1	(@) resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 Local (Local Number present in the XML file). Resolution mode = 2 Global (EV Code of the attachment present in the EudraVigilance Lookup Tables.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.PPI.2	validitydeclaration	int (Enum)	0 - 1	Validity Declaration During an insert of an authorised product, where the referenced PPI attachment is loaded in the XEVMPD, a confirmation must be provided that the referenced attachment is the latest version of the documentation. The value 1 specifies that the attachment is the latest version. During an update of an authorised product, where PPI attachment is referenced, the business rule is relaxed, and it is not required to specify the validity declaration. Business Rules: AP.PPI.2.BR. Change Log: V3, V5.3

3.I.b.13 Pharmaceutical Product (PP)

Figure 41. Pharmaceutical Product element structure (Updated V4.1 [yellow highlight])



This element is used for both development and authorised medicinal products. The element includes several repeatable elements each of which is detailed below.

[Back to development product pharmaceutical products]

Back to authorised product pharmaceutical products

Table 41. The Pharmaceutical Product elements

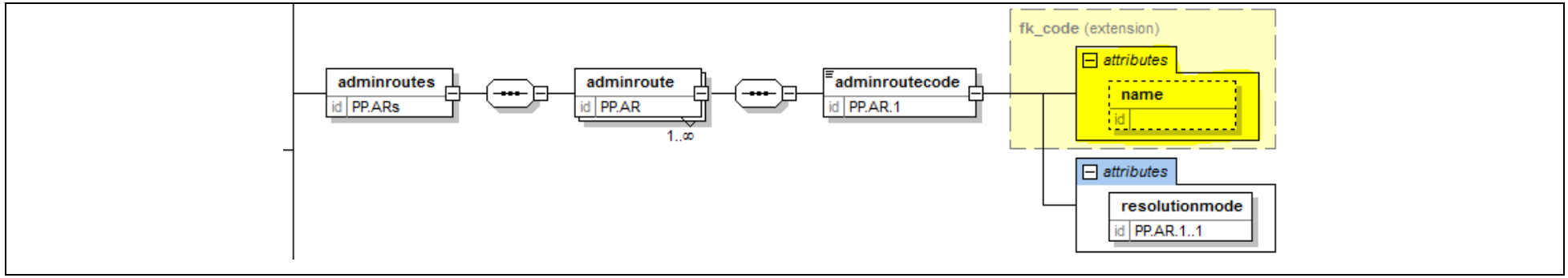
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
AP.PP and DP.PP	pharmaceuticalproduct	Sequence	1 - ∞	This section contains information about each pharmaceutical product. Update Log: V3
PP.1	pharmformcode	string (0-60)	1	Pharmaceutical (Dose) Form Code The pharmaceutical form of the medicinal product must be specified. The pharmaceutical form must have an attribute: Resolution Mode. Business Rules: AllProducts.PP.1.BR.1. Business Rules: AuthProducts.PP.1.BR.1
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains [form type[5]] + name of the pharmaceutical form) - should not be submitted
@ PP.1..1	(@) resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 Local (Local Number present in the XML file) Resolution mode = 2 Global (EV Code present in the EudraVigilance Lookup Tables)
PP.ARs	adminroutes	Sequence	1	This section contains information on all of the routes of administration of the medicinal product. Business Rules: AllProducts.PP.ARs.BR.
PP.ACTs	activeingredients	Sequence	1	This section must contain information about all active ingredients of the medicinal product. Business Rules: AllProducts.PP.ACTs.BR.

[5] Either [Standard], [Proposed] or [Development]

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.EXCs	excipients	Sequence	0 - 1	This section may contain information about all excipients of the medicinal product as required by the product. Business Rules: AllProducts.PP.EXCs.BR.
PP.ADJs	adjuvants	Sequence	0 - 1	This section may contain information about all adjuvants of the medicinal product as required by the product. Business Rules: AllProducts.PP.ADJs.BR.
PP.MDs	medicaldevices	Sequence	0 - 1	This section contains information about all medical devices, which form a integral part of the medicinal product. Business Rules: AllProducts.PP.MDs.BR.

3.I.b.13.1 Pharmaceutical Product – Administration Route (PP.AR)

Figure 42. Pharmaceutical Product element structure (Updated V4.1 [yellow highlight])



Back to parent element

Table 42. The Pharmaceutical Product – Administration Route element.

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.AR	adminroute	Sequence	**1 - ∞**	This section contains information for each route of administration of a medicinal product.
PP.AR.1	adminroutecode	string (0-60)	1	Administration Route The route of administration of the medicinal product must be specified. The administration route must have an attribute: Resolution Mode. Business Rules: AllProducts.PP.AR.1.BR. Business Rules: AuthProducts.PP.AR.1.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains [admin route type[6]] + name of the administration route) - should not be submitted

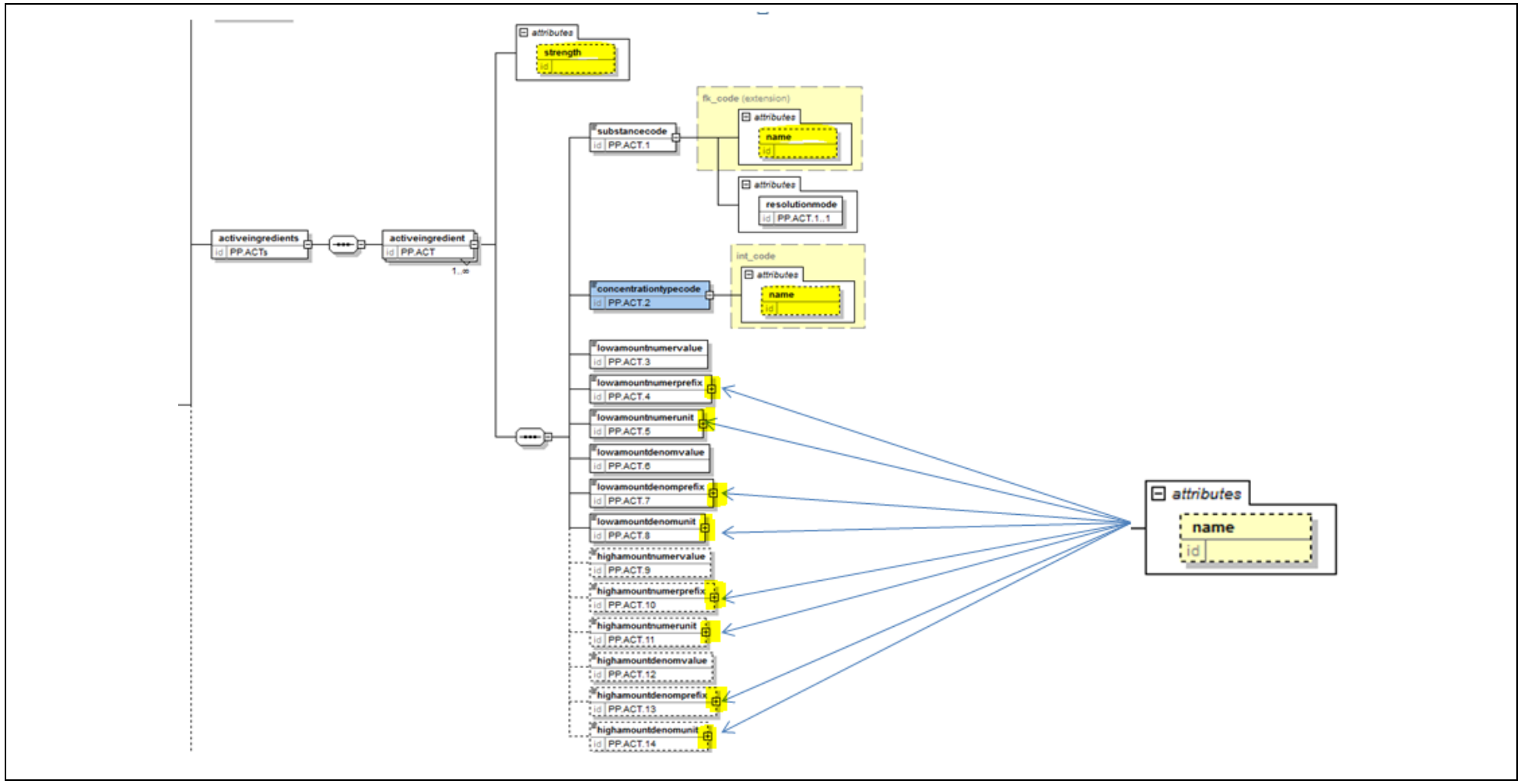
[6] Either [Standard], [Proposed] or [Development]

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
@ PP.AR.1..1	(@) resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 Local (Local Number present in the XML file) Resolution mode = 2 Global (EV Code present in the EudraVigilance Lookup Tables)

3.I.b.13.2 Pharmaceutical Product - Active Ingredient (PP.ACT)

For guidance for the usage of the amount fields please see Appendix 2.

Figure 43. Pharmaceutical Product active ingredient element structure (Updated V4.1 [yellow highlight])



Back to parent element

Table 43. The Pharmaceutical Product – Active Ingredient element

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.ACT	activeingredient	Sequence	1 - ∞	This section contains information for each active ingredient of a pharmaceutical product.
(@) NA	(@) strength	string	0 - 1	Version 4.1: strength attribute for exports (contains a short description of the strength e.g. 300 M G / Tablet) – should not be submitted
PP.ACT.1	substancecode	string (0-60)	1	(Active) Substance Code The reference code for the active substance of the medicinal product must be specified. This element must have an attribute: Resolution Mode. Business Rules: DevProducts.PP.ACT.1.BR. Business Rules: AuthProducts.PP.ACT.1.BR
(@) NA	(@)name	string	0 - 1	Version 4.1: Name attribute for exports (contains [substance type[7]] + substance PREFERRED name) – should not be submitted
@ PP.ACT.1..1	(@)resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 Local (Local Number present in the XML file) Resolution mode = 2 Global (EV Code present in the EudraVigilance Lookup Tables)
PP.ACT.2	concentrationtypecode	integernullable	1	Concentration Type Code The reference code for the concentration type must be specified in accordance with the Controlled Vocabulary: **Concentration Type** Business Rules: AllProducts.PP.ACT.2.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains value of concentration code used) – should not be submitted

[7] Either [Approved] or [Development]

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.ACT.3	lowamountnumervalue	double	1	Low Amount Numerator Value The low limit amount numerator value or for non-range measurements the amount numerator value must be specified.
PP.ACT.4	lowamountnumerprefix	string (0-12)	1	Low Amount Numerator (Unit) Prefix The low limit amount numerator prefix or for non-range measurements the amount numerator prefix must be specified as a value from the Controlled Vocabulary: **XEVMPD Prefix Unit.** Business Rules: AllProducts.PP.ACT.4.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[8] – should not be submitted
PP.ACT.5	lowamountnumerunit	string (0-70)	1	Low Amount Numerator Unit The low limit amount numerator unit or for non-range measurements the amount numerator unit must be specified as a value from the Controlled Vocabulary: **XEVMPD Numerator Unit.** Business Rules: AllProducts.PP.ACT.5.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports – should not be submitted
PP.ACT.6	lowamountdenomvalue	double	1	Low Amount Denominator Value The low limit amount denominator value or for non-range measurements the amount denominator value must be specified.
PP.ACT.7	lowamountdenomprefix	string (0-12)	1	Low Amount Denominator Prefix The low limit amount denominator prefix or for non-range measurements the amount denominator prefix must be specified as a value from the Controlled Vocabulary: **XEVMPD Prefix Unit.** Business Rules: AllProducts.PP.ACT.7.BR.

[8] All ingredient measurement unit @name attributes contain the unit value from the referenced list

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[8] – should not be submitted
PP.ACT.8	lowamountdenomunit	string (0-70)	1	Low Amount Denominator Unit The low limit denominator unit or for non-range measurements the amount numerator unit must be specified as a value from the Controlled Vocabulary: **XEVMPD Denominator Unit** (either Unit of Measurement or Unit of Presentation). Business Rules: AllProducts.PP.ACT.8.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[9] – should not be submitted
PP.ACT.9	highamountnumervalue	double	0 - 1	High Amount Numerator Value The high limit amount numerator value must ONLY be specified when a range is described. Business Rules: AllProducts.PP.ACT.9.BR.
PP.ACT.10	highamountnumerprefix	string (0-12)	0 - 1	High Amount Numerator Prefix The high limit amount numerator prefix must ONLY be specified when a range is described. Must be specified as a value from the Controlled Vocabulary: **XEVMPD Prefix Unit.** Business Rules: AllProducts.PP.ACT.10.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[9] – should not be submitted

[9] All ingredient measurement unit @name attributes contain the unit value from the referenced list

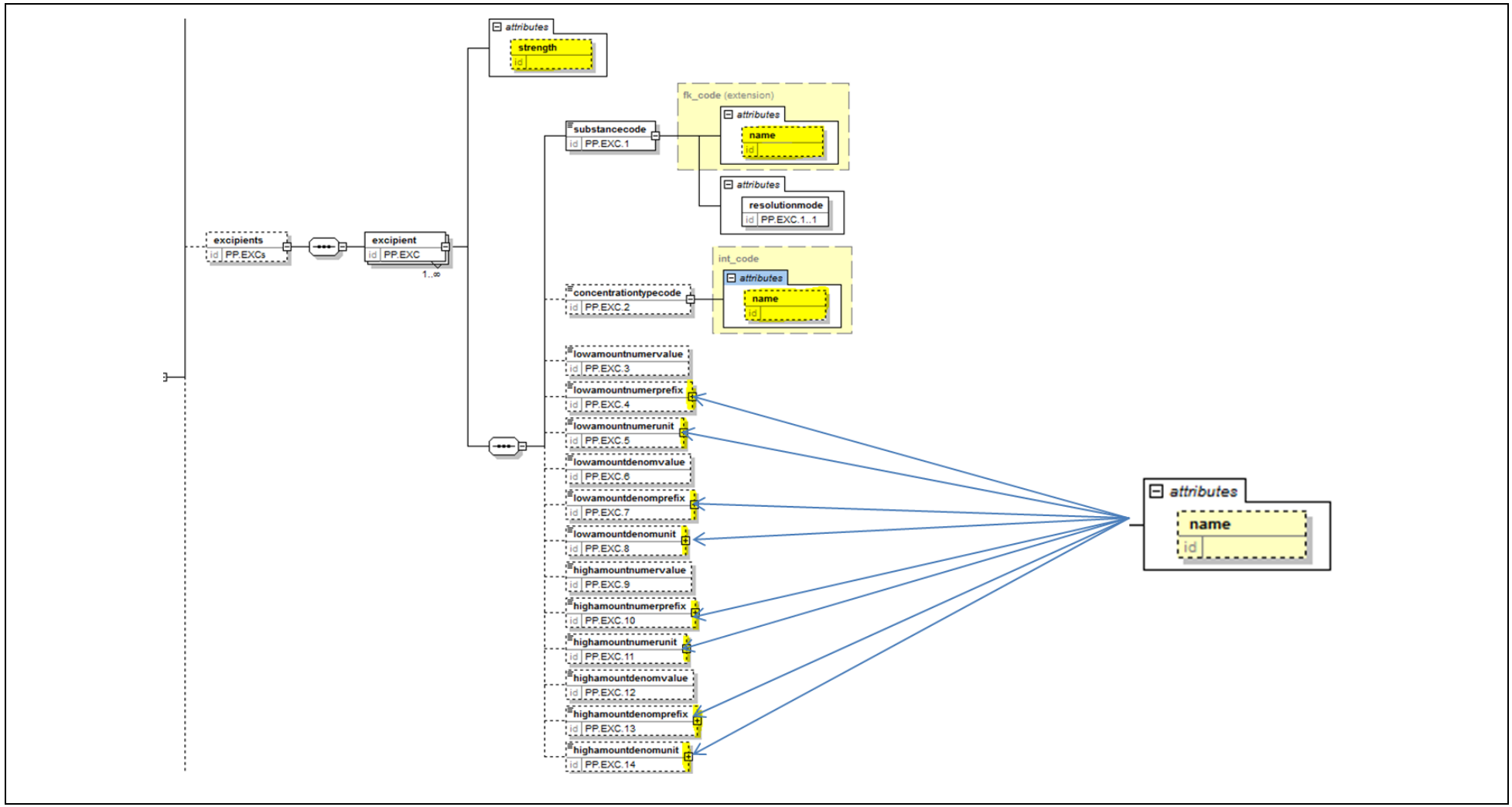
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.ACT.11	highamountnumerunit	string (0-70)	0 - 1	High Amount Numerator Unit The high limit amount numerator unit must ONLY be specified when a range is described. Must be specified as a value from the Controlled Vocabulary: **XEVMPD Numerator Unit.** Business Rules: AllProducts.PP.ACT.11.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[9] – should not be submitted
PP.ACT.12	highamountdenomvalue	double	0 - 1	High Amount Denominator Value The high limit amount denominator value must ONLY be specified when a range is described. Business Rules: AllProducts.PP.ACT.12.BR.
PP.ACT.13	highamountdenomprefix	string (0-12)	0 - 1	High Amount Denominator Prefix The high limit amount denominator prefix must ONLY be specified when a range is described. Must be specified as a value from the Controlled Vocabulary: **XEVMPD Prefix Unit.** Business Rules: AllProducts.PP.ACT.13.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[10] – should not be submitted
PP.ACT.14	highamountdenomunit	string (0-70)	0 - 1	High Amount Denominator Unit The high limit amount denominator unit must ONLY be specified when a range is described. Must be specified as a value from the Controlled Vocabulary: **XEVMPD Denominator Unit** (either Unit of Measurement or Unit of Presentation). Business Rules: AllProducts.PP.ACT.14.BR.

[10] All ingredient measurement unit @name attributes contain the unit value from the referenced list

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[10]– should not be submitted

3.I.b.13.3 Pharmaceutical Product – Excipient (PP.EXP)

Figure 44. Pharmaceutical Product excipient element structure (Updated V4.1 [yellow highlight])



Back to parent element

Table 44. Pharmaceutical Product – Excipient Ingredient element

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.EXC	excipient	Sequence	1 - ∞	This section contains information for each excipient of a pharmaceutical product and should be completed where an excipient forms a part of the pharmaceutical product.
(@) NA	(@) strength	string	0 - 1	Version 4.1: strength attribute for exports (contains a short description of the strength e.g. 300 M G / Tablet) – should not be submitted
PP.EXC.1	substancecode	string (0-60)	1	(Excipient) Substance Code The reference code for the excipient of the medicinal product must be specified. This element must have an attribute: Resolution Mode. Business Rules: DevProducts.PP.EXC.1.BR. Business Rules: AuthProducts.PP.EXC.1.BR
(@) NA	(@)name	string	0 - 1	Version 4.1: Name attribute for exports (contains [substance type[11]] + substance PREFERRED name) – should not be submitted
@ PP.EXC.1..1	(@)resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 Local (Local Number present in the XML file) Resolution mode = 2 Global (EV Code present in the EudraVigilance Lookup Tables)
PP.EXC.2	concentrationtypecode	integernullable	0 - 1	Concentration Type Code The reference code for the concentration type may be specified in accordance with the Controlled Vocabulary: **Concentration Type** Business Rules: AllProducts.PP.EXC.2.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains value of concentration type code used) – should not be submitted

[11] Either [Approved] or [Development]

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.EXC.3	lowamountnumervalue	Double	0 - 1	Low Amount Numerator Value The low limit amount numerator value or for non-range measurements the amount numerator value may be specified. Business Rules: AllProducts.PP.EXC.3.BR.
PP.EXC.4	lowamountnumerprefix	string (0-12)	0 - 1	Low Amount Numerator (Unit) Prefix The low limit amount numerator prefix or for non-range measurements the amount numerator prefix may be specified as a value from the Controlled Vocabulary: **XEVMPD Prefix Unit.** Business Rules: AllProducts.PP.EXC.4.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[12] – should not be submitted
PP.EXC.5	lowamountnumerunit	string (0-70)	0 - 1	Low Amount Numerator Unit The low limit amount numerator unit or for non-range measurements the numerator unit may be specified. If specified then it must be a value from the Controlled Vocabulary: **XEVMPD Numerator Unit.** Business Rules: AllProducts.PP.EXC.5.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[12] – should not be submitted
PP.EXC.6	lowamountdenomvalue	Double	0 - 1	Low Amount Denominator Value The low limit amount denominator value or for non-range measurements the amount denominator value may be specified. Business Rules: AllProducts.PP.EXC.6.BR.

[12] All ingredient measurement unit @name attributes contain the unit value from the referenced list

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.EXC.7	lowamountdenomprefix	string (0-12)	0 - 1	Low Amount Denominator Prefix The low limit amount denominator prefix or for non-range measurements the amount denominator prefix may be specified. If specified, then it must be a value from the Controlled Vocabulary: **XEVMPD Prefix Unit.** Business Rules: AllProducts.PP.EXC.7.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports exports[13] – should not be submitted
PP.EXC.8	lowamountdenomunit	string (0-70)	0 - 1	Low Amount Denominator Unit The low limit denominator unit or for non-range measurements the amount numerator unit may be specified. If specified then it must be a value from the Controlled Vocabulary: **XEVMPD Denominator Unit** (either Unit of Measurement or Unit of Presentation). Business Rules: AllProducts.PP.EXC.8.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[13] – should not be submitted
PP.EXC.9	highamountnumervalue	Double	0 - 1	High Amount Numerator Value The high limit amount numerator value must ONLY be specified when a range is described. Business Rules: AllProducts.PP.EXC.9.BR.

[13] All ingredient measurement unit @name attributes contain the unit value from the referenced list

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.EXC.10	highamountnumerprefix	string (0-12)	0 - 1	High Amount Numerator Prefix The high limit amount numerator prefix must ONLY be specified when a range is described. Must be specified as a value from the Controlled Vocabulary: **XEVMPD Prefix Unit.** Business Rules: AllProducts.PP.EXC.10.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[14] – should not be submitted
PP.EXC.11	highamountnumerunit	string (0-70)	0 - 1	High Amount Numerator Unit The high limit amount numerator unit must ONLY be specified when a range is described. Must be specified as a value from the Controlled Vocabulary: **XEVMPD Numerator Unit.** Business Rules: AllProducts.PP.EXC.11.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[14] – should not be submitted
PP.EXC.12	highamountdenomvalue	Double	0 - 1	High Amount Denominator Value The high limit amount denominator value must ONLY be specified when a range is described. Business Rules: AllProducts.PP.EXC.12.BR.

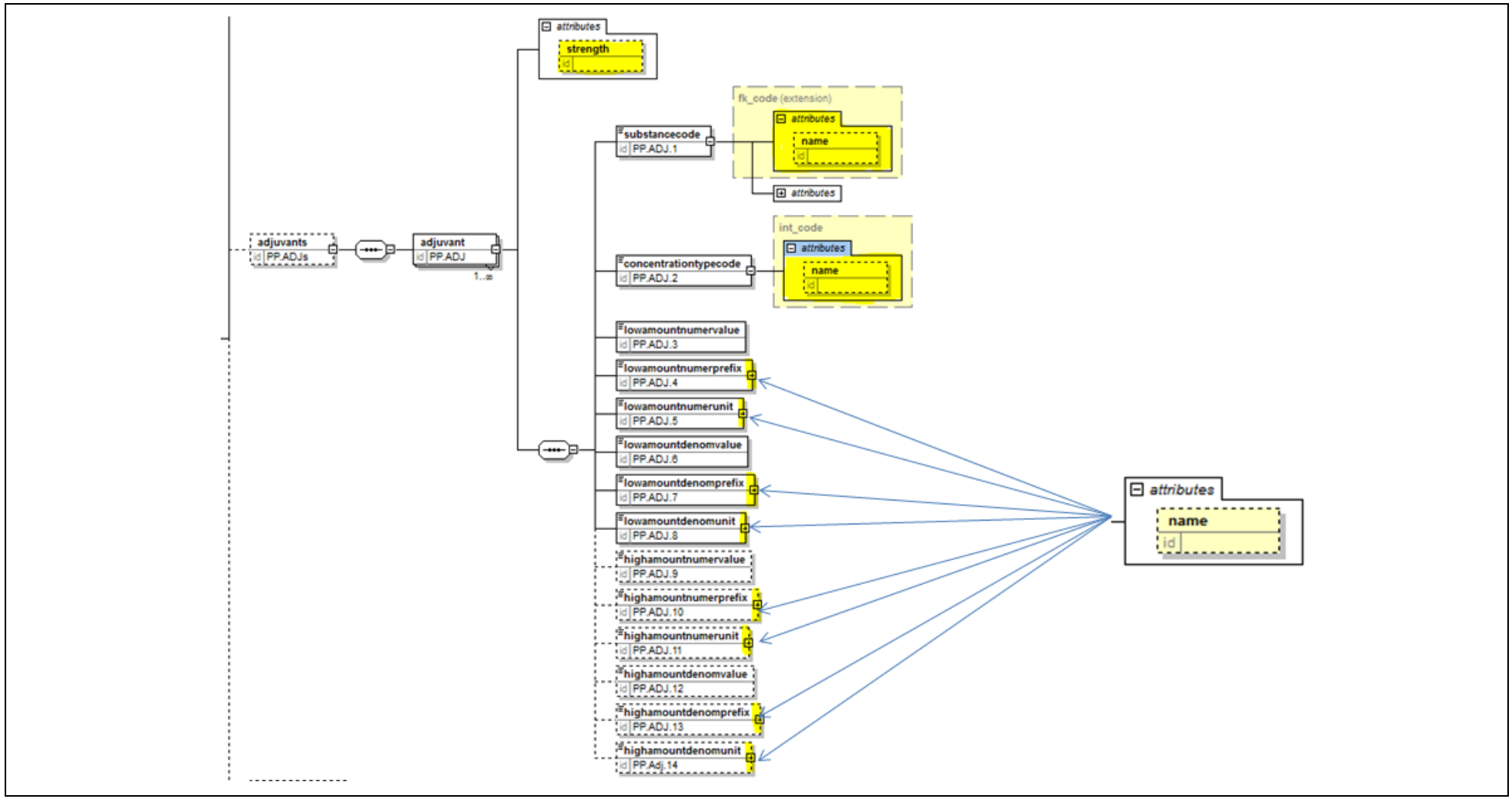
[14] All ingredient measurement unit @name attributes contain the unit value from the referenced list

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.EXC.13	highamountdenomprefix	string (0-12)	0 - 1	High Amount Denominator Prefix The high limit amount denominator prefix must ONLY be specified when a range is described. Must be specified as a value from the Controlled Vocabulary: **XEVMPD Prefix Unit.** Business Rules: AllProducts.PP.EXC.13.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[15] – should not be submitted
PP.EXC.14	highamountdenomunit	string (0-70)	0 - 1	High Amount Denominator Unit The high limit amount denominator unit must ONLY be specified when a range is described. Must be specified as a value from the Controlled Vocabulary: **XEVMPD Denominator Unit** (either Unit of Measurement or Unit of Presentation). Business Rules: AllProducts.PP.EXC.14.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[15] – should not be submitted

[15] All ingredient measurement unit @name attributes contain the unit value from the referenced list

3.I.b.13.4 Pharmaceutical Product – Adjuvant (PP.ADJ)

Figure 45. Pharmaceutical Product adjuvant element structure (Updated V4.1 [yellow highlight])



Back to parent element

Table 45. The Pharmaceutical Product – Adjuvant elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.ADJ	adjuvant	Sequence	1 - ∞	This section contains information for each adjuvant ingredient of a pharmaceutical product.
(@) NA	(@) strength	string	0 - 1	Version 4.1: strength attribute for exports (contains a short description of the strength e.g. 300 M G / Tablet) – should not be submitted
PP.ADJ.1	substancecode	string (0-60)	1	(Adjuvant) Substance Code The reference code for the adjuvant substance of the medicinal product must be specified. This element must have an attribute: Resolution Mode. Business Rules: DevProducts.PP.ADJ.1.BR. Business Rules: AuthProducts.PP.ADJ.1.BR
(@) NA	(@)name	string	0 - 1	Version 4.1: Name attribute for exports (contains [substance type[16]] + substance PREFERRED name) – should not be submitted
@ PP.ADJ.1..1	(@) resolutionmode	int (Enum)	1	Resolution Mode Resolution mode = 1 Local (Local Number present in the XML file) Resolution mode = 2 Global (EV Code present in the EudraVigilance Lookup Tables)
PP.ADJ.2	concentrationtypecode	integernullable	1	Concentration Type Code The reference code for the concentration type must be specified in accordance with the Controlled Vocabulary: **Concentration Type** Business Rules: AllProducts.PP.ADJ.2.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains value of concentration type code used) – should not be submitted

[16] Either [Approved] or [Development]

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.ADJ.3	lowamountnumervalue	double	1	Low Amount Numerator Value The low limit amount numerator value or for non-range measurements the amount numerator value must be specified.
PP.ADJ.4	lowamountnumerprefix	string (0-12)	1	Low Amount Numerator (Unit) Prefix The low limit amount numerator prefix or for non-range measurements the amount numerator prefix must be specified as a value from the Controlled Vocabulary: **XEVMPD Prefix Unit.** Business Rules: AllProducts.PP.ADJ.4.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[17] – should not be submitted
PP.ADJ.5	lowamountnumerunit	string (0-70)	1	Low Amount Numerator Unit The low limit amount numerator unit or for non-range measurements the amount numerator unit must be specified as a value from the Controlled Vocabulary: **XEVMPD Numerator Unit.** Business Rules: AllProducts.PP.ADJ.5.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[17] – should not be submitted
PP.ADJ.6	lowamountdenomvalue	double	1	Low Amount Denominator Value The low limit amount denominator value or for non-range measurements the amount denominator value must be specified.
PP.ADJ.7	lowamountdenomprefix	string (0-12)	1	Low Amount Denominator Prefix The low limit amount denominator prefix or for non-range measurements the amount denominator prefix must be specified as a value from the Controlled Vocabulary: **XEVMPD Prefix Unit.** Business Rules: AllProducts.PP.ADJ.7.BR.

[17] All ingredient measurement unit @name attributes contain the unit value from the referenced list

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[17] – should not be submitted
PP.ADJ.8	lowamountdenomunit	string (0-70)	1	Low Amount Denominator Unit The low limit denominator unit or for non-range measurements the amount numerator unit must be specified as a value from the Controlled Vocabulary: **XEVMPD Denominator Unit** (either Unit of Measurement or Unit of Presentation). Business Rules: AllProducts.PP.ADJ.8.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[18] – should not be submitted
PP.ADJ.9	highamountnumervalue	double	0 - 1	High Amount Numerator Value The high limit amount numerator value must ONLY be specified when a range is described. Business Rules: AllProducts.PP.ADJ.9.BR.
PP.ADJ.10	highamountnumerprefix	string (0-12)	0 - 1	High Amount Numerator Prefix The high limit amount numerator prefix must ONLY be specified when a range is described. Must be specified as a value from the Controlled Vocabulary: **XEVMPD Prefix Unit.** Business Rules: AllProducts.PP.ADJ.10.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[18] – should not be submitted

[18] All ingredient measurement unit @name attributes contain the unit value from the referenced list

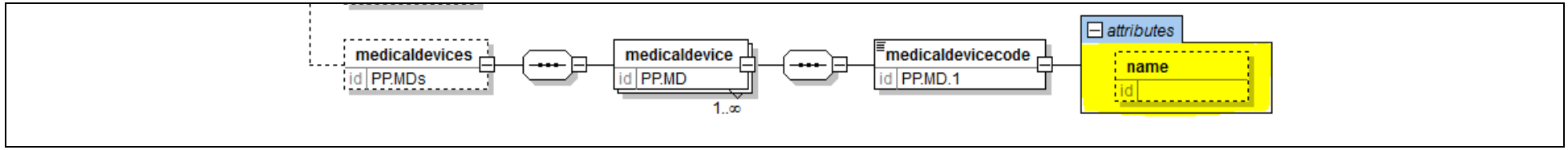
Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.ADJ.11	highamountnumerunit	string (0-70)	0 - 1	High Amount Numerator Unit The high limit amount numerator unit must ONLY be specified when a range is described. Must be specified as a value from the Controlled Vocabulary: **XEVMPD Numerator Unit**. Business Rules: AllProducts.PP.ADJ.11.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[18] – should not be submitted
PP.ADJ.12	highamountdenomvalue	double	0 - 1	High Amount Denominator Value The high limit amount denominator value must ONLY be specified when a range is described. Business Rules: AllProducts.PP.ADJ.12.BR.
PP.ADJ.13	highamountdenomprefix	string (0-12)	0 - 1	High Amount Denominator Prefix The high limit amount denominator prefix must ONLY be specified when a range is described. Must be specified as a value from the Controlled Vocabulary: **XEVMPD Prefix Unit.** Business Rules: AllProducts.PP.ADJ.13.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[19] – should not be submitted

[19] All ingredient measurement unit @name attributes contain the unit value from the referenced list

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.ADJ.14	highamountdenomunit	string (0-70)	0 - 1	High Amount Denominator Unit The high limit amount denominator unit must ONLY be specified when a range is described. Must be specified as a value from the Controlled Vocabulary: **XEVMPD Denominator Unit** (either Unit of Measurement or Unit of Presentation). Business Rules: AllProducts.PP.ADJ.14.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports[19] – should not be submitted

3.I.b.13.5 Pharmaceutical Product – Medical Device (PP.MD)

Figure 46. Pharmaceutical Product medical device element structure



Back to parent element

Table 46. The Pharmaceutical Product – Medical Device elements

Reference Code	Reference Name	Data Type (Length)	Cardinality	Notes
PP.MD	medicaldevice	Sequence	1 - ∞	This section describes the code of a medical device where it forms an integral part of the medicinal product. .
PP.MD.1	medicaldevicecode	int	1	Medical Device Code The reference code for the medical device of the medicinal product must be specified. Must be a value from the Controlled Vocabulary: **Medical devices**. Business Rules: AllProducts.PP.MD.1.BR.
(@) NA	(@) name	string	0 - 1	Version 4.1: Name attribute for exports (contains name value of code) – should not be submitted

3.I.c Business Rules Overview

In addition to the rules implemented within the XEVPRM schema, the Agency has implemented several business rules to control the accuracy and quality of the data supplied, to aid the business process and support the lifecycle management of the XEVMPD entities.

Each of these rules is described in the tables below with a direct reference to the section or field to which the rule applies.

3.I.c.1 Explanation of the meaning of key words used in business rules

Table 47. Definitions used within this document.

Term/Abbreviation	Definition
EV Group	This is a group of senders within the EV Registration System that are affiliates of an HQ organisation and includes that HQ organisation.
present	If rules state that a value must be *,* this means that the element must be *present* and must contain a value that does not equate to white space i.e. removal of all non-printing and whitespace characters still leaves a value with length > 0
empty	If rules state that a value must be *empty* this means that the element must conform to one of the following rules; Be absent Take the form <element></element> Take the form <element/>
available	In order to be available to a sender, the term must conform to certain conditions; If the term is not a development term and is checked (i.e., flagged as 'valid') then it is globally available, If a term is not a development term and is not checked (i.e., flagged as 'valid'), then it is only available to the EV Group of the sender Development terms are only ever available to the EV Group of the sender.
checked	A term within the XEVMPD made 'checked' (i.e., flagged as 'valid') by the EMA. This status means that the data submitted has been validated and accepted by the Agency. Once checked, the visibility of the term becomes global subject to overriding confidentiality rules. Data submitted as development, even if checked, will remain confidential and only visible to the owner organisation and the EMA.
is reserved for the EMA	The referenced element or value must only be *present* if the user is the EMA. Fields that are reserved for EMA use only must be *empty* if the message sender is not the EMA – if any organisation sends data conflicting with the rule the entire message is rejected. "EMA Reserved" fields are included to allow the Agency to perform maintenance operations.
is required for the EMA	If the EMA is the sender of the message, then a value must be *present* in the referenced field. This rule is associated with operations that require the use of fields that are reserved for the EMA.

Term/Abbreviation	Definition
Synonym	A synonym is defined as any current alternative name (translation, alias, or alias translation) by which a substance is identified.
current	The term current refers to any entity stored within the XEVMPD that is not nullified.

3.I.c.2 Conventions used within the business rules section of this document

Where a word or phrase refers to a section within the XEVRM then **bold type** is used.

Where a word or phrase refers to a field within the XEVPRM then *italic type* is used.

Where a word or phrase refers to the meaning of a value within the current XEVPRM then the meaning is enclosed in quotes and the actual field reference/value follows in parenthesis e.g., if the *operation type* is "insert" (field xyz = 1) then ….

Where a word of phrase refers to a value contained within the EVMPD, or lookup lists then ***bold italic type*** is used.

3.I.d Business Rule Tables

The following tables detail each business rule governing the data quality and accuracy within the XEVMPD. Each rule is uniquely referenced and the rules for each element provide a link to the referenced element in the schema documentation section.

3.I.d.1 EVPRM (M)

Table 48. Business rules for (X)EVPRM Root Element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
M Back	M.BR.1	The **EVPRM** element must contain a single **messageheader** element and at least one of the other child elements.	

Failure to comply leads to the generation of an *03* acknowledgement and the entire message is rejected.

3.I.d.2 ICHICSR Message Header Type (M.H)

Table 49. Business rules for the Message Header elements

Element Ref	Rule Ref	Description	Dependent Rules / Notes
H.5 Back	H.5.BR.1	The *message sender identifier* must match an active ***organisation*** registered with the EV System.	
H.6.BR Back	H.6.BR.1	If the message is submitted to the EudraVigilance Production environment, the *message receiver* must be EVHUMAN.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	H.6.BR.2	If the message is submitted to the EudraVigilance Test (External Compliance [XCOMP]) environment, *the message receiver* must be EVTEST.	
H.8 Back	H.8.BR.1	The *message date* must be before the current time/date (GMT) + 12 hours.	
	H.8.BR.2	The format of the data supplied must conform to "CCYYMMDDHHMMSS".	

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

3.I.d.3 Organisations (M.Os)

Table 50. Business rules for the Organisations elements

Element Ref	Rule Ref	Description	Dependent Rules / Notes
M.Os Back	M.Os.BR.1	Key Constraint: Each **organisation** must be uniquely identified within the **Organisations section** by either the *local number* or the *EV Code*.	

Failure to comply leads to the generation of an *03* acknowledgement and the entire message is rejected.

3.I.d.3.1 Organisation Type (O)

Table 51. Business rules for the Organisation element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
O..1 Back	O..1.BR.1	If the **organisation** *operation type* is 2 or 4 then the **message header** *sender organisation* must be part of the same ***EV Group*** as the owner of the ***organisation*** being updated.	
	O..1.BR.2	If the **organisation** *operation type* is 4 then a *comment* must be *present*.	
	O..1.BR.3	If the ***organisation*** is *checked* by the EMA, then it cannot be nullified except by the EMA.	
	O..1.BR.4	If the **organisation** *operation type* is 4, then the ***organisation*** to be nullified must not be referenced by ~~any other current XEVMPD entity~~: • an authorised medicinal product entity referencing the (valid) authorisation statuses 1, 2, 8, and/or 9 and/or • a not-nullified development medicinal product entity.	V5.3 Rule modified

Element Ref	Rule Ref	Description	Dependent Rules / Notes
O.3 Back	O.3.BR.1	The *local number* must be *present* if the value of the *operation type* field (O..1) is 1.	
	O.3.BR.2	If the value of the *operation type* field (O..1) is 2 or 4 then the *local number* must be *empty*.	
O.4 Back	O.4.BR.1	The *EV Code* of the **organisation** must be *present* if the value of the *operation type* field (0..1) is 2 or 4.	
	O.4.BR.2	The *EV Code* of the **organisation** must match an ***EV Code*** for an active ***organisation*** within the XEVMPD.	
	O.4.BR.3	If the value of the *operation type* field (O..1) is 1 then the *EV Code* must be *empty*.	
O.6 Back	O.6.BR.1	If the value of *operation type* is not "nullify" (O..1 ≠ 4) then this field must be *present*.	V3: Rule Added.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
O.9 Back	O.9.BR.1	If the value of *operation type* is not "nullify" (O..1 ≠ 4), then this field must be *present*	V3: Rule Added.
O.10 Back	O.10.BR.1	The *country code* must match a ***two-letter code in the published list*** of acceptable codes.	
O.18 Back	O.18.BR.1	If the *operation type* is "nullification" (O..1 = 4), then a *comment* must be *present*.	O..1.BR.2 O..1.BR.3
0.19 Back	O.19.BR.1	If the value of organisation type is "Sponsor" (O.1 = 2) then this field must be *absent*	V5.0: Rule Added Violation code: 500
	O.19.BR.2	If the value of organisation type is "MAH" (O.1 = 1) AND the *operation type* is "insert" or "update" (O..1 < 4) AND the **message header** *sender* (H.5) is NOT the EMA then this field must be present	V5.0: Rule Added V5.0 Correction Violation code: 501
0.20 Back	O.20.BR.1	If sme_status is empty or "NA" (O.19 *absent* or O.19 = 1), then this field must be *absent*	V5.0 Rule Added V5.0 Correction Violation code: 502
NA	O.DUP.BR.1	If the organisation type is MAH (O.1 = 1) AND the *operation type* is "insert" or "update" (O..1 < 4), then the combination of the following fields must not match those of the same fields for another MAH in the xEVMPD: •Organisation Name (O.3) •Address (O. 6) •City (O.7) •Post Code (O.9) •Country Code (O.10)	V5.0 Rule Added V5.0 Correction Violation code: 503
NA	O.DUP.BR.2	If the organisation type is Sponsor (O.1 =2) AND the operation type is "insert" or "update" (O..1 < 4) then the combination of the following fields must not match those of the same fields for another sponsor in the xEVMPD: •Organisation Name (O.3) •City (O.7) •Country Code (O.10)	V5.0 Correction: Rule Added Violation code: 71

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

3.I.d.4 Sources (M.Ss)

Table 52. Business rules for the sources element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
M.Ss Back	M.Ss.BR.1	Key Constraint: Each **source** must be uniquely identified within the **Sources** section by either the *local number* or the *EV Code*.	

Failure to comply leads to the generation of an *03* acknowledgement and the entire message is rejected.

3.I.d.4.1 Source Type (S)

Table 53. Business rules for the source element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
S..1 Back	S..1.BR.1	If the **source** *operation type* is 2 or 4 then the **message header** *sender organisation* must be part of the same ***EV Group*** as the ***owner*** of the ***source*** in the XEVMPD being updated. From 18 January 2024, sources can only be inserted in the XEVMPD by EMA.	V3.1: Rule amended.
	S..1.BR.2	If the **source** *operation type* is 4 then a *comment* must be *present*.	S.4.BR.1
	S..1.BR.3	If the ***source*** is *checked* by the EMA then it cannot be nullified except by the EMA.	
	S..1.BR.4	If the **source** *operation type* is 4 then the ***source*** to be nullified must not be referenced by any other current XEVMPD entity.	
S.1 Back	S.1.BR.1	The *local number* must be *present* if the value of the *operation type* field (S..1) is 1.	
	S.1.BR.2	If the value of *operation type* field (S..1) is 2 or 4 then the *local number* must be *empty*.	
S.2 Back	S.2.BR.1	The *EV Code* of the source must be *present* if the value of the *operation type* field (S..1) is 2 or 4.	
	S.2.BR.2	The *EV Code* of the **source** must match an ***EV Code*** for a current ***source*** within the XEVMPD.	
	S.2.BR.3	If the value of the *operation type* field (S..1) is 1 then this field must be *empty*.	
S.3 Back	S.3.BR.1	The *source name* must NOT already exist as a current ***source name*** in the XEVMPD.	
S.4 Back	S.4.BR.1	If the *operation type* is "nullification" (S..1 = 4) then a *comment* must be *present*.	S..1.BR.2 S..1.BR.3

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

3.I.d.5 Standard Terminology (M.ST)

3.I.d.5.1 ATCs (ST.ATCs)

Table 54. Business rules for the ATCs element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
ST.ATCs Back	ST.ATCs.BR.1	Key Constraint: Each **ATC** must be uniquely identified within the **ATCs element** by the *ATC Code.*	V.3: Updated Text

Failure to comply leads to the generation of a *03* acknowledgement and the entire message is rejected.

ATC Type (ST.ATC)

Table 55. Business rules for the ATC element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
ST.ATC..1 Back	ST.ATC..1.BR.1	If the **ATC** *operation type* is 2 or 4 then the **message header** *sender organisation* (H.5) must be part of the same ***EV Group*** as the owner of the ***ATC*** in the XEVMPD being updated.	
	ST.ATC..1.BR.2	If the **ATC** *operation type* is 4, then a *comment* must be *present*.	ST.ATC.7.BR.1
	ST.ATC..1.BR.3	If the **ATC** *operation type* is 4, then the ***ATC*** in the XEVMPD to be nullified must not be used in any product.	ST.ATC.7.BR.1
	ST.ATC..1.BR.4	If the **ATC** *operation type* is 4, then the ***ATC*** in the XEVMPD to be nullified must not be referenced by ~~any other current XEVMPD ***product*** entity.~~: • an authorised medicinal product entity referencing the (valid) authorisation statuses 1, 2, 8, and/or 9 and/or • a not-nullified development medicinal product entity.	V5.3 Rule modified
ST.ATC.1 Back	ST.ATC.1.BR.1	**ATC** *type term* = 3 *is reserved for EMA* use only	
ST.ATC.2 Back	ST.ATC.2.BR.1	If the *type term* is "proposed" or "development" (ST.ATC.2 = 1 or 2) and the *operation type* is "insert" (ST.ATC..1 = 1) then the *ATC code* must not match a current standard ***ATC code*** in the XEVMPD.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	ST.ATC.2.BR.2	If the *type term* is "proposed" (ST.ATC.1 = 2) and the operation type is "insert" (ST.ATC..1 = 1) then the *ATC code* must not match a current proposed ***ATC code*** that is *available* to the same *EV Group*	
	ST.ATC.2.BR.3	If the *type term* is "development" (ST.ATC.1 = 1) and the *operation type* is "insert" (ST.ATC..1 = 1) then the *ATC code* must not match a current development ***ATC code*** that was submitted by the same ***EV Group*** in the XEVMPD.	
ST.ATC.3 Back	ST.ATC.3.BR.1	This field *is reserved for EMA* use only.	
	ST.ATC.3.BR.2	If the **ATC** *type term* is 1 then this field *is required for EMA.*	
ST.ATC.4 Back	ST.ATC.4.BR.1	If the *operation type* is "insert" (ST.ATC..1 = 1) then the ATC code description must be *present*.	
	ST.ATC.4.BR.2	If the operation type is "update" then the ATC code description must be *present*.	
ST.ATC.5 Back	ST.ATC.5.BR.1	If the version date (ST.ATC.6) is *present* then this field must be *present*.	V.3 Rule added
ST.ATC.6 Back	ST.ATC.6.BR.1	If the version date format (ST.ATC.5) is *present* then this field must be *present.*	V.3 Rule added
	ST.ATC.6.BR.2	If the version date is *present* then the date supplied must not occur later than the current date/time (GMT) + twelve hours.	V.3 Rule added
ST.ATC.7 Back	ST.ATC.7.BR.1	If the operation type is nullification (ST.ATC..1 = 4) then a comment must be *present.*	V.3. Rule added ST.ATC..1.BR.2 ST.ATC..1.BR.3

Failure to comply with any of the rules above leads to the generation of a *03* acknowledgement and the entire message is rejected.

3.I.d.5.2 Pharmaceutical Forms (ST.PFs)

Table 56. Business rules for the pharmaceutical forms element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
ST.PFs Back	ST.PFs.BR.1	Key Constraint: Each **pharmaceutical form** must be uniquely identified within the **pharmaceutical forms** element by either the *local number* or the *EV Code*.	

Failure to comply leads to the generation of an *03* acknowledgement and the entire message is rejected.

Pharmaceutical Form Type (ST.PF)

Table 57. Business rules for the pharmaceutical form elements

Element Ref	Rule Ref	Description	Dependent Rules / Notes
ST.PF..1 Back	ST.PF..1.BR.1	If the **Pharmaceutical Form** *operation type* is 2 or 4 AND the type term is "*development*" (ST.PF.1 = 1) then the message header *sender organisation* (H.5) must be part of the same ***EV Group*** as the ***owner*** of the ***pharmaceutical form*** being updated in the XEVMPD.	V4.0 Rule updated V4.0 Added related rules ST.PF..1.BR.4/5
	ST.PF..1.BR.2	If the **pharmaceutical form** *operation type* is 4 then a *comment* must be *present*.	ST.PF.9.BR.1
	ST.PF..1.BR.3	The **pharmaceutical form** cannot be nullified if it is referenced by ~~any current ***product*** in the XEVMPD.:~~ • an authorised medicinal product entity referencing the (valid) authorisation statuses 1, 2, 8, and/or 9 and/or • a not-nullified development medicinal product entity.	ST.PF.9.BR.1 V5.3 Rule modified
	ST.PF..1.BR.4	If the *type term* is proposed (ST.PF.1 = 2) then the operation type "Update" (ST.PF..1 = 2) *is reserved for EMA*	V4.0 Rule added
	ST.PF..1.BR.5	If the *type term* is proposed (ST.PF.1 = 2) then the operation type "Nullify" (ST.PF..1 = 4) *is reserved for EMA*	V4.0 Rule added
ST.PF.1 Back	ST.PF.1.BR.1	The *type term* of the **pharmaceutical form** must be specified. Type = 3 *is reserved for EMA* use only.	
ST.PF.2 Back	ST.PF.2.BR.1	The *local number* must be *present* if the value of the *operation type* field (ST.PF..1) is 1.	
	ST.PF.2.BR.2	If the value of **pharmaceutical form** *operation type* (ST.PF..1) is 2 or 4 then the *local number* field must be *empty*.	
ST.PF.3 Back	ST.PF.3.BR.1	The *EV Code* of the **source** must be *present* if the value of field S..1 is 2 or 4.	
	ST.PF.3.BR.2	If the value of **pharmaceutical form operation type** (ST.PF..1) is 1 then the *EV Code* field must be *empty*.	
ST.PF.4	ST.PF.4.BR.1	This field *is reserved for EMA* use only	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
Back	ST.PF.4.BR.2	If there is a value in this field then this must correspond to a valid ***organisation ID*** in the EV system. The referenced user must have permissions to send development pharmaceutical forms to the XEVMPD	
	ST.PF.4.BR.3	If the *operation type* is "insert" (ST.PF..1 = 1) and the *term type* is "development" (ST.PF.1 = 1) then this field *is required for the EMA.*	
ST.PF.5 Back	ST.PF.5.BR.1	If the *type term* is "development" (ST.PF.1 = 1) then the *pharmaceutical form name* must not match a current ***development pharmaceutical form name*** that was successfully submitted to the XEVMPD by the same ***EV Group***.	
	ST.PF.5.BR.2	If the *type term* is "proposed" (ST.PF.1 = 2) then the **pharmaceutical form** *name* must not match a current ***proposed pharmaceutical form name*** that was successfully submitted to the XEVMPD by the same ***EV Group***.	
	ST.PF.5.BR.3	If the *type term* is "proposed" (ST.PF.1 = 2) then the **pharmaceutical form** *name* must not match a current **pharmaceutical form** that is available to the message sender.	
ST.PF.6 Back	ST.PF.6.BR.1	If the *version date* (ST.PF.7) is *present* then this field must be *present*.	
ST.PF.7 Back	ST.PF.7.BR.1	If the *version date format* (ST.PF.6) is *present* then this field must be *present*	
	ST.PF.7.BR.2	The date supplied must not occur later than the current date/time (GMT) + twelve hours.	
ST.PF.8 Back	ST.PF.8.BR.1	If the *term type* is "development" (ST.PF.1 = 1) then this field must be *empty.*	
	ST.PF.8.BR.2	If a value is given then it must match an ***EV Code*** for an existing ***pharmaceutical form*** in the XEVMPD.	
ST.PF.9 Back	ST.PF.9.BR.1	If the value of *operation type* is "nullification" (ST.PF..1 = 4) then a *comment* must be *present.*	ST.PF..1.BR.2

Failure to comply with any of the rules above leads to the generation of a *03* acknowledgement and the entire message is rejected.

3.I.d.5.3 Administration Routes (M.ST.ARs)

Table 58. Business rules for the administration routes element

Element Ref	Rule Ref	Description	Dependent Rules / Notes

Element Ref	Rule Ref	Description	Dependent Rules / Notes
ST.ARs Back	ST.ARs.BR.1	Key Constraint: Each **administration route** must be uniquely identified within the **administration routes** element by either the *local number* or the *EV Code*.	

Failure to comply leads to the generation of a *03* acknowledgement and the entire message is rejected.

Administration Route (ST.AR)

Table 59. Business rules for the administration route elements

Element Ref	Rule Ref	Description	Dependent Rules / Notes
ST.AR..1 Back	ST.AR..1.BR.1	If the **administration route** *operation type* is 2 or 4 AND the type term is "*development*" (ST.AR.1 = 1) then the message header *sender organisation* (H.5) must be part of the same ***EV Group*** as the ***owner*** of the ***administration route*** being updated in the XEVMPD.	V4.0 Rule updated V4.0: Added ST.AR..1.BR4/5 for proposed terms
	ST.AR..1.BR.2	If the **administration route** *operation type* is 4 then a *comment* must be *present*.	ST.AR.9.BR.1
	ST.AR..1.BR.3	The **administration route** cannot be nullified if is referenced by ~~any ***product*** in the XEVMPD.~~ • an authorised medicinal product entity referencing the (valid) authorisation statuses 1, 2, 8, and/or 9 and/or • a not-nullified development medicinal product entity.	ST.AR.9.BR.1 V5.3 Rule modified
	ST.AR..1.BR.4	If the *type term* is proposed (ST.AR.1 = 2) then the operation type "Update" (ST.AR..1 = 2) *is reserved for EMA*	V4.0 Rule added
	ST.AR..1.BR.5	If the *type term* is proposed (ST.AR.1 = 2) then operation type "Nullify" (ST.AR..1 = 4) *is reserved for EMA*	V4.0 Rule added
ST.AR.1 Back	ST.AR.1.BR.1	The *type term* of the **administration route** must be specified. Type 3 *is reserved for the EMA.*	
ST.AR.2 Back	ST.AR.2.BR.1	The *local number* must be *present* if the value of field ST.AR..1 is 1.	V.3 Added rule text.
	ST.AR.2.BR.2	If the **administration route** *operation type* (ST.AR..1) value is 2 or 4 then the *local number* field must be *empty*.	
ST.AR.3 Back	ST.AR.3.BR.1	The *EV Code* of the **administration route** must be *present* if the value of field ST.AR.1 is 2 or 4.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	ST.AR.3.BR.2	If the value of administration route is "insert" (ST.AR..1 = 1) then the EV Code field must be *empty*.	
ST.AR.4 Back	ST.AR.4.BR.1	This field *is reserved for the EMA*.	
	ST.AR.4.BR.2	If the *operation type* is "insert" (ST.AR..1 = 1) and the *type term* is "development" (ST.AR.1 = 1) then this field *is required for the EMA.*	
ST.AR.5 Back	ST.AR.5.BR.1	If the value of *type term* is "development" (ST.AR.1 = 1) then the **administration route** *name* must not match a current ***development administration route name*** that was successfully submitted to the XEVMPD by the same EV Group.	
	ST.AR.5.BR.2	If the value of *type term* is "proposed" (ST.AR.1 = 1) then the **administration route** *name* must not match a current **proposed administration route name** that was sucessfully submitted to the XEVMPD by the same EV Group.	
ST.AR.6 Back	ST.AR.6.BR.1	If this field is present then the *version date* (ST.AR.7) must be present	V.3: Added Rule ST.AR.7.BR.1
ST.AR.7 Back	ST.AR.7.BR.1	The date supplied must not occur later than the current date/time (GMT) + twelve hours.	
	ST.AR.7.BR.2	If this field is present then the *version date format* (ST.AR.6) must be present	V.3: Added Rule ST.AR.6.BR.1
ST.AR.8 Back	ST.AR.8.BR.1	If the value of type term is "development" (ST.AR.1 = 1) then this field must be empty.	
	ST.AR.8.BR.2	If a value is present then it must match an ***EV Code*** for an existing current ***administration route*** in the XEVMPD.	
ST.AR.9 Back	ST.AR.9.BR.1	If the value of *operation type* is "nullification" (ST.AR..1 = 4) then a *comment* must be present.	ST.AR..1.BR.2 ST.AR..1.BR.3

Failure to comply with any of the rules above leads to the generation of a *03* acknowledgement and the entire message is rejected.

3.I.d.6 Attachments (M.ATTs)

Table 60. Business rules for the Attachments element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
M.ATTs Back	M.ATTs.BR.1	Key Constraint: Each **attachment** must be uniquely identified within the **Attachments** element by the *local number*.	

Failure to comply leads to the generation of a *03* acknowledgement and the entire message is rejected.

Attachment (ATT)

Table 61. Business rules for the Attachment element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
ATT..1 Back	ATT..1.BR.1	The only value accepted is 1 for "insert"	
ATT.1 Back	ATT.1.BR.1	The local number must be a unique value within the **attachments** (M.ATTs) section	M.ATTs.BR.1
ATT.6 Back	ATT.6.BR.1	The *language* must be specified using the **two-letter language code** in the published list.	
ATT.7 Back	ATT.7.BR.1	The *language* must be specified using the **two-letter language code** in the published list.	
ATT.9 Back	ATT.9.BR.1	The format of the date must match the pattern:" CCYYMMDD"	
	ATT.9.BR.2	The date supplied must match a valid date.	
	ATT.9.BR.3	The date supplied must not occur later than the current date/time (GMT) + twelve hours.	

Failure to comply with any of the rules above leads to the generation of a *03* acknowledgement and the entire message is rejected.

3.I.d.7 Master File Locations (M.MFs)

Table 62. Business rules for the Master File Locations element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
M.MFs Back	M.MFs.BR.1	Key Constraint: Each **master file location** must be uniquely identified within the **master file locations** element by either the *local number* or the *EV Code*	

Failure to comply leads to the generation of a *03* acknowledgement and the entire message is rejected.

Master File Location (MF)

Table 63. Business rules for the Master File Location elements

Element Ref	Rule Ref	Description	Dependent Rules / Notes
MF..1 Back	MF..1.BR.1	If the **master file location** *operation type* is 2 or 4 then the **message header** *sender organisation* (H.5) must be part of the same ***EV Group*** as the owner of the ***master file location*** being updated in the XEVMPD.	
	MF..1.BR.2	If the **master file location** *operation type* is 4 then a *comment* must be present.	MF.11.BR.1
	MF..1.BR.3	The **master file location** cannot be nullified if it is referenced by ~~any current **product** in the XEVMPD.:~~ • an authorised medicinal product entity referencing the (valid) authorisation statuses 1, 2, 8, and/or 9 and/or • a not-nullified development medicinal product entity.	V5.3 Rule modified
MF.1 Back	MF.1.BR.1	The *local number* must be present if the value of field MF..1 is 1.	
	MF.1.BR.2	If the value of **master file location** *operation type* (M.F..1 is 2 or 4) then the *local number* field must be empty.	
MF.2 Back	MF.2.BR.1	The *EV Code* of the **master file location** must be present if the value of field MF..1 is 2 or 4.	
	MF.2.BR.2	If a value is given then it must match an ***EV Code*** for an existing **master file location** in the XEVMPD	
	MF.2.BR.3	If the value of **master file location** *operation type* is "insert" (M.F..1 =1) then the *EV Code* field must be empty.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
MF.10 Back	MF.10.BR.1	The *country code* must match a **two-letter language code** in the published list.	
MF.11 Back	MF.11.BR.1	If the *operation type* is "nullification" (MF..1 = 4) then a *comment* must be present.	MF..1.BR.2 MF..1.BR.3

Failure to comply with any of the rules above leads to the generation of a *03* acknowledgement and the entire message is rejected.

3.I.d.8 Development Substances (M.DSs)

Table 64. Business rules for the Development Substances element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
M.DSs Back	M.DSs.BR.1	Key Constraint: Each **development substance** must be uniquely identified within the **Development Substances** element by either the *local number* or the *EV Code*.	

Failure to comply leads to the generation of a *03* acknowledgement and the entire message is rejected.

Development Substance (M.DS)

Table 65. Business rules for the Development Substance element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DS..1 Back	DS..1.BR.1	*Operation type* 5 is reserved for the EMA	
	DS..1.BR.2	If the *operation type* is 4 then a *comment* DS.9 must be present.	
	DS..1.BR.3	If the *operation type* is 4 then the **development substance** must not be referenced by any current ***product***.	
	DS..1.BR.4	If the operation type is 2 or 4 then the message sender (H.5) must be in the same *EV Group* as the substance submitter.	
	DS..1.BR.5	The HQ of the sender specified in the H.5 must be EVHUMAN	
DS..2 Back	DS..2.BR.1	This field is reserved for the EMA	
DS.1 Back	DS.1.BR.1	If the value of *operation type* is "insert" (DS..1 = 1) then the local number must be present.	
	DS.1.BR.2	If the *operation type* is 2 or 4 then the *local number* must be empty.	
DS.2 Back	DS.2.BR.1	If the *operation type* is 2 or 4 then the *EV Code* must be present.	
	DS.2.BR.2	If the *operation type* is 1 then the *EV Code* must be empty.	
DS.3 Back	DS.3.BR.1	This field is reserved for the EMA.	
	DS.3.BR.2	For "insert" and "change ownership" operations (DS..1 = 1 or 5) this field is required for the EMA.	
DS.4 Back	DS.4.BR.1	If the sponsor code is a "local number"(DS.4..1 = 1) then DS.4 must match an organisation local number (Os.O.3) within the current message.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	DS.4.BR.2	If the sponsor code is an "EV Code" (DS.4..1= 2) then DS.4 must match an organisation EV Code in the XEVMPD that the sender organisation has privileges to reference.	
DS.7 Back	DS.7.BR.1	If the value of *operation type* is "insert" or "update" (DS..1 = 1 or 2) then the *substance class* must be present.	
	DS.7.BR.2	If the value of *operation type* is "nullification" (DS..1 = 4) then the *substance class* field may be empty.	
	DS.7.BR.3	If the *substance class* field is present then the value given must correspond to the ***code*** of a value within the published **XEVMPD *substance class*** list***.***	
DS.9 Back	DS.9.BR.1	If the value of *operation type* is "nullification" (DS..1 = 4) then this field must be present.	

Failure to comply with any of the rules above leads to the generation of a *03* acknowledgement and the entire message is rejected.

3.I.d.8.1 Repeatable elements within the Development Substance element

i Development Substance Names (DS.DSNs)

Table 66. Business rules for the Development Substance Names element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DS.DSNs Back	DS.DSNs.BR.1	The number of *substance names* per **development substance names** section that have field DS.DSN.2 = 1 must be 1.	

Failure to comply leads to the generation of an *03* acknowledgement and the entire message is rejected.

Development Substance Name (DS.DSN)

Table 67. Business rules for the Development Substance Name element

Element Ref	Rule Ref	Description	Dependent Rules / Notes

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DS.DSN.1 Back	DS.DSN.1.BR.1	If the value of *operation type* for the **development substance** is not "nullification" (DS..1 ≠ 4) then the name specified must not match any ***name*** or ***synonym*** of any other existing current ***development substance*** that was successfully submitted by the same ***EV group*** as the **message header** *sender* (H.5) or *new owner id* of the **development substance**.	
	DS.DSN.1.BR.2	If the value of *operation type* for the **development substance** is not "nullification" (DS..1 ≠ 4) then the name specified must not match any ***name, translation or alias*** of any current ***approved substance*** within the XEVMPD.	

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

ii Development Substance - International Codes (DS.ICs)

Table 68. Business rules for the Development Substance - International Codes container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DS.ICs Back	~~DS.ICs.BR.1~~		V.3: Rule Removed

There is no consequence to contravening this rule.

Development Substance - International Code (DS.IC)

Table 69. Business rules for the Development Substance - International Code element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DS.IC.1 Back	DS.IC.1.BR.1	If DS.IC.1..1 = 1 the value in this field must match one of the S.1 fields in the **sources** (Ss) present in the current **message.**	
	DS.IC.1.BR.2	If DS.IC.1..1 = 2 then the value in this field must match the EV Code of a source that is available for use by the sending organisation.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DS.IC.2 Back	DS.IC.2.BR.1	If the value of DS.IC.1 is "EV Single Substance" (DS.IC.1 = SRCPARSUB1) and the *resolution mode* is "EV Code" (DS.IC.2..1 = 2) then EITHER The value in this field must match the ***EV Code*** of a ***development substance*** that is available to the sender's ***EV Group*** AND the referenced development substance's ***substance class*** must be <= 12 e.g. must not be a specified substance. OR The value in this field must match the ***EV Code*** of an ***approved substance*** AND the referenced substance's ***substance class*** must be <= 12 e.g. must not be a specified substance.	V.3 Rule Added.
	DS.IC.2.BR.2	If the value of DS.IC.1 is "EV Single Substance" (DS.IC.1 = SRCPARSUB1) and the *resolution mode* is "local number" (DS.IC.2..1 = 1) then EITHER The value in this field (DS.IC.2.BR.2) must match the *local number* of another **development substance** within the current XEVPRM and the referenced substance's *substance class* must be <= 12 e.g. must not be a specified substance. OR The value in this field (DS.IC.2.BR.2) must match the *local number* of an **approved substance** within the current XEVPRM and the referenced substance's *substance class* must be <= 12 e.g. must not be a specified substance.	V.3 Rule Added.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	DS.IC.2.BR.3	If the value of DS.IC.1 is "EV Specified Substance Group 1" (DS.IC.1 = SRCPARSUB2) and the *resolution mode* is "EV Code" (DS.IC.2..1 = 2) then EITHER The value in this field must match the ***EV Code*** of a ***development substance*** within the XEVMPSD that is available to the sender's ***EV Group*** AND the referenced development substance's ***substance class*** must be = 13 ("Specified Substance Level 1"). OR The value in this field must match the ***EV Code*** of an ***approved substance*** with the XEVMPD AND the referenced development substance's ***substance class*** must be = 13 ("Specified Substance Level 1").	V.3 Rule Added.
	DS.IC.2.BR.4	If the value of DS.IC.1 is "EV Specified Substance Group 1" (DS.IC.1 = SRCPARSUB2) and the *resolution mode* is "local number" (DS.IC.2..1 = 1) then EITHER The value in this field (DS.IC.2.BR.2) must match the *local number* of another **development substance** within the current XEVPRM and the referenced substance's *substance class* must be = 13 ("Specified Substance Level 1"). OR The value in this field (DS.IC.2.BR.2) must match the *local number* of an **approved substance** within the current XEVPRM and the referenced substance's ***substance class*** must be = 13 ("Specified Substance Level 1").	V.3 Rule Added.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	DS.IC.2.BR.5	If the value of DS.IC.1 is "EV Specified Substance Group 2" (DS.IC.1 = SRCPARSUB3) and the *resolution mode* is "EV Code" (DS.IC.2..1 = 2) then EITHER The value in this field must match the ***EV Code*** of a ***development substance*** within the XEVMPD and available to the sender's ***EV Group*** AND the referenced development substance's ***substance class*** must be = 14 ("Specified Substance Level 2"). OR The value in this field must match the ***EV Code*** of an ***approved substance*** within the XEVMPD and available to the sender's ***EV Group*** AND the referenced substance's ***substance class*** must be = 14 ("Specified Substance Level 2").	V.3 Rule Added.
	DS.IC.2.BR.6	If the value of DS.IC.1 is "EV Specified Substance Group 2" (DS.IC.1 = SRCPARSUB3) and the *resolution mode* is "local number" (DS.IC.2..1 = 1) then EITHER The value in this field must match the *local number* of another **development substance** within the current XEVPRM and the referenced substance's *substance class* must be = 14 ("Specified Substance Level 2"). OR The value in this field must match the *local number* of an **approved substance** within the current XEVPRM and the referenced substance's *substance class* must be = 14 ("Specified Substance Level 2").	V.3 Rule Added.
DS.IC.2..1 Back	DS.IC.2..1.BR.1	If the value of DS.IC.1 is "EV Single Substance" (DS.IC.1 = SRCPARSUB1) then this field must be present	V.3 Rule Added
	DS.IC.2..1.BR.2	If the value of DS.IC.1 is "EV Specified Substance Group 1" (DS.IC.1 = SRCPARSUB2) then this field must be present.	V.3 Rule Added
	DS.IC.2..1.BR.3	If the value of DS.IC.1 is "EV Specified Substance Group 2" (DS.IC.1 = SRCPARSUB3) then this field must be present.	V.3 Rule Added

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	DS.IC.2..1.BR.4	If there is a value in this field then the value in the *source code* (DS.IC.1) field must be one of: SRCPARSUB1, SRCPARSUB2, SRCPARSUB3	V.3 Rule Added

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

iii Development Substance - Attachments (DS.ATTs)

Note that the provision of **attachments** for a **development substance** is optional under all circumstances but if the **attachments** section is present then the schema dictates that there must be at least one valid **attachment** section contained within it.

Table 70. Business rules for the Development Substance - Attachments container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DS.ATTs Back	~~DS.ATTs.BR.1~~		V.3 Rule removed
	DS.ATTs.BR.2	Each **attachment** must be uniquely identified within the **development substances** element by either the *local number* or the *EV Code*..	V.3 Rule added

Failure to comply the rule above leads to the generation of a *03* acknowledgement and the entire message is rejected.

Development Substance - Attachment (DS.ATT)

Table 71. Business rules for the Development Substance - Attachment element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DS.ATT.1 Back	DS.ATT.1.BR.1	If DS.ATT.1..1 = 1 the value in this field must match one of the ATT.1 fields in the **attachments** (ATTs) present in the current XEVPRM.	
	DS.ATT.1.BR.2	If DS.ATT.1..1 = 1 then the referenced **attachment** must be a "printed substance information" (PSI) **attachment** (referenced attachment field ATT.5 = 2)	V.3: Update Text
	DS.ATT.1.BR.3	If DS.ATT.1..1 = 2 then the value in this field must match the ***EV Code*** of an **attachment** that is available for use by the sending organisation.	
	DS.ATT.1.BR.4	If DS.ATT.1..1 = 2 then the ***attachment type*** of the referenced ***attachment*** must be 2 ("printed substance information").	V.3: Updated Text

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DS.ATT.2 Back	DS.ATT.2.BR.1	If DS.ATT.1..1 = 2 then the value in this field must be 1. This denotes that the sender declares that the ***referenced attachment*** is valid for this **development substance.**	

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

iv Development Substance - Structured Substance Informations (DS.SSIs)

Note that the provision of the **structured substance information** element for a **development substance** is currently **not** required by the Agency but if the **structured substance information** section is present then the schema dictates that there must be at least one valid **structured substance information** section contained within it.

Table 72. Business rules for Development Substance -Structured Substance Informations container.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DS.SSIs Back	DS.SSIs.BR.1	If the **message header** *sender* (H.5) is not the EMA and this container is present then only one SSI section may be present	
	DS.SSIs.BR.2	If the **message header** *sender* (H.5) is the EMA and this container is present then any number of SSI sections may be present.	

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

Development Substance - Structured Substance Information (DS.SSI)

Table 73. Business rules for the Development Substance - Structured Substance Information element.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DS.SSII Back	DS.SSI.BR.1	If DS.SSI is present then the content must be in the form of well formed xml that conforms to the substancessi.xsd schema.	

Failure to comply leads to the generation of an *03* acknowledgement and the entire message is rejected.

3.I.d.9 Approved Substances (M.ASs)

Table 74. Business rules for the Approved Substances element.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
M.ASs Back	M.ASs.BR.1	Key Constraint: Each **approved substance** must be uniquely identified within the **Approved Substances** element by either the *local number* or the *EV Code.*	

Failure to comply leads to the generation of an *03* acknowledgement and the entire message is rejected.

Approved Substance (M.AS)

Table 75. Business rules for the Approved Substance element.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS..1 Back	AS..1.BR.1	If the value of *operation type* is "nullification" (AS..1 = 4) then a *comment* (AS.10) must be present and the **message header** *sender* (H.5) must be the EMA	
	AS..1.BR.2	If the value of *operation type* is "nullification" (AS..1 = 4) then the ***approved substance*** must not be referenced by any current ***product***.	
	AS..1.BR.3	If the value of *operation type* is "nullification" (AS..1 = 4) then the ***approved substance*** for nullification must not be checked by the EMA.	
	AS..1.BR.4	The *operation type* "nullification" operation (AS..1 = 4) is reserved for the EMA	
	AS..1.BR.5	The HQ of the sender specified in the H.5 must be EVHUMAN	
AS..2 Back	AS..2.BR.1	This field *is* reserved for the EMA.	
AS.1 Back	AS.1.BR.1	If the value of *operation type* is "insert" (AS..1 = 1) then the *local number* must be present.	
	AS.1.BR.2	If the value of operation type is "update" or "nullification" (AS..1 = 2 or 4) then the *local number* must be empty.	
AS.2 Back	AS.2.BR.1	If the value of operation type is "update" or "nullification" (AS..1 = 2 or 4) then the *EV Code* must be present.	
	AS.2.BR.2	If the value of *operation type* is "insert" (AS..1 = 1) then the *EV Code* must be empty.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.3 Back	AS.3.BR.1	If the *source code* is a "local number" (AS.3..1 = 1) then AS.3 must match one **source** *local number* (Ss.S.1) within the current message.	
	AS.3.BR.2	If the *source code* is an "EV Code" (DS.3..1= 2) then AS.3 must match a ***source EV Code*** in the XEVMPD that the **message header** *sender* (H.5) organisation has privileges to reference.	
AS.4 Back	AS.4.BR.1	If the value of *operation type* is "insert" (AS..1 = 1) then the *substance name* must not match any ***name*** or ***synonym*** of any current ***approved substance in the XEVMPD***.	
	AS.4.BR.2	If the value of *operation type* is "update" (AS..1 = 2) then the *substance name* must not match any name or *synonym* of any approved substance unless the matching *name* is one of the names of the substance to be updated.	
	AS.4.BR.3	If the operation type is not insert (AS..1 <> 1) then the substance name must match the substance name of the previous version of the substance unless the **message header** *sender* (H.5) is the EMA	Added V3.1 Generates operation result code 73
AS.7 Back	AS.7.BR.1	If the value of *operation type* is "insert" or "update" (AS..1 = 1 or 2) then the *substance class* must be *present*.	
	AS.7.BR.2	If the value of *operation type* is "nullification" (AS..1 = 4) then the *substance class* field may be *empty*.	
	AS.7.BR.3	If the *substance class* field contains a value this must correspond to the ***code*** of a value within the published ***substance class list***.	
AS.10 Back	AS.10.BR.1	If the value of *operation type* is "nullification" (AS..1 = 4) then this field must be present	AS..1.BR.1

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

3.I.d.9.1 Repeatable elements within the Approved Substance element

i Approved Substance - Translations (AS.Ts)

Note that for an **approved substance** the **translations** (AS.Ts) element may be *empty*.

Table 76. Business rules for the Approved Substance - Substance Translations container.

Element Ref	Rule Ref	Description	Dependent Rules / Notes

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.Ts Back	~~AS.Ts.BR.1~~		V3: Removed Rule
	AS.Ts.BR.2	Each combination of term (AS.T.2) and language code (AS.T.1) must be unique within the current message.	

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

Approved Substance - Translation (AS.T)

Table 77. Business rules for the Approved Substance - Substance Translation container.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.T.1 Back	AS.T.1.BR.1	The *language* must be specified using the **two-letter language code** in the published list.	
AS.T.2 Back	AS.T.2.BR.1	If the value of *operation type* is "insert" (DS..1 = 1) then the *translation name* must not match any ***name*** or ***synonym*** of any current ***approved substance***.	
	AS.T.2.BR.2	If the value of *operation type* is "update" (DS..1 = 2) then the *translation name* must not match any ***name*** or ***synonym*** of any ***other approved substance***[20].	V3.1: Rule Amended

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

ii Approved Substance - Substance Aliases (AS.SAs)

For **approved substances** the Substance Aliases (AS.SAs) element may be ***empty***

Table 78. Business rules for the Approved Substance - Substance Aliases container.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.SAs Back	AS.SAs.BR.1	Each combination of *term* (AS.SA.2) and *source code* (AS.SA.1) must be unique within the current **message**.	

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

[20] The same translation name may be repeated within the **same** substance to allow the submission of translations where the term is the same in several languages.

Approved Substance - Substance Alias (AS.SA)

Table 79. Business rules for the Approved Substance - Substance Alias container.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.SA.1 Back	AS.SA.1.BR.1	If the value of **alias** *reference source* is a "local code" (AS.SA.1..1 = 1) then the *source code* must match the value in one *local number* (S.1) field within the current **message**.	
	AS.SA.1.BR.2	If the value of **alias** *reference source* is an "EV Code" (AS.SA.1..1 = 2) then the *source code* must match the ***EV Code*** of a current ***source*** in the XEVMPD that the **message header** *sending organisation* (H.5) has privileges to reference.	
AS.SA.2 Back	AS.SA.2.BR.1	If the value of *operation type* is "insert" (AS..1 = 1) then the *alias name* must not match any ***name*** or ***synonym*** of any current ***approved*** **substance** in the XEVMPD.	
	AS.SA.2.BR.2	If the value of *operation type* is "update" (AS..1 = 2) then the *alias name* must not match any ***name*** or ***synonym*** of any ***approved substance*** unless the matching term is one of the ***names*** of the ***substance*** to be updated.	

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

3.I.d.10 Repeatable elements within the Substance Alias element

i Approved Substance - Substance Alias - Translations (SA.Ts)

Note that for each **substance alias** the **translations** (SA.Ts) element may be empty.

Table 80. Business rules for the Approved Substance - Substance Alias - Translations container.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
SA.Ts Back	~~SA.Ts.BR.1~~		V.3 Rule Removed
	SA.Ts.BR.2	Each combination of *term* (SA.T.2) and *language code* (SA.T.1) must be unique within the current **message**.	

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

Approved Substance - Substance Alias - Translation (SA.T)

Table 81. Business rules for the Approved Substance - Substance Alias - Translation container.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
SA.T.1 Back	SA.T.1.BR.1	The *language* must be specified using the **two-letter language code** in the published list.	
SA.T.2 Back	SA.T.2.BR.1	If the value of *operation type* is "insert" (AS..1 = 1) then the *translation name* must not match any ***name*** or ***synonym*** of any current ***approved substance*** in the XEVMPD.	
	SA.T.2.BR.2	If the value of *operation type* is "update" (AS..1 = 2) then the *translation name* must not match any ***name*** or ***synonym*** of any ***approved substance*** unless the matching term is one of the ***names*** of the ***substance*** to be updated.	

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

ii Approved Substance - International Codes (AS.ICs)

Table 82. Business rules for the Approved Substance - International Codes container.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.ICs Back	~~AS.ICs.BR.1~~		V3: Rule removed

Failure to comply leads to the generation of an *03* acknowledgement and the entire message is rejected.

Approved Substance - International Code (AS.IC)

Table 83. Business rules for the Approved Substance - International Code element.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.IC.1 Back	AS.IC.1.BR.1	If AS.IC.1..1 = 1 the value in this field must match one of the S.1 fields in the **sources** (Ss) present in the current **message.**	
	AS.IC.1.BR.2	If AS.IC.1..1 = 2 then the value in this field must match the ***EV Code*** of a ***source*** that is available for use by the sending organisation within the XEVMPD.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.IC.2 Back	AS.IC.2.BR.1	If the value of AS.IC.1 is "EV Single Substance" (AS.IC.1 = SRCPARSUB1) and the *resolution mode* is "EV Code" (AS.IC.2..1 = 2) then the value in this field must match the ***EV Code*** of an ***approved substance*** in the ***XEVMPD*** AND the referenced substance's ***substance class*** must be <= 12 e.g. must not be a specified substance.	V3 Rule Added.
	AS.IC.2.BR.2	If the value of AS.IC.1 is "EV Single Substance" (AS.IC.1 = SRCPARSUB1) and the *resolution mode* is "local number" (AS.IC.2..1 = 1) then the value in this field (AS.IC.2.BR.2) must match the *local number* of another **approved substance** within the current XEVPRM and the referenced substance's *substance class* must be ≤ 12 e.g. must not be a specified substance.	V3 Rule Added.
	AS.IC.2.BR.3	If the value of AS.IC.1 is "EV Specified Substance Group 1" (AS.IC.1 = SRCPARSUB2) and the *resolution mode* is "EV Code" (AS.IC.2..1 = 2) then the value in this field must match the ***EV Code*** of an ***approved substance*** in the **XEVMPD** AND the referenced substance's ***substance class*** must be = 13 ("Specified Substance Level 1").	V3 Rule Added.
	AS.IC.2.BR.4	If the value of AS.IC.1 is "EV Specified Substance Group 1" (AS.IC.1 = SRCPARSUB2) and the *resolution mode* is "local number" (AS.IC.2..1 = 1) then the value in this field (AS.IC.2.BR.2) must match the *local number* of another **approved substance** within the current **XEVPRM** and the referenced substance's *substance class* must be = 13 ("Specified Substance Level 1").	V3 Rule Added.
	AS.IC.2.BR.5	If the value of AS.IC.1 is "EV Specified Substance Group 2" (AS.IC.1 = SRCPARSUB3) and the *resolution mode* is "EV Code" (AS.IC.2..1 = 2) then the value in this field must match the ***EV Code*** of an ***approved substance*** within the **XEVMPD** AND the referenced substance's ***substance class*** must be = 14 ("Specified Substance Level 2").	V3 Rule Added.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	AS.IC.2.BR.6	If the value of AS.IC.1 is "EV Specified Substance Group 2" (AS.IC.1 = SRCPARSUB3) and the *resolution mode* is "local number" (AS.IC.2..1 = 1) then the value in this field must match the *local number* of another **approved substance** within the current **XEVPRM** and the referenced substance's *substance class* must be = 14 ("Specified Substance Level 2").	V3 Rule Added.
AS.IC.2..1 Back	AS.IC.2..1.BR.1	If the value of AS.IC.1 is "EV Single Substance" (AS.IC.1 = SRCPARSUB1) then this field must be present.	V3: Rule Added
	AS.IC.2..1.BR.2	If the value of AS.IC.1 is "EV Specified Substance Group 1" (AS.IC.1 = SRCPARSUB2) then this field must be present.	V3: Rule Added
	AS.IC.2..1.BR.3	If the value of AS.IC.1 is "EV Specified Substance Group 2" (AS.IC.1 = SRCPARSUB3) then this field must be present.	V3: Rule Added
	AS.IC.2..1.BR.4	If there is a value in this field then the value in the *source code* (AS.IC.1) field must be one of: • SRCPARSUB1, SRCPARSUB2, SRCPARSUB3	V3: Rule Added

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

iii Approved Substance - Attachments (AS.ATTs)

Note that the provision of **attachments** for an **approved substance** is optional under all circumstances but if the **attachments** section is present then the schema dictates that there must be at least one valid **attachment** section contained within it.

Change Log: V3

Table 84. Business rules for the Approved Substance - Attachments container.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.ATTs Back	~~AS.ATTs.BR.1~~		V3: Rule Removed
	AS.ATTs.BR.2	Each **attachment** must be uniquely identified within the **approved substance** element by either the *local number* or the *EV Code*.	V3: Rule Added V3.1: Rule Amended

Failure to comply leads to the generation of an *03* acknowledgement and the entire message is rejected.

Approved Substance - Attachment (AS.ATT)

Table 85. Business rules for the Approved Substance - Attachment element.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.ATT.1 Back	AS.ATT.1.BR.1	If AS.ATT.1..1 = 1 the value in this field must match one of the ATT.1 fields in the **attachments** (ATTs) present in the current XEVPRM.	
	AS.ATT.1.BR.2	If AS.ATT.1..1 = 1 then the referenced **attachment** must be a "printed substance information" (PSI) attachment (referenced attachment field ATT.5 = 2)	
	AS.ATT.1.BR.3	If AS.ATT.1..1 = 2 then the value in this field must match the ***EV Code*** of an ***attachment*** that is available for use by the **message header** *sender* (H.5) ***EV Group.***	
	AS.ATT.1.BR.4	If AS.ATT.1..1 = 2 then the *attachment type* of the referenced **attachment** must be 2 ("printed substance information").	
AS.ATT.2 Back	AS.ATT.2.BR.1	If AS.ATT.1..1 = 2 and the **message header** *sender* (H.5) is the EMA then this field may be *empty*.	
	AS.ATT.2.BR.2	If AS.ATT.1..1 = 2 and the **message header** *sender* (H.5) is NOT the EMA then this field must be present.	
	AS.ATT.2.BR.3	If AS.ATT.1..1 = 2 and the **message header** *sender* is NOT the EMA then the value in this field must be 1. This denotes that the sender declares that the referenced ***attachment*** is valid for this ***approved substance***.	

Failure to comply with any of the rules above leads to the generation of an *03* acknowledgement and the entire message is rejected.

iv Approved Substance - Structured Substance Information (AS.SSIs)

Note that the provision of the **structured substance information** element for an **approved substance** is currently not required by the Agency but if the **structured substance information** section is present then the schema dictates that there must be at least one valid **structured substance information** section contained within it.

Table 86. Business rules for Approved Substance - Structured Substance Information.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.SSIs Back	~~AS.SSIs.BR.1~~		V3: Rule removed.
	AS.SSIs.BR.2	If the **message header** *sender* (H.5) is the EMA then this section may contain more than 1 **SSI** each of which must be valid according to the ***SSI schema***.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	~~AS.SSIs.BR.3~~		V3: Rule removed.
	AS.SSIs.BR.4	If the **message header** *sender* (H.5) is NOT the EMA and this section is present then it must contain one and only one **SSI** that must be valid according to the ***SSI schema***.	V3: Rule added.

Approved Substance - Structured Substance Information (AS.SSI)

Table 87. Business rules for Approved Substance - Structured Substance Information

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.SSI Back	AS.SSI.BR.1	If AS.SSI is present then the content must be in the form of well formed xml that conforms to the substancessi.xsd schema.	

Failure to comply leads to the generation of an *03* acknowledgement and the entire message is rejected.

v Approved Substance - Previous EV Codes (AS.PEVs)

Table 88. Business rules for the Approved Substance - Previous EV Codes element.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.PEVs Back	AS.PEVs.BR.1	Each referenced *EV Code* must be unique within the **PEVs** section.	

Failure to comply leads to the generation of an *03* acknowledgement and the entire message is rejected.

Approved Substance - Previous EV Code (AS.PEV)

Table 89. Business rules for the Approved Substance - Previous EV Code element.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AS.PEV.1 Back	AS.PEV.1.BR.1	The value of the *previous EV Code* referenced must match the ***EV Code*** of a ***development substance*** that the **message header** *sender* organisation (H.5) has privileges to reference. When the approved substance is nullified, the development substance EV Code referenced in the 'Previous EV Code' section of the approve substance in not considered; the nullification must be successful even if the entity referenced in the previous EV code is not valid.	V5.3 Rule modified

Failure to comply leads to the generation of an *03* acknowledgement and the entire message is rejected.

3.I.d.11 Development Products (M.DPs)

Table 90. Business rules for the Development Products element.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
M.DPs Back	M.DPs.BR.1	Key Constraint: Each **development product** must be uniquely identified within the **development products** element by either the *local number* or the *EV Code.*	

Failure to comply leads to the generation of an *03* acknowledgement and the entire message is rejected.

Development Product (M.DP)

Table 91. Business rules for the Development Product element.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DP..1 Back	DP..1.BR.1	*Operation type* 5 is reserved for the EMA	
	DP..1.BR.2	If the *operation type* is 4 then a *comment* (DP.7) must be present.	
DP.1 Back	DP.1.BR.1	If the value of *operation type* is "insert" (DP..1 = 1) then the *local number* must be present.	
	DP.1.BR.2	If the value of *operation type* is "update" or "nullification" (DP..1 = 2 or 4) then the *local number* must be empty.	V.3 Removed "3" from list of checked values.
DP.2 Back	DP.2.BR.1	If the value of *operation type* is "update" or "nullification" (DP..1 = 2 or 4) then the *EV Code* must be present.	
	DP.2.BR.2	If the value of *operation type* is "insert" (DP..1 = 1) then the EV Code must be empty.	
DP.3 Back	DP.3.BR.1	This field is reserved for the EMA	
	DP.3.BR.2	If the value of *operation type* is "insert" or "change ownership" (DP..1 = 1 or 5) then this field is required for the EMA.	
DP.5 Back	DP.5.BR.1	If the *sponsor code* is a "local number" (DP.5..1 = 1) then DP.5 must match an **organisation** *local number* (Os.O.3) within the current XEVPRM.	
	DP.5.BR.2	If the *sponsor* code is an *EV Code* (DP.5..1= 2) then DP.5 must match an ***organisation EV Code*** in the XEVMPD that the **message header** *sender* (H.5) organisation has privileges to reference.	
DP.6.1 Back	DP.6.1.BR.1	If the value of *operation type* is not "nullification" (DP..1 ≠ 4) and the field DP.6.2 is *empty* then this field (DP.6.1) must be present.	DP.6.2.BR.1

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	DP.6.1.BR.2	If this field is present then the value must not match any ***name*** or ***synonym*** of any other ***development product*** owned by the same EV group.	
	DP.6.1.BR.3	If this field is present then the value must not match any ***name*** or ***synonym*** of any current ***approved product*** in the XEVMPD.	
DP.6.2 Back	DP.6.2.BR.1	If the value of *operation type* is not "nullification" (DP..1 ≠ 4) and the field DP.6.1 is *empty* then this field (DP.6.2) must be present.	DP.6.1.BR.1
	DP.6.2.BR.2	If this field is present then the value must not match any ***name*** or ***synonym*** of any other ***development product*** owned by the same ***EV group.***	
	DP.6.2.BR.3	If the field is present then the value must not match any ***name*** or ***synonym*** of any current ***approved product*** in the XEVMPD.	
	~~DP.6.2.BR.4~~		V3: Rule Added V3.1: Rule removed ~~DP.6.3.BR.3~~
DP.6.3 Back	DP.6.3.BR.1	If the field is *present* then the value must not match any name or *synonym* of any other development product owned by the same EV group.	
	DP.6.3.BR.2	If the field is *present* then the value must not match any name or *synonym* of any current approved product in the XEVMPD.	
	~~DP.6.3.BR.3~~		V3: Rule Added V3.1: Rule removed ~~DP.6.2.BR.4~~
DP.7 Back	DP.7.BR.1	If the product operation type is nullification (DP..1 = 4) then this field must be *present*.	DP..1.BR.2

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

3.I.d.12 Repeatable elements within the Development Product element

i Development Product - ATCs (DP.ATCs)

Note that the provision of **ATCs** for a **development product** is optional under all circumstances but if the **ATCs** section is present then the schema dictates that there must be at least one valid **ATC** section contained within it.

Table 92. Business rules for the Development Product – ATCs container.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DP.ATCs Back	~~DP.ATCs.BR.1~~		V.3 Rule removed.
	DP.ATCs.BR.2	Each referenced *ATC code* must be unique within the current **development product**.	

Failure to comply with the rule above leads to the generation of an *02* acknowledgement and the individual product is rejected.

Development Product - ATC Code (DP.ATC)

Table 93. Business rules for the Development Product - ATC element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DP.ATC.1 Back	DP.ATC.1.BR.1	If the *resolution mode* is "local number" (DP.ATC..1 =1) then the referenced **ATC** must be present in the current message.	
	DP.ATC.1.BR.2	If the *operation type* is "insert" or "update" (DP..1 < 3) AND the *resolution mode* is "Global ATC Code" (DP.ATC..1 = 2) then the referenced ***ATC*** must be a current ***ATC code*** within the XEVMPD and that is available to the sender.	

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

ii Development Product – Indications (DP.INDs)

Note that the provision of **indications** for a **development product** is optional under all circumstances but if the **indications** section is present then the schema dictates that there must be at least one valid **indication** section contained within it.

Table 94. Business rules for the Development Product - Indications container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DP.INDs Back	~~DP.INDs.BR.1~~		V.3 Rule removed.
	DP.INDs.BR.2	Each referenced ***MEDDRA code*** must be unique for the current product.	

Failure to comply with the rule above leads to the generation of an *02* acknowledgement and the individual product is rejected.

Development Product - Indication (DP.IND)

Table 95. Business rules for the Development Product - Indication element.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DP.IND.1 Back	DP.IND.1.BR.1	If the *operation type* is "insert" or "update" (DP..1 < 3) then the referenced *MedDRA version* must be a known current ***MedDRA version***. For WebTrader users performing a reinsert or an update of a medicinal product in EVWEB, if the MedDRA version referenced in the product that is being reinserted/updated, is a non-current version, then the MedDRA version is automatically updated by the system to the last current MedDRA version during the reinsert/update of the product entity. This automatic update of non-current MedDRA version to the last current version is not applied during a nullification.	V5.3 Rule modified.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DP.IND.3 Back	DP.IND.3.BR.1	If the *operation type* is "insert" or "update" (DP..1 < 3) then the given value must be a current ***MedDRA code*** within the ***MedDRA version*** referenced in DP.IND.1. If the meddralevel is LLT, then the given MedDRA code cannot be deprecated for the given meddraversion. This is not applied during a nullification of the product entity.	V5.3 Rule modified.

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

iii Development Product - PPI Attachments (DP.PPIs)

Table 96. Business rules for the Development Product - Product Printed Informations container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DP.PPIs Back	DP.PPIs.BR.1	Each referenced *EV Code* must be unique within the PPIs section.	
	DP.PPIs.BR.2	Each referenced *local number* must be unique within the PPIs section.	

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

Development Product - PPI Attachment (DP.PPI)

Table 97. Business rules for the Development Product - Printed Product Information element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
DP.PPI.1 Back	DP.PPI.1.BR.1	If the *resolution mode* is "local insert" (DP.PPI.1..1 = 1) then the referenced *local number* must match a value in one of the fields ATT.1 in the **attachments** section.	
	DP.PPI.1.BR.2	If the *resolution mode* is "local insert" (DP.PPI.1..1 = 1) then the referenced *local attachment* must be a "PPI" (ATT.5 = 1)	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	DP.PPI.1.BR.3	If the *resolution mode* is "global" (DP.PPI.1..1) **AND** the field DP.3 is empty then the referenced *attachment code* must match a current ***PPI attachment*** available to the **message header** *sender's* (H.5) ***EV Group*****.**	
	DP.PPI.1.BR.4	If the *resolution mode* is "global" (DP.PPI.1..1) AND the **message header** *sender* (H.5) is the EMA AND the field DP.3 is present then the referenced attachment ***EV Code*** must match a current ***attachment*** available to the ***EV Group*** of the owning organisation referenced in DP.3.	
DP.PPI.2 Back	DP.PPI.2.BR.1	If the *resolution mode* is "global" (DP.PPI.1..1) **AND** the field DP.3 is empty **AND** the operation type is "update" (DP..1 = 2) then this field must be present. When performing an update of a development product where a PPI attachment is referenced, then the business rule is relaxed, and it is not required to specify validity declaration.	V5.3 Rule modified

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

iv Development Product - Pharmaceutical Products (DP.PPs)

The business rules for this element are shared between **development products** and **authorised products** and are detailed in the **pharmaceutical products** business rules section.

3.I.d.13 Authorised Products (M.APs)

Table 98. Business rules for the Authorised Products element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
M.APs Back	M.APs.BR.1	Key Constraint: Each **authorised product** must be uniquely identified within the **authorised products** element by either the *local number* or the *EV Code*.	

Failure to comply leads to the generation of a *03* acknowledgement and the entire message is rejected.

Authorised Product (M.AP)

Table 99. Business rules for the Authorised Product element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP..1 Back	AP..1.BR.1	Operation type 5 is reserved for the EMA	
	AP..1.BR.2	If the *operation type* is "nullification" (AP..1 = 4) then a comment AP.14 must be present.	V4.0: Rule updated.
	AP..1.BR.3	If the *operation type* is "Invalidate MA" (AP..1 = 6) then the *authorisation status* (AP.12.3) must be one of the values in the published **Not Valid** Authorisation Status list.	V3.1: Rule Updated. V4.0: Rule Updated
	AP..1.BR.4	If the operation type is "Insert" or "Update" (AP..1 < 4) then the *authorisation status* (AP.12.3) must be one of the values in the published **Valid** Authorisation Status list	V4.0: Rule Added V5.0 correction: Rule Amended
AP.1 Back	AP.1.BR.1	If the *operation type* is "insert" (AP..1 = 1) then the *local number* must be present.	
	AP.1.BR.2	If the *operation type* is NOT "insert" (AP..1 ≠ 1) then the *local number* must be empty.	
AP.2 Back	AP.2.BR.1	If the operation type is NOT "insert" (AP..1 ≠ 1) then the *EV Code* must be present.	
	AP.2.BR.2	If the operation type is "insert" (AP..1 ≠ 1) then the *EV Code* must be empty.	
	AP.2.BR.3	If the *message sender* (H.5) is not the EMA then the value of authorisation status of the *current* version of the product within the XEVMPD that is referenced in this field must appear in the valid authorisation status sub-list or must be *empty*	V4.0 Rule Added.
AP.3	AP.3.BR.1	This field is reserved for the EMA	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
Back	AP.3.BR.2	If the *operation type* is "change ownership" (AP..1 = 5) then this field is required for the EMA.	
AP.4 Back	AP.4.BR.1	If the *MAH code* is a "local number" (AP.4..1 = 1) then AP.4 must match an **organisation** *local number* (Os.O.3) within the current message.	
	AP.4.BR.2	If the *MAH code* is an "EV Code" (AP.4..1= 2) then AP.4 must match an ***organisation EV Code*** in the XEVMPD that the **message sender** *organisation* (H.5) has privileges to reference.	
AP.5 Back	AP.5.BR.1	If the *operation type* is "insert" or "update" (AP..1 < 4) AND the **message header** *sender* (H.5) is NOT the EMA then this field must be present.	V5.0 Correction: Rule Amended
	AP.5.BR.2	If this field is present and the **message header** *sender* (H.5) is NOT the EMA then the value must match a ***current user*** who is a "designated QPPV" within the ***EV registration system*** and who is a member of the same **EV Group** as the sender organisation (H.5)	
	AP.5.BR.3	If the *operation type* is "insert" or "update" AND the **message header** *sender* is the EMA AND the authorised product is not owned by the EMA then AP.5 must match with the same value from the xEVMPD.	V5.1: New Rule Added V3: Rule Removed
	AP.5.BR.4	If the **message header** *sender* (H.5) is the EMA and this field is *present* then the value must match a ***current user*** who is a "designated QPPV" within the ***EV registration system*** and who is a member of the same ***EV Group*** as the "owner" of the **product**.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	AP.5.BR.5	Integrity constraint validity check is relaxed during a **nullification** and/or **invalidation** of an AMP entity. • If the QPPV entity in an AMP is referencing any user record from HUM_DYNAMIC then a check, if this record exists in HUM_DYNAMIC, is performed. ○ If the record does not exist, then search for the responsible user that is QPPV in HUM_DYNAMIC in the organisation that owns the AMP is performed. ▪ If there is a responsible user that is also QPPV in the organisation, then set the reference in XEMVPD QPPV entity for this user. ▪ Otherwise, NULL is set as a reference to QPPV in the QPPV entity in the XEVMPD. This relaxing business rule **is applied only for nullification and/or invalidation;** if there is a case of violating this integrity constraint **while inserting or updating AMP then a negative Ack is sent instead**.	V5.3: Added rule
AP.6 Back	AP.6.BR.1	If the *operation type* is "insert" or "update" AND the **message header** *sender* is the EMA AND the authorised product is not owned by the EMA then AP.6 must match with the same value from the xEVMPD.	V5.1: New Rule Added V3: Rule Removed.
	AP.6.BR.2	If this field is present and the *resolution mode* is "local number" (AP.6..1) = 1 then the value in this field must match a number in one of the MF.1 fields in the current message.	
	AP.6.BR.3	If this field is present AND the **message header** *sender* is not the EMA AND the *resolution mode* is "global" then the value in this field must match a ***master file location*** successfully submitted by a member of the message sending organisation's (H.5) ***EV Group***.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.7 Back	AP.7.BR.1	If the operation type is "insert" or "update" (AP..1 > 3) AND the message sender (H.5) is not the EMA then this field must be present.	V3: Removed "not" from first clause V5.0 Correction: Rule Amended
	AP.7.BR.2	If the field is present then the value must match the format of a valid e-mail address. E.g. name@org.domain	
AP.8 Back	AP.8.BR.1	If the *operation type* is "insert" or "update" (AP..1 > 3) AND the **message header** *sender* (H.5) is not the EMA then this field must be present.	V3: Removed "not" from first clause V5.0 Correction: Rule Amended
AP.10 Back	AP.10.BR.1	If this field is present then the field AP.11 must be present.	
AP.11 Back	AP.11.BR.1	If this field is present then the field AP.10 must be present.	
	AP.11.BR.2	If this field is present then the format of the data supplied must conform to "CCYYMMDD".	
	AP.11.BR.3	If this field is present then the value must be before the current time/date (GMT) + 12 hours	
AP.12.1 Back	AP.12.1.BR.1	The *authorisation country code* must be a ***two letter code*** from the published ***country list***.	
	AP.12.1.BR.2	If the value of authorisation procedure represents an EU procedure (AP.12.2 <> 5) then the country of authorisation must be a country within the European Economic Area	V5.0: Rule Added Operation result code: 510
AP.12.2 Back	AP.12.2.BR.1	The value given must be a ***code*** from the published ***authorisation procedure list***.	
AP.12.3 Back	AP.12.3.BR.1	If the value of *operation type* is not "nullification" (AP..1 ≠ 4) then this field must be present.	
	AP.12.3.BR.2	If this field is present then the value given must be a valid ***code*** from the published ***authorisation status list (either from the valid or not valid sub-lists)***.	V4.0: Updated

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	AP.12.3.BR.3	If the value of this field appears in the authorisation status not valid sub-list then the *operation type* must be "invalidate MA" (AP..1 = 6)	V4.0: Update to support transfer and renewal of MA. V3: Updated to reflect new authorisation status list values.
	AP.12.3.BR.4	If the value in this field appears in the authorisation status **not valid** sub-list then field AP.12.12 must be present	V4.0: Updated Rule. V3: Updated to reflect new authorisation status list values.
	AP.12.3.BR.5	If the value of this field appears in the authorisation status **valid** sub-list then the value in the field *operation type* must **NOT** be "invalidate MA" (AP..1 <> 6)	V4.0: Updated Rule V3: Rule Added.
AP.12.4 Back	AP.12.4.BR.1	If the *operation type* is "insert", "update" Invalidate MA" (AP..1 = 1, 2 or 6) then this field must be present.	V5.0 Correction: Rule Amended
AP.12.5 Back	AP.12.5.BR.1	If the *operation type* is "insert", "update" or "Invalidate MA" (AP..1 = 1, 2 or 6) AND the **message header** *sender* is not "EMA" then this field must be present.	V5.0 Correction: Rule Amended
	AP.12.5.BR.2	If the value of AP.12.6 is present then this field must be present.	
	AP.12.5.BR.3	If the value of AP.12.6 is "102" then the value in this field must be a valid date that conforms to the format "CCYYMMDD"	
	AP.12.5.BR.4	If the value of AP.12.6 is "610" then the value in this field must be a valid date that conforms to the format "CCYYMM"	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	AP.12.5.BR.5	The value of this field must not be greater than the current date/time (GMT) + 12 hours.	
AP.12.6 Back	AP.12.6.BR.1	If this field is present then AP.12.5 must be present.	
AP.12.7 Back	AP.12.7.BR.1	If the value in the *authorisation procedure* field represents the "EU mutual recognition procedure" or "EU decentralised procedure" (AP.12.2 = 3 or 7) then this field must be present.	V3: Text update
AP.12.8 Back	AP.12.8.BR.1	If the value in the *authorisation procedure* field represents a "CAP product" (AP.12.2 = 1) then this field must be present.	V3: Removed check for "2 or 6"
AP.12.13 Back	AP.12.13.BR.1	If the sender of the message (H.5) is not the EMA and the *operation type* is "insert", "update" or "Invalidate MA" (AP..1 = 1, 2 or 6) then this field must be present.	V5.0: Rule Added V5.0 Correction: Rule Amended Operation result code: 508
	AP.12.13.BR.2	If this field is present, then the value must be a legal basis code value from the published ***legal basis*** list. Validation of the new legal basis: If any of the above legal basis is used in the update, insert, re-insert AMP, then the product must reference also a new authorisation procedure '*EU other approval/authorisation procedure (*13)'. Otherwise, a negative Ack is sent. For nullification, invalidation or change of ownership operations, this business rule is not applied.	V5.3 Rule added V5.0 Rule Added Operation result code: 509
AP.12.9 Back	AP.12.9.BR.1	If the value of *operation type* is "insert" or "update" (AP..1 < 4) AND the **message header** *sender* (H.5) is not the EMA then this field must be present.	V3: Rule Added. V5.0 Correction: Rule Amended
AP.12.10 Back	~~AP.12.10.BR.1~~		V3: Rule Removed

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.12.11 Back	AP.12.11.BR.1	If the *withdrawn date* field (AP.12.12) is present then this field must be present.	
	AP.12.11.BR.2	If the *withdrawn date* field (AP.12.12) is empty then this field must be empty.	
AP.12.12 Back	AP.12.12.BR.1	If the *operation type* is "Invalidate MA" (AP..1 = 6) then this field must be present.	
	AP.12.12.BR.2	If this field is present then the value give must be a valid date that conforms to the format "CCYYMMDD"	
	AP.12.12.BR.3	The value of this field must not be greater than the current date/time (GMT) + 12 hours.	
	~~AP.12.12.BR.4~~		V3: Rule Removed.
	AP.12.12.BR.5	If the value of **authorisation status** does not signify a current valid MA (AP.12.3 <> 1, **2,** 8 or 9) then this field must be present.	V5.1: Rule Updated V4.0: Rule amended V3: Rule added.
	AP.12.12.BR.6	If the value of **authorisation status** signifies a current valid MA (AP.12.3 = 1, **2,** 8 or 9) then this field must be empty.	V5.1: Rule Updated V4.0: Rule amended V3: Rule added

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	DM: AP.12.12.BR.7	To support the voluntary submissions of medicinal product information for medicinal products out of the scope of Article 57 requirements a new authorisation procedure *'EU other approval/authorisation procedure (13)'*, was added to the authorisation procedure values. Validation of the new authorisation procedure value: For operations update, insert, re-insert, the AMP with the authorisation procedure *"EU other approval/authorisation procedure"* must reference any of the below legal basis: • *"Authorisation according to Article 5(1) of Directive 2001/83/EC"*, code = 12 • *"Authorisation according to Article 5(2) of Directive 2001/83/EC"*, code = 13 • *"Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC"*, code = 14 • *"Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC"*, code = 15 • *"Available under Article 83(2) of Regulation (EC) No 726/2004"*, code = 16 For nullification, invalidation or change of ownership operations, this business rule is not applied.	V5.3 Rule added
AP.13.1 Back	~~AP.13.1.BR.1~~		V3: Rule Removed.
AP.13.2 Back	~~AP.13.2.BR.1~~		V3: Rule Removed.
	AP.13.2.BR.2	At least one of this field or the product generic name field (AP.13.3) must be present	V3: Rule Added. See also AP.13.3.BR.2
AP.13.3 Back	~~AP.13.3.BR.1~~		V3: Rule Removed.
	AP.13.3.BR.2	At least one of this field or the product short name field must be present	V3: Rule Added. See also AP.13.2.BR.2
AP.13.4 Back	AP.13.4.BR.1		V3: Rule removed.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	AP.13.4.BR.2	If the short name (AP.13.2) is absent then this field must be present	V3: Rule Added.
AP.13.5 Back	~~AP.13.5.BR.1~~		V3: Rule Removed.
AP.13.6 Back	~~AP.13.6.BR.1~~		V3: Rule Removed.
AP.13.7 Back	~~AP.13.7.BR.1~~		V3: Rule Removed.
AP.14 Back	AP.14.BR.1	If the value of *operation type* is "nullification" (AP..1 = 4) then this field must be present. Replaces:	V4: Rule Amended AP..1.BR.2

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

3.I.d.13.1 Repeatable elements within the Authorised Product.Authorisation element

i Authorised Product – authorisation – medicinal product types (AP.12.MPTs)

Table 100. Business rules for the Authorisation – medicinal product types container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.12.MPTs Back	AP.12.MPTs.BR.1	If the sender (H.5) of the product is not the EMA and the value of product operation type is not "nullify" (AP..1 <> 4) then this element must be *present*.	V5.0: Added Operation result code: 511
	AP.12.MPTs.BR.2	Each referenced *medicinal product type* must be unique for the current product.	V5:0: Added Operation result code 512

Failure to comply leads to the generation of an *02* acknowledgement and the individual product is rejected.

Authorised Product – authorisation – medicinal product type (AP.12.MPT)

Table 101. Business rules for the Authorisation – medicinal product type element

Element Ref	Rule Ref	Description	Dependent Rules / Notes

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.12.MPT.1 Back	AP.12.MPT.1.BR.1	The value in this field must be a value from the published ***Medicinal Product Type*** list	V5.0: Rule Added. Operation result code: 513

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

3.I.d.13.2 Repeatable elements within the Authorised Product element

i Authorised Product – authpharmforms (AP.APFs)

Table 102. Business rules for the Authorised Product - authpharmforms container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.APFs Back	AP.APFs.BR.1	If the sender (H.5) of the product is not the EMA and the value of product operation type is not "nullify" (AP..1 <> 4) then this element must be *present*.	V5.0: Rule Added Operation result code: 504
	AP.APFs.BR.2	Each referenced *authorised pharmaceutical form code* must be unique for the current product.	V5:0: Rule Added Operation result code 505

Failure to comply leads to the generation of an *02* acknowledgement and the individual product is rejected.

Authorised Product – authorised pharmaceutical form (AP.APF)

Table 103. Business rules for the Authorised Product – authorised pharmaceutical form element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.APF.1 Back	AP.APF.1.BR.1	If the value of *resolution mode* is "local number" (AP.APF..1 = 1) then the referenced *pharmaceutical form* code must be present in the pharmaceutical form section (ST.PFs) of the current message and must NOT represent a development pharmaceutical form.	V5.0: Rule Added. Operation result code: 506

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	AP.APF.1.BR.2	If the value of *operation type* is "update", "insert" or "Invalidate MA" (AP..1 <> 4) AND the *resolution mode* is "global" (AP.APF..1 = 2) then the referenced *pharmaceutical form* code must be a ***pharmaceutical form code*** within the XEVMPD that is either standard or proposed and available to the sender.	V5.0: Rule Added. V5.0 correction: Rule Added. Operation result code: 507

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

ii Authorised Product – ATCs (AP.ATCs)

Table 104. Business rules for the Authorised Product - ATCs container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.ATCs Back	AP.ATCs.BR.1	Each referenced *ATC code* must be unique for the current product.	

Failure to comply leads to the generation of an *02* acknowledgement and the individual product is rejected.

Authorised Product – ATC Code (AP.ATC)

Table 105. Business rules for the Authorised Product - ATC element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.ATC.1 Back	AP.ATC.1.BR.1	If the value of *resolution mode* is "local number" (AP.ATC..1 =1) then the referenced *ATC* code must be present in the current message.	
	AP.ATC.1.BR.2	If the value of *operation type* is "update" or "insert" (AP..1 < 4) AND the *resolution mode* is "global" (AP.ATC..1 = 2) then the referenced *ATC code* must be an ***ATC code*** within the XEVMPD that is either standard or proposed and available to the sender.	V4.0: Rule Updated V5.0 Correction: Rule Updated
	AP.ATC.1.BR.3	If the value of *operation type* is "change ownership" or "Invalidate MA", (AP..1 = 5 or 6) AND the *resolution mode* is "global" (AP.ATC..1 = 2) then the referenced ATC code must be a current or deprecated ***ATC code*** within the XEVMPD and that is available to the sender.	V4.0: Rule updated

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

iii Authorised Product – Indications (AP.INDs)

Table 106. Business rules for the Authorised Product - Indications container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.INDs Back	AP.INDs.BR.1	If the value of **authorised product** *operation type* is "insert" or "update" (AP..1 < 4) then this section must be present.	Update: V5.0 Correction
	AP.INDs.BR.2	Each referenced MEDDRA code must be unique for the current product.	

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

Authorised Product - Indication (AP.IND)

Table 107. Business rules for the Authorised Product - Indication element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.IND.1 Back	AP.IND.1.BR.1	The referenced *MedDRA version* must be a known current ***MedDRA version***. This is not applicable during a nullification and/or invalidation of an AMP; the business rule for nullification and invalidation is relaxed and the MedDRA version is not considered during these operation types. For WebTrader users performing a reinsert or an update of a medicinal product in EVWEB, if the MedDRA version referenced in the product that is being reinserted/updated, is a non-current version, then the MedDRA version is automatically updated by the system to the last current MedDRA version during the reinsert/update of the product entity. This automatic update of non-current MedDRA version to the last current version is not applied during a nullification.	V5.3 Rule modified

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.IND.3 Back	AP.IND.3.BR.1	If the value of *operation type* is "insert" or "update" (AP..1 < 4) then the given value must be a current ***MedDRA code*** within the ***MedDRA version*** referenced in AP.IND.1. If the meddralevel is LLT, then the given MedDRA code cannot be deprecated for the given meddraversion. This is not applied during a nullification of the product entity.	V5.0 Correction: Rule amended V5.3 Rule modified
	AP.IND.3.BR.2	If the value of *operation type* is "change ownership" or "Invalidate MA" (AP..1 > 4) then the given value must be a ***MedDRA code*** within the XEVMPD within the ***MedDRA version*** referenced in AP.IND.1	

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

iv Authorised Product - Previous EV Codes (AP.PEVs)

This section is optional but, if present, must contain at least one valid previous EV Code section.

Change Log: V3

Table 108. Business rules for the Authorised Product – Previous EV Codes container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.PEVs Back	AP.PEVs.BR.1	Each referenced ***EV Code*** must be unique within the **PEVs** section.	
	AP.PEVs.BR.2	If the value of **authorisation status** is either: "Valid – Transferred Marketing Authorisation" or "Valid – Renewed Marketing Authorisation" (AP.12.3 = 8 or 9) then this section must be present	V4.0 Rule Added

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	AP.PEVs.BR.3	If the value of **authorisation status** is either: "Valid – Transferred Marketing Authorisation" or "Valid – Renewed Marketing Authorisation" (AP.12.3 = 8 or 9) then this section must contain a **Previous EV Code** section with a reference to a *current* authorised product within field AP.PEV.1 When the authorised product is being nullified or invalidated, the entity referenced in the previous EV code section is not considered; the nullification or invalidation must be successful even if the entity referenced in the previous EV code is not valid.	V4.0 Rule Added V5.3 Rule modified

Failure to comply leads to the generation of an *02* acknowledgement and the individual product is rejected.

Authorised Product - Previous EV Code (AP.PEV)

Table 109. Business rules for the Authorised Product – Previous EV Code element.

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.PEV.1 Back	AP.PEV.1.BR.1	The referenced **EV Code** must match the **EV Code** of a *current* development or authorised product within the XEVMPD. When the authorised product is being nullified or invalidated, the entity referenced in the previous EV code section is not considered; the nullification or invalidation must be successful even if the entity referenced in the previous EV code is not valid.	V4.0 Rule updated. V5.3 Rule modified

Failure to comply leads to the generation of an *02* acknowledgement and the individual product is rejected.

v Authorised Product - PPI Attachments (AP.PPIs)

Table 110. Business rules for the Authorised Product - Printed Product Informations container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.PPIs Back	AP.PPIs.BR.1	Each referenced *attachment EV Code* must be unique within the **PPIs** section.	
	AP.PPIs.BR.2	Each referenced *local number* must be unique within the **PPIs** section.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	AP.PPIs.BR.3	If the **message header** *sender* (H.5) is NOT the EMA **AND** the **authorised product** *operation type* is "insert" or "update" (AP..1 < 4) then this element must be present	V.3.1: Rule Amended. V.5.0 Correction: Rule Amended.
	~~AP.PPIs.BR.4~~		V3: Rule removed

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

Authorised Product - PPI Attachment (AP.PPI)

Table 111. Business rules for the Authorised Product - Printed Product Information element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
AP.PPI.1 Back	AP.PPI.1.BR.1	If the value of *resolution mode* is "local number" (AP.PPI.1..1 = 1) then the referenced *local number* must match a value in one of the fields ATT.1 in the **attachments** section.	V3: Rule text updated.
	AP.PPI.1.BR.2	If the value of *resolution mode* is "local number" (AP.PPI.1..1 = 1) then the referenced local **ATT** must be a "PPI" (ATT.5 = 1)	V3: Rule text updated.
	AP.PPI.1.BR.3	If the value of *resolution mode* is "global" (AP.PPI.1..1) **AND** the field AP.3 is empty then the referenced EV Code must match a current ***attachment*** owned by the sender's (H.5) ***EV Group***, the referenced ***attachment*** must be a ***"PPI"***.	
	AP.PPI.1.BR.4	If the value of *resolution mode* is "global" (AP.PPI.1..1) **AND** the **message header** *sender* (H.5) is the EMA **AND** the field AP.3 is present then the referenced *EV Code* must match a current ***attachment*** available to the ***EV Group*** of the owning organisation referenced in AP.3 the referenced ***attachment*** must be a "***PPI***"	
AP.PPI.2 Back	AP.PPI.2.BR.1	If the value of *resolution mode* is "global" (AP.PPI.1..1) **AND** the field AP.3 is empty **AND** the value of *operation type* is "update" (AP..1 = 2) then this field must be present. When performing an update of a product where a PPI attachment is already referenced, then the business rule is relaxed, and it is not required to specify the validity declaration.	V5.3 Rule modified V5.0 Correction: Rule updated.

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

3.I.d.14 Reused elements with the XEVPRM – Business Rules

3.I.d.14.1 Pharmaceutical Product (PP)

This element is used by both development products and authorised products. In most cases all of the rules below apply to both authorised and development products, however, there are additional rules governing referenced XEVMPD entities that differ between authorised and development products; Where this is the case the phrases; "All Products", "Authorised products only" and "Development products only" are used in the element reference column of the tables below to distinguish these rules.

Back to development product – pharmaceutical products.

Back to authorised product – pharmaceutical products.

Table 112. Business rules for the Pharmaceutical Product - Pharmaceutical Form element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.1 All products Back	PP.1.BR.1	If the *resolution mode* attribute specifies a "local number" (PP.1..1 = 1) then the value in this field must match the value in ST.PF.2 in one of the **pharmaceutical forms** present within the current **XEVPRM**.	
	PP.1.BR.2	If the *resolution mode* attribute specifies a "global number" (PP.1..1 = 2) then the value in this field must match the ***EV Code*** of a ***pharmaceutical form*** that is available to the **message header** *sender* (H.5) ***EV Group***.	V.3: Corrected text V4.0 Updated
PP.1 Authorised products only Back	PP.1.BR.3	If the *resolution mode* attribute specifies a "local number" (PP.1..1 = 1) AND the **product** is an **authorised product** then the referenced **pharmaceutical form** must not be a "development term" (ST.PF.1 ≠ 1)	
	PP.1.BR.4	If the *resolution mode* attribute specifies a "global number" (PP.1..1 = 2) AND the **product** is an **authorised product** then the referenced ***pharmaceutical form*** must not be a ***development term.***	PP.1.BR.2

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

3.I.d.14.2 Repeatable elements within the Pharmaceutical Product element

i Pharmaceutical Product - Admin Routes (PP.ARs)

Table 113. Business rules for the Pharmaceutical Product - Admin Route Codes element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.ARs Back	PP.ARs.BR.1	The combination of *resolution mode* and referenced **administration route** must be unique for each **administration route** within the current **pharmaceutical product**.	

Failure to comply leads to the generation of an *02* acknowledgement and the individual product is rejected.

Pharmaceutical Product - Admin Route (PP.AR)

Table 114. Business rules for the Pharmaceutical Product - Admin Route Code element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.AR.1 All Products Back	PP.AR.1.BR.1	If the *resolution mode* attribute specifies a "local number" (PP.AR.1..1 = 1) then the value in this field must match the value in ST.AR.2 in one of the **administration routes** present within the message.	
	PP.AR.1.BR.2	If the *resolution mode* attribute specifies a "global number" (PP.AR.1..1 = 2) then the value in this field must match the ***"EV Code"*** of a administration route that is available to the **message header** *sender* (H.5) ***EV Group***.	V4.0 Updated rule
PP.AR.1 Authorised products only. Back	PP.AR.1.BR.3	If the *resolution mode* attribute specifies a "local number" (PP.AR.1..1 = 1) AND the **product** is an **authorised product** then the referenced **administration route** must not be a "development term" (ST.AR.1 ≠ 1)	PP.AR.1.BR.1
	PP.AR.1.BR.4	If the *resolution mode* attribute specifies a "global number" (PP.AR.1..1 = 2) AND the **product** is an **authorised product** then the referenced ***administration route*** must not be a ***development term***.	PP.AR.1.BR.2

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

ii Pharmaceutical Product - Active Ingredients (PP.ACTs)

Table 115. Business rules for the Pharmaceutical Product – Active Ingredients container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.ACTs All Products Back	PP.ACTs.BR.1	Each referenced **active substance** must be unique for the current **pharmaceutical product**.	

Failure to comply leads to the generation of an *02* acknowledgement and the individual product is rejected.

iii Pharmaceutical Product - Active Ingredient (PP.ACT)

Table 116. Business rules for the Pharmaceutical Product – Active Ingredient element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.ACT.1 Development products only Back	PP.ACT.1.BR.1	If the *resolution mode* attribute specifies a "local number" (PP.ACT.1..1 = 1) then EITHER: The value in this field must match the value in one DS.1 field in one of the **development substances** present within the current **XEVPRM**. OR: The value in this field must match the value in one AS.1 field in one of the **approved substances** present within the current **XEVPRM**.	
	PP.ACT.1.BR.2	If the *resolution mode* attribute specifies an "EV Code" (PP.ACT.1..1 = 2) then the value in this field must match the ***EV Code of a substance*** that is available to the **message header** *sender* (H.5) ***EV Group***.	
PP.ACT.1 Authorised products only Back	PP.ACT.1.BR.3	If the *resolution mode* attribute specifies a "local number" (PP.ACT.1..1 = 1) then the value in this field must match the value in one AS.1 field in one of the **approved substances** present within the **message**.	
	~~PP.ACT.1.BR.4~~		V.3: Rule removed and replaced with PP.ACT.1.BR.6
	~~PP.ACT.1.BR.5~~		V.3: Rule removed and replaced with PP.ACT.1.BR.6
	PP.ACT.1.BR.6	If the *resolution mode* attribute specifies an "EV Code" (PP.ACT.1..1 = 2) then the value in this field must match the ***EV Code of a current approved substance in the XEVMPD***.	V.3: New rule replacing PP.ACT.1.BR.4/5
PP.ACT.2 All products Back	PP.ACT.2.BR.1	The *code* for the quantity operator must be supplied for the amount of active ingredient. The value must be present in the ***XEVMPD concentration type*** list published by the EMA.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	PP.ACT.2.BR.2	If this field has a value indicating a "range" (PP.ACT.2 = 2) then the following fields must all be present: PP.ACT.9, PP.ACT.10, PP.ACT.11, PP.ACT.12, PP.ACT.13, PP.ACT.14.	
	PP.ACT.2.BR.3	If this field does not specify a "range" (PP.ACT.2. ≠ 2) then the following fields must be absent: PP.ACT.9, PP.ACT.10, PP.ACT.11, PP.ACT.12, PP.ACT.13, PP.ACT.14	V5.0 correction: Rule Added
PP.ACT.4 All products Back	PP.ACT.4.BR.1	The value in this field must match a code from the published ***XEVMPD amount prefix*** list.	
PP.ACT.5 All products Back	PP.ACT.5.BR.1	The value in this field must match a code from the published ***XEVMPD amount numerator unit*** list.	
PP.ACT.7 All products Back	PP.ACT.7.BR.1	The value in this field must match a code from the published ***XEVMPD amount prefix*** list.	
PP.ACT.8 All products Back	PP.ACT.8.BR.1	The value in this field must match a code from the published ***XEVMPD amount denominator unit*** list.	
PP.ACT.9 All products Back	~~PP.ACT.9.BR.1~~		V5.0 Correction Rule removed PP.ACT.2.BR.2
	~~PP.ACT.9.BR.2~~		V5.0 Correction Rule removed PP.ACT.2.BR.3
	~~PP.ACT.9.BR.3~~		V5.0 Correction Rule removed PP.ACT.2.BR.2
PP.ACT.10 All products Back	~~PP.ACT.10.BR.1~~		V5.0 Correction Rule removed PP.ACT.2.BR.2
	~~PP.ACT.10.BR.2~~		V5.0 Correction Rule removed PP.ACT.2.BR.3
	PP.ACT.10.BR.3	If present the value in this field must match a code from the published ***XEVMPD amount prefix unit*** list.	
	~~PP.ACT.10.BR.4~~		V5.0 Correction Rule removed PP.ACT.2.BR.2

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.ACT.11 All products Back	~~PP.ACT.11.BR.1~~		V5.0 Correction Rule removed PP.ACT.2.BR.2
	~~PP.ACT.11.BR.2~~		V5.0 Correction Rule removed PP.ACT.2.BR.3
	PP.ACT.11.BR.3	If present the value in this field must match the value in field PP.ACT.5.	
	~~PP.ACT.11.BR.4~~		V5.0 Correction Rule removed PP.ACT.2.BR.2
PP.ACT.12 All products Back	~~PP.ACT.12.BR.1~~		V5.0 Correction Rule removed PP.ACT.2.BR.2
	~~PP.ACT.12.BR.2~~		V5.0 Correction Rule removed PP.ACT.2.BR.3
	PP.ACT.12.BR.3	If present the value in this field must match the value in field PP.ACT.6.	
	~~PP.ACT.12.BR.4~~		V5.0 Correction Rule removed PP.ACT.2.BR.2
PP.ACT.13 All products Back	~~PP.ACT.13.BR.1~~		V5.0 Correction Rule removed PP.ACT.2.BR.2
	~~PP.ACT.13.BR.2~~		V5.0 Correction Rule removed PP.ACT.2.BR.3
	PP.ACT.13.BR.3	If present the value in this field must match the value in field PP.ACT.7.	
	~~PP.ACT.13.BR.4~~		V5.0 Correction Rule removed PP.ACT.2.BR.2
PP.ACT.14 All products Back	~~PP.ACT.14.BR.1~~		V5.0 Correction Rule removed PP.ACT.2.BR.2
	~~PP.ACT.14.BR.2~~		V5.0 Correction Rule removed PP.ACT.2.BR.3
	PP.ACT.14.BR.3	If present the value in this field must match the value in field PP.ACT.8.	
	~~PP.ACT.14.BR.4~~		V5.0 Correction Rule removed PP.ACT.2.BR.2

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

iv Pharmaceutical Product - Excipients (PP.EXCs)

Table 117. Business rules for the Pharmaceutical Product - Excipients container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.EXCs All Products Back	PP.EXCs.BR.1	Each referenced **excipient substance** must be unique for the current **pharmaceutical product**.	

Failure to comply leads to the generation of an *02* acknowledgement and the individual product is rejected.

Pharmaceutical Product - Excipient (PP.EXC)

Table 118. Business rules for the Pharmaceutical Product - Excipient element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.EXC.1 Development products only Back	PP.EXC.1.BR.1	If the *resolution mode* attribute specifies a "local number" (PP.EXC.1..1 = 1) then EITHER: The value in this field must match the value in one DS.1 field in one of the **development substances** present within the current **XEVPRM**. OR: The value in this field must match the value in one AS.1 field in one of the **approved substances** present within the current **XEVPRM**.	
	PP.EXC.1.BR.2	If the *resolution mode* attribute specifies a "global number" (PP.EXC.1..1 = 2) then the value in this field must match the ***EV Code*** of a current ***substance*** that is available to the **message header** *sender* (H.5) ***EV Group***.	
PP.EXC.1 Authorised products only. Back	PP.EXC.1.BR.3	The value in this field must match the value in one AS.1 field in one of the **approved substances** present within the current **XEVPRM**.	
	~~PP.EXC.1.BR.4~~		V.3: Rule removed and replaced with PP.EXC.1.BR.6

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	~~PP.EXC.1.BR.5~~		V.3: Rule removed and replaced with PP.EXC.1.BR.6
	PP.EXC.1.BR.6	If the *resolution mode* attribute specifies an "EV Code" (PP.EXT.1..1 = 2) then the value in this field must match the ***EV Code of a current approved substance in the XEVMPD***.	V.3: New rule replacing PP.EXC.1.BR.4/5
PP.EXC.2 All products Back	PP.EXC.2.BR.1	If the code for the *quantity operator* for the amount of excipient (this field) is present, it must be a ***code value*** in the ***XEVMPD concentration type*** list published by the EMA.	
	PP.EXC.2.BR.2	If this field is present the following fields must all be present: PP.EXC.3, PP.EXC.4, PP.EXC.5, PP.EXC.6, PP.EXC.7, PP.EXC.8	
	PP.EXC.2.BR.3	If this field is present and has a value of 2 the following fields must all be present: PP.EXC.9, PP.EXC.10, PP.EXC.11, PP.EXC.12, PP.EXC.13, PP.EXC.14	
	PP.EXC.2.BR.4	If this field is absent the the following fields must all be absent: PP.EXC.3, PP.EXC.4, PP.EXC.5, PP.EXC.6, PP.EXC.7, PP.EXC.8, PP.EXC.9, PP.EXC.10, PP.EXC.11, PP.EXC.12, PP.EXC.13, PP.EXC.14	V5.0 Corrected: Added Rule
	PP.EXC.2.BR.5	If this field is present and does not specify a "range" (PP.EXC.2. ≠ 2) then the following fields must be absent: PP.EXC.9, PP.EXC.10, PP.EXC.11, PP.EXC.12, PP.EXC.13, PP.EXC.14	V5.0 Corrected: Added Rule
PP.EXC.3 All products Back	~~PP.EXC.3.BR.1~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.2
	~~PP.EXC.3.BR.2~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.2
PP.EXC.4 All products Back	PP.EXC.4.BR.1	If this field is present then the value in this field must match a ***code*** from the published ***XEVMPD amount prefix list***.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	~~PP.EXC.4.BR.2~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.2
PP.EXC.5 All products Back	PP.EXC.5.BR.1	If this field is present then the value in this field must match a ***code*** from the published ***XEVMPD amount numerator unit list***.	
	~~PP.EXC.5.BR.2~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.2
PP.EXC.6 All products Back	~~PP.EXC.6.BR.1~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.2
	~~PP.EXC.6.BR.2~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.2
PP.EXC.7 All products Back	PP.EXC.7.BR.1	If this field is present then the value in this field must match a ***code*** from the published ***XEVMPD amount prefix list***.	
	~~PP.EXC.7.BR.2~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.2
	~~PP.EXC.7.BR.3~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.2
PP.EXC.8 All products Back	PP.EXC.8.BR.1	If this field is present then the value in this field must match a ***code*** from the published ***XEVMPD amount denominator unit list***.	
	~~PP.EXC.8.BR.2~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.2
	~~PP.EXC.8.BR.3~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.2

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.EXC.9 All products Back	~~PP.EXC.9.BR.1~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.3
	~~PP.EXC.9.BR.2~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.5
	~~PP.EXC.9.BR.3~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.3
PP.EXC.10 All products Back	~~PP.EXC.10.BR.1~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.3
	~~PP.EXC.10.BR.2~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.5
	PP.EXC.10.BR.3	If present the value in this field must match a ***code*** from the published ***XEVMPD amount prefix unit list***.	
	~~PP.EXC.10.BR.4~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.3
PP.EXC.11 All products Back	~~PP.EXC.11.BR.1~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.3
	~~PP.EXC.11.BR.2~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.5
	PP.EXC.11.BR.3	If present the value in this field must match the value in field PP.EXC.5.	
	~~PP.EXC.11.BR.4~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.3

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.EXC.12 All products Back	~~PP.EXC.12.BR.1~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.3
	~~PP.EXC.12.BR.2~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.5
	PP.EXC.12.BR.3	If present the value in this field must match the value in field PP.EXC.6.	
	~~PP.EXC.12.BR.4~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.3
PP.EXC.13 All products Back	~~PP.EXC.13.BR.1~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.3
	~~PP.EXC.13.BR.2~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.5
	PP.EXC.13.BR.3	If present the value in this field must match the value in field PP.EXC.7.	
	~~PP.EXC.13.BR.4~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.3
PP.EXC.14 All products Back	~~PP.EXC.14.BR.1~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.3
	~~PP.EXC.14.BR.2~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.5
	PP.EXC.14.BR.3	If present the value in this field must match the value in field PP.EXC.8.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	~~PP.EXC.14.BR.4~~		V5.0 Corrected: Removed Rule Covered by: PP.EXC.2.BR.3

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

v Pharmaceutical Product - Adjuvant (PP.ADJs).

Table 119. Business rules for the Pharmaceutical Product - Adjuvants container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.ADJs All products Back	PP.ADJs.BR.1	Each referenced **adjuvant** substance must be unique for the current **pharmaceutical product.**	

Failure to comply leads to the generation of an *02* acknowledgement and the individual product is rejected.

Pharmaceutical Product - Adjuvant (PP.ADJ).

Table 120. Business rules for the Pharmaceutical Product - Adjuvant element

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.ADJ.1 Development products only Back	PP.ADJ.1.BR.1	If the *resolution mode* attribute specifies a "local number" (PP.ADJ.1..1 = 1) then EITHER: The value in this field must match the value in one DS.1 field in one of the **development substances** present within the current **XEVPRM**. OR: The value in this field must match the value in one AS.1 field in one of the **approved substances** present within the current **XEVPRM**.	
	PP.ADJ.1.BR.2	If the *resolution mode* attribute specifies an "EV Code" (PP.ADJ.1..1 = 2) then the value in this field must match the ***EV Code*** of a ***substance*** to that is available to the ***EV Group*** of the message header *sender* (H.5).	
PP.ADJ.1 Authorised products only Back	PP.ADJ.1.BR.3	The value in this field must match the value in one AS.1 field in one of the **approved substances** present within the current XEVPRM.	

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	~~PP.ADJ.1.BR.4~~		V.3: Rule removed and replaced by PP.ADJ.1.BR.6
	~~PP.ADJ.1.BR.5~~		V.3: Rule removed and replaced by PP.ADJ.1.BR.6
	PP.ADJ.1.BR.6	If the *resolution mode* attribute specifies an "EV Code" (PP.ADJ.1..1 = 2) then the value in this field must match the ***EV Code of a current approved substance in the XEVMPD***.	V.3: New rule replacing PP.ADJ.1.BR.4/5
PP.ADJ.2 All products Back	PP.ADJ.2.BR.1	The *quantity operator code* supplied for the amount of adjuvant ingredient must be a ***code*** from the ***XEVMPD concentration type list*** published by the EMA.	
	PP.ADJ.2.BR.2	If the *quantity operator* specifies a "range" (PP.EXC.2. = 2) then the following fields must all be present: PP.ADJ.9, PP.ADJ.10, PP.ADJ.11, PP.ADJ.12, PP.ADJ.13, PP.ADJ.14	
	PP.ADJ.2.BR.3	If this field does not specify a "range" (PP.ADJ.2. ≠ 2) then the following fields must be absent: PP.ADJ.9, PP. ADJ.10, PP. ADJ.11, PP. ADJ.12, PP. ADJ.13, PP. ADJ.14	V5.0 correction: Rule Added
PP.ADJ.4 All products Back	PP.ADJ.4.BR.1	The value in this field must match a ***code*** from the published ***XEVMPD amount prefix*** list.	
PP.ADJ.5 All products Back	PP.ADJ.5.BR.1	The value in this field must match a ***code*** from the published ***XEVMPD amount numerator unit*** list.	
PP.ADJ.7 All products Back	PP.ADJ.7.BR.1	The value in this field must match a ***code*** from the published ***XEVMPD amount prefix*** list.	
PP.ADJ.8 All products Back	PP.ADJ.8.BR.1	The value in this field must match a ***code*** from the published ***XEVMPD amount denominator unit*** list.	
PP.ADJ.9 All products Back	~~PP.ADJ.9.BR.1~~		V5.0 Correction Rule removed PP.ADJ.2.BR.2
	~~PP.ADJ.9.BR.2~~		V5.0 Correction Rule removed PP.ADJ.2.BR.3

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	~~PP.ADJ.9.BR.3~~		V5.0 Correction Rule removed PP.ADJ.2.BR.2
PP.ADJ.10 All products Back	~~PP.ADJ.10.BR.1~~		V5.0 Correction Rule removed PP.ADJ.2.BR.2
	~~PP.ADJ.10.BR.2~~		V5.0 Correction Rule removed PP.ADJ.2.BR.3
	PP.ADJ.10.BR.3	If present the value in this field must match a ***code*** from the published ***XEVMPD amount prefix unit*** list.	
	~~PP.ADJ.10.BR.4~~		V5.0 Correction Rule removed PP.ADJ.2.BR.2
PP.ADJ.11 All products Back	~~PP.ADJ.11.BR.1~~		V5.0 Correction Rule removed PP.ADJ.2.BR.2
	~~PP.ADJ.11.BR.2~~		V5.0 Correction Rule removed PP.ADJ.2.BR.3
	PP.ADJ.11.BR.3	If present the value in this field must match the value in field PP.ADJ.5.	
	~~PP.ADJ.11.BR.4~~		V5.0 Correction Rule removed PP.ADJ.2.BR.2
PP.ADJ.12 All products Back	~~PP.ADJ.12.BR.1~~		V5.0 Correction Rule removed PP.ADJ.2.BR.2
	~~PP.ADJ.12.BR.2~~		V5.0 Correction Rule removed PP.ADJ.2.BR.3
	PP.ADJ.12.BR.3	If present the value in this field must match the value in field PP.ADJ.6.	
	~~PP.ADJ.12.BR.4~~		V5.0 Correction Rule removed PP.ADJ.2.BR.2
PP.ADJ.13 All products Back	~~PP.ADJ.13.BR.1~~		V5.0 Correction Rule removed PP.ADJ.2.BR.2

Element Ref	Rule Ref	Description	Dependent Rules / Notes
	~~PP.ADJ.13.BR.2~~		V5.0 Correction Rule removed PP.ADJ.2.BR.3
	PP.ADJ.13.BR.3	If present the value in this field must match the value in field PP.ADJ.7.	
	~~PP.ADJ.13.BR.4~~		V5.0 Correction Rule removed PP.ADJ.2.BR.2
PP.ADJ.14 All products Back	~~PP.ADJ.14.BR.1~~		V5.0 Correction Rule removed PP.ADJ.2.BR.2
	~~PP.ADJ.14.BR.2~~		V5.0 Correction Rule removed PP.ADJ.2.BR.3
	PP.ADJ.14.BR.3	If present the value in this field must match the value in field PP.ADJ.8.	
	~~PP.ADJ.14.BR.4~~		V5.0 Correction Rule removed PP.ADJ.2.BR.2

Failure to comply with any of the rules above leads to the generation of an *02* acknowledgement and the individual product is rejected.

vi Pharmaceutical Product - Medical Devices (PP.MDs)

Table 121. Business rules for the Pharmaceutical Product - Medical Devices container

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.MDs All products Back	PP.MDs.BR.1	Each referenced **medical device** must be unique for the current **pharmaceutical product**.	

Failure to comply leads to the generation of a *02* acknowledgement and the individual product is rejected.

Pharmaceutical Product - Medical Device (PP.MD)

Table 122. Business rules for the Pharmaceutical Product - Medical Device element.

Element Ref	Rule Ref	Description	Dependent Rules / Notes

Element Ref	Rule Ref	Description	Dependent Rules / Notes
PP.MD.1 All products Back	PP.MD.1.BR.1	The value in this field must match a ***code value*** from the published list of ***medical devices***.	

Failure to comply leads to the generation of an *02* acknowledgement and the individual product is rejected.

Appendices

3.I.e Appendix 1 – List of enumerations in the XEVMPD schema

Table 123. Enumerations in use in XEVMPD schema (except Operation Type). The element reference is a hyperlink to the description of the field.

Element name	Element ref	Enumeration value	Value Meaning
messagetype	H.1	XEVPRM	
		xevprm	
messageformatversion	H.2	2	
messageformatrelease	H.3	0	
messagereceiveridentifier	H.6	EVHUMAN	For use in production system only
		EVTEST	For use in test system only
messagedateformat	H.7	204	Corresponds to "CCYYMMDDHHMMSS"
type_org	O.1	1	Marketing Authorisation Holder
		2	Sponsor
sme_status	O.19	1	NA
		2	Micro
		3	Small
		4	Medium
filetype	ATT.3	1	pdf
		2	doc
		3	docx
		4	xls
		5	xlsx
attachmenttype	ATT.5	1	Printed Product Information (PPI)
		2	Printed Substance Information (PSI)
versiondateformat	ATT.9 ST.ATC.5 ST.PF.6 ST.AR.6	102	Corresponds to "CCYYMMDD"
infodateformat	AP.10	102	Corresponds to "CCYYMMDD"
preferred	DS.DSN.2	1	Indicates name is the preferred name
		2	Indicates name is not the preferred name
iscode	DS.DSN.3	1	Indicates name is a code
		2	Indicates name is NOT a code
validitydeclaration	DS.ATT.2 AS.ATT.2 DP.PPI.2 AP.PPI.2	1	Indicates that the attachment is valid
type_term	ST.ATC.1	1	Development Term

Element name	Element ref	Enumeration value	Value Meaning
	ST.PF.1 ST.AR.1	2	Proposed Term (From 18 January 2024 EMA USE ONLY)
		3	Standard Term (EMA Use only)
meddralevel	DP.IND.2 AP.IND.2	SOC	System Organ Class
		soc	
		HLGT	Higher Level Group Term
		hlgt	
		HLT	Higher Level Term
		hlt	
		PT	Preferred Term
		pt	
		LLT	Lower Level Class
		llt	
authorisationdateformat	AP.12.6	102	Corresponds to "CCYYMMDD"
		610	Corresponds to "CCYYMM"
orphandrug	AP.12.9	1	Indicates that the product is an orphan drug
		2	Indicates that the product is NOT an orphan drug
intensivemonitoring	AP.12.10	1	Subject to intensive monitoring
		2	NOT subject to intensive monitoring
withdrawndateformat	AP.12.11	102	Corresponds to "CCYYMMDD"

Table 124. Operation Type Enumerations in use in the XEVMPD schema. The element reference is a hyperlink to the description of the field.

Element	Element ref	Value	Meaning of Value
Organisation	O..1	1	Insert
		2	Update
		4	Nullify
Source	S..1	1	Insert
		2	Update
		4	Nullify
Master File Location	MF..1	1	Insert
		2	Update
		4	Nullify
Attachment	ATT..1	1	Insert
Development Substance	DS..1	1	Insert
		2	Update
		4	Nullify
		5	Change Owner (this value is reserved for the EMA)
Approved Substance	AS..1	1	Insert

Element	Element ref	Value	Meaning of Value
		2	Update
		4	Nullify (this value is reserved for the EMA)
ATC	ST.ATC..1	1	Insert
		2	Update
		4	Nullify
Pharmaceutical Form	ST.PF..1	1	Insert
		2	Update
		4	Nullify
Administration Route	ST.AR..1	1	Insert
		2	Update
		4	Nullify
Development Product	DP..1	1	Insert
		2	Update
		4	Nullify
		5	Change Owner (this value is reserved for the EMA)
Authorised Product	AP..1	1	Insert
		2	Update
		~~3~~	Removed V5.0 (correction)
		4	Nullify
		5	Change Owner (this value is reserved for the EMA)
		6	Invalidate MA

Table 125. Resolution mode enumerations in use in the XEVMPD schema. Each element reference is a hyperlink to the description of the field.

Element	Element ref	Enumeration value	Value Meaning
All Resolution mode attributes	DS.4..1 DS.IC.1..1 DS.IC.2..1	1	Local number (Reference is the reference number of an element in the current message)

Element	Element ref	Enumeration value	Value Meaning
	DS.ATT.1..1 AS.3..1 AS.SA.1..1 AS.IC.1..1 AS.IC.2..1 AS.ATT.1..1 DP.5..1 DP.ATC..1 DP.PPI.1..1 AP.4..1 AP.6..1 AP.ATC..1 AP.PPI.1..1 AP.APF.1..1 PP.1..1 PP.AR.1..1 PP.ACT.1..1 PP.EXC.1..1 PP.ADJ.1..1 AP.APF.1..1	2	Global EV Code (Reference is the EV Code of an element in the XEVMPD)

3.I.f Appendix 2 – Use of amount fields in the ingredient sections.

The following guidance is given for the use of each of the amount fields in the pharmaceutical products section. The amount fields appear in the active ingredient, excipient and adjuvant sections. The guidance assumes that the field concentration type contains a value.

Scenario 1; (Substance is present at 1 milligram per tablet) specify the following

Field	XML Value	XEVMPD Data Entry Tool (EVWEB) Field Value
low amount numer value	1	1
low amount numer prefix	M	milli (1x10^-3)
low amount numer unit	G	Gram(s)
low amount denom value	1	1
low amount denom prefix	1	single
low amount denom unit	1{TABLET}	Tablet

Scenario 2; (Substance is present in a solution at 1000 International Units in 100 ml)

Field	XML Value	XEVMPD Data Entry Tool (EVWEB) Field Value
low amount numer value	1000	1000
low amount numer prefix	1	single
low amount numer unit	[IU]	International Units
low amount denom value	100	100
low amount denom prefix	M	milli (1x10^-3)
low amount denom unit	L	Litre(s)

Scenario 3; (Substance in a solution at 45% measured by weight volume)

Field	XML Value	XEVMPD Data Entry Tool (EVWEB) Field Value
low amount numer value	45	45
low amount numer prefix	1	single
low amount numer unit	%{W/V}	Percent Weight/Volume
low amount denom value	1	1
low amount denom prefix	1	single
low amount denom unit	1	Each

Scenario 4; (Substance is present in a solution in range between 1000 and 1100 Allergy Units per litre)

Field	XML Value	XEVMPD Data Entry Tool (EVWEB) Field Value
low amount numer value	1000	1000
low amount numer prefix	1	single
low amount numer unit	*[U]{ALLERGY}*	*Allergy Units*
low amount denom value	*1*	*1*
low amount denom prefix	*1*	*single*
low amount denom unit	*L*	*Litre(s)*
high amount numer value	1100	1100
high amount numer prefix	1	single
high amount numer unit	*[U]{ALLERGY}*	*Allergy Units*
high amount denom value	*1*	*1*
high amount denom prefix	*1*	*single*
high amount denom unit	*L*	*Litre(s)*

NB: In this scenario the values in *italic* must match between the low and high field pairs i.e. low amount denom value must match high amount denom value.

3.I.g Appendix 3 – Change log

Changes to this document are listed below. The changes are listed in descending version order and then by reference. Where applicable a hyperlink is provided between the reference and the area in this document that has been amended.

Reference	Summary of Change	Reason for Change	Applied Document Version
	Addition of cardinality for all operationtype attributes.	Consistency.	3
	Update of "product attachment information" to product "information attachment" throughout document.	Correction.	3
	Added Appendix 2.	Examples of how to complete ingredient amount section	3
AP.12.10.BR.1	Removed rule.	Product Intensive monitoring is not a required field.	3
AP.12.12.BR.4	Rule removed.	To allow suspended products to have a withdrawn date.	3
AP.12.12.BR.5	Rule added.	Change of EMA Policy	3
AP.12.12.BR.6	Rule added.	Change of EMA Policy	3
AP.12.3.BR.3	Rule updated.	To reflect new authorisation status list values	3
AP.12.3.BR.4	Rule updated.	To reflect new authorisation status list values	3
AP.12.3.BR.5	Rule added.	Change of EMA Policy	3
AP.12.5	Added clarification about when this field is required.	Clarification.	3
AP.12.7.BR.1	Text update	To reflect change in available list value text. No material change in rule	3
AP.12.8.BR.1	Removed procedures 2 and 6 from check clause.	Values no longer available in the parent list	3
AP.12.9.BR.1	Rule added.	Change of EMA policy.	3
AP.13.1.BR.1	Removed rule	Change of EMA policy.	3
AP.13.2	Updated cardinality to 0-1. Updated guidance.	Change of EMA Policy; either this or AP.13.3 must be specified.	3

Reference	Summary of Change	Reason for Change	Applied Document Version
AP.13.2.BR.1	Removed rule.	Change of EMA policy.	3
AP.13.2.BR.2	Added rule.	Either this or AP.13.3 must be specified.	3
AP.13.3	Updated guidance.	Either this or AP.13.2 must be specified.	3
AP.13.3.BR.1	Removed rule.	Change of EMA policy.	3
AP.13.3.BR.2	Added rule.	Either this or AP.13.2 must be specified.	3
AP.13.4	Updated guidance.	To clarify use of short name, generic name and company name	3
AP.13.4.BR.1	Removed rule.	Change of EMA policy.	3
AP.13.4.BR.2	Added rule.	Must be present if AP.13.2 is absent.	3
AP.13.5.BR.1	Removed rule.	Change of EMA policy	3
AP.13.6.BR.1	Removed rule.	Change of EMA policy.	3
AP.13.7.BR.1	Removed rule.	Change of EMA policy.	3
AP.5	Clarified circumstances under which this field is mandatory. Format of QQPV code specified as a number in the guidance.	Clarification. Correction.	3
AP.5.BR.3	Removed rule.	No circumstances exist under which the rule could generate an error.	3
AP.6	Clarified that the MFL Code is optional under all circumstances.	Change of EMA policy. MFL always optional.	3
AP.6.BR.1	Removed rule.	Change of EMA policy. MFL always optional.	3
AP.7.BR.1	Removed "not" from first check clause.	Error in rule wording	3
AP.8.BR.1	Removed "not" from first check clause.	Error in rule wording	3
AP.ATC	Corrected cardinality.	Error in V2	3
AP.ATC..1	Guidance updated for resolution mode 1.	Incorrect reference to foreign key.	3
AP.ATC.1	Corrected cardinality.	Error in V2.	3

Reference	Summary of Change	Reason for Change	Applied Document Version
AP.INDs	Added mandatory conditions to guidance.	Clarification of mandatory conditions.	3
AP.INDs Preamble	Clarified use of indications section.	Clarification	3
AP.PEVs	Guidance updated.	Clarification of usage.	3
AP.PP and DP.PP	Changed reference.	To clarify reuse of the section for both authorised and development products.	3
AP.PPI.1	Field name changed. Guidance updated.	Correction to reflect the field name in the schema. Update of guidance to clarify format of the data required.	3
AP.PPI.1.BR.1	Replaced "local insert" with "local number".	Correction of resolution mode meaning.	3
AP.PPI.1.BR.2	Replaced "local insert" with "local number".	Correction of resolution mode meaning.	3
AP.PPI.2	Guidance updated.	Clarification and consistency with DP.PPI.2.	3
AP.PPIs.BR.4	Removed rule.	No circumstances exist under which the rule could generate an error.	3
AS.1	Added mandatory for insert in guidance.	Consistency.	3
AS.6	Corrected use of empiric.	Scientific correction.	3
AS.7	Field name changed to substanceclass. Updated guidance to reflect mandatory usage conditions.	Correction to reflect schema and clarification of use.	3
AS.ATT.1	Guidance updated.	Update of guidance to clarify format of the data required.	3
AS.ATT.2	Guidance corrected.	Replaced reference to "development substance" with reference to "approved substance".	3
AS.ATTs Preamble	Added optional nature of the section.	Replacing AS.ATTs.BR.1.	3
AS.ATTs.BR.1	Rule removed.	The rule could never generate a failure.	3
AS.ATTs.BR.2	Rule added.	Omitted from V.2.	3
AS.IC.2	Guidance updated.	Clarification of usage.	3
AS.IC.2..1	Change of reference from AS.IC.2..2. Update of guidance.	Reference corrected. Clarification and correction guidance.	3

Reference	Summary of Change	Reason for Change	Applied Document Version
AS.IC.2..1.BR.1 to AS.IC.2..1.BR.4 (inc)	Rule added.	Clarification and control of use of AS.IC.2 and related fields.	3
AS.IC.2.BR.1 to AS.IC.2.BR.6 (inc)	Rule added.	Clarification and control of use of AS.IC.2 and related fields.	3
AS.ICs.BR.1	Rule removed.	Change of EMA policy.	3
AS.SSIs	Guidance changed.	Updated to reflect that at the current time the SSI section is not required by the EMA.	3
AS.SSIs.BR.1	Rule removed.	Change of EMA policy.	3
AS.SSIs.BR.3	Rule removed.	Change of EMA policy.	3
AS.SSIs.BR.4	Rule added.	Change of EMA policy.	3
AS.Ts.BR.1	Rule removed.	The rule could never generate a failure.	3
ATT.4	Made file name mandatory	Change of EMA policy	3
DP.1.BR.2	Removed "3" from the list of values checked.	"3" (variation) is not a viable option for development products. Also removed the value 3 from the schema enumeration.	3
DP.6.2.BR.4	Rule added.	Change of EMA Policy	3
DP.6.3.BR.3	Rule added.	Change of EMA Policy	3
DP.ATC..1	Guidance updated for resolution mode 1.	Incorrect reference to foreign key.	3
DP.ATCs.BR.1	Removed rule.	The rule could never generate a failure.	3
DP.IND.1 to DP.IND.3 (inc)	Made mandatory.	If the section is present then these three fields are all mandatory.	3
DP.INDs.BR.1	Rule removed.	The rule could never generate a failure.	3
DP.PPI.1	Guidance updated.	Update of guidance to clarify format of the data required.	3
DP.PPI.1..1	Removed references to foreign from keys.	Consistency.	3

Reference	Summary of Change	Reason for Change	Applied Document Version
DP.PPI.2	Added to fuller explanation to guidance.	Increased clarity.	3
DS.3	Added further explanation about the use of the newownerid field.	Clarification.	3
DS.6	Corrected use of empiric.	Scientific correction.	3
DS.7	Field name changed to substanceclass. Updated guidance to reflect mandatory usage conditions.	Correction to reflect schema and clarification of use.	3
DS.ATT.1	Field name changed. Guidance updated.	Correction to reflect the field name in the schema. Update of guidance to clarify format of the data required.	3
DS.ATT.1.BR.2	Wording changed.	Consistency – no material change to rule.	3
DS.ATT.1.BR.4	Wording changed.	Consistency – no material change to rule.	3
DS.ATTs.BR.1	Rule removed.	The rule could never generate a failure.	3
DS.ATTs.BR.2	Rule added.	Omitted from V.2.	3
DS.DSN.3	Guidance update.	Clarification of the use of the field and its relationship with substance name.	3
DS.IC	Guidance update.	To clarify the use of international code for specified substances.	3
DS.IC.2	Guidance update.	To clarify the use of international code for specified substances (when the code specified is an EV Code).	3
DS.IC.2..1	Guidance update.	To clarify the use of international code for specified substances (when the code specified is an EV Code).	3
DS.IC.2..1.BR.1 to DS.IC.2..1.BR.4 (inc)	Rule added.	Clarification and control of use of AS.IC.2 and related fields.	3
DS.IC.2.BR.1 to DS.IC.2.BR.6 (inc)	Rule added.	Clarification and control of use of AS.IC.2 and related fields.	3

Reference	Summary of Change	Reason for Change	Applied Document Version
DS.ICs.BR.1	Rule removed.	The rule could never generate a failure.	3
DS.SSIs	Guidance changed.	Updated to reflect that at the current time the SSI section is not required by the EMA.	3
H.2	Added guidance that the only value accepted is "2".	Clarification.	3
O.6	Updated guidance.	To clarify conditional mandatory – new EMA policy	3
O.6.BR.1	Rule Added.	New EMA policy	3
O.9	Updated guidance.	To clarify conditional mandatory – new EMA policy	3
O.9.BR.1	Rule Added.	New EMA policy	3
PP.1.BR.2	Replaced "pharmaceutical route" with "pharmaceutical form".	Correction of referenced XEVMPD entity.	3
PP.ACT.1.BR.4	Removed rule and replaced with PP.ACT.1.BR.6.	Change of EMA policy.	3
PP.ACT.1.BR.5	Removed rule and replaced with PP.ACT.1.BR.6.	Change of EMA policy.	3
PP.ACT.1.BR.6	Added rule to replace PP.ACT.1.BR.4 & PP.ACT.1.BR.5.	Change of EMA policy.	3
PP.ADJ.1.BR.4	Removed rule and replaced with PP.ADJ.1.BR.6.	Change of EMA policy.	3
PP.ADJ.1.BR.5	Removed rule and replaced with PP.ADJ.1.BR.6.	Change of EMA policy.	3
PP.ADJ.1.BR.6	Added rule to replace PP.ADJ.1.BR.4 & PP.ADJ.1.BR.5.	Change of EMA policy.	3
PP.EXC.1.BR.4	Removed rule and replaced with PP.EXC.1.BR.6.	Change of EMA policy.	3
PP.EXC.1.BR.5	Removed rule and replaced with PP.EXC.1.BR.6.	Change of EMA policy.	3
PP.EXC.1.BR.6	Added rule to replace PP.EXC.1.BR.4 & PP.EXC.1.BR.5.	Change of EMA policy.	3
SA.Ts.BR.1	Rule removed.	The rule could never generate a failure.	3
ST.AR.2.BR.1	Rule added.	Omitted in error	3
ST.AR.6.BR.1	Rule added.	Omitted from V.2.	3

Reference	Summary of Change	Reason for Change	Applied Document Version
ST.AR.7.BR.2	Rule added.	Omitted from V.2.	3
ST.ATC.5.BR.1	Rule added.	Omitted from V.2.	3
ST.ATC.6.BR.1	Rule added.	Omitted from V.2.	3
ST.ATC.6.BR.2	Rule added.	Omitted from V.2.	3
ST.ATC.7.BR.1	Rule added.	Omitted from V.2.	3
ST.ATCs.BR.1	Amended text.	Previous text referenced uniqueness within pharmaceutical forms in error – ATC must be unique within ATCs element.	3
Table 20 Heading	Renamed "Structured Substance Information".	Element name corrected.	3
xxxx**..1**	Operation type cardinality is always 1 within each section.	Made consistent throughout document.	3
AP..1.BR.3	Rule updated (correction).	To reflect update to referenced list values	3.1
AP.11	Guidance updated	Cross reference to Chapter3.II added.	3.1
AP.12.7	Guidance updated	Removed references to procedure types from guidance.	3.1
AP.12.8	Guidance updated	Removed references to procedure types from guidance.	3.1
AP.5	Updated schema to restrict the format of this field to an integer of maximum 10 digits.	Submission of data in this field in the incorrect format was causing parser failures.	3.1
AP.PPIs.BR.3	Rule amended.	Change of policy. Mandatory for all authorisation procedures.	3.1
Appendix 4	Added	To disseminate message process order to users	3.1
Appendix 5	Added	To disseminate result codes to users	3.1
AS.4	Added comment that approved name cannot be changed	Control of data integrity	3.1
AS.4.BR.3	Added rule to prevent change to approved substance name	Control of data integrity	3.1
AS.ATTs.BR.2	Rule amended	Replacement of "approved substance" with "attachment"	3.1

Reference	Summary of Change	Reason for Change	Applied Document Version
AS.T.2.BR.2	Amended text	To clarify; translation names must to be unique inter substance but not intra substance.	3.1
ATT.7	Length increased to 5 in schema.	To allow better versioning	3.1
DP.6.2.BR.4	Rule removed.	Rule added in error in version 3	3.1
DP.6.3.BR.3	Rule removed	Rule added in error in version 3	3.1
S..1.BR.1	Amended text	Replaced “organisation” with “source” to correct rule.	3.1
AP..1.BR.2	Amended text	Rule relaxed to mandate a comment only if the operation type is “nullification”	4.0
AP..1.BR.3	Amended text	To reflect new authorisation status list supporting transfer of MA and renewal of MA	4.0
AP..1.BR.4	Rule added	To support transfer of MA and renewal of MA	4.0
AP.12.11	Guidance Updated	To reflect concept of invalidating the MA rather than withdrawal of the authorised product	4.0
AP.12.12	Guidance Updated	To reflect concept of invalidating the MA rather than withdrawal of the authorised product	4.0
AP.12.12.BR.5	Rule updated	To reflect additions to the number of valid authorisation statuses	4.0
AP.12.12.BR.6	Rule updated	To reflect additions to the number of valid authorisation statuses	4.0
AP.12.3.BR.2	Rule updated	To support splitting of authorisation list into two sub lists and simplify the text of the rules	4.0
AP.12.3.BR.3	Rule updated	To support splitting of authorisation list into two sub lists and simplify the text of the rules	4.0
AP.12.3.BR.4	Rule updated	To support splitting of authorisation list into two sub lists and simplify the text of the rules	4.0
AP.12.3.BR.5	Rule updated	To support splitting of authorisation list into two sub lists and simplify the text of the rules	4.0

Reference	Summary of Change	Reason for Change	Applied Document Version
AP.14.BR.1	Rule updated	To reduce number of operations for which a comment is required	4.0
AP.2.BR.3	Rule added	To prevent operations on products with Non Valid authorisation status	4.0
AP.ATC.1.BR.2	Rule updated	To allow use of deprecated ATC codes and clarify that code chosen must be either a standard or proposed term	4.0
AP.ATC.1.BR.3	Rule updated	To reflect new values for operation types and clarify that code chosen must be either a standard or proposed term	4.0
AP.PEV.1	Amended Guidance	To support transfer of MA and renewal of MA	4.0
AP.PEV.1.BR.1	Amended text	To support transfer of MA and renewal of MA	4.0
AP.PEVs.BR.2	Rule added	To support transfer of MA and renewal of MA	4.0
AP.PEVs.BR.3	Rule added	To support transfer of MA and renewal of MA	4.0
PP.1.BR.2	Rule updated	To allow the use of deprecated standard pharmaceutical forms	4.0
PP.AR.1.BR.2	Rule updated	To allow the use of deprecated standard administration routes	4.0
ST.AR..1.BR.1	Rule updated	To facilitate restrictions for updates and nullification of proposed Administration Routes	4.0
ST.AR..1.BR.4	Rule added	To prevent non EMA users from updating proposed Administration Routes	4.0
ST.AR..1.BR.5	Rule added	To prevent non EMA users from nullifying proposed Administration Routes	4.0
ST.PF..1.BR.1	Rule updated	To facilitate restrictions for updates and nullification of proposed pharmaceutical forms	4.0
ST.PF..1.BR.4	Rule added	To prevent non EMA users from updating proposed pharmaceutical forms	4.0

Reference	Summary of Change	Reason for Change	Applied Document Version
ST.PF..1.BR.5	Rule added	To prevent non EMA users from nullifying proposed pharmaceutical forms	4.0
3.I.a.6	Explanatory section added	To explain the inclusion of optional decoding attributes to fields referencing codes within the system to make them more human friendly for exports	4.1
AP..1	Enumeration correction	Development products have never had a variation operation available	5.0(correction)
AP..1 (enumeration)	Enumeration Update	Removed Variation product operation	5.0(correction)
AP..1.BR.4	Rule Amended	Removed reference to variation product operation.	5.0(correction)
AP.12.1.BR.2	Rule Added	To improve data quality	5.0
AP.12.13	Section Added	To update schema in line with new reporting format	5.0
AP.12.13.BR.1	Rule Added	To make the field mandatory for specific operation types	5.0
AP.12.13.BR.1	Rule Amended	Removed reference to variation product operation.	5.0(correction)
AP.12.13.BR.2	Rule Added	To ensure referential integrity of the data provided	5.0
AP.12.4.BR.1	Rule Amended	Removed reference to variation product operation.	5.0(correction)
AP.12.5.BR.1	Rule Amended	Removed reference to variation product operation.	5.0(correction)
AP.12.MPT.1.BR.1	Rule Added	To ensure referential integrity of the data provided	5.0
AP.12.MPTs	Section Added	To update schema in line with new reporting format	5.0
AP.12.MPTs.BR.1	Rule Added	To make the field mandatory for specific operation types	5.0
AP.12.MPTs.BR.2	Rule Added	To prevent duplicate values in the product	5.0
AP.5.BR.1	Rule Amended	Removed reference to variation product operation.	5.0(correction)
AP.7.BR.1	Rule Amended	Removed reference to variation product operation.	5.0(correction)
AP.8.BR.1	Rule Amended	Removed reference to variation product operation.	5.0(correction)
AP.APF	Section Added (AP_APF, APF.1, APF.1..1)	To update schema in line with new reporting format	5.0

Reference	Summary of Change	Reason for Change	Applied Document Version
AP.APF.1.BR.1	Rule Added	To ensure local number references correct pharmaceutical form	5.0
AP.APF.1.BR.2	Rule Added	To ensure that EV Code is valid and of the correct type.	5.0
AP.APF.1.BR.2	Rule Amended	Removed reference to variation product operation. Added reference to invalidate MA	5.0(correction)
AP.APFs	Section Added	To update schema in line with new reporting format	5.0
AP.APFs.BR.1	Rule Added	To make the section mandatory for all but nullified data	5.0
AP.APFs.BR.2	Rules Added	To prevent duplicate values in the product	5.0
AP.ATC.1.BR.2	Rule Amended	Removed reference to variation product operation.	5.0(correction)
AP.IND.3.BR.1	Rule Amended.	Removed reference to variation product operation.	5.0(correction)
AP.INDs	Guidance Amended.	Removed reference to variation product operation.	5.0(correction)
AP.INDs section preamble	Preamble Amended.	Removed reference to variation product operation.	5.0(correction)
AP.INDs.BR.1	Rule Amended.	Removed reference to variation product operation.	5.0(correction)
AP.PPI.2.BR.1	Rule Amended	Removed reference to variation product operation.	5.0(correction)
AP.PPIs.BR.3	Rule Amended.	Change of policy. Mandatory for all authorisation procedures.	5.0(correction)
Appendix 8	Text removed	Textual representation of the schema was removed and replaced with a link to a zip file containing the forthcoming XEVMPD schema and ackonwledgement	5.0(correction)
DP..1	Enumeration correction	Development products have never had a variation operation available	5.0(correction)
O.19	Added Element	New format for reporting Organisation data	5.0
O.19.BR.1	Rule Added	To prevent Sponsors having SME status	5.0
O.19.BR.2	Rule Added	To enforce SME status for current MAHs	5.0

Reference	Summary of Change	Reason for Change	Applied Document Version
O.19.BR.2 O.DUP.BR.1	Rule Corrected	MAH is enumeration value 1 not 2	5.0(correction)
O.20	Added Element	New format for reporting Organisation data	5.0
O.20.BR.1	Rule Added	To ensure that only SMEs have an SME number	5.0
O.20.BR.1	Rule Corrected	Corrected text of conditions	5.0(correction)
O.DUP.BR.1	Rule Added	To prevent duplicate MAH values within the xEVMPD	5.0
O.DUP.BR.2	Rule Added	To prevent duplicate sponsor values within the xEVMPD	5.0(correction)
Operaration result 11	Removed	Removed reference to variation product operation.	5.0(correction)
PP.ACT.2.BR.3	Rule Added	To facilitate removing complex rules at each field level in the active ingredient strength section. Note that the effect of this rule and the other ACT.2 rules is the same as the previous rule set which were detailed in many different fields at ACT level. The duplicate rules which are removed are shown below.	5.0(correction)
PP.ACT.9.BR.1 PP.ACT.9.BR.3 PP.ACT.10.BR.1 PP.ACT.10.BR.4 PP.ACT.11.BR.1 PP.ACT.11.BR.4 PP.ACT.12.BR.1 PP.ACT.12.BR.4 PP.ACT.13.BR.1 PP.ACT.13.BR.4 PP.ACT.14.BR.1 PP.ACT.14.BR.4	Rule Removed	Rules identified as having duplicate effect as rule PP.ACT2.BR.1 (if value of concentration type = 2 then all strength fields must be completed). Removed to aid clarity.	5.0(correction)

Reference	Summary of Change	Reason for Change	Applied Document Version
PP.ACT.9.BR.2 PP.ACT.10.BR.2 PP.ACT.11.BR.2 PP.ACT.12.BR.2 PP.ACT.13.BR.2 PP.ACT.14.BR.2	Rule Removed	Rules identified as having duplicate effect as rule PP.ACT.2.BR.3 (if value of concentration type ≠ 2 then all high amount strength fields must be absent). Removed to aid clarity.	5.0(correction)
PP.ADJ.2.BR.3	Rule Added	To facilitate removing complex rules at each field level in the active ingredient strength section. Note that the effect of this rule and the other ADJ.2 rules is the same as the previous rule set which were detailed in many different fields at ADJ level. The duplicate rules which are removed are shown below.	5.0(correction)
PP.ADJ.9.BR.1 PP.ADJ.9.BR.3 PP.ADJ.10.BR.1 PP.ADJ.10.BR.4 PP.ADJ.11.BR.1 PP.ADJ.11.BR.4 PP.ADJ.12.BR.1 PP.ADJ.12.BR.4 PP.ADJ.13.BR.1 PP.ADJ.13.BR.4 PP.ADJ.14.BR.1 PP.ADJ.14.BR.4	Rule Removed	Rules identified as having duplicate effect as rule PP.ADJ.2.BR.1 (if value of concentration type = 2 then all strength fields must be completed). Removed to aid clarity.	5.0(correction)

Reference	Summary of Change	Reason for Change	Applied Document Version
PP.ADJ.9.BR.2 PP.ADJ.10.BR.2 PP.ADJ.11.BR.2 PP.ADJ.12.BR.2 PP.ADJ.13.BR.2 PP.ADJ.14.BR.2	Rule Removed	Rules identified as having duplicate effect as rule PP.ADJ.2.BR.3 (if value of concentration type ≠ 2 then all high amount strength fields must be absent). Removed to aid clarity.	5.0(correction)
PP.EXC.2.BR.4	Rule Added	To facilitate removing complex rules at each field level in the excipient strength section. Note effect of this rule and the other EXC.2 rules is the same as the previous rule set which were detailed at EXC level and are shown as removed below.	5.0(correction)
PP.EXC.2.BR.5	Rule Added	To facilitate removing complex rules at each field level in the excipient strength section. Note effect of this rule and the other EXC.2 rules is the same as the previous rule set which were detailed at EXC level and are shown as removed below.	5.0(correction)
PP.EXC.3.BR.1 PP.EXC.3.BR.2 PP.EXC.4.BR.2 PP.EXC.5.BR.2 PP.EXC.6.BR.1 PP.EXC.6.BR.2 PP.EXC.7.BR.2 PP.EXC.7.BR.3 PP.EXC.8.BR.2 PP.EXC.8.BR.3	Rule Removed	Rules identified as having duplicate effect as rule PP.EXC.2.BR.2 (if concentration type is present then fields EXC 3 – 8 must be present). Removed to aid clarity.	5.0(correction)

Reference	Summary of Change	Reason for Change	Applied Document Version
PP.EXC.9.BR.1 PP.EXC.9.BR.3 PP.EXC.10.BR.1 PP.EXC.10.BR.4 PP.EXC.11.BR.1 PP.EXC.11.BR.4 PP.EXC.12.BR.1 PP.EXC.12.BR.4 PP.EXC.13.BR.1 PP.EXC.13.BR.4 PP.EXC.14.BR.1 PP.EXC.14.BR.4	Rule Removed	Rules identified as having duplicate effect as rule PP.EXC.2.BR.3 (if value of concentration type = 2 then all high amount strength fields must be present). Removed to aid clarity.	5.0(correction)
PP.EXC.9.BR.2 PP.EXC.10.BR.2 PP.EXC.11.BR.2 PP.EXC.12.BR.2 PP.EXC.13.BR.2 PP.EXC.14.BR.2	Rule Removed	Rules identified as have duplicate effect as rule PP.EXP.2.BR.5 (if concentration type ≠ 2) then all high amount strength fields must be absent). Removed to aid clarity.	5.0(correction)
AP.12.12.BR.5	Rule updated	To reflect additions to the number of valid authorisation statuses by modifying check to include code 2.	5.1
AP.5.BR.3	New Rule Added	Rule to check QPPV code is same as current value where EMA is not product owner	5.1
AP.6.BR.1	New Rule Added	Rule to check MFL code is same as current value where EMA is not product owner	5.1
DS..1	Added Rule DS..1.BR.5	To centralize substancies registration in one system	5.1
AS..1	Added Rule AS..1.BR.5	To centralize substancies registration in one system	5.1

Appendix 4 – Message Process Order

The list below shows the order in which elements within a message are processed. Note that for errors that give rise to an 03 error acknowledgement at the message level only the first element that generates an error is shown.

Messages are processed in the following order of elements;

Attachment Elements

Master File Location Elements

Organisation Elements

Reference Source Elements

Development Substance Elements

Approved Substance Elements

ATC Elements

Pharmaceutical Form Elements

Administration Route Elements

Development Product Elements

Authorised Product Elements

If an 03 error code is received for (for instance) an approved substance in a message that contains Organisation elements (i.e. any element that is processed before the element that caused the business rule violation) then it can be assumed that ***at the time of processing*** the data contained in the each Organisation Element conformed to the business rules. Note all elements in the message will require resubmission since the entire message is rejected if an 03 acknowledgement is generated.

3.I.h Appendix 5 – Element Acknowledgement Codes

In the corrections to version 5.1 of this document the element acknowledgment codes detailed here have been removed. The codes can now be found on the Agencys guidance documents webpage at the following public link under the "Related links" section where users can download the file:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000336.jsp&mid=WC0b01ac05804d8b2b&jsenabled=true

3.I.i Appendix 6 – Elements with decoding attributes for product exports

Back to technical explanation

The fields in the table below have had a name attribute added to aid reading of product export xml files.

Table 126. Export decoding attributes

Reference Type	Parent xEVMPD Element Name	Field Name	Field ID(s)
Reference to an EV Code	authorisedproduct	mahcode	AP.4
		mflcode	AP.6
	ppiattachment	attachmentcode	AP.PPI.1/DP.PPI.1
	authorised or development product: pharmaceuticalproduct	pharmformcode	PP.1
	authorised or development product: pharmaceuticalproduct adminroutes.adminroute	adminroutecode	PP.AR.1
	authorised or development product: pharmaceuticalproduct activeingredient excipient adjuvant	substancecode	PP.ACT.1 PP.EXP.1 PP.ADJ.1
	developmentsubstance	sponsorcode	DS.4
	developmentsubstance.internationalcode	sourcecode	DS.IC.1
	developmentsubstance.attachment	attachmentcode	DS.ATT.1
	approvedsubstancee	sourcecode	AS.3
	approvedsubstance.substancealias	sourcecode	AS.SA.1
	approvedsubstance.internationalcode	sourcecode	AS.IC.1

Reference Type	Parent xEVMPD Element Name	Field Name	Field ID(s)
	approvedsubstance.attachment	attachmentcode	AS.ATT.1
	developmentproduct	sponsorcode	DP.5
	developmentproduct.atc	atccode	DP.ATC.1
Reference to a look up value	authorisedproduct.authorisation	authorisationcountrycode	AP12.1
		authorisationprocedure	AP12.2
		authorisationstatus	AP12.3
	authorised or development product: pharmaceuticalproduct productatc	atccode	AP.ATC.1 DP.ATC.1
	authorised or development product: pharmaceuticalproduct productindication	meddracode	AP.Ind.3 DP.Ind.3
	authorised or development product: pharmaceuticalproduct activeingredient/excipient/adjuvant	concentrationtypecode	PP.ACT.2 PP.EXP.2 PP.ADJ.2
		lowamountnumerprefix	PP.ACT.4 PP.EXP.4 PP.ADJ.4
		lowamountnumerunit	PP.ACT.5 PP.EXP.5 PP.ADJ.5
		lowamountdenomprefix	PP.ACT.7 PP.EXP.7 PP.ADJ.7
		lowamountdenomunit	PP.ACT.8 PP.EXP.8 PP.ADJ.8
		highamountnumerprefix	PP.ACT.10

Reference Type	Parent xEVMPD Element Name	Field Name	Field ID(s)
			PP.EXP.10 PP.ADJ.10
		highamountnumerunit	PP.ACT.11 PP.EXP.11 PP.ADJ.11
Reference to a look up value (cont)	authorised or development product: pharmaceuticalproduct activeingredient/excipient/adjuvant	highamountdenomprefix	PP.ACT.13 PP.EXP.13 PP.ADJ.13
		highamountdenomunit	PP.ACT.14 PP.EXP.14 PP.ADJ.14
	Authorised or development product: pharmaceuticalproduct medicaldevice	medicaldevicecode	PP.MD.1
	organisation	countrycode	O.10
	masterfilelocation	mflcountrycode	MFL.10
	authorised or development product: ppiattachment	Attachmentcode	AP.PPI.1 DP.PPI.1
	authorisedproduct.previousevcode	devevcode	AP.PEV.1
Reference to registration system	authorisedproduct	qppvcode	AP.5
Reference to an enumeration	authorisedproduct.authorisation	orphandrug	AP.12.9
		intensivemonitoring	AP.12.10

3.I.j Appendix 7 – Previous version Summaries

Back to executive summary

Version 3.0

The following changes affect **Authorised Products**:

- Product Short Name, Generic Name and Company Name become a trio of fields where mandatory depends on the presence/absence of the other two fields in the trio.
- Master File Location becomes optional under all circumstances.
- Orphan Drug Status becomes mandatory unless the operation type is nullification or withdrawal.
- Intensive Monitoring becomes optional under all circumstances.
- Package Description becomes optional under all circumstances.
- The requirement for all updates, insertions and variations to reference substances with a valid SSI is removed.
- Withdrawn date becomes mandatory if the authorisation status is any value other than "valid"

The following changes affect **Approved Substances**:

- The submission of the Structured Substance Information section is not required by the Agency.

The following changes affect **Organisations**:

- The organisation address and postcode become mandatory if the operation type is not nullification.

The following changes are included in the document to improve understanding of the technical guidance and rules:

- The document contains the addition of a section explaining the use of enumerations in the schema.
- Tables providing the built in schema enumeration values available are provided in Appendix 1. Links are provided between these tables and each element that uses any given enumeration.

- Guidance is provided for the use of the amount fields within the Pharmaceutical Product Ingredient sections, Active Ingredients, Excipients and Adjuvant see Appendix 2.
- All material changes, corrections and clarifications are detailed within a change log contained in Appendix 3. Links are provided between each element or rule that has been changed and the change log.

Back to executive summary

Version 3.1

Back to executive summary

The following changes affect **Authorised Products**:

- Business rule AP.PPIs.BR.3 extended to include all authorisation procedures.
- Business rule AP..1.BR.3 corrected to reflect updated list values.
- Length of attachment version (ATT.7) increased to 5 characters.
- Data type of QPPV field (AP.5) changed to positive integer max length 10 digits
- Business rule AS.ATTs.BR.2 corrected.
- Business rule S..1.BR.1 corrected.
- Business rules DP.6.2.BR.4 & DP.6.3.BR.3 removed.
- AP.11 Guidance Updated.
- The following changes affect **Approved Substances**:
- Business rule AS.4.BR.3 added to prevent changes to the substance name.

The following changes are included in the document to improve understanding of technical process order and acknowledgment codes:

- Added Appendix 4 – Process Order.
- Added Appendix 5 – Result Codes.

Back to executive summary

Version 4.0

This version of the document should be used in conjunction with version 4.0 of the XEVMPD schema. There is no technical difference between V3.1 of the schema and V4.0. The annotations in the schema have been updated to reflect the changes contained within this version of Chapter 3.I.

The following changes apply **throughout the document**:

- The operation type description for "withdrawal" was updated throughout to "Invalidate MA" throughout this document to reflect the new usages of this operation type in the process to support renewal and transfer of Marketing Authorisation.
- All amendments that appeared in version V3.1 in strikethrough font were removed.
- All amendments where a material change occurred in this version show the value from the previous version in strikethrough font.

The following changes apply to **Authorised Products**:

- Business rules AP..1.BR.2 & AP.14.BR.1 updated to relax mandating comment for product operations.
- Business rules AP..1.BR.3, AP.12.3.BR.2, AP.12.3.BR.3, AP.12.3.BR.4, AP.12.3.BR.5, AP.12.12.BR.5 & AP.12.12.BR.6 updated to reflect updated list values supporting transfer and renewal of Marketing Authorisation.
- Business rule AP..1.BR.4 added to reflect updated list values supporting transfer and renewal of Marketing Authorisation.
- Business rule AP.2.BR.3 added to prevent operations on products which are not in a valid authorisation status.
- Guidance for use of previous EV Code (AP.PEV.1) changed to support transfer and renewal of MA.
- Business rules AP.PEVs.BR.2 & AP.PEVs.BR.3 added to support transfer and renewal of MA.

- Business rule AP.PEV.1.BR.1 updated to support transfer and renewal of MA.
- Business rules AP.ATC.1.BR.2, AP.ATC.1.BR.3, PP.1.BR.2 & PP.AR.1.BR.2 updated to allow use of deprecated standard terms.

The following changes apply to Standard Terms (Routes of Administration and Pharmaceutical Forms):

- Added business rules (ST.PF..1.BR.4, ST.AR..1BR.4) to prevent update and nullification of proposed standard terms.
- Updated operation types allowed table to reflect current situation

Back to executive summary

Version 4.1

This version of the document details the schema changes that are made to support the export of products from the xEVMPD. Note that there are no changes to the business rules in force as described in Version 4.0.

The changes that have been made to the schema have no technical impact on the submission of messages which are prepared against Version 4.0 and are all designed to allow EV Codes and list values to be decoded into human readable form in exports, and in each case involve the addition of an optional "name" attribute to imported coded fields. For an example and technical explanation please refer to section 3.I.a.6 below

The presence or absence of any of the "name" attributes in a submitted message will not affect the loading of the message and the value of the data in the attribute will be ignored and not loaded in the xEVMPD. The user should **NOT** assume that a value in any name attribute will have any impact on the underlying referenced entity or list. A list of fields which have had the name attribute added is shown below. Note that since there are no technical or business rule changes associated with Version 4.1 the document was not published as a stand-alone version.

Back to executive summary

Version 5.0

Republished on 8th April (Version 5.0.correction):

As of 16th June 2014 and by 31 December 2014 at latest, marketing authorisation holders are requested to update, complete, improve the quality and submit to the Agency information on all medicinal products submitted under Article 57(2) provisions and in compliance with the new XEVPRM format as publish by the Agency on 31st January 2014.

This version of the document shows the changes to the schema and business rules in support of this new format.

The following changes apply to **Organisation (O) element**

- New element called sme_status (O.19) added.
  - Business rules: O.19.BR.1 & O.19.BR.2
- New element called sme_number (O.20) added.
  - Business rules: O.20.BR.1
- New business rule (O.DUP.BR.1) added.

The following changes apply to **Authorised Products**:

- New business rule for the authorisation country code (AP.12.1.BR.2)
- New repeatable element called authpharmforms (AP.APFs) added, this contains the new AP.APF element for specifying the pharmaceutical forms of a product as authorised.
  - Business rules (AP.APFs): AP.APFs.BR.1 & AP.APFs.BR.2,
  - Business Rules (AP.APF): AP.APF.1.BR.1 & AP.APF.1.BR.2
- New repeatable element called medicinal product types (AP.12.MPTs) added to the authorisation section, this contains the new AP.12.MPT element for specifying the medicinal product types of a product.
  - Business rules (AP.12.MPTs): AP.12.MPTs.BR.1 & AP.12.MPTs.BR.2

- Business Rules (AP.12.MPT): AP.MPT.1.BR.1

- New element called legal basis (AP.12.13) added to the authorisation section
  - Business rules: AP.12.13.BR.1 & AP.12.13.BR.1

Corrections published (4th April 2014) are shown in Appendix 9

In addition to the list of corrections;

- A description of the values returned in all @name fields (decoding attributes for exports) was added in the schema tables.
- Removal of references to the variation operation for authorised products. These are individually logged where applicable.
- Appendix 8 (textual view of XEVPRM schema removed. (See section 3.I.a.2 for details of schema locations)
- Simplification of strength section rules for AP/DP.EXC, AP/DP.ACT and AP/DP.ADJ – note the net effect of these rules is no change to the rules currently in force, the change is an attempt to make them easier to understand.

NOTE: Chapter 5 of the detailed guidance has also been updated and published on the 4th April 2014 to detail minor changes to the XEVMPD_ACK schema to support notifying product submitters when the EMA has substituted a known duplicate value with a preferred value.

Version 5.1

- All text in strikethrough font (rules that are removed or amended plus amended guidance) where the change occurred before version 5.0 was removed
- Change summary for versions 4.0 and 4.1 moved to appendix 7
- Added new error code "95" to be displayed in Ack for failure of rule S..1.BR.3
- Removed "Appendix 5 – Element Acknowledgement Codes" to separate guidance document for ease of maintenance.
- Rule to check MFL & QPPPV Code is same as current value where EMA is not product owner.

Version 5.3

- O..1.BR.4 – organisation nullification.
- ST.ATC..1.BR.4 – ATC code nullification.
- ST.PF..1.BR.3 – pharmaceutical forms nullification.
- ST.AR..1.BR.3 – administration route nullification.
- MF..1.BR.3 – master file location nullification.
- AS.PEV.1.BR.1 - previous EV Code approved substances.
- AP.PEVs.BR.1 - previous EV Code authorised products.
- AP.PEVs.BR.3 - previous EV Code authorised products.
- DP.PPI.2, DP.PPI.2.BR.1 – relax declaration validity when updating development products.
- AP.PPI.2, AP.PPI.2.BR.1 – relax declaration validity when updating authorised products.
- AP.IND.1, AP.IND.1.BR.1 – relax MedDRA version validation for operation nullification for AMP.
- DP.IND.1.BR.1 – relax MedDRA version validation for operation nullification for DMP.
- AP.IND.1, AP.IND.1.BR.1 – relax MedDRA version validation for operation invalidation for AMP.
- AP.5.BR.5 – relax QPPV integrity constraint validity check for the operations nullification and invalidation.
- Added rule: AP.12.12.BR.7 - new authorisation procedure.
- Modified rule AP.12.13.BR.2 - new legal basis.
- Modified rules - DP.IND.1.BR.1, AP.IND.1.BR.1 – Added automatic update of non-current MedDRA version to the last current version
- Modified rules - DP.IND.3.BR.1, AP.IND.3.BR.1 – Added validation for deprecated LLT terms.

Appendix 8 – Version 5 xEVMPD schema

In the correction to version 5.0 of this document the textual representation of the XEVMPD schema contained here was removed. At the same time as the corrected version of the document was published the schema that will come into force on 16th June 2014 became available for download and extraction from the following zip file:

http://eudravigilance.ema.europa.eu/schema/emaxempd_v50_schemas.zip

3.I.k Appendix 9 – Version 5.0 Corrections

The following corrections have been make following feedback from stakeholders:

- Section 3.I.a.1: replaced "Withdrawn" with "Invalidate MA"
- Table 3: Cardinality of Country Code @name – given as 0. Corrected to 0-1
- Table 15: Reformated to prevent orphan lines
- Table 40: Attachment code – name and reference – corrected to and @name and @N/A repectively
- Figure 31: Corrected title reference from schema version 5.1 to schema version 5.0
- Figure 31: Correction to figure – wrong element shown in enlarged section
- Table 31: MAH code name content clarified
- Table 31: MFL code name attribute content clarified
- Table 32: Legal basis name attribute – name and reference – corrected to and @name and @N/A repectively
- Page 98: Was blank and is now removed
- Table 33: @name - note added that this should not be submitted for consistency
- Table 35: @name - note added that this should not be submitted for consistency
- O.19.BR.2: value in organisation type check corrected to "(O.1 = 1)"
- O.20.BR.1: value in sme_status check corrected to "(O.19 *absent* or O.19 = 1)"
- O.DUP.BR.1 value in organisation type check corrected to "(O.1 = 1)"
- Table 103: Erroneous references to ATC replaced with references to pharmaceutical forms
- Table 128: Wrong field id for development substance sponsor code – corrected from DS.1 to DS.4
- Various locations: removed references to the authorised product variation operation type.

- Appendix 8 text replaced with a link to a downloadable version of the schema that will come into force on 16th June 2014